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A Randomized Trial of a Diet and Exercise Intervention for Overweight and Obese Women from Economically Disadvantaged Neighborhoods: Sisters Taking Action for Real Success (STARS)

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Abstract

Background—Lower socioeconomic status at both the individual and neighborhood level is associated with increased health risks. Weight loss can reduce this risk, but few high quality weight loss studies target this population.

Objectives—STARS tests a culturally-appropriate, group-based behavioral and social support intervention on body weight and waist circumference in women from financially disadvantaged neighborhoods.

Design—A stratified (by BMI) randomized trial. Randomization to group was generated by a random numbers table with allocation concealment by opaque envelopes.

Methods—Participants 25–50 years who had a BMI ≥ 25 kg/m² and a waist circumference ≥ 88 cm were recruited from 18 census tracts in Columbia, SC with high rates of poverty between November 2008 and November 2010. All participants received a dietary and exercise counseling session. Intervention participants then receive 16 theoretically-based and tailored weekly group sessions followed by 8 weeks of telephone maintenance counseling. Control participants receive 16 weekly health education mailings. Measurements correspond to baseline, post-group intervention, and post-telephone counseling, and for intervention participants, after a 12-week no-contact period. Measurement staff was blinded to group assignment.

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Results—Participants (N=155; n=80 intervention, n=75 minimal intervention control) were primarily African American (86.5%) and averaged 38.9 years with a mean BMI of 40.1 kg/m² and waist circumference of 115.4 cm. Food insecurity was reported by 43% of participants.

Summary—STARS targets an underserved population with an innovative, tailored, and theoretically-grounded, group-based intervention followed by telephone maintenance. If effective, the approach has the potential to be feasible and cost-effective for community delivery.

Keywords

exercise; physical activity; diet; African American; health disparities; women

1. Introduction

Minority race/ethnicity and lower socioeconomic status (SES), at both the individual and neighborhood level, are associated with increased risk of morbidity and mortality for numerous health conditions [1, 2]. Risk factors for cardiovascular disease (CVD), the leading cause of death in the United States [3], include high blood pressure, high cholesterol, diabetes, smoking, physical inactivity, and obesity. African Americans and persons with lower socioeconomic status are more likely than other groups to have two or more CVD risk factors [4], and these groups also have higher rates of hypertension [3], poorly controlled diabetes [5], and obesity [6], and lower rates of physical activity participation [7], fitness [8], and healthy dietary practices [9]. Furthermore, among African American women, lower neighborhood SES has been associated with 10-year weight gain even after adjustment for individual-level variables [10].

A healthy diet, regular physical activity, and a healthy body weight are desirable targets for intervention studies because they are modifiable and, if changed successfully, can prevent and control many chronic diseases. Interventions that target these behaviors in underserved populations, however, must be sensitive to the larger socioeconomic forces that shape them including lower availability of healthy food options and greater availability and lower cost of less healthy food options [11], as well as less access to physical activity-related resources. Furthermore, important cultural factors likely must be considered, including desire and motivation (or lack of) to lose weight; cultural food preferences, symbolism, and traditions; and cultural perceptions regarding physical activity [12].

A large number of studies have targeted weight loss in overweight and obese samples [13]. Studies generally show maximal weight loss, using a variety of strategies, at six months followed by some but generally not complete weight regain over time. Although many studies have examined associations between low socioeconomic status and obesity-related factors, fewer interventions have specifically targeted disadvantaged populations. A recent meta-analysis set out to review weight loss interventions in minorities [14]. However, due to the small number of studies that included all-minority samples (n=9), they chose to also include studies with samples that included at least 25 minority participants or were at least 50% minority (n=15). Of the 24 studies reviewed, the majority were clinical-based (n=19) rather than community-based (n=5). The authors found that interventions (n=6) that targeted three out of four strategies (energy consumption, energy expenditure, counseling or medication) were more successful than one- (n=6) or two-component (n=13) interventions. Kumanyika [12], who provided a commentary on this review as well as the state of weight control research in ethnic minorities, concluded that the evidence-base is “still rudimentary” (p. 585) and greatly in need of more high quality studies. Yancey et al. [15] conducted a review of community-based interventions with communities of color that focused on healthy eating and active living. Of the 23 interventions included, less than half presented outcome

data. In addition, statistically significant effects were rare, and only five studies used a randomized design.

Since the time of these reviews, several additional studies have focused on weight in African Americans and socioeconomically disadvantaged populations. A subanalysis of weight loss by race and gender in the Diabetes Prevention Program found that black women lost significantly less weight than other race-gender groups in the intensive lifestyle intervention group (−8.1% in white women, −4.5% in black women), although they lost more weight than is typical of other studies of black women [16]. The authors discussed the importance of environmental and sociocultural factors that might have limited the success of the program. The Weight Wise program [17], examined a 16-week group weight loss intervention for low-income women, modeled after The Diabetes Prevention Program and PREMIER but designed to be more cost effective, found significant but fairly modest reductions in weight which proved to be cost effective [18]. Kumanyika and colleagues [19] formally tested the impact of social support and found that African American participants who enrolled in a weight loss program with a family member or friend did not lose more weight than those who enrolled alone; however, greater participation in the program and greater weight loss by the significant other was associated with greater weight loss in the participant. Still another study found no augmentation of weight loss when motivational interviewing was added to a culturally-targeted behavioral program, although the sample size was small [20]. Three other studies [21, 22, 23], two of which are ongoing [21, 23], have taken place in primary care settings, and a number of non-randomized studies have been conducted in African American churches [24, 25].

Thus, despite the moderate amount of research available on the antecedents and correlates of healthy diet and exercise among financially disadvantaged and ethnic/racially diverse populations, most of what we know of effective behavioral approaches is from research conducted entirely or predominantly with Caucasian women. It is unknown how, or if, these strategies can be reframed within a culturally appropriate community-based context, with significant input from the community via formative research, nor if extended support by telephone can lead to long-term maintenance of behavior change and weight loss. The purpose of this paper is to describe the development of such a study, Sisters Taking Action for Real Success (STARS). While the theoretical and behavioral principles employed in STARS are evidence-based, the adaptation and application of these principles to meet the personal, environmental, and economic challenges of this population of women has rarely been done. Socioecologic models of health behavior change contend that people have a greater chance of success if multiple levels of influence on behavior receive attention. The intervention in this randomized controlled trial will address multiple levels: individual and family-level behavioral change; participation in a group setting of mutual support and reciprocity; and engaging community contextual issues within a creative group-based, action-oriented approach to barriers and inequities (e.g., community action, enhanced resource utilization, self-help).

