THE EFFECTS OF KNOWLEDGE, ATTITUDES, AND SIGNIFICANT OTHERS ON DECISIONS TO ENROLL IN A CLINICAL TRIAL ON OSTEOPOROSIS: IMPLICATIONS FOR RECRUITMENT OF OLDER AFRICAN-AMERICAN WOMEN

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This preliminary study explored the roles of knowledge, attitudes, and significant others on decisions of older African-American women to enroll in a clinical trial involving estrogen and osteoporosis. Sixteen older African-American women (average age 75 years) participated in three focus groups. Twelve of the women had enrolled in the clinical trial and four, although eligible, refused to enroll. Discussions revealed that knowledge of osteoporosis and estrogen and expectations of personal rewards and group benefits from medical research appear to differentiate the women who participated in the clinical trial from those who refused. The women who participated also perceived the research institution as accessible. In addition, assuring full disclosure of testing procedures and test results eased their apprehensions about participation. However, the women who refused to enroll saw no personal benefit and were unwilling to expose themselves, in part because of their age, to the risks of taking estrogen and the uncertain outcomes of the clinical trial. The study illustrates how focus groups can be used to develop multiple strategies to enable recruitment of older African-American women with different demographic characteristics, levels of knowledge, and attitudes toward a disease and medical research. (*J Natl Med Assoc.* 2001;93:392–401.)

Key words: recruitment ♦ older African-American women ♦ osteoporosis ♦ significant others ♦ knowledge ♦ attitudes

Disproportionately low rates of minority volunteers enrolled in clinical trials are well documented,[1–3] and concerns about the underrepresentation of minorities and women have been clearly reflected in the National Institutes of Health Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (1994). One barrier to recruitment of older minority participants is that few studies have systematically examined the influence of psychosocial factors on their decisions to participate, despite the fact that the ultimate goal of recruitment is the adoption of a bundle of behaviors associated with a clinical trial.[4] Most studies on minority recruitment have focused on sources of potential recruitment (e.g., doctors' offices), and few have considered research volunteers beyond demo-

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graphics and exclusion criteria.[4] Studies have shown that determinants of adoption and maintenance of a behavior include psychosocial factors, such as knowledge and attitudes toward a behavior, and the influence of significant others.[5,6]

Awareness and comprehension mark the beginning of the behavior change process.[5,6] Knowledge about a disease being investigated[2] and the relevance of a clinical trial to a community[7] have been associated with enhanced minority participation in clinical trials. Understanding of the research process, including terms such as *placebo* and *informed consent*, was found to be critical to recruitment. This is particularly true of economically disadvantaged minorities because they are likely to have limited access to health services and little exposure to clinical trials.[1,8]

Attitudes toward a behavior are based on an overall evaluation of the expected costs and benefits of engaging in a behavior.[9] When perceived benefits outweigh the costs of performing a behavior, individuals are more likely to form positive attitudes and to act on that behavior.[10] In one study, those who cited many benefits to research participation and viewed test burdens such as giving blood and answering questionnaires positively were more likely to volunteer.[11] In contrast, the perception that little or no direct benefits could be gained from a clinical trial has been shown to deter participation.[2,12] Some of the benefits that older adults hope to obtain from involvement in clinical trials are opportunities to (1) help others, (2) socialize, (3) become involved in scientific research, (4) have novel experiences, (5) augment their income, (6) learn more about their health, (7) or find a cure for a diagnosed disease.[3,13] Significant costs of participation are the time and effort involved, adverse side effects of the intervention under investigation, loss of privacy, exposure to risk, and discomfort from test burdens, among others.[4] Participation costs such as transportation, foregone wages, child-care, and the costs of medication and treatment associated with a clinical trial are particularly difficult for economically disadvantaged populations to bear.[2,4]

The opinions of significant others regarding a behavior has been shown to predict behavior change because people seek approval or avoid rejection, or value some individuals as valid sources of information and emotional support.[14,15] Several studies on recruitment have advocated tapping the influence of family members, personal physicians, and community leaders as an essential minority recruitment strategy.[3,12] However, other studies have also shown that credibility of health care professionals, the medical care system, and of academic research is a key barrier to minority recruitment.[4,12] Lack of trust in the medical system may stem from unethical research practices of the past, limited access to medical services, and racial disparities in the application of medical procedures.[8,16]

