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Sistas Inspiring Sistas Through Activity and Support (SISTAS): Study Design and Demographics of Participants

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Introduction: Recruiting racial, ethnic, and other underserved minorities into conventional clinic-based and other trials is known to be challenging. The Sistas Inspiring Sistas Through Activity and Support (SISTAS) Program was a one-year randomized controlled trial (RCT) to promote physical activity and healthy eating among AA women in SC to reduce inflammatory biomarkers, which are linked to increased breast cancer (BrCa) risk and mortality. This study describes the development, recruitment, and implementation of the SISTAS clinical trial and provides baseline characteristics of the study participants.

Methods: SISTAS was developed using community-based participatory research (CBPR) approaches. At baseline, study participants completed assessments and underwent clinical measurements and blood draws to measure C-reactive protein (CRP) and interleukin-6 (IL-6). Participants randomized to the intervention received 12 weekly classes followed by nine monthly booster sessions. Post-intervention measurements were assessed at 12-week and 12-month follow-ups.

Results: We recruited a total of 337 women who tended to: be middle-aged (mean age 48.2 years); have some college education; be employed full-time; have Medicare as their primary insurance; be non-smokers; and perceive their personal health as good. On average, the women were pre-hypertensive at baseline (mean systolic blood pressure = 133.9 mm Hg; mean diastolic blood pressure = 84.0 mm Hg) and morbidly obese (mean BMI >40.0 kg/m^2); the mean fat mass and fat-free mass among participants were 106.4 lb and 121.0 lb, respectively.

Conclusion: The SISTAS RCT addresses some of the gaps in the literature with respect to CBPR interventions targeting AA women, such as implementing diet and physical activity in CBPR-based studies to decrease BrCa risk. *Ethn Dis*. 2018;28(2):75-84; doi:10.18865/ed.28.2.75.

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Introduction

There are racial disparities in breast cancer (BrCa) mortality across the United States (US). Although disease incidence is approximately equal in African American (AA) women and European American (EA) women, AA women have a higher rate of mortality (30.6 deaths per 100,000 women in 2002-2011, 50% higher than EA women).[1] As found for national rates, one of the most alarming health disparities in South Carolina (SC) is associated with increased BrCa mortality rates among AA women: despite ~15% lower incidence rates in AA women, mortality is ~60% higher per unit incidence.[2,3] Lifestyle changes such as increasing physical activity and implementing a healthy diet (ie, increasing fruit and vegetable intake) have been shown to reduce the risk of various comorbidities often seen with BrCa,[4] as well as BrCa incidence itself.[5]

Community involvement has been a staple among AA populations when addressing various health issues. The use of community-based participatory research (CBPR) methods has been shown by previous studies to enhance recruitment and retention efforts.[6-11] Community engagement at every stage of the research process is the

hallmark of CBPR-based recruitment strategies.[6,11] Research also has shown that group-based interventions may be significant in creating large changes in a multitude of health outcomes.[12]

Collaborations between AA communities and universities are vital in delivering culturally appropriate, evidenced-based health-promotion messages that can effectively reach the intended audience. Numerous CBPR-based clinical trials have targeted AA men and women with regard to specific outcomes,[13] including assessment of cancer risk knowledge[14] and reduction of cancer risk.[15] Statistically significant increases in colorectal cancer knowledge were shown in one study,[16] and statistically significant decreases in weight, BMI, and percent body fat occurred among participants recruited from five churches were reported in another study.[17] Only two studies have used the CBPR approach to direct a BrCa-prevention intervention among AA women.[18,19]

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The purpose of this article is to describe the development and implementation of the Sistas Inspiring Sistas Through Activity and Support (SISTAS) research study, a CBPR RCT aimed at promoting physical activity and healthy diets among overweight and obese AA women in SC with the overall goal of reducing BrCa risk. In addition, we also provide baseline characteristics of the SISTAS participants.

Methods

Setting and Population

South Carolina has a large rural population compared with the overall US population, with 33.7% of the population of SC living in rural counties in 2010[20] compared with 18.2% of the population living in rural counties nationwide.[21,22] Thus, we selected a rural area and a metropolitan area in SC (based on population) in which to conduct SISTAS intervention classes and clinic visits.

