RESPONSE OF AFRICAN-AMERICAN AND CAUCASIAN WOMEN IN A RURAL SETTING TO A LIFESTYLE INTERVENTION FOR OBESITY

By

KATIE ALLISON RICKEL

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To my mother, my father, and my sister

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Katie Allison Rickel

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African-American and Caucasian individuals exhibit differential patterns of weight loss and regain, with African-Americans achieving smaller initial losses but better maintenance of lost weight than their Caucasian counterparts. However, this disparity has not been studied in medically underserved rural populations. The current study examined the response of obese, rural women aged between 50 and 75 years (African-American, n = 43; Caucasian, n = 181) to a 6-month lifestyle intervention for weight management followed by randomization to one of two 12-month personal extended care programs (group office-based sessions or individual telephone-based counseling) or to an educational control condition. Mean weight losses immediately following initial lifestyle treatment were smaller for African-American participants than for Caucasian participants (Ms = -6.99 $\pm$ 4.30 kg, -10.67 $\pm$ 5.14 kg, respectively, $p < .001$), but weight regain during extended care was comparable between the two groups. In addition, although Caucasians randomized to either of the extended care programs regained less weight than Caucasians

assigned to the control condition (*M*s = 1.03 $\pm$ 6.14 kg vs. 4.23 $\pm$ 6.45 kg, for the extended care and control groups, respectively, $p = .002$), the provision of extended care did not influence weight regain among African-Americans (*M*s = 1.67 $\pm$ 5.58 kg vs. 1.34 $\pm$ 4.68 kg for the extended care and control groups, respectively, $p = .85$). Exploratory analyses revealed that both African-Americans and Caucasians made significant improvements in various cardiovascular/metabolic (e.g., systolic and diastolic blood pressure, hemoglobin A1c, C-reactive protein, fitness) and behavioral (e.g., caloric and saturated fat intake, physical activity) factors during the lifestyle intervention. Further, African-Americans generally exhibited superior maintenance of these changes during the extended care period. Collectively, these findings suggest that a) racial/ethnic differences in weight loss during lifestyle intervention are observed in rural settings, b) despite disparate weight loss outcomes, African-Americans are able to achieve and maintain significant physiological and behavioral improvements, and c) the effectiveness of and necessity for extended care programs among weight-reduced African-Americans deserve increased attention in future research.

CHAPTER 1
INTRODUCTION

Obesity, defined as a Body Mass Index, BMI, ≥ 30 kg/m^2, is a leading risk factor for the development of a vast array of health conditions. Moreover, it has been well-established that lifestyle interventions can produce clinically significant weight reduction, leading to health benefits across a variety of these domains (Klein et al., 2004; Wadden, Butryn, & Byrne, 2004; Wing & Gorin, 2003). However, the existing research has largely ignored African-Americans and residents of rural areas, two populations with perhaps the greatest need for effective obesity treatments.

The few studies that have compared treatment response of African-Americans to that of Caucasians have found mixed outcomes. Although some interventions have produced similar weight reductions and health improvements in both groups (Gower, Weinsier, Jordan, Hunter, & Desmond, 2002; Weinsier et al., 2000; Weinsier, Hunter, Schultz, Zuckerman, & Darnell, 2002), others seem to be less effective in African-American than in Caucasian participants (Darga, Holden, Olson, & Lucas, 1994; Foster, Wadden, Swain, Anderson, & Vogt, 1999). Further, the vast majority of these data come from efficacy trials delivered to urban populations within academic medical settings. Thus, the current study attempted to fill this gap in the literature by evaluating how race/ethnicity is related to response of rural participants to a lifestyle intervention for obesity. Specifically, we examined racial/ethnic differences in 1) response immediately following lifestyle intervention, 2) maintenance of response during a follow-up period, and 3) the influence of modality of extended care.

Relationship between Obesity, Level of Urbanization, and Race/Ethnicity

Obesity is generally more prevalent in rural communities than in urban communities (23% vs. 16%) (Eberhardt et al., 2001). However, trends appear to vary by geographic region. Specifically, in the west, urban communities have the highest rates of obesity, whereas in the South, obesity is more prevalent in rural than in urban settings (Eberhardt et al., 2001). One manifestation of this latter trend is the presence of the “stroke belt,” the largely rural southeastern portion of the United States in which stroke mortality (to which obesity contributes) is particularly high. Differences between Midwest and Southern rural populations across a variety of factors (e.g., diet composition, level of occupational physical activity, racial/ethnic make-up, mean household income level, access to health care services) have been cited as possible explanations for their opposite patterns of obesity prevalence (Martin et al., 2005).

The relationship between race/ethnicity and prevalence of obesity has not been well-studied in rural populations. Across the United States, the prevalence of obesity is higher among African-Americans adults than among Caucasians adults (45.0% vs. 30.6%, Ogden et al., 2006). However, some investigators have demonstrated that this racial/ethnic difference in obesity prevalence does not replicate when assessed in rural communities (e.g., Appel, Harrell, & Deng, 2002; Hayward, Pienta, & McLaughlin, 1997; Patterson, Moore, Probst, & Shinogle, 2004). These researchers postulate that this difference in obesity prevalence disappears because there may be fewer racial/ethnic differences in the presence of certain risk factors for obesity (e.g., physical inactivity, high-fat diet) within rural communities.

Studies that have examined this hypothesis explicitly have found that physical activity patterns are more similar among African-Americans and Caucasians in rural areas than in urban communities (e.g., Parks, Housemann, & Brownson, 2003). By contrast, qualitative differences in diet are found in both rural and urban communities (e.g., Champagne et al., 2004), with African-Americans consuming less optimal diets (i.e., higher fat, fewer fruits and vegetables) than Caucasians. Thus, it is possible that homogeneity across other domains (e.g., educational attainment, income level) may be contributing to the absence of a racial/ethnic disparity in obesity in some rural communities.

Consequences of Obesity in African Americans and Caucasians

Interestingly, obesity may exert a differential impact on mortality in African-American compared to Caucasian populations. For example, Calle and colleagues (Calle, Thun, Petrelli, Rodriguez, & Heath, 1999) found a 20 to 30% increase in all-cause mortality in black women with BMIs exceeding 35; however, white women in this obesity category exhibited an elevated mortality risk of 75 to 100%. Further, although Caucasians in the highest category of obesity status exhibited greater mortality risk than did Caucasians at a healthy body weight, this relation was not found among African-Americans. Others have observed that these relations persist even after controlling for differences in age, income, or gender (Durazo-Arvizu et al., 1997; Sanchez, Reed, & Price, 2000). Nonetheless, treating obesity in both racial/ethnic groups leads to significant health benefits. As previously mentioned, lifestyle intervention has emerged as an effective means to improve health via weight reduction.

Lifestyle Interventions: Impact of Behavioral Factors

Dietary Intake

Traditional racial/ethnic dietary practices. Arguably the most potent ingredient of lifestyle interventions, dietary modification is an important determinant of success in obesity treatment programs. Typically, participants follow a low-calorie diet (i.e., a deficit of 500 to 1000 kilocalories below steady state) with some attention to improving quality of diet composition (e.g., reducing fat intake, increasing fruit and vegetable consumption). Given that community-dwelling African-Americans often fail to meet national dietary guidelines with respect to fruit, vegetable, and fat intake, the dietary prescriptions given in lifestyle interventions may differ substantially from what African-Americans are accustomed to consuming (Gary et al., 2004). Indeed, the average African-American woman eats proportionately more high-fat meats and fried foods, as well as fewer fruits, vegetables, and low-fat dairy products when compared to a typical Caucasian woman (Ard, Skinner, Chen, Aickin, & Svetkey, 2005). Thus, African Americans participating in lifestyle interventions are likely asked to make more dramatic changes in their eating habits than are their Caucasian counterparts.

Further, some research has suggested that there are specific qualitative differences between the African-American and the Caucasian diet. For example, in terms of source of dietary fat intake, African-Americans consume dietary fat primarily from red meat, poultry, and fish. In contrast, Caucasian participants tend to consume fat primarily in the forms of added fat, dairy foods, baked goods, mixed dishes, and vegetables/salads (Kristal, Shattuck, & Patterson, 1999). This distinction becomes important when considering the ease with which dietary modifications might be made; African-Americans have to alter what is likely the “main dish,” whereas Caucasians would alter foods that supplement a meal. Collectively, these factors suggest that the African-American diet may be less amenable to traditional caloric restriction techniques than is the Caucasian diet.

Barriers to dietary modification. Assuming that African-Americans need to make more drastic dietary changes than do their Caucasian counterparts, it would follow that African-Americans also may face more barriers when attempting these dietary modifications. Kumanyika (2002) has described a number of structural (e.g., targeted marketing of high-calorie foods on black television channels, abundance of fast food establishments and shortage of supermarkets in minority communities, food choice at social gatherings), economic (e.g., reliance on homemade foods, lower family income), and sociocultural (e.g., traditional high-fat preparation of foods, food insecurity, distrust of recommendations from medical field) challenges with which African-Americans must grapple.

Existing research on dietary modification. Very few studies have examined racial/ethnic differences with regard to changes in dietary intake during and/or after participation in a lifestyle change program. In the analyses that have been conducted, African-American participants do appear to be able to make similar and significant dietary improvements when compared to Caucasians participants (Glass, Miller, Szymanski, Fernhall, & Durnstine, 2002; Kristal et al., 1999; Svetkey et al., 2005). For example, after completing a nutrition education intervention focused on adopting a low-fat diet, reductions in fat from dairy foods, baked goods, poultry, and fish actually were greater in African-American than in Caucasian participants (Kristal et al., 1999). Racial/ethnic differences in weight change outcome were not assessed in this research. Further, in a study that did target weight loss, both African-American and Caucasian participants achieved comparable reductions in saturated fat and comparable increases in fruits, vegetables, and low-fat dairy products (Svetkey et al., 2005). In spite of these comparable behavioral changes, however, African-American women in this study lost significantly less weight than Caucasian women.

Intervention strategies. Several program-related factors seem to be especially important when implementing dietary modifications in a multi-ethnic population. The inclusion of clear and simple nutrition education, the use of individualized counseling, and instruction in estimating caloric and fat content appear to be particularly beneficial for African-American women (Bronner & Boyington, 2002). Additionally, the use of ethnic recipes (modified to be lower in calories and fat) is an effective way to facilitate dietary change in minority populations (Agurs-Collins, Kumanyika, Ten Have, & Adams-Campbell, 1997).

Assessment of dietary intake. The present study used a food frequency questionnaire to assess changes in dietary intake. However, a number of researchers (e.g., Tucker et al., 2005) have posited that the surveys and questionnaires used to collect information about dietary patterns may not be valid for use in multicultural samples. Nonetheless, many studies have found support for the cross-cultural validity of food frequency questionnaires by comparing these data to those derived from food diaries, 24-hour dietary recalls, and/or biological markers (e.g., Knutsen, Fraser, Linsted, Beeson, & Shavlik, 2001; Resnicow et al., 2000). Kristal and colleagues (Kristal et al., 2000) found similar associations among food frequency questionnaires, 24-hour recalls, and food diaries across racial/ethnic groups. Similarly, Knutsen and colleagues (Knutsen et al., 2001) found consistent associations between food frequency questionnaires, serum nutrient levels, and 24-hour recalls when data derived from African-American participants were compared to data derived from Caucasian participants.

However, others (e.g., Tucker et al., 2005) still argue that traditional assessments (e.g., food frequency questionnaires, telephone surveys) need to be tailored because they often fail to include questions about specific ethnic foods that make up large parts of the diets of minority populations. Some research has experimented with this concept by modifying measures for use in populations of interest.

For example, Mayer-Davis and colleagues (Mayer-Davis et al., 1999) designed a food frequency interview for an epidemiological study conducted in the southern U.S. (Insulin Resistance Arteriosclerosis Study, IRAS). After consultation with nutritionists who were familiar with participants' traditional diets, modifications to the assessment included adding regional food choices, such as ham hock and red chili. When compared to nutrient intake data derived from eight 24-hour dietary recalls, the food frequency interview had comparable validity across racial/ethnic groups (rural non-Hispanic Caucasians, $r = 0.61$; non-Hispanic African Americans, $r = .50$). This study was limited by its failure to compare the validity of this tailored measure to standard food frequency questionnaires.

Subsequently, another group (Tucker et al., 2005) completed a comparative analysis. Specifically, a similar modification technique was used to tailor a food frequency questionnaire for use in the impoverished rural region of the Lower Mississippi Delta. To this end, Tucker and colleagues (Tucker et al., 2005) added numerous regional foods (e.g. turnip greens, chitterlings, squirrel) and modified suggested portion sizes to customize a standardized food frequency instrument (Block – FFQ, Block et al., 1986) for use in their study. Using 24-hour dietary recall to assess convergent validity, the modified questionnaire appeared to yield more accurate data than the standard food frequency questionnaire. Evaluation of these tailored assessment tools continue, and these investigations may provide a means toward more valid data about dietary practices of minority groups. Nonetheless, despite the possible limitations of standardized dietary assessment instruments, the Block FFQ's cross-cultural validity in previous work justifies the use of this tool in the current study.

Physical Activity

Patterns and predictors of physical activity. As with their dietary practices, community-dwelling African-American and Caucasian participants differ in their usual patterns of leisure time physical activity. McGuire and colleagues (McGuire, Ahluwalia, & Strine, 2006) found that Caucasians accrue higher amounts of leisure time physical activity than do African-Americans. This pattern is particularly pronounced in the southern part of the country, even after controlling for age, income, and BMI (Washburn, Kline, Lackland, & Wheeler, 1992). Some authors have suggested that African-Americans' lower levels of leisure time physical activity might be offset by higher levels of occupational physical activity (e.g., Kumanyika, 2002). However, when data from doubly-labeled water experiments are examined (which do not differentiate between leisure-time or occupational activities), African-Americans still exhibit lower energy expenditure, largely due to overall lower levels of physical activity (Carpenter et al., 1998; Starling, Toth, Matthews, & Poehlman, 1998; Tuten, Petosa, Sargent, & Weston, 1995).

In addition, the correlates of participation in physical activity in African-American women deserve attention. Ransdell and Wells (1998) found marital status to be a reliable correlate of physical activity in African-American women, with married women participating in higher levels of activity than those who are single, widowed, or divorced.

