Challenges to recruitment and retention of African Americans in the gene-environment trial of response to dietary interventions (GET READI) for heart health

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Abstract

In this paper, challenges to recruiting African Americans specifically for a dietary feeding trial are examined, learning experiences gained and suggestions to overcome these challenges in future trials are discussed. A total of 333 individuals were randomized in the trial and 234 (167 sibling pairs and 67 parents/siblings) completed the dietary intervention and required DNA blood sampling for genetic analysis. The trial used multiple strategies for recruitment. Hand distributed letters and flyers through mass distribution at various churches resulted in the largest number (n = 153, 46%) of African Americans in the trial. Word of mouth accounted for the second largest number (n = 120, 36%) and included prior study participants. These two recruitment sources represented 82% (n = 273) of the total number of individuals randomized in GET READI. The remaining 18% (n = 60) consisted of a combination of sources including printed message on check stubs, newspaper articles, radio and TV appearances, screening events and presentations. Though challenging, the recruitment efforts for GET READI produced a significant number of African American participants despite the inability to complete the trial as planned because of low recruitment yields. Nevertheless, the recruitment process produced substantial numbers that successfully completed all study requirements.

Introduction

Achieving recruitment goals within a specified time period for clinical research trials is fundamental and crucial to the research process and especially important in projecting sufficient retention for final data evaluation. Failure to reach and retain the required sample size in the allotted time period reduces power to address the central scientific question and severely constrains ability to examine secondary endpoints [1, 2]. Previous research experience has shown that recruiting minorities into clinical research trials in general can be challenging [3]. Some of these challenges include issues with transportation, work related and family responsibilities, fear and/or suspicion of research institutions and their motives, lack of interest, cultural factors, influence of family members, emotional stress and inconvenience [4–9].

Behavioral trials such as dietary interventions often pose even greater challenges to recruitment. For example, participants must be willing to change their diet, eat at least one meal each weekday at the clinical...
center and eat only foods prepared according to trial specifications during the feeding phase of the trial. In the GET READI trial, investigators sought to identify the link between a healthy diet, genetic factors and their underlying biological mechanisms. To accomplish this task required recruiting two-generational families of African American decent. Thus, an added recruitment challenge for the GET READI trial was that it required sibling pairs, or occasionally triads that further compounded the challenge because individually one size and taste, does not fit all.

Published literature on recruitment of African American participation in research on genetic risk factors was limited even though attitudes about genetic testing may be less favorable [10–12]. For example, only 15% of African American women enrolled in a cancer genetics registry compared with 36% of Caucasian women [13, 14]. Furthermore, African Americans are reluctant and less likely than Caucasians to provide consent for their blood samples to be included in a national registry for genetics research [15]. Although many articles are published on recruitment of African Americans generally into clinical research trials [16, 17], there is a paucity of published data on recruitment for dietary feeding trials [18]. Though labor intensive and challenging, the few published dietary feeding trials involve multicenters and provide less on challenges and more on success stories for recruitment of minorities [1, 19]. In this paper, challenges to recruiting and retaining African Americans specifically for a dietary feeding trial are examined, learning experiences gained and suggestions to overcome these challenges in future clinical research trials are discussed. This paper adds to the literature regarding challenges in recruitment of African Americans into feeding trials and genetics research.

**Methods**

The purpose of the GET READI trial was to examine the variability in cardiovascular disease (CVD) risk factor response to changes in diet composition known to favorably affect major CVD risk factor levels and to identify both the genetic and non-genetic determinants of this response in two-generational families of African American decent. African Americans were chosen as the target population because in the United States and particularly in the South CVD, associated with hypertension, is the most prevalent cause of death among African American residents [20, 21]. Generally, Louisiana residents who are older, poorer, have lower education or are African American have higher CVD prevalence and are more prone for risk factors of CVD [22]. Unfortunately, this trial was not completed as planned due to low recruitment yields.

