

# A Randomized Trial of Breast Cancer Risk Counseling: The Impact on Self-Reported Mammography Use

## ABSTRACT

**Objectives.** We evaluated the impact of individualized breast cancer risk counseling on mammography use among women at risk for breast cancer.

**Methods.** Participants (n = 508) were randomized to the breast cancer risk counseling intervention or a general health education control intervention, and 85% completed follow-up.

**Results.** In multivariate modeling, a significant group-by-education interaction demonstrated that among less-educated participants, breast cancer risk counseling led to reduced mammography use. There was no intervention effect among the more-educated participants.

**Conclusions.** These results suggest that standard breast cancer risk counseling could have an adverse impact on the health behaviors of less-educated women. (*Am J Public Health*. 1999;89:924-926)

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The most important risk factors for breast cancer are age and family history of breast cancer.<sup>1</sup> Relatives of breast cancer patients have surprisingly low rates of mammography use, despite their increased risk.<sup>2-5</sup> Inaccurate risk perceptions and elevated levels of distress may serve as barriers to mammography use in this population.<sup>6,7</sup> Thus, interventions designed to improve risk comprehension, decrease distress, and enhance mammography use are needed.<sup>8</sup>

We conducted a randomized trial comparing the efficacy of breast cancer risk counseling with that of a general health education control intervention among women with a family history of breast cancer. The premise of breast cancer risk counseling is that more accurate comprehension of breast cancer risk, along with recommendations for mammography, will lead to reduced distress and improved mammography adherence. Previously, we documented the efficacy of risk counseling in improving breast cancer risk comprehension<sup>9</sup> and reducing psychological distress.<sup>10</sup> Here, we examine the impact of risk counseling on mammography use one year after intervention. We predicted that risk counseling participants would have higher rates of mammography use than general health education participants. Further, on the basis of our previous research,<sup>10</sup> we predicted that the beneficial effect of risk counseling would be greatest in women with fewer years of formal education.

## Methods

Study procedures were described previously in a report of an interim analysis examining risk comprehension.<sup>9</sup> In brief, participants were identified by relatives who were under treatment for breast cancer. Eligible unaffected first-degree relatives received a letter describing the study, and those who did not decline participation were contacted by telephone to complete a baseline interview. Following the baseline interview, individuals were invited to participate in the trial. Those who accepted were randomized to either the breast cancer risk counseling or the general health education group. Participants did not know which group they had been assigned to

until the intervention session began. One year after the intervention, participants were contacted for a blinded follow-up interview.

Eligible participants were women 40 years and older with a family history of breast cancer in at least one first-degree relative. Women with a prior cancer diagnosis (except basal or squamous cell skin cancers) were excluded. Sixty-one percent of those interviewed agreed to be randomized and 71% of those randomized actually completed their intervention visit (for an overall acceptance rate of 43%). Characteristics of women who declined to participate were provided in a previous report.<sup>11</sup> Those women who attended the counseling visit (n = 508) constituted the study sample for this trial. Of those who completed a counseling visit, 85% (n = 430) completed the 12-month follow-up interview and served as participants in this report. There was no evidence of differential dropout rates between the groups (16% for breast cancer risk counseling [BCRC] vs 14.9% for general health education [GHE];  $\chi^2$  [df = 1, n = 508] = 0.15, P = .70).

The risk counseling protocol consisted of the following elements: (1) discussion of breast cancer risk factors, (2) presentation of individualized risk figures, (3) recommendations for annual mammography based on National Cancer Institute recommendations for women with familial risk, and (4) instruction in breast self-examination. The general health education control protocol contained the following components: (1) assessment of current health practices, (2) age-specific cancer screening recommendations, (3) encouragement to quit smoking, (4) suggestions for reducing dietary fat intake, and (5) recommendations for regular aerobic exercise. Both

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This paper was accepted November 4, 1998.

interventions were designed to convey similar advice about breast cancer screening but varied in whether specific risk estimates were provided (breast cancer risk counseling) and whether health promotion information was included (general health education).

