OUTCOMES OF BEHAVIORAL WEIGHT LOSS TREATMENT: A COMPARISON OF MIDDLE-AGED AND OLDER ADULTS

By

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Controversy exists regarding whether weight loss treatment is advisable for older obese adults. Epidemiological studies have found that weight loss in elderly individuals is associated with adverse health outcomes. However, weight loss may be a consequence, not a cause, of disease and declining health. Further, much research substantiates the numerous positive health outcomes resulting from weight loss in obese individuals, though research on older populations is lacking. Thus, we sought to examine the response of elderly, obese women to a lifestyle treatment for weight loss and to compare outcomes to those of a group of middle-aged women.

All participants completed a 6-month lifestyle intervention for weight loss followed by 1 year of extended care. Results indicated that elderly women lost equivalent amounts of weight as compared to middle-aged women ($M = 9.5\%$, $SD = 5.5\%$ and $M = 10\%$, $SD = 5.8\%$, respectively) at 6 months. Additionally, elderly women experienced significant improvements in blood pressure, glycemic control, and inflammation. The proportion of older women reporting a musculoskeletal adverse event during active treatment ($23\%$) was neither significantly different than, nor equivalent to, the proportion of middle-aged women reporting an injury ($18\%$). Additional studies are needed to evaluate potential negative outcomes of weight loss treatment in older adults.
CHAPTER 1
INTRODUCTION

Obesity is associated with numerous health problems including diabetes, hypertension, dyslipidemia, osteoarthritis (Must et al., 1999), and all-cause mortality (Manson et al., 1995). Additionally, the prevalence and severity of many obesity-related health conditions and metabolic risk factors increases with age (Villareal, Apovian, Kushner, & Klein, 2005). However, excess weight in elderly persons (65 years and older) may also protect against bone loss, osteoporosis, and hip fracture (Felson, Zhang, Hannan, & Anderson, 1993; Rossner, 2001). Further, several epidemiological studies have demonstrated that weight loss in older adults is related to increased mortality, disability, functional limitation and institutionalization (Thomas, 2005; Wallace & Schwartz, 2002). These studies, however, have typically failed to control for a number of confounding variables such as weight status prior to weight loss, intentionality of weight loss, underlying disease or pathology, and smoking status. Thus, at present, it remains unclear whether intentional weight loss in older, obese adults can produce significant improvements in health, and whether these benefits outweigh potential risks of weight loss treatment.

For obese middle-aged and young adults, the benefits of behavioral weight loss treatment generally outweigh potential risks. Lifestyle interventions are typically recommended as the first line of treatment due to their minimal risk and the significant improvements in health that even moderate weight losses can produce (Wadden & Osei, 2002). However, it is largely unknown whether obese, older adults experience a similar profile of positive and negative effects from behavioral weight loss interventions, as the majority of research has been conducted using younger and middle-aged adults (Villareal et al., 2005). At present, few studies have examined the effects of behavioral weight loss treatment in older adults (Rossner, 2001; Zamboni, Mazzali,
Zoico, & Harris, 2005), both in terms of potential improvements in health parameters as well as adverse events. Thus, the current study examines both the beneficial and adverse consequences of weight loss treatment in older adults and whether these effects are comparable to those experienced by middle-aged adults.

**Obesity**

**Prevalence**

According to reports from the National Health and Nutrition Examination Survey (NHANES), the prevalence of obesity in the United States had increased at an alarming rate over the past several decades, from 13.4% in 1960–1962 to 30.9% in 1999–2000 (Flegal, Carroll, Kuczmarski, & Johnson, 1998). Current estimates from the most recent NHANES data suggest that overall, 32.2% of adults in the United States are obese (Ogden et al., 2006). While the obesity epidemic has impacted virtually all segments of the population, certain sub-groups are disproportionately affected. Women, ethnic and racial minorities, those of low socio-economic status, and those who live in rural counties all display higher rates of obesity than the overall population (Flegal, Carroll, Ogden, & Johnson, 2002; Hedley et al., 2004; Sobal, Troiano, & Frongillo, 1996).

Prevalence of obesity also differs by age. Data from the 2003–2004 NHANES suggest that obesity is less prevalent among younger adults (age 20 to 39) than in middle aged adults (40 to 59 years) or adults 60 and older. While 28.5% of younger adults were obese, 36.8% of middle-aged adults and 31.0% of adults over 60 were obese (Ogden et al., 2006). Women between 40 and 59 years of age were nearly three times more likely to be obese than women 20 to 39 years of age (OR: 2.95, 95% CI: 2.55–3.42), as were women between 60 and 79 (OR: 2.95, 95% CI: 2.57–3.39). However, women 80 years and above were not at greater risk for obesity than women under 40 (OR: 1.20, 95%CI 0.93–1.56; Ogden et al., 2006). These data suggests that
although the highest rates of obesity are seen among middle-aged adults, obesity is a significant problem among older adults as well, affecting nearly one-third of individuals over 60 years of age. Nonetheless, the bulk of research related to obesity and weight loss has typically excluded persons over 65 years of age.

**Aging Trends**

Although the NHANES data are cross-sectional and therefore not indicative of age-related weight change, several large longitudinal studies have described a fairly robust pattern of weight gain over time. Epidemiological studies indicate that body weight and body mass index (BMI) tends to increase gradually throughout adult life, peaking between 50 and 59 years of age and remaining stable or declining slightly after age 60 (Grinker, Tucker, Vokonas, & Rush, 1995). Other data from longitudinal studies suggest that mean body weight remains relatively stable after age 60 (Fogelhorn, Kujala, Kapiro, & Sarna, 2000; Grinker et al., 1995; Rissanen, Heliovaara, & Aromaa, 1988). However, cohort effects and premature mortality in obese younger and middle-aged adults might lead to a general underestimate of mean BMI for the population of older adults.

Although weight may remain stable or even decline slightly after age 60, body composition changes continually with age. There is a considerable reduction in lean body mass and an increase in fat mass after age 20 (Beaufrere & Morio, 2000). After age 30, lean body mass decreases by approximately 0.3 kg per year (Baumgartner, Heymsfield, & Roche, 1995). Additionally, there is a relative increase in intra-abdominal fat with age, which is associated with increased risk of insulin resistance and metabolic diseases (Beaufrere & Morio, 2000). Thus, weight stability in old age may mask substantive changes in body composition. These changes in body composition, specifically an increase in intra-abdominal fat and a reduction in lean body mass.
mass, may place older adults at greater risk for metabolic disorders as well as injury and functional decline.

**Associated Comorbidities and Risk Factors**

Evidence supporting the link between obesity and increased morbidity and mortality continues to accrue. Obesity correlates with a heightened risk of several diseases and health conditions such as hypertension (Brown et al., 2000; Mokdad et al., 2003), dyslipidemia (Brown et al., 2000), type 2 diabetes (Colditz, Willet, Rotnitsky, & Manson, 1995; National Task Force on the Prevention and Treatment of Obesity, 2000), coronary heart or cardiovascular disease (Gregg et al., 2005; Manson et al., 1990), stroke (Cooper et al., 2000), osteoarthritis (Hart & Spector, 1993), sleep apnea and other respiratory problems (Vgontzas et al., 1994), as well as endometrial, breast, prostate, pancreatic and colon cancers (Dumitrescu & Cotarla, 2005; Freedland & Aronson, 2005; Garfinkel, 1985; Lowenfels, Sullivan, Fiorianti, & Maisonnueve, 2005).

**Associated Risk Factors and Comorbidities over the Lifespan**

The prevalence of most obesity-related comorbidities and metabolic risk factors (e.g., hypertension, diabetes, cardiovascular disease, osteoarthritis) increases with age (Villareal, Banks, Siener, Sinacore, & Klein, 2004; Villareal et al., 2005; Klein et al., 2004). Nearly 90% of men and women over 50 years of age will develop hypertension at some point in their lifetime (Vasan et al., 2002). The odds for developing the Metabolic Syndrome, a constellation of weight-related risk factors including excess abdominal fat, insulin-resistance, dyslipidemia and hypertension, are 4.9 and 5.8 times higher for women and men over 65 years of age, respectively, as compared to young adults (Park et al., 2003). Fasting blood glucose increases with age, by approximately one to two mg/dL each decade (Kahn, Schwartz, Porte, & Abrass, 1991). Higher incidences of type 2 diabetes and glucose intolerance have historically been
attributed solely to aging, but are likely compounded by a greater degree of abdominal obesity and physical inactivity in older adults (Villareal et al., 2005). Obesity has been implicated in the pathogenesis of arthritis, the leading cause of physical disability in older adults (Villareal et al., 2005). By age 65, over two-thirds of women suffer from osteoarthritis, as well as 58% of men (Cicuttini & Spector, 1995). Obesity in older adults is also etiologically related to urinary incontinence (Mommsen & Foldspang, 1994) and cataracts (Glynn, Christen, Manson, Bernheimer, & Hennekens, 1995).

The link between obesity and related diseases and risk factors is not wholly consistent across the lifespan. Longitudinal studies have found that obesity is related to heightened risk of coronary heart disease, fatal and nonfatal myocardial infarction, and cardiovascular disease mortality in older men, but not older women (Dey & Lissner, 2003; Stevens et al., 1998). Additionally, obesity has been implicated as a protective factor against bone loss in older adults (Rossner, 2001), as well as contributing to reduced risk of osteoporosis and hip fracture (Felson et al., 1993).

In sum, the constellation of weight-related diseases and risk factors is more severe in older adults, suggesting that they may be in great need of weight loss treatment to ameliorate some of these negative health risks. However, excess weight in older adults has been linked to certain positive health benefits such as reduced bone loss and risk of hip fractures. Thus, additional research is needed to determine whether the benefits of weight loss treatment outweigh potential risks in older adults.

**Psychosocial Consequences of Obesity**

Obese individuals report higher levels of depression, anxiety and lower quality-of-life than their normal weight counterparts (Fontaine & Barofsky, 2001; Wadden, Womble, Stunkard, & Anderson, 2002). Aging is related to a decline in physical functioning, largely due to reduced
muscle mass and increased joint disease and arthritis (Ensrud et al., 1994; Jordan et al., 1996). Obesity appears to exacerbate this age-related decline in physical functioning, and has been implicated as a cause of frailty in older adults (Blaum, Xue, Michelon, Semba, & Fried, 2005). Additionally, obesity has been associated with significant impairment in health-related quality of life in older individuals (Villareal et al., 2004).

