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Previous research has shown that women often lack knowledge regarding the kinds of information that are required to determine inherited risk as well as on the process and content of risk assessment/genetic testing. This lack of information leads them to feel unprepared for risk assessment/genetic testing, if they choose to seek it. The present study will evaluate an enhanced intervention's ability to increase a women's knowledge of: 1) the factors that determine genetic predisposition to breast/ovarian cancer, 2) their personal family history and other risk factors, 3) the benefits and drawbacks of genetic testing for breast/ovarian cancer, 4) the range of surveillance and preventive behaviors available, and 5) the actual process of risk assessment/genetic testing. Participants are 200 women who contact the Cancer Information Service (CIS) requesting information on inheritable breast/ovarian cancer, risk assessment and/or genetic testing. Women are randomly assigned to either the standard or enhanced intervention. A randomized study in which the two interventions are compared will test the effectiveness of the CIS in increasing women's knowledge of inheritable breast/ovarian cancer and the process of risk assessment/genetic testing.

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Introduction

Previous research has shown that women often lack knowledge regarding the kinds of information that are required to determine inherited risk as well as on the process and content of risk assessment/genetic testing. This lack of information leads them to feel unprepared for risk assessment/genetic testing, if they choose to seek it. This pilot study will develop an enhanced intervention, from material gathered during focus groups and structured interviews, to increase a woman's knowledge of: 1) the factors that determine a genetic predisposition to breast/ovarian cancer, 2) personal family history and other risk factors, 3) the benefits and drawbacks of genetic testing for breast/ovarian cancer, 4) the range of surveillance and preventive behaviors available, and 5) the actual process of risk assessment/genetic testing. The intervention will be guided by the leading "information processing" theory, the Cognitive-Social Health Information Processing Model (C-SHIP) (Miller & Diefenbach, 1998). Participants are 200 women who contact the Atlantic Region of the National Cancer Institute's (NCI) Cancer Information Service (CIS) requesting information on inherited breast/ovarian cancer as well as those women calling specifically for information about risk assessment services and genetic testing. Women are randomly assigned to either the standard intervention or the enhanced intervention. A randomized study in which the standard intervention is being compared to the enhanced intervention will test the effectiveness of the CIS in increasing a woman's knowledge of inherited breast/ovarian cancer and the process of risk assessment/genetic testing.

Body

The identification of specific genes that predispose individuals and families to certain cancers is a milestone in medical research. Understanding the genetic basis of inherited cancers may lead to new approaches to treating and even preventing disease. For those in the general population who perceive themselves to be at risk, however, the identification of these cancer causing genes is as unsettling and unnerving as it is exciting and fraught with possibilities. The identification of the BRCA 1 and BRCA 2 genes were highly publicized and created a demand for genetic information and counseling. A review of articles dating from 1994 shows a growing interest in providing risk assessment, information, education and counseling about genetic risk and testing, options for 'at risk' individuals and surveillance recommendations for non-affected persons. Although public awareness has increased, women may not have the information they need, may have inaccurate risk perceptions (Hopwood, 2000) and may overestimate their risk for inherited disease (Iglehart, Miron et al. 1998). This project is designed to identify and address the needs of women who have concerns about their risks for inherited breast/ovarian cancers. In addition, for those women who intend to pursue high risk counseling and/or genetic testing, the pilot aims to educate and prepare them for that process.

Project Implementation

The Atlantic Region Cancer Information Service (CIS) continued to recruit female callers to the *Facilitating Breast and Ovarian Cancer Genetic Counseling through Information, Preparation and Referral: A Pilot Study Using the Cancer Information Service* project

throughout the past year. Women calling the CIS who are over age 18 and who express concerns about their risks for breast or ovarian cancer and/or request information about risk assessment services or genetic testing are asked to consent to the study. Those who agree are randomized to receive a standard or enhanced intervention over the telephone. They are contacted and consented again at two weeks, two months and six months for follow-up telephone surveys.

Cancer Information Specialists gain consent and conduct the baseline interviews using the Computer Assisted Telephone Interview (CATI) system designed for the project. Those who agree to participate are automatically randomized to receive the standard or enhanced intervention. The data is stored in the CATI system that is shared by the CIS and the Psychosocial and Behavioral Medicine Program at Fox Chase Cancer Center (FCCC). Researchers from that program are then able to access participants' information for follow-up interviews.

