Testing a Program for Increasing Healthy Behaviors among Black Men

Melicia C. Whitt-Glover, PhD; Steven P. Hooker, PhD; Tiffany D. Williams, MPH; Ziya Gizlice, PhD; Marcus Murray; Derek Griffith, PhD; O. Steven Hughes; Amani McMillan

AFFILIATIONS:
1 Gramercy Research Group, Winston-Salem, North Carolina
2 San Diego State University, San Diego, California
3 University of North Carolina at Chapel Hill, Chapel Hill (retired)
4 Project Brotherhood, Chicago, Illinois
5 Vanderbilt University, Nashville, Tennessee

Institution Receiving Award: Gramercy Research Group
Original Project Title: Active and Healthy Brotherhood: A Program for Chronic Disease Self-Management for Black Men
PCORI ID: AD-1403-11098
HSRProj ID: HSRP20152055
ClinicalTrials.gov ID: NCT02362737

# TABLE OF CONTENTS

ABSTRACT .......................................................................................................................... 3

BACKGROUND .................................................................................................................... 6

PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS ............................................. 8

METHODS ............................................................................................................................ 13

- Study Overview ................................................................................................................ 13
  - Figure 1. AHB Design ..................................................................................................... 14
- Study Setting ................................................................................................................... 14
- Participant Recruitment .................................................................................................. 15
- Participant Random Assignment .................................................................................... 18
- Interventions and Comparators or Controls .................................................................... 19
  - Table 1. AHB Intervention Group Sessions Topics ...................................................... 22
  - Table 2. Long-Term Maintenance Postcard Topics ....................................................... 25
- Study Outcomes ............................................................................................................ 25
  - Table 3. Study-Related Outcomes, Assessment Tools, and Outcome Level<sup>a</sup> ............. 26
- Sample Size Calculations and Power ............................................................................. 30
  - Table 4. Sample Size Estimates to Detect Various Effect Sizes with 80% Power ............. 32
- Time Frame for the Study ............................................................................................... 33
- Data Collection and Sources ......................................................................................... 33
- Analytical and Statistical Approaches ............................................................................ 33
- Changes to the Original Study Protocol .......................................................................... 35
- Qualitative Data Design and Analysis .......................................................................... 37

RESULTS ............................................................................................................................. 39

- Quantitative Data Analysis ............................................................................................ 39
  - Figure 2. CONSORT Flow Diagram .............................................................................. 40
  - Table 5. Baseline Participant Characteristics .................................................................. 41
  - Table 6a. Six-Month Follow-Up Changes in Lifestyle Behaviors .................................. 43
  - Table 6b. Six-Month Follow-Up Changes in Health-Related Clinical Markers and QOL Outcomes ......................................................................................................................... 45
  - Table 7a. Twelve-Month Follow-Up Changes in Lifestyle Behaviors .............................. 49
  - Table 7b. Twelve-Month Follow-Up Changes in Health-Related Clinical Markers and QOL Outcomes ......................................................................................................................... 51
- Qualitative Data Analysis ............................................................................................... 53
ABSTRACT

Background: Compared with other groups in the United States, African American men are more likely to have high blood pressure, diabetes, and heart disease, which increase the risks for early death, stroke, other sickness, and poor quality of life (QOL). African American men are also less likely to engage in health-related behaviors known to reduce or prevent chronic disease. Combined, the high rates of preventable chronic disease and poor morbidity-related QOL translates to African American men having an average lifespan 7 to 9 years less than nearly all segments of the US adult population.

Objectives: The objectives of this study were to 1) test the immediate postintervention (6 postrandomization) effects of the Active & Healthy Brotherhood (AHB) intervention compared with the control condition on lifestyle behaviors (eg, physical activity, diet, stress management), health-related outcomes (eg, blood glucose, hemoglobin A1c [HbA1c], blood pressure), and help-seeking behaviors (eg, medication adherence) in African American men; (2) test the immediate postintervention effects of the AHB intervention compared with the control condition on mediators of behavior change (eg, social support, motivation, self-efficacy); and (3) test the longer-term effects (12 months postrandomization) of the AHB intervention compared with the control condition. The study was powered to detect a difference of 30 minutes/day in accelerometer-assessed physical activity between intervention and control participants at 6 months (primary outcome at $\alpha = .05$ level).

Methods: This study was a community-based randomized controlled trial. African American men ($N = 333$) were recruited to participate in a 12-month study. Participants were randomly assigned to either the 6-month culturally tailored AHB program ($n = 167$) or an information-only control group ($n = 166$). The AHB intervention included a basic health education session, 16 weekly group sessions led by a trained group leader, and 3 booster calls facilitated by the group leader. Control participants received the basic health education session, written materials with advice on improving health-related behaviors, and encouragement to improve health over the next 6 months. Data on primary (change in total physical activity minutes/day at 6 month) and secondary outcomes (lifestyle behaviors, health-related clinical markers and quality outcomes, and mediators of behavior change) were collected at baseline and immediately after the 6-month intervention (primary end point). In months 6 to 12, intervention and control participants received monthly postcards with general health information. The purpose of the postcards was to maintain contact with participants to increase the likelihood that they could be reached for the final follow-up visit. All measures (primary and secondary outcomes) were collected again at 12 months (secondary end point).

For the current report, we tested the immediate (after 6 months) and long-term (after 12 months) effect of the AHB intervention compared with the control condition on change in total physical activity using a simple $t$ test (unadjusted analyses). We used the same strategy to assess the impact of the AHB intervention compared with the control condition on secondary outcomes at 6 and 12 months. We used an analysis of covariance model that allows us to account for the impact of each participant’s baseline value and add covariates to adjust for
baseline values (model 1) and baseline values and age, income, education, and body mass index (model 2) for each outcome variable. To account for missing data, we used PROC MI to impute at least 10 data sets and PROC MIANALYZE to combine the results. We also used a longitudinal analysis that included all 3 data points and the last observation carried forward to account for missing data. Results from the strategies to account for missing data were not substantially different from the completer analysis, so data from the completer analysis are reported herein.

**Results:** We recruited 333 men for the current study, which was below the desired goal of 400 participants. Of those recruited, 211 completed the 6-month follow-up data collection visit and 218 completed the 12-month follow-up data collection visit; thus, power to detect meaningful differences in the primary outcome of interest (daily physical activity) was reduced. There were no baseline differences by randomization assignment for any of the participant characteristics. We did not observe any statistically significant changes in daily physical activity between intervention and control participants at either of the follow-up data collection time points. At 6 months (immediately postintervention), we observed unadjusted between-group improvements (difference [95% CI]) in systolic blood pressure (−4.22 mm Hg; 95% CI, −7.87 to −0.56 mm Hg), diastolic blood pressure (−2.88 mm Hg; 95% CI, −5.74 to −0.02 mm Hg), and scores on the NutritionQuest Block Sodium Screener (−3.49; 95% CI, −6.98 to −0.01). After adjusting for baseline values and age, statistically significant differences in systolic blood pressure remained and new improvements in HbA1c (−0.24%; 95% CI, −0.45% to −0.04%) and blood glucose (−11.8 mg/dl; 95% CI, −21.1 to −2.51 mg/dl) emerged. After 12 months we observed unadjusted *between-group* improvements in scores on the NutritionQuest Block Sodium Screener (−3.00; 95% CI, −5.99 to −0.00), daily calories from saturated fat (−0.81; 95% CI, −1.36 to −0.27), total fat scores (−3.49; 95% CI, −5.82 to −1.16), general self-efficacy (6.01; 95% CI, 0.92-11.10), and exercise self-efficacy (0.58; 95% CI, 0.07-1.09). After 12 months we observed a decrease in daily steps (−1095 steps/day; 95% CI, −2029 to −160 steps/day). After adjusting for baseline values and age changes, daily calories from saturated fat, total fat scores, and daily steps remained statistically significant.

**Conclusions:** The aim of the current study was to determine the impact of the 6-month AHB program, compared with a health education control condition, on health-related behaviors associated with chronic disease among African American men. The study identified *between-group* improvements, favoring the intervention, for nutrition-related behaviors, but not for daily physical activity, which was the primary study outcome. Because African American men have historically been a relatively understudied group, little is known about effective strategies for engaging them in research and improving health-related behaviors. This study contributes to the knowledge of methods that can be used to improve health among African American men.

**Limitations:** A few limitations of this study were noted, including under-recruitment of participants (N = 333 of 400 planned) and low participation at follow-up data collection visits, which reduced power to detect meaningful differences in the primary outcome of interest; limited participation in intervention sessions among those assigned to the AHB program; the potential positive impact that providing culturally relevant basic health education might have had on control participants; and the fact that the current study was implemented in a single state in
the Southeastern United States and that findings might not be generalizable to men in other states or men who are not African American.
BACKGROUND

African American men across the lifespan have disproportionately higher rates of chronic disease and lower rates of effective chronic disease management than men in other racial/ethnic groups. The precise causes of death and morbidity disparities observed for African American men remain unknown; however, evidence indicates that racial inequality in health behaviors strongly associated with the most common chronic diseases is a significant contributor. National data show disproportionately high rates of obesity among African American men, and significant increases in obesity prevalence for African American men across all adult age groups from 1999 to 2000 (28.1%) through 2007 to 2008 (37.3%) and 2013 to 2014 (38%), even as rates stabilized in other population subgroups. African American men across all levels of education and perceived health status reported lower rates of physical activity and fitness, higher rates of physical inactivity, and lower likelihood of engaging in sufficient physical activity to help modulate chronic conditions than other population subgroups. African American men also reported lower fruit/vegetable and higher dietary fat intake than other population subgroups. Faced with higher rates of incarceration and unemployment, lower levels of education, prejudice, discrimination, substandard housing, and expectations to fulfill traditional gender roles, African American men are subject to greater real and perceived stressors and negative impacts on quality of life (QOL) than most other men in the United States. Physiologic responses to constant stress impair physical and mental health and are hypothesized as precursors to chronic disease incidence, morbidity, and mortality. Unfortunately, maladaptive stress management skills in African American men (eg, food, alcohol, and drug abuse) also negatively impact their health and QOL. Combined, the high rates of preventable chronic disease and poor morbidity-related QOL translate to African American men having an average lifespan 4 to 13 years less than African American women and White men and women.

The scientific literature on evidence-based strategies to promote and sustain healthy lifestyle behaviors and reduce chronic disease among African American men is severely limited, primarily because African American men traditionally have not been included as participants or
have comprised a small minority of the total sample without gender- or race-specific outcomes being reported.\textsuperscript{28-30} This is possibly because previous interventions have not integrated components relevant to the masculine identity, cultural traditions, and personal needs and preferences of African American men. Effective strategies are needed, specifically for African American men who are vulnerable to developing and having greater complications from chronic disease, that can assist men with making healthier lifestyle choices and health care decisions, which can, in turn, improve health-related outcomes.

The overall goal of this project was to refine, implement, and evaluate the Active & Healthy Brotherhood (AHB) intervention through a randomized controlled trial (RCT). The specific aims for the research study were to (1) test the immediate (6 months postrandomization) effects of the AHB intervention compared with the control condition on lifestyle behaviors and health-related outcomes; (2) test the immediate effects of the AHB intervention compared with the control condition on mediators of behavior change; and (3) test the longer-term (12 months postrandomization) effects of the AHB intervention compared with the control condition for all outcomes of interest.
PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS

Patients and stakeholders were engaged in every aspect of the study, including planning and writing the contract proposal; developing, implementing, and evaluating the intervention; interpreting study results; and presenting study-related findings at scientific conferences. Three patients were included as study co-investigators; all were recruited through previous relationships and collaborations with the study principal investigator (PI). Before writing the contract proposal, the investigative team, including the patient co-investigators, participated in biweekly phone calls over approximately 2 months to conceptualize the study. Approximately 15 adult African American men were recruited to participate in a focus group that was led by the study PIs to weigh in on aspects of the proposed intervention and to offer suggestions and strategies for revising the intervention content and to identify relevant study outcomes. Patient partners serving as co-investigators had strong opinions about factors within the intervention that should be measured (mediators and moderators) and that could impact participant engagement and success (eg, previous incarceration, transportation). They also made substantial contributions to the design of the booster intervention calls and the delayed intervention option for the control group. They helped the research team engage in healthy dialogue about the merits of an RCT vs a pre-post study design, which impacted the final study design. Initially, the investigative team met monthly via conference call to discuss any changes/updates with the project and the advisory team met in person, on average once a month. As the study progressed, our methods of contact changed to be more suitable for each team. We found it more effective for the project to meet, as needed, via emails and direct calls.

Once the study was funded, an advisory team consisting of 7 African American men residing in Winston-Salem, North Carolina, was assembled to provide input about the study design, participant recruitment, intervention content, and study implementation. Advisory team members varied in terms of presence of chronic disease and participation in health-related behaviors (eg, healthy eating and physical activity). We deliberately chose advisory board members with varying health profiles to ensure that the investigative team could benefit from men who fit the criteria for study eligibility and from men who were successfully engaging
in the behaviors being promoted in AHB. While in their advisory role, at least 2 participants became more proactive about their health, based on their informal conversations with study staff and/or the visible changes in their appearance (ie, weight loss). The advisory board members were also qualified to advise on the study because of their lived and work experiences, including the daily stressors of being an African American man, and involvement in the local community. Their ages ranged from the 20s to upper 50s, and they worked in various industries, including, but not limited to, ministry, banking, higher education, and self-employment. All advisory team members were compensated for their time. Advisory team members reviewed draft versions of the intervention content and provided suggestions for topics, discussion points, and session formats that would engage African American men. For example, as a way to engage the participants with the intervention content, African American men, including the key patient stakeholders, suggested the development of and contributed to the script for a miniseries, entitled “Talc” About It. The short series featured a group of characters throughout their participation in the AHB, with the plot being set in a local barbershop (hence the “talc” in the title). Episodes of the miniseries included dialogue about the changes men were experiencing during their participation in the fictitious study and the impact of the study on their overall lives. The advisory team and group facilitators directed, filmed, and starred in the miniseries, which helped to reiterate some of the program’s key points in an entertaining way.

Investigative team members, including patient co-investigators, visited Winston-Salem, North Carolina (project site) twice during the study to work collectively on developing intervention content, including scripts for the educational videos and participant manuals. Joint meetings of the investigative team and advisory team were held during each visit. The project’s consultants also attended. These meetings effectively provided an opportunity for the stakeholders, advisory team (patients), and researchers to meet each other and to collaborate in 1 physical location. During the second visit, the investigative team sat in during intervention sessions as well as group leader and study staff debriefing sessions, and provided insight on recruitment efforts. Each meeting attendee completed a stakeholder engagement form to help
the study staff better understand each person’s role and motivation, and how to improve the study. The worksheet asked the following questions:

1. What is your role on the project?
2. Why are you involved?
   a. What motivates your involvement?
3. What keeps you involved?
4. How do you spread the word about the program to potential participants?
5. What have you enjoyed the most about working with the AHB program?
6. What are the areas of improvement for the project?

Stakeholders cited the importance of the program as their motivation for involvement. For example, advisory board members stated that they were involved “to help keep the community informed” and to “help them help themselves.” Another stated that the program motivated him because it was “for and about me!” Pilot participants and other advisory board members stated that they most enjoyed “knowledge, fellowship, free flow of thinking, and communication among men of many walks, learning and sharing.”

When a prefinal draft of the intervention was ready, we recruited a pilot group of 4 African American male patients to review all of the program’s content before delivery to study participants. Sessions were conducted by trained group leaders, who were African American men who would be considered patients. The pilot group met weekly, and sessions were delivered as closely as possible to the way they would be delivered in actual intervention sessions. Intervention sessions were not considered final until they were tested and approved by the pilot study participants. Upon completion of the intervention sessions as a pilot participant, 1 participant applied to be and was hired as a group leader. When the study concluded, 2 study participants completed participation, applied, and were hired as group leaders.

Patients and stakeholders played an integral role in recruiting study participants. The advisory team helped develop the study’s recruitment materials during the early meetings. One
team member, a media marketing consultant, completed the drafted recruitment materials. Another advisory team member was the videographer for the filming sessions during the study, and another edited the footage. Team members also voluntarily provided the study staff with contacts of individuals within their business and social networks. In addition, they attended meetings with community members in efforts to recruit and present on behalf of the project. A pilot participant was also interviewed during a local radio station’s public affairs segment. During community events attended by the study staff, the staff often saw participants advocating for the program and encouraging their peers to sign up. A study participant who worked in the marketing field assisted our team in improving messaging on social media platforms. Following his advice continued to bring exposure to the program and was also incorporated into a revamp of the recruitment flyer, later reviewed by the investigative team and patient stakeholders. The draft flyer was then edited and completed by the advisory board. An African American male faculty member and subject matter expert in Greensboro attended information sessions with the study’s staff as well as recruitment events to assist with recruitment efforts.

