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14. ABSTRACT: Even though mammography has been proven to be effective in reducing breast cancer mortality this simple screening measure is underutilized by women who are at an inordinately high risk for developing breast cancer. The effect of a reminder telephone call intervention has not been studied in this high-risk population where the need for compliance is crucial. The hypothesis for this study is that a simple reminder telephone call will significantly increase mammography frequency in high-risk women compared to a control group. Four-hundred and twenty-eight women have consented to participate in the study. Interestingly, 332 (76%) reported obtaining annual mammography for at least the past two years. Therefore, only subjects who were non-compliant by self-report (n=32) were randomized to the intervention or control group. Reminder and follow-up telephone calls have been completed on 30 (94%) of the women randomized to the study. A preliminary statistical analysis was conducted. A statistical difference (p=0.0027) was seen between the two groups. In conclusion, these findings support the hypothesis that mammography compliance in high risk women can be increased if an intervention such as a simple reminder call is implemented thereby leading to an early diagnosis and potential cure.						
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Introduction

Annual screening mammography is a simple tool that can prove to be life-saving for women who are identified to be at an inordinately high risk for developing breast cancer due to their family history or their BRCA1 or BRCA2 genetic status. The risk for developing breast cancer in this group of women can be as high as 85% by age 70. Therefore, annual mammography is recommended in these women starting at age 25. Unfortunately, the rate of annual mammography screening is suboptimal.

According to findings from Tinley, et. al. (2004) only 66-88% of women who are at high risk for developing breast cancer adhere to annual mammography. In addition, Issacs, et. al. (2002) reported that “prior to obtaining genetic counseling or testing, 50% of high risk women ages 30-39, 83% of those age 40-49, 69% of those 50-64, and 53% of those >65 reported having a mammogram in the prior year.” These recent studies further support the need for interventions to increase mammography compliance in these high risk women.

The purpose of this study is to determine if a simple reminder telephone call will increase mammography compliance in women who have been identified as being at high risk due to their family history or BRCA1/2 genetic status. This is a randomized prospective study in which recruited women were assigned to an intervention group wherein they received a reminder telephone call 1-2 months before their mammogram was due or to a control group wherein they did not receive a reminder telephone call prior to when their mammogram was due. All women received a follow-up call 1-2 months after their mammogram was due to determine if they indeed had received a mammogram.

Body

Women who are part of a HBOC family and have a first-degree relative with breast or ovarian cancer are at a high risk for developing breast cancer. Therefore, it is vital these women adhere to the recommended screening measures, inclusive of annual mammography beginning at age twenty-five. A simple reminder telephone call from a receptionist may promote increased compliance in mammography among these women.

Methods

One-thousand and fifty-eight women were identified as being eligible for the study and were therefore invited to participate in this research study. See Appendix A for Study Flowchart. Four-hundred and twenty-eight (40.5%) responded and 630 (59.5%) did not respond. Of the 428 women who responded, 332 (78%) reported that they were already compliant with annual mammography and had been for at least the past two years. Only 32 (7%) women who responded reported that they were not compliant with annual mammography. Therefore, these 32 women were randomized to either the intervention or control group. Sixty-four (15%) women declined participation in the study. Twenty-seven of these women who declined did not provide a specific reason, 15 had underwent a prophylactic bilateral mastectomy, 6 had developed breast cancer, and 6 did not have health insurance to cover the annual mammogram.

Reminder and follow-up telephone calls have been completed on the 30 women randomized to the study. Two women assigned to the control group have not responded to phone messages or letters to indicate if they had received a mammogram. A comparison analysis was conducted at this time of the results of the 30 women.

Preliminary Statistical Analysis

Of the experimental group (n=14) twelve women received their annual screening mammogram (86%) and 2 (14%) did not. Of the control group (n=16) 5 women received their annual screening mammogram (31%) and 11 women (69%) did not. See Appendix B. A Chi square value of 9.0199 and probability of $p=0.0027$ was found. Therefore, the hypothesis of this study was supported. A simple reminder telephone call can increase the compliance of annual mammography in high risk women. Additional statistical comparisons will be done on the two groups to determine if the two groups differ in annual income, education, health insurance coverage, etc. This will be reported in the final report.

Tasks as described in the approved statement of work are on target.

