

STRATEGIES TO REDUCE BARRIERS TO RECRUITMENT AND PARTICIPATION

Margaret Pribulick, RN, MS, PhD^{1*}
 Ishan Canty Willams, PhD²
 Pamela Stewart Fahs, RN, DSN³

¹Clinical Instructor, [Decker School of Nursing](#), Binghamton University, mag419_78@hotmail.com

²Research Assistant Professor, [School of Nursing](#), University of Virginia, icw8t@eservices.virginia.edu

³Professor and Decker Chair in Rural Nursing, [Decker School of Nursing](#), Binghamton University, psfahs@binghamton.edu

*Contact Author

PRÉCIS

Barriers to subject recruitment and participation are explored and solutions used in a Phase-II, nurse-run intervention study are presented.

ABSTRACT

Purpose To identify barriers encountered and solutions employed to improve research recruitment and retention of rural subjects for participation in the Promoting Heart Health in Rural Women (PHH) study.

Methods This article provides an examination of experiences encountered by nurse researchers in recruiting rural women from two locations to a randomized, controlled trial. Problem solving through broadening recruitment areas and inclusion criteria, community liaison assistance, identification of rural-specific strategies in the literature, and perseverance helped to overcome barriers to subject recruitment and retention in this rural Phase-II nurse-run intervention study.

Clinical Relevance Research studies need to be conducted in order to build a body of evidence for nursing interventions to reduce cardiovascular disease risk factors in rural women. A study is strengthened by a robust sample that provides power to statistical analysis. Without discussion of real-world experiences and appropriate and effective recruitment and retention strategies in nursing research, there is little chance of conducting research with appropriate power to build evidence-based practice.

INTRODUCTION

The purpose of this article is to address barriers encountered and strategies used to improve rural research recruitment and participation in the Promoting Heart Health in Rural Women (PHH) study. An essential aspect of research is recruitment. For research to be successful, it is necessary to obtain a sample size appropriate for the design and in large enough numbers to provide adequate power for the study findings to protect against errors in hypothesis testing. Sampling for the PHH study took place in two locations: a rural county in upstate New York (NY) and one in central Virginia (VA). Using Rural Urban Continuum Codes (RUCC), both counties scored a 6 on the scale of 1-9 (United States Department of Agriculture, Economic Research Service [USDA, ERS], 2004). The RUCC system is county based with levels 1-3 indicating metropolitan and levels 4-9 for nonmetropolitan counties (Bigbee & Lind, 2007). Both counties in this study were classified as rural and were chosen based on contacts already established from previous studies. The VA site was also chosen in hopes of obtaining a sample representative of African American rural women as approximately 12% of that county is African

American, compared to only 1.4% in the NY rural county. In 2003 cardiovascular disease (CVD) was reported as 44.7% among black females and 32.4% for white females of the total 33.9% total female prevalence (American Heart Association [AHA], 2007), yet black females are often underrepresented in studies of CVD.

Barriers to participation in research have been reviewed in order to better understand the perspective of an individual's participation. Of specific interest were recruitment of women and ethnic subpopulations, such as African American women that are underrepresented in rural research. Understanding the barriers to research study recruitment and participation within a population can assist the researcher in developing tailored recruitment strategies. Though recruiting a sample of participants is cumbersome and time consuming, by understanding the population's barriers to participation in research and carefully planning recruitment efforts, costly obstacles may be circumvented.

RECRUITMENT AND BARRIER—THE LITERATURE

In reviewing two well-known nursing research textbooks, the discussion of recruiting and retaining subjects is limited to two to three pages (Burns & Grove, 2005; Polit & Beck, 2008). Textbooks generally incorporate recruitment into a chapter on sampling. Searching an online database, however, can produce a plethora of articles on the topic of recruitment. Although there is common ground in recruitment and barriers to participation in research, cultural differences may also be a recruitment challenge.

