

ENHANCING RECRUITMENT OF HEALTHY AFRICAN AMERICAN VOLUNTEERS IN A CITY WITH A SMALL AFRICAN AMERICAN COMMUNITY: RESULTS FROM A DIETARY SUPPLEMENT CROSSOVER TRIAL

Objective: To describe strategies for enhancing recruitment of African Americans to a long-term intervention study requiring frequent blood draws and follow-up visits, in a city with relatively few African Americans.

Design: The intervention study was a 14-month, double-blind, crossover study evaluating the effects of three oral folic acid doses on blood homocysteine levels. The goal was to have 40 African Americans complete the study, in addition to 160 participants from other races and ethnicities.

Results: Of 707 healthy, adult men and women recruited, 57 were African Americans. Recruitment advice was sought from African American community leaders interested in health research and the advice can be attributable to the success of recruitment. As suggested by the community leaders, our female African American project manager made oral presentations to select community groups. Word-of-mouth support from community leaders and study participants helped recruitment. Although the adult Seattle population is 7.4% African American, the group completing the study comprised 15% African Americans. Retention in the dietary intervention was 74% (31 out of 42) among African Americans, 81% (158 out of 196) among non-African Americans – a statistically non-significant difference.

Conclusions: Advice from African American community leaders about targeting appropriate civic/professional groups, churches, and community organizations can lead to effective recruitment of African Americans. Advice should be sought before beginning recruitment and endorsement for the study should be obtained. Effective retention of African American participants is possible for intervention studies requiring multiple blood draws and follow-up visits. (*Ethn Dis.* 2007;17:555–559)

Key Words: Recruitment, Retention, African Americans, Folic Acid

From the Department of Epidemiology, University of Washington (CA, SB); Cancer Prevention Research Program, Fred Hutchinson Cancer Research Center (SB, JL), Department of Medicine, University of Washington (RK), Departments of Medicine (Medical Genetics) and Genome Sciences (AM) Seattle, Washington.

Cheryl A. M. Anderson, PhD, MPH; Shirley A. A. Beresford, PhD;
Johanna Lampe, PhD, RD; Robert H. Knopp, MD;
Arno G. Motulsky, MD

INTRODUCTION

Recruiting and retaining African American clinical research participants can be challenging, particularly for long-term non-clinical trials that require a high level of participant commitment for participation. Numerous published reports document specific approaches to successful recruitment or retention of racial and ethnic minorities for clinical trials,^{1–5} screening trials,^{6,7} and behavior change and health promotion interventions.^{8–11} Missing in this research, however, is a lack of focus on approaches to successful recruitment in cities with small minority communities. This intervention study assessing the effect of folic acid on total homocysteine blood levels over-enrolled African Americans as part of the general recruitment effort and was conducted in a city with a relatively small (7.4%) African American population.¹² The study aimed to evaluate the homocysteine response to folic acid supplementation within individuals with different genotypes for methylenetetrahydrofolate reductase (MTHFR). The TT genotype of MTHFR C677T is too infrequent in persons of African origin (1–3%), as compared to non-Africans (10–12%),¹³ to allow meaningful studies on the TT

genotype in African Americans. However, it was our aim to study the blood homocysteine response to folic acid in African Americans regardless of TT genotype. Therefore, we over-enrolled African American volunteers to allow for a separate estimate of the folic acid-homocysteine dose-response relationship for African Americans.

The aim of this article is to describe strategies used to enhance the recruitment and retention of African Americans for a relatively long-term intervention study with oral folic acid requiring eleven blood draws and clinic visits over 14 months. Our results will be useful to researchers who seek to recruit and retain African Americans for studies of this kind.

METHODS

Description of Study

This study was conducted in Seattle, Washington. We recruited healthy, male and female, volunteers, 18 to 69 years of age. The study aimed to evaluate the effect, in a healthy popula-

The aim of this article is to describe strategies used to enhance the recruitment and retention of African Americans for a relatively long-term intervention study...

