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Mammography Screening after Risk-Tailored Messages: The Women Improving Screening through Education and Risk Assessment (WISER) Randomized, Controlled Trial

Joann Bodurtha, M.D., M.P.H.,[1] John M. Quillin, Ph.D., M.P.H.,[1] Kelly A. Tracy, Ph.D.,[1] Joseph Borzelleca, M.D.,[2] Donna McClish, Ph.D.,[3] Diane Baer Wilson, Ed.D., M.S., R.D.,[4] Resa M. Jones, Ph.D., M.P.H.,[5] Julie Quillin, M.T.,[6] and Deborah Bowen, Ph.D.[7]

Abstract

Aims: A randomized trial investigated the impact of risk-tailored messages on mammography in diverse women in the Virginia Commonwealth University Health System's gynecology clinics.

Methods: From 2003 to 2005, 899 patients ≥40 years of age were randomized to receive risk-tailored information or general information about breast health. Multiple logistic regression analyses summarize their breast health practices at 18 months.

Results: At baseline, 576 (64%) women reported having a mammogram in the past year. At 18-month follow-up, mammography rates were 72.6% in the intervention group and 74.2% in the control group (N.S.). Women (n = 123) who reported worrying about breast cancer "often" or "all the time" had significantly higher mammography rates with the intervention (85.0%) vs. the controls (63.5%). No significant differences existed in clinical breast examination, self-examination, or mammography intentions between the two study arms. However, intervention women with lower education reported significantly fewer clinical breast examinations at follow-up.

Conclusions: The brief intervention with a risk-tailored message did not have a significant effect overall on screening at 18 months. However, among those who worried, mammography rates in the intervention group were higher. Individual characteristics, such as worry about breast cancer and education status, may impact interventions to improve breast cancer prevention practices.

Introduction

BREAST CANCER REMAINS A MAJOR CONCERN in the United States, where an estimated 182,460 new cases were expected in 2008.[1] Heightened public discussion of breast cancer does not necessarily translate into improved breast health practices, although research suggests early detection through mammography can improve survival.[2] Over the past 10 years, all major U.S. medical organizations have come to recommend mammography for women aged ≥40; however, even this guidance is tempered by the suggestion of individual consultation with one's physician.[3] Many barriers have been examined, such as worry, perceived risk, and ease of appointment, that might be addressed with interventions.[4–6] Still, mammography rates may be declining.[7] Women may hear varied information about other aspects of breast health practices, including utility of breast self-examinations (BSE), clinical breast examinations (CBE), hormone use, imaging techniques, and genetic testing.[8–10] A recent meta-analysis of tailored interventions to promote mammography screening found that tailored interventions that used the Health Belief Model (HBM) and included a physician recommendation produced the strongest effects.[11]

In the face of complex and changing information, tiered tailored risk information using categories (usual or weak, moderate, and strong) may be one approach to providing individual patient screening recommendations. It is, for example, the approach taken by the Centers for Disease Con-

[1]Human and Molecular Genetics, Massey Cancer Center, Virginia Commonwealth University, Richmond, Virginia.
[2]Obstetrics and Gynecology, Virginia Commonwealth University, Richmond, Virginia.
[3]Biostatistics, [4]Internal Medicine, and [5]Epidemiology and Community Health, [6]Massey Cancer Center, Virginia Commonwealth University, Richmond, Virginia.
[7]Boston University School of Public Health, Boston, Massachusetts.

trol and Prevention (CDC) in its Healthware software (*www.cdc.gov/genomics/about/family.html*). Genetic testing can supplement risk classification, but it is imperfect, not universally accessible, and not appropriate as a population screen.[12] Family history is increasingly understood as a risk factor for cancer,[13] and its incorporation into computerized risk assessment tools, such as the Gail Model, has a much better chance for accessible population triage and tailored health promotion.[14] Although the Gail Model has limitations, it represents a paradigm for assessing risk, including family history.[15] Unfortunately, attempts to integrate computer-based information in breast healthcare often focus on high-risk women[16] or women with higher access or motivation.[17] What is needed is a validated, accessible tool to triage risk in general clinic settings.

