

# ORIGINAL REPORTS: RESEARCH DESIGN

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## RECRUITMENT OF AFRICAN AMERICAN AND WHITE POSTMENOPAUSAL WOMEN INTO CLINICAL TRIALS: THE BENEFICIAL EFFECTS OF SOY TRIAL EXPERIENCE

**Objective:** To describe the strategies and costs associated with recruiting both African American and White postmenopausal women into a randomized controlled trial.

**Design:** The Beneficial Effects of Soy Trial (BEST) was a randomized, controlled trial designed to determine the effects of a dietary soy supplement on lipoproteins, lipoprotein subclasses, and menopausal symptoms in African American and White postmenopausal women. The goal was to have  $\geq 80$  African American and  $\geq 80$  White women complete the study.

**Results:** A total of 705 postmenopausal women (381 African American, 324 White) were screened, and of those, 217 were randomized (105 African American, 112 White), and 192 (91 African American, 101 White) completed the study. Direct mailings to targeted zip codes proved the most successful recruitment strategy for recruiting African Americans (52% of African Americans recruited) and the second most effective for recruiting Whites (32% of Whites recruited). Newspaper advertisements yielded the highest number of White participants (36%) but proved less successful for recruiting African Americans (8%). Airing advertisements on the radio was the second most effective strategy for recruiting African Americans (15%), yet it was one of the least effective approaches for recruiting Whites (5%). The total cost of recruitment was \$49,036.25, which averaged \$255.40 per participant who completed the study. The three most successful strategies, direct mailings, newspaper ads, and radio ads, were the three most expensive approaches but yielded 73% of all participants who completed the study.

**Conclusions:** A variety of targeted recruitment strategies are required to ensure a diverse response to advertisements and promotions. Given the extra time and effort needed to recruit minorities, researchers must include adequate resources to cover the cost of recruitment in their budgets. (*Ethn Dis.* 2006;16:938–942)

**Key Words:** Clinical Trials, Minority, Recruitment, Women

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### INTRODUCTION

Reducing health disparities in minority populations has become an increasingly important goal in the public health community. One way to address this is through a deeper understanding of these populations, which have traditionally been left out of medical research. Federal agencies now mandate the inclusion of minority groups in study samples; however, researchers face many obstacles when reaching out to these underrepresented groups.<sup>1–7</sup>

Numerous studies have examined the challenges of recruiting participants into research investigations. In the African American community, historical events gave rise to a lack of trust in medical professionals, whose motivations and credibility are commonly questioned.<sup>8,9</sup> A commonly held opinion in this community is that one gives up his or her rights by signing a consent form, and the perception is widespread that researchers lack cultural sensitivity.<sup>10,11</sup> Mistrust also stems from the general belief that minorities endure most of the risks of medical research.<sup>12</sup> Therefore, investigators must understand the culture with which they are working and be sensitive to their differences. By collaborating with the community, researchers can incorporate their own goals with those of the minority group, thereby establishing a mutual interest in the research.<sup>5,13–17</sup>

Several strategies have been documented as useful ways to recruit minority participants. Hinshaw et al encouraged flexible and adaptive treatment designs, as well as alternative options for individuals who do not meet inclusion criteria.<sup>18</sup> Others have emphasized the importance of flexibility in appointment time and place, in addition to providing adequate reimbursement for participation.<sup>4,17,19,20</sup>

Despite the abundance of literature on this subject, little attention has been given to the costs and return on investment related to the recruitment process. This paper describes the strategies and costs associated with the recruitment of both African American and White postmenopausal women into a randomized, controlled trial.

### DESIGN

The Beneficial Effects of Soy Trial (BEST) was a double-blind, placebo-controlled, parallel-group, randomized trial designed to determine the effects of a dietary soy supplement containing isoflavones on lipoproteins and lipopro-

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**Table 1. Baseline sample characteristics**

Characteristic	African American <i>n</i> =105	White <i>n</i> =112	<i>P</i> value
Sociodemographic			
Age, mean (SD)	55.67 (4.98)	57.85 (5.94)	.004
Education, %			.26
Less than high school	5.71	2.68	
High school or more	94.29	97.32	
Annual income, %			.34
<\$20,000	9.80	7.48	
\$20,000–\$40,000	18.63	13.08	
>\$40,000	71.57	79.44	
Clinical, mean (SD)			
BMI, kg/m <sup>2</sup>	29.40 (4.55)	26.57 (4.36)	<.001
Lipoproteins, nmol/L			
Total cholesterol	5.62 (.65)	5.88 (.67)	.005
LDL cholesterol	3.59 (.57)	3.68 (.59)	.28
HDL cholesterol	1.49 (.32)	1.59 (.36)	.04
Triglycerides	1.18 (.56)	1.35 (.54)	.02
Menopausal symptoms, mean (SD)			
Vasomotor	3.62 (1.81)	2.83 (1.87)	.002
Psychosocial	2.51 (1.52)	2.65 (1.37)	.53
Physical	2.57 (1.14)	2.59 (1.07)	.99
Sexual	1.95 (1.45)	1.92 (1.33)	.84

To convert total cholesterol, LDL cholesterol, and HDL to mg/dL, divide by .0259; to convert triglycerides to mg/dL, divide by .0113.