The increasing prevalence of single-parent families (usually consisting of a mother and her children) in the African-American community suggests that this relationship may be a particularly important one for future study (U.S. Census Bureau, 2006). Further, Eyler and colleagues (Eyler et al., 2003) suggested that observing others who are physically active appears to be a significant predictor of activity for rural African-Americans but not for rural Caucasians. Because rural settings often are not conducive to physical activity participation in public places (i.e., due lack of sidewalks, poor street lighting, dangerous traffic patterns), African-Americans are not likely to see others in the community engage in physical activity.

Barriers to increasing physical activity. When attempting to increase physical activity as part of a weight-loss program, African-Americans face a number of barriers usually not addressed in traditional lifestyle interventions. For example, African-Americans endorse a preference for lifestyle activities (e.g., walking, gardening) over formal exercise programs (Wanko et al., 2004). Although these lifestyle activities may provide health benefits, the relatively modest amount of energy expended is unlikely to result in weight loss. However, this caveat is not always made clear to participants. In addition, almost half of African-American patients in an urban diabetes clinic indicated that pain was a substantial barrier to exercise (Wanko et al., 2004). Although Caucasians also cite pain as an exercise deterrent, African-Americans seem to suffer greater levels of disability (in terms of mobility and functionality) associated with obesity (Houston, Stevens, & Cai, 2005). It is possible that this differential burden in disability serves to further compound weight management difficulties for African-Americans; that is, reductions in mobility will likely result in lower overall energy expenditure, which helps maintain obesity. Lastly, Kumanyika (2002) identified unique economic (e.g., lack of discretionary time and money) and sociocultural (e.g., prestige of living a comfortable "sedentary" lifestyle) barriers African Americans face when attempting to adopt and maintain a program of physical activity.

Existing research on physical activity modification. Research evaluating racial/ethnic differences in physical activity during and after participation in a weight-loss intervention is even scarcer than the data comparing dietary modifications. Weinsier and colleagues (Weinsier et al., 2002) found that, after weight loss, Caucasian participants became more physically active, whereas African-American participants became less physically active. A parallel pattern emerged when comparing changes in weight-adjusted aerobic capacity (ml/kg/min), a likely correlate of changes in physical activity. African-Americans appeared to exhibit decreased aerobic capacity after weight loss, whereas Caucasians made increases in aerobic capacity. (Data concerning aerobic capacity unadjusted for body weight were not presented in the study. Thus, these outcomes are difficult to interpret.) Others in this group (Walsh, Hunter, Sirikul, & Gower, 2004) have hypothesized that physical activity is more aversive to African-Americans after weight loss, due to decreases in aerobic capacity, strength, and flexibility. It is important to note that these data have not been replicated independently in weight-reduced African-American participants. Thus, caution is warranted again when interpreting these observations.

Intervention strategies. Nonetheless, increases in physical activity are possible for African-Americans and are facilitated when weight-loss programs utilize culturally-sensitive programs. Incorporating religion and spirituality (Underwood & Powell, 2006), offering exercise programs and equipment at residential sites (Belza et al., 2004), building relationships among participants and emphasizing social support for exercise (Young & Stewart, 2006), and teaching pain management techniques (Golightly & Dominick, 2005), all have been effective in helping African-Americans increase physical activity during and/or after attempts at weight reduction.

Assessment of physical activity. Daily physical activity patterns have been assessed in a variety of ways, including self-report measures and interviewer-administered questionnaires, but the validity of methods of physical activity assessment has been a matter of controversy. One way in which researchers have attempted to establish validity of these methods is to correlate these data with physiological criteria, such as changes in cardiovascular fitness, heart rate, adiposity, or blood pressure. However, measures often have been validated in predominately Caucasian samples (Singh, Fraser, Knutsen, Lindset, & Bennett., 2001). Therefore, it remains unclear whether these instruments are equally valid for use in minority populations.

Resnicow and colleagues (Resnicow et al., 2003) sought to examine the validity of the Community Healthy Activities Model Program for Seniors (CHAMPS) physical activity questionnaire in a sample of African-American adults. Prior to their study, the CHAMPS had only been validated in Caucasian and Asian-American populations (Harada, Chiu, King, & Stewart, 2001). Resnicow's group compared CHAMPS data to the physiological measures of estimated VO_2 max, blood pressure, and BMI. The study revealed only a moderate correlation between CHAMPS indices and estimated VO_2 max. However, this study was limited in its approach to validity testing. Changes in the physiological measures assessed usually require significant increases in vigorous intensity activity. Thus, because the CHAMPS questionnaire emphasizes activities of moderate intensity, it is perhaps not surprising that few significant findings emerged. The use of accelerometry might have provided the authors with a more sensitive measure of change in overall physical activity level.

Physiological Responses to Lifestyle Treatment

A computerized literature search of PubMed and PsychInfo using the terms "obesity" combined with "African-American," "black," "ethnic differences," "Caucasian," "white," "weight control," "weight loss," or "obesity treatment" uncovered 16 independent intervention studies that have compared African-American and Caucasian participants' physiological response to lifestyle interventions. Because this research includes data covering a variety of outcome measures, only several key physiological responses will be described in detail below.

Weight loss

Relatively few studies have directly compared weight loss achieved by African-Americans to that achieved by Caucasians in the context of the same weight-loss trial (Kumanyika, 2002). In the small body of existing literature, none of the data suggest that African-Americans lose more weight than Caucasians. In fact, in half of the sixteen studies that have examined racial/ethnic differences in weight loss, (Darga et al., 1994; Foster et al., 1999; Kumanyika et al, 2002; Kumanyika, Doroskeka, Self, Bahnson, & Robertson, 1997; Kumanyika, Obarzanek, Stevens, Hebert, & Whelton,1991; Wing & Anglin, 1996; Wylie Rosett et al., 1993; Yanovski, Gormally, Lesser, Gwirtsman, & Yanovski, 1994), Caucasian participants clearly achieved weight losses of greater magnitude than did African-American participants. Of the remaining studies, 4 do not suggest racial/ethnic differences in amount of weight lost during treatment (Glass, Miller, Szymanski, Fernhall, & Durstine, 2002; Hong, Li, Wang, Elashoff, & Heber, 2005; Nicklas et al, 2003; Weinsier et al., 2002) and 4 yielded more complicated patterns (e.g., interactions between weight category and race/ethnicity, interactions between race/ethnicity and time).

In one of these latter studies, Djuric and colleagues (Djuric et al., 2002) found a racial/ethnic difference only among the heaviest women in their study, with African-Americans losing less weight than Caucasians. In another study, analyzing data from the Diabetes Prevention Program (DPP), a greater proportion of Caucasians met the study's weight-loss goal than did African-Americans by the end of the 6 month intensive treatment period (57% vs. 36%, respectively, Wing et al., 2004). However, after a variable follow-up period (*M* time to follow-up = 3.2 years), this difference disappeared (38% vs. 32%). Similar trends were noted by Wassertheil-Smoller and colleagues (Wassertheil-Smoller et al., 1985) and Stevens and colleagues (Stevens et al., 2001) in other multi-center weight-loss trials. These latter three studies highlight the possibility that African-Americans may experience a different rate and pattern of weight change during and after weight-loss attempts. This issue will be discussed in a later section.

Improvements in Metabolic Risk Factors

Although weight-loss outcomes are largely mixed, African-American and Caucasian women appear to reap similar metabolic benefits from weight loss. In studies wherein African-Americans and Caucasians lost similar amounts of weight, both Djuric and colleagues (Djuric et al., 2002) and Nicklas and colleagues (Nicklas et al., 2003) observed similar and significant improvements in both groups in HDL-cholesterol, LDL-cholesterol, triglycerides, systolic and diastolic blood pressure, fasting blood glucose, and insulin sensitivity.

These findings also have been replicated in studies where racial/ethnic differences in weight change existed. For example, Darga and his researchers (Darga et al., 1994) found that, even though Caucasians lost more weight than African-Americans, both groups experienced similar and significant improvements in blood pressure and in lipid profiles. One explanation of this surprising outcome may be that African-Americans exhibit a lower threshold at which weight loss produces physiological changes (Nicklas et al., 2003). Another equally plausible explanation is that the threshold at which weight loss confers metabolic benefits is low for all individuals, regardless of race/ethnicity. Therefore, even though weight losses were smaller for African-Americans in Dargas's research, the losses were sufficient to produce metabolic improvements.

Improvements in Cardiorespiratory Fitness

In contrast to this similarity in metabolic response, some studies suggest robust racial/ethnic differences in cardiorespiratory response to weight loss. Weinsier and his group (Weinsier et al., 2002) observed that, after weight loss, African-American women became less fit (i.e., exhibited increases in weight-adjusted VO_2 max) whereas Caucasian women became more fit (i.e., exhibited decreases in weight-adjusted VO_2 max). Further, both Nicklas and colleagues (Nicklas et al., 1999) and Hunter and colleagues (Hunter, Weinsier, Zuckerman, & Darnell, 2004) found increases in weight-adjusted VO_2 max to be greater in Caucasian than in African-American participants. The latter group also determined that African-Americans experienced significantly more physiologic difficulty during exercise, as evidenced by higher heart rates, lower ventilation, and higher ratings of perceived exertion. It may be important to note that the participants in these studies did not exercise during their weight-loss attempts. Thus, these outcomes may not be representative of outcomes associated with more comprehensive lifestyle treatments.

Role of Social Support in Weight-loss Interventions

Caucasian women receive more naturalistic social support for weight loss than do African-Americans (Nothwehr, 2004). The lack of social support for weight loss in the African-American community is related to multiple factors. For one, the African-American "ideal" body type is indeed larger than the Caucasian "ideal" (Kumanyika, Wilson, & Guilford-Davenport, 1993). African-Americans tend to endorse more positive body image and to experience less cultural pressure to lose weight, even after controlling for age, BMI, and education (Smith, Thompson, Raczynski, & Hilner, 1999). In addition, Kumanyika (2002) points out that, in many minority cultures, food serves as an important form of social currency, such that individuals show appreciation of each other through the serving and eating of large quantities of traditional (often high-calorie, high-fat) foods. Thus, restricting one's calories would likely not be supported among one's family and friends.

The general lack of support for weight loss within the African-American community suggests that a social support network built into the intervention itself may be particularly important for African-American participants. Indeed, African-American women seem to particularly benefit from treatments that are delivered in a group-session format (Bronner & Boyington, 2002). Enhanced perceived control and bolstered self-efficacy have been suggested as the variables mediating the relationship between social support and success in group weight-loss interventions among African-American women (Wolfe, 2004).

Racial/ethnic Differences in Patterns of Weight Change

As previously mentioned, African-Americans and Caucasians may lose and regain lost weight at different rates. Two independent multi-center trials (Wassertheil-Smoller et al., 1985; Stevens et al., 2001) found that African-Americans lost less weight during initial treatment than did Caucasians; however, at long-term follow-up, net weight losses became similar. In the DISH (Dietary Intervention Study of Hypertension) trial, Caucasians and African-Americans achieved weight changes of -2.5 and -1.7 kg, respectively, at 8 weeks; however, at 56 weeks, the net changes were -4.1 and -5.0 kg for Caucasians and African-Americans, respectively (Wassertheil-Smoller et al., 1985). Similarly, in the TOHP II (Trials of Hypertension Prevention, Phase II) study, Stevens and colleagues (Stevens et al., 2001) found that Caucasians exhibited greater net changes than African-Americans at 6 months (-2.4 kg vs. –1.0 kg, respectively, $p < .01$) and at 18 months (-1.0 kg vs. 0.2 kg, respectively, $p < .03$) but that groups exhibited similar net change by 36 months (0.6 kg vs. 1.4 kg, respectively, $p > 0.2$). It is possible, however, that the relatively small weight changes reported in these studies limit the utility of these data in illustrating racial/ethnic disparities in response to lifestyle interventions. These studies were not designed to evaluate such differences, and they likely lacked the power necessary to detect meaningful patterns.

Further, the interpretation of these data is potentially flawed. In both studies, the authors suggest that weight loss achieved by African-Americans is comparable to that achieved by Caucasians when participants are assessed long-term. This interpretation is based upon the observation that the differences between Caucasian and African-American losses are no longer significant at follow-up. However, the authors overlook an important distinction between their findings, “lack of evidence for a difference”, versus their interpretation of the data, “evidence for lack of a difference” (Gomberg-

Maitland, Frison, & Halperin, 2003). In other words, being unable to detect a difference between values does not imply that the values are equivalent.

A statistical procedure called an equivalence trial, however, can provide this "evidence for lack of a difference." To employ this method, an equivalence margin – the smallest difference between values that would be clinically meaningful – is chosen a priori on the basis of both clinical judgment and existing data in the literature. In an equivalence trial, the null hypothesis states that the difference between the values exceeds the equivalence margin. The objective of the analysis is to gather evidence that rejects this hypothesis, thereby supporting the alternative hypothesis that the two values are clinically equivalent (Tamayo-Sarver, Albert, Tamayo-Sarver, & Cydulka., 2005).

Nonetheless, there are a number of factors that could indeed produce a true convergence in these data. For one, it is possible that African-Americans continue to lose weight after the initial treatment period ends, whereas Caucasians only maintain lost weight during follow-up. Alternatively, African-Americans might be better able to sustain their behavioral changes and weight losses because they both are generally of smaller magnitude than the change and loss achieved by Caucasians after initial treatment. In the Trial of Nonpharmacologic Interventions in the Elderly, Kumanyika and colleages (Kumanyika et al., 2002) found support for both explanations. Their data revealed that, among participants who failed to lose 3.6 kg or more at 6 months, African-Americans were more successful than Caucasians in continuing to lose weight and in maintaining lost weight during the follow-up period.

A more recent study (Kumanyika et al., 2005) examined program-related factors that might influence maintenance of lost weight in African-American participants. After completion of an initial weight-loss program, participants were randomized to (a) further group sessions, (b) staff-facilitated self-help program, or (c) a clinic visit only control condition. The authors were surprised to find that neither of the maintenance programs was superior to clinic visits only. In fact, none of the groups exhibited significant weight changes during the 10-month follow-up period. This is the only study to our knowledge that has studied the effectiveness of extended care approaches in an exclusively African-American population; thus, it is possible that aspects of the content and/or delivery specific to these programs were responsible for their ineffectiveness. Further, no study to date has directly *compared* the responses of African-American and Caucasian individuals to different extended care programs in the context of a single trial. Given the established importance of social support for African-Americans attempting to manage weight (Boyington & Bronner, 2002), group support may be superior to individualized counseling for this population.

