

## CHAPTER 1

### INTRODUCTION

There is currently an epidemic of overweight and obese individuals in the United States and other developed countries (World Health Organization, 1998). According to the body mass index criteria ( $BMI = kg/m^2$ ), the rate of overweight ( $BMI = 25-29.9 kg/m^2$ ) and obese ( $BMI = 30+kg/m^2$ ) individuals has risen rapidly over the past four decades. However, it was only after the research by Kuczmarski and colleagues (1994), indicating that one third of people who were overweight and obese had increased their weight without any obvious cause, that obesity was identified as a serious public health issue. Sadly, data published over the last decade demonstrated a continued increase in the percentage of overweight and obese individuals (Wadden & Osei, 2002). By the mid 1990's, 55% of Americans met BMI criteria for being overweight or obese (Jeffrey et. al, 2000). Data published in 1999 by the National Center for Health Statistics indicate that 61% of adult Americans are now either overweight (34%) or obese (27%). The escalating incidence and prevalence rates demonstrate continued increases in the number of overweight and obese individuals to epidemic proportions. In fact, Hill and colleagues (2003) estimate that by the year 2008, 39% of Americans will be obese.

Obesity has profound costs both at an individual and societal level (National Institute of Health / National Heart Lung and Blood Institute, 1998). Financially, consumers spend over \$50 billion per year to achieve weight loss (Wolf & Colditz, 1998). At the federal level, the direct costs associated with obesity account for approximately 9.4% of the United States health care expenditures each year. For example, in 1995, obesity among U.S. adults cost \$99.2 billion, of which \$51.6 billion was for direct medical care costs (Center for Disease Control, 2003). There are also clear emotional costs to the overweight and obese individual. Overweight and obese individuals are at greater risk for experiencing symptoms of depression, low-self esteem, and impaired quality of life (Han, Tjihuis, Lean, & Seidell, 1998; Johnson, 2002; Roberts, Deleger, Strawbridge, & Kaplan, 2003). In addition, these individuals are more likely to face discrimination and social stigma (Wadden & Osei, 2002).

Obesity has now been reclassified as a medical disease. As such, there are stages of progression in the disease process associated with morbidity and mortality. According to

the third report from the National Cholesterol Education Program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (ATP III), the first stage of the disease involves metabolic and neuroendocrine changes which includes excess fat weight (% body fat of total weight: Men > 20%, Women >30%) and at least two of the following risk factors: 1] impaired fasting glucose ( $\geq 100$  and  $< 126$ ); 2] triyglycerides ( $\geq 150$ ); 3] high-density lipoprotein cholesterol (Men  $< 40$ , Women  $< 50$ ), 4] low-density lipoprotein cholesterol (100-159); 5] elevated blood pressure (systolic 130-139 and diastolic 85-89); and 6] central obesity measured as waist circumference (Men  $> 102$  cm, Women  $> 88$  cm) [National Cholesterol Education Program (NCEP), 2001]. Most individuals are unaware of the potential health risk as these levels are considered sub-clinical and typically do not result in the need for direct medical intervention in the initial stage. Therefore, the disease is likely to progress from asymptomatic metabolic alterations to clinical manifestations of chronic diseases such as hypertension, dyslipidemia, Type II diabetes mellitus, some forms of cancer, and cardiovascular disease (CVD) [Bray, 1998; Chan, Rimm, Colditz, Stampfer, & Willett, 1998; Colditz, et al., 1995; Field et al, 2001; Manson, Skerrett, Willett, 2002; Michaud et al., 2001; Vega, 2001]. This further contributes to an increased risk for all-cause mortality (Pi-Sunyer, 1999). In a recently released article by Fontaine and colleagues (2003), based on several national databases, they found that obesity appears to decrease life expectancy markedly regardless of age, sex, and race. Clearly, the consequences of obesity are sobering.

### **FACTORS CONTRIBUTING TO DEVELOPING OBESITY**

Three major factors are thought to contribute to becoming overweight and obese: genetics, nutrition, and physical activity. As such, examining each component individually, and in combination, is necessary in order to have a better understanding how each may be implicated in the growing trend of obesity in the United States.

#### **Genetics**

For over half a century, researchers have been aware that specific genes are associated with obesity. Bouchard and colleagues (1990, 1994) made a major contribution to the field with two classic twin studies examining the impact of individual

differences in response to nutrition and physical activity changes. Bouchard et al (1990) looked at the effects of weight gain with overeating and constant energy expenditure. For 100 days, 12 pairs of monozygotic twin adults ate a surplus of 1000 calories/day, 6 days a week, resulting in an average weight gain of 18 pounds for the group. However, the amount of weight gain was highly variable, ranging from 9.5 to 29 pounds. It is important to note that little variation was found within twin dyads in the amount of weight gain, whereas differences between twin dyads were significant. In the second study, Bouchard and colleagues (1994) examined the effects of caloric expenditure on weight loss. Seven pairs of adult monozygotic twins exercised on cycle ergometers twice a day, 9 out of 10 days, for 93 days while consuming a diet to support weight maintenance. Although the average weight loss was 11 pounds, the range was 2 to 17 pounds. Again, there was remarkable similarity in weight change within twin dyads, whereas significant differences were found between twin dyads.

Taken together, Bouchard et al's work provides strong evidence that genes do impact the propensity for an individual to gain weight or respond optimally to a weight loss program. Furthermore, there is considerable variability in response to exercise and caloric intake. However, it has been suggested that the rapid rise in the incidence of obesity cannot be accounted for by genetics alone (Ribisl, McInnis, Melanson, & Rippe, 2001; Weinsier, Hunter, Heini, Goran, & Sell, 1998). While genes may increase the likelihood that an individual could gain weight rather easily, it is now clear that 'a toxic environment' (i.e., behavioral factors) directly contribute to whether an individual will/will not become overweight or obese (Brownell, 2002). Therefore, gaining a better understanding of the influence of nutrition and physical activity on weight is also crucial.

### **Nutrition and Physical Activity**

While there are several contributing variables (both genetic and environmental), the fundamental determinant of body weight is energy balance (Postin & Foreyt, 1999). Energy balance involves the ratio between caloric or nutritional intake and energy expenditure through physical activity. More specifically, if the energy balance is positive, an individual will gain weight, whereas if the energy balance is negative, an individual will lose weight. Both independently, and in combination, nutritional intake

and physical activity have been hypothesized as ‘toxic’ variables responsible for escalating obesity rates (Brownell, 2002).

It has long been assumed that the increasing prevalence of overweight and obese individuals is due primarily to increased caloric consumption. However, the existing studies examining food intake have yielded inconsistent findings. Data from two national dietary surveys indicate that caloric intake has been declining (Borrud, Wilkinson-Enns, Mickle, 1997; Norris et al., 1997), whereas another national survey reported an overall increase in caloric intake (CDC, 1994). Although research has documented that self-reported dietary intake can yield inaccurate and often-underestimated caloric intake (Shaefer, et al., 2000; Lichtman, et al., 1992), particularly in overweight individuals, it continues to be the standard. Thus, inconsistencies between dietary surveys may be attributable to reliance on participant reported food logs. In order to address these conflicting findings, Harnack and colleagues (2000) completed an ecological survey regarding the quantities and types of food and nutrients available to Americans. Consistent with trends in the obesity literature, data from the survey suggested that caloric/nutritional intake has increased over the past several decades and is likely a major contributor to increased body weight throughout the population (Harnack, Jeffrey & Boutelle, 2000). While conclusive data is lacking, these findings suggest that Americans diets are higher in calorie-dense foods. Although nutritional intake is necessary for weight gain, nutritional factors are not sufficient to account for the current epidemic.

Researchers are now suggesting that the rapid increase in body weight is also attributed to marked declines in energy expenditure through physical activity (Blair & Leermakers, 2002; Hill, Wyatt, Reed, & Peters, 2003). There is now ample evidence to demonstrate a significant decline in physical activity beginning in the early to mid 1900’s. Increased mechanization (automobiles, elevators, escalators, computers, phones) has directly impacted the level of daily physical exertion required in both job-related and leisure-time activities. Concerned with the marked decline in activity and increases in associated chronic disease, the American College of Sports Medicine (ACSM) in the mid 1970’s recommended that individuals engage in regular vigorous physical activity. More specifically, ACSM recommended engaging in vigorous physical activity for 20 minutes continuously at least three days a week in order to gain the associated health benefits.

Despite this recommendation, levels of activity only continued to decline. Some health care professionals suggested that the proposed intensity (i.e., vigorous) level of activity required for individuals was aversive, and seemingly unattainable (ACSM, 1998; Dunn et al, 1999). Therefore, most individuals would not even attempt to initiate an exercise program. Simultaneously, evidence was beginning to emerge suggesting that it was the accumulation, not intensity of activity that was most important for health benefits (Paffenbarger, Blair, & Lee, 2001).

Led by the pioneering work of Paffenbarger and Blair (Blair, Cheng, & Holder, 2001), the argument was put forth that moderate 'lifestyle' activity could be a more effective health prescription to reduce all-cause mortality. As a result, in 1996 the National Institutes of Health (NIH) issued a consensus statement that Americans should engage in 30 minutes of moderately intense physical activity (e.g., brisk walking) on most, if not all days of the week in order gain multiple health benefits. At that time, the Surgeon General's Report on Activity and Health (US Department of Health and Human Services, 1996) stated that more than 60% of American adults engaged in occasional leisure-time physical activities and 25% did not engage in any physical activity. Notably, only 10% of Americans participated regularly in vigorous physical activity. Data over the past decade has shown little change in these trends toward extremely sedentary lifestyles (CDC, 2003).

Taken together, the existing literature suggests that increased caloric consumption, decreased physical activity, and a genetic vulnerability are multifaceted factors contributing to the present obesity epidemic. Understanding how to effectively treat and modify risk factors associated with obesity has become a major public health challenge.

### **TREATMENT OF OBESITY**

It is now well established that even moderate weight loss (i.e., 5-10% of initial body weight) has a beneficial effect on cardiovascular risk factors associated with obesity (Andersen et al, 1999; Jakicic, Winters, Lang, & Wing, 1999; Kern, Ong, Saffari, & Carty, 1990; Vidal, 2002). In addition, large-scale clinical trials have shown that moderate weight reductions are very effective in preventing Type II diabetes and

hypertension in overweight and obese individuals (Knowler et al, 2002; Tuomilehto et al, 2001).

There are currently three major interventions used to promote weight loss including: drug therapy, surgery, and lifestyle modifications (diet, exercise, and cognitive-behavioral therapy). Although alternative therapies (e.g. acupuncture, hypnosis) have also been marketed as methods for weight loss, existing data does not support any added benefits beyond that of placebo (Allison & Faith, 1995; Ernst, Sempos, Briefel, & Clark, 1997).

