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The Faith, Activity, and Nutrition (FAN) Program: Design of a participatory research intervention to increase physical activity and improve dietary habits in African American churches

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Abstract

Background—African Americans are at increased risk for cardiovascular disease and cancer morbidity and mortality. Physical activity and healthy dietary practices can reduce this risk. The church is a promising setting to address health disparities, and community-based participatory research is a preferred approach.

Objectives—Using a community-based participatory approach and the social ecologic model, the FAN trial aims to increase self-reported moderate-intensity physical activity and fruit and vegetable consumption and reduce blood pressure in African American church members. Secondary aims are to increase objectively measured moderate-intensity physical activity and fiber/whole grain consumption and reduce fat consumption.

Design—FAN is a group randomized trial (GRT) with two levels of clustering: participants (N=1,279; n=316 accelerometer subgroup) within church and church within church cluster. In the first wave, seven clusters including 23 churches were randomized to an immediate intervention or

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delayed intervention. In subsequent waves, 51 churches were randomized to an immediate or delayed intervention.

Methods—Church committee members, pastors, and cooks participate in full-day trainings to learn how to implement physical activity and dietary changes in the church. Monthly mailings and technical assistance calls are delivered over the 15-month intervention. Members complete measurements at baseline and 15-months. A detailed process evaluation is included.

Summary—FAN focuses on modifying the social, cultural, and policy environment in a faith-based setting. The use of a community-based participatory research approach, engagement of church leaders, inclusion of a detailed process evaluation, and a formal plan for sustainability and dissemination make FAN unique.

Keywords

Community-based participatory research; Physical activity; Diet; Nutrition; African American; Faith-based

1. Introduction

Marked health disparities exist in cardiovascular disease [1] and cancer [2] morbidity and mortality, with African Americans experiencing higher rates than non-Hispanic whites. Physical activity, along with a diet high in fruits and vegetables and whole grains and low in fat (especially saturated and trans fats) and sodium, reduce the risk of these diseases [3–5]. Despite pronounced health disparities, there are notable strengths within the African American community which could be drawn on to address these disparities, and the importance of the church is one of them. Churches are well-suited to identify and prioritize the health problems within their congregations and to address the needs of fellow members in a setting of prayer, support, and trust. Faith-based programs involving nutrition, cancer screening, cardiovascular disease, diabetes education, and others have been evaluated [6–14]. Results are generally positive [15]. Recently, community-based participatory research has become a preferred process by which scientists and the community come together for the development, implementation, and evaluation of health interventions [16]. This approach is highly applicable to faith-based interventions. The purpose of this paper is to describe the development and methodology of a community-based participatory research study in African American churches: Faith, Activity, and Nutrition (FAN). FAN uses a unique approach to increase physical activity and promote dietary practices consistent with the DASH diet [4,17].

2. Methods

This study was funded by the National Heart, Lung, and Blood Institute (HL083858) and is registered in clinicaltrials.gov (NCT00379925). The study protocol was approved by the Institutional Review Board at the University of South Carolina on March 17, 2006.

2.1. Setting and population

The study represents a partnership between the 7th Episcopal District of the African Methodist Episcopal (AME) church (representing the state of South Carolina), the University of South Carolina, the Medical University of South Carolina, Clemson University, and Allen University. The measurements and intervention take place within the church; therefore, an overview of the AME church is described in some detail. Within the 7th Episcopal District, there are six geographically based conferences, and within each conference, two to three districts, for a total of 17 districts. Within many of the districts, churches are further organized into clusters, which represent geographically adjacent churches. Pastors, who are supervised by the presiding

elders, are appointed by the bishop, and are in full charge of the church and are ex-officio members of all boards, organizations, and clubs of the church in which they pastor. There are approximately 593 AME churches in the state of South Carolina with an estimated 276,000 members. Close to 25% of African Americans in the state affiliate with the AME church.

The AME church has an active health ministry. The goals of the ministry are to: (1) help the denomination understand health as an integral part of the faith of the Christian Church, (2) promote the health concerns of its members, (3) advocate access to health care as a right and not a privilege, (4) challenge and work to reform the unjust structure of the health delivery system, (5) seek to make the denomination a healing faith community, (6) collaborate with community organizations to improve the health care system, and (7) encourage each connectional organization to include a health component in its life and work. During the 2001 and 2002 annual conference year, each local church was asked to name a health director. Based on the annual report of the 7th District health director, approximately 78% of the local churches (in the aforementioned years) had a health director. Health directors coordinate health-related screenings and programs.

For this study, we initially selected one conference (Palmetto Conference) and the three districts and churches within it to participate in the project. However, in order to meet recruitment goals, we later added an additional district (from the Columbia Conference). In total, 131 churches are located within these four districts.

2.2 Approach to partnership

This community-based participatory research study builds on an existing partnership. Beginning in 1996 the Medical University and AME church began partnering together in the areas of cancer screening and nutrition. In 2002, the AME church, the Medical University of South Carolina, and the University of South Carolina received funding from the Centers for Disease Control and Prevention (CDC) to conduct a community-based participatory research project to promote physical activity [18,19]. Shortly after this study ended, the National Institutes of Health issued a request for applications to conduct community-based participatory research. After making a joint decision to pursue funding, two of the study co-authors (SW and AP) met regularly to develop the proposal, with each seeking input from their communities (i.e., church and academic communities). The proposal was submitted by the University of South Carolina with subcontracts to the AME church (through a 501c3 established by several church leaders), the Medical University of South Carolina, and Clemson University. Allen University later joined this partnership. Once funded, a planning committee was formed that was comprised of church leaders, church lay members, and university faculty and staff. This committee met monthly for the first year of the study to plan the intervention and evaluation, and continues to meet quarterly to oversee study activities. Table 1 presents the principles of community-based participatory research [20] that we strive to follow and how we apply them in this study.