Pilot participants assisted the recruitment process by calling individuals who were eligible to participate but had not attended an information session. Call lists were generated from the participant database by the study staff. All individuals on the lists had provided their contact information during an encounter with either the study staff or study recruiters and were screened for eligibility. During prescreening calls, the pilot participant was available to answer any questions the individual had that led to their hesitation to schedule and attend an information session. A group of participants who were the first to complete the study met with the study staff and provided insight on locations to recruit participants and on organizations the staff could contact. They also stated that they would recruit within their personal networks. Study participants were invited to join conference calls with the study staff and PCORI staff to gain a better understanding of recruitment challenges and to provide their personal insight.

Besides inviting study representatives to recruit at events with presentations and flyers, community stakeholders showed support for the study in unconventional ways. While
attending funeral services for a family member who succumbed to a preventable illness, the PI was unexpectedly asked to speak about the AHB study. The widow of the deceased wanted to stress the importance of Black men taking care of their health, seeking medical help, and paying attention to what their bodies are telling them. Numerous participants requested study flyers during data collection appointments, randomly visited the study site with friends or family members they wanted to introduce the study to, and/or invited the study staff to present at their social gatherings or places of worship.

Several community members, pilot participants, and current study participants volunteered to film testimonials detailing their personal accounts of the benefits of the AHB program for other African American men. At the conclusion of data collection appointments for most participants, former study participants, recruiters, and group leaders filmed a minidocumentary about the program in which the cast shared their personal experiences with the study.
METHODS

Study Overview

Our study was an RCT implemented in community-based settings, designed to test the efficacy of a 6-month culturally tailored intervention (AHB) compared with enhanced general health education (control condition) on chronic disease management among African American men. Participants were randomly assigned to either the AHB program or an information-only control group. Data on primary and secondary outcomes of interest were collected at baseline, immediately after the 6-month intervention, and after 6 months of no-intervention long-term follow up (at 12 months). The primary hypothesis was that men assigned to the AHB intervention would have a greater increase in total physical activity minutes/day at 6 months (immediately postintervention) compared with control participants. The study also evaluated the improvements in secondary outcomes in AHB compared with control group participants after 6 months. Long-term improvements in primary and secondary outcomes were evaluated at 12 months (6 months postintervention). Figure 1 provides an overview of the study design.

AHB’s overarching goal was to enhance chronic disease management and reduce risk for chronic disease among African American men. We identified the behavioral outcomes that were the focus of the AHB intervention based on focus groups, interviews, and surveys with African American men who indicated a desire to learn how to manage their own health through successful adoption and maintenance of the lifestyle behaviors they identified as associated with health. These behaviors included basic health knowledge, nutrition/healthy eating, physical activity, stress management, and weight control.
Study Setting

The AHB program was implemented in community-based settings in 4 counties in North Carolina—Forsyth, Guilford, Mecklenburg, and Durham. Participants were recruited from barbershops, libraries, fast food restaurants, sporting events (children’s leagues, high school, and college), places of worship, and community events (e.g., concerts, street fairs, festivals), by word of mouth, and through referrals. In addition, television, radio, newspaper, and social media advertisements were purchased for recruitment purposes. Data collection visits occurred at Gramercy Research Group offices or at locations that were mutually convenient for study staff and participants (e.g., churches, rented meeting space in communities outside Winston-Salem, public libraries). The duration of data collection visits varied depending on how quickly participants read and responded to questionnaires. In addition, how much participants
conversed with the study staff, and other factors, for example, retaking blood pressure measurements or removing/putting shoes back on after weight measurements, caused data collection visit times to vary.

**Participant Recruitment**

Participants were made aware of the study via the recruitment strategies listed in the “Study Setting” section. Trained study staff approached potential participants and asked for permission to provide a brief overview of the AHB study. Interested participants were provided with a 1- to 2-minute overview of the study and an opportunity to ask brief questions. Participants who were interested and recruited at in-person settings (e.g., community events, barber shops, churches, sporting activities, gas stations, fast food restaurants, car washes) provided study recruiters with contact information that included name, telephone number and email address, best time to contact, and county of residence. Study recruiters returned contact information forms to the study office and trained staff members called and/or emailed participants to establish a time for a prescreening visit via telephone to determine study eligibility.

Participants were also recruited via print, television, radio, newspaper, and social media advertisements. Advertising materials included a phone number to call a study staff member for additional information about the study. Advertisements also included a website that participants could access to provide their contact information if they wanted a study staff member to contact them directly about the study. Those who contacted the study directly either participated in a prescreening visit when they called or, if the time was inconvenient, established a more convenient time for a telephone prescreening visit.

During the prescreening call (prescreen level 1), a study staff member provided an overview of the study and allowed potential participants an opportunity to ask questions. If the potential participant remained interested in the study, the study staff member used an online survey to assess study eligibility. The survey assessed each of the study inclusion/exclusion criteria, which included the following: (1) self-reported African American; (2) self-reported male; (3) ≥21 years of age; (4) noninstitutionalized (i.e., community dwelling and not living in
assisted living facilities, nursing homes, prison/jail, or other facilities where health-related behaviors could be controlled by others); (5) at high risk for developing chronic disease (eg, not meeting current guidelines for physical activity and/or fruit and vegetable intake); or (6) currently diagnosed with diabetes, hypertension, or cardiovascular disease; (7) residents of Forsyth County, Mecklenburg County, Guilford County, or Durham County, North Carolina (or surrounding areas) and able to attend group sessions in those counties; and (8) English speaking. The prescreen level 1 call usually lasted about 15 minutes.

Questions were asked in the same order for every participant. If a participant provided a response that indicated he was not eligible for the study, he was immediately informed that he was not eligible for the study and the rationale for exclusion, and thanked for his time. Per IRB guidelines, no further questions were asked once a participant was deemed ineligible for the study. If a participant answered all of the prescreening questions and was deemed eligible for the study, he was invited to participate in an in-person information session at the study office (Forsyth County participants) or a convenient location in the community (Guilford, Durham, and Mecklenburg County participants).

Attendance at an information session (or individual session with study staff) was required before official study enrollment. The information session typically lasted 30 to 45 minutes. The project coordinator or other trained staff member described the study, requirements for study participants, and the benefits of study participation. Information sessions were set for a time and location convenient for study staff and the potential participant. Potential participants were encouraged to ask questions before completing additional screening forms (prescreen level 2) to determine the presence of health conditions that required further screening or that would preclude participation. Participants who indicated positive responses on the Physical Activity Readiness Questionnaire, had blood pressures >180/>110 mm Hg (assessed by study staff using a digital blood pressure monitor), or had self-reported health conditions that could preclude changes to diet (eg, irritable bowel syndrome, celiac disease) were required to obtain medical approval from a health care provider before participation in the study. Participants were excluded if they indicated that they (1) had had a
cardiovascular procedure (eg, heart surgery), myocardial infarction, heart failure, or stroke in the last 6 months; (2) had cognitive, visual, auditory, physical functional (eg, unable to walk unassisted), or language impairment precluding participation in group discussion, learning activities, or data collection; (3) were currently enrolled in a chronic disease management program; (4) were unwilling to accept random assignment or planned to move from the local area in <2 years; or (5) were currently receiving chemotherapy/radiation treatments.

Those who remained interested in participating after the information session signed the informed consent form. If participants had available time, they were able to begin the baseline data collection visit immediately after providing informed consent. Otherwise, a baseline data collection appointment was scheduled. The baseline data collection visit was divided into 2 parts to minimize participant burden associated with completing data collection forms. Participants completed half of the data collection forms during the initial baseline visit (baseline visit 1, approximately 45-60 minutes). At the end of baseline visit 1, participants received instructions and paperwork labeled with their study-assigned identification number for LabCorp for a blood draw. We selected LabCorp because it offered standardized, comprehensive clinical laboratory services and had locations in each of the counties included in the study. Participants were instructed to fast for at least 12 hours before their LabCorp visit. The participant paperwork included instructions for the laboratory tests needed for the study. Appointments could either be prescheduled or walk-in appointments during LabCorp’s regular office hours, which allowed participants to schedule visits at a location and time most convenient for them. Once blood draw data were processed and results were available, LabCorp faxed the results directly to the study team.

Also at the end of the baseline visit 1, participants were scheduled for the second baseline visit (baseline visit 2), which typically occurred within 1 week. Participants were expected to complete the LabCorp visit between baseline visits 1 and 2. During baseline visit 2, which lasted approximately 45 minutes, participants completed the remaining data collection forms. A study staff member reviewed the LabCorp report to ensure that participants did not meet the final exclusion criteria (hemoglobin A1c [HbA1c] >12% and/or triglycerides >500
mg/dL). Those who met exclusion criteria were referred to their primary care provider for further follow-up. After completing the final data collection forms, participants received a copy of their LabCorp report, explanation of the results, and basic patient education.

**Participant Random Assignment**

Following baseline data collection and basic education, participants were randomly assigned to the AHB intervention or control group in a 1:1 ratio using a permuted block randomization with block sizes of 2, 4, and 6. Participants were recruited in waves to ensure sufficient numbers to fill intervention groups. We adopted a permuted block design with varying block size, as this can lower the time that randomly assigned individuals wait for intervention groups to develop and ensure a degree of balance. A list of random study group assignments was generated and used to make sequential assignments. Randomization was managed via the subcontracted data management team’s system; computer-generated randomization assignments were provided electronically after participant baseline data were entered into the secure database used to manage participant data. Study team members were unaware of treatment allocation assignments until the computer-generated randomization assignment was made. Randomization allocation was managed within the data management team’s system, and study staff were not able to alter assignments. To reduce potential for dropout or noncompliance, participants were advised of the day and time for the next AHB intervention groups. If a participant indicated that he would not be able to participate on that day and time, he was not randomly assigned at that time. Instead, randomization was “on hold” until a suitable group session/time was identified. The change to the randomization method was made to reduce the number of participants randomly assigned to the AHB program, but who were not available to attend group sessions. Participants still had an equally likely chance of being randomly assigned to the intervention or control group. Holding randomization until a participant could actually attend an intervention group if assigned helped to decrease group absences.
Interventions and Comparators or Controls

Basic Patient Education

Both intervention and control participants received basic chronic disease management information, which was designed to increase knowledge of chronic disease management and resources to improve health-related and help-seeking behaviors. For consistency and to ensure that the basic education could be delivered easily in the future, we created 2 brief educational videos (~15 minutes each) to deliver content. African American men from the study team and community presented the content in the videos, which also addressed aspects of masculinity that could impact health care-seeking and decision-making. We provided written patient education materials about health behaviors (eg, nutrition, physical activity, stress management). We provided men with referrals to local health care providers, including free clinics, clinics for Medicare/Medicaid recipients, and self-pay clinics. In addition to the aforementioned basic health education, participants received publicly available (free for consumers) chronic disease management tools and programs (eg, the National Institute on Aging booklet *Exercise & Physical Activity*\(^{35}\)) to review on their own.

AHB Intervention Content

The AHB content was initially informed by a pilot study conducted by one of the study investigators (S.P.H.).\(^{36}\) The 8-week pilot intervention, during which men met twice per week (16 sessions total) included 28 African American men (55 years ± 6 years), who were divided into teams of 4 to 5 participants to foster camaraderie, social support, accountability, and fun. Intervention discussion topics included identifying barriers and solutions to healthy living, setting goals, monitoring progress, gaining social support, and avoiding relapse. The following statistically significant \((P < .05)\) results emerged from the pilot study:

- Decrease in body mass index (BMI; −2%)
- Increase in self-reported moderate to vigorous intensity physical activity (PA; 155%) and total PA (107%)
• Increase in self-efficacy for PA (12%) and social support for PA from friends (53%) and family (28%)
• Increase in aerobic fitness (9%), lower body strength (23%), and lower body flexibility (144%)

Session attendance was 86% ± 7% across the 16 sessions (90 min, 2×/week for 8 weeks). Completion of weekly PA logs was 82% ± 8%. In addition, participants rated the overall program and specific intervention components very favorably (10 items, average score of 4.78 on a 1-5 scale: 1 = strongly disagree to 5 = strongly agree).

Themes of the gender and ethnically relevant nutrition sessions were “healthy grilling” and “healthy southern cooking” and involved modified preparation, cooking, and tasting of foods commonly consumed by African American men (e.g., oven-fried chicken, low-calorie banana pudding). Barriers to healthy eating were discussed, as were strategies to reduce intake of foods high in calories, fat, sodium, and sugar. Dietary intake was not measured. However, nutrition knowledge demonstrated favorable changes over time.

Based on the pilot study results, our review of the literature, previous research, and communications with African American men and care providers, our behavioral intervention directly addressed barriers to health-related behaviors associated with prevention and control of chronic diseases. A major barrier to chronic disease management identified by African American men was poor knowledge about chronic disease and self-management practices. Based on feedback from preintervention focus groups, African American men were interested in learning how they could control their own health, as opposed to relying on someone else (e.g., health care providers). Particularly for populations less likely to seek medical care to manage chronic conditions (e.g., African American men), teaching behavioral strategies to effectively manage chronic conditions is critical for reducing morbidity and mortality and increasing quality years of life.
Group Sessions (Months 1-4)

AHB group intervention sessions were led by trained group facilitators. Four group leaders were trained by the PI and the study staff to implement the study. Group leaders received about 60 hours of training. First, group leaders participated in an abbreviated version of each of the intervention sessions as participants to help them understand the intervention content and to understand the program from the participant’s point of view. Next, group leaders received specific training on general health statistics, effective listening, and group facilitation skills topics. After learning the intervention content, group leaders practiced facilitating sessions by co-leading pilot group sessions with 4 men who met eligibility criteria for the study and who were willing to participate in the pilot study. As previously mentioned, some study participants who completed the full 12-month study requested the opportunity to serve as group leaders. Two additional group leaders who were previously study participants attended sessions and were subsequently trained as group leaders after they completed their participation in the study.

We recruited ~12 to 15 study participants for each group, which we have found to be an acceptable number to promote group discussion and demonstrate activities. Participants were asked to attend 16 weekly meetings (see Table 1) of ~120 minutes duration for 4 months, which was identified as an acceptable number of sessions in the pilot study by our 15-member community advisory board during planning for the current trial, and confirmed in a survey of 40 African American men in the specified community. Key intervention components shown to be effective during the AHB pilot project were included. Topics and processes in the group sessions aimed to maximize the men's success and enhance self-efficacy. This included gradual implementation, tailored goals to meet each man's lifestyle and preferences, consideration of how making lifestyle changes would help fulfill masculine and cultural identities, verbal reinforcement, skills for managing stress and anxiety, and the presence of social models.

Facilitators were trained on how to purposefully and systematically integrate the concept of masculinity and gender role strain into group discussions. We were not intervening on masculine identity, but rather on the stressors and challenges associated with living up to
gender-role norms and the barriers African American men faced regarding being active, eating healthy, and effectively managing stress. For example, African American men on the advisory panel discussed household norms that could preclude them from taking on roles associated with meal preparation, which was a role typically reserved for the woman/partner in the household. Intervention content discussed strategies men could implement that would allow them to share in meal preparation responsibilities (eg, providing suggestions, taking on meal preparation duties) that would not cause unnecessary strife within the household. Men who did not feel that the strategies were feasible discussed options for ensuring meals eaten outside the home were healthy (eg, breakfast and lunch during working hours). Men also discussed the notion that men should not recognize or acknowledge pain and the notion that men, historically, had been trained to “play through” pain. The intervention content identified when men could ignore symptoms of illness or injury vs making an appointment with a primary care provider vs seeking urgent care or visiting the emergency department.

