

Contemp Clin Trials. Author manuscript; available in PMC 2011 January 1.

Published in final edited form as:

Contemp Clin Trials. 2010 January; 31(1): 49. doi:10.1016/j.cct.2009.10.002.

Overall and Minority-Focused Recruitment Strategies in the PREMIER Multicenter Trial of Lifestyle Interventions for Blood Pressure Control

Betty M. Kennedy, PhD, Shiriki Kumanyika, PhD, Jamy D. Ard, MD, Patrice Reams, BS, Cheryl A. Johnson, EdM, Njeri Karanja, PhD, Jeanne B. Charleston, MSN, Lawrence J. Appel, MD, Vallerie Maurice, MSW, and David W. Harsha, PhD

The Pennington Biomedical Research Center, Baton Rouge, Louisiana (B.M. K., D.W.H.); the University of Pennsylvania School of Medicine (S.K.); the University of Alabama at Birmingham, Alabama (J.D.A.); the Duke Hypertension Center and the Sarah W. Stedman Nutrition and Metabolism Center, Duke University Medical Center, Durham, North Carolina, (P. R.); the Kaiser Permanente Center for Health Research, Portland, Oregon (C. A. J., N. K.); the Welch Center for Prevention, Epidemiology, and Clinical Research, Johns Hopkins University, Baltimore, Maryland (J. B. C., L. J. A.); and the University of Wisconsin Colleges & University of Wisconsin-Extension (V.M.).

Abstract

Recruitment strategies employed by four clinical centers across the US and a coordinating center were examined to identify successful overall and minority-focused recruitment strategies for the PREMIER multicenter trial of lifestyle changes for blood pressure control. The goal was to recruit 800 adults (40% African Americans) with systolic blood pressure of 120-159 mmHg and diastolic of 80-95 mmHg, not taking antihypertensive medication. Clinical centers used combinations of mass distribution of brochures, mass media, email distribution lists, screening events, and a national website. Culturally appropriate strategies for African Americans were designed by a Minority Implementation (MI) committee. Diversity training was provided for study staff, and African Americans were included in the study design process. Main recruitment outcomes were number overall and number of African Americans recruited by each strategy. Of the 810 randomized PREMIER participants, 279 (34%) were African American with site specific percentages of 56%, 46%, 27%, and 8%. Of African Americans recruited, 151 (54%) were from mass distribution of brochures (mailed letter, flyer included in Val-Pak coupons, or other), 66 (24%) from mass media (printed article, radio, TV story or ads, 52 (19%) from word of mouth, and 10 (3%) from email/ website and screening events combined. Yields for Non-Hispanic Whites were 364 (69%) from brochures, 71 (13%) from mass media, 49 (9%) from word of mouth and 47 (9%) from email/website and screening events. Mass distribution of brochures was relatively more effective with Non-Hispanic Whites, while African Americans responded relatively better to other recruitment strategies.

Corresponding author: Betty Monroe Kennedy, PhD, Instructor-Research, Dietary Assessment and Food Analysis Core, Pennington Biomedical Research Center, 6400 Perkins Road, Baton Rouge, LA 70808, Phone: 225-763-3090. Fax: 225-763-3045, Betty.Kennedy@pbrc.edu.

Address reprint requests to Betty M. Kennedy, PhD; P. O. Box 80025, Baton Rouge, LA. 70898; (225) 763-3090; (225) 763-3045 (fax); Betty.Kennedy@pbrc.edu

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Keywords

Cultural Appropriateness; Mass Distribution; Minority Participants

Introduction

Disparities in health status continue to persist particularly for African Americans compared to Non-Hispanic Whites, despite overall decreases in mortality and advances in health care. Cardiovascular disease disparities affecting African Americans are of major concern [1-4]. The elimination of cardiovascular disease and other health disparities requires culturally relevant research and the inclusion of minority participants in clinical trials [5-6]. Securing a sufficient sample of minorities in a clinical trial is essential for addressing research questions, testing hypotheses, and generating research findings that are specific to high risk populations and informative with respect to solving social and health problems [5].

Strategies to increase participation in clinical trials more and more are including culturally and contextually sensitive materials and methods to overcome barriers to minority participation [7]. The factors identified as possible impediments to African American participation include but are not limited to, problems with transportation, family and work-related responsibilities, distrust of the medical/scientific community, study design issues, influence of family members, emotional distress, the failure of researchers to recruit African Americans actively, the alienation of minority health professionals, lack of knowledge about clinical trials, language and cultural barriers [7].

