

Recruiting Diverse Patients to a Breast Cancer Risk Communication Trial—Waiting Rooms Can Improve Access

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Low participation among underserved populations in health research constrains progress in public health practices. From 2003 to 2005, Women's Health Clinic patients at the VCU Health System were recruited to a trial investigating breast cancer risk communication. In secondary analyses, we examined dimensions of the recruitment of these diverse women. The sample characteristics (age, insurance, race and previous mammograms) were compared to the overall clinic. Of recruitment attempts for eligible women, 45% consented; of those who declined, the top cited reasons were lack of time (40%) and lack of interest (18%). Of 899 participants, 35% qualified for the indigent care program, compared to 31% of the overall clinic ($P < 0.001$). Forty-five percent of participants were African American, compared to 54% of overall clinic patients ($P < 0.001$). Participants were younger (50 vs. 53 years, $P < 0.001$) than the overall clinic population. Nonrepresentative enrollment of patients in clinical trials is common and could lead to suboptimal applicability of findings. Although there were statistically significant race and age differences between the study sample and the overall population, we demonstrate that waiting room recruitment can engage diverse women in a clinical trial and cancer risk communication.

Key words: clinical investigation ■ women's health

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INTRODUCTION

Engagement of the broadest possible population in health prevention and promotion practices offers the potential for improved national health. Failures to engage representative communities in translational research can lead to biased recommendations, and deficiencies in access and outcomes.¹ Gaps exist in enrollment of underrepresented populations to clinical trials.² Challenges to recruiting minority participants include inadequate budgets, recruitment time, low community involvement, cultural adaptations, comorbidities, cancer beliefs and experiences, and others.^{1,3-10} Recruitment methods that integrate culturally competent communication and support from trusted others may be the most efficacious.^{1,11} For example, waiting room recruitment may be more efficient than physician referrals in some subgroups but may also need to emphasize good and regular contact.^{12,13} It has the potential to expand the diversity of women in clinical trials.^{13,14}

Race disparities in health are widespread, from mammography adherence to uptake of genetic risk assessment.¹⁵ Richmond, VA, is a majority African-American city with an academic health center providing most of the indigent care. Local hospital clinics have the potential to recruit a diverse sample to clinical trials.¹⁶

This report describes our recruitment experience engaging diverse women, seeking routine gynecologic care in a process of calculating their breast cancer risk as part of a large randomized controlled trial. Our recruitment design and experience provide insight into the engagement of a diverse group of women who might not typically be successfully recruited for clinical trials.

METHODS

Description of the Study

The Women Improving Screening through Education and Risk Assessment (WISER) study had a randomized, controlled design. Target recruitment was 900 participants, allowing 80% power to detect a 10% difference

in mammography practices ($p=0.05$) at 18-month follow-up, assuming 10% attrition. Women eligible for the study were ≥ 40 years old, not pregnant, nonparticipants in the trial's pilot study, and had not had breast cancer or carcinoma in situ. We hoped for but did not specifically target a diverse recruitment pool. The intervention consisted of a printout characterizing a participant's breast cancer risk and risk-tailored prevention recommendations. The intervention was based on the expanded Health Belief Model.¹⁷ The Virginia Commonwealth University (VCU) institutional review board approved the study. Recruitment took place three days weekly for 24 months. Days were chosen due to overall highest patient volumes and the availability of the recruiters.

Setting

Recruitment occurred in the waiting rooms of four women's health clinics in the VCU Health System (VCUHS). Overall, the clinics include approximately 50% nonwhite patients, and about 50% of patients are ≥ 40 years old. Patients are typically residents of the Richmond metropolitan area, which has >1.5 million people and settings from rural to inner city. Approximately 57% of Richmond residents are African American.¹⁸ Approximately 17% of adults (ages 19–64) in central Virginia are uninsured.¹⁹ Two academic downtown practices (one resident and one faculty clinic) served as the main sites of the study (98% of enrolled participants). Two smaller clinics were located on the outskirts of the city (data not used for analyses). About 45% of patients in the resident clinic and 10% of faculty practice patients, do not have traditional, governmental or private health insurance. Financial assistance programs are available in VCUHS to assist indigent patients who qualify. These clinics have some experience in waiting room recruitment.²⁰ All of our recruiters were Caucasian. One was >40 years of age. They were male and female genetic counselors with extensive experience in teaching and counseling. No specific tailoring of the script of invitation was done.

