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Feasibility test of a community-relevant intervention designed to promote African American participation in translational, breast cancer disparities research: Know about Health Options for Women (Know HOW)

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Abstract

Background—There are marked racial differences in breast cancer, the second leading cause of death among US women. Understanding causes of these differences is essential to eliminate breast cancer inequities. More prevalent in African American than in Caucasian women, metabolic syndrome has been associated with breast cancer outcomes. Further research is needed to understand metabolic syndrome's role in breast cancer disparities, thus novel strategies to increase minority participation in research are important.

Aims—We embedded two approaches (Comprehensive, Focused) to increase African American participation in breast cancer research in a state-wide service program and pilot tested both approaches in rural African American women.

Methods—We conducted three Comprehensive and three Focused Outreach Programs (n=48) and assessed research participation through consent and actual provision of data for four types of data: survey, anthropometric, blood, and mammography records.

Results—The majority of participants provided written consent for all data collection procedures (96% survey; 92% anthropometric; 94% blood; 100% mammography). There were no between group differences in consent rates. There was variation in the overall proportion of participants who provided data (96% survey; 92% anthropometric; 73% blood; 40% mammography). Women in the Comprehensive approach were less likely to return for a scheduled mammogram than women in the Focused approach (19% v 64%, $p=0.0236$).

Discussion—Both Outreach Programs promoted African American engagement in research. Differences in the provision of data by type may have been due to participant burden (i.e. time required to provide data). Study designs that embed research in service programs have promise to increase minority research participation.

Keywords

Research participation; minority; African American; breast cancer; metabolic syndrome; disparities

Introduction

Breast cancer is the second leading cause of cancer death among US women[1]. Racial differences in stage at diagnosis and survival are well established, and racial differences in breast cancer mortality and morbidity persist even when controlling for disease stage at diagnosis[2] and type of treatment[3]. Understanding what is driving these racial differences is essential to eliminate inequities in breast cancer outcomes.

More prevalent in African American than in Caucasian women[4], metabolic syndrome or its components has been associated with diabetes, cardiovascular disease[5, 6], and breast cancer morbidity/mortality[7-10]. Converging data from diverse areas of investigation reveal a need for programmatic research examining associations among health behaviors and metabolic dysregulation that are relevant to the etiology of breast cancer. It is critical to include minorities in this research, yet racial/ethnic minority groups continue to be underrepresented [11, 12] [13]. Thus novel strategies to increase minority participation are critically important[14].

Community-based participatory approaches have the potential to facilitate equitable partnerships between researchers and underserved communities to encourage minority participation in research [15]. In addition, approaches that are presented comprehensively to include various health outcomes (e.g. research on chronic disease, including breast cancer) rather than in a traditionally disease-focused manner (e.g. research on breast cancer) have potential to increase minority research engagement [16] [17].

Thus the purpose of our study was to develop and test the feasibility of a community-based, comprehensive intervention designed to promote African American participation in translational research examining behavioral and biological processes associated with breast cancer disparities. The comprehensive intervention was compared to a focused intervention that concentrated on breast cancer prevention only.

Methods

Study Setting

The study took place in the rural Arkansas Lower Mississippi River Delta (LMD). The population of the region consists primarily of Caucasian and African Americans[18], and 16–22% of households have incomes below the federal poverty level[18]. Rates of chronic diseases, including cancer, are significantly higher in the Delta than in the rest of the nation[18]. The Institutional Review Board at the University of Arkansas for Medical Sciences reviewed and approved study procedures.

Intervention Development

We used results from previous formative work conducted with the community[19] to develop a presentation addressing the prevention and management of heart disease, diabetes, and breast cancer in the context of cultural attitudes promoting community well-being. The presentation incorporated elements of surface-structure (e.g. peripheral factors such as packaging and images) and deep-structure (e.g. socio-cultural norms such as importance of family) cultural components[20]. Community and academic investigators worked together to adapt this presentation for use in a state-wide public service program that promotes screening mammography in socioeconomically disadvantaged counties (Witness Project Outreach Programs)[21].