Approach to Partnership/ Recruitment

Formation of Advisory Panels

The Project Leader and Project Coordinator identified key stakeholders in the participating regions who were selected for participation in the Community Advisory Panel and the Professional Advisory Panel. These panels critiqued and made edits to all assessment packets, intervention materials, study name and logo.

Recruitment of Participants

Multiple avenues were utilized for participant recruitment, including church services, bible studies, community health fairs, local libraries, and social events. Additionally, all church and community partners advertised and marketed the study in each of their domains through church newsletters, bulletins, and bible studies. The first intervention wave in the rural area began in September 2011, and the first intervention wave in the metropolitan area began in September 2013. We recruited 132 (39.2%) women in the metropolitan area and 205 (60.8%) women in the rural area, for a total of 337 women enrolled in the study.

Inclusion and Exclusion Criteria

Women were eligible to participate in the study if they were AA, aged ≥30 years, had a body mass index (BMI) ≥30 kg/m^2, had no previous cancer diagnosis (except non-melanoma skin cancer), had no inflammation-related diseases (eg, lupus, rheumatoid arthritis), were physically able to exercise (including walking), and were willing to be randomized and participate fully in the research study for one calendar year.

Intervention

The SISTAS intervention held eight waves in the rural region of SC and three waves in the metropolitan area for a total of 11 waves. Ran-

Table 1. Overview of the 12 weekly intervention sessions

Week	Education Session	Activity
1	SISTAS overview	Physical activity
2	Health disparities; anti-inflammatory foods; types of exercise	Food and physical activity log; self-monitoring/SMART goals; cooking demonstration
3	Physical activity basics; SMART goals; healthy protein	Group walk
4	Nutrition basics	Food label demonstration; cooking demonstration
5	Empowerment; strength training; review logs; eating out	Review food and physical activity logs; healthy snacking
6	Changing recipes; cooking demonstration; hot & cold weather exercising	Cooking demonstration
7	Stages of change; support and overcoming barriers; group aerobic training; dining out	Review food and physical activity logs; group choice physical activity
8	Menu planning; portion distortion	Menu planning
9	Burning calories w/physical activity	Review food and physical activity logs; group activity strength training; Jeopardy game
10	Program adherence	Cooking demonstration
11	Stress management	Massages; group aerobic activity
12	Planning for lapses	Healthy pot luck

domization to the intervention or control group occurred immediately after the baseline clinic visit. Women randomized to the intervention arm received 12 weekly classroom sessions (consisting of exercise regimes, emphasis on making healthy food choices, and cooking demonstrations) and educational binders (Table 1). The second clinic visit took place after three months of weekly sessions. Thereafter, nine monthly booster sessions containing additional exercise modules and cooking classes (Table 2) were held, with the final clinic visit conducted at one year after baseline.

Data Collection/Measures

Data collection

All potential participants who contacted the study staff (eg, in person, via telephone, electronically) were screened to assess eligibility, added to the tracking database, and assigned a study identification number. General demographic information (including age, race, employment status, etc.) was entered into the SISTAS database. Information on active participants included completion of clinic visits, class attendance, all communication attempts, and their outcomes during the course of the study. To ensure security and confidentiality of participant information, the study database was hosted on a secure server in a folder to which only key study personnel had access.

Measures

Data were collected at three time points. Participants were scheduled for clinic appointments immediately before and after the 12-week intervention and at the end of one year. Clinics were held at the same local churches and academic centers where intervention classes were conducted for each wave. Participants who could not attend follow-up clinic visits after the start of their participation were contacted by study personnel to attend make-up clinics to obtain blood samples and pertinent information. At all three clinic visits (baseline, three months, and one year), questionnaire data were obtained, anthropometric measurements were