The CIS and the Psychosocial and Behavioral Medicine Program have worked closely together with the Biostatistics Department at FCCC to assure smooth and timely implementation of the interventions, accurate retention and transmission of research data within the CATI system and extrapolation of data to the Statistical Package for the Social Sciences (SPSS). Any problems that have arisen with the database have been minor performance issues that have been readily identified and resolved. The CATI system has proven to be a dependable and easily accessible method of gathering, maintaining and collating data.

Baseline Interviews

Since the inception of the project, CIS Information Specialists have introduced the study to 375 eligible callers; 257 of whom (69%) agreed to participate. Thirty-eight (15%) women had to "break off" the initial call before the intervention was complete. Reasons for breaking off include insufficient time, call too stressful or personal, and lack of interest. Of those who agreed to participate, 219 (85%) completed the baseline interventions. Randomization has been successful, with 108 women receiving the standard intervention and 111 women receiving the enhanced intervention.

Interviews are conducted and data entered using the web-based CATI system designed for the project. Analysis of length of time per call demonstrated more time, on average, than original estimates. Those estimates were based on the time it took to go through the interviews with limited questions from the participants. Study subjects, however, have been active participants in the interviews, and the time to complete the call has increased accordingly. The Informed Consent was revised to reflect more accurately the time commitment for the initial baseline interview. Instead of the fifteen to twenty minutes previously reported, the consent now reads fifteen to thirty minutes (Appendix A).

We originally estimated that we would need to recruit 275 women during a 16-month accrual period. With an anticipated 90% participation rate and an 80% response rate to the two-month follow-up interview (figures based on previous studies conducted within

the CIS), we calculated a final sample size of 200 participants (100 per intervention group). A reassessment of those figures indicated a need to increase the number of women recruited based on a study participation rate of 69% and an overall completion rate of almost 60%. Accordingly, we requested and were granted an unfunded extension to continue recruiting women to the study so as to assure statistical validity.

Follow-up Interviews

Research staff from the Psychosocial and Behavioral Medicine Program of the Fox Chase Cancer Center conduct follow-up interviews. They use the CATI system to track outstanding interviews as well as to conduct the follow-up calls.

Participant Attrition - Rates and Reasons: To date we have recruited 257 participants, of whom 38 withdrew from the study, with lack of interest as the primary reason for withdrawal. Thus, we are able to retain over 85% of participants through the baseline interview. The likelihood of withdrawal during the baseline assessment is not related to study condition.

From the 219 women who completed baseline assessments, 155 2-week follow-ups were completed; one 2-week follow-up is in the process of being completed, we were unable to reach 52 participants after attempting calls an average of 12 times, and 11 women dropped out of the study at this point. Our retention rate for the 2-week follow-up is 71% (156 of a possible 219 have been completed). The women who could not be reached for the 2-week contact were retained in the study for subsequent assessments.

From the 208 women who were retained in the study after the 2-week follow-up, 146 2-month follow-ups were completed; 18 2-month assessments are in the process of being completed, we were unable to reach 33 participants after attempting calls an average of 14 times, and 11 women withdrew from the study at this point. Our retention rate for the 2-month follow-up is 77% (146 of a possible 190 assessments have been completed). The women who could not be reached for the 2-month contact were retained in the study for subsequent assessments.

Finally, from the 197 women retained in the study after the 2-month follow-up, 82 6-month follow-ups have been completed, with the majority of participants (77) not due for their 6-month assessment at the time of this report. Four women dropped out of the study at the 6-month assessment point and 34 women were not available for the assessment (i.e., we were unable to contact them after an average attempt of 13 calls). Our retention rate for the 6-month follow-up is about 68% (i.e., 82 of a possible 120 assessments have been completed).

Therefore, we have had a total of 60 women withdraw from the study (i.e., 26 withdrawals and 34 participants we were unable to contact) - an attrition rate of 27%. There has not been differential attrition across the study conditions. Reasons given for withdrawing from the study include: participant no longer interested, personal health reasons, believing that there was nothing to gain from participation, family health

problems, not wanting to think about cancer risk and, a disconnected phone. Overall, these data indicate that we are: 1) retaining participants in the study sufficiently to meet our recruitment goals, and 2) there is no differential attrition across study conditions.