Dibartolo and McCrone (2003) studied recruitment and barriers to research participation among rural community-dwelling older adults. Obvious barriers within this age group are physical and mental changes along with an increase in chronic disease, which Dibartolo and McCrone place in two categories: health-related barriers and social barriers. One social barrier seen in rural research is mistrust of outsiders, thus the inclusion of those who are insiders in the community such as health care providers (Dibartolo & McCrone) and community-based organizations or involved community members (Fahs, Findholt, & Daniel, 2003) can help in overcoming this barrier to study recruitment. Morgan, Fahs, & Klesh (2005) in a study of 865 randomly chosen rural subjects in upstate NY found that the presence of an illness increased one's willingness to participate in research, but a hypothetical fatal illness was most often a barrier. Other barriers were inconvenience of times or sites for joining a study as well as having to drive more than 30 miles. Trust barriers included not knowing the researchers, not knowing others in the study, and not trusting the researchers. However, nurses were identified as a group as trust worthy to conduct research. Rural-specific barriers in the Morgan et al. study were transportation, work-related, and outsider issues.

Another study focused on the recruitment of black Americans as subjects (Brown, 2004a). The recruitment process was qualitatively recorded and was preliminary to the parent study of *Everyday Life for Black American Adults* (Brown, 2004b). Seven weeks of intensive activities including the distribution of fliers, announcements, seeking referrals, newspaper and internet advertisement were spent in a community recruiting black Americans via festivals, community agencies, beauty shops, churches, and senior centers (Brown, 2004a). Recruitment for this study (Brown, 2004b) was attainable demonstrating that black Americans were interested in participating in research. The Brown (2004b) study included a one-time measurement of blood pressure with the administration of three questionnaires on site. Study participation burden was limited to a one-time, on-site data collection without intervention. Distance, time, and cost issues

often influence the intensity of recruitment efforts and study participation burden in rural areas. Study participation burden may influence both subject recruitment and retention.

Linden and colleagues (2007) undertook focus groups with 58 African American women who discussed attitudes toward participation in breast cancer clinical trials. The researchers reported on themes regarding African American women's concerns about participating in research studies. These women suggested factors that may exclude research participation include: a mistrust of research, "the system" including funding of research, and reliance on religion and God for healing (Linden et al.). These researchers had 100% attendance rate for all focus groups, and 80% were at least open to the idea of participating in a hypothetical randomized trial. The study recruitment and focus group sites were located in area African American churches to increase participation convenience for the subjects. This study further suggests that researchers be aware of their own biases and prejudices concerning access to participation and willingness of subjects to participate in research. Linden et al. suggest continuously educating the community throughout the duration of the study, reducing logistic barriers to participation, and avoiding prejudice by offering equal treatment options to subjects regardless of race. Further information may be warranted to ensure informed consent due to potential misunderstanding of the concept of randomization. This study supports the idea that African American women are willing to participate in research, although barriers do exist. The study included only urban-dwelling African American women.

Schutta and Burnett (2000) also explored participation in a cancer clinical trial for both genders. Participation in this study, as in several other oncological studies, was driven by hope for a cure, despite information on the purposes of a Phase-I clinical trial which included safe dosing and exploration of potential toxicities, not cures. Jones et al. (2006) also believe there is poor understanding of clinical trials, the process of randomization, and distrust of research and researchers among potential subjects. Their triangulation study focused on what patients knew about clinical trials, if they ever participated in a clinical trial, and reasons and willingness for or against participation. One hundred patients out of 141 approached at a clinic agreed to complete a survey of 11 quantitative and two qualitative questions. Barriers to participation were identified as uncertainty about trials and unwillingness to increase personal risk, standard treatment was working well or treatment would be delayed, possibility of getting a placebo, and unwillingness to endure future tests. Interestingly, those people who were younger or more educated were less likely to participate in clinical trials.

Mann, Hoke, and Williams (2005) presented an overview of five pilot studies they conducted among rural Mexican American women. Mann et al. addressed several issues ranging from appropriate compensation to setting time boundaries and noted "...the extensive time, expense, and effort required to conduct research with a rural population experiencing health disparities" (p. 141). Issues of recruitment and participation are problematic in research studies regardless of setting. Rural recruitment often requires drawing a large number of people from a smaller subset of the population, thus making it more difficult to recruit needed numbers and loss of participants can reduce power of the study. It is essential to have effective recruitment strategies and to maintain subject retention to have meaningful research that can be generalized to the rural population.