Aims and Hypotheses of Current Study

There were three aims of the current study. The primary aim was to evaluate racial/ethnic differences in weight change (a) immediately after completing a 6-month lifestyle intervention (Month 0 to Month 6), and (b) during a 12-month extended care period (Month 6 to Month 18). It was hypothesized that (a) Caucasians would lose more weight than African-Americans between Month 0 and Month 6, (b) Caucasians would exhibit greater weight regain during the 12-month extended care period, between Month 6 and Month 18.

The secondary aim was to compare the effects of two extended care programs (office-based group sessions vs. telephone-based individual counseling) on changes in weight within each racial/ethnic group. African-Americans, perhaps even more so than

Caucasians, may derive benefit from social support built into the intervention. Thus, it was hypothesized that African-Americans assigned to the office-based group extended care program would exhibit smaller weight regain than African-Americans assigned to the telephone-based individualized extended care program. The effect was not expected to occur among Caucasian participants.

The tertiary aim was to evaluate racial/ethnic differences in changes along a variety of physiological and behavioral domains, including (a) systolic and diastolic blood pressure, (b) LDL-cholesterol, (c) triglycerides, (d) HbA1c, (e) C-reactive protein, (f) distance covered during 6-minute walk test (a measure of fitness), (g) daily caloric intake, (h) daily saturated fat intake, and (i) energy expended during activities of moderate or greater intensity. In addition, racial/ethnic differences in adherence and program satisfaction were explored. Because these tertiary aims were exploratory, no a priori hypotheses were postulated.

CHAPTER 2
RESEARCH METHODS AND PROCEDURES

Parent Study: Treatment of Obesity in Underserved Rural Settings (TOURS)

TOURS was conducted as a three-arm randomized controlled trial to evaluate the effectiveness of interventions designed to improve long-term weight management in obese women from medically underserved rural counties. Participants were randomized to one of three 18-month treatment programs delivered in rural counties through Cooperative Extension Service offices. Each treatment program began with an identical 6-month lifestyle intervention for weight loss (Phase I), and treatment conditions differed in the extended care program delivered during the 12 months following the lifestyle intervention (Phase II). The three extended care programs included two intervention conditions, (a) continued office-based group sessions, (b) individual telephone counseling, and (c) a control condition providing health education via mail. Assessments were conducted at baseline (Month 0), post-lifestyle intervention (Month 6), and post-extended care period (Month 18).

Participating County Cooperative Extension Service (CES) Offices

All assessments and interventions were carried out in CES offices of the six participating rural counties in north Florida. All six counties have been designated in whole or in part as “Health Professional Shortage Areas” by the U.S. Department of Health and Human Services. The demographic characteristics of the six counties (based on the 2000 Census) indicate that the population is largely white (80.2%), with African-Americans (15.8%) making up the next largest racial/ethnic category. As a group, the participating counties are characterized by relatively low levels of educational attainment. The mean percentage of adults who are high school graduates is 63.4%, compared with the U.S. national average of 84.1%. Compared to the U.S. population as a whole, the participating counties have relatively low household income levels ($26, 517 vs. $50,890) and relatively high levels of poverty (21.3% vs. 11.3%).

Participants

Participants were 224 obese women (African-American, n = 43; Caucasian, n = 181) from medically underserved rural counties who volunteered to take part in an 18-month lifestyle obesity treatment program. For the parent study, three cohorts of participants were recruited and randomized at 6-month intervals. Eligibility requirements included age between 50 and 75 years, body mass index (BMI) of 30 kg/m^2 or greater, and current residence in a rural county in North Central Florida. Individuals who were unwilling or unable to give informed consent, who were unwilling to accept random assignment, or who were participating in another research project were not accepted. Potential participants were excluded if, at screening, their medical history, clinical examination, or laboratory results revealed underlying disease likely to limit lifespan and/or increase risk of interventions (e.g., cancer within 5 years, chronic or recurrent respiratory or gastrointestinal conditions, history of musculo-skeletal conditions) or that revealed metabolic abnormalities despite appropriate treatment (e.g., fasting blood glucose > 125 mg/dl, fasting serum triglycerides > 400 mg/dl, resting blood pressure > 140/90). Also, participants were excluded if they were unable to travel to their local CES office for intervention sessions, were diagnosed with a major psychiatric disorder, or had lost more than 10 pounds in the 6 months prior to screening.

Procedures

Recruitment and Screening

Participants were recruited through a variety of methods, including direct mailings, media articles, radio announcements, and community presentations. Both culturally-sensitive approaches and direct solicitation to community groups were used to attract a demographically representative sample. For example, African-American members of our recruitment staff gave presentations to churches with predominately African-American congregations.

Following a preliminary telephone screening, prospective participants were invited to an in-person assessment at their local CES office. This assessment included completion of informed consent and a medical evaluation conducted by a mobile clinical assessment team led by a licensed registered nurse.

Data Collection

Race/ethnicity. As part of a demographic questionnaire, participants were asked to report the race/ethnicity with which they most strongly identified. Only participants identifying as African-American or as Caucasian were used for analyses in the present study.

Weight. Weight (assessed in light clothing and without shoes) was measured to the nearest 0.1 kilogram with a calibrated and certified balance beam scale.

Blood pressure and blood analysis. Systolic and diastolic blood pressure were measured by a registered nurse, who used a standardized protocol. Three readings were taken, spaced one minute apart, and the last two were averaged. The registered nurse or a study phlebotomist drew 22 ml of blood, and Quest Diagnostics Clinical Laboratories analyzed the sample for a metabolic and lipid profile. Of the levels assessed, only LDL-cholesterol, triglycerides, C-reactive protein, and HbA1c were considered in the current study.

Dietary intake. The Block 95 Food Questionnaire (Block et al., 1986) is a validated self-report instrument that asks respondents to estimate their consumption of a wide variety of foods over the past year. Scoring yields estimates of macro- and micro-nutrient intake, as well as intake by specific food group. A recent validational study showed a strong correlation between the Block 95 Food Frequency Questionnaire and four-day food records (Subar et al., 2001).

Physical activity. The CHAMPS Physical Activity Questionnaire (Stewart et al., 2001) is a 41-item self-report measure developed specifically for the assessment of physical activity in adults aged 50 years and older. The CHAMPS measure yields estimates of energy expended per week in all physical activities and in activities of at least moderate intensity. Two-week test-retest reliability coefficients ranged from .62 to .76, and discriminant validity has been established in groups of older adults with varied physical activity levels (Stewart et al., 2001).

Physical fitness. The 6-Minute Walk Test (6MWT) is a commonly used assessment procedure designed to evaluate changes in fitness in people with low exercise capacity. Participants walk along an indoor course, trying to cover as much ground as possible in 6 minutes. Distance walked is measured and recorded to the nearest foot. The reliability of the 6MWT in low-fit populations is high (Kervio, Ville, Leclercq, Daubert, & Carre, 2004), and its validity as a measure of fitness is supported by its high correlation ($r = 0.68$) with peak oxygen uptake during maximal exercise testing (Zugck et al., 2002).

Adherence to behavioral modification. Participants were supplied with food and exercise diaries in which they were instructed to record information about daily eating (type, amount, and caloric content of foods consumed) and daily physical activity (steps measured by pedometer). During the lifestyle intervention, diaries were to be completed each day, and participants were instructed to submit the previous week's food and exercise diaries at each group meeting. During the extended care period, diaries were to be completed at least three times each week, and participants were encouraged to submit diaries every two weeks during this 12-month extended care period.

Satisfaction with lifestyle intervention. Participants also completed a 36-item questionnaire (specifically designed for the present study) that yields composite scores assessing their (a) overall satisfaction with the lifestyle intervention, (b) perceived usefulness of strategies taught during the lifestyle intervention, and (c) current use of strategies taught during the lifestyle intervention. It is important to note that this questionnaire has not been validated.

Intervention

During the lifestyle intervention (Month 0 – Month 6), all participants completed the same obesity treatment program. The intervention consisted of 24 weekly 90-minute group (n = 10-14 participants/group) sessions led by bachelor's and/or master's level interventionists who followed a structured protocol. During sessions, participants (a) reported on, and received feedback about, their previous week's progress in reaching eating and physical activity goals; (b) learned skills related to cognitive-behavioral self-management, healthful eating behaviors, and physical activity practice; and (c) identified specific behavioral goals for the coming week, receiving encouragement from fellow group participants.

Certain procedures of this initial lifestyle treatment were culturally tailored to suit the special needs and issues of rural women. These included provision of a recipe booklet, "Down Home Healthy Cookin'"(National Institutes of Health, 2000), which provides recipes and cooking tips for preparing traditional African-American and Southern dishes with lower fat, lower calorie, and lower sodium ingredients. Cooking demonstrations and food tastings were incorporated into selected intervention sessions in order to expose participants to healthful menu items. In addition, a simplified version of the self-monitoring materials was made available to those in need of assistance.

At the conclusion of the lifestyle intervention (Month 6), participants were notified of their randomization assignment to one of the three 12-month extended care conditions: an office-based extended care program, a telephone-based extended care program, or an educational control condition.

Office-based extended care program. In this condition, participants continued to meet at their CES office for on-site group sessions every other week. At each session, participants submitted any eating or exercise diaries completed since the last session and were weighed. Session format and content were guided by social problem solving theory, which utilizes a 5-stage problem solving model consisting of (a) problem orientation, (b) problem definition and formulation, (c) generation of alternatives, (d) decision making, and (e) solution implementation. During the session, interventionists led the participants in group problem solving with the goal of generating a solution plan for dealing with one of the problem situations described by a particular group member. Sessions concluded with each participant identifying specific behavioral goals for the following two-week period and receiving feedback and support from fellow group members.

Telephone-based extended care program. Participants randomized to this condition received two scheduled telephone contacts each month from their lifestyle intervention leader. During the telephone call, leaders attempted to (a) prompt participants to continue using key weight-management strategies, (b) use the previously described problem-solving model to identify specific problems and to generate a plan, (c) provide support and reinforcement for continued efforts at weight management, and (d) collect participant's self-reported weight as well as information recorded on any eating and exercise diaries completed. (Participants were then encouraged to submit their diaries and self-reported weight by mail.) Interventionists followed a specific protocol when interacting with participants.

Education control condition. Participants randomized to this condition received biweekly newsletters with educational information about proper eating and physical activity. The newsletters included low-fat, low-calorie recipes, as well as tips for leading a lifestyle conducive to weight maintenance. In addition, a summary of the problem-solving model was provided. Participants were asked to mail their self-reported weights, as well as any completed eating and exercise diaries, to our laboratory every two weeks.

Statistical Procedures and Analyses

Only Phase I treatment completers (i.e., participants who had attended at least half of the lifestyle intervention sessions including at least one session between weeks 18 and 24) were included in the statistical analyses. Further, because the literature suggests that African-American and Caucasian individuals exhibit differential patterns of weight change during and after lifestyle intervention (Kumanyika, 2002), it would have been imprudent to impute values for missing weight data. Thus, when no data were available for a participant on a certain outcome measure, the participant was excluded from that analysis. This is reflected in the *n*'s reported in the tables at the end of chapter 3.

Preliminary analyses using ANOVA procedures were carried out to determine whether the African-American and Caucasian participants differed with respect to baseline demographic (e.g., age, weight, education) characteristics. Differences uncovered were included as covariates in the subsequent analyses.

Primary aim. To address the study's primary aim, weight changes achieved between (a) Month 0 and Month 6 and between (b) Month 6 and Month 18 were calculated. We expected to observe (a) a greater magnitude of weight loss by Caucasians between Months 0 and 6 and (b) a greater magnitude of weight regain by Caucasians between Months 6 and 18. An analysis of variance (ANOVA), with race/ethnicity as the categorizing variable, was used to examine racial/ethnic differences in weight change between Months 0 and 6, and a parallel ANOVA was conducted with respect to racial/ethnic differences in weight change between Months 6 and 18. Analyses were also conducted for body mass index and percentage of initial weight lost.

Secondary aim. For the secondary aim, in which the influence of the type of extended care condition was evaluated with respect to weight change, African-American participants and Caucasian participants were examined separately. For each racial/ethnic group, a 2 X 2 repeated measures ANOVA was conducted, with two time points (Month 6 and Month 18) and two categories of extended care condition (office-based group sessions and telephone-based individual counseling).

Tertiary aim. Lastly, the tertiary aim entailed examination of racial/ethnic differences along a variety of other parameters. Changes in systolic and diastolic blood pressure, LDL-cholesterol, triglycerides, HbA1c, distance covered during 6MWT, daily caloric intake, daily saturated fat intake, and energy expended during activities of moderate intensity were assessed as outcome measures. Adherence measures (i.e., attendance at group sessions, completion of food and exercise logs) and program satisfaction were also considered. For each tertiary aim outcome measure, two 2 x 2 repeated measures ANOVA were employed, one for changes during the lifestyle intervention and one for changes during the extended care program. Thus, the first repeated measures ANOVA used two assessment points (Month 0 and Month 6) and two racial/ethnic categories (African-American and Caucasian), and the second used two time periods (Month 6 and Month 18) and two racial/ethnic categories (African-American and Caucasian). Estimated marginal means (using Bonferroni corrections) were calculated and used to decompose significant interactions. For all analyses, significance testing was conducted at α = 05.

CHAPTER 3
RESULTS

Recruitment and Screening

A consort statement summarizing the results of the screening and assessment process is displayed in Figure 3-1. The reasons for exclusion by racial/ethnic group (for exclusions verified during the telephone screen or at the in-person assessment visit) are presented in Table 3-1. There were no significant differences in the proportion of African-American compared to Caucasian participants who were excluded for a non-musculoskeletal medical condition [$\chi^2(1) = 2.07$, $p = .15$] or on the basis of screening visit results (e.g., elevated blood pressure, abnormal lipid panel) [$\chi^2(1) = 1.94$, $p = .16$]. However, a marginally greater proportion of Caucasians (relative to African-Americans) were excluded for a musculoskeletal condition [$\chi^2(1) = 3.55$, $p = .06$].

