



HHS Public Access

Author manuscript

Contemp Clin Trials. Author manuscript; available in PMC 2021 January 01.

Published in final edited form as:

Contemp Clin Trials. 2020 January ; 88: 105897. doi:10.1016/j.cct.2019.105897.

The Nutritious Eating with Soul (NEW Soul) Study: Study design and methods of a two-year randomized trial comparing culturally adapted soul food vegan vs. omnivorous diets among African American adults at risk for heart disease

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Abstract

Background: Previous research has found that African American (AA) vegetarians/vegans have a significantly lower body mass index and risk of hypertension compared to omnivores.

Objectives: The Nutritious Eating with Soul (NEW Soul) study partnered with local soul food restaurants/chefs to deliver two behavioral nutrition interventions to AA adults. NEW Soul examines the impact of two different culturally tailored diets (vegan and omnivorous low-fat) on changes in risk factors for cardiovascular disease (CVD).

Methods: AA adults with overweight or obesity are recruited from the community in the Midlands of South Carolina. Eligible participants are randomized to follow one of two different culturally-adapted, soul food diets: a vegan diet emphasizing minimally-processed whole foods from plants or a low-fat omnivorous diet. Participants attend weekly group classes for the first six months, bi-weekly for the next six months, and monthly meetings for the last year. In addition to face-to-face content, participants also have access to private Facebook groups for their diet, podcasts, and online newsletters starting at six months. Primary outcomes include changes in body weight and CVD risk factors (lipids, blood pressure, glucose, and insulin) at 12 months. Secondary outcomes include changes in dietary intake. Participants complete assessments at baseline and at months 6, 12, and 24.

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Conclusions: The NEW Soul study is an innovative intervention aimed at improving dietary intake while maintaining traditional AA cultural food choices. Primary outcomes are expected by 2021.

Keywords

African Americans; diet therapy; vegan diet; low-fat diet

1. Introduction

In the US, African Americans (AAs) have the highest rates of obesity and heart disease as compared with whites and Hispanics [1]. More AA men and women die from cardiovascular disease (CVD) than any other chronic disease condition [2]. Although CVD mortality has declined over the previous four decades, rates of CVD mortality among AAs have remained disproportionately high [3]. Overweight and obesity are associated with a number of chronic diseases, including type 2 diabetes, hypertension and CVD [4, 5], as well as an increased risk of several cancers [6, 7].

Vegan diets “are healthful, nutritionally adequate, and may provide health benefits in the prevention and treatment of certain diseases” (Position of the Academy of Nutrition and Dietetics) [8]. Data from the Adventist Health Study-2 (AHS-2) have shown that people following vegan diets have the lowest body mass indices (BMIs) and the lowest prevalence of type 2 diabetes compared to other diet patterns [9]. In addition, findings from the European Prospective Investigation into Cancer and Nutrition (EPIC-Oxford) study have shown that vegans gain significantly less weight as they age compared with omnivores. Converting to a more plant-based diet also appears to be protective against weight gain, as does following a pesco-veg diet in women [10].

The AHS-2, which has a considerable population of both vegans and AAs, has examined diet and health outcomes among both whites and AAs. Research from the AHS-2 has found that compared with AA omnivores, AA vegetarians/vegans had significantly lower risk of hypertension, diabetes, and high total and LDL cholesterol [11]. In addition, vegan diets were protective against overall cancer incidence and female-specific cancers as compared with four other plant-based dietary patterns [12]. Plant-based diets may confer even more protection against chronic disease for AAs than for whites. For example, in an AHS-2 cohort study examining diabetes risk, diet pattern, and race, researchers found that AAs following vegan, vegetarian, or semi-vegetarian diets had a lower risk of diabetes than those following an omnivorous diet [13]. This study concluded that being AA was an independent risk factor for development of type 2 diabetes, but this risk was offset by the protection offered by following a vegan diet, suggesting that plant-based eating styles are a potential strategy to counterbalance the increase diabetes risk among AAs [13]. These prior studies examining dietary pattern and health outcomes among AAs were all observational, which limited their ability to determine causality, leading to the development of the present intervention.

In 2017, our team received funding from the National Institutes of Health (R01HL135220) to conduct a two-year randomized trial comparing two diets rich in plant-based foods, an entirely plant-based (vegan) diet and a low-fat, reduced animal product, omnivorous diet,

among AA adults who were at risk for CVD. The objective of this study was to determine which diet allowed for greater sustained changes in body weight, lipids, and blood pressure. An innovative aspect of the Nutritious Eating with Soul (NEW Soul) study is that it partners with local soul food restaurants (both omnivorous and vegan) and chefs in order to ensure culturally relevant and palatable versions of each diet.