The following table summarizes the follow-up interviews to date.

Table 1. Summary of Follow-up Interviews

Summary of Follow-up Interviews			
	2-week follow-up n=219	2-month follow-up n=208	6-month follow-up n=197
Number Pending	1	18	77
	n=218 (%)	n=190 (%)	n=120 (%)
Number Completed	155 (71%)	146 (77%)	82 (68.34%)
Number not reached (no answer) *Average number of attempts*	52 (24%) *12*	33 (17%) *14*	34 (28.33%) *13*
Number of Withdrawals	11 (5%)	11 (6%)	4 (3.33%)
Retention Rate	71%	77%	68%

Other

A clinical psychologist, Victoria Green, who was listed as the contact person in the event of any adverse event caused by the intervention (e.g., distress, anxiety, etc.), is no longer on staff at Fox Chase Cancer Center. Therefore, we have changed our adverse event reporting procedure as follows: If severe distress or other problems occur, referrals will be made to a clinical psychologist in the Psychosocial and Behavioral Medicine Program at the discretion of Dr. Suzanne Miller, to the FCCC Social Work Department, or to other resources as required

Implementation of the Study

Summary of the Implementation

At the time of submission of this report we have randomized 257 women to either the standard or enhanced treatment condition. Thirty-eight (38) women withdrew from the study after randomization; lack of interest was the primary reason for withdrawal (71% of cases). Thus, 219 baseline interviews have been completed. From this sample, 155 2-week interviews have been completed; 146 2-month interviews have been completed, and 82 6-month interviews have been completed. Our attrition rate is approximately 27%.

For this Annual Report, our analyses focused on accomplishing 4 specific aims, as outlined below. The aims for this Annual Report do not include assessing immediate or long-term differences between study conditions since we are continuing to accrue the follow-up data and considered our current sample size to be insufficient to allow for meaningful assessment of follow-up data.

Aim 1. To describe the overall sample of participants in terms of: 1) background variables (i.e., demographic variables, reason for calling the CIS, medical status, and past utilization of risk assessment services), 2) screening variables (e.g., mammography, readiness to pursue risk assessment and genetic testing), 3) knowledge concerning breast/ovarian cancer risk factor (e.g., age), 4) perceived breast/ovarian cancer risk, 5) emotional distress related to perceived breast/ovarian cancer risk, 6) overall and specific knowledge concerning breast/ovarian cancer risk assessment and genetic testing procedures, and 7) immediate responses to the intervention (i.e., satisfaction with information received, likelihood of referring others to the CIS. These analyses will allow for the preliminary assessment of the external validity of the present study.

Aim 2. To examine any and all potential differences between enhanced intervention participants and standard intervention participants in order to verify that the randomization methods have been successful in distributing any possible confounding or extraneous variables evenly across the two study conditions. Specifically, we assessed potential differences between treatment conditions in terms of the 7 types of variables listed in Aim 1.

Aim 3. To examine rates of, and reasons for, participant attrition in order to verify our ability to retain participants in the study, assess whether there is differential attrition across study conditions, and substantiate our ability to meet our recruitment goals.

Aim 4. To highlight baseline levels of knowledge concerning breast/ovarian cancer risk assessment and genetic testing, and breast/ovarian cancer etiology and prevention. This analysis was intended to offer to the Review Committee further

data from our population supporting the need for the development and refinement of an enhanced intervention that would prepare women as they pursue information and services for breast/ovarian cancer risk assessment and genetic testing.

Summary of Baseline Data

The results of our analyses to address each aim described above are delineated below in the respective sections. The Statistical Package for the Social Sciences (SPSS) was used for the statistical analyses. The specific procedures used to address the respective aim are described within the respective sections.

Overall Sample Description at Baseline: For ease of presentation and evaluation, the results are presented in tabular format (see Tables 2-8). Means and standard deviations were calculated for interval or ratio scale variables and frequency distributions were computed for nominal or ordinal scale variables. Since our data is collected through a web-based program and require technical transformation for data analysis, we present sample description for data collected 2 weeks prior to the preparation of this report. Thus, at the time of submission, our sample sizes for this report accurately reflect the funded period.