Participants Starting and Completing Phase I

Of the African-American and Caucasian participants eligible for randomization, 3 African-Americans and 26 Caucasians were not randomized. Of the African-American individuals not randomized, one participant reported a work conflict, another no longer met the study's weight criteria, and a third was lost to follow-up. Caucasians who were not randomized had endorsed a variety of reasons (e.g., conflict with the group meeting time, incipient illness/injury, lost to follow-up). As described previously, participants were categorized as having completed Phase I of the study if they a) attended at least half of the Phase I group sessions and b) attended at least one session between weeks 18 and 24. Proportion of participants classified as Phase I completers did not differ by racial/ethnic group [χ^2 (1) = 2.80, p = .094]. Of the 61 African-Americans who began the study, 43 (70.5%) were classified as Phase I completers. Of the 225 Caucasians who began the study, 181 (80.4%) were classified as Phase I completers.

Baseline Characteristics

Table 3-2 displays the baseline demographic characteristics of the African-American (n = 43) and Caucasian (n = 181) women who completed Phase I of the trial. African-American participants were significantly younger than Caucasian participants (for African-American and Caucasian participants, 58.01 $\pm$ 5.71, 60.06 $\pm$ 6.07 years, respectively, $p < .05$). Thus, age was used as a covariate in all subsequent analyses that included both African-American and Caucasian participants. Consequently, all such data presented are estimated marginal means (EMM) with standard errors (SE). In all but one analysis (i.e., change in distance covered during the 6-minute walk test between Months 0 and 6), the effect of this covariate was not significant. Overall, groups were similar with regard to baseline body weight and BMI, employment status, marital status, education level, and annual household income (ps > .05).

Primary Aim: Changes in Body Weight

As shown in Table 3-3, Caucasians lost more weight than African-Americans between Months 0 and 6 [$F(1, 221) = 20.70$, $p < .001$]. Racial/ethnic differences in weight change between Months 6 and 18 were not significant (p = .535). Within-group analyses revealed that both groups exhibited significant reductions in weight between Months 0 and 6 (ps < .001), whereas only Caucasian participants exhibited significant regain between Months 6 and 18 ($p < .001$). Weight regain by African-Americans did approach significance, however (p = .066).

Further (also described in Table 3-3), parallel findings emerged for percentage weight lost from baseline and for changes in BMI, with one exception. Namely, although African-Americans did not exhibit significant increases in weight gain or BMI between Months 6 and 18, this group did exhibit a significant percent weight change during that period (p = .040).

Table 3-4 and Figure 3-2 further describe weight losses achieved at Month 6 and at Month 18 by African-American and Caucasian participants. Chi-square analyses revealed that a greater proportion of Caucasians (compared to African-Americans) achieved weight losses of at least 10% of initial body weight at both Month 6 and Month 18 (Month 6, $\chi^2(1) = 16.21$, $p < .001$; Month 18, $\chi^2(1) = 11.77$, $p = .001$). The modal loss for African-Americans at Months 6 and 18 was between 5.00 and 9.99%, whereas the modal loss for Caucasians at Months 6 and 18 was greater than 10.0%.

In addition to these analyses of those participants who completed Phase I, additional analyses were conducted using all available data from both Phase I completers and Phase I non-completers (African-Americans, n = 50, Caucasians, n = 197). Identical findings emerged, with one exception. Although African-Americans' weight regain between Months 6 and 18 only approached significance in the completers analyses, their regain did reach significance when Phase I non-completers were included (p = .006).

Secondary Aim: Effect of Extended Care Program within each Racial/Ethnic Group

The study's original secondary aim entailed comparing, within each racial/ethnic group, the weight changes of participants in the two extended care programs (office-based group sessions versus telephone-based individual counseling). These analyses did not reveal a significant interaction between time and type of extended care program assignment in either the African-American or Caucasian participants. African-American participants assigned to the office-based group sessions regained 3.02 ± 4.38 kg, whereas those assigned to the telephone-based individual counseling regained 1.03 ± 6.07 kg (p = .35). Although this difference is not statistically significant, it may have clinically meaningful implications. However, Caucasian participants assigned to the office-based group sessions exhibited levels of weight regain (M = 0.76 ± 6.19 kg) that were neither statistically nor clinically different from weight regain exhibited by those assigned to the telephone-based individual counseling (1.39 ± 6.12 kg, p = .55).

Further consideration prompted two additional post hoc analyses, however. Again for each racial group, those assigned to either of the extended care programs were compared to those assigned to the control condition. As displayed in Figure 3-3, participation in a extended care program was unrelated to weight regain for African-Americans (extended care program, 1.67 ± 1.03 kg; control condition, 1.34 ± 1.56 kg, p = .85). However, Caucasians assigned to an extended care program regained significantly less weight than those assigned to the control condition (extended care program, 1.03 ± 0.58 kg; control condition, 4.23 ± 0.83 kg, p = .002). Parallel analyses using all available data (i.e., data for both Phase I completers and Phase I non-completers) revealed the same pattern of findings.

Tertiary Aim: Changes in Selected Outcomes

Changes during lifestyle intervention (Months 0 – 6)

Systolic blood pressure. As shown in Table 3-5 and Figure 3-4, repeated measures ANCOVA revealed significant main effects for time [$F(1, 221) = 58.51$, $p < .001$] and ethnicity [$F(1, 221) = 3.88$, $p = .050$] between Month 0 and Month 6, but the interaction effect was not significant (p = .554). There were no racial/ethnic differences in systolic blood pressure at either Month 0 or Month 6. Further, at Month 6, both

African-Americans and Caucasians had exhibited a significant decrease from Month 0 (*p*s $< .001$).

Diastolic blood pressure. Significant main effects for time [$F(1, 221) = 20.97$, $p < .001$] and ethnicity [$F(1, 221) = 7.97$, $p = .005$] emerged with respect to diastolic blood pressure during the lifestyle intervention (see Table 3-5 and Figure 3-5). However, the interaction between time and race/ethnicity did not reach significance ($p = .441$). African-Americans were found to have significantly higher diastolic blood pressure than Caucasians at Month 0 ($p = .043$) and at Month 6 ($p = .007$), and both groups exhibited significant decreases in diastolic blood pressure during this period (for African-Americans and Caucasians, $p = .036$ and $p < .001$, respectively).

It should be noted that 69.8% of African-Americans and 44.2% of Caucasians were being treated with hypertensive medications over the course of the study. However, including medication status as a covariate in these analyses had no apparent effect on the outcomes just described.

Triglycerides. Repeated measures ANCOVA uncovered significant main effects for time [$F(1, 217) = 10.06$, $p = .002$] and race/ethnicity [$F(1, 217) = 14.16$, $p < .001$], but no interaction was apparent between time and race/ethnicity with respect to triglycerides ($p = .183$, see Table 3-6 and Figure 3-6). Caucasian participants presented with higher levels of triglycerides at both Month 0 (p < .001) and at Month 6 ($p = .009$) when compared to African-Americans. Further, only Caucasians demonstrated significant decreases in triglycerides over the course of the lifestyle intervention ($p < .001$).

LDL-cholesterol. Table 3-6 and Figure 3-7 illustrate that repeated measures ANCOVA did not find main effects for either time (p = .236) or race/ethnicity (p = .589) with regard to LDL-cholesterol. A marginally significant interaction between time and race/ethnicity did emerge, however [$F(1, 215) = 3.34$, $p = .069$]. African-American and Caucasian participants did not differ in LDL-cholesterol at either Month 0 or at Month 6, and only Caucasians achieved significant decreases in LDL-cholesterol between those two assessment points ($p = .001$).

Although 66.7% and 40.2% of African-Americans and Caucasians, respectively, were being treated with lipid-lowering medications, inclusion of medication status in the analyses did not influence the outcomes presented.

Hemoglobin A1c. As shown in Table 3-7 and Figure 3-8, there were main effects for time [$F(1, 218) = 53.30$, $p < .001$] and race/ethnicity [$F(1, 218) = 36.68$, $p < .001$] with regard to HbA1c assessed at Months 0 and 6. The interaction between time and race/ethnicity was not significant ($p = .295$). African-Americans exhibited higher HbA1c at both assessment points when compared to Caucasians (ps < .001), but both groups made significant decreases in HbA1c during the lifestyle intervention (ps < .001). Moreover, 45.6 % of African-Americans and 28.7% of Caucasians were being treated with diabetic medications. However, including diabetic medication status as a covariate did not affect these results.

C-reactive protein. Repeated measures ANCOVA revealed only a main effect for time with respect to C-reactive protein [$F(1, 218) = 43.07$, $p < .001$, see Table 3-8 and Figure 3-9]. Neither the main effect for race/ethnicity nor the interaction effect was significant (for the main effect of race/ethnicity and the interaction effect, $p = .618$ and p

= .811, respectively). African-American and Caucasians did not differ in terms of C-reactive protein levels at Month 0 or at Month 6, but both groups achieved significant decreases during the lifestyle intervention (for African-American and Caucasian participants, $p = .001$ and $p < .0001$, respectively).

Six-minute walk test. Table 3-8 and Figure 3-10 show significant main effects for time [$F(1, 215) = 38.21$, $p < .001$] and race/ethnicity [$F(1, 215) = 10.71$, $p = .001$], and the interaction between time and race/ethnicity approached significance [$F(1, 215) = 2.86$, $p = .092$] with respect to distance covered during the 6-minute walk test. In terms of statistical significance, Caucasian participants' performance was superior to African-American participants' performance at both Month 0 ($p = .024$) and at Month 6 ($p < .001$), but these differences were not clinically meaningful. Further, both groups made significant increases in distance covered between Months 0 and 6 (for African-American and Caucasian participants, $p = .014$ and $p < .001$, respectively).

Energy expenditure during activities of at least moderate intensity. Repeated measures ANCOVA uncovered main effects for time [$F(1, 214) = 47.65$, $p < .001$] and race/ethnicity [$F(1, 214) = 3.95$, $p = .048$] with regard to self-reported weekly energy expenditure during activities of at least moderate intensity, but there was no interaction effect ($p = .235$). As shown in Table 3-8 and Figure 3-11, African-American participants reported lower energy expenditure than Caucasians at Month 0 ($p = .014$) but not at Month 6. Further, both racial/ethnic groups reported increased weekly energy expenditure over the course of the lifestyle intervention (for African-American and Caucasian participants, ps < .001).

Caloric intake. As displayed in Table 3-9 and Figure 3-12, repeated measures ANCOVA uncovered a significant main effect for time [$F(1, 199) = 32.64$, $p < .001$] as well as an interaction between time and race/ethnicity [$F(1, 199) = 4.44$, $p = .036$] for self-reported daily caloric intake. Caucasians reported higher daily caloric intake than African-Americans at Month 0 ($p = .040$) but not at Month 6. Further, both racial/ethnic groups reported significant decreases in caloric intake between Month 0 and Month 6 (for African-American and Caucasians, $p = .050$ and $p < .001$, respectively).

Saturated fat intake. There emerged significant main effects for time [$F(1, 199) = 70.59$, $p < .001$] and race/ethnicity [$F(1,199) = 6.78$, $p = .010$], as well as a significant interaction between time and race/ethnicity [$F(1, 199) = 10.14$, $p = .002$], in terms of self-reported saturated fat intake during the lifestyle intervention (see Table 3-9 and Figure 3-13). Caucasians reported higher intakes of saturated fat than African-Americans at Month 0 ($p = .002$) but intakes were comparable at Month 6 ($p = .621$). Nonetheless, both groups reported significant decreases in saturated fat intake from Month 0 to Month 6 (for African-American and Caucasian participants, $p = .005$ and $p < .001$, respectively).

Outcomes during extended care (Months 6 - 18)

Systolic blood pressure. Repeated measures ANCOVA uncovered only a main effect for time [$F(1, 203) = 4.24$, $p = .041$] for systolic blood pressure during the extended care period. As shown in Table 3-10 and Figure 3-4, there were no racial/ethnic differences at either Month 6 or at Month 18, and only Caucasian participants exhibited a significant increase in systolic blood pressure between Months 6 and 18 ($p = .001$).

Diastolic blood pressure. Table 3-10 and Figure 3-5 display main effects for both time [$F(1, 203) = 5.85$, $p = .016$] and race/ethnicity [$F(1, 203) = 7.91$, $p = .005$] with regard to diastolic blood pressure from Month 6 to Month 18. African-Americans exhibited higher diastolic blood pressure when compared to Caucasians at both Month 6 ($p = .014$) and at Month 18 ($p = .030$). However, only Caucasian participants exhibited significant increases in diastolic blood pressure during the extended care period ($p = .001$).

Triglycerides. As shown in Table 3-11 and Figure 3-6, only a main effect for race/ethnicity [$F(1, 198) = 10.49$, $p = .001$] emerged in a repeated measures ANCOVA examining triglyceride level during the extended care period. Neither the main effect for time ($p = .466$) nor the interaction effect ($p = .183$) was significant. Caucasians had higher triglyceride levels than African-Americans at both Month 6 ($p = .006$) and at Month 18 (p = .002), and neither group demonstrated significant changes in triglyceride level between Months 6 and 18.

LDL-cholesterol. There were no significant main effects for time ($p = .311$) or race/ethnicity ($p = .589$) with respect to LDL-cholesterol during extended care, but a significant interaction between time and race/ethnicity emerged [$F(1, 195) = 6.11$, $p = .014$]. As Table 3-11 and Figure 3-7 illustrate, there were no racial/ethnic differences in LDL-cholesterol at Month 6, but Caucasians exhibited marginally higher levels than African-Americans at Month 18 ($p = .067$). Further, only Caucasian participants showed significant increases in LDL-cholesterol during extended care ($p < .001$).

Hemoglobin A1c. Repeated measures ANCOVA revealed main effects for time [$F(1, 200) = 4.01$, $p = .047$], race/ethnicity [$F(1, 200) = 48.14$, $p < .001$], and a marginally significant interaction between time and race/ethnicity [$F(1, 200) = 3.59$, $p = .060$] for HbA1c during extended care (see Table 3-12 and Figure 3-8). African-Americans exhibited higher HbA1c compared to Caucasians at both Month 6 and 18 (*p*s

< .001), and only African-American participants showed a significant increase in HbA1c (p = .033) during extended care.