Address correspondence and reprint requests to Cheryl A. M. Anderson, PhD, MPH; Assistant Scientist, Epidemiology; Johns Hopkins University Bloomberg School of Public Health; Welch Center for Prevention, Epidemiology, and Clinical Research; 2024 E. Monument Street, Ste 2-622; Baltimore, MD 21205, USA; 410-614-076; 410-955-0476 (fax); chanders@jhsp.edu

tion, of three modest doses (0, 200, and 400 µg) of folic acid taken by mouth on blood levels of total homocysteine—an independent risk factor for vascular diseases.¹⁴ The study design was a double-blind, crossover, trial with a 30-week washout period between intervention periods. After screening, participants were randomized to a folic acid treatment order and received an invitation to begin a 6-week run-in period. During the “run-in,” participants’ compliance with study requirements, such as taking study pill daily and restraining from eating foods heavily fortified with folic acid, was assessed. Only individuals who successfully completed the “run-in” continued in the trial phase that required clinic visits every six weeks during 14 months. Clinic visits consisted of a fasting, venous blood draw, completion of an informed consent and questionnaires, and distribution of study pills. A subset of screened individuals was invited to enroll in the study. It was necessary to screen 707 individuals to enroll a sufficient number of individuals with the MTHFR TT genotype (MTHFR TT prevalence of 10%–12% in population) while also allowing for attrition in this group. In contrast, all African Americans who were screened were invited to enroll to allow for a separate estimate of the folic acid and homocysteine dose-response relationship for African Americans.

To partially offset study burden, each participant received \$10 per fasting blood draw and a bonus of \$30 for the final study visit, for a possible total of \$130. All protocols and materials were approved by the University of Washington (UW) institutional review board.

Strategies for General and Enhanced Recruitment

General recruitment included : 1) flyers posted in high-traffic areas of the local medical and research centers; 2) targeted letters to homes in zipcodes neighboring the study clinic and to

women previously screened (but not participants) for the Women’s Health Initiative Study in the Seattle Clinical Center; 3) no-cost public service announcements in local newspapers and on two local radio stations; and 4) paid advertisements in the University daily newspaper. General recruitment progressed using these methods, but African American recruitment was slower than desired leading to the conclusion that different strategies were required to enhance recruitment of African Americans. To gain advice about African American recruitment, meetings were held with African American community leaders interested in community health promotion. These individuals included physicians, local clergy (Baptist, African Methodist Episcopal (AME), and non-denominational churches), those in leadership positions in African American sororities, fraternities or other service-oriented groups, and staff from UW offices who serve minority faculty and students. Based on these meetings, flyers were placed in key locations and mailed to UW African American graduate students, presentations were given, and advertisements were placed in certain newspapers, and church bulletins.

Specifically, flyers were placed in a library, barber/beauty shops, and housing communities in the south central area of Seattle (a residential area with a high density of African Americans), the UW Office of Multicultural Affairs, community health clinics, and non-profit organizations that serve African Americans such as Technology Access Foundation and Central Area Youth Association. Names and campus addresses of minority graduate students were obtained from the UW’s Office of Multicultural Affairs and flyers were sent to those students.

Presentations were given to the Seattle African American Health Care Professionals group, two area churches with large African American congregations—Mt. Zion Baptist and First AME,

and to groups such as Blacks at Microsoft, Black Lunch Group, and Alpha Kappa Alpha Sorority to obtain support and endorsement. Presentations were also given at the UW quarterly, minority graduate student forum. Individualized follow-up discussions about study methods or rationale were held with those who desired. All presentations (~30 hours) were given by the study’s African American female project coordinator.

Advertisements were placed in church bulletins, two newspapers and an employment journal that are widely circulated in the African American community. The newspapers are printed bi-weekly and advertisements ran for ~3 months. Churches were asked to not only run the ads in church bulletins but to also read the information during church services if it was customary to do so.

All advertisements and flyers included age requirement, clinic location, study length, purpose of blood draw, monetary compensation, pregnancy exclusion criteria and study office phone number to call if interested in participating. Some flyers specified that “African Americans were needed for a vitamin study.”

Strategies for Retention

Retention was defined as percentage of volunteers who, after a baseline visit, completed the entire study. Retention strategies were the same for all study participants, regardless of race or ethnicity. Efforts to maximize retention included reminder calls by study personnel on the day before appointments. A call was also made to participants three weeks into each intervention period to ensure participants were still engaged and complying with the intervention. Participants who missed clinic visits were telephoned immediately to reschedule and were mailed a notecard encouraging them to reschedule. Within the constraints of the study, there was flexibility in scheduling

Table 1. Comparison of recruitment and retention rates for African Americans and non-African Americans