2.3 Study aims

Using a community-based participatory approach, the primary aim of the study is to test whether a 15-month combined physical activity and dietary intervention that targets social, cultural, and policy influences within the church results in increased self-reported moderate-intensity physical activity and fruit and vegetable consumption and greater improvements in blood pressure (primary outcomes) as compared to a delayed intervention control group. Secondary outcomes include objectively measured moderate-intensity physical activity, fat consumption, and fiber/whole grain consumption. Another aim is to assess the role of pastor support of and participation in the intervention. Our final aim is to disseminate the program statewide at the completion of the randomized trial.

2.4 Study design and randomization

We used a cluster randomized design with three waves of implementation. In the first wave of the study, we randomized clusters of churches to receive the intervention immediately after baseline assessments (immediate intervention group) or at the end of a 15-month period (delayed intervention group). We chose to randomize by clusters because of their geographic proximity. In practice, however, we found that communication among these churches was not consistent and did not pose a substantial threat of contamination. Thus, all future randomizations in waves two and three were made at the church level. This change in study design afforded us greater power as we had more available units of randomization (i.e., churches rather than clusters of churches).

Randomization is conducted by the study statistician who has no direct contact with churches. Within each District, randomization is done such that the number of churches and the projected number of participants are balanced. Churches and staff are notified of randomization after the completion of baseline measures.

Outcome measures are conducted at baseline and 15 months later (post-program). Given the size and scope of the project, it was not feasible to collect intermediate outcome measures. Process measures, however, are collected more frequently. The delayed intervention group receives the complete intervention at the end of the 15-month measurement, but they are not reassessed after that time.

2.5 Church and participant selection

Pastors from the identified districts were sent a letter from their presiding elder introducing the FAN program and inviting participation. Interested churches were asked to complete and return a contact information form to the FAN staff. Follow up telephone calls to the pastors were made by the FAN staff to address questions or concerns. If the FAN staff was unable to reach the pastor via telephone, an additional letter inviting the church to take part in the FAN program was mailed to both the pastor and the church's health director. Churches agreeing to participate in the FAN program were asked to sign a memorandum of agreement. Churches that agreed to participate in the program were asked to recruit members of their congregation to take part in a baseline measurement session. Study staff provided flyers and announcements that churches could use to recruit members. Pastors typically asked the health director or another church member (FAN coordinator) to act as the liaison between the church and the FAN program staff to schedule and coordinate measurement sessions and church committee trainings.

2.6 Inclusion and exclusion criteria

To be eligible for the study, churches have to agree to be randomized and agree to assist the FAN team in scheduling baseline and post-program measurement sessions. They also have to agree to take part in all required trainings. Participants within churches have to be 18 years of age or older, free of serious medical conditions or disabilities that would make physical activity difficult, not planning to move from the area over the next two years, and attend worship services or church activities at least one time per month. These criteria are presented in the informed consent form; thus, participants self-exclude themselves.

2.7 Intervention

2.7.1 Intervention development—Based on our prior research and the organizational structure of the church, the likely intervention approach and theoretical framework were described in the grant proposal, but the specific components of the intervention resulted from the monthly meetings of the planning committee within the first year of the study. To initiate

this process, we engaged in a group brainstorming activity that occurred over several months. The session was co-facilitated by two of the study investigators: one from the church (AP) and one from the university (SW). The committee was asked to share their ideas as to what an "ideal church that promotes physical activity and healthy nutrition" (later named a "health promoting church") might look like. They were reminded to keep the project goals in mind when thinking about "physical activity" (30+ minutes per day, 5 or more days per week, of moderate-intensity physical activity such as brisk walking) and "healthy eating" (eating a diet high in fruits and vegetables and grains and low in saturated and trans fats and sodium).

Responses were organized into similar types of themes and approaches. Because these themes and approaches were highly consistent with our proposed theoretical framework, we describe that framework next. Cohen and colleagues' structural model of health behavior [21] was proposed a priori because it appeared to be highly compatible with organizations such as churches. According to this model, behavior is influenced by the availability and accessibility of products and physical structures that are associated with health outcomes (harmful or protective), social structures that promote or inhibit behaviors through organizational guidelines and support, and cultural and media messages that people see and hear frequently through large or small media and through stories and cultural practices. Table 2 lists each of these structural factors and ideas generated by the planning committee. Based on this process and a discussion of how we would assist churches in creating "health promoting churches," we developed a logic model (see Figure 1). The committee decided to train the churches by holding two distinct trainings: one for church committees and a second for church cooks. In addition, the committee agreed that monthly contact with churches in the form of mailings of materials would be useful. Finally, regular contact through telephone and in-person visits was viewed as important. Each of these components is outlined below.

2.7.2 Committee trainings—With input from the planning committee, a full-day committee training was designed and is being implemented. The pastor, health director, FAN coordinator (if different than health director), and cook or lead kitchen staff are required to attend the training. Depending on their size, churches are encouraged to send up to five committee members for training. The training and intervention materials were based on the structural ecologic model and ideas generated by the planning committee for a "health promoting church," as shown in Table 2.

The one-day training includes didactic and interactive components. It is led by the FAN Intervention Coordinator who is an employee of the University of South Carolina and a member of the AME church. The training provides an overview of study goals, links study goals to relevant scripture and the health mission of the AME church, defines what is meant by physical activity and healthy eating (focusing on DASH diet goals), and links physical activity and healthy eating to health disparities in South Carolina. A brainstorming session is held to discuss what it means to be a "FAN Pastor" (i.e., how pastors can support FAN goals) and to share ideas of activities already being done in the church to promote physical activity and healthy eating. Physical activity breaks are included in the training and provide examples of activity breaks the churches could adopt. A healthy breakfast and lunch are served.

