

AD _____

Award Number: DAMD17-94-J-4333

TITLE: Psycho Educational Group Intervention for Women at
Increased Risk for Breast Cancer

PRINCIPAL INVESTIGATOR: Kathryn M. Kash, Ph.D.

CONTRACTING ORGANIZATION: Strang Cancer Prevention Center
New York, New York 10021

REPORT DATE: October 1998

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE			Form Approved OMB No. 074-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503				
1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE October 1998		3. REPORT TYPE AND DATES COVERED Annual (30 Sep 97 -29 Sep 98)
4. TITLE AND SUBTITLE Psycho Educational Group Intervention for Women at Increased Risk for Breast Cancer			5. FUNDING NUMBERS DAMD17-94-J-4333	
6. AUTHOR(S) Kathryn M. Kash, Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Strang Cancer Prevention Center New York, New York 10021 E-MAIL: kmkash@earthlink.net			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited			12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 Words) The goals of this study are to: 1) examine the impact of a psychoeducational intervention on the intermediate outcome variables of knowledge of breast cancer and risk factors, breast cancer beliefs, cancer attitudes, and coping skills in women at increased risk for breast cancer; 2) examine the impact of a psychoeducational intervention on the endpoint variables of quality of life and adherence to screening in women at increased risk for breast cancer; and 3) explore the mechanisms by which the psychological intervention may improve quality of life and increase adherence to breast cancer screening in women at increased risk for breast cancer. The design is a randomized two-group design in which women are assigned to either the experimental or control arm. The intervention (experimental) components include; social support enhancement, education, cognitive restructuring, and problem solving. As of November 1998, 409 women have agreed to participate in the study and 212 have completed Time 1 assessments, 130 have completed Time 2 assessments; 106 women have completed Time 3 assessments, and 86 women have completed Time 4 assessments. Preliminary data indicates that knowledge of breast cancer is increased ($p<.001$), knowledge of risk factors is increased ($p<.001$), overestimation of risk is decreased ($p<.02$), and breast cancer specific anxiety is decreased ($p<.01$) in the women in the experimental arm.				
14. SUBJECT TERMS Breast Cancer Genetic Risk Behavioral Intervention Anxiety Psychological Distress Screening Adherence			15. NUMBER OF PAGES 27	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT	

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

N/A Where copyrighted material is quoted, permission has been obtained to use such material.

N/A Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

N/A Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

N/A In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

NA KMK For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

N/A In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

N/A In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

N/A In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Kathryn M. Kask, Ph.D. 29 July 1999
PI - Signature Date

TABLE OF CONTENTS

	Page
I. Front Cover	1
II. SF 298 Report Documentation Page	2
III. Foreword	3
IV. Table of Contents	4
V. Introduction	
a. Nature of problem	5
b. Background of previous work	5
c. Purpose of present work	6
d. Methods of approach	7
VI. Progress Report	
a. Experimental methods used	7
b. Work to date as related to goals	8
VII. Conclusions	14
VIII. References	15
IX. Appendix	
A. Statement of Work from grant proposal	16
B. Tables 1, 2, 3, 4, 5, & 6	18
C. Figures 1 & 2	25

V. INTRODUCTION

a. Nature of the problem.

With the increased media attention focused on the importance of the early detection of breast cancer, more women were beginning to recognize the need for breast cancer screening and to look for places (programs, clinics, doctors) where they could obtain quality breast care. As women learn about their family history of breast cancer, they begin to speculate about their own risk. In addition, many women have heard that there are gene mutations on the BRCA1 and BRCA2 genes that may be responsible for a small portion of breast cancer cases that was cloned last year. Already these women are requesting genetic testing as soon as it is available on a clinical level. We need to think about the psychological consequences for these women, as well as the ethical implications. Without adequate information, many women overestimate their risk and become quite fearful that they too could develop breast cancer. Our previous study identified anxiety as predictive of poor adherence to both clinical breast examinations and breast self-examination, as well as delay in having a mammogram (Kash et al, 1992). Thus adherence to breast cancer screening poses a major problem for women at increased risk who need timely screening. The emotional distress may also diminish a woman's quality of life, if the fear of developing breast cancer interferes with goal directed behaviors and problem solving activities. This information compelled us to intercede with women at increased risk for breast cancer and develop an intervention that could help to improve quality of life and increase adherence to breast cancer screening. Since women at increased risk increasingly identify themselves and look for programs where they can not only find out appropriate surveillance guidelines but share their feelings and concerns with others, the efficacy of a group intervention needed to be tested in a controlled trial. This study was designed to examine the role of such an intervention in improving quality of life and increasing adherence to screening behaviors (mammogram, breast self-examination, clinical breast examination). Our previous work, described below, piloted this intervention and found it to be extremely helpful to women in decreasing risk perception and increasing adherence to screening.

b. Background of previous work

Prior to the grant proposal, we conducted preliminary work on piloting a group psychoeducational intervention. There were three important components to this six week, structured intervention. The first was educating women: a) providing their objective risk status by giving them their own family tree (pedigree), b) clarifying information about breast cancer and risk factors for breast cancer; c) providing information on ways to take control of their lifestyle by changing their eating patterns; d) instructions on breast self-examination using both active and passive methods; and e) reinforcing the importance of adherence to screening guidelines. The second component revolved around cognitive restructuring, which helps to facilitate problem-solving. That is, we encouraged women to use active coping rather than avoidance or denial in dealing with their risk status. In addition, changing cognitions can help to alleviate anxiety and the sense of helplessness. The last component was that of emotional support which helped: a) to decrease the sense of isolation; b) to encourage sharing feelings and thoughts with others; and c) to provide reassurance by and rapport with other women.

