UNDERSTANDING THE EFFECTIVENESS OF INTERVENTIONS FOR CANCER PATIENTS: A STUDY OF PATIENT CHARACTERISTICS AND INTERVENTION EVALUATIONS

DISSERTATION

Presented in Partial Fulfillment of the Requirements for the Degree Doctor of Philosophy in the Graduate School of The Ohio State University

By

Rebecca Ann Shelby, M.A.

* * * * *

The Ohio State University
2006

Dissertation Committee

Professor Barbara L. Andersen, Adviser
Professor Charles Emery
Professor Michael Vasey

Approved by
Adviser
Graduate Program in Psychology
ABSTRACT

Managing cancer-related sequelae has become increasingly important as individuals live longer with the burdens of cancer and its treatments. Data suggest that psychosocial and behavioral interventions provide a feasible way of reducing the burdens experienced by cancer patients. Understanding intervention efficacy is a central question that must be addressed. Patient characteristics (e.g., age, income, and type of surgery) and intervention evaluations (e.g., satisfaction, group experiences, group cohesion, and utilization of intervention techniques) may influence treatment outcomes. Past studies with cancer patients have not examined these variables. The present study used data from the Stress and Immunity Breast Cancer Project to 1) identify patient characteristics that moderate treatment outcomes, 2) examine patient characteristics associated with intervention evaluations, utilization of intervention techniques, and attendance, and 3) examine the association between treatment outcomes, utilization of intervention techniques, and attendance. Our data suggest that the intervention was particularly beneficial for women who had greater cancer-related distress, fewer educational resources, and surgical treatment with mastectomy. We found significant associations between use of intervention techniques and positive treatment outcomes: a) relaxation was associated with decreased emotional distress, b) assertive communication and
strategies for increasing social support were associated with improved perceptions of family support, c) techniques for eating less fat and communicating with medical providers were associated with improved dietary habits, d) exercise was associated with lower treatment side effects, and e) techniques for communicating with medical providers and exercise were associated with better compliance with recommended chemotherapy regimens. Finally, women with more personal resources (higher education, higher income, and a larger social network), lower levels of neuroticism, and greater feelings of group cohesion were more likely to attend intervention sessions. Findings from the current study provide valuable and unique information for designing dismantling studies and developing future interventions for cancer patients.
Dedicated to Mark Olberding, Michael Shelby, and Roseann Shelby.
ACKNOWLEDGMENTS

I am grateful to Dr. Barbara Andersen for her expertise and support during the preparation of this document.

I thank my committee members, Dr. Charles Emery and Dr. Michael Vasey, for their comments and suggestions.

I wish to thank the study participants for their assistance.

I am indebted to all the members of the Stress and Immunity Breast Cancer Project, past and present, who have committed countless hours interviewing participants, obtaining medical records, and managing data.

This research was supported by grants from the National Cancer Institute, the American Cancer Society, the National Institutes of Mental Health, the Army Initiative on Cancer, and the Department of Psychology at The Ohio State University.
VITA

EDUCATION

May 27, 1975…………………………………....Born – St. Marys, Ohio, U.S.A.

1997……………………………………………. B.A. Psychology, Saint Mary’s College

2003……………………………………………. M.A. Psychology, Ohio State University

PUBLICATIONS


**FIELDS OF STUDY**

Major Field: Psychology
TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Abstract</th>
<th>ii</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dedication</td>
<td>iv</td>
</tr>
<tr>
<td>Acknowledgments</td>
<td>v</td>
</tr>
<tr>
<td>Vita</td>
<td>vi</td>
</tr>
<tr>
<td>List of Tables</td>
<td>x</td>
</tr>
<tr>
<td>List of Figures</td>
<td>xii</td>
</tr>
</tbody>
</table>

Chapter 1: Introduction ................................................................. 1
  Intervention Efficacy ................................................................. 3
  Intervention Characteristics ..................................................... 17
  Patient Characteristics ............................................................. 29
  Intervention Evaluations and Use of Techniques ...................... 37
  The Current Study ................................................................. 43
  Study Aims ........................................................................... 46

Chapter 2: Method ........................................................................ 50
  Sample Description ................................................................. 50
  Procedure ........................................................................... 51
  Measures ............................................................................ 52
  Analytic Strategy and Power Analyses .................................... 59

Chapter 3: Results ........................................................................ 65
  Participants .......................................................................... 65
  Moderators of the Intervention ............................................. 66
  Patient Characteristics and Intervention Evaluations ............. 70
Table of Contents

Correlations Among Intervention Evaluations ............................................................. 74
Intervention Outcomes and Utilization of Techniques ................................................. 77

Chapter 4: Discussion ....................................................................................................... 84
  Moderators of the Intervention ..................................................................................... 85
  Intervention Evaluations ............................................................................................... 88
  Utilization of Intervention Techniques ......................................................................... 90
  Attendance .................................................................................................................... 96
  Strengths and Limitations ............................................................................................. 98
  Future Directions ........................................................................................................ 100
  Unique Contributions of the Present Study ................................................................. 104
  Conclusions and Recommendations ........................................................................... 106

List of References ........................................................................................................... 108

Appendix A: Tables and Figures .................................................................................... 129

Appendix B: Tables of Intervention Studies with Cancer Patients................................. 163

Appendix C: SIBCP Intervention Description .................................................................. 190

Appendix D: SIBCP Intervention Outcomes 0 to 4 Months ........................................... 203
LIST OF TABLES

Table 1. Summary of outcomes for randomized intervention studies with cancer patients ................................................................. 130

Table 2. Intervention targets, sessions, components, and measured variables ............ 132

Table 3. Initial equivalence of study arms on sociodemographic, prognostic, and treatment variables. Percentages or means and standard deviations (in parentheses) are provided .......................................................................................................................... 134

Table 4. Repeated measures ANOVAs testing potential moderators of the intervention effect. F values and effect sizes (Eta squared in parentheses) are provided .............. 135

Table 5. Descriptive statistics for satisfaction with intervention topics, group cohesion, perceptions of important group experiences, utilization of intervention techniques, and attendance ....................................................................................................................... 137

Table 6. Correlations between participant characteristics and satisfaction with intervention topics, group cohesion, perceptions of important group experiences, utilization of intervention techniques, and attendance ....................................................................................................................... 139

Table 7. Inter-correlations for satisfaction with intervention topics, group cohesion, perceptions of important group experiences, utilization of intervention techniques, and attendance ....................................................................................................................... 142

Table 8. Repeated measures ANOVAs testing the association between intervention outcomes and utilization of intervention techniques. F values and effect sizes (Eta squared in parentheses) are provided ................................................................................................................................. 144

Table 9. Summary of study results ................................................................................. 147

Table 10. Intervention studies with cancer patients targeting emotional distress .......... 164

Table 11. Intervention studies with cancer patients targeting cancer-specific traumatic stress ................................................................................................................................. 169
Table 12. Intervention studies with cancer patients targeting quality of life

Table 13. Intervention studies with cancer patients targeting social adjustment

Table 14. Intervention studies with cancer patients targeting diet or nutrition

Table 15. Intervention studies with cancer patients targeting exercise

Table 16. Intervention studies with cancer patients targeting smoking

Table 17. Intervention studies with cancer patients targeting biologic outcomes

Table 18. Intervention studies with cancer patients examining length of survival

Table 19. Intervention targets, sessions, components, and measured variables

Table 20. Initial equivalence of study arms on sociodemographic, prognostic, treatment and performance status variables. Percentages or means and standard deviations (in parentheses) are provided

Table 21. Initial equivalence of study arms on individual differences in stress and outcome variables. Means and standard deviations (in parentheses) are provided
LIST OF FIGURES

Figure 1. The biobehavioral model of stress and disease course ................................... 150

Figure 2. Experimental design and study flow diagram ................................................ 151

Figure 3. Intervention participants with higher cancer-related distress demonstrate the greatest decrease in POMS Total Mood Disturbance .................................................... 152

Figure 4. Intervention participants with lower levels of formal education demonstrate greater decreases in POMS Anxiety compared to assessment-only participants with lower levels of education ........................................................................................................ 153

Figure 5. Intervention participants treated with mastectomy demonstrate the greatest increase in perceptions of family support .................................................................................... 154

Figure 6. Intervention participants with lower levels of formal education demonstrate greater increases in KPS compared to intervention participants with lower levels of education ........................................................................................................ 155

Figure 7. Greater utilization of relaxation techniques is associated with decreases in POMS Total Mood Disturbance ........................................................................................................ 156

Figure 8. Greater utilization of relaxation techniques is associated with greater decreases in POMS Anxiety .................................................................................................................................. 157

Figure 9. Greater utilization of assertive communication techniques is associated with increases in perceptions of family support .................................................................................... 158

Figure 10. Greater utilization of social support techniques is associated with increases in perceptions of family support ........................................................................................................ 159
Figure 11. Greater utilization of techniques for communicating with medical providers is associated with improved dietary habits................................................................. 160

Figure 12. Greater utilization of techniques for reducing fat intake is associated with improved dietary habits................................................................................................... 161

Figure 13. Greater utilization of exercise techniques is associated with fewer treatment side effects .............................................................................................................. 162

Figure 14. Experimental design and flow diagram.......................................................... 244

Figure 15. Example of significant effects for Con A induced proliferation. Optical density readings for 5.0 µg/mL dilution are displayed with error bars representing one standard error ................................................................................................................... 245

Figure 16. Example of significant effects for PHA induced proliferation. Optical density readings for 5.0 µg/mL dilution are displayed with error bars representing one standard error........................................................................................................... 246
CHAPTER 1

INTRODUCTION

Cancer remains a significant burden, as a total of 1,399,790 new cancer cases are expected this year [American Cancer Society (ACS), 2006]. With advances in medical care, individuals survive longer with cancer and with greater disease severity (ACS, 2006). Cancer survivors may experience continuing problems including emotional distress, fatigue, loss of stamina, and disruptions in relationships and social support (Broeckel, Jacobsen, Balducci, Horton, & Lyman, 2000; Ganz, Coscarelli, Fred, Kahn, Polinsky, & Petersen, 1996; Michael, Kaciwachi, Berkman, Holmes, & Colditz, 2000; Stegina, Occhipinti, Dunn, Gardinier, Heathcote, & Yaxley, 2001). A cancer history can also lead to financial difficulties, limit insurance coverage, and reduce employment options (Hewitt, Breen, & Devesa, 1999; Mor, Masterson-Allen, Houts et al., 1992; O’Hare, Yost, & McCorkle, 1993; Siegel, Raveis, Houts et al., 1991). If unaddressed, these problems can contribute to a poorer recovery and long-term disruptions in quality of life (Gotay & Muraoka, 1998; Green, Krupnick, Rowland et al., 2000). Managing cancer-related sequelae is increasingly important as individuals live longer with the burdens of cancer and its treatments.
Several recent reviews suggest that psychosocial and behavioral interventions for cancer patients are effective for reducing cancer-related problems (e.g., Andersen, 2002; Compas, Haaga, Keefe, Leitenberg, & Williams, 1998; Edelman, Craig, & Kidman, 2000; Fawzy & Fawzy, 1998; Helgeson & Cohen, 1996; Meyer & Mark, 1995; Meyerowitz, Richardson, Hudson, & Leedham, 1998; Rehse & Pukrop, 2003). Meyer and Mark (1995) conducted a meta-analysis of 45 randomized psychosocial interventions for adult cancer patients. Compared to no-treatment control patients, intervention patients demonstrated improved emotional and functional adjustment. Similarly, Rehse and Pukrop (2003) conducted a meta-analysis of 37 intervention studies and found that intervention patients experienced improvements in quality of life. Despite demonstrated efficacy, little is known about the factors that contribute to positive treatment outcomes for cancer patients.

The proposed study examines factors associated with intervention efficacy in the context of an existing randomized trial, the Stress and Immunity Breast Cancer Project (SIBCP; Andersen, Farrar, Golden-Kreutz et al., 2004). SIBCP tested the hypothesis that a cognitive-behavioral intervention can reduce emotional distress, improve health behaviors, and enhance immune responses. The intervention also targeted potential cofactors including social support and treatment compliance. Below we review controlled intervention studies conducted with cancer patients. Findings of the SIBCP trial are reported in this context. We also discuss intervention characteristics that impact efficacy (e.g., intervention approach, length, and timing) and we consider these variables when evaluating the advantages and limitations of utilizing data from SIBCP.
Specifically, we are interested in the effects patient characteristics, intervention evaluations (satisfaction, important group experiences, and feelings of group cohesion), and utilization of intervention techniques may have had on intervention efficacy. Using data from the SIBCP trial, we plan to identify patient characteristics that interact with treatment and examine associations between intervention evaluations, use of techniques, and treatment outcomes. Below we discuss patient characteristics that may interact with treatment. We consider patient characteristics associated with adjustment in correlational studies and review intervention studies that tested for interactions between patient characteristics and outcomes. We also discuss intervention evaluations that may be relevant for treatment efficacy including satisfaction, group experiences, group cohesion, and utilization of intervention techniques. Because little data are available for cancer patients, our discussion includes studies of individual and group psychotherapy.

**Intervention Efficacy**

The Biobehavioral Model of cancer stress and disease course (see Figure 1; Andersen, Kiecolt-Glaser, & Glaser, 1994) specifies psychological (e.g., emotional distress, quality of life, social functioning), behavioral (e.g., treatment compliance and health behaviors), and biologic (e.g., immune functioning) variables that may impact disease outcomes. Below we review controlled intervention studies with a focus on target variables specified by the Biobehavioral Model. We have chosen the Biobehavioral Model as a framework for the literature review because it corresponds to the structure of the SIBCP intervention and represents all outcomes targeted by this trial. For each target variable, we briefly discuss its relevance for cancer patients and review past intervention studies. When applicable, SIBCP findings are reported in this context.
Most intervention studies include target variables from multiple domains and thus, some studies overlap across outcomes. Table 1 displays a summary of intervention targets and the number of studies examining each outcome.

*Emotional Distress*

Cancer patients may experience mood and anxiety problems in response to diagnostic tests for cancer (Melendez & McCrank, 1993), cancer diagnosis (Weisman & Worden, 1976), surgery (Thomas, Maden, & Jehu, 1987), adjuvant treatment (Andersen, Karlsson, Anderson et al., 1984; Jacobsen, Widows, & Hann, 1998; Morrow, Roscoe, Hickok et al., 2002), or cancer symptoms (Redd, Montgomery, & DuHamel, 2001). Between 15 to 40% of cancer patients develop clinically significant depression or anxiety (Derogatis, Morrow, Fetting et al., 1983, Massie & Holland, 1990; Parle, Jones, & Maguire, 1996). If untreated, these problems may worsen and interfere with daily functioning, long-term adjustment, and compliance with medical recommendations (Bunston & Mings, 1995).

The majority of interventions for cancer patients focus on emotional distress. We reviewed 109 randomized intervention studies conducted with cancer patients between 1979 and 2005. Of these studies, 66% \((n=72)\) examined emotional distress including symptoms of depression, anxiety, or mood disturbance. Overall, interventions were effective in reducing emotional distress: 64% demonstrated reductions in anxious symptoms, 55% found decreases in depressive symptoms, and 60% showed improvements in mood (see Table 1). Appendix B, Table 10 provides a complete listing of studies and intervention outcomes. Interventions used multiple approaches including cognitive-behavioral therapy (a combination of stress management, problem-solving
skills, coping skills, and therapeutic techniques to improve cognitive and behavioral processes), supportive counseling, educational programs, behavioral strategies (e.g., relaxation, imagery), and supportive-expressive therapy. Intervention effectiveness did not vary by intervention approach.

Consistent with past studies, SIBCP demonstrated benefits for emotional distress. Analysis showed a greater reduction of anxious mood in the intervention group compared to the assessment-only control group. This outcome is of particular relevance because the intervention focused on reducing stress and anxiety.

*Cancer-specific traumatic stress*

Studies of cancer-specific traumatic stress report that symptoms occur in up to 50% of cancer patients (for a review see Gurevich, Devins, & Rodin, 2002). Three symptom clusters characterize traumatic stress symptoms: reexperiencing (e.g., intrusive thoughts or dreams about cancer), avoidance and numbing (e.g., avoidant behaviors, denial of thoughts, restricted range of affect), and arousal (e.g., hypervigilance, irritability). While most cancer patients experience declines in traumatic stress after treatment has ended, some studies suggest that over one-third will continue to experience chronic symptoms (Andrykowski, Cordova, McGrath, Sloan, & Kenady, 2000; Shelby, Golden-Kreutz, & Andersen, 2002). Traumatic stress symptoms are associated with reductions in quality of life, long-term disruptions in psychological adjustment, and problems in social functioning (Jacobsen, Sadler, Booth-Jones et al., 2002; Smith, Redd, Peyser, & Vogl, 1999).

