



# Recruitment and Retention of Healthy, Postmenopausal Women of African and European Ancestry: Results from a Dietary Intervention with Repeated Biospecimen Collections

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## ABSTRACT

Recruitment of minority participants to clinical trials, especially studies without therapeutic intent, has been historically challenging. This study describes barriers to and successes of recruitment and retention strategies to dietary studies. A flaxseed study was conducted in healthy, postmenopausal women of African ancestry (AA) and European ancestry (EA) to assess associations between gut microbial community composition and host metabolism (NCT01698294). To ensure equitable participation by AA and EA women, multiple forms of recruitment were utilized, including advertisements, posters, e-mail, word of mouth, and community outreach. Successful recruitment and retention of AA women to the intervention depended upon the specific methods used. AA women compared with EA women were more likely to respond to direct recruitment and community-based methods, rather than general advertisements. However, once women expressed interest, similar rates of consent were observed for AA and EA women (AA and EA: 51.6% vs. 55.7%, respectively;  $P > 0.05$ ), supporting the willingness of minority populations to participate in clinical research. Retention, however, was lower among AA compared with EA women (AA and EA: 57.6% vs. 80.9%, respectively;  $P < 0.01$ ), which may be related to multiple factors, including health reasons, intolerance to flaxseed, noncompliance with study requirements, time constraints, and nonspecified personal reasons. This study confirms the utility of direct community-based strategies for recruitment of diverse populations into nontherapeutic dietary intervention studies. The methods used successfully identified eligible women who expressed willingness to consent to the trial and were able to achieve >70% of recruitment goals for AA women. Future efforts are warranted to improve retention to complex studies. This trial was registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) as NCT01698294. *Curr Dev Nutr* 2022;6:nzac012.

**Keywords:** recruitment, retention, dietary interventions, African ancestry, European ancestry

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Abbreviations used: AA, African ancestry; EA, European ancestry; OCHDR, Office of Cancer Health Disparities Research.

## Introduction

Recruitment of diverse participants to clinical trials, especially studies without therapeutic intent, has been historically challenging (1). Underrepresentation of minority populations threatens the external validity and generalizability of research results. In 1993, the NIH Revitalization Act was passed, which required specific attention to the inclusion of women and minorities in clinical research (2). Despite this legislation, participation by minorities in clinical trials remains low. Among African Americans, participation in NIH clinical research between 2016 and 2018 ranged from 9% to 19%, whereas participation by Whites ranged from 67% to 72% (3).

Many factors contribute to willingness to participate in clinical research. These include trust/distrust, language incompatibility, religiosity, educational level, and socioeconomic factors, as well as concerns by family and community, interest in and awareness of the research, how well the study is explained, study burden, and access to transportation (4–8). A review of the literature describing recruitment and retention strategies among low-income groups, minorities, and ethnically diverse samples between 2004 and 2014 supported the use of community engagement but suggested that community-based participatory research was relatively underrepresented, with 38% of reviewed studies reporting the use of community engagement strategies (5). This review also supported the efficacy of proactive or direct methods, rather than passive

(e.g., advertisements, e-mail) recruitment among minorities (5). More recent studies involving diet reflect the tenets summarized in the 2015 review (9, 10).

In addition to participation in clinical research in general, relatively few studies have addressed the willingness of diverse populations to provide biospecimens. Collection of biospecimens increases study burden and is often associated with issues of trust, confusion about how specimens are to be collected, and whether specimens will be used for non-research purposes (7, 8, 11). Availability of biospecimens from diverse participants in clinical research also contributes to generalizability of research findings.

Finally, retention to clinical studies is also important. Supportive strategies for retention include incentives, personal communication, dedicated study resources, participant convenience, and repeated contact with participants to enhance engagement (5).

We conducted a flaxseed intervention study in healthy, postmenopausal women of African ancestry (AA) and European ancestry (EA) with the goal of assessing the contribution of race/ethnicity to associations between gut microbial community composition and metabolism (12). As we had specific recruitment goals, we used a variety of methods to ensure equal recruitment and retention of both AA and EA women to the study, which we report herein. Understanding barriers to and successes of recruitment and retention to dietary studies is critical for future efforts in the field.