This preliminary study explored the influence of psychosocial factors including knowledge and attitudes on the decisions of older African-American women to enroll in a clinical trial involving estrogen and osteoporosis. Osteoporosis is a bone-weakening disease and is a major cause of hip fractures in older women. Studies suggest that African-American women lose bone at the same rate as white women but have higher peak bone mass and fewer hip fractures.[17,18] But because more African-American women die after hip fracture replacement surgeries than white women, preventing hip fractures by reducing bone loss remains important for the African-American community.[19]

To qualify for the clinical trial, the women had to be at least 65 years old, in general good health, and not taking medication that could affect bone. The trial examined racial/ethnic differences in how older women respond to low dose estrogen and calcium for the prevention of osteoporosis. To be able to compare differences in response to treatment across racial/ethnic groups, 45% of the 180 volunteers had to be African-American or Hispanic women.

Because little is known about motivations of older African-American women to participate in osteoporosis research, the goal was to inform the development of appropriate recruitment approaches through exploratory research techniques. This study employed focus group methodology, a qualitative approach particularly well-suited for research that is either exploratory[20] or confirmatory[21] in nature. Focus groups are commonly used to discover more about phenomena that involve personal and social constructs.[22] Specifically, focus groups were conducted to help design effective strategies to recruit and retain older women from the major racial/ethnic populations of a metropolitan city in New England for the clinical trial.

METHODS

Based on previous experiences with recruiting minority older women and lessons of other researchers as described in the literature, the following areas of exploration were identified: (1) knowledge and beliefs about osteoporosis and estrogen, (2) attitudes toward research and the research institution, and (3) influence of significant others on their decisions to participate.

Sample

Three community-based focus groups were conducted with four to six older African-American women per group. Participants included eligible African-American women who either enrolled in the clinical trial or had refused to participate. The two groups of six women who chose to participate in the clinical trial differed in the way they had been recruited. The women in group 1 enrolled in the study after receiving a letter inviting them to participate (names and addresses were drawn from the Department of Motor Vehicles mailing lists of suburban towns). Participants in group 2 were recruited after attending a community talk on osteoporosis usually held in churches or senior centers in the metropolitan city's predominantly African-American neighborhoods, receiving an osteoporosis screening (bone mineral density test), and after one-on-one discussion with the principal investigator regarding the results of their screening. Group 3, comprised of four women who chose not to enroll, had also received an osteoporosis screening and one-on-one discussion prior to their decision not to enroll. Only two of the four women had attended a community talk on osteoporosis.

All 14 African-American women enrolled in the clinical trial agreed to take part in the focus group discussions; however, one canceled because of illness, and another failed to arrive on the day of the discussion. Of the 12 women who were eligible but declined to enroll in the trial, only four agreed to participate in the focus group discussion. Six of the eight women who refused to participate were either too ill to travel or had a prior engagement; two refused to participate in the focus groups because of a lack of interest. All 12 had participated in the osteoporosis screening program. All three sessions were held close to where the women lived. Participants were provided lunch and reimbursed for any transportation costs. Each participant also completed a questionnaire about personal, family and medical history prior to the focus group sessions.

Data Analysis

A focus group guide was developed by a multidisciplinary team with training in medicine, gerontology, social marketing, and health communication, using qualitative approaches similar to the long interview.[21] Through standardized probes to open-ended questions, focus group participants were encouraged to give detailed comments about: (1) their perceptions of research, especially its benefits and test burdens; (2) knowledge of osteoporosis; (3) influence of family, friends, and personal physician in their decisions to participate; and (4) impressions of the research institution sponsoring the study. Each session lasted approximately 1 hour and 15 minutes.

The focus group discussions were recorded on newsprint (including direct quotations when possible). Participants confirmed the accuracy of these comments at the close of discussion for each issue. Sessions were audiotaped to allow for later clarification of points and for identification of supportive quotations. Recorded data were transcribed and analyzed line by line to identify and interpret discussion content. Content analysis was performed in accordance with standard qualitative research techniques.[23,24] Through a group process of consensus, major concepts were organized into distinct, recurrent themes. Transcripts were reviewed and quotes organized using the constant comparative method,[25] until no new themes emerged.