2. Methods

This study was funded by the NIDDK (DK074666) and is registered in clinicaltrials.gov (NCT01172340). The study protocol was approved by the Institutional Review Board at the University of South Carolina on 6/17/2007. CONSORT reporting guidelines were followed in this paper [26, 27].

2.1 Study aims

The primary aim of STARS is to test the effects of a 16-week behavioral/social support group-based intervention on body weight and waist circumference compared to a minimal

intervention control group. This study has four secondary aims: (a) test the effects of the 16-week group-based intervention on the secondary outcomes of physical activity, dietary composition, and dietary behaviors; (b) test the effect of an 8-week telephone-delivered maintenance intervention on primary and secondary outcomes; (c) assess long-term maintenance of primary and secondary outcomes after a 12-week no-contact maintenance phase that begins after the telephone maintenance phase ends; and (d) examine whether changes in psychosocial constructs consistent with our theoretical model mediate the relationship between the intervention and outcome measures at each of the measurement periods.

2.2 Setting and population

This study is being conducted in Columbia, SC. According to the 2000 Census [28], Columbia is the largest city in SC, with a total population of 116,278, within a standard metropolitan statistical area (SMSA) of 536,691. Of persons naming one race, 46% of residents were African American (non-Hispanic) and 49% Caucasian (non-Hispanic). Among all residents, 3% report Hispanic ethnicity. Almost one-quarter (22%) of the city's residents are below poverty (compared to 14% for the state, which ranks 12th poorest in the nation), and 18% have less than a high school education. Among female-headed households with children under age 5, 57% live below poverty. Of 61 census tracts in the city, 18 tracts have at least 25% of all residents living below poverty (mean 39.1%, range = 25% to 62%). STARS participants were recruited from these 18 census tracts, which have a combined population of 44,317 and a median household income of \$20,719.

2.3 Recruitment

A community outreach approach was used to recruit participants. A community advisory board of women who live and/or work in service organizations in the neighborhoods within the identified 18 Census tracts was formed to provide guidance and assistance identifying recruitment strategies, contact persons, and venues, as well as to promote trust and research acceptability within the community. Contact persons from neighborhood associations, public housing, adult education, churches, day care centers, beauty salons, social service organizations, small businesses, physicians' offices and primary health care clinics posted recruitment fliers and made verbal referrals to the program. Project staff recruited participants at community meetings and events in the identified areas.

2.4 Study design

A schematic of the study design, including intervention activities and measurement periods, is shown in Figure 1. We proposed to randomize 180 women to the intervention ($n = 90$) or minimal intervention control condition ($n = 90$) after they met eligibility requirements and provided baseline data. We enrolled and randomized one cohort each year for three years. For each year's cohort, two intervention groups were formed in order to keep the group size to around 15 women. Because many studies targeting underserved populations have reported retention difficulties, the enrollment goal was increased to accommodate losing up to one-third of the sample due to attrition at the final visit (i.e., final sample of 120 participants). Intervention group participants complete measurement sessions at four time periods: baseline (time 1), immediate posttest after 16 weeks of the group intervention (time 2), and delayed posttest after 8 weeks of the telephone maintenance intervention (time 3). Control group participants complete measurement sessions at these same times. Intervention group participants also complete an additional measure of long-term maintenance after 12 weeks of no contact (time 4). Women assigned to the control condition are offered an abbreviated group intervention (8 weeks in duration) after their final measurement (time 3) has been completed.

A minimum of two weeks are required to complete an assessment so that each participant can wear an accelerometer for one week, receive three telephone interviews for 24-hour dietary recall, and receive in-person interviews and anthropometric measures. In order to allow time to recruit adequate numbers of women and complete measurements for all women, measurement periods are generally longer than two weeks (see Figure 1).

2.5 Inclusion and exclusion criteria

To be eligible for the study, women must (a) live within the identified economically disadvantaged census tracts; (b) have a body mass index (BMI) of at least 25 kg/m² and a waist circumference of at least 88 centimeters; (c) be between the ages of 25 and 50 years at their last birthday; (d) be English speaking; and (e) be willing to accept random assignment to condition.

Women are excluded from the study if they: (a) are pregnant; (b) are unable to participate in any type of moderate intensity exercise due to physical limitations; (c) have positive (risk) response(s) on the Physical Activity Readiness Questionnaire (PAR-Q) [29] and physician disapproval on the subsequent Physical Activity Readiness Medical Examination (PAR-MED-X) [30]; (d) have uncontrolled elevated blood pressure ($\geq 140/90$); (e) have cognitive, visual, auditory, physical functional, or language impairment(s) that would preclude participation in group discussion, learning activities or data collection interviews; (f) have insulin-dependent diabetes; or (g) weigh more than 430 pounds (the limit of our scale).

Women who expressed an interest in enrolling in the study were screened by telephone for initial inclusion/exclusion criteria. If the woman appeared initially eligible, an in-person visit was scheduled to determine all inclusion/exclusion criteria and conduct baseline measurements. If the woman required medical clearance to participate or other needs were discovered (e.g., food insecurity, elevated depressive symptoms), appropriate referrals were made. For those women needing medical clearance, they were required to obtain approval prior to randomization or else were excluded. Women who were identified through the PAR-Q and/or blood pressure screening as being at elevated risk, but did not have a family physician, were helped to find a local clinic that accepts Medicaid or has a sliding fee scale for under- or uninsured patients.

2.6 Randomization

Randomization to group for each cohort occurred after baseline data collection was complete and all medical releases were obtained (where necessary); therefore, any attrition during the data collection period occurred before randomization. Stratified random sampling was used to ensure the groups contained similar numbers of women with a BMI ≥ 40.0 kg/m² (the median in our first cohort of women). Using a random numbers table, the biostatistician designated 60 slips of paper as intervention (labeled "Group A") or control (labeled "Group B") and placed them into opaque envelopes (30 intervention, 30 control). Two boxes were prepared: one for women with a BMI < 40.0 kg/m² and one for women with a BMI ≥ 40.0 kg/m². After the end of the visit in which the participant received her diet and exercise counseling session (and after she received medical approval if needed), she went to a separate room and another staff member selected and opened the next envelope from the appropriate box in the participant's presence. This randomization protocol was typically conducted by the Program Coordinator or Principal Investigator, and occasionally by another member of the intervention staff (none of whom take follow up measurements). Upon notification of the group assignment, the staff person described what would happen next and entered the woman's name, participant number, and group assignment into a tracking database. Participants assigned to "Group A" were told that group sessions would begin shortly (date provided) whereas those assigned to "Group B" were told that they

would receive weekly health education materials by mail for 16 weeks and would receive information about the group weight loss sessions at their next study visit (time 2). The terms “intervention” and “control” group were not used in the randomization scripts or in the informed consent form.