Few (N=13) controlled intervention studies have examined traumatic stress. Four studies reported reduced traumatic stress for intervention patients compared to control
patients. The remaining nine studies reported no group differences (see Appendix B, Table 11 for a complete listing of studies and outcomes). Twelve studies used the Impact of Events Scale (IES; Horowitz, Wilner, & Alvarez, 1979), which assesses intrusive and avoidant symptoms. Only one study (Levine, Eckhardt, & Targ, 2005) measured arousal symptoms, and found that these symptoms decreased during both cognitive-behavioral and supportive counseling interventions. Studies used a variety of intervention strategies (supportive counseling, supportive-expressive therapy, educational programs, behavioral strategies, and cognitive-behavioral therapy). We could not evaluate intervention effectiveness by approach, as few approaches were used in multiple studies. SIBCP assessed traumatic stress symptoms, but this variable is examined as a patient characteristic (i.e., individual difference) that may interact with treatment rather than a treatment outcome.

Quality of Life

Quality of life is a broad construct that includes general health perceptions as well as physical, mental, and social role functioning (e.g., ability to perform usual activities). Cancer treatments may have long-term effects on quality of life. For example, studies focusing on the impact of chemotherapy report significant disruptions in both physical and mental quality of life (Kiebert, Hanneke, deHaes, Kievit, & van de Velde, 1990; Palmer, Walsh, McKinna, & Greening, 1980; Schover, Yetman, Tuason et al., 1995). These studies suggest that chemotherapy side effects interrupt the gradual recovery in quality of life that usually occurs after surgery (Royak-Schaler, 1991). Lasting treatment sequelae can include fatigue, loss of stamina, reductions in physical functioning, difficulty concentrating, and pain (Broeckel et al., 2000; Michael et al., 2000). In an
observational study of 87 women with local or regional breast cancer, quality of life
disruptions remained for more than five years after treatment including difficulty
performing occupational tasks and daily activities, reduced sexual functioning, declines
in cognitive functioning (e.g., memory, concentration), and decreased emotional well-
being (e.g., increased tension, depression, and worries; Holzner, Kemmler, Kopp,
are clinically relevant, as these problems can impact compliance with medical
recommendations and subsequent affective illness (Bunston & Mings, 1995).

Twenty-nine controlled intervention studies examined quality of life (see Table
1). Most studies ($n=20$) used a global measure of quality of life that included both mental
and physical functioning. Forty-five percent of these studies found benefits for
intervention patients compared to control patients (see Appendix B, Table 12 for a
complete listing of studies and outcomes). Few studies assessed mental and physical
quality of life separately. Four of the seven studies assessing mental quality of life and
four of the eight studies examining physical quality of life reported improvements for
intervention patients. For all quality of life outcomes, approximately half of the studies
found benefits for patients in the intervention. Studies used a variety of intervention
strategies including supportive counseling, supportive-expressive therapy, psycho-
educational techniques, behavioral strategies, and cognitive-behavioral therapy.
Intervention effectiveness did not vary by approach for global, mental, or physical quality
of life outcomes.
SIBCP demonstrated benefits for nurse-rated physical functioning and treatment side effects. Analysis showed that the assessment-only control group was more symptomatic and restricted in their daily activities (including self-care) compared to the intervention group. In addition, women in the assessment-only group showed a greater increase in symptoms, signs, and illness related to cancer treatment toxicity relative to women in the intervention. From initial to 12-month assessment, physical symptoms increased by 32% in the assessment-only arm but only by 15% in the intervention arm.

**Social Adjustment**

Social support is an important resource for cancer patients. Cross-sectional and prospective studies report a positive association between social support and psychological adjustment (e.g., Bloom, Stewart, Johnston, Banks, & Fobair, 2001; Funch & Metlin, 1982; Helgeson & Cohen, 1996; Komblith, Herndon, & Zuckerman, 2001), better quality of life (Michael et al., 2000), and positive health outcomes (Reynolds, Hurley, Torres et al., 2000). Cancer represents a stressful life event that may negatively impact relationships, strain social support resources, and limit social activity (Bloom & Kessler, 1994; Bloom & Spiegel, 1984; Peters-Golden, 1982). Thus, cancer patients may experience disruptions in social support when it is needed most (Dakof & Taylor, 1990). Despite the interest in social support and the established relationship between social support and outcomes, few controlled intervention studies have assessed social adjustment. For example, Owen and colleagues (2001) reviewed 65 intervention studies, but found only two studies assessing social adjustment.
In our review of 109 studies, we identified twelve studies assessing social adjustment (see Appendix B, Table 13 for a complete listing of studies and outcomes). These studies used both supportive counseling and cognitive-behavioral strategies. Three of the seven studies using supportive counseling strategies found that these interventions increased social activities and relationship satisfaction. Two of the five studies using cognitive-behavioral strategies reported improvements for intervention patients in perceptions of social support and relationship satisfaction. These studies suggest that interventions have varying affects on measures of social adjustment. Table 1 displays the percent of intervention studies that showed benefits on several measures of social adjustment. Over half of the interventions showed benefits for social activities (67%) and relationship satisfaction (50%), but only one study found benefits for perceptions of social support. However, only limited conclusions can be drawn from these studies, as only one study included more than one measure of social adjustment.

In contrast, SIBCP examined four measures of social adjustment including social network, perceived support from family, perceived support from friends, and relationship satisfaction among married or cohabitating participants. SIBCP demonstrated benefits for perceived support from family. Analysis showed that perceived support from family increased in the intervention group but decreased in the assessment-only control group. Group comparisons for other measures of social adjustment did not reach statistical significance.
Health Behaviors

Distressed individuals may experience appetite disturbances or dietary changes (e.g., eating meals with lower nutritional value), increase smoking and caffeine intake, and reduce exercise or physical activity (Grunberg & Straub, 1992; Miller, Cohen, & Herbert, 1999; Pinto, Eakin, & Maruyama, 2000). Cancer patients may encounter additional difficulties, as some treatment side effects (e.g., food restriction, taste aversion, nausea, fatigue, and pain) may alter eating habits and exercise. Reducing unhealthy behaviors such as smoking, poor diet, and lack of exercise may reduce the risk of cancer recurrence and other chronic illnesses (e.g., cardiovascular disease, obesity, hypertension, diabetes), as is reviewed below.

Diet. For cancer patients, nutritional improvements could reduce rates of infection, improve quality of life, and contribute to disease-free survival (Galban, Montejo, Mesejo et al., 2000). To date, four controlled studies have targeted dietary changes using nutritional or dietary change interventions (see Appendix B, Table 14). All four studies found improvements in diet for intervention patients compared to control patients. In addition, two studies reported significant weight loss among intervention patients. These findings suggest that nutritional or dietary interventions are effective for cancer patients.

SIBCP included an intervention component targeting dietary change. Participants received information on an eating plan to reduce fat intake and increase fiber intake. The intervention emphasized the influence of discriminative stimuli for eating, the substitution of low-fat food items for high fat foods, and setting step-wise goals for lowering fat intake. Analyses of overall dietary habits indicated significant increases in
healthy food habits for intervention patients compared to control patients. Specifically, intervention patients were more likely to avoid fat and use healthy food substitutions.

*Exercise.* Cancer patients may discontinue exercise or reduce physical activity when undergoing and recovering from treatment. Six controlled studies examined exercise interventions for cancer patients (see Appendix B, Table 15 for a complete listing of studies and outcomes). These exercise interventions examined physical functioning, treatment side effects, and mood or quality of life outcomes. Three studies conducted in-hospital interventions and three studies conducted interventions with outpatients. The in-hospital studies included patients undergoing bone marrow transplant and interventions consisted of in bed cycling or resistive exercises (e.g., leg raises, sit-ups). Two of the in-hospital studies reported benefits for intervention patients including improved physical functioning, shorter length of hospital stay, and reduced anxiety. A third study did not find significant group differences. All three outpatient studies were conducted with breast cancer patients. These studies used a variety of exercise interventions (e.g., cycling, walking), and all three studies reported improvements in physical functioning for intervention patients. In addition, two of these interventions showed benefits for treatment side effects. Overall, exercise interventions demonstrated benefits for cancer inpatients and outpatients.

SIBCP included an at home walking protocol. The intervention sessions for this component included setting realistic goals, schedules for rest, techniques for increasing energy expenditures during daily activities, and coping strategies for setbacks. A 7-day
report of moderate and vigorous physical activity assessed exercise. Analysis showed an increase in physical activity among intervention patients compared to control patients ($p=.08$).

**Smoking.** Among cancer patients, continued smoking may increase rates of infection (Hussain, Kish, & Cain et al., 1991) and the risk of recurrence or death (Browman, Wong, Hodson et al., 1993; Stevens, Gardiner, Parkin, & Johnson, 1983). Four randomized smoking cessation studies have been conducted with cancer patients (see Appendix B, Table 16). Two studies reported higher abstinence rates among intervention patients compared to control patients, but the remaining two studies reported no group differences. The studies reporting null results conducted brief educational interventions, which may be insufficient for increasing quit rates beyond the high post-operative smoking cessation rate found in cancer patients (e.g., 50% to 60%; Andersen, 2002). The two studies reporting significant findings conducted longer interventions with several components: discussion of smoking habits, the development of smoking alternatives, progressive muscle relaxation training, and maintenance strategies. Additional studies are needed to test smoking cessation strategies such as nicotine replacement.

SIBCP provided intervention patients with information on smoking cessation and specific referral to community/self-help resources for smokers. Self-report smoking status and daily cigarette intake were recorded. Analyses for smoking showed that the number of cigarettes smoked daily decreased for intervention patients but increased for assessment-only patients. In addition, there were changes in smoking status from 12
months prior to diagnosis to the post-treatment assessment. Compared to assessment-only control patients, intervention patients were less likely to resume or continue smoking (90% vs. 30%, respectively).

*Treatment compliance*

Compliance with cancer treatment impacts the ability to control local and distant disease. For example, chemotherapy noncompliance can hasten recurrence or death (Budman, Berry, Cirrincione et al., 1998). Patients may experience multiple barriers for compliance including difficulty understanding treatment recommendations, financial problems, and lack of transportation. In addition, treatment toxicities (e.g., nausea, sleep disturbance, hair loss) may contribute to noncompliance. Treatment regimens for some disease sites (e.g., head/neck, lung, and vulva cancers) include extensive surgery, high doses of chemotherapy, and combined radiation and chemotherapy. These difficult regimens result in considerable toxicity (Huang, Wilkie, Schubert, & Ting, 2000). Despite the importance of patient compliance, few studies have targeted compliance directly or indirectly (Andersen, 2002). We identified one controlled intervention study with cancer patients that directly addressed patient compliance.

Richardson and colleagues (1987) conducted a study comparing medication shaping versus home visit for improving medication and chemotherapy compliance among patients with hematologic malignancies. Ninety-two patients were randomized to one of four conditions: 1) no-treatment control, 2) education and medication shaping, 3) education and home visit, or 4) education, medication shaping, and home visit. The education component included disease and treatment information with a focus on the importance of treatment compliance. Project nurses conducted the home visit
component, which included developing a “cue” system for pill taking. Finally, nurses conducted the in-hospital medication shaping component with medication shifting from nurse-administered to patient-initiated requests. Patients were followed for six months. Analysis indicated improved compliance (assessed by self-report and serum samples) for all intervention groups compared to the no-treatment control group. Medication shaping and home visit groups did not differ. Additional studies are needed to test strategies for improving treatment compliance. To date, intervention studies have not addressed treatment refusal, premature termination of treatment, or receipt of less treatment than recommended (e.g., fewer radiation sessions than prescribed). This area needs immediate study, as noncompliance directly impacts disease outcomes (Vokes, Haraf, Stenson et al., 2000).

SIBCP included an intervention component targeting treatment compliance. Intervention patients received disease and treatment information, relaxation and distraction techniques for coping with treatment side effects or anxiety, and assertive communication strategies to enhance communication with health care professionals. Overall, SIBCP participants had high rates of treatment compliance (i.e., 67% of patients received 90% of their recommended regimen dose). The variance of dose-intensity in the assessment arm was significantly greater, suggesting more individual variability in dose-intensity for control patients compared to intervention patients. In addition, 10 of the 13 patients who discontinued chemotherapy or were lost to medical follow-up were from the control group.
Biologic Outcomes

Immune functioning is important for cancer patients, as it may impact risk of recurrence or death. The immune system may contribute to host resistance against cancer progression through several mechanisms including detection of cancer cells, mounting an effective response to existing cancer cells, and eradicating newly formed cancer cells (Andersen, 2002). Studies suggest that stress impacts the immune system through activation of the sympathetic nervous system (Felten, Ackerman, Wiegand, & Felten, 1987) or through neuroendocrine-immune pathways (e.g., Evans, McCartney, & Nemeroff et al., 1986; Joffe, Rubinow, Denicoff, Maher, & Sindelar, 1986; McDaniel, Musselman, Porter, Reed, & Nemeroff, 1995). In addition, hormones released under stress (e.g., cortisol, epinephrine, norepinephrine, and prolactin) have been associated with immune modulation (for a discussion see Maier, Watkins, & Fleshner, 1994).

To date, nine controlled intervention studies have attempted to enhance immune functioning by reducing levels of distress or levels of stress-related hormones (see Table 1 and Appendix B, Table 17 for a complete listing of studies and outcomes). Findings are mixed, with five studies reporting benefits for intervention patients and four studies reporting null results. Studies using behavioral strategies (e.g., relaxation, imagery) found benefits for quantitative and functional measures of immune functioning. Overall, generalization is limited, as studies included small samples (13 to 96 patients) and most studies were conducted with breast cancer patients. To date, studies have used non-specific immune measures, which may not be relevant for cancer. Additional studies are needed to test intervention effectiveness for biologic outcomes and future studies should include cancer-related outcomes such as tumor-specific immune responses.
SIBCP demonstrated benefits for immune functioning. T-cell proliferation in response to concanavalin A (Con A) increased for intervention patients, but declined for assessment-only control patients. Similarly, t-cell proliferation in response to phytohemagglutinin (PHA) remained constant for the intervention group, but significantly declined for the assessment-only group. Follow-up analyses showed that these effects replicated across all dilutions of Con A and PHA.

Survival

Research, medical, and patient communities have shown considerable interest in linking psychosocial interventions with length of survival. To date, ten controlled studies have examined survival outcomes (see Appendix B, Table 18 for a complete listing of studies and findings). Four studies reported survival benefits for intervention patients and six studies reported no group differences. Studies used various intervention strategies including supportive-expressive therapy, cognitive-behavioral therapy, and supportive counseling interventions. Findings did not differ by intervention approach. We can reach only limited conclusions from current studies of survival, as most studies had small or selective samples, high attrition rates, and some studies were not designed to test survival effects. Importantly, three of the four studies that found survival benefits were not designed to examine survival outcomes (Fawzy, Fawzy, Huyn et al., 1993; Richardson, Zarnegar, Bisno, & Levine, 1990; Spiegel, Bloom, Kraemer, & Gottheil, 1989). Later studies designed to replicate their findings reported null results (e.g., Cunningham, Edmonds, Jenkins et al., 1998; Goodwin, Leszcz, Ennis et al., 2001).
Survival outcomes reported by studies that were not designed to test survival should be interpreted with caution. These studies did not assess or control for potential confounding factors (e.g., self-care behaviors).

**Conclusions and recommendations**

Overall, data suggest that interventions provide a feasible way of reducing the burdens experienced by cancer patients. Of the 109 studies reviewed, 79% demonstrated benefits for intervention participants on at least one outcome. Most studies target emotional distress or quality of life, with few studies (i.e., one to twelve studies per outcome) targeting other outcomes. Treatment compliance represents the area in most need of study. Despite the influence of treatment compliance on disease course, only two controlled intervention studies have been conducted (Andersen et al., 2004; Richardson et al., 1987). Additional studies are needed to test whether interventions can reduce treatment refusals, premature termination of treatment, or receipt of less treatment than recommended. Other areas in need of attention include health behaviors, social adjustment, and biologic outcomes. Review of past intervention studies suggests that psychosocial and behavioral interventions are promising strategies for improving compliance, health behaviors, social adjustment, and biologic outcomes.

**Intervention Characteristics**

The above review provides outcome-specific discussions, but several key issues apply to all intervention studies. Intervention characteristics may impact treatment efficacy, generalizability, and clinical applications. These factors must be considered when evaluating the advantages and limitations of utilizing data from SIBCP. Below we discuss relevant intervention characteristics including 1) intervention approach, 2)
intervention format (group vs. individual), 3) intervention leaders (e.g. professional, volunteer), 4) intervention timing, 5) intervention length, 6) length of follow-up, 7) assessment of outcomes, and 8) sample characteristics.

*Intervention approach*

Interventions for cancer patients include a variety of approaches: supportive counseling, supportive-expressive therapy, education, behavioral therapy, and cognitive-behavioral therapy. These approaches yield similar results with the exception of behavioral strategies (e.g., relaxation, imagery), which most consistently demonstrate benefits. Some studies use interventions based on theory (e.g., cognitive-behavioral therapy, supportive-expressive therapy) or empirical support (e.g., dietary interventions), but many studies use interventions that do not have a clear basis. Without this foundation, it is difficult to understand the mechanisms responsible for improvements, and replication of interventions is difficult. For example, supportive counseling interventions represent the most frequently used approach for cancer patients. Yet, these interventions vary widely (e.g., nurse interview and support, peer support, support groups) complicating study comparisons. If we aim to include interventions in the management and treatment of cancer patients, interventions must have a theoretical or empirical foundation and we must identify empirically supported treatments (Compas et al., 1998).