Table 1. AHB Intervention Group Sessions Topics

<table>
<thead>
<tr>
<th>Session</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>Let’s go! Welcome/Getting Started <em>(Introduction to the program)</em></td>
</tr>
<tr>
<td>Week 2</td>
<td>Healthy Livin’ 101 <em>(Review of national recommendations for nutrition, physical activity, and emotional well-being)</em></td>
</tr>
<tr>
<td>Week 3</td>
<td>Check under the hood <em>(Laboratory test results, clinical biomarkers, and the potential short- and long-term impact of poor control of chronic disease)</em></td>
</tr>
<tr>
<td>Week 4</td>
<td>What’s up, doc? Accessing the health care system <em>(Taking charge of your own health care; patient-provider interactions)</em></td>
</tr>
<tr>
<td>Week 5</td>
<td>Y’all gonna make me lose my mind. . . up in here, up in here! <em>(Stress management demonstration)</em></td>
</tr>
<tr>
<td>Week 6</td>
<td>Move...get out the way: addressing barriers to healthy behaviors <em>(Identify barriers and problem solve to overcome them)</em></td>
</tr>
<tr>
<td>Week 7</td>
<td>Now you’re cooking! <em>(Healthy cooking demonstration; basic kitchen setup, knife skills, healthy salads and homemade dressing)</em></td>
</tr>
<tr>
<td>Week 8</td>
<td>Ain’t nobody got time for that...or do they? <em>(Time management)</em></td>
</tr>
<tr>
<td>Week 9</td>
<td>Let’s get physical! <em>(Physical activity demonstration; creating a physical activity routine at home)</em></td>
</tr>
<tr>
<td>Session</td>
<td>Topic</td>
</tr>
<tr>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td>Week 10</td>
<td>Prior proper planning prevents poor performance: Avoiding pitfalls/barriers (Handling potential pitfalls/barriers that might derail plans for healthy behaviors)</td>
</tr>
<tr>
<td>Week 11</td>
<td>I don’t feel like dirtying up all these pots! (Healthy cooking demonstration; healthy grilling)</td>
</tr>
<tr>
<td>Week 12</td>
<td>Pressure! Stress management (Physical activity demonstration)</td>
</tr>
<tr>
<td>Week 13</td>
<td>I’ve got this! Gaining confidence (Additional skills to improve shopping and cooking experiences)</td>
</tr>
<tr>
<td>Week 14</td>
<td>What’s new?: Exploring new topics (Smoothie demonstration, herbs, spices, and juicing)</td>
</tr>
<tr>
<td>Week 15</td>
<td>What’s next? (Relapse prevention, maintaining behavior)</td>
</tr>
<tr>
<td>Week 16</td>
<td>So . . . what did you think?: Lessons learned (Wrap-up and next steps)</td>
</tr>
</tbody>
</table>

To cultivate social support, camaraderie, and accountability (identified as vital in our pilot studies), participants in each group were initially assigned to teams of 4 to 5 men during session 1. Based on poor session attendance during the first session, group leaders suggested that small-group team assignments occur between sessions 1 and 3 depending on the session attendance. Within teams, men shared successes and challenges, offered encouragement, and proposed solutions. They identified a weekly “MVP,” a team member with significant progress in meeting a weekly goal. Each team reported to the larger group a summary of their discussions and identified their weekly team MVP. Healthy competition was integrated by facilitators comparing the number of men from each team who achieved their weekly behavioral goals. With the aid of the facilitators, the men learned how to ask for and receive support from friends and family members, especially those responsible for shopping and cooking at home. Group problem-solving activities identified solutions to sociocultural and built environmental challenges (eg, healthy outdoor grilling, healthy eating when traveling, eating out or at family reunions, avoiding pitfalls and negotiating barriers; lack of neighborhood or community healthy food and/or PA resources; and unpleasant environments).

AHB participants also engaged in experiential learning opportunities for behavioral skill-building (eg, cooking, PA, and stress management demonstrations; mock patient/provider interactions). To facilitate adherence, we provided modest incentives related to group session
content and designed to assist participants with achieving behavioral goals (eg, cooking equipment, water bottles, fitness towels).

AHB participants wore an Actical fitness monitor (Mini Mitter) during the intervention to track their exercise goals and diet, and as a way to foster social support within the teams. The monitor allowed each individual to keep a record of their PA, diet, and sleep patterns. Participants were also asked to use approved apps or paper/pencil logs to record dietary and stress management behaviors, as a way to monitor these behaviors during the intervention.

**Maintenance Booster Calls (Months 5-6)**

Following the intensive-intervention phase, participants received 3 structured, individual phone calls, lasting approximately 15 minutes, with the group facilitator to review progress, identify barriers to and solutions for healthy behaviors, recognize success, and reset (or set new) goals.

**Control Group**

Following the basic health education visit, other than data collection visits, the patients assigned to the control condition had no further planned contact with research staff. At each data collection visit, we assessed their participation in other chronic disease self-management programs.

**Long-Term Maintenance**

To assess long-term maintenance, we followed participants for 6 months postintervention. The long-term maintenance period was designed to allow the research team to maintain minimal contact with participants to ensure that they could be reached for the 12-month follow-up period. A 6-month appointment reminder postcard was mailed to all participants, as well as a 12-month appointment reminder letter. Monthly postcards were mailed to the address on file for intervention and control participants. Postcards included a general health tip. Health tip topics are included in Table 2.
Table 2. Long-Term Maintenance Postcard Topics

<table>
<thead>
<tr>
<th>Card no.</th>
<th>Mo</th>
<th>Topic and content</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6</td>
<td>Setting goals for success: Reminder to set SMART goals (Specific, Measurable, Achievable, Relevant or Realistic, and Time-Based), with an example of a bad and a good goal.</td>
</tr>
<tr>
<td>2</td>
<td>7</td>
<td>Keeping your “slips” from becoming “relapses”: Reminder to anticipate having “high-risk” situations, and plan in advance how to deal with them when they happen. The key to recovering from a slip is to act fast and get back on track as soon as possible.</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
<td>Staying active during football season: Examples of ways to fit activity into a football schedule such as performing indoor exercises during commercials or halftime.</td>
</tr>
<tr>
<td>4</td>
<td>9</td>
<td>Staying motivated: Tips to help stay motivated such as celebrating accomplishments and considering the benefits gained from practicing healthy behaviors.</td>
</tr>
<tr>
<td>5</td>
<td>10</td>
<td>Brrr...being active in cold weather: Simple tips that can be used to ensure safety and comfort while maintaining a physical activity routine during winter months.</td>
</tr>
<tr>
<td>6</td>
<td>11</td>
<td>The importance of stretching: Basic stretching tips such as to stretch slowly and smoothly, including a general background on when to stretch (any time, morning, before and after exercise, etc).</td>
</tr>
<tr>
<td>7</td>
<td>12</td>
<td>Nutrition tips for surviving the holidays or special occasions: Tips to navigate buffets and holiday parties (eg, use the meals served at home as a balance for the meals eaten outside of the home).</td>
</tr>
</tbody>
</table>

Study Outcomes

In our focus groups, patients reported being able to self-manage their health through successful attainment of lifestyle behavioral goals (eg, PA, diet, stress management) as behaviors that were the most important outcomes (ie, patient-centered outcomes). The primary outcome on which the study was powered was minutes per day of accelerometer-assessed PA. As secondary outcomes of interest, and in line with the patient-centered focus of the study, we also assessed variables that were of interest to patients (based on formative assessment work), including daily walking as assessed by pedometer, dietary behaviors, stress, medication adherence, and help-seeking behaviors. We selected additional clinical outcomes as secondary measures that could provide evidence of the impact of the intervention on markers of risk factors for chronic disease. We also explored mediators of behavior change to
understand factors that might have indirectly impacted outcomes (eg, self-efficacy, social support, motivation). Measures are included in Table 3.

Table 3. Study-Related Outcomes, Assessment Tools, and Outcome Level

<table>
<thead>
<tr>
<th>Measure</th>
<th>Assessment tool</th>
<th>Outcome level</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participant demographics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>Demographics questionnaire assessing age, household income, educational status, employment status, smoking status, length of time residing in county, marital status, and military service</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Lifestyle behaviors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily PA</td>
<td>• Actical accelerometer</td>
<td>Primary</td>
</tr>
<tr>
<td></td>
<td>• Modified International Physical Activity Questionnaire</td>
<td>Secondary</td>
</tr>
<tr>
<td>Sedentary behavior</td>
<td>Actical accelerometer</td>
<td>Secondary</td>
</tr>
<tr>
<td>Daily walking</td>
<td>Pedometer (Garmin Vivofit 2)</td>
<td>Secondary</td>
</tr>
<tr>
<td>Dietary behavior</td>
<td>• NutritionQuest Block Sodium Screener</td>
<td>Secondary</td>
</tr>
<tr>
<td></td>
<td>• NutritionQuest Block Dietary Fat Screener</td>
<td>Secondary</td>
</tr>
<tr>
<td></td>
<td>• NutritionQuest Block Fruit-Vegetable-Fiber Screener</td>
<td>Secondary</td>
</tr>
<tr>
<td>Medication adherence</td>
<td>Morisky Medication Adherence Scale-8</td>
<td>Secondary</td>
</tr>
<tr>
<td>Stress management</td>
<td>• Perceived Stress Scale</td>
<td>Secondary</td>
</tr>
<tr>
<td></td>
<td>• Brief Symptoms inventory</td>
<td>Secondary</td>
</tr>
<tr>
<td></td>
<td>• Holmes-Rahe Stress Inventory</td>
<td>Secondary</td>
</tr>
<tr>
<td>Help-seeking behaviors</td>
<td>Help-Seeking Behaviors Questionnaire</td>
<td>Secondary</td>
</tr>
<tr>
<td><strong>Health-related clinical markers and QOL outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight status</td>
<td>Height, weight, calculated BMI</td>
<td>Secondary</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Digital sphygmomanometer</td>
<td>Secondary</td>
</tr>
<tr>
<td>Biometrics</td>
<td>Glucose, HbA1c, serum creatinine levels, GFR, lipid panel</td>
<td>Secondary</td>
</tr>
<tr>
<td>QOL</td>
<td>CDC Health-Related Quality of Life Questionnaire</td>
<td>Secondary</td>
</tr>
<tr>
<td><strong>Mediators of behavior change</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Masculinity</td>
<td>Multidimensional Measures of Masculinities and Health Questionnaire</td>
<td>Secondary</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>• Eating Habits Confidence survey</td>
<td>Secondary</td>
</tr>
<tr>
<td></td>
<td>• Exercise Self-Efficacy Questionnaire</td>
<td>Secondary</td>
</tr>
<tr>
<td>Measure</td>
<td>Assessment tool</td>
<td>Outcome level</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Social support for diet and PA</td>
<td>• Social Support and Eating Habits survey</td>
<td>Secondary</td>
</tr>
<tr>
<td></td>
<td>• Group Social Provisions Scale</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Social Provisions Scale</td>
<td></td>
</tr>
<tr>
<td>Behavior change skills</td>
<td>Relapse Prevention and Maintenance subscale</td>
<td>Secondary</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index; CDC, Centers for Disease Control and Prevention; GFR, glomerular filtration rate; HbA1c, hemoglobin A1c; N/A, not applicable; QOL, quality of life; PA, physical activity.

aAside from the Holmes-Rahe Stress Inventory, all measures were assessed at baseline, 6 months, and 12 months.
bThe Holmes-Rahe Stress Inventory assessed stressful factors over the previous 12 months and was only administered at baseline and 12 months.

### Lifestyle Behaviors

PA (primary study outcome) was assessed with a wrist-mounted Actical monitor for 14 consecutive days at each data collection visit. Standard protocols and cut points for accelerometer data collection previously employed by the PI were used to determine time spent in light, moderate, and vigorous PA. Wear and non-wear time and time spent in sedentary behavior was also derived from the accelerometer based on an established algorithm and cut point. Participants also wore pedometers for the same 14-day period to assess daily walking. Participants were instructed to wear the pedometer during all waking hours, clipped to the waistband and directly above the outside of the right knee. Participants were instructed to remove the pedometer if asleep, immersed in water, or changing clothing, and to resume wearing the pedometer upon waking, getting out of water, or after getting dressed. Pedometers were sealed to prevent participants from using feedback from the pedometers to alter their PA during data collection periods. To increase translatability to clinical settings, we also used the 7-item self-administered modified International Physical Activity Questionnaire to assess PA participation.

Dietary behavior was assessed using validated screeners, including the NutritionQuest Block Sodium Screener, Block Dietary Fat Screener, and Block Fruit-Vegetable-Fiber Screener ([https://nutritionquest.com/assessment/list-of-questionnaires-and-sCREENERS/](https://nutritionquest.com/assessment/list-of-questionnaires-and-sCREENERS/)). Each screener has been validated for use in adult populations. Importantly, screeners were relatively
inexpensive ($0.75-$1.00 per respondent administration) and were self-scoring for clinical application.

Current medication use was assessed at each data collection visit using the widely used and well-validated 8-item Morisky Medication Adherence Scale (MMAS-8), which specifically addresses adherence to prescribed medication regimens.\textsuperscript{41} Summary scores on the MMAS-8 range from 0 to 8 and have been trichotomized into 3 levels of adherence: (1) high adherence is indicated by a score of 8; (2) medium adherence is indicated by a score of 6 to 7; (3) low adherence is indicated by a score of <6. The MMAS-8 was validated in a sample of 1367 primarily African American patients with hypertension (76.5\%) and found to have a Cronbach $\alpha$ of .83.\textsuperscript{41}

Several instruments were used as proxy measures of stress management. The Perceived Stress Scale (PSS) is a 14-item self-report measure that assesses the degree to which situations in one’s life are appraised as stressful.\textsuperscript{42} The Brief Symptom Inventory (BSI) is a 53-item short form of the Symptom Checklist 90-Revised and BSI.\textsuperscript{43,44} Individuals endorsed each item of the BSI on a 5-point Likert scale of distress. The $\alpha$ coefficients ranged from .79 to .85 on the depression scale. The 3 subscales are for depression, anxiety, and somatization. The Holmes-Rahe Stress Inventory measured “life events” that happened to participants during the previous year.\textsuperscript{70} Each situation had a designated point value. Examples of events include, but are not limited to, marriage, death of spouse, and changes in residence. The final score provided an estimated outlook for the participant to have a “stress-induced health breakdown.” Help-seeking behaviors (eg, routine check-ups, emergency departments visits, other visits) were measured using questions from the Forsyth County Department of Public Health’s Community Health Survey, the Health Information National Trends Survey, and the Behavioral Risk Factor Surveillance System. We also used questions from each survey to assess sources of information about health, medical treatment, or rehabilitation.
Health-Related Clinical and Quality Outcomes

Weight and height were measured with a portable digital scale and height stadiometer, and used to calculate BMI (weight in kilograms divided by height in square meters). Duplicate measures were taken and the average was used. Height was only collected at the baseline data collection visit and was not repeated at the 6- and 12-month data collection visits. Weight was assessed at each data collection visit.

Baseline, 6-, and 12-month glucose, HbA1c, serum creatinine levels, glomerular filtration rate, and lipids were obtained by a trained phlebotomist from LabCorp. Participants received paperwork and directions to a LabCorp facility that was conveniently located in each city. Participants reported to LabCorp and had blood drawn after at least 12 hours of fasting. Blood samples were processed by LabCorp personnel using the organization’s standard techniques, and participant results were faxed to Gramercy Research Group for use in analyses.

Seated blood pressure was measured after 5 minutes of rest using a digital sphygmomanometer (Omron 907XL) and appropriately sized cuff on the right arm. A duplicate measurement was taken, after a 60-second interval, and the average was used. Blood pressure measures differing by >5 mm Hg were repeated.

To measure QOL, we used a modified version of the CDC’s Health-Related QOL questionnaire. The modified form included 3 questions instead of 4, due to 1 question being loaded, measuring physical and mental health, simultaneously. The administered questionnaire asked participants to rate their general health and mental health (without using the words “stress,” “problems,” and “depression”). To measure physical pain and other health problems, examples of daily activities were provided (eg, driving).

Mediators of Behavior Change

Masculinity was measured with the Multidimensional Measures of Masculinities and Health Questionnaire. Five scales were derived from the questionnaire: Gender Role Conflict, Provider Role Strain, Subjective Norms, Health Hardiness, and Masculine Gender Role Stress. Self-efficacy for initiating and maintaining a healthy diet and PA program was assessed using
self-report questionnaires, Eating Habits Confidence survey and, the Exercise Self-Efficacy Questionnaire.\textsuperscript{49} Social support for diet and PA was measured using self-report questionnaires.\textsuperscript{49} We also measured social relations/social support in the intervention group using the Social Provisions Scale,\textsuperscript{50} which measures social integration, reassurance of worth, reliable alliance, opportunity for nurturance, attachment, and guidance to provide a summary score of group cohesion. Use of behavior change skills was measured with the Relapse Prevention and Maintenance scale assessing the ability to avoid/respond to relapse.\textsuperscript{51}

**Sample Size Calculations and Power**

The primary outcome, on which the study was powered, was change in daily PA as assessed using an accelerometer. Sample size and power calculations were based on change in total PA minutes per day as measured by an accelerometer at 6 months for several reasons: (1) Measures of nutrition are subjective, whereas measures of PA are objective; (2) we have estimates of variance in objectively measured PA for the population of interest; and (3) the calculations indicated ample power to detect meaningful differences in other health-related behaviors and clinical measures.