**Economic Consequences of Obesity**

Obesity and related comorbidities impose a substantial financial burden on the U.S., approximately 10% of the nation’s healthcare expenditures are related to obesity, representing nearly 80 billion dollars each year (Finkelstein, Fiebelkorn, & Wang, 2003; Thompson, Edelsberg, Colditz, Bird, & Oster, 1999). The costs associated with obesity rise with increasing BMI, and the relative rise in cost is substantially greater with age (Wee et al., 2005). In other words, aging compounds the relationship between health care costs and obesity, perhaps due to the greater severity and prevalence of weight-related health conditions with age. Adults over 65 years of age, though comprising only 15% of the population, account for more than one-third of all healthcare expenditures in the U.S. (Spillman & Lubitz, 2000). This number is expected to rise due to increased longevity and the growing number of elderly persons in the population (Spillman & Lubitz, 2000). The expanding prevalence of obesity in elderly populations could also exacerbate these rising healthcare costs. Whether weight loss treatment for older adults can provide a significant cost offset remains unknown.

**Obesity and Mortality**

Obesity is related to marked reductions in life expectancy (Fontaine, Redden, Wang, Westfall, & Allison, 2003). The number of excess annual deaths attributable to obesity range from 111,909 (Flegal, Graubard, Williamson, & Gail, 2005) to 414,000 (Mokdad, Marks, Stroup, & Gerberding, 2004). Although smoking has been found to be responsible for the greatest level
of mortality, accounting for 18.1% of total US deaths in 2000, poor diet and physical inactivity were responsible for 16.6% of deaths in 2000, and may soon overtake tobacco as the leading cause of death in the U.S. (Mokdad et al., 2004). Results from the Framingham Heart Study demonstrated that adults of normal weight lived six to seven years longer than adults who were obese at age 40 (Peeters et al., 2003). Further, reviews of data from the National Health and Nutrition Examination Surveys found that extreme obesity (BMI above 45 kg/m²) in individuals between 20 and 30 years of age was associated with a minimum of eight years of life lost for women and 13 years of life lost for men (Fontaine et al., 2003).

Epidemiological research suggests that mortality risk begins to increase with BMIs over 25 kg/m², and climbs precipitously with BMIs over 30 kg/m² (Troiano, Frongillo, Sobal, & Levitsky, 1996). For most age groups, the lowest risk of mortality occurs for individuals in the normal body weight range (20 to 24.9 kg/m²), with obese persons standing a 50% to 100% greater risk of all-cause mortality than their normal weight counterparts (Troiano et al., 1996). Underweight is also associated with greater mortality risk, creating a U or inverse J-shaped curve between BMI and mortality (Calle, Thun, Petrelli, Rodriguez, & Heath, 1999; World Health Organization, 1995).

**Obesity and mortality across the lifespan.** Although the relationship between body mass index and mortality is well established, some research suggests that the nature and strength of this relationship is not uniform across the lifespan. The relationship between high BMIs and mortality weakens over the lifespan (Stevens et al., 1998), such that BMIs in the overweight range are actually associated with the lowest risk of mortality in older adults (Durazo-Arvizu, McGee, Cooper, Liao, & Luke, 1998; Heiat, Vaccarino, & Krumholz, 2001). These epidemiological studies have often failed to control for confounding effects of smoking or
underlying disease pathology which could contribute to lower body weights in older adulthood (Losonczy et al., 1995). Additionally, a survival bias may play a role, whereby individuals sensitive to the negative health consequences of obesity may have died at younger ages, resulting in older age cohorts that are more resistant to obesity-related comorbidities (National Heart, Lung, and Blood Institute, 1998). Thus, at present, it remains unclear whether excess weight increases mortality risk in older adults, and subsequently, whether weight loss treatment should be recommended to older persons.

**Behavioral Weight Loss Treatment**

Behavioral or lifestyle weight loss treatments seek to modify eating and activity patterns through a variety of cognitive-behavioral strategies (Wadden, Crerand, & Brock, 2005). These strategies typically include self-monitoring through the use of daily food and activity records, setting calorie and activity goals (e.g., a deficit of 500–1000 kcal/day combined with 30 min/day of moderate physical activity), performance feedback, reinforcement, stimulus control, and cognitive restructuring (Wadden & Foster, 1992). Reviews of randomized trials demonstrate that lifestyle interventions, typically delivered in 15 to 24 weekly group sessions, produce an average weight loss of 8.5 kg (Jeffery et al., 2000; Perri & Fuller, 1995; Wadden et al., 2005), or approximately 5–10% of initial body weight, post-treatment (Perri & Corsica, 2002; Wilson, 1994; Wing, 2002). Reductions of this magnitude can have beneficial effects on a variety of weight-related health conditions and risk factors (National Heart, Lung, and Blood Institute, 1998).

**Weight Loss: Beneficial Health Outcomes**

**Hypertension**

Moderate weight losses of 5% to 10% of initial body weight have been shown to reduce blood pressure, even without concomitant dietary sodium reduction. Two long-term studies
demonstrated 21% to 34% reduction in risk of hypertension with only 4% to 5% weight losses among 30 to 54 year old men and women with high blood pressure (TOHP Collaborative Research Group, 1992; 1997). A recent meta-analysis of 25 randomized controlled trials reported that a mean weight loss of 5.1 kg produces reductions of 4.4 mm Hg and 3.6 mm Hg in systolic and diastolic blood pressure, respectively (Neter, Stam, Kok, Grobee, & Geleijnse, 2003). In addition, modest weight losses of 5% to 10% initial body weight are sufficient to reduce blood pressure to normal levels among obese individuals if the weight loss is maintained over the long term, even if participants remain significantly obese (Mertens & Van Gaal, 2000). Generally, low to moderate weight losses (5% to 10% initial body weight) have been effective in lowering blood pressure and reducing the risk of hypertension.

Among older populations (60 to 80 years), the treatment of hypertension results in substantial health benefits including the prevention of stroke, heart failure and other coronary events (MacMahon & Rodger, 1993). The Trial of Nonpharmacologic Interventions in the Elderly (Whelton et al., 1998) reported that participants assigned to the weight loss condition experienced a 30% reduction in combined incidence of hypertension, stroke, transient ischemic attack, congestive heart failure, and arrhythmia, but this effect was largely driven by reductions in hypertension risk. Presently, it is unclear whether the reductions in blood pressure and hypertension risk seen in older adults completing weight loss programs are comparable to those achieved by middle-aged or younger adults.

**Hyperlipidemia**

The effects of weight loss on lipid profile have been enumerated by a substantial body of research. A meta-analysis by Dattilo and Kris-Etherton (1992) indicated that a weight loss of only one kg decreases serum cholesterol values by 2.28 mg/dL, LDL cholesterol by 0.91 mg/dL, and triglycerides by 1.54 mg/dL. A weight loss of approximately ten pounds (4.5 kg) can reduce
LDL cholesterol by 5% to 10% (Fletcher et al., 2005). Additionally, the American Heart Association (AHA) recently suggested that lifestyle interventions encouraging diets low in saturated fat and cholesterol can lower LDL cholesterol by approximately 11% to 15% (Fletcher et al., 2005). In persons over 65 years of age, LDL-lowering therapies have been effective in reducing the risk of coronary heart disease, and therapeutic lifestyle changes are recommended as the first line of therapy for older individuals (National Cholesterol Education Program, 2001), though it is unclear whether older adults experience similar reductions in risk as compared to middle-aged or younger samples.

**Diabetes**

Several studies have documented improvements in diabetic risk after participation in behavioral weight loss treatment. A meta-analysis of randomized controlled trials of lifestyle interventions and type 2 diabetes risk found that the one-year incidence of diabetes was reduced by approximately 50% (RR 0.55, 95% CI 0.44–0.69) in participants receiving a lifestyle intervention as compared to control groups (Yamaoka & Tango, 2005). The Finnish Diabetes Prevention Study (Tuomilehto et al., 2001) randomized 522 middle-aged overweight, glucose impaired individuals to an intensive lifestyle intervention or control group. After a follow-up of approximately three years, the intervention group, who had lost an average of 4.7% initial body weight, had a 58% reduced risk of diabetes as compared to the control group. After a mean follow-up of seven years, there was a slightly reduced, but still significant relative risk reduction of 43% in the intervention group as compared to the control group (Lindstrom et al., 2006). The Diabetes Prevention Program (DPP), a randomized clinical trial of over 3200 obese men and women at high risk for developing type 2 diabetes, demonstrated a 58% reduced incidence of diabetes in individuals receiving an intensive lifestyle intervention for weight loss (Diabetes Prevention Program Research Group, 2002). Interestingly, intensive lifestyle intervention was
significantly more effective at reducing the incidence of diabetes with increasing age of participants (Diabetes Prevention Program Research Group, 2006). The incidence of diabetes per 100 person years was 6.3 in the young group (25–44 years), 4.9 in the middle-aged group (45–59 years), and 3.3 in the oldest group (60–85 years) receiving intensive lifestyle treatment. By contrast, in the placebo arm, there was no difference in diabetic incidence by age (11.0 in the young group, 10.8 in the middle-aged group, and 10.3 in the oldest group). This pattern of results suggests that lifestyle interventions for weight loss may produce greater reductions in diabetic risk among older adults as compared to middle-aged or younger samples, however more research is needed.

Health-Related Quality of Life (HrQoL)

Weight loss has been associated with significant improvements in health-related quality of life (HrQoL; Fine et al., 1999), a set of constructs related to physical, psychological, and social functioning, and general well-being. For example, a study of persons participating in a Weight Watchers program reported that those who had lost approximately 6.1 kg demonstrated significant improvements on the Physical Functioning, Role Limitations due to Physical Health Problems, and General Mental Health subscales of the SF-36 than individuals in the control condition (Rippe et al., 1998). However, a recent meta-analysis of 34 randomized controlled trials of weight loss treatment demonstrated little improvement in HrQoL, as measured by over a dozen different generic and disease-specific instruments (Maciejewski, Patrick, & Williamson, 2005).