2. Study design

Adults with obesity or overweight (BMI 25-49.9 kg/m²) who self-identified as AA were randomized to follow one of two diets emphasizing soul food cuisine: (1) Vegan: whole foods, plant-based vegan diet or (2) Omni: low-fat omnivorous diet. The NEW Soul study is a randomized behavioral intervention with a recruitment goal of a minimum of 130 participants over two cohorts separated by one year. All participants provide informed consent prior to participation.

2.1 Screening

Participants are recruited through media interviews (TV, radio, and newspaper), radio commercials, community outreach, and word of mouth. Participants are directed to a study website where they can learn more about the study and complete an online screener questionnaire. Because physical activity was a component of the NEW Soul study, participants completed the Physical Activity Readiness Questionnaire [14] as part of the online screener and were asked to get physician consent to participate if they were currently on medications for blood pressure or a heart condition. If they indicated “yes” on any of the other questions (e.g., “Do you feel pain in your chest when you perform physical activity?”), then they were excluded from the study. Participants who are not eligible are sent an email thanking them for their interest in the study. Participants who are eligible are contacted by a study coordinator to complete a brief phone screener. Eligible and interested participants are given a choice of meeting times to attend an orientation session. Nine inclusion and six exclusion criteria were used for the study (Table 1). Because of the amount of activities and information that needed to be covered in order to explain the study, the orientation session was split into two separate sessions. Participants receive training on how to complete the 24-hour recall and complete one at the orientation in order to have time to ask questions and receive assistance from study staff. In addition, participants are provided with an overview of what the study entails. This includes a detailed description of each diet, along with sample meal ideas. Because vegan diets are unfamiliar to most participants, dinner is provided to participants that is catered from a local vegan soul food restaurant. This allows participants to get a better understanding of the diets in the study. Finally, participants sign up for their baseline laboratory assessment time.

2.2 Baseline data collection

Data are collected both in-person and online (Table 2). Data collected includes survey-based data, dietary recalls, anthropometric data, and laboratory assessments. More information about these assessments is provided below.

2.3 Randomization

Participants who complete all baseline assessments are randomized to one of the two diet conditions. Randomization is stratified by gender and carried out in blocks of 10 to ensure equal distribution between the groups (since randomization is conducted on a rolling basis as participants complete assessments). The study statistician creates the allocation sequences with a computerized random number generator and a research assistant who is blinded to participant identification randomizes the participants into each group using the sequences.

2.4 Single-blind

The NEW Soul study is single-blinded, as it is not possible to blind study participants to their study assignment. It is also not possible to blind intervention staff to study assignment. All assessment staff are blinded to group assignment, however, and staff involved in randomization are blinded to study participant identity. Participants are instructed not to tell assessment staff of their assignment.

2.5 Staggered cohorts

To accommodate a minimum of 130 participants in the study, the intervention is conducted in two cohorts separated by one year. Cohort 1 began the study in May 2018 and Cohort 2 began the intervention in June 2019. Cohorts are utilized and staggered in order to ensure adequate recruitment, accommodate space limitations of our demonstration kitchen and teaching classroom, guarantee appointments for laboratory assessments, and account for the number of available accelerometers.

2.6 Hypotheses

The NEW Soul study has one primary aim and one secondary aim, along with corresponding hypotheses. The primary aim is to examine differences in risk factors at 12 months for CVD (changes in lipids, glucose, insulin, and blood pressure) and body weight between participants randomized to the omni or vegan group. We hypothesize that CVD risk factors and body weight will improve to a greater extent in the vegan group as compared with the omni group. The secondary aim is to examine long-term changes in CVD risk factors and body weight at 24 months. We hypothesize that the greatest improvements in CVD risk factors and body weight will be seen within the vegan group as compared with the omni group, demonstrating maintenance of health-related behaviors.

3. Intervention Protocol

3.1 Group-based classes

The NEW Soul intervention consists of weekly in-person meetings lasting 75 minutes for six months (26 meetings), followed by bi-weekly meetings for six months (13 meetings), and then monthly meetings for the last 12 months (12 meetings). Participants are given a choice of two different meeting times on two different days in order to accommodate work, childcare, and church schedules. All classes for both cohorts and both groups are led by the same core staff (MS, RDN-trained nutrition interventionist, MPH-trained project manager, and a discussion facilitator from the community). In addition, AA soul food restaurant

owners and chefs provide cooking demonstrations for study participants or provide food items to sample.

Treatment fidelity is assessed on three occasions per year by a research assistant in class, without knowledge of the intervention staff. A checklist of required class elements is used to ensure A) that required topics are covered and B) both classes are receiving equal treatment in terms of topics covered and duration of the classes. These treatment fidelity reports are then reviewed during the weekly study staff team meetings and any issues are addressed in future classes. Participants are given a choice of two days and class times per week to attend their intervention group sessions. While participants could attend either day and time for their group (and switch between those days and times each week), they are not permitted to attend a day and time that was not for their assigned diet.