SD=standard deviation; BMI=body mass index; LDL=low-density lipoprotein; HDL=high-density lipoprotein.

tein subclasses in African American and White women with elevated low-density lipoprotein (LDL) cholesterol. The secondary aim of the study was to assess the impact of soy on menopausal quality of life in these women.

Based on sample size calculations, the goal was to have  $\geq 80$  African American and  $\geq 80$  White postmenopausal women complete the study. A total of 216 participants (104 African American, 112 White) were randomized, and 192 completed the trial (91 African American, 101 White). These women were recruited from various sources, but all met certain inclusion and exclusion criteria. To qualify as postmenopausal, women needed to have been without a menstrual period for  $\geq 12$  months or have a follicle-stimulating hormone level  $>30$  U/mL if they had a hysterectomy. They were excluded for having LDL cholesterol levels  $<130$  mg/dL or  $>190$  mg/dL, triglyceride levels  $>400$  mg/dL, or a history of diabetes or fasting blood glucose levels  $>125$  mg/dL. Women also were excluded for being  $>79$  years of age,

having used hormone-replacement therapy or oral contraceptives in the past six months, having a history of cardiovascular disease or stroke, currently using lipid-lowering medication, consuming more than two alcoholic drinks per day, or having a body mass index  $>39$  kg/m<sup>2</sup>. Additionally, they were excluded for having a history of breast cancer or for being at high risk of developing breast cancer, based on a score of 1.7% or greater on the Breast Cancer Risk Assessment Tool.<sup>21</sup> Women were excluded for having uterine cancer, kidney disease, liver disease, thyroid disease, chronic gastrointestinal disorders, or for participation in a conflicting clinical trial. Finally, women were excluded if they were not willing to avoid soy products for the four months of the study.

Sample baseline characteristics are described in Table 1. The overall mean age for participants was 56.8 years. There were differences between African Americans and Whites in that African Americans were older; had higher body mass indices; had lower total cholesterol,

ol, high-density lipoprotein cholesterol, and triglycerides; and reported more vasomotor symptoms.

After a series of screening visits, all qualifying participants were given nutritional counseling to follow the National Cholesterol Education Program Step I diet, a supply of casein placebo supplement, and advice on how to incorporate the supplement into their daily diet. After a four-week placebo run-in period, participants were randomized to one of two groups, soy or casein placebo supplement, to take daily for 12 weeks. Both study personnel and participants were blinded to the group assignments.

At the baseline visit, the participant's weight was measured, and a blood sample was taken for a fasting lipid profile and analysis of lipoprotein subclasses. A urine sample was collected to test for isoflavones as a baseline measure to determine compliance. Each woman completed three study questionnaires: menopausal quality of life,<sup>22</sup> physical activity,<sup>23,24</sup> and a food frequency questionnaire.<sup>25</sup> All of these measurements and questionnaires were repeated at two follow-up visits, 6 and 12 weeks after randomization.

## RESULTS

### Recruitment

A variety of recruitment strategies were used to reach the goal of  $\geq 160$  completed participants, 50% African American and 50% White. A total of 29 advertisements were placed in assorted newspapers in the Baltimore metropolitan area. Two newspapers specifically target the African American community, while the others appeal to a more diverse audience. Advertisements for BEST also aired on several radio stations, targeting both African American and White listeners in the Baltimore area; 159 advertisements were aired, each 10–60 seconds long, with the race of the narrator based on the demo-

graphics of the targeted audience. Another mass-media approach was direct mailings of promotional brochures to targeted zip codes in urban and suburban communities surrounding the study sites. A total of 53,700 culturally sensitive brochures were mailed. The brochures were mailed in batches of 2,500 approximately every two months throughout the recruitment period.

Referrals to BEST were made by numerous sources. Other research teams at Johns Hopkins shared study information with qualified participants, as did several healthcare providers. Participants themselves became great resources, in that they informally referred friends and family members while sharing their experiences about the study.

One of the most successful sites for recruitment was a nearby government workplace. Conveniently located a few blocks from one of BEST's clinic sites was the headquarters of the Social Security Administration. Employee demographics proved a good match for the study, as most of its staff members were middle-aged African American women. During various health fairs, tables were set up to advertise the study, and study staff were available to answer questions of potential participants.

A Johns Hopkins employee newsletter was used as another means of recruiting participants. Approximately every month, an informative advertisement was placed in an internal flyer, which reaches  $\approx 12,000$  employees. Finally, women were recruited from numerous local churches surrounding the study sites. The BEST staff held several educational workshops on natural approaches to menopause in the churches in hopes of recruiting women interested in study participation. Advertisements were also placed in the churches' bulletins and lobbies.