Table 2. Overview of the nine intervention booster sessions

Month	Topic	Activity
1	Program refresher	Discussion on best practices
2	Grocery store tour	Guided tour
3	Mindful eating	Aerobic exercise
4	Selecting exercise equipment	Resistance bands exercise
5	Smart snacking	Strength and balance exercises
6	Preventing strains	Guest speaker
7	Planning for success	Menu and meal planning
8	Healthy grocery savings	Tips on vegetarian diet
9	Sustaining lifestyle change	Healthy pot luck

Table 3. Questionnaire-derived data

Questionnaire	Baseline	Three-month follow-up	One-year follow-up
Health and lifestyle	X	x	x
Center for Epidemiologic Studies Depression Scale (CESD-10)	X	x	x
Everyday Discrimination Scale	X		
Perceived Stress Scale	X	x	x
Pittsburgh Sleep Quality Index	X	x	x
Self-efficacy for diet	X	x	x
Self-efficacy for exercise	X	x	x
Social support	X		
Social support and eating habits/exercise	X	x	x
The Health Care Systems Distrust Scale	X		
Racial Pride Scale (urban AA women)	X		
Demographics	X		

taken, and a blood sample was collected. For the current analysis, only baseline measures were utilized.

Questionnaire-derived Data

Prior to their clinic visits, participants were mailed questionnaire packets (see Table 3 for a list of questionnaires included at the baseline, three-month, and one-year clinics). Participants brought completed questionnaires to their clinics, where they were reviewed for completeness and accuracy.

Data Collected in Clinic

All blood pressure and anthropometric measurements, including height, hip circumference, waist circumference, weight, and percent body fat (including fat mass and fat-free mass) were taken during the clinic visits by trained study staff following standardized data collection protocols.[23]

Body Mass Index (BMI)

BMI, based on measured height and weight (BMI = weight [kg]/height [m^2]), was also examined and categorized using the following groups: normal weight (BMI 18.5 to <25 kg/m^2); overweight (BMI 25 to <30kg/m^2); obese (BMI 30 to <40 kg/m^2); and morbidly obese (BMI >40 kg/m^2). Body fat and lean body mass were obtained through bioelectrical impedance assessment (BIA).[8,11,24]

Dietary Data

Estimates of energy and intake of nutrients and food groups were derived from participant self-report of food consumption. This information was collected using a single, telephone-administered, 24-hour dietary recall interview (24HR). Although this method is not devoid of measurement error, it is considered an imperfect "gold standard" for estimating dietary intake[25] in a nutrition intervention. Although a single 24HR is not adequate to characterize dietary intake on the individual level, it can be used to calculate group-level mean intake[26] and compute centiles of the distribution using standard statistical techniques.[27]

Calculation of the dietary inflammatory index (DII) has been described previously.[28] Micro- and macronutrient values (known as food parameters) derived from the 24HR were assigned inflammatory article scores based on research summarizing findings from 1,943 articles.[28] These food parameters were divided by energy intake and multiplied by 1,000 to create values per 1,000 kilocalories to account for variation in energy intakes between participants. DII calculation is linked to a regionally representative world database (food consumption from 11 populations around the world) that provided a mean and standard deviation for each food parameter per 1,000 calories consumed. A z-score was created by subtracting the standard mean from the actual intake and dividing by its standard deviation. This z-score was then converted to a percentile (to minimize the effect of outliers or right-skewing) and centered by doubling the value and subtracting 1. The product for each food parameter and adjusted article score was calculated and then summed across all food parameters to create the DII score for each participant. More positive DII scores represent more pro-inflammatory diets; more negative values indicate more anti-

inflammatory diets.[28] Based on a previous study on the design and the development of a literature-derived, population-based dietary inflammatory index (DII) that was aimed at comparing diverse populations on the inflammatory potential of their diets, the maximum pro-inflammatory diet had a DII score of +7.98, the maximal anti-inflammatory diet had a DII score of -8.87, and the median DII score was +.23.

Other Variables

The baseline characteristics examined were: age (years); educational status (high school graduate or less, some college, completed college, and more than college); marital status (married, single, divorced/separated, widowed); and employment status (full-time, part-time, retired, unemployed). Body fat and lean body mass were obtained through bioelectrical impedance assessment (BIA).[8,24] Other baseline characteristics examined were insurance status, categorized as Medicare, Medicaid, privately insured, or uninsured, and perceived health status, which was a subjective report by participants and was categorized as excellent, very good, good, fair, or poor.