2.7 Intervention

2.7.1 Intervention overview—The development of the intervention was guided by our conceptual model, what we learned from the formative focus groups, as well as by the broader exercise, diet, and weight loss literatures. The intervention includes behavioral strategies shown to be effective in the areas of exercise, healthy eating, and weight loss [31], but with content and experiential learning activities tailored to the financially disadvantaged population we targeted. The major components of the intervention included one-on-one counseling with individual goal setting (provided to both intervention and control participants) along with group sessions and maintenance telephone counseling (provided only to intervention participants).

2.7.2 Conceptual model—The conceptual model for the intervention is shown in Figure 2. The behavioral strategies emphasized in the groups were based on principles of Social Cognitive Theory (SCT) [32], Social Support [33], and Relapse Prevention [34]. SCT, which emphasizes the interaction between an individual, his/her environment, and behavior, has guided numerous successful behavior-change interventions. A key construct in SCT is self-efficacy, or one’s confidence to execute a behavior. High self-efficacy, combined with positive expectations and evaluations about expected outcomes of the behavior change, enhance the success of achieving and maintaining change. Self-efficacy is enhanced by successful experiences with behavior (facilitated by gradual changes), observation of successful role models, verbal persuasion or encouragement, and physiological states (e.g., positive mood, enjoyment). Other important constructs of SCT include behavioral capacity (trying new exercises, engaging in meal planning), emotional coping responses (training in stress management and learning how to refute cognitive distortions), and self-regulation (self-monitoring, setting goals, problem solving, self-rewards).

In addition, the four major types of social support that assist a person in undertaking behavior change [33] are emphasized: instrumental (tangible aid such as childcare or transportation), appraisal (information to assist in self-assessment – e.g., How am I doing?), emotional (providing understanding and a sense of acceptance), and informational support (providing knowledge to help in behavior change). Participants receive these types of social support from the interventionists and other group members, and they also learn how to identify and request the support they need outside of the group setting.

Relapse prevention strategies [34] teach the individual skills to anticipate and resist situations that could lead to relapse (e.g., eating out with friends) as well as how to view lapses in behavior as normal rather than catastrophic, thereby avoiding total relapse and return to previous behavioral patterns. These strategies also help individuals learn effective ways to manage stress so that stressful situations do not prompt eating or sedentary behavior as coping responses. Identifying potential problem situations and planning effective coping strategies, as well as opportunities for practice and feedback of the skills, are incorporated into the sessions.

2.7.3 Intervention development: focus groups—A series of focus groups were conducted to guide the tailoring of the intervention to the target population. Four focus groups were conducted with African American women who resided in the targeted census tracts: two pertained to physical activity/exercise (n = 14) and two pertained to healthy

eating and weight loss (n = 19). The facilitator's guides were pretested prior to implementation with a group of four women. Eleven questions in the physical activity guide focused on such topics as barriers to physical activity, ways to motivate women to be active, past history of experiences with physical activity (including reactions of significant others), perceptions of a physically fit woman, cultural and neighborhood influences on physical activity, and desired program elements. Eleven questions in the healthy eating and weight-loss guide focused on such topics as perceptions of what constitutes "eating healthy," past history of experiences with healthy eating and weight loss (focusing on successes and difficulties), perceptions of a woman who wants to lose weight, barriers to healthy eating for weight loss, ways to help and motivate women to eat healthy, desired program elements, and ways that food cost can influence eating and shopping habits.

Physical activity focus group findings: Focus groups uncovered the major barriers, supportive or motivating factors, programmatic suggestions, and other important themes as related to physical activity and exercise. Similar to what has been reported in other studies of African American women, the major barriers to exercise included family and other competing responsibilities, perceptions that their community was unsafe for outdoor exercise and lacked places to exercise, the high cost of gym memberships, and a woman's low motivation to exercise. Somewhat unique to this study, women also discussed experiences and concerns about being ridiculed by others, because of their body size, when exercising. The women believed receiving social support from a group or exercise partner, focusing on health benefits, learning to incorporate exercise into their daily lives, and involving children in their exercise would help to motivate them to exercise. Participants provided suggestions for the type of exercise program they wanted. They wanted a free or affordable group-based program (held in the evenings) that provided exposure to a variety of exercises. They suggested that the program provide incentives, transportation (or be close to bus line), and childcare. The program should include education about exercise and healthy eating, should use music, and should include regular weigh-ins. A suggestion unique to this population was that they wanted sessions held in a location without windows or mirrors. Finally, several instructor/facilitator characteristics were important to women: not too skinny, nonjudgmental, ability to work with different people, patient, supportive, outgoing, motivating, and caring. Several other important and unique themes were raised. Women discussed their desire to retain their "curves," they discussed how they were satisfied with a larger body size, and they described the need for immediate and continuous results in order to motivate them to continue with the program.

Healthy eating focus group findings: Similar barriers were noted in the healthy eating/weight loss focus groups (competing responsibilities, high cost, unsupportive family and friends). Other barriers were more unique to healthy eating. For example, "low calorie," "low fat," and "healthy" foods were perceived as unappealing, and unhealthy foods were often used for comfort, especially when experiencing interpersonal stress. Similar to exercise, health benefits (including mental health benefits and the diagnosis of a medical condition) and social support were viewed as motivating factors to eat healthy and lose weight. Women discussed how meal planning, making small gradual changes, and having the right "mindset" were helpful. Women also believed that eating better would help their children to prevent obesity and other health problems. Programmatic suggestions not previously mentioned included nutrition education, cooking demonstrations and tastings, tips for inexpensive healthy foods, instruction in meal planning, address stress eating and stress management, and inclusion of a dietitian as one of the instructors. Women in these groups also discussed the body image issue noted in the exercise group, and also stated that it is difficult to stick with a weight loss program, especially if a rigid diet plan is used.

As described in detail in Section 2.7.5, the group weight loss sessions incorporated the majority of these themes and programmatic suggestions.