Table 4 presents sample size estimates to detect various differences in mean changes in total PA minutes/day between the 2 groups at $\alpha = .05$ using a 2-sided simple $t$ test. We expected the AHB intervention to have an effect size of $\geq 0.30$ with 30 minutes/day difference between the 2 study groups. Sample size calculations indicated that we needed to recruit 352 participants ($n = 176$ per group). Based on our experience (11% withdrawal in the pilot study\textsuperscript{36}) and 10% to 16% attrition in similar studies with African American women,\textsuperscript{52} we conservatively assumed 20% attrition at 6 months. Thus, we initially planned to enroll 424 African American men (212 in each study group), providing 80% power to detect a 30-minute/day difference between the 2 study groups at 6 months. This sample size also provided 80% power to detect an $\alpha$ of .6 servings/day difference in fruit and vegetable intake between the 2 groups based on an SD of 2 fruit and vegetable servings/day. Based on SDs of pre-post changes from the Heart Healthy Lenoir Study of African American patients (Z. Gizlice, PhD, unpublished data, 2014), this sample size also provided 80% power to detect the following differences in pre-post mean
changes between the 2 groups: systolic blood pressure, 5.70 mm Hg (SD, 19 mm Hg); diastolic blood pressure, 3.30 mm Hg (SD, 11 mm Hg); HbA1c, 0.24% (SD, 0.8%); and BMI, 0.33 (SD, 1.1).

Because we had some difficulty with recruiting a sufficient number of participants, we also calculated the differences we would be able to detect between the 2 study groups at 6 months if we recruited smaller samples, ranging from 100 to 165 African American men in each study group. The first line in Table 4 is our initial sample size estimate. The other lines in the table represent the differences we would be able detect between the 2 study groups with various sample sizes.
Table 4. Sample Size Estimates to Detect Various Effect Sizes With 80% Power

<table>
<thead>
<tr>
<th>Power, ( 1 - \beta )</th>
<th>Effect size, ( \delta/\sigma )</th>
<th>n</th>
<th>N</th>
<th>Total with 20% attrition, N</th>
<th>Total PA change, min/d</th>
<th>F and V servings/d</th>
<th>Systolic BP, mm Hg</th>
<th>Diastolic BP, mm Hg</th>
<th>HbA1c</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.801</td>
<td>0.30</td>
<td>176</td>
<td>352</td>
<td>424</td>
<td>30</td>
<td>0.60</td>
<td>5.70</td>
<td>3.30</td>
<td>0.24</td>
<td>0.33</td>
</tr>
<tr>
<td>0.802</td>
<td>0.31</td>
<td>165</td>
<td>330</td>
<td>396</td>
<td>31</td>
<td>0.62</td>
<td>5.89</td>
<td>3.41</td>
<td>0.25</td>
<td>0.34</td>
</tr>
<tr>
<td>0.802</td>
<td>0.32</td>
<td>155</td>
<td>310</td>
<td>372</td>
<td>32</td>
<td>0.64</td>
<td>6.08</td>
<td>3.52</td>
<td>0.26</td>
<td>0.35</td>
</tr>
<tr>
<td>0.802</td>
<td>0.33</td>
<td>146</td>
<td>292</td>
<td>352</td>
<td>33</td>
<td>0.66</td>
<td>6.27</td>
<td>3.63</td>
<td>0.26</td>
<td>0.36</td>
</tr>
<tr>
<td>0.801</td>
<td>0.34</td>
<td>137</td>
<td>274</td>
<td>329</td>
<td>34</td>
<td>0.68</td>
<td>6.46</td>
<td>3.74</td>
<td>0.27</td>
<td>0.37</td>
</tr>
<tr>
<td>0.803</td>
<td>0.35</td>
<td>130</td>
<td>260</td>
<td>312</td>
<td>35</td>
<td>0.70</td>
<td>6.65</td>
<td>3.85</td>
<td>0.28</td>
<td>0.39</td>
</tr>
<tr>
<td>0.803</td>
<td>0.36</td>
<td>123</td>
<td>246</td>
<td>296</td>
<td>36</td>
<td>0.72</td>
<td>6.84</td>
<td>3.96</td>
<td>0.29</td>
<td>0.40</td>
</tr>
<tr>
<td>0.801</td>
<td>0.37</td>
<td>116</td>
<td>232</td>
<td>280</td>
<td>37</td>
<td>0.74</td>
<td>7.03</td>
<td>4.07</td>
<td>0.30</td>
<td>0.41</td>
</tr>
<tr>
<td>0.801</td>
<td>0.38</td>
<td>110</td>
<td>220</td>
<td>264</td>
<td>38</td>
<td>0.76</td>
<td>7.22</td>
<td>4.18</td>
<td>0.30</td>
<td>0.42</td>
</tr>
<tr>
<td>0.803</td>
<td>0.39</td>
<td>105</td>
<td>210</td>
<td>252</td>
<td>39</td>
<td>0.78</td>
<td>7.41</td>
<td>4.29</td>
<td>0.31</td>
<td>0.43</td>
</tr>
<tr>
<td>0.804</td>
<td>0.40</td>
<td>100</td>
<td>200</td>
<td>240</td>
<td>40</td>
<td>0.80</td>
<td>7.60</td>
<td>4.40</td>
<td>0.32</td>
<td>0.44</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index; BP, blood pressure; F and V, fruits and vegetables; HbA1c, hemoglobin A1c; PA, physical activity.
Time Frame for the Study

The AHB study was implemented over a 3-year period. Each participant was enrolled in the study for a 12-month period, including baseline data collection (month 0), a 6-month intervention or control group period, postintervention follow-up (month 6), a 6-month no-intervention maintenance period, and final data collection (month 12). Once control group participants completed the 12-month study period, they were eligible to participate in the intervention; subsequent postprogram data for control group participants who enrolled in the intervention \((n = 8)\) were not included in study data analyses.

Data Collection and Sources

Patient data were collected at months 0, 6, and 12 using standardized data collection procedures and validated questionnaires. Trained data collectors collected the data. All survey instruments, including validity and test-retest reliability information, and measurement protocols had been used in previous studies conducted by the research team. We also collected process evaluation measures (eg, session evaluations and intervention fidelity) throughout the study, which were used in weekly case management meetings with group leaders to ensure that all session content was covered within the session and to identify adjustments that needed to be made within the groups (eg, adding content to subsequent sessions if all content was not covered within a session; addressing any negative feedback received in session evaluations).

Analytical and Statistical Approaches

Primary aim 1 tested the immediate postintervention (6 months postrandomization) effect of the AHB intervention compared with the control condition on healthy lifestyle behaviors, health-related outcomes, and help-seeking behaviors in African American men. The primary hypothesis was that African American men assigned to the AHB intervention would have greater improvements in daily accelerometer-assessed minutes of PA compared with the control group. The secondary hypothesis was that African American men assigned to the AHB intervention would have greater improvements in secondary outcomes of interest (ie, lifestyle behaviors and health-related outcomes) compared with the control group at 6 months postrandomization. We first tested the hypotheses under the intention-to-treat (ITT) principle
by including data on all participants randomly assigned using the analysis of covariance model, which allowed us to account for the impact of each participant’s baseline values.\textsuperscript{53,54} To further explore the effect of the intervention, we fitted regression models that (1) adjusted for baseline covariates of interest, considered a priori, relevant to change in outcomes; (2) adjusted for any baseline variables distributed differently between treatment groups; and (3) examined completers only.

Primary aim 2 tested the immediate effects of the AHB intervention compared with the control condition on mediators of behavior change (eg, social support, motivation, self-efficacy). Baranowski noted that few interventions measure or assess the impact of theoretically suggested mediating variables on behavior changes.\textsuperscript{55} Consistent with our theoretical models,\textsuperscript{56} we measured consistent mediators associated with PA, diet, stress, and help-seeking behaviors. Mediating models were tested per suggestions in the literature on mediation effects in interventions.\textsuperscript{57-59} Behavior change was regressed on a group variable (intervention/comparison) and adjusted for a mediator.

Primary aim 3 tested the longer-term effects of the AHB intervention compared with the control condition for primary and secondary outcomes of interest, using the same analysis methods as for primary aim 1.

**Missing Data**

We made every effort to minimize attrition; however, there was some dropout for various reasons, which we documented in the secured study database. We compared baseline characteristics of dropouts and retained participants; variables that differed for those sample characteristics in any systematic way were used in our supplemental analysis as covariates.

We used validated methods to deal with missing data. The study statistician (Z.G.) implemented the standardized protocol for dealing with missing data that is used in the Department of Health Promotion and Disease Prevention at the University of North Carolina at Chapel Hill. The ITT analysis included a multiple imputation approach and sensitivity analyses using pattern mixture models. For the multiple imputations approach, we used PROC MI to
impute at least 10 data sets, analyzed each imputed data set, and combined the results using PROC MIANALYZE. For sensitivity analyses, we assumed various dropout patterns (increase and/or decrease in PA minutes with various variances) for intervention and control groups such as 0-, 5-, and 10-minute decreases in PA minutes for intervention dropouts and no change for control dropouts with various variances. We created multiple data sets and analyzed them similarly to the multiple imputation approach to estimate the intervention effect and assess the sensitivity of our results for each scenario. We note that the results from the strategies used to account for missing data were not substantially different from the completer analyses (ie, analyses of individuals who did not have missing data); thus, the data reported herein are only for those who completed the study. We note that, because many secondary outcomes were examined, significant findings (ie, 95% CIs that do not include zero) should be interpreted cautiously unless highly significant, as results were not adjusted for multiple comparisons.

Changes to the Original Study Protocol

During the study, several changes to the original study protocol were implemented in an attempt to reach the stated recruitment goal (400 African American men). The original study inclusion criteria focused on men aged 30 to 64 years; however, because many men from the community who were <30 years or >64 years of age expressed interest in participating in the study, and because there was no biological rationale to limit the age range, the inclusion criterion for age was changed to ≥21 years during the first month of recruitment. Appropriate approval from the PCORI project officer and the study IRB (Copernicus Group) was obtained before officially changing the recruitment criteria.

All participants received $75 for completing the study. At the beginning of the study, compensation was provided in graduated amounts ($10, $15, and $50) that were disbursed upon completion of the baseline, 6-month, and 12-month data collection sessions, respectively. There was some concern among study staff, investigators, and patient stakeholders that a standard amount for each data collection visit would be more desirable for participants; thus, the compensation schedule was changed to $25, provided at the completion of each data collection visit.
In the original study protocol, all study participants were to be recruited from 1 community, Winston-Salem, North Carolina; however, after approximately 9 months of recruitment during which all recruitment possibilities were exhausted, the study investigators, staff, and stakeholders suggested expanding to additional large cities within the state in an attempt to reach recruitment goals. The contingency plan for recruitment was outlined in the original study proposal. The study team identified 3 satellite locations—Charlotte, Greensboro, and Durham—all North Carolina cities within a 2-hour driving radius of the study office (Winston-Salem) where study team members had local community contacts and partners who could potentially assist with recruitment. The plan for expanding recruitment cities was discussed with and approved by the PCORI project officer before we implemented the change. The change in recruitment sites was also approved by the study IRB.

An additional adjustment to the study protocol was implemented to boost participation in group sessions among intervention participants. During the start of the first 2 intervention waves, some participants did not consistently attend the weekly sessions. To overcome this challenge, group leaders were asked to contact participants before the start of each wave of sessions, to ensure participants were familiar with their group leader before coming to the first session. The group leaders then contacted participants at least once during the week before each session for the first 4 to 6 sessions, or until a solid relationship was established. While the change in protocol increased contact time between group leaders and participants, the revised contact plan also helped to identify potential barriers to participation in group sessions.

Finally, intervention participants initially received a Garmin Vivofit 2 pedometer before the start of group sessions. However, given the number of participants who were assigned to group sessions but who either did not attend any sessions, or did not attend any sessions after the first session, we realized we were losing monitors at a rapid rate. To conserve resources and based on feedback from group leaders, the team decided to distribute monitors during week 6 of the program instead.
Qualitative Data Design and Analysis

Upon completion of 12-month data collection sessions (final data collection), all participants were asked to participate in a one-on-one exit interview, consisting of 8 main questions with follow-up prompts. Participants who did not complete a 6-month follow-up were still asked to interview upon completing the 12-month data collection session. The interview was conducted face to face by a study staff member (research assistant, assistant project coordinator, or project coordinator) to learn more about participants’ experiences in the study, and facilitators and barriers to study participation. Each staff member was involved in the investigators’ development of the interview guide, trained in qualitative interviewing, practiced interviewing with their supervisor, and provided and received feedback before interviewing participants. Each interview was recorded, with the participant’s permission, while the staff member took written notes. Interviews were transcribed verbatim by the study staff. All transcripts were reviewed for accuracy by other staff members. Of 206 total interviews, we analyzed a random sample of 75 participant exit surveys, in addition to 7 files selected for training purposes (total of 82 interviews). A total of 43 control participant interviews and 39 intervention participant interviews were analyzed using NVivo 12 Plus (QSR International) for Windows. A qualitative data expert, in collaboration with study staff, created an initial codebook of themes and subthemes that were used to categorize participant statements from the interviews (see the Appendix). The PI and qualitative data expert decided to code ~75 interviews instead of the entire data set to account for saturation (ie, reaching a point in the analyses where participants state the same or very similar responses). Two staff members reviewed and edited the codebook, comparing transcripts (intervention and control) to ensure that all themes were included. Six staff members coded 5 interviews to identify an initial set of themes and subthemes. The qualitative data expert coded the same 5 interviews, using the initial set of codes, and added additional codes as needed. The 2 staff coders coded 10 transcripts by consensus, met with the expert, and then coded an additional 10 transcripts. The expert coded all 20 files as well for the purpose of consensus coding. The files were then coded by randomization assignment. The separately coded transcripts were merged and compared in order to calculate agreement between coders. Double coding among the 2 main coders was
repeated until agreement reached 100% (interrater reliability). Additional staff members and 1 of the coders analyzed the study data for each parent and child node (main category and subcategories).
RESULTS

Quantitative Data Analysis

Baseline

A total of 3777 potential participants expressed initial interest in participating in the study. Of these, 333 participants (9% of those expressing initial interest) completed the health education visit and were randomly assigned to either the AHB intervention (n = 167) or control condition (n = 166). Figure 2 provides a detailed CONSORT flow diagram with an overview of participant flow through the study intervention.

Our initial goal was to recruit 400 participants, but we recruited 67 fewer participants than were needed to detect a significant difference of 30 minutes per day of PA between intervention and control participants. Thus, power to detect statistically significant differences was already reduced at baseline. In addition, while there were very few participants who officially dropped out of the study, a significant number of participants missed data collection visits at each time point (see Figure 2). Participants who did not formally drop out of the study but missed their 6-month visit were still contacted by the study staff to complete a 12-month visit.

Because many secondary outcomes were examined, significant findings (ie, 95% CIs that do not include 0) should be interpreted cautiously unless highly significant, as results were not adjusted for multiple comparisons.
Figure 2. CONSORT Flow Diagram
Table 5 presents baseline participant characteristics for participants who completed study enrollment. There were no statistically significant differences between groups for any variables at baseline.

Table 5. Baseline Participant Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>AHB group (n = 167), mean ± SD</th>
<th>Control group (n = 166), mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>50.1 ± 12.4</td>
<td>51.3 ± 11.6</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>106.9 ± 28.9</td>
<td>101.9 ± 23.4</td>
</tr>
<tr>
<td>BMI</td>
<td>34.4 ± 8.8</td>
<td>33.1 ± 7.5</td>
</tr>
<tr>
<td>Steps/d</td>
<td>4407.7 ± 1478.3</td>
<td>4355.2 ± 1296.8</td>
</tr>
<tr>
<td>Sedentary, min/day</td>
<td>666.6 ± 166.9</td>
<td>647.8 ± 165.7</td>
</tr>
<tr>
<td>Light PA, min/day</td>
<td>654.6 ± 138.6</td>
<td>664.6 ± 126.1</td>
</tr>
<tr>
<td>Moderate PA, min/day</td>
<td>117.6 ± 71.4</td>
<td>125.7 ± 88.8</td>
</tr>
<tr>
<td>Vigorous PA, min/day</td>
<td>1.1 ± 4.0</td>
<td>1.9 ± 5.6</td>
</tr>
<tr>
<td>Total PA, min/day</td>
<td>773.3 ± 166.9</td>
<td>792.1 ± 165.7</td>
</tr>
<tr>
<td>Systolic blood pressure, mm Hg</td>
<td>129.6 ± 16.8</td>
<td>130.2 ± 18.4</td>
</tr>
<tr>
<td>Diastolic blood pressure, mm Hg</td>
<td>78.4 ± 11.4</td>
<td>77.0 ± 13.7</td>
</tr>
<tr>
<td>HbA1c, %</td>
<td>6.5 ± 1.8</td>
<td>6.4 ± 1.6</td>
</tr>
<tr>
<td>Cholesterol, mg/dL</td>
<td>181.0 ± 41.3</td>
<td>176.8 ± 39.8</td>
</tr>
<tr>
<td>HDL, mg/dL</td>
<td>47.2 ± 13.5</td>
<td>49.3 ± 13.0</td>
</tr>
<tr>
<td>Blood glucose, mg/dL</td>
<td>108.7 ± 54.2</td>
<td>105.7 ± 46.4</td>
</tr>
</tbody>
</table>

Abbreviations: AHB, Active & Healthy Brotherhood; BMI, body mass index; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; PA, physical activity.