In the pilot group ten women were randomly chosen from a group of 100 who responded affirmatively to participating in a group. These ten women completed baseline and six-week assessments. Perceived susceptibility for developing breast cancer significantly decreased ($p < .02$) on paired t-tests during the six weeks and approximated their actual risk, based on risk analysis tables. All of the women reported that their knowledge of breast cancer increased and

misconceptions were clarified. Anxiety and fears about developing breast cancer and its consequences were diminished in 90% of these women. Thirty percent who had never performed BSE began to do so and expressed their intent to perform it monthly. Women felt that the emotional support provided by the group was extremely important, as well as the opportunity to exchange feelings and information with women facing the same problems who coped with them daily, using a range of strategies. At a two month follow-up session, all women reported performing monthly BSE. At six months, one year, two years, and three years, there was 90% adherence to mammogram schedule and CBE; 100% were performing BSE monthly. Seventy-five percent of women also reported using the information from the dietician to reduce their fat intake (Kash, 1991).

Using the information from the above mentioned pilot group, we refined our intervention and developed a structured format for the group leader and session leaders to follow. We collected baseline data via a telephone questionnaire on 20 women and randomized them to either the intervention or control group. Analyses of variances on baseline data revealed no significant differences between the groups on any of the demographic, independent, or outcome variables. Within this model our goals were; to provide women with accurate and clear information on actual risk status, breast cancer, risk factors, methods of risk reduction (e.g., low fat diet), appropriate surveillance procedures; and help women learn how to actively cope with their risk. The group then met for six consecutive weeks. The structure and content of these sessions was similar to that of the pilot group and is described in the manual below.

At the end of the six week group intervention telephone assessments were conducted by a trained interviewer. The interviewer was blind as to which group the woman belonged. Within the intervention group there was a significant increase in knowledge ($p < .05$), a significant decrease in perceived risk or susceptibility ($p < .015$), and a significant decrease in perceived barriers to screening ($p < .05$) between baseline and six weeks (the end of the group). Analyses of variances at Time 2 revealed several changes between the groups: 1) a significant increase ($p < .005$) on knowledge of breast cancer in the experimental group; 2) a significant decrease ($p < .02$) on perceived barriers in the experimental group; and 3) a significant increase ($p < .03$) on knowledge of the risk factors for breast cancer in the experimental group. For example, at Time 2 there were still women in the control group (30%) who thought that being "hit in the breast" increased your chances of developing breast cancer. There were also significant differences between the two groups on perception of risk ($p < .001$) with only the experimental group accurately reporting their risk status. There were no differences between the groups on tension or depression at the end of six weeks. Our preliminary data was reported earlier this year (Kash et al, 1995).

c. Purpose of the present work

The purpose of this study is to address quality of life and adherence to screening issues associated with being at increased risk for breast cancer. The specific aims are: 1) to examine the impact of a psychoeducational intervention on the intermediate outcome variables of knowledge of breast cancer and risk factors, breast cancer beliefs, cancer attitudes, and coping skills in women at increased risk for breast cancer; 2) to examine the impact of a psychoeducational intervention on the endpoint variables of quality of life and adherence to screening in women at increased risk for breast cancer; and 3) to explore the mechanisms by which the psychological intervention may improve quality of life and increase adherence to breast cancer screening in women at increased risk for breast cancer.

d. Methods of approach

The research design uses a randomized controlled trial to test the psychoeducational group intervention. The intervention components (as identified above) include; social support enhancement, education, cognitive restructuring, and problem-solving. A total sample size of 360 is sufficient to allow hypotheses testing. Data will be collected at four points in time; baseline, six weeks, six months, and one year. The variables to be examined are: demographic; risk status; selection method; stressful life events; knowledge of breast cancer and risk factors; breast cancer beliefs; cancer attitudes; coping strategies; quality of life (psychological distress, role, work and family functioning, life satisfaction, satisfaction with health care, and participant goal-directed behaviors); and adherence to CBE, mammogram, and BSE. Preliminary analyses include descriptive statistics, correlational, and principal components analysis. Multivariate analysis of variance with repeated measures and appropriate covariates will be used to test the hypotheses.

VI. PROGRESS REPORT

We applied for and have been granted a one year no-cost extension from November 1998 to October 1999. Thus, this is not the final report but an annual progress report.

A. Experimental methods used

The medical and family histories for all women enrolled in the Strang Breast Surveillance Program are reviewed by Dr. Kash (PI) for eligibility to participate in the study. Women are classified as being at low (13 to 19%), moderate (20 to 34%), or high (35 to 50%) risk based on their family histories of breast and/or ovarian cancer (Claus et al, 1991). Examples of low risk are having a mother who developed breast cancer at the age of 40 or a mother who developed breast cancer at age 52 and a maternal grandmother who developed breast cancer at age 60. An example of moderate risk is having a mother, maternal grandmother, and a maternal aunt, all who developed breast cancer in their 50's. Some examples of high risk are: 1) having a mother, maternal grandmother, and three maternal aunts who developed breast cancer in their 40's or 50's; 2) having a mother who developed bilateral breast cancer in her 50's, a father with breast cancer at age 60, a paternal aunt with breast cancer at age 50, and a sister with breast cancer at age 38; or 3) having a mother who developed breast cancer in her 40's, a maternal grandmother who had ovarian cancer in her 50's, and a maternal cousin with bilateral breast cancer in her 40's.

Names of eligible women are randomly selected. Those women selected were sent a letter explaining the purpose and requirements of the study. Each woman who does not respond within a two week period was contacted by telephone by the research assistant and told of the study project and exactly what is being asked of them. It was explained to each woman that after baseline data was obtained they would be randomized to either the experimental (standard care plus an intervention group) or the control (standard care) condition. If the participant agreed, an informed consent was obtained from her prior to the beginning of the study. Part of the informed consent process was to obtain permission from the participants to audio tape record each session and video tape some sessions in order to conduct quality checks and make sure that the outline was adhered to for each session. Baseline data was obtained prior to randomization to either the experimental or control condition. The research assistant remained blind as to which group each woman belonged so as not to influence the interview process.

