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TITLE: Cognitive-Affective Predictors of the Uptake of, & Sustained Adherence to Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

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14. ABSTRACT Approximately 20-30% of women develop lymphedema (LE) following breast cancer treatment. Effective symptom management requires that women recognize early signs of lymphedema, and maintain precautionary practices over time. Data indicates that knowledge and use of symptom minimization precautions are poor. Little is known about how breast cancer survivors perceive their LE risk, and the cognitive-affective factors that promote the uptake and adherence to LEsymptom minimization precautions. Guided by the Cognitive-Social Health Information Processing (C-SHIP) model, we conducted a longitudinal study, to assess barriers and facilitators associated with knowledge and adherence to LE symptom-minimization practices among breast cancer survivors. We are exploring the mediating role of cognitive-affective variables, and the moderating role of attentional style, on knowledge, uptake and adherence of symptom minimization precautions at baseline, 6-, and 12-month follow-up post treatment. Little is known about how individuals understand and make sense of these issues, and few resources have been developed to address this problem. Through systematic investigation of these factors, we will be able to develop a profile of the role of cognitive-emotional processing in the management of lymphedema. These data will ultimately be used to design and evaluate enhanced management protocols, tailored to the individual's cognitive-emotional signature.					
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INTRODUCTION

Improvements in breast cancer treatments have greatly reduced mortality rates (Petrek 2000; Passik 1998; Erickson, 2001; Tasmuth 1996). The number of breast cancer survivors continues to increase due to improved methods of detection and treatment. Consequently, more women are dealing with the impact of lymphedema on their everyday lives and well-being (Armer, J.M. et al., 2005; Jeffs, 2005). Thus, it has been recognized that greater attention needs to be given to survivorship issues, such as the management of post-treatment side effects such as lymphedema (LE), that compromise physical and psychological functioning and quality of life (Passik & McDonald 1998; Erickson, Pearson, et al., 2001; Brenes, Mihalko, et al., 2001). Yet, little is currently known about women's knowledge and practice of precautionary behaviors to prevent or lessen the impact of this condition (Coward, 1999; Clark, Wasilewska, et al., 1997). Guided by the Cognitive-Social Health Information Processing (C-SHIP) model (Miller, Shoda, et al., 1996; Miller & Rodoletz, 1996; Miller & Diefenbach, 1998), the overarching objective of the present study is to explore the cognitive-affective factors associated with knowledge about LE symptom-minimization practices, their initiation, and the sustained maintenance of these practices among breast cancer survivors currently unaffected by LE.

The specific aims of this project are as follows:

Aim 1: To delineate the underlying cognitive-affective mediating mechanisms (i.e., women's self-construals, expectancies, values and goals, affects, and self-regulatory strategies) that facilitates or undermine the uptake of LE symptom-minimization practices, and their sustained adherence over time. These cognitive-affective patterns will be assessed and related to levels of knowledge and the practice of symptom minimization precautions, at three points in time: baseline (within 6 weeks post-surgery), and again at 6- and 12-month follow-up post-baseline. It is hypothesized that greater LE-knowledge, greater intent to establish practices and/or adhere to existing practices, as well as greater uptake of additional practices and sustained adherence will be associated with heightened risk perceptions; greater self-efficacy, greater perceived benefits of, and fewer barriers to, enacting symptom minimization practices; lower LE-related distress; and greater ability to perform self-regulatory strategies.

Aim 2: To assess the moderating role of stable differences in the individual's cognitive-emotional profile or "psychological signature" on the uptake and adherence of LE symptom minimization practices and personalized cancer threats and challenges, over time (Miller, 1995). Specifically, it is predicted that high monitors (i.e. those who attend to, focus on, and personalize cancer threats) will show greater knowledge, uptake, and adherence than low monitors (i.e. those who distract from and downplay the significance of cancer threats and challenges).

To accomplish these objectives, we conducted a longitudinal study of LE symptom- free women who are in remission following sentinel or axillary node surgery for Stages I-

IIIa, primary breast cancer ($N = 104$). From two recruitment sites, the Breast Evaluation Clinic at Fox Chase Cancer Center and Virtua Memorial Hospital, a nurse educator and a primary site coordinator, Dr. Eric Miller, respectively, made potential participants aware of the study through the provision of a leaflet describing involvement in the study upon registration for their clinic appointment. A member of the FCCC research team reviewed FCCC's electronic medical records, the Soarian Clinical Access Database to identify clinic patients and to determine patient eligibility (i.e., diagnosis, surgery status). The research staff then contacted eligible patients by telephone to describe the study, solicit participation, and obtain verbal consent for participation. Eligible, consenting participants then complete psychosocial measures and a written informed consent at their next post-surgery follow-up appointment, usually within two weeks of initial contact and verbal consent. Upon completion of the baseline questionnaire, each participant was given a copy of the American Cancer Society Lymphedema booklet containing hand and arm care recommendations following surgery or radiation therapy for breast cancer. The suggested precautionary actions that they can follow were also briefly summarized verbally to each participant. Relevant psychosocial and behavioral variables were reassessed by telephone at each of the follow-ups, 6- and 12-months post-baseline. Participants who experienced a breast cancer recurrence were excluded from follow-up and were replaced in the study design.