Intervention Overview

Community and academic investigators developed materials and procedures that were integrated in Witness Project Outreach Programs that are routinely conducted as a public service to promote screening mammography throughout Arkansas. All women attending these public service programs who are eligible for screening mammography (40 years of age; >one year since last screening) are invited to schedule an appointment for a mammography screening event; those without third-party coverage for screening mammography are enrolled in the Arkansas Department of Health BreastCare Program, which provides screening, diagnostic follow-up, and treatment to eligible women at no cost. The Witness Project routinely documents mammography outcomes of program participants in order to navigate women with abnormal findings to appropriate follow up.

In this study, project staff implemented three Comprehensive Outreach Programs (treatment condition) and three Focused Outreach Programs (comparison condition). Each of the programs consisted of a presentation about either general preventive health (Comprehensive) or breast cancer prevention (Focused) and the role of metabolic syndrome indicators. This was followed by an overview of the research study, and then the opportunity to have health data collected at various stations. All interventions were held in local churches or community-based organizations. Water was provided to participants. Women were not told in advance about the length of the program, and were not provided transportation or childcare to participate in the study.

The structure of the intervention reflected basic principles of Social Cognitive Theory including: 1) information about the association of metabolic risk factors with breast cancer morbidity/mortality intended to promote accurate and realistic outcome expectations; 2) role models demonstrating attitudes and behaviors supporting participation in comprehensive preventive-health services and prevention research; 3) goal-setting and problem solving to enhance self-efficacy for providing research data. Incorporation of the intervention in Witness Project Outreach Programs enabled the application of basic principles of Diffusion Theory with the Witness Project providing a homogeneous social system with strong opinion leaders promoting attitudes towards cultural values, physical health, and community well-being that were expected to support participation in research addressing health disparities.

Comprehensive Outreach Programs—addressed behavioral and biological risk factors associated with diabetes, heart disease, and breast cancer. Program content included a 40-minute PowerPoint presentation on how components of metabolic syndrome increase the risk of developing some chronic illnesses (i.e. diabetes, heart disease) and emphasized the importance of comprehensive health care to prevent and manage these chronic conditions. The presentation also described the preliminary research between metabolic syndrome and breast cancer risk and the need for further research to understand these relationships. Women were given the opportunity after the presentation to provide health information at four health stations, where they could receive immediate feedback and risk reduction recommendation based on the health information provided. The feedback was provided in the form of a one-on-one discussion. A form was provided to the participants in the comprehensive intervention with the information received so they could take it with them and share with their health care provider if they chose. The form provided their screening numbers from the event along with how their numbers related to the normal ranges and recommendations for preventative care screening. Research staff told women that the results were preliminary and encouraged women to share their results with their primary care physician, who could provide more accurate screening assessments. The stations included: 1) a self-report survey to assess medical history and behavioral risk factors; 2) anthropometric measurements (body mass index (BMI), waist circumference, and blood pressure), 3) a blood sample to examine measures of metabolic dysregulation (cholesterol, triglycerides, and glycosylated hemoglobin); and 4) an invitation to a screening mammography event for women overdue for screening mammography. At the conclusion of the presentation, women were invited to participate in a study addressing the role of metabolic risk in comprehensive health promotion. To participate in the research study, women were asked to selectively provide or withhold consent to use one or more of the measures that were collected at the health stations for research purposes: a) self-reported medical history and behavioral risk factors; b) height, weight, waist circumference, and blood pressure; c) a blood sample to examine measures of metabolic dysregulation (cholesterol, triglycerides, glycosylated hemoglobin); and d) Witness Project records documenting screening mammography and mammography results. Women who completed the survey received a \$20 gift card. The entire program, including receiving personalized feedback from the health stations, ranged from 1 to 3 hours, depending on the number of participants attending a program.

