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13. ABSTRACT (Maximum 200 Words) A randomized controlled trial of a psychoeducational group intervention was conducted. The specific aims were to examine the impact of the intervention on knowledge of breast cancer and risk factors, breast cancer beliefs, breast cancer anxiety, coping skills, quality of life and adherence to screening. The intervention components included social support enhancement, education, cognitive restructuring, and problem solving. Group sessions (5 to 10 women in each group) met for one and half-hours each of six weeks, with six-month and one year booster sessions. Interviews were conducted prior to randomization (Time 1), at the end of the six-week intervention (Time 2), at six months (Time 3) and one year (Time 4). 247 healthy, asymptomatic women at high risk for breast cancer (control condition N=108); treatment condition N=139) participated in the study. The mean age is 43, primarily white (90%), with 39% having a college education. At baseline, 73% of women overestimated their risk, 17% accurately estimated their risk and 10% underestimated their risk for developing breast cancer. A repeated measures analysis of variance (ANOVA) found a significant reduction in breast cancer specific anxiety within the treatment condition from Time 1 to Time 4 ($p < .02$), and a decrease in perception of risk ($p < .01$). Women in the treatment condition significantly improved their knowledge of breast cancer ($p < .02$) and risk factors for breast cancer at Time 4 ($p < .002$). ANOVA found that women in the treatment condition used more active coping and less behavioral disengagement than women in the control condition ($p < .04$). A logistic regression analyses found that women in the treatment condition adhered to age appropriate mammogram recommendations at Time 4 ($p < .01$) more than women in the control condition. These findings suggest that the intervention helps to decrease anxiety, increase knowledge, improve coping strategies, and improve adherence to mammography.				
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INTRODUCTION

Psychoeducational groups have been shown to be effective in reducing emotional distress and promoting quality of life. The purpose of this study was to address quality of life and adherence to screening issues associated with being at increased risk for breast cancer. The specific aims were: 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. The research design used a randomized controlled trial to test the psychoeducational group intervention. The intervention components included; social support enhancement, education, cognitive restructuring, and problem solving. A total sample size of 247 was recruited and completed baseline assessments and 148 remained in the study at the end of one year. Data was collected at four points in time; baseline (Time 1), six weeks (Time 2), six months (Time 3), and one year (Time 4). The variables examined were: demographic; risk status; knowledge of breast cancer and risk factors; breast cancer beliefs; coping strategies; quality of life in terms of life satisfaction and satisfaction with participant goal-directed behaviors; and adherence to mammogram, clinical breast examination (CBE), and breast self-examination (BSE).

BODY

Theoretical Framework

The most integrated theoretical framework relevant to breast cancer screening adherence (particularly for women at increased risk) is that of self-regulation (Leventhal et al, 1984; Leventhal et al, 1992). This theory was developed in order to explain how people cope with stressful situations, or, how people adapt to health threats. The model reflects two ways of information processing; one by the objective representation of a health threat, and the other by a subjective representation of emotion, in terms of fear or distress associated with the health threat. Both the objective and the subjective representations rely on coping procedures used to manage the health threats, as well as the evaluation or appraisal of coping outcomes. The stressful situation is a cue for the beginning of the process of self-regulation. An essential component to this theory is that of a schema (cognitive representation) which guides the processing of information and interpretation of a health threat. Another important component is the appraisal of coping outcomes, which provides a feedback loop for monitoring the coping procedures and the behavior. There are two underlying issues that help in understanding how people cope with health threats. One is the content of the representations and the second issue is the process by which the representations are appraised and changed over time.

Based on this theory women, who do not receive objective information regarding their risk for breast cancer, focus only on their subjective representation which is reflected in their overestimation of risk and emotional distress. Helping women to obtain and focus on concrete objective information (risk status, breast cancer knowledge, etc.) rather than emotional distress can encourage more effective coping skills. The functions of coping with being at risk are twofold; to reduce the sense of emotional distress, and to minimize the negative impact on their lives through the regulation of goals (problem solving). Chronic worry about developing breast cancer causes disruption to women's' goals, thus interfering with their quality of life. In turn, as

women appraise the information and coping over time, this process will help support their goal directed behavior (e.g., use of screening behaviors) and interfere less with other life goals.

Research Design

The study was a randomized two group design in which women at increased risk for breast cancer were assigned to either the treatment or control condition. In the treatment condition, 16 groups of 5 to 10 women in each group (N=139), met for one and a half hours for each of six consecutive weeks and two "booster" sessions at six months and one year post-intervention. They were assessed at four points in time; baseline, at the end of the group intervention (six weeks), and post-intervention (six months and one year). This sequence will be repeated successively for each of 16 groups. Groups were conducted every two months, with follow-up assessments at six months and one year for each group. In the control condition (N=108), women were provided with standard care (described below) and assessed at the same four points in time as those women in the treatment condition.

Participants

The participants were accrued from the Strang Breast Surveillance Program at the Strang Cancer Prevention Center in New York City. This program was designed for women at increased risk for breast cancer. This program was established in 1987 by Dr. Michael Osborne and Dr. Daniel G. Miller and was under the direction of Dr. Anthony C. Cahan at the time of this study. Initially this was a no fee program as part of ongoing clinical and research programs. To qualify for the program women fell into one of four categories for increased risk for breast cancer: 1) two or more first degree relatives (mother, sister, daughter) with breast cancer; 2) a first degree relative with bilateral premenopausal breast cancer; 3) a mother and maternal grandmother with breast cancer; or 4) a first degree relative with unilateral breast cancer developed under the age of 40. These criteria were selected to include women whose lifetime risk for developing breast cancer based on their family histories is between 11 and 50% (Claus et al, 1991).

Eligibility criteria for participating in the study were:

1. currently enrolled in the Strang Breast Surveillance Program;
2. relative diagnosed with breast cancer at least six months prior to study (to avoid confounding concerns about relative vs. self);
3. no prior or current neoplasm;
4. over 20 years of age;
5. the ability to read and write the English language; and
6. live near enough to New York City in order to participate in the six week group.

Procedures

The medical history for all women enrolled in the Strang Breast Surveillance Program was reviewed by Dr. Kash and one of the genetic counselors for eligibility to participate in the study. Names of eligible women were randomly selected and sent a letter explaining the purpose and requirements of the study. It explained to each woman that after baseline data was obtained, they would be randomized to either the treatment (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 is adhered to for each session.

Baseline data was obtained prior to randomization to either the treatment or control condition. The research assistant remained blind as to which group each woman belonged to so as not to influence the interview process (at T2, T3, and T4).

Description of the Intervention

The intervention consisted of six weekly sessions of one and a half-hours each conducted by a psychiatric social worker (who was at increased risk for breast and ovarian cancer) leading each group and two “booster” sessions — to reinforce what has already been learned. Each session included an opportunity to discuss feelings and concerns about breast cancer. The first session was co-led by the group leader and Dr. Kash and revolved around the theme of getting to know one another. In the second session one of the genetic counselors provided information on genetics and the risk of breast cancer. The third session was open-ended in that the participants could ask a breast surgeon any questions they had about breast cancer or treatment. The fourth session revolved around how to cope with being at risk for breast cancer, including stress management and was conducted by Dr. Kash, in conjunction with the group leader. In the fifth session a nutritionist discussed the role of nutrition as it related to lifestyle in cancer prevention. The last session included a film on the importance of early detection for breast cancer and how to do breast self-examination by the nurse practitioner. In this last session each woman was given reminders regarding their next appointments for mammography and clinical breast examination. The booster sessions at six months and one year post-intervention were used as an opportunity to reinforce the importance of adhering to screening guidelines. Women were also encouraged to talk about the changes in their fears and worries about breast cancer and their life goals.

Description of Standard Care

Standard care in the Strang Breast Surveillance Program is provided as follows. The screening guidelines for the women are: 1) to have a baseline mammogram 10 years younger than the age at which the relative developed breast cancer, but not before age 30, one mammogram between the ages of 30 and 34, a mammogram every 18 to 24 months from ages 35 to 39 (based on family history), and a yearly mammogram from age 40 on; 2) to have a CBE every six months by the nurse practitioner or a physician; and 3) to be taught BSE and given reminder stickers to put on their calendars. Women are sent cards two months in advance to remind them that it is time for an appointment (either CBE or mammogram, or both). Women who need to reschedule an appointment are offered an appointment within one week of the first appointment date.