After 24 months of recruitment, the goal for enrolling White participants had been met, but a significant number of African American participants were

**Table 2. Recruitment strategy by race**

Strategy	Screened			Completed Study		
	Total	AA	W	Total	AA	W
Newspaper ads	152	37	115	43	7	36
Radio ads	78	61	17	19	14	5
Direct mailings	289	178	111	79	47	32
Referrals from other studies	30	10	20	8	2	6
Healthcare provider referrals	24	13	11	10	4	6
Participant referrals	35	23	12	9	4	5
Health fairs	47	38	9	14	12	2
Internal newsletter	48	20	28	9	1	8
Church	2	1	1	1	0	1
<b>Total</b>	<b>705</b>	<b>381</b>	<b>324</b>	<b>192</b>	<b>91</b>	<b>101</b>

AA=African American; W=White.

still needed (only 50 out of a goal of 80 African American women had completed the study). Consequently, BEST staff directed their recruitment strategies to focus on enrolling African Americans. For the next three months, brochures were sent exclusively to African American communities, and radio advertisements specifically targeted African American female listeners. Twenty-seven months after recruitment began, total enrollment goals were reached.

### Return on Investment

A total of 705 postmenopausal women (381 African American, 324 White) were screened for BEST, and of those, 217 were randomized (105 African American, 112 White), and 192 (91 African American, 101 White) completed the study. As evident in Table 2, direct mailings to targeted zip codes proved the most successful recruitment strategy. Forty-one percent (79/192) of all participants who completed the study were recruited in this manner. Newspaper advertisements also returned a high volume of participants, 22% (43/192) of those recruited.

When these strategies were evaluated based on race, some differences emerge. Direct mailings of brochures remained the most effective strategy for recruiting African Americans (52% [47/91] of African Americans recruited) and the second most effective strategy for recruiting Whites (32% [32/101] of

Whites recruited). Newspaper advertisements yielded the highest number of White participants (36% [36/101]) but proved less successful for recruiting African Americans (8% [7/91]), despite the fact that advertisements were placed in several newspapers specifically targeting African Americans. Airing advertisements on the radio was the second most effective strategy for recruiting African Americans (15% [14/91]), yet it was one of the least effective approaches for recruiting Whites (5% [5/101]). Recruiting participants at Social Security headquarters also proved to be very successful for recruiting African Americans (13% [12/91]) but unsuccessful for recruiting Whites (2% [2/101]), which can be attributed to the employee demographics.

The total cost for each strategy was calculated by adding labor expenses and the direct expenses for materials, supplies, and advertising. Labor costs were estimated by combining the annual salary of the recruiter (\$38,000) with 31% fringe benefits (\$11,780) for a total annual salary of \$49,780. As seen in Table 3, the total cost of recruiting for BEST was \$49,036.25, which averaged \$255.40 for each of the 192 participants who completed the study. However, this cost per participant varied considerably when looking at each individual recruitment strategy. Referral by word of mouth was the least expensive approach, yet it yielded few participants and was

**Table 3. Return on investment per recruitment strategy**

Strategy	Cost	Participants Recruited and Completed Study	Cost/Completed Participant
Newspaper ads	\$16,795.25	43	\$390.59
Radio ads	6,153.00	19	323.84
Direct mailings	21,109.00	79	267.20
Referrals from other studies	383.00	8	47.86
Healthcare provider referrals	383.00	10	38.30
Referrals from participants	0	9	0
Social Security health fairs	3,159.75	14	225.70
Internal newsletter	287.25	9	31.92
Church	766.00	1	766.00
<b>Total</b>	<b>\$49,036.25</b>	<b>192</b>	<b>\$255.40</b>

not easily controlled. Recruiting in the internal newsletter and healthcare provider referrals both proved to be expensive (\$31.92 and \$38.30/participant), but neither were effective in recruiting large numbers of participants. The three most successful strategies, direct mailings, newspaper ads, and radio ads, were the three most expensive approaches but yielded 73% of the participants who completed the study. The materials and services associated with these strategies were expensive, although little recruiter labor was required.

## DISCUSSION

The recruitment of minorities remains a challenging process. Investigators must be aware of potential barriers

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and costs and plan accordingly. A variety of recruitment strategies are required to ensure a diverse response to advertisements and promotions. Referrals from healthcare providers or existing participants can help overcome common misconceptions of researchers, as recommendations from trusted professionals or personal friends can help dispel suspicions toward the medical community and research. However, this approach may be unreliable and may not recruit the necessary numbers of participants. Attracting sufficient numbers of healthy volunteers may require more elaborate strategies, such as the use of mass media. The effectiveness of individual approaches will vary considerably depending on the population being recruited, so a flexible recruitment plan must be prepared. Given the extra time and effort needed to recruit minorities, combined with the monetary restraints of sponsored projects, researchers must include adequate resources to cover the cost of recruitment in their budgets. Balancing cost-effectiveness with yield of participants is not always possible; thus, investigators must use multiple recruitment methods and flexible recruitment plans in a way that achieves optimal results.

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