Designing brochures, newspaper ads and articles to include pictures of African Americans is one way of targeting this population. Employing experts from the field to conduct cultural diversity training for study investigators and staff may further increase participation and retention of minority participants. In this paper, the recruitment strategies employed by four clinical centers across the US and a coordinating center were examined to determine which were successful overall and for recruiting minority participants in the PREMIER multicenter trial.

Methods

PREMIER was an 18-month multicenter randomized clinical trial to determine the effects of two multi-component lifestyle interventions, relative to an advice-only control condition, on blood pressure (BP) [8]. Centers participating in the PREMIER trial included the NHLBI Project Office, the Coordinating Center (Kaiser Permanente Center for Health Research in Portland, Oregon) and four clinical centers (Johns Hopkins University, Baltimore, MD; Pennington Biomedical Research Center, Baton Rouge, LA; Duke University Medical Center, Durham, NC; and Kaiser Permanente Center for Health Research, Portland, OR). The PREMIER design and rationale [8] and main results [9] have been published.

The PREMIER trial aimed to recruit 800 adult men and women (half female, 40 percent African American, and 30 percent hypertensive), ages 25 and older, with a systolic BP of 120-159mmHg and diastolic BP of 80-95 mmHg. The rationale for choosing this BP range was to enroll persons who were candidates for non-drug intervention programs designed to reduce BP. Individuals with normal but above-optimal BP and those with stage 1 hypertension were therefore eligible to participate in the trial. Eligibility criteria excluded individuals who had health problems requiring immediate attention, or who were candidates for aggressive antihypertensive drug therapy. Each center received prior approval from their institutional

review boards; an external protocol review committee approved the trial protocol; and each PREMIER participant provided written informed consent.

African Americans have a higher prevalence and greater severity of hypertension than other minorities (e.g., Mexican Americans) and Non-Hispanic Whites [10]. Because of the disproportionate burden of hypertension in African Americans and because of the possibility that several intervention components (reduced salt intake and the DASH dietary pattern) may reduce BP to a greater extent in African Americans than in other groups [11,12], about 320 (40%) of the 800 trial recruitment goal was set for this population. Baltimore, Durham, and Baton Rouge clinical sites each were to recruit 50% African Americans, while Portland was designated to recruit 10% of this population. As described below, PREMIER researchers, therefore, devised specific strategies to recruit African American participants and to deliver an intervention program that would incorporate their cultural perspectives.

Minority Implementation Committee

The PREMIER investigators placed a high priority on developing lifestyle interventions appropriate for African Americans at high risk for hypertension and obesity. A Minority Implementation (MI) committee with representatives from all clinical centers was therefore established in the PREMIER trial to address issues of importance in recruiting and retaining African American participants. The MI committee consisted of principal investigators, clinic coordinators, recruitment coordinators, a consultant (SK) with experience in cultural adaptation of lifestyle interventions, and other investigators and staff members with a special interest in minority research. The MI committee adapted the recruitment and intervention materials to be culturally appropriate for African Americans. Cultural appropriateness is defined as the concept of being congruent with the cultural framework of the target population, or presenting no significant disagreement with the cultural value system [13].

The MI committee recommended several actions [14] for enhancing cultural appropriateness in the PREMIER trial, to which each clinical center favorably responded:

- Conduct diversity training for each PREMIER team at each clinical center.
- Hire, train, and support a diverse staff.
- Build a relationship with the African American community at each site to attract participants.
- Communicate study procedures to minority study participants (i.e., remain sensitive to participants' privacy, use a humanistic approach, and treat participants as equals) [15].
- Give participants and their larger communities feedback in lay terms at the end of the study.

Diversity Training Process

The goal of the diversity training was to increase awareness of the climate of diversity within each clinical center; increase knowledge of the needs, values and attitudes of leadership necessary to address the climate of diversity within each clinical center; enhance skills to improve the work climate and productivity; and enhance recognition of styles of conflict and methods of handling conflict in ways that build respect for the individual. Because these same goals were those of the Louisiana State University (LSU) Agricultural Center, the MI committee selected their veteran Director of Multicultural Diversity (VM), to implement the diversity training for the PREMIER trial.