## Methods

### Study design

The methods for this study have been described in detail previously (12). Briefly, we conducted a randomized, crossover flaxseed intervention study in healthy, postmenopausal AA and EA women recruited from the western New York region between March 2013 and February 2017 (clinicaltrials.gov registration NCT01698294). The study protocol was conducted according to established ethical guidelines, approved by the Roswell Park Comprehensive Cancer Center (Roswell Park) Institutional Review Board, and women provided signed, informed consent before participation. Participants in the study were women 45 to 75 y of age; without a menstrual cycle in the past 12 mo; and not currently taking hormones, flax supplements, or antibiotics in the past 2 mo. Women were randomly assigned equally by self-reported race/ethnicity (confirmed by ancestry informative genetic markers) to consume 10 g/d of ground flaxseed for 6 wk or to maintain their usual diet; and after a 2-mo washout period, each participant crossed over to the other diet condition for an additional 6 wk. We also collected fasting blood draws, overnight urine samples, and fecal samples at the beginning and end of each 6-wk study period for a total of 4 biospecimen collections. Accrual and retention goals were 200 participants (100 each AA and EA) completing all study activities. As one of the aims of the study included examination of the impact of host genetic variation, we restricted recruitment to non-Hispanic ethnicity to reduce potential genetic heterogeneity.

### Study procedures

We used multiple forms of recruitment, including newspaper advertisements, posters, e-mail, websites, AVON Army of Women ([www.lover](http://www.lover)

[searcharmy.org](http://searcharmy.org)), word of mouth, and community outreach. Advertisements were directed to increase the likelihood of reaching the demographics of women of interest and included local neighborhood publications, websites, and advertisements on Buffalo city buses. Posters were placed in senior centers, grocery stores, and senior housing complexes, as well as other locations in areas with higher proportions of older residents. To enhance recruitment of AA participants, we collaborated with the Roswell Park Office of Cancer Health Disparities Research (OCHDR; currently Community Outreach and Engagement) to assist with community outreach and liaison with the community through presentations at programs designed to improve breast cancer screening behaviors (Witness Project<sup>®</sup>, University of Arkansas for Medical Sciences). We also employed a dedicated community outreach AA staff member to recruit from communities with high proportions of AA postmenopausal women. Finally, we provided additional incentives for current participants to recruit friends and associates to the study, as described below.

Western New York residents were informed of the study as described above. For nondirect strategies, such as advertisements, posters, websites, and e-mail listservs, a study telephone number was provided for interested women to call for more information. For community-based strategies such as the Witness Project<sup>®</sup> programs and community outreach (churches, health fairs, community centers, neighborhood associations, etc.), potential participants were provided with a brief verbal description of the study and a mini-screener contact form. The contact form queried minimal eligibility information and, if interested, the woman provided contact information for follow-up by study staff.

We attempted to contact by telephone each potential participant up to 5 times before designating that individual as a passive refusal. Women successfully contacted were provided with a thorough explanation of the study, and were screened for eligibility, if possible. If eligible and interested in participating, an appointment was made for an in-person pre-study visit. At this visit, the requirements of the study were thoroughly detailed, questions answered, and screening was repeated to confirm eligibility. Signed informed consent was obtained from women participating in the study, instructions for sample collection were explained, the participant was provided with a bag containing study instructions and a kit for home collection of feces and urine, and an appointment was made for the baseline study visit within 2 wk.

Active study visits occurred at weeks 0, 7, 15, and 22. Blood, urine, and fecal samples were collected at each active study visit. Participants were enrolled and randomly assigned to treatment group at the baseline study visit. Participants were telephoned frequently throughout the study to collect up to 12 interviewer-administered 24-h dietary recalls and symptom information and to provide reminders for sample collection and study visit appointments. Participants received a \$25 gift card to a local grocery store for each completed active study visit.

During telephone contact, women were asked how they heard about the study and this information was recorded. We also tracked the mini-screener used at Witness Project<sup>®</sup> programs and other community events. Recruitment and retention were carefully monitored through bi-weekly recruitment reports and staff meetings to discuss recruitment strategies and prioritize methods to increase success. To improve retention to the study, approximately halfway through recruitment we increased the financial incentive to include an extra \$25 gift card for participants who completed the final study visit. We also provided a \$25

**TABLE 1** Recruitment status of women interested in participating in a flaxseed intervention study by AA and EA women<sup>1</sup>