Prior to the beginning of each intervention group, twenty women were randomly selected from the pool of available participants. The assessment instrument was mailed to these twenty participants and a time set for the baseline assessment telephone interview (T1). After the baseline assessment women were randomized to either the experimental and control condition. When the six session intervention group ended (T2), the assessment instrument was mailed to all participants and a

telephone time set for the post-intervention interviews. A stamped, self-addressed envelope was mailed to the participant with the assessment instrument. Once the telephone interview was finished, the participant mailed the interview back so we could have a hard copy of the data.

Several measures were chosen to assess cognitive, psychological, and behavioral variables. The majority of these measures consist of structured questions and require about 30 minutes to complete. One of the Quality of Life measures, the Patient-Centered Methods, is semi-structured and takes about 20 minutes during the telephone interview, which is done after recording the responses to the structured measures. These measures are assessed at four points in time: T1 – baseline (prior to randomization); T2 – within one week after the six week intervention has ended; T3 – six months after the beginning of the intervention; and T4 – one year after the beginning of the intervention. The measures are listed below.

Measures used

Mammogram adherence
 Clinical breast examination (CBE)
 Breast self-examination (BSE)
 Revised Rand General Well-Being Scale
 Social Adjustment Scale-Self Report
 Patient Satisfaction Subscales
 Life Satisfaction Index
 Patient-Centered Methods
 Knowledge about Breast Cancer and Breast Cancer Screening
 Breast Cancer Beliefs
 Cancer Attitude Scales (Anxiety, Hopelessness, and Adjustment)
 Coping Strategies
 Sociodemographic information
 Stressful Life Events
 Risk status

B. Work to date as related to goals

1. There have been two major reasons why the progress of this study has not proceeded as planned. One is programmatic issues and the other is staff changes. Some of these reasons were stated in the last report but will be restated here and the new issues added. Because of the earlier issues we halted recruitment to the study for six months (January through June 1997) in order to deal with the problems and improve our recruitment and retention rates. Listed below is what the problems were and what has been done to correct them. Below, in B2, is the work to date as it relates to the Statement of Work. While it is clear that this project is moving forward, recruitment is slower than anticipated as related to the decreasing number of women in the program.

a) Programmatic Issues. We began recruiting for the third wave in October 1996. However, two major changes were made to the surveillance program (Strang Breast Surveillance Program) which is the source of women for this study. For the past ten years the Strang Cancer Prevention Center has provided mammograms (at an outside radiology service) to women in the program at no fee. Insurance assignment was accepted as payment. If women did not have any insurance, the mammogram was provided at no charge and the cost was absorbed by Strang. In January 1997 the administration of Strang withdrew funding for mammograms for women in the surveillance program. While women in this study were exempt from this fee change, approximately 100

women withdrew from the program before we had the opportunity to recruit them. The women who withdrew from the program in order to receive their care elsewhere did so because their insurance company did not cover a mammogram at the radiology associates used by Strang or they were able to obtain a mammogram at a significantly lower price (approximately \$125 while it is \$200 at the radiology associates Strang uses) at a different facility. In addition, the nurse practitioner who was conducting many of the clinical breast examinations resigned and was not replaced. While we still had two examiners (an internist and a breast surgeon), we lost an additional 50 to 100 women who followed the nurse practitioner to her new office.

In January of 1998 the administration of Strang withdrew funding for clinical breast examinations for women in the surveillance program. While women in this study were exempt from this fee change, approximately 200 women withdrew from the program before we had the opportunity to recruit them. These women decided to have their clinical breast examination performed elsewhere, along with their mammograms. Most often women reported that they intended to have their clinical breast examination done as part of their annual gynecological examination. While the current recommendation for women with strong family histories is to have a clinical breast examination every six months, women are choosing to have an annual breast examination. The main issue with these women is that a clinical breast examination as a preventive measure is not covered by their health insurance, while a clinical breast examination as part of their annual gynecological examination is covered or reimbursable by insurance companies. Some women who are in this study stated that they would rather go to a mammogram facility that is covered by their insurance.

b) **Staff Changes.** We have experienced two major staff changes that impacted adversely on this study during the past year. Initially in January 1996 another research assistant was hired in order to focus on recruitment and retention. The research assistant was paid with funds from Strang, not from the grant, as we thought we needed another staff member for this project. The research assistant who was hired first worked under Annie Hernandez, M.A. (until she resigned in November 1996) and then Caroline Moore, M.A. While this research assistant was hired specifically to work on recruitment and retention, she was terminated in December 1996 because of inconsistent work and poor follow through with patient contact. Many of our dropouts in year 2 were the result of this lack of continuity with patients. The other staff change related to the research assistant who was the data manager from the beginning of the study. She was responsible for coding the data, data entry, and data analyses. She resigned in March 1997. Upon examining the data, it was discovered that there were serious mistakes in the data (double entries, coding errors, entry errors, etc.). While recruitment was halted, the entire data set was completely re-entered by Caroline Moore, M.A. (after being instructed and evaluated by the PI on how to code and enter data) while awaiting the arrival of a new data manager, Jamie McGee, B.A. (who was hired in July 1997). All data errors were corrected and accurate numbers of participants were generated. The data set is now entirely clean. However, Jamie McGee, B.A. resigned in January 1998 and we did not hire a new person (Karina Ortega-Verdejo, B.A.) until June 1998. Caroline Moore, M.A. resigned in September 1998 to accept a position in a different state. While Karina Ortega-Verdejo, B.A. is very quick to learn, knows the statistical package quite well, and has been excellent at recruiting participants and organizing the participant records, initially she needed to be oriented to the myriad of responsibilities. Currently, Dr. Kash and Ms. Karina Ortega-Verdejo, B.A., are the only two working on this project and are working in good faith to fulfill the goals of this study.