The cultural diversity trainer utilized the training curriculum prepared for the LSU Agricultural Center employees and clientele to train the then recruitment coordinator (BMK) to conduct diversity workshops and to assist (VM) in the training. The diversity training was tailored to be culturally appropriate sensitivity training for the PREMIER study staff. The 24-hour training was presented over three days. All sessions were non-confrontational, interactive and experiential in nature. A safe environment was provided for open dialogue and discussion through articulating group rules and using small groups. The training covered definitions of such key concepts as culture, diversity, and racism. Exercises encouraged discussion of the effects of prejudicial behavior toward others and enhanced communication skills.

The expected outcome of the diversity training was to develop clinical center leadership necessary to manage the change process related to PREMIER, which reflected the interaction between the majority white culture and minorities in the general population. Therefore, it was important for each PREMIER team to become sensitized on how to interact with participants in ways that were genuinely respectful. It was also expected that the training could develop unity, trust, and cooperation necessary for each clinical center staff member to become a more highly effective team member. A half day of diversity training facilitated by consultant (SK) via teleconferencing initiated the process. All clinical centers staff and personnel involved with PREMIER especially those interacting with participants were included in the training. Each center had at least 3-5 key staff members (at least one or more minorities) along with the principal investigators from each clinical center present for the training. Each new added staff member could then be trained utilizing "train the trainer" approach to continue the process.

PREMIER Pilot Study

To test success of the diversity training and elicit perceptions of attitudes and beliefs about the study administration and procedures from the African American segment, a PREMIER pilot study was conducted. Participants in the two month pilot study were not eligible for the main trial. Three clinical sites; Baltimore, Baton Rouge, and Durham had sufficient numbers of African American participants to conduct focus group evaluations. A total of sixty participants (twenty from each clinical site) with at least half African American participants, participated in one of two focus group sessions.

The PREMIER pilot study was generally found interesting, beneficial, and recommendable. Materials and procedures, while deemed not specifically tailored to minority populations, were not found objectionable. The racial makeup of the intervention staff was also not a particular issue. The mixed racial makeup of the intervention groups was generally well received. At Baltimore and Baton Rouge sites the pilot was found engaging and interesting. Self-monitoring was found somewhat difficult in Baltimore but less problematic in Baton Rouge and Durham, although it was found dull and repetitive by some in the latter site. Finally, there were two strong points that emerged:

- 1. There was a consistent desire for ethnic foods, recipes, and preparation procedures to be included in intervention materials.
- **2.** Emphasis on group dynamics for social support both within and between races was considered important and, by implication, underappreciated.

Overall, the PREMIER pilot study was perceived as acceptable. Criticisms made were readily addressed and resolved engendering considerable confidence in the practical utility of the basic Premier trial approach. The favorable pilot study experience provided confidence and credibility for staff who were subsequently involved in efforts to recruit African American participants.

Recruitment Methods

PREMIER clinical centers used a combination of strategies to recruit participants including mass distribution of brochures (mailed letter, flyer included in Val-Pak coupons—a nationwide direct marketing tool various organizations use to advertise their products, goods, and services, or other), mass media (printed article, radio, TV story or ads), word of mouth including prior study participants, email/website, and screening events. Some of these methods were those used previously in recruiting for similar multicenter trials (DASH and DASH- Sodium) [16]. To enhance recruitment and retention of minority participants, more attention was focused on various cultural variables of the targeted population.

Cultural variables can affect African American persons' perceptions of the feasibility of certain behavior modifications such as health interventions, and affect their perceptions of clinical research [5]. Thus PREMIER implemented culturally appropriate strategies for recruiting African American participants. These strategies included ethnically appropriate recruitment mailings targeted to zip codes known to be home to many African Americans, community-based screening events in African American neighborhoods, public service announcements on radio stations with primarily African American listening audiences, advertisements in local newspapers strategically placed in the (faith section, sports page for men, food section for women), and those endorsed by prominent African American community leaders. With permission, photographs of community leaders and others were used in advertisements in the Durham and Portland clinical sites to appeal and to attract African American men and women. In addition, the Durham clinical site used a photo in its media efforts (Figure 1) to demonstrate the diversity among its staff.

The recruitment coordinator at each of the four clinical centers was African American, and each was responsible for suggesting and implementing strategies including keeping a log to record how many African Americans were recruited. African American recruiters were hired in part because of their experience or skills in working with the community. Research has suggested in some cases that African Americans may provide an important source of modeling to enable effective interactions with, and to allow ease in addressing participants within their cultural context [15]. Although the recruitment coordinators were solely responsible for recruitment of participants, all staff including principal investigators were engaged and/or assisted in the process.