Laboratory-derived Data

Blood samples from all eligible participants were collected during clinic visits for the analysis of inflammatory markers (C-reactive protein [CRP] and interleukin 6 [IL-6]). Blood samples were collected by trained phlebotomists/nurses and sent to the University of South Carolina School of Medicine for processing and analysis. Details about blood handling, analysis protocols, and procedures have been described elsewhere.[25]

Table 4. Baseline demographics of study population

Characteristic	Frequency (%); n = 337
Age, mean ± SD	48.2 ± 11.0
Marital status	
Married/living with partner	135 (40.1)
Widowed, divorced, separated, single	202 (59.9)
Education status	
High school or less	70 (20.7)
Some college	142 (42.1)
Completed college	59 (17.5)
Postgraduate	66 (19.6)
Employment status	
Full time	183 (54.3)
Part time	38 (11.3)
Retired/not employed	116 (34.4)
Smoking status	
Current	109 (32.8)
Non-smoker	223 (67.2)
Perceived health	
Excellent	9 (2.7)
Very good	87 (26.1)
Good	182 (54.6)
Fair	50 (15.0)
Poor	5 (1.5)
Insurance	
Medicare	139 (41.9)
Medicaid	44 (13.3)
Private	22 (6.6)
Uninsured/self-pay	61 (18.4)
Other	66 (19.9)
Characteristic	Mean ± SD; n = 337
Body mass index, kg/m^2	39.0 ± 7.4
Waist-to-hip ratio, inches	.87 ± .07
Fat mass, lbs	106.4 ± 32.1
Fat-free mass, lbs	121.0 ± 18.3
Systolic blood pressure, mm Hg	133.9 ± 21.9
Diastolic blood pressure, mm Hg	84.0 ± 13.7
Dietary Inflammatory Index, DII[a]	2.15 ± 2.17

a. Mean DII values have not been found to exceed the bounds of -10 and +10. More negatives scores are indicative of more anti-inflammatory diets; more positive scores are indicative of more pro-inflammatory diets.
Column percentages may not equal 100 because of rounding. Frequencies may not equal population total because of missing data.

Retention of Participants

We collected contact information from participants during the initial recruitment and at baseline. Follow-up reminder calls were made to participants in the intervention arm two days prior to each session, and all participants were contacted multiple times for the clinic visits. Any changes in contact information were recorded in the participant database profile for future use. All participants were sent monthly incentives (ie, appreciation gifts) through the mail at various intervals throughout the duration of

their participation. These gifts were not related to diet or physical activity. Intervention participants also were given certificates at the end of the 12-week intervention period, and those with perfect attendance were entered into a drawing for a monetary gift. All participants received a $50 incentive for attending all three clinics.

Statistical Analyses

Baseline descriptive statistics were computed using frequencies or means and standard deviations; these values were obtained via SAS Version (9.4).

Results

Baseline demographic characteristics of the participants are presented in Table 4. We recruited a total of 337 women; there were 132 (39.2%) women from the metropolitan/urban areas, and 205 (60.8%) women from the rural areas. Participants tended to: be middle-aged (mean age 48.2 years); have some college education (42.1%); be employed full-time (54.3%); have Medicare as their primary insurance (41.9%); be non-smokers compared with current smokers (67.2%); and perceive their personal health as good as reported in the Health and Lifestyle questionnaire (54.6%). On average, the women were pre-hypertensive at baseline (mean systolic blood pressure = 133.9 mm Hg; mean diastolic blood pressure = 84.0 mm Hg) and morbidly obese; we defined obese as having a BMI ≥ 30 kg/m^2 to 39.9 kg/m^2 and morbidly obese as having a BMI ≥ 40 kg/m^2. The mean fat mass and fat-free mass among participants were 106.4 lb and 121.0 lb, respectively (Table 4). The mean DII score (2.15 ± 2.17) indicated that the participants consumed a relatively pro-inflammatory diet; the average score is above 1.00, which we define as pro-inflammatory while a score below 1.00 would have been denoted as an anti-inflammatory diet. However, it should be noted that ~41% of the population had negative DII values at baseline, which indicates an anti-inflammatory diet.