Chambless and Hollon (1998) set forth criteria for empirically supported treatments and outline differing levels of empirical support. Empirically supported treatments must demonstrate efficacy in controlled research with a clearly defined population. The intervention must be conducted using a manual (or the logical
equivalent) and reliable and valid measures must be used to assess the variables targeted for change. A treatment is considered efficacious if it demonstrates statistical superiority to a control in at least two independent studies. Possibly efficacious treatments are those demonstrating statistical superiority in one study (or multiple studies by the same research group) with an absence of conflicting data. Last, a treatment is efficacious and specific if it demonstrates superiority to an alternative bona fide treatment, pill, or psychological placebo in at least two independent studies. Below we review the efficacy of several intervention approaches frequently used with cancer patients.

**Educational interventions.** Educational interventions aim to provide needed information, reduce feelings of helplessness through knowledge, and give patients a feeling of mastery or control (Fawzy, Fawzy, Arndt, & Pasnau, 1995). Patients and family members may be more comfortable in educational group formats compared to support focused groups and educational groups may provide a format for patients, who want to learn more, but are uncomfortable talking about their feelings (Dunkel-Schetter, 1984; Fobair, 1997). To date, 14 controlled intervention studies have used educational formats. Overall, educational interventions were brief ($M=4$ sessions, range=1 to 11), delivered in group formats, and most provided written information (e.g., booklets, brochures). These studies examined emotional distress, traumatic stress, and quality of life outcomes, with most studies demonstrating benefits for intervention patients. Educational interventions have not examined social adjustment, biologic, or survival outcomes. According to the criteria established by Chambless and Hollon (1998), educational interventions can be considered a possibly efficacious treatment for emotional distress and quality of life.
Supportive-expressive therapy. Supportive-expressive therapy focuses on the development of supportive relationships among group members and leaders. Emphasis is placed on the expression of deep emotional reactions to cancer experiences including concerns about death, facing grieving and loss, and finding meaning in the cancer experience through helping other patients and their families. Some supportive-expressive interventions also include pain management strategies and assertiveness in dealing with medical professionals. Spiegel and colleagues have conducted the most comprehensive development and evaluation of supportive-expressive therapy for cancer patients (Spiegel & Bloom, 1983; Spiegel et al., 1989; Spiegel, Bloom, & Yalom, 1981). To date, five controlled studies have examined the impact of supportive-expressive therapy on emotional distress, cancer-specific traumatic stress, quality of life, and survival. While survival outcomes were inconsistent, supportive-expressive therapy demonstrated benefits for psychological outcomes in several independent studies and can be considered an efficacious treatment. However, all studies were conducted with metastatic breast cancer patients and thus, additional studies are needed to replicate supportive-expressive therapy’s benefits in other cancer populations.

Behavioral strategies. Behavioral interventions include relaxation training (e.g., progressive muscle-relaxation), guided imagery, and biofeedback. These strategies have been widely used with cancer patients to treat chemotherapy side effects (e.g., nausea, vomiting, and anxiety) and can be considered an efficacious treatment for these outcomes (Compas et al., 1998). A smaller number of studies have examined emotional distress and biologic outcomes. Eight of the nine studies assessing emotional distress and both studies examining biologic outcomes reported benefits for intervention patients.
Behavioral interventions represent an efficacious treatment for emotional distress, as benefits were replicated in multiple independent studies. While behavioral strategies demonstrated efficacy for biologic outcomes in two independent studies, one study (Gruber, Hersh, Hall et al., 1993) included an extremely small sample ($N=13$). Thus, for biologic outcomes, behavioral interventions should be considered possibly efficacious until additional studies replicate these findings.

Cognitive-behavioral therapy. Interventions that rely on cognitive-behavioral techniques are widely used with cancer patients in group and individual formats. These interventions include a variety of components: basic coping skills, problem-solving skills, stress management, relaxation training, health education, assertiveness training, communication skills, management of emotions, and support. Most interventions dedicate one to three sessions per topic. To date, 29 controlled studies have used cognitive behavioral interventions. Studies demonstrated benefits for emotional distress and quality of life. Too few studies have assessed traumatic stress, social adjustment, and immune functioning to draw conclusions about the efficacy of cognitive-behavioral therapy for these outcomes. In spite of generally favorable results for psychological outcomes, cognitive-behavioral interventions meet criteria for a possibly efficacious treatment rather than an efficacious treatment. Interventions included many common elements, but studies did not involve replications of the same intervention.

*Intervention format*

Interventions for cancer patients have used individual and group formats. Across the 109 studies we reviewed, approximately half used group formats. A clear pattern of results did not emerge by format. In contrast, Sheard and Maguire (1999) conducted a
meta-analysis of intervention studies examining anxiety and depression among cancer patients. For anxiety, group interventions demonstrated an effect size that was 50% larger than the effect size for interventions delivered in an individual format. A similar trend was found for studies of depression, but the difference in effect sizes did not reach statistical significance. To date, it is unclear whether an advantage exists for individual or group interventions. However, many patients report a preference for group interventions. In nine studies reviewed by Petersson and colleagues (2000), the opportunity to meet other patients in the same situation was rated as most beneficial or helpful.

*Intervention leaders*

The characteristics of intervention leaders (in both individual and group formats) may impact treatment outcomes. Schopler and Galinsky (1993) describe several important leader qualities including experience, knowledge, skill, and approach to treatment. Leaders from various backgrounds conduct interventions with cancer patients: nurses, social workers, psychologists, volunteers, and cancer survivors. The experience, skill, and approach of these leaders may vary widely. In a meta-analysis of psychological interventions for cancer patients, Sheard and Maguire (1999) found that intervention leader experience was positively associated with treatment outcomes for both depression and anxiety. Among the 109 intervention studies we reviewed, data did not show differential outcomes across professional leaders.

Data does suggest that peer leaders are less effective for support group or supportive counseling interventions (Helgeson, Cohen, Schulz, & Yasko, 1999; McArdle, George, McArdle et al., 1996). In fact, Helgeson and colleagues (1999) found that peers
negatively affected women who started the intervention with high levels of support. One intervention study with cancer patients has directly compared treatment outcomes for groups with professional and peer leaders. Samarel and colleagues (1997) compared an eight-week professionally led support group with a peer-only support group. Patients in the professionally led group experienced greater improvements compared to patients in the peer-only group or no-treatment control group, and patients in the peer-only group did not differ from no-treatment control patients. In contrast, studies suggest that peers or lay volunteers may be effective for content-specific informational (e.g., diet, nutrition) or behavioral (e.g., relaxation training) interventions (Kristal, Shattuck, Bowen, Sponzo, & Nixon, 1997). Additional studies are needed to directly test for leader characteristics associated with positive treatment outcomes.

**Intervention timing**

Samples included in intervention studies vary widely in time since diagnosis and treatment. Owen and colleagues (2001) reviewed 65 randomized studies of psychosocial interventions for cancer patients. With regard to timing of treatment, only 32% of studies recruited patients at a specific point in cancer treatment or follow-up and the remaining 68% recruited patients regardless of when they received a cancer diagnosis. Our review of 109 intervention studies revealed similar findings. Krupnick and colleagues (1993) assert that interventions will be more effective if designed for the changing needs and concerns of patients over the course of illness, treatment, and recovery. Based on a review of the literature, Fawzy et al. (1995) and Krupnick et al. (1993) suggest that newly diagnosed patients or patients in the early stages of treatment may benefit most from structured interventions that focus on education, stress management, and development of
problem-solving or coping skills. During this time, patients are often distressed or anxious and may be unable to utilize their typical coping efforts. For patients who are post-treatment and disease-free, Krupnick and colleagues (1993) recommend interventions that focus on adjusting to the sequelae of cancer, coping with survivorship issues, managing emotions, and support. Studies are needed to test whether patients gain more benefit from different intervention techniques across the course of diagnosis, treatment, and recovery.

*Intervention length*

Intervention length varies across treatment strategies. Most supportive counseling and cognitive-behavioral interventions include 6 to 12 weekly sessions (1 to 1.5 hours). In contrast, psycho-educational and behavioral interventions are usually brief, with most treatments including one to four sessions (range = 1 to 11). Supportive-expressive therapy interventions are on average the longest, with patients attending weekly sessions for at least 12 months. Intervention length is positively associated with the magnitude of treatment effects. Rehse and Pukropp (2003) conducted a meta-analysis of 37 intervention studies with cancer patients. Studies with 12 or more sessions had an effect size of .51, but studies with less than 12 sessions had an effect size of .23. Intervention length was the most powerful predictor of effect size. In an effort to increase the magnitude and duration of treatment effects, some studies have increased intervention length (Howard, Kopta, Krause, & Orlinsky, 1986; Maling, Gurtman, & Howard, 1995). This strategy may increase treatment effects, but limited resources and cost exclude increasing intervention length as an option in clinical settings. Future
studies should focus on other strategies for increasing effects such as limited inclusion criteria (e.g., high distress patients only) or including treatment components with demonstrated efficacy (e.g., relaxation training).

Length of follow-up

The duration or maintenance of treatment effects is important for cancer patients due to the long-term impact of diagnosis and treatment (e.g., recurrence, financial difficulties, support disturbances, physical functioning problems). Most studies report short-term intervention effects (e.g., immediately post-treatment, 1 month post-treatment), but these effects may not be present at later follow-up. Among the 109 studies we reviewed, 16 studies reported intervention effects 6-months post-treatment and 21 studies reported effects at 12-month follow-up or later (longest follow-up 36 months). Seventy-six percent (n=28) of these studies found that intervention effects were maintained (12 studies with 6-month follow-up and 16 studies with follow-up at 12-months or later). Most studies providing long-term follow-up report data for psychological adjustment, quality of life, or survival outcomes. Few studies report long-term data for health behaviors or biologic (immune or endocrine data) outcomes. The results of studies with long-term data are promising, but additional studies with long-term follow-up are needed.

Assessment of outcomes

Most intervention studies assess emotional distress or quality of life outcomes. While these outcomes are important for cancer patients, few studies have assessed other important outcomes such as social functioning, health behaviors, treatment compliance, and immune functioning. Some interventions include components for targeting these
outcomes, but fail to assess related variables. Without specifying and measuring all appropriate outcomes, intervention comparisons will not be of equal standard (Compas et al., 1998). In addition, the efficacy of interventions cannot be determined when studies inconsistently assess outcomes or dependent measures vary across studies (Fries & Singh, 1996). Future intervention studies should include psychological, behavioral, and biologic outcomes. Assessing all relevant target variables with well-validated and similar measures will allow for comparisons across studies.

Assessment strategies also need attention. Studies use various dependent measures, which vary in reliability, validity, and sensitivity for detecting change. Reliable and valid self-report measures for emotional distress and quality of life have been developed and tested with cancer patients (e.g., Profile of Mood States, SF-36, FACT-scales, CES-D). These measures are appropriate for most cancer samples and can detect group differences or changes over time. However, studies including cancer patients with high levels of distress or past psychiatric diagnoses may need to incorporate measures designed to assess psychopathology (Andersen, 2002). Further, studies rely heavily on self-report measures, which may be inaccurate when used alone. Efforts should be made to include biologic measures, observational data, and other objective assessments to corroborate self-report data.

Sample characteristics

A number of patient characteristics should be considered when designing cancer interventions including disease site, disease severity, and the type of cancer treatments (Andersen, 1992; Compas et al., 1998). Disease and treatment characteristics may be associated with risk for specific psychological morbidities, physical functioning
difficulties, or socio-demographic characteristics. For example, breast cancer patients and head/neck cancer patients differ in the etiology of disease, the psychological responses to their illness and treatment, and their socio-demographic characteristics (e.g., gender). Interventions may have different effects due to these factors (Compas et al., 1998). An intervention designed for one group of cancer patients may be inappropriate for individuals with other types of cancers, as some topics may not apply and other important topics may not be addressed. To date, most intervention studies have been conducted with breast cancer patients. It is unclear whether findings will replicate in patients with other disease sites.

Other important patient variables include socio-demographic characteristics and pre-cancer psychological and physical functioning. To date, intervention research has understudied cancer patients who are men, non-Caucasian, under 40 years of age, over 65 years of age, low income, or low education (Andersen, 2002). Yet, these patients experience the greatest disease burden including higher rates of diagnosis, more aggressive cancers, less access to treatment, and higher mortality rates (ACS, 2004; Bradley, Given, & Roberts, 2002; National Cancer Institute, 2000). Interventions that have benefits for middle-class, Caucasian women may not be effective for other cancer patients. Finally, most intervention studies exclude patients with prior psychological or physical conditions. These patients have the highest risk for developing adjustment problems following cancer diagnosis and treatment (Satariano, 1992). Excluding these patients may attenuate intervention effect sizes and limit our ability to generalize findings.
Conclusions and recommendations

While evidence strongly supports intervention efficacy for cancer patients, study differences limit our ability to make specific recommendations for clinical settings. Interpretation of conflicting results is complicated by differences in treatment components, study design, and dependent measures. In addition, findings cannot be generalized to many of the patients found in clinical settings. Men, patients with low income, young (<40) and old (> 65) patients, non-Caucasian patients, and patients with previous psychological or physical illness have been underrepresented in study samples. If we aim to routinely include interventions in cancer treatment, more concrete and empirically based recommendations are needed. Future research should focus on decreasing methodological inconsistencies between studies, improving accrual strategies to capture underrepresented populations, and formal testing of factors (including intervention and sample characteristics) that influence treatment outcomes.

For the proposed study, we must consider intervention characteristics when evaluating the advantages and limitations of utilizing SIBCP data. SIBCP provides several important advantages that increase our ability to generalize findings. First, this intervention used a cognitive-behavioral approach in a group format, which is consistent with past intervention studies demonstrating positive treatment effects. The factors associated with treatment outcomes in SIBCP should generalize to other cognitive-behavioral group interventions. Second, similar to past cognitive-behavioral interventions, SIBCP used intervention leaders who were trained professionally (i.e., psychologists). Data suggest that having professionally trained leaders contributes to positive treatment outcomes. Third, SIBCP measured multiple treatment outcomes
corresponding to each of the intervention components (see Table 2). The inclusion of multiple measures increases the likelihood that SIBCP assessed outcomes similar to those measured in past studies. Finally, the timing of the intervention was controlled so that all participants entered the study after surgery but prior to the start of adjuvant therapy. Controlled timing allows us to generalize findings to patients undergoing cancer treatment.

Several intervention characteristics may limit the generalizability of SIBCP data. First, the SIBCP intervention is longer than past interventions. While the average cognitive-behavioral intervention includes 6 to 12 sessions, SIBCP included 18 weekly sessions. Maintenance components were also included within the intervention, which differs from most past studies. Second, outcomes were assessed immediately post-treatment and it is unknown whether these intervention effects will persist. Findings from the current study may not generalize to long-term intervention outcomes. Finally, this sample is representative of other breast cancer samples, which limits our ability to generalize findings to patients with other disease sites.

Patient characteristics

Cancer patients experience significant burdens (e.g., treatment side effects, financial difficulties), which psychological or behavioral interventions may reduce. Before making treatment recommendations, we must understand for whom interventions are most effective, least effective, non-effective, or even harmful. Patient characteristics may impact treatment efficacy (Schopler & Galinsky, 1993). For example, studies of psychotherapy report that patient characteristics can be a stronger predictor of outcome than treatment factors (Neimeyer & Weiss, 1990). More information should be obtained
from intervention studies than is currently learned. In addition to intervention main effects, randomized clinical trials can provide information about interactions between patient characteristics and interventions (Kraemer, Wison, Fairburn, & Stewart, 2002). For cancer patients, several characteristics should be examined. Below we discuss socio-demographic variables (e.g., socio-economic status, age, marital or partner status, social network), disease and treatment characteristics (e.g., cancer site, stage, type of surgery, type of adjuvant therapy), individual differences (e.g., initial level of distress), and personality characteristics (e.g., neuroticism).

*Socio-demographic variables*

An individual’s personal resources influence adjustment to major life stressors, including cancer. Population studies consistently find higher rates of morbidity and mortality among individuals with low socio-economic status (Geronimus, Bound, & Waidmann, 1999). For cancer, low socio-economic status is associated with higher cancer incidence and mortality (Freeman, 1989; Yabroff & Gordis, 2003). Circumstances associated with low socio-economic status may contribute to poorer disease and psychological outcomes including sub-standard housing, unemployment, poor nutrition, lack of transportation, higher rates of comorbid illness, and diminished access to healthcare. In this context, cancer becomes an additional stressor and individuals have fewer resources for coping with the illness. Intervention studies with cancer patients have used education and income as a proxy for socio-economic status. In a controlled intervention study with 73 African-American breast cancer patients, Taylor, Lamdan, Siegel et al. (2003) found an interaction showing that the intervention was most effective for women with low income. Lepore, Helgeson, Eton, and Schulz (2003)
evaluated educational and peer discussion interventions among 250 men with prostate cancer. Analysis revealed an interaction between education level and treatment outcomes. Education and peer discussion interventions improved physical functioning for men without a college degree, but did not benefit men with a college degree or more.