**Intervention Implementation**

The AHB intervention included 16 group sessions and 3 booster calls. All intervention participants also received reminder calls or text messages before group sessions to remind them to attend upcoming sessions. Individuals who missed group sessions received additional reminder calls encouraging them to attend group sessions. All 16 intervention sessions and all 3 booster calls were implemented as designed for the AHB group. Session attendance ranged
from 0 to 16 sessions. A total of 42 participants who were assigned to group sessions did not attend any of the sessions. Among the 125 participants who attended at least 1 session, mean \( \pm \) SD session attendance was 9.8 \( \pm \) 4.9 out of 16 sessions.

**Primary Aim 1—Immediate Intervention Effects**

Tables 6a and 6b provide data for immediate postintervention changes. After 6 months, we did not observe any statistically significant difference between group changes in weekly minutes of accelerometer-assessed PA (primary outcome), pedometer-assessed daily step counts, or self-reported total PA. We observed unadjusted between-group changes (difference [95% CI]) in measures of lifestyle behaviors, including scores on the NutritionQuest Block Sodium Screener (−3.49; 95% CI, −6.98 to −0.01, indicating reduction in overall sodium); reduced self-reported sodium intake (−415; 95% CI, −829 to 1.74; \( P = .05 \)); and a reduction in the number of positive symptoms on the BSI (−1.81; 95% CI, −3.63 to 0.01; \( P = .05 \)). We observed a statistically significant change in self-reported perceived stress as measured by the PSS (1.77; 95% CI, 0.09-3.45), though not in the expected direction (perception of stress *increased* rather than decreased in the AHB group compared with the control group).

We further adjusted models for age, income, education, BMI, and baseline values (full model). Using the adjusted full model, we observed statistically significant between-group differences favoring the AHB group in HbA_1c (−0.25; 95% CI, −0.46 to −0.03), cholesterol (−7.93; 95% CI, −15.6 to −0.26), blood glucose (−13.4; 95% CI, −23.3 to −3.52), and systolic blood pressure (−3.52 mm Hg; 95% CI, −7.01 to −0.03). Unadjusted and adjusted between-group changes for other lifestyle behaviors, clinical markers, and quality outcomes were not statistically significant after 6 months.

We also used baseline observation carried forward to account for missing data; however, the results for these analyses did not change the findings presented above for 6-month changes in primary and secondary outcomes of interest and thus are not presented here.
### Table 6a. Six-Month Follow-up Changes in Lifestyle Behaviors

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Study group</th>
<th>n</th>
<th>Baseline mean (SD)</th>
<th>Follow-up mean (SD)</th>
<th>Change in mean (95% CI)</th>
<th>Unadjusted difference in mean changes (95% CI)</th>
<th>Fully adjusted difference in mean changes (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total average PA, min/wk</td>
<td>1. AHB</td>
<td>85</td>
<td>5220 (1303)</td>
<td>5390 (1181)</td>
<td>169.5 (–52.0 to 391.1)</td>
<td>13.07 (–274 to 300.2)</td>
<td>–145 (–398 to 107.6)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>113</td>
<td>5575 (1131)</td>
<td>5731 (1062)</td>
<td>156.5 (–26.8 to 339.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-reported daily PA, min</td>
<td>1. AHB</td>
<td>89</td>
<td>176.3 (201.1)</td>
<td>201.0 (184.1)</td>
<td>24.66 (–10.1 to 59.5)</td>
<td>22.91 (–26.5 to 72.3)</td>
<td>22.74 (–23.5 to 69.0)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>120</td>
<td>182.0 (196.6)</td>
<td>183.8 (204.3)</td>
<td>1.75 (–33.4 to 36.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total average sedentary time, min/wk</td>
<td>1. AHB</td>
<td>85</td>
<td>4860 (1303)</td>
<td>4690 (1181)</td>
<td>–170 (–391.0 to 52.0)</td>
<td>–13.1 (–300.0 to 274.0)</td>
<td>145.3 (–108 to 398.2)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>113</td>
<td>4505 (1131)</td>
<td>4349 (1062)</td>
<td>–156 (–340 to 26.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steps/d</td>
<td>1. AHB</td>
<td>71</td>
<td>4474 (1381)</td>
<td>6097 (3080)</td>
<td>1623 (966-2280)</td>
<td>–714 (–1775 to 347)</td>
<td>–406 (–1440 to 628.5)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>87</td>
<td>4457 (1227)</td>
<td>6794 (3682)</td>
<td>2336 (1502-3171)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily servings of fruits and</td>
<td>1. AHB</td>
<td>87</td>
<td>3.61 (1.82)</td>
<td>3.79 (2.09)</td>
<td>0.18 (–0.24 to 0.60)</td>
<td>0.22 (–0.28 to 0.71)</td>
<td>0.24 (–0.19 to 0.66)</td>
</tr>
<tr>
<td>vegetables</td>
<td>2. Control</td>
<td>116</td>
<td>3.77 (1.87)</td>
<td>3.73 (1.64)</td>
<td>–0.04 (–0.30 to 0.23)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily sodium intake, mg</td>
<td>1. AHB</td>
<td>86</td>
<td>3615 (1837)</td>
<td>2957 (1293)</td>
<td>–658 (–998 to –318)</td>
<td>–415 (–829 to –1.74)</td>
<td>–200 (–525 to 124.3)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>113</td>
<td>3301 (1349)</td>
<td>3058 (1312)</td>
<td>–242 (–479 to –5.48)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily calories from saturated fat, g</td>
<td>1. AHB</td>
<td>87</td>
<td>11.48 (2.34)</td>
<td>10.65 (2.27)</td>
<td>–0.83 (–1.12 to –0.38)</td>
<td>–0.27 (–0.82 to 0.28)</td>
<td>–0.14 (–0.63 to 0.35)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>116</td>
<td>11.17 (1.99)</td>
<td>10.61 (2.02)</td>
<td>–0.56 (–0.87 to –0.24)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total fat score from NutritionQuest Block Nutrition Screener</td>
<td>1. AHB</td>
<td>87</td>
<td>23.78 (10.15)</td>
<td>20.21 (9.72)</td>
<td>–3.57 (–5.52 to –1.63)</td>
<td>–1.17 (–3.54 to 1.20)</td>
<td>–0.58 (–2.70 to 1.53)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>116</td>
<td>22.39 (8.62)</td>
<td>19.98 (8.68)</td>
<td>–2.41 (–3.76 to –1.05)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NutritionQuest Block Sodium Screener</td>
<td>1. AHB</td>
<td>86</td>
<td>31.76 (15.39)</td>
<td>26.24 (10.77)</td>
<td>–5.51 (–8.37 to –2.65)</td>
<td>–3.49 (–6.98 to –0.01)</td>
<td>–1.68 (–4.42 to 1.05)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>13</td>
<td>29.10 (11.29)</td>
<td>27.08 (10.97)</td>
<td>–2.02 (–4.01 to –0.02)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcome measures</td>
<td>Study group</td>
<td>n</td>
<td>Baseline mean (SD)</td>
<td>Follow-up mean (SD)</td>
<td>Change in mean (95% CI)</td>
<td>Unadjusted difference in mean changes (95% CI)</td>
<td>Fully adjusted difference in mean changes (95% CI)</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------</td>
<td>----</td>
<td>-------------------</td>
<td>---------------------</td>
<td>------------------------</td>
<td>-----------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>MMAS-8</td>
<td>1. AHB</td>
<td>43</td>
<td>3.30 (1.56)</td>
<td>3.06 (1.47)</td>
<td>−0.23 (−0.60 to 0.14)</td>
<td>0.03 (−0.53 to 0.58)</td>
<td>−0.17 (−0.76 to 0.43)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>51</td>
<td>4.05 (1.52)</td>
<td>3.79 (1.71)</td>
<td>−0.26 (−0.67 to 0.15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSS</td>
<td>1. AHB</td>
<td>87</td>
<td>16.20 (7.11)</td>
<td>17.67 (6.68)</td>
<td>1.47 (0.21-2.73)</td>
<td>1.77 (0.09-3.45)</td>
<td>1.28 (−0.27 to 2.83)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>116</td>
<td>18.10 (8.29)</td>
<td>17.80 (8.11)</td>
<td>−0.30 (−1.42 to 0.81)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BSI (no. of positive symptoms)</td>
<td>1. AHB</td>
<td>90</td>
<td>12.28 (10.22)</td>
<td>9.91 (8.79)</td>
<td>−2.37 (−3.73 to −1.00)c</td>
<td>−1.81 (−3.63 to 0.01)c</td>
<td>−1.62 (−3.37 to 0.14)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>120</td>
<td>11.53 (10.14)</td>
<td>10.97 (10.75)</td>
<td>−0.56 (−1.77 to 0.65)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: AHB, Active & Healthy Brotherhood; BSI, Brief Symptom Inventory; MMAS-8, 8-item Morisky Medication Adherence Scale; PA, physical activity; PSS, Perceived Stress Scale.

aFully adjusted model is adjusted for baseline value, age, income, education, and BMI.

bP < .0001.

cP < .01.

dP < .05.
Table 6b. Six-Month Follow-up Changes in Health-Related Clinical Markers and QOL Outcomes

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Study group</th>
<th>n</th>
<th>Baseline mean (SD)</th>
<th>Follow-up mean (SD)</th>
<th>Change in mean (95% CI)</th>
<th>Unadjusted difference in mean changes (95% CI)</th>
<th>Fully adjusted difference in mean changes (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight, kg</td>
<td>1. AHB</td>
<td>85</td>
<td>106.9 (30.08)</td>
<td>106.2 (29.28)</td>
<td>−0.73 (−1.64 to 0.19)</td>
<td>0.04 (−1.22 to 1.14)</td>
<td>0.04 (−1.14 to 1.23)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>113</td>
<td>102.4 (24.21)</td>
<td>101.7 (24.43)</td>
<td>−0.69 (−1.44 to 0.07)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>1. AHB</td>
<td>85</td>
<td>34.43 (8.76)</td>
<td>34.17 (8.50)</td>
<td>−0.25 (−0.54 to 0.04)</td>
<td>−0.04 (−0.41 to 0.34)</td>
<td>−0.02 (−0.40 to 0.36)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>113</td>
<td>33.15 (7.31)</td>
<td>32.94 (7.44)</td>
<td>−0.22 (−0.46 to 0.03)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure, mm Hg</td>
<td>1. AHB</td>
<td>89</td>
<td>131.4 (15.21)</td>
<td>126.3 (14.00)</td>
<td>−5.09 (−7.76 to −2.42)</td>
<td>−3.49 (−7.15 to 0.16)</td>
<td>−3.52 (−7.01 to −0.03)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>114</td>
<td>130.9 (17.59)</td>
<td>129.3 (18.11)</td>
<td>−1.60 (−4.10 to 0.91)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diastolic blood pressure, mm Hg</td>
<td>1. AHB</td>
<td>88</td>
<td>80.25 (10.94)</td>
<td>77.06 (11.25)</td>
<td>−3.19 (−5.53 to −1.06)</td>
<td>−2.73 (−5.68 to 0.22)</td>
<td>−1.41 (−4.11 to 1.29)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>114</td>
<td>76.80 (13.81)</td>
<td>76.33 (12.40)</td>
<td>−0.46 (−2.51 to 1.58)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>1. AHB</td>
<td>84</td>
<td>6.40 (1.63)</td>
<td>6.09 (1.03)</td>
<td>−0.31 (−0.53 to −0.09)</td>
<td>−0.22 (−0.47 to 0.04)</td>
<td>−0.25 (−0.46 to −0.03)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>112</td>
<td>6.52 (1.53)</td>
<td>6.43 (1.59)</td>
<td>−0.09 (−0.21 to 0.02)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood glucose, mg/dL</td>
<td>1. AHB</td>
<td>72</td>
<td>102.8 (47.27)</td>
<td>96.15 (22.23)</td>
<td>−6.61 (−17.0 to 3.81)</td>
<td>−9.93 (−22.8 to 2.95)</td>
<td>−13.4 (−23.3 to −3.52)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>85</td>
<td>105.8 (49.98)</td>
<td>109.1 (47.85)</td>
<td>3.32 (−4.28 to 10.91)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol, mg/dL</td>
<td>1. AHB</td>
<td>84</td>
<td>181.4 (46.13)</td>
<td>171.1 (38.46)</td>
<td>−10.20 (−17.8 to −2.70)</td>
<td>−7.40 (−16.2 to 1.40)</td>
<td>−7.93 (−15.6 to −0.26)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>112</td>
<td>180.4 (40.98)</td>
<td>117.5 (39.56)</td>
<td>−2.84 (−7.41 to 1.73)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HDL, mg/dL</td>
<td>1. AHB</td>
<td>84</td>
<td>47.29 (14.63)</td>
<td>47.52 (15.75)</td>
<td>0.24 (−1.79 to 2.27)</td>
<td>−0.00 (−2.47 to 2.47)</td>
<td>0.04 (−2.44 to 2.51)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>112</td>
<td>49.04 (11.75)</td>
<td>49.28 (13.27)</td>
<td>0.24 (−1.18 to 1.66)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum creatinine level</td>
<td>1. AHB</td>
<td>84</td>
<td>1.16 (0.39)</td>
<td>1.17 (0.50)</td>
<td>0.01 (−0.03 to 0.05)</td>
<td>−0.00 (−0.06 to 0.05)</td>
<td>−0.03 (−0.08 to 0.03)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>112</td>
<td>1.14 (0.26)</td>
<td>1.16 (0.34)</td>
<td>0.01 (−0.02 to 0.05)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcome measures</td>
<td>Study group</td>
<td>n</td>
<td>Baseline mean (SD)</td>
<td>Follow-up mean (SD)</td>
<td>Change in mean (95% CI)</td>
<td>Unadjusted difference in mean changes (95% CI)</td>
<td>Fully adjusted difference in mean changes (95% CI)</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------</td>
<td>----</td>
<td>--------------------</td>
<td>---------------------</td>
<td>-------------------------</td>
<td>-----------------------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>GFR</td>
<td>1. AHB</td>
<td>84</td>
<td>90.06 (23.39)</td>
<td>89.20 (23.67)</td>
<td>−0.86 (−3.37 to 1.66)</td>
<td>0.08 (−3.13 to 3.29)</td>
<td>0.83 (−2.28 to 3.93)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>112</td>
<td>89.32 (21.79)</td>
<td>88.38 (21.57)</td>
<td>−0.94 (−2.94 to 1.07)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: AHB, Active & Healthy Brotherhood; BMI, body mass index; GFR, glomerular filtration rate; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; PA, physical activity; QOL, quality of life.

\( ^a \)Fully adjusted model is adjusted for baseline value, age, income, education, and BMI.

\( ^b \)\( P < .01 \).

\( ^c \)\( P < .05 \).
Primary Aim 2—Immediate Intervention Effects on Mediators of Behavior Change

Mediators of behavior change included masculinity, self-efficacy, social support for diet and PA, and behavior change skills. After 6 months, we saw statistically significant differences between group changes in discouragement of healthy habits from family members (1.20; 95% CI, 0.24-2.16), which was not in the expected direction. We also saw a statistically significant decrease in perceived total social support (−3.12; 95% CI, −5.17 to −1.06) in AHB participants compared with control participants. We attribute both of these unexpected findings to AHB participants understanding the meaning of, and recognizing, encouragement and social support during the intervention and recognizing that such support was not available outside group settings. After adjusting for age, income, education, BMI, and baseline values, the observed statistically significant increase in discouragement of healthy habits from family members remained (1.02; 95% CI, 0.10-1.95). In the adjusted full model, we observed a statistically significant increase in self-reported exercise self-confidence that favored the AHB group (5.74; 95% CI, 1.04-10.44). We did not observe any statistically significant differences between group changes for any of the other mediators of behavior change after 6 months.