### **Drug Therapy**

Medications are one method of treatment utilized predominantly with individuals with mild-to-moderate obesity ( $BMI > 30 < 40$ ). The use of medication to promote weight loss is done through one of three mechanisms: appetite suppression, increasing metabolic rate, and decreasing caloric absorption (Shepherd, 2003). The four medications most commonly used for weight loss are sibutramine and fluoxetine (suppressants), ephedra (stimulant), and orlistat (absorption). While these medications have been efficacious during short-term treatment, research regarding the ability of medication to promote and maintain long-term weight loss is lacking (Weintraub et al, 1992). Following withdrawal of the medication, individuals have been shown to gain a significant portion of weight back over time (Devlin, Goldfein, Carino, Wolk, 2000). Notably, in a comprehensive review of pharmacological interventions (Perri, 1998), the long-term effectiveness of medication was reported to be more effective in promoting weight loss when the medication was part of a multifaceted treatment program that incorporates behavior therapy, dietary counseling, exercise, and frequent contacts with health care providers. Moreover, research suggests that pharmacological intervention alone, without lifestyle intervention, actually may decrease an individual's ability to lose weight (Wadden, Berkowitz, Sarwer, Prus-Wisniewki, & Steinberg, 2001). While weight loss medications are routinely prescribed to patients to be used in conjunction with reduced-calorie diets and regular exercise, the importance of lifestyle modification appears to be key to long-term weight management.

## **Surgery**

Based on recommendations from NIH related to gastrointestinal surgery for obesity (1991), surgical intervention is reserved for morbidly obese individuals (BMI > 40) due to the risk of morbidity (10% perioperatively) and mortality (> 1% perioperatively). The two primary surgical approaches involve reducing the size of the stomach to decrease the volume of intake (gastroplasty) and to create a malabsorption condition to decrease absorption of calories (intestinal bypass). However, the combination of both procedures has shown to be superior to either surgical intervention alone (Sugerman, 2000).

Average weight loss for the procedures is approximately 30% of excess body weight (Corcisa & Perri, 2002). Prior to being considered for surgery, individuals typically must show previous unsuccessful attempts at weight loss through other means including exercise and a low calorie diet. In general, surgical treatment for obesity is considered to be a last resort to weight management after all other lifestyle modification attempts have failed. Learning how to effectively promote weight loss prior to such drastic methods of intervention has become a major focus of research in the area of obesity.

## **Lifestyle Modifications**

Because of the known importance of lifestyle factors such as diet in the development of obesity, understanding how to successfully modify these behaviors (e.g., diet composition, eating patterns, caloric density, physical activity) has become paramount (Miller, DiRienzo, & Miller, 2001; Perusse & Bouchard, 2000). Behavior modification procedures are the foundation of lifestyle interventions for weight loss (Wadden & Foster, 1992). In a behavioral treatment program, participants are taught to modify their eating and exercise habits in order to produce weight loss through a negative energy balance (energy expenditure > energy intake). The key components in behavioral treatment programs as described by Corcisa and Perri (2002) include: 1] goal setting and daily self-monitoring of eating and physical activity; 2] nutritional training aimed at the consumption of a balanced low-calorie diet sufficient to yield a weight loss of 0.5 kg per week; 3] increased physical activity through the development of a walking program and/or increased lifestyle activities; 4] arrangement of environmental cues and behavioral reinforcers to support change in eating and exercise behaviors; 5] cognitive restructuring techniques to identify and change negative thoughts and feelings that interfere with

weight-loss progress; and 6] training in problem solving or relapse prevention procedures to enhance coping with setbacks and overcome obstacles impeding lifestyle modification (Corcisa & Perri, 2002).

There are now more than 150 studies spanning three decades of research examining the effects of interventions encompassing lifestyle modification changes (Jeffrey et al, 2000; NHLBI, 1998; Perri & Fuller, 1995; Wadden, Sarwer, & Berkowitz, 1999). During this time, the greatest achievement has been in the ability to enhance the total amount of weight lost. Specifically, weight loss in behavioral treatment studies increased by over 75% between 1974 and 1994 (Perri & Fuller, 1995). However, the treatment factor associated with improved weight loss during treatment appears to be consistently increased duration of treatment. These programs are typically delivered in group settings and are on average 20 weeks in duration (range 8-26 weeks). The rate of initial weight loss is rapid and then gradual until weight loss asymptotes at approximately six months after initiation of treatment. The average weight loss with these treatments is approximately 8.5 kg or, 9% reduction in excess or total body weight (Corcisa & Perri, 2002). Fortunately, attrition rates are relatively low, averaging only 20% over six months compared to 50% within six months the area of physical activity and exercise (Dishman & Buckworth, 1996). For individuals in lifestyle modification programs, weight regain typically begins at six months and continues gradually until weight stabilizes somewhat below baseline (Jeffrey et al, 2000). There is some evidence that greater initial weight loss does result in greater overall results for up to two years after the initiation of treatment (Astrup & Rossner, 2000; Jeffrey et al, 2000). However, within four years following treatment, individuals will have an average weight loss of only 1.8 kg compared to pre-treatment weigh-in (Perri & Corcisa, 2002). Unfortunately, across more lengthy follow-up periods, the remittances of weight loss to baseline levels are similar for individual's exhibiting larger and smaller initial weight loss. Therefore, long-term weight management and maintenance remains a significant public health issue.

### **THE PROBLEM OF MAINTENANCE**

Unfortunately, although interventions designed to promote weight loss are reasonably effective in producing short-term changes, promoting long-term behavior



change has proven to be a much more difficult task. Factors responsible for substantial weight regain have not been clearly identified and are a cause for debate. However, poor maintenance appears to stem from a complex set of physiological, psychological, and environmental factors.

Physiological factors such as a reduced metabolic rate (Dulloo & Jacquet, 1998; Ravussin & Swinburn, 1993), adaptive thermogenesis (Leibel, Rosenbaum, & Hirsch, 1995; Stock, 1999), and increased adipose tissue lipoprotein lipase activity (Kern, 1997; Kern, Ong, Saffari, & Cartly, 1990) are known to prime the body for weight regain. The ‘toxic environment’ of high-fat, high calorie foods also is a constant temptation for non-adherence (Brownell, 2002; Hill & Peters, 1998). The traditional dieting-induced avoidance of palatable foods increasingly challenges the individual to maintain dietary control (Rodin, Schank, & Streigal-Moore, 1989).

The ongoing problem of poor maintenance of weight loss has prompted researchers to examine psychological factors. Many individuals present for weight-loss treatment seeking to achieve their “ideal” body weight (Foster, Wadden, Vogt, & Brewer, 1997). For the typical participant in behavioral treatment, reaching “ideal” weight often requires a reduction of 20-30% in total body weight, a loss 2-3 times greater than typical results achieved through behavioral treatment (i.e., 9% total body weight). Thus, individual’s expectancies may be unrealistic and may require modification to appreciate small, yet significant, change. Additional psychological factors that have been found to contribute to the lack of weight maintenance include poor coping or problem-solving skills and low self-efficacy (Bryne, 2002). While other psychological factors may impede weight maintenance (e.g., depressive symptoms, deficient social support, there is a paucity of research to date that have examined the role of such factors in long-term weight management and maintenance. Notwithstanding, the combination of physiological, psychological, and behavioral factors, understandably, makes long-term maintenance following weight loss a challenge to the overweight and obese individual as well as to the health service providers attempting to develop weight management programs.

### **Research on Improving Long-Term Weight Loss**

In an attempt to identify possible mechanisms involved, over the past 15 years many different treatment strategies have been used in hopes of increasing long-term

maintenance of weight loss. Strategies have included enhancing motivation through monetary incentives, enhancing social support, supervised group exercise, the assistance of personal trainers, the availability of portion-controlled meals, and telephone prompts by non-therapists. Unfortunately, none of these techniques has proven effective in improving long-term maintenance of weight loss (Perri & Corcisa, 2002). However, several other treatment approaches have yielded more initial success and are of particular interest.

### **Extending the Length of Treatment**

One major area of research that is gaining widespread support suggests the need for a more continuous care model for the treatment of obesity. Intervention studies to date examining the effects of continuous care include extended treatment programs (beyond six months) and multi-component post-treatment programs. Indeed, in a review by Perri and Corcisa (2002), clear benefits have been demonstrated with extended treatment (over 2 years) in producing greater weight loss maintenance compared to no post-treatment intervention. In addition, Perri and colleagues (Perri, McAdoo, Spevak, & Newlin, 1984; Perri, McAdoo, McAllister, Lauer, & Yancey, 1986; Perri, McAllister, Gange, Jordan, & McAdoo, 1988) they that providing some form of ongoing patient-therapist contact has improved weight maintenance by almost 50% at two year follow-up compared to no post-treatment intervention. While current research supports extending the length of treatment to promote weight maintenance, Wing (2000) argued that there is a need to develop alternative intervention designs that may inherently promote greater long term weight maintenance without extensive contact being necessitated.

### **Caloric Goals**

Conventional studies have focused on low calorie diets (1000-1200 calories; LCD) to promote weight loss. While these studies were successful at promoting initial weight loss, weight gain would begin almost immediately following the end of treatment. In an attempt to promote more drastic initial weight loss, and possibly weight maintenance, some studies have required participants to restrict their food intake to approximately 600-800 calories [aka, very low calorie diets (VLCD) (National Task Force on the Prevention and Treatment of Obesity, 1993)] for several months. Unfortunately, this approach has not produced the desired outcomes. In one notable study by Wadden and colleagues (1989), while initial weight loss in the VLCD group exceeded the low calorie diet (LCD), within four years both groups were back at pre-intervention weight with a trend of continued increase in weight. However, in a recent meta-analysis (Andersen, Konz, Frederich, and Wood, 2001), it was found that greater initial weight loss resulted in

greater long-term maintenance of weight loss compared to more modest weight reduction during treatment. The current consensus regarding modifications of caloric goals to promote more significant weight loss over time suggests that larger, not smaller, weight loss during treatment will result in greater long-term maintenance of weight. However, there is a growing area of literature suggesting that regardless of the potential benefits of larger weight loss during treatment, this drastic approach for weight loss is aversive to some individuals and may promote feelings of deprivation.