PROMOTING HEART HEALTH

Statistics from the American Heart Association (AHA, 2007) and Center for Disease Control and Prevention (Center for Disease Control [CDC], 2007) show that cardiovascular disease among women is the number one cause of mortality. Promoting Heart Health was a Phase-II study. Phase-II studies may be done to “ascertain the feasibility of launching a more rigorous test...” (Polit & Beck, 2008, p. 313) and may be used as a pilot study for future clinical trials. A Phase-II study allows the researcher flexibility to refine areas of the process that are not effective or working as efficiently as desired. One advantage of a Phase-II intervention study is that changes can be made since finding the problems and problem solving is one of the reasons for conducting this level of research. Therefore, the researchers of the PHH study had the ability to address unforeseen barriers to recruitment; however, each protocol change needed to be approved by the funding agency and the appropriate Institutional Review Board (IRB) involved. In this study, the protocol was approved through the Binghamton University Human Subjects Research Review Committee (HSRRC) protocol 259-05 and the University of Virginia Institutional Review Board for Health Sciences Research (IRB-HSR) protocol 12415.

Polit and Beck (2008) believe that researcher’s sampling plans are frequently the weakest portion of the study. Promoting Heart Health began by completing a power analysis based on repeated measures on two groups with an alpha of .05, effect size of .30, and power of .80. This calculation showed a minimum number of 80 subjects in each group (N=160). A sample size of 176 participants was selected to guard the power of the study against attrition. The initial design included two enrollment periods: one before a planned community intervention and one following the community intervention.

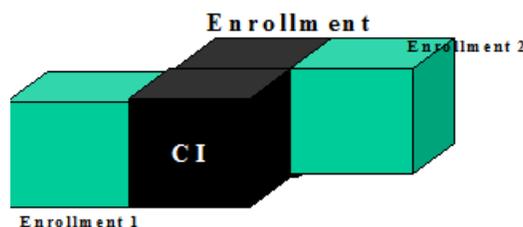


Figure 1. Original enrollment design.

All subjects were to receive the community intervention. Half of the sample was to receive the Stage Matched Nursing and Community Intervention (SMNCI) which was to include four nurse visits, half of the experimental group were scheduled to get the nurse visits prior to the Community Intervention (CI) and the other half, after the CI. After several months of recruitment screenings, it became clear the needed sample size was unattainable using a two-enrollment period model within the projected time frame and cost constraints of the grant funding. Consequently, a rolling enrollment strategy was used, and the design of the study was changed to look simply at the effect of SMNCI versus CI only, on outcome variables as opposed to looking at a combination of effect and time with a repeated measures analysis. A recalculation of the power analysis was conducted which projected a power of .80, but with a reduced target sample of N = 128.

In this study, a thorough cardiovascular screening was used for two purposes: 1) as a participant recruitment tool as suggested by Mann et al. (2005) and 2) to provide a service to the rural communities where the research was conducted. Screening procedures for the PHH included blood pressure, height, weight, waist circumference, nonfasting finger stick total and high-density lipids cholesterol, and an electrocardiogram (ECG). The screenings were offered at no charge and initially advertised as open to women, with no history of diabetes or known heart disease, between 45 and 65 years of age. The costs of the screening for this study was supported through separate funding, that allowed us to offer the screening to women beyond those who strictly met the study inclusion criteria. For example, two of those screened were less than 35 years of age and nine were older than 66 years old. As part of the effort to build trust within the community of interest, the research team did not turn women away from the screening.