Results

Table 1 shows the number of randomized participants recruited by clinical sites, race, and strategy. Overall, 810 participants were randomized in PREMIER. Of the 810 randomized PREMIER participants, 279 (34%) were African American with site-specific percentages of 56%, 46%, 27%, and 8%. Of African Americans recruited, 151 (54%) were from mass distribution of brochures (mailed letter, flyer included in Val-Pak coupons, or other), 66 (24%) from mass media (printed article, radio, TV story or ads, 52 (19%) from word of mouth, and 10 (3%) from email/website and screening events combined. Non-Hispanic Whites yielded 364 (69%) from mass distribution of brochures, 71 (13%) from mass media, 49 (9%) from word of mouth and 47 (9%) from email/website and screening events combined.

The Baltimore center randomized a total of 211 (118 African American) participants. Baltimore relied heavily on mailed brochures and as a result, 92 African American participants were randomized using this strategy alone. A total of 223 (103 African American) participants were randomized in the Durham clinical center focusing their efforts on word of mouth and print media with visual depictions of African Americans. Employing various recruitment strategies, a total of 148 (40 African American) participants were randomized in the Baton Rouge center. The Portland center randomized a total of 228 (18 African American) participants. Using the

same photograph of an African American man and woman on a flyer, brochure, and poster in venues frequented by African Americans assisted the Portland center in recruiting this population.

Although the percentage of African Americans was small in the population of Portland, Oregon (6.6%) [17], African Americans constituted a similar proportion (8%) of the Portland PREMIER participants. The Baton Rouge clinical center was the only center that relied heavily on flyers placed in Val-Pak coupons and as a result, 60 Non-Hispanic White participants were recruited using this strategy alone.

Selected baseline characteristics of the 810 PREMIER study participants are illustrated in Table 2. Mean age was 50 (\pm 8.9) years with 75% in the range of 40-59 years. The majority 63% of study participants in the PREMIER trial was Non-Hispanic White, and 62% were women with an initial recruitment goal of 50% women. Education, marital status, employment, and household income were comparable for all PREMIER participants i.e., 89% of African American participants attended college and/or graduate school, as compared to 91% overall. Fifty-one percent of African Americans were married, compared to 66% overall, and more than 78% were employed full time, compared to 75% overall. Additionally, 76% of African American household incomes ranged from \$30,000 to more than \$60,000 annually, compared to 86% overall. Mean body mass index was high for both men (32.4 \pm 5.6 kg/m²) and women (33.5 \pm 5.9 kg/m²). Mean systolic blood pressure was 134.9 \pm 9.6 mm Hg, and mean diastolic blood pressure was 84.8 \pm 4.2 mm Hg.

Discussion

This paper highlights the recruitment strategies employed by four clinical centers and a coordinating center participating in the PREMIER multicenter trial to determine which were successful overall and for recruiting minority participants for a lifestyle behavior change trial. The number of African American participants recruited overall was very close to the study recruitment goal of 40%. The Baltimore and Durham clinical sites exceeded this goal with 56% and 46% respectively in recruiting African American participants, whereas the Durham site recruited fewer African Americans than expected. Differences among sites in the number and percent of randomized participants probably reflect a combination of regional population characteristics and different emphases with respect to recruitment strategies.

The primary strategy for recruiting participants in the PREMIER trial was the mass distribution of brochures (mailed letter, flyer included in Val-Pak coupons, or other). This strategy alone attracted the largest number of African American and Non-Hispanic White participants in the Baltimore clinical site. Direct-mail recruitment has advantages for recruiting in large trials; it can provide a continual flow of participants and is less labor-intensive than other forms of recruitment, such as cold-calling [18].

The secondary strategy for recruiting participants in the PREMIER trial was through mass media (print, radio, TV, and Email/website). The Durham clinical site used this strategy to recruit a little less than half of its African American participants and Non-Hispanic White participants. As demonstrated in previous research, mass media complemented mass distribution of brochures in recruitment of participants [16]. Intervention trials using mass distribution of brochures as the primary recruitment strategy may benefit more from simultaneously including mass media and other strategies [19].