While the area of weight management continues to promote LCD, if not VLCD, emerging evidence suggests that this may not be necessary. In fact, in a small pilot study by Sbrocco and colleagues (1999), 40 obese women involved in a 13-week intervention showed significant weight loss through moderate exercise, an average caloric intake of 1800 calories per day, and a client-centered therapy based change program called behavioral choice treatment (BCT) compared to a traditional behavioral therapy (TBT) group prescribed a 1200 calorie diet. While individuals in the higher calorie group were encouraged to eat a low-fat diet, they were also encouraged not to restrict the type of food they ate. At the end of the 13-week treatment intervention, individuals in the traditional behavioral therapy group lost significantly more weight in comparison to the BCT. However, at the end of one year, individuals in the BCT had continued to lose weight across time while individuals in the TBT had begun to gain weight. Perhaps more interestingly, at two-year follow-up, participants in BCT continued to show significant weight-loss while individuals in the TBT continued to show steady weight gain (Sbrocco, 2002). To date, this is the only known study to show continued weight loss at 2-years post treatment.

Given the uniqueness of the Sbrocco's findings, a few points need to be addressed. First, while participants were no longer attending weekly treatment intervention meetings, participants were encouraged to continue weighing weekly and were provided a data sheet turned in at 'follow-up' meetings every three months for two years. Therefore, it could be argued that individuals in this treatment program were actually receiving an extended 2-year treatment program. Second, due to the difference in behavioral versus cognitive-behavioral treatment programs, as well as different caloric goals, it is unclear as to whether it was the treatment, the caloric goal, or the combination

that resulted in the impressive results. Third, all women in the BCT group were prescribed the same calorie goal even though there was great variability in their baseline caloric intake and body weight. It has been suggested that individualized caloric goals is a more beneficial, and accurate way to promote a negative energy balance (ACSM, 2000). While further studies with larger numbers of men and women are needed, this unique approach of modest reductions in caloric intake may be a key component more long-term weight management. Notwithstanding, individualizing calorie goals based on individual's energy needs may result in even better outcome and long-term maintenance compared to a more 'one size fits all' approach.

### **Physical Activity & Aerobic Exercise**

Historically, obesity treatment studies primarily focused on diet restriction to promote weight loss. Only of late, has greater attention been given to exercise and its potentially significant role in weight loss and weight maintenance (Jeffrey et al, 2000). Correlational studies have shown that long-term weight loss is associated with increased physical activity (e.g., Harris, French, Jeffrey, McGovern, & Wing, 1994; Sherwood, Jeffrey & Wing, 1999). In addition, several controlled trials have now shown that the combination of diet plus exercise produces greater initial weight loss, and better maintenance at up to two years post-treatment compared to later than just LCD or VLCD diets alone (Pavlou, Krey & Steffee, 1989; Perri, McAdoo, McAllister, Lauer, & Yancey, 1986; Sikand, Kondo, Foreyt, Jones & Gotto, 1988). Further, findings from the National Weight Control Registry (NWCR) also provide strong support for the importance of physical activity in maintaining weight loss (McGuire, Wing, Klem, Seagle, & Hill, 1999). The NWCR consists of a group of 1,047 women and men who have lost at least 30 pounds (13.6kg) and maintained that loss for at least one year. Among these individuals, one common factor was engaging in an average of one hour of moderate to vigorous physical activity per day. Clearly exercise appears to be a critical element involved in long-term weight management. More recently, however, debate has evolved as to whether structured moderate-to-vigorous exercise is any more beneficial than lifestyle activity (daily physical activity independent of intensity).

While reports in the early 1990's suggested that aerobic training was synonymous with physical activity, more recent data suggest that physical fitness and physical activity

may be important, but separate, factors which reduce the likelihood for the development of chronic disease. In a comprehensive review of existing aerobic training and physical activity interventions done to date, Williams (2001) found clear delineations between low fitness and low levels of activity in the development of heart disease. That is, individuals below the 25<sup>th</sup> percentile of the fitness distribution (according to gender and age) are at a substantially higher risk for heart disease compared to those with higher levels of fitness. Further, reductions in cardiovascular risk were found to be almost two-fold greater for fitness compared to physical activity (Williams, 2001). Moreover, emerging research suggests that short duration, but prescriptive, aerobic sessions may provide the same benefits as a much larger volume of physical activity (Winett & Carpinelli, 2000; 2001). Overall, it is now possible to suggest that both fitness, achieved through a more intense level of activity, and physical activity are both important factors and should be targeted for intervention.

Few studies exist that examine the impact of structured exercise versus ‘lifestyle’ activity on weight management (Stefanick, 1999). However, in one exemplary study, by Andersen and colleagues (1999), examined the effectiveness of lifestyle activity compared with structured activity on weight loss in 40 obese women. For 16 weeks, participants followed a LCD diet (1,200 kcals) in combination with 30 minutes of active time on most days of the week versus attending three step aerobics classes three days a week. At the end of treatment, participants in both groups were encouraged to continue exercising, however, participants in neither group were contacted during the next 12 months. Participants in both groups lost similar amounts of weight, but at one-year follow-up, participants in the ‘lifestyle’ oriented group maintained their weight while participants in the structured exercise group regained almost 20% of the weight lost during treatment (Blair & Leemakers, 2002).

Taken together, there are several important points about physical activity and aerobic exercise. First, the addition of activity, whether aerobic or lifestyle, to a weight loss program is beneficial. In addition, regular physical activity appears to be a crucial component involved in the ability to maintain long-term weight loss. Finally, emerging research suggests that short duration, high intensity, aerobic sessions may stimulate improvements in strength and fitness. As such, two initial conclusions are suggested.

The first conclusion points to the benefit of incorporating short duration higher intensity aerobic exercise into a weight management program in order to help promote better adherence and long-term maintenance of behavior. Second, increasing daily lifestyle activity, regardless of intensity, may help promote calorie expenditure necessary to produce weight loss and lead to continued moderate changes in lifestyle. Furthermore, the time-efficiency combined with the palatability of low-levels of levels of physical activity that are easily accomplished in almost any environment may help promote better maintenance of behavior compared to more traditional center-based, long-duration, high intensity workout programs.

### **Nutritional Content**

Another component of weight management programs that has attracted particular attention recently is in the area of dietary recommendations. Conventional dietary treatment of obesity typically involved a reduction in fat consumption (Pawlak, Ebbeling, & Ludwig, 2002). However, long-term clinical trials have provided little evidence that reducing dietary fat can lead to weight loss (Pirozzo, Summerbell, Cameron & Glasziou, 2002; Willett, 1998; Willett & Liebel, 2002). More recently, controversy has developed regarding the optimal macronutrient recommendations for Americans.

The prevailing dietary guidelines from the United States Department of Agriculture emphasize intake of specific macronutrients (e.g. not exceeding 30% of calories from fat, 50% of calories from carbohydrates, 10% of calories from protein, and 10% of calories from sugar). However, it has been argued that such numerical criteria are not based on solid evidence (Hu & Willett, 2002). Alternatively, it has been argued that a mildly hypocaloric and moderate fat diet that allows for greater variety in food choice and better long-term compliance compared to a more low-fat diet. Specifically, Dr. Walter Willett, along with the department of nutrition at Harvard University, has proposed a “New Healthy Pyramid.” The New Healthy Pyramid recommends that an individual's diet include non-hydrogenated unsaturated fats as the predominant form of fat, whole grains as the main form of carbohydrate, an abundance of fruits and vegetables, and adequate omega 3-fatty acids (Willett, 2001). This combination of foods and macronutrients has been shown to provide significant protection against cardiovascular disease (Hu & Willett, 2002). While this pyramid has yet to be directly tested with obese individuals, it

is likely that it may offer a more “realistic” set of nutritional guidelines for a weight management program, coupled with possible added benefits that may promote long-term maintenance of dietary changes and weight loss.

### **Resistance Training**

Resistance training, also known as strength training or weight training, has been identified as beneficial form of exercise for over two decades. These beliefs are based on the known benefits of strength training, which include increased functional capacity, decreased risk of falls, decreased risk of fracture, and reduced disability (ACSM, 1998). However, in a recent review of the strength training literature (Winett and Carpinelli, 2001), several important associations between weight training and health outcomes were noted. For example, while traditional weight-loss programs drastically reduce caloric intake while increasing caloric expenditure through physical activity and aerobic exercise, recent physiological data contraindicate this approach to weight management. Even though body weight is reduced through this approach, individuals also reduce their lean body mass (muscle mass). As a result, there is a decrease in resting metabolic rate (the minimum number of calories needed for the body to function). Subsequently, further weight loss or maintenance becomes extremely difficult, often resulting in subsequent weight (fatty mass) gain.

*Strength training also has observable benefits on physical outcomes.* Recent data show that more intense activities, such as strength training, can positively impact a multitude of disease risk factors. For example, Parker and colleagues (1996) showed significant reductions in heart rate, systolic blood pressure, and rate pressure product following involvement in a strength-training program. Regular strength training has also improved insulin action, glucose metabolism, and thereby reducing risk of diabetes (Dustan, et al, 2002; Maiorana, O’Driscoll, Goodman, Taylor & Green, 2002; Miller et al, 1994). Ross (1997) found strength training to reduce percent of visceral body fat, a factor now highly linked to coronary heart disease, diabetes and cancer, in middle-aged obese men. However, studies examining the impact of resistance training on lipid profiles have been mixed. Elliot and colleagues (2002) examined the effects of resistance training on lipids in postmenopausal women. After 8 weeks of strength training 3 times per week, there were no significant alterations in blood lipid concentrations between

women in the strength training versus control group. Conversely, Fahlman and colleagues (2002) found significant changes in lipid profiles following a 10-week resistance training with elderly women. Specifically, participants had significant increases in HDL while having a significant decrease in triglycerides. Notably, neither of the aforementioned studies manipulated dietary intake. While further study is needed with regard to the impact of resistance training on lipids, there appear to be multiple health benefits to resistance training.

Unfortunately, although resistance training has been an integral part of many adult health and fitness settings since the early part of the century, its clinical significance, has only been minimally recognized as a general treatment component in obesity management interventions (Southern et al, 2000). Alternatively, programs relied more heavily on calorie restriction and increased energy expenditure through aerobic exercise. Although recent research has suggested that benefits from strength training can be gained in as little as 20 minutes per week (Winett et al, in press), few studies have looked at strength training as a potential solution to the “time barrier” for exercise (Burton & Turrell, 2000; Eyler et al, 2002; McKenna, Naylor & McDowell 1998; Sciamanna et al., 2002; Tegerson & King, 2002; Wilcox, Castro, King, Housemann & Brownson, 2000). While the mechanisms involved in strength training which lead to a decreased risk of disease remain unclear, the benefits of time-limited weight resistance programs in conjunction with comprehensive weight management treatment warrants further investigation.