- Task 1: Development of Study Tracking, Months 1-2
 - a. A tracking system in Excel has been created to track all subjects who were invited to participate in the study.
 - b. All eligible subjects were identified from the Hereditary Cancer Institute database.
 - c. A separate excel spreadsheet was developed to track the randomized subjects as to their mammogram due month so that a schedule of reminder and follow-up telephone calls can be followed.
 - d. A consent form and Healthcare Insurance Portability and Accountability (HIPAA) forms were developed according to institutional and federal regulations.
 - e. An invitation letter was developed which provided a brief description of the study.
 - f. Institutional Review Board (IRB) approval was obtained for the study, consent and HIPAA form.
 - g. Training of the research assistant was conducted so that reminder and follow-up telephone calls are conducted in a consistent and accurate manner.
- Task 2: Recruitment of Eligible Subjects, Months 2-5
 - a. All eligible women were invited to participate and were mailed an invitation letter, our IRB approved consent form and HIPAA form along with the Pre-Intervention Assessment (PIA) questionnaire.
 - b. Follow-up letters were mailed to 778 individuals who did not respond to the initial invitation letter. When an adequate number of responses were received, it was noted that the majority of the women consenting to participate already reported themselves as being compliant with annual mammography for at least the past two years. Therefore, only non-compliant women were randomized to the study. Approval for this change in protocol change was obtained from the Department of Defense.
 - c. Another Excel spreadsheet was developed to enter all of the PIA information on the subjects who responded to the invitation letter.
 - d. As mentioned in 2b, only women who stated that they were not compliant with annual mammography for at least the past two years (n=32) were randomized to either the intervention or control group.
 - e. A schedule was established in Excel as to when each subject randomized to the study would receive their reminder and/or follow-up telephone calls.
- Task 3: Conduct Scheduled Reminder and Follow-Up Calls, Months 5-22
 - a. Reminder telephone calls have been conducted as scheduled. To date, 30 of the 32 women have received a reminder and/or follow-up telephone call.
 - b. Follow-up telephone calls have been conducted as scheduled for women in the intervention and control groups. Two women in the control group have not been

- reached to determine if they had received their mammogram in the schedule month. The research assistant has tried to reach them by leaving phone messages and by letter.
- c. The PI has continually monitored the research assistant and data entry for the study. Both the research assistant and data entry person have come to the PI for questions and clarification throughout the study, which were addressed and resolved.
 - d. Since a one-year no cost extension has been granted to recruit additional subjects into the study and pursue an answer from the two women mentioned in 3c this task has not been completed. However, this will be completed over the final year and results will be presented in the final report.
 - e. As described in 3d.
 - f. Annual report is written and submitted.
- Task 4: Final Analysis and Report Writing, Months 23-26:
 - a. A preliminary analysis has been conducted and the findings are described above.
 - b. An annual report has been written and submitted due to the permission of a one-year no cost extension to increase recruitment and contact the two individuals in the control group.
 - c. Manuscript preparation will begin this year.

Key Research Accomplishments

A key research finding of this study is the statistically significant result of the intervention of a simple reminder call on increasing mammography compliance in high risk women. In addition, it was surprising yet encouraging to note that 78% of high risk women reported themselves as being compliant with annual screening mammography.

Reportable Outcomes

- Poster presentation at the International Society of Nurses in Genetics Annual Conference held October 23-26, 2004 in Toronto, Canada.
- Poster presentation at the Era of Hope 2005, Department of Defense held June 8-June 11, 2005 in Philadelphia, PA.
- Through the support of this grant the PI will obtain a Masters of Science in Nursing following the Adult Clinical Nurse Specialist track with a focus in oncology in August 2006.

Conclusion

Women who are determined to be at high risk for developing breast cancer whether it be due to their family history alone or due to carrying a deleterious BRCA1 or BRCA2 genetic mutation need to adhere to annual screening mammography to detect a breast tumor at an early stage. Unfortunately, the compliance rate of annual mammography among high risk women is not ideal and can and should be improved. Interventions such as reminder telephone calls and mailed reminder postcards have been utilized to increase mammography compliance. Taplin, et al (2000) reported that women who received a reminder call were more likely to get mammograms (HR = 1.9; 95% CI = 1.6-2.4) than women who received reminder postcards. Taplin also compared the effect of a more complex motivational call compared to a simple reminder call. It was determined a simple reminder call was just as effective as a more time-consuming motivational call. This study used a simple reminder telephone call as the intervention to increase mammography compliance. This intervention was found to significantly (p=0.0027) increase mammography compliance in high risk women.