Based on 1a and 1b above, we have made several changes to the study. Initially we revised the recruitment letter sent to the women in the surveillance program. The new letter, which went out in July 1997, explained the study and asked women to call an 800 to decline participation in the study. The letter also mentioned that if we did not hear from them within two weeks we would call them and send out the time 1 questionnaire. In this manner we were asking women to take some

responsibility for not wanting to be part of the study. Of the 100 women initially contacted in this way only six women called to decline participation. Women were telephoned by the research associate and mailed the questionnaire. This has been very successful as we obtained participation from 67 women in five months. In order to step up the recruitment further, we have now begun to contact each woman, not already enrolled in the study (or declined participation), just prior to their clinical appointment and ask them for a few minutes of their time to discuss participation in the study at the time of their visit. This began in December 1997 and women are very receptive in a face-to-face approach. In addition, we have put flyers in the breast center for women with breast cancer to give to their first degree relatives. The flyers outline the purpose of the study and the eligibility criteria. In January 1999 we sent out a letter to all the women (N=234) who have not responded to previous letters, stating that this is the last opportunity to join the study.

2. Statement of Work (Appendix A)

All five items in **Task 1** have been accomplished. They are as follows.

- a) All the materials to be used with those subjects in the experimental condition were ordered and received. They have been used in each of the experimental groups conducted and will be ordered and used in each year.
- b) All questionnaires to be used in this study were completed. Other paperwork, such as labels being generated, envelopes addressed, and questionnaires copied for distribution to subjects, was also completed.
- c) The Quality of Life measures were finalized and included in the interview packet for subjects.
- d) The psychoeducational intervention manual was completed.
- e) The new research assistant and the research associate were both trained on how to carry out their various responsibilities, which included, but was not limited to, patient contacts, interviewing subjects, and coding and entering data.

In the Statement of Work the items in **Task 2** have been completed as follows.

- a) In the first wave, 170 women were contacted and asked to participate in the study. As anticipated 101 women agreed to participate in the study (59% response rate).
- b) In the second wave, 200 women were contacted and asked to participate in the study. Only 82 women agreed to participate rather than the 120 women we anticipated (41% response rate). Women who declined participation cited their main reasons as; live too far away, can't make commitment to every week for six weeks, inconvenient time (would rather have it on weekends), feel they don't need support right now, and not interested in groups.
- c) In the third wave, 125 women were contacted and asked to participate in the study. This number was significantly less than predicted as we halted recruitment for six months. Sixty-seven (54% response rate) agreed and 40 women (60%) completed the Time 1 assessment.
- d) In the fourth wave, 240 women were contacted and asked to participate in the study. One hundred and twenty five (52% response rate) agreed and 64 women (51%) completed the Time 1 assessment.

In the Statement of Work all the items in **Task 3** have been completed (or are ongoing) as scheduled.

- a) In Table 1 is listed the number of women who completed time 1, time 2, time 3, and time 4 questionnaires. The most common reasons women were not interested in participation were: 1) could not commit for six weeks; 2) had small children and did not want to leave them with a babysitter every week; 3) hours of groups inconvenient (prefer a weekend day); and 4) wanted to be randomized to the opposite condition.
- b) See Table 1.

c) Data entry began in the seventh month and is being done on an ongoing basis.

In the Statement of Work all the items in **Task 4** have been completed (or are ongoing) as scheduled.

a) All five groups were completed in the first year as planned. Two groups out of six, that were planned, were completed in the second year. Three groups were conducted in year three and four groups were conducted in year four.

b) The six month "booster" session was conducted for 12 groups and the one year "booster" session was conducted for 10 groups.

c) Dr. Paul Jacobsen, a consultant in behavioral medicine, has conducted quality checks on the consistency and accuracy of the content of the sessions by listening to the audio cassettes.

In the Statement of Work all the items in **Task 5** have begun. Table 2 lists the demographics of the participants in the study. Table 3 lists the family histories of the women who participated in this study to-date. Table 4 lists the risk levels and Table 5 lists the important intermediate outcome measures differences. Table 6 lists adherence to screening behaviors of the participants. T-tests are reported for differences between the groups on several intermediate variables: perception of risk; breast cancer risk factors; breast cancer knowledge; barriers and benefits of screening; and breast cancer anxiety.

VII. RESULTS

This research project will take at least five years to complete and we will be examining effects over time. We currently have a one year no-cost extension to complete the study. A total of 212 women completed Time 1 and to date there are 154 women still in the study. Of the 58 who are no longer in the study, 21 refused the experimental assignment and 1 refused the control assignment. Thirty-six women dropped out of the study; 1) one woman in the experimental arm left the study because her mother had a recurrence of breast cancer and died within two weeks; 2) two women in the control group developed breast cancer; 3) seven women moved away (four from the experimental arm and three from the control arm); 4) 13 women never showed for the experimental arm and did not respond to phone calls; and 5) 13 women were lost to follow-up (nine from the experimental arm and four from the control arm). There were a total of 120 women assigned to the experimental arm and 92 randomized to the control arm. The preliminary data are presented below.