### **Non-Dieting Approaches**

Even though behavioral treatments have evolved to multi-component programs, it has been suggested that these programs continue to promote a “dieting mentality” (Brownell & Rodin, 1994). The dieting movement has come under attack by a growing contention that “diets don’t work” and that the adverse psychological and physical effects far outweigh the benefits of short-term weight loss (Berg, 1999; Goodrick & Foreyt, 1991; McFarlane, Polivy & McCabe, 1999; Robinson, 1997). The “non-dieting” approach is appealing for many reasons and has gained increased attention in the literature (Foster & McGuckin, 2002). The basic premise of “non-dieting” is that individuals should only modestly reduce caloric intake, modestly improve food quality



and frequency, while not ‘taking out’ foods from one’s diet. Early non-dieting studies were encouraging with regard to their ability to promote long-term moderate weight loss as well as improvements in quality of life (Carrier, Steinhardt, and Bowman, 1994; Omichinski & Harrison, 1995; Polivy & Herman, 1992; Roughan, Seddon, and Verenon-Roberts 1990). Unfortunately, the descriptive nature of these studies led health professionals to question the findings. However, a second generation of randomized clinical trials examining non-dieting have recently emerged and with extremely encouraging results.

In one study by Tanco and colleagues (1998) an 8-week “non-dieting” approach was compared to a standard weight loss treatment and a weight list control and demonstrated greater improvements in psychological functioning but minimal weight loss. However, at 6-month follow-up, the nondieting group had lost over twice as much weight compared to the traditional group (8.9 and 4.9 kg, respectively). Unfortunately, only 57% of the sample returned for follow-up testing, greatly limiting the ability to make causal statements in the effectiveness to produce long-term change. In another study by Rapport and colleagues (2000) examined the impact of a non-dieting approach compared to a standard behavioral treatment in preventing weight gain and producing change in other risk factor variables including lipids, glucose, and blood pressure. At the end of the 10-week treatment program, while the standard behavioral group lost more weight (3.8 kg) compared to the nondieting group (1.3kg), both groups reported significant increases in self-esteem, body image, and decreased symptoms of depression. At 12 months, both groups continued to show modest weight loss (2-4 kg) with further improvements in blood pressure, total cholesterol, and low-density lipoprotein cholesterol along with additional positive changes in psychological functioning. However, there were no significant differences between groups at follow-up on any of these variables. Together, both studies show promising results but fall short in producing differences beyond that of traditional treatments on psychological or physical outcomes.

Perhaps one of the most exciting new approaches suggested to date is Behavioral Choice Treatment (BCT). Sbrocco and colleagues (1999) compared a traditional behavioral treatment (TBT) program (1200 kcal diet recommendation) compared to a behavioral choice treatment (BCT) program that coupled elements of “nondieting” with a

more moderate caloric goal (1800 kcal diet recommendation) in a 13-week treatment program. At the end of treatment, both groups showed significant improvements in psychological functioning, but the TBT group lost over twice as much weight (5.6 kg lost vs. 2.5kg lost). However, at one-year follow-up, the results were almost reversed. Both groups maintained improved psychological functioning. However, individuals in the TBT gained a significant portion of their weight lost, while individuals in the BCT group continued to lose weight at consistent rate (4.3 gained vs. 10.1 kg lost). Moreover, this trend continued through 2-year follow-up (Society of Behavioral Medicine, 2002). These results are truly atypical in the field and have stirred much discussion about the validity, applicability, and generalizability of this study. One noted strength of this study was the investigators' ability to retain almost their entire sample. However, several limitations precluding generalizability include its focus only on women, requiring a 2-week pre-dietary record to screen out non-compliers, using palm pilots for individual's to complete food records, and ongoing contact through 2-year follow-up. While questions remain about this new nondieting treatment, Sbrocco's BCT offers promise for the future of weight management. Specifically this non-guilt, no-forbidden food, moderation approach may be more acceptable to individuals, and thus, may promote better long-term maintenance of behavior and weight management.

### **Training Maintenance Specific Skills**

Of all theories that address the issue of behavioral maintenance, relapse prevention has been the most widely used maintenance approach in the area of weight management (Jeffrey et al, 2000). The basic elements of this model include identifying high-risk situations and then developing plans for dealing with the situations. The relapse prevention approach is based on the idea that short-term violations of "rules" about behavioral adherence can often lead to a negative psychological reaction that result in a return to pretreatment patterns if not addressed directly. Because of the importance of relapse prevention skills for weight management, most behavioral programs now incorporate these elements. However, to date, studies have not systematically studied the efficacy of relapse prevention training independent of other treatment variables on producing long-term maintenance of behavior. Further, with the exception of the three

studies discussed below, few have attempted specifically to design and test relapse prevention skills alone as maintenance-specific skills.

Wing and colleagues (1996) tested the effects of an applied relapse prevention-training program in a clinical trial with obese individuals. Following participation in a six-month behavioral weight loss treatment including an outpatient feeding component to enhance dietary adherence, groups were assigned to either a no-contact group for the next 12 months or had the option to reinitiate the outpatient feeding program if weight regain began. Unfortunately, 12-month follow-up data showed no differences between the group's ability to maintain weight loss. Although it was noted that individuals in the relapse prevention group did not take advantage of the service, it could be argued that this approach was merely an extended treatment program rather than a relapse prevention-training program.

Recently, Riebe and colleagues (2003) conducted an innovative study examining the effects of a multidisciplinary weight management program on multiple objective and self-reported outcomes at mid treatment (three months) and post treatment (six months). Specifically, the treatment program included healthy eating, regular exercise, and behavior change skills within a maintenance-oriented framework. In this study, maintenance was conceptualized as including relapse prevention training with gradually reducing clinical contact over time (from months three to six). At mid treatment, participants experienced several significant health benefits including decreases in weight, percentage body fat, BMI, total cholesterol, LDL-D, total caloric intake, and the percentage of energy intake from fat, as well as an increase in VO<sub>2</sub> fitness. By the end of the transitioning phase at six months, although changes in weight, percentage body fat and BMI were maintained, all biochemical analyses were remitting back to pre-treatment levels. An additional limitation associated with this maintenance-oriented approach is that it did not appear to be theoretically-based. Regardless, the overall treatment was innovative in its maintenance-oriented approach and has much to offer as a foundation for future research endeavors in this area. Further, as this group is currently being followed for a two-year period, favorable long-term maintenance outcomes are anticipated.

Another innovative approach of training maintenance specific skills, coupled with psychological variables involved in weight loss and maintenance was recently developed by Cooper and Fairburn (2002). They formulated an innovative cognitive-behavioral explanation of weight regain that addresses the impact of psychological factors on weight loss, which include improving appearance or body image, attractiveness, self-confidence and self-esteem, as well as developing weight maintenance skills. While a major clinical trial is currently ongoing, data has yet to be published as to the actual impact of this approach.

There have been a small number of innovative approaches focused on maintenance of weight loss, there continues to be a paucity of data examining the impact of promoting maintenance-specific techniques. In addition, theoretical models and techniques are lacking which consistently provide behavior maintenance and long-term weight loss. As such, there is a need for exploration and/or modification of existing theories in order to develop increased maintenance of health behaviors (Wing, 2000).

### **USING LEARNING THEORY TO IMPROVE MAINTENANCE**

For over 35 years Alan Kazdin has been a pivotal figure in the field of behavior change and maintenance in applied settings. In his most recent work addressing the issues of maintenance, he outlined both a definition of maintenance and several techniques implemented within a stage-based program that have been shown to increase behavior maintenance based on operant theory. This is also known as a response maintenance and transfer of training techniques model which involves both stimulus and response generalization (Kazdin, 2001).

#### **Kazdin's Definition of Maintenance**

Though there currently exists many definitions of maintenance, Kazdin offers what is thought to be a more accurate definition of this concept. According to Kazdin (2001), maintenance is defined as “whether behavior change is maintained after a program has been terminated or a person leaves treatment” (p.370). In this view, maintenance can only begin once all contact with a program is terminated. Consequently, all other contact prior to the last treatment contact would be defined as compliance rather than maintenance. Therefore, while many current treatments discuss post-treatment

maintenance programs and intervention, it would be argued that these merely show the impact of extended treatment rather than maintenance. Given this definition of maintenance, few studies currently examine maintenance as a process independent of interventionist contact.

### **Promoting Behavior Maintenance**

Based on this definition, Kazdin then described nine techniques that could be implemented during the intervention to aid in the transfer of training and generalization of the behaviors to new situations.

The first technique that should be implemented involves bringing the behavior under control of the natural contingencies. That is, individuals who perform the behavior in their natural (ordinary) environment will automatically have reinforcing and punishing consequences that may be adequate enough to maintain the behavior once it has been well established. It is suggested that these behaviors can either be initiated in, or transferred to, the natural environment with similar success in “trapping” the behavior into their everyday routine. The key to successful transfer is that the individual performs the behavior in his/her natural environment successfully prior to the end of treatment. Unfortunately, this technique alone infrequently leads to successful maintenance. As such, further techniques are likely involved and should be used in tandem with the natural environment training (Kazdin, 2001).

The second technique also relates to a focus on the natural environment. This technique involves programming naturally occurring reinforcers by focusing on targeting others in the natural environment and teaching them to provide reinforcers for appropriate behaviors. Specifically, individuals in the participant’s natural environment should be identified and then systematically trained to help promote the continuation of the behavior once the treatment program ends. Some examples of programming natural reinforcers include having family or friends provide verbal praise or tangible rewards for engaging in the goal/intended behavior. The key to successful transfer is directly intervening with the family to put the contingency program in place prior to the end of treatment (Kazdin, 2001).

The next three techniques, aimed at improving behavior maintenance and transfer of training, involve gradually removing or fading the contingencies. The first of the three

techniques involve making consequences increasingly intermittent over time. Specific to an activity program, it is suggested that, once the behavior is at the desired level, reinforcers (e.g. praise, rewards) become more infrequent over time prior to the end of the program. The second of these techniques involves delaying reinforcement. Specifically, after behavior is at the desired level, a higher number of successful behaviors are required before reinforcement is given. The third of the techniques involves the use of progressive stages, where contact is systematically decreased at each stage based on performance. Individuals would not move to the next stage until they can successfully complete the behaviors at a higher level of interaction. The assumption underlying all three techniques is that loss of behavioral gains following an intervention program may result from abruptly withdrawing the reinforcing (and punishing) consequences. Therefore, as individuals progress through the stages of the program based on performance, contact is simultaneously decreased in order to gradually decrease the reliance on contact as a reinforcer (Kazdin, 2001).