There is a paucity of research on health related quality of life and weight change in older adults. The Arthritis, Diet, and Activity Promotion Trial (ADAPT), a study of 316 overweight and obese older adults with knee osteoarthritis, described significant improvements in HrQoL, particularly with regards to physical health and functioning, after an 18-month combined diet and
exercise intervention that produced a mean weight loss of 4.4% (Rejeski et al., 2002). Another study including 2364 older men and women (over 60 years of age) in Spain, described a significant decrement in the domains of role limitations due to emotional functioning and self-perceived general mental health (Leon-Munoz et al., 2005). These results are in contrast to the positive pattern of HrQoL improvements typically seen with weight loss treatment among younger or middle-aged samples. At present, no studies have compared changes in health-related quality of life between elderly and middle-aged obese individuals undergoing weight loss treatment. Further, given the varied results among existing studies, the impact of intentional weight loss on HrQoL remains unclear.

Adherence to Diet and Activity Recommendations

Facilitating adherence to medical and behavioral interventions is critical to outcome effectiveness (Vitolins, Rand, Rapp, Ribisl, & Sevick, 2000). However, adherence to treatment is a challenge across all age groups. Research on adherence among samples of older men and women undergoing weight loss treatment has produced conflicting results. Serdula et al. (1999) reported that most people trying to lose weight do not follow the recommendations to reduce caloric intake and increase leisure-time physical activity. In this study, older individuals attempting to lose weight were less likely than younger persons to follow national guidelines suggesting a minimum of 150 minutes per week of physical activity (Serdula et al., 1999).

Conversely, older adults in the DPP reported greater weight loss and levels of recreational activity, were more likely to achieve the exercise goal of 150 minutes per week, and more likely to reach the weight loss goal of 7% as compared to younger participants (Diabetes Prevention Program Research Group, 2006). At the final visit, 63% of participants over 65 years of age met the weight loss goal as compared to 27% of participants under 45 years of age (Diabetes Prevention Program Research Group, 2002). There were no reported differences in caloric
intake, but older participants were more likely to complete self-monitoring records (Diabetes Prevention Program Research Group, 2002). Additionally, with increasing age, the lifestyle intervention arm of the DPP was significantly more effective than the metformin condition, suggesting that older participants were able to adhere quite well to dietary and activity recommendations.

There is little research with regards to levels of adherence, dietary intake and physical activity in older individuals participating in behavioral weight loss programs. Studies comparing the response of elderly and younger participants to lifestyle interventions are also lacking. The few existing studies that report on adherence to eating and activity recommendations offer conflicting results with regards to the response of older participants. Thus, more research is needed related to older individuals’ adherence to diet and activity recommendations.

**Weight Loss: Negative Outcomes**

Weight loss in older adults has been associated with a variety of negative outcomes, such as the loss of lean muscle mass and bone mineral density, which may be particularly detrimental for older adults (Gregg & Williamson, 2002). Indeed, weight loss between middle- and old-age has been associated with doubling of relative risk of hip fracture and loss of mobility (Ensrud, Cauley, Lipschutz, & Cummings, 1997; Langlois et al., 1998; Launer, Harris, Rumpel, & Madans, 1994). Although these particular results are confounded by a failure to account for intentionality of weight loss, a more recent observational study of over 1300 older men reported a significant increase in hip bone loss even among obese men who were trying to lose weight (Ensrud et al., 2005). A similar pattern was observed in a study of older obese women, whereby modest intentional weight loss was an independent risk factor for hip fracture in later life (Ensrud et al., 2003).
Weight loss in elderly persons has also been linked to greater mortality risk. For example, a study of nearly 5,000 older adults found that weight losses of 5% or more over three years were associated with a substantial increase in mortality rates (Hazard ratio (HR) = 1.67, 95% CI = 1.29–2.15) over a four year follow up period (Newman et al., 2001). Hypothesized mechanisms for this finding include adverse effects of weight loss on lean body mass and subsequent hip fractures or injury, nutritional deficits from long-term caloric restriction, or underlying disease pathology (e.g., depression, gastrointestinal disorders, cancer) or weight-related comorbidities (Knudtson, Klein, Klein, & Shankar, 2005; Wallace & Schwartz, 2002).

Although unintentional weight loss is more frequently linked to morbidity and mortality (Gregg, Gerzoff, Thompson, & Williamson, 2004; Yang, Fontaine, Wang, & Allison, 2003), some studies have also demonstrated a relationship between intentional weight loss and increased mortality (Newman et al., 2001; Yaari & Goldbourt, 1998), leading some researchers to argue that weight loss may not be beneficial for older adults, even if they are overweight (Newman et al., 2001; Thomas, 2005). However, these studies have typically failed to control for premorbid health status or disease; other research has established no discernable link between mortality and voluntary weight loss. For example, a large study of intentional weight loss and mortality among over 5,200 older adults reported no increase in 5-year cumulative mortality risk in men, and a reduction in risk for women who voluntarily lost 4.4 kg, as compared to participants who were weight stable or described an unintentional weight loss (Diehr et al., 1998). Even thought weight loss treatment can produce a host of improvements in metabolic risk factors, it may be that for older adults, these reductions occur too late in life to have a significant impact on health and longevity. At present, the relationship between intentional weight loss and mortality risk in older obese adults remains unclear.
In sum, there is a small body of research to substantiate the claim that weight loss treatment can produce metabolic benefits for older adults. Intentional weight loss in older obese adults could also ameliorate weight-related diseases and conditions such as joint pain, psychological symptoms and quality of life (Rossner, 2001), but could simultaneously present a degree of risk with regards to musculoskeletal injury, bone and muscle loss. Additionally, it is unknown whether older adults demonstrate similar levels of adherence to dietary and physical activity recommendations during the course of lifestyle interventions as compared to younger or middle-aged individuals (Rossner, 2001).

**Specific Aims and Hypotheses**

This study aims to describe the response of women 65 years and older to a lifestyle intervention for weight loss and to compare their outcomes to those of a group of middle-aged women (ages 50 to 59 years). The primary aims of the present study were to determine: (a) if older obese women experience significant benefits (i.e., weight loss, reductions in metabolic risk factors) from a lifestyle intervention for weight loss; (b) if behavioral weight loss treatment is associated with negative outcomes (i.e., musculoskeletal injury) for older obese women; and (c) if weight loss and adverse event outcomes are equivalent in older and middle-aged participants.

We hypothesized that older women would experience significant reductions in weight, blood pressure (systolic), lipid profile (LDL-cholesterol), glycemic control (HbA1c), and inflammation (C-reactive protein). We hypothesized that weight loss outcomes would be equivalent in older and middle-aged participants. Additionally, we hypothesized that women in the older age group would report similar levels of musculoskeletal adverse events as compared to women in the middle-age group. No formal hypotheses with regards to metabolic risk factor changes were postulated, as we did not anticipate having sufficient power to determine if older and middle-aged participants would experience equivalent reductions in risk factors.
A secondary aim of this study was to describe and compare the responses of older and middle-aged participants along several psychological and behavioral variables and outcomes including: dietary intake, adherence, physical fitness and quality of life. As this aim was largely exploratory, no a priori hypotheses are offered.
CHAPTER 2
MATERIALS AND METHODS

Research Methods and Procedures

This study is a secondary analysis of data collected in the TOURS (Treatment of Obesity in Underserved Rural Settings) project. TOURS is a randomized controlled trial of behavioral weight loss treatment in six medically underserved rural counties in Northern Florida (Perri et al., 2005).

Participants

Participants consisted of 298 women ranging from 50 to 75 years of age ($M = 59.3$, $SD = 6.2$ years). Among all participants, 75.5% classified their race/ethnicity as Caucasian, 20.5% as African American, 1.7% as Hispanic American, 2.0% as American Indian, and 0.3% as Hawaiian. The mean pretreatment weight was 96.5 kg ($SD = 14.9$ kg), and mean baseline BMI was 36.8 kg/m$^2$ ($SD = 5.0$ kg/m$^2$). Most of the sample (64.4%) completed at least 12 years of education, with 43.3% reporting at least trade, vocational, or associate training. The majority of participants were married (72.5%), and nearly half of women were employed full or part time (47.3%). Over two-thirds of the sample (67.9%) reported a total household income of less than $50,000. Additional baseline demographic characteristics can be seen in Table 2-1.

Although there was no upper limit placed on BMI, women who weighed in excess of 159 kg (350 lbs) were excluded to permit the use of a standard balance beam scale. Other exclusion criteria included a history of prior health conditions likely to limit five-year life expectancy (e.g., cancer within the past 5 years; serious infectious diseases; myocardial infarction, cerebrovascular accident, or unstable angina within the previous 6 months; congestive heart failure; chronic hepatitis; cirrhosis; irritable bowel syndrome; previous bariatric surgery, or organ transplantation; musculoskeletal conditions that limit walking; chronic lung disease
limiting physical activity; serum creatinine > 1.5 mg/dL; anemia). Women with controlled
diabetes were allowed to enroll with the approval of their primary health care provider, but those
with a fasting blood glucose > 125 mg/dL at screening were excluded if not known to be
diabetic. Women with fasting serum triglycerides > 400 mg/dL, or resting blood
pressure > 140/90 mmHg at screening were excluded, regardless of whether they were receiving
appropriate drug treatment. Exclusionary medications included antipsychotics, monoamine
oxidase inhibitors, systemic corticosteroids, antibiotics for HIV or TB, chemotherapeutic drugs,
or prescription weight-loss drugs. Women who reported a major psychiatric disorder, excessive
alcohol intake, or a weight loss in excess of ten pounds in the six months prior to screening were
not eligible to participate. Finally, women unable or unwilling to give informed consent, unable
to read English at a 5th grade level, or unwilling to accept random assignment were excluded
from enrollment.