Measures

1) Mammogram: Each participant recorded the date of her last mammogram. A woman was considered adherent if she had a mammogram within the past year. This prior adherence was decided on an individual basis since every woman does not have a mammogram every year (women under 40 years of age are not on a yearly schedule). Consequently, some women had one mammogram in their lives, while others had none. For these women adherence was measured as their adherence to the recommended guidelines for their age group. This information provided the baseline data for adherence to mammogram. Adherence to mammogram at Time 4 was considered positive if a woman had an appointment within the last 13 months. In this manner, women who had to reschedule an appointment were given an extra month's time frame.

2) Clinical breast examination (CBE): Each participant recorded the date of her last clinical

breast examination. A woman was considered adherent if she had a last clinical breast examination within the past six months. This information provided the baseline data for adherence to clinical breast examination. Adherence to last clinical breast examination at Time 4 was considered positive if a woman had an appointment within the last six and a half months. In this manner, women who had to reschedule an appointment were given an extra time frame.

3) Breast self-examination (BSE): At baseline (T1) we obtained subjective estimations of BSE performance (frequency) during the past six months. Adherence to BSE was measured whether or not women had performed BSE within the last six months, the number of times they performed it, and whether or not they were adherent to the recommendation of monthly BSE.

4) Quality of Life was measured in two ways. One was a compilation of standardized measures and the other was an open-ended coding method of looking at one's personal goals in life. The standardized measures included the Revised Rand General Well-Being Scale (38 items), the Social Adjustment Scale-Self Report (42 items), Patient Satisfaction Subscales (14 items), and the Life Satisfaction Index (5 items). The open-ended measure was the Patient-Centered Methods. This measure asked women to: 1) describe the personal goals most important to quality of life in terms of things they want to accomplish, problems they want to solve and to avoid, relationships and activities they want to maintain, and obligations and ties they want to relinquish; 2) describe things that they have done (or attempted) over the last month to pursue these goals; 3) rate goal attainment activities in terms of difficulty and need for support; and 4) identify goals they could not pursue due to health problems.

5) Knowledge about Breast Cancer was a 10 item measure about breast cancer incidence and treatment.

6) Knowledge about Breast Cancer Screening was a 10 item measure about risk factors for breast cancer.

7) Breast Cancer Beliefs which includes their perceived risk for breast cancer, barriers to screening (8 items), and benefits of screening (5 items).

8) Cancer Attitude Scales is a 19 item self-report inventory that assessed the women's general cancer anxiety (6 items), sense of helplessness (8 items), and adjustment to cancer (5 items).

9) Coping Strategies were measured by 12 scales which are: active coping; planning; use of social support; positive reframing; acceptance; venting of emotions; denial; humor; self-distraction; behavioral disengagement; religion; and alcohol/drug use.

10) Stressful Life Events were measured by a 37 item measure, which recorded events over the past six months.

11) Risk status: Each participant's risk was completed, based on objective risk analysis tables, by one of the genetic counselors.

12) Sociodemographic: The demographic data (age, ethnicity, race, marital status, education, and occupation) was reported by each participant. In addition, information was collected on the number of relatives (both first and second degree) with breast cancer and ovarian cancer, as well as other relevant cancers.

Work Accomplished as Related to Statement of Work (see 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 treatment arm were ordered and received. They were used in each of the 16 treatment groups conducted.

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, were 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 research assistant, research associate, and social worker were all trained in 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** were all completed.

- 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). Of the 101 women who agreed to participate, 83 completed the baseline assessment (82%) and of those 83 women, 68 (82%) completed the Time 4 assessment.
- 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). Of the 82 women who agreed to participate, 25 completed the baseline assessment (30%) and of those 25 women, 9 (36%) completed the Time 4 assessment.
- c) In the third wave, 125 women were contacted and asked to participate in the study. The number recruited was significantly less than predicted as we halted recruitment for six months (see problems in accomplishing tasks). Sixty-seven (54% response rate) agreed and 40 women (60%) completed the Time 1 assessment. Of the 40 women who completed the baseline assessment, 26 (65%) completed the Time 4 assessment.
- d) In the fourth wave, 240 women were contacted and asked to participate in the study. One hundred and fifty-nine (66% response rate) agreed and 99 women (62%) completed the Time 1 assessment. Of the 99 women who completed the baseline assessment, 45 (45%) completed the Time 4 assessment.

In the Statement of Work all the items in **Task 3** have been completed.

- 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 participating 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); 4) wanted to be randomized to the opposite arm; 5) not interested in groups; and 6) felt they did not need any support.
- b) In Table 2 is listed the number of treatment and control arm participants at all four times.
- 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.

- 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, and two groups were completed in year five (no-cost extension).
- b) The six-month "booster" session and the one-year "booster" session were conducted for all 16 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 audiocassettes.

In the Statement of Work most of the items in **Task 5** have been accomplished.

- a) Preliminary data analyses have been completed.
- b) Tests of differences between the treatment and control conditions have been completed.
- c) Repeated measures analyses of variance have been completed. Post-hoc and paired t-tests

have been completed.

d) The Patient Centered Methods open-ended coding has not been completed. We expect to complete this within the next two months. This has taken longer than expected as we had only two judges performing this coding to reduce coding errors. In this manner, we will attain the most accurate inter-rater reliability.

Problems In Accomplishing Tasks as related to Statement of Work

1. There were two major reasons why the progress of this study did not proceed as planned. One was programmatic issues and the other was staff changes. These reasons will now be restated in the final report.

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 was the source of women for this study. From 1987 to 1997 the Strang Cancer Prevention Center 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 Strang absorbed the cost. 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 were in this study stated that they would rather go to a mammogram facility that is covered by their insurance.

There were six women who withdrew from the program and went elsewhere for their care and also withdrew from this study. We believe that many of the 36 women who were lost to follow-up for this study also moved their care to another facility.

b) Staff Changes. We have experienced two major staff changes that impacted adversely on this study. 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 was 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 was entirely cleaned. 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. was very quick to learn, knew the statistical package quite well, and was excellent at recruiting participants and organizing the participant records, initially she needed to be oriented to the myriad of responsibilities.

Based on the above problems, we 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 was very successful as we obtained participation from 67 women in five months. In order to step up the recruitment further, we began to contact each woman, not already enrolled in the study (or declined participation), just prior to their clinical appointment and asked 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 were very receptive to a face-to-face approach. In addition, we put flyers in the breast center for women with breast cancer to give to their first-degree relatives. The flyers outlined the purpose of the study and the eligibility criteria. In January 1999 we sent out a letter to all the women (N=234) who had not responded to previous letters, stating that this was the last opportunity to join the study.

RESULTS

This research project took five years to complete and we examined effects over four points in time (Time 1-baseline; Time 2-six weeks; Time 3-six months; Time 4-one year). A total of 247 women completed the Time 1 assessment and there were 139 women randomized to the treatment arm and 108 randomized to the control arm (see Table 2).

A total of 148 women completed the Time 4 assessment. Of the 99 who were no longer in the study at Time 4, 26 refused the treatment assignment and 1 refused the control assignment. Thirty-six women dropped out of the study for the following reasons; 1) one woman in the treatment arm left the study because her mother had a recurrence of breast cancer; 2) two women in the control group developed breast cancer; 3) twelve women moved away (nine from the

treatment arm and three from the control arm); 4) fourteen women never showed for the treatment arm and did not respond to phone calls; 5) 36 women were lost to follow-up (twenty from the treatment arm and sixteen from the control arm); and 6) one woman in the control arm died of causes other than breast cancer.

We compared the women who completed the Time 4 assessment (N=148) with those who did not complete the Time 4 assessment (N=99) on all the variables in the study. The one significant difference was that the women who did not complete the study were more likely to have a college degree. That is, women with less than a college degree or more than a college education were more likely to stay in the study ($p<.02$).

