



## Video Breast Health Kits for Older Women

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### Abbreviated Abstract

The goal of this project is to further development and clinical validation of high-impact, ethnically sensitive video breast health kits to promote self-monitored breast cancer screening practices of women over 60. Interactive African American and Caucasian kits have been completed and will be tested in a dual-site study to demonstrate the effectiveness of the product in recruiting older women to undergo mammograms, teaching proficient breast self-examination (BSE), and enhancing knowledge about breast cancer risks and early detection.

As consumers become more proactive in monitoring their own health, the increased availability of home VCRs and the demand for interactive health promotion television programming is driving the market for high-quality instructional videos. Commercialization of this product will target insurers interested in early detection to reduce the cost burden of advanced disease, as well as providers using home television instruction as a cost-effective alternative to one-on-one patient teaching. Breast health kits as innovative channels for information dissemination to high-risk populations are expected to promote health by decreasing mortality and morbidity from breast cancer.

### Primary Investigator

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### Research Team & Affiliations

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### Total Budget

\$684,712

### Research Objectives

#### AIMS

1. Clinical validation of high-impact, age- and ethnically-sensitive video breast health kits to promote self-monitored breast cancer screening of women over 60 years

### Theory/Hypothesis

- After using a home video breast health kit, will women who used the intervention score significantly higher than non-users on posttest measures of breast cancer knowledge and BSE proficiency, have significantly higher screening rates than non-users, and comply with recommended screening procedures significantly more often than non-users?
- Are there significant differences between users/non-users from two sites (Northeast and Southeast) on posttest measures of breast cancer knowledge and BSE proficiency, screening rates, or compliance with recommended screening practices?



- Are there significant differences between Black and White users/non-users on posttest measures of breast cancer knowledge and BSE proficiency, screening rates, or compliance with recommended screening practices?

Will users find component parts of the kit easy to understand, appealing, informative, useful, and appropriate?

## Experimental Design

A pretest-posttest quasi-experimental design was used. Subjects were assigned to experimental or control conditions based on VCR availability. Two 1-hour interviews were conducted by registered nurse research assistants in homes or community centers. Testing site selection was based on participant preference. At Interview #1, subjects were assessed for demographic characteristics, general health and functional abilities, and breast health and screening practices. At the end of the interview, they were pretested on knowledge about breast cancer and BSE proficiency (skills and lump detection) using a vested simulation breast model containing seven lumps.

Experimental subjects were given breast health kits to use for 2 weeks at home and instructed to view the video as many times as they wished but at least once. Control subjects were given an age-appropriate NCI/AARP pamphlet to read at home. After 2 weeks, subjects were again interviewed and posttested on the knowledge and BSE proficiency measures. At that time, data were obtained on perceived desirability and usefulness of the kits by the subjects who used them. Six to 12 months following the intervention, followup telephone calls were made to determine if subjects had received a mammogram and/or clinical breast exam and were practicing BSE.

## Final Sample Size & Study Demographics

Subjects were a volunteer sample of 439 women recruited from senior centers and elder housing projects in metropolitan Boston, MA, and Atlanta, GA. The sample was 70 percent non-White (predominantly African American) and 22 percent White (Caucasian). Mean age was 71.6 years (range 60-105 years). Most subjects lived in private homes (45%) or elder housing (24%). This was a low-income sample, with 64 percent reporting annual household income below \$10,000. The majority of subjects were high school graduates (53%), although a significant segment of the sample (24%) had completed only 7 or fewer years of formal education. The Mean Mini-Mental Status Exam (MMSE) score was 25.5/30, with a range of 13 to 30. Most women (99%) had at least one television in the home and most also had VCRs (60%), but only 44 percent had cable TV. Most women (64%) reported their general health as good to fair, with arthritis being the most common health problem (66%). Very few had a family history of breast cancer (11%). Fifty-five percent of the sample had not received a mammogram within the previous 2 years, and 20 percent had never had a mammogram. Only 43 percent of these women had had a professional breast exam within the previous year. Exposure to prior BSE education was relatively high (72%), and 54 percent reported performing BSE at least six times a year.

## Data Collection Methods

Interviews

### Outcome Measures

Knowledge about breast cancer risk and early detection

2. BSE proficiency, measured by demonstration of inspection/palpation skills and detection of lumps in a simulation model
3. Mammogram obtained within 6 to 12 months after intervention
4. Desirability, usability of the kits as evaluated by kit users. Tools used to collect this information included the following:



- The Breast Self-Examination Proficiency Rating Instrument, a criterion-referenced checklist, scored proficiency in BSE skills as participants demonstrated on customized breast models. Two separate proficiency scores were obtained. First, a 10-point BSE skill check was used to score BSE skills. The second score was number of lumps found in the vested simulation model during the skill check.
- The Medical Outcomes Short-Form (SF-36) assessed selected medical conditions, arthritis symptoms, functional impairment, and general well-being.
- The Mini-Mental Status Exam tested cognitive ability.
- The Breast Cancer Knowledge Scale, a 10-item, multiple-choice written test, assessed knowledge about breast cancer risk and early detection.

## Evaluation Methods

Pre- and post-intervention mammography use and receipt of a breast exam were compared. Experimental and control group change scores obtained through interviews were also compared using analysis of covariance analyses.