During the training, churches go through an active "assessment and planning" process that is organized along Cohen's structural model of health behavior [21]. A workbook is provided for each church to facilitate this process. For each of the structural factors within the model (see Table 2), churches assess current activities and select ways to address, enhance, or expand them. Churches have a great deal of flexibility in how they address each of the structural factors. All churches are asked to implement a set of core activities (e.g., distribute bulletin inserts, share messages from the pulpit about physical activity and healthy eating, pass out educational materials, create a FAN bulletin board, suggest guidelines and practices that the pastor can set)

and choose additional activities that are suited to the needs and interest of their congregation. During the training, they use their assessment and planning workbook to develop a formal plan to address each factor within the model and a budget to support these activities. Upon submission of the plan and budget, the church receives a stipend (up to $1000 depending on church size and attainment of recruitment goals). Each church receives a binder that contains educational materials, a directory of local physical activity programs and facilities, and a directory of local farmer markets. They also receive personal and church incentives (e.g., pedometers, cups, church fans, etc.).

2.7.3 Cook trainings—Church kitchen staff and cooks have considerable influence over the types of foods served to members in addition to how these foods are prepared. Thus, a separate cook training entitled Cooking with a Chef (adapted from the Clemson University Cooking and Healthy Eating Food Specialists) [22–25] was held for these individuals. Preliminary focus groups with AME church cooks demonstrated that food has important meanings within the church. For example, cooks want to nurture members and prepare foods that are comforting and flavorful. Traditional practices and traditional foods are seen as culturally important. Having an abundance of food can also represent greater status as a church. The importance of these sociocultural factors is addressed in the training.

The major objectives for the cook trainings are to provide a participatory training workshop to improve healthy meals and snacks within the church foods program, enlist cooks in hands-on cooking with chef training, participate in menu building exercises, and demonstrate the development of flavor in foods through healthy ingredients. It is anticipated that as cooks increase their level of confidence through instruction and practice of basic culinary skills, healthy menu planning techniques, culinary terms and recipe modifications they will incorporate recommendations of the DASH diet plan to increase fruits, vegetables, and fiber; and to decrease fat and sodium in menus. The specific topics of the cook training include: make menu planning easy, color the plate and create centerpiece trays with vegetables and fruits, center of the plate meats and substitutes, whole grains sampling and recipes, and active participation in a tasting panel by incorporating the sensory evaluation process.

Each church that participates in the study sends up to two individuals to the cooks training; these individuals function in the church as cooks or hospitality/kitchen committee members. These individuals are identified by the pastor and/or FAN coordinator. The training is held at a centrally-located church that has a large kitchen appropriate for demonstrations, sit down meal service, and taste-tests. The culinary nutrition training emphasizes economical meal planning, healthy ingredient selection, and the use of spices and herbs to ensure flavorful recipes. The church cook works alongside a professional chef and a dietitian during the workshop. The training and recipes emphasize regional flavors of the Southeastern United States.

The day begins by the team providing inspirational messages regarding how healthy cooking is serving the people by relating health messages and Scripture. Throughout the training, regional and cultural tailoring continues to ensure ingredients are appropriately selected for dishes. Over the course of the day, the cooks create a fruit and a vegetable centerpiece with accompanying cold sauces, an appetizer selection, and a complete meal. These foods are shared and discussed during a morning and an afternoon break and during a luncheon. During each “breaking the bread” meal or snack-time the chef and the dietitian join the cooks around the table and participate in a group question and answer session and culinary nutrition conversation.

In the afternoon the cooks write out a menu for their church as an individual activity then share these plans with a partner from a different church. During this process the menus are constructively evaluated and modified according to the criteria of customer appeal,

appropriateness for the budget, staff, and needs of the congregation, and the DASH diet plan targeted qualifications with the dietitian as coach. Each cook approaches the podium and practices a 'public speaking' role play by inviting the group to enjoy their menu and creatively describes their fare.

The cooks training provides church cooks a learning environment in which to identify the ingredients that "go together" in regional dishes and cultural cuisine and then follows a systematic approach to demystifying the recipe. Each ingredient and recipe is evaluated as to its contribution to flavor, sensory appeal (appearance, aroma, texture, and taste), and nutrition goals (increase fruits, vegetables, and whole grains and reduce saturated fat and sodium). Attention to providing flavor profiles and ingredients commonly used in their church menus are emphasized. Cooks are encouraged to share their experiences, tricks of the trade, and recipes that are popular with their church congregations throughout the workshop. Recipes are modified and continually updated based on the feedback from the cooks and their experiences with their church congregants.

2.7.5 Monthly mailings and quarterly newsletters—After trainings, committees (including cooks) and pastors receive a monthly packet over the 15 months of the program to help support implementation of the program. Each month highlights a health behavior change strategy consistent with Social Cognitive Theory [26] (e.g., setting goals) and a health condition related to physical inactivity and diet (e.g., hypertension). Most monthly mailings include program incentives for the church and/or committee members. The committee member mailing contains: a personalized letter emphasizing the key behavior change strategy and the health condition, a listing of the contents of the packet and how they can be used, handouts for distribution to members (a bulletin insert plus one or more educational brochures or skills-based worksheets), tools for FAN cooks (e.g., recipes, tips), and resource updates (suggested activities to implement with the congregation). Pastors are sent a separate mailing that is also personalized and contains information to motivate the pastor, a FAN goal of the month along with a corresponding activity for the pastor to personally try (e.g., wearing a pedometer), and strategies for how to share his/her learnings with the congregation to support FAN goals.

2.7.6 Technical assistance—Follow-up calls are made by the FAN intervention staff to pastors, FAN coordinators, and cooks to learn what programs and activities are being implemented, help problem-solve challenges they face, and provide technical assistance for implementing FAN activities. Site visits to the churches are also conducted, where possible, to show support of the church's program and to answer questions and provide assistance.

2.7.7 Sustainability and Dissemination Planning—An important principle in conducting faith-based research [27], and public health research in general [28], is the need to "leave something behind." All intervention activities were designed to promote capacity building within the church, with the intent of maximizing the likelihood of program sustainability. For example, rather than having research staff deliver the intervention, these staff members train members in the church to develop the skills needed to deliver the intervention. Furthermore, by training more than one individual within the church and targeting the pastor, church cook, and health ministry staff in trainings, the likelihood of sustainability is also enhanced.