**Procedure**

Participants were recruited using direct mailings, newspaper advertisements, and through
presentations at churches, community centers, and events. Interested individuals were screened
by telephone and scheduled for a baseline visit. At the baseline visit, the study was explained in
detail to eligible women, and informed consent was obtained. Additionally, participants
completed several questionnaires on demographic information, medical history, medication
inventory, dietary intake, physical activity, health-related quality of life, depressive symptoms,
and problem-solving skills. Participants’ height, weight, abdominal circumference, resting heart
rate and blood pressure were taken, and blood was drawn and analyzed for metabolic profile.
The 6 Minute Walk Test (6MWT) was administered to assess functional mobility. A pre-start
visit was conducted within two weeks of the start of group sessions to ensure weight stability
prior to the initiation of treatment and to repeat the 6MWT. Participants who had gained or lost
in excess of 4.5 kg underwent an additional blood-draw to ensure that their metabolic profile had not changed from baseline. Measures were assessed at baseline, six, and 18 months.

**The TOURS Intervention**

All participants received a six-month lifestyle intervention (Phase I) carried out through Cooperative Extension Offices in six rural counties in North Florida. These women were then randomized to one of three follow-up programs (Phase II): an office-based (in-person) maintenance program, a telephone-based maintenance program, or an education control condition.

Phase I was comprised of 24 weekly group meetings (10 to 14 participants per group), 90 to 120 minutes in duration, designed to decrease caloric intake and increase moderate intensity exercise to facilitate a safe and nutritionally sound weight loss of approximately 0.4 kg per week. Participants were instructed to reduce their energy intake by 500 to 1000 kcal per day, maintain a balanced diet consisting of no more than 25 to 30% of total kcal from fat, approximately 15% from protein, and the remaining 60 to 65% from carbohydrates. Other dietary recommendations included consuming at least five servings of fruits and vegetables per day, as well as three or more servings of whole grains. Physical activity goals were set at 180 minutes per week of moderate intensity (e.g., brisk walking) exercise, roughly 30 minutes per day on six days of the week. Participants were given pedometers and instructed to strive for at least an additional 3000 steps per day above baseline levels.

In addition to targeting dietary and physical activity habits, Phase I included cognitive and behavioral strategies for weight loss such as self-monitoring, goal-setting, self-reinforcement, stimulus control, cognitive restructuring, and enhancing social support. Each session included a weekly weigh in, review of progress towards goals, a discussion of nutrition and/or physical activity, feedback from interventionists and other group members, and skills training related to
behavioral strategies for weight loss. Participants were encouraged to keep detailed, daily records of their food intake and physical activity.

The TOURS intervention included segments tailored to the specific needs and issues of women living in the rural south. Weekly cooking demonstrations were included to supplement information provided on low-calorie, low-fat food preparation, with a special focus on Southern Cooking. Additional lessons included strategies to enhance coping with stress and depression, how to eat healthy outside of the home. The overall dietary objectives were consistent with the Therapeutic Lifestyle Changes recommended in the Adult Treatment Panel III Report of the National Cholesterol Education Program (2001), and the physical activity component of the intervention follow guidelines set by the Surgeon General (US Department of Health and Human Services, 1996) and the American College of Sports Medicine (2001).

Measures

**Weight.** Weight was measured to the nearest 0.1 kilogram using a calibrated and certified balance beam scale. Participants were dressed in light indoor clothing without shoes and with pockets emptied when weight was taken. Percent weight change was calculated by subtracting participants’ weight at six and 18 months from month zero, and dividing by month zero weight.

**Musculoskeletal adverse events.** Participants were asked to report all adverse events (AEs) experienced throughout the duration of the study. Adverse events were categorized for review by a local Institutional Review Board (IRB) and by a specially constituted Data Safety and Monitoring Board (DSMB). Additionally, all events were separately recoded as representing a musculoskeletal injury or other type of adverse event. Musculoskeletal adverse events were chosen because there is a slight increase risk of this type of injury with lifestyle treatment. In the DPP, within the youngest group of participants (25–44 years), approximately 16% in the control condition reported a musculoskeletal AE as compared to 20% in the lifestyle condition (Diabetes
Prevention Program Research Group, 2006). In the older participants (60–85 years), 26.7% of individuals in the control group reported a musculoskeletal AE as compared to 28% in the lifestyle intervention (Diabetes Prevention Program Research Group, 2006).

**Blood pressure.** Resting systolic and diastolic blood pressure were measured by a Registered Nurse (RN), using a standardized protocol (Chobanian et al., 2003). Three blood pressure readings were taken, spaced one minute apart, and the last two readings were averaged. If large discrepancies were observed between the last two readings, an additional reading was taken and mean values for the last three readings was used. In the present study, only systolic blood pressure was examined due to its relation to cardiovascular disease risk (Prospective Studies Collaboration, 2002; Vasan et al., 2001). It has been estimated that a 3 mm Hg reduction in systolic BP could lead to reductions of 8% in stroke mortality and 5% in coronary heart disease mortality (Stamler, 1991).

**Blood analyses: LDL-Cholesterol, HbA1c, C-reactive protein.** Blood samples were drawn by the study RN and sent to Quest Diagnostics Clinical Laboratories to be analyzed for lipid and metabolic profile. In the present study, lipid profile was measured using LDL-cholesterol, due to its strong association with cardiovascular disease risk (National Cholesterol Education Program, 2001). Lowering LDL-cholesterol can significantly reduce the risk of stroke, coronary events, coronary artery procedures, and mortality (National Cholesterol Education Program, 2001). Glycemic control, which is highly related to diabetic risk (American Diabetes Association, 2001), was assessed via Hemoglobin A1c (HbA1c), which is a more durable measure of glycemic control than fasting glucose (Centers for Disease Control and Prevention, 2001). C-reactive protein is a marker of inflammation, which is associated with atherosclerosis and cardiovascular disease (Libby, Ridker, Maseri, 2002).
**Dietary intake.** The Block 98 Food Frequency Questionnaire is a revised version of a previously validated survey (Block et al., 1986) that asks respondents to estimate consumption of a wide variety of foods. Scoring yields estimates of daily caloric intake, macro- and micro-nutrient intake, as well as intake by specific food groups (e.g., fruits, vegetables, grains, etc.). Estimated daily caloric intake was extracted for months zero, six, and 18.

**Adherence.** Participants were asked to complete food and activity records throughout the study, on a daily basis during Phase I and at least three times per week during the 12 months of extended care. Self-monitoring of dietary intake and physical activity levels is arguably the most critical component of behavioral weight loss treatment (Brownell, 2000; Wing, 1998). The total number of food records kept is a better predictor of successful weight loss outcome than the actual content of dietary records (Streit, Stevens, Stevens, & Rossner, 1991). As such, in the present study, the total number of daily records completed was used as a proxy for adherence to the intervention.

**Physical fitness.** The 6 Minute Walk Test (6MWT) is a performance-based measure of physical fitness that can be used in populations with low exercise capacity (e.g., elderly persons, those with functional limitations), for whom rigorous fitness tests such as treadmill exercise tests would be inappropriate (Peeters & Mets, 1996). Participants were asked to walk along a course marked by colored tape for six minutes, and instructed to cover as much ground as possible. Distance covered was measured to the nearest foot. Participants completed this task twice at pre-start and the first 6MWT results were discarded due to known practice effects. The 6MWT has demonstrated high levels of reliability in populations with low exercise capacity (Kervio, Carre, & Ville, 2003) as well as convergent evidence of validity, as suggested by a strong correlation with peak oxygen uptake during maximal exercise testing ($r = .68$; Zugck et al., 2000).
Health-related quality of life. Health-related quality of life was assessed using the Medical Outcomes Survey Short-Form 36 Health Survey (SF-36; Ware, Kosinski, & Keller, 1994), which assesses eight constructs related to quality of life including Physical Functioning, Role Limitations due to Physical Health Problems, Social Functioning, Bodily Pain, General Mental Health, Role Limitations due to Emotional Problems, Vitality and General Health Perceptions. The SF-36 has demonstrated excellent psychometric properties in a number of research studies (Fontaine & Barofsky, 2001; Jenkinson, Wright, & Coulter, 1994; Ware et al., 1994) and with a wide range of populations, including obese adults (Fontaine & Barofsky, 2001).

Design and Statistical Analyses

The data analyses were performed using both a per-protocol (PP) and an intention-to-treat (ITT) approach. Use of only treatment completers (per-protocol) is consistent with a recent CONSORT statement regarding appropriate use of equivalence testing (Piaggio, Elbourne, Altman, Pocock, & Evans, 2006). Use of ITT analyses in equivalence testing can increase the risk of type I error, as it suppresses observed mean differences between groups. All randomized participants were included in the ITT analyses. For participants who were lost to follow-up, baseline or last known values were substituted for missing data at six and 18 months. Use of this “worst case” scenario is consistent with the findings from long-term studies of weight loss that show a reliable return to baseline weights over time (Kramer, Jeffery, Forster, & Snell, 1989; Stalonas, Perri, & Kerzner, 1984). Extrapolating from these findings, use of an ITT approach assumes that treatment non-completers will similarly evidence a return to baseline values of other variables of interest including metabolic risk factor levels, dietary intake and composition, physical fitness, and quality of life.

Descriptive statistics are reported as means and standard deviations (SDs). Two change scores were calculated for each participant, for each variable of interest. Phase I change score
represents pre- to post-treatment, where month six values were subtracted from month zero values. Net change scores (pre-treatment to long-term follow-up), were calculated as month 18 values subtracted from month zero values.

**Primary Aims**

To determine if older obese women experience significant benefits from a lifestyle intervention for weight loss, we conducted a series of mixed between-within ANOVAs to examine within-group changes over time for weight and metabolic risk factors (i.e., systolic blood pressure, LDL-cholesterol, HbA1c, C-reactive protein) from month zero to month six and month 18. To adjust for multiple tests, family-wise type I error was constrained to $\alpha = .05$; thus, using a Bonferroni correction, the criterion for significance for individual tests was set at $\alpha = .01$.