Ethnicity	Recruitment goal	Screened	Run-In	Baseline	Completed	Retention %*†
African American	40	57	46	42	31	74
Non-African American	160	650	207	196	158	81
TOTAL	200	707	253	238	189	79

* Retention = Completed/baseline

† The difference in retention rates between African Americans and non African-Americans was not statistically significant ($X^2 = .607, P=.4$)

visits. We mailed questionnaires and/or pills to some participants who were unable to keep an appointment. On occasion, a phlebotomist drew blood at locations other than the clinic that were convenient for the participants. Additionally, holiday cards were mailed to participants in December, if appropriate. Phone calls were placed to those individuals who dropped out to determine reasons for withdrawal. Participants who were not reached after daily phone calls for one month were no longer contacted.

RESULTS

Of the 707 volunteers screened, 253 completed run-in activities to assess compliance with the study protocol. Of those 253, 235 had a baseline visit. As shown in Table 1, 57 African Americans consented to screening and 46 completed run-in procedures. Four African Americans withdrew before the

baseline visit. Our recruitment goal was to enroll a total of 40 African Americans and 31 out of 42 who completed the baseline visit completed the entire study. This represents a retention rate of 74%. A retention rate of 74% is similar to the 81% retention rate in the non African-American group (chi-square=.61, $P=.40$).

Table 2 summarizes recruitment strategies used during screening, and shows numbers of African American and non-African American participants obtained from each strategy. The enrollment patterns for each strategy are presented. The greatest number of volunteers (80%), regardless of race or ethnicity, came from mass distribution of information through flyers, other advertisements and mailed letters. These methods were inexpensive and effective for overall recruiting and worked particularly well for recruiting women (AA women: 42%, $n=18$; AA men: 14%, $n=2$). Although total numbers were small, African Americans were also

effectively recruited by presentations (AA women: 42%, $n=18$; AA men: 57%, $n=8$) and word-of-mouth (AA women: 16%, $n=7$; AA men: 14%, $n=2$).

Table 3 shows reasons for study withdrawal. Most African Americans who withdrew moved out of Seattle. Most non-African Americans withdrew for unknown reasons, and could not be contacted to determine reasons. The top three known reasons that non-African Americans withdrew were: a move out of Seattle, illness unrelated to study participation, or wanting to resume use of vitamins containing folic acid.

DISCUSSION

Although this study recruited a relatively small number of African Americans, recruitment was challenging because of the low percentage of African American residents in Seattle and the level of commitment necessary for par-

Table 2. Recruitment strategies used to attract screening participants, by race and gender

Recruitment Strategy	Total Screened <i>n</i> (%)	Female <i>n</i> =493 (70%)		Male <i>n</i> =214 (30%)	
		African American	Non-African American	African American	Non-African American
Flyer	406 (57)	18 (42)	269 (60)	2 (14)	117 (59)
Targeted letter to NWLRC patients and women screened for WHI studies	45 (6)	0	27 (6)	0	18 (9)
Targeted letter to zipcodes close to study clinic	122 (17)	0	103 (23)	0	19 (10)
Public service announcement	19 (3)	0	7(<1)	0	12 (6)
Classified ad	3 (<1)	0	1 (<1)	1 (7)	1 (<1)
Presentations	38 (5)	18 (42)	9 (2)	8 (57)	3 (2)
Word-of-mouth	40 (6)	7 (16)	12 (3)	2 (14)	19 (10)
Internet search	3 (<1)	0	1 (<1)	0	2 (1)
Unknown	31 (4)	0	21 (5)	1 (7)	9 (5)
TOTAL	707	43	450	14	200

NWLRC=Northwest Lipid Research Clinic; WHI=Women's Health Initiative

Table 3. Reasons given by study participants for withdrawal from the study

Reason	Total withdrawn n (%)	African American n (%)	Non-African American n (%)
Moved out of Seattle area	14 (28.6)	4 (36.4)	10 (26.3)
Unrelated study illness	8 (16.3)	1 (9.1)	7 (18.4)
Personal desire or physician recommendation to take folic acid	6 (12.2)	0	6 (15.8)
Desire to become pregnant or unplanned pregnancy	2 (4.1)	1 (9.1)	1 (2.6)
Death of spouse	1 (2.0)	1 (9.1)	0
Unable to extend length of time in study when study protocol changed	2 (4.1)	0	2 (5.3)
Became too busy/schedule changed	3 (6.1)	2 (18.1)	1 (2.6)
Tired of being in study	2 (4.1)	0	2 (5.3)
Unknown (did not respond to our calls for > 1 month)	11 (22.4)	2 (18.1)	9 (23.7)
Total	49	11	38