The other single effective strategy utilized by the Baltimore and Durham clinical sites was word of mouth. Research has shown that African American individuals are likely to participate in clinical trials on the basis of whom they know [20]. In addition, African Americans who have successfully completed a clinical trial are more likely to enroll in similar future trials, and

word of mouth is another very useful method, especially when previous participants express positive messages about their clinical trial experiences [21].

Furthermore, African Americans displayed in newspaper print ads and articles appeared to convey the message that African Americans were encouraged to join the research study. African Americans may be more likely to participate in clinical research trials when other African Americans are seen visibly portrayed and when informational meetings about the clinical trial are conducted by other African Americans [22]. Although each clinical center had African American recruitment coordinators, more involvement and interaction from each clinical center's staff including the principal investigators appeared to be a very important aspect in attracting and retaining some African American participants. The Durham clinical site for example, had a very diverse staff and exemplified a tremendous amount of racial diversity as recommended by the MI committee.

The following strategies have been suggested to improve minority participation in clinical trials to foster effective communication and interaction between the clinical trials team and the minority community and building trust by developing culturally sensitive research teams [23-25]. Possessing effective communication skills (verbal or nonverbal) is a vital cultural characteristic when dealing with African Americans [26]. The PREMIER multicenter trial suggests that developing a culturally diverse and sensitive research team including commitment and involvement especially from the principal investigators, is likely to yield a higher number of African American participants. In turn, this approach may serve to build renewed trust as a result of past historical experiences, especially if African Americans are made to feel that because of their participation their contribution to research is valuable [27]. PREMIER research teams engaged in building trust during the research process by explaining clearly the participation criteria, risks and benefits of participation, and including African Americans in the study design process from project inception, all found to be critical components overall, and especially in obtaining African American participation in clinical research trials [28,29].

In summary, mass distribution of brochures was relatively more effective with Non-Hispanic Whites while African Americans responded relatively better to other recruitment strategies. PREMIER recruitment was enhanced by pursuing culturally and contextually sensitive strategies to overcome barriers to minority participation that yielded one-third African American participants.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The author wishes to thank all participants and especially those prominent citizens from across all four clinical centers that endorsed PREMIER. The author would like to thank Martha Swain and Dr. Laura Svetkey for edits to the manuscript, and Gayle Meltesen for handling data requests and providing data outputs in a timely manner.

Supported by National Institutes of Health grants U01 HL60570, U01 HL60571, U01 HL60573, U01 HL60574, U01 HL62828, and M01 RR00052.

References

- American Heart Association. Cardiovascular Diseases. [July 16, 2003]. Available at: http://www.americanheart.org/statistics/03cardio.html
- 2. American Heart Association. High Blood Pressure Statistics. [July 16, 2003]. Available at: http://www.americanheart.org/heart_and_stroke_A_Z-guide/hbps.html

3. Harris-Hooker S, Sanford G. Lipids, lipoproteins and coronary heart disease in minority populations. Atherosclerosis 1994;108:83–104S. [PubMed: 7980709]