The next three techniques focus on expanding stimulus control. One technique involves training the general case through a four-step process. These steps include: 1] specifying the set of situations across which the behavior should be performed after the training program has ended; 2] defining the characteristics that might vary in these situations; 3] determining a range of responses to all possible outlined situations; and 4] selecting and teaching examples that sample from all the different situations (Kazdin, 2001). With this technique individuals, for example, identify several possible scenarios that they may encounter in trying to maintain an activity program, create a list of possible solutions, then exercise in some of the identified situations in order to determine the most effective strategies for maintenance prior to the end of treatment. The second technique for training the general case involves the use of peer facilitators. For this technique, interventionists involve people associated with those to whom the intervention is targeted (e.g. classmates, peers, co-workers) to help deliver the intervention, given their potential increased contact with individuals across various situations. It is suggested that the more exposure individuals have with people performing the behavior, across different situations, the more likely it is that the behavior will be performed (Kazdin, 2001). The last technique promotes the use of self-control procedures. Specifically, the individual is

asked to self-monitor his/her own behaviors, learn how to provide self-reinforcement when activity goals are achieved, and assess his or her own performance thereby not relying on others for feedback. These strategies have been used to achieve transfer of training across situations (Ninness, Fuerst, Rutherford, & Glenn, 1991).

The final technique suggests extending the duration of intervention. An approximate range of time should be at least several months to a few years in order for an intervention to have enough time to potentially impact long-term behavior following the intervention. However, it is believed that it is the combination of maintenance strategies encompassed in a longer duration study, rather than the duration of the intervention itself, leads to long-term maintenance (Kazdin, 2001).

Taken together, Kazdin's transfer of training model incorporates several different strategies aimed at improving long-term maintenance of behavior following termination from a treatment program. Therefore, from the beginning of the treatment program, maintenance of behavior is the goal. In addition, as discussed earlier, it is believed that the outlined combination of elements, rather than extending the duration of treatment, is critical to maintenance of behavior. However, it is important to note that one of the major assumptions of the transfer of training model is that the targeted behaviors for maintenance must be realistic in nature, in that it can be assumed that these behaviors can be reasonably and reliably performed both initially and long-term. Logically then, it could be argued that behaviors that are more likely to be initially adopted would be easier to transition compared to more difficult, time-consuming, and unachievable behaviors, which expected/anticipated during a treatment intervention program. However, to our knowledge, this theory-based intervention framework has rarely, if ever, been fully implemented in an obesity management program.

## **OVERVIEW OF THE CURRENT STUDY**

Based on extant literature, the purpose of the present study is to evaluate the effectiveness of a maintenance-oriented weight management program that incorporates several lifestyle changes for producing short-and-long-term beneficial health outcomes. Specifically, the present investigation developed a multi-faceted lifestyle change program, called Behavioral Choice Treatment, utilizing several realistic behaviors that

could be maintained using the transfer of training maintenance framework. Based on the assumption of the transfer of training model that behaviors must be realistic and reasonable, the following treatment variables were chosen as components of the program: 1] high intensity, short-duration strength and aerobic training; 2] promoting regular lifestyle physical activity; 3] nutritional counseling utilizing the new healthy pyramid; and 4] a non-dieting cognitive-behavioral change approach using Sbrocco's behavioral choice treatment. Subsequently, all treatment components were implemented within Kazdin's stage-based intervention approach in order to improve the potential for successful behavioral maintenance (including a 3-stage decreased contact over time approach, direct environmental training, and intervening with family and friends). The primary outcome measures will include weight and intra-abdominal fat, cardiovascular fitness, and physical activity as they have been identified as ideal objective measurements for a weight management program. However, due to the accumulation of several innovative treatment components, in addition to other variables that are of interest, secondary outcomes will include BMI, waist and hip circumference, total body fat, strength, total cholesterol, triglycerides, LDL, HDL, and resting systolic and diastolic blood pressure.

To our knowledge, no studies currently exist examining this particular set of treatment variables in combination with multiple health outcomes at post-test and follow-up, or in comparison to other weight loss treatment programs. Therefore, the study will attempt to identify the effectiveness of this innovative maintenance-oriented approach through a two-phase process:

### **Phase One**

The first phase of the study serves to determine the efficacy of the BCT program compared to a more educationally-based lifestyle change program utilizing the USDA food guide pyramid (USDA), coupled with the high intensity, short-duration strength and aerobic training center-based program and a waiting-list control group (WLC) on producing changes in multiple health outcomes at post treatment. In this phase, the following hypotheses are made:



- 1) Participants in both the BCT and USDA groups will show greater improvements in weight loss, intra-abdominal fat, aerobic fitness, and physical activity at post-treatment compared to the WLC group.
- 2) With the exception of fitness, it is expected that participants in the BCT will exhibit greater changes in weight, intra-abdominal fat, and physical activity compared to the USDA group at post-treatment.

### **Phase Two**

Following completion of the first treatment phase of the study, the second phase of the study examines the impact of different treatment interventions on participants' abilities to maintain their multiple health benefits following a non-intervention period of time. Specifically, we are interested in examining the ability of the BCT to promote behavior maintenance 12 weeks following completion of a treatment program. Therefore, participants in the USDA and BCT groups will not be contacted for a period of three months prior to coming back for follow-up testing. However, due to the complexity of the BCT treatment, it would be impossible to identify what, if any, treatment component was responsible for either good or poor behavior maintenance. As such, the second phase of the study will serve to determine whether the addition of the maintenance-oriented programmatic outline results in any greater changes in the primary outcomes at either post treatment or follow-up over and above the other treatment variables incorporated in the innovative weight management program. In order to achieve this goal, participants from the WLC group will be immediately transitioned into a treatment program following post-test assessment. The treatment program will incorporate the same components as the BCT treatment group with the exception of the transfer of training maintenance program outlined by Kazdin. Following completion the BCT treatment program (12 weeks), these individuals would also not be contacted for a period of three months before coming back for their follow-up testing. Therefore, for phase II the following hypotheses are made:

- 1) With the exception of fitness, it is hypothesized that participants in both BCT treatment groups will exhibit great initial outcomes in weight loss, intra-abdominal fat, and physical activity (although BCT w/o maintenance will exhibit relatively smaller changes due to the decreased intervention time)

compared to the USDA group and will exhibit greater maintenance at three-month follow-up.

- 2) With the exception of physical activity, participants in the BCT group will exhibit greater maintenance on all primary measures compared to participants in the BCT without maintenance group at three-month follow-up.

## CHAPTER II

### METHODS

#### **Participant Recruitment**

Newspaper articles (See Appendix A) and a radio interview featuring the ‘VTactive4life’ study were used to recruit one cohort of adults. Inclusion criteria for the study included: 1] males (ages 27-45) and females (ages 27-55); who were 2] either overweight or obese based on a body mass index (BMI) in excess of 25 kg/m<sup>2</sup>; and 3] maintaining a sedentary lifestyle (<30 minutes of moderate to vigorous exercise per week). Participants were excluded for the following reasons: 1] presence of any cardiovascular, thyroid, or metabolic disease; 2] were taking medications that would affect their body weight, other metabolic parameters, or both; 3] did not have active health insurance; 4] were pregnant within the last 3 months, currently pregnant, or planned on becoming pregnant in the next 10 months; and 5] presence of any other physical or psychological condition perceived by an individual as limiting his or her ability to participate fully in the program.

All participants were initially screened via a website that provided information about the study, including study criteria and requirements of study participants (see Appendix B). Individuals with continued interest were instructed to complete an on-line screening form (see Appendix C) to evaluate their appropriateness for participating in the program. Following submission of the screening form, participants’ responses were examined, and eligibility was determined through an automated screening algorithm developed within the website. Participants (and staff members) were immediately informed as to the individual’s study eligibility. Individuals without computer access were instructed to contact the study center directly and completed the eligibility survey with a staff member on the telephone. Individuals completing the telephone survey were also informed immediately of their eligibility status.

Individuals determined eligible were contacted by telephone and scheduled for an initial individual orientation session. During the orientation session, participants met with either the principal investigator or the project director and received a detailed explanation of the study procedures and purpose. Special attention was paid to the issue of group randomization and the demands on participants with regard to the intervention and

assessments. Individuals agreeing to the study requirements then provided written informed consent (see appendix D). Following completion of the consent form, participants' had their height and weight measured to confirm their BMI, had blood pressure taken to screen for hypertension  $\geq 160/100$  mmHg, and were scheduled for three subsequent assessment visits to verify their eligibility for participation in the study. The institutional review board at Virginia Polytechnic and State University approved the informed consent and all procedures for the present study.