Focused Outreach Programs—included an oral presentation on the use of breast self-exam, clinical breast exam, screening mammography, and breast biopsy as important strategies to reduce risk for breast cancer. Role models talked about their cancer experience in a culturally appropriate context, providing a “witness” that attributes their screening, treatment, and survival to faith and community support. Lay Advisors presented facts about breast and cervical cancer, taught breast self-exam, and informed participants about available cancer screening resources. A research assistant then presented a PowerPoint presentation that invited women to participate in a study examining the role of metabolic risk in breast cancer. Women who elected to participate in the study were able to selectively provide or withhold consent to have collected one or more of the following measures: a) self-reported medical history and behavioral risk factors; b) height, weight, waist circumference, and blood pressure; c) a blood sample to examine measures of metabolic dysregulation

(cholesterol, triglycerides, glycosylated hemoglobin); and d) Witness Project records documenting screening mammography and mammography results. At the same meeting, women were then asked to provide research data that they consented for at the health stations. These measures were used only for research purposes; study participants were not given immediate feedback on their results. Women who completed the questionnaire received a \$20 gift card. The duration of the entire program, including giving data to health stations, ranged from 1.5-3.5 hours.

Intervention Delivery Training

The first and last authors used training procedures that incorporated didactic education, experiential learning, behavioral rehearsal, and written and verbal feedback to train project staff to present the Outreach Programs. Project staff was also trained to provide feedback to women in the Comprehensive Outreach Program condition about their survey, anthropometric, and blood sample results. Training procedures built knowledge about associations between metabolic syndrome, breast cancer risk, and breast cancer disparities; and developed behavior management skills intended to promote participation in research addressing behavioral and biological processes contributing to health disparities.

Recruitment

The Witness Project routinely invites women to Witness Outreach Programs using endorsements from community leaders, announcements at church functions and community events, flyers posted in high-traffic locations, advertisements and public-service announcements in local print and electronic media, and word-of-mouth through community residents. We sought to recruit 30 participants across three intervention programs per arm, for a total of 60 participants across six intervention programs (three Comprehensive Outreach Programs, three Focused Outreach Programs).

Measures

We assessed six domains of information relevant to minority representation in breast cancer disparities research. These domains included research participation, metabolic syndrome, health care engagement, health behaviors and perceived risk, and demographics.

Measures of Research Participation—The proportion of women who provided written informed consent to collect research data was calculated as a measure of *intent* to participate in research. The proportion of women who consented to *and* completed data collection procedures was calculated as a behavioral measure of *actual* research participation. These two measures of research participation were obtained for four types of data collection procedures: survey, anthropometric measures, blood samples, and mammography records. Self-reported health information included medical history and behavioral risk factors. Anthropometric measures included height, weight, waist circumference, and blood pressure. Blood samples were used to examine measures of metabolic dysregulation, including cholesterol, triglycerides, and glycosylated hemoglobin. Mammography records included documentation of screening mammography and mammography results. Participants also self-reported whether they had been in any kind of research study (yes/no).

Metabolic Syndrome—Biometric data (anthropometric measures and results of blood assays) were used to determine the presence of metabolic syndrome. Project staff assessed height using a stadiometer, weight using a Tanita scale, and blood pressure using the Omron. Blood samples were collected by finger-stick and processed using CLIA-waived, point-of care analysis methodology. Lipid assays were processed using the Cholestech LDX System. Hemoglobin assays were processed using the Afinion AS-100 system. Participants meeting 3 of the following 5 criteria were classified as positive for metabolic syndrome: BMI greater than 30 or Waist circumference greater than 35, systolic blood pressure over 130 or diastolic blood pressure over 85, HbA1c greater than 6, HDL is less than 50, triglycerides greater than 150.

To identify metabolic syndrome in participants who did not provide biometric data, participants were asked to report height and weight, and whether a health professional had told them they have problems with blood pressure, blood sugar, or cholesterol. Self-reported criteria identified 8 of 9 women with metabolic syndrome confirmed using biometric measures ($\kappa=.7222$)

Health Care Engagement—Project staff administered a survey that asked whether the respondent had a primary care health professional (PCP) and when the respondent last had a check-up[22].