ticipation. Substantial recruitment of African Americans was important because it was hypothesized that homocysteine response to folic acid supplementation might be different in persons of African origin. Our experience suggests that an African American project coordinator can help build community trust in research. This study was fortunate to have an African American staff member to fill this role, and this may not be generalizable. Nonetheless, investigators from other ethnicities and races should make efforts to build relationships with the community to change the negative image that prevails. The benefits of recruiting African Americans at local venues using face-to-face interviews where participant concerns can be more fully addressed have been documented.⁷ African Americans can be recruited for studies with a blood-draw component that demand an investment of time, as well as a commitment to return for follow-up visits.

Many (46%, $n=26$) African American participants volunteered after attending a presentation given by the African American project coordinator, who was also a doctoral student. Four aspects of the presentations may have contributed to their success as a recruitment strategy. First, they included an educational component addressing health benefits of the study for African Americans such as the potential to identify a cheap and effective way to lower plasma homocysteine. Second, the African American project coordinator explained that study

data would be used in her doctoral work. Many participants expressed desire to support work of a minority graduate student. Third, there were discussions of political and social factors that may affect participation by African Americans. For example, the impact of the Tuskegee Syphilis Study on African American mistrust for university research was acknowledged.¹⁵ One African American male attendee commented that an African American project coordinator could not necessarily be trusted to disclose all information regarding the use of blood because Mrs. Evers—the nurse who recruited for the Tuskegee study—was African American. Other useful considerations for recruitment were revealed by community members. For example, some people said they were mistrustful of advertisements with “African Americans needed for a research study...” and were more willing to participate if all racial groups were recruited. Fourth, we conducted presentations in churches. Although university research may be greeted with skepticism, faith-based organizations are trusted by their members and can facilitate conversations about community research. Churches may be good places to meet members and leaders of social/service groups. For example, the Association of Black Health Care Professionals and other social/service organizations met in churches.

It was easier to recruit women than men. While this sex difference is true for non-African Americans, it is pronounced for African Americans (women

75%, $n=43$; men 25%, $n=14$). Anecdotal reports suggest it is easier to recruit women than men in other studies, but we are not aware of any published reports documenting this. Most published reports addressing sex issues in recruitment focus on the lack of representation of women in clinical trials of cardiovascular outcomes because of issues of study design and perceived risk. This study's experience with African American men is corroborated by studies where mass publicity campaigns and targeted mailings were ineffective in recruiting adequate numbers of African American volunteers.¹⁶ These observations indicate that recruitment strategies for non-minority populations cannot be solely employed to recruit African Americans.

Although recruitment goals for screening were met, the retention rate (74%) for African Americans was lower than required to reach the desired intervention sample size. However, it was not significantly different from the retention rate among non-African Americans (81%). The most common reason given by African American participants for dropping out of the study was moving away from the Seattle area. Recently published reports from a weight management study showed that 82% retention was achieved for African Americans at 12 months into the study.¹¹ Their retention rate is high, but their study population was ≥ 45 years of age, less likely to be transient than our group. More than

half of the African American participants completing this study were <45 years of age.

A few limitations exist for these results. First, although we enhanced the recruitment of African Americans, the total numbers participating were still relatively ($n=57$) small. Second, a small number were male ($n=14$, 25%), consistent with overall study recruitment of males (30%). Male and female attendance at presentations seemed fairly equal but men may have had less exposure to our other recruitment strategies. It is uncertain whether all recruitment efforts did not reach men or whether men made conscious decisions to not participate.

In summary, for intervention studies which require a relatively high level of participant commitment, we recommend the use of strategies that include hiring African American staff to recruit African Americans, seeking advice and endorsement of African American community leaders before recruitment, making presentations that educate about the health issues being addressed by the study, and make provision for individualized follow-up of potential participants.

ACKNOWLEDGMENTS

The authors wish to thank our study volunteers for their contributions to the study. We also thank leaders from the Seattle African American community for their insight and guidance in directing our recruitment efforts, especially Dr. Millie Russell, Dr. Alvin Thompson, and Ms. Robin Kirkland. We would also like to thank the Nutrition Laboratory Core of the University of Washington Clinical Nutrition Research Unit (NIH DK035816) for assistance with assays for this study.