Table 2. Overall Description of the Entire Sample (N = 219).*

Grouping Variable		
Variable	**Frequency**	**Percentage**
Treatment Condition		
Enhanced	111	51%
Standard	108	49%
Background Variables		
Variable	**Frequency or Mean**	**Percentage or Standard Deviation**
Age	46.6 years	12.67 years
Education		
Some High School	11	5%
High School Grad	50	23%
Some College	59	27%
College Grad	55	25%
Post-graduate	41	19%
Race/Ethnicity		
Asian	2	1%
African American	10	5%
Hispanic	2	1%
Native American	2	1%
Caucasian	194	89%
Other	6	3%
Reason for Calling CIS		
For breast cancer risk information	166	76%
For ovarian cancer risk information	24	11%
For both breast and ovarian cancer risk information	25	11%
Cancer Diagnosis		
Yes	53	24%
No	165	75%
Past Use of Risk Assessment Services		
Yes	26	12%
No	191	87%

Table 3. Screening Variables

Screening Variables		
Variable	**Frequency**	**Percentage**
Mammography		
Once every few months	5	2%
A couple time per year	16	7%
Once a year	131	60%
Once every few years	28	13%
Almost never	8	4%
Never	27	12%
Breast Self-Exam		
More than once per week	14	6%
At least once per week	24	11%
A couple times per month	28	13%
At least once per month	87	40%
A few times per year	28	13%
At least once per year	5	2%
Almost never	16	7%
Never	13	6%
Pelvic Exam		
Yes	31	14%
No	188	86%
Trans-vaginal Ultrasound		
Yes	10	5%
No	209	95%
CA125		
Yes	14	6%
No	205	94%
Readiness to Pursue Risk Assessment/Genetic Testing		
Precontemplation	43	20%
Contemplation	105	48%
Preparation	57	26%
Action	13	6%
Preparedness to Pursue Risk Assessment/Genetic Testing		
Not at all	35	16%
Somewhat	85	39%
Quite	39	18%
Very	45	21%
Request for Referral to a Risk Assessment/Genetic Testing Program		
Yes	126	58%
No	93	42%

Table 4. Perceived Risk Factors

Perceived Risk Factors		
Variable "What things do you think contribute to your risk for breast/ovarian cancer?"	**Frequency**	**Percentage**
Age		
Yes	31	14%
Not Mentioned	188	86%
Early Menarche		
Yes	18	8%
Not Mentioned	201	92%
Late Menopause		
Yes	6	3%
Not Mentioned	213	97%
Family History/Genetics		
Yes	175	80%
Not Mentioned	44	20%
Personal History of Cancer		
Yes	37	17%
Not Mentioned	182	83%
Pregnancy		
Yes	32	15%
Not Mentioned	187	85%
Previous Breast Biopsies		
Yes	25	11%
Not Mentioned	194	89%
Lifestyle		
Yes	78	36%
Not Mentioned	141	64%
Diet		
Yes	46	21%
Not Mentioned	173	79%
Smoking		
Yes	42	18%
Not Mentioned	177	81%
Exercise		
Yes	11	5%
Not Mentioned	208	95%
Alcohol		
Yes	8	4%
Not Mentioned	211	96%

Stress		
Yes	8	4%
Not Mentioned	211	96%
Personal Health History		
Yes	20	14%
Not Mentioned	189	86%
Hormone Replacement Therapy		
Yes	16	7%
Not Mentioned	203	93%
DES		
Yes	1	.5%
Not Mentioned	218	99.5%
Abortion		
Yes	1	.5%
Not Mentioned	218	99.5%
Oral Contraceptives		
Yes	9	4%
Not Mentioned	210	96%
Environment		
Yes	24	11%
Not Mentioned	195	89%

Table 5. Perceived Breast/Ovarian Cancer Risk

Perceived Breast/Ovarian Cancer Risk		
Variable	**Frequency**	**Percentage**
Breast cancer risk vs. other women the same age		
Very low	4	2%
Somewhat low	21	10%
Average	44	20%
Somewhat high	81	37%
Very high	56	27.0%
Ovarian cancer risk vs. other women the same age		
Very low	20	9%
Somewhat low	36	16%
Average	56	26%
Somewhat high	45	21%
Very high	18	8%
Breast cancer risk vs. other women the same age with family history		
Very low	9	4%
Somewhat low	24	11%
Average	51	23%
Somewhat high	71	32%
Very high	50	22%
Ovarian cancer risk vs. other women the same age with family history		
Very low	22	10%
Somewhat low	38	17%
Average	60	27%
Somewhat high	36	16%
Very high	22	10%