Recruitment Flow

During the study recruitment period, patients in the clinics typically registered with a receptionist and were asked to wait in the waiting room. Patients usually stayed there for 5–15 minutes before being escorted to a private patient room, where more waiting might occur. These waiting times provided opportunities for recruitment, completion of baseline surveys, and the breast cancer risk assessment and communication intervention. Before leaving the waiting room, potential participants were recruited by a research assistant who obtained signed informed consent.

Participants were asked initially to complete a brief baseline survey. Survey responses provided information on the primary project outcomes (mammography behavior and intentions), other breast health screening practices, psychosocial measures (e.g., risk perceptions, breast cancer worry, etc.) and demographics. The research assistants recorded reasons women declined participation.

Randomization and Intervention

After completing the baseline survey, participants were randomized to either the treatment or control group. A biostatistician conducted block randomization assignments before the study. Control participants were given a handout giving recommendations for monthly breast self-examinations, annual clinical exams and mammograms.

Participants in the intervention group were brought to a computer, where five-year and lifetime probabilities for breast cancer were calculated using the Internet NSABP-2 version of the Gail model.^{21,22} Use of a portable laptop computer maximized flexibility of location for conducting the intervention (e.g., an exam room or other private area) to allow confidential interaction with the participant while minimizing practice disruption. Information sheets given to participants described a lifetime risk of $<15\%$ as usual risk, $15\text{--}30\%$ as moderate risk, and $>30\%$ lifetime risk as strong risk—a classification system that has been used elsewhere.^{23,24} The handouts for the treatment group also addressed other traditional constructs of the Health Belief Model, including barriers to mammog-

Table 1. Reasons for nonparticipation and participation (among 2,332 attempts)

	Number	% Eligible
Nonparticipation		
Did not have adequate time to participate	511	39.8
Not interested and did not participate	233	18.1
Previously asked to participate and refused again	201	15.7
Experienced stressors and did not participate	120	9.3
Had language or writing barriers and did not participate	41	3.2
Otherwise not willing to proceed	178	13.9
Participation		
Obtained informed consent	1,048	44.9
Able to complete baseline and randomization	899	38.6

raphy, breast cancer seriousness, individual risk for developing breast cancer and the benefits of getting a yearly mammogram.²⁵ The intervention also included information about how to make a genetic counseling appointment. Instructions for how to schedule mammogram and genetic counseling visits, and encouragement to talk to health professionals addressed less-studied expanded Health Belief Model constructs, i.e., self-efficacy and cues to action.²⁶ The availability of a psychological counselor was mentioned verbally as well as on the consent forms and on the tailored handouts.

Statistical Analysis

Data were entered into a Microsoft® Access™ database²⁷ and reviewed by the investigative team to ensure quality. Statistical analyses were performed using SAS® 9.1.²⁸ We generated the frequency of reasons for not participating. “Commercial insurance” referred to nongovernmental insurance that was not managed care requiring primary care provider referrals and preapprovals. “Indigent care” referred to the health system’s program for financial screening, while “self-pay” referred to individuals who had not completed financial screening or were ineligible for financial screening; “self-pay” best approximated the category “uninsured” which is used in the healthcare literature. Medicaid, Medicaid managed care and Medicare referred to the public programs available for healthcare coverage in Virginia. Electronic administrative data on the overall Women’s Health Clinic population of women ≥40 years old were used to investigate the sample’s representativeness for mammography screening prevalence, age, race and insurance status, using t tests for age and Chi-squared tests for the other variables, which were categorical. A Chi-squared test compared the recruitment rates of our two main recruiters.

RESULTS

Figure 1 includes information on the number of women recruited. Approximately 4,500 women ≥40 years of age were seen in the primary study sites during the recruitment period. On average, women in the overall clinic population had two visits during this time period. A total of 2,733 patient recruitment attempts were made, and 2,332 (85%) attempts were for patients identified as eligible.

Reason for ineligibility was obtained for 401 recruitment attempts. Fifty-eight percent (n=232) of women were not eligible because they had already been enrolled in the study at a previous visit. Approximately 26% (n=106) of attempts involved ineligible patients because they had breast cancer. Of the remaining attempts, 16% (n=63) were ineligible because of other study criteria (i.e., participated in pilot study, were pregnant, were <40 years of age, or had previous genetic counseling).