REFERENCES

- Swanson GM, Ward AJ. Recruiting minorities into clinical trials: Toward a participant-friendly system. *J Natl Cancer Inst.* 1995;87:1747-59.
- Lindenstruth KA, Curtis CB, Allen JK. Recruitment of African American and White postmenopausal women into clinical trials: the beneficial effects of soy trial experience. *Ethn Dis.* 2006;16(4):938-942.
- Jeffries SK, Choi W, Butler J, Harris KJ, Ahluwalia JS. Strategies for recruiting African American residents of public housing developments into a randomized controlled trial. *Ethn Dis.* 2005;15(4):773-8.
- Appel LJ, Vollmer WM, Obarzanek E, et al. Recruitment and baseline characteristics of participants in the Dietary Approaches to Stop Hypertension trial. DASH Collaborative Research Group. *J Am Diet Assoc.* 1999;99: S69-75.
- Fouad MN, Corbie-Smith G, Curb D, et al. Special populations recruitment for the Women's Health Initiative: successes and limitations. *Control Clin Trials.* 2004;25:335-352.
- Trauth JM, Jernigan JC, Siminoff LA, Musa D, Neal-Ferguson D, Weissfeld J. Factors affecting older African American women's decisions to join the PLCO Cancer Screening Trial. *J Clin Oncol.* 2005;23(34):8730-8738.
- Ford ME, Havstad SL, Davis S. Randomized trial outcomes for older African American men recruited to the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. *Clin Trials.* 2004;1:343-351.
- Story M, Sherwood NE, Obarzanek E, et al. Recruitment of African American pre-adolescent girls into an obesity prevention trial: the GEMS pilot studies. *Ethn Dis.* 2003;13(1 Suppl 1):S78-S87.
- Coleman EA, Tyll L, LaCroix AZ, et al. Recruiting African American older adults for a community-based health promotion intervention: which strategies are effective? *Am J Prev Med.* 1997;13(6 Suppl):51-56.
- Yancey AK, Miles OL, McCarthy WJ, et al. Differential response to targeted recruitment strategies to fitness promotion research by African American women of varying body mass index. *Ethn Dis.* 2001;11:115-123.
- Parra-Medina D, D'antonio A, Smith SM, Levin S, Kirkner G, Mayer-Davis E. POWER study. Successful recruitment and retention strategies for a randomized weight management trial for people with diabetes living in rural, medically underserved counties of South Carolina: the POWER study. *J Am Diet Assoc.* 2004;104(1):70-75.
- U.S. Census Bureau, Census 2000. *Table of Race, Hispanic or Latino, and Age. Data Set: Census 2000 Redistricting Data (Public Law 94-171) Summary File; Geographic Area: Seattle city, Washington.* 2000.
- Wilcken B, Bamforth F, Li Z, et al. Geographical and ethnic variation of the 677C>T allele of 5,10 methylenetetrahydrofolate reductase (MTHFR): findings from over 7000 newborns from 16 areas world wide. *J Med Genet.* 2003;40(8):619-625.
- Boushey CJ, Beresford SA, Omenn GS, Motulsky AG. A quantitative assessment of plasma homocysteine as a risk factor for vascular disease. Probable benefits of increasing folic acid intakes. *JAMA.* 1995;274(13):1049-1057.
- Gamble VN. Under the shadow of Tuskegee: African Americans and health care. *Am J Public Health.* 1997;87:1773-1778.
- Lacey L. Cancer prevention and early detection strategies for reaching underserved urban, low-income black women. Barriers and objectives. *Cancer.* 1993;72(3 Suppl):1078-1083.

AUTHOR CONTRIBUTIONS

Design concept of study: Beresford, Lampe, Knopp, Motulsky
Acquisition of data: Anderson, Beresford, Lampe, Knopp, Motulsky
Data analysis and interpretation: Anderson, Beresford, Lampe, Knopp, Motulsky
Manuscript draft: Anderson, Beresford, Lampe, Knopp, Motulsky
Statistical expertise: Anderson, Beresford, Lampe, Motulsky
Acquisition of funding: Beresford, Lampe, Knopp, Motulsky
Administrative, technical, or material assistance: Anderson, Beresford, Lampe, Knopp, Motulsky
Supervision: Anderson, Beresford, Lampe, Knopp, Motulsky