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

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4. TITLE AND SUBTITLE
Cognitive-Affective Predictors of the Uptake of, and Sustained Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

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13. ABSTRACT (Maximum 200 Words)
Approximately 20-30% of women develop lymphedema (LE) following breast cancer treatment; this condition has been associated with psychological distress and diminished quality of life. Effective symptom management requires that women not only recognize early signs of this condition, but that they uptake and maintain precautionary practices over their lifetime. Yet, the limited data available indicate that knowledge and use of symptom minimization precautions are poor, particularly over time. Unfortunately, little is known about how breast cancer survivors perceive their LE risk status, and the cognitive-affective factors that promote the uptake of, and adherence to, LE symptom minimization precautions. Further, the moderating role of individual differences in attentional style has not been explored. Guided by the Cognitive-Social Health Information Processing (C-SHIP) model, we will conduct a longitudinal study, to assess the barriers and facilitators associated with knowledge about, and adherence to, LE symptom-minimization practices among breast cancer survivors currently unaffected by LE. We will explore the mediating role of cognitive-affective variables, and the moderating role of attentional style, on knowledge, uptake and adherence over time. Toward this end, we will survey levels of knowledge, and the practice of symptom minimization precautions at baseline, and again at 6-, and 12-month follow-up.
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INTRODUCTION

Improvements in breast cancer treatments have greatly reduced mortality rates (Petrek 2000; Passik 1998; Erickson, 2001; Tasmuth 1996). Consequently, 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 & Rodolitz, 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 facilitate 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 recommendations 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 (who attend to, focus on, and personalize cancer threats) will show greater knowledge, uptake, and adherence than low monitors (who distract from and downplay the significance of cancer threats and challenges).

To accomplish these objectives, we are conducting a longitudinal study of LE symptom-free women who are in remission following sentinel or axillary node surgery for early-stage (Stages I-II), primary breast cancer (N = 178). A Nurse Educator from one of the two FCCC recruitment sites, the Breast Evaluation Clinic at FCCC campus or FCCC’s Bryn Mawr satellite location, will make 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 will review FCCC’s
electronic medical records, the Health Information Management System (HIMS), to identify clinic patients and to determine patient eligibility (i.e., diagnosis, surgery status). The research staff will then contact eligible patients by telephone to describe the study, solicit participation and obtain verbal consent for participation. Eligible, consenting participants will complete psychosocial measures and a written informed consent at their next post-surgery follow-up appointment, usually within two weeks of initial contact and consent. Upon completion of the baseline questionnaire, each participant will be given a copy of the American Cancer Society Lymphedema booklet containing hand and arm care following surgery or radiation therapy for breast cancer and the recommended precautionary actions that they can follow will be briefly summarized verbally. Relevant psychosocial and behavioral variables will be reassessed by telephone at each of the follow-ups, 6- and 12-months post-baseline. Participants who experience a breast cancer recurrence will be excluded from follow-up and will 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, to be initiated in year one and completed in year two, are as follows:

a. Recruit Participants, Conduct Longitudinal Study (Months 2-21)

b. Establish Database and Enter Data (Months 2-21)

While the anticipated accrual of participants has not been met as planned, task 2 is underway as scheduled. Due to the request and approval of a one-year no-cost extension for this study, recruitment will continue for the next year and the initiation of task 3 will be delayed for 12 months.

The aims of Task 3, also to be initiated in year 1 and completed in year 2 are as follows:

a. Analyze Preliminary Data (baseline to 6-month follow-up) (Months 4-21)

b. Annual Reports Prepared (Months 4-21)