FINDINGS

The demographic characteristics of focus group participants are depicted in Table 1. The mean age of each group was 75. Group 1 reported higher levels of education (college or higher) and higher annual household incomes ($20K-39K) than the other two groups. The only women who reported a family history of osteoporosis were in group 1. Half of the women in this group also had a hysterectomy. Eleven of the 16 women reported that they did not know or were uncertain about the effectiveness of hormone replacement therapy in the prevention of osteoporosis. The main emergent themes are reflected in Table 2.

Table 1. Participant Characteristics

	Focus group 1 (n = 6)	Focus group 2 (n = 6)	Focus group 3 (n = 4)
Recruitment method			
—Random mailing	6	0	0
—Talk	0	6	2
—Osteoporosis screening	0	6	4
Study status	Enrolled	Enrolled	Not enrolled
Age (range)	72–79	67–86	73–79
Education	College+	High school	8th grade
Income	$20–39K	<$20K	$20K
Family history osteoporosis	2 (33%)	0	0
Hysterectomy	3 (50%)	2 (33%)	1 (33%)
Is HRT effective in preventing osteoporosis?			
Yes	1	0	0
No	0	0	1
I Don't Know	5	4	2

Knowledge of Osteoporosis and Estrogen

Osteoporosis. Knowledge of osteoporosis and estrogen was assessed by the question, "What had you heard about osteoporosis before deciding to join the study?" Groups 1 and 2 were able to describe osteoporosis, its consequences, and some of the risk factors. Members of group 3 had limited awareness of osteoporosis. Participants reported osteoporosis is a condition of the bone that occurs when people get older. They identified hip fractures and curved back (kyphosis) as consequences and calcium deficiency and heredity as risk factors. Descriptors included: "bones becoming brittle as you get older," "hunched all over," "bent over for lack of calcium," and "it [osteoporosis] is hereditary." Some participants were not aware of the risk of hip fractures or did not associate osteoporosis with African-American women, as expressed here: "I used to work in a hospital—one of the things that we learned—that it [osteoporosis] was just around white women."

Estrogen. Groups 1 and 2 offered a greater number of comments about estrogen than those who refused to be in the study. They associated estrogen with increased risk for breast cancer and as a prescription given after a hysterectomy or to control menopausal symptoms. This point is supported by the observation: "When I started the change of life, the doctor asked me did I want to take estrogen—that was 30 years ago or more. They said sometimes in cases, it has caused breast cancer." Some of the women in groups 1 and 2 were uncertain of estrogen's relation with osteoporosis and whether prescribing it at their age was beneficial. This is illustrated by the statement: "I wondered if it would help at this age because I understand that you're supposed to take estrogen at menopause—you should be taking it in your 50s; so 20 years later, how do you think it would help you?" The women in group 3 had little knowledge of estrogen as illustrated by questions raised during the discussion. Questions included: "What is estrogen supposed to be for? Just what does it do?" and "Is it oral, liquid, or injection?" They also associated taking estrogen at their age with recurrence of menstrual bleeding and ovulation.

Attitudes Toward Research and Research Institution

To gain an understanding of participants' attitudes regarding clinical research, the focus group discussions opened with the exploratory question, "Describe what research means to you."

Benefits. Participants were asked to comment on both the benefits and concerns with research. Participants enrolled in the study identified more benefits than concerns, whereas nonenrollees raised more concerns than benefits. Four thematic benefits of research emerged: (1) scientific knowledge, (2) societal benefits, (3) African-American women's health, and (4) personal health.