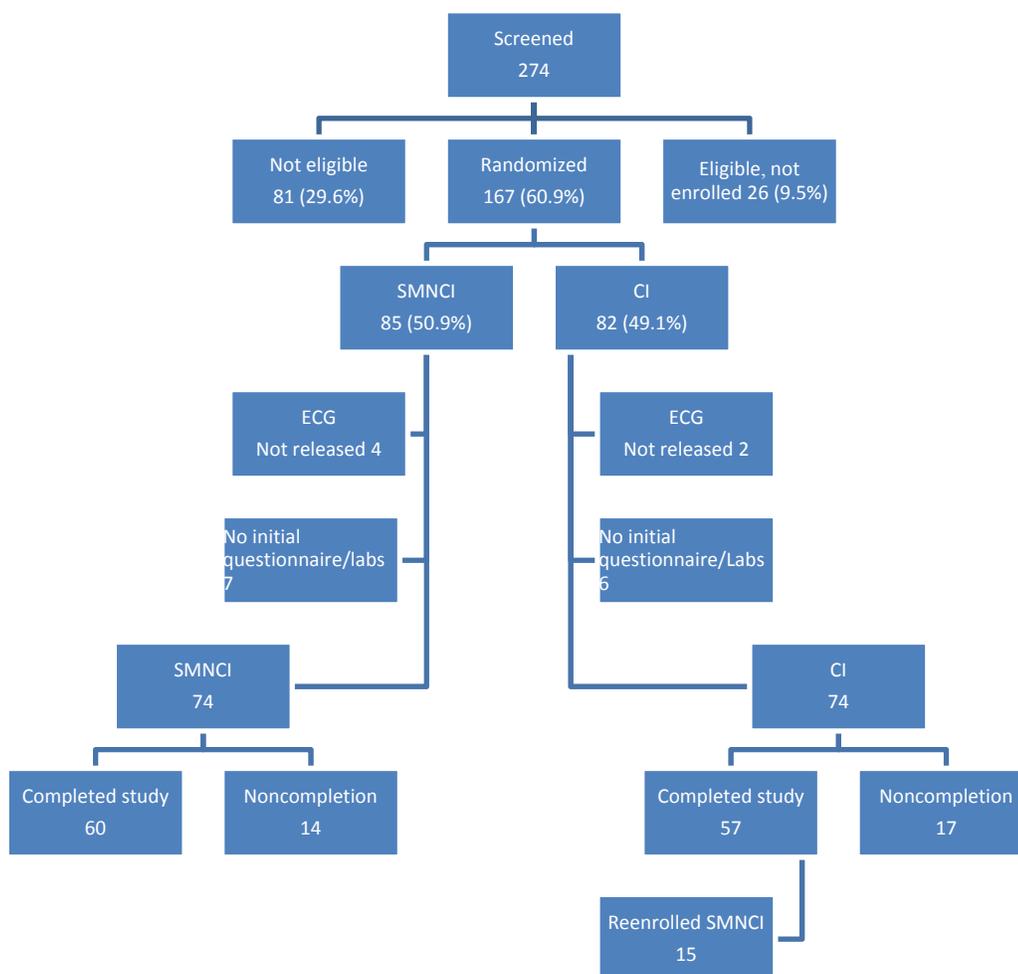


Figure 2. Promoting Heart Health screening, enrollment, attrition and completion data

Figure 2 shows those screened and their disposition through randomization if eligible as well as those completing the study (N = 117) or 79% of those actually receiving an intervention. One of the challenges in setting inclusion and exclusion criteria is creating criteria that are tight

enough to control extraneous variables, but not so tight that the sample is not representative of the population to which the findings are to be applied. The initial criteria were identified as problematic early in the screening process. The initial exclusion and revised exclusion criteria (Table 1) were set based on the literature and interest in a target population of African American and Caucasian, rural, women with up to moderate CVD risks.

Table 1. Initial and Revised Inclusion Criteria

Variable	Initial Inclusion	Revised Inclusion
Age	45-65 years	35-65 years
Gender	Female	
Location	Rural (≥ 3 RUCC)	
ECG	Normal	Normal or abnormal with release by cardiologist
Blood Pressure	$\leq 160/90$	
Total Cholesterol	≤ 240	≤ 240 or release by cardiologist
BMI	≤ 40	≤ 40 or release by cardiologist
Pulse Pressure	≥ 60 mmHg	
Framingham CHDRS	$\geq 20\%$	
Behavioral Change Need	1 or more of 3 areas: diet, physical activity, or smoking	
Personal Health History	No Diabetes, Heart Disease or Stroke.	