Table 1 provides reasons for nonparticipation among the eligible sample. Inadequate time, either because they perceived inadequate time or were actually called from the waiting room before consent, was indicated as a cause for nonparticipation in 40% of attempts. Participants declined in 18% of attempts because they were simply not interested. In approximately 3% of attempts, women declined participation due to comprehension issues, such as hearing difficulties and English reading problems. In total 1,048 women provided informed consent for the study. Of these, 149 were not able to complete enrollment and undergo randomization, primarily due to lack of time. Information about when participants completed the baseline survey (before or after their clinic appointment) was documented for 884 participants. Most (66%) participants completed their baseline surveys after their doctor’s visit, although 26% of participants were able to complete the entire baseline process

Table 2. Comparison of the study population and clinic population (4/03-3/05, women ≥40)

	Participants	Overall Clinic
N	899	4,456
Average Age (Years)	50	53
Age Range (Years)	40–82	40–90+
Race		
White, Caucasian or European	451 (50.2%)	1,763 (39.6%)
African American or black	404 (44.9%)	2,429 (54.5%)
American Indian	15 (1.7%)	6 (0.1%)
Asian, Hawaiian or Pacific Islander	9 (1.0%)	31 (0.7%)
Hispanic or Latino	8 (0.9%)	45 (1.0%)
Other	12 (1.3%)	182 (4.1%)
Insurance		
Commercial	417 (46.4%)	40.7%
Indigent care	182 (20.2%)	24.0%
Medicaid, including managed care	42 (4.7%)	7.9%
Medicare	123 (13.7%)	20.3%
Self-pay	131 (14.6 %)	6.8%
Other	4 (0.4%)	0.04%

(survey, randomization and risk feedback) before their actual appointment. The 899 participants completed the baseline questionnaires and were randomized to control (n=450) and treatment (n=449) groups.

Table 2 gives the demographic comparison of the study population with the overall clinic population. The study sample was significantly younger (mean participant age was 50 years vs. 53 years for the overall clinic population ($P < 0.001$), and participants were less likely to describe themselves as black (45% vs. 55%; $P < 0.001$). Nearly 31% of the overall clinic population was in fiscal categories that may present a challenge to enrollment in research or follow-through, i.e., 24% indigent care and 7% self-pay. In contrast, 35% of the recruited sample were in the indigent care program (20.2%) or self-pay (14.6%). This difference was significant at the $P < 0.001$ level. Identifying information and demographic characteristics were not recorded for women who declined enrollment. Roughly 37% of study participants had had a mammogram at VCUHS within one year of the study period, and 48.2% had had one within two years, which was not statistically different from the overall clinic population, in which 34% had had a mammogram within

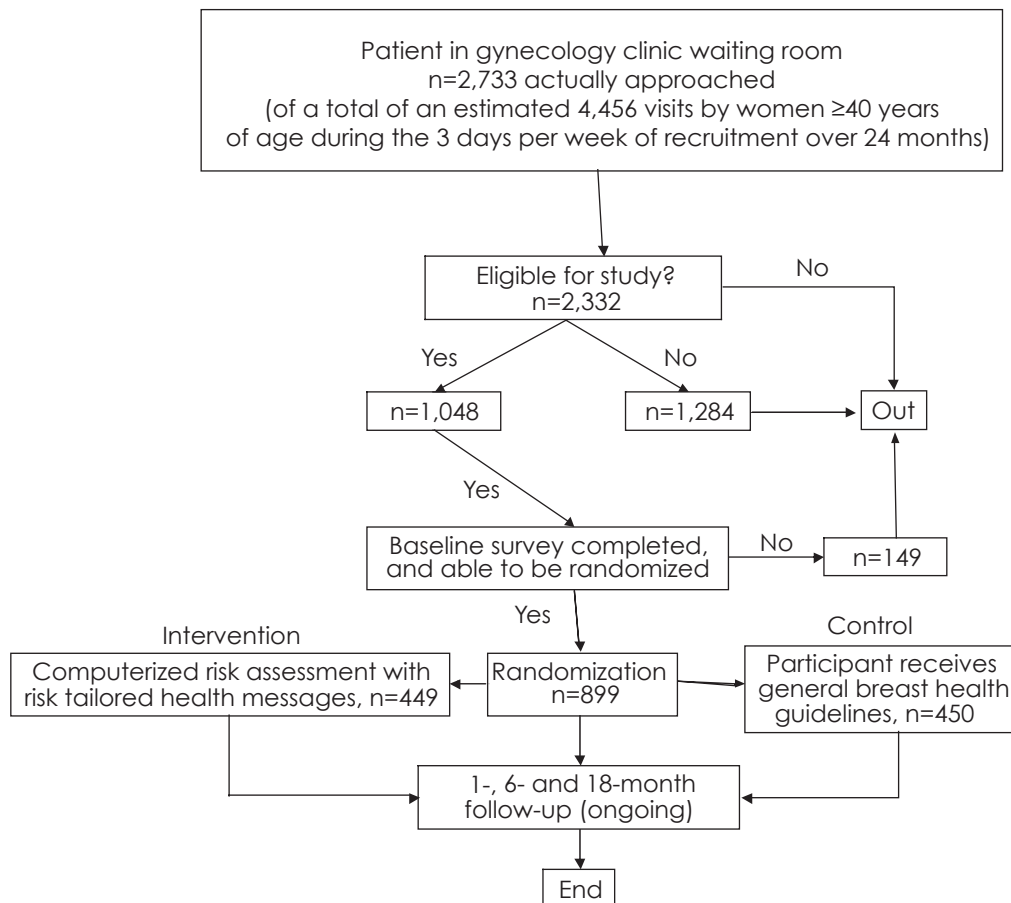
one year of the study period and 48.2% had had one within two years.