To date, preliminary baseline data have been entered and descriptive statistics have been performed. Since August 15, 2003 a total of 523 patients have visited the Breast Evaluation Clinic at FCCC. Since August 2003, 236 of the 523 clinic patients (45%) 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 236 eligible women, our research team has successfully contacted 77 (32%) by using a maximum of 20 attempts to contact women by telephone. Attempts are still being made to contact the remaining eligible women. Of the women contacted, 38 (49%) provided verbal consent to participate. Thirty-three of the women contacted (43%) declined participation with 20 women stating that they were “not interested” with no additional explanation provided and 13 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. To date, 33 of the 35 consenting eligible participants have completed baseline data. Five originally consenting eligible participants have attrited from the study (4 participants through passive attrition [i.e., not showing up; not returning telephone calls], 1 participant through active attrition [i.e., changing their minds about participation.]). Collection of six-month follow-up questionnaires began in August 2003 and 39 questionnaires have been completed. To date, 6-month follow-up questionnaires have been completed by all participants who had originally consented to participate with the exception of one participant who is experiencing bone metastases and wished to discontinue her participation in the study. Collection of 12-month follow-up questionnaires began in April 2004 and, to date, all 8 expected questionnaires have been collected. Telephone calls are placed on a regular basis to collect the remaining follow-up questionnaires.

KEY RESEARCH ACCOMPLISHMENTS

- Continue to hold weekly project staff meetings.
- 35 new participants have completed baseline measures since August 2003. Thirty-three 6-month follow-up questionnaires and 8 12-month follow-up questionnaires have been collected since August 2003.
- Twice weekly, members of the research team continue to access the FCCC electronic Health Information Management System (HIMS) to identify new patients attending the Breast Evaluation Clinic at either site. Approximately, 5-10 new potential participants are identified on a weekly basis. Potential participants are FCCC patients who are initiating their breast cancer treatment or women who have come to FCCC for an initial consultation or post-diagnosis/pre-treatment second opinion.
- Potentially eligible women continue to be tracked on a regular basis until their full eligibility (i.e., cancer stage, post-surgery status, receiving treatment at FCCC) can be determined. Using HIMS, a subset of approximately 20 patients are systematically tracked for eligibility in the course of a typical week. Eligible patients are contacted by telephone to solicit participation in the study after their medical records indicate that they have completed their surgery.
- Members of the research team have been trained in the use of the Soarian Clinical Access database. This is the new electronic medical records database being used by FCCC and will replace HIMS.
- 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 date.

In order to clearly ascertain the course of adjuvant treatment breast cancer patients will receive, 2 questions have been added to the questionnaire to assess their anticipated treatment. This will allow for a more accurate report of perception of risk among participants who are aware of any upcoming adjuvant treatment.

In an effort to enhance recruitment, procedures have been developed to extend recruitment to breast cancer patients receiving care at Virtua Memorial Hospital, in New Jersey. The amendment to add Virtua as a recruitment site is currently being reviewed by the Department of Defense.

Further efforts to enhance enrollment include the extension of the inclusion criteria to solicit patients with Stage 11a disease since breast cancer treatment and symptoms pose similar issues for patient with Stage II and IIIa disease. The FCCC IRB approved this amendment in September 2003 and the Department of Defense in December 2003.

The FCCC IRB audited this study in February 2004 and found it to be in accordance with compliance regulations.

The FCCC IRB and the US Department of Defense have approved a one-year no-cost extension to continue recruitment for another year in an effort to reach the anticipated sample size.

Published 7 papers that analyze literature on adherence and adjustment in breast cancer disease/risk context and integrated findings obtained with our guiding theoretical model.


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


REPORTABLE OUTCOMES

BACKGROUND CHARACTERISTICS OF STUDY PARTICIPANTS

To date, 55 participants have completed baseline measures. The following section provides an update of the baseline statistics as compared with the report from last year, which reflected only 20 participants. Sample characteristics from these preliminary data include: a mean age of 53 years (range 35-81 years), 80% Caucasian, 73% married or living with a partner, 98% have children, 43% have earned a college degree or higher, and 78% have an annual household income of $45,000 or greater. Approximately half the sample (57%) have been diagnosed with Stage 1 breast cancer and 43% have been diagnosed with Stage 2 breast cancer. With regard to treatment methods the overwhelming majority of the sample (93%) received multiple treatment methods (lumpectomy and lymph node dissection 65%; lumpectomy, mastectomy, and dissection 11%; lumpectomy, dissection and radiation 29%; mastectomy and dissection 40%; mastectomy, dissection, and chemotherapy 15%). 51% of the lymph node dissections
were sentinel node and 44% were axillary node. 5% of the sample received both a sentinel and axillary dissection.