BODY

During year 1, the plan was to initiate Tasks 1 and 2 and complete Task 1, as outlined in our approved Statement of Work.

The specific aims of Task 1 were:

- a. Modify provisional measures according to Institutional Review Board (Months 1-2)
- b. Establish Recruitment Procedures/Train Staff (Months 1-2)

Task 1 was accomplished according to schedule.

The aims of Task 2, were:

- a. Recruit Participants, Conduct Longitudinal Study (Months 2-33)
- b. Establish Database and Enter Data (Months 2-33)

Task 2 longitudinal data collection is still ongoing. Database construction has been completed and follow-up data entry is ongoing.

In July of 2006, Fox Chase Cancer Center (FCCC) sent a formal request to further extend the period for additional 12-months to fully complete Task 2 and Task 3 for no additional funding support. The extension has allowed for the continuation of recruitment and the completion of follow-up data collection.

The aims of Task 3, initiated in year 1 and continued in year 3 were:

- a. Analyze Preliminary Data (baseline to 6- (Months 4-33)

month and 12-month follow-ups)

b. Annual Reports Prepared (Months 4-33)

As of late, follow-up data is still being collected at the 6- and 12-month time points. Since all data collection has not been completed, we offer the following preliminary findings.

To date, preliminary baseline data have been entered and descriptive statistics have been performed. Since August 15, 2003 a total of 1449 patients have visited the Breast Evaluation Clinic at FCCC. Since August 2003, 232 (16%) of the 1449 clinic patients have been identified as eligible for the study (i.e., early stage at diagnosis, LE symptom free, receiving treatment at FCCC). To date, of the 232 eligible women, our research team has successfully contacted 146 by using a maximum of 20 attempts to contact women by telephone. Of the women contacted, 132 provided verbal consent to participate. Sixty-nine of the women contacted declined participation with 48 women stating that they were “not interested” with no additional explanation provided and 21 women cited non-study specific related factors (i.e., language/communication barriers, already participating in another research study, lack of transportation) as reasons for non-participation. Only 81 of the 132 verbal consenting eligible participants completed baseline data. Collection of six-month follow-up questionnaires began in August 2003 and 69 questionnaires have been completed. Sixteen participants failed to complete their 6-month follow-up in the allotted time. Collection of 12-month follow-up questionnaires began in April 2004 and, to date, 48 of the expected 64 questionnaires have been collected. Telephone calls are placed on a regular basis to collect the remaining follow-up questionnaires.

At the Virtua site, 35 participants signed informed consents, however, only 23 participants returned completed baseline questionnaires. Of the 23 that have completed baselines, 7 have completed 6-month follow-up questionnaires and 4 women have 12-month follow-ups due in the near future.

BACKGROUND CHARACTERISTICS OF STUDY PARTICIPANTS

A total of 104 participants completed baseline measures. The current section provides a quick view of the background characteristics collected at baseline. Table 1 represents basic characteristics of women from both research sites (e.g. Breast Evaluation Clinic and Virtua Memorial Hospital). Sample characteristics from these preliminary data include: a mean age of 55.43 years (range 32-81 years), 82.7% Caucasian, 74% married or living with a partner, 89.1% have children, 42.4% have earned a college degree or higher, and 72.1% have an annual household income of \$45,000 or greater. Approximately 43.3% of the sample was diagnosed with Stage 1 breast cancer and 26% were diagnosed with Stage 2 breast cancer. With regard to treatment methods the majority of the sample (96%) received multiple treatment methods (lumpectomy and lymph node dissection 66%; lumpectomy, mastectomy, and dissection 7.6%; lumpectomy, dissection and radiation

16.3%; mastectomy and dissection 34.6%; mastectomy, dissection, and chemotherapy 18.2%). About half (51.9%) of the lymph node dissections were sentinel node, 20.2% were axillary node and 8.7% reported having both sentinel and axillary dissection.