Breast cancer risk factors, sociodemographics, and risk perceptions were measured during the baseline telephone interview. Characteristics of the affected relative (e.g., time since diagnosis) were abstracted from medical records. Self-reported mammography use, measured at the baseline and 12-month interviews, was the primary outcome. Participants were classified as to whether or not they had obtained a mammogram in the year prior to participating in the study and in the year since the intervention visit. We chose annual mammography as our outcome for all participants since most physicians and medical organizations recommend annual mammograms beginning at 40 years of age for women with a family history of breast cancer.<sup>12,13</sup>

Data analysis was performed in 2 steps. To identify potential confounders, we compared the 2 groups on background sociodemographics and characteristics of the affected relative. All variables that differed ( $P < .15$ ) between groups at baseline were controlled in subsequent modeling. Next, we conducted a logistic regression analysis with hierarchical variable entry. Variables were entered in the following order—step 1: potential confounders; step 2: the education main effect; step 3: the group main effect; step 4: the group-by-education interaction term. This approach allowed evaluation of the incremental contributions of each predictor variable along with the independent effects of each variable included in the final model.

## Results

Despite random assignment, the breast cancer risk counseling group had a higher proportion of non-White participants (18% vs 9%;  $P = .008$ ) and the mean time since the diagnosis of the affected relative was greater for general health education participants (3.8 years vs 3.1 years;  $P = .06$ ). These variables were controlled in multivariate analyses.

The mean age of the study sample was 51 years (range = 40–75). The majority of participants were White (86%), married (74%), employed (58%), and well educated (57% had at least some college). Eighty-six percent had only one affected first-degree relative, and 39% had had their first child after 25 years of age.

The groups did not differ significantly in baseline mammography use (BCRC = 75%, GHE = 71%;  $\chi^2 [1, n = 430] = 1.2, P > .15$ ) or

**TABLE 1—Determination of Mammography Use by Logistic Regression**

| Step | Variable                       | $\chi^2$ Change | Final OR | 95% CI     |
|------|--------------------------------|-----------------|----------|------------|
| 1    | Baseline mammography           |                 | 2.21**   | 1.38, 3.53 |
|      | Race/ethnicity <sup>a</sup>    |                 | 1.12     | 0.60, 2.11 |
|      | Time since diagnosis (y)       | 12.47**         | 1.02     | 0.96, 1.08 |
| 2    | Education <sup>b</sup>         | 6.02**          | 1.06     | 0.56, 2.02 |
| 3    | Treatment group (BCRC vs GHE)  | 2.46            | 0.44*    | 0.23, 0.83 |
| 4    | Group-by-education interaction | 4.15*           | 2.49*    | 1.03, 6.00 |

Note. Chi-square model ( $df = 5, n = 430$ ) = 25.11,  $P < .01$ . OR = odds ratio; CI = confidence interval; BCRC = breast cancer risk counseling; GHE = general health education.

<sup>a</sup>White vs African American or Hispanic.

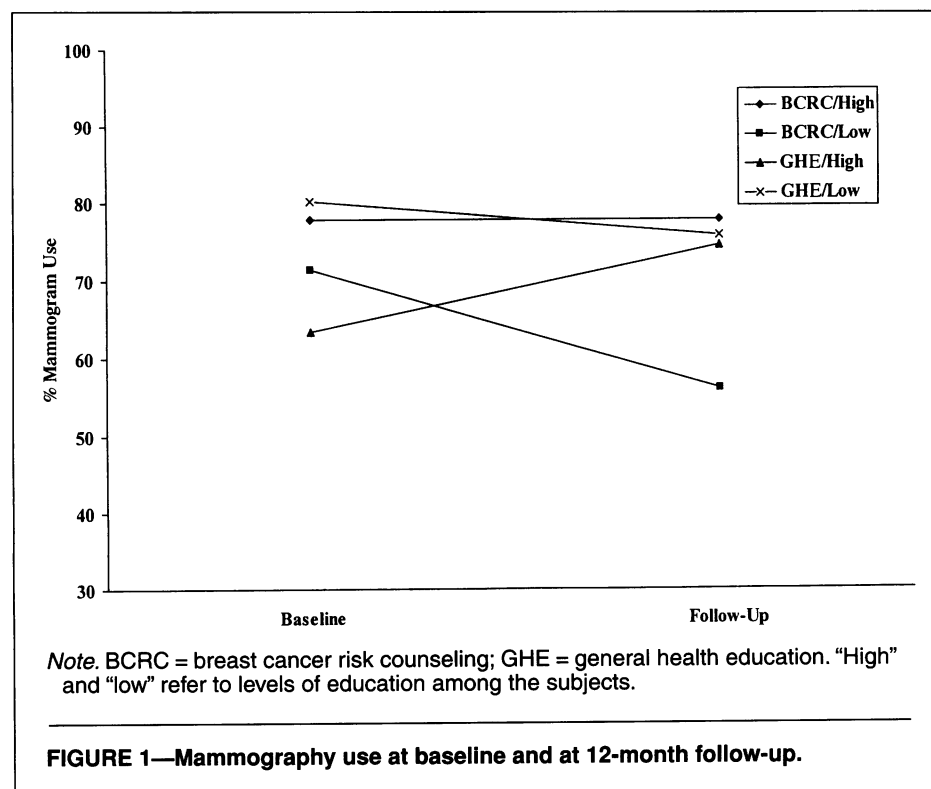
<sup>b</sup>Greater than high school education vs high school education or less.