Demographics (Table 2)

From our initial review of the demographics data (N=212) there are no differences between those assigned to the experimental or control conditions on the following variables: racial/ethnic background, highest grade completed, employment status, occupation, religion, income, or actual risk level (as determined by the genetic counselor). There are significant differences between the control and experimental conditions on; 1) age (M=41.19 [SD=11.2] for the experimental arm, and 45.41 [SD=11.16] for the control arm) ($p < .005$); and 2) marital status, with more women in the experimental arm reporting they were single than women in the control arm ($\chi^2 [4, N=212] = 10.16, p < .04$). While the difference in age is significant, four years does not seem to be a meaningful time frame. Regarding the difference in marital status, we are not sure why the number of married women is the same in both the experimental and control arms, but the number of single women is higher in the experimental arm.

Family History of Participants

As shown in Table 3, 85% of the participants had at least one first-degree relative with breast or ovarian cancer and 70% had at least one second-degree relative with breast or ovarian cancer, in addition to their first-degree relatives. The mean age of the participants' mothers when they were

diagnosed was 49.52, with 52% diagnosed under the age of 50 and 25% diagnosed under the age of 40. Twenty-nine percent of the study participants were pre-adolescent (under age of 14) when their mothers were diagnosed with breast cancer. One-half (N=106) of the study participants' mothers died of breast cancer. The mean age of the sisters at diagnosis was 42, with 57% diagnosed under the age of 40. Two women in this study had fathers with breast cancer. One of these two women had both a father and a mother die of breast cancer.

Once all of the data have been collected, we plan to: 1) look at the effect of the number of FDR's (one versus two or three) on sense of well-being (anxiety, depression, etc.), screening behaviors, and quality of life; and 2) explore the impact of being young when a mother was diagnosed with breast cancer and having a mother die of the disease, on sense of well-being (anxiety, depression, etc.), screening behaviors, and quality of life (especially goal attainment).

Objective and Subjective Risk

In Table 4, the three categories of medical risk, based on the consultation of the genetic counselor, are listed and there were no differences between the two arms. There was also no difference between the treatment and control arms on perception of risk (subjective risk) at time 1. However, Figure 1 shows there were significant differences between the treatment and control arms, as well as within the treatment arm (see Figure 1).

Intermediate Outcome Variables (Table 5)

- 1) Knowledge of breast cancer - consists of 10 items and has an internal consistency of .75. There were no significant differences between the two conditions at Time 1. There was a significant difference between the treatment and control arms at Times 2, 3, & 4, as well as a significant difference within the treatment group from Time 1 to Time 2, 3, & 4.
- 2) Knowledge of breast cancer risk factors - consists of 10 items and has an internal consistency of .72. There were no significant differences between the two conditions at Time 1. There was a significant difference between the treatment and control arms at Times 2, 3, & 4, as well as a significant difference within the treatment group from Time 1 to Time 2, 3, & 4.
- 3) Barriers to breast cancer screening - consists of 10 items and has an internal consistency of .83. There were no significant differences between the two conditions at Time 1.
- 4) Benefits of breast cancer screening - consists of 9 items and has an internal consistency of .62. There were no significant differences between the two conditions at Time 1.
- 5) Breast cancer anxiety - consists of 21 items and has an internal consistency of .90. There were no significant differences between the two conditions at Time 1. There was a significant difference within the treatment group from Time 1 to Time 2, 3, & 4 (see Figure 2).
- 6) Cancer attitude scales - consists of 6 items for anxiety, 8 items for helplessness, and 5 items for adjustment and has an internal consistency of .84, .79, and .80, respectively. There were no significant differences between the two conditions at Time 1.
- 7) Coping Strategies - consists of 24 items and has an internal consistency of .78. There were no significant differences between the two conditions at Time 1.
- 8) General anxiety - consists of 20 items and has an internal consistency of .94. There were no significant differences between the two conditions at Time 1. There was a significant difference between the treatment and control arms at Times 2, 3, & 4.
- 9) Depression - consists of 20 items and has an internal consistency of .77. There were no significant differences between the two conditions at Time 1. There was a significant difference between the treatment and control arms at Time 4.

Quality of Life Outcomes

- 1) Social Adjustment Scale - consists of 42 items and has an internal consistency of .71. There

were no significant differences between the two conditions at Time 1.

- 2) General Well-Being Scale - consists of 38 items and has an internal consistency of .74. There were no significant differences between the two conditions at Time 1.
- 3) Patient Satisfaction Scale - consists of 14 items and has an internal consistency of .69. There were no significant differences between the two conditions at Time 1.
- 4) Life Satisfaction Scale - consists of 5 items and has an internal consistency of .89. There were no significant differences between the two conditions at Time 1.
- 5) Patient Centered Goals - consists of 15 open-ended questions, one question on a seven-point scale regarding satisfaction with prospects for the future, and prioritizing the open ended questions into how likely it is they will accomplish their goals. During the course of this study there have been only two people who have categorized the goals and their attributes in order to increase the inter-judge reliability.

Adherence to Screening (Table 6)

- 1) Mammogram - 92% of women had ever had a mammogram. We are looking at the two mammograms prior to entering the study for a baseline score of adherence. For follow-up, we are asking the women to report when their last mammogram was, as well as checking their clinical record. We are still collecting data on pre-randomization screening behaviors because 20% of women inaccurately estimate the last time they had a mammogram. For example, a woman will state that her mammogram was in April but upon checking the medical record we see it was really in June.
- 2) Clinical Breast Examination - only one woman never had a clinical breast examination. While it is recommended that women with a family history come in every six months for a clinical breast examination, many women postpone it for a longer period of time. In comparing when the woman states she had her last clinical breast examination with the clinical record, we find a similar situation to that of mammography. That is, that women can be off by a couple of months as to when they had their last clinical breast examination.
- 3) Breast Self-Examination - only 16% of women perform BSE on a monthly basis. We are also performing open ended coding on the techniques of BSE as well as examining the confidence a woman has in her ability to detect a lump. Hopefully this information will provide us with insight in how to motivate women to perform BSE.