2.7.4 Individual counseling session: intervention and control group—In order to promote program acceptability in the community, it was important that all women receive some level of intervention related to physical activity and diet. Thus, all participants in the study (intervention and control groups) received an initial one-on-one in-person physical activity and dietary counseling session. For the dietary session, a dietician counseled all participants for about 30 minutes. Participants received a report that outlined the results of their 24-hour dietary recalls (described in a later section) and were counseled to set an initial goal of a 10% reduction in their weight at a rate of about one to two pounds per week. Women received a suggested meal plan that was tailored to their caloric needs. Tip sheets on various topics were used to support counseling messages (e.g., fats and oil, weight loss tips). The dietary recommendations incorporated evidence-based eating plans such as the DASH diet [35]. The later part of the session was devoted to creating a plan for change (identifying one or two initial goals for change), identifying potential barriers to this plan, and identifying strategies to overcome these barriers. All participants received a community resource guide related to healthy eating. Participants who were diabetic also received a diabetes tip sheet. This tip sheet was created by two doctoral-level nursing faculty with expertise in diabetes care and was based on information provided by the American Diabetes Association (www.diabetes.org/). The tip sheet strongly emphasized the need for women to consult with their doctor to monitor the impact of weight loss on their diabetes control. It also provided information regarding warning symptoms (hyper and hypoglycemia), safety tips, and the importance of monitoring glucose levels and foot care. The health care providers of these women, as well as other women with health conditions, also received a letter informing them of their patient's participation in the trial, a description of the intervention, and a request to contact the study principal investigator or registered dietician with questions or concerns. Participants provided signed consent for the research staff to communicate with their health care providers regarding their participation in the study.

For the physical activity session, all participants received 30 minutes of counseling from an exercise specialist. This session covered moderate-intensity exercise, physical activity recommendations (30 minutes/day, 5 days/week), and the option to accumulate exercise in 10- or 15-minute bouts. Tip sheets were provided to support these key counseling messages. Participants also received a report that summarized their physical activity results from the seven days in which they wore an accelerometer (described in a later section). Like the dietary counseling portion, the later part of the session was devoted to creating an exercise plan, identifying potential barriers to this plan, and identifying strategies to overcome these barriers. All participants received a list of community resources related to exercise, an exercise safety tip sheet, and a chair exercise routine (designed for women who may not be ready for brisk walking).

2.7.5 Group-based behavioral sessions: intervention group—Group-based interventions are common in weight-loss intervention studies and were a preferred mode of delivery for women in our focus groups. We designed a 16-week group-based program that was based on our conceptual model and tailored to the unique issues of the target population, as informed by the focus group findings. An outline of the 16 sessions is presented in Table 1. Interventionists include a health educator, an exercise specialist, and a staff member with a master's degree in food and nutritional sciences. At least two interventionists are present at every session. Participants receive a stipend for attending each session that they can apply to transportation and/or childcare costs. Sessions are held within walking distance of a bus stop and at a location that has free and ample parking. The sessions are held in a large room that includes a demonstration kitchen, chairs for group

discussion, and open space for exercise. Numerous incentives and tools are provided to women over the course of the 16 weeks. These include measuring cups, measuring spoons, lunch bags, water bottles, recipe booklets, pedometers, sport watches, resistance bands, yoga mats, exercise DVDs, relaxation/stress reduction DVDs, exercise towels, and tote bags. Participants receive binders to hold all of their class handouts and receive a weekly journal to record goals and to self-monitor.

The sessions address barriers in the environment and economic challenges, such as finding a safe and affordable way to exercise (e.g., identifying public resources such as parks and recreation centers near the woman's home or worksite) and eating healthfully on a limited budget and with time constraints (e.g., economical shopping and meal planning). Women learn how to adapt existing recipes to be healthier. Group sessions include cooking demonstrations and tastings of foods that use affordable and available ingredients. These tastings help to counter the myth that healthy food does not taste good.

Demonstrations and opportunities for participation in various types of exercise are also provided during the sessions. To provide exercise opportunities that can be done at home for convenience, safety reasons, or in times of bad weather, all women receive an exercise DVD geared for women who are at a beginner fitness level that is led by an African American instructor (our baseline assessment found that all women had a DVD player and a 2006 survey of US households found that 81.2% owned at least one DVD player [36]). Ample time during group sessions is provided for group discussion and support. Group-based problem-solving activities support the women to identify their own challenges, develop creative solutions, use available resources and supports, or engage in community action to bring about changes. Women learn and practice how to negotiate with family members regarding meals and how to obtain needed support. Group activities are designed to increase self-efficacy, develop group support, and facilitate a context of reciprocity.

2.7.6 Telephone maintenance counseling: intervention group—After time 2 measurements are complete, an additional eight weeks of weekly telephone contact is provided to all intervention women. These calls provide an opportunity for women to receive positive reinforcement and to obtain support for continued behavior change. A telephone support script was created based on similar scripts used in other behavior change programs [37, 38]. All study participants have a phone. Data from 2010 indicates that only 2% of US households had neither a landline nor a cell phone [39].

Each call begins with a health assessment to ensure that no new health issues or symptoms occurred since the last contact. The women chose which behavior they wish to discuss first (e.g., exercise or healthy eating first, followed by the other behavior). For both behaviors, the interventionist assesses progress toward the goal set in the previous call (or in the case of the first call, an initial goal is set), whether the woman continued to use her journal to self-monitor, what went right or facilitated the target behavior over the past week, and what got in the way of the target behavior or made it difficult in the past week. When a woman identifies a barrier to behavior change, the interventionist guides her in problem-solving to overcome the barrier. Women are also asked to anticipate barriers in the upcoming week and how they could be addressed (relapse prevention). Finally, the woman is asked to set new goals that are specific, realistic, and measurable. After all of these behavioral topics are addressed, the interventionist assesses weight loss progress, satisfaction, and goals. The main points of the call are then summarized back to the participant, and the next call time is confirmed.

2.7.7 Weekly health education mailings: control group—Women in the control group receive the same frequency of contact (but via mail) as do intervention women. This

design was chosen in order to establish a consistent relationship with women in both groups so as to maximize retention rates. Each week during the 16 weeks while the intervention participants meet in group behavioral sessions, the control group receives by mail printed health education materials developed by health and governmental organizations, along with a small incentive. Examples of topics for the print materials include sleep, hand-washing, stroke, and mammograms. The materials do not emphasize dietary change, physical activity, or weight loss.

2.7.8 Delayed group-based behavioral sessions: control group—After the time 3 data collection session, control participants are invited to participate in an abbreviated (8-session) group-based program, based upon what is provided to intervention participants. Although it increased cost and time, offering the intervention to the control group, after a delay, is essential in community-based projects to ensure acceptability of the research to the community.

2.8 Measures

To the extent possible, measurement staff members are blind to participant intervention assignment for all follow up visits. Intervention staff members assist in measurement sessions only at the baseline visit before random assignment. One staff member, however, is involved in the randomization and in subsequent measurement visits, but she does not deliver the intervention to participants. Primary and secondary outcome measures are completed at all measurement visits. Participants receive incentives for completing the measurement session, returning their accelerometer, and completing the 24-hour dietary recalls.

2.8.1 Screening measures—The following three measures are not research outcomes but are used during the screening visit to identify women who might need to be excluded, who need referrals for medical clearance or care, or who need assistance locating emergency food and/or food stamps.