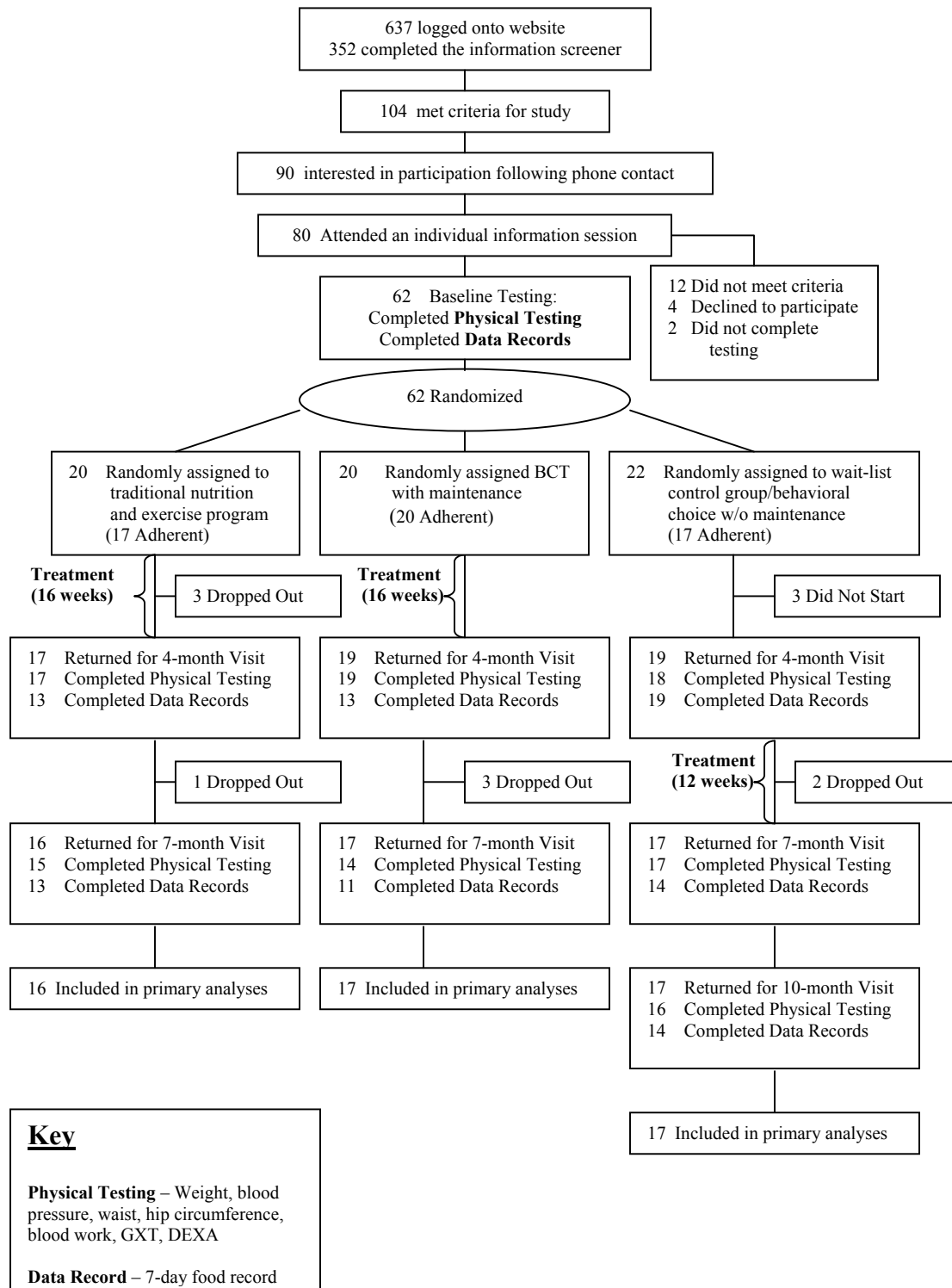
### **Randomization**

As shown in Figure 1, of the 637 people that logged onto the website, 352 people completed the on-line screening form, and 104 passed the initial screening criteria. There were 90 people interested in scheduling an appointment following telephone contact and 80 people attended the individual information session. Following a full outline of the study, 4 people declined participation (due to the randomization), 12 did not meet criteria based on the initial screening at the consent meeting, and 2 people did not complete the three assessments to confirm eligibility. Therefore, 62 participants were randomized to one of three treatment conditions: 1] A traditional center-based exercise program with a weekly psychoeducational program focused on nutrition and physical activity changes based on the United States Department of Agriculture program (USDA,  $n = 20$ ), 2] a comprehensive treatment program incorporating a center-based exercise program, a theory-based treatment program focused on nutrition and physical activity changes called behavioral choice treatment, and a theory-based programmatic framework designed to improve-maintenance (BCT with maintenance,  $n = 20$ ), or 3] a delayed treatment group, which following a waiting period of 16 weeks, received BCT without the maintenance-oriented framework (WLC/BCT without maintenance,  $n = 22$ ). Randomization was stratified by BMI ( $<30.0$  vs.  $>30.0$ ) and sex (male vs. female) to ensure equal numbers of heavier and lighter men and women in each treatment group.

Overall, 85% of the study sample that began the trial was retained from baseline to follow-up. Outcome data are presented only for participants remaining in the study who completed at least one assessment appointment for treatment baseline, post, and follow-up testing ( $N = 50$ ). A series of ANOVAs showed no that there was no difference between those who completed versus those who dropped out of the study on any

demographic or pre-treatment variables. Therefore, it can be assumed that the final sample of the participants was fairly representative of the entire randomized sample.

Figure 1. Recruitment of participants into the VTactive4Life study.



## **Measures**

Participants completed a demographic and medical history questionnaire at the time of recruitment. A comprehensive assessment protocol including anthropometric measures, body composition and biochemical analyses, cardiorespiratory fitness, strength as well as nutrition and physical activity logs was completed over 3 separate assessment days each testing period. The assessment protocol was completed at baseline, week 16, week 28, and again at week 40 for the WLC/BCT without maintenance treatment group. The outcome variables utilized in the present study are outlined below.

*Anthropometrics and Body Composition.* Total body weight, BMI ( $\text{kg}/\text{m}^2$ ), waist and hip circumference (cm), total body fat (%), and intra-abdominal fat (%) were utilized as dependent measures. A doctoral trained nutritionist blind to treatment condition performed all body composition and biochemical assessments with the exception of waist and hip measurements. An undergraduate interventionist not blind to treatment condition completed the waist and hip assessments. Weight (without shoes) was measured to the nearest .2 pound using a calibrated balance-beam scale. Height (without shoes) was measured to the nearest 1 centimeter using a calibrated stadiometer upright. Waist and hip measurements were taken to the nearest .2 cm using a gulick tape measure. Body composition was assessed via a dual energy X-ray absorptiometry (DXA) scanner (Hologic, QDR 1500, Hologic Inc, Waltham, Mass). With the participant lying supine on the examination table, a scan of the body was performed. This procedure took approximately 5 minutes to complete. The DXA scan has been determined to be a valid and reliable method of obtaining body fat and bone density measurements of the body (Deurenberg et al, 2001; Lukaski, Marchello, Hall, Scafer & Siders, 1999; Maddalozzo, Cardinal & Snow, 2002; Tsui, Gao & Zinman, 1998).

*Blood Lipid Analyses.* Total plasma cholesterol (TC; mg/dl), High Density Lipoprotein Cholesterol (HDL-C: mg/dl), Triglycerides (mg/dL), and glucose (mg/dL) were utilized as outcome measures. A phlebotomist blind to treatment condition completed all of the blood draws. Participants abstained from all food and drink except water for at least 12-hours and from vigorous activity for at least 12-hours prior to the blood draw. Blood (10ml) was drawn from a superficial forearm vein for the measurement of TC, HDL-C, LDL-C, Triglycerides, and fasting glucose concentrations.

Blood samples were centrifuged at 2500 x g for 15 minutes. Plasma was stored at -80 degrees and assayed once all measurements for each assessment period were collected (i.e., assays were run at 4 time points). Plasma levels of TC, HDL-C, and Triglycerides were measured using calorimetric assays. The LDL-C (mg/dl) was calculated using the formula:  $LDL-C = TC - [HDL-C - (triglycerides/ 5)]$ . Glucose was measured with a Beckman Glucose Analyzer.

*Cardiorespiratory Fitness.* Predicted maximal oxygen consumption ( $VO_2max$ ) (L/min); resting systolic blood pressure, and resting diastolic blood pressure were assessed for the dependent measures. Certified exercise physiologists (master's level and doctoral level graduate students in exercise physiology) blind to treatment condition completed all cardiorespiratory fitness tests. Heart rate and rhythm were assessed using a 12-lead electrocardiogram, blood pressure was assessed using a standard mercury sphygmomanometer and stethoscope, and  $VO_2$  was assessed using an automated gas analyzer (MedGraphics®, CPX-D, Minneapolis, MN). All measures were taken at rest, continuously monitored during the exercise test, and again following test completion in order to ensure maximum safety. Prior to the start of the exercise test, a calculation for test termination was determined for each individual based on 80% of his or her age-predicted maximum heart rate  $[(220-age)*.8]$ . A linear relationship exists between heart rate and  $VO_2$  in overweight adults (Jakicic, Donnelly, Prink, Jawa, & Jacobson, 1995). Therefore, linear regression incorporating the heart rate and  $VO_2$  collected at each minute of exercise and at the point of termination was used to assess the relationship between heart rate and  $VO_2$  for the prediction of absolute peak  $VO_2$  (ml/kg/min). This method of prediction has been previously used and deemed appropriate for interpretation (Jackicic, Winters, Lang, & Wing, 1999; Winett et al, in press). However, given that the present study was specifically aimed at examining the effects of weight loss (change in kg) on fitness, we determined that examining cardiorespiratory fitness independent of weight change (L/min) was the most appropriate approach.

A submaximal graded exercise test (SGXT) was completed on a Monarch cycle ergometer. Initial work rate was 30W (women) and 40W (men) of resistance at a cycling rate of 60 revolutions per minute (RPM) and increased by the same workload at 3-minute intervals until the subject achieved 80% of age-predicted maximal heart rate. The

exercise test was discontinued prior to achieving 80% of predicted heart rate max if any of the following occurred: 1] angina (chest pain); 2] lightheadedness; 3] a drop in systolic blood pressure of greater than 4 mm Hg; 4] excessive rise in systolic blood pressure to more than 250 mm Hg; 5] excessive rise in diastolic blood pressure to more than 120 mm Hg; or 6] more than 4-mm down-sloped depression on any of the electrocardiogram leads. The tests of two participants were terminated early due to a down-sloping depression on the electrocardiogram leads. These individuals were referred to their family physician and were asked to provide written medical clearance prior to continuing participation in the program. Both participants were subsequently cleared and were provided written authorization to participate in the study. Following completion of all tests, results were reviewed to determine if criteria for validity was met, including: 1] heart rate generally increased linearly with exercise time and load; and 2]  $\text{VO}_2$  measurements generally increased linearly with time and load. Two tests were deemed invalid due to non-increasing  $\text{VO}_2$  with heart rate increases. Therefore, these tests are not included in data analyses.

*Strength.* Total body strength [total pounds lifted/number of machines] was calculated and used as a dependent measure in the analyses. Trainers (two undergraduate exercise science students, one post-undergraduate nutritionist, one post-masters' health and exercise science student) completed all strength tests using eight air-powered Keiser resistance exercise machines (Keiser Corp., Fresno, CA). Participants were asked to complete 1 set of 6 repetitions on 8 different strength-training machines designed to work all major muscle groups in the body. Participants received a verbal explanation from a personal trainer concerning the proper operation of each machine which included: leg press, leg extension, leg curl, chest press, seated row, military press, seated curl, and back extension. Participants were instructed specifically on how to complete the set of repetitions that included six, 12-second repetitions consisting of a 6-second duration for both the concentric and eccentric phase of the movement. After practicing the entire circuit of machines one time at a low level of resistance, participants completed a full strength test with the six-repetition maximum (6RM) on each machine at a determined weight based on participant's report of effort on the practice trial.



*Dietary and Physical Activity Assessment.* Total calories, total servings of fruits and vegetables, and average steps per day [steps taken each day for 7 days/7] were assessed. Interventionists (one post-undergraduate nutritionist and one post-masters' health and exercise science student) initiated the dietary and physical activity assessments using a 7-day food and physical activity record. For the dietary assessment, participants were instructed in how to measure quantities of food and were provided with a visual aid to facilitate reporting portion sizes prior to, and during, the 7-day dietary assessment. For the physical activity assessment, participants were instructed on how to use and were provided a pedometer to record the amount of steps taken throughout the day. The pedometer, also called a step counter, was placed on the waistband directly above the knee on the individual. Participants were asked to put on the pedometer first thing in the morning, wear it all day, and then record the number steps at the end of the day.