Primary Aim 3—Long-Term Intervention Effects

Tables 7a and 7b provide data for changes at 12 months postbaseline (after the 6-month postintervention follow-up) when participants were expected to maintain postintervention behavior changes. At 12 months, compared with baseline values, we observed a statistically significant between-group difference in pedometer-assessed daily steps (−1072; 95% CI, −2011 to −134) that favored the control group rather than the AHB group. We also observed statistically significant between-group improvements in NutritionQuest Block Sodium Screener scores (−3.00; 95% CI, −5.99 to −0.00), daily sodium intake (−356; 95% CI, −712 to −0.52), daily calories from saturated fat (−0.81; 95% CI, −1.36 to −0.27), and total fat scores (−3.49; 95% CI, −5.82 to −1.16). Between-group differences in the percentage of calories from saturated fat (−0.55; 95% CI, −1.05 to −0.06) and total fat (−2.34; 95% CI, −4.47 to −0.22) remained after adjustment in the full model.
After 12 months, we observed statistically significant between-group changes in some mediators of behavior change, including exercise self-efficacy (0.58; 95% CI, 0.07-1.09) and encouragement of healthy habits from family members (1.27; 95% CI, 0.01-2.53), but the changes disappeared after further adjusting the model. We observed a statistically significant between-group difference in 1 of the Multidimensional Measures of Masculinities and Health Questionnaire subscales, Provider Role Strain, in the full adjusted model (0.12; 95% CI, 0.01-0.23). Between-group changes in self-reported confidence in the ability to reduce calories were statistically significant (0.29; 95% CI, 0.05-0.52), and the changes remained after adjusting for baseline values, age, income, education, and BMI. Overall self-efficacy was also statistically significant after 12 months (6.01; 95% CI, 0.92-11.10); however, the changes disappeared in the adjusted models.

We also used the last observation carried forward to account for missing data; however, the results for these analyses did not change the findings presented above for 12-month changes in primary and secondary outcomes of interest and thus are not presented here.
<table>
<thead>
<tr>
<th>Primary or secondary outcome measure</th>
<th>Study group</th>
<th>n</th>
<th>Baseline mean (SD)</th>
<th>Follow-up mean (SD)</th>
<th>Change in mean (95% CI)</th>
<th>Unadjusted difference in mean changes (95% CI)</th>
<th>Fully adjusted difference in mean changes (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total average PA, min/wk</td>
<td>1. AHB</td>
<td>96</td>
<td>5298 (1259)</td>
<td>5499 (1051)</td>
<td>201.4 (–18.2 to 420.9)</td>
<td>219.2 (–67.7 to 506.2)</td>
<td>–0.44 (–243 to 242.2)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>112</td>
<td>5712 (1013)</td>
<td>5694 (1023)</td>
<td>–17.9 (–203 to 167)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-reported daily PA, min</td>
<td>1. AHB</td>
<td>101</td>
<td>169.7 (203.3)</td>
<td>193.2 (226.2)</td>
<td>23.5 (–18.6 to 65.6)</td>
<td>38.0 (–21.2 to 97.3)</td>
<td>18.90 (–33.6 to 71.37)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>114</td>
<td>207.8 (209.8)</td>
<td>193.3 (209.9)</td>
<td>–14.5 (–56.3 to 27.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total average sedentary time, min/wk</td>
<td>1. AHB</td>
<td>97</td>
<td>4772 (1257)</td>
<td>4632 (1163)</td>
<td>–140 (–389 to 109.8)</td>
<td>–249 (–584 to 84.9)</td>
<td>24.6 (–322 to 272.8)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>114</td>
<td>4359 (1007)</td>
<td>4469 (1197)</td>
<td>109.7 (–113 to 332.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steps/d</td>
<td>1. AHB</td>
<td>78</td>
<td>4622 (1380)</td>
<td>6301 (2824)</td>
<td>1679 (–1.53 to 0.68)</td>
<td>–1072 (–2011 to –134)</td>
<td>–557 (–1439 to 326.3)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>85</td>
<td>4536 (1284)</td>
<td>7287 (3149)</td>
<td>2752 (2010-3494)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily servings of fruits and vegetables</td>
<td>1. AHB</td>
<td>99</td>
<td>3.66 (1.79)</td>
<td>3.62 (1.72)</td>
<td>–0.04 (–0.39 to 0.30)</td>
<td>0.06 (–0.38 to 0.51)</td>
<td>0.04 (–0.35 to 0.42)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>113</td>
<td>3.83 (1.79)</td>
<td>3.73 (1.66)</td>
<td>–0.10 (–0.39 to 0.18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily sodium intake, mg</td>
<td>1. AHB</td>
<td>97</td>
<td>3524 (1540)</td>
<td>3066 (1413)</td>
<td>–458 (–726 to –191)</td>
<td>–356 (–712 to –0.52)</td>
<td>–144 (–452 to 163.4)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>110</td>
<td>3261 (1370)</td>
<td>3158 (1310)</td>
<td>–102 (–338 to 133.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily calories from saturated fat, g</td>
<td>1. AHB</td>
<td>98</td>
<td>11.50 (2.32)</td>
<td>10.40 (2.35)</td>
<td>–1.11 (–1.53 to –0.68)</td>
<td>–0.81 (–1.36 to –0.27)</td>
<td>–0.55 (–1.05 to –0.06)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>113</td>
<td>11.10 (1.98)</td>
<td>10.81 (2.11)</td>
<td>–0.29 (–0.63 to 0.05)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total fat score from NutritionQuest Block Nutrition Screener</td>
<td>1. AHB</td>
<td>98</td>
<td>23.87 (10.06)</td>
<td>19.13 (10.05)</td>
<td>–4.73 (–6.55 to –2.92)</td>
<td>–3.49 (–5.82 to –1.16)</td>
<td>–2.34 (–4.47 to –0.22)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>113</td>
<td>22.11 (8.53)</td>
<td>20.86 (9.12)</td>
<td>–1.25 (–2.72 to 0.22)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NutritionQuest Block Sodium Screener</td>
<td>1. AHB</td>
<td>97</td>
<td>30.96 (12.86)</td>
<td>27.14 (11.81)</td>
<td>–3.81 (–6.06 to –1.56)</td>
<td>–3.00 (–5.99 to –0.00)</td>
<td>–1.21 (–3.80 to 1.38)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>110</td>
<td>28.77 (11.48)</td>
<td>27.95 (10.98)</td>
<td>–0.82 (–2.80 to 1.16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary or secondary outcome measure</td>
<td>Study group</td>
<td>n</td>
<td>Baseline mean (SD)</td>
<td>Follow-up mean (SD)</td>
<td>Change in mean (95% CI)</td>
<td>Unadjusted difference in mean changes (95% CI)</td>
<td>Fully adjusted difference in mean changes (95% CI)</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>------------</td>
<td>-------</td>
<td>--------------------</td>
<td>---------------------</td>
<td>------------------------</td>
<td>-----------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>MMAS-8</td>
<td>1. AHB</td>
<td>46</td>
<td>3.38 (1.49)</td>
<td>3.58 (1.63)</td>
<td>0.21 (–0.25 to 0.67)</td>
<td>0.47 (–0.16 to 1.09)</td>
<td>0.23 (–0.36 to 0.83)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>53</td>
<td>3.84 (1.50)</td>
<td>3.58 (1.58)</td>
<td>–0.26 (–0.68 to 0.16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSS</td>
<td>1. AHB</td>
<td>98</td>
<td>16.95 (7.02)</td>
<td>17.35 (7.66)</td>
<td>0.40 (–0.88 to 1.67)</td>
<td>1.04 (–0.69 to 2.76)</td>
<td>0.62 (–0.89 to 2.13)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>113</td>
<td>18.25 (8.38)</td>
<td>17.61 (7.94)</td>
<td>–0.64 (–1.81 to 0.54)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-mo Holmes-Rahe Stress Inventory</td>
<td>1. AHB</td>
<td>101</td>
<td>180.4 (118.2)</td>
<td>158.4 (118.5)</td>
<td>–22.0 (–44.6 to 0.52)</td>
<td>–3.40 (–33.0 to 26.21)</td>
<td>–9.05 (–34.9 to 16.80)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>114</td>
<td>189.3 (134.8)</td>
<td>170.6 (128.4)</td>
<td>–18.6 (–37.9 to 0.59)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BSI (No. of positive symptoms)</td>
<td>1. AHB</td>
<td>101</td>
<td>12.72 (10.29)</td>
<td>10.40 (10.08)</td>
<td>–2.33 (–4.01 to 0.65)</td>
<td>–1.11 (–3.28 to 1.07)</td>
<td>–0.76 (–2.84 to 1.32)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>114</td>
<td>12.10 (10.39)</td>
<td>10.88 (11.04)</td>
<td>–1.22 (–2.60 to 0.16)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: AHB, Active & Healthy Brotherhood; BSI, Brief Symptom Inventory; HbA1c, hemoglobin A1c; MMAS-8, 8-item Morisky Medication Adherence Scale; PA, physical activity.

aFully adjusted model is adjusted for baseline value, age, income, education, and BMI.
bP < .0001.
cP < .01.
dP < .05.
Table 7b. Twelve-Month Follow-up Changes in Health-Related Clinical Markers and QOL Outcomes

<table>
<thead>
<tr>
<th>Primary or secondary outcome measure</th>
<th>Study group</th>
<th>n</th>
<th>Baseline mean (SD)</th>
<th>Follow-up mean (SD)</th>
<th>Change in mean (95% CI)</th>
<th>Unadjusted difference in mean changes (95% CI)</th>
<th>Fully adjusted differences in mean changes (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight, kg</td>
<td>1. AHB</td>
<td>97</td>
<td>106.2 (29.47)</td>
<td>105.1 (29.12)</td>
<td>−1.03 (−2.10 to 0.03)</td>
<td>−0.89 (−2.29 to 0.51)</td>
<td>−0.80 (−2.20 to 0.59)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>114</td>
<td>102.7 (24.47)</td>
<td>102.5 (24.87)</td>
<td>−0.14 (−1.06 to 0.77)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>1. AHB</td>
<td>97</td>
<td>34.26 (8.63)</td>
<td>33.91 (8.55)</td>
<td>−0.35 (−0.69 to −0.01)</td>
<td>−0.32 (−0.76 to 0.13)</td>
<td>−0.30 (−0.75 to 0.14)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>114</td>
<td>33.33 (7.75)</td>
<td>33.30 (7.99)</td>
<td>−0.03 (−0.32 to 0.26)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure, mm Hg</td>
<td>1. AHB</td>
<td>101</td>
<td>129.9 (14.95)</td>
<td>127.7 (17.29)</td>
<td>−2.17 (−5.11 to 0.77)</td>
<td>−1.05 (−5.07 to 2.98)</td>
<td>−1.82 (−5.69 to 2.05)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>115</td>
<td>130.7 (17.02)</td>
<td>129.6 (19.06)</td>
<td>−1.12 (−3.88 to 1.64)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diastolic blood pressure, mm Hg</td>
<td>1. AHB</td>
<td>101</td>
<td>78.74 (10.85)</td>
<td>76.53 (11.79)</td>
<td>−2.21 (−4.29 to −0.13)</td>
<td>−0.83 (−3.63 to 1.98)</td>
<td>−0.55 (−3.10 to 2.00)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>115</td>
<td>76.85 (13.97)</td>
<td>75.47 (13.36)</td>
<td>−1.38 (−3.27 to 0.51)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c, %</td>
<td>1. AHB</td>
<td>95</td>
<td>6.36 (1.78)</td>
<td>6.20 (1.30)</td>
<td>−0.16 (−0.42 to 0.11)</td>
<td>−0.05 (−0.34 to 0.24)</td>
<td>−0.05 (−0.28 to 0.19)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>114</td>
<td>6.40 (1.25)</td>
<td>6.30 (1.32)</td>
<td>−0.10 (−0.22 to 0.01)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood glucose level, mg/dL</td>
<td>1. AHB</td>
<td>82</td>
<td>105.1 (50.65)</td>
<td>100.2 (43.70)</td>
<td>−4.88 (−14.5 to 4.76)</td>
<td>−4.59 (−16.9 to 7.76)</td>
<td>−3.13 (−13.5 to 7.26)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>86</td>
<td>103.2 (45.27)</td>
<td>102.9 (40.58)</td>
<td>−0.29 (−8.04 to 7.46)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol, mg/dL</td>
<td>1. AHB</td>
<td>99</td>
<td>182.4 (43.66)</td>
<td>171.2 (35.39)</td>
<td>−11.2 (−18.3 to −4.06)</td>
<td>−7.13 (−16.1 to 1.83)</td>
<td>−4.97 (−12.7 to 2.75)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>115</td>
<td>175.1 (36.56)</td>
<td>171.1 (36.11)</td>
<td>−4.07 (−9.51 to 1.37)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HDL, mg/dL</td>
<td>1. AHB</td>
<td>99</td>
<td>48.09 (14.35)</td>
<td>48.20 (13.85)</td>
<td>0.11 (−1.56 to 1.78)</td>
<td>0.37 (−1.81 to 2.55)</td>
<td>0.12 (−2.05 to 2.28)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>115</td>
<td>49.88 (12.92)</td>
<td>49.62 (13.72)</td>
<td>−0.26 (−1.67 to 1.15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum creatinine level</td>
<td>1. AHB</td>
<td>99</td>
<td>1.12 (0.38)</td>
<td>1.16 (0.43)</td>
<td>0.04 (−0.00 to 0.08)</td>
<td>0.02 (−0.02 to 0.07)</td>
<td>0.01 (−0.03 to 0.06)</td>
</tr>
<tr>
<td></td>
<td>2. Control</td>
<td>115</td>
<td>1.15 (0.26)</td>
<td>1.16 (0.30)</td>
<td>0.02 (−0.01 to 0.04)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GFR</td>
<td>1. AHB</td>
<td>99</td>
<td>91.14 (24.24)</td>
<td>89.89 (22.90)</td>
<td>−1.25 (−4.09 to 1.59)</td>
<td>0.48 (−3.20 to 4.17)</td>
<td>1.68 (−1.77 to 5.12)</td>
</tr>
</tbody>
</table>

a Significant at P < 0.05
<table>
<thead>
<tr>
<th>Primary or secondary outcome measure</th>
<th>Study group</th>
<th>n</th>
<th>Baseline mean (SD)</th>
<th>Follow-up mean (SD)</th>
<th>Change in mean (95% CI)</th>
<th>Unadjusted difference in mean changes (95% CI)</th>
<th>Fully adjusted differences in mean changes (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Control</td>
<td>114</td>
<td>88.96 (22.42)</td>
<td>87.22 (21.73)</td>
<td>−1.74 (−4.09 to 0.62)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: AHB, Active & Healthy Brotherhood; BMI, body mass index; GFR, glomerular filtration rate; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; QOL, quality of life.

aFully adjusted model is adjusted for baseline value, age, income, education, and BMI.

bP < .05.

cP < .01.
Qualitative Data Analysis

To fully understand the impact of the AHB program on study participants, we also analyzed qualitative data collected during exit interviews from a sample of AHB and control participants (N = 44). Several key themes emerged that provided additional insight about the impact of the program. The themes were generally categorized under positive aspects of the program, barriers to health behavior change, barriers to program attendance, facilitators of behavior change maintenance, benefits of participation, helpful aspects of the program, facilitators or enablers of program attendance, and enablers or facilitators of health behavior change. A brief overview of the findings within each category is included here; a detailed report and interview transcripts can be made available upon request.

Positive Aspects of the Program

Participants were asked to consider specific aspects of the program they liked or that increased their satisfaction with the program; their responses were then coded to this category when they described these aspects. Information coded here included responses to the question, “Is there anything else you want to tell us about the program?” Emergent themes included enjoyment of the program (n = 23), program meets needs of Black community (n = 16), individuals delivering the program (n = 19), camaraderie or relationship building with men in the group (n = 14), and group discussions (n = 5). Numbers in parentheses represent the number of times a phrase or statement was coded to a particular theme.

Barriers to Health Behavior Change

Participants were asked to describe what prevented them from changing their diet and PA behaviors during the study. Themes that emerged from the participants’ responses included difficulty learning new habits (n = 34); time or competing responsibilities, including work schedules and home and community responsibilities and financial instability due to loss of job or home (n = 20); lack of prioritization of healthy behaviors (n = 14); lack of personal motivation and lack of accountability (n = 10); lack of availability of healthy food due to financial constraints (n = 6); poor health status (n = 5); and those who stated there were no barriers (n =
Randomization assignment did not appear to impact the factors noted as barriers to health behavior change.