Two well-controlled diets were provided to participants: one similar to the average American diet and a diet similar to the Dietary Approaches to Stop Hypertension (DASH) combination diet but with slightly lower levels of total fat and saturated fat [19]. In both DASH and DASH-Sodium multicenter trials [1, 19], a 3-week and 2-week run-in period was required. The GET READI trial was a 12-week randomized outpatient feeding trial. The trial included a 1-week run-in period or ‘practice’ meals to familiarize participants with the routine, followed by 5 weeks of a standard American diet, 1 week break and 5 weeks of a diet high in fruits and vegetables and low fat food items. Order of the two diets was randomized. The run-in period was also used to identify and exclude individuals who did not comply with the trial’s eating and data collection requirements, and to determine for each participant, the appropriate energy level needed to maintain weight. Participants were required to eat the dinner meal at the clinical center served between 4:30–6:30 p.m. each weekday with breakfast, lunch and snacks packed to go daily. After completing the dinner meal on Friday, breakfast, lunch, dinner and snacks for Saturday and Sunday meals were packed to go and included breakfast, lunch and snacks for Monday meals.

In an effort to reduce participant burden, retain and increase enrollment of participants, off-site feeding venues were established late in the recruitment drive in strategic areas of Baton Rouge [East Baton Rouge (EBR) Parish] more convenient and accessible to participants. Two of these feeding venues were launched at churches and an off-site clinical center for feeding and recruitment of former
Bogalusa Heart Study participants was established in Bogalusa, Louisiana; about 90 miles from Baton Rouge. Vans and drivers were secured and hired for the purpose of transporting meals to these various sites. Clinical and off-site centers received prior approval from the institutional review board, an external protocol review committee approved the trial protocol, and each GET READI participant and parent provided written informed consent.

Participants
The GET READI trial aimed to recruit families of African American decent with a minimum of two adult biological siblings. The recruitment goal was to enroll a total of 400 individuals that would provide a minimum of 200 sibling pairs depending on family structure which would require enrolling between 150 and 200 families over the course of 4 years. A secondary goal of recruitment was to enroll 11 sibling pairs of participants per month. This required participants to enroll into cohorts that started and stopped feeding together. Families were selected based on: (i) at least two adult full siblings willing and eligible to participate in a 12-week dietary feeding trial and at least one biological parent available for DNA sampling or (ii) at least three adult full siblings willing and eligible as noted above without regard to the availability of biological parents for DNA sampling. African American men and women aged 18–65 years, willing to eat only foods provided by the trial during the feeding periods, willing to abstain from the consumption of alcohol for 48-hours prior to blood draw days and willing to provide genetic material for testing were eligible to participate in the trial.

Eligibility criteria were selected to exclude individuals with special dietary requirements, those taking medications that would affect cholesterol, blood pressure or micronutrient metabolism, and individuals with other potentially serious chronic health conditions. Participants were required to comply with dietary guidelines and eat at least one meal each weekday at the clinical center. A computer-based randomization process selected diets, and only study foods were permitted during the feeding phases of the trial.

Recruitment sources
Multiple strategies were used simultaneously to recruit two-generational families of African American decent and may have created a spillover effect causing participants to enroll in the trial because of no one specific strategy. While traditional advertisement mediums were heavily used for recruitment, previous recruitment experience for other multicenter feeding trials revealed that more novel, labor intensive and simultaneous strategies were required to recruit African Americans [1, 19].

Hand distributed letters (Fig. 1) and flyers (Fig. 2) through mass distribution at various churches with significant numbers of African American congregants in EBR Parish were the primary recruitment source. To aid in the distribution of letters and flyers at these churches, African American consultants and their staff experienced in and having close ties to the African American community politically, socially and otherwise were hired to assist the clinical center’s recruitment staff in this capacity. Consultants and staff were educated by investigators at the clinical center on the eligibility criteria for GET READI using a PowerPoint presentation. The presentation provided full details of the trial with time allotted for consultants to ask questions and provide answers that would equip them for responding to questions encountered in the field. Consultants and their staff were also provided with a quick fact sheet summarizing the details of the trial while recruiting in the community. The secondary recruitment source was word of mouth and included prior study participants. This approach included talking with co-workers, friends, neighbors and other acquaintances about GET READI. Using the clinical center’s recruitment database, prior study participants were contacted by telephone to inform them of the criteria and to peak their interest for enrolling in the trial.