Discussion

We successfully recruited a population of AA women with high BMI values to participate in a physical activity and diet randomized intervention trial in rural and urban SC. Overall, we found that women in the study were morbidly obese, pre-hypertensive, and consumed a pro-inflammatory diet. We have evidence of widespread interest in the study and its components, as we had 812 women either contact us directly or request direct contact about the study, with 337 eligible women ultimately being enrolled. Participant DII values were indicative of more pro-inflammatory diets, although ~41% of the population had scores indicating more anti-inflammatory diets. This novel dietary measurement tool has distinct advantages over other dietary measures in that it is based on peer-reviewed literature focusing on a specific outcome (ie, inflammation) and is standardized to world intake values.[28] The DII has been found to be associated with inflammatory biomarkers, including CRP and IL-6,[29] increased odds of asthma and reduced forced expiratory volume (FEV_1), shiftwork, the glucose intolerance component of metabolic syndrome among police officers, anthropometric measurements, cardiovascular disease incidence, and colorectal, prostate, and pancreatic cancer risk in previous studies.[30,31] Additionally, chronic low-grade inflammation in the blood has been linked to both diabetes and obese status.[32] Future analyses using SISTAS data will examine changes in DII scores after completion of the intervention compared with baseline and whether these changes correspond to healthier levels of inflammation markers.

We expected somewhat high BMI values among our population because a higher percentage of AA women in SC are overweight compared with the national average (~78.0% vs 56.6%, respectively).[33] However, even among obese women, the BMI values measured among our participants were extremely high compared with national standards (39.0 kg/m^2 vs 30.0 kg/m^2, respectively.[34] The participants' average blood pressure measurements were consistent with being pre-hypertensive per American Heart Association guidelines,[35] which also was confirmed by crosschecking some of the medications the women reported taking.

Despite adhering to the principles of CBPR in these university-community collaborations, limitations exist that the SISTAS program attempted to focus on. In the last decade, some studies targeted research for churches,[14] focus groups,[36] or case studies.[37] The SISTAS program utilized a RCT model as a guide for the intervention adapted for AA women. Interventions that are personalized

for high-risk populations, such as AA women, have been shown to reduce obesity and adverse health outcomes associated with added weight.[38] Most cancer-based CBPR interventions focus on screening for cancer to combat health disparities,[39,40] promotion of general overall health,[41] or participation rates among AAs.[42]

The SISTAS trial is unique for several reasons. Most importantly, it is one of the only RCTs of dietary and physical activity among African American women that measured biological biomarkers of disease (inflammatory markers). Additionally, it investigated multiple outcomes, including BMI, waist-to-hip ratio, body fat percentage and DII, which distinguishes it from other previous trials that focused mainly on weight loss.[43-51] The SISTAS study focused on AAs at the population level instead of medically at-risk AAs, which makes it different from the studies reviewed by Fitzgibbon et al that showed that medically at-risk AAs have better weight loss outcomes.[43] The CBPR strategy utilized by SISTAS study was designed to address barriers such as lack of motivation, lack of knowledge, and lack of physically active role models, which were identified by Joseph et al.[44] Thus, the SISTAS study is further distinguished for incorporating a CBPR strategy to address previously identified barriers.[44] Additionally, the CBPR strategy aimed to address retention and adherence challenges, as identified by Whitt-Glover et al.[49]

The SISTAS study was also designed to conduct a comprehensive assessment of discrimination and health beliefs within the social context in which our minority population lives and works, as well as motivators for behavior changes, through the questionnaires addressing overall health and lifestyle and self-efficacy for diet and physical activity. We were also able to incorporate physical activity along with a dietary component to our trial, as compared with previous studies that focused solely on increasing physical activity among AA women.[43-51] Also, the SISTAS study was modeled to be experiential with a "hands-on" curriculum and AA lay instructors leading the activities. The initial screening performed by the research team occurred in person, where we were able to assess objective measures as well as self-reported items. This aspect makes SISTAS different from the assessments in the home-based individually tailored physical activity print (HIPP) trial, which were done via telephone.[46-47] Our trial was exclusive to AA women compared with other trials that recruited other populations, and we also had a relatively large sample size given the study design vs other previously published papers with small sample sizes.[45-47] Additionally, compared with some other studies on weight loss among AAs,[43-52] the SISTAS trial incorporated a novel DII measure in its design.