Table 1: Patient Characteristics

Patient Demographics (N=104)		
Age, years (median (min, max)): 54 (32, 81)		
	N	Percentage (%)
Race		
White	86	82.7
Black	15	14.4
Asian	1	1
Missing/Refused	2	1.9
Ethnicity		
Hispanic or Latino	2	1.9
Non-Hispanic or Latino	97	93.3
Missing/Refused	5	4.8
Marital Status		
Single, never married	10	9.6
Married/Partnered	77	74
Separated	1	1
Divorced	7	6.7
Widowed	9	8.7
Education		
High School or Below	29	27.9
Vocational/Technical School	5	4.8
Undergraduate College/University	44	42.3
Graduate/Doctoral Degree	25	24.1
Missing/Refused	1	1
Treatment History*		
Lumpectomy	73	70.2
Mastectomy	37	35.6
Lymph node dissection	97	93.3
Chemotherapy	43	41.3
Radiation	20	19.2

* Overlapping categories

LYMPHEDEMA-RELATED KNOWLEDGE

Lymphedema-related knowledge was assessed by a theory-based 19-item true/false questionnaire. The theory-based knowledge information was drawn from the FCCC Patient Information Guidelines for post-operative Arm and Hand Care. These guidelines were current when data collection was initiated in 2003. At baseline, 104 women completed knowledge questionnaires, and 43.3% of those women answered majority of questions (at least 17 out of 19) accurately. Three women (2.9%) did not answer a

significant percentage of the questions; therefore they were not included in the following analyses. The mean knowledge score was 15 out of 19. At least 96.2% of the women responded true to the belief that keeping your LE affected arm very clean and well moisturized, and avoiding blood pressure readings and injections on the affected arm are suggested strategies for minimizing LE risk. However, 59.6% responded true to the belief that it is acceptable to wear tight jewelry around the affected fingers and arm and, 55.8% of the women responded true to the belief that an inflammation or infection in the affected arm is not a sign of lymphedema. Four and 6 women, respectively, choose not to answer the latter two questions, suggesting even more uncertainty regarding LE-related knowledge. Table 2 reflects selected items that women responded as true. Since early action to treat lymphedema is essential to managing this condition, a lack of awareness about typical symptoms and onset of lymphedema among this sample is concerning, and suggests a need for more effective patient education approaches regarding lymphedema risk. Following baseline assessment, all study participants were given an information booklet outlining lymphedema risk for breast cancer patients. This publication aids in summarizing suggested precautionary measures one should uptake in order to minimize risk of developing lymphedema. Preliminary analysis of the 6-and 12-month data reveal a significant increase in levels of lymphedema-related knowledge at 6-months (mean = 17.2) compared to baseline (mean = 12.7) [$t=-8.14$, $df=74$, $p<0.001$] and a significant decrease from 6-months to 12-months (mean = 16.0) [$t=3.32$, $df=47$, $p<0.005$]. Knowledge, however, is not indicative of whether women are adhering to these suggested strategies or heeding warning signs and symptoms.

Table 2: Lymphedema Related Knowledge

Lymphedema Knowledge Items**	
It is recommended that you keep your affected arm very clean and well moisturized	96.2% True
It is advisable to avoid blood pressure readings and injections on the affected arm	96.2% True
It is advisable that you always wear gloves when doing housework or gardening	94.2% True
It is acceptable to wear tight jewelry around the affected fingers or arm.	59.6% True
When manicuring your nails, it is recommended that you always cut the cuticles.	59.6% True
An inflammation or infection in the affected arm is not a sign of lymphedema.	55.8% True

** Findings are based on available data from baseline questionnaire (N=104)

UPTAKE OF LYMPHEDEMA MINIMIZATION PRACTICES

Using a dichotomous yes/no item format, baseline data show that uptake to certain LE-risk minimization strategies at baseline is high, especially those that entail more passive acceptance strategies. Specifically, 93.3% are avoiding tight jewelry around the affected fingers or arms; 89.4% of the women are currently avoiding blood pressure readings and

injections on the affected arm; 86.5% are keeping their affected arm very clean and well moisturized; 79.8% are avoiding exposing the affected arm to the sun; and 78.8% are avoiding heavy lifting and carrying handbags with over the shoulder straps. However, 50% of the women are not using an electric razor to remove hair under their affected arm, 51% are not wearing gloves when doing housework or gardening, and 28.8% are not avoiding extreme temperature changes when bathing or washing dishes. These are three important, and rather routine, behaviors suggested to prevent LE that require more active initiation. Moreover, 18.3% reported that they do not consult with the doctor if they have any slight increase of swelling in the affected arm, hand, fingers, or chest wall. This may be related to the participants' lack of awareness of lymphedema symptoms as identified in the assessment of lymphedema-related knowledge. Table 3 displays the top utilized minimization practices women reported at baseline. After baseline assessments are completed, participants are given further information regarding suggested guidelines and precautionary action they can take to minimize their LE risk. Preliminary analyses of 6- and 12-month data indicate that 39.7% (29 out of 73) and 42.6% (20 out of 47) reported, respectively, that the booklet was useful to them. In addition, the 6- and 12-month data reveal a significant increase in the number of preventive strategies practiced at 6-months (mean = 10.4) compared with baseline (mean = 9.3) [$t=-2.52$, $df=75$, $p<0.05$]. No differences were found between 6- and 12-months on the number of preventative strategies practiced.