Understanding patients' perspectives about the risks and benefits of screening may be particularly important for informed decision making.[18] Our approach was based on the HBM,[19] which suggests that perceived susceptibility and barriers predict behaviors. The intervention was based on formative audience research.[20] Our study was designed to evaluate an accessible, theoretically driven, individually tailored health promotion intervention for a racially and economically diverse population. This paper summarizes our main outcome, mammography screening, and secondary outcomes, CBE, BSE, and mammography intentions, at 18-month follow-up.

Materials and Methods

Objectives and outcomes

The long-term objectives were to reduce breast mortality by promoting screening, increase breast health awareness, and promote supportive resources to women; triage women for psychosocial and genetic counseling services in a clinical environment; and effectively deliver new health information in accessible environments to reduce potential healthcare disparities. We hypothesized that the intervention would increase mammography practice and intentions, BSE, and CBE.

Participants

The Women Improving Screening through Education and Risk Assessment (WISER) study used a randomized, controlled design. Target recruitment was 900 participants, allowing 80% power to detect a 10% difference in mammography practices ($\alpha = 0.05$) at 18-month follow-up, assuming 10% attrition. Women eligible for the study were at least 40 years old, not pregnant, nonparticipants in the trial's pilot study, with no history of breast cancer or carcinoma *in situ* (CIS). Of 2733 women approached to participate in the study, 2332 were eligible, and 1048 of those consented to participate. A total of 899 women were able to complete baseline survey and randomization, with 449 women randomized to the intervention group and 450 women randomized to the control group.

Recruitment

Recruitment occurred in waiting rooms of four women's health clinics in the Virginia Commonwealth University Health System (VCUHS) in Richmond, Virginia. Two academic downtown practices (one resident and one faculty clinic) served as the main sites of the study (98% of participants). The two additional sites were added near the end of the study to enhance slow enrollment from the main clinics, but that effort was not successful. A research assistant recruited and consented participants in clinic waiting rooms. Women completed the baseline survey either before or after their office visit and were then randomized to either the treatment or control group. A biostatistician prepared stratified (by clinic) block randomization assignments before the study. A more detailed description of participant recruitment is available elsewhere.[21]

Intervention

The intervention was based on the expanded HBM.[19] Participants in the intervention group had 5-year and lifetime probabilities for breast cancer calculated using the Internet National Surgical Adjuvant Breast and Bowel Project (NSABP-2) version of the Gail Model.[22,23] After being reviewed on the computer, information sheets were given to participants. They described lifetime risk as Usual (<15%), Moderate (15%–30%), or Strong (>30%), a previously established classification system.[24] The handouts for the treatment group addressed other traditional constructs of the HBM, including barriers to mammography, breast cancer seriousness, individual risk for breast cancer, and the benefits of a yearly mammogram.[25] Nutrition and physical activity recommendations were also included.

Instructions for scheduling mammogram and genetic counseling visits and encouragement to talk to health professionals addressed less studied HBM constructs, that is, self-efficacy and cues to action.[26] The availability of a psychological counselor was mentioned verbally, on the consent forms, and on the tailored handouts. Control participants received general information about breast cancer prevention practices, including mammography, which was not tailored to their risk level and did not address HBM factors.

The VCU Institutional Review Board approved the study. No adverse outcomes occurred.