C-reactive protein. As displayed in Table 3-12 and Figure 3-9, there was a main effect for time [F(1, 188) = 4.99, p = .027] and a marginally significant main effect for race/ethnicity [F(1, 188) = 2.69, p = .102] for C-reactive protein during extended care. The interaction between time and race/ethnicity did not reach significance (p = .814). African-Americans and Caucasians did not differ in C-reactive protein levels at Month 6 or at Month 18. Further, only Caucasians demonstrated significant reductions in C-Reactive protein during extended care (p = .015).

Six-minute walk test. Table 3-13 and Figure 3-10 indicate that a main effect for race/ethnicity [F(1, 182) = 8.57, p = .004] emerged in a repeated measures ANCOVA conducted for distance covered during 6-minute walk test. There was neither a significant main effect for time (p = .946) nor a significant interaction between time and race/ethnicity (p = .707). African-Americans covered less distance than Caucasians at both Month 6 (p = .024) and Month 18 (p = .009) assessments, and neither group exhibited significant changes in performance between Month 6 and Month 18.

Energy expenditure during activities of at least moderate intensity. Repeated measures ANCOVA resulted in a marginally significant main effect for time [F(1, 197) = 2.61, p = .108] during extended care (see Table 3-13 and Figure 3-11). However, neither the main effect for race/ethnicity nor the interaction effect reached statistical significance (for main effect of race/ethnicity and interaction, p = .379 and p = .945, respectively). There were no racial/ethnic differences in self-reported energy expenditure at Month 6 or at Month 18, and only Caucasians exhibited marginally significant decreases in self-reported energy expenditure during extended care (p = .077).

Caloric intake. As displayed in Table 3-14 and Figure 3-12, a main effect for race/ethnicity [$F(1, 187) = 6.37$, p = .012] and an interaction between time and race/ethnicity [$F(1,187) = 6.34$, p = .013] were observed for self-reported caloric intake during extended care. The main effect for time was not significant (p = .158). African-Americans and Caucasians did not report significantly different caloric intakes at Month 6, but Caucasians reported significantly higher caloric intake than African-Americans at Month 18 (p = .001). Further, only African-Americans reported significant decreases in caloric intake during extended care (p = .031).

Saturated fat intake. A significant main effect for race/ethnicity [$F(1, 187) =$ 7.79, p = .006] and a significant interaction between time and race/ethnicity [$F(1,187) =$ 11.17, p = .001] emerged for self-reported saturated fat intake between Months 6 and 18 (see Table 3-14 and Figure 3-13). No main effect for time was observed (p = .879). African-American and Caucasian participants did not report significantly different intakes of saturated fat when assessed at Month 6, but Caucasians endorsed significantly higher intakes of saturated fat when compared to African-Americans at Month 18 (p < .001). Further, Caucasians reported significant increases in saturated fat during extended care (p < .001), whereas the increases reported by African-Americans only approached significance (p = .079).

Adherence and program satisfaction. The percentage of lifestyle intervention sessions attended by African-American and Caucasian participants were not significantly different (Ms = 89.70 $\pm$ 8.91, 89.51 $\pm$ 10.33%, respectively, p = 0.914). In addition, both groups completed similar percentages of the requested food (*M*s = 85.45 ± 17.60, 89.95 ± 15.23%, respectively, p = .237) and exercise (*M*s = 83.35 ± 18.31, 85.15 ± 18.38%, respectively, p = 0.605) records between Months 0 and 6. Of those participants assigned to either of the extended care interventions (i.e., office-based groups sessions or telephone-based individual counseling), racial/ethnic differences in percentage of sessions attended approached significance (for African-Americans and Caucasians, *M*s = 53.40 ± 37.12, 42.20 ± 41.01%, respectively, p = .086), with African-Americans attending a greater percentage of sessions.

In addition, subscale totals derived from responses on a questionnaire designed to assess participants' satisfaction with the program were analyzed via independent t-tests, with race/ethnicity as the categorizing variable. These analyses revealed that African-Americans expressed higher levels of overall satisfaction [$t(203) = 3.09$, $p = .003$], perceived the strategies taught to be more useful [$t(203) = 2.74$, $p = .007$] , and endorsed higher levels of current use of the strategies [$t(203) = 2.40$, $p = .017$] when compared to their Caucasian counterparts. Further, African-American and Caucasian participants expressed similar satisfaction with their group leaders [$t(218) = 0.06$, $p = .954$] Because this questionnaire has not been validated, results should be interpreted with caution.

Table 3-1. Reasons for exclusion by racial/ethnic group.

Exclusionary Criteria	African-American (N = 148) Number (%)	Caucasian (N = 779) Number (%)
<50 or >75 years old	19 (12.8)	30 (3.9)
<30 or >50 BMI	16 (10.8)	121 (15.5)
Non-medical reason	16 (10.8)	137 (17.6)
Did not complete assessment	26 (17.6)	100 (12.8)
Medical condition (not musculoskeletal)	20 (13.5)	134 (17.2)
Musculoskelatal condition	16 (10.8)	124 (15.9)
Screening visit result	35 (23.6)	133 (17.1)

Table 3-2. Participant demographics at baseline.

Characteristic	African-American (N = 43) Mean ± SD or n (%)	Caucasian (N = 181) Mean ± SD or n (%)
Body weight (kg)	99.87 ± 16.79	95.82 ± 14.46
Body Mass Index (kg/m^2)	38.13 ± 6.16	36.49 ± 4.52
Age (yrs)	58.01 ± 5.71	60.06 ± 6.07[a]
Employed (full- or part- time, %)	21 (48.8)	86 (47.5)
Marital Status		
Never married	1 (2.3)	2(1.1)
Divorced or separated	9 (20.9)	16 (8.8)
Widowed	6 (14.0)	15 (8.3)
Presently married	27 (62.8)	142 (78.5)
Cohabitating with partner	0 (0.0)	6 (3.3)
Annual Income		
< $19,000	8 (18.6)	38 (21.0)
$20,000—34,000	13 (30.2)	40 (22.1)
$35,000—49,000	9 (20.9)	37 (20.4)
$50,000—74,000	8 (18.6)	38 (21.0)
$75,000—99,000	5 (11.6)	17 (9.4)
>$100,000	0 (0.0)	7 (3.9)
Don't know	0 (0.0)	4 (2.2)
Education		
< High School	3 (7.0)	9 (5.0)
GED	1 (2.3)	10 (5.5)
High School diploma	6 (14.0)	41 (22.7)
Vocational training	3 (7.0)	33 (18.2)
Some college/Associates degree	14 (32.6)	55 (30.4)
Bachelor's degree	5 (11.6)	14 (7.7)
Post-bachelor's study or degree	11 (25.6)	19 (10.5)

[a] $p<.05$ for between-group differences

Table 3-3. Weight-related outcomes of African-American and Caucasian participants.

Outcome	African-American (N = 43) Estimated Mean ± SE	Caucasian (N = 181) Estimated Mean ± SE
Body weight (kg)		
Month 0	99.87 ± 16.79	95.82 ± 14.46
Change between Month 0 and 6	-6.83 ± 0.76 [b]	-10.10 ± 0.37[ab]
Change between Month 6 and 18	1.49 ± 0.99	2.18 ± 0.48[b]
% weight change from baseline		
Change between Month 0 and 6	-6.90 ± 0.80[b]	-11.20 ± 0.40[ab]
Change between Month 6 and 18	1.70 ± 1.00[b]	2.30 ± 0.50[b]
Body Mass Index (kg/m^2)		
Month 0	38.00± 0.75	36.52 ± 0.36
Change between Month 0 and 6	-2.60 ± 0.29[b]	-4.08 ± 0.14[ab]
Change between Month 6 and 18	0.55 ± 0.38	0.82 ± 0.18[b]

[a]$p < .05$ for racial/ethnic difference, [b]$p < .05$ for within-group difference

Table 3-4. Percentage of weight change from baseline.

Assessment time	African-American (N = 43) Count (%)	Caucasian (N = 181) Count (%)
Month 6		
Weight gain	1 (2.3)	3 (1.7)
0.00-4.99% loss	10 (23.3)	18 (9.9)
5.00-9.99% loss	21 (48.8)	52 (28.7)
> 10.00% loss [a]	11 (25.6)	108 (59.7)
Month 18		
Weight gain	5 (12.5)	23 (13.5)
0.00-4.99% loss	14 (35.0)	45 (26.3)
5.00-9.99% loss	15 (37.5)	27 (15.8)
> 10.00% loss [b]	6 (15.0)	76 (44.4)

[a] $\chi^2(1) = 16.21$, $p < .001$, [b] $\chi^2(1) = 11.77$, $p = .001$

Table 3-5. Systolic and diastolic blood pressure during lifestyle intervention.

Outcome	African-American Estimated Mean ± SE	Caucasian Estimated Mean ± SE
Systolic blood pressure (mm Hg)[ab]		
N	43	181
Month 0	127.70 ± 1.37	125.57 ± 0.67
Month 6	120.53 ± 1.71[e]	117.18 ± 0.83[e]
Diastolic blood pressure (mm Hg)[ab]		
N	43	181
Month 0[d]	77.23 ± 1.16	74.61 ± 0.56
Month 6[d]	74.55 ± 1.23[e]	70.83 ± 0.59[e]

[a]$p < .05$ for overall main effect of time, [b]$p < .05$ for overall main effect of race/ethnicity, [c]$p < .05$ for overall interaction effect, [d]$p < .05$ for time-specific racial/ethnic difference, [e]$p < .05$ for change from Month 0.

Table 3-6. Triglycerides and LDL-cholesterol during lifestyle intervention

Outcome	African-American Estimated Mean ± SE	Caucasian Estimated Mean ± SE
Triglycerides (mg/dL)[ab]		
N	40	180
Month 0[d]	110.33 ± 9.49	152.67 ± 4.46
Month 6[d]	101.18 ± 9.87	130.12 ± 4.63[e]
LDL-cholesterol (mg/dL)		
N	40	178
Month 0	116.33 ± 4.69	123.47 ± 2.21
Month 6	117.92 ± 5.08	115.99 ± 2.40[e]

[a]$p < .05$ for overall main effect of time, [b]$p < .05$ for overall main effect of race/ethnicity, [c]$p < .05$ for overall interaction effect, [d]$p < .05$ for time-specific racial/ethnic difference, [e]$p < .05$ for change from Month 0.

Table 3-7. Hemoglobin A1c and C-Reactive protein during lifestyle intervention.

Outcome	African-American Estimated Mean ± SE	Caucasian Estimated Mean ± SE
Hemoglobin A1c (%)[ab]		
N	40	181
Month 0[d]	6.48 ± 0.10	5.86 ± 0.05
Month 6[d]	6.15 ± 0.08[e]	5.61 ± 0.04[e]
C-Reactive protein (mg/dL)[a]		
N	40	181
Month 0	6.23 ± 0.95	5.94 ± 0.44
Month 6	3.82 ± 0.54[e]	3.34 ± 0.25[e]

[a]$p < .05$ for overall main effect of time, [b]$p < .05$ for overall main effect of race/ethnicity, [c]$p < .05$ for overall interaction effect, [d]$p < .05$ for time-specific racial/ethnic difference, [e]$p < .05$ for change from Month 0.

Table 3-8. Performance on 6-minute walk test (6MWT) and weekly energy expenditure during lifestyle intervention.

Outcome	African-American Estimated Mean ± SE	Caucasian Estimated Mean ± SE
Distance covered on 6MWT (ft)[ab]		
N	42	176
Month 0[d]	1351.55 ± 27.15	1420.48 ± 13.19
Month 6[d]	1407.24 ± 27.09[e]	1518.50 ± 13.16[e]
Weekly energy expenditure in activities of at least moderate intensity (kcal/wk)[ab]		
N	43	174
Month 0[d]	619.64 ± 207.93	1195.25 ± 102.88
Month 6	1629.54 ± 235.47[e]	1906.58 ± 116.51[e]

[a]$p < .05$ for overall main effect of time, [b]$p < .05$ for overall main effect of race/ethnicity, [c]$p < .05$ for overall interaction effect, [d]$p < .05$ for time-specific racial/ethnic difference, [e]$p < .05$ for change from Month 0.

Table 3-9. Daily caloric and saturated fat intake during lifestyle intervention.

Outcome	African-American Estimated Mean ± SE	Caucasian Estimated Mean ± SE
Daily caloric intake (kcal/day)[ac]		
N	37	165
Month 0[d]	1506.39 ± 104.33	1745.61 ± 48.92
Month 6	1315.10 ± 69.14[e]	1327.32 ± 32.42[e]
Daily saturated fat intake (g/day)[abc]		
N	37	165
Month 0[d]	17.28 ± 1.70	23.25 ± 0.80
Month 6	12.86 ± 0.91[e]	13.37 ± 0.43[e]

[a]$p < .05$ for overall main effect of time, [b]$p < .05$ for overall main effect of race/ethnicity, [c]$p < .05$ for overall interaction effect, [d]$p < .05$ for time-specific racial/ethnic difference, [e]$p < .05$ for change from Month 0.

Table 3-10. Systolic and diastolic blood pressure during extended care.

Outcome	African-American Estimated Mean ± SE	Caucasian Estimated Mean ± SE
Systolic blood pressure (mm Hg)[a]		
N	40	166
Month 6	120.22 ± 1.75	116.70 ± 0.86
Month 18	121.50 ± 1.90	119.80 ± 0.93[e]
Diastolic blood pressure (mm Hg)[ab]		
N	40	166
Month 6[d]	74.14 ± 1.28	70.62 ± 0.61
Month 18[d]	75.60 ± 1.15	72.81 ± 0.56[e]

[a]$p < .05$ for overall main effect of time, [b]$p < .05$ for overall main effect of race/ethnicity, [c]$p < .05$ for overall interaction effect, [d]$p < .05$ for time-specific racial/ethnic difference, [e]$p < .05$ for change from Month 6.

Table 3-11. Triglycerides and LDL-cholesterol during extended care.