Table 3: Uptake of Lymphedema Minimization Practices

Lymphedema-Related Practices**	
Avoiding wearing tight jewelry around the affected fingers and arms	93.3%
Wearing loose dresses or shirt/blouse sleeves	92.3%
Avoiding trauma in the affected arm	91.3%
Currently avoiding blood pressure readings and injections on the affected arm	89.4%
Keeping their affected arm very clean and moisturized	86.5%
Avoiding exposing affected arm to the sun	78.9%

** Findings are based on available data from baseline questionnaire (N=104)

PSYCHOSOCIAL PROFILE OF STUDY PARTICIPANTS

Attentional Style

Mean scores for the Monitor-Blunter Style Scale (MBSS) are comparable to those found in related research (Mean monitoring score=9.02, SD=2.72; Mean blunting score=4.12, SD=2.19). High and low monitors are relatively split among this sample (53.8% and 45.2%, respectively).

Background Affect (Depression & Anxiety)

As part of the psychosocial profile, we assessed the depressive symptomology of the women with the Centre for Epidemiological Studies scale for Depression (CES-D)-short form. Participants that score greater than 10 on this scale are considered depressed. At baseline, 28.8% of the women scored above 10 and were considered to have been depressed. In addition, the Trait Anxiety scale of the Spielberger State-Trait Anxiety Inventory (STAI) was also administered to assess relatively stable individual differences in anxiety proneness. The mean STAI score was 41.15; the scores ranged from 20 to 67 points.

Risk Perceptions

At baseline, participants tended to underestimate their risk of developing LE. Specifically, when asked to rate their risk for developing LE on a 5 point Likert-type scale ranging from 1="much lower than average" to 5="much higher than average", 83.7% of the sample reported that they were at an average to lower than average risk for developing LE, despite the fact that in all cases the lymph node surgery they received placed them at an increased risk in comparison to breast cancer patients who do not have lymph node dissection or radiation. Moreover, of the women sampled who had received axillary node dissection (N=21), a treatment associated with an even higher risk for LE than sentinel surgery, 71.4% reported that they had an average to below average risk for LE despite the higher risk for LE development associated with this type of surgery. The actual risk of developing LE following axillary lymph node dissection increases to 38% to 56% when adjuvant radiation is provided, however no participants have had this treatment combination.

Expectancies

With respect to outcome related expectations, using a 5 point Likert-type scale ranging from 1="not at all" to 5="very much", a subset of women at baseline endorsed that LE is a serious condition (i.e., 32.7% "quite a bit"; 46.2% "very much"), that developing LE would interfere with their lives (i.e., 42.3% "quite a bit"; 26% "very much"), and that LE-related problems would last a long time (i.e., 29.8% "quite a bit"; 20.2% "very much"). A majority of the women endorsed a belief that there are measures they can take to prevent LE (i.e., 43.3% "quite a bit"; 15.4% "very much") and that practicing the recommended hand and arm procedures will minimize their chances of developing LE (i.e., 43.3% "quite a bit"; 28.8% "very much").

With regard to self-efficacy expectations, using the same Likert-type scale, a majority of the sample indicated that they did "not at all" believe that whether or not they developed LE was God's will (52.9%) or that the development of LE is just luck (54.8%), implying that they did not take a fatalistic view of LE development. A majority of the sample were certain that they could effectively adhere to recommended procedures to minimize LE risk (i.e., 41.3% "quite a bit"; 26.9% "very much") and that they would be regularly checking themselves for signs of LE (i.e., 32.7% "quite a bit"; 23.1% "very much"). The data indicate that although a majority of the women have positive expectations regarding LE preventive actions and a belief in their ability to carry them out, there is a large subset

of individuals for whom this may not be the case. Table 4 displays reported frequencies of responses on selected expectancies and beliefs items.