*Perceived Skills Questionnaire.* In order to evaluate the fidelity of the proposed treatment intervention program, we developed a self-report questionnaire. Specifically, a 21-item measure was developed intended to elicit differential responses based on group randomization. While all questions related to general health behaviors such as exercise and nutrition, questions were oriented towards specific topics outlined in the behavioral choice treatment such as emotional eating, lapses in exercise, social support, dealing with barriers, and the importance of regular goal setting (see Appendix E for the Perceived Skills Questionnaire). At the end of the treatment program, participants were asked to report their level of self-efficacy in doing each behavior on a 5-point likert scale ranging from 1 (Do not feel at all confident) to 5 (Completely confident). A total score was then computed on the 21 items to comprise an overall confidence rating ranging from 21 to 105.

*Counselor Evaluation Form.* In order to examine the participant's level of satisfaction with their interventionist in each group, a 10-item questionnaire was developed intended to have participants rate their counselor independent of the subject material (1 "strongly disagree" to 5 "strongly agree"). At the end of the treatment program, participants were asked to evaluate specific aspects of the leader's style, genuineness, knowledge, professionalism, and their interest in working with them in the future on a 5-point scale (see Appendix F). Two of the questions were reverse coded in

order to identify any individuals completing the questionnaire with no variance in response style. The two items were recoded, summed with the other 8-items and then divided by 10 in order to provide an overall mean score of the counselor's evaluation. The range of possible scores ranged from 1-5.

## **TREATMENT PROCEDURES**

The USDA and the BCT with maintenance treatment groups immediately started the 16-week intervention programs while the WLC group was asked to continue "life as usual" for the next 16 weeks. After the 16-week intervention period, all participants completed all assessments again. At this point, individuals in the wait-list control group began the BCT treatment w/o maintenance intervention protocol, while participants in the USDA and BCT with maintenance were not contacted for a period of 12 weeks. All participants returned for testing again at week 28. After the intervention, participants in the WLC/BCT without maintenance were not contacted for a period of 12-weeks at which time (week 40) they returned for the follow-up testing.

### **Common Treatment Components**

All participants received treatment components that were common across conditions. First, during the intervention phase of the program, participants were not weighed during the first month of the program. Participants receiving active treatment were weighed bi-weekly for the remainder of the program. Second, participants receiving active treatment completed the same strength and aerobic training protocol at the study center during the intervention period. Specifically, participants worked one-on-one with a personal trainer for each exercise session that included a 12-15 minute graded exercise protocol (GXP), a 15-20 minute strength training protocol, and a 5-minute stretching and flexibility component.

For the aerobic exercise portion, participants alternated between a treadmill and cycle ergometer. Each aerobic session encompassed a graded warm-up for approximately 3-5 minutes until the participant reached their target heart rate (THR). The THR range for each exercise session was determined individually by calculating the HR that correlated with the following intensities: 60% of predicted  $VO_2$ max for weeks 1 and 2, 65% of predicted  $VO_2$ max for week 3, and 70% predicted  $VO_2$ max from week 4 until the

end of the intervention program. Participants exercised for 3 steady-state minutes staying within two beats a minute of their target HR for the first 4 weeks, then moved up to staying within their THR range for 4 steady-state minutes for the remainder of program. A 3-minute cool-down followed the steady-state regimen, which is sufficient time for a recovery HR of 100 beats per minute (bpm). The GXP exercise protocol has been used elsewhere and shown to improve fitness even with this limited duration of exercise (Winett et al, in press).

For the resistance training portion of the exercise session, participants performed one set of repetitions which included 6, 12-second, repetitions consisting of a 6-second duration for both the concentric and eccentric phase of the movement. Resistance was increased 3-5% on each machine for the next training session after six repetitions were completed with the correct form and timing (72 seconds total for 6 repetitions), as well as participant's subjective report on how many additional repetitions they could complete. The longer duration repetition resistance training protocol using only one set of each exercises has been previously shown to be effective in increasing absolute strength across time (Winett & Carpinelli, 2001; Winett et al, in press). Each session was ended with six standard stretching exercises for flexibility to minimize stiffness associated with the aerobic and weight training. The total time for each strength and aerobic session was approximately 45 minutes.

### **USDA Group**

Participants randomized to the USDA group attended two center-based visits per week for 16 weeks. Participants were told that the purpose of the program was to promote positive lifestyle changes in physical activity and nutrition. The format for this treatment program was based on a traditional education-based nutrition and physical activity-counseling program augmented with 2 days of weekly center-based exercise. Each session, participants completed the strength and aerobic training program as outlined above.

One time per week (before or after the exercise session), participants met one-on-one with a nutritionist (post-undergraduate student) to receive a manualized treatment program 'Dietary Guidelines for Americans' related to nutrition and physical activity changes developed by the USDA and USDHHS ([www.health.gov/dietaryguidelines/](http://www.health.gov/dietaryguidelines/)). As

shown in Table 1, participants in the USDA group met for approximately 15-minutes to discuss topics related to fitness, building a healthy base of food knowledge, and making good food choices utilizing the USDA food guide pyramid. Each session, participants were provided handouts downloaded directly from their website for the content discussed during the meeting in order for the participant to have a reference of topics discussed. At week 8 of the intervention, participants were asked to complete a 7-day diet and physical activity record in order to provide feedback to participants with regard to their progress towards the physical activity and nutritional guidelines (in comparison to their baseline assessment food and activity record). For the remainder of the program, participants continued working through the USDA manualized program. Women in the program were encouraged not to eat more than 1600 kilocalories (kcal) per day and men were encouraged not to eat more than 2000 kcal per day consistent with the current USDA dietary guidelines. Across the 32 center-based sessions, participants received a total contact time of approximately 28 hours (i.e., nutrition and physical activity counseling 4 hours; Strength and aerobic training 24 hours).

Table 1. Weekly topics in the USDA dietary guidelines for Americans program.

<b>Week:</b>	<b>Session Objectives:</b>	<b>Other Interventions:</b>
1	Aim for a healthy weight	
2	Be physically active each day	
3	Let the pyramid guide your food choices	
4	Choose a variety of grains daily, especially whole grains	
5	Choose a variety of fruits and vegetables daily	
6	Keep food safe to eat	
7	Choose a diet that is low in saturated fat and cholesterol and moderate in total fat	
8	Choose beverages and foods to moderate your intake of sugars	Records
9	Choose and prepare foods with less salts	Feedback
10	Drink alcoholic beverages in moderation	
11	Aim for a healthy weight	
12	Be physically active each day	

### **BCT with Maintenance**

Participants randomized to the BCT with maintenance group received a comprehensive treatment program incorporating a center-based exercise program, a theory-based treatment program focused on nutrition and physical activity changes called

behavioral choice treatment, and a theory-based programmatic framework designed to improve-maintenance. Prior to a description of each treatment component, it is important to understand the format of the intervention program.

Participants received a 3-stage, combined center-based and home-based program for 16 weeks. The 1<sup>st</sup> stage of the program began with a 9-week phase where participants attended two center-based sessions per week. Each session during this stage consisted of participants completing the aerobic and strength protocol as outlined previously. In addition, once a week participants met one-on-one with a behaviorist (doctoral student in clinical health psychology with a master's degree in health and exercise science) to discuss cognitive and behavioral techniques associated with physical activity and nutritional changes outlined in the manualized 'Behavioral Choice Treatment' (see Appendix G).

Following completion of the 1<sup>st</sup> stage of the program, participants moved onto the 2<sup>nd</sup> stage of the program consisting of a 3-week transitional phase. Participants continued to meet at the center once a week to complete their aerobic and strength-training program, as well as to meet with the behaviorist to continue working on the lifestyle changes (i.e., physical activity and nutritional changes). However, for the 2<sup>nd</sup> session on two of the weeks, the behaviorist accompanied the participant to some identified location in the community (i.e., local gym, community center, home) where they were interested in continuing their strength and aerobic training program once they completed the treatment program. Participants were familiarized with available equipment and a program was demonstrated that would help them continue their strength and aerobic training program. It is important to note that participants were encouraged to identify different activities and exercises that would be 'most realistic' for them to maintain as a lifestyle habit. As such, participant's programs were tailored to provide maximum possibility for success given their abilities, preferences, and energy expenditure requirements. Also, during the third week of the transitional stage, the behaviorist conducted a social support intervention session with a person identified as important by the participant, discussing ways to continue to reinforce positive lifestyle changes.

Next, participants entered the 3<sup>rd</sup> and final stage of the program consisting of a 4-week tapering phase. Here participants attended only one center-based exercise session

every other week, for a total of 2 visits. In addition, at each center-based visit, participants met briefly with the behaviorist in order to complete the final two components of the BCT manual. Overall, as shown in Table 2, the BCT treatment program is a multi-faceted, stage-based program aimed to promote maintenance of lifestyle behavior change.

Table 2. Program outline, session objectives, and interventions in the BCT with maintenance program.