\* $P < .05$ ; \*\* $P < .01$ .

follow-up use (BCRC = 69%, GHE = 75%;  $\chi^2 [1, n = 430] = 2.3, P > .15$ ). We chose to adjust for baseline mammography in our multivariate modeling, however, owing to its relationship with follow-up mammography use. To determine the impact of breast cancer risk counseling on mammography after controlling for potential confounders, we conducted a logistic regression analysis with hierarchical variable entry (see Table 1). Mammography use at the 12-month follow-up assessment served as the criterion. The final odds ratios (ORs) revealed a significant group-by-education interaction (OR = 2.49, 95% confidence interval [CI] = 1.03, 6.00) (see Figure 1).

Calculation of the group effect for each of the 2 education strata<sup>14</sup> revealed that

among less-educated participants, those receiving risk counseling showed reduced mammography use relative to the general health education group (OR = 0.44, 95% CI = 0.23, 0.83). There was no group effect among the more-educated participants (OR = 1.08, 95% CI = 0.59, 1.98). We also conducted an intent-to-treat analysis in which all dropouts were assumed not to have had a follow-up mammogram. This analysis did not differ substantively from the primary analysis (i.e., the significance level of the group-by-education interaction remained at  $P < .05$  and the level of significance for all confounders and main effects remained identical to that of the original analysis).



## Discussion

We evaluated the impact of individualized breast cancer risk counseling on self-reported mammography use among relatives of breast cancer patients. The treatment groups did not differ in mammography use at baseline or follow-up, suggesting that risk counseling did not lead to increased mammography use. This could be due to self-selection into the study; that is, the 43% of potential participants who were sufficiently motivated to participate in this trial may also have been highly motivated to obtain a mammogram.

The breast cancer risk counseling intervention did lead to *reduced* mammography use among less-educated participants. The majority of participants overestimated their breast cancer risk at baseline.<sup>9</sup> Less-educated participants might have misinterpreted the lower-than-expected risk estimates as suggesting that their breast cancer risk was not particularly high. This may have led to false reassurance and decreased motivation to obtain mammograms. The possibility of false reassurance is consistent with our finding that risk counseling led to reduced distress among less-educated participants.<sup>10</sup>

Breast cancer risk counseling using numerical risk estimates is increasingly common. The possibility that risk counseling could have an adverse impact on health behaviors may have important public health implications. Future research should evaluate alternative risk counseling strategies that can be targeted to this population. This study was limited by its use of self-report. Future research should independently validate self-reported mammography use. □

## Contributors

M. D. Schwartz led the manuscript preparation and data analysis and contributed to the research project implementation. C. Lerman, B. K. Rimer, and M. Daly contributed to the research project design and implementation and to manuscript preparation. C. Sands was primarily responsible for study management and implementation and contributed to manuscript preparation.

## Acknowledgments

This work was approved by the institutional review board at Fox Chase Cancer Center, Duke University Medical Center, and Georgetown University Medical Center. It was supported by National Cancer Institute grants RO1 CA57767 to Caryn Lerman and KO7 CA65597 to Marc Schwartz.

The authors are grateful to Agnes Masny, Susan Montgomery, Janet Seay, and Caryn Brunatti for their assistance with intervention delivery; Irene Angel for her assistance with participant interviewing; Andrew Balshem and David Main for data management; Suzanne Miller for her earlier input on study development; and Jon Kerner for his helpful comments on an earlier version of the manuscript.

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