Qualitative

Anecdotal reports from women in the experimental condition indicate that they have obtained a tremendous amount of knowledge and feel less anxious about carrying out early detection behaviors for breast cancer. One woman in the treatment group, who came in on time for her mammogram, was told there were microcalcifications on her film and she needed to have a biopsy. When she was scheduling it with a breast surgeon she told the Principal Investigator that she was not worried. In her words, "I came in right on time for a mammogram and a breast examination because I learned the importance of early detection in the [group] sessions. I'm not really anxious about the procedure or the outcome because my group asked questions about biopsies and I also know that most of these [mammogram findings] are benign. If it weren't for the group, I would not have come in when I was suppose to and I would be really nervous that I do have breast cancer." Another woman in the treatment arm developed breast cancer one year after her participation in the study ended. She called the Principal Investigator to say that she knew from the group sessions that she had done everything right and it was indeed found early (Stage 1 cancer). The two women who had to drop out of the study because they developed breast cancer were diagnosed as Stage II and Stage IV.

Conclusions

At this point the data looks very promising in terms of our aims of decreasing the perception of risk and decreasing anxiety as well as increasing both knowledge of breast cancer and risk factors for breast cancer. Once we have finished collecting all of the data for all the variables, we will be able to apply the full model of MANOVA to test our hypotheses. It is our ultimate goal to increase adherence to screening as well as help women to enjoy the quality of their lives.

REFERENCES

Claus EB, Risch N, & Thompson WD. (1991). Genetics analysis of breast cancer in the cancer and steroid hormone (CASH) study. American Journal of Human Genetics, 48, 232-242.

Kash KM. (1991). How high risk women cope with breast cancer fears. Paper presented at the 144th meeting of the American Psychiatric Association, New Orleans. May 13-16, 1991.

Kash KM, Holland JC, Halper M, & Miller DG. (1992). Psychological distress and surveillance behaviors of women with a family history of breast cancer. J. Natl. Cancer Inst., 84, 24-30.

Kash KM, Holland JC, Osborne MP, & Miller DG. (1995). Psychological counseling strategies for women at high risk for breast cancer. Monogr Natl Cancer Inst, 17, 73-79.

Kash KM, Holland JC, Osborne MP, Miller DG. (1997). Improving quality of life and increasing adherence to breast cancer screening in women at risk. Annals of Behavioral Medicine, 17, p.43.

APPENDIX A

PSYCHOEDUCATIONAL GROUP INTERVENTION FOR WOMEN AT INCREASED RISK FOR BREAST CANCER

Task 1. Preparation of materials, intervention manual & training of staff– Months 1-3:

- a. Materials to be used with experimental condition will be ordered.
- b. Questionnaires copied, labels created, and envelopes addressed.
- c. Quality of life measures are finalized.
- d. The psychoeducational intervention manual will be completed.
- e. The research assistant, research fellow, and the social worker will be trained in their various responsibilities.

Task 2. Randomization of sample and recruitment of participants– Months 3-36

- a. Eligible women will be randomly sampled and recruited for participation. Recruitment for participation in this study will be done at one year intervals so that all the recruitment will not be done in the first year. In the first wave we will contact 170 women for the first year as we anticipate a 60% response rate and a need for 100 women.
- b. Second wave of recruitment begins (month 12), 200 women will be contacted to insure that we have 120 women for study.
- c. Third wave of recruitment begins (month 24), 200 women will be contacted to insure that we have 120 women for study.
- d. Fourth wave of recruitment begins (month 36), 34 women will be contacted to insure that we have 20 for study.

Task 3. Assessments collected– Months 3-48:

- a. Baseline assessments are collected prior to randomization to experimental (N=180) or control (N=180) condition for a total of eighteen cycles (N=360), with new intervention groups (experimental condition) starting every two months beginning in the third month (months 3-36).
- b. Six week, six month and one year assessments are collected on those in the experimental (intervention group) and control conditions.
- c. Data entry begins in month 5.

Task 4. Intervention groups and “booster” sessions conducted– Months 3-48:

- a. An intervention group (experimental condition) begins every two months, starting in month 3 (5 in the first year, 6 in the second year, 6 in the third year, and 1 in the fourth year).
- b. Six month and one year “booster” sessions are conducted for those in the experimental condition.
- c. Quality checks on consistency and accuracy of content of sessions are performed through the use of audio and video tapes.

Task 5. Data analyses– Months 44-48:

- a. Preliminary data analyses are begun in month 44.
- b. Tests of differences between experimental and control conditions on several variables (e.g., age, referral source, prior screening behavior, psychological distress) are begun in month 44.
- c. MANOVA and MANCOVA with repeated measures are performed starting in month 44.
- d. Final analyses are completed in month 48.

APPENDIX B

Table 1. Recruitment and Retention Data

<u># Recruited</u>	<u># Agreed to Participate</u>	<u>Time 1</u>	<u>Time 2</u>	<u>Time 3</u>	<u>Time 4</u>
Year 01 — 170	101	83	75	65	68
Year 02 — 200	82	25	11	10	9
Year 03 — 125 (6 months)	67	40	26	23	9(17)
Year 04 — 240	159	64	18(24)	8(48)	(51)
TOTAL — 735	409	212	130(24)	106(48)	86(68)

() indicates the number waiting for or not due back yet

Table 2. Demographics of study participants (N=212)

Age: range is from 22 to 76 years with a mean of 41 years ($p < .005$)