Table 6. Emotional Distress Concerning Cancer Risk

Emotional Distress Concerning Cancer Risk		
Variable	**Frequency**	**Percentage**
Have thoughts about getting breast cancer		
Not at all	41	19%
Sometimes	72	33%
Often	55	25%
A lot	48	22%
Have thoughts about getting ovarian cancer		
Not at all	133	61%
Sometimes	41	19%
Often	19	9%
A lot	18	8%
Thoughts about breast cancer risk affect mood		
Not at all	109	50%
Sometimes	60	27%
Often	25	11%
A lot	22	10%
Thoughts about ovarian cancer risk affect mood		
Not at all	159	73%
Sometimes	38	17%
Often	13	6%
A lot	6	3%
Thoughts about breast cancer risk affect daily activities		
Not at all	171	78%
Sometimes	34	16%
Often	6	3%
A lot	6	3%
Thoughts about ovarian cancer risk affect daily activities		
Not at all	194	89%
Sometimes	17	8%
Often	5	2%
A lot	1	.5%

Table 7. Knowledge Variables

Knowledge Variables		
Variable	**Frequency or Mean**	**Percentage or Standard Deviation**
Rating of overall knowledge about risks and assessment		
Not at all knowledgeable	23	11%
Not very knowledgeable	63	29%
Somewhat knowledgeable	109	50%
Very knowledgeable	21	10%
Many women who do not have any of the known risk factors still get breast cancer		
Correct	207	94%
Incorrect	21	6%
Over a lifetime, 1 out of 8 women will develop breast cancer		
Correct	198	86%
Incorrect	21	10%
Women who are over 50 years of age are more likely to get breast cancer than are younger women		
Correct	161	74%
Incorrect	58	26%
A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer		
Correct	145	66%
Incorrect	74	34%
Early detection means a greater chance of surviving breast cancer		
Correct	219	100%
Incorrect	0	0%
Women over age 40 should have mammograms at least every two years		
Correct	167	76%
Incorrect	52	24%
A woman whose mother was diagnosed with breast cancer at age 69 is considered to be at high familial risk for breast cancer		
Correct	61	28%
Incorrect	158	72%
A woman can inherit breast cancer gene mutations from her father		
Correct	123	56%
Incorrect	96	44%

Most women who develop breast cancer do not have a family history of the disease		
Correct	131	60%
Incorrect	88	40%
Ovarian cancer and breast cancer in the same family can be a sign of hereditary breast cancer		
Correct	187	85%
Incorrect	32	15%
Testing for breast cancer gene mutations can tell a woman if she has breast cancer		
Correct	130	59%
Incorrect	89	41%
Men cannot inherit breast cancer gene mutations		
Correct	187	85%
Incorrect	32	15%
If there are other types of cancer in my family, I may have a higher than average risk of developing breast or ovarian cancer		
Correct	156	71%
Incorrect	63	29%
The process of risk assessment and genetic testing is simple, involving only a physical exam and blood test		
Correct	44	20%
Incorrect	175	80%
One of the advantages of risk assessment and genetic testing is that, finding out your risk, can help you make decisions about pursuing risk reduction options, such as surgery and medications		
Correct	208	95%
Incorrect	11	5%
There are no real disadvantages to pursuing risk assessment and genetic testing		
Correct	124	57%
Incorrect	95	43%
A woman who develops breast cancer at an early age is more likely to have inherited breast cancer		
Correct	119	54%
Incorrect	100	46%
Knowledge Total Score (Out of 17)	9.73	1.8

Table 8. Responses to the CIS

Responses to the CIS		
Variable	**Frequency**	**Percentage**
Level of satisfaction with information received		
Not at all	0	0%
A little	5	2%
Moderately	13	6%
Quite a bit	60	27%
Very much	135	62%
Degree to which they will recommend the CIS to others		
Definitely no	0	0%
Probably not	0	0%
Maybe	7	3%
Probably yes	183	84%
Definitely yes	23	11%

Note. * indicates that frequencies do not always total 219, since participants may have omitted answering particular questions.