Measures

Baseline and follow-up surveys assessed breast heath practices, relevant theoretical constructs, and sociodemographic variables. Baseline surveys were self-administered paper questionnaires filled out in the waiting room. Follow-up surveys were conducted through phone interviews whenever possible. Participants who could not be reached by telephone within 3 weeks of the scheduled follow-up date were mailed a survey to be completed and mailed back. Surveys received by mail comprised 15% of follow-up surveys at 1 month, 28% of follow-up surveys at 6 months, and 20% of follow-up surveys at 18 months. A mammogram was described as "an x-ray taken only of the breast by a machine that presses against the breast." At baseline, women were asked: Have you ever had a mammogram? If you have had a mammogram, when did you have your most recent mammogram? Responses were: 2 or more years ago; 1–2 years ago; 1 year ago; more recent than 1 year ago; I have never had a mammogram. At follow-up women were reminded of their enrollment date and asked, Since you enrolled in the study, have you had a mammogram? In addition to the survey, evidence of a mammogram was sought from the

VCUHS electronic information system, and for those lacking a survey or evidence of a mammogram in the information system, medical records were reviewed. A woman was classified as having had a mammogram at baseline if she responded Yes on the baseline survey or had information system or medical record evidence of a mammogram within 365 days prior to enrollment (including the day of enrollment). A woman was classified as having been screened for follow-up if there was a response of Yes on the survey at any follow-up (1, 6, or 18 months) or evidence of a mammogram from the information system or medical record. Of the 660 subjects classified as having a follow-up mammogram, 380 were so identified by both self-report and information system/medical record review, an additional 229 were self-report only, and 57 were information system/medical record review only.

The CBE and BSE outcome measures were based entirely on self-report. In the baseline survey, women were asked how many CBEs they had in the past 6 years. For analysis, this was dichotomized to at least three times in the last 6 years vs otherwise. At follow-up, subjects were asked, Since you enrolled in the study, have you had a clinical breast exam? If a subject responded Yes at any of the follow-up times (1, 6, or 18 months), she was categorized as having a follow-up CBE. At baseline, women were asked how many BSEs they had done in the last 12 months. The outcome measure was based on the survey question at 18 months, asking how many BSEs they had done since entering the study. For purpose of analysis, both the baseline and 18-month self-reported responses were dichotomized according to whether or not the subject had done at least six BSEs.

To assess mammography intentions, women were asked to rate how likely they were to get a mammogram in the coming year. These responses were skewed toward the positive and were dichotomized as Definitely or Very likely vs. Unlikely, Somewhat likely, or Not sure. Data on first-degree relatives with breast cancer was obtained from the table in the survey assessing "biological (blood-related)" family members who had been diagnosed with different types of cancer. Perceived risk was assessed by asking, Compared to most women, what do you think your chances are that you will get breast cancer? Responses on a 5-point scale were trichotomized (lower, average, higher) for analyses. The frequency of breast cancer worry was derived from a specific item with a 4-point scale, Rarely or never, Sometimes, Often, or All the time.[27] Because of a scarcity of responses to the latter two categories, Often and All the time were combined.

Age, race, and education were obtained from surveys, and medical insurance was obtained from administrative data.

Statistical analysis

Data were stored in Microsoft Access (Redmond, WA Microsoft Corporation). Statistical analyses used SAS 9.1 (SAS Institute, Cary, NC). Variables for the primary analyses were prespecified by the hypotheses. Univariate differences between subjects randomized to the intervention and control groups were tested by chi-square tests. Multiple logistic regression compared outcome measures, controlling for clinic (the stratification factor used in randomization) and the baseline value of the outcome measure. To assess possible moderating effects with age, race (white, nonwhite), risk group, education, family history of breast cancer, previous screening (mammogram, CBE, BSE, or baseline mammography intentions as appropriate), and frequency of breast cancer worry, models were fit including interaction of group (intervention/control) with each of the moderating variables. If significant, odds ratios (ORs) were calculated separately at each level of the potential moderating variable. For the CBE, BSE, and intentions outcome measures, the data were reanalyzed using multiple imputations (propensity method), which preserves the intention to treat to check for any biases that may have resulted from the loss-to-follow-up and resultant main, complete case analysis.[28]

Results

Eight hundred ninety-nine women were randomized to the study. Data about CBE was available for 773 (84%) subjects, and BSE and mammography intentions were available for approximately 74%. Subjects without follow-up data for CBE, BSE, or mammogram intentions tended to be nonwhite, younger, less likely to have gone to college, and less well insured. They were also less likely to have had a mammogram in the year prior to enrollment, to definitely intend to have a mammogram in the next year, or to have had a CBE in the previous 6 years. Equal numbers of women in the two study groups provided follow-up data.