3.2 Remotely-delivered content

In addition to the face-to-face group classes, content is provided remotely. Each week when a face-to-face class is offered, participants also receive a weekly email. This email provides a link to the study participant website where participants can access the handouts from the class, copies of the recipes, and additional notes from study staff (such as feedback from participants about how to alter a recipe). If a participant misses a class, they have the option of completing a make-up class online. A video of the class slides with instruction about what is covered in class is available to participants and they complete a brief quiz at the end of the make-up session to verify completion. In addition to these online make-up sessions, monthly face-to-face sessions are offered during lunch time for participants who wish to make up content missed in person.

At six months, when the frequency of the weekly meetings changes to bi-weekly, participants are provided with private Facebook groups for their diet groups. This allows participants to continue to provide social support to one another and allows study staff to post information about their diets on weeks when classes are not held. At 12 months, when classes change frequency to monthly meetings, participants receive a podcast, newsletter, or face-to-face meeting each week. The schedule of delivery is to provide a podcast on the first week of the month, followed by an online newsletter in the second week, a face-to-face meeting in the third week, and another podcast in the fourth week of the month. This allows for weekly delivery of content for the study.

Podcasts are developed using Social Cognitive Theory [15] and are designed to emphasize behavioral strategies useful for dietary maintenance. Specific diets are not mentioned, and the podcasts are the same for both groups. Weekly newsletters provide information about upcoming classes and recipes and are different for each of the diet groups.

3.3 Intervention diets

The objective of the NEW Soul study is to compare two different diets for CVD prevention. Participants are randomized to follow either a vegan or omnivorous (omni) diet. Both diets focus on soul food and traditional African cuisine and both emphasize plant-rich, low-fat eating styles (Table 3). The vegan diet recommends a whole food, plant-based dietary approach [16, 17], meaning a focus on minimally processed plant foods and avoiding refined

foods, including oils. Participants are encouraged to meet their fat requirements through whole foods (e.g., nuts, nut butters, avocados, and seeds). The omni diet follows the Therapeutic Lifestyle Changes dietary guidelines in order to have guidance on portion sizes for foods like lean meats [18]. Both diets are guided by the Oldways African Heritage Pyramid [19], which emphasizes intake of fruits, vegetables, particularly leafy greens and tubers, and whole grains. The pyramid was adapted for the vegan diet group (e.g., legumes in place of meat). The omni diet also included the intake of fish, poultry, and low-fat dairy, and modest amounts of red meat, as outlined by the Oldways pyramid.

3.4 Theory-based content and similarities in intervention content and strategies

The dietary recommendations are the only differences between the groups. Both groups have the same intensity with regards to intervention delivery and have the same instructors and discussion facilitators. Social Cognitive Theory [15] guided the class curriculum with a specific emphasis on building self-efficacy and goal setting. Participants follow a gradual approach to adopting their diets in order to build self-efficacy for dietary change. They focus only on following their assigned diet for breakfast the first week, then add in lunch in week two, and finally add dinner for week three. Participants are provided with training on how to write a SMART goal [20] and then are asked to create a SMART goal each week around the topic discussed. Goals from the previous week are then discussed at the beginning of each class. The general class structure for the NEW Soul study and the constructs from Social Cognitive Theory that are targeted in each class are detailed in Table 4.

In addition to dietary goals, both groups are given the same exercise and stress management goals and techniques. While the focus of the NEW Soul study is to examine the impact of diet on health outcomes, physical activity and stress management were also components of the classes. These health behaviors were included because participants were interested in improving in these areas and these behaviors are also important components of cardiovascular health and weight loss. It is important to note, however, that the recommendations for these behaviors were identical between the groups. For physical activity, participants are encouraged to meet the Physical Activity Guidelines for Americans including achieving 150–300 minutes of moderate-intensity aerobic activity [21]. Participants are encouraged to build up to that goal and achieve it through activities they enjoy or can do for free (e.g., brisk walking). In addition, participants are encouraged to do strength-training activities at least twice per week. Participants are given resistance bands and shown how to use them for strength-training activities. Further, participants are encouraged to find ways to regularly stretch to increase flexibility. A yoga instructor attends two of the classes to demonstrate chair yoga techniques, and a massage therapist attends a class session to demonstrate stretching techniques. The yoga instruction is also used to demonstrate stress management techniques. Participants are given stress management information based on the Diabetes Prevention Program [22], and a licensed counselor discusses ways to handle emotional and stress eating.

