SUCCESSFULLY RECRUITING A MULTICULTURAL POPULATION: THE DASH-SODIUM EXPERIENCE

Betty M. Kennedy, PhD; Paul R. Conlin, MD; Denise Ernst, MA; Patrice Reams; Jeanne B. Charleston, RN, MSN; Lawrence J. Appel, MD, MPH

Recruiting practices employed by the four clinical centers participating in the Dietary Approaches to Stop Hypertension (DASH)-Sodium trial were examined to assess the most successful method of obtaining participants and to describe pertinent learning experiences gained as a result of the trial. The primary recruitment strategies employed by each center were mass mailing brochures (direct, coupon packs, or other) and mass media (advertisements in newspapers, radio, and television spots). Of 412 randomized participants, 265 (64%) were from mass distribution of brochures, 62 (15%) mass media, and 85 (21%) were prior study participants, referred by word-of-mouth, or reported coming from screening events and presentations. Although the most successful method of recruitment was mass mailing brochures, three times as many brochures were distributed to obtain similar success as in the initial DASH trial. (*Ethn Dis*. 2004;15:123–129)

Key Words: African Americans, Mass Mailings, Multicenter Trials, Recruitment

From the Pennington Biomedical Research Center, Baton Rouge, Louisiana (BMK); the Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts (PC); the Kaiser Permanente Center for Health Research, Portland, Oregon (DE); the Duke Hypertension Center and the Sarah W. Stedman Nutrition and Metabolism Center, Durham, North Carolina (PR); and the Welch Center for Prevention, Epidemiology, and Clinical Research, Johns Hopkins University, Baltimore, Maryland (JBC, LJA).

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

INTRODUCTION

Recruiting participants for multicenter trials can be tedious, time-consuming, and costly.[1] Failure to obtain and enroll the required sample size in the time allowed reduces power to address the central scientific question of the trial.[2] Thus, devising and using efficient, inexpensive, and high-yield recruitment techniques are vital. Common recruitment techniques include media campaigns (advertisements in newspapers, radio, and television), various on-site and off-site screening events, and presentations to groups of potentially eligible individuals. In addition, various lists, including the Department of Motor Vehicle (DMV) registrants, voter registrants, and lists from private vendors, have been used to recruit participants through targeted mass mailings. Mass mailings were first employed 34 years ago by investigators of the National Diet-Heart Study (NDHS).[3] This recruitment technique reaches a large number of people at a relatively low cost.[4–7] In addition, for reasons of cost and ease of implementation, mail surveys, for example, are more frequently used than either telephone or face-to-face interviews.[8] Furthermore, an examination of all federal surveys approved by the US Office of Management and Budget concluded that at least 90% of self-administered surveys were mailed.[9]

As recruitment of participants from the general public for multicenter trials continues, understanding the efficacy of various techniques is crucial. The recruitment experiences of the Dietary Approaches to Stop Hypertension (DASH)[10] and DASH-Sodium outpatient feeding trials both enrolled a demographically heterogeneous study population while exceeding recruitment goals. This type of recruitment success should be useful to researchers and staff planning to conduct trials that enroll generally healthy individuals. In addition, providing selected demographic characteristics of participants who enroll in these kinds of trials should assist research recruiters, clinical staff, and investigators in recognizing characteristics of individuals most likely to enroll in multicenter trials.

In this article, the recruiting practices employed by the four clinical centers participating in the DASH-Sodium trial are examined to assess the most successful method of obtaining participants and to describe learning experiences gained from the trial.

METHODS

The DASH-Sodium Trial was a 14-week randomized multi-center outpatient feeding study. The study included a 2-week run-in period (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), followed by three 30-day feeding periods, separated by breaks of 0–4 days. The purpose of the study was to compare effects on blood pressure of

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two dietary patterns (control diet, that is typical of what many Americans eat, and the DASH diet—lower in fat and emphasizing fruits, vegetables, and low-fat dairy foods) and three levels of sodium intake (higher, medium, and lower) in a population of adult men and women with above optimal blood pressure to stage 1 hypertension (systolic blood pressures of 120 mm Hg to 159 mm Hg and diastolic blood pressures of 80 mm Hg to 95 mm Hg).[11] The rationale and design of the trial has been described elsewhere.[12–13] Each center received prior approval from their institutional review boards, an external protocol review committee approved the trial protocol, and each DASH-Sodium participant provided written informed consent.