An early concern voiced by church members in preparing the grant proposal was the need to reach all churches within the state. There was a feeling that it was not fair and was inconsistent with the church's values to only offer the program for a small number of churches. Thus, the grant proposal was written such that the final year of the study is devoted to disseminating the program and findings statewide.

2.8 Measures

Prior to data collection, participants complete an informed consent form that describes the purpose of the study and informs participants that their church will either be selected (at random) to receive the program now or 15-months from now. Participant data are collected at baseline and 15 months later (post-program). Participants complete a survey and participate in physical measurements to obtain primary and secondary outcomes. Randomization status is not revealed to churches, participants, or staff until after the completion of baseline measures. Although the measurement coordinator is aware of group assignment after baseline measures are completed, other measurement team members are blind to group assignment at the 15-month assessment. Given the need for coordination with churches over the course of the project, it is not feasible in this type of community-based study to keep the measurement coordinator blind to group assignment beyond the baseline assessments.

2.8.1 Demographic and health-related measures—Participants report their gender, age, race, marital status, employment status, highest grade or years of education completed, and income. They report whether they care for a sick or frail older relative and whether they have any grandchildren who live in their home and whether they are responsible for their basic needs.

Participants rate their general health status on a scale from 1 (excellent) to 5 (poor). Participants are asked their current smoking status, whether a health care provider was seen in the last 12 months, and the presence or absence of health care provider-diagnosed diabetes, hypertension (“high blood pressure”), myocardial infarction (“a heart attack, also called myocardial infarction”), angina or coronary heart disease (“angina (chest pain) or coronary heart disease”), stroke, arthritis (“some form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia”), osteoporosis (“osteoporosis (weak bones)”), asthma, and hypercholesterolemia (“high blood cholesterol”). Participants also report if they are limited in any activities because of physical problems and whether they use special equipment because of any health problems. Finally participants report whether they have had their blood pressure and blood sugar levels checked by a health professional and whether they have had a prostate-specific antigen (PSA) test (men only), a mammogram (women only), or a Pap test (women only). For each of these tests, participants report when this test occurred (i.e., past year, past 2 years, past 5 years, 5+ years).

2.8.2 Primary outcome measures—Because the intervention targets two health behaviors, there were multiple a priori primary outcomes. The DASH Diet was developed to reduce blood pressure [29–37]. Furthermore, regular moderate- to vigorous-intensity physical activity reliably reduces blood pressure [38]. Thus, resting blood pressure was chosen as a primary outcome. Seated blood pressure measurements (systolic and diastolic) are made on the right arm using an automated DinaMap ProCare Monitor (DPC-100X-EN) after sitting quietly, with legs uncrossed, for five minutes [39]. Blood pressure is measured three times and the average of the second and third readings will be used in statistical analyses.

The Community Health Activities Model Program for Seniors (CHAMPS) questionnaire is used to measure physical activity [40]. This 41-item measure was designed to measure the frequency and duration of various physical activities that older adults complete “in a typical week during the past 4 weeks.” Frequency is assessed as the number of times per week, and duration is assessed as the total time per week using a 6-item scale that ranges from “less than 1 hour a week” to “9 or more hours per week.” The CHAMPS has strong psychometric properties, including demonstrated validity [41], test-retest reliability [41], and sensitivity to change [40,42–45]. Resnicow and colleagues [46] validated a modified version of the original CHAMPS questionnaire in a population of adult African Americans (age range: 21 to 68 years). We used a 36-item modified version of the CHAMPS questionnaire, similar to the one

described by Resnicow et al. [46]. Several items assessing social activities and recreational/hobbies that are not used in the scoring algorithm were excluded to reduce participant burden, and a single item measuring frequency of dancing/moving during church services was added [46]. The primary study outcome is hours per week of moderate- to vigorous-intensity physical activity. We will also compute hours per week of light-, moderate-, and vigorous-intensity physical activity (i.e., total physical activity) and moderate- to vigorous-intensity leisure time physical activity. Classification of intensity level is based on the MET values reported in the Ainsworth et al. [47] compendium, adjusted for the recommendations made by Stewart et al. [48] and Resnicow et al. [46].

Although 24-hour recalls are considered the gold standard in dietary research, this approach was not deemed feasible in the settings in which our study is based. Thus, we relied on self-reported diet. The National Cancer Institute fruit and vegetable all-day screener asks about different types of fruits and vegetables and portion sizes for each [49]. We include 9 of the 10 items (French fry consumption was excluded). This scale has been shown to correlate moderately with 24-hour recall measures of fruit and vegetable consumption (Men: r = 0.66; Women: r = 0.51) [50]. A very similar measure was used as a primary outcome in *Black Churches United for Better Health* [10], and the correlation between this measure and 3-day food records was moderate (r = .51).

2.8.3 Secondary outcome measures—The ActiGraph accelerometer (GT1M model, ActiGraph, LLC, Fort Walton Beach, FL) is used to objectively measure physical activity in a subsample of participants. Participants are instructed to wear the ActiGraph on the right hip during all waking hours (except while in water) for 5–7 consecutive days. A 60-second epoch (time interval) is used. The GT1M model, which is the newer version of the 7164 Model, self-calibrates and utilizes a direct USB connection to initialize and download data. Freedson et al. [51] assessed the validity of the ActiGraph Model 7164 in a sample of adults, across 3 speeds on the treadmill (slow walk, fast walk, jog), and found that activity counts were highly correlated with energy expenditure (r =0.93) across all speeds.

The cutpoints from Freedson et al. [52] will be used to convert the activity count data into mean minutes of physical activity (moderate intensity: 1952–5724 counts per minute; vigorous intensity: ≥ 5725 counts per minute). As recommended by Matthews et al. [53], we will define sedentary behavior as < 100 counts per minute. Thus, light intensity will be considered 101–1951 counts per minute. In exploratory analyses, we will consider examining the range of 760 – 1951 counts per minute as “moderate lifestyle” intensity [54]. As recommended by Trost et al. [55], ActiGraph data will only included in analyses if the participant wore the monitor for a minimum of three days and for at least ten hours per day. We will assume that 60 minutes or more of consecutively recorded zeros indicates non-wear time and these data will be removed from analyses. Mean minutes per day of sedentary, light, moderate, and vigorous activity will be computed.