Outcome	African-American Estimated Mean ± SE	Caucasian Estimated Mean ± SE
Triglycerides (mg/dL)[b]		
N	36	165
Month 6[d]	99.76 ± 10.64	132.17 ± 4.95
Month 18[d]	101.86 ± 10.27	137.21 ± 4.78
LDL-cholesterol (mg/dL)[c]		
N	36	162
Month 6	116.08 ± 5.02	115.57 ± 2.44
Month 18	112.53 ± 5.65	124.04 ± 2.65[e]

[a]$p < .05$ for overall main effect of time, [b]$p < .05$ for overall main effect of race/ethnicity, [c]$p < .05$ for overall interaction effect, [d]$p < .05$ for time-specific racial/ethnic difference, [e]$p < .05$ for change from Month 6.

Table 3-12. Hemoglobin A1c and C-Reactive protein during extended care.

Outcome	African-American Estimated Mean ± SE	Caucasian Estimated Mean ± SE
Hemoglobin A1c (%)[ab]		
N	37	166
Month 6[d]	6.18 ± 0.08	5.59 ± 0.04
Month 18[d]	6.36 ± 0.11[e]	5.59 ± 0.05
C-Reactive protein (mg/dL)[a]		
N	32	159
Month 6	4.11 ± 0.62	3.28 ± 0.28
Month 18	3.16 ± 0.45	2.51 ± 0.20[e]

[a]$p < .05$ for overall main effect of time, [b]$p < .05$ for overall main effect of race/ethnicity, [c]$p < .05$ for overall interaction effect, [d]$p < .05$ for time-specific racial/ethnic difference, [e]$p < .05$ for change from Month 6.

Table 3-13. Performance on 6-minute walk test (6MWT) and weekly energy expenditure during extended care.

Outcome	African-American Estimated Mean ± SE	Caucasian Estimated Mean ± SE
Distance covered on 6MWT (ft)[b]		
N	37	148
Month 6[d]	1428.23 ± 29.21	1525.17 ± 14.49
Month 18[d]	1431.21 ± 30.20	1520.88 ± 14.98
Weekly energy expenditure in activities of at least moderate intensity (kcal/wk)		
N	38	162
Month 6	1682.98 ± 254.33	1894.05 ± 122.66
Month 18	1410.69 ± 283.74	1644.24 ± 136.84

[a]$p < .05$ for overall main effect of time, [b]$p < .05$ for overall main effect of race/ethnicity, [c]$p < .05$ for overall interaction effect, [d]$p < .05$ for time-specific racial/ethnic difference, [e]$p < .05$ for change from Month 6.

Table 3-14. Daily caloric and saturated fat intake during extended care.

Outcome	African-American Estimated Mean ± SE	Caucasian Estimated Mean ± SE
Daily caloric intake (kcal/day)[bc]		
N	34	156
Month 6	1254.61 ± 71.97	1344.57 ± 33.22
Month 18[d]	1101.10 ± 80.18[e]	1388.27 ± 37.01
Daily saturated fat intake (g/day)[bc]		
N	34	156
Month 6	12.18 ± 0.97	13.41 ± 0.45
Month 18[d]	10.62 ± 1.08	15.12 ± 0.50[e]

[a]$p < .05$ for overall main effect of time, [b]$p < .05$ for overall main effect of race/ethnicity, [c]$p < .05$ for overall interaction effect, [d]$p < .05$ for time-specific racial/ethnic difference, [e]$p < .05$ for change from Month 6.

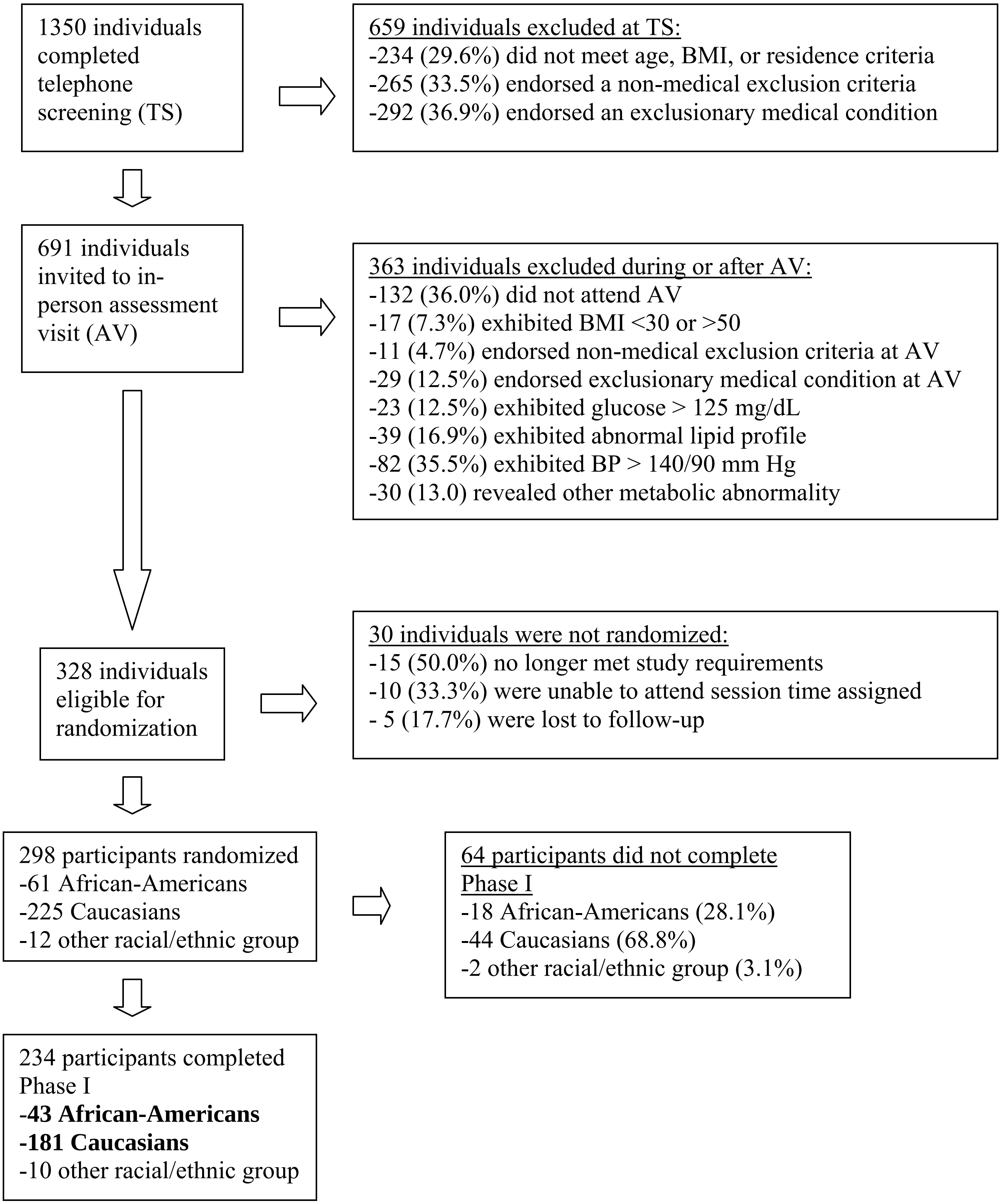

Figure 3-1. Screening and assessment of individuals for the parent study.

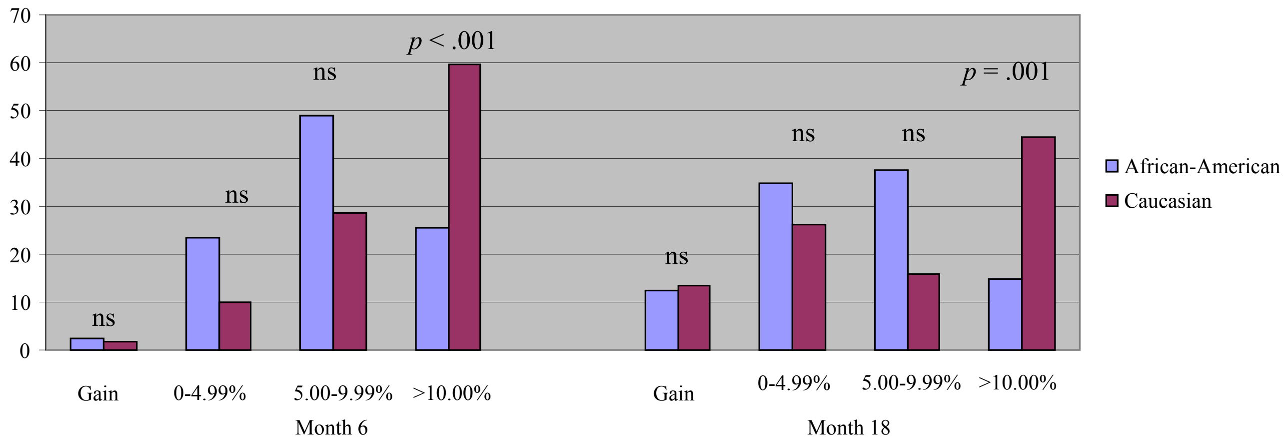

Figure 3-2. Categories of weight lost from baseline.

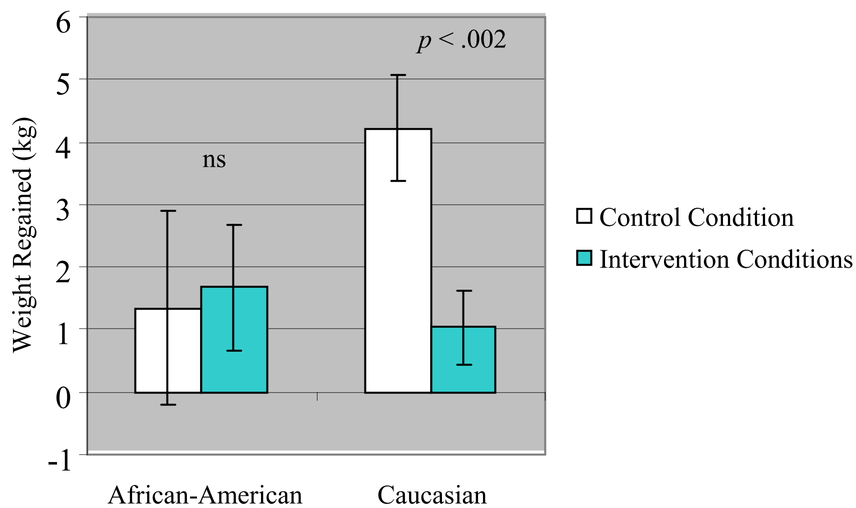

Figure 3-3. Weight regain of African-American and Caucasian participants assigned to control versus intervention conditions (EMM $\pm$ SE).

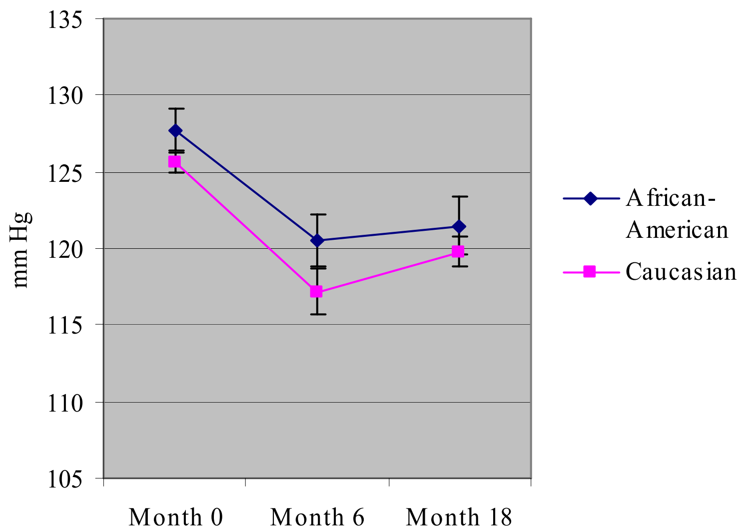

Figure 3-4. Systolic blood pressure at Months 0, 6, and 18 (EMM ± SE)

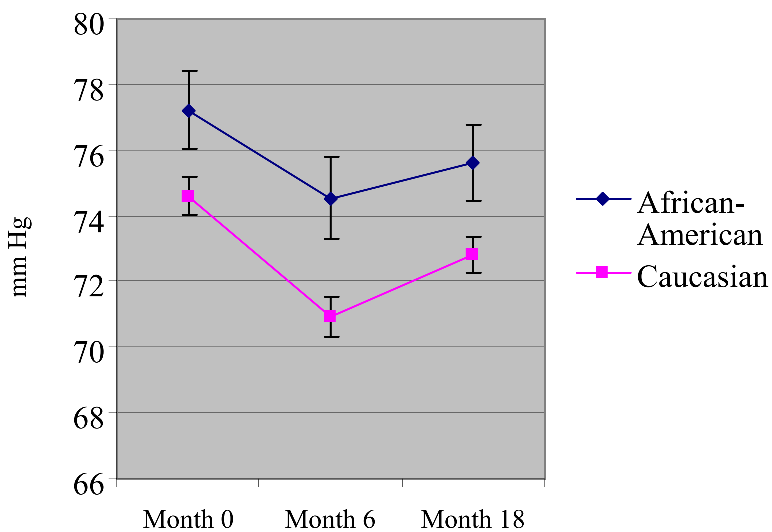

Figure 3-5. Diastolic blood pressure at Months 0, 6, and 18 (EMM ± SE).

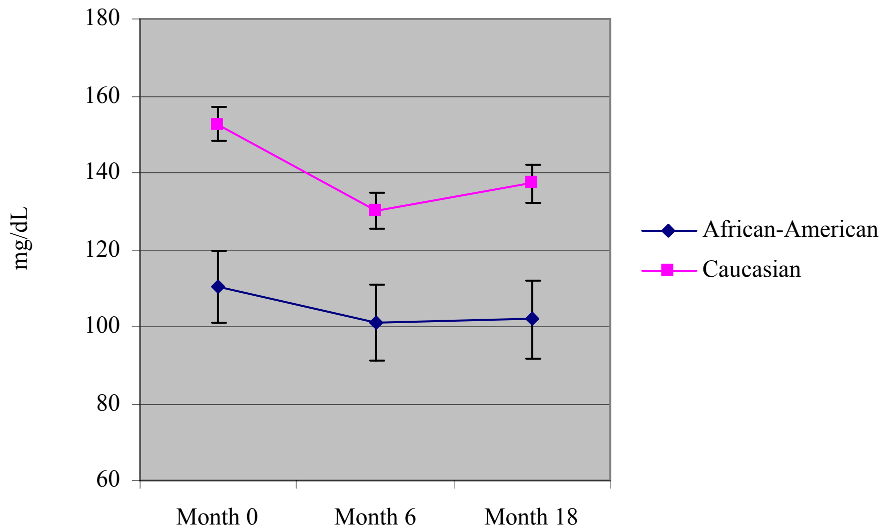

Figure 3-6. Triglycerides at Months 0, 6, and 18 (EMM + SE).