Table 4: LE- Related Expectancies**

	Not at all (%)	A little bit (%)	Somewhat (%)	Quite a bit (%)	Very much (%)
Do you believe that LE is a serious condition?	0	2.9	16.3	32.7	46.2
Do you believe that LE would interfere with life?	1.9	1.9	26	42.3	26
Do you believe LE-related problems would last a long time?	3.8	8.7	35.6	29.8	20.2
Do you believe practicing the recommended arm and hand precautions will minimize your chances of developing Lymphedema?	1.9	4.8	18.3	43.3	28.8
Do you believe that whether or not you develop lymphedema is god's will?	52.9	11.5	17.3	6.7	9.6
To what extent do you believe that you can effectively adhere to recommended arm and hand procedures to minimize lymphedema risk?	1	3.8	24	41.3	26.9

** Findings are based on available data from baseline questionnaire (N=104)

Distress

As measured by responses on the Revised Impact of Events Scale (RIES), participants reported low to low-moderate LE risk-related distress, as defined by the presence of intrusive and avoidant risk-related ideation (Mean intrusion scale score=2.97, SD=5.05; Mean avoidance scale score=5.25, SD=7.67).

Using a 5-point Likert-type scale ranging from 1="not at all" to 5="very much", women were asked to rate their LE-risk related affect. Overall, women reported low levels of risk-related affect. Table 5 displays reported frequencies of responses on selected distress items. Specifically, a majority of women endorsed "not at all" or "a little bit" when asked if they were experiencing thoughts of LE that affected their mood or ability to perform daily activities (mood: 59.6% "not at all", 23.1% "a little bit"; ability to perform daily activities: 70.2% "not at all", 17.3% "a little bit"), or the experience of LE-risk related worry (36.5% "not at all", 44.2% "a little bit"), sadness/depression (47.1% "not at all", 31.7% "a little bit"), scared/anxious (38.5% "not at all", 39.4% "a little bit"), or anger (64.4% "not at all", 18.3% "a little bit"). However, despite this tendency to manage LE-risk related emotions, there is a subset of women for whom risk related affect was more present. For example, there is a group of women who endorse "somewhat", "quite a bit", or "very much" when asked if they have LE-related thoughts that have affected their mood (4.8% "somewhat", 11.5% "quite a bit") or daily activities (6.7% "somewhat", 3.8% "quite a bit", 1% "very much"), or feel worried (7.7% "somewhat", 7.7% "quite a bit", 2.9% "very much"), sad/depressed (12.5% "somewhat", 4.8% "quite a bit", 2.9%

“very much”), scared/anxious (12.5% “somewhat”, 4.8% “quite a bit”, 3.8% “very much”), or angry (10.6% “somewhat”, 1.9% “quite a bit”, 3.8% “very much”) regarding their LE risk. Moreover, a number of women report that they are “somewhat” (22.1%), “quite a bit” (9.6%), or “very much” (1%) worried about knowing when to contact the doctor about any LE symptoms they experience. Paired t-tests revealed significant decreases in levels of lymphedema-related ability to perform daily activities from baseline (mean=1.59) to 6-months later (mean=1.28) [$t=2.48$, $df=75$, $p<.05$]. In addition, compared with baseline, at 6-months participants reported fewer cases of feeling LE risk-related worry (baseline=, 6-months=) [$t=2.073$, $df=75$, $p<0.05$]; feelings of sadness or depression in relation to lymphedema risk (baseline=1.97; 6-months=1.56) [$t=2.49$, $df=74$, $p<.05$]; and feeling scared/anxious regarding lymphedema risk (baseline=2.07; 6-months=1.67) [$t=2.29$, $df=75$, $p<.05$]. Further, participants reported fewer cases of feeling worried about knowing when to contact the doctor about LE symptoms at 6-months compared to baseline (baseline=2.11; 6-months=1.57) [$t=3.35$, $df=74$, $p<.005$]. No differences were found between 6-months and 12-months regarding any of the above affect items.

Table 5: LE-Related Distress**

	Not at all (%)	A little bit (%)	Somewhat (%)	Quite a bit (%)	Very much (%)
How often have thought about Lymphedema affected your mood?	59.6	23.1	4.8	11.5	0
How often have thought about Lymphedema affected your ability to perform your daily activities?	70.2	17.3	6.7	3.8	1
Have you been worried about you risk for lymphedema?	36.5	44.2	7.7	7.7	2.9
Have you felt sad or depressed when thinking about your risk for lymphedema?	47.1	31.7	12.5	4.8	2.9

** Findings are based on available data from baseline questionnaire (N=104)

Values and Goals

Overall, women reported placing a large degree of value on their physical appearance and physical functioning. Using a 5-point Likert-scale ranging from “not at all” to “very much,” the entire sample reported “functioning well” to be “quite a bit” (14.4%) to “very much” (82.7%) important to them. Similarly, the entire sample reported “feeling well” to be “quite a bit” (17.3%) to “very much” (80.8%) important to them. In addition, the majority of the sample reported the following to be “quite a bit” to “very much” important to them: the way in which they perceive their own bodies (46.2% and 29.8%, respectively), feeling attractive (35.6% and 31.7%, respectively). Eight-five percent of the baseline sample reported the way in which their partner perceives their body to be “somewhat” (25%), “quite a bit” (39.4%), or “very much” (21.2%) important to them. Table 6 displays reported frequencies of responses on selected values and goals items.