	AA and EA	AA (n = 350)	EA (n = 400)	Total <sup>2</sup> (n = 750)
Not screened, n	169			
Passive refusal	78 (45.8)	—	—	—
Active refusal, no reason	6 (3.6)	—	—	—
Already eating flax, not willing to stop	1 (0.6)	—	—	—
Ineligible (not fully screened)	34 (20.2)	—	—	—
Not interested	24 (14.3)	—	—	—
Sample collection	1 (0.6)	—	—	—
Time commitment	23 (13.7)	—	—	—
Transportation issues	2 (1.2)	—	—	—
Screened				
Ineligible	—	94 (26.9)	147 (36.8)*	241 (32.1)
Eligible	—	256 (73.1)	253 (63.3)	509 (67.9)
Consented				
Yes	—	132 (51.6)	141 (55.7)	273 (53.6)
No	—	124 (48.4)	112 (44.3)	236 (46.4)
Passive refusal	—	65 (53.3)	36 (29.7)*	98 (41.5)
Active refusal	—	4 (3.3)	5 (4.5)	9 (3.8)
Already eating flax	—	3 (2.5)	5 (4.5)	8 (3.4)
Became ineligible	—	7 (5.7)	18 (16.2)	25 (10.6)
Not interested	—	30 (24.6)	25 (22.5)	55 (23.3)
Sample collection	—	1 (0.8)	1 (0.9)	2 (5.5)
Time commitment	—	10 (8.2)	24 (21.6)	34 (14.4)
Transportation issue	—	2 (1.6)	0	2 (5.5)

<sup>1</sup>Values are n (%). n = 933. Differences in categorical variables by self-reported race assessed with Pearson's chi-square, \*P < 0.01. AA, African ancestry; EA, European ancestry.

<sup>2</sup>Excluding women screened and ineligible because of self-reported race other than non-Hispanic White or non-Hispanic African American (n = 14).

gift card per referral to participants who completed the baseline visit and referred a friend or colleague to the study who enrolled and completed the baseline visit. Finally, transportation was provided to women who indicated no reliable means of transportation.

### Statistical analyses

Analyses were conducted in SAS for Windows version 9.4 (SAS Institute, Cary, NC). All comparisons were 2-sided and considered statistically significant at  $P < 0.05$ . Differences in categorical variables were assessed with Pearson's chi-square test.

## Results

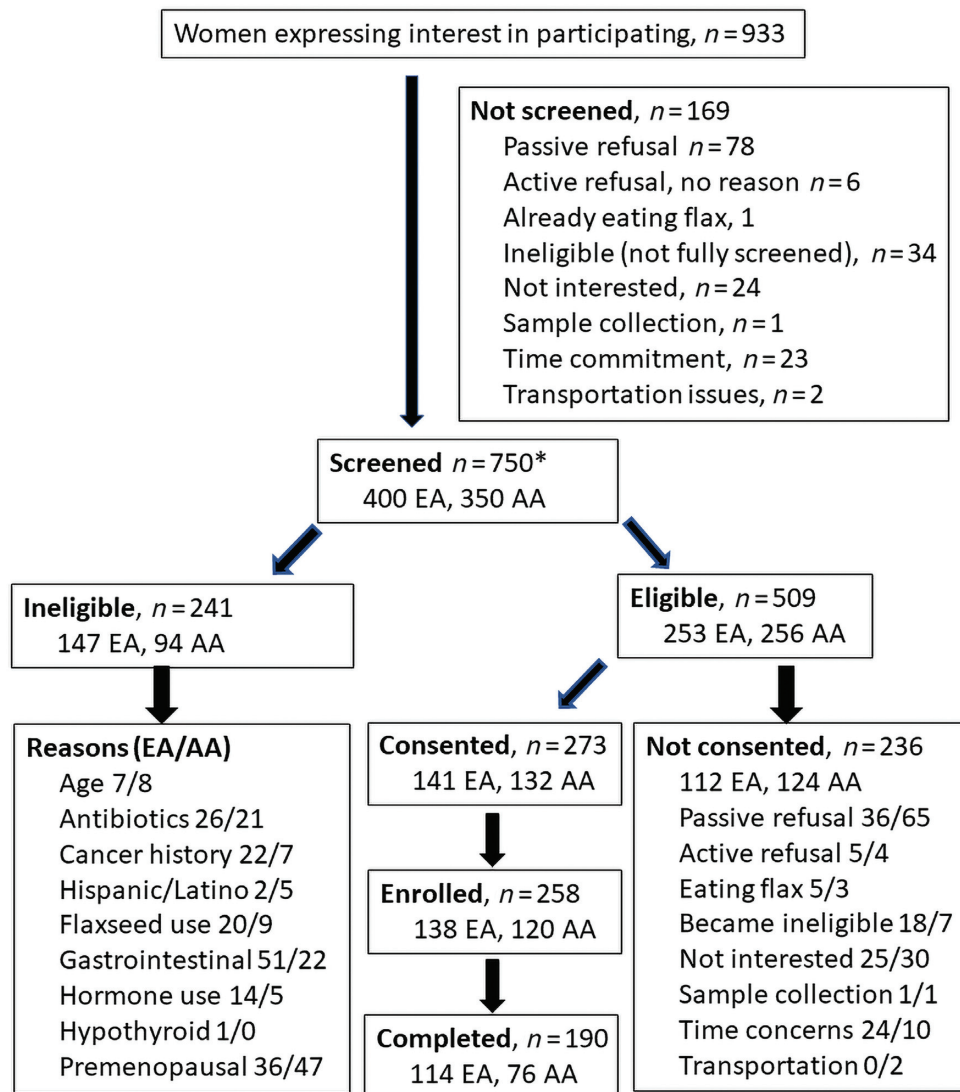
We received notice of interest in participation from 933 women. The disposition of our attempts to contact interested women is detailed in [Table 1](#) and [Figure 1](#). We were able to complete eligibility screening for 82% of the women (n = 764). Of the 169 women not screened for eligibility, 45.8% were passive refusals (i.e., no further contact was successful). Additional reasons for not being screened were active refusal with no reason given (3.6%), already eating flaxseed and unwilling to stop (0.6%), ineligible (not fully screened, ineligible because of age, self-reported race/ethnicity, or sex; 20.2%), not interested (14.3%), sample collection requirements (0.6%), time commitment (13.7%), or transportation issues (1.2%).