Margins of equivalence ($\Delta$) for weight and the proportion of each group (older women and middle-aged women) reporting a musculoskeletal adverse event were set a priori based on the smallest value that would represent a clinically significant difference, as determined by reviews of the literature. Weight outcomes for older and middle-aged participants were regarded as equivalent if the difference between group means (using a 95% CI of the difference) was less than or equal to 2.5%. That is to say, if the 95% CI of the difference was wholly contained within the margins of equivalence ($\pm 2.5\%$), we reject the null hypothesis that the groups differ by more than this minimally clinically significant amount at $\alpha = .05$. Similarly, the proportions of each group reporting a musculoskeletal adverse event were regarded as equivalent if the 95% CI of the difference was contained within $\pm \Delta$ ($\pm .04$). The mean difference in percent weight change between older and middle-aged groups was obtained from analysis of variance. Confidence Intervals of the difference in proportions of older and middle-aged women reporting a musculoskeletal AE were calculated using methods described by Newcombe (1998).
Secondary Aims

To evaluate our secondary aims, which included comparing older and middle-aged women on a variety of behavioral and psychological variables, we conducted a series of mixed between-within ANOVAs. Criterion variables included: daily caloric intake, distance covered during the 6MWT, and health-related quality of life. Additionally, one-way ANOVAs were used to compare levels of adherence (measured as the number of daily food records completed) between age groups. Family-wise error was again constrained to \( \alpha = .05 \) and Bonferroni corrections were applied to control the risk of type I error.

All statistical analyses were conducted using SPSS statistical software (version 13.0 for Windows Graduate Student Version).
Table 2-1. Baseline demographic characteristics of the sample of 298 women

<table>
<thead>
<tr>
<th></th>
<th>M</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>59.3</td>
<td>6.2</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>96.5</td>
<td>14.9</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>36.8</td>
<td>5.0</td>
</tr>
</tbody>
</table>

Percent of Sample

Race/ethnicity (%)

- Caucasian: 75.5%
- African American: 20.5%
- Hispanic American: 1.7%
- American Indian: 2.0%
- Hawaiian: 0.3%

Education

- < 12 years: 36.6%
- Trade/vocational training: 43.3%
- Bachelor's degree: 10.4%
- Post-Bachelor's: 9.7%

Employment

- Full- or part-time: 47.3%
- Retired: 24.8%
- Not working: 8.7%
- Homemaker: 4.7%
- Disabled: 1.7%
- Other: 1.7%
- More than 1 category: 11.1%

Total Income

- < $10,000: 6.0%
- $10,000–19,000: 16.1%
- $20,000–34,999: 24.5%
- $35,000–49,999: 20.8%
- $50,000–74,999: 19.1%
- $75,000–99,999: 11.4%
- Don't know/Didn’t report: 2.0%
CHAPTER 3
RESULTS

Demographic Characteristics by Age

Older women (i.e., women between 60 and 75 years of age; \( n = 56 \)) in this study were more likely to be Caucasian, \( \chi^2(1) = 4.6, p < .05 \), Cramer’s \( V = 0.21 \), and less likely to be employed, \( \chi^2(1) = 57.2, p < .001 \), Cramer’s \( V = 0.64 \), than middle-aged women (i.e., women between 50 and 59 years of age; \( n = 162 \)). Older women weighed significantly less than middle-aged women at baseline, \( t(216) = 2.28, p < .025, r = .15 \), but this difference was not clinically significant, and both groups fell in the Class II obesity range (BMI 35 to 39.9 kg/m²) at pretreatment. Additional comparisons of demographic characteristics by age can be seen in Table 3-1.

Previous analyses of the TOURS data have suggested that Caucasian women and African-American women respond differently to treatment in terms of magnitude of weight loss, changes in metabolic risk factors and a number of behavioral variables (Rickel et al., 2006). The older age group was comprised of a significantly greater proportion of Caucasian women, thus race/ethnicity was included as a covariate in all subsequent analyses of variance, and equivalence testing was conducted separately for Caucasian and African-American women. However, given that the older age group contained only six African-American women, we did not have enough power to perform formal tests of equivalence with this sub-sample. Thus, only descriptive statistics are provided.

Pretreatment Metabolic Risk Factors by Age

Older women did not differ from middle-aged women on any metabolic risk factor at pretreatment with the exception of systolic blood pressure, which was higher in the older group,
\( t(216) = -3.60, p < .001, r = .24 \). Pretreatment metabolic risk factors by age can be seen in Table 3-2.

**Primary Aims**

**Within-Group Analyses**

**Weight change**

Using a per-protocol approach (i.e., treatment completers; \( n = 45 \)), we conducted a one-way repeated measures ANOVA to examine within-group changes in weight, while controlling for race/ethnicity. The proportion of older women who completed the study (80%) was not significantly different than the proportion of middle-aged women (73%), \( \chi^2(1) = 1.2, p = .26 \). Bonferroni-adjusted pair-wise comparisons of the estimated marginal means indicated that older women evidenced a significant reduction in weight from pretreatment to month six, \( t(42) = 13.08, p < .001, r = .90 \). This weight loss was largely maintained at month 18, \( t(42) = 6.06, p < .001, r = .68 \) (Figure 3-1). Using an ITT approach (\( n = 56 \)), substituting baseline values for missing data, older women also demonstrated a significant reduction in weight from pretreatment to month six, \( t(53) = 3.95, p < .01, r = .48 \); as well as pretreatment to month 18, \( t(53) = 3.17, p < .01, r = .40 \) (see Figure 3-2).

**Metabolic risk factors**

Using a per-protocol approach, older women experienced significant reductions in systolic blood pressure from month zero to month six, \( t(28) = 4.14, p < .01, r = .62 \), and maintained these improvements at month 18, \( t(28) = 2.98, p < .02, r = .49 \). Changes in LDL cholesterol were not significant over time. HbA1c was significantly reduced from month zero to months six, \( t(28) = 4.14, p < .01, r = .62 \); and from month zero to month 18, \( t(28) = 4.21, p < .001, r = .62 \). C-reactive protein was also significantly reduced from month zero to months six, \( t(28) = 2.72, p < .04, r = .46 \); these changes were maintained at month 18, \( t(28) = 3.28 \),
Figure 3-3 illustrates the changes in metabolic risk factors over time using a per-protocol approach.

Using an ITT approach, a similar pattern of results emerged. Older women (n = 56) also evidenced significant reductions in systolic blood pressure from month zero to month six, \( t(53) = 3.95, p < .001, r = .48 \); as well as month zero to month 18, \( t(53) = 3.17, p < .01, r = .40 \). Changes in LDL cholesterol were not significant over time. HbA1c declined from month zero to months six, \( t(53) = 4.07, p < .001, r = .49 \); these changes were maintained at month 18, \( t(53) = 4.06, p < .001, r = .49 \). Similarly, C-reactive protein decreased from pretreatment to month six, \( t(53) = 3.37, p < .005, r = .42 \), as well as from pretreatment to month 18, \( t(53) = 3.81, p < .001, r = .46 \). Figure 3-4 illustrates the changes in metabolic risk factors over time using an ITT approach.

**Equivalence Testing**

Equivalence testing was conducted using a 95\% CI of the difference between group means (older women vs. middle-aged women) for weight change and the proportion of participants reporting a musculoskeletal adverse event. Margins of equivalence were set a priori, based on previous literature. A weight change of 2.5\% was determined to be the smallest amount that would represent a clinically meaningful change, and thus groups would be regarded as equivalent if the 95\% CI of the difference was less than or equal to this margin. The margin of equivalence for musculoskeletal adverse events was set at 4\%. Thus, if the proportion of older and middle-aged women reporting musculoskeletal AE differed by 4\% or less, using a 95\% CI of the difference, we would regard the groups as equivalent.

**Weight change**

Among treatment completers, older Caucasian women (n = 44) lost a mean of 9.5\% (SD = 5.5\%) initial body weight from pretreatment to month six, which was not significantly
different than the 10.0% \((SD = 5.8\%)) weight loss achieved by middle-aged Caucasian women \((n = 103)\). The 95% CI of the difference (-1.6 to 2.5) was contained within the margin of equivalence \((±2.5\%))
, thus older and middle-aged Caucasian women lost equivalent amounts of weight from pretreatment to month six. At long-term follow up, older women had lost a mean of 7.6% \((SD = 8.9\%)) body weight, again, not significantly different than the 8.4% \((SD = 8.9\%)) weight loss evidenced by middle-aged women. However, the groups were not equivalent with respect to weight loss at month 18, as the 95% CI of the difference exceeded the margin of equivalence \((95\% CI: -2.7 to 4.3)\).

Older African-American women lost a mean of 7.9% body weight from month zero to month six, as compared to 6.6% for the middle-aged African-American women. At long-term follow up, there was a trend for older African-American women to maintain a greater weight loss than middle-aged African-American women; the older women los 9.0% body weight as compared to 5.0% for the middle-aged women, \(F(1,42) = 2.3, p = .14\), a difference that may have reached significance with a larger sample size.

**Adverse events**

During active treatment (month zero to six), 23% of older Caucasian women reported at least one musculoskeletal adverse event, as compared to 18% of middle-aged Caucasian women. The 95% CI of the difference in proportions, calculated according to the methods described by Newcombe (1998), was -20.6% to 7.2%, well outside the margin of equivalence \((±4\%))\). The proportion of older women reporting a musculoskeletal AE over the course of the entire study (month zero to 18) was 47%, as compared to 36% of middle-aged Caucasian women, \(\chi^2(1) = 1.7, p = .19\). Again, the 95% CI of the difference in proportions fell outside the margin of equivalence \((95% CI: -27.3 to 5.2)\).
During active treatment, 11% of older African-American women reported a musculoskeletal AE, as compared to 26% of middle-aged women. At long-term follow up, 42% of middle-aged African-American women had reported at least one adverse event, as compared to only 11% of older African-American women. There was a trend for older African-American women to be less likely to report a musculoskeletal AE overall than middle-aged African-American women, $\chi^2(1) = 3.1, p < .08$, a difference that may have reached significance with a larger sample size.

To further investigate the risk of musculoskeletal injury, we divided all participants into five-year age cohorts. The occurrence of musculoskeletal AEs by five year age cohorts can be seen in Figure 3-5. Although there were no significant differences in the occurrence of musculoskeletal injury by age, 56% of Caucasian participants over 70 years of age ($n = 16$) reported at least one adverse event over the course of the study as compared to 37% of Caucasian women ages 50 to 69 years ($n = 209$), $\chi^2(1) = 2.25, p = .13$. Again, this difference may have reached significance with a larger sample of women over 70 years of age.