Younger cancer patients may be at greater risk for long-term psychological adjustment problems compared to older patients. Younger women are more likely to be candidates for aggressive treatments, experience more cancer-related life disruptions, and experience greater distress during diagnosis and treatment (Dean, 1987; Hughson, Cooper, McArdle, & Smith, 1988; Meyerowitz, Watkins, & Sparks, 1983; Northhouse & Swain, 1987; Schover, 1994; Vinokur, Thrett, Vinokur-Kaplan, & Satariano, 1990). For example, Vinokur and colleagues (1990) followed 274 women with breast cancer during the year after their diagnosis. Younger age exacerbated the impact of physical impairment on mental health. Further, impaired younger patients experienced greater psychological problems than similarly impaired older patients. Consistent with these findings, Van’t Spijker, Trijsburg, and Duivenvoorden (1997) conducted a meta-analysis of 58 studies and found that younger patients (< 50 years) demonstrated more depression, anxiety, and general distress compared to older patients (> 50 years). One controlled intervention study has tested for the impact of age on treatment outcomes. Burton and Parker (1995) conducted a preoperative supportive counseling intervention with 200 breast cancer patients. Younger (< 60 years) breast cancer patients benefited most from the intervention.

Social support impacts psychological and physical functioning following cancer (Bloom et al., 2001; Funch & Metlin, 1982; Helgeson & Cohen, 1996; Kornblith et al.,
2001). While marital status and size of social network are not substitutes for measures of social support, studies suggest that these variables may be an adequate proxy for identifying individuals at risk (Andersen, 2002). For example, married persons live longer and have lower mortality rates for all illnesses compared to single, widowed, divorced, or never married persons. Population based studies of cancer patients indicate that patients with small social networks and unmarried patients have decreased survival rates, poorer treatment response, present with more advanced disease, and have a higher likelihood of being untreated for cancer (Goodwin, Hunt, & Samet, 1987). Helgeson and colleagues (2000) conducted education and discussion interventions for 312 breast cancer patients. Women with low support from partners and medical professionals benefited most from the education and discussion groups on physical QOL outcomes. Interestingly, peer support groups had a negative impact on women who entered the study with high levels of support.

Disease and treatment characteristics

Multiple studies demonstrate that disease and treatment characteristics covary with psychological adjustment (Andersen, 1994). Cancer patients with greater disease severity, more extensive surgery, more aggressive treatments, and poorer prognosis experience the greatest disruptions in psychological and functional adjustment (Bloom, 1987; Ganz, Schag, Lee, Polinsky, & Tan, 1992; Ganz, Rowland, Desmond, Meyerowitz, & Wyatt, 1998; Kemeny, Wellisch, & Shane, 1988; Kiebert et al., 1990; Lasry, Margolese, Poisson et al., 1987; Meyerowitz et al., 1983; Palmer et al., 1980). For example, clinical trials comparing surgical treatments for breast cancer also examined the impact of surgery on psychological adjustment. Kemeny et al. (1988) examined
psychosocial outcomes among women randomized to either mastectomy or breast conserving surgery in a prospective clinical trial. Women who received breast conserving surgery reported less anxiety, less sadness, and a more positive body image than those with mastectomies. Lasry and colleagues (1987) investigated psychological and social adjustment among women randomized to total or partial mastectomy. Total mastectomy patients showed higher levels of depression and less satisfaction with body image. Disease and treatment characteristics may impact the effectiveness of psychosocial interventions. To date, one study has examined the association between extent of treatment and intervention efficacy. Burton et al (1995) conducted a preoperative supportive counseling intervention with 200 breast cancer patients. Analysis showed that the intervention was more effective for women who received mastectomy compared to breast conserving surgery.

*Individual differences*

The individual difference variable chosen for study should be relevant for intervention outcomes. Among cancer patients, those with past psychiatric disorder or high levels of distress at diagnosis may be at risk for long-term disruptions in psychological adjustment (Lansky, List, Herman et al., 1985; Maunsell, Brisson, & Deschenes, 1992; Nordin & Glimelius, 1998; Plumb & Holland, 1981). Maunsell et al. (1992) examined emotional distress in a longitudinal study of 200 women with breast cancer. At 18 months post-treatment, 63% of patients with a history of depression reported distress compared to only 14% of patients without a history of depression. Graydon (1988) examined the association between pre-treatment emotional distress and psychological adjustment following radiotherapy in a sample of 79 patients with breast or
lung cancer. Initial distress was the only predictor of post-treatment psychological adjustment and follow-up analysis showed that the tension-anxiety component of distress was the best predictor of adjustment. Similarly, Schag and colleagues (1993) examined distress and psychological adjustment among 227 newly diagnosed breast cancer patients. One year later, women with high distress at diagnosis had significantly more problems with greater severity than low distress women in multiple areas (physical, psychosocial, medical interaction, sexual, and marital).

To test for an interaction between individual differences and treatment outcomes, the individual difference variable should differ from the treatment outcome. Using the same variable can result in spurious findings due to regression to the mean (i.e., extreme values will regress to the mean giving the appearance of an interaction). To date, two studies have examined the association between treatment outcomes and pre-intervention emotional distress (Goodwin et al., 2001; Taylor et al., 2003). Taylor et al. (2003) tested a cognitive-behavioral intervention among 73 African American breast cancer patients. For mental adjustment and cancer-specific traumatic stress, the intervention was most effective among women who entered the study with high levels of cancer-related psychosocial problems (CARES-SF Psychosocial subscale). Goodwin et al. (2001) found a similar interaction. They conducted a controlled study of supportive-expressive therapy among 235 women with metastatic breast cancer. Women with high initial distress benefited from the intervention, whereas women with low distress did not experience benefits. However, Goodwin and colleagues (2001) used the same variable for the individual difference and outcome.
Personality

Personality variables may impact adjustment by influencing stress and coping responses. For example, Carver and colleagues (1993) examined optimism, coping, and psychological adjustment among 59 women with Stage I or II breast cancer. Optimism was associated with lower distress and its effect on distress was mediated by coping responses. Compared to women with low levels of optimism, individuals high in optimism chose more positive coping responses (e.g., acceptance, humor, or positive reframing). One study has examined the association between optimism and treatment outcomes. Antoni and colleagues (2001) conducted a 10-week cognitive-behavioral stress management intervention with Stage I or II breast cancer patients. Analysis demonstrated greater intervention effects for depressive symptoms and benefit finding among women low in optimism.

Studies demonstrate a link between high levels of neuroticism and poor psychological adjustment among cancer patients (Harrison & Maguire, 1994; Thomas et al., 1987). Neuroticism is described as a stable and pervasive personality trait that impacts all aspects of subjective experience (Clark, Beck, & Stewart, 1990). Individuals high in neuroticism experience increased levels of negative and distressing emotions, increased dissatisfaction in all situations, are more introspective, are more likely to dwell on personal failures and short-comings, and have a less favorable view of the self (Costa & McCrae, 1985; Costa & McCrae, 1987; Watson & Clark, 1984). Ogrodniczuk et al. (2003) examined the relationship between personality and treatment outcomes among
107 patients participating in short-term therapy for complicated grief. Neuroticism predicted poorer treatment outcomes. Studies with cancer patients have not examined the impact of neuroticism on treatment outcomes.

Conclusions and recommendations

Patient characteristics may influence treatment outcomes (Paul, 1969). Moderator analyses, or testing for patient by treatment interactions, can specify for whom or under what conditions a treatment works (Barron & Kenny, 1986; Kraemer et al., 2002). Testing for moderators can help clarify appropriate inclusion criteria, identify the most appropriate stratification for maximizing power, and guide hypothesis generation and testing (Kraemer et al., 2002). Without this type of analysis, we may base future studies on flawed assumptions or misinterpret findings. For example, a treatment that appears non-effective in group comparisons could demonstrate benefits for individuals with high levels of pre-treatment distress. Overly generous inclusion criteria caused this treatment to appear non-effective. Testing for moderators is frequently recommended (e.g., Kazdin & Wiesz, 1998; Kraemer et al., 2002), but there is little formal emphasis on this type of analysis. Most intervention studies with cancer patients examine moderators post hoc (e.g., Goodwin et al., 2001; Stanton, Danoff-Berg, Sworowski et al., 2003; Taylor et al., 2003). To date, one study (Helgeson, Cohen, Schulz, & Yasko, 2001) has formally examined potential moderators, but analyses were limited to support variables. A rich intervention literature exists, which could provide many opportunities to formally test for treatment moderators.
**Intervention evaluations and utilization of intervention techniques**

Understanding how interventions work is a central question that must be addressed. Patient perceptions, experiences, or evaluations of treatment may impact intervention outcomes. For example, a lack of satisfaction or a negative experience during treatment can impact patient compliance, comfort or trust in intervention leaders, and patient emotional adjustment (Alpert, 1964; Perrone & Sadlacek, 2000; Wilson & McNamara, 1982). Studies of psychotherapy outcomes have examined the influence of patient evaluations in both individual and group treatment formats, but little data are available for interventions with cancer patients. Potentially important variables include satisfaction with intervention content, group experiences, group cohesion, and utilization of intervention techniques.

**Satisfaction**

Patient satisfaction is a desirable goal, as it is an important determinant of patient compliance (Ley, 1988). Past studies with psychotherapy and primary care outpatients have identified an association between patient satisfaction and compliance including appointment keeping (Alpert, 1964; Becker, Drachman, & Kirsch, 1972; Francis, Korsch, & Morris, 1969), intentions to comply with treatment recommendations (Wilson & McNamara, 1982), and medication use (Ludy, Gagnon, & Caiola, 1977). In group psychotherapy, patient satisfaction is also associated with willingness to participate or be active in groups and with group cohesion (Perrone & Sdlacek, 2000). Assessing patient satisfaction can provide valuable information for improving intervention design, content, and compliance. In addition, because positive intervention outcomes are dependent on compliance, patient satisfaction may be related to treatment efficacy.
Among cancer patients, responses to general questions about treatment satisfaction are generally positive and often fail to capture important information (Bottomley, 1998). Questions for specific program components may yield greater response variability and richer information (Heinrich & Schag, 1985). For example, Petersson and colleagues (2000) reviewed nine intervention studies with cancer patients that assessed satisfaction. When patients were asked to rate interventions overall, most patients reported being highly satisfied. In contrast, patients expressed different levels of satisfaction when asked about various intervention components. When relaxation was included in the intervention, patients rated this component as most helpful (Petersson et al., 2000; Bottomley, 1998; Heinrich & Schag, 1985). Other intervention components rated highly include educational information about disease/treatment and discussions about treatment side effects (Berglund, Petersson, Eriksson, & Haggman, 2003; Gray, Fitch, Davis, & Phillips, 1997; Heinrich & Schag, 1985; Petersson et al., 2000).

For group interventions, satisfaction with group composition can impact patient compliance, group cohesion, and willingness to participate in groups. Plant and colleagues (1987) assessed satisfaction among cancer patients participating in a monthly support group. This intervention allowed new members to join the group at any time. Patients reported being reluctant to speak openly and feeling restricted when they did not know all the people attending the group. These data suggest that patients may participate and benefit most in interventions with closed enrollment. Some intervention groups include a combination of patients, significant others, and family members. Petersson and colleagues (2000) assessed cancer patients’ preference for including significant others in interventions. Most patients (67% of men and 90% of women) preferred a group for
patients only and did not want significant others present in the intervention. However, approximately half of men and women wanted a separate intervention available for significant others.

*Group experiences*

The frequency of positive or important group experiences may be an important determinant of patient compliance. Glajchen and Magen (1995) examined group experiences among 392 cancer patients participating in community-based cancer support groups. Positive experiences rated as most important included 1) realizing others were experiencing similar problems, 2) feeling that group members provided comfort, 3) emotional support, 4) advice, and 5) the opportunity to ventilate feelings. Similarly, in all nine studies reviewed by Petersson and colleagues (2000) and in their own data (Berglund et al., 2003; Petersson et al., 2000), group members rated the opportunity to meet other patients in the same situation as most important. Patients have reported that groups reduce feelings of social isolation and that they often obtain new information through group members (Fobair, 1997). Assessing which group experiences patients find important or meaningful can provide valuable information for improving intervention design, content, and compliance.

In group interventions, patients may encounter positive and negative experiences. While positive experiences enhance the perceived benefits of treatment and increase participation, negative experiences can lead to patient drop out (Glajchen & Magen, 1995). Studies have assessed negative group experiences in group leaders and cancer patients. Schopler and Galinsky (1993) surveyed 20 group leaders to identify factors associated with negative group experiences. The problems most frequently reported by
group leaders included group members who engage in defensive behaviors, monopolize the conversation, moralize, are silent, or scapegoat other group members. Additional problems were irregular attendance and differing levels of involvement among group members. Studies have examined negative group experiences among patients participating in community-based support groups and controlled intervention studies. The most frequently reported negative experiences were disruptive or controlling group members, pressure to conform, feeling overwhelmed or inadequate in group, group members who monopolize the conversations, conflict between groups members, and content that some patients found scary or depressing (Brandberg, Bergenmar, Michelson et al., 1996; Cella, Tulsky, Gray et al., 1993; Diekmann, 1988; Hammerlid, Persson, Sullivan, & Westin, 1999; Gregoire, Kalogeropoulos, & Corcos, 1997; Glajchen & Magen, 1995; Schopler & Galisky, 1992). Negative group experiences can lead to reductions in group participation or patient drop out. Glajchen & Magen (1995) found that cancer patients who declined group participation reported that they felt alone in their thoughts/feelings, were unable to relate to other group members, or felt that the content was scary or depressing.

*Group cohesion*

Group cohesion involves multiple therapeutic relationships among group members and group leaders (Burlingame, Fuhriman, & Johnson, 2002). The term cohesion refers to a bonding, collaborative, working alliance among group members. In a review of group intervention studies, Braaten (1991) identified a five-factor model of group cohesion comprised of attraction and bonding, support and caring, listening and empathy, self-disclosure and feedback, and process performance/goal attainment. Group
cohesion is a key component of effective group counseling (Yalom, 1995). Cohesiveness has been positively associated with attendance, involvement in treatment, and positive intervention outcomes in multiple psychotherapy studies (Braaten, 1990; Budman, Soldz, & Demby et al., 1989; Evans & Jarvis, 1980; Hurley, 1989). These relationships have been demonstrated in studies targeting spousal abuse (Taft, Murphy, King, Musser, & DeDeyn, 2003), cardiac patients (van Andel, Erdman, Karsdorp, Appels, & Trijsburg, 2003), borderline personality disorder (Marziali, Munroe-Blum, & McClearly, 1997), and distress (Budman et al., 1998). To date, intervention studies with cancer patients have not assessed group cohesion. Studies are needed to provide data on cohesiveness in cancer interventions.

Utilization of intervention techniques

Intervention outcomes may be directly impacted by utilization of intervention techniques. For example, studies examining treatment efficacy for depression found that homework completion and patient use of intervention techniques predicted positive therapeutic outcomes (e.g., Baker & Neimeyer, 2003; Hoberman, Lewinsohn, & Tilson, 1988; Steinmetz, Lewinsohn, & Antonuccio, 1983). Few studies with cancer patients have assessed patient use of intervention strategies. Dodd (1987, 1988) assessed the use of self-care behaviors provided in an educational intervention for cancer patients undergoing radiation or chemotherapy. Intervention patients reported more self-care behaviors compared to controls, but relationships between utilization and outcomes were not examined. Similarly, Larsson and Starrin (1992) and Lerman, Rimer, Blumberg et al. (1990) assessed use of the relaxation techniques taught in their interventions, but the associations between utilization and outcomes were not examined. Finally, multiple
studies have assessed patient knowledge as a proxy for utilization, but the association between changes in knowledge and treatment outcomes has not been examined (DeWit, Van Dam, Zandbelt et al., 1997; Hack, Pickles, Bultz et al., 1999; Taylor et al., 2003). Studies examining the association between use of intervention techniques and treatment outcomes are needed. Identifying associations between specific intervention techniques and outcomes could suggest potential mechanisms of treatment efficacy and aid in the design of dismantling studies.