Variable	Experimental (N)	Control (N)	
Marital Status			
Single or never married	43	17	$p < .04$
Married or living as married	59	58	
Separated or divorced	15	11	
Widowed	1	4	
Other	2	2	
Ethnic/Racial			
White	108	82	
African American	5	2	
Hispanic	6	4	
Asian	.0	2	
Other	.1	2	
Grade			
Less than high school	1	0	
High school or GED	3	12	
Technical/Vocational	.1	1	
Some college	16	17	
College	50	34	
Graduate school	40	20	
Post-graduate school	10	8	
Employment			
Full time	70	53	
Part time	18	17	
Retired	11	9	
Homemaker	12	9	
Disabled	1	0	
Student	4	1	
Unemployed	4	3	

Table 3. Family history of study participants (N=212)

<u>First degree relatives (FDR) with breast and/or ovarian cancer</u>	<u>Percentage</u>
One	85
Two	14
Three	1
<u>Second degree relatives (FDR) with breast and/or ovarian cancer</u>	<u>Percentage</u>
None	30
One	43
Two	23.5
Three	3
Four	0.5
<u>Mothers' diagnoses</u>	<u>Number</u>
Unilateral breast cancer	128
Bilateral breast cancer	46
Ovarian cancer	10
<u>Sisters' diagnoses</u>	
Unilateral breast cancer	40
Bilateral breast cancer	8
Ovarian cancer	2

Table 4. Risk levels and screening behaviors of study participants (N=212)

Risk levels	Percentage
Medical risk categories	
Low: 13 - 19%	31.6
Moderate: 20 -34%	34.6
High: 35-50%	33.8
Medical risk continuum	
13% to 50% based on family history	Mean = 30.14
Perception of risk of developing breast cancer (from 0% to 100%)	
9% to 100%	Mean = 55.68
Perception of risk - categorization of accuracy	
Underestimators	8.3
Accurate perception	16.7
Overestimators	75.0

Table 5. Differences between the means of intermediate outcome measures

	<u>Time 1</u>	<u>Time 2</u>	<u>Time 3</u>	<u>Time 4</u>
Knowledge of breast cancer				
Treatment arm ^a	7.66	8.90	8.79	8.54
Control arm	7.76	7.77***	8.16**	7.87*
Risk factors for breast cancer				
Treatment arm ^a	8.19	9.00	9.00	9.08
Control arm	8.13	8.01***	8.10***	8.25***
Breast cancer anxiety				
Treatment arm ^a	22.08	20.32	19.45	17.53
Control arm	20.68	22.07	22.01	19.67
General anxiety				
Treatment arm	38.30	36.51	36.48	32.15
Control arm	39.92	41.45*	39.78	40.47*
Depression				
Treatment arm	12.22	12.11	12.43	9.3
Control arm	13.94	15.01	14.62	13.55*

*** p<.001

** p<.01

* p<.05

^aSignificant difference between Time 1 and Time 2, 3, & 4, but not between Time 2 & 3 or Time 3 & 4.

Table 6. Screening Behaviors for Breast Cancer

Screening Behaviors	Percentage
Breast self-examination (BSE)	
Yes	76.4
No	23.6
BSE-how often in the past <u>six</u> months from 0 to 180 times	Mean = 7 times
Never	23.6
Less than monthly	49.1
Monthly	16.0
More than monthly	11.3
Clinical breast examination (ever had one)	
Yes	99.5
No	0.5
Mammogram (ever had one)	
Yes	92.0
No	8.0