Physical Activity Readiness Questionnaire (PAR-Q): The PAR-Q [29] is a seven-item tool for initial screening of adults who need medical clearance to participate in a moderate intensity physical activity program. Women who answer yes to one or more questions but wish to enroll were required to see their physician for medical clearance to participate. Staff assisted women who did not have a physician through referral to clinics that accept Medicaid or under- or uninsured patients.

Blood pressure was measured three times over the course of the 90-minute visit, with quiet sitting prior to each reading [40]. Participants with readings suggestive of hypertension ($\geq 140/90$) [40], based on the average of the three readings, were required to receive medical clearance to participate and were referred for evaluation for hypertension. The Omron HEM-711DLX blood pressure monitor was used to obtain the three measurements. If a participant's arm was too large for this monitor, the LifeSource UA-789 digital monitor with the AccuFit extra large cuff was used instead.

Food security was assessed with the six-item Short Form of the US Household Food Security Module [41]. This assessment was included for ethical reasons to insure that no woman who volunteers to participate was in need of food. If a woman answered affirmatively to more than one item, a staff person discussed food security with the participant, and if indicated, referred her to local food banks for emergency supplies and to the Department of Social Services for a Food Stamp application. All women received a list

of community resources for emergency financial, clothing and food assistance, social services, mental health services, and medical clinics that serve the uninsured.

2.8.2 Primary outcome measures

Weight: Weight was measured with a Seca 882 scale to the nearest tenth of a pound.

Waist Circumference: Using the measurement protocol from the National Health and Nutrition Examination Survey (NHANES) [42], waist circumference was measured to the nearest tenth of a centimeter just above the ilium by a trained staff member. A waist circumference measurement of 83 cm and above indicates elevated disease risk [43, 44]. To ensure that enrolled women were in need of significant weight loss, they were required to have a waist circumference of at least 88 cm to participate in the study.

2.8.3 Secondary outcome measures

Dietary intake: The dietary outcomes for this study are total caloric intake; percent of calories from total fat, saturated fat and trans fat; and servings per week of fruits and vegetables determined through three, unannounced multiple-pass 24-hour recalls. During the baseline visit, participants received one-on-one training in estimating portion sizes. Our training was based on existing training methods that use the Food Portion Visual (The 2D Food Portion Visual, 1996, Nutrition Consulting Enterprises, Framingham, MA) [45], but was substantially enhanced to include a one-on-one 20-minute session with the use of food models, utensils, cups, bowls, and plates. This training was pretested during our formative work to confirm its applicability to the study population. Minor edits were made to the script. Directly after the training, participants completed their first 24-hour recall by telephone during the measurement visit (an off-site registered dietician calls the study office and completes the call). The remaining two calls were completed by telephone within the next 15 days. The Nutrient Data System for Research (NDS-R, Version 5.0_35) software (licensed from the Nutrition Coordinating Center at the University of Minnesota) was used for estimations. Interviewers are a team of experienced and trained master's level, registered dietitians. The average daily intake across the three interviews was computed. Twenty-four hour recalls have established validity and reliability [46].

Objective measurement of physical activity: The ActiGraph accelerometer (GT1M model, ActiGraph, LLC, Fort Walton Beach, FL) was used to objectively measure physical activity at each measurement period for seven days. This monitor is a uniaxial accelerometer that measures acceleration in the vertical plane ranging in magnitude from 0.05 to 2.00 Gs with frequency response of 0.25 to 2.50 Hz. Participants were instructed to wear the ActiGraph on the right hip during all waking hours (except while in water) for seven consecutive days. They also kept a physical activity diary over the same period. A 60-second epoch (time interval) was used. The GT1M model is the newer version of the extensively validated 7164 Model [47]. The actigraph protocol and physical activity diary can be obtained at <http://prevention.sph.sc.edu/tools/index.htm>.

In order for each woman's data to be considered adequate, she was required to wear the accelerometer for at least 4 days during a week and at least 10 hours per day. For adults, three to four days of monitoring is required to achieve acceptable reliability estimates [48] and four days were required for the 2003–2004 NHANES [49]. Ten hours per day is a common cut-point in accelerometer studies [50], and was the cut-point used in NHANES [49].

We propose to use the cutpoints defined by Lopes et al. [51] to classify activity counts as sedentary (< 1.5 METs; <200 counts/minute), light (1.5 to 1.9 METs; 200–1239), moderate

(3.0–5.9 METS; 1240–2399), or vigorous (≥ 6 METS; ≥ 2400). These cutpoints were validated for overweight and obese participants. If other validity studies with population groups similar to the STARS participants are published prior to when our data analyses are conducted, they will be considered.

Estimated cardiorespiratory fitness: We estimated the participants' level of cardiorespiratory fitness based on an equation by Jurca and colleagues [52]. Estimates from this equation have been shown to correlate highly with maximal and submaximal exercise tests in three different samples that included men and women ages 20–70 (multiple correlation coefficient ranged from 0.76 to 0.81). Participants are asked to choose one activity category (out of 5) that best describes their usual pattern of daily physical activities. These categories are assigned physical activity scores of 0.00 (level 1), 0.32 (level 2), 1.06 (level 3), 1.76 (level 4), or 3.03 (level 5). Their estimated MET level of cardiorespiratory fitness is then calculated as: $[\text{Gender (women}=0, \text{men}=1) \times 2.77] - [\text{age} \times 0.10] - [\text{BMI} \times 0.17] - [\text{resting heart rate} \times 0.03] + [\text{physical activity score} \times 1.00] + [\text{constant of } 18.07]$.

Low-fat eating and emotional eating practices: Eight items from the low-fat eating and four items from the emotional eating subscales of the Eating Behavior Patterns Questionnaire [53] were administered. The wordings of several items were modified very slightly. These subscales have been shown to have acceptable internal consistency ($\alpha = .84$ and $\alpha = .77$ for the two subscales, respectively). The measure has demonstrated construct validity with African American women.

Fast food frequency: The frequency of fast food visits in the past 7 days was assessed with a question from the Early Childhood Longitudinal Study [54]. Participants were asked how often in the past 7 days they ate a meal or a snack from a fast food restaurant (examples of fast food restaurants were provided).

2.8.4 Mediating variables

Exercise self-efficacy: The Exercise Self-Efficacy Questionnaire [55] consists of 14 items to rate confidence to exercise (ranging from 0% to 100%) when faced with commonly-cited barriers (e.g., when tired, during bad weather). Ratings were averaged to form a composite scale score. This scale was found to have construct, criterion-related, and convergent validity and high internal consistency reliability ($\alpha > .90$) across age, race, gender, and education subgroups, and was significantly and positively associated with physical activity level [56].