Demographics (Table 3)

There were no differences between those assigned to the treatment or control arms on the following variables: racial/ethnic background, employment status, occupation, religion, or income. There was a significant difference between the control and treatment arms on age ($M=42.17$ [$SD=11.59$] for the treatment arm) (45.53 [$SD=11.52$] for the control arm) [$F(1,245)=5.14, p<.024$]. While the difference in age is significant, three years does not seem to be a meaningful time frame. There was also a marginal significant difference in education. Women in the treatment arm were more likely to have graduate degree than women in the control arm ($p=.06$). When we stratified women by less than college, college, or more than college, there were no significant differences between the two arms. However, we used both age and education as covariates in our analyses.

Family History of Participants

As shown in Table 4, the medical risk level (as determined by the genetic counselor using tables and pedigree analysis) was not significantly different between those assigned to either arm. There were also no significant differences between those women assigned to the treatment or control arm on perception of risk or the degree to which they underestimated or over estimated their risk for breast cancer.

As expected, there were no differences between the treatment and control arm with respect to the number of first or second-degree relatives with breast or ovarian cancer. Eighty-one percent of the participants (N=201) had at least one first-degree relative with breast or ovarian cancer, 16% (N=39) had two first-degree relatives with breast or ovarian, and 3% (N=7) had three first-degree relatives with breast or ovarian cancer. There were a total of 200 mothers, 71 sisters, two fathers, and two brothers affected with breast cancer. Thirty one percent of the participants (N=74) had a maternal grandmother with breast cancer and 6% (N=16) had a paternal grandmother with breast cancer. Fifteen percent (N=36) had at least one paternal aunt with breast cancer, 31% (N=76) had at least one maternal aunt with breast cancer and 25% (N=62) had another second degree relative with breast cancer. The mean age of the participants' mothers when they were diagnosed was 49, with 52% diagnosed under the age of 50 and 25% diagnosed under the age of 40. Twenty-nine percent of the study participants (N=69) were pre-adolescent (under age of 14) when their mothers were diagnosed with breast cancer. One-half (N=126) of the study participants' mothers died of breast cancer. The mean age of the sisters at diagnosis was 45, with 44% diagnosed under the age of 40.

Screening Behaviors - Adherence to Screening (Table 5)

1) Mammogram - 93% of women reported that they had at least one mammogram. For the baseline score of adherence we considered women over the age of 40 adherent if they had a mammogram within the prior year to study entry. For women under the age of 40, they were

considered adherent if they followed the age appropriate screening recommendations (see standard care for recommendations). At Time 4 we asked the women to report the date of their last mammogram. Women were considered adherent if, at Time 4, they had a mammogram within 13 months of their last mammogram. Initially we were going to check the clinical record because we thought that women were inaccurate in their reporting of the mammogram date. However, there was only a small percentage (2%) that was inaccurate. If there appeared to be some confusion about the dates, we consulted the clinical record. Table 5 indicates that there were no differences between the two arms on ever had a mammogram or adherence to mammography at baseline.

2) Clinical Breast Examination - only one woman in the control arm reported never having a clinical breast examination. For the baseline score of adherence, we considered women adherent if they had a clinical breast examination within six months prior to study entry. At both Time 3 and Time 4 we asked them to provide us with the date of their last clinical breast examination. Women were considered adherent at both Times 3 and 4 if they had a clinical breast examination within six and a half months of their last clinical breast examination. Table 5 indicates that there were no differences between the two arms on ever had a clinical breast examination or adherence to clinical breast examination at baseline.

3) Breast Self-Examination - 75% of women report ever performing BSE and only 16% report doing so on a monthly basis. There are extremes within this method of early detection as some women report never doing it and other women report doing it almost every day. There were no differences between the two arms with respect to performance of BSE, confidence in ability to do BSE, confidence in ability to remember to do BSE, competence to perform BSE, or confidence in ability to find a lump at baseline.

Intermediate Outcome Variables

- 1) Knowledge of breast cancer consisted of 10 items and had an internal consistency of .70. There were no significant differences between the two arms at Time 1.
- 2) Knowledge of breast cancer risk factors consisted of 10 items and had an internal consistency of .70. There were no significant differences between the two arms at Time 1.
- 3) Barriers to breast cancer screening consisted of 10 items and had an internal consistency of .81. There were no significant differences between the two arms at Time 1.
- 4) Benefits of breast cancer screening consisted of 9 items and had an internal consistency of .62. There were no significant differences between the two arms at Time 1. There were also no significant differences at Times 2, 3, and 4.
- 5) Breast cancer anxiety consists of 21 items and had an internal consistency of .90. There were no significant differences between the two arms at Time 1.
- 6) Cancer attitude scales consisted of 6 items for anxiety, 8 items for helplessness, and 5 items for adjustment and had internal consistencies of .84, .79, and .80, respectively. There were no significant differences between the two arms at Time 1. There were also no significant differences at Times 2, 3, and 4.
- 7) Coping Strategies consisted of 24 items and 12 scales and had an internal consistency of .78. There was one significant difference between the two arms at Time 1. There was more positive reframing in the treatment arm ($p < .02$).
- 8) General anxiety consisted of 20 items and had an internal consistency of .94. There were no significant differences between the two arms at Time 1.
- 9) Depression consisted of 20 items and had an internal consistency of .77. There was a significant difference between the two arms at Time 1. Those in the control group reported

more depression ($p < .04$).

Quality of Life Outcomes

- 1) Social Adjustment Scale consisted of 42 items and had an internal consistency of .57. There were no significant differences between the two arms at Time 1. There were also no significant differences at Times 2, 3, and 4.
- 2) General Well-Being Scale consisted of 38 items and had an internal consistency of .64. There were no significant differences between the two arms at Time 1. There were also no significant differences at Times 2, 3, and 4.
- 3) Patient Satisfaction Scale consisted of 14 items and had an internal consistency of .65. There were no significant differences between the two arms at Time 1. There were also no significant differences at Times 2, 3, and 4.
- 4) Life Satisfaction Scale consisted of 5 items and had an internal consistency of .88. There were no significant differences between the two arms at Time 1.
- 5) Patient Centered Goals consisted of a) 15 open-ended questions, b) one question on a seven-point scale regarding satisfaction with prospects for the future, and c) prioritizing the open-ended questions into how likely it was they would accomplish their goals. During the course of this study there have been only two staff who have categorized the goals and their attributes in order to increase the inter-judge reliability.

Significant Findings

Does the psychoeducational intervention improve the intermediate outcome variables of knowledge of breast cancer, knowledge of breast cancer risk factors, breast cancer beliefs, cancer attitudes, and coping skills?

Multivariate analysis of covariance (MANCOVA) indicated no significant differences between arms or within time assessment (Time 1, Time 2, Time 3, and Time 4) on breast cancer screening benefits, barriers to breast cancer screening, cancer anxiety, cancer helplessness, or cancer adjustment.

ANCOVA using perception of risk scores at four points in time yielded a significant difference between the conditions at time 2 [$F(1,177) = 4.80, p < .03$], time 3 [$F(1,150) = 9.77, p < .001$], and a marginal significance at time 4 [$F(1,140) = 3.22, p < .07$] (see Table 5). These results suggest that the treatment arm had a lower perception of risk at times 2, 3, and 4 (see Figure 1).

Repeated measures analysis of covariance (ANCOVA) using knowledge of breast cancer scores at four points in time yielded a significant main effect for time [$F(3,138) = 11.70, p < .001$], a significant main effect for arm [$F(1,141) = 11.98, p < .001$], and an interaction effect between arm and time [$F(3,140) = 5.56, p < .01$] (see Table 6). These results suggest that the intervention impacted on the treatment arm at Time 2 and continued for the duration of the intervention (see Figure 2).

Repeated measures analysis of covariance (ANCOVA) using knowledge of risk factors for breast cancer scores at four points in time yielded a significant main effect for time [$F(3,138) = 5.70, p < .01$], a significant main effect for arm [$F(1,141) = 9.11, p < .003$], and an interaction effect between arm and time [$F(3,140) = 7.18, p < .04$] (see Table 6). These results suggest that the intervention impacted on the treatment arm at Time 2 and continued for the duration of the intervention (see Figure 3).