The 33-item Fat and Fiber-Related Behavior Questionnaire [14,56] is used to assess dietary behaviors associated with eating a diet that is low in fat and high in fruits, vegetable, and grains. The summary scores for fat and fiber are moderately correlated with a food frequency questionnaire (r = .53 and r = .50, respectively). This measure also produces five fat subscales: (1) avoid fat as flavoring, (2) substitute specially manufactured low-fat foods, (3) modify meats to be low in fat, (4) replace high-fat meats with low-fat alternatives, and (5) replace high-fat foods with fruits and vegetables. It also produces three fiber subscales: (1) cereals and grains, (2) fruits and vegetables, and (3) substitute high-fiber for low-fiber foods. High test-retest correlations have been reported for 3 months (r = .60 to .79) and 12 months (r = .53 to .74). An important quality of this measure is that has been shown to be more responsive to change in a dietary intervention than a more detailed food frequency questionnaire [56,57]. A review

of dietary fat indices recommended this measure as it has been shown to be valid in multiple populations and is a simple, quick, and inexpensive way to assess fat-related patterns and behaviors [58].

2.8.4 Other measures—In addition to the more extensive fruit and vegetable questionnaire used as a primary outcome measure, we also included a simple 2-item measure (appearing later in the questionnaire packet). One item asked, "How many servings of fruit do you usually eat each day" and the second asked, "How many servings of vegetables to you usually eat each day?" These items were used in *Healthy Body / Healthy Spirit* [12,59] and *Eat for Life* [13, 60]. Another study conducted in African American churches found that 2-, 7-, and 36-item fruit and vegetable questionnaires correlated similarly with total serum carotenoids (excluding lycopene) (r = .22 to .35) [13].

Weight is measured (to the nearest 0.1 kg) using a portable Seca 880 High Capacity Digital Floor Scale. Height (measured to the nearest 0.25 inch) is obtained using a stadiometer at baseline only. Participants are asked to remove their shoes prior to both measurements. Body mass index (BMI) is calculated as weight (kg)/height squared (m^2).

Waist circumference is measured (to the nearest 0.1 cm) by locating the narrowest part of the torso, which is located between the participant's ribs and the iliac crest. Participants remove all excess clothing prior to the measurement and smooth the remaining clothing against the skin so that it is not gathered around the waist. Two measurements are taken on each participant. If the difference between the two measures is more than 2.0 cm, a third measurement is taken. The average of the two closest measures (< 2 cm difference) will be used in statistical analyses.

Self-efficacy for physical activity and self-efficacy for fruit and vegetable consumption are being assessed as potential mediators of intervention outcome. Self-efficacy for physical activity is measured with an adapted 12-item version of Sallis' scale [61]. It assesses a participant's confidence to exercise when faced with common barriers. In order to make the response options for the diet and physical activity measures comparable, and consistent with *Healthy Body / Healthy Spirit* [12,59] and *Body and Soul*,[62] we are using a Likert scale with four rather than five response options ("not at all confident", "a little confident," "moderately confident," and "very confident"). Self-efficacy for fruits and vegetables is measured with a 10-item scale used in *Healthy Body / Healthy Spirit* [12,59] and *Body and Soul* [62]. Like physical activity, it measures a participant's confidence to eat fruits and vegetables when faced with common barriers.

Social support for physical activity (3 items) and fruit and vegetable consumption (3 items) from family, friends/colleagues, and members of church are also being assessed as potential mediators of intervention outcome. Participants are asked, "How much encouragement do you get from your (family / friends or work colleagues / people at your church) to (get more physical activity / eat more fruits and vegetables)?" The items assessing family and friend/colleague support were derived from Eyler and colleagues' (1999) study involving minority women [63], which were adapted from the Sallis et al. scale [64]. The items assessing support from people at church were similar to those used in *Healthy Body / Healthy Spirit* [59]. All items are measured on a four point response scale ("none," "a little," "some," and "a lot").

2.9 Retention of participants

During the baseline measurement session, participants are asked to provide the name and contact information for two individuals who do not live with them but would be able to provide contact information in the event that the study loses contact. All participants are sent a quarterly retention mailing which includes a postage-paid postcard to report changes in contact information. FAN staff also attends AME events to remain visible to leaders and members.

2.10 Process evaluation

Few studies achieve full implementation of the intervention in field settings [65] and researchers have noted the importance of measuring program implementation due to documented variability in intervention implementation and policy adoption in community and school settings [66–71], including faith settings [9,62,72,73]. Process evaluation may be especially important in randomized trials of complex interventions (i.e., multi-component interventions strongly influenced by social context) [74]. Furthermore, a recent review concluded that there is strong evidence that level of implementation directly impacts study outcomes [75].

FAN process evaluation planning incorporated recommended practices for implementation monitoring. The process evaluation plan was guided by a conceptual model (structural ecologic model) and developed in collaboration with the planning committee beginning with the detailed description of a "health promoting church" (described previously, see Table 2) [66,67,71,74–76]. The elements of a "health promoting church" describe "complete and acceptable delivery" of FAN [76,77] (although it is not expected that churches deliver all activities listed in Table 2), guiding both the intervention and process evaluation. We used a logic model to guide planning [66,74,75,78] and developed a comprehensive set of process evaluation questions to assess fidelity, dose, reach, recruitment activities, and contextual factors using multiple data sources and using multiple qualitative and quantitative methods [66,70,74,75,79]. The core FAN process evaluation questions are listed in Table 3.