Self-efficacy for healthy eating: An 8-item measure developed to assess self-efficacy for eating a low fat diet in financially disadvantaged women was modified to assess self-efficacy for “making healthy food choices, such as choosing fruits or vegetables, choosing lower fat foods, and watching how much you eat” when faced with common barriers (e.g., when upset, eating out at a restaurant with others). This scale has three domains: positive affect, negative affect, and availability. The original scale has demonstrated construct and convergent validity, as well as internal consistency reliability ($\alpha \geq .82$) [57].

Social support: Two 11-item scales assessing social support (one related to healthy eating and another for exercise) were developed and evaluated. Participants were instructed to think about the most recent time they tried to engage in the target behavior and to report how often “family members, friends, co-workers, or anyone else close to you” engaged in 11 supportive behaviors, with response options being 1=not at all, 2=a little, 3=somewhat, 4=quite a bit, and 5=very much. These scales have construct validity and internal

consistency reliability, with all factor loadings greater than 0.60 and all coefficient alphas exceeding 0.90 in a sample of middle-aged women (60% African American) [58].

Goal setting, restructuring plans, and relapse prevention and maintenance: A 16-item instrument was administered to assess goal setting (6 items), restructuring plans (4 items), and relapse prevention and maintenance (6 items) [59]. Although this measure was developed to capture constructs important in physical activity interventions, the questions do not make reference to physical activity. The relapse prevention and maintenance scale and the goal setting scales have been reported to have acceptable internal consistency (.70 to .79) and test-retest reliability for three time periods (0 to 6 months, 0 to 12 months, 6 to 12 month) (.59 to .76). The restructuring plans scale, however, had lower internal consistency (.49 to .60) but similar levels of test-retest reliability as the other two subscales (.57 to .66).

2.8.5 Other variables

Sociodemographic characteristics: Age, educational status, race, Hispanic ethnicity, employment status, health insurance coverage, marital status, and number of children less than 18 years of age at home were assessed with self-report questions.

Depressive symptoms: Participants completed the widely-used 10-item [60] Center for Epidemiological Studies Depression Scale (CES-D) [61]. Participants rated the frequency with which they experienced symptoms of depression during the past week. Possible scores can range from 0 to 30 with higher scores indicating greater depressive symptoms.

2.9 Data Safety and Monitoring

The funding agency did not require a data safety and monitoring board due to the low-risk nature of the intervention; however, a Data Safety Monitor reviews quarterly reports of enrollment, recruitment, data management and security, attrition and any reports of adverse events (no adverse events have been reported to date). As part of the data safety plan, symptoms and health status are assessed at each measurement. If a potential adverse event is reported or discovered by the staff at another time (e.g., group session, study reminder call), the Principal Investigator (PS) is notified and an adverse events form is completed within 24 hours. This form captures the incident or symptoms and assesses the event in terms of severity, association with the intervention, and duration (e.g., resolved or ongoing). The Principal Investigator reports adverse events to the university's Office of Research Compliance via an electronic reporting system. In addition, all investigators, staff, and students are required to maintain up-to-date certification in research ethics and human subjects.

2.10 Process evaluation

The process evaluation assesses reach, attendance and participation, dose, fidelity (implementation integrity), and compatibility [62]. All intervention contacts (groups and telephone calls) are audio recorded. Interviews, questionnaires, tracking databases, and observational ratings are used to assess the components of the process evaluation.

2.11 Sample size justification

Sample size was chosen to provide greater than 80% statistical power to detect differences between intervention and control groups for each of the primary anthropometric outcomes as well as secondary behavioral outcomes. Our own research data and various published studies were consulted for estimates of the effect sizes from physical activity and nutrition interventions to guide sample size determination. Alpha was set at 0.05 and our calculations allowed for the loss of up to one-third of the sample due to attrition (remaining $n = 120$).

With these assumptions, we had 0.996 power to detect a 2.0 kg difference in weight between groups (effect size = 0.85) and 0.942 power to detect a 2.6 cm difference in weight circumference between groups (effect size = 0.65). Our power was at least 0.89 to detect expected group differences in fruits and vegetables (0.43 servings per day), total kilocalories (449 kcal/day), percentage of kilocalories from fat (6.5%), and physical activity (36.2 min/day).

2.12 Statistical analyses

Prior to inferential procedures, extensive descriptive analyses and examination of distributions will be conducted for all variables at each time point in the intervention and control groups. *The primary analysis* will be an analysis of covariance (ANCOVA) comparing each outcome at immediate post-test by group assignment, adjusting for the baseline value and potential confounding variables. An analysis for each outcome will use baseline, immediate post-test, and delayed posttest (3 measurement points) to estimate a growth curve model [63]. This procedure can accommodate missing data at one or more time points while testing for statistically significant associations between group assignment and individual trajectory parameters in the study population. Both the ANCOVA and mixed models will be estimated separately for weight and waist circumference. In addition, growth curve models for the four measurement points available in the intervention group will assess longer-term maintenance of the intervention effects. *Secondary* models identical to the primary analyses will examine physical activity, total energy intake; percent of calories from total fat, saturated fat and trans fat; fruit and vegetable intake; self-efficacy for diet and exercise; social support for diet and exercise; and behavior skills for healthy diet and exercise.

Attrition—To examine effects of attrition, we will compare all baseline demographic, cognitive, and behavioral variables of participants lost to follow-up with baseline data of the cohort, to determine possible differential (by treatment condition) attrition. Presence of differential attrition (difference in dropouts between treatment conditions) will be considered a threat to internal validity. Analysis for the primary and secondary hypotheses will be done under the intent-to-treat principle with missing data handled by the methodology proposed by Little and Yau [64].

Mediation analyses—Baranowski and colleagues [65] have noted that few interventions measure or assess the impact of theoretically suggested mediating variables (e.g. social support, self-efficacy) on behavior changes. This study assesses self-efficacy for healthy eating and exercise as well as social support for healthy eating and exercise. In addition, the process evaluation will assess program fidelity and others factors that could affect the intervention's success. Mediation analyses will be conducted as outlined by MacKinnon [66]. Asymmetric confidence limits based on the distribution of the product ($\alpha*\beta$) will be constructed using the PRODCLIN program [67]. This approach has been shown to be more powerful than other analytic approaches in simulation studies [68].