Multivariate analysis of covariance (MANCOVA) using the 12 coping scales at all four assessment times yielded a significant main effect for arm on positive reframing [$F(1,143) = 6.05, p < .01$], active coping [$F(3,140) = 3.84, p < .05$], and behavioral disengagement [$F(3,140) = 4.56, p < .03$]. Analysis of variance with repeated measures suggests that the treatment arm

used more positive reframing at Time 4 (controlling for significant differences at Time 1), more active coping, and less behavioral disengagement. There was also a main effect for the covariate of age on emotional social support [$F(1,140) = 5.82, p < .02$]. Post-hoc comparisons found that younger women in the treatment arm used significantly more social support than older women [$F(1,63) = 9.41, p < .003$]. There was no significant difference for age on social support in the control arm.

ANCOVA using general anxiety scores at four points in time yielded a significant difference between the conditions at time 2 [$F(1,177) = 8.91, p < .003$] and time 4 [$F(1,140) = 4.8, p < .03$] (see Table 6). These results suggest that the treatment arm had a lower general anxiety at times 2 and 4 (see Figure 4).

ANCOVA using depression scores at four points in time yielded a significant difference between the conditions at time 2 [$F(1,177) = 5.77, p < .02$] and time 4 [$F(1,140) = 3.88, p < .05$] (see Table 6). These results suggest that the treatment arm had less depression at times 2 and 4 (see Figure 5).

ANCOVA using breast cancer specific anxiety scores at four points in time yielded a significant difference between the conditions at time 2 [$F(1,140) = 3.85, p < .05$] and a marginal significance at Time 4 ($p < .07$). There was also a significant difference within the control condition at time 3 [$F(1,81) = 3.99, p < .04$] and at time 4 [$F(1,81) = 5.80, p < .02$] (see Table 6). These results suggest that women in the treatment condition experienced less breast cancer specific anxiety than women in the control condition at Time 2. However, women in the control condition also experienced less breast cancer specific anxiety (see Figure 6).

Is quality of life and adherence to screening improved by the psychoeducational intervention?

Multivariate analysis of covariance (MANCOVA) indicated no significant differences between arms or within time assessment (Time 1, Time 2, Time 3, and Time 4) on social adjustment, general well being, and satisfaction with care. These measures were dropped from further analyses.

ANCOVA with repeated measures yielded a significant main effect for time on the global life satisfaction scale at Time 2 [$F(1,177) = 5.13, p < .02$], and for Time 4 [$F(1,150) = 4.88, p < .03$]. These findings suggest that the treatment arm had significantly more life satisfaction than the control arm at Times 2 and 4.

To determine adherence to mammography, clinical breast examination, and breast self-examination we conducted two separate logistic regression analyses (mammography and clinical breast examination) and a discriminant function analysis for breast self-examination. For all these analyses we used perception of risk, breast cancer specific anxiety, and general anxiety as predictors, as well as age and education as covariates. The logistic regression for clinical breast examination and discriminant function analysis for breast self-examination yielded no significant results. The logistic regression analysis for mammography (controlling for education and previous mammography use) indicated that women in the treatment arm adhered to recommendations significantly more than women in the control arm ($p < .001$) (OR= 0.31, 95% CI= 0.16. 0.57) with 77% of the cases correctly classified. There was also a significant effect for age (regardless of arm) in that women over the age of 43 (median split) were significantly less likely to adhere to mammography guidelines than women under the age of 43 ($p < .001$) (OR= 0.12, 95% CI= 0.05. 0.29).

KEY RESEARCH ACCOMPLISHMENTS

- Increased knowledge of risk factors for breast cancer in the treatment condition
- Increased knowledge of breast cancer in the treatment condition

- Decreased perception of risk in the treatment condition
- Decreased both breast cancer specific and general anxiety in the treatment condition
- Decreased levels of depression in the treatment condition
- Improved using the coping skills of positive reframing and active coping in the treatment condition
- Decreased using the coping strategy of behavioral disengagement in the treatment condition
- Improved global life satisfaction in the treatment condition
- Increased adherence to mammogram recommendations in the treatment condition

REPORTABLE OUTCOMES

1) Plenary Speaker at the XVIIIth Congress of the French Society of Psycho-Oncology on October 4th, 2001. (see Appendix C)

CONCLUSIONS

The main goal of this study was to see if a psychoeducational intervention could increase adherence to early detection methods for breast cancer and to improve the quality of life of women who were at increased risk for this disease. During the course of the intervention we wanted to see if we were able to have an impact on outcomes that were directly related to the content of the intervention sessions. These outcomes were: knowledge of risk factors for breast cancer; knowledge of breast cancer; perception of risk for developing breast cancer; cancer beliefs (benefits of screening and barriers to screening); cancer attitudes (anxiety, helplessness, and adjustment to cancer); breast cancer specific anxiety; general anxiety; depression; and coping skills.

At the end of six-week intervention, the treatment arm had more knowledge, were significantly less anxious and depressed, and appeared to use better coping strategies. These findings were anticipated as we had found similar results with the pilot data for this randomized trial (Kash, 1991). We did expect to see more benefits and less barriers to screening among women in the treatment condition, in keeping with the health belief model. In addition, we also expected to see changes in cancer attitudes. However, while there were no main effects for these variables, we may see that they are predictors in future sub-analyses of the data.

At the end of the six month time assessment, the impact on knowledge of both risk factors for breast cancer and breast cancer screening and a decrease in perception of risk for the treatment condition still held while there were no significant differences on any of the distress measures. It appears that for general anxiety and depression the scores in the treatment condition began to increase and shift toward the baseline levels. For breast cancer specific anxiety, the scores for the treatment condition continued to decrease (not significantly), however, the scores for the control condition also began to decrease. One possible explanation is that there was no continued reinforcement on a weekly basis for the treatment condition and that one booster session at six months was insufficient to make any meaningful differences.

At the end of one year, the impact on knowledge of both risk factors for breast cancer and breast cancer screening still continued to be significantly improved for the treatment condition. Perception of risk within the treatment condition began to increase and so there was only a marginal significance between the treatment and control condition. General anxiety scores and depression scores decreased and were significantly lower in the treatment condition. Breast cancer specific anxiety levels within the control condition were significantly reduced while levels within the treatment arm continued to decline. Perception of risk has always been a moving target. This means that depending on what is going on in a woman's life at the assessment time (new relative diagnosed with cancer, relative had recurrence, woman had a

biopsy, going for a mammogram, etc.) influences her current perception of risk. (Kash et al, 1992; Kash et al, 1995). As for general anxiety and depression levels further decreasing, it may have been the impact of the last booster session that encouraged women to think about decreasing their levels of distress around breast cancer without an intervention available. One of the outcomes of this study was to see if we could improve the coping strategies women in the treatment condition. We saw a significant increase in active coping and a significant decrease in behavioral disengagement. These two strategies are the opposite of each other and we specifically attempted to change these through the content of one session that focused on stress management and coping skills.

For the long-term goals of this study, we wanted to see if we could improve quality of life and improve adherence to screening behaviors. In terms of quality of life, there were no changes in the general well being scale, the social adjustment scale, or satisfaction with care scale. Women complained about these measures. Specifically, they stated that they thought the social adjustment scale was "outdated" and unrelated to anything in their life. This scale asked questions about work, relationships (partners, children, and friends), sex, finances, etc., and women felt it was too intrusive and too long (48 items). They reported that they thought the general well being scale was redundant with other measures of distress they answered in the questionnaire and again was too long (38 items). Indeed the questions were a different way of measuring anxiety, tension, depression, etc. These three measures were placed farther back in the questionnaire and may have placed a burden on women by the length of the questionnaire. In future research, using shorter measures may be less burdensome and a better way to obtain meaningful responses. Perhaps this is why global life satisfaction was significantly improved in the treatment condition at time 4. This measure had only five items and was not redundant with any other measures. We have yet to finish coding the Patient Centered Methods. Once this is finished we plan to compare it with the life satisfaction scale and also use both of these measures in looking at adherence to screening.