Participants from all three groups described the first theme, *scientific knowledge*, with the following illustrative descriptors: "studying all sorts of medi-

Table 2. Content Areas and Main Themes from Discussions with Older African-American Women Who Partricipated and Refused to Participate in a Clinical Trial on Osteoporosis and Estrogen

Content area	Main theme	Participants	Nonparticipants
Knowledge	Knowledge of osteoporosis	Bone disease associated with aging, hip fractures, and kyphosis	Very limited
	Knowledge of estrogen	Associated with breast cancer and menopausal symptoms but not with osteoporosis	Very limited
Attitudes toward research and research institution	Benefits of research	Scientific knowledge, societal benefits, African-American women's health, personal benefits; (learn more about one's health and prevent osteoporosis)	Scientific knowledge and societal benefits; no personal benefits reported
	Costs of research participation	Withholding of test rseults	Feared "being used" in an experiment; perceived high risk of participation
	1. Blood draws	Not a concern	Not a concern
	2. Research site access	Not a concern	Had limited access
	3. Taking medication	Concerned with side effects of estrogen and calcium; had developed ways to cope with concerns	Concern about multiple medications and recurrence of menstrual bleeding
Influence of significant others	Impressions of research institution	Positive impression and/or experiences	Negative impression and/or experiences
	Influence was limited	Family, friends and personal physicians had no apparent influence on decision to participate; mistrust of physicians	Family, friends and personal physicians had no apparent influence on decision to participate; mistrust of physicians

cines to see which is the right one," and "to research things we don't know about, to get more information." The second theme, *societal benefits*, was expressed as: "people [researchers] thinking of the future generations," and "helping the community to progress." Research also generates knowledge that would benefit *African-American women's* health, "that's why they [researchers] are trying to get black women to participate because from what I understand, the studies that have been done in the last 50 years were on a group of white women." Several participants in groups 1 and 2 cited *personal benefits* of research. The most common personal benefits were that research would enable them to learn more about their health: "prolongs your life by doing different studies—then you know how to take care of yourself better" and "we'd be more healthy with whatever they [researchers] would be able to find."

Preventing osteoporosis was an important motivator for participating in the clinical trial, particularly with women who felt they were susceptible because of family history of osteoporosis. The following comment illustrates this: "I have a younger sister who has osteoporosis and she's walking bent over—that was one of the reasons why [I joined the study]—I want to walk straight up." Others enrolled to avoid disfigurement: "my grandmother was 90, she used to walk straight—I always said I wanted to be like she was." Others were prompted by consequences of hip fractures. "I was interested in knowing the condition of my bones. I've seen other people that have been bent over and often if they fall, they are in trouble." The women choosing not to participate (group 3) did not cite any personal benefit.

Costs of Research. Themes regarding the personal costs of research emerged in response to the questions: (a) "What are your concerns about research?"; (b) "What did you think about taking es-

trogen and calcium as part of the study?"; (c) "How do you feel about giving blood and/or urine?"; and (d) "How do you feel about traveling to the research institution six times over nine months?" Four themes were identified related to personal costs of research: (1) skepticism regarding clinical research, (2) risks of medication, (3) fear and inconvenience of giving blood and urine, and (4) lack of access to the research site.

Skepticism. Members of group 3 (women who have refused to participate) expressed *skepticism* about research. Their comments centered on the adverse risks of participation and exploitation. Although they recognized that participation in research could benefit everyone, they believed it involved uncertain outcomes and risks that they were not prepared to take, partly because of their age—"If I was ten years younger, maybe I would, but at 76, I wouldn't want to start anything." They preferred that somebody else take the risk as illustrated by this comment: "You don't want to be the first one to try it. You want it to be where there is much more faith. We would learn more about it, but maybe not with ourselves, maybe with somebody else. And then when it is established as good, we would probably all be running there." Group 3 expressed their fear of "being used" in an experiment: "It [research] is an experiment—it is not the best [feeling] being a guinea pig, you know, [it feels] like [they are] using you." Groups 1 and 2 were initially concerned that their individual test results would not be revealed to them or sent to their personal physicians. Their concerns were allayed when research staff provided them copies of their test results.

Risks of Medication. The *risks associated with taking medication* in general, and estrogen in particular, appeared to be an important consideration for all groups. All participants shared concerns about side effects from the medication, including constipation, calcium deposits, and difficulty in swallowing large pills. One aspect concerned multiple medications as illustrated by comment: "I was taking enough medications and didn't want to pile more."