We have evidence of widespread interest in the study and its components, as we had 812 women either contact us directly or request direct contact about the study, with 337 eligible women ultimately being enrolled.

It is seldom that we find studies with a CBPR framework that implement diet and exercise collectively to reduce the risk of chronic disease as assessed through objective biomarkers; a project that promotes increased physical activity as well as proper consumption of fruits, vegetables, and whole grains would likely have a large impact on reducing the risk of BrCa. Finally, a limitation that the SISTAS study faced was some non-response issues for some of the measures. The advisory panel suggested that we not use paper assessments for diet and physical activity and indicated that interviews would be the more suitable choice for this population. However, we had issues with interview completion because some participants did not want to stay on the line for lengthy phone calls or did not answer the calls. We determined that the latter issue was due to women not recognizing the phone number from which study personnel called. Once this issue became apparent, participants in subsequent waves were alerted during clinic visits and any additional contacts with the study coordinator that they would be receiving calls to conduct the interviews from an unfamiliar number and were encouraged to answer.

Conclusion

Among diet and physical activity interventions geared toward the female AA population, rarely has a

CBPR framework been used in those projects that seek to reduce BrCa risk. Because of the strong community support and resources provided by the grant in this project, we hypothesize that women in this trial will retain the lessons learned than if they had been enrolled in a conventional clinic-based trial. The SISTAS program gives us initial indicators of a positive impact on the community, given our relative success with recruitment,[6] and a positive overall impact on motivating AA women in rural and metropolitan SC to live a healthier lifestyle.[53] Our study is also one of the few studies to assess impact at one year after baseline. We hypothesize that the CBPR approach will lead to more lasting change in the AA community.

The SISTAS RCT addresses some of the gaps in the literature with respect to CBPR interventions targeting AA women, such as implementing a diet and physical activity intervention in CBPR-based studies to decrease BrCa risk. Recruitment and retention plans and process evaluation were built in to the trial to assess the program's ability to effect meaningful change. Future projects aimed at BrCa and other chronic diseases call for epidemiologists to consider utilizing the CBPR approach in designing and administering clinical trials to under-represented and underserved populations.

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Disclosure

Dr. James R. Hébert owns controlling interest in Connecting Health Innovations LLC (CHI), a company planning to license the right to his invention of the DII™ from the University of South Carolina in order to develop computer and smart applications for patient counselling and dietary intervention in clinical settings. Dr. Michael Wirth is an employee of CHI.

Conflict of Interest

No conflicts of interest to report.

Author Contributions

Research concept and design: Heiney, Brandt, Hurley, Johnson, Warren, Murphy, Hébert, Adams; Acquisition of data: Babatunde, Heiney, Hurley, Khan, Johnson, Wineglass, Murphy, Sercy, Thomas, Hébert, Adams; Data analysis and interpretation: Bevel, Babatunde, Brandt, Wirth, Hurley, Khan, Warren, Murphy, Thomas, Hébert, Adams; Manuscript draft: Bevel, Babatunde, Heiney, Wirth, Hurley, Khan, Johnson, Wineglass, Warren, Murphy, Sercy, Thomas, Hébert, Adams; Statistical expertise: Babatunde, Wirth, Hurley, Hebert, Adams; Acquisition of funding: Brandt, Murphy, Hébert, Adams; Administrative: Bevel, Babatunde, Heiney, Brandt, Khan, Johnson, Wineglass, Sercy, Thomas, Hebert; Supervision: Babatunde, Heiney, Hurley, Adams

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