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Recruitment of African American and White Postmenopausal Women into Clinical Trials: The Beneficial Effects of Soy Trial Experience

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Abstract

OBJECTIVE—To describe the strategies and costs associated with recruiting both African American (AA) and White (W) 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 AA and W postmenopausal women. The goal was to have at least 80 AA and 80 W women complete the study.

RESULTS—A total of 705 post-menopausal women (381 AA, 324 W) were screened, and of those, 217 were randomized (105 AA, 112 W), and 192 (91 AA, 101 W) completed the study. Direct mailings to targeted zip codes proved the most successful recruitment strategy for recruiting AA's (52% of AA's recruited) and the second most effective for recruiting W's (32% of W's recruited). Newspaper advertisements yielded the highest number of W participants (36%), but proved less successful for recruiting AA's (8%). Airing advertisements on the radio was the second most effective strategy for recruiting AA's (15%), yet it was one of the least effective approaches for recruiting W's (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, it is essential that researchers include adequate resources to cover the cost of recruitment in their budgets.

Keywords

Recruitment; Minority; Clinical Trials; Women

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 into study populations; however, researchers are facing many obstacles while reaching out to these underrepresented groups. [1–7]

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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. [8;9] It is a commonly held opinion in this community that one gives up his or her rights by signing a consent form and there is a widespread perception that researchers lack cultural sensitivity. [10;11] Mistrust also stems from the general belief that minorities endure most of the risks of medical research. [12] Therefore, it is imperative that investigators understand the culture with which they are working and are 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. [5;13–17]

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

Despite the abundance of literature on this subject, there is a lack of attention 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 lipoprotein 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 at least 80 African American and 80 White post-menopausal 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 post-menopausal, women needed to have been without a menstrual period for at least 12 months or a follicle stimulating hormone level of greater than 30mlU/ml if they had a hysterectomy. They were excluded for having LDL cholesterol levels less than 130mg/dL or greater than 190mg/dL, triglyceride levels greater than 400mg/dL, or a history of diabetes or fasting blood glucose levels greater than 125mg/dL. Women also were excluded for being over 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 greater than 39. 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. [21] 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, HDL, and triglycerides; and reported more vasomotor symptoms.

Following a series of screening visits, all qualifying participants were given nutritional counseling to follow the National Cholesterol Education Program (NCEP) 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 for testing for the presence of isoflavones as a baseline measure to determine compliance. Each woman completed three study questionnaires: menopausal quality of life, [22] physical activity, [23;24] and a food frequency questionnaire.[25] All of these measurements and questionnaires were repeated at two follow-up visits, six and twelve weeks after randomization.

RESULTS

Recruitment

A variety of recruitment strategies were utilized to reach the goal of at least 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 of the newspapers chosen for advertising specifically target the African American community, while the others appeal to a more diverse audience. Advertisements for BEST also were aired on several radio stations, targeting both African American and White listeners in the Baltimore area. One hundred fifty nine ads were aired, each ranging from 10 to 60 seconds, with the race of the narrator based on the demographics 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 the BEST Study 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 the majority 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 about 12,000 employees. Finally, women were recruited from numerous local churches surrounding the study sites. 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 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 post-menopausal 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 percent (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]) while unsuccessful for recruiting Whites (2% [2/101]), which can be attributed to the employee demographics.

Analysis of the costs of the various recruitment strategies yielded important results. 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 percent 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 certainly wasn't a strategy that was easily controlled. Recruiting in the internal newsletter and healthcare provider referrals both proved to be inexpensive ($31.92 and $38.30/participant), but neither were terribly 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 very little recruiter labor was required.

DISCUSSION

It is evident from this study and many others that the recruitment of minorities remains a challenging process. It is necessary for investigators to be aware of potential barriers and cost, and to 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 towards the medical community and research. However, this approach may be unreliable and 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 it is important to have a flexible recruitment plan prepared. Given the extra time and effort needed to recruit minorities, combined with the monetary restraints of sponsored projects, it is essential that researchers include adequate resources to cover the cost of recruitment in their budgets. It is clearly not always possible to balance cost-effectiveness with yield of participants, thus investigators must use multiple recruitment methods and flexible recruitment plans in a way that achieves optimal results.

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Table 1

Baseline Sample Characteristics

Characteristic	African American n=105	White n=112	*P*value
Sociodemographic			
Age, mean (SD)	55.67 (4.98)	57.85 (5.94)	0.004
Education, %			0.26
< High school	5.71	2.68	
≥High school	94.29	97.32	
Annual Income, %			0.34
< $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^2	29.40 (4.55)	26.57 (4.36)	<0.001
Lipoproteins, nmol/L			
Total cholesterol	5.62 (0.65)	5.88 (0.67)	0.005
LDL cholesterol	3.59 (0.57)	3.68 (0.59)	0.28
HDL cholesterol	1.49 (0.32)	1.59 (0.36)	0.04
Triglycerides	1.18 (0.56)	1.35 (0.54)	0.02
Menopausal Symptoms, mean (SD)			
Vasomotor	3.62 (1.81)	2.83 (1.87)	0.002
Psychosocial	2.51 (1.52)	2.65 (1.37)	0.53
Physical	2.57 (1.14)	2.59 (1.07)	0.99
Sexual	1.95 (1.45)	1.92 (1.33)	0.84

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

To convert total cholesterol, LDL cholesterol, and HDL to mg/dL, divide by 0.0259; to convert triglycerides to mg/dL, divide by 0.0113.

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
Total	**705**	381	324	**192**	91	101

AA, African American; W, White.

Table 3

Return on Investment per Recruitment Strategy

Strategy	Cost	Participants Recruited & 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
Total	**$49,036.25**	**192**	**$255.40**