**Barriers to Program Attendance**

To discover what prevented participants from attending their visits and sessions, they were asked the question, “What made it hard for you to attend data collection visits and study sessions?” Themes that emerged from the participants’ responses were competing responsibilities such as work, family, social commitments, and other responsibilities (n = 48); issues with transportation, including lack of transportation and issues with the public transportation system that prohibited direct and efficient travel for study-related activities (n = 7); and physical location or distance between the program and work (n = 6). Several participants resided in the community where the program was being implemented but worked in a different community, which impacted travel and attendance at program and data collection sessions; traffic was often cited as a barrier, as well as poor health status (n = 3). Some participants had no issues at all (n = 23).

**Facilitators of Behavior Change Maintenance**

Participants were asked to describe what needs to be done to continue the behaviors they learned throughout the program. Themes that emerged from the participants’ responses were prioritization of healthy behaviors (n = 34), personal motivator or support (n = 13), staying healthy (n = 12), habit formation (n = 11), reminders or check-ins from study staff (n = 11), an increased awareness or understanding of health and health behaviors (n = 9), and achieving and maintaining independence with regard to cooking for themselves and identifying stable housing (n = 5).

**Benefits of Participation**

In their responses to the exit interview questions, participants described how participation in the program benefited them personally, including improved health, improved QOL, feeling better, etc. Motivation (n = 5) was identified as a theme and was used when
participants stated that being involved in the program encouraged them to make positive changes to their diet, health, or overall well-being. There were 3 participants from the control group and 2 from the AHB group who stated that motivation was a benefit of participation.

**Helpful Aspects of the Program**

Participants were asked to describe things about the program that they thought were most helpful to them with regard to changing behaviors. The following themes emerged from the participants’ responses: the information provided (n = 44), including eating habits (11 out of 44); receiving feedback about health, including specific results from laboratory testing results (n = 24); the classes in general (16 out of 44); the discussions in the AHB sessions, including the opportunity for discussion and fellowship with other African American men (n = 10); the cooking and exercise demonstrations (n = 10); self-monitoring tools, including pedometers, PA monitors, and tools to monitor nutrition intake (n = 8); every aspect of the program (n = 6); simply being able to participate in the program (n = 4); the questions/questionnaires (3 out of 44); and the postcards sent in the mail (3 out of 44).

**Facilitators or Enablers of Program Attendance**

Participants were asked to describe or give their perceptions on what facilitated program attendance. Themes that emerged from the participants’ responses were having time to participate in the program and the staff’s flexibility with identifying times for program sessions and data collection visits (n = 24); making the program a priority (n = 23); their relationship with the staff (n = 14); enjoyment of the sessions (n = 13); having free time or a flexible schedule (n = 11); the location (n = 9); using study-provided transportation (n = 4); their relationships with other men in the group, including social support and accountability (n = 3); desire to improve poor health status (n = 2); and having transportation (n = 1).

**Enablers or Facilitators of Health Behavior Change**

Participants’ responses pertaining to enablers of health behavior change came from the question, “What made it easy to change your health habits?” Responses also emerged from
other questions relating to what they liked about the program. The themes that emerged from the participants’ responses included the following: making the program a priority (n = 24); accountability to the other men in the program, the leaders of the program, friends, family, and/or one’s self (n = 18); support of family, friends, or others outside the program (n = 18); the education, knowledge, or information they received about health, diet, PA, etc (n = 16); poor health as a motivator for behavior change (n = 11); no enabler to change (n = 6); support from men within group, listening to the men’s stories, and learning from other men in the program (n = 5); enhanced skills such as cooking or PA that they learned through the program (n = 4); recipes learned (n = 3); and self-monitoring of diet or PA (eg, use of pedometer to track PA; n = 3).

### Negative Aspects of the Program or Study

Participants described negative aspects of the program throughout their responses to interview questions. There was no interview question that directly asked participants what they felt were the least favorable components of the study. Two main themes emerged from their responses—location and not being able to participate in the AHB sessions. When participants in the control group said that they wished they could have attended AHB sessions or discussed not being assigned to the AHB group, their responses were categorized as being a negative aspect of the study (n = 14). Responses were categorized to the location subtheme when participants described the location of the program as a negative aspect or something that made them like the program less (n = 1). The participant who stated he was not pleased with the location was randomly assigned to the control group. One participant assigned to the intervention discussed having not been a part of the intervention sessions.

### Least Helpful Aspects of the Study

Participants were asked to describe the least helpful aspects of the study (not limited to the AHB group). Two subthemes emerged from their responses: no least helpful aspects and the paperwork. We defined “no least helpful aspects of the study” as when participants indicated they could not think of any unhelpful aspects or commented that they found every
aspect to be helpful (n = 46). Nine participants discussed having too much paperwork to complete or generally referenced paperwork as an unhelpful aspect of the study.
DISCUSSION

This study was designed to test the impact of a 6-month behavior change intervention (AHB) on lifestyle behaviors, health-related clinical markers and QOL outcomes, and mediators of behavior change compared with a 6-month information-only control group. The study was powered to detect a 30-minute/day difference in daily minutes of PA (primary outcome) between AHB and control participants immediately postintervention (primary end point). Participants were followed for an additional 6 months (ie, 12 months postrandomization) to observe the long-term impact of the AHB intervention, compared with the control condition, on study-related outcomes.

A total of 333 African American men were randomly assigned for participation in the AHB program. To date, this is the largest randomized, controlled community-based chronic disease intervention focused exclusively on African American men to be conducted in the United States. A 2014 systematic review of health behavior interventions among African American men identified only 17 publications from 14 studies published before January 1, 2013; only 4 of the studies were specifically designed for and focused on African American men. A 2018 review of PA interventions with African American or Latino men identified 9 articles representing 7 studies, 3 of which focused exclusively on African American men. Sample sizes for the studies identified in the 2 review papers ranged from 31 to 479; all but 1 of the studies were uncontrolled and the largest study (N = 479 participants) was noncommunity based. Although the current study is the largest of its kind among African American men (N = 333 participants), despite our best efforts we were unable to recruit and retain enough participants to have sufficient power to detect a difference of ≥30 minutes per day in PA between AHB and control participants. The under-recruitment reduced our power to detect small changes in PA between randomization groups.

The primary outcome on which the current study was powered was daily PA, and we used an accelerometer to assess daily PA intensity levels. To our knowledge, ours is the first intervention study focused on African American men to assess PA using an objective measure. We did not observe any statistically significant between-group differences in light-, moderate-,
or vigorous-intensity PA or sedentary behavior at any time point. Interestingly, accelerometer-assessed PA levels trended in the anticipated direction (reduced sedentary behavior, increased light- and moderate-intensity PA, and total PA), even though changes were not large enough to reach statistical significance. To our knowledge, there are no intervention studies focused on African American men that reported accelerometer data with which to compare our findings, highlighting the need for additional studies that use objective measures to assess outcomes of interest.

Daily walking was also assessed as a measure of PA in the current study at baseline, 6 months, and 12 months. At baseline, participants walked an average of 4408 ± 1478 steps/day (AHB) and 4355 ± 1297 (control) and met the definition of sedentary (defined as <5000 steps/day); daily walking was assessed by pedometer. Immediately postintervention, we observed statistically significant within-group changes in pedometer-assessed daily steps among AHB and control participants. Curiously, the average increase among AHB participants was 1610 ± 2763 steps/day and the average increase among control participants was 2279 ± 3817 steps/day. At 12 months, we observed statistically significant between-group differences in PA that favored the control group rather than the AHB group.

For the current study, we expected to see changes in accelerometer-assessed total daily PA in line with changes in daily walking. One reason that we did not observe the changes we expected could be because our sample size, and the number of participants who were retained at each of the follow-up data collection visits, did not provide sufficient power to detect between-group differences in accelerometer-assessed daily PA that were <30 minutes per day. Another reason that we did not see a difference could be the tools used to track daily PA among AHB participants. In the current study, AHB participants received a Vivofit, which allowed them to monitor daily step counts on the watch. Information about PA intensity level was also available, but the information required use of the program app and a computer to view the information. Several of the study participants expressed difficulty with using the app function. It is possible that participants focused on achieving step count goals, which they could monitor in “real time” using the Vivofit, to the exclusion of PA intensity-related goals. The lack
of statistically significant findings is in line with a previous study we conducted with African American women, where we found statistically significant increases in pedometer-assessed walking but no changes in accelerometer-assessed PA. As with our previous study in women, it is also possible that men in the current study perceived that they were engaging in more PA than was actually occurring. As mentioned, at baseline, study participants had low activity; any increased PA could have been perceived as more intense than it actually was.

The average daily step count in the current study was 6048 ± 3048 (AHB) and 6706 ± 3678 (control) after 6 months, moving participants from the sedentary to the low-active category. While the increase among control participants was slightly larger than the increase among AHB participants after 6 months, the difference was not statistically significant. At 12 months, the average daily step count for both groups was 6291 ± 2808 (AHB) and 7264 ± 3160 (control); after 12 months the increase among control participants was significantly greater than the increase among AHB participants (P = .03). Although both groups remained in the low-active category, control group participants came close to meeting the definition of “somewhat active” (7500-9999 steps).

We were somewhat surprised to observe no differences in daily walking among AHB participants compared with control participants at 6 months and greater increases among control participants compared with AHB participants at 12 months. We note that all participants received general health education at baseline, which included verbal and written information about the recommended level of PA for adults, along with a written guide for increasing PA. Anecdotally, we observed that most control participants expressed disappointment at not being assigned to the AHB group and vowed to improve their health on their own. Many control participants also reported purchasing PA monitoring devices (eg, a Fitbit) to track their daily PA. It is possible that control participants who wanted to be assigned to the intervention may have been motivated to increase PA on their own, thus masking any potential benefits that would have come from being assigned to the AHB group.

Our findings are in line with other studies focused on African American men that implemented interventions focused on, or including, changing PA levels. In an 8-week pilot
intervention focused on increasing PA among 31 African American men (no control group), participants experienced statistically significant within-group increases in self-reported moderate to vigorous PA and overall weekly PA (the pilot study was cited in both of the aforementioned review papers and was the basis on which the current study was designed).\textsuperscript{36} A 6-week intervention that included 42 African American men and implemented 6 culturally tailored obesity and diabetes education sessions, workout activities, healthy eating/lifestyle demonstrations, and identification of health care providers and community resources (no control group) found within-group increases in self-reported weekly PA and decreases in overweight/obese status.\textsuperscript{20} Men on the Move\textsuperscript{64} and Men on the Move–Nashville\textsuperscript{65} recruited 41 and 40 African American men, respectively, to participate in a male-focused PA intervention; both studies implemented a single group pre-post-test design with no control group. Men on the Move showed statistically significant within-group improvements in perceived self-efficacy to sustain PA, endurance, overall health status, and perceived stress. Men on the Move–Nashville showed statistically significant within-group increases in self-reported levels of light, moderate, vigorous, and sports-related PA, total minutes of PA, caloric expenditure, and high-density lipoprotein cholesterol, and significant decreases in weight and body fat percentage.

The current study found statistically significant improvements in self-reported daily sodium intake, intake of calories from saturated fat, and total fat intake scores. Improvements in sodium, saturated fat, and total fat were significantly greater among AHB participants than among control participants. Our findings of improved nutrition measures are in line with previous studies among African American men. A study of 192 African American men from 30 neighborhoods focused on reducing risk factors for cardiovascular disease and anger management over a 6-week period (no control group) and found positive improvements in consumption of fruit juices, fruits, and vegetables, and reductions in consumption of fried potatoes, French fries, and potato chips.\textsuperscript{66} An 8-month RCT that compared the effect of brochure plus telephone education on prostate cancer (control) with brochure plus tailored telephone education on fruit and vegetable intake (intervention) among 479 African American men who were part of a health care union found that intervention participants consumed more
daily servings of fruits and vegetables, fruit alone, and vegetables alone compared with control group participants.\textsuperscript{67} It is possible that men enrolled in the current study focused more attention on health behaviors in which they felt they needed the most improvement. Although many participants were comfortable with their understanding of PA anecdotally, most expressed some concerns about their nutrition knowledge and cooking skills. Within the intervention, the cooking demonstrations were the most popular sessions, and it is possible that participants were more motivated to implement new skills learned rather than PA, which most participants felt they had mastered.

We also observed improvements in systolic and diastolic blood pressure and cholesterol among AHB participants after 6 months, with significantly greater reductions in systolic blood pressure among AHB participants compared with control participants. The changes in blood pressure and cholesterol are in line with the self-reported changes in sodium and fat intake. Although the current study was not designed to serve as a comprehensive blood pressure reduction program, our findings are in line with other studies that focused on reducing blood pressure among African American men.\textsuperscript{68,69} Given the absence of significant improvements in PA and the concurrent improvements in several nutrition-related factors, it is plausible that the improvements in health-related clinical markers can be attributed to changes in diet. Additional research is needed to confirm these findings.

Subpopulation Considerations

The current study focused specifically on African American men. Additional exploratory analyses of the current study data set are underway that will include consideration of subpopulations within African American men in the study group. Examples of subpopulations that will be explored include adherers vs nonadherers to randomization assignment, age, education level, family structure, and other factors that will be selected based on statistical considerations and a priori knowledge of factors known to influence our outcomes of interest.
Study Limitations and Strengths

The current study had some limitations that could have impacted our findings. While recruitment in the current study was higher than any other community-based RCTs focused on African American men and chronic disease, we fell short of the original goal of recruiting 400 participants. The study staff employed every strategy suggested internally and externally to recruit participants. Recruitment efforts were expanded to a larger geographic area to help increase participation in the study. Expansion to satellite locations caused the study staff to travel frequently for data collection appointments and intervention sessions, so to ensure coverage for participants at the original site, the staff had to be strategic about scheduling. Office hours were extended so that early morning and late evening appointments were offered. This allowed participants with varying schedules to complete their data collection.

Despite our best efforts, many unforeseen circumstances that directly and indirectly affected African American men impacted our recruitment efforts, including flooding at 1 site due to a hurricane, ice storms that impacted recruitment events, rioting near recruitment events because an African American man was killed by a police officer, picketing in 1 city because an African American man was assaulted in his home by a police officer, and personal tragedies that impacted study team members and thus impacted their availability for recruitment. A key lesson learned is that engaging patients as part of the investigative team means that team members are impacted by many of the negative health concerns and social determinants that plague the population being researched. While the “insider” perspective of patient researchers is key, it is important to understand the unintended impact on study implementation.

Participation at each of the follow-up data collection visits was poor. After 6 months, only 91 and 119 AHB and control participants completed data collection (54% and 72%, respectively). After 12 months, 102 AHB and 115 control participants completed data collection (61% and 70%, respectively). The poor attendance at the data collection visits impacted our ability to detect statistically significant findings because of small sample size. Future analyses will explore the impact of the AHB intervention among those who actually attended
intervention sessions at various levels (eg, 1-9 sessions [low attenders] vs 10-16 sessions [high attenders]).

Although intervention sessions were implemented as intended, 25% of AHB participants did not attend any sessions. Essentially, this means that these AHB participants received the same basic education as the control participants. Among those who attended at least 1 AHB session, participants only attended 61% of the sessions. As indicated in the qualitative findings, participants frequently cited time and competing priorities as reasons for missing AHB sessions and data collection visits. We also learned from several participants that transportation was a major barrier to attending study-related appointments and AHB sessions. Even when participants did not indicate transportation as a barrier, the study staff were able to identify the issue based on participants’ behaviors (eg, participants arriving to appointments at least an hour in advance or remaining on site after sessions, until their transportation arrived). To mitigate this barrier, the project staff used toolkit funds to provide transportation to some participants in the form of cab arrangements and bus passes. Providing transportation enabled participants to attend sessions without having to be excessively late or completely missing scheduled study-related activities. Some participants provided support to each other by carpooling.

All participants in the current study received basic health education, including results from baseline data collection, an explanation of the findings, and health education via video that featured African American male health care providers. It is possible that the level of detail provided in the health education materials and the culturally sensitive health education video provided sufficient motivation for control participants to engage in health-related behaviors at the same level as AHB participants, which could have masked differences between AHB and control participants.