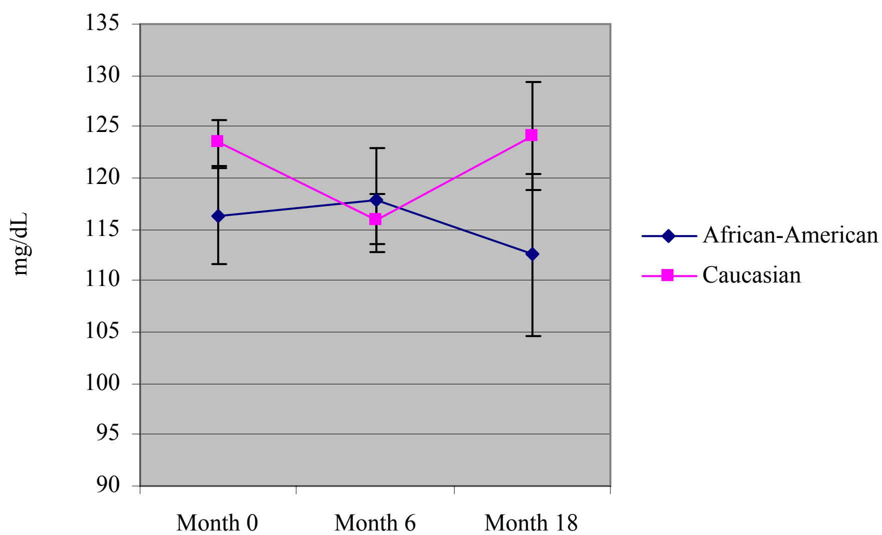

Figure 3-7. LDL-cholesterol at Months 0, 6, and 18 (EMM ± SE).

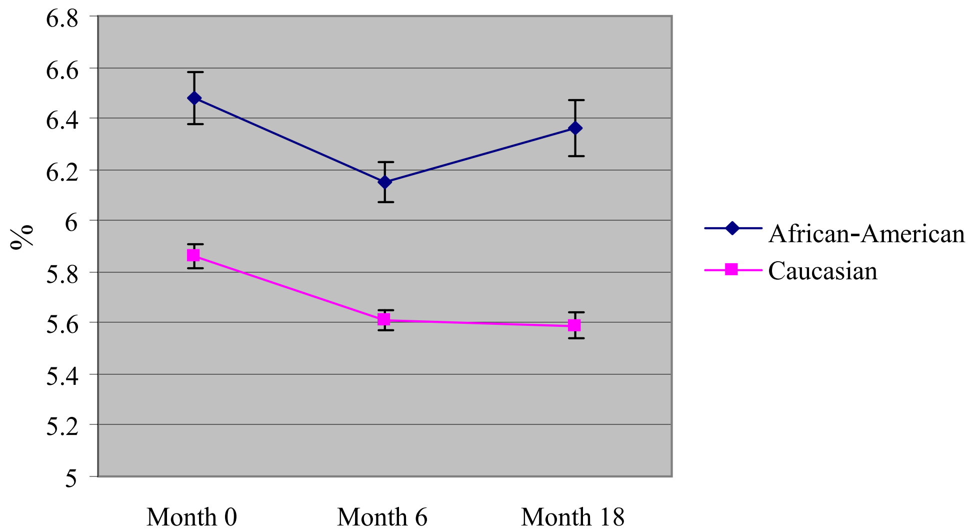

Figure 3-8. Hemoglobin A1c at Months 0, 6, and 18 (EMM + SE).

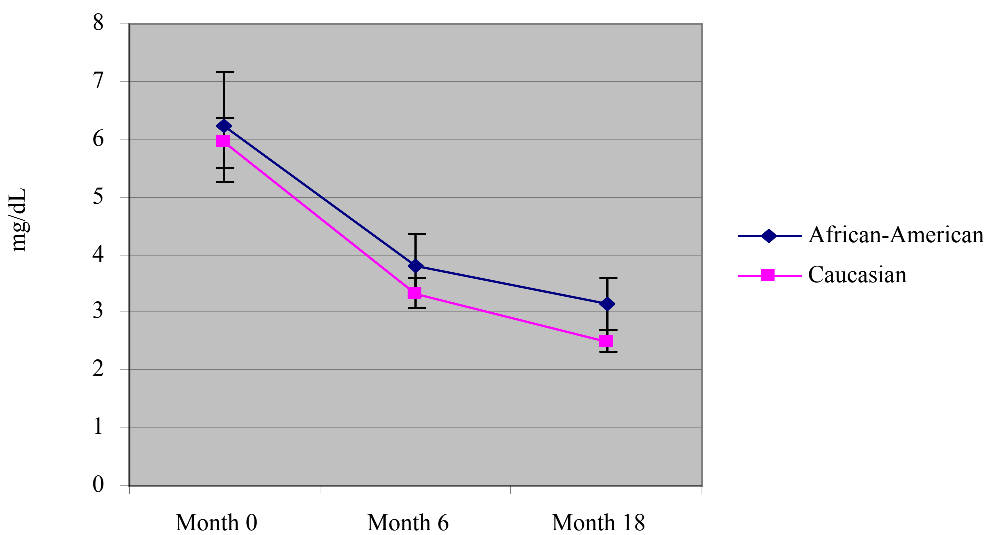

Figure 3-9. C-reactive protein at Months 0, 6, and 18 (EMM + SE).

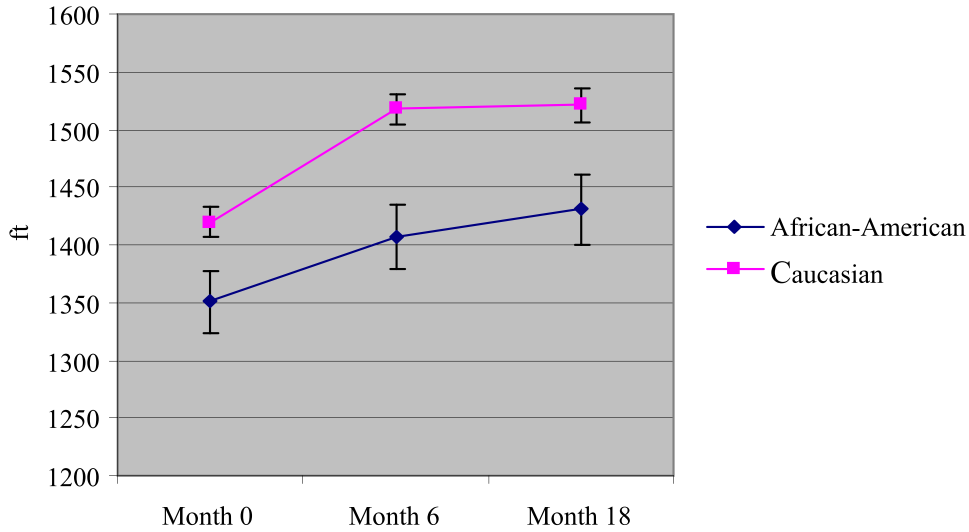

Figure 3-10. Distance covered on 6-minute walk test at Months 0, 6, and 18 (EMM ± SE).

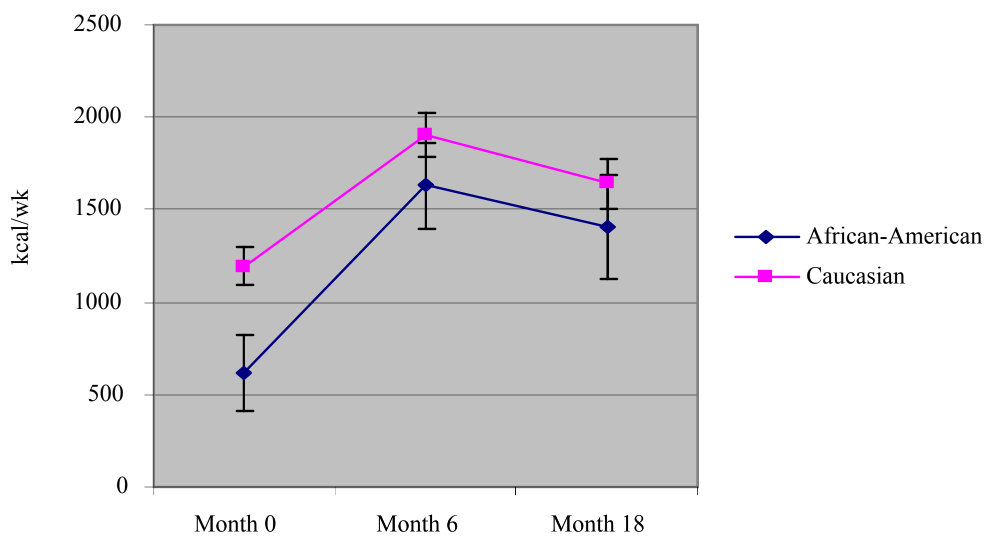

Figure 3-11. Weekly caloric expenditure in activities of at least moderate intensity at Months 0, 6, and 18 (EMM + SE).

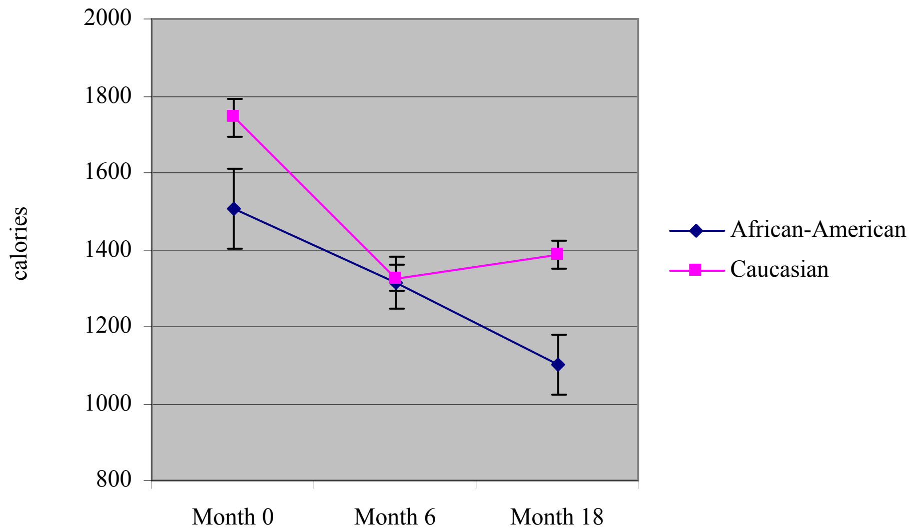

Figure 3-12. Self-report caloric intake at Months 0, 6, and 18 (EMM + SE).

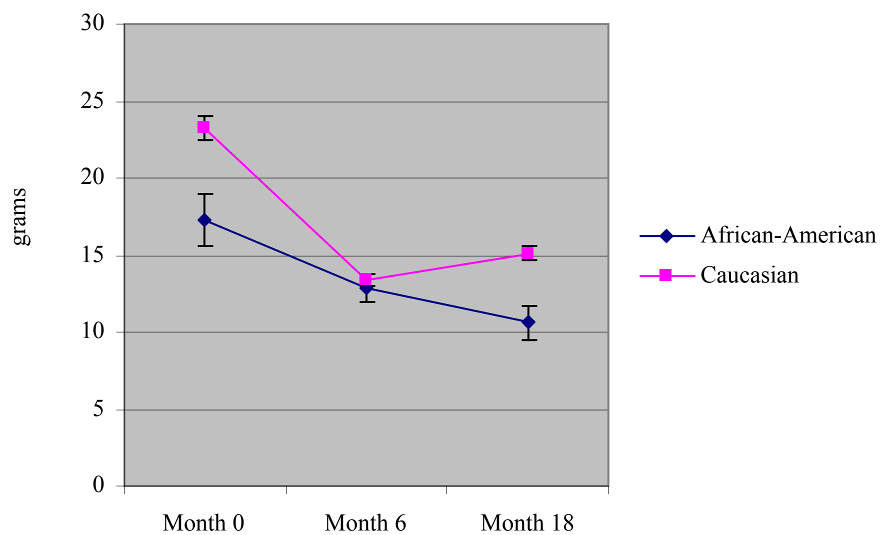

Figure 3-13. Self-reported saturated fat intake at Months 0, 6, and 18 (EMM + SE).

CHAPTER 4
DISCUSSION

Main Findings

The primary aim of this study was to examine racial/ethnic differences in weight changes achieved (a) between Month 0 and Month 6 and (b) between Month 6 and Month 18. Consistent with our hypothesis, the magnitude of weight loss exhibited by Caucasians was greater than that achieved by African-Americans between Months 0 and 6. Contrary to our hypothesis, however, there was no statistically significant racial/ethnic difference in weight change achieved between Months 6 and 18. Both groups exhibited significant weight reductions between Months 0 and 6, and in Phase I completer analyses, only Caucasians exhibited significant weight regain between Months 6 and 18.

The secondary aim of this study was to investigate whether African-American and Caucasian participants responded differentially to the types of extended care programs offered. Initial plans were to compare the effectiveness of the office-based group condition to the individualized telephone counseling condition. For both African-Americans and Caucasians, the weight regain exhibited by those assigned to the office-based condition was not significantly different than the weight regain exhibited by those assigned to the telephone-based counseling condition. However, this difference may have been clinically meaningful among African-American participants, with those assigned to the telephone-based counseling exhibiting smaller regain than those assigned to the office-based group condition.

An additional analysis collapsed data across extended care programs and compared these to outcomes achieved by those in the educational control condition. We found that assignment to an extended care program was associated with smaller weight regain in Caucasian, but not African-American, individuals. In fact, African-Americans exhibited only small and non-significant weight regain whether assigned to an extended care program or to the control condition.