LYMPHEDEMA-RELATED KNOWLEDGE

At baseline, LE-related knowledge was moderate, with only 21% of the women answering the majority of questions (17 out of 19) correctly. The mean knowledge score was 12.5 out of 19. At least 90% of the women were able to correctly identify that it is recommended to keep your LE affected arm very clean and well moisturized, 98% to avoid blood pressure readings and injections on the affected arm, and 96% to wear gloves when doing housework or gardening. However, despite the generally high level of LE knowledge, 40% of the women answered at least one quarter of the more detailed LE-related knowledge questions incorrectly. The questions most frequently answered incorrectly were related to LE-related symptoms (“An inflammation or infection in the affected arm is a sign of LE”, 52% incorrect), its onset (“LE can ONLY occur within the first month following surgery for breast cancer”, 56%), BRCA treatment risk-related factors (“Breast cancer treatment increases your chances of developing LE”, 18%; “Women who have axillary node surgery followed by radiation therapy have a higher risk of developing LE”, 10%), and frequently performed risk-related behaviors (“It is advisable that you wear a well-fitted bra with wire support”, 63%; “Only use an electric razor to remove hair from under your arm”, 21%). 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. Paired t-tests revealed a significant increase in levels of lymphedema knowledge at 6-months (mean = 17.2) compared with baseline (12.5) (t=-10.1, df=36, p<.0001).

ADHERENCE TO LYMPHEDEMA MINIMIZATION PRACTICES

Using a dichotomous yes/no item format, preliminary baseline data show that adherence to certain LE-risk minimization strategies is high, especially those that entail more passive acceptance strategies. Specifically, 84% of the women are not cutting the cuticles of their affected arm (i.e., arm associated with the surgery); 91% are keeping their affected arm very clean and well moisturized; 85% are avoiding heavy lifting and carrying handbags with over the shoulder straps; 93% are avoiding tight jewelry around the affected fingers or arms; 79% are avoiding exposing the affected arm to the sun; and 93% of the women are currently avoiding blood pressure readings and injections on the affected arm. However, 60% of the sample are not currently using an electric razor to remove hair under their affected arm, 54% are not wearing gloves when doing housework or gardening, and 30% are not avoiding extreme temperature changes when bathing or washing dishes. These are three important, and rather routine, behaviors recommended to prevent LE that require more active strategies. Moreover, 22% report 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, possibly related to the participants’ lack of awareness of
lymphedema symptoms identified in the assessment of lymphedema-related knowledge. Paired t-tests revealed a significant increase in the number of preventive strategies practiced at 6-months (mean = 10.4) compared with baseline (9.4) (t=2.82, df=36, p<.01).

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=8.96, SD=2.74; Mean blunting score=3.89, SD=2.09).

Risk Perceptions

Overall, 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", 86% 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, a treatment associated with an even higher risk for LE than sentinel surgery, 71% 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 to date have had this treatment combination. There were no changes in perceptions of lymphedema risk from baseline to 6-months.

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 endorsed that LE is a serious condition (i.e., 29% “quite a bit”; 55% “very much”), that developing LE would interfere with their lives (i.e., 49% “quite a bit”; 24% “very much”), and that LE-related problems would last a long time (i.e., 31% “quite a bit”; 20% “very much”). A majority of the women endorsed a belief that there are measures they can take to prevent LE (i.e., 51% “quite a bit”; 15% “very much”) and that practicing the recommended hand and arm procedures will minimize their chances of developing LE (i.e., 48% “quite a bit”; 28% “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 (51%) or that the development of LE is just luck (62%), implying that they did not take a fatalistic view of LE development. A majority of the sample were certain that they can effectively adhere to recommended procedures to minimize LE risk.
(i.e., 43% “quite a bit”; 29% “very much”) and that they will be regularly checking themselves for signs of LE (i.e., 35% “quite a bit”; 26% “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. No differences in lymphedema-related expectancies and beliefs were reported from baseline to 6-month follow-up.

**Distress**

As measured by 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=3.64, SD=5.46; Mean avoidance scale score=5.74, SD=7.87). There were no significant differences in levels of intrusive and avoidant ideation from baseline to 6-months.