Enrollment through the initial screenings was more limited than anticipated as many women in this age range, particularly the upper limits of 55-65 years of age, had too high a Framingham Coronary Heart Disease Risk Score (CHDRS) (>20 points), which was above the moderate risk level targeted in this study, had a history of diabetes, or had an abnormal ECG.

Originally, any abnormality in the ECG was considered exclusion criteria. Approximately 25% of the ECGs had some type of abnormality which would exclude the very women the study sought as the target population. Because there is a paucity of statistical data in the literature concerning the number of abnormal ECGs in women and nothing on abnormal ECGs in rural women, this serendipitous finding warrants further analysis. Although the researchers found more abnormal ECGs than expected, often the ECG changes were minor in nature. A modification to both IRBs allowed a review of abnormal ECG by a cardiologist who functioned as an unpaid consultant for the study. Those subjects with minor ECG changes were allowed to participate. Those women who had ECG changes that the cardiologist felt merited further medical evaluation were told of this review and follow-up evaluations were strongly encouraged, but they were not allowed to participate in the study. If they had been enrolled prior to review of ECG, they were administratively withdrawn. Women were also administratively withdrawn for failing to complete the first questionnaire and fasting blood work, which was needed prior to intervention ($n = 13$).

Originally, the finger stick screening, non-fasting total cholesterol of ≥ 240 mg/dl was identified as an exclusion criterion. Review of the fasting blood work after entry into the study revealed 24 women whose total cholesterol was now > 240 mg/dl, indicating the fasting cholesterol was a more sensitive measure than nonfasting cholesterol levels.

Twenty-three women had a screening BMI of 40 or higher. Obesity is not a factor used in calculating the Framingham Coronary Heart Disease Risk score. One woman with a BMI of >70 was excluded due to an abnormal ECG that needed further medical evaluation. Twelve women were excluded from consideration for the study based on the original exclusion criteria and 10 women with a BMI >40 were randomized into group after IRB modification. The ECG, blood pressure, cholesterol, and weight data were reviewed by the cardiologist as needed. Modifications approved by both IRBs included change in the age range, allowance for inclusion after review of abnormal ECG, elevated cholesterol, or BMI by a cardiologist (Table 1). While the AHA suggests adults 20 years of age or older establish baseline cholesterol, BMI, and blood pressure, our data supports that at the age of 55, a woman's risk of a heart attack increases (Community Memorial Hospital, 2000).

Beginning April 2006, approximately 274 women were screened for possible participation in the PHH study. Of these, 193 were found to be eligible for the study based on screening data, 26 chose not to enroll, and 167 were randomized to group. Eighty-one (29.6%) women were immediately identified as non-eligible. With the revision of protocol, the screening and initial lab data for those with an abnormal EKG or cholesterol >240 were reviewed by the study cardiologist. After review, an additional six subjects--four from the SMNCI and two from the CI group--were administratively withdrawn from the study. Another 13 subjects were administratively withdrawn when they did not return the day after the screening for fasting blood work or submit an initial questionnaire.

Final exclusion criteria included abnormal ECG or cholesterol >240 mg/dl not cleared by a cardiologist, diabetes, history of a myocardial infarction (MI) or stroke, Framingham scores of >20 %, or no need of behavioral change. Eleven women were excluded because of an abnormal ECG not cleared by the study cardiologist. Nine women had a Framingham CHDRS $>20\%$ and were also excluded from participation; only two women had no identifiable need for behavioral change in the areas of diet, physical activity, or smoking cessation. Thus, 148 women began the study after being randomized to group, SMNCI ($n = 74$) and CI ($n = 74$). A total of 117 of the initially randomized women finished the study with final lab work drawn 14 months after entry. Thirty-one did not complete the study (21%), i.e. 14 from the SMNCI group and 17 from the CI group. The most frequently cited reasons for dropping out of the study was being too busy ($n = 8$) and felt the study was not helping ($n = 4$). With permission from the IRB and funding agency, NY state women who had originally been randomized to the CI group and completed the study were offered the opportunity to reenroll for future analysis. From the group that completed the CI, 16 were reenrolled and received nurse visits. This data will be used to analyze specific aim 5 regarding order of intervention at a later date.