Health Behaviors and Perceived Risk—Adopted from the Health Information National Trends Survey (HINTS)[22], questions assessed servings of fruits and vegetables a week[23], physical activity[23], and smoking[22]. Participants were also asked to rate their chances of developing breast cancer on a scale ranging from 0% chance to 100% chance.

Demographics—Demographics included age, race, employment, marital status, education, and income[23].

Data Analysis

Studies examining factors predicting research participation face the challenge of obtaining data to characterize individuals who do not participate in research. To address this challenge, a de-identified data set derived from Witness Project service program records was released to investigators, which distinguished individuals who elected to participate in research from those who did not.

Descriptive statistics were calculated to characterize factors relevant to research participation and cancer disparities in the total sample and in each group. Fisher's Exact tests were conducted to test the main effect of group assignment on measures of intention to participate in research (written informed consent) and behavioral measures (consent + completion of data collection procedures) for four types of data collection procedures: survey, anthropometric measures, blood samples, and mammography records. Measures of research participation related to mammography records were calculated only for the subset of participants who had not had a mammogram within the past year and currently were eligible for screening mammography.

We conducted chi-square tests for categorical variables or t-tests for continuous variables to examine participant characteristics associated with measures of breast cancer research participation, including previous research participation, health care engagement, metabolic risk, and health behaviors and perceived risk. For categorical variables with cell counts less than 5, we conducted a Fisher's Exact test. Given the exploratory nature of these analyses, we used a p-value cut point of 0.10 to identify factors that warranted further investigation.

Results

Descriptive Statistics/Sample Characteristics (Table 1)

All study participants (n=48) were African American women with a mean age of 63 years. Nearly 80% reported having a routine check-up during the preceding 12 months, 75% had a PCP, and more than 90% reported having some type of health insurance. Although few participants met the national recommendations for fruit and vegetable intake (27%) and physical activity (40%), the majority were non-smokers. The average rating for perceived chance of getting breast cancer was 22% and more than half of the sample met the criteria for metabolic syndrome. The majority had never been part of a research study.

Main Effects of Treatment Assignment on Research Participation (Table 2)

All of the participants who attended an Outreach program (n=48) participated in the study either through providing identified data through their research consent, or through deidentified data obtained through the Witness Project. The majority of participants in the Focused and Comprehensive approaches provided written consent for all data collection procedures (96% survey; 92% anthropometric; 94%, blood; 100% mammography). There were no statistically significant between group differences in consent rates. There was more variation in the overall proportion of participants who completed data collection procedures (consent + actual provision of data) (96% survey; 92% anthropometric; 73% blood; 40% mammography). Women in the Comprehensive approach were less likely than women in the Focused approach to return for a scheduled mammogram (19% v 64%, p=0.0236).

Variables Associated with Research Participation

Previous research participation, metabolic syndrome, health care engagement, and health behaviors and perceived risk were not significantly associated with research participation in the self-report survey, as measured by provision of written informed consent or survey completion. However, several variables predicted the completion of data collection procedures for blood samples, anthropometric, and mammography measures.

Four characteristic groups of women were less likely to complete the procedures for obtaining blood samples compared with their counterparts: women who have a PCP (67% v 100%; p=0.0438); women who had a routine check-up within the preceding 12 months (68% v 100%; p=0.0870); women who met fruit and vegetable recommendations (46% v 85%; p = 0.0104); and women who had a higher mean perceived risk of getting breast cancer (39% (SD=33.2%) v 16% (SD=27.1%); p=0.0228).