In terms of adherence to screening behaviors, there were no differences in clinical breast examination and breast self-examination (BSE). This was somewhat explainable in that BSE was never performed by 25% of either the treatment or control condition. Women frequently hear in the media that BSE does not decrease mortality and so they should focus on having mammograms and clinical breast examinations. As for the lack of differences in clinical breast examination adherence, the recommendation of every six months may be more problematic than having one every year (as do women in the general population). Women tend to come in for a clinical breast examination at the same time they come in for their mammogram. In other words, women do not make the extra trip for a clinical breast examination every six months. While we were able to improve adherence with annual mammography, we were not able to get women to come in every six months for a clinical breast examination. The most significant impact of adherence to screening behaviors was for mammography, which is one of the best early detection methods for breast cancer. Women in the treatment condition were significantly more adherent to mammogram recommendations than women in the control condition. Further sub-analyses will be conducted to explore the mechanisms of our significant findings. Once the Patient Centered Methods, or changes in women's' goals over the course of time, can be analyzed, more questions may be answered.

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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 treatment arm 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 treatment (N=180) or control (N=180) arm for a total of eighteen cycles (N=360), with new intervention groups (treatment arm) 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 treatment (intervention group) and control arms.
- c. Data entry begins in month 5.

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

- a. An intervention group (treatment arm) 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 treatment arm.
- c. Quality checks on consistency and accuracy of content of sessions are performed through the use of audio and videotapes.

Task 5. Data analyses– Months 44-48:

- a. Preliminary data analyses are begun in month 44.
- b. Tests of differences between treatment and control arms on several variables (e.g., age, referral source, prior screening behavior, and 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 – number at each point in time.

	Recruited	Agreed to Participate	Time 1	Time 2	Time 3	Time 4
Year 01	170	101	83	75	65	68
Year 02	200	82	25	11	10	9
Year 03	125	67	40	26	23	26
Year 04	240	159	99	68	55	45
Total Number	735	409	247	180	153	148

Table 2. Number of women in treatment and control arms at each assessment time.

	Baseline Time 1	Six Weeks Time 2	Six Months Time 3	One Year Time 4
Treatment Arm	139	83	65	65
Control Arm	108	97	88	83

Table 3. Demographics of study participants (N=247)

Variable	Treatment (N=139)	Control (N=108)	
Age	Mean=42.17 (range from 22-76)	Mean=45.53 (range from 23-75)	$p=.024$
Marital Status	Number (%)	Number (%)	
Single or never married	49 (35)	23 (21)	
Married or living as married	66 (48)	66 (61)	
Separated or divorced	20 (14)	12 (11)	
Widowed	2 (1.5)	5 (5)	
Other	2 (1.5)	2 (2)	
Ethnic/Racial			
White	123 (88)	96 (89)	
African American	8 (6)	2 (2)	
Hispanic	6 (4)	5 (5)	
Asian	0 (0)	3 (3)	
Other	2 (2)	2 (2)	
Grade			
Less than high school	1 (1)	0 (0)	
High school or GED	5 (4)	14 (13)	
Technical/Vocational	1 (1)	1 (1)	
Some college	18 (13)	19 (18)	
College	56 (40)	41 (38)	
Graduate school	47 (34)	23 (21)	$p=.06$
Post-graduate school	11 (7)	10 (9)	
Employment			
Full time	81 (58)	59 (55)	
Part time	23 (16)	19 (17)	
Retired	13 (9)	11 (10)	
Homemaker	12 (9)	12 (11)	
Disabled	1 (1)	0 (0)	
Student	5 (3)	3 (3)	
Unemployed	4 (3)	4 (4)	
Occupation			
Semi-Skilled	2 (1)	0 (0)	
Clerical	7 (5)	14 (13)	
Mid-Level Manager	54 (39)	43 (40)	
High-Level Manager	50 (36)	32 (30)	
Executive/Professional	13 (9)	9 (8)	
Other	13 (9)	10 (9)	

Table 4. Risk levels of study participants (N=247)

Medical (Objective) Risk levels	Treatment Arm (%)	Control Arm (%)	
Medical risk categories			
Low: 13 - 19%	40 (28.8)	29 (26.9)	
Moderate: 20 -34%	48 (34.5)	35 (32.4)	
High: 35-50%	51 (36.7)	44 (40.7)	
Medical risk continuum			
13% to 50% based on family history (Mean)	30.14	29.72	
Perception of Risk (Subjective)	Treatment Arm (%)	Control Arm (%)	
Perception of risk - categorization of accuracy			
Underestimators	12 (8.8)	12 (11.3)	
Accurate perception	22 (16)	18 (17)	
Overestimators	105 (75.2)	78 (71.3)	
Perception of risk of developing breast cancer (range from 0% to 100%) (Mean)	55.96	56.81	
Perception of risk over four assessments:			
	Treatment Arm (N)	Control Arm (N)	p
Time 1	55.96 (139)	56.81 (108)	ns
Time2	49.45 (83)	57.34 (97)	.02
Time 3	44.09 (65)	57.48 (88)	.001
Time 4	48.25 (65)	55.54 (83)	.07 (marginal significance)

Table 5. Screening Behaviors for Breast Cancer

Screening Behaviors	Treatment (%)	Control (%)
Breast self-examination (BSE)		
Yes	104 (75)	80 (74)
No	35 (25)	28 (26)
BSE-how often in the past six months		
from 0 to 180 times (both arms)	Mean = 7 times; Median = 3	
Never	35 (25)	27 (25)
Less than monthly	63 (45)	54 (50)
Monthly	23 (17)	16 (15)
More than monthly	18 (13)	11 (10)
Clinical breast examination (ever had one)		
Yes	139 (100)	107 (99)
No	0 (0)	1 (1)
Clinical breast examination adherence (Time 1)		
(within the last six months)		
Yes	95 (69)	69 (64)
No	44 (31)	39 (36)
Mammogram (ever had one)		
Yes	128 (92)	102 (94)
No	11 (08)	6 (6)
Mammogram adherence (Time 1)		
(adherence to age recommended guidelines)		
Yes	113 (81)	95 (88)
No	26 (19)	13 (12)

Table 6. 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	7.60	8.77	8.72	8.73
Control arm	7.63	7.78	8.09	7.93
Risk factors for breast cancer				
Treatment arm	8.19	8.88	8.83	8.88
Control arm	8.06	8.07	8.15	8.00
Breast cancer anxiety				
Treatment arm	22.66	19.37	18.32	17.02
Control arm	20.67	22.69	21.74	19.88
General anxiety				
Treatment arm	37.80	35.77	36.95	34.32
Control arm	40.48	41.45	40.17	40.37
Depression				
Treatment arm	11.64	11.23	11.78	10.11
Control arm	14.30	15.13	13.85	13.38