3. Results

3.1 Participant recruitment

Figure 3 shows the flow of participants through the recruitment and randomization phase of the study. A total of 746 telephone inquiries were received to obtain the final sample of 155 participants (21% yield). We completed telephone screenings with 88% of those who made initial inquiries. Only 47% of those remained potentially eligible after the telephone screen. The most common reasons for ineligibility included not residing in the targeted Census tracts (66%), not falling between 25 to 50 years of age (17%), being unable to attend study

visits or sessions (logistics or schedule, 6%), and not being overweight (6%). Of those who were initially eligible by telephone, 75% were consented and attended the first measurement visit; 25% did not show up for the visit or cancelled the visit. Prior to randomization, but after the baseline measurement was conducted, 12% of consented participants were excluded from the study, largely due to medical contraindications (81%) and 20% did not attend the visit that included randomization. Thus, 68% of those consented and measured at baseline were randomized to an intervention condition.

3.2 Participant characteristics

Demographic and health-related baseline characteristics of the study sample are presented in Table 2. Intervention and Control participants did not differ significantly ($p > .05$) on any characteristic at baseline. Most participants (86%) self-identified their race as Black or African American, and less than three percent reported Hispanic ethnicity. Participants averaged about 40 years of age and most were college educated and employed. Nonetheless, 43% of the sample reported food insecurity. The largest proportion of women were never married (40%), followed by married (23%). Eighty percent of participants reported having health insurance of some type. By design, all women were overweight (6%) or obese (94%) with average waist circumference readings substantially above the at-risk range. The most common chronic health conditions reported by participants were hypertension (26%), arthritis (14%), heart disease (10%), and diabetes (9%).

4. Summary

Ethnic minorities and those who are of lower socioeconomic status, at both the individual and environment level, are at increased risk for health-related morbidity and mortality [1, 2]. Yet these individuals are underrepresented in exercise, dietary, and weight loss interventions [12, 14], and there is some evidence that African American women do not respond as well to weight loss interventions as other race-gender groups [12, 15, 16]. This theoretically- and community-based randomized trial will examine the impact of a tailored diet and exercise intervention on weight loss, waist circumference, and dietary and exercise behaviors in a sample of women residing in financially disadvantaged neighborhoods. A limitation of our study should be considered: the requirement for several study visits may reduce generalizability as initially less motivated participants may have been screened out due to nonattendance at study visits.

Nonetheless, the strengths of the study design include randomization to intervention group, state-of-the-art measures of both exercise and diet (very rarely have accelerometers been used to capture physical activity in weight loss interventions), a unique analysis plan (growth curve modeling), inclusion of potential mediating variables, inclusion of a detailed process evaluation, and inclusion of a no-intervention maintenance period. Engaging a community advisory board of women who live in and/or work in service organizations in our target neighborhoods was also a unique aspect of the study. Their involvement helped us to develop a more relevant and tailored approach to the research, enhanced recruitment activities, and helped to garner trust and acceptability of the research within the community. The intervention is also unique in a number of ways. First, it specifically targets women who reside in disadvantaged neighborhoods, as defined by the Census. The study thus targets an important segment of the population and addresses multiple levels of change, including individual and family-level behavioral change; participation in a group setting of mutual support and reciprocity; and engaging community contextual issues within a creative group-based, action-oriented approach to barriers and inequities. Second, the use of formative work and the inclusion of a community advisory board help to ensure that the intervention is tailored to the unique circumstances of this population. Third, the intervention includes a group-based format for the initial period and then transitions to telephone-based support for

the maintenance period. Most interventions use just one mode of delivery, particularly in African American samples. This dual-approach could be more effective and efficient at sustaining behavior change. Finally, the intervention promotes the gradual implementation of healthier dietary choices and exercise and the reduction of less desirable foods and sedentary behavior through behavioral strategies and does not stress calorie counting. This type of healthy lifestyle approach may be more feasible, palatable, and sustainable for the target population. The participants recruited into this study were experiencing substantial health risks and could benefit greatly from lifestyle change. Although we proposed rigorous and time-intensive outcome measures for this efficacy study, which thereby necessitated a longer recruitment and measurement period, these measures would not be necessary if the program were to be delivered in clinical or community settings. We believe the intervention approach has the potential to be feasible and cost-effective for community delivery.

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Figure 1.

STARS Study Design

Note: Boxes in bold represent the delivery of the behavioral intervention.

Figure 2.
Model of a behavioral/support intervention for underserved women to promote healthy diet and exercise for weight loss

Figure 3.
STARS Recruitment flow chart

Table 1

Outline of the Topics Covered in the 16-Week Group Sessions

Session	Topics	Behavioral Skills or Strategies
1	<ul style="list-style-type: none"> • Introduction to writing objectives • Exercise overview (with group exercise) • Diet overview 	<ul style="list-style-type: none"> • Self-regulation: self-monitoring, setting goals, & self-reward • Knowledge/self-efficacy • Knowledge
2	<ul style="list-style-type: none"> • Writing objectives • Staying Safe when Exercising Outdoors • Counting your Steps (with group exercise) 	<ul style="list-style-type: none"> • Self-regulation: self-monitoring, setting goals, & self-reward • Behavioral capacity • Self-monitoring/goal setting/behavioral capacity/self-efficacy
3	<ul style="list-style-type: none"> • Eating More Vegetables • Meal Planning • Food demo & tasting 	<ul style="list-style-type: none"> • Behavioral capacity • Behavioral capacity (planning) • Behavioral capacity/self-efficacy
4	<ul style="list-style-type: none"> • Aerobic Activity (with group exercise) • Eating More Fruits • Food demo & tasting 	<ul style="list-style-type: none"> • Behavioral capacity/self-efficacy • Behavioral capacity • Behavioral capacity/self-efficacy
5	<ul style="list-style-type: none"> • Dealing with Triggers • Eating More Whole Grains • Food demo & tasting 	<ul style="list-style-type: none"> • Stimulus control/barriers • Behavioral capacity • Behavioral capacity/self-efficacy
6	<ul style="list-style-type: none"> • Modifying Recipes: ROSE Method • Food demo & tasting (group meal) 	<ul style="list-style-type: none"> • Behavioral capacity (cooking substitutions) • Behavioral capacity/self-efficacy
7	<ul style="list-style-type: none"> • Avoiding Roadblocks • Managing Stress 	<ul style="list-style-type: none"> • Problem solving/relapse prevention • Stress management
8	<ul style="list-style-type: none"> • Target Heart Rate (with group exercise) • Reading Food Labels • How to Shop and Eat Right 	<ul style="list-style-type: none"> • Behavioral capacity (gauging intensity) • Behavioral capacity (label reading) • Behavioral capacity (planning & shopping)
9	<ul style="list-style-type: none"> • Supermarket Tour 	<ul style="list-style-type: none"> • Behavioral capacity (shopping)/self-efficacy
10	<ul style="list-style-type: none"> • Rating of Perceived Exertion (with group exercise) • Meats and Meat Alternative 	<ul style="list-style-type: none"> • Behavioral capacity (gauging intensity)/self-efficacy • Behavioral capacity
11	<ul style="list-style-type: none"> • Flexibility (with group exercise) • Dairy/Calcium • Food demo & tasting 	<ul style="list-style-type: none"> • Behavioral capacity/self-efficacy • Behavioral capacity • Behavioral capacity/self-efficacy
12	<ul style="list-style-type: none"> • Community Resources 	<ul style="list-style-type: none"> • Environmental opportunities