Participants

The DASH-Sodium trial (described elsewhere[11–13]) aimed to recruit 400 adult men and women, age 22 years and older. Eligibility criteria were selected to exclude individuals with special dietary requirements, those taking medications that would affect blood pressure or micronutrient metabolism, and those with potentially serious chronic health conditions. Participants were required to comply with dietary changes and eat at least one meal each weekday at the clinical center. A computer-driven randomization process selected diets, and only study foods were permitted during the feeding phase of the study.

Recruitment Goals

The recruitment sites for DASH-Sodium were the same as those for DASH. Participants for the DASH-Sodium trial were recruited at the four clinical centers (Baltimore, Md; Baton Rouge, La; Boston, Mass; and Durham, NC), and each site had a recruitment goal of 100 participants. Fifty percent of those targeted were African American because of the disproportionate burden of hypertension and its complications in this group. Each center planned to recruit participants in four to five cohorts (25–20 participants per cohort).

Active recruitment occurred in distinct periods prior to the commencement of feeding for each cohort. For the first cohort, all centers recruited from September 1997 until the start of feeding in January of 1998. For the remaining cohorts, the actual recruitment and feeding periods varied by site. For each site, however, the feeding periods were the same for all members of that cohort. Recruitment activities for the last three cohorts overlapped with feeding in some cases so that all sites would reach the recruitment goals in a timely manner and the study would be completed by November 1999.

Recruitment Techniques

Recruiting practices were examined to assess the most successful method of obtaining participants in large quantities within a given period of time. Mass distribution of brochures, previously shown to be successful in DASH and other trials was done at each clinical center.[14–18] The primary recruitment technique employed by each center was mass mailing brochures. Trifold brochures in various color schemes with center-specific and general study information were mailed to licensed drivers, registered voters, and others residing near the clinical centers. Lists for participants were obtained from federal and state agencies, private companies, legislators, retired teacher organizations, civic and social clubs (including fraternities and sororities), American Association of Retired Persons, and commercial mailing companies. Some centers sent out brochures that were endorsed by previous DASH participants and public officials. Study brochures and flyers were also distributed commercially in coupon packs. One center had a subsidiary of the local newspaper hang brochures in a bag on doors of residents in subdivisions within a 20-mile radius of the clinical center. Messages about DASH-Sodium were printed on some centers' employee check stubs, and flyers were placed in envelopes with employee checks at some centers. Potential participants contacted the clinical center by calling or returning prepaid postcards.

During the second through fifth stages of recruitment, repeat mailings to households in the same zip code areas, men's groups (to increase participation of men), and previous DASH participants were interspersed with primary mailings to maintain a constant influx of potential participants.

Mass media, including advertisements in newspapers, radio, and television, were used by each center. To attract the largest number of potential participants in a single setting, several recruitment activities were employed simultaneously. For example, to attract the largest number of African-American participants, one center placed 3″ x 5″ display ads in the food section of the newspaper to attract female participants and in the sports section to attract male participants. In addition, the recruitment coordinator and investigators broadcasted from the center and appeared on an African-American radio station. Investigators made appearances on morning television shows, and the center mass mailed brochures before an open house. For tracking purposes, brochures were color coded for each open house event, and the date, time, and location of the open house was noted inside each brochure. Refreshments were often provided for potential participants attending the open house.

Other techniques used to recruit participants included screening events and presentations, letters to DASH study participants or participants from

previous trials, and word-of-mouth. Blood pressure measurements and other screenings were conducted at community health and job-site wellness fairs. Presentations occurred at various organizations, including churches, colleges, and community forums. Limitations were placed on the number (20%) of DASH study participants who could enroll in DASH-Sodium.

Recruitment Process

The DASH-Sodium recruitment coordinators were primarily responsible for developing and implementing the recruitment drive. In DASH, a community advisory board, including ministers, state and local officials, and lay community leaders, reviewed brochures and flyers before distribution. This practice was continued during the DASH-Sodium trial and was successful, especially in recruiting African Americans. Recruitment coordinators at each clinical center solicited participants enrolled in another trial or who had already completed a trial to help promote DASH-Sodium. Duke's recruitment coordinator used (with permission) photos of participants who had completed a cohort in DASH-Sodium to attract others. Recruitment coordinators at each clinical site supplied brochures and flyers to entities that helped recruit participants. A recruitment subcommittee consisted of the recruitment coordinators from the four clinical centers, representatives from the coordinating center, a representative from the National Heart, Lung, and Blood Institute, and an investigator who chaired the group.