Adverse side effects of estrogen were also a significant obstacle to enrollment, particularly the recurrence of menstrual bleeding. "But people our age don't want to go back to all that [menstrual bleeding]. Once you're through with it, that's enough of that. And then you don't know what this bleeding is for either. You could be bleeding because of something else. You may have cancer of the cervix. You never know. All these things cross your mind."

Although all groups had raised concerns about taking estrogen and calcium, participating volunteers had developed ways to cope. Women who had complained about taking calcium coped by chewing the tablets to overcome difficulties of swallowing or by taking it with a "lot of water" or "mineral oil" to avoid constipation. Women apprehensive about taking estrogen coped by rationalizing that the risks were worth taking. They also minimized threats by focusing on the chance that they were on a placebo or on a low dose as illustrated by this comment: "I didn't have any concern about it because I had no idea whether I was getting the estrogen itself or whether it was the placebo. I went into the study knowing I would not know, so I accepted it."

Giving Blood. Many reported that *giving blood* was an unpleasant experience but one that did not deter them from participating in the study. Giving blood was not an unusual experience because "You do that with your regular doctor, it is part of your physical."

Impressions of Research Institution and Access. Participants were asked to give their impressions of the research institution before they volunteered for the study. There was generally a positive impression of the research institution, although group 3 participants expressed misgivings about access by lower-income individuals. Groups 1 and 2 perceived the research institution as primarily involved in research, a concept that had both negative and positive aspects. Although the research institution was highly regarded, they did not obtain services there because of the transient nature of the medical staff. Participants who had used or known someone who was treated at the research institution were impressed with the services received. "[The research institution is] great—because they do so much research up there. I highly recommend it."

Participants were asked how they felt about traveling to the research institution six times over 9 months, as required by the clinical trial. Although frequently discussed in the literature as a critical consideration for enhancing participation in clinical research, access to the research institution did not appear to present major concerns for groups 1 and 2. But group 3 did indicate that there would be some inconvenience in getting to the research center, especially in bad weather. Travel to the research institution was also inconvenient because of limited

public transportation service especially on weekends. "Since they are making a study of you, they should provide a means to get there and back. Because you don't know how the weather is going to be. You don't know whether the bus is going to be running—so many things can happen. I am a senior citizen too—you've got to look out for yourself."

Group 3 participants perceived the research institution as especially inaccessible to individuals with low incomes. Members of group 3 agreed with this comment made by one of their group members "Being from here [the city], I wouldn't want to go up there [research institution] because I didn't think it was for us, for the poor—travel that far, you know." The women also believed that the research institution exclusively serves patients who have been referred, as shown by this comment "You have to be recommended. You just can't go. You know what you want but you just couldn't. They [research institution] want to know who referred you out there."

Influence of Significant Others

Participants were asked whether family members, their personal physicians, or other individuals had influenced their decision to become or not become a research volunteer. They were also asked their impressions of the research institution. Three themes emerged from this discussion. In general, these women did not rely on other people for help with their decision, had misgivings about the medical profession, and/or had opposing views regarding the credibility of the research institution.

Limited Influence of Others. Participants, especially from group 1, asserted that they had made the decision on their own—"When you get my age, you should make your own decisions anyhow, you know, because you know it is your body, and you know what you want to do with it." Some participants had spoken to friends and family members about their participation simply to inform and not to seek their advice.

Some participants, particularly in groups 2 and 3, did not involve family and friends because they wanted to avoid disapproval. They believed that their friends and family members have a negative impression of research—"most people are kinda skeptical [of research]." They also avoided consultation because they were "afraid of a negative reaction," expected to get only "negative attitudes [toward research]," or be told, "you'll only be used for this and used for that."

On the whole, personal physicians had little influence on the decision to volunteer. Only a few participants consulted their personal physicians before they joined the clinical trial. A few others informed their physicians about their participation (or nonparticipation) after they had already enrolled. Those who spoke to their physicians said that regardless of their physicians' advice, they would still have made the decision on their own.