Table 1 describes the enrollees at baseline. The intervention and control groups did not statistically differ on any of the demographic measures. Mean age was 50.1 years, with more women in the 40–49-year-old age group (55.7%) than in the 50-year and older group. Approximately 45% of the sample was African American. Thirteen percent of the sample had a first-degree relative with breast cancer. Fourteen percent of both groups worried about breast cancer Often or All the time.

There were no baseline differences by intervention condition regarding breast health practices or mammography intentions (Table 2). Roughly 64% of the intervention and control groups had a mammogram within 1 year prior to enrollment. Approximately 20% reported having seven or more CBEs in the last 6 years, and 16.5% reported doing no BSE in the past year. Eighty-five percent reported they would Very likely or Definitely get a mammogram in the coming year.

Table 3 displays follow-up results, both crude, unadjusted rates as well as ORs, adjusting for baseline and clinic (the stratification variable). Three hundred twenty-eight (73.1%) subjects in the intervention group and 338 (75.1%) controls had a mammogram by 18 months. There was no significant difference between groups ($p = 0.4810$ unadjusted, $p = 0.4621$ adjusted). However, those who worried about breast cancer Often or All the time had significantly higher rates if they were in the intervention group (crude rates: 85.0% vs. 63.5%; adjusted OR and 95% CI: 3.06, 1.22-7.68). Intervention group rates showed a tendency to be lower compared with controls for those who worried about breast cancer only sometimes (crude rates: 73.7% vs. 79.1%; adjusted OR and 95% CI: 0.80, 0.49-1.30) or rarely/never (crude rates: 68.1% vs. 75.3%; adjusted OR and 95% CI: 0.62, 0.37-1.04) (p for interaction 0.0115). None of the other potential moderators (age, race, family history, perceived risk) was significant. No differences existed in rates of BSE or mammography intentions by intervention condition overall, and none of our potential moderators were found significant. Analyses using multiple imputations gave similar results.

Table 1. Cohort Description[a]

	Intervention (n = *449*)	*Control* (n = *450*)	*Total* (n = *899*)
Race (n = 899)			
Caucasian	221 (49)[b]	230 (51)	451 (50)
African American	205 (46)	199 (44)	404 (45)
Other	23 (5)	21 (5)	44 (5)
Age (n = 899)			
40–49	242 (54)	259 (58)	501 (56)
50–64	170 (38)	167 (37)	337 (37)
65+	37 (8)	24 (5)	61 (7)
Education (n = 899)			
<High school	60 (14)	65 (15)	125 (14)
High school	121 (27)	117 (26)	238 (27)
College	262 (59)	264 (59)	526 (59)
Insurance (n = 899)			
Commercial	200 (45)	219 (49)	419 (47)
Medicare	72 (16)	52 (12)	124 (14)
Medicaid	21 (5)	20 (4)	41 (5)
Indigent	88 (20)	96 (21)	184 (20)
Self-pay	68 (15)	63 (14)	131 (15)
First-degree relative with breast cancer (n = 899)			
Yes	57 (13)	59 (13)	116 (13)
No	392 (87)	391 (87)	783 (87)
Risk comparison (n = 890)			
Little/much lower	202 (45)	181 (41)	383 (43)
Average	168 (38)	173 (39)	341 (38)
Little/much higher	76 (17)	90 (20)	166 (19)
Breast cancer worry frequency (n = 890)			
Rarely/never	166 (37)	178 (40)	344 (39)
Sometimes	217 (49)	206 (46)	423 (48)
Often/all the time	60 (14)	63 (14)	123 (14)

[a]No significant differences between intervention and control groups for these variables ($p \geq 0.18$).
[b]Frequency (%).