Differences Between Study Conditions: In order to assess for the presence of any potential extraneous or confounding variable, we examined differences between the study conditions in terms of baseline measures described in Aim 1. For ordinal, interval, or ratio data (e.g., age, rate of mammography, perceived risk, emotional distress, level of satisfaction) the ANOVA procedure was used, with the two intervention groups serving as the levels of the independent variable. For nominal data (e.g., ethnicity, perceived risk factors, knowledge items), the chi-square test of association procedure was utilized.

With regard to all background variables (i.e., demographic variables, reason for calling, cancer history, past use of risk assessment services), there were no significant differences between the study conditions (i.e., all p's $> .05$). Likewise, there were no significant differences between study conditions with regard to baseline measures of: 1) breast and ovarian cancer screening, readiness to pursue risk assessment and genetic testing, and degree to which participants felt prepared to pursue risk assessment and genetic testing; 2) level of endorsement of the CIS (i.e., satisfied with information received, recommend CIS to others), 3) degree of perceived risk of developing breast or ovarian cancer, 4) level of emotional distress concerning developing breast or ovarian cancer, and 5) participant's total level of knowledge about breast and ovarian cancer and about risk assessment procedures (i.e., all p's $> .05$). Likewise, there were no significant differences between enhanced and control participants with regard to the endorsement of specific breast and ovarian cancer risk factors (i.e., all p's $> .05$). Finally, baseline levels of correct responses to the true or false assessment of knowledge about breast and ovarian cancer risk assessment and genetic testing and etiology were contrasted across the two study conditions. No significant differences were detected.

We did, however, find that the likelihood that participants would request a referral for genetic testing and risk assessment was related to the treatment condition ($\square^2$ [1] = 12.15, $p < .01$). In particular, a greater proportion of women in the standard condition requested a referral (75%), compared to the enhanced intervention (47%). This difference may reflect the enhanced interventions ability to improve the accuracy of risk perception and educate women, thereby discouraging women with low objective risk from pursuing formal risk counseling. Subsequent analyses where objective risk is considered may indeed reveal that the reduction in the referral requests among the enhanced condition participants is a reflection of the enhanced interventions ability to enhance the accuracy of women's risk perceptions. These analyses will be conducted when the follow-up data is complete.

Levels of Knowledge About Risk Assessment Procedures and Breast/Ovarian Cancer Etiology and Prevention: As a rationale for implementing this study, we highlight findings that indicate that women interested in pursuing breast/ovarian cancer risk assessment and genetic testing are unprepared and lack important knowledge about this issue to make informed decisions. We present this analysis in order to provide additional evidence-based support for the overall rationale supporting the initiation of this study.

Indeed, as shown in Table 3, about 54% of women indicated that they are inadequately prepared to purse risk assessment and genetic testing. In addition, women were found to be lacking important information that would enable them to make informed decisions about pursuing risk assessment and genetic testing. When women were asked to rate their degree of knowledge concerning breast and ovarian cancer risks and the process of risk assessment and genetic testing, close to 40% of them indicated that they have inadequate knowledge. Further, on the 17-item knowledge survey, the average of correct responses was 9.73 (SD = 1.8). Examination of the specific questions revealed that a high proportion of the sample (at least 40% of women) were responding incorrectly to questions concerning: 1) the relationship between age at diagnosis of cancer and risk for inherited breast or ovarian cancer; 2) the potential for fathers to pass along genetic mutations linked to breast and ovarian cancer risk; 3) the link between ovarian and breast cancer risk; 4) the complexity of risk assessment and genetic testing procedures; and 5) the possible disadvantages of risk assessment and genetic testing. Each of these areas of knowledge is targeted by the enhanced intervention. Thus, we expect to see improved knowledge among enhanced participants at follow-up assessments, compared to participants receiving the standard intervention.