Conclusions and recommendations

Examining intervention evaluations and utilization of intervention techniques may yield valuable information for understanding intervention efficacy. Studies of efficacy for psychological treatments suggest that patient satisfaction, group experiences, group cohesion, and utilization of techniques are all important factors that influence patient involvement in treatment and treatment outcomes. Intervention studies with cancer patients have assessed levels of satisfaction (Bottomley, 1998; Heinrich & Schag, 1985; Petersson et al., 2000) and group experiences (Brandberg et al., 1996; Glajchen & Magen, 1995; Schopler & Galinsky, 1992), but the association between these variables and treatment compliance has not been examined. In addition, little data are available regarding the association between utilization of techniques and treatment efficacy for interventions with cancer patients. While interventions have demonstrated benefits for cancer patients, we currently lack understanding of the processes contributing to positive intervention outcomes.
The current study

Review of the literature suggests that we need studies examining the factors associated with positive treatment outcomes to advance cancer intervention research. The proposed study examines the association between patient characteristics, intervention evaluations (satisfaction, group experiences, and feelings of cohesion), utilization of intervention techniques, attendance, and treatment outcomes in the context of an existing randomized trial, the Stress and Immunity Breast Cancer Project (SIBCP). This trial provides a unique opportunity to systematically examine variables associated with treatment efficacy. SIBCP is the first intervention study with cancer patients to 1) assess intervention processes (e.g., intervention evaluations, utilization of intervention techniques) that may contribute to positive outcomes, 2) test the association between intervention processes and outcomes, and 3) match intervention techniques with outcomes. Below we provide a description of SIBCP and discuss the advantages and limitations of utilizing this data.

SIBCP tested the hypothesis that a cognitive-behavioral intervention can reduce emotional distress, improve health behaviors, and enhance immune responses. The intervention also targeted potential cofactors including social support, quality of life, and treatment compliance. The trial included 227 women who were diagnosed with Stage II or III breast cancer. Women joined the study after surgical treatment, but prior to the start of adjuvant therapy. After completing an initial assessment, women were randomized to intervention or assessment-only conditions. Figure 2 provides a diagram of the study design and flow.
Women assigned to the intervention condition participated in 18 weekly sessions (27 therapy hours during four months) and 8 monthly maintenance sessions. To provide the intervention in small groups (8 to 12 women), participants were divided into cohorts and two clinical psychologists conducted each session. The topics and techniques used in this intervention were similar to other cognitive-behavioral interventions, but also included components for diet, exercise, smoking, and treatment compliance. Table 2 describes intervention targets, components, and the measured variables associated with each topic. For a detailed description of each intervention component, see Appendix C. Importantly, this study assessed outcomes corresponding to the psychological, behavioral, and biologic intervention targets. Participants completed measures prior to randomization, following the intensive phase of the intervention (at 4 months), and after completion of the maintenance sessions (at 12-month follow-up). For intervention participants, the 4-month post-intensive phase assessment included measures of patient satisfaction, group cohesion, group experiences, and utilization of intervention techniques. We also assessed utilization of intervention techniques during the maintenance sessions (at 8 months).

Both study arms had excellent retention (93%; see Figure 2). Data were analyzed according to intention to treat. Thus, findings include data from 15% of the intervention patients who did not participate in the intervention, but remained in the trial. As reviewed above, analyses revealed statistically significant benefits for intervention patients across psychological, behavioral, physical functioning, and biologic outcomes (Andersen et al., 2004). Patients receiving the intervention experienced reductions in anxiety, increases in perceptions of social support, improvements in health behaviors
(i.e., increased healthy food habits, increased physical activity, and decreased cigarette smoking), improved chemotherapy compliance, increased physical functioning, reduced treatment side effects, and improved immune functioning. For a detailed description of intervention outcomes, see Appendix D.

Data from SIBCP are particularly useful for examining factors associated with treatment efficacy. Because this intervention demonstrated efficacy for multiple outcomes, we can test for patterns in the associations between specific treatment outcomes and potential contributing factors (e.g., patient characteristics or intervention evaluations). Several intervention characteristics increase the advantages of using data from this trial. First, the intervention was delivered in a group format, which is consistent with past cognitive-behavioral intervention studies and interventions offered in the clinical setting. The ability to generalize to group interventions is important, as rising costs and limited resources have caused many clinics to implement group rather than individual interventions. Second, group leaders followed a manual, had similar training backgrounds, and were trained and monitored. These procedures reduced the impact of therapist characteristics on treatment outcomes. Third, patients were recruited at a specific point in cancer treatment. All patients began the study after surgical treatment and prior to the start of adjuvant therapy. This strategy reduced the threat of confounding variables, as cancer patients needs or concerns change over the course of illness. Finally, the sample is homogeneous for disease, treatment, and prognostic variables. Sample homogeneity increases our ability to interpret findings by decreasing variability in treatment side effects, physical functioning problems, mortality threat, and patient needs.
Several characteristics of SIBCP may limit the generalizability of our findings. First, only one intervention is examined and thus, our findings will be limited to the design characteristics of SIBCP. Findings may not generalize to interventions with other characteristics (e.g., a different approach, timing, length, or type of leader). Second, sample homogeneity for ethnicity and socio-economic status limit our ability to generalize findings to some clinical populations. Cultural background may influence treatment efficacy and the factors that are associated with positive treatment outcomes. In addition, the personal resources available to intervention participants may be important for treatment outcomes.

Study Aims

Using data from the SIBCP trial, the present study has three aims: 1) to identify patient characteristics that moderate treatment outcomes, 2) to examine patient characteristics associated with intervention evaluations, utilization of intervention techniques, and attendance, and 3) to examine the association between treatment outcomes and utilization of intervention techniques and attendance.

Patient characteristics as moderators of the intervention

Systematic and formal study of potential moderators is needed to determine for whom and under what conditions interventions are successful. Kraemer and colleagues (2002) suggest an operational definition of moderators that is consistent with Barron and Kenny (1986), but extends their definition for randomized intervention studies. This definition requires that 1) moderators precede the intervention (moderators always precede what they moderate, which in turn precedes the outcome), 2) moderators cannot be correlated with study arm (i.e., treatment status), 3) moderators cannot be part of the
definition of treatment (e.g., attendance), and 4) moderators have an interactive effect with study arm on the outcome. Importantly, moderators cannot be examined in one study arm. The treatment effect can only be evaluated in comparison to a control condition, as changes in one study arm may be confounded by placebo effect, statistical regression to the mean, or the passage of time (Kazdin, 1998).

The choice of variables tested as potential moderators should be based on theory or empirical evidence (Kraemer et al., 2002). In the current study, we examine socio-demographic, cancer treatment, social support, individual difference, and personality variables that may impact treatment outcomes. The variables chosen for study have demonstrated a relationship with adjustment in correlational studies or an interaction with treatment in prior intervention studies. For socio-demographic variables, we examine age, income, and education. Based on prior studies with cancer patients (Burton et al., 1995; Helgeson et al., 2001; Taylor et al., 2003), we expect that the intervention will be most effective for women who are younger, have lower income, or less formal education. We examine type of surgery (lumpectomy vs. mastectomy) and receipt of adjuvant therapy (chemotherapy and radiation therapy) to test for interactions between cancer treatment and the intervention. We expect the intervention to be more effective for women who received more aggressive treatment (e.g., mastectomy). For social support, we examine marital status and size of social network. Past studies suggest that the intervention may be more beneficial for women who are unmarried or have a smaller social network (Goodwin et al., 1987). To examine individual differences, we test for an interaction between the intervention and cancer-specific traumatic stress. Consistent with past studies (Goodwin et al., 2001; Taylor et al., 2003), we expect the intervention to be
most beneficial for women with greater distress at diagnosis. Finally, we examine neuroticism as a potential moderator of the intervention. We expect that the intervention will be less effective for women with high levels of neuroticism.

**Patient characteristics, intervention evaluations, use of techniques, and attendance**

With the exception of satisfaction, few studies with cancer patients have assessed intervention evaluations or utilization of intervention techniques. Cancer support groups have collected data on group experiences (Brandberg et al., 1996; Glajchen & Magen, 1995; Schopler & Galisky, 1992), but most (85%) controlled intervention studies have failed to include similar measures. Importantly, no study has collected multiple intervention evaluation measures for cancer patients and thus, little is known about how these variables relate to patient characteristics or how these variables interrelate. In the current study, participants completed measures of satisfaction, important group experiences, feelings of group cohesion, and utilization of intervention techniques. Intervention leaders also collected data on intervention attendance. This study provides descriptive data, associations with patient characteristics, and intercorrelations for these variables. For associations with patient characteristics, we expect that having greater personal resources (e.g., higher income, more formal education, larger social network) will be positively associated with intervention evaluations, use of techniques, and attendance. In contrast, we expect that higher cancer-related distress and neuroticism will be negatively associated with these variables. Consistent with studies of group psychotherapy, we anticipate positive associations between intervention evaluations, use of techniques, and attendance.
While interventions have demonstrated benefits for cancer patients, we lack understanding of the processes contributing to positive intervention outcomes. Studies of group psychotherapy in individuals without cancer suggest that use of techniques or homework completion and attendance are associated with positive treatment outcomes (Baker & Neimeyer, 2003; Braaten et al., 1990; Budman et al., 1989; Evans & Jarvis, 1980; Hoberman et al., 1988; Hurley, 1989; Steinmetz et al., 1983). Currently, data are not available regarding the association between these variables and treatment outcomes for cancer patients. The intervention conducted for this study demonstrated efficacy for reducing psychological distress, improving perceptions of family support, improving health behaviors, improving compliance with chemotherapy, increasing physical functioning, reducing treatment side effects, and improving immune functioning. For each of these outcomes, we examine the contribution of utilization of relevant intervention techniques and attendance. Based on studies of group psychotherapy, we expect that these variables will be positively related to treatment outcomes.
CHAPTER 2

METHOD

Sample Description

Women in the current study included 227 women diagnosed with Stage II or III breast cancer, surgically treated, and awaiting adjuvant therapy (chemotherapy and/or radiation therapy). Exclusion criteria included a) prior cancer diagnosis, b) refusal of cancer treatment, c) age < 20 or > 85 years, d) residence more than 90 miles from the research site, e) diagnosis of mental retardation, severe or untreated psychopathology (e.g., schizophrenia), neurologic disorders, or dementia, and f) diagnosis of an immunologic condition or disease.

Accrual rate for the clinical trial was 57%, which was higher than similar trials (Antoni et al., 2001; Cunningham et al., 1998; Goodwin et al., 2001). Contrasts between participants and non-participants found no significant differences on demographics, disease and prognostic characteristics, or cancer treatment variables (all $p > .10$). Appendix D provides a complete description of study accrual, reasons for refusal, and randomization procedures.
Procedure

Assessment Only. All participants came to the General Clinical Research Center at the university or a regional outpatient breast cancer clinic of the Cancer Center. The initial assessment occurred after breast surgery, but prior to randomization and the start of adjuvant therapy. The initial assessment gathered informed consent, psychological, and behavioral data via interviews and questionnaires. Medical and treatment information was obtained from medical records and confirmed by physicians. A 60-mL blood sample was also drawn. Assessments were scheduled in the morning to maintain routine and minimize diurnal variability. Patients were paid $25.00 per assessment. At four months (corresponding to the end of the intensive phase of the intervention) and at 12 months (corresponding to the end of the maintenance phase of the intervention), patients were similarly re-assessed.

Intervention. An identical initial assessment protocol was used. Following the initial assessment and randomization, the intervention was provided in small cohorts (N=13), ranging from 8 to 12 patients. Two clinical psychologists conducted each session. Cohorts met weekly for 1.5 hours for 18 sessions (27 therapy hours during 4 months) and then monthly for 8 maintenance sessions. For absences, a therapist telephoned the patient to provide support and discuss the session’s topic. At four months (end of intensive phase of the intervention) and 12 months (end of maintenance phase of the intervention), patients were re-assessed. The four month assessment included additional questionnaires regarding satisfaction, important group experiences, group
cohesion, and utilization of intervention techniques. Women also completed a questionnaire regarding utilization of intervention techniques during the maintenance phase of the intervention (at 8 months).

Measures

Patient Characteristics

Evidence suggests that interventions may be differentially effective depending on patient characteristics (Antoni et al., 2001; Goodwin et al., 2001; Helgeson et al., 2000). The following variables are examined as potential moderators of treatment efficacy.

Sociodemographic characteristics. Patient age, income, education, and marital status were assessed during the initial interview. Patient age and education is reported in years. We computed age by subtracting patient date of birth from the interview date. Family/household income was recorded as total annual gross (pre-tax) wages in thousands. Marital status is coded as married (1) versus unmarried (0).

Treatment characteristics. Treatment information was obtained from medical records and confirmed by physicians. Surgical treatment is coded as lumpectomy/breast conserving surgery (0) versus modified radical mastectomy (1). Variables for adjuvant radiation and chemotherapy are coded as 0=no treatment and 1=receipt of treatment.

Individual differences. We test a measure of the most relevant type of stress, cancer-specific traumatic stress, as an individual difference variable. The Impact of Events Scale (IES; Horowitz et al., 1979) examines stress-related intrusive thoughts (e.g., “I had dreams about being a cancer patient”), denial of thoughts (e.g., “I tried not to think about it”), and avoidant behaviors (e.g., “I stayed away from reminders of cancer”) relevant to cancer diagnosis and treatment. Women rated the frequency of these 15
feelings or events during the previous week using a four-point Likert scale (not at all=0, rarely=1, sometimes=3, and often=5). Items are summed for a total score, which can range from 0 to 75 with higher scores reflecting greater cancer-specific stress. For the present sample, coefficient alpha reliability is .87 and 4-month test-retest reliability is .78.

Social network. The Social Network Index (SNI; Berkman, 1977) is a 10-item measure of the number of an individual’s social ties and involvement within their social network. The SNI is composed of 4 major components: marital status, number of close friends and relatives and frequency of monthly contact with these individuals, church group membership, and membership in other groups (social, vocational, child-related, service-oriented, other). Intimate contacts are weighted more heavily than church affiliations and group memberships in the calculation of the SNI. Social Network scores range from 1 to 12 with higher scores representing greater social involvement. In order to achieve a low score, an individual must have a very limited number of intimate contacts and limited group memberships. To be classified as having a High SNI, an individual must have several intimate contacts (regardless of group memberships) or a moderate number of intimate contacts with both church and group memberships.

Personality. The Goldberg (1992) factor markers are used to assess Neuroticism. Eighteen unipolar trait adjectives were rated on a 9-point scale reflecting how accurately the word describes the rater. Items were summed to compute a total score, which can range from 0 to 144 with higher scores indicating more neuroticism. Extensive psychometric analyses of this measure have been performed (Goldberg, 1992) including factor structure replication, alpha reliability ranging from .88 to .97, and coefficients of
congruence ranging from .93 to .99. In the present sample, coefficient reliability is .88 and 18-month test-retest reliability is .63.

**Intervention evaluations, utilization of techniques, and attendance**

To achieve reliability, therapists followed a session-by-session manual and patients received a companion manual. Equivalence of content was evaluated with session videotapes and patient ratings. Analyses of variance (ANOVAs) found no significant differences (all \( p > .40 \)) between the 13 cohorts for the measures described below: satisfaction, group experiences, group cohesion, and utilization of topics/techniques. There was no difference between cohorts in attendance (\( p > .20 \)).

**Satisfaction.** A 10-item measure assessing the helpfulness of intervention components was used to assess satisfaction. Participants rated the helpfulness of each intervention component using a 4-point Likert scale (1=not at all helpful to 4=very helpful). We conducted exploratory factor analysis to determine a scoring method. Examination of the scree plot, stability of factor loadings, and coefficient alphas suggested a single factor solution. Thus, items were averaged to compute a total score, with higher scores reflecting greater satisfaction. Coefficient reliability is .76.

**Important group experiences.** The Group Experiences Inventory (Roberts, 1987) is a 22-item measure that assesses which group experiences are perceived as most important. Participants were instructed to read through all 22 items before making ratings of importance. Items were rated on a 5-point Likert scale (1=did not apply to 5=one of the two or three most important experiences). Exploratory factor analysis revealed a three-factor solution (RMSEA=.08): feeling accepted/belonging in group (e.g., “Belonging to and being accepted by a group”), changing my behaviors/attitudes (e.g.,...
“Developing a new attitude toward life”), and getting information/advice (e.g., “Getting direct advice or suggestions”). We computed subscales corresponding to each of the three factors by averaging the items that loaded on each factor. These subscales exhibited adequate internal consistencies (coefficient alphas: feeling accepted/belonging=.82, changing behaviors/attitudes=.76, getting information/advice=.76).

Group cohesion. Two items assessed group cohesion: “How involved did you become in this group experience?” and “How supported by this group did you feel?” Participants rated each item using a 10-point Likert scale (0=not at all to 10=extremely). Items were averaged for a total score, with higher scores suggesting greater cohesiveness. Coefficient alpha is .61.

Utilization of intervention techniques. An 11-item measure assessed utilization of techniques for each intervention component: stress management, relaxation, communication with medical providers, social support, assertiveness, problem solving, sexuality, body image, eating less fat, increasing fiber, and exercise. One item was included for each component, with the exception of diet, which used separate items for fat and fiber intake. Participants indicated how frequently they used each intervention technique on an 8-point scale that ranged from 0=“not at all” to 8=“two or more times a day/all the time.” Utilization ratings were collected during the intensive phase (at 4 months) and maintenance phase (at 8 months) of the intervention. To obtain a more reliable estimate of technique utilization, intensive phase and maintenance phase ratings for each technique were averaged. The correlation between intensive phase and maintenance phase ratings ranged from \( r=.30 \) to \( r=.50 \).
Attendance. Attendance was taken at each intervention session (absent=0, present=1). For participants who were absent, telephone sessions were used to provide support for the patient and discuss the intervention topics covered in the missed session. Absences were due to employment obligations or treatment toxicities requiring home stay. Participants attended (in person or by telephone) an average 14 ($SD=6$) of the 18 intensive phase intervention sessions and an average 6 ($SD=3$) of the 8 maintenance phase intervention sessions. For analyses in this study, attendance was coded as 0=absent and no phone session vs. 1= present or completed phone session. We chose to include phone sessions for attendance because participants who completed phone sessions received the intervention material and time/attention from study therapists.