3.5 Addressing dietary adherence with study participants

Participants in Cohort 1 are emailed a link to a brief survey each week that a face-to-face class is held. This survey asks participants about their degree of adherence to dietary

guidelines for their group. The questionnaire has 10 food categories (e.g., whole grains, legumes, red meat, eggs, etc.) and asks participants to select the frequency in which they consumed those food groups over the last seven days. Participants can also indicate if they would like to be contacted regarding their diet adherence. Due to low completion rates for the online survey, a brief, paper, in-class survey was provided to Cohort 2 participants (with the option to complete online if a participant missed a class). Participants having difficulty adhering to the dietary recommendations (and indicated they are willing to be contacted) are contacted via phone by a study coordinator. Adherence calls to participants who are willing to be contacted are conducted weekly during the first six months, bi-weekly for the next six months, and monthly for the last 12 months of the study. The study coordinator asks the study participant to identify barriers to following the diet and then collaboratively discusses with the participant potential solutions (e.g., batch cooking to save time) and resources (e.g., recipes) that may be helpful. If a participant continues to have difficulties, they are offered in-person counseling with a registered dietitian. These additional contacts are offered to all participants in order to ensure participants have the ability to ask questions and problem solve outside of class time if questions were not adequately address during classes.

3.6 Methods of contacting participants

To accommodate the varied ways that participants want to be contacted, a study database includes methods of emailing or texting participants. Participants are sent information about upcoming classes, reminders about assessment appointments, and reminders to complete surveys via text message, email, and phone. The study database tracks contact methods and frequency.

3.7 Iterative intervention adaptation and development

Based on feedback from Cohort 1, the order of the first classes were slightly altered for Cohort 2 (Appendix A). Namely, the grocery store tour, which occurred in week 7 for Cohort 1 was moved up to Week 4 for Cohort 2. In addition, participants in Cohort 1 requested that cooking demonstrations and recipes for more typical and traditional soul foods occur earlier in the intervention versus a focus on recipes from the Oldways African Heritage program. Therefore, sample breakfast, lunch, and dinner meals were prepared in the initial weeks of the intervention for Cohort 2 that more closely mirrored traditional soul food, such as vegan or low-fat versions of grits, macaroni and cheese, and red beans and rice. In addition, Cohort 1 requested more frequent hands-on cooking classes and more guest chefs from the community. Both were added to Cohort 1 and were continued for Cohort 2. While these changes occurred in Cohort 2, it is important to note that they occur for both diet groups in Cohort 2. Because these changes were fairly minor, did not include major changes in the intervention design or content, and occurred for both diet groups equally, we do not anticipate an impact on study outcomes. An overview of class topics for the study can be found in Appendix A.

4. Assessment protocol

All assessment measures are collected at baseline, six months, 12 months and 24 months except for DXA scans, which are not collected at 6 months (Table 2). Assessments take

place at the Clinical Exercise Research Center at a large research university. In addition, surveys and dietary recalls are also collected at three months. Below details how primary outcomes (weight and CVD risk factors) and secondary outcomes (e.g., diet, body fat, etc.) were assessed.

4.1 Dietary assessment

Dietary intake is assessed using the National Cancer Institute's Automated Self-administered 24-hour recall (ASA24) [23]. Intake is assessed on three unannounced days including one weekend day (Friday, Saturday, or Sunday) and two weekdays at each assessment time point. Dietary recalls are collected within a three-week window to allow for enough time to contact participants and allow them to complete all three recalls. The ASA24 can be accessed either online or via a smartphone or tablet. Participants with low computer literacy or without consistent access to these devices are offered the ability to complete the recalls over the phone with an interviewer who used the ASA24 system to guide participants through the recall or can be completed in person in the university computer lab. As described earlier, all participants receive an in-person training on ASA24 at baseline and complete their initial dietary recall in-person in order to have opportunities to ask questions. After the initial recall, all other recalls are completed remotely. Participants are contacted on unannounced days to complete their recall. The ASA24 system allows for the participant to complete the recall at any time on the day in which they are prompted up until midnight. If a recall is not completed on that day, participants are then prompted on another non-consecutive unannounced day. Participants are contacted via text message, email, and phone to remind them to complete a recall.

4.2 Physical activity assessment

Physical activity is assessed via accelerometers (GT1M model) worn on the hip. Participants are instructed on how to wear the accelerometers at their orientation session. Participants are asked to wear the monitors during all activities except sleeping and those that involved water (bathing, swimming, etc.) and to wear them for 10 days. The goal is to have a minimum of 4 days with at least 10 hours of wear per day, including at least one weekend day. Accelerometers are checked upon return and those without the minimum required data are asked to wear the monitors again. Actigraph data are converted from counts based on 60-second epochs to categories of inactivity or physical activity using cutpoints from Freedson [24]. Activity counts are classed as sedentary (<1.5 METs; <=100 cpm), light (1.5 to 2.9 METS; 100–1951cpm), moderate (3.0–5.9 METS; 1952–5724cpm), or vigorous (≥ 6 METS; ≥ 5725cpm). Any continuous sequence of 60 or more zero counts is considered a period of Actigraph non-wear. For each wave of data collection (baseline through 24-month) each participant's activity is summarized into average minutes per day of inactivity and physical activity categories of light, moderate, vigorous, and combined moderate-to-vigorous physical activity. Only days on which wear time was compliant with the 10-hour minimum are used in the activity summary variables.