2.10.1 Process evaluation measures and instruments—All recruitment and training activities, including attendance, are documented by lead staff. Training evaluations are collected immediately after the training session ends, including attendees' evaluation of the cook and committee trainings along with trainers' self-evaluations of the trainings (recruitment, dose delivered, and reach: training participants). Organizational assessment interviews are conducted pre- and post-program by measurement staff with pastors, FAN coordinators (or health directors), and cooks (fidelity and context). The content of these interviews maps onto the key factors in the structural ecologic model. End-of-program interviews are also conducted with the FAN coordinators in the immediate intervention churches to assess the extent to which FAN activities were implemented as well as barriers and successes to implementation (dose received and fidelity). Food and media observations are completed at pre- and post-program measurement sessions to assess the types of food served at church events (direct observation and interviews with kitchen staff) and the display of physical activity and healthy eating materials in the church (fidelity). Measurement and intervention staff members complete ratings at pre- and post-program to rate pastor, FAN coordinator (or health director), and cook support of FAN and church and committee function (context). Intervention staff documents all technical assistance calls and visits, including the nature of the call, implementation of FAN, barriers, successes, and support provided (dose delivered). Finally, church congregants complete 15 questions on their pre-and post-program surveys that map onto planned intervention activities (dose received).

Strengths of our process evaluation include working with the planning committee to define what constitutes implementation, developing a logic model to guide planning, using multi-item indexes rather than single measures, obtaining data from multiple sources, including measures for both intervention and comparison churches, collecting data on factors that influence implementation (context), and the ability to use level of implementation in outcome analyses to better understand findings.

2.11 Sample size justification

The primary analyses focus on evaluating the impact of the intervention by comparing churches receiving the immediate intervention to those in the delayed intervention group. The study design is a group randomized trial (GRT) with two levels of clustering: participants within church and church within church cluster (i.e., geographic units). In the first wave, seven clusters including 23 churches were randomized to an immediate intervention or delayed intervention condition. In subsequent waves, 51 churches were randomized to immediate or delayed intervention. Recruitment goals were based on church size and were inflated to account for a 25% attrition rate. Although the number of respondents per church is variable due to different congregation sizes, all calculations are based on the arithmetic mean of number of respondents.

In a previous study we conducted with the AME church [18,19], the individual pre-post correlation was 0.60 (standard deviation = 2.11) for fruit and vegetable consumption and 0.44 for physical activity (measures differed). The standard deviation for moderate to vigorous physical activity (CHAMPS) was 240–294 minutes per week among African Americans participating in the Active for Life study [80]. Blood pressure estimates were based on Project Joy [9]; the pre-post correlation was 0.60, with the standard deviation ranging from 10 (diastolic) to 20 (systolic) mmHg. In our previous church-based intervention, the intraclass correlation (ICC) was 0.011 for physical activity and 0.02 for fruit and vegetable consumption within church. At the church level, pre-post correlations of 0.2 for physical activity and 0.3 for fruit and vegetable consumption are assumed. The ICC for churches within cluster is estimated at 0.005.

All calculations assume 80% power. Because there are three primary outcomes and because all tests are two-sided, sample size calculations assume α=.008 (0.05/2/3). For analytic purposes, the study includes 58 clusters: seven clusters comprised of 23 churches in wave one and 51 churches in waves two and three. Using the final number of participants measured at baseline and adjusting for attrition (N=1,279; average of 17/church at baseline and 13/church after attrition), the study can detect a 0.214 effect size for physical activity (51–63 minutes/week), a 0.206 effect size for fruit and vegetable consumption (0.44 servings/day), and a 0.194 effect size for blood pressure (1.9 mm Hg for diastolic; 3.8 mm Hg for systolic). These effect sizes refer to differences in pre-post changes between immediate intervention and delayed intervention groups and adjust for multiple tests. For accelerometer measures, the average sample size is four participants per church (n=316). With this smaller subgroup, and adjusting for attrition, the detectable effect size is 0.32, for an absolute difference of 29.28 minutes per week.

2.12 Statistical analyses

The primary outcomes for this study are blood pressure, self-reported minutes per week of moderate- to vigorous-intensity physical activity (CHAMPS), and servings per week of fruits and vegetables. Study hypotheses will be tested by comparing the follow-up assessments between the two conditions using mixed linear models (SAS PROC MIXED) with each of the outcome measures. Independent variables will include intervention group, baseline level of the outcome measure, and potential confounders (selected covariates including age, education, BMI, gender). Church and church cluster will be included in all analyses as random effects nested within the experimental condition (immediate vs delayed intervention); for waves two and three, cluster and church are indistinguishable. Differences in outcome measures across the two conditions, adjusted for baseline scores, reflect intervention differences from baseline to follow-up. A limited number of pairwise interactions between selected covariates and intervention group will also be examined in secondary exploratory analyses, to evaluate whether the intervention was more effective for certain groups of respondents than others as a hypothesis generating exploration of the data. For all hypotheses tested, p values and the

magnitude of association will be reported to reflect the statistical significance. Model assumptions will be assessed using standard residuals-based diagnostic procedures, and normalizing or variance stabilizing transformations (e.g., square-root transformation) will be made as appropriate.

If actual attrition is the same as projected attrition (25%), we will conduct analyses with complete cases. If, however, actual attrition exceeds projected attrition (>25%), we will use more conservative last observation carried forward analyses.

3 Summary

Partnerships between faith communities and universities provide a way to deliver health promotion messages in a culturally and ethnically relevant manner, and they have great potential to contribute to eliminating health disparities (a Healthy People 2010 [81] objective). Several faith-based interventions have targeted fruit and vegetable consumption [10,12–14, 62]. These interventions have been successful in increasing fruit and vegetable consumption by 0.6 to 1.4 servings/day [13,59,62,72,73], similar to secular interventions [82]. Furthermore, few culturally-tailored, faith-based interventions have targeted physical activity [9,12,19,59, 73,83–86], and of these, only three reported statistically significant increases in physical activity [59,73,83]. Only two studies reported using a community-based participatory research approach to guide the intervention [19,83].

Although these studies provide useful information regarding university-faith partnerships, there are several gaps and limitations that FAN aims to address. First, most studies have focused primarily on individual behaviors [9,12–14,62,87], with relatively little attention given to environmental factors and church policy, thus limiting reach and perhaps sustainability of the programs. FAN uses a social ecological model to guide the culturally tailored intervention.