Mistrust of Physicians. Underlying this lack of physician influence is an apparent mistrust of the medical profession. Some women in groups 2 and 3 appeared to question their physician's trustworthiness and concern for patients. These women saw their physicians as unreliable sources of information because they perceived that their physicians withheld information from them. Physicians were seen to be looking after their own interests first than the welfare of their patients. Others felt that doctors lose interest in older patients—"the older you get, the less interest they [personal physician] have in you." The following comments reflect these perceptions:

> I told him [personal physician] I was thinking of going into the study. He said, "It's up to you." He wouldn't give me a direct answer. That left me kinda of hanging. I felt as although he didn't want me to do it. I feel as although if he had agreed with going along with the study, he would have said yes. I came to the conclusion myself that the fact that he did not say yes, that he meant no.

> I don't want to speak negative about doctors. . . but it seems to me that you tell them about taking a study and going off to the hospital or something. . . they always are a little reluctant. But my feelings are if they were doing the study, they'd tell you to come on.

DISCUSSION

The goal of recruitment in clinical trials is to persuade eligible individuals to become research volunteers. Research on the role of knowledge, attitudes, and significant others in recruitment strategies for older African-American women is limited. This study explored the influence of these factors on older African-American women's decision to enroll in a clinical trial on osteoporosis. Focus groups generated discussion about participants' experiences and beliefs about osteoporosis. Transcripts

reveal how older African-American women conceive of and talk about clinical research. The study illustrates how focus groups can be used to develop targeted recruitment strategies and materials for populations with different levels of knowledge and attitudes toward a specific disease and the research process. In addition, the study sheds light on an important void in the existing literature—the motivations and concerns about clinical research of older women from different demographic segments within an African-American community. This study could only begin to explore the heterogeneity among the African-American population; future research in this area is needed.

The women who had enrolled in the clinical trial had known more about osteoporosis and estrogen prior to enrollment, viewed research more favorably, and the research institution as more accessible than the women who had not enrolled. These differences suggest that a single recruitment strategy may be ineffective. To achieve a broader representation of the community in a clinical trial, multiple segments whose members have similar demographic characteristics, knowledge levels and attitudes toward research may have to be identified and uniquely targeted.[5,26] As suggested in prior literature, unique recruitment strategies should be designed for each segment based on varying levels of knowledge and attitudes about participation. For example, a recruitment strategy targeting economically disadvantaged women who lack both awareness of osteoporosis and access to the research site may require an education component and a transportation subsidy. Conversely, a recruitment strategy targeting wealthier, more educated women may not need these two components.

It appears that increasing awareness and understanding of the disease under study is an important element of a recruitment strategy for population segments who know little about their susceptibility to the disease. Lack of knowledge about a behavior has been shown in several studies to be typical of individuals who refuse to adopt the behavior.[10] Recruitment strategies targeting this population segment may include conducting educational sessions on osteoporosis and estrogen, distributing educational materials at community events, and offering free osteoporosis screenings in targeted areas. Recruitment approaches targeting women who already have some knowledge of a disease under study could more narrowly focus on aspects that could motivate women to enroll in a clinical trial. In this case, knowledge that osteoporosis may cause disfigurement and hip fractures and may be preventable appears to have motivated women to enroll.

In this exploratory study, those who participated in the clinical trial identified greater benefits to participation and had fewer concerns than those who refused to enroll. In contrast, nonparticipants cited fewer benefits and more concerns than their enrolled counterparts. These perspectives are typical of individuals who have chosen to adopt a behavior and those who have not.[10] To shift the balance in favor of participation among individuals reluctant to participate, recruitment teams could promote potential benefits and inform on ways to cope with adverse effects. The perception of benefits can be increased by providing material incentives, such as financial compensation and transportation reimbursements, especially to disadvantaged population segments. In addition to providing more information about benefits and material incentives, recruitment materials targeting individuals anxious about participation could inform them about ways to cope with potentially undesirable side effects. Although participants in the clinical trial had also expressed misgivings about taking estrogen and calcium, they had developed ways to cope with them. Coping strategies for stressful situations have been found to be important in enabling an individual to maintain a behavior.[27]