In addition to the accelerometers, participants complete the International Physical Activity Questionnaire - Short Form (IPAQ) [25]. The IPAQ provides an additional way to collect

data on physical activity and provided information on total physical activity in metabolic equivalent for task (MET)-minutes/week and time spent sitting.

4.3 Weight, height and waist circumference

Height was measured at baseline only using a calibrated, wall-mounted stadiometer (Model S100, Ayerton Corp., Prior lake, MN). A calibrated digital scale (Healthometer® model 500 KL, McCook, IL) is used to collect body weight at each assessment time point. A spring-loaded tape measure is used for all waist circumference measurements. Waist circumference is measured at the iliac crest [26], and hip circumference is measured at the maximum protuberance of the buttocks [27]. Two measurements are taken and if they are not within 4 mm of one another, then a third measurement is taken.

4.4 Dual-energy X-ray absorptiometry (DXA) scan

Upon arrival at the Clinical Exercise Research Center, participants who are not wearing appropriate clothing (such as sweatpants and a t-shirt), are asked to change into hospital “scrubs.” A DXA scan is conducted to assess lean tissue mass and fat mass for the entire body, as well as for the trunk only. Intra-instrument variability for DXA is <5.2%, and DXA has been shown to be valid across differences in race, gender, body fatness and size and athletic status [28]. A certified technician performs and provides the results of each DXA scan to study personnel. The body composition assessment takes approximately 45 minutes. Fat (g) and lean (g) mass of arms, legs, trunk, and total body is recorded.

4.5 Blood pressure

After a 5-minute rest period, blood pressure is assessed using an Omron Hem 705 CP Auto Inflate Blood Pressure Monitor. A minimum of two readings (and a maximum of four) are taken, and the average of those readings is used. If there is a >5 mmHg difference between the first and second readings, an additional one or two readings are obtained, and the average of these multiple readings is used [29].

4.6 Blood samples and analysis

A lipid panel (total, LDL and HDL cholesterol, and triglycerides) and fasting glucose and insulin are performed at baseline, six months, 12 months, and 24 months. These tests are performed on serum or plasma using commercially available assay kits. All samples from the same participant will be analyzed on the same plate and, thus, under the same conditions. Therefore, participants do not receive any of the results of these tests until after all cohorts have completed their 24-month assessments. A standard curve will be constructed using standards provided in the kits, and the sample concentrations will be determined from the standard curves. Inter-assay and intra-assay variability will be assessed.

4.7 Psychosocial questionnaires

Participants complete a variety of questionnaires at baseline, three months, six months, 12 months, and 24 months (Table 2). The following are assessed as part of the questionnaires: demographic variables (collected at baseline only), socioeconomic status variables (education, income, own or rent home, etc.), use of nutrition assistance programs,

composition of family household, and environmental changes [30, 31] (changes in neighborhood, housing, access to food, etc.), self-efficacy (SE) for adoption of healthy diets [32], medications (current medications and dosages and any changes), dietary acceptability [33–35], perceived stress [36], perception of food spending [37], health-related quality of life [38], food insecurity [39], physical activity [25], dietary restraint, disinhibition, and hunger [40], appetite for palatable foods [41].

4.8 Data safety and monitoring

The funding agency required a Data Safety and Monitoring plan (DSMP) and a board (DSMB) consisting of three NIH-funded researchers from the same institution who are not involved with the study. The DSMB receives a report semi-annually from study staff that details subject accrual, status of enrolled subjects, adherence data regarding intervention attendance, and any adverse events. Any serious adverse events are to be reported immediately to the institution's IRB and DSMB. The role of the DSMB is to review the data and results of any interim analyses from an ethical standpoint, to ensure the safety, rights and wellbeing of the trial participants. In addition to reports provided via email, the DSMB also meets in-person on an annual basis and the chair of the DSMB prepares a confidential report advising the PI on whether the trial should continue or not.

4.9 Process evaluation

Process evaluation allows for the examination of a program's reach and implementation fidelity and participants' self-reported impressions, satisfaction, and behavior [42]. Process data are collected before, during, and after the intervention. The process evaluation plan is based on Saunders, et. al. [43] and includes assessment of reach, attendance and participation, dose, treatment fidelity, and compatibility/satisfaction. An online database was created that allows study team members to track attendance and utilization of intervention materials, as well as contacts with participants (i.e., appointment reminders) and completion of make-up classes.