Table 6: LE-Related Values and Goals**

	Not at all (%)	A little bit (%)	Somewhat (%)	Quite a bit (%)	Very much (%)
Importance of functioning well?	1	1	0	14.4	82.7
Importance of feeling well?	0	0	1	17.3	80.8
To what extent is the way you perceive your body important to you?	0	1.9	21.2	46.2	29.8
To what extent is the way your partner perceives your body important to you?	2.9	2.9	25	39.4	21.2

** Findings are based on available data from baseline questionnaire (N=104)

Self-Regulatory Strategies

Using a 5-point Likert-type scale ranging from 1=“not at all” to 5=“very much”, women were asked to rate their ability to manage LE-related thoughts and strategic plans to reduce their risk of developing LE. Table 7 displays reported frequencies of responses on selected self-regulatory strategy items. Overall, women reported a positive sense of control over their ability to manage LE-related feelings and the behaviors in which they were able to engage. Specifically, majority of the sample felt that they were “quite a bit” (37.5%) to “very much” (43.3%) able to make the necessary lifestyle changes in order to carry out recommended LE minimization precautions and that they were “quite a bit” (41.3%) to “very much” (31.5%) able to follow the recommended behaviors that may minimize LE symptoms. A majority of the sample felt that they were “quite a bit” (35.6%) to “very much” (35.6%) able to limit the amount of stress they experience when they perform the recommended symptom minimization practices, that they were “quite a bit” (34.6%) to “very much” (28.8%) able to limit the amount of stress they experience about their LE risk, and that they were “quite a bit” (30.8%) to “very much” (31.7%) able to calm themselves down when they experience anxiety or worry about developing LE. Paired t-tests revealed a significant increase in self-regulatory skills from baseline to 6-months with participants reporting being better able to calm down when feeling anxious about lymphedema risk (baseline=3.74; 6-months=4.16)[$t=-2.42$, $df=69$, $p<.05$].

Table 7: LE-Related Self-Regulatory Strategies**

	Not at all (%)	A little bit (%)	Somewhat (%)	Quite a bit (%)	Very much (%)
I am able to limit the amount of stress I experience about my lymphedema risk.	1.9	4.8	28.8	34.6	28.8
I am able to make necessary lifestyle changes to carry out recommended precautions to minimize lymphedema symptoms?	1.9	2.9	13.5	37.5	43.3

** Findings are based on available data from baseline questionnaire (N=104)

PLANNED ANALYSES FOR PRIMARY STUDY AIMS

Follow-up data collection is still ongoing for our partner site (Virtua Memorial Hospital). When data collection is complete, we will attempt to assess the main study goals. All data analyses will be conducted with the assistance of the Behavioral Research Core Facility (BRCF) at FCCC. For Aim 1 (*to delineate underlying cognitive-affective mediating mechanisms promoting the uptake of LE symptom-minimization practices, and their sustained adherence over time*), we plan to conduct the following analyses. The association of mediational units to each outcome will be assessed through logistic regression for adherence, uptake, maintenance, intention to adhere and likelihood of practice establishment outcomes and least squares regression for knowledge, and longitudinal assessment of the minimization practices. Adjustments will be made for relevant factors, such as age and disease stage, by including these variables as covariates in the regression models. For each minimization practice, a Mann-Whitney test will be used to compare persons who are and are not currently undertaking the practice in terms of each of the cognitive-affective variables (e.g., risk-related distress, perceived risk). In particular, we will conduct one-sided tests to determine if women practicing a given LE-precaution have, relative to those not engaging in the behavior, higher perceived vulnerability to LE, higher self efficacy and perceived benefits of, and lower barriers to, enacting symptom-minimization practices, lower LE-related distress and greater ability to perform self-regulatory strategies. Spearman rank correlation coefficients will assess the association between each cognitive-affective variable and each ordinal and continuous outcome.