Other recruitment approaches consisted of mailed letter/flyer/printed message on check stubs, radio story/ad, article print/ad, screening event/presentations and TV story/ad. Mailed letters and flyers were sent to 31 African American presidents of fraternities and sororities in Baton Rouge and surrounding communities to distribute to their combined 2000 plus
Dear Friend: GET READI TO EARN $950

Do you or your family members have high cholesterol or high blood pressure? If so, you and your siblings may be at risk for heart disease. Maybe you know what a challenge it is to control this disease.

Furthermore, can heart and blood vessel disease be inherited? Yes. A tendency toward heart disease or fatty buildups in arteries seems to be hereditary. That means children of parents with heart and blood vessel diseases may be more likely to develop them. Race is also a factor. African Americans have moderate high blood pressure twice as often as Caucasians and severe high blood pressure three times as often. Therefore, the risk of heart disease and stroke increases for African Americans.

Previous research has shown that reducing dietary saturated fat and cholesterol is effective in lowering the risk of heart and blood vessel disease in the general population. And that’s where we come in.

The Pennington Biomedical Research Center’s mission is to promote longer healthier lives through nutrition research, education, and preventive medicine. Our goal is to conduct a 12-week feeding study consuming foods that may lower the risk of heart disease in adults who are at risk.

We won’t ask you to do anything scary or make a life-long commitment. What we’d like to offer is a 12-week vacation from your kitchen. Let us prepare all of your meals and snacks for 12 weeks.

If you and the members of your organization would like to learn more about how to reduce the risk of heart disease and best of all, take time off from the grocery store, the kitchen and fast food lines, please call us today at (225) 763-2644 or (225) 763-3090 to learn more about GET READI including scheduling an appointment. We look forward to talking with you soon!

Sincerely,

Mike Lefevre, Ph.D.
Principal Investigator

6400 Perkins Road, Baton Rouge, Louisiana 70808-4124 • Phone: (225) 763-2500, Fax: (225) 763-2525
members. Mail Comm, a local commercial company, was hired to provide mailing lists of potential African American participants who resided in designated zip codes closest to the clinical center. Additionally, mailed letters and flyers were sent to colleagues and students at the predominantly African American

Fig. 2.
Southern University and A&M College, Baton Rouge, for distribution to students and faculty during registration. Flyers were sent to businesses, organizations and subdivisions housing large numbers of African Americans within a 20 mile radius of the clinical center some of which included banks, corporations, telemarketing companies, community centers, alumni centers, apartment complexes, several subdivisions and many other outlets frequented by African Americans. Finally, a printed message was placed on paycheck stubs of all African Americans employed at Louisiana State University inviting them to enroll in GET READI.

Radio story/ads consisted of 30 s and 1 min commercial ads or spots about the trial to diverse or predominantly African American listening audiences and included jazz, Gospel, soul and light rock radio stations. In addition, several appearances by investigators, clinical center staff and consultants were made on the Jaguar Journal live radio talk show. Listeners were able to call into the show and ask questions about enrolling in GET READI. Two siblings completing the trial gave testimonials on the show about their experience in GET READI to entice others to enroll in the trial.

Late in the recruitment drive the Office of Group Benefits for the State of Louisiana provided an ad free of charge in their booklet listing physicians and other providers for its 100,000 members. The principal investigator (M.L.) was interviewed by the main local newspaper as a public service announcement to launch GET READI. Display and regular newspaper ads were placed in the same local paper and other printed sources in EBR Parish and surrounding communities. Interfax Daily, another printed source, was used to fax information about GET READI directly to businesses and employees, and advertisement billboards were placed inside of the city bus and local malls to attract potential participants.