5. Analysis plan

5.1 Sample size justification

The primary aims for the NEW Soul study are, using a randomized design, determine the impact at 12 months of two different, culturally tailored diets (omni and vegan) on changes in (Primary Aim 1) risk factors for CVD, including LDL cholesterol and blood pressure, and (Primary aim 2): body weight. The NEW Soul study is powered to detect differences in both CVD risk measures and weight loss. Weight loss has been used to determine power in other NIH-funded dietary trials in which both CVD risk factors and body weight were outcomes [44, 45]. Based on our pilot data using both AA and white participants, we observed a standard deviation (SD) of 4.1 kg for weight change averaged across the arms. A minimum important difference of 2.3 kg between arms would correspond to a 0.56 effect size. A 2.3 kg weight difference is similar to what has been observed in other weight loss interventions using plant-based diets [46]. Based on SDs from previous intervention studies using both AA and white participants [47, 48], for changes in waist circumference, diastolic blood pressure, and fasting glucose, this effect size corresponds to minimum important differences

of, respectively, 0.50 cm, 4.8 mmHg, and 28 mg/dL. To detect an effect size of 0.56 with 51 persons per arm, the power is 80%. In addition, we also used observational studies that examined only AA vegan participants as compared with AA non-vegan participants to calculate power. In one such study [49], AA vegan participants had significantly lower LDL cholesterol and BMI as compared to non-vegan AA participants. Using the observed 0.11 mmol/L SD for LDL and 0.43 kg/m² SD for BMI yielded minimum important differences of 0.062 mmol/L for LDL and 0.24 for BMI at 80% power and a sample size of 51 participants per group. We accounted for ~25% attrition (by month 12) with a goal of recruiting a minimum of 130 participants (65 per group).

5.2 Statistical analyses

Data from all study measures will undergo initial data cleaning to identify potential outliers, assess normality and enumerate loss to follow-up and other missing data. Adherence will be examined, at a descriptive level, separately for men and women. Sex may be associated with adherence or primary outcomes; therefore, randomization was balanced with respect to sex in addition to its inclusion as a covariate in outcome models. Primary study aims will be addressed using repeated-measures, mixed models with maximum likelihood estimation and robust computation of standard errors as provided by PROC MIXED in the SAS[®] system. Under the assumption that missing data are missing at random, these models provide an intent-to-treat analysis in the presence of attrition after baseline. For each component of CVD risk and weight, a model will be estimated using factors of time (baseline vs. 12 months), intervention-arm (omni vs. vegan) and time by intervention-arm interaction. The model will include covariates adjusting for any differences due to socioeconomic status, BMI, use of nutrition assistance programs, composition of family household, self-efficacy for eating behaviors, sex, age, and change in medication or physical activity. A measure of diet adherence (assessed by absence of proscribed foods on dietary recalls as has been used in previous studies [50, 51]) will also be used as a covariate in each model. In addition to the models for the primary outcome (changes in body weight, lipids, glucose, insulin, and blood pressure), a continuous measure of compliance will be modeled using the same time, intervention-arm, interaction term, and covariates. The same models for CVD risk factors and weight will be used to address our secondary aim examining maintenance at 24 months, as well as in assessing other continuous outcomes, including changes in psychosocial variables, body composition and markers of inflammation.

6. Discussion

Previous research has identified barriers to consuming healthy or plant-based diets among AA adults, including the perception that eating healthy means giving up a part of one's cultural identity [52–54]. Participants trying to adhere to a vegan diet have reported having more difficulty with meal preparation than a standard healthy diet (i.e. dietary guidelines from the American Diabetes Association) [55]. In addition, a commonly cited perceived barrier to consuming plant-based diets is difficulty finding appropriate meals when dining out [56–58]. Prior public health research in South Carolina has demonstrated that soul food restaurants have the potential to be a meaningful setting for dietary intervention among AA

[59]. Therefore, our team designed a study to address these barriers to adoption of plant-based eating styles among AA adults living in the southeast in order to reduce risk of CVD.

The NEW Soul study is examining the impact of a vegan, plant-based diet or low-fat omnivorous diet on risk factors for CVD, such as blood pressure, lipids, and body weight. Because both diet interventions promote increasing plant-based foods and decreasing (or eliminating) animal-based foods, we anticipate that both groups will see health improvements, but hypothesize that the improvements will be greater among vegan group participants. While the NEW Soul study is housed in an academic setting, at its core, it is a community-based trial. NEW Soul collaborates with several community partners with a focus on AA-owned businesses. This includes strong partnerships with numerous local soul food restaurants and chefs, as well as exercise and yoga instructors, licensed counselors, and massage therapists. NEW Soul aims to address barriers to adopting healthy diets that are unique to AAs living in the southeastern United States.

Recommending diets that focus on plant-based eating styles, such as the diets used in NEW Soul, has the potential to improve public health. Diets viewed as strict, such as vegan diets, have not been the norm in nutrition recommendations [60, 61]; however, more strict dietary recommendations may yield greater dietary changes than more modest recommendations [62]. Additionally, plant-based diets move participants to diets that are higher in foods that are protective against CVD (e.g., fruits and vegetables, fiber) while avoiding red and processed meats, which have been associated with developing CVD [63, 64].