<b>Week:</b>	<b>Session Objectives:</b>	<b>Other Interventions:</b>
	<b><i>Phase 1: Center Based Program</i></b>	
1	Understanding the principles of the behavioral choice treatment program: Identifying Costs and Benefits of lifestyle change.	
2	Understanding the common patterns of eating and activity: Learning how to accurately monitor your food and activity patterns.	Feedback
2b	Learning how to set short-term, challenging, but achievable goals each week for your physical activity nutrition: One goal at a time.	
3	Tough choices for food: Why turning to the USDA food pyramid is a mistake. Introducing the New Healthy Pyramid from Harvard.	Records, feedback, & goal setting
4	Healthy weight: Daily activity is the key.	Records, feedback, & goal setting
5	Carbohydrates: For better or worse?	Records, feedback, & goal setting
6	Learning about the different types of fats: The importance of examining the quality, quantity and frequency of foods.	Records, feedback, & goal setting
7	Proteins: Choosing healthy sources.	Records, feedback, & goal setting
8	Calcium: The pros and cons.	Records, feedback, & goal setting
9	Finishing off the pyramid: Making your food choices reasonable.	Records, feedback, & goal setting
	<b><i>Phase 2: Transitioning the Program Home and Building Support</i></b>	
10	Understanding the importance of social support and how to get some. Assignment: building a new social support network.	Support intervention with family/friends;
11	Social Eating: Learning new skills to make better choices.	Environmental visit;
12	Environmental Cues: Barriers to change. Assignment: Developing strategies to overcome your barriers. Relapse Prevention.	Environmental visit;
	<b><i>Phase 3: Low Contact/Maintenance Training</i></b>	
13	NO MEETING	
14	Emotions and Eating. Assignment: Determine if you emotionally eat and develop strategies to deal with the situations.	Records, feedback, & goal setting
15	NO MEETING	
16	Reassessment and goal setting.	Records, feedback, & goal setting

The format for the BCT with maintenance program was unique in a number of ways. First, the BCT manual developed for the present study was adapted from

Sbrocco's (1999) 13-week behavioral choice group treatment protocol that is grounded in Decision Making Theory (Sbrocco, Lewis, 1995). Consistent with Sbrocco's treatment, participants in this group were instructed that they would be taught to stop "dieting" and to view eating as a choice. Further, participants were told that they could expect slower weight loss than they may have experienced in the past, but that this approach was designed to promote permanent change. Health behavior, including food choices, eating behavior, and exercise were discussed as choices designed to achieve certain outcomes (i.e., alleviate hunger, lose weight, feel better, and rest). Participants were challenged to no longer 'feel guilty' after eating certain foods or quantities. Rather, they were encouraged to look at it from a choice standpoint and short-versus-long-term consequences of making those choices with regard to the impact on future decisions. Cognitive restructuring was implemented when people employed "black or white" thinking about food choices, activity, and body image.

The present treatment differed from Sbrocco's treatment in several significant ways. First, instead of promoting one calorie goal for all participants, calorie goals were individualized based on each participant's resting energy expenditure (REE) utilizing the Harris Benedict Equation, total energy expenditure (activity level based on participants step counts at baseline), and total caloric intake at baseline. The equation varied by gender [Women REE =  $655.1 + 9.56 * W \text{ (kg)} + 1.85 * H \text{ (cm)} - 4.68 * \text{Age (yrs)}$ ; Men REE =  $66.5 + 13.75 * W \text{ (kg)} + 5.0 * H \text{ (cm)} - 6.78 * \text{Age (yrs)}$ ]. Therefore, women's calorie goals during the program ranged from approximately 1600-2000 while men's calorie goals were between 1900-2400 kcals a day.

Second, due to the recent conflict regarding the safety and validity of the USDA food guide pyramid for providing health benefits, we used the new healthy pyramid put forth by Walter Willet from Harvard University (Willet, 2001). Willett's pyramid recommends daily physical activity and weight control through a diet high in dietary fiber, fruits and vegetables, but low in saturated fat. However, participants were also encouraged to eat foods higher in unsaturated and monounsaturated fats.

Third, instead of a general recommendation to increase walking to 5-6 days a week, participants were encouraged to increase their daily activity throughout the program with the aid of a pedometer. Specifically, compared to their baseline physical

activity levels, participants were instructed to walk at least 500 more steps throughout the day (approximately 5 minutes per day), each week, for 6 weeks. Over the six-week period, the increase would result in approximately 3000 more steps per day (i.e., 30 minutes of physical activity per day) compared to their baseline level of activity. Participants were able to set goals above or below the outlined numbers each week based on individual level of motivation and ability. However, overall goal of the program was to increase physical activity by approximately 30 minutes per day by the end of the treatment program. In addition, it was deemed important that individuals gain a firm understanding of appropriate exercise intensity and strength training techniques at our center-based facility prior to transitioning to be a home-based program.

Fourth, rather than going from a structured weekly program to no regular contact, the present study used a 3-stage program. Varying the contact and type of contact was adapted from Kazdin's operant theory-based techniques oriented towards improving maintenance of behavior. The present study's format was consistent with Kazdin's recommendations hypothesized to improve maintenance incorporating decreased contact across time, intervening with family and friends to enlist support for maintenance of behavior, and training individuals in their own environment to promote transfer of the trained behavior (i.e., aerobic and strength training protocol).

Throughout the intervention program, participants set challenging, yet achievable, goals in relation to nutrition, physical activity, or cognitive-behavioral issues related to weight management. Participants kept detailed food and physical activity records and received weekly feedback on the quality, quantity, and frequency of their food intake to help guide their next set of choices. Across the 27 center-based and community sessions, participants received a total contact time of approximately 28 hours (i.e., BCT 6 hours; strength and aerobic training 19 hours; environmental training 2 hours; social support session; 1 hour).

### **WLC/BCT w/o Maintenance**

Participants randomized to the Delayed Treatment /BCT w/o maintenance group served as a wait list control group for the first 16 weeks of the study. Following completion of the assessments at week 16, participants received the behavioral choice treatment described above with one important exception. Based on the time and energy



involving in the stage-based component of the program developed by Kazdin, we were interested to see whether this component of the program had a significant impact on changes made during, and following a treatment program. Specifically, we wanted to identify if the addition of decreasing contact over time, transitioning participant's programs into their own environment, and directly intervening with family and/or friends, in addition to the BCT treatment, would impact treatment outcome or participant's abilities to maintain their benefits. Therefore, participants in the group received the BCT treatment with the exception of the 3-stage, transfer of training component. Participants attended 2 center-based visits each week for 12 weeks consisting of aerobic and strength training each session followed by meeting one-on-one with a behaviorist (post-undergraduate nutritionist trained to deliver the intervention; See Appendix H for manual). As shown in Table 3, in each meeting, together with the behaviorist, participants completed all of the modules that were given to the BCT with maintenance group. However, some modules had to be combined in order to complete the entire treatment in 12 weeks. Similar to the BCT group, participants also completed weekly food and physical activity records utilizing a pedometer, used the new healthy pyramid for their dietary recommendations, and had individualized calorie goals based on the method outlined above.

Table 3. Weekly topics in the behavioral choice treatment w/o maintenance program.

<b>Week:</b>	<b>Session Objectives:</b>	<b>Other Interventions:</b>
1	Understanding the principles of the behavioral choice treatment program: Identifying costs and benefits of lifestyle change. Understanding the common patterns of eating and activity: Learning how to accurately monitor your food and activity patterns.	
2	Learning how to set short term, challenging, but achievable goals each week for your physical activity nutrition: One goal at a time. Healthy weight: Daily activity is the key.	Records & feedback
3	Tough choices for food: Why turning to the USDA food pyramid is a mistake. Introducing the New Healthy Pyramid from Harvard. Carbohydrates: For better or worse?	Records, feedback, & goal setting
4	Learning about the different types of fats: The importance of examining the quality, quantity, and frequency of foods.	Records, feedback, & goal setting
5	Proteins: Choosing healthy sources.	Records, feedback, & goal setting
6	Calcium: The pros and cons.	Records, feedback, & goal setting
7	Finishing off the pyramid: Making your food choices reasonable.	Records, feedback, & goal setting
8	Understanding the importance of social support and how to get some. Assignment: Building a new social support network.	Records, feedback, & goal setting
9	Social & emotional eating: Learning new skills to make better choices. Assignment: Determine if you emotionally eat and develop strategies to deal with the situations.	Records, feedback, & goal setting
10	Environmental cues: Barriers to change. Assignment: Developing strategies to overcome your barriers.	Records & feedback
11	Preventing relapse & resources for help.	
12	Reassessment and goal setting.	Records, feedback, & goal setting

Across the 24 center-based visits, participants received a total contact time of approximately 24 hours (i.e., BCT 6 hours; strength and aerobic training 18 hours).

### **FOLLOW-UP**

Following completion of the USDA, BCT with maintenance and the BCT w/o maintenance intervention programs, none of the participants were contacted for the next 12 weeks prior to their follow-up assessment appointments. This was done specifically to examine how well participants in the three groups maintained their changes without any additional intervention.

## STATISTICAL ANALYSES

All data were analyzed using SPSS version 11.0 software (SPSS Inc, Chicago, Ill). Prior to analyzing the outcome data, the baseline data, assessment of sample representation, and manipulation checks were completed using one-way ANOVA's to examine group differences. Based on the literature identifying major risk factors for disease associated with obesity, body weight, intra-abdominal fat, cardiorespiratory fitness, and physical activity were examined as the primary outcomes of interest. However, due to the multi-component nature of the present study, secondary outcomes, including BMI, total body fat, waist and hip circumference, triglycerides, HDL, LDL, total cholesterol, resting systolic and diastolic blood pressure, and strength, were also examined. The low adherence rate for returned and accurately completed nutrition records precluded the use of these as dependent measures. However, the general nutritional information is used to describe the demographics of the present sample.

For all outcome variables, a series of repeated measures ANOVA's was performed with experimental condition (USDA, BCT, and WLC/BCT w/o maintenance) as the between-subjects variable and time as the within subjects variable. This approach to statistical analysis was selected over a MANOVA because multiple ANOVA's are more appropriate when investigating how a treatment variable affects each of the outcome variables rather than a linear composite of the outcome variables (Huberty & Morris, 1989). In addition, no covariates were used in the present analyses due to the lack of statistical differences on any baseline measures.

For Phase I analyses, 3 x 2 (group x time) repeated measures ANOVA's will be used to compare BCT with maintenance and USDA to WLC from baseline to post-test. For phase II analyses 3 x 3 (group x time) repeated measures ANOVA's will be used to compare BCT with maintenance and BCT without maintenance to USDA at baseline, posttest, and follow-up. Post-hoc analyses involving significant between group differences were examined through a one-way ANOVA. Post-hoc analyses involving significant within group differences were examined through paired-t tests. Results are reported as means (*M*) and standard deviations (*SD*).

## CHAPTER III

### RESULTS

#### Participant Characteristics

As shown in Table 4, the study population ( $N = 50$ ) consisted of mostly middle-aged, moderately educated, Caucasian (94%) men and women. Sixty-four percent of the participants were female. A series of ANOVAs showed that participants in the three conditions (USDA, BCT, and WLC/BCT w/o maintenance) did not differ significantly on any demographic or outcome measures at baseline. In order to assess any potential differences between participants' data from Phase I to Phase II, a series of ANOVAs were conducted for the treatment baseline data of Phase II. Results showed that, with the exception of physical activity,  $F(2, 43) = 3.24, p < .05$ , there were no significant differences between the three treatment groups on any demographic or outcome variables. Post-hoc analysis showed that participants in the BCT w/o maintenance group had significantly higher step counts ( $M = 7243.78, SD = 2332.23$ ) compared to the USDA group at baseline ( $M = 5286.75, SD = 1881.19$ ),  $p < .01$ . This difference was most likely due to the change in season (winter to spring) rather than a deliberate change in activity.