**Secondary Aims**

**Dietary Intake**

Prior to conducting analyses, basal metabolic rate (BMR) at baseline was calculated according to the Harris-Benedict equation (Equation 3-1), where BMR is expressed in kcal/day, height in cm, and weight in kg (Arciero et al., 1993).

\[
\text{BMR} = (1.8 \times \text{Height}) + (9.6 \times \text{Weight}) - (4.7 \times \text{Age}) + 655
\] (3-1)

Potentially invalid observations on the FFQ, defined as individuals who reported daily caloric intakes less than 56% of BMR or greater than 144% of BMR, respectively (values outside two $SD$s from the mean), were removed from the data. Using these cutoffs, there were 60 invalid observations at month zero, 42 at month six, and 41 at month 18. There were no differences by
age. This method of screening for biologically implausible energy intake values is consistent with that reported by Huang, Roberts, Howarth, & McCrory (2005), although they suggest an even more stringent cutoff of ± 1.4 SDs, which would have substantially reduced the sample size. Finally, daily caloric intake values were logarithmically transformed to approximate a normal distribution. Daily caloric intake at pretreatment, month six and month 18 for older and middle-aged treatment completers can be seen in Figure 3-6.

Among treatment completers, we conducted a mixed between-within ANOVA with two between-subjects factors (age group and ethnicity) and one within-subjects factor (daily caloric intake). Baseline BMR values were included as a covariate in order to control for energy needs. Mauchly’s test indicated that the assumption of sphericity had been broken, thus Greenhouse-Geisser corrected degrees of freedom are reported ($\varepsilon = .91$). There was no within-group main effect of caloric intake over time, $F(1.8,164.3) = 0.06, \text{ns}$. The between-group effect of age was not significant, $F(1,90) = 0.28, \text{ns}$. There was no age by time interaction, indicating that older and middle-aged participants did not experience differential reductions in caloric intake over the course of the study.

The intention-to-treat analysis yielded a similar pattern of results (see Figure 3-7). Mauchly’s test indicated that the assumption of sphericity was violated, thus Greenhouse-Geisser corrected degrees of freedom are reported ($\varepsilon = .89$). The main effect of caloric intake over time was not significant, $F(1.8,274.8) = 0.01, \text{ns}$. The main between-group effect of age was not significant, $F(1,154) = 0.09, \text{ns}$. The age by time interaction was not significant.

**Adherence**

Controlling for race/ethnicity, no differences emerged related to the number of food records completed during Phase I (month zero to six) of treatment between middle-aged and older participants, $F(1,217) = 1.15, p > .05, r = .08$. During Phase II (month six to 18) however,
older women completed a significantly greater number of daily food records, $F(1,217) = 4.69$, $p < .03$, $r = .30$. On average, middle-aged women completed 116 daily food records in Phase I and 73 food records in Phase II. By comparison, older women completed 125 food records in Phase I and 106 food records in Phase II.

**Physical Fitness**

Among treatment completers, a mixed between-within ANOVA was conducted with two between-subjects factors (age group and ethnicity) and one within-subjects factor (distance covered in the 6MWT). The main within-group effect of physical fitness over time was not significant. There was a significant between-group effect of age, $F(1,153) = 31.8$, $p < .001$, whereby older participants were less physically fit at all time points as compared to middle-aged participants (pretreatment, $t(152) = 5.0$, $p < .001$, $r = .38$; six months, $t(152) = 5.1$, $p < .001$, $r = .38$; 18 months, $t(152) = 5.2$, $p < .001$, $r = .39$). Mean distances covered in the 6MWT by age can be seen in Figure 3-8. Bonferroni-adjusted pair-wise comparisons indicated that older women experienced a significant increase in physical fitness from pretreatment to month six, $t(152) = 2.6$, $p < .03$, $r = .21$. These gains were also apparent at month 18, $t(152) = 2.5$, $p < .04$, $r = .20$. Middle-aged women also experienced significant improvement in physical fitness from pretreatment to months six and 18, $t(152) = 5.9$, $p < .001$, $r = .43$, and $t(152) = 6.1$, $p < .001$, $r = .44$, respectively.

Using an ITT analysis, the main within-group effect of physical fitness over time was not significant (see Figure 3-9). There was a significant between-group difference by age, $F(1,212) = 35.8$, $p < .001$, by which older adults were less physically fit at all time points. There was no age by time interaction effect.
Health-Related Quality of Life

A series of mixed between-within ANOVAs were conducted for each of the eight subscales on the SF-36 with two between-subjects factors (age group and ethnicity) and one within-subjects factor (subscale of the SF-36). Notably, higher scores on the subscales indicate better perceived health status.

Physical Functioning

Among treatment completers, Mauchly’s test indicated that the assumption of sphericity was violated \( p < .005 \), thus Greenhouse-Geisser corrected degrees of freedom are reported \( \epsilon = .93 \). There was no main within-group effect of Physical Functioning over time. However, analyses indicated a significant between-group effect of age, \( F(1,173) = 6.0, \ p < .02 \), as well as a significant age by time interaction, \( F(1.9,323.1) = 3.1, \ p < .05 \). Means, \( t \)-statistics, and Bonferroni-adjusted probability values can be seen in Table 3-3. At pretreatment, there was no difference in reported physical functioning between middle-aged and older adults. However, older adults reported lower degrees of physical functioning than middle-aged participants at six and 18 months. Additionally, middle-aged participants reported a significant improvement in physical functioning from pretreatment to month six, \( t(173) = 4.5, \ p < .001, r = .32 \). Older women did not demonstrate a significant improvement in physical functioning at any time point. Changes in Physical Functioning by age can be seen in Figure 3-10.

Similar results were observed with an ITT analysis. Mauchly’s test indicated that the assumption of sphericity was violated \( p < .005 \), thus Greenhouse-Geisser corrected degrees of freedom are reported \( \epsilon = .93 \). The analysis indicated no main within-group effect of Physical Functioning over time. There was a significant between-group effect of age, \( F(1,215) = 5.7, \ p < .02 \), as well as a significant age by time interaction, \( F(1.9, 401.2) = 3.9, \ p < .025 \). Bonferroni-adjusted pair-wise comparisons indicated that older women describe significantly
worse physical functioning at six and 18 months than middle-aged women, $t(215) = 2.9$, $p < .005$, $r = .19$, and $t(215) = 2.7$, $p < .01$, $r = .18$, respectively. While middle-aged women demonstrated an improvement in physical functioning from pretreatment to month six, $t(215) = 4.8$, $p < .001$, $r = .31$, older women did not demonstrate an improvement in physical functioning over time.

**Role Limitations due to Physical Health Problems**

Among treatment completers, there was no significant main effect of role limitations over time. There was a significant main between-group effect of age, $F(1,173) = 13.0$, $p < .001$, as well as a significant age by time interaction, $F(2,346) = 3.0$, $p < .05$. Means, $t$-statistics, and Bonferroni-adjusted probability values can be seen in Table 3-4. At pretreatment, there was no difference in role limitations due to physical health problems between middle-aged and older women. However, older women reported a greater degree of role limitations due to physical health problems than middle-aged participants at six and 18 months. Additionally, older women demonstrated a significant increase in role limitations due to physical health problems from pretreatment to month 18, $t(173) = 4.0$, $p < .001$, $r = .29$. Changes in Role Limitations due to Physical Health Problems by age can be seen in Figure 3-11.

An ITT analysis revealed a similar pattern of results. As Mauchly’s test indicated that the assumption of sphericity was not met ($p < .04$), Greenhouse-Geisser corrected degrees of freedom are reported ($\varepsilon = .97$). There was no significant within-group effect of role limitations over time. There was a significant between-group effect of age, $F(1,214) = 12.1$, $p < .001$, although Levene’s test indicated a violation of the assumption of homogeneity of variances, thus any between-group effects should be interpreted with caution. Bonferroni-adjusted pair-wise comparisons of the estimated marginal means suggested that older women report a significantly greater degree of role limitations at six and 18 months than middle-aged participants.
\(t(214) = 3.2, p < .002\) and \(t(214) = 3.5, p < .001\), respectively). Additionally, there was a significant age by time interaction, \(F(1.9,414.9) = 4.5, p < .015\). Middle-aged women demonstrated no change in role limitations over the course of the study, while older women actually worsened from pretreatment to month six \(t(214) = 2.4, p < .05, r = .16,\) and \(t(214) = 4.1, p < .001, r = .27,\) respectively).

**Social Functioning**

There were no significant within- or between-group effects on the Social Functioning subscale of the SF-36 using both a PP and ITT analysis.

**Bodily Pain**

There were no significant within- or between-group effects on the Bodily Pain subscale of the SF-36 using both a PP and ITT analysis.

**General Mental Health**

There were no significant within- or between-group effects on the General Mental Health subscale of the SF-36 using both a PP and ITT analysis.

**Role Limitations due to Emotional Problems**

There were no significant within- or between-group effects on the Role Limitations due to Emotional Problems subscale of the SF-36 using both a PP and ITT analysis.

**Vitality**

Using only treatment completers, there was no significant main within-group effect of vitality over time. However, there was a significant age by time interaction, \(F(2,346) = 3.5, p < .03\). Means, \(t\)-statistics, and Bonferroni-adjusted probability values can be seen in Table 3-5. Bonferroni-adjusted pair-wise comparisons suggest that at pretreatment, older women reported significantly higher levels of vitality than middle-aged participants, \(t(173) = 2.4, p < .01, r = .18\). However, older women did not demonstrate any improvement in vitality over time. By contrast,
middle-aged participants reported a significant increase in vitality from pretreatment to months six and 18, \( t(172) = 7.0, p < .001, r = .47 \), and \( t(172) = 2.7, p < .02, r = .20 \), respectively. Changes in Vitality by age can be seen in Figure 3-10.

An ITT analysis of the Vitality subscale indicated no significant main or interaction effects.