There are limitations and strengths to the research design of NEW Soul. Limitations include a lack of a true control group either receiving no treatment or usual care. Participants in both groups are receiving an active treatment, both of which emphasize plant-focused diets. The goal of this study was to examine differences in weight loss and CVD risk factors between a group receiving an all vegan diet recommendation compared to the currently recommended diet approach for CVD risk reduction, which is more moderate, yet still emphasizes plant-based foods. In addition, the intervention requires multiple assessment visits and in-person intervention classes, which may limit the generalizability of the findings.

Because this is not a feeding study with provided meals, participants must prepare their own foods or find foods to consume that fit their diets while dining out. This may lead to lower rates of dietary adherence, but this also increases the generalizability of the intervention. There are also numerous strengths to the study design. This study is innovative in both its use of a vegan diet and partnership with soul food restaurants. In addition, AA participants have been largely underrepresented in behavioral obesity interventions [65], so the NEW Soul study is directly addressing that issue. While participants and intervention staff cannot be blinded to participants' dietary assignment, the assessment staff is blinded. In addition, objective measures of physiological outcomes (such as body fat percentage and lipids) will be collected and three days of unannounced 24-hour dietary recalls are used to assess dietary intake. Participants in both groups are matched on all intervention content except for dietary recommendations to follow. This includes equal lengths class time and interaction with intervention staff.

The goal of the NEW Soul study is to help participants move to a more optimal dietary profile—while maintaining AA traditional cultural food choices. In turn, the results of this study can inform current dietary CVD-prevention recommendations and shape how future dietary interventions for AAs may be delivered. The resulting developed innovative intervention, with both in-person and remotely delivered content, has the potential to be scaled up and disseminated through community restaurants or health clinics.

Acknowledgments

Funding:

Research reported in this publication was supported by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health under award number R01HL135220. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Appendix A:: Class topics for the Nutritious Eating with Soul (NEW Soul) Study

Class Number	Class Topics*
Weekly classes	
Class 1	Orientation & Introduction to the NEW Soul Study/Breakfast Ideas
Class 2	Basic Nutrition Guidelines/Lunch Ideas
Class 3	Dinner Ideas
Class 4	Batch Cooking
Class 5	Motivation - What is your WHY?
Class 6	Making a Meal Plan
Class 7	Grocery Store Tour
Class 8	Movement and Physical Activity
Class 9	Greens
Class 10	Carbohydrates & Whole Grains
Class 11	Volumetrics
Class 12	Protein
Class 13	Tips for Dining Out and Traveling
Class 14	Nuts/Seeds/Fats
Class 15	Tubers and Starchy Vegetables/Fiber
Class 16	Recipe Redux: Making Over Family Favorite Recipes
Class 17	Mind the Salt
Class 18	Fruits and Vegetables
Class 19	Emotional Eating
Class 20	Mock Meats - Beef/Burgers
Class 21	Social Support
Class 22	Desserts
Class 23	Snacks

Class Number	Class Topics*
Class 24	Celebration: The Six-month Mark
Bi-weekly classes	
Class 25	Back to the WHY: Keeping your Motivation
Class 26	Stress Management
Class 27	Religion and Diet: Part 1
Class 28	Inflammation
Class 29	Holiday Tips
Class 30	Reading Menus and Meal Planning
Class 31	Diabetes & Carbohydrates
Class 32	Chopped!
Class 33	Fad Diets
Class 34	Staying on Track
Class 35	Cholesterol
Class 36	Setting Goals
Monthly classes	
Class 37	Frozen Food Taste Test
Class 38	Religion and Diet: Part 2
Class 39	Dementia and Diet
Class 40	Massage for Stress Management and Meal Planning
Class 41	Appetizers
Class 42	Diet and the Environment
Class 43	Cooking/Storage Tips
Class 44	Physical Activity
Class 45	Being a Savvy Shopper
Class 46	Holiday Planning
Class 47	Summary and Reflections
Class 48	Conclusion & Certificate of Completion

* Class topics for Cohort 2 were updated throughout the study, although the order and content largely remained the same

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Table 1:

Inclusion and exclusion criteria for the Nutritious Eating with Soul (NEW Soul) study

Inclusion criteria	Exclusion criteria
self-identify as African American	currently following a vegan diet
18-65 years of age	pregnant (or have been pregnant in the last 6 months), anticipating on becoming pregnant in the next 24 months, or currently breastfeeding
BMI between 25- 49.9 kg/m ²	current participation in a weight loss program or taking weight loss medications (although participants may be trying to lose weight on their own)
live in the Columbia, SC area	recent weight loss (>10 lbs in the last 6 months)
be able to attend all monitoring visits	has type 2 diabetes that is controlled with medications (vs. controlled with diet and exercise)
be willing to be randomized to either diet	has an uncontrolled thyroid condition
be free of major health or psychiatric diseases, drug or alcohol dependency	
be free of an eating disorder as screened by the Eating disorder Screen for Primary care [ESP] [66]	
be free on either of the two meeting nights (e.g., Monday or Wednesday)	