Also shown in [Table 1](#) are details related to screening and consenting. We successfully screened 764 women (350 AA, 400 EA, 14 other race/ethnicity). Excluding women ineligible because of race/ethnicity,

EA compared with AA women were more likely to be ineligible for the study (EA and AA: 36.8% vs. 26.9%, respectively;  $P < 0.01$ ). This finding is most likely a result of differences in recruitment strategies, described below. Among those eligible, the overall consent rate was 53.6%. Women who consented were slightly older than those who did not consent ( $59.3 \pm 6.2$  vs.  $58.2 \pm 8.2$  y;  $P = 0.05$ ; data not shown). Despite differences in eligibility, the consent rate was similar by AA and EA women (AA and EA: 51.6% vs. 55.7%, respectively;  $P > 0.05$ ). Among women who did not consent, passive refusal (did not attend scheduled pre-study visit) was the most common reason (41.7% overall), particularly among AA women (AA and EA: 53.3% vs. 29.7%, respectively;  $P < 0.01$ ). The next most common reasons for not consenting were lack of interest (23.3%), time commitment (14.4%), and newly identified ineligibility (10.6%).

Reasons for ineligibility are detailed in [Table 2](#) and differed between AA and EA women ( $P < 0.01$ ). Among AA women, the most frequently reported reasons for ineligibility were recent antibiotic use (22.3%) and gastrointestinal diagnoses (23.4%). Among EA women, the most frequently reported reasons for ineligibility were age (23%), gastrointestinal diagnoses (31.6%), and recent antibiotics use (16.1%). AA women were more likely than EA women to be ineligible because of antibiotic use (AA and EA: 22.3% vs. 16.1%, respectively).

As described above in Methods, recruitment methods differed for AA compared with EA women ( $P < 0.01$ ), partly by design ([Table 3](#)). However, all women in the western New York area had the opportunity to respond to any of the methods used. Despite placing advertisements in community-focused publications (including AA-owned newspapers), websites, and on city buses, advertisement was more



**FIGURE 1** CONSORT diagram for disposition of attempts to contact women interested in participating in a flaxseed intervention study. \*Excluding 14 women ineligible because of race not EA or AA. AA, African ancestry; CONSORT, Consolidated Standards of Reporting Trials; EA, European ancestry.

effective for recruiting EA women than for AA women (EA and AA, respectively: advertisement, 52.6% vs 16.2%; AskRPCI, 18.7% vs. 5.4%). Conversely, community-based strategies were more successful for recruiting AA women (community events and contacts: 16.8% vs. 6.2%; Witness Project: 47.3% vs. 2.0%; and friends/colleagues: 13.4% vs. 7.0% for AA and EA, respectively).