APPENDIX C

Perception of Breast Cancer Risk

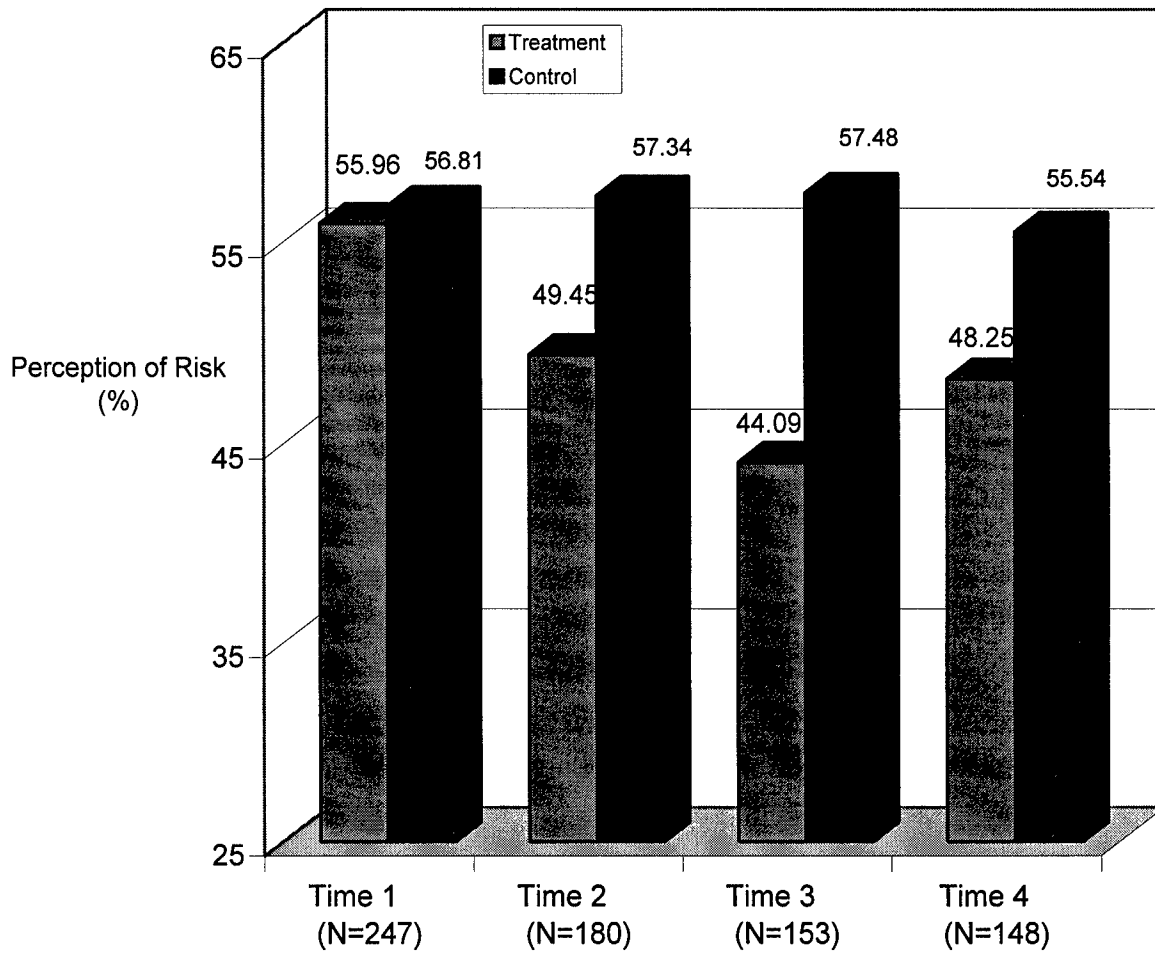


Figure 1. No difference between groups at Time 1. There was a significant difference between the groups at Time 2 ($p < .03$) and Time 3 ($p < .001$), and a marginal significance at Time 4 ($p < .07$).

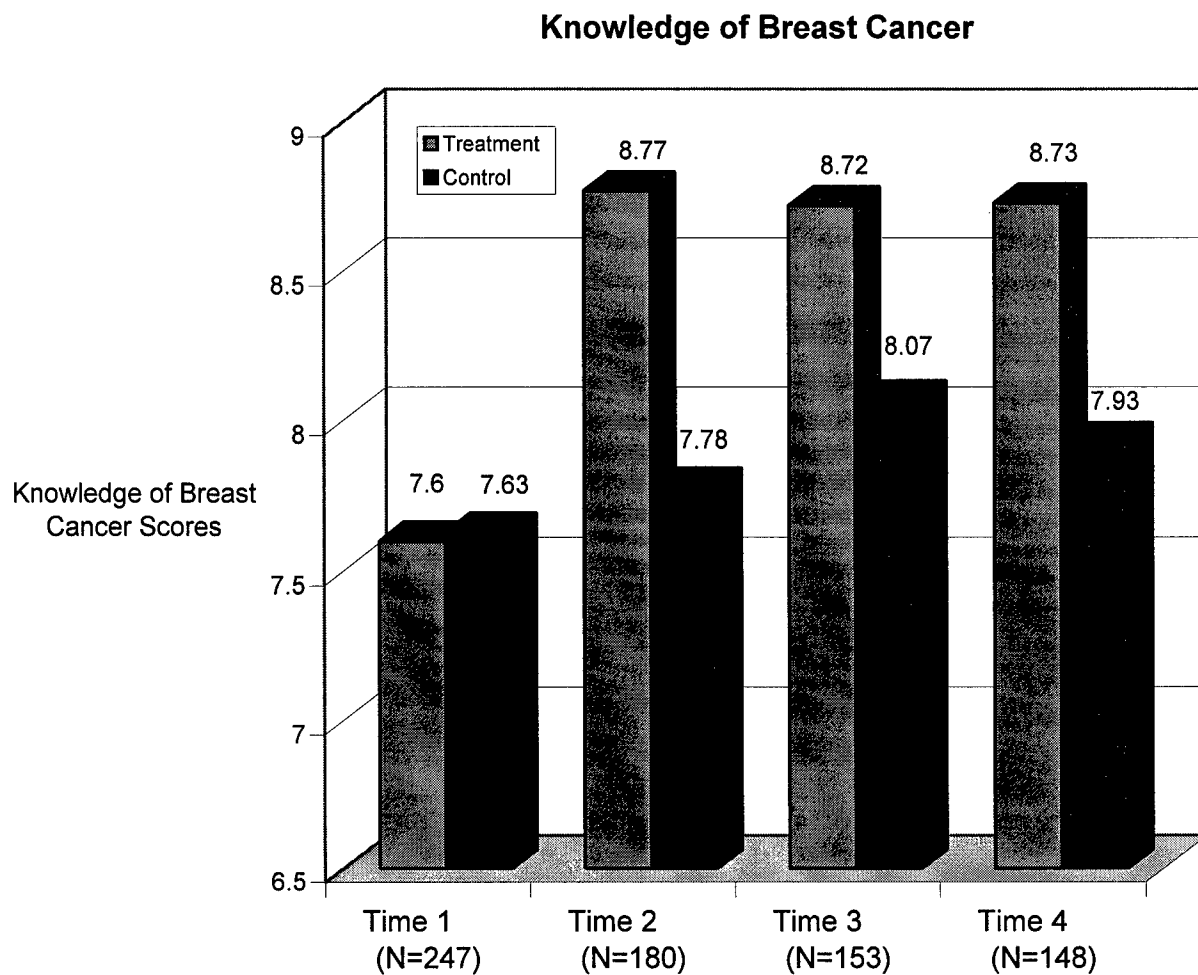


Figure 2. No difference between groups at Time 1. There was a significant difference between the groups at Times 2 ($p < .001$), 3 ($p < .003$), and 4 ($p < .002$).