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Table 2:

Measurements collected at each time point in the NEW Soul study

Study Year	Year 1 Months				Year 2 Months			
	0	3	6	12	15	18	21	24
Questionnaire measures								
Demographic Information	X							
Perceived Stress Scale [36]	X	X	X	X				X
Short Form Health Survey (SF-12) [38]	X	X	X	X				X
Self-Efficacy for Diet Behaviors [32]	X	X	X	X				X
U.S. Adult Food Security Survey Module [67]	X	X	X	X				X
Food Spending Items (adapted from [37])	X	X	X	X				X
Three-Factor Eating Questionnaire [40]	X	X	X	X				X
Power of Food Scale [41]	X	X	X	X				X
Dietary Intake (ASA-24) [23]	X	X	X	X				X
International Physical Activity Questionnaire (IPAQ) short version [25]	X	X	X	X				X
Current Medications	X		X	X				X
Dietary Adherence and Acceptability [33–35]		X	X	X				X
Lab-based assessments								
Height and Weight	X		X	X				X
Physical Activity (ActiGraph Accelerometer GT1M model)	X		X	X				X
Blood Pressure	X		X	X				X
Fasting Lipids, Glucose, and Insulin	X		X	X				X
Body Fat (DEXA Scan)	X			X				X
Waist-to-Hip Circumference	X		X	X				X

Table 3:

Dietary recommendations for the NEW Soul study participants randomized to follow the Vegan or Omnivorous diets

Dietary Guidelines	Vegan	Omnivorous
Grains	Focus on whole grains with at least 3 g of fiber per serving.	Eat 6 or more servings of grains and make most of your grains whole grains.
Vegetables	Ensure that 20-50% of your plate should be vegetables, including leafy greens.	Eat 3-5 servings of vegetables a day.
Legumes	Eat 1-1½ cups of legumes a day (beans, peas or lentils).	Eat ½-1 cup of legumes a day (beans, peas or lentils).
Fruit	Eat 2-4 servings of fruit each day.	Eat 2-4 servings of fruit each day.
Vegetable oils/ Essential fatty acids	Avoid vegetable oils. Eat 1 tablespoon of ground flax seed, hemp or chia seeds every day for omega-3 fatty acids.	Use small amounts of healthy oils, like sesame or olive oil for dressings, and canola oil for cooking.
Nuts/seeds	Eat high fat plant foods (e.g., avocados, olives, coconut, nuts, seeds and nut butters like peanut butter) as condiments to flavor a meal or as a recipe ingredient, but not a snack.	Add nuts and seeds to at least one meal a day or eat as a snack.
Treats	Limit treats to one time per month. Treats are foods that are higher in fat and sweeteners than the recommendations provide.	Limit treats to one time per month. Treats are foods that are higher in fat and sweeteners than the recommendations provide.
Beverages	Avoid drinking liquid calories.	Avoid drinking liquid calories.
Meat, fish, poultry, eggs	Avoid all meat, fish, poultry, and eggs.	Eat no more than 3-5 ounces of lean meat per day and no more than 2 egg yolks per week. • In addition, eat two servings of fish per week.
Dairy	Avoid all dairy.	Consume dairy in small portions, and if you are lactose intolerant, enjoy other calcium-rich foods like greens, beans, and almonds. • Consume 2-3 servings of low- or no-fat dairy products a day. • Cheese should have no more than 3g of fat per ounce.
Sodium and seasonings	Limit use of sodium and use herbs and spices to flavor your food.	Limit use of sodium and use herbs and spices to flavor your food.
Vitamin B12	Take a B12 vitamin daily.	Take a B12 vitamin daily.
Alcohol	Limit or avoid alcohol: If you do drink, have no more than one drink a day for women and two a day for men.	Limit or avoid alcohol: If you do drink, have no more than one drink a day for women and two a day for men.

Table 4:

Class structure for the NEW Soul study and Social Cognitive Theoretical constructs targeted

Order and structure of each NEW Soul class	Social Cognitive Theory constructs targeted
Review of SMART goal from previous week	Self-efficacy
Group problem solving of challenges from the week	Facilitation
Addressing stress and management techniques for stress	Emotional Coping Responses
Cooking demonstration (or hands-on cooking class)	Observational Learning (or Behavioral Capability)
Prize drawing for those who attend class each week	Incentive Motivation
Setting of SMART goal related to the topic of the week	Self-regulation

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