The tertiary aim of this study inspected a variety of other outcome measures for racial/ethnic differences. African-American and Caucasian participants exhibited comparable attendance at group sessions and similar completion of self-monitoring instruments. Between Months 0 and 6, both African-Americans and Caucasians exhibited significant improvements in systolic blood pressure, diastolic blood pressure, hemoglobin A1c, C-reactive protein, and performance on the 6-minute walk test. Further, only Caucasians exhibited significant reductions in triglycerides and LDL-cholesterol between Months 0 and 6. Both groups reported increased weekly energy expenditure and decreased caloric and saturated fat intake during the lifestyle intervention phase.

Between Month 6 and 18, Caucasians (but not African-Americans) exhibited significant increases in systolic blood pressure, diastolic blood pressure, and LDL-cholesterol, as well as decreases in C-reactive protein. In addition, African-Americans reported significant decreases in caloric intake between Months 6 and 18, whereas Caucasians reported significant increases in saturated fat intake during the same period.

Comparison to Previous Studies

Overall, our findings concur with existing literature that suggests African-Americans lose smaller amounts of weight during lifestyle intervention relative to

Caucasians. The two most recent clinical trials that have examined this pattern are the Trials for Hypertension Prevention (TOHP) and the Trial of Nonpharmacologic Interventions in the Elderly (TONE). In TOHP, Stevens and colleagues (Stevens et al., 2001) found that Caucasians exhibited greater weight reductions relative to African-Americans at 6 months (from baseline, -2.4 kg vs. –1.0 kg, respectively, $p < .01$) and at 18 months (from baseline, -1.0 kg vs. 0.2 kg, respectively, $p < .03$). These reductions are smaller but consistent with the weight losses achieved by our Caucasian and African-American participants at 6 months (from baseline, -10.7 kg vs. -6.9 kg, respectively, $p < .001$) and at 18 months (from baseline, -8.6 kg vs. -5.2 kg, respectively, $p = .009$). It is interesting to note that the magnitude of regain between Months 6 and 18 were similar in these two studies, despite TOHP's continuing intensive intervention versus the present study's transitioning into a less intensive extended care period.

In TONE, Kumanyika and colleagues (Kumanyika et al., 2002) also observed that Caucasian participants lost significantly more weight than African-American participants at 6 months (-5.9 kg vs. -2.7 kg, respectively, p < .001) and at the end of a variable follow-up period (*M* time to follow-up = 27 weeks; -4.9 kg vs. -2.0 kg, respectively, p < .01). It is difficult to compare magnitude of regain in TONE with that in TOURS due to the latter's earlier endpoint. Nonetheless, it is noteworthy that the present effectiveness study was able to replicate the patterns observed in TOHP and TONE, given that the latter two were conducted in an academic medical setting. These parallels lend support to the contention that racial/ethnic discrepancies in weight loss during lifestyle intervention are robust across study setting and sample.

Some of the racial/ethnic patterns observed in metabolic changes were also consistent with those found in the existing literature. For example, our data regarding similar improvements in blood pressure concur with the findings of Nicklas and colleagues (Nicklas et al., 2003) and those of Stevens and colleagues (Stevens et al., 2001). However, the racial/ethnic differences that emerged with respect to changes achieved in LDL-cholesterol and triglyceride are discrepant with those of previous studies. In their lifestyle interventions, Gower and associates (Gower et al., 2002) did not find racial/ethnic differences in changes in LDL-cholesterol, and Nicklas and colleagues (Nicklas et al., 2003) did not find racial/ethnic differences with respect to improvements in triglycerides. It should be noted, however, that African-Americans lost similar amounts of weight (but less body fat) when compared to their Caucasian counterparts in each of these studies. Thus, it is possible that the smaller weight changes achieved by African-American participants in our study were responsible for the observed pattern of outcomes.

Change in Energy Balance as a Mediator for Discrepant Weight Outcome

There are a variety of possible mechanisms that may contribute to the discrepant weight losses achieved by African-American and Caucasian participants during lifestyle interventions. The most obvious possible mediator would be differential changes in diet and exercise, thus resulting in different magnitude of weight change. Unfortunately, however, the cost and labor of utilizing unbiased biomarkers of energy intake (such as doubly labeled water, Trabulsi & Schoeller, 2001) is usually not feasible for use in lifestyle intervention. Self-report measures of dietary intake and energy expenditure are notoriously inaccurate (e.g., Hill & Davies, 2001), and their validity may be especially suspect when used in diverse populations (e.g., Resnicow et al., 2003; Tucker et al., 2005).

Nonetheless, the current study did collect self-report data related to caloric intake (via the Block Food Frequency questionnaire) and to energy expenditure during daily activities (via the CHAMPS questionnaire). As previously described, there were no racial/ethnic differences in changes in energy expenditure, but Caucasian participants did report larger decreases in caloric intake between Months 0 and 6 and between Months 0 and 18. Thus, it is possible that Caucasians' greater caloric reduction contributed to this group's superior weight losses. To examine this possibility quantitatively, projected weight loss can be calculated by combining a) changes in self-reported caloric intake on the Block Food Frequency questionnaire and b) changes in self-reported energy expenditure during all activities on the CHAMPS questionnaire.

Such analyses revealed that African-Americans' projected weight loss of 7.96 kg approximated their actual weight loss of 6.99 kg between Months 0 and 6. Similarly, the projected weight loss of 10.99 kg for Caucasians approached their actual loss of 10.67 kg during the same time interval. It may be important to note that the Block 95 food frequency questionnaire asks participants to consider their intake patterns over the previous year when making responses. However, the agreement between projected and actual losses suggests that participants were reporting their most recent patterns of intake at Month 6 (i.e., rather than averaging their intake over the past year, which would have included a period prior to the beginning of the study).

There are two major implications of these analyses. First, it does appear that differential reduction in caloric intake may have been responsible for the differential weight outcomes observed. Caucasians reported greater caloric reductions and lost more weight between Months 0 and 6. The other important implication is that projected and actual losses appear to be comparably correlated in each racial/ethnic group. Thus, these outcomes lend support to the cross-cultural validity of the instruments.

Implications for Clinical Services

The design of this study, consisting of an intensive weekly intervention followed by a less demanding extended care program, allows for examination of the possibility that the intensity of an intervention may have differential impact for African-American and Caucasian participants. On the basis of weight outcome and dietary change, Caucasian participants appear to have benefited more from the intensive portion. On the other hand, African-Americans' superior maintenance of metabolic improvements and continued dietary changes during the follow-up period suggests that they fared better in the program of lower intensity. African-Americans commonly cite transportation difficulties and lack of time to attend meetings as barriers to successful participation in weight loss groups (Maillet, D'Eramo, & Spollett, 1996). Thus, the increased convenience of the follow-up programs (i.e., attending in-person sessions only every other week, receiving telephone calls in their own homes) may have been particularly beneficial to African-American participants.

This pattern bears implications for the types of weight loss programs that might best be recommended to African-American individuals. For instance, the primary care clinic has been suggested as a possible venue in which to deliver weight loss interventions (Rippe, 1998; Simkin-Silverman & Wing, 1997). Primary care offers the potential convenience (i.e., individuals can receive services during normal clinic visits) and the semi-frequent contact that may have been helpful to the American-American participants in the current study. In addition, accessing services via primary care may allow individuals to circumvent the stigma that the African-American community commonly associates with formal weight loss programs. Martin and colleagues (Martin et al., 2006) found that six monthly outpatient visits (each lasting approximately 15 minutes) administered to African-American patients in their primary care clinics produced a mean 2.0 kg weight loss by Month 6. This reduction is comparable to losses achieved during a group lifestyle intervention (designed for African-American participants) requiring 10 to 16 hours of participant contact (Kanders, Ullman-Joy, Foreyt, 1994). Thus, although lifestyle intervention remains the gold standard, primary care weight management may be a promising alternative, especially for African-Americans.

Limitations and Strengths

In considering the implications of these findings, a few potential limitations should be considered. Because African-Americans and Caucasians were not recruited in equal numbers by the parent study, all of the racial/ethnic comparisons utilized a smaller number of African-American than Caucasian participants. Unequal groups lead to a variety of potential statistical confounds (e.g., violations of homogeneity of variance); however, these were considered and corrected for in the analyses (e.g., using Levene's statistic). Additionally, larger sample sizes (as opposed to smaller ones) are generally more representative of the population from which the sample is drawn. Thus, it is possible that our results better represent the referent Caucasian population than they do the referent African-American population.

Further, the preponderance of Caucasian participants in the lifestyle intervention groups (as compared to the minority of African-American participants) represents another potential problem. Although the intervention was tailored for use in a multi-ethnic sample, our African-American participants may have faced more barriers developing a sense of belonging or common experience with the others in the group. However, this potential limitation is mitigated by our finding that African-Americans were highly satisfied with the program. Moreover, the African-Americans in our study were able to achieve weight losses comparable to or better than those participating in studies with exclusively African-American samples (e.g., Kumanyika, 2002).

Additional limitations of the study relate to the statistical analyses and procedures employed. For one, we were unable to complete a full intent-to-treat analysis because much of the data related to Phase I non-completers were missing. As mentioned previously, common methods of imputing weight data (e.g., carrying last observation forward, substituting baseline weights for missing values) were deemed inappropriate due to the inconsistent patterns of weight loss and regain observed when comparing African-American and Caucasian participants. To account for this deficiency, analyses using all available data (which included both Phase I completers and Phase I non-completers) were conducted, and these revealed a similar pattern of outcomes overall. The only difference lay in the significant within-group weight regain exhibited by African-Americans between Months 6 and 18. This discrepancy, coupled with the finding that a marginally higher percentage ($p = .09$) of African-Americans (compared to Caucasians) were classified as Phase I non-completers, suggests that the outcomes for African-Americans may be limited in generalizability.

The other limitation related to our statistical analyses is the sheer number of tests conducted, especially with respect to our tertiary aims. However, we considered these analyses exploratory rather than definitive, as we were interested in exploring trends that might help explain findings related to our primary and secondary aims.

Despite these limitations, the current study has a number of important strengths. A major limitation of many other studies in this area is the confounding of race/ethnicity and socioeconomic status (e.g., Juhaeri et al., 2003; Kumanyika et al., 1991), wherein African-American participants are of lower income, employment, and educational status. However, the African-American and Caucasian participants in our sample were comparable on variables related to socioeconomic status. Similar patterns of employment were observed in each racial/ethnic group, with 48.8% of African-American and 47.5% of Caucasian participants holding a full- or part-time job. In addition, similar percentages of African-American and Caucasian participants reported annual incomes between $50,000 and $99,000 (30.2 and 30.4%, respectively). In terms of education, approximately twice as many African-Americans had earned at least a bachelor's degree as had Caucasian participants (37.2 and 18.2%, respectively). Thus, it is unlikely that the racial/ethnic differences in weight change observed for our participants were driven by differences in resources.

Another strength of the present study is that our lifestyle intervention was useful and satisfying for our African-American participants, per their self-report on our program satisfaction questionnaire. A great deal of research is currently being conducted to design weight loss programs that are acceptable to African-American participants (e.g., Kim et al., 2006; Smith West, Dilillo, Bursac, Gore, & Greene, 2007). The majority of these new programs target specific aspects of African-American culture (e.g., spirituality, community) and build weight loss interventions into pre-existing infrastructures (e.g., churches, community groups). Although this approach has merit, it is possible that such programs discard elements of lifestyle intervention that have proven efficacious in the established literature. The TOURS program, on the other hand, was able to accommodate African-American participants with only minor adjustments to a protocol that has produced successful outcomes in previous research.

Future Directions

To our knowledge, the current study is the first to directly compare African-American and Caucasian response to programs of extended care. The extended care programs utilized in this study differed in modality (i.e., in-person group counseling vs. individualized telephone based counseling) but were similar in their theoretical underpinnings (i.e., social problem solving). Our finding that extended care did not influence weight change of African-American participants can be interpreted in two ways. One interpretation is that African-American participants are able to maintain weight losses without the support of a personal extended care program. Our African-American participants did exhibit superior maintenance of metabolic improvements and behavior change when compared to their Caucasian counterparts. Further, some have argued that African-Americans' smaller changes may simply be easier to maintain biologically (e.g., Kumanyika, 2002).

However, an alternative interpretation is that an extended care program grounded in social problem solving is not effective for African-American participants. To this end, future research should examine how extended care programs governed by other theoretical orientations might influence weight maintenance among African-Americans. For example, the use of peer educators has emerged as a powerful tool in the treatment of obesity with African-American individuals (e.g., Auslander, Haire-Joshu, Houston, Rhee,

& Williams, 2002; Kennedy et al., 2005; Williams et al., 2006). The majority of this research has been based in pre-existing social networks, such as churches or community centers, and has focused on initiation of weight loss. However, this strategy has not been evaluated within a program of extended care following weight loss. The use of peer support as a maintenance strategy has demonstrated mixed effectiveness in samples comprised of Caucasian and minority individuals (e.g, Perri et al., 1987; Verheijden, Bakx, van Weel, Koelen, & van Staveren, 2005), but benefits specific to African-American participants may have been obscured by the unfavorable responses of other racial/ethnic groups.

Summary and Conclusions

The present study found that a) Caucasians lost more weight than African-Americans during lifestyle intervention, b) Caucasians, but not African-African-Americans, benefited from extended care programs utilizing social problem solving, and c) despite disparate weight losses, similar metabolic and behavioral (i.e., diet and physical activity) improvements were achieved by African-American and Caucasians participating in lifestyle intervention. These findings can be utilized in future clinical and research endeavors that strive to improve the treatment of obesity for African-Americans. Given the dearth of research targeting these underserved and high-risk individuals, our pattern of findings might inform ways in which future treatment can be more effective, more convenient, and better suited to the goals of this population.

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BIOGRAPHICAL SKETCH

Katie Allison Rickel was born December 21, 1980 to Jody Rickel and David Rickel. She was raised in Elkins Park, Pennsylvania, with her younger sister, Emily. She graduated from Cheltenham High School in 1999, and she earned a bachelor's degree in psychology from Duke University in 2003.

Since 2003, Katie has been a doctoral student at the University of Florida in the Department of Clinical and Health Psychology, specializing in medical psychology. Katie will return to Duke University to complete her predoctoral internship at Duke University Medical Center, from 2007-2008, after which she will have fulfilled all requirements for her doctorate. Her ultimate goal is to be a psychologist in a medical setting.