Intervention Outcomes

Emotional Distress. The Profile of Mood States (POMS; McNair, Lorr, & Droppleman, 1971) assesses negative mood. The POMS is a 65-item self-report inventory asking the subject how she has felt during the past week. Each item is rated on a 5-point scale from 0 to 4 (0=not at all to 4=extremely). The POMS yields six mood subscales: Tension-Anxiety, Depression-Dejection, Anger-Hostility, Vigor-Activity, Fatigue-Inertia, and Confusion-Bewilderment and one Total Mood Disturbance Score. A Total Mood Disturbance score is the sum of five scales (Anxiety, Depression, Anger, Fatigue, and Confusion) minus the score of a Vigor scale. Cronbach’s alpha reliability is .92 and test-retest reliability is .78.

Social Adjustment. The Perceived Social Support Scale for Family (PSS-Fa; Procidano & Heller, 1983) assesses need for and perception of receiving support from family members (e.g., ‘‘I have a deep, sharing relationship with a number of members of"
Participants rated 20 items (no=0, yes=1) and items were summed to create a total score. Scale scores range from 0 to 20 with higher scores reflecting more perceived social support. Factor analysis suggests that this instrument measures a single domain (Procidano & Heller, 1983). Alpha reliability is .88 and test-retest reliability is .80.

**Dietary Patterns.** The Food Habits Questionnaire (FHQ; Kristal, Shattuck, & Henry, 1990) assesses dietary choices and eating patterns with five scales: avoiding fat, food substitution with lower-fat alternatives, modification of food preparation, replacing high fat with low fat foods, and fruit and vegetable intake. Using a five-point Likert scale, patients rated the frequency of dietary routines (1=not applicable, 2=rarely, 3=often, and 4 = usually or always). For each scale, items are summed with higher scores indicating more frequent use. Alpha reliability is .79 and test-retest reliability is .77.

**Exercise.** A 7-day report of moderate and vigorous physical activity, based on the Seven-Day Exercise Recall of the Stanford Heart Disease Prevention Program (Blair, Haskell, Ho et al., 1985), provided a summary index of energy expenditure. The respondents indicated the activities that they engaged in during the prior week. Standard energy expenditure values are used to calculate a summary index of energy expenditure. Normative data are available (Blair et al., 1985).

**Physical functioning.** A research nurse evaluated functional status using the Karnofsky Performance Status Scale (KPS; Karnosky & Burchenal, 1949). The KPS is a widely used measure of functional status in cancer. The scale ranges from 100 (Normal, no complaints, no evidence of disease) to 0 (Dead) with 10-point intervals each
containing differential criteria (e.g., 90 = able to carry on normal activity, minor signs/symptoms of disease; 80 = normal activity with effort, some signs/symptoms of disease). Lower scores indicate that the patient experiences more restrictions in the performance of daily and self-care activities. Across cancer studies inter-rater reliability for the scale ranges from .70 to .97 (Mor, Laliberte, Morris et al., 1984; Yates, Chalmer, & McKegney, 1980).

_Treatment side effects._ A rating scale developed by the Southwest Oncology Group (SWOG) documented symptoms, signs, and illness. The SWOG documented the type and severity of toxicities from cancer treatments as well as other common symptoms/signs of illnesses (e.g., infection). Items are grouped within 22 body categories (e.g., hematological, gastrointestinal, neurosensory, pain). A severity rating is provided for each sign/symptom (e.g., nausea: 0=none, 1=reasonable food intake, 2=intake significantly decreased, and 3=no significant intake). Items were averaged for a total score, with higher scores indicating greater signs/symptoms. Internal consistency is .83 in the current sample.

_Compliance with recommended chemotherapy regimens._ Relative dose-intensity for each chemotherapy drug was calculated (average dose received/recommended dose; Hryniuk, 1988; Hryniuk & Levine, 1986). Chemotherapy drugs included Doxorubicin (Adriamycin), Cyclophosphamide (Cytoxan), Methotrexate, Fluorouracil (5-FU), and Paclitaxel (Taxol). Because most patients receive multiple chemotherapy agents, we computed an overall dose-intensity variable for each patient. The overall dose-intensity value is the sum of the relative dose-intensities divided by the number of chemotherapy drugs received.
Immune: T cell responses. Appendix D provides a detailed description of procedures for blood separation, quantification of cells, and measurement of blastogenic response. In the current study, we examine blastogenic response to phytohemagglutinin (PHA) and concanavalin A (Con A). The serial dilutions for PHA and Con A used were 2.5, 5.0, and 10.0 µg/mL. The amount of proliferation was determined via optical density readings (see Appendix D). The present analyses used a summary measure of blastogenic response for each assay. We computed summary measures by standardizing (Z scores) the dilutions (2.5, 5.0, and 10.0 µg/mL) and then averaging the standardized scores. Thus, PHA blastogenesis and Con A blastogenesis were expressed as the mean of standardized scores from their three dilutions.

Analytic Strategy and Power Analyses

Patient characteristics as moderators of the intervention

We tested 10 patient characteristics as potential treatment moderators: age, income, education, marital status, social network, type of surgery, receipt adjuvant treatment (chemotherapy and radiation therapy), cancer-specific traumatic stress, and neuroticism. Consistent with Kraemer and colleagues’ (2002) criteria for moderators, these variables precede the intervention, are not associated with study arm, and are not part of the intervention. To test for potential moderators, we conducted repeated measures analyses of variance (ANOVA) for each of the outcome variables. Group (assessment only=0 vs. intervention=1) was the between-subjects factor and time (initial, 4-month, and 12-month follow-up) was the within-subjects factor. Potential moderators were tested using a group x time x potential moderator interaction. Effect size will be computed using Eta squared ($\eta^2 = \frac{SS_{effect}}{SS_{total}}$), which provides the proportion of the
total variance that is attributed to the interaction. We assessed potential moderators at the initial assessment: age (dichotomized at the median=50 years), education (dichotomized at the median=14 years), family income (dichotomized at the median=$50,000), marital status (unmarried=0 vs. married=1), social network (dichotomized at the median=6), cancer-related distress (dichotomized at the median=26), type of surgical treatment (lumpectomy=0 vs. mastectomy=1), adjuvant therapy (no radiation=0 vs. radiation=1; no chemotherapy=0 vs. chemotherapy=1), and neuroticism (dichotomized at the median=57). For significant interactions, simple effects analyses (paired t-tests) were conducted.

Ten treatment outcomes were examined including emotional distress (POMS TMD and POMS Anxiety), social adjustment (PSS-Family), dietary patterns (FHQ, Replacing High Fat Foods), exercise (Seven-Day Exercise Recall), physical functioning (KPS, SWOG), and immune functioning (PHA, Con A). Prior studies do not suggest a pattern of association for patient characteristics and specific treatment outcomes. Thus, separate repeated measures ANOVAs were conducted for each patient characteristic and each treatment outcome, resulting in a total of 10 ANOVAs for each treatment outcome. Conducting each ANOVA separately allowed us to test for patterns between potential moderators and outcomes. We tested power for the interaction term using an estimated effect size of $\eta^2 = .03$. We selected this effect size as the smallest effect that would be important to detect. For alpha =.05 and power .80, analysis indicated a sample size of 128 is needed, suggesting adequate power for the current study.

Patient characteristics, intervention evaluations, use of intervention techniques, and attendance
Understanding the relationship between patient characteristics and intervention evaluations might assist in designing future interventions tailored to patient preferences and needs. For descriptive purposes, we examined means, standard deviations, medians, and ranges for each of the intervention evaluation variables (satisfaction, important group experiences, and feelings of group cohesion), utilization of techniques, and attendance. We report data for the subscales of the important group experiences scale rather than a total score. Pearson product-moment correlation coefficients and point-biserial correlations were computed to examine the association between patient characteristics and intervention evaluation variables, use of techniques, and attendance. Patient characteristics examined include age, education, family income, marital status (unmarried=0 vs. married=1), social network (SNI), cancer-related distress (IES), type of surgical treatment (lumpectomy=0 vs. mastectomy=1), adjuvant therapy (no radiation=0 vs. radiation=1; no chemotherapy=0 vs. chemotherapy=1), and neuroticism. Finally, Pearson product-moment correlation coefficients were used to examine the intercorrelations among intervention evaluations, utilization of techniques, and attendance variables. These analyses were conducted in the intervention arm only, as this data was not collected in the control arm.

*Intervention outcomes, utilization of intervention techniques, and attendance*

Within the intervention arm, we examined the association between treatment outcomes and utilization of techniques and attendance. We conducted repeated measures ANOVAs for the following treatment outcomes: emotional distress (POMS TMD and POMS Anxiety), social adjustment (PSS-Family), dietary patterns (FHQ, Replacing High Fat Foods), exercise (Seven-Day Exercise Recall), physical functioning (KPS, SWOG),
and immune functioning (PHA, Con A). For utilization of intervention techniques, we conducted separate repeated measures ANOVAs for each treatment outcome and each relevant utilization variable. We did not test utilization of techniques for sexuality and body image because related treatment outcomes were not examined. The distributions of the utilization variables were highly skewed (skew = -1.4 to .38) and/or had bimodal distributions. We created categorical variables (low use vs. high use) using each utilization variable’s median: stress management (0= less than five times per week, 1= five or more times per week), relaxation (0= once per week or less, 1= two or more times per week), communicating with medical providers (0=less than four times per week, 1=four or more times per week), social support (0= once per week or less, 1=two or more times per week), assertive communication (0= less than five times per week, 1=five or more times per week), problem solving (0=less than four times per week, 1=four or more times per week), eating less fat (0=six times per week or less, 1= once per day or more), increasing fiber (0=six times per week or less, 1=once per day or more), and exercise (0=less than four times per week, 1=four or more times per week). In repeated measures ANOVAs, utilization of the intervention technique was the between-subjects factor and time (initial, 4-month, and 12-month follow-up) was the within-subjects factor. We tested the associations between intervention outcomes and utilization of relevant intervention techniques using a technique utilization x time interaction. Effect size was computed using Eta squared ($\eta^2 = SS_{\text{effect}}/SS_{\text{total}}$), which provides the proportion of the total variance attributed to the interaction. For significant interactions, we conducted simple effects analyses (paired t-tests).
We used a similar analytic strategy to test the association between intervention outcomes and attendance. Because attendance variables had a negatively skewed distribution (skew = -1.5), we created categorical variables based on the median (0=attended 23 sessions or fewer, 1= attended 24 or more sessions). We conducted repeated measures ANOVAs for total attendance (intensive and maintenance phase) with each treatment outcome variable. Attendance was the between-subjects factors and time (initial, 4-month, and 12-month follow-up) was the within-subjects factor. The association between treatment outcomes and attendance was tested using an attendance x time interaction. Effect size was computed using Eta squared (\( \eta^2 \)). For significant interactions, we conducted simple effects analyses (paired t-tests).

Power for repeated measures ANOVAs was computed using Sample Power 1.0 (Borenstein, Rothstein, & Cohen, 1997). We tested power for the interactions using an estimated effect size of \( \eta^2 = .03 \). This estimate assumes that interaction accounts for approximately 3% of the variance in the outcome. For alpha = .05 and power .80, analysis indicated a sample size of 90 is needed. The current sample includes 106 women with data from the initial to 12-month assessment, suggesting adequate power.

Finally, we tested the association between women’s compliance with their recommended chemotherapy regimens (relative dose-intensity=average dose received/recommended dose) and utilization of intervention techniques (communication with medical provider, relaxation, and exercise). We used StatXact (Cytel Software Corporation, 2004) to compute permutation one-way ANOVAs with general scores (Gibbons, 1985) for each chemotherapy drug (Doxorubicin, Cyclophosphamide, and Paclitaxel) and the overall dose-intensity value. We did not conduct tests for
Methotrexate and Fluorouracil because too few participants received these chemotherapy agents ($n=11$ and $n=19$, respectively). We chose this analytic strategy because dose-intensity variables were not normally distributed and violated the assumptions of ANOVA. The permutation one-way ANOVA with general scores uses exact permutational distributions rather than F distributions and does not depend on assumptions of normality. We tested the null hypotheses that the two groups (low use of intervention technique vs. high use of intervention technique) were identically distributed. Exact $p$-values were estimated using Monte Carlo sampling (1000 tables sampled for each $p$ value).
CHAPTER 3

RESULTS

Participants

Table 3 provides descriptive data. Participants were 227 women newly diagnosed with Stage II (90%) or Stage III (10%) breast cancer and surgically treated with lumpectomy (57%) or mastectomy (43%). At the time of the 4-month assessment, the majority of participants (85%) were receiving adjuvant treatment. All women had completed radiation therapy and chemotherapy by the 12-month assessment. For adjuvant therapy, 6% received radiation alone, 36% received chemotherapy alone, and 48% received both radiation and chemotherapy. In addition, 75% of women received hormonal therapy. Participants ranged in age from 28 to 84 years ($M=50.82; SD=10.76$) with the majority (74%) having a spouse/partner. Ninety percent of the sample was Caucasian (African American=9%; Hispanic=1%). The distribution of total years of education was some high school=4%, high school graduate=24%, some college=29%, college graduate=18%, and post-graduate=25%. Most participants (67%) were employed part-time or full-time outside of the home. Distribution of annual household income was <$15,000=10%, $15-29,000=16%, $30-49,000=22%, $50-79,000=23%, and $>80,000=29%. Analyses of sociodemographic variables revealed no significant
differences between study arms (all \( p \) values > .27). Furthermore, there were no significant differences in disease, prognostic factors, or treatments received or planned (all \( p \) values > .23).

Both trial arms had excellent retention. See Figure 2 for trial flow diagram and available data at the 4 and 12 month assessments. Excluding the cases of recurrence/death (11 of 227; 5%), there was 93% retention (201 of 216) at 12 months. Availability of data was equivalent between study arms. At the 12 month assessment, complete data were available as follows: Emotional distress (POMS) 91%; Social adjustment (PSS Family) 91%; Food habits 91%; and Exercise 76% (these data are lower due to modification of the exercise assessment shortly following the start of this trial).

When blood draw amounts or cell counts were low, assays were prioritized. Data were available from 79% of the participants for the Con A and PHA assays. Contrasts comparing women with available data versus women without available data found no significant differences on sociodemographic variables, disease or prognostic variables, treatments received, or SIBCP trial arm (all \( p \) values > .16).

**Patient characteristics as moderators of the intervention**

We sought to determine whether the intervention had a greater impact among subgroups of participants and thus, identify individuals who might benefit most from psychological intervention. Each of potential moderators was tested in a separate repeated measures ANOVA using a group x time x potential moderator interaction. Table 4 displays all \( F \) values for significant group x time x potential moderator interactions. For significant interactions, simple effects analyses (paired t-tests) were conducted.
Emotional distress. For POMS TMD, there was a significant group x time x initial cancer-related distress interaction \([F (1, 175) = 3.75, p=.02, \eta^2=.02; (see Figure 3)]\). Simple effects analyses indicated that intervention participants with high initial cancer-related distress showed a significant decrease in POMS TMD at the 4-month assessment \([t (48) = -3.78, p=.02]\), and POMS TMD scores in this subgroup did not change from 4 to 12-months \((p=.34)\). These results suggest that the intervention assisted participants with high cancer-related distress in decreasing total mood disturbance during the intervention and maintaining their improved level of psychological adjustment for up to 8 months following the intervention. POMS TMD did not change over time among high-distress participants in the assessment arm or low-distress participants in the intervention (all \(p\) values >.18). Assessment-only participants with low distress showed a moderate reduction in POMS TMD at 4 months \((t (47)=-2.18, p=.03)\). For POMS TMD, no other moderators were identified (group x time x potential moderator interaction \(p\) values > .07).

For POMS Anxiety, there was a significant group x time x education interaction \([F (1, 175) = 3.07, p=.05, \eta^2=.02; (see Figure 4)]\). Intervention participants with less formal education showed significant decreases in POMS Anxiety at 4 months \((t (49) = -4.19, p<.001)\) and maintained this level of improved psychological adjustment at 12-month follow-up. In contrast, assessment-only participants with less formal education did not change over time \((p=.26)\). Women with a high level of formal education showed significant decreases in POMS Anxiety whether they were in the intervention \((t (56)=-2.94, p=.005)\) or assessment-only arms \((t (41) = -4.00, p<.001)\). These results suggest that the intervention assisted women with less formal education in reducing anxiety.
Intervention participants with less formal education reported POMS Anxiety scores at 4 and 12 months that were similar to scores for women with a high level of education. For POMS Anxiety, no other moderators were identified (group x time x potential moderator interaction $p$ values $> .11$).