Key Research Accomplishments

- 219 women recruited to the study who have completed baseline interviews
- 155 completed 2-week follow-up interviews
- 146 completed 2-month interviews
- 82 completed 6-month interviews
- 70 completed interviews at all time points
- Participant retention in the study is sufficient to meet our recruitment goals
- There is no differential attrition across study conditions.
- Randomization has been successful with no significant differences between the two groups
- Baseline data confirm the rationale and need for studies such as this, particularly in the areas of:
  - Helping women feel more prepared to pursue risk assessment and genetic testing
  - Providing information to assist in decision-making
  - Raising awareness of the role of heredity in breast and ovarian cancers
  - Educating women about risk factors other than family history
  - Clarifying the process and complexity of formal risk assessment
  - Conveying an understanding of the advantages and disadvantages to risk assessment and genetic testing
  - Informing women of the link between inherited breast and ovarian cancers
  - Explaining the potential to inherit breast and ovarian cancer gene mutations from one's father
- Participants are very satisfied with the information provided by the Cancer Information Service

Reportable Outcomes

Manuscripts

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Abstracts & Presentations

2001 Annual Retreat for Cancer Research: April 25, 2001. Princeton, NJ

WOMEN'S SELF-REPORTED KNOWLEDGE ABOUT CANCER RISKS, RISK ASSESSMENT AND GENETIC TESTING: PRELIMINARY FINDINGS* - *Linda Fleisher, M.P.H., Nancy McKeown-Conn, M.BE. Atlantic Region CIS and Suzanne Miller, Ph.D., Robert Schnoll, Ph.D., Lisa Brower, B.A., Fox Chase Cancer Center (*Supported by the US Army Medical Research & Materiel Command DAMD 17-98-1-8306)*

American Society of Preventive Oncology (ASPO): *25th Annual Meeting:* March 11-13, 2001. New York, New York.

WOMEN'S SELF-REPORTED KNOWLEDGE ABOUT CANCER RISKS, RISK ASSESSMENT AND GENETIC TESTING: PRELIMINARY FINDINGS* - *Linda Fleisher, M.P.H., Nancy McKeown-Conn, M.BE. Atlantic Region CIS and Suzanne Miller, Ph.D., Robert Schnoll, Ph.D., Lisa Brower, B.A., Fox Chase Cancer Center (*Supported by the US Army Medical Research & Materiel Command DAMD 17-98-1-8306)*

Era of Hope: Department of Defense Breast Cancer Research Meeting: June 8-11, 2000. Atlanta, Georgia.

DEVELOPMENT OF AN INTERVENTION TO INCREASE WOMEN'S KNOWLEDGE OF CANCER RISK & RISK PROGRAMS - Linda Fleisher, M.P.H., Suzanne M. Miller, Ph.D., Robert Schnoll, Ph.D, Nancy McKeown-Conn, B.A., Lisa Brower, B.A, Fox Chase Cancer Center, Atlantic Region Cancer Information Service

Fox Chase Cancer Center: National Cancer Institute Core Grant Site Visit: Overview of Population Science Facilities, October, 2000.

DEMONSTRATION OF CATI SYSTEM* - Elyse Slater, Susan Raysor, Fox Chase Cancer Center *(*Supported by the US Army Medical Research & Materiel Command DAMD 17-98-1-8306)*

Fox Chase Cancer Center: Information Technology Information Exchange Seminar, February 1, 2001.

CREATING A WEB-BASED, COMPUTER ASSISTED TELEPHONE INTERVIEW SYSTEM* - Elyse Slater, Susan Raysor, Fox Chase Cancer Center

*(*Supported by the US Army Medical Research & Materiel Command DAMD 17-98-1-8306)*

Pennsylvania Public Health Association (PPHA): *Public Health Challenges 2010.* Oct. 4-6, 2000. Harrisburg, PA

DEVELOPMENT OF AN INTERVENTION TO INCREASE WOMEN'S KNOWLEDGE OF CANCER RISK & RISK PROGRAMS* - *Nancy McKeown-Conn, M.BE., Fox Chase Cancer Center (*Supported by the US Army Medical Research & Materiel Command DAMD 17-98-1-8306)*

Funding applied for based on work supported by this grant.