## Research Results

- The results of the knowledge test for the experimental group showed improvement on every item from pretest to posttest. Analysis of covariance for knowledge scores revealed that, after removing the influence of age, education, cognitive ability, and pretest knowledge scores, experimental subjects had significantly higher knowledge scores than those in the control group ( $F=58.3$ ,  $p>0.000$ ).
- The results indicate that the video breast health kits can successfully teach older women to become proficient self-examiners. Analysis of covariance for skill scores revealed that, after removing the influence of age, education, cognitive ability, and pretest skill scores, experimental subjects had significantly higher skill scores than those in the control group ( $F=53.6$ ,  $p>0.000$ ).
- The results also indicate that video breast health kits can successfully teach older women to become proficient at detecting existing breast lumps. Analysis of covariance for lump detection scores revealed that, after removing the influence of age, education, cognitive ability, and pretest lump detection scores, experimental subjects had significantly higher lump detection scores than those in the control group ( $F=88.5$ ,  $p>0.000$ ).
- Chi-square analysis revealed a significant difference between the groups on the mammography variable ( $X^2=5.0$ ,  $df=1$ ,  $p=0.016$ ), indicating that the video intervention had a positive effect on mammography screening rates for this sample. After accounting for differences by state and removing the influence of age, education, cognitive ability, and pretest scores, significant differences remained between users and non-users in posttest knowledge ( $F=41.9$ ,  $p>0.000$ ), skills ( $F=39.6$ ,  $p>0.000$ ), and lump detection ( $F=65.0$ ,  $p>0.000$ ). It is evident that women who use the kits in both the Northeast (MA) and the Southeast (GA) can improve their knowledge about breast cancer and their BSE skills.
- After controlling for the confounding influences of age, education, cognitive ability, and pretest scores, significant differences were noted in posttest skills but not in posttest lump detection. African American women had significantly better BSE skills than did Caucasian women ( $F=5.5$ ,  $p<0.001$ ), but the groups were similar in successful lump detection ( $F=2.2$ ,  $p>0.05$ ).

## Barriers & Solutions

A limitation of this study is that it was quasi-experimental. True randomization of subjects into experimental or control conditions was not possible because the intervention relied on a VCR to view the video. Therefore, assignment of subjects to experimental or control conditions was based on VCR availability. Consequently, generalizing findings to the population at large must be



undertaken with some reservation. It may be that the poorest and least educated of the general public do not have access to VCRs at this time, and other interventions or a modification of this intervention should be explored for this population. However, approximately 60 percent of this sample did have VCR access, a finding that was consistent with current VCR ownership statistics in the United States. Some barriers and/or problems arose during the study period and were addressed as follows:

- **HMO sample:** The original proposal included a subsample of health maintenance organization (HMO) subscribers in the design. After 6 to 8 months of negotiating with the HMO site, it was clear that the HMO would require indirect cost fees in excess of 90 percent. In our original discussions with the HMO officials during proposal development, the costs were significantly less. Therefore, the projected budget was not sufficient to absorb the excessive indirect costs. Following a discussion with our NCI Project Director, it was agreed that we would remove the HMO site to expedite the progress of the entire study. Therefore, two sites (MA and GA) were used instead of the three original sites proposed (MA, GA, and HMO).
- **IRB approval:** After the study was funded and initiated, we learned from NCI and the Office of Protection from Research Risks (OPRR) that our original plans for institutional review board (IRB) assurance from Boston College would apply to the Massachusetts subjects but not apply to the Georgia subjects because of geographic regulations. Therefore, we had to seek IRB approval from agencies in Georgia that met OPRR standards. After negotiating with potential Georgia IRBs for approximately 10 months, our study was reviewed and certified by the Georgia State University IRB and was subsequently approved by OPRR. As a result of this delay in beginning the study in Georgia, we received a 1-year, no-cost extension for the project, which was completed within 3 years of the start date.
- **Recruitment:** Original estimates were that we would enroll 600 subjects from three sites into the study. We learned early in the project period that recruitment of subjects fitting the criteria of no mammogram within the previous 18 months was difficult in the urban areas of Massachusetts and Georgia, where Centers for Disease Control and Prevention breast cancer initiatives had affected mammography screening rates. However, many women who had had a mammogram within 18 months indicated an interest in participating in the study. Following discussion with our NCI Program Director, we decided to lower the criterion to no mammogram within 12 months of enrollment, anticipating that the intervention would have a beneficial effect on mammography rescreening as well as mammography screening rates. This change significantly affected the pool of participants from which we could draw for recruitment into the study. Later in the project period, when recruitment again became difficult and enrollments were dwindling, we initiated a strategy whereby we asked women already enrolled as subjects to recruit other women into the study. Financial incentives of \$25 per enrolled subject were offered to these women. The strategy was very successful in continuing enrollment to the final figure of 439 subjects.
- **Geriatric breast model:** In Phase I, we designed a prototype of a geriatric breast model appropriate for testing BSE with older women. Problems with the usability and durability of that model (Wood & Brucker 1997) were to be addressed with the manufacturer and rectified prior to initiating the Phase II study. However, the manufacturer did not follow through on redesign and refused to rebuild the model after we had begun Phase II. Several months were spent exploring redesign with companies in Georgia and California, but neither of these companies was prepared to work with us immediately. Finally, we determined that further delay related to producing geriatric breast models would compromise the study by postponing interview scheduling. As a compromise, we purchased generic breast models that were consistent with the validity and reliability of the study outcomes because they were vested and had imbedded lumps.

## Product(s) Developed from This Research

Breast Health Over 60