**General Health Perceptions**

There were no significant main or interaction effects on the General Health Perceptions subscale of the SF-36 using both a PP and ITT analysis.
Table 3-1. Baseline demographic characteristics of older and middle-aged participants

<table>
<thead>
<tr>
<th></th>
<th>Older (65–74 years)</th>
<th>Middle-aged (50–59 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
</tr>
<tr>
<td>Age (years)</td>
<td>69.1*</td>
<td>2.9</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>92.3*</td>
<td>14.7</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>35.7*</td>
<td>4.3</td>
</tr>
</tbody>
</table>

Percent of Sample

<table>
<thead>
<tr>
<th>Race/ethnicity (%)</th>
<th>Older</th>
<th>Middle-aged</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasian</td>
<td>83.9%</td>
<td>69.1%*</td>
</tr>
<tr>
<td>African American</td>
<td>12.5%</td>
<td>25.9%</td>
</tr>
<tr>
<td>Hispanic American</td>
<td>1.8%</td>
<td>1.2%</td>
</tr>
<tr>
<td>American Indian</td>
<td>0.0%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Hawaiian</td>
<td>1.8%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Education</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 12 years</td>
<td>51.8%</td>
<td>27.8%</td>
</tr>
<tr>
<td>Trade/vocational training</td>
<td>41.1%</td>
<td>45.7%</td>
</tr>
<tr>
<td>Bachelor's degree</td>
<td>3.6%</td>
<td>13.6%</td>
</tr>
<tr>
<td>Post-Bachelor's</td>
<td>3.6%</td>
<td>13.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Employment</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Full- or part-time</td>
<td>10.7%</td>
<td>69.1%**</td>
</tr>
<tr>
<td>Retired</td>
<td>55.4%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Not working</td>
<td>8.9%</td>
<td>6.2%</td>
</tr>
<tr>
<td>More than 1 category</td>
<td>19.6%</td>
<td>9.9%</td>
</tr>
</tbody>
</table>

Note: * p < .05, ** p < .001

Table 3-2. Pretreatment metabolic risk factors of older and middle-aged participants

<table>
<thead>
<tr>
<th></th>
<th>Older (65-74 years)</th>
<th>Middle-aged (50-59 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
</tr>
<tr>
<td>Systolic BP (mm Hg)</td>
<td>129.5*</td>
<td>8.2</td>
</tr>
<tr>
<td>LDL-cholesterol (mg/dL)</td>
<td>116.0</td>
<td>27.4</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>6.1</td>
<td>0.7</td>
</tr>
<tr>
<td>C-reactive protein (mg/dL)</td>
<td>5.2</td>
<td>6.0</td>
</tr>
</tbody>
</table>

Note: * p < .001
Table 3-3. Physical functioning by age, adjusted for race/ethnicity (PP)

<table>
<thead>
<tr>
<th></th>
<th>Middle-aged (n = 118)</th>
<th>Older (n = 38)</th>
<th>Mean Difference</th>
<th>SE</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month 0</td>
<td>78.3</td>
<td>76.7</td>
<td>1.5</td>
<td>3.3</td>
<td>0.46</td>
<td>0.643</td>
</tr>
<tr>
<td>Month 6</td>
<td>85.6**</td>
<td>78.0**</td>
<td>7.8</td>
<td>2.6</td>
<td>3.00</td>
<td>0.003</td>
</tr>
<tr>
<td>Month 18</td>
<td>80.6*</td>
<td>70.8*</td>
<td>9.8</td>
<td>3.8</td>
<td>2.56</td>
<td>0.011</td>
</tr>
</tbody>
</table>

Note: Significant within-group changes from month zero to six for middle-aged women were observed, \( p < .001 \).

Table 3-4. Role limitations due to physical health problems by age, adjusted for race/ethnicity (PP)

<table>
<thead>
<tr>
<th></th>
<th>Middle-aged (n = 118)</th>
<th>Older (n = 38)</th>
<th>Mean Difference</th>
<th>SE</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month 0</td>
<td>87.8</td>
<td>83.6</td>
<td>4.2</td>
<td>4.6</td>
<td>0.90</td>
<td>0.368</td>
</tr>
<tr>
<td>Month 6</td>
<td>87.8*</td>
<td>71.6*</td>
<td>16.2</td>
<td>5.3</td>
<td>3.06</td>
<td>0.003</td>
</tr>
<tr>
<td>Month 18</td>
<td>79.1**</td>
<td>58.3**</td>
<td>20.8</td>
<td>6.5</td>
<td>3.17</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Note: Significant within-group changes from month zero to month 18 for older women were observed, \( p < .001 \).

Table 3-5. Vitality by age, adjusted for race/ethnicity (PP)

<table>
<thead>
<tr>
<th></th>
<th>Middle-aged (n = 118)</th>
<th>Older (n = 38)</th>
<th>Mean Difference</th>
<th>SE</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month 0</td>
<td>57.1*</td>
<td>64.8*</td>
<td>7.7</td>
<td>3.2</td>
<td>2.39</td>
<td>0.018</td>
</tr>
<tr>
<td>Month 6</td>
<td>67.5</td>
<td>67.6</td>
<td>0.1</td>
<td>3.2</td>
<td>0.01</td>
<td>0.990</td>
</tr>
<tr>
<td>Month 18</td>
<td>61.6</td>
<td>63.8</td>
<td>2.2</td>
<td>3.4</td>
<td>0.66</td>
<td>0.511</td>
</tr>
</tbody>
</table>

Note: Significant within-group changes from month zero to months six and 18 observed for middle-aged participants, \( p < .001 \) and \( p < .02 \), respectively.
Figure 3-1. Within-group changes in weight in older participants, adjusted for race/ethnicity (PP, *n = 45*). Significant within-group changes were observed, *p < .001*.

Figure 3-2. Within-group changes in weight in older participants, adjusted for race/ethnicity (ITT, *n = 56*). Significant within-group changes were observed, *p < .01*. 
Figure 3-3. Within-group changes in risk factors in older participants, adjusted for race/ethnicity (PP, \( n = 45 \)).

Figure 3-4. Within-group changes in risk factors in older participants, adjusted for race/ethnicity (ITT, n = 56). A) Systolic blood pressure. B) LDL-cholesterol. C) C-reactive protein. D) HbA1c
Figure 3-5. Proportion of participants reporting a musculoskeletal adverse event by age.
Figure 3-6. Daily caloric intake by age, adjusted for race/ethnicity (PP, n = 45). No significant within- or between-group differences were observed.

Figure 3-7. Daily caloric intake by age, adjusted for race/ethnicity (ITT, n = 56). No significant within- or between-group differences were observed.
Figure 3-8. Physical fitness by age, adjusted for race/ethnicity (PP, n = 45). All within-group changes significant from pretreatment to months six and 18, \( p < .001 \); all between-group differences significant, \( p < .001 \).

Figure 3-9. Physical fitness by age, adjusted for race/ethnicity (ITT, n = 56). All between-group differences significant, \( p < .001 \).
Figure 3-10. Physical functioning by age, adjusted for race/ethnicity (PP). Significant within-group changes from month zero to six for middle-aged women were observed, $p < .001$.

Figure 3-11. Role limitations due to physical health problems by age, adjusted for race/ethnicity (PP). Significant within-group changes from month zero to month 18 for older women were observed, $p < .001$. 
Figure 3-12. Vitality by age, adjusted for race/ethnicity (PP). Significant within-group changes from month zero to months six and 18 observed for middle-aged participants, \( p < .001 \) and \( p < .02 \), respectively.
Primary Aims

The present study examined both the positive and negative outcomes of a lifestyle intervention for weight loss in a sample of older and middle-aged adults, and whether these outcomes were comparable between age groups. With regards to our primary aims, older women achieved significant reductions in weight and metabolic risk factors from pre- to post-treatment and at long-term follow-up. Older women who completed treatment lost a mean of 9.5% initial body weight at six months, and maintained a 7.6% loss at 18 months. This group of women also experienced a significant reduction in systolic blood pressure from pre- to post-treatment ($M=6.3$ mm Hg, $SD=12.2$ mm Hg), and largely maintained this decrease at 18 months ($M=4.6$ mm Hg, $SD=12.1$ mm Hg). Additionally, older women showed significant reductions in HbA1c from month zero to month six ($M=0.2\%, SD=0.5\%$) and from month zero to month 18 ($M=0.3\%, SD=0.4\%$). C-reactive protein also decreased significantly from month zero to month six ($M=2.0\%, SD=4.2\%$) and month zero to month 18 ($M=2.7\%, SD=4.6\%$). There was no significant within-group change over time in LDL-cholesterol levels. Results are consistent with previous research demonstrating marked reductions in weight and metabolic risk factors among older adults participating in lifestyle interventions (Diabetes Prevention Program Research Group, 2002; 2006; Lindstrom et al., 2006; MacMahon & Rodger, 1993; Tuomilehto et al., 2001; Whelton et al., 1998; Yamaoka & Tango, 2005).

In the present study, 23% of older Caucasian women reported at least one musculoskeletal injury during active treatment, and 47% reported this type of adverse event over the course of the 18-month intervention. These proportions were not significantly different than the 18% of middle-aged women reporting an injury during active treatment and 36% reporting an injury
throughout the 18 month study. The Diabetes Prevention Program Research Group (2006) described a similar pattern of results for participants in the lifestyle condition, by which participants between 60 and 85 years of age reported 28 musculoskeletal adverse events per 100 person-years, in contrast to 25 to 40 year old participants, who reported 20 musculoskeletal AEs per 100 person-years. This difference did not reach statistical significance.

When we further categorized the sample into five-year age increments, 56% of Caucasian women over 70 years of age reported at least one musculoskeletal injury throughout the 18 months, as compared to only 37% of Caucasian participants 50 to 69 years of age. Given that only 16 women fell into the above 70 age range, we did not have enough power to examine differences in the proportion of women over 70 reporting a musculoskeletal injury, as compared to younger age groups. However, this discrepancy warrants further investigation regarding the safety of behavioral weight loss treatment for older adults.