Although recruitment to the study was important, we were also concerned about retention through the duration of the study. Retention methods did not differ for AA and EA women. Dropout occurred throughout the study and was more likely to occur earlier in the study compared with later (Table 4). Overall enrollment was 94.5% of women who consented, with EA women more likely to enroll (complete baseline and randomization) compared with AA women (97.9% vs. 90.9% for EA and AA, respectively;  $P < 0.05$ ). When possible, we determined reasons for dropout. The most common reason for failure to com-

plete the study was removal by study staff for loss of eligibility (medical/antibiotics; 40.2% overall; 54.3% vs. 32.8% for EA and AA, respectively). AA compared with EA women were more likely to passively drop out between consent and enrollment (26.9% vs. 17.1% for AA and EA, respectively) and after enrollment (20.9% vs. 11.4% for AA and EA, respectively). Other reasons for dropout included health reasons, intolerance of flaxseed taste or side effects, noncompliance with study requirements, time constraints, and nonspecified personal reasons.

## Discussion

Recruitment of minority participants to clinical trials, especially to studies without therapeutic intent, has been a longstanding challenge in

**TABLE 2** Reasons for ineligibility of women screened for participation in a flaxseed intervention study by AA and EA<sup>1</sup>

	AA (n = 94)	EA (n = 161)	Total (n = 278)
Age	8 (8.5)	7 (23.0)	15 (5.1)
Antibiotics, recent use	21 (22.3)	26 (16.1)	47 (16.1)
Cancer history	7 (7.4)	22 (13.7)	29 (9.9)
Hispanic/Latino ethnicity	5 (5.3)	2 (1.2)	7 (2.4)
Flaxseed, current consumption	9 (9.5)	20 (12.4)	29 (9.9)
Gastrointestinal diagnoses	22 (23.4)	51 (31.6)	73 (25.0)
Hormone use	5 (5.3)	14 (8.7)	19 (6.5)
Hypothyroid, not stable	0	1 (0.6)	1 (0.3)
Perimenopausal	47 (50.0)	36 (22.3)*	83 (28.4)

<sup>1</sup>Values are n (%). Among women completing screening; percentages will sum to >100% as women could be ineligible for multiple reasons. \* $P < 0.01$ , Pearson's chi-square. AA, African ancestry; EA, European ancestry.

research (1). The lack of minority participation in dietary intervention studies has also been evident, reducing the generalizability of diet studies to a diverse population. In this study, we found that successful recruitment and retention of AA women to the flaxseed intervention depended upon the specific methods used. AA women compared with EA women were more likely to respond to direct, in-person recruitment methods by concordant outreach staff, rather than general, public advertisements. However, although identification of potential participants depended on the recruitment method used, once women expressed interest, we observed similar rates of consent by AA and EA women, which is consistent with the experience of others (9, 10, 13) supporting the willingness of AA women to participate in clinical trials.

Although consent rates were similar between AA and EA women, retention to the study was higher among EA women. The intervention was burdensome as the protocol required 5 study visits; 4 collections each of feces, overnight urine, and blood; up to 12 randomly administered telephone-based 24-h dietary recalls; and daily consumption of flaxseed for 6 wk. We explained the study in detail during initial telephone contact; however, it is likely that the study burden did not become evident until the consenting visit, at which time we thoroughly explained the study requirements, demonstrated the collection kits, and the participant was instructed to collect the first set of samples. We were unable to definitively determine respondent burden as a cause of study dropout since most of the women who did not complete the study failed

to return for the baseline visit and we were not able to contact them further.

Several factors, such as sociodemographic characteristics, have been identified as contributing to participation and retention in studies by individuals from underrepresented populations. Although we did not collect data on household income, the majority of the AA women who expressed interest in and participated in the study were from the city of Buffalo, whereas the majority of the EA women were recruited from the suburban areas, with likely impact on household income. Additionally, marital status differed by race, with AA women less likely to be married than EA women [17% vs. 57% for AA and EA, respectively (12)], which probably also impacted household income. Education also differed by race, with 22% of AA women reporting a Bachelor's degree or higher, compared with 59% of EA women (12). Although these factors have been previously associated with participation in trials, there did not seem to be a strong effect in our study as consent rate did not differ between AA and EA women. Our findings confirm a willingness of AA women to participate in clinical research that has been reported by others (14). However, some or all of these factors could have impacted the willingness of women to complete the study after agreeing to participate as retention was lower among the AA women (57.6%) compared with the EA women (80.9%).