Of the 449 women who completed enrollment in the intervention arm of the study, 13% had ≥ 1 relative contributing to the family history question in the Gail risk model. No recruited individuals called the psychological counselor, who was available by phone. Most participants (92%) answered the question about overall satisfaction with care at the Women's Health Clinic. On a 10-point scale with 10 being "extremely satisfied," the mean was 9.17 (SE=1.43).

DISCUSSION

Waiting room recruitment, with a goal to test the provision of Gail model-based risk information's impact on mammography adherence, was successfully implemented in an inner-city outpatient gynecology practice. Recruiting diverse patients into research, incorporating risk information in ongoing healthcare and improving adherence to prevention guidelines are all challenges. Some factors that impact mammography adherence in low-income minority women, such as trust in provider and insurance status, could also impact enrollment in clinical

Figure 1. Flow chart of recruitment in the WISER study



trials.^{29,30} In addition, the cultural competency of recruiters may vary.⁷

Most studies reporting success of recruitment strategies do not use waiting room recruitment. Waiting room recruitment has frequently been used in combination with other recruitment strategies.^{12,13} Typical strategies include provider-initiated recruitment (perhaps with system reminders), use of registries or other databases followed by direct patient contact or the media.¹¹ Waiting room recruitment may be more appropriate for studies with minimally restrictive eligibility criteria. Further, waiting room recruitment has the potential advantage of immediately available follow-up with a health professional, without significantly disrupting clinic flow.

The current study recruited from, and enrolled, a population including many women not traditionally represented in clinical trials. Participants included a high percentage of uninsured women (15%) compared to the overall clinic population (7%). Only aggregate race and age data were available for the overall clinic population, so it was impossible to see if these factors explained differences in insurance status between participants and the rest of the clinic patients. The study sample was racially diverse and broadly representative of the clinic population, though there is still room for improvement.

Importantly, this study demonstrated the clinic waiting room can effectively be used to provide risk-tailored cancer messages and potentially triage for further genetic assessment. Given a growing focus on genomics and health disparities concerns, including minority and underserved populations, trials that address the real-life issues of family history may be particularly important. The translation of research findings (e.g., Gail risk model) and prevention guidelines³¹ into practice requires testing of implementation strategies. The path from optimal information sharing, understanding of risk and adherence to preventive health behaviors is complex³²⁻³⁴ and an ongoing challenge to women and clinicians.

These data are subject to several limitations. Details about recruitment are often difficult to obtain, particularly when individuals declining participation give no additional information. Also, the ability to compare the study sample to the overall clinic population was limited to age, ethnicity, health insurance status and mammograms documented in the health system's administrative records. Individual-level information on education, age and insurance status for the overall clinic population was not available. This study experience demonstrated the intervention was practicable, but other clinic settings, recruitment strategies and patient populations may impact feasibility.^{29,35-37} This study's recruitment might have been further enhanced with more diversity in our recruiters. The recruiters had prior training in cultural competency and were experienced in working with diverse populations.

A gap in this work is an explicit connection between

the waiting room information sharing and the actual visit. Anecdotally, some patients shared the information sheets with their physician; however, there are varied planned outlines and impromptu aspects to physician visits. Women were coming to the clinic both for annual exams as well as new health concerns. A "recruitment belief model" might be broadly and preliminarily considered to have some analogies to the Health Belief Model or other well-studied theories of health behaviors. Recent work suggests that clinical trial acceptance may not be based on a rational decision-making model. This may impact both the ethics of informed consent and research conceptual models.³⁸

CONCLUSIONS

Despite the potential barriers of research recruitment, a financially challenged population and the specific characteristics of any particular clinical setting, this work justifies further investigation of a waiting room model for clinical trial recruitment and risk communication.

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