- 4. National Hearth Lung and Blood, panel E. Clinical guidelines on the identification, evaluation and treatment of overweight and obesity in adults: The evidence report. Bethesda, MD: National Heart Lung and Blood Institute; 1998.
- Giuliano AR, Mokuau N, Hughes C, et al. Participation of minorities in cancer research: the influence of structural, cultural, and linguistic factors. Ann Epidemiol 2000;10(suppl 8):S22–S34. [PubMed: 11189089]
- 6. Kumanyika SK, Morssink C, Angurs T. Models for dietary and weight change in African American women: identifying cultural components. Ethn Dis 1992;2:166–175. [PubMed: 1467754]
- Shavers-Hornaday VL, Lynch CF, Burmeister LF, Torner JC. Why are African Americans underrepresented in medical research studies? Impediments to participation. Ethn Health 1997;2(12):31– 45. [PubMed: 9395587]
- 8. Svetkey LP, Harsha DW, Vollmer WM, Stevens VJ, Obarzanek E, Elmer PJ, Lin PH, Champagne C, Simons-Morton DG, Aickin M, Proschan MA, Appel LJ. Premier: a clinical trial of comprehensive lifestyle. Ann Epidemiol 2003;13(6):462–471. [PubMed: 12875806]
- Appel LJ, et al. Effects of comprehensive lifestyle modification on blood pressure control: Main results of the PREMIER clinical trial. JAMA 2003;289:2083–2093. [PubMed: 12709466]
- Burt VL, Whelton P, Roccella EJ, Brown C, Cutler JA, Higgins M, et al. Prevalence of hypertension in the U.S. adult population: Results from the Third National Health and Nutrition Examination Survey, 1988-1991. Hypertension 1995;25:305–313. [PubMed: 7875754]
- 11. Whelton PK, Appelgate WB, Ettinger WH, Espeland M, Kostis JB, Appel LJ, et al. Efficacy of weight loss and reduced sodium intake in the Trial of Nonpharmacologic Interventions in the Elderly (TONE). Circulation 1996;94:1–178. [PubMed: 8964107]
- 12. Svetkey LP, Simons-Morton D, Vollmer WM, Appel LJ, Conlin PR, Ryan DH, Ard J, Kennedy BM, DASH Research Group. Effects of dietary patterns on blood pressure: Subgroup analysis of the Dietary Approaches to Stop Hypertension (DASH) randomized Clinical trial. Arch Intern Med 1999; (159):285–293. [PubMed: 9989541]
- Ard JD, Carter-Edwards L, Svetkey LP. A new model for developing and executing culturally appropriate behavior modification clinical trials for African Americans. Ethn & Dis 2003;13:279– 285.
- 14. Karanja N, Vuckovic NL, Svetkey LP, Harsha D, Fisher J, Simons-Morton D, Conlin P, Charleston J, Jarrett RL, Morgan DL, DASH Collaborative Group. A qualitative study of factors that influence participation in clinical trials by African Americans. Unpublished.
- 15. Rucker-Whitaker C, Flynn KJ, Kravitz G, Eaton C, Calvin JE, Powell LH. Understanding African American participation in a behavioral intervention: Results from focus groups. Contemp Clin Trials 2006;27(3):274–86. [PubMed: 16427365]
- 16. Kennedy BM, Conlin PR, Ernst D, Reams P, Charleston JB, Appel LJ. Successfully recruiting a multicultural population: The DASH-Sodium experience. Ethn & Dis 2005;15:123–129.
- 17. Portland (city) QuickFacts from the US Census Bureau. Nov 9. 2007 http://quickfacts.census.gov/qfd/states/41/4159000.html
- 18. Valanis B, Blank J, Glass A. Mailing strategies and costs of recruiting heavy smokers in CARET, a large chemoprevention trial. Control Clin Trials 1998;19:25–38. [PubMed: 9492967]
- 19. Tworoger SS, Yasui Y, Ulrich CM, et al. Mailing strategies and recruitment into an Intervention trial of the exercise effect on breast cancer biomarkers. Cancer Epidemiol Biomarkers Prev 2002;11:73–77. [PubMed: 11815403]
- Corbie-Smith G, Thomas SB, Williams MV, Moody-Ayers S. Attitudes and beliefs of African Americans toward participation in medical research. J Gen Intern Med 1999;14:537–546. [PubMed: 10491242]
- 21. Kennedy BM, Burnett MF. Clinical research trials: A comparison of African Americans who have and have not participated. J Cult Divers 2002;9(4):95–101. [PubMed: 12674885]
- Kennedy BM, Burnett MF. Clinical research trials: Factors that influence and hinder participation. J Cult Divers 2007;14(3):141–147. [PubMed: 18314816]

23. Harris Y, Gorelick PB, Samuels P, Bempong I. Why African Americans may not be participating in clinical trials. J Natl Med Assoc 1996;88:630–634. [PubMed: 8918067]

- Roberson NL. Clinical trial participation. Viewpoints from racial/ethnic groups. Cancer 1994;24(9 Suppl):2687–2691. [PubMed: 7954287]
- 25. Gauthier MA, Clark WP. Gaining and sustaining minority participation in longitudinal research projects. Alzheimer Dis Assoc Discord 1999;13(Suppl):S29–S33.
- 26. Kennedy BM, Ard JD, Harrison L Jr, Conish BK, Kennedy E, Levy EJ, Brantley PJ. Cultural characteristics of African Americans: Implications for the design of trials that target behavior and health promotion programs. Ethn Dis 2007;17(3):548–554. [PubMed: 17985512]
- 27. Thomas CR Jr, Pinto HA, Roach M 3rd, Vaughn CB. Participation in clinical trials: Is it state-of-the art treatment for African Americans and other people of color? JNMA 1994;(86):172–182.
- Shavers-Hornaday VL, Lynch CF, Burmeister LF, Torner JC. Why are African Americans underrepresented in medical research studies? Impediments to participation. Ethn Health 1997;2(12):31– 45. [PubMed: 9395587]
- 29. Herring P, Montgomery S, Yancey AK, Williams D, Fraser G. Understanding the challenges in recruiting African Americans to a longitudinal cohort study: the Adventist health study. Ethn Dis 2004;14(3):423–430. [PubMed: 15328945]



Figure 1.