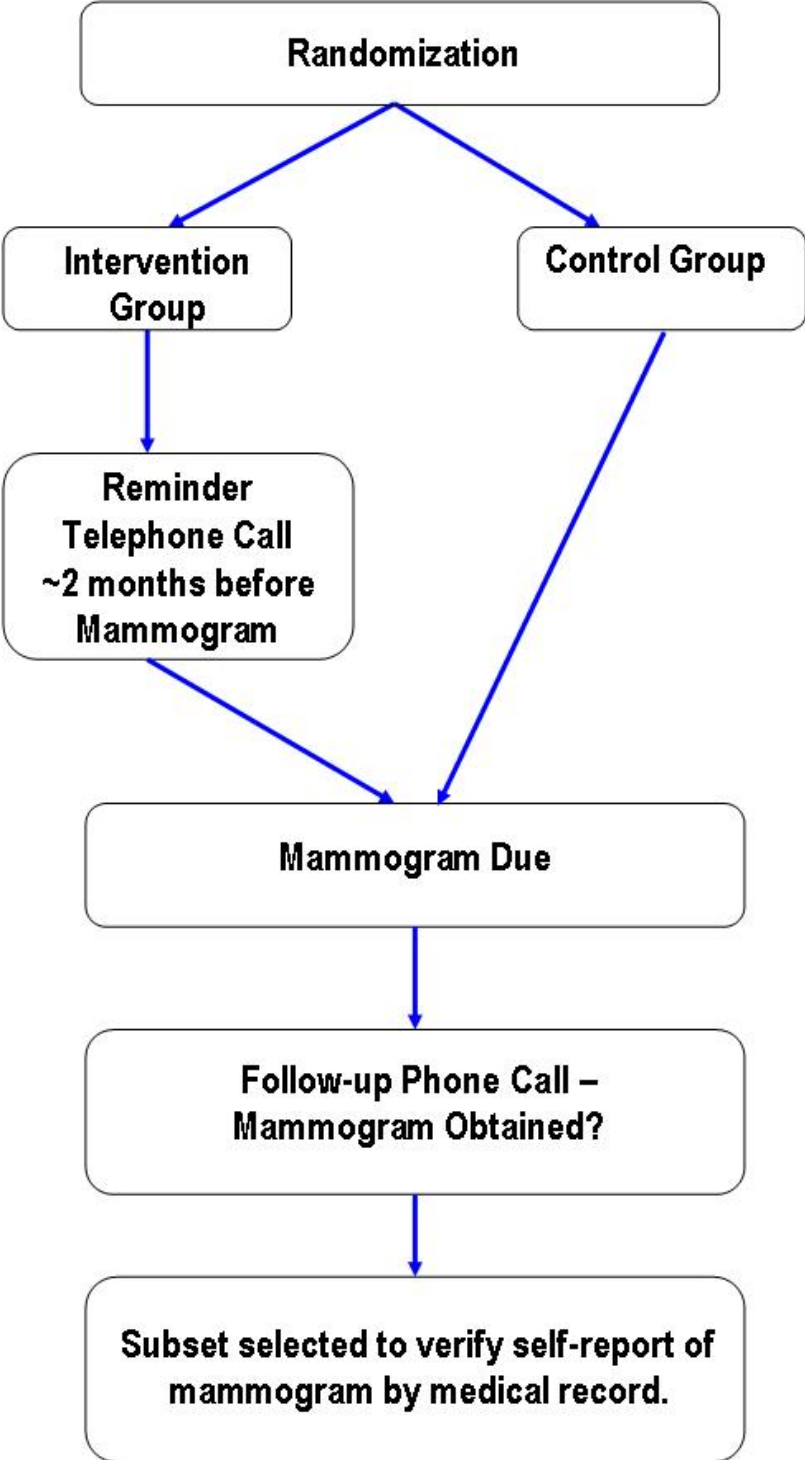
These findings are significant for advanced practice nurses who work in a breast cancer center or in cancer centers and wish to increase compliance with annual mammography. This study was purposefully designed to replicate a clinic setting wherein a receptionist could conduct the reminder telephone call to women who are due for an annual mammogram. An advanced practice nurse could develop and oversee this process and intervene with those high risk women who do not respond to the simple intervention. An advanced practice nurses' time would be better utilized by focusing on those women who need additional motivation, support or education regarding the benefits of mammography.

This study has provided the PI with extremely valuable experience and skills in conducting a randomized study. Through the guidance and mentorship of Drs. Henry Lynch and Patrice Watson the PI has gained invaluable knowledge and experience. The preliminary statistical analysis on the data provided in the study was conducted by the PI and then reviewed by Dr. Watson. Since the simple intervention of a reminder telephone was determined to significantly increase mammography compliance in high-risk women this intervention may be considered to be used in breast cancer and high risk clinics thereby increasing the number of breast cancers detected at an early stage and then hopefully cured.

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Appendix A: Study Flowchart



Appendix B: Results