For Aim 2 (*to assess the moderating role of monitoring attentional style on the uptake of, and adherence to, lymphedema symptom minimization practices over time*), we plan to conduct the following analyses. MBSS scores will be analyzed both by classifying persons as high or low monitors according to a median split of their MBSS scores, and as a continuous variable using the actual MBSS score. The association of attentional style to each outcome will be assessed through logistic (binary and ordinal outcomes) and least squares (continuous outcomes) regression. Adjustments will be made for relevant factors, such as age and disease stage, by including these variables as covariates in the regression models. A Mann-Whitney test will then be conducted to compare high and low monitors with respect to intention to adhere to each *LE* precaution. Specifically, we will conduct one-sided tests to determine whether high monitors have, on average, higher intention to adhere to recommended practices. The relationship between attentional style and intention to adhere to *LE* precautions will also be explored with Spearman rank correlation coefficients. To assess the relationship between attentional style and the uptake of precautions, a two-sample test of binomial proportions will determine if high and low monitors differ with respect to the proportion of women performing each, or at least one, practice. A Mann-Whitney test will assess whether high and low monitors differ in terms of each ordinal and continuous outcome.

KEY RESEARCH ACCOMPLISHMENTS

- 104 new participants have completed baseline measures, 76 completed 6-month follow-up questionnaires and 48 completed 12-month follow-up questionnaires since August 2003.
- Twice weekly, members of the research team accessed the FCCC electronic Soarian Clinical Access Database to identify new patients attending the Breast Evaluation Clinic at either site. Approximately, 5-10 new potential participants are identified on a weekly basis.
- Members of the research team continue to enter data from all study questionnaires as they are collected.
- The research team maintains an Access database to track participant follow-up. After a participant completes the baseline survey they are entered into the Access database and monitored to coordinate their follow-up interview dates.
- In an effort to enhance recruitment, in 2005, we extended recruitment to breast cancer patients receiving care at Virtua Memorial Hospital, in New Jersey.
- The FCCC IRB audited this study in February 2004 and found it to be in accordance with compliance regulations.

REPORTABLE OUTCOMES AND BIBLIOGRAPHY of PUBLICATIONS

We have compiled 5 papers that analyze literature on adherence and adjustment in breast cancer disease/risk context and integrated findings obtained with our guiding theoretical model.

- o Miller, S.M. & Sherman, K.A. (2004). Cancer screening. In N. Anderson (Ed.) The Encyclopedia of Health and Behavior. CA: Sage Publications.
- o Miller, S.M., Bowen, D. J., Campbell, M.K., Diefenbach, M.A., Gritz, E.R., Jacobsen, P.B., Stefanek, M., Fang, C.Y., Lazovich, D., Sherman, K.A., Wang, C. (2004). Current research promises and challenges in behavioral oncology: Report from the American Society of Preventive Oncology Annual Meeting. Cancer Epidemiology, Biomarkers and Prevention, 13, 171-180.
- o Miller, S.M., Fleisher, L., Roussi, P., Buzaglo, J.S., Schnoll, R.A., Slater, E., Rayser, & Popa-Mabe, M. (2005). Facilitating informed decision making about breast cancer risk and genetic counseling among women calling the NCI's Cancer Information Service. Journal of Health Communication, Special Issue on The National Cancer Institute's Cancer Information Service: A New Generation of Service and Research to the Nation, 10, 119-36.
- o Miller, S.M., Roussi, P., Daly, M.B., Buzaglo, J.S., Sherman, K.A., Godwin, A.K., Balshem, A., & Atchison, M.A. (2005) Enhanced counseling for women undergoing BRCA1/2 testing: Impact on

subsequent decision making about risk prevention behaviors. Health Education and Behavior, Special Issue on Implications of Genomics for Health Behavior and Health Education, 32(5), 654-667.

- o Sherman, K.A., Miller, S.M., Sheinfeld-Gorin, S. (in press). Psychosocial determinants of participation in breast cancer risk counseling programs and screening regimens among African American women. In: Breast Cancer in African American Women. NY: Susan G. Komen Foundation and African American National Advisory Committee.

We are also prepared two volumes that will integrate our ongoing study with the larger field of behavior and oncology.

- o Miller, S.M., McDaniel, S., Rolland, J., & Feetham, S. (Eds.) (2006) Individuals, families and the new era of genetics: Biopsychosocial perspectives. New York: Norton Publications.
- o Miller, S.M., Bowen, D., Croyle, R. & Rowland, J. (Eds.) (in press) Handbook of behavioral science and cancer. Washington, D.C.: American Psychological Association.

CONFERENCE PRESENTATIONS AND DISTINGUISHED VISITORSHIPS

Miller, S.M., Fleisher, L., Rodoletz, M., Buzaglo, J.S., Glenn, M., Higman, S., Cornfeld, M., Schnoll, R.A., Balshem, A., & Engstrom, P.F. Implementation of a Worksite Cancer Control Program: Enhancing Cancer Prevention-related Intentions and Attitudes Among Worksite Employees. Paper presented at Translating Research Into Practice (TRIP): Advancing Excellence from Discovery to Delivery, Symposium on Innovation in TRIP for Prevention, Washington, D.C., July, 2004.