BARRIERS AND SOLUTIONS

Every study has specific circumstances that need to be addressed before entering into the recruitment phase. In developing the Promoting Heart Health study, recruitment of rural women was strategically planned yet recruitment and retention for the PHH study to reduce CVD risk

factors in rural women was a relentless task where seeking solutions to barriers was a critical issue.

Long and Weinert (1989) cited concepts such as isolation and distance, insider/outsider, health beliefs including health as the ability to work, self-reliance, and independence as factors in how rural dwellers assess the need for and access health care. Morgan et al. (2005) related how some of these rural concepts influence participation in research. Transportation in rural areas is often a concern and potential problems may be solved by using informal networks, although this is not always a reliable solution. Several of these concepts were apparent to the PHH researchers during study recruitment and subject retention. Rural women are often self-reliant in meeting their needs. For example a NY participant rode her bike seven miles after milking cows in order to have her fasting blood work drawn for this study. Another issue of transportation that arose was the unprecedented rise in the cost of gasoline during the study. At one point, gas prices climbed slightly over \$4.00 a gallon in rural NY. The study did offer to transport women to the data collection site for final lab work or reimburse them for the cost of transportation. This strategy, although not frequently requested, may have limited further attrition as women were finishing the study. Placing data collection sites in rural communities rather than having subjects commute to urban areas was helpful in recruiting and retaining subjects, since it limited issues of distance and minimized transportation issues for the subjects.

Distance and Isolation

Not only do the issues of distance and isolation influence the participation of subjects, but these same concepts can influence the efforts and cost of recruiting rural subjects. To reach rural recruitment sites, the study team traveled 4-16 hours, much of this on two lane roads. Screening protocols required a large team of faculty and students with equipment. These trips were complex and involved renting vans, planning for overnight stays in VA, or consecutive very early-morning to late-evening drives for the NY screenings. Planning for trips was tightly scheduled and undertaken with consideration of students' class and clinical schedules as well as participant's lifestyles and community events such as health fairs.

There are some barriers to recruitment and retention of subjects not discussed in textbooks. Natural disasters can occur, regardless of location, without warning halting recruitment efforts and stalling participation while communities recover. Rural areas are often slow recovering from these natural disasters where resources for recovery may be limited and focus on recovery is generally centered on the more urban areas affected. The first recruitment screening for PHH took place in June of 2006 in Delaware County, NY. Late that month, the village where screenings occurred, along with several surrounding towns, received record flooding rains, destroying bridges, washing out portions of roads, and heavily damaging local businesses and homes. Participants enrolled at this point were contacted and arrangements were made to delay their participation until they had made some dimension of recovery. This 100-year flood also delayed recruitment and reduced attendance at screening sessions for several months. In general, recruiting in rural areas requires a great deal of personal attention as there is not the large pool of potential subjects that is available in more urban centers, and additional care is needed when working in a community that has experienced a natural disaster.

Perceptions of Research in Rural Communities

During the study, education about the problem being studied, in this case, cardiovascular disease in women, is appropriate and may be used as a recruitment strategy. Internet usage and

public awareness campaigns, whether for education or study recruitment may present distinctly different barriers for rural versus more urban areas. Rural areas may lag in internet connection. Also, public awareness campaigns may not reach rural areas with the same intensity that they do in more urban centers. Public health departments (HD) may have lower funding levels and health messaging may be generated in more urban HD and pushed out to rural health districts.

The PHH study used multiple avenues as well as the availability of no-fee cardiovascular screenings and the opportunity to participate in the study to communicate the message about heart disease in rural women. Radio interviews, public service announcements (PSA), articles specific to heart disease written for local newspapers, as well as inserts in church bulletins were tools used. Using multiple sources of information advertising the study and public screening events for recruitment are crucial in rural area. Foresight in anticipating the various means of advertisement and planning for these potential channels of communication including advanced IRB approval helps eliminate delays in advertisement and recruitment activities.