- **American Cancer Society**, Pilot Study to Access the Feasibility of a Cognitive-Behavioral Smoking Cessation and Relapse Prevention Intervention for Pregnant, Low-income Minority Women
- **Department of Defense**, Behavioral Center of Excellence, Project 1, Understanding Breast Cancer Risk Assessment and Screening among the Underserved
- **Department of Defense**, Behavioral Center of Excellence, Communications Core
- **National Cancer Institute,** Pilot Projects To Overcome The Digital Divide (PRODD) – Communities Addressing the Digital Divide
- **National Cancer Institute,** R21, Communities Addressing the Digital Divide
- **National Cancer Institute,** Specialized Program of Research Excellence (**SPORE**) in Ovarian Cancer

Conclusions

Preliminary data corroborate current literature suggesting that women lack knowledge about and are unprepared for the process of cancer risk assessment and genetic testing. In addition, the data supports the rationale and need for this study and others like it. The majority of women (54%) who have agreed to participate in this pilot have indicated that they would not feel adequately prepared to pursue risk assessment services. In addition, women were found to be lacking important information that would enable them to make informed decisions about pursuing risk assessment and genetic testing. When women were asked to rate their degree of knowledge concerning breast and ovarian cancer risks and the process of risk assessment and genetic testing, close to 40% of them indicated that they have inadequate knowledge. This self-reported lack of knowledge is substantiated by a large proportion of incorrect responses to questions about age as a risk factor, inheriting breast cancer gene mutations from one's father, and the links between breast and ovarian cancers, among others. We expect to see an increase in knowledge and a greater sense of preparedness among those in the enhanced group at follow-up. Nevertheless, baseline data confirm the need for more and better information about breast/ovarian cancer risks, risk assessment and genetic testing.

When this project was first conceived in the mid-1990s, information about genetics and cancer, particularly genetic predisposition to cancer, was novel and callers flooded the CIS with questions about risk, risk assessment and genetic testing. Since that time, calls to the service on this topic have leveled off with fewer women calling specifically about risk assessment services. Nonetheless, interest in cancer risk and prevention are still frequent enough to allow us to recruit sufficient numbers for this study, although not at the rate originally projected. Those who are recruited to the study, however, are overwhelmingly satisfied with the information they receive, demonstrating the ability of the CIS to provide this kind of information in a way that is acceptable and agreeable to the caller. Further analysis will determine the feasibility of using the CIS as a conduit for giving women the information they need to make decisions and to prepare them to pursue risk assessment, but for now, we know that they are at least satisfied with the information they have received.

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Appendices

Revised consent

New Informed Consent

Thank you for calling today. The Cancer Information Service can provide you with information and free materials about understanding your risk for inherited cancer. I can share information over the phone, as well as send you materials that you might find helpful. You may also be interested in participating in a special research study we are conducting. We are working to improve our services and to tailor our information to women calling with concerns about inherited breast/ovarian cancer. To do so, we are currently evaluating two different approaches to providing information about inherited risk, genetic testing and risk assessment. Participation in this study is completely voluntary and all your answers will be confidential. Only the researchers will have access to the information you provide, which will be stored in a secure computer file. We will certainly provide appropriate information and materials should you decide not to participate. Participation would require two things on your part: First, you would agree to be randomly chosen for one of two educational programs. Second, you would need to agree to participate in a telephone interview that would help us to compare the effectiveness of these two programs and get your reactions to the material. Questions would be answered over the phone today, and then at three time points in the future—two weeks, two months and then six months from now. Today's interview will take anywhere from fifteen to thirty minutes depending on any questions you might have. Subsequent interviews should take no more than fifteen minutes. You may refuse to answer any questions and can withdraw at any time. There is little risk involved in answering these questions and what we learn from your responses will help our service improve the way we deliver information about inherited cancer risk, risk assessment and genetic testing services. Would you be willing to participate in this evaluation?

☐ (1) **YES**, agree
☐ (2) **NO**, do not agree— **Complete CIS Electronic Call Record Form, demographic information and then go to standard counseling**

Before we get started with the information that you are requesting, we need to get your name, address and telephone number so we can send you materials and call you in a few weeks. Please be assured that all information provided by you will be kept strictly confidential.

Contact Information

First name _____

Last name _____

Address_____

City _____ State _____ Zip Code _____

Country _____

Phone Number ( ) _____ - _____

When is the best time to reach you?

☐ Morning ☐ Afternoon ☐ Early Evening

Is there another number where we can reach you?

(_____) _____ - _____

☐ Relative ☐ Work ☐ Other

Randomization: Use last number of phone number to randomize

☐ Standard Counseling (Odd Numbers: 1,3,5,7,9)

☐ Enhanced Counseling (Even Numbers: 0,2,4,6,8)