Discussion

This study examined the impact on breast health practices of a short waiting room intervention using risk-tailored messages based on the Gail Model, at 18 months, in a diverse sample of women aged ≥40 years. There were not statistically significant differences between the intervention and control groups in overall mammography, CBE, BSE, or mammography intentions. A Cochrane Review[29] concluded that interventions with a "personalized risk communication element" may have a small effect on increasing uptake of screening tests. Although the women in the control group did not get the risk-tailored message, they did receive an instruction sheet that recommended physical activity, healthy eating, and screening.

Women who reported breast cancer worry Often or All the time at baseline had higher rates of mammograms in the intervention group compared with controls at follow-up. There was a statistically significant trend for women with higher breast cancer worry to perceive themselves to be of higher breast cancer risk. Moderate levels of breast cancer worry may facilitate, rather than undermine, mammography use.[4] It could be that women who worry more about breast cancer risk attend to the messages in the intervention more. This would be consistent, for example, with health behavior theories of coping, in which both cognitive and emotional appraisal mechanisms are necessary for action. Perhaps the cognitive and prevention information presented through the WISER intervention led to mammography only if emotional appraisal (manifested as breast cancer worry) was already activated.

Women with less than a high school education reported fewer CBEs after the intervention. It is possible that women in the intervention group, learning of their low risk, scheduled fewer gynecology visits after the intervention or asked for fewer breast examinations. Although set in clinics, the intervention did not directly involve providers, so any connection between the components of the actual visit with the provider and the participants was indirect, spurious, or related to communication initiated by the participant. It is also certainly possible that these moderator effects are chance findings, particularly as they were not hypothesized in advance. In light of their statistical significance and possible rationale, future studies are warranted.

Study limitations and strengths

Limitations of our study include the general problem of validity of mammography self-reports. Agreement rates among self-reports, medical records, and administrative

Table 2. Baseline Values of Outcome Measures[a]

	Intervention	*Control*	*Total*
Mammogram within 1 year of enrollment ($n = 899$)			
Yes	288 (64.1)[b]	288 (64.0)	576 (64.0)
No	161 (35.9)	162 (36.0)	323 (36.0)
Frequency of CBE in last 6 years ($n = 897$)			
None	17 (3.8)	26 (5.8)	43 (4.8)
1–2	102 (22.8)	109 (24.2)	211 (23.5)
3–6 times	230 (51.5)	211 (46.9)	441 (49.2)
6 times	90 (20.1)	92 (20.4)	182 (20.3)
Don't know	8 (1.8)	12 (2.7)	20 (2.2)
Frequency of BSE in past year			
None	79 (17.6)	69 (15.4)	148 (16.5)
1–6 times	183 (40.8)	200 (44.5)	383 (42.6)
7–12 times	91 (20.3)	109 (24.3)	200 (22.3)
>12 times	80 (17.8)	57 (12.7)	137 (15.3)
Don't know	16 (3.6)	14 (3.1)	30 (3.3)
Mammogram intentions ($n = 891$)			
Unlikely	17 (3.8)	14 (3.1)	31 (3.4)
Somewhat likely	29 (6.5)	26 (5.8)	55 (6.2)
Very likely	146 (32.8)	138 (30.9)	284 (31.9)
Definitely	234 (52.6)	240 (53.8)	474 (53.2)
Not sure	19 (4.3)	28 (6.3)	47 (5.3)

[a]No significant differences between intervention and control groups ($p > 0.13$).
[b]Frequency (%).