Although the recruitment strategies started in two specific locations, a primarily African American church in VA and a Critical Access Hospital in NY, the recruitment plan was broadened in scope and distance to improve recruitment. Offering the screening and study enrollment to county employees in both areas and school district employees in NY helped enrollment. Other worksite screenings could help improve enrollments but need to be planned with the employee's scheduling constraints in mind.

Literature supports that utilizing community liaisons or key informants reduces barriers to participation (Burns & Grove, 2005). The Promoting Heart Health team was able to connect with a church in VA that held an annual health fair for their community. The research team had previously completed a small descriptive study at this church's annual health fair. The church health outreach coordinator and health fair organizer served as a community liaison for the study and worked closely with the PHH team to present the study to the church leaders and members. Providing cardiovascular health screenings broadened the scope of the church health fair while providing a sampling frame of predominantly African American rural women for PHH; however, after attending two fairs, the available targeted population had been screened. Attempts were made to establish contact with other African American churches in the area for recruitment, but were not successful. More lead time to work with other churches would have been helpful. A second community liaison approached the team after hearing about the project at a research conference. This liaison lived in the area and had many contacts at the community level. She was able to provide support and assistance as PHH widened its recruitment strategies and area to the general population of rural women within a one-and-half-hour travel radius of Orange County VA. The change in recruitment venues and geographic location to include surrounding rural counties also required a protocol change from the appropriate IRB.

Promoting Heart Health used similar recruitment techniques as Brown's (2004a) study previously discussed; however, time spent in each community in the PHH study was limited to no more than two-three days for each recruitment trip. Six recruitment trips were made to VA and six to NY over a two-year period of time. Brown (2004a) describes a community immersion of seven weeks for recruitment into a study. The Brown (2004b) study used two blood pressure measures and three questionnaires in a one-time data collection without intervention. Promoting Heart Health used a screening process that generally took at least an hour to complete which included blood pressure, height and weight, BMI, finger stick cholesterol, Framingham scale, and ECG. Each woman spoke with a researcher, trained in providing informed consent, and, if they agreed to participate, they were asked to return the next day for fasting blood draws with the

completed first questionnaire. Study enrollment was for 14 months. The PHH study required more time and effort for both the screening and participation than did the Brown (2004b) study; however, the PHH screenings provided the community and individuals with a more in-depth CVD risk assessment than that conducted by Brown (2004b).

Efforts were made to accommodate participants to reduce barriers to both study recruitment and retention. For example, screenings were scheduled on weekends unless it was a work site screening which was scheduled during the work week. Once enrolled, subjects in the intervention group were offered a choice of where the nurse visits should take place: their home, the work site during breaks, or some common place in the community such as the health department or local diner. This has worked well with many participants as it provided a defined time limit for the visit that the subject could better control. This option also kept their home-life private and separate, if desired.

The PHH research team had developed a relationship with both rural communities prior to the study. In VA, the NY team had supported previous health fairs at one of the primarily African American churches in the area. Even so, it was anticipated that the NY team might be perceived as outsiders in rural VA. In addition, all of the researchers on the NY team were caucasian, although our undergraduate student population is diverse and many of our African American student nurses were part of the research team, traveling to VA and participating in the cardiovascular community screenings. Promoting Heart Health was fortunate to have three UVA faculty members on the research team, one of whom was African American. Enrollment of African American women ($n = 14$) and those completing the study ($n = 9$) remained lower than anticipated.

CONCLUSION

Rural recruitment can be successful, but often means more events or efforts to recruit subjects than would be needed in a more densely populated area. The pool of possible subjects in rural areas is more limited than those in larger population centers. A researcher may need to draw subjects from a wider and more geographically diverse area to recruit an adequate sample size reflective of the rural population of interest. Thus barriers that occur but are not particularly related to rurality, including subject burden regarding time commitment, possible pain or discomfort with procedures, and issues of mistrust particularly within minority communities can be more burdensome in rural studies. Barriers often recognized as issues in rural areas, such as distance, isolation, transportation, and insider / outsider status need to be addressed in a culturally appropriate manner. Each barrier regarding recruitment and participation requires careful planning for possible solutions to conduct a rural study with an adequate sample size and to limit attrition, thus strengthening the science.

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