Women who met self-report criteria for metabolic syndrome were more likely than those who did not meet criteria to provide anthropometric measures (100% v 80%, $p=.0325$). In contrast, women who met the self-report criteria for metabolic syndrome were less likely than those who did not meet criteria to return for a scheduled mammogram (23.5% vs 66.7% $p=0.0287$). Further, women with a PCP were less likely to return for a scheduled mammogram compared to women without a PCP (29% v 67%; $p=.10$).

Discussion

Both Outreach Programs promoted African American engagement in research addressing behavioral and biomedical processes associated with cancer disparities. In contrast to our hypotheses, the Comprehensive approach did not produce higher consent rates than the Focused approach. The Witness Project has long, trusted relationships with Arkansas communities and Witness staff engaged the Project's networks to recruit participants for both the Focused and Comprehensive approaches. Participants may have been more willing to participate in our research because of the good reputation of The Witness Project; thus a Comprehensive approach may have not been necessary to generate increased research engagement. Study designs that embed research in community-trusted service programs warrant further evaluation as a potentially effective strategy to enhance participation among at risk populations. Future studies may also compare and contrast research engagement outcomes between studies that utilize community service networks vs. more traditional, academic strategies to engagement minority research participation.

Also in contrast to our hypotheses, the Comprehensive approach did not produce higher actual research participation (consent + provision of data) rates than the Focused approach. Instead, women in the Comprehensive approach had lower mammography rates than those in the Focused approach. The Focused approach included a presentation solely on breast cancer risk and reduction through screening mammography, whereas the Comprehensive approach described the need for further research to understand relationships between breast cancer and metabolic syndrome. Thus women in the Comprehensive approach may not have felt as compelled to receive a screening mammography given that the presentation did not definitively communicate metabolic syndrome as a breast cancer risk factor. Consistent with this interpretation, women who met criteria for metabolic syndrome did not see themselves as being at higher risk for breast cancer and were significantly less likely to complete screening mammography than were women who did not meet criteria.

Although the consent rates obtained from both intervention arms were high, participant burden remained a significant factor in research participation, as illustrated in Figure 1. The self-report questionnaire and the anthropometric measures required minimal time. Research participation rates for these measures were the same as consent rates. In contrast, the time required to complete the blood station was considerable. The blood sample station entailed providing a blood sample, waiting for the results, and then receiving personalized feedback based on the results. The process took approximately 10-15 minutes per person. For some programs that included 10 or more participants, some waited 30 minutes or more to provide a blood sample. With this small increase in participant burden, the proportion of women who completed procedures for obtaining a blood sample was only 72.9%. The proportion of

women who returned for a scheduled mammogram (highest participant burden) was even lower (40%). Since effective management of cancer and other chronic diseases requires regular use of preventive resources that present more than minimum burden (e.g. scheduling and attending appointments for health services; participating in longitudinal studies) these results reinforce the importance of conducting further research examining factors contributing to perceived cost/benefit ratios that influence decisions to use preventive services or participate in prevention research.

Lower participation rates among women actively engaged in preventive behaviors were not expected (Identified PCP, Recent check-up, fruit and vegetable consumption). It is possible that these women saw themselves as already taking adequate steps to protect their health and did not recognize the additional benefit of research participation.

Despite limited external validity, this study provides preliminary data regarding the engagement of African American women in cancer research. Community-salient programs embedded in current health service networks have promise to increase African American participation in breast cancer research. Further research is needed to better understand the role of attitudes regarding risk behaviors, measures of metabolic risk, and strategies to promote research participation and use of preventive services. Examining the potential of embedding research in the context of current service networks to facilitate the wide-spread dissemination of research activities is also needed.