Second, to date, most faith-based dietary interventions have focused on fruit and vegetable consumption [12,13,62,72]. An intervention that targets increased fruit and vegetables, decreased saturated fat and sodium, and increased whole grains consumption is likely to have greater impact on cardiovascular disease and cancer risk factor reduction. Furthermore, it is the combination of physical activity and healthy diet that leads to the greatest reduction in risk of chronic diseases [88–90], yet only a few faith-based studies [9,12,73] have included physical activity as a primary outcome, and none have included an objective measure (e.g., accelerometer) of physical activity.

Third, a community-based participatory research framework has rarely been used in faith-based physical activity and dietary interventions. As a result, the community may be less likely to sustain changes beyond the research period due to lack of resources and capacity, ultimately returning to pre-intervention lifestyles and health status.

Fourth, while many studies have anecdotally stated the importance of pastors in the success of the interventions [8,9,72,91], none have measured or assessed this factor in a systematic way. Furthermore, few interventions have engaged other key leaders (e.g., pastors) and decision makers (e.g., church cooks), whose policies and choices directly affect the health behaviors of their congregations.

Finally, Lasater and colleagues [8] identified four levels of church involvement in interventions, ranging from Level 1 (the church is a vehicle for recruitment, tracking, or program delivery) to Level 4 (church members deliver programs and behavior change efforts incorporate spiritual elements). Many of the faith-based interventions have been Level 1 or 2 interventions. FAN is a Level 4 intervention.

FAN is unique in that it addresses these gaps in the literature and also includes a detailed process evaluation so that we will be able to better characterize factors related to program success and challenges. Furthermore, sustainability and dissemination planning was incorporated from the very beginning of the project.

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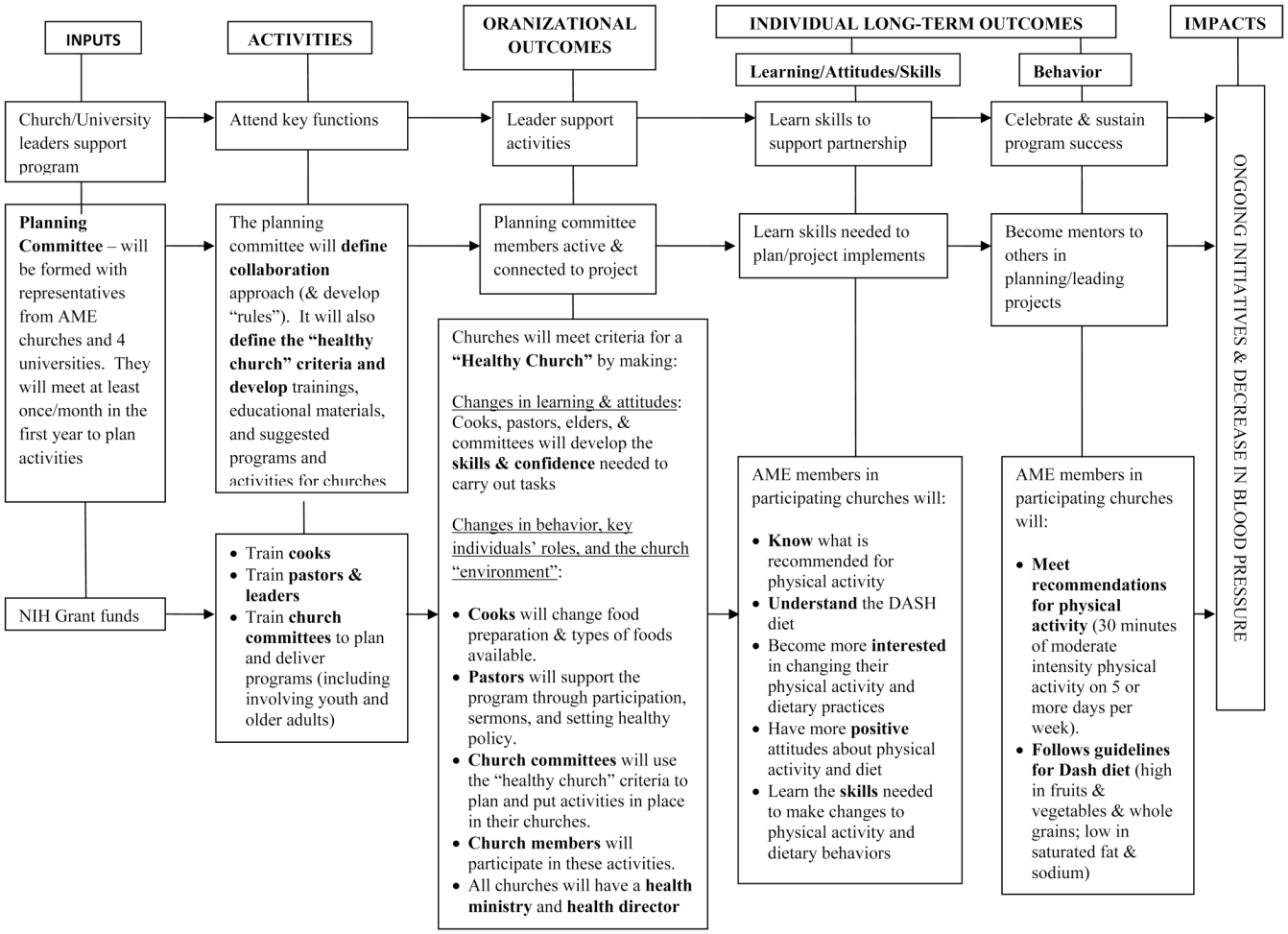

Figure 1.
FAN Logic Model

Table 1

Principles of Community-based Participatory Research and Application in the Faith, Activity, and Nutrition (FAN) Program