Although more costly and time consuming, community screening events and presentations were used as an opportunity to recruit participants in the GET READI trial. At each community screening and/or presentation, an overview of the eligibility requirements for enrolling in the trial was provided. The clinical center’s recruitment staff set-up tables with flyers and sign-up sheets and conducted blood pressure screenings at events such as: 100 Black Men back to school expo, Baranco-Clark YMCA, women and men conferences at various churches and clinical centers, employees and clients of the Office of Motor Vehicles, Delmont Service Center (Meet Your Neighbor Day), Southern University’s Homecoming and state Representative Sharon Weston-Broome health fairs and numerous other church sponsored health fairs. An African American investigator (B.M.K.) served as community liaison on the trial and made presentations to employees and visitors at the US Postal Service (main office), EBR Parish Council on Aging, EBR Parish Retired Teachers Association, Department of Health and Hospitals, Department of Labor, Department of Social Services, Louisiana Healthcare Authority, Home Instruction for Parents of Preschool Youngsters (HIPPY), Mayors of the nearby Cities of Baker, Port Allen, St Gabriel, Carville and Brusly, South Baton Rouge and Baton Early Risers Kiwanis groups, Southern University baseball, basketball and football coaches and players (accompanied by NIH program officer, E.B.B. and study coordinator, Y.R.H.). Presentations were also made to faculty and students at Scotlandville and McKinley Magnet, Glen Oaks and Capitol High schools.

The final recruitment source was TV story/ad. The principal investigator appeared on Tune-In and to Your Health popular TV segments to discuss the GET READI trial and to encourage viewers to consider enrolling. Additionally, commercial spots were cast on a local Cox Media Gospel Show.

Recruitment process
The recruitment department consisted of one African American and two non-Hispanic White full time recruiters primarily responsible for screening all potential participants in-person or by telephone. A recruiter administered standard clinical initial screening form consisting of two-pages was completed to determine basic eligibility and interest of those inquiring about the trial. Recruiters also entered all initial screening information into the database, returned all messages left by telephone and
followed up on all potential leads provided by consultants and their staff during the recruitment drive. Three consecutive screening visits (SVs) to the clinical center were required: SV1, SV2 and SV3. Challenges to this process were the number and amount of time necessary to complete each SV. For example, SV1 ranged from 1 1/2 to 2 hours, SV2 (1 1/2 hours) and SV3 was at least 3 hours.

Early activities of the recruitment committee consisted of developing study specific questions, recruitment letters, flyers and other materials necessary for planning and timing of each recruitment strategy. Planning and timing was crucial as the recruiters were also responsible for recruiting as many as 10 or more trials concurrently. Prior to distribution of any recruitment letters and flyers, community stakeholders and lay community leaders were asked to review the materials for acceptance by the African American community. Members of the recruitment committee held weekly meetings and included the principal investigator, other investigators, consultants and staff and program officer via conference call.

The center tracked the number of persons scheduled at each step in the screening process using a computer-based tool developed by the data manager (C.D.M.) and staff to provide updated projections and recruitment sources that worked best during weekly meetings.

As an incentive and retention tool, each participant received items such as (T-shirts, umbrellas, vinyl lunch bags and ink pens). All incentive items were branded with the GET READI Logo. In addition, each sibling completing the feeding trial received a total cash stipend of $950, and each parent/sibling providing a blood sample received a stipend of $20. Siblings completing the first 5 weeks of the study received $300 and balance of $650 at end of study. It was believed that paying stipends in two phases would provide an additional incentive as well as to increase retention.

### Results

Table I depicts the total number of randomized individuals enrolled in GET READI by recruitment source. Hand distributed letters and flyers through mass distribution at various churches through out EBR Parish resulted in the largest number (n = 153, 46%) of African Americans in the trial. The second largest number (n = 120, 36%) were from word of mouth and included prior study participants. These two recruitment sources represented 82% (n = 273) of the total number of individuals randomized in GET READI. The remaining 18% (n = 60) were the result of a combination of mailed letter/flyer/printed

### Table I. Recruitment source and number of randomized (NR) individuals in the GET READI trial

<table>
<thead>
<tr>
<th>Source</th>
<th>Distribution</th>
<th>NR</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Church mass distribution</td>
<td>15 000</td>
<td>153</td>
<td>46</td>
</tr>
<tr>
<td>Word of mouth</td>
<td>200</td>
<td>120</td>
<td>36</td>
</tr>
<tr>
<td>Mailed letter/flyer/printed message</td>
<td>50 000</td>
<td>20</td>
<td>6</td>
</tr>
<tr>
<td>Radio story/ad</td>
<td>210</td>
<td>20</td>
<td>6</td>
</tr>
<tr>
<td>Article print/story/ad</td>
<td>129</td>
<td>11</td>
<td>3</td>
</tr>
<tr>
<td>Screening event/presentations</td>
<td>25</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>TV story/ad</td>
<td>52</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>N/A</td>
<td>333</td>
<td>100</td>
</tr>
</tbody>
</table>

N/A, not applicable.