Our study demonstrates that direct contact and race-concordant community-based strategies were more effective than passive methods (e.g., advertisements) to recruit AA women. Community-based

**TABLE 3** Recruitment source of women interested in participating in flaxseed intervention study by AA and EA<sup>1</sup>

	AA (n = 351)	EA (n = 401)	Other races (n = 14)	Total (n = 766)
Advertisement	57 (16.2)	211 (52.6)*	7 (50.0)	275 (35.9)
AskRPCI	19 (5.4)	75 (18.7)	3 (21.4)	97 (12.7)
Avon Army of Women	0	24 (6.0)	0	24 (3.1)
Community event	59 (16.8)	25 (6.2)	0	84 (11.0)
Friend/colleague	47 (13.4)	28 (7.0)	1 (7.1)	76 (9.9)
Witness Project	166 (47.3)	8 (2.0)	2 (14.3)	176 (23.0)
Other, not specified	3 (0.9)	30 (7.5)	1 (7.1)	34 (4.4)

<sup>1</sup>Values are n (%). Excludes women unable to be contacted after leaving message of interest. \* $P < 0.05$ , Pearson's chi-square. AA, African ancestry; EA, European ancestry.

**TABLE 4** Enrollment and study completion by women consented to participate in flaxseed intervention study by AA and EA<sup>1</sup>

	AA (n = 132)	EA (n = 141)	Total (n = 273)
Enrolled (completed baseline and randomization)	120 (90.9)	138 (97.9)*	258 (94.5)
Dropout after consent	67 (50.8)	35 (24.8)**	102 (37.4)
Did not enroll	18 (26.9)	6 (17.1)	24 (23.5)
Did not return after enrollment	14 (20.9)	4 (11.4)	18 (17.7)
Became ineligible (medical/antibiotics)	22 (32.8)	19 (54.3)	41 (40.2)
Health reasons	3 (4.5)	1 (2.9)	4 (3.9)
Could not tolerate flaxseed taste/unacceptable side effects	1 (1.5)	1 (2.9)	2 (2.0)
Did not return samples	2 (3.0)	1 (2.9)	3 (2.9)
Personal reasons	2 (3.0)	0	2 (2.0)
Time constraints	5 (7.5)	3 (8.6)	8 (7.8)
Completed study	76 (57.6)	114 (80.9)**	190 (69.6)

<sup>1</sup>Values are n (%). n will not sum as women could drop out at any point in the study. \* $P < 0.05$ ; \*\* $P < 0.01$  (Pearson's chi-square). AA, African ancestry; EA, European ancestry.

strategies required a multidisciplinary team science approach from the beginning, including collaboration with our OCHDR, community-directed resources such as the Witness Project<sup>®</sup>, and inclusion of diverse members on the research staff/team who are experienced in engaging the minority population. Through our collaboration with the OCHDR, we were able to leverage existing partnerships and relationships previously established by this office to enhance the reach of our trial to AA women who were potentially eligible for the study. Our recruitment approaches to engage AA women required more active than passive strategies that yielded sufficient numbers of EA women to the study. For example, community-based recruitment at events hosted by AA community partners and organizations entailed event registration, table setup in vendor/sponsor area, and study personnel to staff the table and actively engage program attendees during the event to disseminate study information and/or deliver the mini-screener form.

These strategies are also generally more labor-intensive and expensive than the public advertising methods. Our community outreach staff person dedicated approximately 10 h/wk to in-person recruitment. We estimate, given our experience, that our community-based methods resulted in a cost-per-participant of approximately \$111 compared with \$11–\$15 per participant recruited through advertisements. The community outreach strategy was unique to AA recruitment and was not required to enroll sufficient numbers of EA women to the study.

Particularly relevant, the Witness Project<sup>®</sup> model is built on a lay health advocate peer-to-peer engagement approach (15, 16). By extending this strategy to our study we were able to reach not only the intended population but also recruit eligible women into the study and enhance retention through repeated contact via the acceptability of representative study staff. Additionally, community-engaged approaches aided in linking research opportunities to minority communities by using direct peer-to-peer interactions that build trust and effectively communicate the research to the community, increasing relevance to the population (17). These measures enhanced our reach to AA women and contributed to equitable representation from AA women in the clinical trial (18).

In conclusion, our study confirms the utility of community-based strategies for recruitment of diverse populations into nontherapeutic dietary intervention studies. We successfully identified eligible women

who expressed willingness to consent to the trial and achieved >70% of our retention goals for AA women. Future efforts are warranted to improve retention to complex studies.

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### Data Availability

The data underlying this article will be shared on reasonable request to the corresponding author and with appropriate data use agreements.

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