Principle	Application of the principle in the FAN Program
CBPR recognizes community as a unity of identity	• Within the church, members share values, norms, common interests, and a commitment to helping others holistically.
CBPR builds on strengths and resources within the community	• The church provides a physical space for worship, fellowship, activities, and meals. The inclusion of fruits, beans, and greens/vegetables in the southern diet is an asset. • Working with lay volunteers to deliver the program will allow us to capitalize on inherent strengths and foster sustainability.
CBPR facilitates collaborative, equitable partnerships in all phases.	• All partners have power (decision making and finances) and consensus is used to arrive at decisions.
CBPR promotes co-learning and capacity building among all partners.	• Our goal is to develop an approach that is sustainable over time and imparts growth and capacity in the church.
CBPR integrates and achieves a balance between research and action.	• The project will advance science but at the same time engages the community to benefit congregations
CBPR emphasizes local relevance of public health problems and ecological perspectives that recognize and attend to the multiple determinants of health and disease.	• A needs assessment along with a review of major health problems affecting African Americans in South Carolina, led us to focus on physical activity. Church leaders wanted to expand the current project to include dietary factors • A social ecological framework guides the study.
CBPR involves systems development through a cyclical and iterative process.	• All partners are engaged in all processes and phases.
CBPR disseminates findings and knowledge gained to all partners and involves all in the process.	• The last year of the study is devoted to dissemination.
CBPR involves a long-term process and commitment.	• We are building on an existing partnership between the AME church, MUSC, and USC. All partners are committed to work together to eliminate health disparities

CBPR principles are from Israel and colleagues [20]

Table 2

Structural Factors from the Structural Ecologic Model and Examples of Corresponding Strategies Offered by the FAN Planning Committee

Structural Factor (name used on Church materials)	Physical Activity (PA)	Healthy Eating	Cross-Cutting Ideas
Availability & Accessibility and Physical Structures (Provide opportunities)	• Offer **PA programs** at church (e.g., group walks, exercise to videotape, aerobic class) • Offer **PA before or during service** (e.g., Meet & Greet, Praise & Worship, "organ stretches," active songs like "Lift Jesus Higher") • Provide **exercise equipment** at churches (e.g., treadmills, bicycles) • Use the **10-min PA CD** prior to Board & other church meetings • Offer **skills-based classes** to help people learn & try PA • Have Pastors & churches negotiate with health clubs & YMCA for **discounted memberships** • Lobby to get **community centers** added in towns	• Serve **healthy snacks** after exercise (e.g., smoothie station) • Offer **skills-based classes** to help people learn & try healthy eating practices • Have Pastors lead effort in growing **F&Vs & herb gardens** & **farmer's markets** could showcase local produce	• Make sure programs are **maintained** over time (put new spins on activities).
Availability & Accessibility (Make Opportunities appropriate & fun)	• Make PA **convenient**: build it into existing activities (e.g., aerobics before choir practice, PA during service). • **Involve youth** in programs (parents/grandparents will come) • Offer exercises appropriate for **older adults**	• Have a **weight loss contest** and post results on website • Have a **taste of healthy eating** monthly • Make food **flavorful** with spices (church cooks) • Have **healthy food fairs** • Offer **menu plans** for church cooks (e.g., suggestions for meals for after meetings, funerals, etc)	• Use **competitions** between churches to make activities fun • Offer **incentives** for contests • Tie health messages to **scripture**
Social Structures (Set Organizational guidelines & provide support)	• If meetings last one hour or longer, include **PA break** (coordinate through meeting chairs) • Have a physical activity **Ambassador** who works to incorporate physical	• Have churches/Pastors set **policies to include healthy food** (e.g., F&V at all events) & **drink options** (e.g., water & Crystal Light) at **all events**. • Help **cooks** prepare healthy foods by bringing them together in trainings &	• Develop criteria churches can meet to be considered a **"Healthy Church"** (& list on their marquees). • Each Church should have a **Health Commission**

Structural Factor (name used on Church materials)	**Physical Activity (PA)**	**Healthy Eating**	**Cross-Cutting Ideas**
	activity into church activities and functions	providing guidelines. Provide **certificates** for those who attend.	• Include PA & healthy eating activities in **Pastor reports** to make churches accountable.
Cultural & Media Messages (Get the message out)	• **Church leaders** (Bishop, Elders, Pastors) need to be knowledgeable about health & be **role-models & support PA & nutrition changes** - if church leaders "say it" it is more likely to happen! For example, Pastors should: (a) give Health Directors time to talk about health during services, (b) disseminate health information from the pulpit, & (c) wear pedometers. • Get PA & nutrition messages out through **church channels**: Health Moments, bulletin inserts, posters, flyers, buttons, bulletin boards, auxiliary meetings, & church announcements. Also develop program t-shirts, caps, buttons, & billboards. • **Dispel myths** about healthy eating & PA through training to **change attitudes** (e.g., "I'm going to die from something anyway.") • Host **events** to make people more aware of PA & nutrition: e.g., Health Bowl, DASH recipes at the Taste of Health • **Educate congregations** about PA & nutrition – e.g., tell them WHY it is important to eat health (e.g., reduce disease) • Help churches to have at least one **computer with internet access** so that youth can help adults search for health-related info online		

Note: PA = physical activity

F&V = fruits and vegetables

Table 3

Primary Questions Addressed by the FAN Process Evaluation

Area Addressed	Question
Dose delivered or completeness	To what extent were FAN training components and follow up technical assistance provided to the FAN committee members, cooks, and pastors?
Dose received	To what extent did training and follow up activities prepare FAN committee members, cooks, and pastors to carry out FAN (knowledge, confidence, and skills)?
	To what extent were AME members exposed to planned messages?
Reach: Training participants	To what extent did designated FAN committee members, cooks, and pastors attend training?
Fidelity-implementation	To what extent did the FAN committee members, cooks, and pastors carry out planned activities based on “health-promoting church” guidelines?
Fidelity-organizational change	To what extent was the church organization and environment consistent with “health-promoting church” policies and practices?
Context	What activities within the church could affect FAN implementation or outcomes?
Recruitment	What approaches to recruitment were used? What approaches to recruitment were effective or ineffective?