claims may be a particular challenge in low-income women.[30] Although administrative records have some theoretical appeal compared with self-reports (e.g., overreporting or telescoping), discrepancies between administrative records and self-reports may depend on how the question is asked.[31] Because women in our clinics may get their mammograms elsewhere, the available administrative records were not necessarily more complete than self-reports. However, these administrative reports should not have been influenced by any social desirability differences between treatment groups. In an effort to have the most complete data, a woman was considered to have had a mammogram if she reported such during the study follow-up or if her administrative data indicated she had a mammogram or if there was evidence in her medical record. It was assumed that subjects missing self-report with no evidence of a mammogram from the information system or medical records review had not had a follow-up mammogram. It is possible that this was a

Table 3. Outcome Analysis Results. Unadjusted Rates and Adjusted ORs with 95% CI[a] Testing Differences in % Mammography, CBE, BSE, and Screening Intentions between Intervention and Control Study Participants, Overall and for Statistically Significant Moderators

		Unadjusted rates		*Adjusted OR*
		Intervention	*Control*	*OR (95% CI)*
Mammography	Overall ($n = 899$)	73.1	75.1	0.89 (0.65, 1.22)
	By BC worry frequency** ($n = 890$)[b]			
	Rarely/never	68.1	75.3	0.62 (0.37, 1.04)
	Sometimes	73.7	79.1	0.80 (0.49, 1.30)
	Often/all the time	85.0	63.5	3.06 (1.22, 7.68)
CBE	Overall ($n = 773$)	91.4	91.0	1.00 (0.60, 1.66)
	By education*** ($n = 766$)[b]			
	Less than high school	83.0	96.3	0.17 (0.03, 0.90)
	High school	89.0	89.4	0.82 (0.32, 2.07)
	College	93.8	91.3	1.50 (0.74, 3.05)
BSE at least 6 times	Overall ($n = 680$)	56.8	57.6	0.95 (0.67, 1.33)
Definite intentions	Overall ($n = 677$)	59.7	61.4	0.97 (0.70, 1.33)

[a]Adjusted for clinic (used for stratified randomization) and the baseline value of outcome measure.
**Significance of interaction: $p = 0.0115$; ***significance of interaction: $p = 0.0497$.
[b]Nine subjects missing worry frequency and 7 missing education at baseline cause missing values in analysis.

misclassification. Because subjects missing self-report were evenly distributed between intervention and control groups, we do not expect that there was any bias. Missing data for secondary outcomes (CBE, BSE, and mammography intentions) were not imputed and could possibly bias or limit our findings. Additional limitations include a higher attrition rate than we anticipated in spite of multiple phone calls and mailings, the Gail Model applicability in diverse populations;[32] and no adjustment of alpha for multiple testing of moderators (six for each outcome variable). Given that the interpretation by women of questions involving recall of the past may vary, that these women were generally younger and better educated than the national population, and that these women had a usual source of medical care, generalizability to other populations may be limited.

These limitations notwithstanding, this study benefited from a randomized, controlled experimental design. Furthermore, this racially diverse sample within a clinical practice setting likely increases the generalizability of results and addresses research among populations that have historically been underrepresented in research trials.

Conclusions

It appears that a brief intervention in the waiting room with the computer-based Gail Model did not increase mammography rates in the overall group of diverse women. It was, however, associated with improved rates in those women most worried about breast cancer. For those who worried about breast cancer, communication about family history and risk factors may have been partially addressed by an intervention that was information based but delivered in a friendly personal way. We were surprised by the finding of lower CBE reports in women of lower education. This could be a spurious finding but needs to be examined in the future. To the extent that family history risk represents an area of growing technical and educational complexity, some attention to it in the routine medical setting where diverse patients have access may represent a bridge to the challenges of personalized medicine.

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Disclaimer Statement

No competing financial interests exist.

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Address reprint requests to:
Joann N. Bodurtha, M.D., M.P.H.
Virginia Commonwealth University–Human Genetics
Box 980033
Richmond, VA 23298

E-mail: bodurtha@vcu.edu