*Percentage of number randomized (NR).

_items include hand-distribution of letters and flyers.

Word of mouth and prior study participants.

_Items included mailed letters, pay-stub messages and inserts, or single-sheet flyers.

Values represent number of spots and/or events.

Values given as number of days advertisements were printed.
message on check stubs, radio story/ad, article print/ad, screening event/presentations and TV story/ad.

Table II (similar to design used in the DASH multicenter feeding trial) [19] displays the number of visits conducted, number of persons starting run-in and number randomized, along with yields from the preceding visit, prescreening visits and from SV1. Of the 1565 prescreen contacts, 1104 (71%) were eligible to continue the screening process. Of the 1104 who were prescreening eligible, 539 (49%) completed SV1. The remainder (51%) failed to return to clinic for SV1 most likely due to lack of interest. Of the 539 contacts completing SV1, 429 (80%) completed SV2 and, of these, 365 (85%) completed SV3. Once eligible individuals completed SVs two and three, the likelihood of continuing to randomization increased such that 343 (93%) started the run-in phase of the trial. Of these, 333 (98%) of those starting run-in were randomized. The yield from initial prescreen contact to randomization was 21.3% and from SV one to randomization was 61.8%. Of the 539 who attended SV1, 55% were ineligible as a result of lab results (range in cholesterol levels) and 15% were excluded due to other medical exclusions. Another 10% were excluded due to sibling/parent unwillingness to proceed, and 20% decided not to participate due to diet and scheduling issues. The pattern of eligibility tended to be similar by age and gender.

A total of 40 feeding cohorts began over the course of the trial ranging from numbers (1–60) for feeding sites in EBR >Parish and in Bogalusa (150–157). Number of siblings in each cohort ranged from (0–11) and although the goal was to enroll 11 sibling pairs per cohort, only 1 of 60 cohorts in EBR Parish fulfilled that target. Of the 333 randomized participants in the trial, 99 (30%) dropped or were excluded during dietary feeding or the run-in period. Participants dropped or were excluded because one or more siblings were unwilling to proceed and for diet and scheduling issues noted by staff. Of the remaining 234 (70%) completing the trial, 167 (50%) were sibling pairs and 67 (20%) were parents or siblings providing a blood sample for DNA testing.

Selected baseline characteristics of the 234 African Americans completing the GET READI trial along with overall population data for EBR and State of Louisiana are presented in Table III. The average age of participants was 33.4 ± 11.6 years (range 18–64). The mean age of citizens in EBR is 31.5 with African Americans accounting for 40.1% of the population [23]. The overall population in EBR reflects approximately 48% men, with 27% (n = 63), of African American men enrolled in GET READI. Married individuals accounted for 35% as did those who never married in the trial.

### Table II. GET READI recruitment experience by visit/period

<table>
<thead>
<tr>
<th>Period or visit</th>
<th>Total</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%a</td>
</tr>
<tr>
<td>Prescreen contact</td>
<td>1565</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescreen eligible</td>
<td>1104</td>
<td>71</td>
</tr>
<tr>
<td>SV1 completed</td>
<td>539</td>
<td>49</td>
</tr>
<tr>
<td>SV2 completed</td>
<td>429</td>
<td>80</td>
</tr>
<tr>
<td>SV3 completed</td>
<td>365</td>
<td>85</td>
</tr>
<tr>
<td>Run-in started</td>
<td>341</td>
<td>93</td>
</tr>
<tr>
<td>Randomized</td>
<td>333</td>
<td>98</td>
</tr>
<tr>
<td>Yield: prescreen contact to randomizationb</td>
<td>N/A</td>
<td>21.3</td>
</tr>
<tr>
<td>Yield: SV1 to randomizationc</td>
<td>N/A</td>
<td>61.8</td>
</tr>
</tbody>
</table>

N/A, not applicable.

aYield from preceding step.

bPercentage of prescreen contacts who were randomized.