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. 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: 55% “not at all”, 27% “a little bit”; ability to perform daily activities: 64% “not at all”, 20% “a little bit”), or the experience of LE-risk related worry (29% “not at all”, 51% “a little bit”), sadness/depression (38% “not at all”, 38% “a little bit”), anxiety (25% “not at all”, 40% “a little bit”), or anger (60% “not at all”, 20% “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% “somewhat”, 15% “quite a bit”) or daily activities (9% “somewhat”, 6% “quite a bit”, 2% “very much”), or feel worried (4% “somewhat”, 13% “quite a bit”, 4% “very much”), sad/depressed (13% “somewhat”, 7% “quite a bit”, 4% “very much”), scared/anxious (14% “somewhat”, 7% “quite a bit”, 4% “very much”), or angry (15% “somewhat”, 5% “very much”) regarding their LE risk. Moreover, a number of women report that they are “somewhat” (24%), “quite a bit” (9%), or “very much” (2%) 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 worry from baseline (mean=2.08) to 6-months later (mean=1.63) (t=2.25, df=37, p<.05); feelings of sadness or depression in relation to lymphedema risk (baseline=1.84; 6-months=1.42) [t=2.59, df=37, p<.02]; lymphedema risk-related anxiety (baseline=1.97; 6-months=1.50) [t=2.90, df=37, p<.01]; and anger regarding lymphedema risk (baseline=1.66; 6-months=1.34) [t=2.78, df=37, p<.01]. In addition, compared with baseline, at 6-months participants reported fewer cases of having thoughts about lymphedema risk influence their mood (t=2.162, df=37, p<.05) or affecting their ability to perform daily activities (t=2.49, df=37, p<.02).
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” (13%) to “very much” (86%) important to them. Similarly, the entire sample reported “feeling well” to be “quite a bit” (13%) to “very much” (86%) 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% and 36%, respectively), feeling attractive (35% and 35%, respectively). Ninety-three percent of the baseline sample reports the way in which their partner perceives their body to be “somewhat” (23%), “quite a bit” (49%), or “very much” (21%) important to them. No differences in values and goals were evident from baseline to 6-month follow-up.

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. 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, the majority of the sample felt that they were “quite a bit” (40%) to “very much” (40%) able to make the necessary lifestyle changes in order to carry out recommended LE minimization precautions and that they were “quite a bit” (44%) to “very much” (37%) able to follow the recommended behaviors that may minimize LE symptoms. A majority of the sample felt that they are “quite a bit” (38%) to “very much” (36%) able to limit the amount of stress they experience when they perform the recommended symptom minimization practices, that they are “quite a bit” (35%) to “very much” (26%) able to limit the amount of stress they experience about their LE risk, and that they are “quite a bit” (34%) to “very much” (25%) able to calm themselves down when they experience anxiety or worry about developing LE. Paired t-tests revealed significant increases 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=3.58; 6-months=4.33)[t=−4.49, df=32, p<.0001], and to limit the amount of stress experienced when practicing lymphedema risk-minimisation strategies (baseline=4.06; 6-months=4.57)[t=−2.60, df=34, p<.02].

CONFERENCE PRESENTATIONS AND DISTINGUISHED VISITORSHIPS


Miller, S. M. 8th International Congress of Behavioral Medicine. Paper on: Tailoring Monitoring vs. blunting in the preparation for stressful medical procedures. Part of


CONCLUSIONS

Although the number of participants is lower than had been anticipated, we expect that the addition of a recruitment site will improve our accrual rates. Recruitment will begin at this additional site upon approval from the US Department of Defense. Further, with the approval of the no-cost extension to continue recruitment we can expect our study sample to double over the next year. Due to a change in the electronic medical records database at FCCC, research efforts were delayed for a short period of time while members of the research team were trained in the navigation of this system. However, as this training is completed and as recruitment continues, we anticipate no further obstacles in conducting our study as scheduled, and we expect no additional delays in the progress of this project.

With the addition of 35 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 recommendations into their daily lives, especially those that may constitute active strategies. Moreover, our early data 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.

REFERENCES


APPENDICES

None