*Social adjustment.* For PSS-Family, there was a significant group x time x type of surgery interaction [$F (1, 174) = 3.20, p = .04, \eta^2 = .02$; (see Figure 5)]. Simple effects analyses indicated that the intervention assisted women who underwent a mastectomy in increasing perceptions of family support at 4 months [$t (59) = 2.36, p = .02$] and maintaining improved perceptions of family support at 12 months. PSS-Family scores did not change over time among women in the assessment-only arm ($p$ values $>.23$) or women in the intervention who underwent lumpectomy ($p = .15$). We conducted a post-hoc repeated measures ANCOVA to test whether the group x time x type of surgery interaction was related to older age and/or greater disease severity (number of positive nodes) among women who underwent mastectomy. The post-hoc analysis yielded similar results after controlling for age and disease severity. For PSS-Family, no other moderators were identified (group x time x potential moderator interaction $p$ values $> .27$).

*Dietary patterns.* No moderators were identified for FHQ (group x time x potential moderator interaction $p$ values $> .07$) or Food Substitution with Lower-Fat Alternatives (group x time x potential moderator interaction $p$ values $> .20$).

*Exercise.* No moderators were identified for Seven-Day Exercise Recall (group x time x potential moderator interaction $p$ values $> .13$).
Physical functioning. For KPS, there was a significant group x time x education interaction \[ F (1, 174) = 3.81, p = .02, \eta^2 = .02; \text{ (see Figure 6)} \]. Simple effects analyses indicated that intervention participants with less formal education maintained KPS scores from the initial to the 4-month assessment and showed significantly improved KPS scores at 12-month follow-up \[ t(43) = 2.19, p = .03 \]. In contrast, assessment-only participants with less formal education showed a significant decline in KPS at 4-months \[ t(46) = -2.23, p = .03 \]. This result suggests that the intervention assisted women with less formal education in maintaining physical functioning during the period of time when most participants were receiving adjuvant therapy. Women with high levels of formal education also maintained physical functioning during this time period. For KPS, no other moderators were identified (group x time x potential moderator interaction \( p \) values > .11). No moderators were identified for the SWOG (group x time x potential moderator interaction \( p \) values > .13).

Immune functioning. No moderators were identified for PHA (group x time x potential moderator interaction \( p \) values > .08) or Con A (group x time x potential moderator interaction \( p \) values > .18).

Summary. Across intervention outcomes, few moderators were identified. Education moderated the impact of the intervention on POMS Anxiety and KPS suggesting that the intervention had benefits for women with low levels of formal education. Type of surgery moderated the impact of the intervention on perceptions of family support. Women who underwent mastectomy benefited more from the intervention than women who underwent lumpectomy. Finally, analyses suggest that the intervention assisted women with high levels of cancer-related distress in reducing mood
disturbance during the intervention and maintaining improved psychological adjustment following the intervention. Consistent with past studies, our results suggest that the intervention was particularly beneficial for women with greater distress, fewer educational resources, and surgical treatment with mastectomy.

Patient characteristics, intervention evaluations, use of techniques, and attendance

Understanding patient intervention experiences might assist in designing future interventions tailored to patient preferences and needs. We examined participants’ intervention evaluations (satisfaction with intervention topics, feelings of group cohesion, and perceptions of important group experiences), utilization of intervention techniques, and attendance. First, we computed descriptive statistics for each variable (see Table 5). Second, we examined the association between patient characteristics and each of these variables (see Table 6). Finally, we examined the interrelationships among intervention evaluations, utilization of intervention techniques, and attendance (see Table 7).

Satisfaction with intervention topics. Table 5 displays descriptive statistics for ratings of satisfaction with intervention topics. Overall, participants rated intervention topics as moderately to very helpful ($M=3.5$, $SD=.36$, range = 2 – 4) using a four-point scale (1=not at all helpful, 2=a little bit helpful, 3=moderately helpful, and 4=very helpful). The intervention topics that received the highest ratings were diet information on lowering fat and increasing fiber ($M=3.9$, $SD=.36$), relaxation and relaxation practice with tapes ($M=3.7$, $SD=.58$), and information about stress and immunity ($M=3.7$, $SD=.60$). When examining the association between patient characteristics and satisfaction, only one significant correlation was identified (see Table 6). Receiving
adjuvant chemotherapy was significantly associated with rating relaxation and relaxation practice with tapes as more helpful \((r=.21, p=.05)\). No other significant associations were identified \((all \ p \ values >.12)\).

**Group cohesion.** To assess group cohesion, we asked women to rate how involved and how supported they felt by the group. Overall, women rated group cohesion as high \((M=7.8, SD=1.0, range=4 – 9)\). When examining the association between patient characteristics and group cohesion, one significant correlation was identified \((see \ Table \ 6)\). Having a larger social network \((SNI)\) was significantly associated greater feelings of group cohesion \((r=.30, p=.01)\). No other significant associations were identified \((all \ p \ values >.16)\).

**Important group experiences.** Women were presented with 22 group experiences and asked to rate how important each group experience was to them \((1= \ did \ not \ apply \ or \ got \ in \ the \ way; \ 5=one \ of \ the \ two \ or \ three \ most \ important \ experiences)\). Exploratory factor analysis revealed three factors: 1) experiences of feeling accepted/belonging in group, 2) changing behaviors/attitudes, and 3) getting information/advice. Women rated the importance of group experiences as follows: getting information/advice \((M=4.14, SD=.63)\), changing behaviors/attitudes \((M=3.5, SD=.76)\), and feeling accepted/belonging in group \((M=3.01, SD=.78)\). Specific experiences rated as the most important included “getting support and encouragement” \((M=4.5, SD=.76)\), “getting direct advice or suggestions” \((M=4.2, SD=.88)\), and “gaining access to important information” \((M=4.2, SD=.88)\). Women rated the following specific experiences as the least important: “modeling myself after other group members” \((M=2.3, SD=1.07)\), “deepening my spiritual life” \((M=2.4, SD=1.28)\), and “being encouraged to talk more” \((M=2.6, SD=1.28)\).
When examining the association between patient characteristics and each of the three important group experiences factors, two significant correlations were identified (see Table 6). Higher initial cancer-related distress was significantly associated with rating experiences of changing behavior/attitudes as more important \((r=.24, p=.02)\). Having a mastectomy was significantly correlated with rating experiences of feeling accepted/belonging in the group as more important \((r=.22, p=.04)\). No other significant associations were identified (all \(p\) values >.07).

**Utilization of intervention techniques.** Women indicated how frequently they utilized techniques taught in the intervention. Table 5 displays descriptive statistics for utilization of intervention techniques. Overall, women reported regular use of techniques for improving health behaviors (diet and exercise). Strategies for changing diet were the most frequently used techniques, as women reported utilizing techniques for eating less fat (e.g., substituting skim milk for whole milk, eating baked chicken instead of fried chicken) and increasing fiber (e.g., eating more vegetables, eating more beans) five to six times per week \((M=6.6, SD=1.4\) and \(M=6.6, SD=1.3\), respectively). On average, women reported using exercise strategies (i.e., walking program) two to three times per week \((M=4.3, SD=1.7)\).

Women reported frequent use of techniques for managing stress and emotional distress. Women indicated using information about stress and stress management strategies (e.g., recognizing limits, prioritizing tasks) an average of four times per week \((M=5.2, SD=1.7)\). Progressive muscle relaxation techniques were used an average of
once per week \( (M=3.4, SD=1.9) \). Finally, women reported using problem solving techniques (e.g., generating many possible solutions, thinking about the consequences of change) two to three times per week \( (M=4.0, SD=1.8) \).

Strategies for improving social support and communication were used one to four times per week. Techniques for increasing social support (e.g., distinguishing between need for emotional vs. physical support, identifying who would be best to ask for particular types of support, asking for support) were used at least once per week \( (M=3.6, SD=1.9) \). Women reported using assertive communication techniques an average of four times per week \( (M=4.9, SD=1.9) \) and using strategies for communicating with medical providers (e.g., writing questions down beforehand, taking notes) two to three times per week \( (M=4.2, SD=2.6) \).

When examining the association between patient characteristics and utilization of intervention techniques, several significant correlations were identified (see Table 6). Older women were more likely to use strategies for improving health behaviors including increasing fiber in their diet \( (r=.27, p=.02) \) and exercise \( (r=.26, p=.02) \). More formal education was significantly associated with using more strategies to reduce dietary fat \( (r=.25, p=.03) \), and neuroticism was negatively associated with use of techniques for increasing fiber \( (r=-.24, p=.04) \). Finally, women who received adjuvant chemotherapy were less likely to use strategies for exercise \( (r=-.25, p=.03) \), but they were more likely to use assertive communication techniques \( (r=.24, p=.03) \). No other significant associations were identified (all \( p \) values >.06).
Attendance. Overall, attendance was excellent (see Table 5). Women in the intervention attended an average of 14 ($SD=6$, range=0-18) of the 18 intensive phase intervention sessions and 6 ($SD=3$, range=0-8) of the 8 maintenance sessions. We examined the association between attendance and patient characteristics (see Table 6). Greater attendance (including both intensive phase intervention sessions and maintenance sessions) was associated with more formal education ($r=.27$, $p=.004$), higher income ($r=.24$, $p=.01$), being married ($r=.29$, $p=.002$), and having a larger social network as measured by the SNI ($r=.26$, $p=.005$). Neuroticism was negatively associated with attendance ($r=-.25$, $p=.01$). In contrast to expectations, higher initial cancer-related distress was not associated with lower attendance ($r=.07$, $p=.48$).

Correlations among intervention evaluations, utilization of intervention techniques, and attendance. Table 7 displays intercorrelations among satisfaction, group cohesion, important group experiences, utilization of intervention techniques, and attendance. For satisfaction with intervention topics, we used a total score that averaged ratings for each intervention topic. Intercorrelations revealed that satisfaction was positively associated with feelings of group cohesion ($r=.45$, $p<.001$) and the three subscales of the important group experiences scale ($r=.26$ to .30, $p<.05$). Group cohesion was positively associated with feeling accepted/belonging in group ($r=.22$, $p=.05$). We tested for associations between intervention evaluations and utilization of intervention techniques and only one pattern of association was identified. Utilization of techniques for increasing social support was positively associated with satisfaction ($r=.30$, $p=.01$), feeling accepted/belonging in group ($r=.22$, $p=.06$), and getting information/advice ($r=.21$, $p=.07$).
Utilization of techniques for stress management (e.g., recognizing limits, prioritizing tasks) was positively associated with use of all other intervention techniques \((r=.23\text{ to } .44, p<.05)\). Relaxation use was significantly associated with more utilization of health behavior techniques [eating less fat \((r=.28, p=.01)\), increasing fiber \((r=.26, p=.02)\), exercise \((r=.21, p=.07)\)], assertive communication skills \((r=.35, p=.002)\), and techniques for increasing social support \((r=.32, p=.005)\). Techniques for increasing social support, assertive communication, and problem solving were positively associated \((r=.35\text{ to } .47, all \ p \ values <.003)\). Finally, health behavior techniques (eating less fat, increasing fiber, and exercises) were positively associated \((r = .39 \text{ to } .70, all \ p \ values < .001)\).

To further understand the relationship between participants’ satisfaction with intervention topics and utilization of corresponding techniques, we computed Pearson product-moment correlation coefficients for each intervention topic. There was one significant association; satisfaction with relaxation was positively associated with the use of relaxation \((r=.47, p<.001)\). In contrast to our expectations, we found no association between satisfaction and utilization for the majority of intervention topics/techniques. These findings suggest that participants may view topics/techniques as helpful, but these perceptions may not lead to behavior change.

Overall attendance (intensive phase and maintenance sessions) was significantly associated with greater feelings of group cohesion \((r=.34, p=.002)\) and more use of assertive communication techniques \((r=.24, p=.04)\). In contrast to expectations, attendance was not associated with total satisfaction \((r=.05, p=.67)\). We examined whether attendance was associated with ratings of satisfaction for each of the intervention
topics. One significant association was identified; women who reported greater satisfaction with the social support topic were more likely to attend intervention sessions ($r=.25, p=.02$).

**Summary.** Overall, women reported high levels of group cohesion and satisfaction with intervention topics. No clear pattern of association emerged between participant characteristics and feelings of cohesion or satisfaction. For important group experiences, women rated experiences related to getting information/advice as the most important. Feeling accepted/belonging in group was rated higher by women who received a mastectomy, and behavior/attitude change was rated higher among women who had high levels of cancer-related distress. On average, women indicated regular (at least weekly) utilization of intervention techniques. Strategies for eating less fat and increasing fiber were used most frequently. Older women were more likely to use relaxation and health behavior techniques (eating less fat, increasing fiber, and exercise), but they were less likely to use assertive communication strategies. Women who underwent chemotherapy were more likely to use assertive communication strategies, but they were less likely to use exercise. Finally, overall attendance was high, with women attending an average 20 of the 26 intervention sessions. Women with more personal resources (higher education, higher income, married, and a larger social network) were more likely to attend intervention sessions.

When examining correlations among intervention evaluation variables, utilization of intervention techniques, and attendance, several patterns of association emerged. First, satisfaction, feelings of group cohesion, and important group experiences were positively associated. There were few associations between intervention evaluation variables and
utilization of intervention techniques. Only one pattern of association emerged; use of social support techniques was positively associated with satisfaction, feeling accepted/belonging in group, and getting information/advice. Among utilization of intervention techniques, several patterns were identified: 1) use of strategies for managing stress was positively associated with use of all other intervention techniques, 2) use of relaxation, eating less fat, increasing fiber, and exercise were significantly correlated, and 3) strategies for assertive communication, increasing social support, and problem solving were associated. For attendance, only two associations were identified. Women who reported greater feelings of group cohesion and more use of assertive communication were more likely to attend intervention sessions.

**Intervention outcomes, utilization of intervention techniques, and attendance**

To better understand the processes that contributed to positive treatment outcomes, we examined whether utilization of intervention techniques and attendance at intervention sessions were associated with intervention outcomes. The SIBCP intervention significantly reduced emotional distress (POMS TMD and POMS Anxiety) and significantly improved social adjustment (PSS-Family), dietary patterns (FHQ, Replacing High Fat Foods), exercise (Seven-Day Exercise Recall), physical functioning (KPS, SWOG), immune functioning (PHA, Con A), and compliance with recommended chemotherapy regimens. We conducted separate repeated measures analyses of variance (ANOVA) for the outcome variables (with the exception of chemotherapy compliance) with utilization of relevant intervention techniques and attendance. Table 8 displays all F values for significant interactions. For significant interactions, simple effects analyses
(paired t-tests) were conducted. Finally, we conducted separate permutation one-way ANOVAs for general scores for each of the chemotherapy dose-intensity variables with relevant technique utilization variables.

*Emotional distress.* For POMS TMD, we tested the association between intervention outcomes and utilization of techniques for problem solving, stress management, and relaxation. There was a significant relaxation use x time interaction \( F(1, 71) = 3.29, p=.04, \eta^2=.04; \) (see Figure 7). Simple effects analyses indicated that participants with higher use of progressive muscle relaxation showed a significant decrease in POMS TMD at the 4-month assessment \( t(39) = -4.59, p<.001 \), and POMS TMD scores in this group did not change from 4 to 12-months \( p=.26 \). These results suggest that the use of relaxation assisted women in decreasing emotional distress during the period of time when most participants were receiving adjuvant therapy. Women with less frequent use of relaxation showed no change in POMS TMD at 4 months \( p=.64 \), but this group experienced a decrease in distress from 4 to 12 months \( t(33) = -2.28, p=.03 \). For POMS TMD, tests examining utilization of other intervention techniques and attendance were not significant (all interaction \( p \) values > .17).

We tested the association between POMS Anxiety and utilization of techniques for problem solving, stress management, and relaxation. There was a significant relaxation use x time interaction \( F(1, 71) = 3.66, p=.03, \eta^2=.04; \) (see Figure 8). Similar to findings for POMS TMD, simple effects analyses indicated that the use of relaxation was associated with decreases in anxiety at four months \( t(39) = -5.07, p<.001 \), and women maintained lowered anxiety at 12 months. Participants with less relaxation use showed no change in anxiety at 4 months \( p=.18 \), but experienced a
significant reduction in anxiety from 4 to 12 months $[t (33) = -2.23, p=.03]$. For POMS Anxiety, tests for other intervention techniques and attendance were not significant (all interaction $p$ values $>.42$).

**Social adjustment.** For PSS Family outcomes, we tested utilization of techniques for increasing social support and assertive communication. There was a significant assertive communication x time interaction $[F (1, 71) = 3.53, p=.03, \eta^2=.05]$; (see Figure 9)]. Simple effects analyses indicated that use of assertive communication techniques was associated with improvements in perceived family social support. Participants with higher use of assertive communication techniques showed a significant increase in PSS Family at the 4-month assessment $[t (34) = 2.34, p=.03]$, and women in this group maintained increased perceptions of social support at the 12-month assessment. PSS Family scores did not change over time among women with lower use of assertive communication techniques ($p$ values $>.20$).