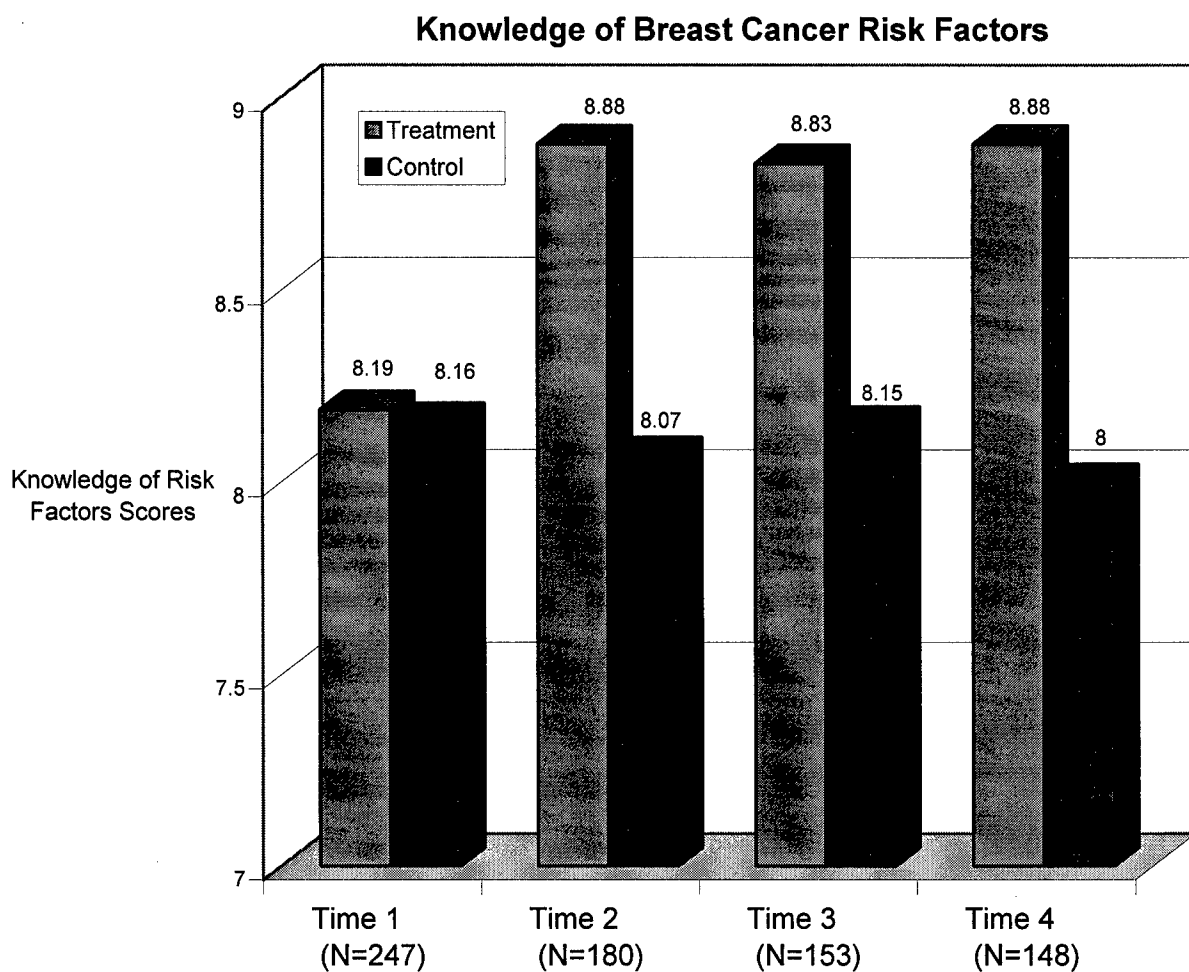


Figure 3. No difference between the groups at Time 1. There was a significant difference between the groups at Time 2, Time 3, and Time 4 ($p < .001$).

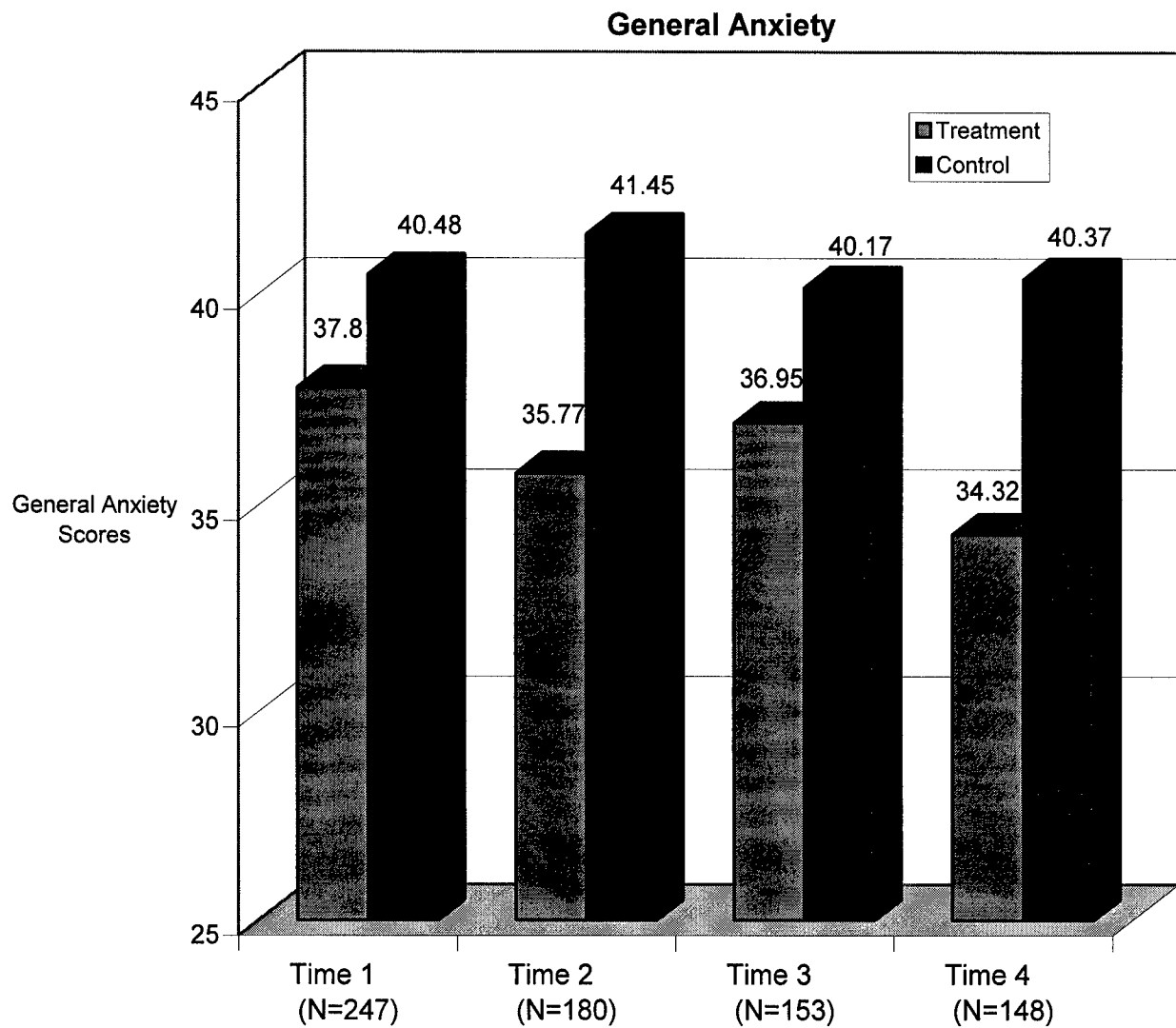


Figure 4. There were no significant differences at Time 1. There was a significant difference between the groups at Time 2 ($p < .003$) and Time 4 ($p < .03$).