Members of the committee held monthly conferences by telephone. During active recruitment, each center tracked the number of persons scheduled at each step in the screening process. A computer-based tool developed by the coordinating center during the initial DASH,10 allowed up-to-date projections on the number of participants needed at each stage of screening based on yields from the initial DASH trial and the first cohort of DASH-Sodium.

Each clinical center provided participants with incentives (eg, coffee mugs, T-shirts, umbrellas, water bottles, duffel bags, and social events), and at the end of the study, each site provided a cash stipend to each participant (range=$150 to $600 across centers). Each clinical center paid the same cash stipend for 11 weeks of feeding in the initial DASH trial.[10] Although DASH-Sodium was three weeks longer than DASH, the cash stipend remained the same and potentially eligible participants were attracted in spite of the additional time added.

Recruitment Data Collection

A recruitment activities log tracked the quantity and type of activity each clinical center used. At the end of each week, coordinators recorded a description of weekly recruitment activities. The Recruitment Activities Log included reports on the number of: brochures/fliers and other print material distributed (other than those mailed); nonpaid radio/print/TV stories picked up by the media; screening events/health fair held; presentations conducted; media spots print/radio/TV advertisements purchased; and email messages sent via email distribution lists. The log determined which method was most useful, while counts of visits other than the prescreen visit were determined from the trial database. Coordinators could use the log to identify techniques most likely to attract participants.

RESULTS

Table 1 illustrates recruitment techniques and the number of participants each technique attracted at each clinical center. All centers mailed a large number of brochures (range=218,361 to 414,875). A total of 1,150,544 brochures were distributed by mail. One center distributed items in coupon packs. The volume of brochures distributed through other means was also substantial (207,545). A common technique employed at Baton Rouge was mass media (print, radio, and TV); of 62 total participants recruited from mass media, 23 were from the Baton Rouge center. All clinical centers conducted screening events and presentations. Counts of informal contacts, eg, word-of-mouth, are not easily documented; they are displayed in Table 1.

In total, 412 participants (12 more than the target sample size of 400) were randomized in DASH-Sodium. Table 1 illustrates the sources of randomized participants by recruitment techniques utilized in the trial. Of the participants, 265 (64%) were recruited from mass distribution of brochures, 62 (15%) from mass media, and 85 (21%) from screening events and presentations, previous study participants, or word-of-mouth. Little difference was observed in recruitment techniques across clinical centers; for example, the number of randomized participants recruited by mass mailing brochures was 44 to 69.

Yields from mass mailing, unlike most recruitment techniques, can be calculated, since the number of mailed brochures is readily available. Overall, the yield from mass mailing brochures was 1.9 enrollees per 10,000 mailings. The range of yields from mass mailing brochures across all 4 centers was 1.3 to 2.6 enrollees per 10,000 mailings.

The four clinical centers collectively received 6,915 prescreen contacts (self-reported systolic blood pressure $\geq$120 mm Hg, diastolic blood pressure $\geq$80 mm Hg, and not on any blood pressure medication) as potential participants. At each of three screening visits, adult men and women with above optimal blood pressure to stage 1 hypertension (systolic blood pressures of 120 to 159 mm Hg and diastolic blood pressures of 80 to 95 mm Hg, were eligible to continue the screening process. Of the 6,915 prescreen contacts (range=1471 to 2441 across centers) 3,619 (52%) were eligi-

Table 1. Recruitment techniques and number of randomized (NR) participants in the DASH-Sodium Trial by clinical center

Clinical Center→ Mass Distribution	Baltimore	NR	Baton Rouge	NR	Boston	NR	Durham	NR	Total	NR
Mailed brochures	265,235	69	252,073	44	414,875	54	218,361	56	1,150,544	223
Coupon packs*	0	0	0	0	340,000	14	0	0	340,000	14
Other†	10,000	6	165,820	6	18,413	6	13,312	10	207,545	28
Total	**275,235**	**75**	**417,893**	**50**	**433,628**	**74**	**231,673**	**66**	**1,698,089**	**265**
Mass media										
Print‡	5	6	62	19	28	12	46	19	141	56
Radio§	0	0	78	3	15	0	0	0	93	3
TV§	0	0	5	1	0	0	31	2	36	3
Total	**5**	**6**	**145**	**23**	**43**	**12**	**77**	**21**	**270**	**62**
Other										
Screening events and presentations	4	2	34	3	2	0	7	1	47	6
Word-of-mouth		2		7		12		14		35
Prior study participants		19		11		3		11		44
Total	**4**	**23**	**34**	**21**	**2**	**15**	**7**	**26**	**47**	**85**
Grand Total	**275,244**	**104**	**418,072**	**94**	**433,673**	**101**	**231,757**	**129**	**1,698,406**	**412**