cPercentage of SV1 contacts who were randomized.
In the overall population, EBR shows 34.2% as never married, 47.4% married and similarities to those divorced, widowed and separated in the GET READI trial [23]. Current smoking history for adults (18 years and over) in the State of Louisiana revealed that 20.5% smoke [24] compared with only 7% in the trial. Only 3% in the trial drank alcohol once per week compared with the prevalence of binge drinking in Louisiana at 14.4% [24]. Mean body mass index (BMI) was high, 28.4 ± 5.3 (range 17.3–50.3) for participants enrolled in GET READI with Louisiana having a prevalence of obesity equal to or greater than 30% [24]. The distribution range was wide in blood pressure for both systolic and diastolic measurements. Mean systolic blood pressure was 118.1 mmHg ± 11.7 (range 89–159) and mean diastolic blood pressure 76.4 mm Hg ± 8.4 (range 55–100).

**Discussion**

In this paper, challenges to recruiting African Americans specifically for a dietary feeding trial are examined, learning experiences gained and suggestions to overcome these challenges in future clinical research trials are discussed. The challenges to recruitment of African Americans in GET READI exceeded those experienced by other noteworthy multicenter feeding trials [1, 19]. For example, the DASH and DASH-Sodium multicenter trials presented researchers with dual challenges of having strict dietary requirements (11

### Table III. Baseline characteristics of 234 (167 sibling pairs and 67 parents/siblings) African American individuals in GET READI

<table>
<thead>
<tr>
<th>Age (y), (mean ± SD)</th>
<th>EBR censusa</th>
<th>33.4 ± 11.6</th>
<th>31.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range (18–64)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (%)</td>
<td></td>
<td>27</td>
<td>47.9</td>
</tr>
<tr>
<td>Men</td>
<td></td>
<td>73</td>
<td>52.1</td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marital status (%)</td>
<td></td>
<td>35</td>
<td>34.2</td>
</tr>
<tr>
<td>Never married</td>
<td></td>
<td>35</td>
<td>47.4</td>
</tr>
<tr>
<td>Married</td>
<td></td>
<td>10</td>
<td>9.9</td>
</tr>
<tr>
<td>Divorced</td>
<td></td>
<td>10</td>
<td>N/A</td>
</tr>
<tr>
<td>No answer</td>
<td></td>
<td>7</td>
<td>6.1</td>
</tr>
<tr>
<td>Widowed</td>
<td></td>
<td>3</td>
<td>2.3</td>
</tr>
<tr>
<td>Separated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking history (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
<td>76</td>
<td>Unavailable</td>
</tr>
<tr>
<td>Formerly</td>
<td></td>
<td>9</td>
<td>Unavailable</td>
</tr>
<tr>
<td>No answer</td>
<td></td>
<td>8</td>
<td>N/A</td>
</tr>
<tr>
<td>Current</td>
<td></td>
<td>7</td>
<td>20.5b</td>
</tr>
<tr>
<td>Alcohol history (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
<td>59</td>
<td>Unavailable</td>
</tr>
<tr>
<td>Less than twice a month</td>
<td></td>
<td>29</td>
<td>Unavailable</td>
</tr>
<tr>
<td>No answer</td>
<td></td>
<td>9</td>
<td>N/A</td>
</tr>
<tr>
<td>Once a week</td>
<td></td>
<td>3</td>
<td>5.1b</td>
</tr>
<tr>
<td>BMIc (mean ± SD), Range (17.3–50.3)</td>
<td></td>
<td>28.4 ± 5.3</td>
<td>≥ 30b</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg), (mean ± SD), Range (89–159)</td>
<td></td>
<td>118.1 ± 11.7</td>
<td>Unavailable</td>
</tr>
<tr>
<td>Diastolic blood pressure (mm/Hg), (mean ± SD), Range (55–100)</td>
<td></td>
<td>76.4 ± 8.4</td>
<td>Unavailable</td>
</tr>
</tbody>
</table>