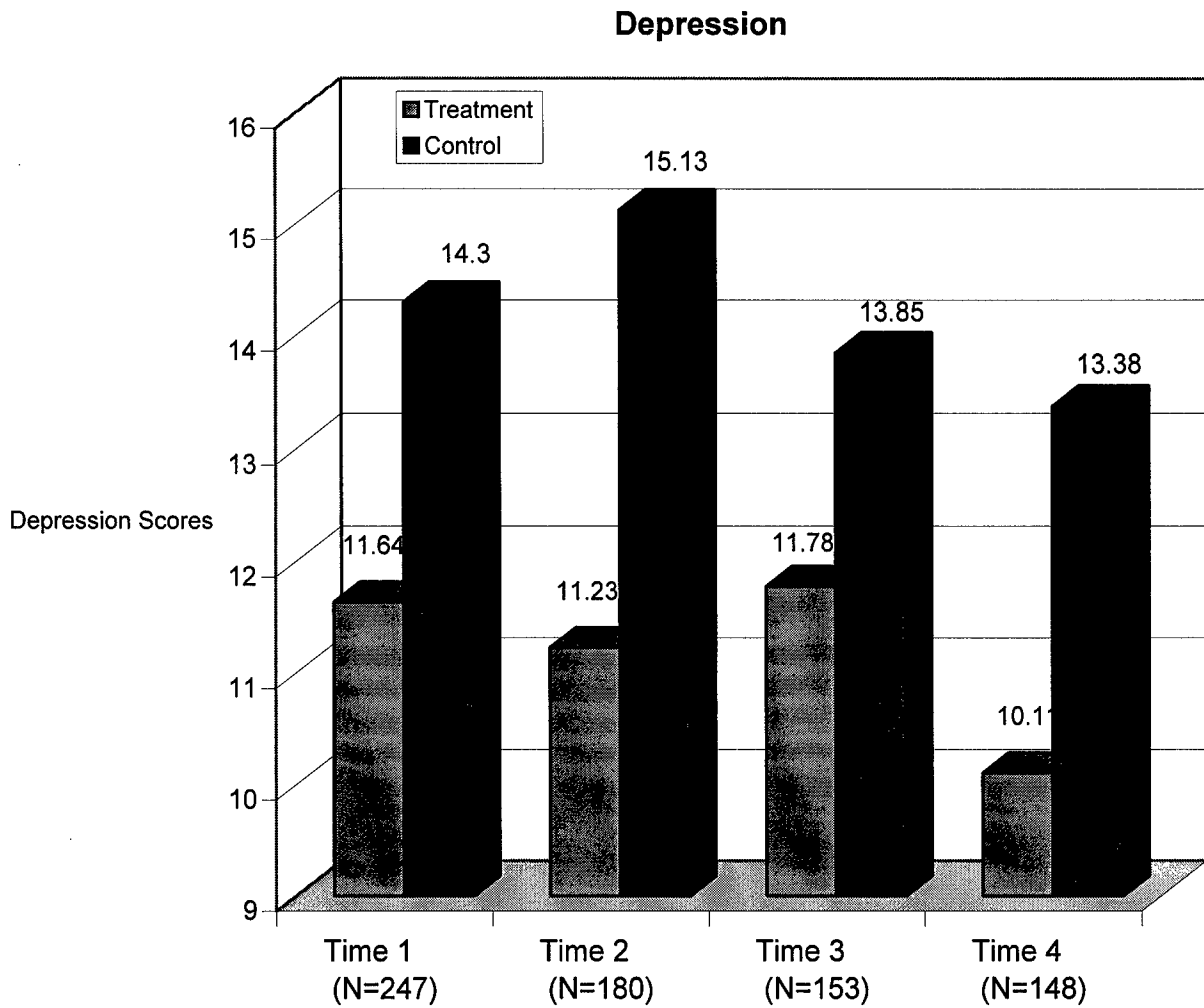


Figure 5. There was a significant difference between the groups at Time 1 ($p < .05$), Time 2 ($p < .02$), and Time 4 ($p < .05$).

Breast Cancer Anxiety Scores by Time

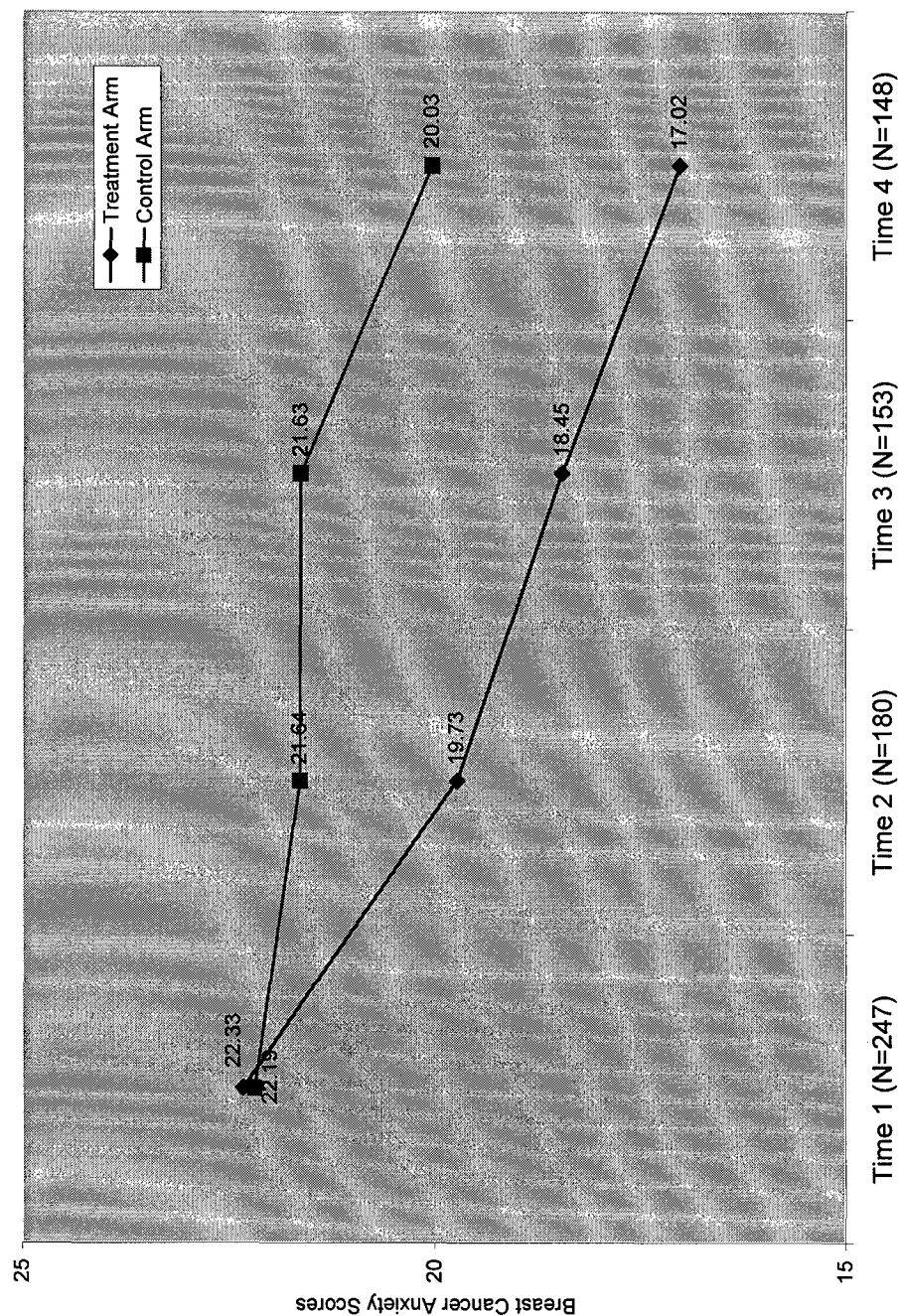


Figure 6. There were no significant differences between the groups at Time 1. There is a significant difference between the groups at Time 2 ($p < .05$) and a marginal difference at Time 3 ($p < .07$).

APPENDIX D

List of Personnel Receiving Pay from this Research

Salaried Staff

Kathryn M. Kash, Ph.D.

Annie Hernandez, M.A.

Melissa Gronert, M.A.

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Barbara Levine, Ph.D.

Gail Winters, M.S.W.

EDUCATIVE AND COGNITIVE GROUPS IN ONCO-GENETICS

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A randomized controlled trial of a psychoeducational group intervention was conducted. The specific aims were to examine the impact of the intervention on knowledge of breast cancer and risk factors, breast cancer beliefs, breast cancer anxiety, coping skills, quality of life and adherence to screening. The intervention components included social support enhancement, education, cognitive restructuring, and problem solving. Group sessions (5 to 10 women in each group) met for one and half-hours each of six weeks, with six-month and one year booster sessions. Interviews were conducted prior to randomization (Time 1), at the end of the six-week intervention (Time 2), at six months (Time 3) and one year (Time 4). 247 healthy, asymptomatic women at high risk for breast cancer (control condition N=108; treatment condition N=139) participated in the study. The mean age is 43, primarily white (90%), with 39% having a college education. At baseline, 73% of women overestimated their risk, 17% accurately estimated their risk and 10% underestimated their risk for developing breast cancer. A repeated measures analysis of variance (ANOVA) found a significant reduction in breast cancer specific anxiety within the treatment condition from Time 1 to Time 4 ($p < .02$), and a decrease in perception of risk ($p < .01$). Women in the treatment condition significantly improved their knowledge of breast cancer ($p < .02$) and risk factors for breast cancer at Time 4 ($p < .002$). ANOVA found that women in the treatment condition used more active coping and less behavioral disengagement than women in the control condition ($p < .04$). A logistic regression analyses found that women in the treatment condition adhered to age appropriate mammogram recommendations at Time 4 ($p < .01$) more than women in the control condition. These findings suggest that the intervention helps to decrease anxiety, increase knowledge, improve coping strategies, and improve adherence to mammography.

Plenary Speaker at the XVIIIth Congress of the French Society of Psycho-Oncology
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26 Aug 02

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2. Point of contact for this request is Ms. Kristin Morrow at DSN 343-7327 or by e-mail at Kristin.Morrow@det.amedd.army.mil.

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