Session	Topics	Behavioral Skills or Strategies
13	<ul style="list-style-type: none"> Resistance Training (with group exercise) Eating Out 	<ul style="list-style-type: none"> Behavioral capacity/self-efficacy Behavioral capacity/self-monitoring
14	<ul style="list-style-type: none"> Relapse Prevention Keeping your Motivation to Exercise What's Next for Exercise 	<ul style="list-style-type: none"> Relapse prevention & cognitive restructuring Motivation & reward Motivation & reward
15	<ul style="list-style-type: none"> Social Support Yoga (with group exercise) 	<ul style="list-style-type: none"> Instrumental, appraisal, emotional, & informational social support/assertiveness training Behavioral capacity/self-efficacy
16	<ul style="list-style-type: none"> Review of Skills and What Worked Group Exercise: dancing Celebration 	<ul style="list-style-type: none"> Review of behavioral skills

Note: Each session started with group sharing and support (problem solving) and recording of daily steps and minutes of exercise (self-monitoring). Each session concluded with setting weekly goals/objectives in participant's journal (goal setting). A healthy snack was provided in each session that did not contain a food demonstration and tasting (except for session 9).

Table 2

Baseline Characteristics of Study Participants, Overall and by Group Assignment

Characteristic	Intervention (n=80)	Control (n=75)	Total Sample (N=155)
Race, % (n)			
White	6.3 (5)	10.7 (8)	8.4 (13)
Black/African American	87.5 (70)	85.3 (64)	86.5 (134)
> 1 category	6.3 (5)	4.0 (3)	5.2 (8)
Hispanic ethnicity, % (n)			
Yes	2.5 (2)	2.7 (2)	2.6 (4)
No	97.5 (78)	96.0 (72)	96.8 (150)
Missing	0.0 (0)	1.3 (1)	0.6 (1)
Age in years, Mean $\pm$ SD	38.6 $\pm$ 7.2	39.3 $\pm$ 7.9	38.9 $\pm$ 7.5
Education, % (n)			
Never attended school	0.0 (0)	0.0 (0)	0.0 (0)
Grades 1–8	0.0 (0)	1.3 (1)	0.7 (1)
Grades 9–11	2.5 (2)	8.0 (6)	5.2 (8)
Grade 12 or GED	11.3 (9)	14.7 (11)	12.9 (20)
Some college	48.8 (39)	49.3 (37)	49.0 (76)
College grad	37.5 (30)	26.7 (20)	32.3 (50)
Insurance, % (n)			
Yes	77.5 (62)	82.7 (62)	80.0 (124)
No	22.5 (18)	17.3 (13)	20.0 (31)
Marital status, % (n)			
Married	25.0 (20)	20.0 (15)	22.6 (35)
Divorced	21.3 (17)	17.3 (13)	19.4 (30)
Widowed	1.3 (1)	1.3 (1)	1.3 (2)
Separated	6.3 (5)	9.3 (7)	7.7 (12)
Never married	42.5 (34)	37.3 (28)	40.0 (62)
Couple	3.8 (3)	14.7 (11)	9.0 (14)
Employment status, % (n)			
Employed	75.0 (60)	77.3 (58)	76.1 (118)
Not employed	10.0 (8)	12.0 (9)	11.0 (17)
Student	6.3 (5)	5.3 (4)	5.8 (9)
Retired	1.3 (1)	1.3 (1)	1.3 (2)
Unable to work	2.5 (2)	2.7 (2)	2.6 (4)
Employed and student	5.0 (4)	1.3 (1)	3.2 (5)
Number of children in household, Mean $\pm$ SD	1.10 $\pm$ 1.32	0.81 $\pm$ 0.97	0.96 $\pm$ 1.17
Number of children in household, % (n)			
0	48.8 (39)	49.3 (37)	49.0 (76)
1	17.5 (14)	26.7 (20)	21.9 (34)
2	15.0 (12)	18.7 (14)	16.8 (26)
3	13.8 (11)	4.0 (3)	9.0 (14)

Characteristic	Intervention (n=80)	Control (n=75)	Total Sample (N=155)
4 or 5	5.0 (4)	1.3 (1)	3.2 (5)
Food Insecurity, % (n)			
Secure	52.5 (42)	62.7 (47)	57.4 (89)
Insecure w/o hunger	31.3 (25)	29.3 (22)	30.3 (47)
Insecure with hunger	16.3 (13)	8.0 (6)	12.3 (19)
Weight in pounds, Mean $\pm$ SD	242.1 $\pm$ 62.7	234.3 $\pm$ 53.6	238.4 $\pm$ 58.4
BMI (kg/m ²), Mean $\pm$ SD	40.4 $\pm$ 9.8	39.7 $\pm$ 8.2	40.1 $\pm$ 9.1
BMI category, % (n)			
BMI < 25 kg/m ²	0.0 (0)	0.0 (0)	0.0 (0)
BMI 25.0 – 29.9 kg/m ²	6.3 (5)	6.7 (5)	6.5 (10)
BMI $\geq$ 30.0 kg/m ²	93.7 (75)	93.3 (70)	93.5 (145)
Waist circumference, % (n)	116.0 $\pm$ 18.7	114.7 $\pm$ 17.1	115.4 $\pm$ 17.9 (155)
Self-reported health conditions Heart condition, % (n)			
Yes	8.8 (7)	10.7 (8)	9.7 (15)
No	91.2 (73)	89.3 (67)	90.3 (140)
Cancer, % (n)			
Yes	3.8 (3)	0.0 (0)	1.9 (3)
No	96.2 (77)	100.0 (75)	98.1 (152)
Diabetes, % (n)			
Yes	10.0 (8)	8.0 (6)	9.0 (14)
No	90.0 (72)	92.0 (69)	91.0 (141)
Hypertension, % (n)			
Yes	31.3 (25)	21.3 (16)	26.5 (41)
No	68.7 (55)	78.7 (59)	73.5 (114)
Arthritis, % (n)			
Yes	16.3 (13)	10.7 (8)	13.6 (21)
No	83.8 (67)	89.3 (67)	86.4 (134)