SD, standard deviation

aEBR census data 2000.
cBMI measured as kg m⁻²
and 14 weeks of controlled feeding respectively) with visits to the clinical center 5 days a week and strict eligibility criteria [1, 19]. In addition to 12 weeks of controlled feeding at the clinical or off-site center each weekday, an added challenge for GET READI was that it required full sibling pairs, or occasionally triads that further compounded the challenge. If one of two or two of three siblings had to drop from the trial, all were excluded because of protocol violations. Previous research has shown that African Americans during a random digit survey were more likely than Caucasians to believe that genetic screening would be harmful to society [13]. Perhaps, this is one reason why many siblings/parents were unwilling to proceed through the screening process. Therefore, researchers must do more planning in advance of the recruitment process to provide educational seminars on genetics research and exactly what it entails to create a forum for questions or concerns to be addressed within the targeted community [20].

Although the trial included a 1-week run-in period to familiarize participants with the routine and to exclude individuals who did not comply with the trial’s eating requirements, it was not enough to reduce and/or hinder a sibling(s) from dropping out of the trial. One of the reasons participants dropped or were excluded during the run-in period was due to dietary dislikes. This is not uncommon as participants previously cited repetition of menus as a factor that made it most difficult to meet daily demands, lack of cultural preferences and variety of foods were seen as some of the most difficult dietary factors [25, 26]. It was challenges and obstacles aforementioned that created havoc for investigators and staff not being able to retain participants from inception to completion of the trial. Additionally, variations in cohort number, size and multiple feeding sites had major logistical implications especially for staffing. As a result, the GET READI trial was not completed as initially planned due to low recruitment yields.

Though traditional advertisement mediums were heavily used for recruitment, previous recruitment experience for other multicenter feeding trials suggested that more novel, labor intensive and simultaneous strategies were required to recruit African Americans especially in the GET READI trial [1, 19]. For this reason, multiple strategies were used simultaneously and may have caused participants to enroll for no one specific strategy. Consultants experienced in and having close ties with the African American community and their staff were hired to further assist in this enormous endeavor. Consultants were hired because the clinical center’s research recruiters were additionally responsible for recruiting for as many as 10 other clinical trials concurrently. Hand delivered flyers and distribution of letters at various churches by the clinical center’s recruitment staff and consultants and their staff, yielded the largest number (46%) of participants in the trial. This method was most useful for recruiting GET READI participants at church sites because direct contact with church representatives (pastors, deacons, ministry leaders, etc.) was made to discuss the trial and its importance, along with risks and benefits associated with participation. Research has shown that partnering with churches, community leaders and organizations, including providing logistical assistance or financial enticement may reduce barriers to recruiting minorities into clinical trials [27]. It is likely that this method accrued the largest number of participants because flyers and letters were hand delivered and thus provided a personal touch as opposed to mailing brochures, flyers, etc. as done in other multicenter feeding trials [1, 19]. The challenge to this approach was the amount of time and staff required to implement it. Yet, this method was most beneficial for recruiting African Americans in the GET READI trial regardless of the initial recruitment goal.

Because word of mouth proved to be effective in recruiting African Americans in the DASH multicenter trial [19], the perception was that it would have the same or similar effect in this trial. As a result, the second largest number (36%) of participants enrolled in GET READI evolved from word of mouth and included prior study participants. Word of mouth meant spreading the word about GET READI to co-workers, friends, neighbors, prior study participants and others. Word of mouth has been shown to be extremely effective
in recruiting African Americans as they are likely to participate in clinical trials based on whom they know [28, 29]. Furthermore, when African Americans hear positive messages from others who have completed a clinical trial, they are more likely to take part in similar trials [30]. The challenge to this recruitment approach is that it required conversations with sibling pairs, a parent and/or triads without the availability of a parent for genetic testing; whereas in other and multicenter feeding trials [1, 19], one-on-one conversations with individuals about the trial was the only necessity. Nevertheless, this method and prior method indicate that when recruiting African Americans, to be effective may require more personal interactions [1].