Messages that emphasize personal benefits primarily and community benefits secondarily can also enhance formation of positive attitudes toward research. Participants in the clinical trial were primarily motivated by personal benefits whereas nonparticipants cited no personal benefits. These discordant views suggest personal benefits of research participation could be a critical message in recruitment strategies, especially when targeting population segments who tend to be reluctant to participate. The primacy of personal benefits over community benefits in motivating individuals to adopt a behavior has been observed in health and environmental studies.[28]

An altruistic appeal may be ineffective in persuading individuals who believe that it is not in their interest to contribute to a common good.[29] Although nonparticipants realize that everyone benefits from medical research, they prefer that others assume the risks. The motivation to help others has been found to be ineffective in influencing a behav-

ior when the personal costs of engaging in that behavior are perceived to be high.[30] This assessment of risk stems from nonparticipants' perceptions that they will be unable to withstand the negative effects because of their age. However, promoting the interests of one's community has been found to be effective in this circumstance because of a desire to serve one's group and see it succeed.[29] The promotion of the African-American women's health motivated some women to participate in the clinical trial.

Whereas the benefits of participating in a study are disclosed as part of the consenting procedure, disclosing this earlier in the recruitment process could make participation more attractive. In addition, early disclosure of the risks of participation accompanied by information on how exposure to risk can be minimized could ease concerns about personal safety. This information may include procedures for reporting and monitoring adverse events and applying stopping rules. Recruitment materials could also contain assurances that test results would be shared with participants and that they would receive regular feedback on their progress. Careful and thorough disclosure of testing procedures, benefits and risks, and test results because they could help allay fears of "being used" appear to be particularly critical for individuals reluctant to participate.

Trust and access to the research institution also appear to be a differentiating factor. As has been observed in other studies, nonparticipants viewed the research institution as not serving disadvantaged city residents because of its location in a prosperous suburban area and because they perceived that it only served referrals.[4] Overcoming mistrust in the clinical and medical research profession appears to be crucial in recruiting older women reluctant to participate. Part of the process of overcoming this mistrust is the need to make the sponsoring research institution familiar and accessible to these individuals. This can be accomplished through efforts that include community-based health educational programs and health services, establishment of local sites where clinical tests can be conducted, reimbursement of transportation costs, and substantive participation of the research institution in community events in disadvantaged city neighborhoods. [4,12]

Utilizing the influence of significant others may not be an effective recruitment strategy. Contrary to what has been theorized, family, friends, and personal physicians did not appear to play an important role in the decisions of older African-American women to participate (or not participate) in the clinical trial. Most members of group 1 and group 2 made their decision independently; some women in groups 2 and 3 did avoid unwanted influence by not consulting family and friends. In addition, some women in groups 2 and 3 reported that they did not view their personal physicians as a reliable source of information.

Findings of this preliminary study must be considered in the light of several limitations. Although focus group methodology using three groups is acceptable in terms of qualitative research standards, any differentiation among groups can only be speculative and must be validated using larger-scale quantitative approaches. Second, there was a low response rate among women who refused to participate in the focus group discussion. Nevertheless, this preliminary study provides data regarding motivations not previously reported and offers suggestions for framing future work in this area.

CONCLUSIONS

The focus group methodology was useful in exploring the roles of psychosocial factors in the decisions of older African-American women to participate in a clinical trial and in developing recruitment strategies for multiple population segments. Knowledge of the disease being investigated and attitudes toward research and the research institution appear to differentiate older African-American women who participated in the clinical trial from those who refused. To achieve broader representation of a community in clinical trials, multiple population segments whose members have similar demographic characteristics, knowledge, and attitudes may have to be identified and unique recruitment strategies designed for each segment. Targeting older African-American women with little knowledge about the disease under study and negative attitudes toward medical research and the research institution may require recruitment strategies that increase awareness of the research process and the disease being investigated, impart skills to cope with potentially harmful side-effects from the intervention, activities that build trust in the research institution, and transportation subsidies to increase access. Recruiting strategies targeting older African-American women who are familiar with the disease and have positive attitudes toward medical

research need not be as elaborate. Recruitment strategies that emphasize personal and community benefits and assure disclosure of individual medical test results appear to have been sufficient in encouraging these women to participate.

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