APPENDIX C

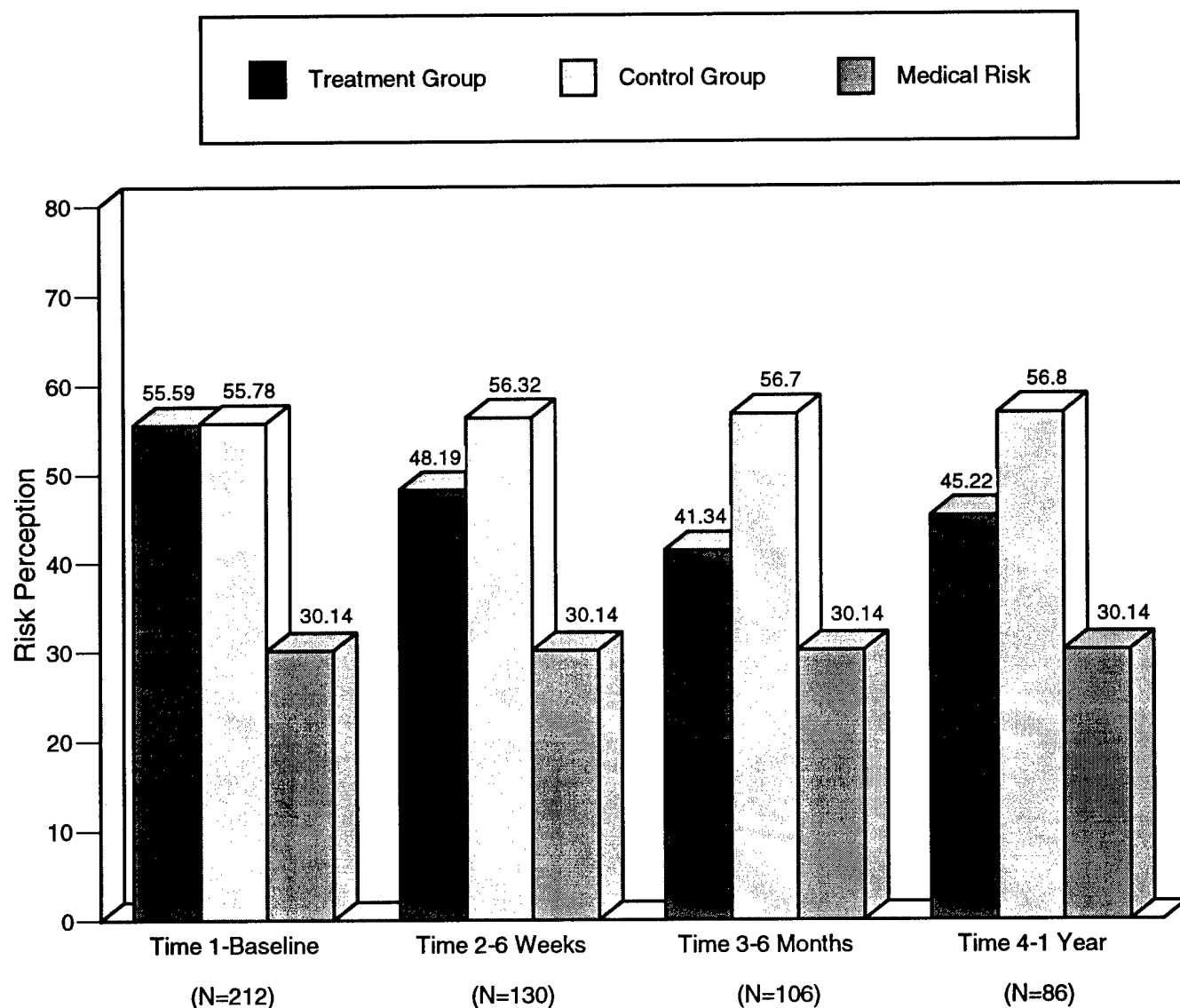


Figure 1. Significant difference between treatment and control groups at Time 2 ($p < .05$), Time 3 ($p < .002$), and Time 4 ($p < .03$), as well as significant difference within the treatment group at Time 2 ($p < .05$), Time 3 ($p < .001$), and Time 4 ($p < .02$).

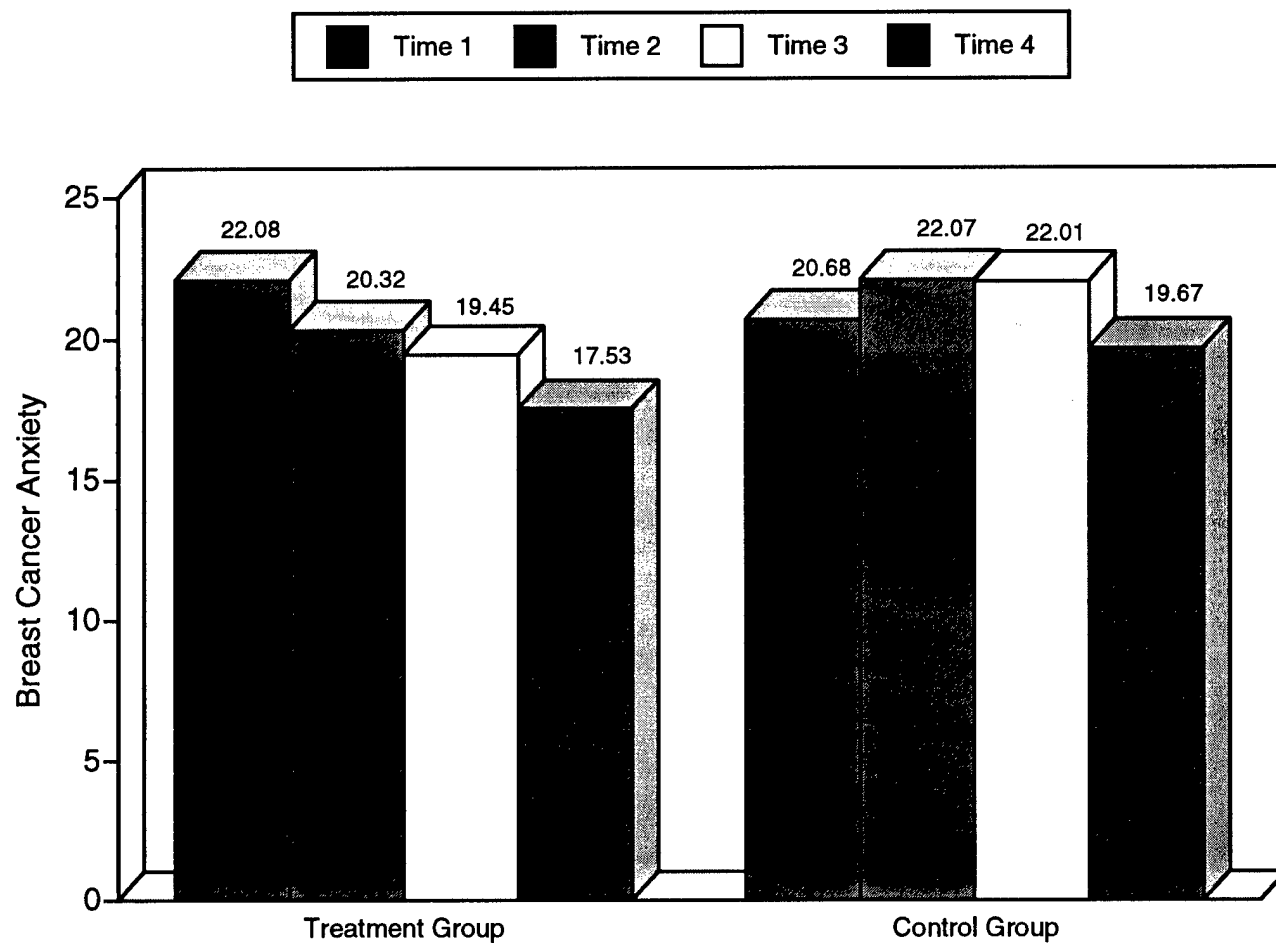


Figure 2. No significant difference between treatment and control groups at any time. Significant differences within the treatment group at Time 2 ($p < .01$), Time 3 ($p < .05$), and Time 4 ($p < .001$).