The remaining total (18%) of participants enrolled in GET READI resulted from a combination of mailed letter/flyer/printed message about the trial on pay check stubs, radio story/ad, article print/ad, TV story/ad and screening event/presentations. Although radio story/ad, article print/ad and TV story/ad had the potential to reach large numbers of potential participants, these methods were not as effective when utilized in this trial. For example, placing an ad in the sports section of the local newspaper did not render a large number of African American men in the trial. Likewise, screening event/presentations were not as effective in this trial as was in other multicenter trials [19]. These events included church health fairs and GET READI specific events, often at worksites and occasionally at other community sites, such as back to school expos. The primary advantage to this approach was establishing personal contact early on in the recruitment process. The disadvantage of screening events and presentations included the time and effort required for personnel to staff the event due to concurrent obligations of the trial. In addition, the number of potential participants attending the events was unpredictable and often small. Overall, these combined sources of recruitment were done simultaneously which complimented and enhanced previously discussed strategies [1, 31].

Reasons for participation and non-participation of potential participants and baseline characteristics of those randomized as compared with the general population in the targeted area provide some insights into the types of persons who enrolled in GET READI. Among persons who attended at least the first official SV, the reasons for non-participation were primarily related to medical exclusions, most often too low or high ranges in cholesterol, rather than availability of a sibling/parent. This finding can be explained partially by the fact that persons with a sibling/parent and uninterested in participation could choose not to attend the SV, while much of the medical eligibility, particularly level of cholesterol, could only be determined during a clinic visit.

Trial participants were demographically heterogeneous and reflected the trial’s eligibility criteria. Age distribution range was wide with mean age comparable to the general targeted population, as were several other sociodemographic variables (i.e. marital status, current alcohol history and BMI). Despite avenues such as meetings with coaches at Southern University baseball, basketball and football teams, along with 100 Black Men and men conferences to recruit African American men in GET READI, women far exceeded men in the trial as opposed to the overall general population of men and women being pretty evenly distributed within the targeted area.

Limitations
One of the limitations of this study is that it is not possible to disentangle whether challenges to recruitment are related to the feeding intervention, genetic component and/or research in general. As noted earlier, researchers must do more planning prior to the recruitment process to provide educational seminars on genetics research including focus groups to create a forum for questions or concerns to be addressed especially when targeting African Americans [20, 26]. Another limitation was the unknown educational level of participants recruited for the trial. Perhaps, the level of education had some bearing on understanding the importance of this type research and the benefits that it may have on reducing future risk factors for CVD. Finally, the large number of prescreen contacts revealed a high interest level in the trial but may only indicate great intentions to
participate, as prior research has shown that intentions do not translate into actual participation especially for those involving genetic testing [32, 33].

Conclusions and lessons learned
Despite the inability to complete the trial as planned because of low recruitment yields, recruitment efforts for GET READI produced a significant number of African American participants. Eighty-two percent of those randomized in the trial were a result of African American church sites and word of mouth. Church sites not only served as optimal recruitment sources but also as a place of familiarity, convenience and practical feeding sites.

Free food, money ($950 stipend) or extra-added incentives did not make a difference in retaining participants for this trial. More research is needed especially for dietary interventions requiring only African American participation. For example, food preparation techniques should be examined for cultural preferences so that participation or lack thereof is not based only on dietary dislikes. As a result, dropout rates in future clinical research feeding trials may be minimized. To promote future recruitment of African Americans, researchers must be cognizant of this cultural barrier and acknowledge it and then proceed to overcome it by developing innovative and creative strategies that are culturally and contextually relevant [20, 34].

Lessons learned from this feeding trial experience were the necessity (i) to use a wide range of recruitment approaches including hiring consultants, (ii) to be willing and ready to expand in a timely manner to additional recruitment and feeding sites, (iii) to continuously monitor recruitment yields and strategies and when warranted, make adjustments immediately and (iv) to require a longer than 1 week run-in period to lessen dropout rates during the intervention phase of the trial. In summary, recruitment of a heterogeneous population of African Americans is feasible. However, the effort is substantial and requires simultaneous implementation of several recruitment strategies [19]. Researchers seeking African Americans in future dietary feeding trials involving genetics testing may want to consider a multicenter approach and should plan educational seminars involving the targeted population prior to grant submission. A pre-existing advisory board and other African American constituents along with the churches may create a forum for the community at large to be engaged in the research process, thus developing ownership and buy-in so that collaborative efforts can be leveraged to ease future recruitment and retention challenges especially in trials of this magnitude.

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Conflict of interest statement

None declared.

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