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Figure 1.
Comparison of intention to participate vs. actual participation in clinical cancer research

Table 1

Demographic Characteristics

	Focused	Comprehensive	Overall
Variable	N=19	N=29	N=48
Age (mean,std)	61.1 (13.4) (n=17)	63.7 (13.6) (n=21)	62.52 (13.4) (n=38)
Last routine check-up			
Within last year	18 (94.7%)	20 (69.0%)	38 (79.2%)
One year or more	1 (5.3%)	9 (31.0%)	10 (20.8%)
Primary care doctor/specialist (Yes)	14 (73.7%)	22 (75.9)	36 (75.0%)
Health care coverage			
Private Insurance	7 (36.8%)	0 (0.0%)	7 (14.6%)
Medicare only	7 (36.8%)	9 (31.0%)	16 (33.3%)
Medicaid and other public	2 (10.5%)	18 (62.1%)	20 (41.7%)
None	2 (10.5%)	2 (6.9%)	4 (8.3%)
Other & Medicare/other	1 (5.3%)	0 (0.0%)	1 (2.1%)
Fruit & Veg per day (continuous) (mean,std)	4.1 (3.5)	3.3 (2.5)	3.6 (2.9)
Fruit & Veg met (Yes)	5 (26.3%)	8 (27.6%)	13 (27.1%)
Physical Activity per wk (continuous) (mean,std)	261.3 (378.8)	206.6 (261.3)	228.2 (310.4)
Physical Activity met (Yes)	9 (47.4%)	10 (32.3%)	19 (39.6%)
Smoker (Yes)	2 (10.5%)	5 (17.2%)	7 (14.6%)
Anthropometric - met syndrome (Yes)	4 (44.4%) (n=9)	11 (64.7%) (n=17)	15 (57.7%) (n=26)
Survey - met syndrome (Yes)	8 (42.1%) (n=19)	17 (58.6%) (n=26)	25 (55.6%) (n=45)
Chance of developing breast cancer (%) (mean,std)	23.1 (34.5) (n=16)	20.6 (28.1) (n=28)	21.6 (30.2) (n=44)
Ever been in a health research study (Yes)	1 (5.3%)	7 (24.1%)	8 (16.67%)

Table 2

Comparison across group assignments

Variable	Comprehensive (n=29) (n, %)	Focused (n=19) (n, %)	p-value
Survey			0.5155
Consented	27 (93.10)	19 (100.00)	
Did not consent	2 (6.90)	0 (0.00)	
Survey			NA
Completed	29 (100.00)	19 (100.00)	
Did not complete	0 (0.00)	0 (0.00)	
Survey			0.5155
Research (completed & consented)	27 (93.10)	19 (100.00)	
Did not participate in research	2 (6.90)	0 (0.00)	
Anthropometric (N=consented on all)			1.0000
Consented	27 (93.10)	17 (89.47)	
Did not consent	2 (6.90)	2 (10.53)	
Anthropometric (N=completed all)			NA
Completed	29 (100.00)	19 (100.00)	
Did not complete	0 (0.00)	0 (0.00)	
Anthropometric			1.0000
Research (completed & consented)	27 (93.10)	17 (89.47)	
Did not participate in research	2 (6.90)	2 (10.53)	
Blood			1.0000
Consented	27 (93.10)	18 (94.74)	
Did not consent	2 (6.90)	1 (5.26)	
Blood			0.3103
Completed	19 (67.86)	16 (84.21)	
Did not complete	9 (32.14)	3 (15.79)	
Blood			0.3103
Research (completed & consented)	19 (67.86)	16 (84.21)	
Did not participate in research	9 (32.14)	3 (15.79)	
Mammogram (N=eligible+ineligible)			0.9228
Consented	21 (72.41)	14 (73.68)	
Did not consent	8 (27.59)	5 (26.32)	
Mammogram (N=30 eligible)			NA
Consented	16 (100.00)	14 (100.00)	
Did not consent	0 (0.00)	0 (0.00)	
Mammogram (N=30 eligible)			0.0236
Completed	3 (18.75)	9 (64.29)	
Did not complete	13 (81.25)	5 (35.71)	
Mammogram (N=30 eligible)			0.0236

Variable	Comprehensive (n=29) (n, %)	Focused (n=19) (n, %)	p-value
Research (completed & consented)	3 (18.75)	9 (64.29)	
Did not participate in research	13 (81.25)	5 (35.71)	