**Equivalence Testing.** We found support for our hypothesis that older and middle-aged women lose equivalent amounts of weight from pre- to post-treatment. Among treatment completers, older Caucasian women lost a mean of 9.5% initial body weight at six months, which was statistically equivalent to the 10.0% weight loss achieved by middle-aged Caucasian women. At 18 months, the difference between older and middle-aged participants exceeded the margin of equivalence, thus we were unable to determine equivalence, likely due to the small sample size of older adults. A comparison of middle-aged and older African-American women revealed a trend for older women to lose more weight than middle-aged women from pretreatment to month 18 (9.0% initial body weight as compared to 5.0%, respectively). Given that there were only six African-American women over 65 years of age, this difference in weight loss may have reached significance with larger samples.
Results did not support our hypothesis regarding the equivalence of musculoskeletal injury between middle-aged and older women. The difference in proportions of middle-aged and older women reporting this type of adverse event during active treatment and over the course of the entire study exceeded our specified margin of equivalence (±4%). Post-hoc power analyses suggested we would have needed over 800 participants per group to determine equivalence, even if we had used a wider 10% margin. Further, beyond rejecting our hypothesis that older and middle-aged women experience comparable rates of injury, it appears that older Caucasian women may be at greater risk for injury than middle-aged Caucasian women. This increased risk may be particularly pronounced for women over 70 years of age, 56% of whom reported at least one musculoskeletal adverse event during the 18 month study. However, given limits in power, we could not examine differences between five-year age cohorts.

Secondary Aims

**Dietary Intake and Adherence**

There were no significant within-group changes in caloric intake over the course of the study, nor were there differences between older and middle-aged participants. These findings are consistent with results from the DPP, whereby there was no significant difference in daily caloric intake between participants over 65 years of age and those under 45 (Diabetes Prevention Program Research Group, 2006). There was a difference, however, in the number of daily food records completed between older and younger participants, such that older individuals were more likely to complete self-monitoring records than younger participants (Diabetes Prevention Program Research Group, 2004). In the present study, there were no differences between older and middle-aged participants with regards to the number of daily food records completed during active treatment. However, consistent with results reported in the DPP, older women completed a significantly greater number of daily food records than middle-aged participants during Phase
II of the study (106 and 73, respectively). It may be that older individuals have fewer competing demands (e.g., full-time employment, child care), and therefore have more time to devote to a lifestyle intervention program. Additionally, due to the greater number and degree of health problems in older adults, elderly individuals may be more motivated to make lifestyle changes to improve their health.

**Physical Fitness**

Physical fitness, as measured by the 6MWT, improved for both older and middle-aged participants from month zero to months six and 18. Additionally, middle-aged women performed significantly better than older women on the 6MWT at each assessment. Results are consistent with previous research demonstrating an inverse relationship between age and physical fitness as measured by the 6MWT (Enright et al., 2006). Further, some research has found that older adults may be less likely to use physical activity as a tool for weight loss. For example, in an analysis of data from the Behavioral Risk Factor Surveillance System (BRFSS), Serdula et al. (1999) reported that the likelihood of utilizing physical activity for weight loss decreased with age. It may be that older adults are less willing to engage in exercise and activity prescriptions throughout the course of behavioral weight loss treatment for fear of injury, or lack of opportunity to participate in programmed activities such as group sports. However, other research has demonstrated the opposite pattern of results. In the DPP, older participants (60 to 85 years of age) were *more* likely to meet the exercise goal of 150 minutes per week than participants between 25 and 40 years of age (Diabetes Prevention Program Research Group, 2006). However, while older participants in the DPP spent more *time* exercising, younger participants may have spent a greater proportion of time in higher intensity activities. These trends may result in parallel increases in physical fitness among younger and older participants,
as we found in the present study. However, neither the intensity of physical activity nor physical fitness levels were reported in the DPP.

Health-Related Quality of Life

Analyses of Health-Related Quality of Life (HrQoL), as measured by the SF-36, indicated that older women did not experience significant improvements in various domains of HrQoL over the course of the study, whereas middle-aged women experienced several significant improvements. In the domain of Physical Functioning, middle-aged participants experienced a significant improvement over time, while older adults reported no change. Additionally, older women reported lower degrees of Physical Functioning at every assessment point, as compared to middle-aged participants. Further, in the domain of Role Limitations due to Physical Health problems, older women scored higher than middle-aged women at each assessment point. Additionally, older women reported a significant increase in Role Limitations due to Physical Health Problems over time, while middle-aged women described no change in this domain over the course of the study. Somewhat unexpectedly, older women reported higher levels of Vitality at pretreatment than middle-aged women. However, middle-aged women reported significant increases in this domain over the course of the study, while older participants did not experience significant changes over time. No changes over time were noted for middle-aged or older women in the domains of Social Functioning, Bodily Pain, General Mental Health, Role Limitations due to Emotional Problems, or General Health Perceptions. Generally, it appears that weight loss treatment was not effective in improving various domains of health-related quality of life for older women. In fact, older women experienced a significant increase in role limitations due to physical problems over the course of the study. By contrast, middle-aged participants demonstrated significant improvements in the domains of Physical Functioning and Vitality.
Previous research on HrQoL in older adults undergoing weight loss treatment has produced conflicting results. In contrast to our findings, a study of older adults with knee osteoarthritis described significant improvements in HrQoL after an 18-month lifestyle intervention producing a mean weight loss of 4.4% initial body weight (Rejeski et al., 2002). Yet, a prospective, observational study of 2354 adults in Spain described significant decrements in the domains of Role Limitations due to Emotional Functioning and General Mental Health among individuals who were obese at baseline and lost weight over two years (Leon-Munoz et al., 2005).

As we have no control group of older women not undergoing a lifestyle intervention, we cannot determine whether the increase in role limitations due to physical health problems is related to participation in weight loss treatment, or a natural consequence of aging. Further, we cannot say whether older obese women not receiving weight loss treatment may actually demonstrate a decline in HrQoL. Thus, it is possible that participation in the lifestyle program may prevent or slow a natural age-related decline in HrQoL. At this point, it remains unclear whether a lifestyle intervention for weight loss can facilitate positive changes in HrQoL for older adults.

**Limitations**

There are several limitations to the present study. First, we had a relatively small sample of older women, offering limited power to detect small differences in a variety of outcomes. Further, equivalence testing typically requires samples approximately 10% larger than those needed for traditional difference testing (Djulbegovic & Clarke, 2001). Subsequently, we did not have enough power to use equivalence testing on metabolic risk factor outcomes. A post-hoc power analysis indicated that we would have needed over 800 women per group to determine
equivalence with respect to musculoskeletal injury, even if we had broadened the margin of
equivalence to 10%.

A second limitation of this study was the lack of an untreated control group of older
women. Although there appeared to be a slight increase in risk of musculoskeletal injury for
older women, we cannot determine if this increase was related to participation in the study, or the
consequence of typical aging. Future research should compare the rate of musculoskeletal injury
in older women not undergoing weight loss treatment to those participating in the lifestyle
program to clarify if this type of treatment is associated with greater risk of injury in older adults.

Additionally, individuals with serious health conditions (e.g., uncontrolled diabetes or
hypertension) were excluded from participation in the study. The inclusion of relatively healthy
women may have implications with regard to the magnitude of changes seen across metabolic
risk factor outcomes. That is to say, there may be a floor effect by which participants without
significantly elevated risk factors can achieve only incremental reductions, whereas persons with
more severe health conditions have more potential to improve. There is some evidence to
suggest that obese individuals with more severe metabolic risk factors experience greater degrees
of change over the course of weight loss treatment than relatively healthy individuals. For
example, McLaughlin et al., (2001) compared insulin-resistant and insulin-sensitive obese
women undergoing four months of a caloric-restricted diet plus sibutramine. Though insulin-
resistant and insulin-sensitive women did not differ with regards to weight loss, insulin-resistant
women achieved significant reductions in metabolic risk factors such as LDL-cholesterol and
plasma triglyceride concentrations, while insulin-sensitive women did not.

Further, given that the severity of weight-related risk factors and diseases is typically
compounded with age, the exclusion of older women with serious health conditions at baseline
may have resulted in a sample of older women that is not representative of the larger population of women over 65 years of age. This would limit the generalizability of our results to older women with greater metabolic abnormalities. Generalizability is also limited by the exclusion of men, younger age groups, as well as the under-representation of older racial/ethnic minority participants.

Our is also limited by the potential confound of medication changes over the course of the study. For example, some participants may have experienced reductions in blood pressure or cholesterol such that their physicians discontinued or lowered their medication. Alternatively, metabolic risk factors may have worsened for some participants, warranting the initiation of, or increase in medication use. There is no reason to believe that these changes would occur differentially for middle-aged and older participants, but future analyses of the TOURS data should include an examination of this issue.

Finally, given that the adverse event data in this study are based on self-reports, results are subject to potential biases. It is possible that older adults were more attentive to the occurrence of relatively minor injuries, or more willing to report an injury than middle-aged participants. An increased vulnerability to injury, or an increased vigilance, or both may contribute to a greater likelihood of reported adverse events among older participants (Weingart et al., 2005). As there were no measures of muscle mass or bone density, we could not assess potentially important changes in body composition that may place older adults at risk of injury. Future studies examining the safety of weight loss treatment for older adults should include measures of body composition in order to explore potential mechanisms by which older adults may be at increased risk for musculoskeletal adverse events.
Clinical Implications

Our study has important clinical implications with regards to the safety and efficacy of behavioral weight loss interventions for older adults. Overall, it appears that older women can achieve significant improvements in health over the course of behavioral weight loss treatment. Results of the present study indicate that older women may be at greater risk for adverse consequences during participation in a lifestyle intervention for weight loss than middle-aged women. Thus, lifestyle interventions including older adults should take particular precautions to educate participants about safe ways to achieve exercise goals and avoid injury. Future research should also explore ways to prevent muscle and bone loss during weight loss treatment, such as the addition of strength or resistance training to physical activity programs.

In sum, it appears that older, obese women can experience substantial benefits over the course of a lifestyle intervention, including significant reductions in weight, blood pressure, glycemic control, and inflammation. However, the occurrence of negative outcomes potentially associated with participation in a lifestyle intervention for weight loss, namely musculoskeletal injury and decrements in health-related quality of life, warrant further exploration in older adults.
LIST OF REFERENCES


BIOGRAPHICAL SKETCH

Lauren Mari Gibbons was born on April 30, 1981, in Boston, Massachusetts. She grew up in Weston, Massachusetts, where she graduated from Weston High School in 1999. In 2003, she earned her B.A. from the University of Pennsylvania, with distinction in Psychology. After graduation, she worked as a research coordinator for 2 years at the University of Pennsylvania’s School of Medicine. In 2005, Lauren enrolled in the Clinical and Health Psychology program at the University of Florida. While at the University of Florida, she completed a number of research projects prior to graduating with her M.S. degree in May, 2007.