* Items included brochures or single-sheet flyers and coupons.
† Items included email/web, pay-stub messages and inserts, and hand-distribution of brochures and flyers.
‡ Values given as number of days advertisements were printed.
§ Values represent number of spots.

ble to continue the screening process. Of these, 2,415 (67%) completed screening visit one. Of the 2,415 completing screening visit one, 935 (39%) completed screening visit two, and, of these, 654 (70%) completed screening visit three. A total of 480 persons or 73% of those completing screening visit three started the run-in phase of the study. Of those who started run-in, 412 (86%) were randomized in DASH-Sodium. The total yield from screening visit one to randomization was 17.1% (range between clinics=9.7% to 25.2%) (Table 2).

Selected baseline characteristics of the 412 participants are illustrated in Table 3. The mean age was 48 years, and the largest number of participants in the trial was between the ages of 40 and 59 years. More than half of the participants were African-American, with more than half women. The majority (83%) of participants attended college and/or graduate school, and the largest number (47%) were married. Forty-five percent of participants were employed

Table 2. DASH-Sodium recruitment experience by visit/period and by clinical center

Period or Visit	Baltimore		Baton Rouge		Boston		Durham		Total	
	N	%*	*N*	%	*N*	%	*N*	%	*N*	%
Prescreen contact	1471	N/A	1501	N/A	2441	N/A	1502	N/A	6915	N/A
Prescreen eligible	1153	78	1427	95	586	24	453	30	3619	52
Screening visit 1 completed	592	51	968	68	406	69	449	99	2415	67
Screening visit 2 completed	228	39	220	23	216	53	271	60	935	39
Screening visit 3 completed	177	78	151	69	148	69	178	66	654	70
Run-in started	129	73	104	69	119	80	128	72	480	73
Randomized	104	81	94	90	101	85	113	88	412	86
% Prescreen contacts who were randomized		7.1		6.3		4.1		7.5		6.0
% Screening visit 1 contacts who were randomized		17.6		9.7		24.9		25.9		17.1

N/A=not applicable.
* Yield from preceding step.

full-time, and distribution of household income was wide. Mean body mass index was high (28.6) for men and (29.6) for women. Forty-six percent of the participants had been previously diagnosed by a physician with hypertension, 17% ever took medication, and no participants underwent medication withdrawals before enrollment in the trial. Mean systolic blood pressure was 135 mm Hg, and 32% had stage 1 systolic hypertension. Mean diastolic blood pressure was 86 mm Hg, and 21% had stage 1 diastolic hypertension.

Table 3. Baseline characteristics of 412 DASH-Sodium study participants

Age (y), (mean ± SD*)	48.2 ± 10.0
22–39 (%)	18
40–59 (%)	68
60 (%)	14
Race (%)	
Non-Hispanic White	39
African-American	57
Other	4
Sex (%)	
Men	43
Women	57
Education (%)	
≤High school	17
College (>0–4 y)	60
Graduate school	23
Marital status (%)	
Single	24
Married	47
Other	29
Employment (%)	
Full-time	45
Part-time	22
Other	33
Household income (%)	
<$30,000	33
$30,000–$60,000	37
>$60,000	30
Hypertension history	
Prior diagnosis of hypertension (%)	46
Ever took BP medication (%)	17
BP mass index† (mean ± SD)	
Men	28.6 ± 4.0
Women	29.6 ± 5.4
Systolic blood pressure (mm Hg), (mean ± SD)	134.8 ± 9.5
110–129 (%)	36
130–139 (%)	33
140–162 (%)‡	32
Diastolic blood pressure (mm Hg), (mean ± SD)	85.7 ± 4.5
74–84 (%)	48
85–89 (%)	31
90–98 (%)‡	21

* SD=standard deviation.
† Body mass index measured as kg/m^2.
‡ Stage 1 hypertension.