Kennedy et al.

Table 1

PREMIER Randomized Participants by Race and Recruitment Strategy

| | io^d story/ad TV^d story/ad Email/website Screening event Word of mouth e Total | 0 0 1 20 118 | 5 0 0 1 7 40 | 0 2 0 5 24 103 | 0 	 0 	 2 	 1 	 1 	 18 | 5 2 8 52 279 | about PREMIER? | ilo story/ad TV story/ad Email/website Screening event Word of mouth Total | 0 0 1 0 10 93 | 2 2 108 | 0 1 1 1 20 120 | 0 0 41 0 7 210 | 2 3 45 2 49 531 | 7 5 47 10 101 810 | |
|---|--|--------------|--------------|----------------|------------------------|--------------|---|--|---------------|-------------|------------------|------------------------|-----------------|---------------------------|----|
| | | 20 | 7 | 24 | 1 | 52 | | | 10 | 12 | 20 | 7 | 49 | 101 | |
| | Screening event | 1 | 1 | 5 | 1 | 8 | | Screening event | 0 | 1 | 1 | 0 | 2 | 10 | |
| | Email/website | 0 | 0 | 0 | 2 | 2 | | Email/website | 1 | 2 | 1 | 41 | 45 | 47 | |
| IER? | TV ^d story/ad | 0 | 0 | 2 | 0 | 2 | IIER? | TV story/ad | 0 | 2 | 1 | 0 | 3 | 5 | |
| hear about PREM | Radio ^d story/ad | 0 | 5 | 0 | 0 | 5 | u hear about PREM | Radio story/ad | 0 | 2 | 0 | 0 | 2 | 7 | |
| African Americans How did you hear about PREMIER? | Article print $^{\mathcal{C}/\mathrm{ad}}$ | 5 | 4 | 49 | 1 | 65 | Non-Hispanic Whites How did you hear about PREMIER? | Article print/ad | 1 | 11 | 95 | 4 | 99 | 125 | |
| African Am | Other b mass distribution | 0 | 3 | 2 | 1 | 9 | Non-Hispani | Other mass distribution | 0 | 11 | 0 | 3 | 14 | 20 | |
| | Coupon pack ^a | 0 | 8 | 0 | 0 | 8 | | Coupon pack | 0 | 09 | 0 | 0 | 09 | 89 | |
| | Mailed letter/brochure | 92 | 12 | 21 | 12 | 137 | | Mailed letter/brochure | 81 | 7 | 47 | 155 | 290 | 427 | |
| | Clinical Sites | Baltimore | Baton Rouge | Dugham | Po te land | Clin L | Tric | Clinical Sites | Ba∰more | Bagon Rouge | Dugham | 豆. Po 哩 land | av ā il | Gr <mark>æ</mark> d Total | in |

Items and coupons.

Items and coupons.

Items and prochares or single-sheet flyers and coupons.

Items and pay-stub messages and inserts, and hand-distribution of brochures and flyers.

Cyalus given as number of days advertisements were printed.

 e Word-of-mouth and prior study participants.

Page 11

Table 2

Kennedy et al.

Baseline Characteristics of 810 PREMIER Study Participants

| Age (y), (mean \pm SD ^d) | 8.9 |
|--|-----|
| 22-39 (%) | Ξ |
| 40-59 (%) | 75 |
| (%) 09 | 14 |
| Race (%) | |
| Non-Hispanic White | 63 |
| African-American | 34 |
| Other | 3 |
| Sex (%) | |
| | 38 |
| Women | 62 |
| | I |
| | |
| | 6 |
| College (>0-4 y) | 59 |
| Graduate school | 32 |
| Marital Status (%) | |
| | 12 |
| | 99 |
| Other | 22 |
| Employment (%) | |
| Full-time | 75 |
| Part-time | 10 |
| Other | 15 |
| Household income (%) | |

Page 12

Kennedy et al.

 b Body mass index measured as ${\rm kg/m^2}$ a SD = standard deviation

 $90-98 \; (\%)_{\mathcal{C}}$

Page 13