Finally, we note that participants in the current study were recruited from a single state in the Southeastern United States. Findings may not be generalizable to men from other states or to men who are not African American.
The current study has several major strengths, including the focus on a high risk population, the successful recruitment of 333 participants, trends in the appropriate direction for between-group improvements in other outcomes of interest, the positive impact of the AHB intervention on nutrition-related behaviors, and the use of objective measures to assess PA change. To our knowledge, this is the largest study focused on improving individual-level health-related behaviors associated with chronic disease in a community-based setting among African American men.
The aim of the current study was to determine the impact of the 6-month AHB program, compared with a health education control condition, on health-related behaviors associated with chronic disease among African American men. The study identified several within-group improvements in nutrition-related behaviors, daily steps, blood markers, and blood pressure. The study also identified between-group improvements, favoring the intervention, for nutrition-related behaviors. Despite these positive findings, most outcomes, including the primary outcome (daily PA assessed with an accelerometer) were not statistically significant. The lack of significant findings could be attributed to limited participation in AHB sessions among participants randomly assigned to the intervention, and attrition at follow-up visits, which led to reduced power to detect statistically significant differences between AHB and control group participants. African American men are at high risk for chronic diseases associated with poor health-related behaviors. Because African American men have historically been a relatively understudied group, little is known about effective strategies for engaging them in research and improving health-related behaviors. This study contributes to the knowledge of methods that can be used to conduct research and improve health among African American men. If successful, these strategies may serve to reduce disparities in chronic disease between African American men and other population subgroups.
REFERENCES


23. Courtenay WH. *Dying to Be Men: Psychosocial, Environmental and Biobehavioral Directions in Promoting the Health of Men and Boys*. Routledge; 2011.


<table>
<thead>
<tr>
<th></th>
<th>Reference</th>
</tr>
</thead>
</table>


ACKNOWLEDGMENTS

The authors acknowledge the support of the many individuals who were instrumental in ensuring the successful implementation of the AHB programs including the following.

Advisory Team

- Mr Alvin Atkinson, Mr Bob Brower, Mr Antonio Davis, Mr Melvin Hinson, Rev. Anthony Jones, Mr Gary Lash, and Mr Lydell Thompson

Group Leaders

- Mr Larry Aiken, Mr Kenneth Archie, Mr Alvin Borders, Mr Raymond Glover, Mr Vernard Lowery, and Mr Samuel Thomas

Study Recruiters

- Mr Larry Aiken, Mr Sabur Abdul-Baqui, Ms Felecia Bennett-Giles, Ms Angela Burroughs/Ethos Excel, Dr Josh Kirven, Ms Crystal Dixon, Mr Tone Muhammad, and Mr Ervin Wilson

Pilot Study Participants

- Mr Larry Aiken, Mr Horace Bonner, Mr Raymond Glover, and Mr Lester Whitt

Study Team Members

- Mr George Bailey, Mr Tim Haskins, Ms Melissa Higgs, Ms Yashonda Mobley, Ms Betty Morton, Mr Sean Neville, and Ms Millicent Woodruff

Study Consultants

- Dr Jamy Ard, Dr Alain Bertoni, and Dr David Mount
APPENDIX: CODING MANUAL
Active and Healthy Brotherhood Program
Coding Manual

1. Perceptions about study- This is the parent node or code for responses to the question “What did you think about being part of a research study?” This code represents the category but can also be used to capture program perceptions that do not fit below.
   a. Satisfied with program – Use this code when participants indicate they liked the program, loved the experience, it met their expectations, it was “on par” or other similar phrases about the program.
   b. Exceeded expectations- Use this code when participants indicated the program exceeded their expectations, was better than their expectations or other similar phrases
   c. Expectations not met- Use this code when participants explain why the program did not meet expectations
   d. Unsure – Use this code when participants express that they were either uncertain about what to expect from participating in the program and/or if their expectations were met.

2. Positive aspects of program- Use this code when the participants describe specific aspects of the program they liked or increased their satisfaction with the program. Information coded here may include responses to the question, “Is there anything else you want to tell us about the program?”
   a. Comradery or relationship building- Use this code when participants describe the relationships, friendships, support of other male participants, or comradery as an aspect of the program they particularly liked.
   b. People who delivered the program- Use this code when the participants describe positive characteristics of the individuals who delivered the program. For example, “People real friendly and they...they concerned. They seem like they care about your well-being”
   c. Discussions- Use this code when participants describe the discussions as an integral or useful part of the program
   d. Location- Use this code when participants describe the location of the program as a positive aspect or something that made them like the program more e.g. nice environment, easy to get to, etc.
   e. Enjoyment- Use this code when participants indicate they liked or enjoyed the program
   f. Meets needs of black community- Use this code when participant describes the program as meeting the needs of the Black community (e.g., imperative to promote health in black community, important to educate about good health habits)

3. Negative aspects of the program or study- Use this code when the participants describe specific aspects of the program or study they disliked
   a. Location- Use this code when participants describe the location of the program as a negative aspect or something that made them like the program less
   b. Didn’t get to participate in the sessions- Use this code when participants indicate they wish they could have attended the sessions or they didn’t get assigned to the group
they wanted

4. Screening Process Perceptions – This is the parent node or code for responses to the question, “What do you remember about the screening process you went through to get into the program?”
   a. Advertisements- Use this code when the participants describe aspects of the advertisement or recruitment process used to enroll participants including how participants heard about the study (e.g., word of mouth, location of flyers or brochures, etc.)
   b. Assessments- Use this code when participants describe remembering the assessments or measures taken as part of the screening process. This can include the self-reflective nature of the assessment process (e.g., brutally honest reflection)
   c. Ease of screening process- Use this when participants describe the process as good or easy, not challenging, enhanced likelihood of study participation, etc.
   d. Screening process challenges- Use this code when the participants describe challenges experienced during the screening process or things that made the screening process difficult
   e. Message Framing – Use this when the participant describes the messages or advertising as the right balance of scientific versus layman terms, positive rather than negative, focused on the African-American community or other aspects of the messaging or advertisement from the screening process. This is not to be used when participants describe challenges they experienced with the screening process such as not hearing about the study.
   f. Don’t remember - Use this code when participants indicate they don’t remember a lot about the screening process.
   g. No screening - Use when participants state that they weren’t screened. Do not use when participants indicate they don’t remember what the screening process was.
   h. Incentive- Use this when the participant discusses receiving money or any other incentive as a reason for joining the program

5. Barriers to program participation- This is the parent node for responses to the question, “What made it hard for you to attend data collection visits and study sessions?”
   a. Competing responsibilities- Use this code when participants describe competing responsibilities as a barrier to participating in the program or data collection
      i. Work
      ii. Schedule
      iii. Other social commitments
   b. Transportation- Use this when the participant describes a lack of transportation to/from the program as a barrier to participation
      i. No transportation
      ii. Bus issues
   c. Location- Use this when the participant describes the physical location or distance to the program as a barrier to participation
      i. Distance from work
      ii. Traffic
   d. Health- Use this code when the participant describes their health conditions or illnesses as a barrier to participation
e. No issues- Use this code when participants had no issues with program participation or indicates they did not experience any barriers to participation
   i. Schedule availability-Use this when participants describe their schedule as making it easier to attend data collection visits and study sessions

6. Facilitators or enablers of program participation- This is the parent node for descriptions or perceptions about what made it easy or helped participants to take part in the PROGRAM. This does not include factors that made it easy for participants to change their health behaviors; there is a separate node for enablers of behavior change.
   a. Priority- Use this code when participants indicated they made the program a priority, set their minds to it or similar ideas as a facilitator or enabler of program participation
      i. Scheduling
      ii. Putting forth effort
   b. Time-Use this when participants describe the time of day the program was offered or factors related to the program schedule as factors that enabled or facilitated program participation
      i. Staff flexibility
      ii. Personal schedule availability
   c. Relationships with men in groups- Use this code when participants describe the relationships formed with other men, social support of other men, accountability to or comradery with other men, or intimacy of meetings as factors that facilitated participation in the program
   d. Transportation- Use this code when participants describe having transportation including use of public transportation as facilitators to program participation. If the participants indicate that receiving transportation opportunities from the study code as study provided transportation
   e. Study provided transportation- Use this code when participants describe having access to transportation vouchers, bus passes, shared rides, and/or taxi service as a means to attend program and/or staff taking to and from the program as a facilitator of program attendance.
   f. Enjoyment- Use this code when participants describe liking or enjoying the program as a factor that contributed to program participation
      i. Just participating
      ii. Seeing results
   g. Health status- Use this code when participants describe a health condition, illness or concern as a motivator to attend the program (e.g., diagnosis of type 2 diabetes)
   h. Availability- Use this code when participants indicate program attendance was due to having free time.
      i. Being retired
      ii. Not having a job
      iii. Schedule flexibility or availability
   i. Location- Use this when participants describe the location or distance to the program as being helpful to their participation
      i. Proximity of location
   j. Relationships with staff- Use this code when participants describe the relationships created with staff members or the intimacy felt from meetings in facilitating their
participation
i. Flexibility of staff
ii. Reminders
iii. Personality of staff

7. Health Behavior Changes- This is the parent node for participants’ descriptions of the changes they made to their health behaviors (e.g., started eating healthier, started moving more, did not make any changes to health behaviors). Please use the child nodes below as appropriate.
   a. Reinforced health behaviors - Use this code when the participants indicate they did not make changes to their health behaviors, their behaviors remained the same, they were already engaging in good health behaviors before the program and didn’t really make additional changes, etc.
   b. No changes made- Use this code when participants describe not making any changes to their health behaviors. Note, this code is only applied when participants say they did not improve or change their health behaviors. If they say they were already engaging in good health behaviors and the program reinforced these behaviors it should be coded under reinforced health behaviors
   c. Changed diet- Use this code when participants indicate they changed any aspect of their dietary behaviors such as decreased fat intake, improved fruit and vegetable intake, etc.
   d. Changed physical activity – Use this code when participants indicated they increased or changed their physical activity or exercise behaviors due to program participation (e.g., walking more, parking further away, taking the stairs, etc.)
   e. Increased knowledge- Use this code to capture when the participants describe increasing their knowledge, understanding, or awareness of health or health behaviors as a result of program participation but also indicate they did NOT change their health behaviors
   f. Other health behaviors- Use this code to capture behaviors other than physical activity or diet that changed or improved as a result of the study

8. Barriers to health behavior change- Use this when participants describe barriers or changing health behaviors. This is different from maintaining the health behavior changes learned in the program.
   a. Health- Use this code when participants describe or indicate their current health condition, illness, etc., as barriers to health behavior change.
   b. Time or competing responsibilities- Use this when the participants describe a lack of time to engage in physical activity, healthy eating, or other behaviors as a barrier to changing their behaviors. This can include statements such as “my schedule”, “my job”, or other responsibilities that hindered behavior change
      i. Job or work schedule
      ii. Financial instability
      iii. Family
   c. Availability of food- Use this when participants describe not having enough food to eat as a barrier to health behavior change (also not having healthy foods available)
      i. Finances
   d. No barriers to change- Use this when the participants indicate they did not have any difficulties, challenges, or barriers to changing their behavior
   e. New habit- Use this when the participants describe learning a new habit or learning to do
something new as a barrier to changing the behavior.

i. Eating habits or food-This can include when participants have to give up something they like (e.g., sweets) to achieve health behavior change.

f. Lack of motivation- Use this code when participants indicate difficulty changing health habits due to lack of motivation from self or others.

i. Group-Use this when participants discuss the group as a mechanism that could have possibly held them accountable as an individual.

g. Lack priority- Use this code when participants describe or indicate they did not make changing health behaviors (physical activity, healthy eatings, or other behaviors) a priority or as something important in their life. For example a participant may state, “I didn’t make the sacrifices…” or “I didn’t carve out time in my schedule to exercise.”

i. Remaining conscious of healthy foods

ii. Mindset-willpower

9. Enablers or facilitators of health behavior change- Use this code when the participants provide a response to, “What made it easy to change your health habits?” This may also emerge from other questions such as what did the participants like about the program.

a. Information provided- Use this when participants describe the education, knowledge or information they received about health, diet, physical activity, etc. as important or useful for changing health behaviors. This can include having the use of a program manual as a source of information. It can also include when a participant indicates the materials helped reinforce current health behaviors.

b. Support from others- Use this when the participants describe the support of family, friends or others outside of the program as facilitators or enablers of behavior change. This should not include the support of men IN the program.

c. Skills- Use this when the participants describe enhanced skills such as cooking or physical activity related skills as an enabler for behavior change

i. Yoga

d. Recipes- Use this when the participants describe the recipes provided as a facilitator or enabler of behavior change

e. Self-monitoring- Use this when the participants describe self-monitoring of diet or physical activity (e.g., use of a pedometer to track physical activity) as an enabler of behavior change.

f. Priority- Use this code when participants indicate the need to take initiative, recognize the importance of behavior change, make it a priority or other similar phrases. Do not use this code when participants indicate they are making the change for health reasons. Code this to enablers, health status.

g. Support of men within group- Use this when participants describe the support of the men in the program, listening to the men’s stories, learning from the other men in the program as helpful in the behavior change process.

h. Health Status- Use this code when the participants describe a health issue (diabetes, prediabetes, bad back, etc.) as a factor that motivated them to change health behaviors or when they indicate they are making a change for health reasons (better one’s health)

i. Outward appearances

ii. Awareness

i. Accountability- Use this when the participants describe being accountable to others as a
facilitator of behavior change. This can include accountability to the other men in the program, the leaders of the program, friends and family or one's self.

j. No enabler to change
i. Experienced difficulty

10. Helpful aspects of the study- Use this code in response to the question, “What things about the study were most helpful to you?”
   a. Enjoyment- Use this code when the participants describe liking or enjoying the program as positive or helpful aspects of the study
   b. Feedback- Use this code when the participants describe receiving feedback about health or health as a helpful aspect of the study.
      i. Clinical results- Use this code when participants describe getting feedback from lab work or lab results as helpful to them.
   c. Being able to participate- Use this code when the participants describe having the opportunity to participate or having the program available as most helpful.
   d. Information provided- Use this code when participants describe the information they received from participating in the program as the most helpful aspect of the study.
      i. Questionnaires
      ii. Postcards
      iii. Eating habits
   iv. Classes (intervention sessions) in general
   e. Discussion- Use this code when the participants describe the discussions as the most helpful aspect of the program
      i. Fellowshipping with guys
   f. Everything - Use this code when participants indicate that everything about the study or “all of it” was helpful.
   g. Self-monitoring-Use this code when the participant describes the use of tools to monitor physical activity (e.g., accelerometer or pedometers) or diet as helpful part of program or study
      i. Encouragement
   h. Demonstrations- Use this code when participants indicate the session demos were helpful aspects of the study
      i. Exercise
      ii. Cooking
      iii. Both (cooking and exercise)

11. Least helpful aspects of the program
   a. No least helpful aspects identified- Use this when the participants indicate they cannot think of any unhelpful aspects of the program or every aspect of the program was helpful
   b. Paperwork- Use this when participants discuss having paperwork or too much paperwork as an issue of the program

12. Facilitators of behavior change **maintenance**- Use this code when participants describe what needs to happen to **continue engaging** in the behaviors they learned
   a. Habit formation- Use this when the participants indicate they have made a habit out of
the health behavior, they have the health behaviors “down pat”

i. Independence

b. Priority- Use this when the participants describe the need to make the health behavior change a priority in their life in order to maintain the behavior change

i. Being aware of actions

ii. Beginning habit formation

iii. Age as a factor

c. Independence-Use this when participants indicate they need to do more on their own or take charge of their own health (cooking for themselves, housing stability and/or living on their own).

i. Stop depending on others

d. Staying Healthy- Use this code when participants describe wanting to maintain their health or stay healthy (e.g., stay healthy, prediabetes not becoming diabetes, etc.) as motivators for maintaining the behavior changes (e.g., diet or physical activity)

i. Already have health issues or physical ailments

e. Knowledge or awareness- Use this code when participants describe an increased awareness, knowledge level or understanding of health, health behaviors as a motivating factor for continued behavior

f. Reminders or check-ins- Use this code when participants state receiving a reminder or check-in will ensure behavior change maintenance.

i. Phone calls

ii. Mail

g. Personal motivator or support

i. Family

ii. A partner

13. Benefits of Participation- Use this node when participants describe how participation in the program has benefitted them personally including improved health, improved quality of life, feeling better, etc. Please note this is not to be used to describe changes in behavior (e.g. improved diet or physical activity)

i. Motivation- Use this code when participant states that being involved in the program encouraged them to make positive changes to their diet, health, or overall wellbeing.

14. Not sure where to code- Use this code when there is a quote or passage that doesn’t seem to fit into the coding scheme or you aren’t sure where it should go. Then, in the memo section, copy and paste the quote to the memo with a potential new code name and your thoughts about the quote.

15. Excellent quote- Use this node to capture examples of excellent quotes that illustrate a concept

16. Misinterpretations about the study- Use this code when participants indicate events that were not accurate to the study or were not what they expected (Only staff affiliated with the study will be able to ascertain this information)

17. Participation status

   a. Intervention

   b. Control

Disclaimer:
The [views, statements, opinions] presented in this report are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

Acknowledgment:
Research reported in this report was funded through a Patient-Centered Outcomes Research Institute® (PCORI®) Award (#AD-1403-11098). Further information available at: https://www.pcori.org/research-results/2014/testing-program-increasing-healthy-behaviors-among-black-men