DISCUSSION

In this article, the recruiting practices employed by the four clinical centers participating in the DASH-Sodium trial were examined to assess the most successful method of obtaining participants, and to describe pertinent learning experiences gained as a result of the trial. The DASH-Sodium trial presented researchers with challenges to recruit patients for a trial with strict dietary requirements (14 weeks of controlled feeding with visits to the centers five days a week) and strict eligibility criteria. Overall, recruitment was successful in DASH-Sodium, exceeding established goals in all aspects, including minority recruitment goals.

Several factors may have implications for recruitment in future trials. DASH-Sodium had a low yield for randomized participants recruited from mass mailing brochures. The estimated cost of mailing brochures was $149,571, not including design and printing costs. Although the cost to mass mail brochures was substantial, and a great deal of effort was spent arranging, responding, and following up to enroll participants, mass mailing attracted the largest number of participants.

Mass mailing brochures was decided to be the primary recruitment technique by all four clinical centers. Although costly, this technique confirmed existing literature that suggests direct-mail recruitment strategies have advantages for large trials: they can provide a continual flow of subjects and are less labor-intensive than other forms of recruitment, such as cold-calling.[1]

Mass media (advertisements in newspapers, radio, and television) and other methods also contributed to recruitment success. The number of participants randomized (N=56 participants or 14%) as a result of newspaper advertisements demonstrates that this form of mass media complemented mass mailings in recruiting participants for the trial. Therefore, as the literature suggests, intervention trials using mass mailing as the primary recruitment

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strategy may benefit from including additional mass media and other strategies.[7] Future trials should assess the cost-effectiveness of advertising strategies as a supplement to mass mailing.[1]

Prior study participants (N=44) were the third-largest source of randomized participants in the trial, followed by word-of-mouth (N=35). Although each center was limited to recruiting 20 DASH participants for DASH-Sodium because of protocol requirements, most prior study participants (those having participated in any other clinical trials at the center) had previously participated in the DASH trial.[10]

Most prior study and word-of-mouth randomized participants were African Americans. This finding implies that African Americans are likely to participate in clinical trials on the basis of who they know and the experiences of others who have already participated.[19] Hands-on recruiting techniques included attending social events such as football and basketball games, black tie affairs (100 Black Men Mardi Gras Galas, Kiwanis International), screening events and presentations (at state departments, the Social Security Administration, community health fairs, grocery stores, barber shops, beauty salons, and nail shops). Hands-on recruiting was essential to acquire African-American participants in both DASH and DASH-Sodium trials. Since the Baltimore, Baton Rouge, and Durham sites were asked to over-recruit African-American participants, coordinators at these centers participated in some of the trials' activities, such as having blood drawn, having blood pressure measured, and pilot-tasting foods to be served as part of the trial. This type of participation served as a testimonial for potential African-American participants and increased participants' comfort and satisfaction. Research has shown that a trusting relationship helps African Americans feel comfortable participating in clinical trials.[17–21]

African Americans who have successfully completed a clinical trial are likely to enroll in similar future trials, and word-of-mouth can also help recruit African-American participants, especially when previous participants express positive messages and experiences.[21]

Trial participants were demographically heterogeneous, reflecting the trial's eligibility criteria. Age distribution was wide, as were several sociodemographic variables (ie, employment and marital status). Many participants had been diagnosed previously with hypertension, and some had been taking antihypertensive medication. This kind of diversity enhances the generalizability of the trial results.

In conclusion, successfully recruiting a heterogeneous study population that includes a large number of African Americans is an achievable goal. Though recruiting African Americans was labor-intensive and expensive, these techniques were required for DASH-Sodium to succeed. However, when considering the cost of mass mailing brochures, hands-on recruiting may be more cost-effective and an option for recruiting participants in future multicenter clinical trials.

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AUTHOR CONTRIBUTIONS

Design and concept of study: Kennedy, Conlin, Earnst, Reams, Appel
Acquisition of data: Kennedy, Conlin, Earnst, Reams, Charleston, Appel
Data analysis and interpretation: Kennedy, Conlin, Earnst, Reams, Appel
Manuscript draft: Kennedy, Conlin, Earnst, Reams
Statistical expertise: Kennedy
Acquisition of funding: Appel
Administrative, technical, or material assistance: Kennedy, Conlin, Earnst, Reams, Appel
Supervision: Kennedy, Conlin, Earnst, Reams, Appel

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