Miller, S. M. 8th International Congress of Behavioral Medicine. Paper on: Tailoring Monitoring vs. blunting in the preparation for stressful medical procedures. Part of Invited Symposium on: Psychological Preparation for Medical Intervention. Mainz, Germany. August, 2004.

Miller, S.M. University of Michigan School of Public Health. Invited Speaker on: Facilitating Risk Processing in at-risk populations as part of Symposium on The Challenge Ahead: Implications of Genomic Information in Public Health Education and Behavior Change. Ann Arbor, MI, October, 2004.

Miller, S.M. 29th Annual Meeting of the American Society of Preventive Oncology, San Francisco, CA. March, 2005.

Miller, S.M., Sponsored by American Associates, Ben-Gurion University, Philadelphia Chapter, and Fox Chase Cancer Center. Invited speaker on: Fighting Breast Cancer March , 2005.

Miller, S.M. Invited Speaker on: A Developmental Perspective Cancer Risk and Responses. University of the Sacred Heart, Tokyo, Japan, March 2005.

Miller, S.M. Invited Speaker: Psychosocial Factors in Cancer. Choju Medical Research Center, Mie, Japan, March, 2005.

Miller, S.M., Chair, Invited Symposium and Roundtable Session on Decision Making in the Cancer Context – Translation from Basic Science through Population Health. Annual Meeting of the Society of Behavioral Medicine. Boston, MA. April, 2005.

Miller, S.M. Invited Colloquium on Coping with Cancer Risk and Disease: Is There a Role for Behavioral Science? Sponsored by Case Western Comprehensive Cancer Center, Case Western Reserve University, Cleveland, OH. April 29, 2005.

Miller, S.M. University of Padova (sponsored by the Department of Pediatrics). Invited Speaker on Monitoring vs. Blunting Styles of Coping: To See or Not to See?, Padova, Italy, May 2005.

Miller, S.M. Invited Speaker, Presented as part of Invited Symposium on Educating Women about Risk Counseling/Genetic Testing Makes a Difference in Intended Use of Services, Especially among those at High-Risk: Results of a Randomized Trial Among Callers to the Cancer Information Service. The Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.

Miller, S.M. Invited Co-Chair, Invited Symposium on People and Populations. The Department of Defense(DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.

Miller, S.M. Invited Speaker on Tailored Communication to Enhance Adaptation across the Breast Cancer Spectrum. Presented as part of Invited Symposium on Behavioral Centers of Excellence: Treating More Than the Tumor. The Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.

Miller, S.M. Invited Speaker. Stress and Anxiety Research Society (STAR). Crete, July, 2006.

CONCLUSIONS

Although the number of participants is lower than had been anticipated, we expect that continued follow-up at the Virtua Memorial Hospital site recruitment site will improve accrual rates. Recruitment began at the additional site in late 2005, but was unsuccessful

due to the late approval, and we were not able to contact a number of women in time for them to still be eligible. Thus, last year a request was made to extend the study for additional 12-months. Also, due to a change in the electronic medical records database at FCCC, research efforts were delayed and therefore further delayed recruitment efforts for our study. From that point, we anticipated no further obstacles in completing recruitment and follow-up for our study.

With the addition of 29 participants over the past year, descriptive data continue to indicate that there is a need for increased LE education and improved adherence to LE-related behaviors. Although a number of women are aware of LE minimization practices and their potential benefits, preliminary data suggest that they are not incorporating all of the suggested minimization practices into their daily lives, especially those that may constitute active strategies. Moreover, our early findings suggest that promoting the maintenance of LE preventive/minimization behaviors and enhancing the management of LE risk-related emotions over time may be a worthwhile focus for a subset of individuals. Taken together, our preliminary findings support the importance of this study in increasing LE-related knowledge and improving health behaviors to reduce women's risk for developing LE.

This research will fill a void in the breast cancer literature with respect to lymphedema. Survivors of breast cancer need to attend to the types of precautionary measures they can employ to prevent and control the occurrence of symptoms. However, little is known about how individuals understand and make sense of these issues, and few resources have been developed to address this problem. Hence, it is important to explore the psychosocial factors that facilitate or undermine the uptake of preventive behaviors, as well as their sustained maintenance over time.

Through more systematic investigation of these factors, we will be able to develop a profile of the role of cognitive-emotional processing in the management of lymphedema. These data will ultimately be used to design and evaluate enhanced management protocols, tailored to the individual's cognitive-emotional signature.

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LIST OF KEY PERSONNEL

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