Analysis also revealed a trend for a social support technique x time interaction for PSS Family $[F (1, 71) = 2.60, p=.08, \eta^2=.04]$; (see Figure 10)]. Similar to the pattern of results for assertive communication techniques, simple effects analyses indicated that use of techniques for increasing social support was associated with improvements in perceived family social support. Participants with higher use of techniques for increasing social support showed a significant increase in PSS Family at the 4-month assessment $[t (37) = 2.15, p=.04]$, and women in this group maintained increased perceptions of social support at the 12-month assessment. PSS Family scores did not change among women with lower use of social support techniques ($p$ values $>.26$). For PSS Family, the test examining attendance was not significant ($p=.31$).
Dietary patterns. We tested the association between FHQ total score and utilization of techniques for eating less fat, increasing fiber, and communicating with medical providers. For FHQ total scores, there was a significant communicating with medical providers x time interaction \( F(1, 68) = 3.16, p = .05, \eta^2 = .04; \) (see Figure 11). Simple effects analyses revealed that higher use of techniques for communicating with medical providers was associated with improved dietary patterns at the 4-month assessment \( t(36) = 3.40, p = .002 \), and women in this group showed continued improvements in FHQ total scores at 12 months \( t(36) = 2.40, p = .02 \). In contrast, there was no change in FHQ total scores among women with lower use of techniques for communicating with medical providers \( (p \text{ values} > .20) \).

For the FHQ total score, there was a trend for a techniques for an eating less fat x time interaction \( F(1, 68) = 2.72, p = .07, \eta^2 = .03; \) (see Figure 12). Simple effects analyses indicated that greater use of techniques for eating less fat was associated with improved dietary patterns. Women with higher use of these techniques showed a significant increase in the FHQ total score from initial to four months \( t(30) = 2.88, \) \( p = .007 \), and this group maintained improved dietary patterns at 12 months. There was no change in dietary patterns among women with lower utilization of techniques for eating less fat \( (p \text{ values} > .08) \). For the FHQ total score, tests for increasing fiber and attendance were not significant \( (p \text{ values} > .28) \).

We tested the association between the Food Substitution with Lower-Fat Alternatives FHQ subscale and utilization of techniques for eating less fat, increasing fiber, and communicating with medical providers. We also tested the relationship
between Food Substitution and attendance. Tests examining utilization of intervention techniques and attendance were not significant (all interaction $p$ values > .15).

**Exercise.** We tested the association between Seven-Day Exercise Recall and utilization of techniques for increasing exercise and communicating with medical providers. We then tested the relationship between Seven-Day Exercise Recall and attendance. All tests examining utilization of intervention techniques and attendance were not significant (all interaction $p$ values > .09).

**Physical functioning.** We tested the association between KPS and SWOG scores and 1) utilization of techniques for stress management, relaxation, exercise, and communicating with medical providers, and 2) attendance. For SWOG, there was a significant exercise technique x time interaction [$F (1, 72) = 3.71, p=.03, \eta^2=.04$; (see Figure 13)]. Simple effects analyses indicated that all participants experienced a significant increase [low exercise use $t (43) = 5.05, p<.001$; high exercise use $t (34) = 2.15, p=.04$] in SWOG scores from initial to 4-month assessment, which covers the period of time when most participants were receiving adjuvant therapy. However, participants with lower exercise use reported an increase in SWOG scores that was approximately 2.75 times greater than women who reported higher utilization of exercise techniques (an increase of .11 vs. .04, respectively). For KPS and SWOG, all other tests examining utilization of intervention techniques and attendance were not significant (all interaction $p$ values > .18).

**Immune functioning.** For PHA and Con A, we examined the association between assays and utilization of techniques for stress management, relaxation, and exercise. We
also tested the association between immune assays and attendance. For both PHA and Con A, tests examining utilization of intervention techniques and attendance were not significant (all interaction \(p\) values > .11).

*Compliance with recommended chemotherapy regimens.* We tested the association between compliance with chemotherapy regimens and utilization of techniques for relaxation, exercise, and communication with medical providers. Analysis revealed a trend for greater compliance with the recommended Doxorubicin (Adriamycin) regimen among women who frequently used intervention techniques for communicating with medical providers (four or more times per week) compared to women with low use of these techniques \((T=3.43, p=.06)\). The average dose-intensity for women who frequently used these techniques was 96\% \((SD=5)\) compared to 92\% \((SD=9)\) among women with low use of these techniques.

Analysis revealed a significant association between utilization of exercise techniques and receipt of recommended dose-intensity for Paclitaxel \((T=6.10, p=.003)\). Women with high use of exercise techniques (four or more times per week) were more likely to receive their recommended Paclitaxel regimen compared to women with low use of exercise techniques. The average dose-intensity for women with high exercise use was 99\% \((SD=3)\) compared to 88\% \((SD=11)\) among women with low exercise use. For overall dose-intensity, tests examining utilization of intervention techniques were not significant (all \(p\) values > .10). We did not conduct tests for Methotrexate and Fluorouracil because too few participants received these chemotherapy agents \((n=11\) and \(n=19\), respectively).
Summary. Across intervention outcome variables, several patterns were identified for utilization of intervention techniques. First, use of relaxation was associated with decreased emotional distress (POMS TMD and POMS Anxiety) at 4 months, and women maintained improved psychological adjustment at 12 months. In contrast to expectations, use of techniques for stress management and problem-solving were not associated with emotional distress. Second, improvement in perceived family support (PSS Family) at 4 months was significantly associated with use of assertive communication techniques, with women maintaining improved perceived family support at 12 months. A similar trend was identified for use of techniques for increasing social support and perceived family support. Third, utilization of techniques for communicating with medical providers was associated with improvements in dietary habits at 4 months and continued improvement from 4 to 12 months. There was a trend for an association between use of techniques for eating less fat and improvement in dietary habits at 4 months, but there was no association between techniques for increasing fiber and dietary habits. Fourth, there was a significant exercise technique utilization x time interaction for the SWOG, which indicated that use of exercise was associated with fewer side effects during adjuvant therapy. Finally, using techniques for communicating with medical providers was associated with greater compliance with recommended Doxorubicin (Adriamycin) regimens and use of exercise was associated with greater compliance with Paclitaxel (Taxol) regimens. Surprisingly, attendance was not associated with intervention outcomes.
CHAPTER 4

DISCUSSION

Psychosocial and behavioral interventions are effective for reducing the burdens experienced by cancer patients. Of the 109 randomized intervention studies we reviewed, 79% demonstrated benefits for patients on one or more outcomes. Interventions resulted in improved emotional adjustment, quality of life, social adjustment, health behaviors (diet, exercise, and smoking cessation), and immune functioning. Yet, we know little about the factors that contribute to positive treatment outcomes. We need to develop a better understanding of these processes to design and deliver effective interventions in the clinical setting.

For the current study, we examined the factors associated with positive treatment outcomes in the SIBCP intervention trial. Findings are summarized in Table 9. Our findings fall into four major categories: moderators of intervention effects, intervention evaluations (associations with patient characteristics and intercorrelations), utilization of intervention techniques, and attendance. First, we identified several moderators of SIBCP intervention effects. Our results suggest that the intervention was particularly beneficial for women who had greater cancer-related distress, fewer educational resources, and surgical treatment with mastectomy. Second, women reported positive
intervention evaluations including high levels of satisfaction with intervention topics, strong feelings of group cohesion, and regular use of intervention techniques. Third, we found significant associations between use of intervention techniques and positive treatment outcomes: a) relaxation was associated with decreased emotional distress, b) assertive communication and strategies for increasing social support were associated with improved perceptions of family support, c) techniques for eating less fat and communicating with medical providers were associated with improved dietary habits, d) exercise was associated with lower treatment side effects, and e) techniques for communicating with medical providers and exercise were associated with better compliance with recommended chemotherapy regimens. Finally, attendance was extremely high. Women with more personal resources (higher education, higher income, married, and a larger social network), lower levels of neuroticism, and greater feelings of group cohesion were more likely to attend intervention sessions. In contrast to expectations, attendance was not associated with treatment outcomes. Below we discuss these findings.

*Moderators of the Intervention*

Before making treatment recommendations for cancer patients, we must understand for whom interventions are most effective, least effective, or even harmful. Most clinical settings have limited resources for psychological and behavioral interventions. These limited resources should be directed toward patients who are most likely to benefit from treatment. We examined whether socio-demographic, cancer treatment, social support, cancer-related distress, and neuroticism moderated SIBCP intervention effects. Consistent with past studies (e.g., Goodwin et al., 2001; Taylor et
al., 2003), our results suggest that the intervention provided the most benefits for women with greater cancer-related distress, fewer educational resources, and surgical treatment with mastectomy. Surprisingly, income and receipt of chemotherapy did not moderate intervention effects. Sample homogeneity for income and adjuvant therapy may have limited our ability to test these variables as moderators. For example, 84% of women received adjuvant chemotherapy.

The SIBCP intervention assisted women with high levels of cancer-related distress reduce mood disturbance during cancer treatment and maintain improved psychological adjustment following cancer treatment. These findings are especially important as distress at diagnosis predicts later depressive symptoms (Golden-Kreutz & Andersen, 2004), lower quality of life (Golden-Kreutz, Thornton, Frierson et al., 2005), poorer psychological adjustment (Graydon 1988; Schag et al., 1993), and greater marital difficulties (Schag et al., 1993). If untreated, distress at the time of diagnosis can produce a poorer trajectory in cancer survivorship (Green et al., 2000; Gotay & Muraoka, 1998; Hjerl, Andersen, Keiding, Mortensen, & Jorgensen, 2002; Yabroff, Lawrence, Clauser, Davis, & Brown, 2004). Our data indicate that patients with high levels of distress benefit from psychological intervention. Among SIBCP participants, baseline cancer-related distress did not impact satisfaction with intervention topics, attendance, or use of intervention techniques. However, distressed women identified group experiences related to behavior or attitude change as most important. Additional research is needed to identify the intervention strategies and/or processes that benefit distressed cancer patients.
Past studies suggest that cancer patients with fewer educational or economic resources benefit most from psychological and behavioral interventions (Lepore et al., 1999, 2003; Helgeson et al., 2000). Women with low levels of formal education benefited most from the SIBCP intervention on anxiety and physical functioning outcomes. Women with 12 or fewer years of education showed the most improvement. Interventions may help reduce disparities in cancer outcomes associated with socio-economic status. Patients with high levels of formal education have greater resources for learning about cancer and coping with the disease. Psychological and behavioral interventions may assist patients with fewer resources by providing a supportive context for receiving information about cancer and strategies for coping with it.

Cancer patients with greater disease severity and more aggressive treatments experience the greatest disruptions in psychological and functional adjustment (Bloom, 1987; Ganz et al., 1992; Ganz et al., 1998; Kemeny et al., 1988; Kiebert et al., 1990; Lasry et al., 1987; Meyerowitz et al., 1983; Palmer et al., 1980). For example, women who receive mastectomies report more anxiety, greater depression, and a more negative body image than those who receive breast conserving surgery (Kemeny et al., 1988; Lasry et al., 1987). Patients who have undergone mastectomy or more aggressive treatments may benefit from psychological or behavioral interventions. SIBCP showed the greatest benefits for women with mastectomies on family support outcomes. These findings persisted after controlling for age and disease severity (number of disease positive lymph nodes), highlighting the unique impact of undergoing a mastectomy. Data
also indicated that feelings of support were especially important to women who received mastectomies. These women rated experiences of feeling accepted or belonging in group as most important.

Neuroticism is described as a stable and pervasive personality trait that impacts all aspects of subjective experience (Clark et al., 1990). We hypothesized that women with high levels of neuroticism would benefit less from the SIBCP intervention. Neuroticism was associated with poorer attendance, but it did not moderate intervention effects. These findings are particularly important, as neuroticism is associated with increased negative emotions, increased dissatisfaction in all situations, having a less favorable view of the self (Costa & McCrae, 1985; Costa & McCrae, 1987; Watson & Clark, 1984), and poor psychological adjustment among cancer patients (Harrison & Maguire, 1994; Thomas et al., 1987). Cancer patients with high levels of neuroticism may be among those most in need of treatment. Our findings suggest that these patients can benefit from psychological intervention.

*Intervention Evaluations*

Patients’ evaluations of treatment may impact their willingness to attend interventions (Alpert, 1964, Becker et al., 1972), participate in treatment (Perrone & Sedlancek, 2000), and use strategies taught in interventions (Wilson & McNamara, 1982). Examining intervention evaluations can provide valuable information for improving intervention design, content, and compliance. In the current study, we examined patient satisfaction with intervention topics, important group experiences, feelings of group cohesion, and utilization of intervention techniques.
We assessed satisfaction with intervention topics by asking women to rate the helpfulness of each topic. Women rated all intervention topics as moderately to very helpful. Dietary strategies, relaxation, and stress management received the highest ratings. We expected to find positive associations between ratings of helpfulness and use of techniques for each intervention topic. We found only one significant association; women who rated relaxation as more helpful were more likely to use relaxation techniques. These data suggest that women may view intervention components as helpful, but these perceptions do not translate into behavior change. Our data also indicate that ratings of helpfulness did not indicate whether intervention techniques would benefit patients. For example, assertive communication training and strategies for communicating with medical providers received the lowest ratings. Yet, use of these techniques was associated with improved family support and increased compliance with recommended chemotherapy regimens.

Satisfaction with intervention content may impact patients’ willingness to participate in group discussions and build relationships with other group members (Perrone & Sedlacek, 2000). We examined the association between overall satisfaction (average of ratings for each topic), important group experiences, and feelings of group cohesion. Satisfaction was positively associated with experiences of feeling accepted or belonging in group, changing behaviors or attitudes, and getting information/advice. Women who perceived the intervention content as helpful had more important or meaningful group experiences. We also found a positive association between satisfaction and feelings of group cohesion. Because these data are correlational, we cannot determine the direction of this relationship. Feelings of group cohesion may have
contributed to greater satisfaction with session content and group discussions. Likewise, women who were more satisfied may have participated more actively in the group or may have been more engaged in group discussions.

Feelings of cohesion have been identified as a key component of effective group interventions (Yalom, 1995). In studies of group psychotherapy, group cohesion has been associated with better attendance and positive intervention outcomes (Braaten et al., 1990; Budman et al., 1989; Evans & Jarvis, 1980; Hurley, 1989). Women in our intervention reported high levels of group cohesion, and we found that cohesion was positively associated with intervention attendance. Group composition may have contributed to high ratings of group cohesion. All intervention participants shared similar disease and treatment characteristics, and all women were at a similar place in the disease course (e.g., in the first year after diagnosis or undergoing treatment). Studies of group psychotherapy suggest that a homogeneous group composition positively impacts feelings of group cohesion, willingness to participate in sessions, and attendance (Plant et al., 1987). Cancer patients attending support groups rate the opportunity to meet other patients in the same situation as the most important or valuable support group experience (Berglund et al., 2003; Petersson et al., 2000).

*Utilization of Intervention Techniques*

Studies of psychotherapy suggest that utilization of intervention techniques and homework completion predict positive therapeutic outcomes (Baker & Neimeyer, 2003; Hoberman et al., 1988; Steinmetz et al., 1983). Studies with cancer patients have not tested these relationships. We examined the association between use of SIBCP intervention techniques and intervention outcomes. Analyses revealed significant
associations between relaxation and decreased emotional distress, assertive communication and improved family support, social support strategies and improved family support, techniques for eating less fat and improved dietary habits, communicating with medical providers and improved dietary habits, exercise and lower treatment side effects, communicating with medical providers and better compliance with Doxorubicin (Adriamycin) regimens, and exercise and better compliance with Paclitaxel (Taxol) regimens. Below we discuss these findings.

Our data suggest that patients who practiced relaxation at least once per week experienced reductions in emotional distress during the intervention and maintained improvements in emotional adjustment at 12-month follow-up. Relaxation training can be delivered in a time efficient and cost efficient manner, which makes this strategy feasible for most clinical settings. Patients can obtain relaxation training in person (individual or group settings), using audio recordings, by telephone, or over the Internet. Relaxation training has been used to manage chemotherapy side effects and cancer-related pain (e.g., Arakawa, 1997; Baider, Peretz, Hadani, & Koch, 2001; Kolcaba & Fox, 1999). Our findings suggest that relaxation training could also be used to help patients manage emotional distress.

Social support is an important resource for cancer patients (Bloom et al., 2001; Funch & Metlin, 1982; Helgeson & Cohen, 1996; Kornblith et al., 2001), but cancer-related stressors may negatively impact relationships, strain social support resources, and limit social activity (Bloom & Kessler, 1994; Bloom & Spiegel, 1984; Peters-Golden, 1982). We found that women who used intervention strategies for increasing social support experienced improvements in perceptions of family support. SIBCP used a
unique approach to impact the patient’s social environment: 1) identifying salient individuals in the patient’s support network, 2) identifying the capacities of these individuals to provide tangible and/or emotional support, 3) having patients identify their specific tangible or emotional needs, and 4) matching the patient’s needs to individuals capable of meeting them. This intervention approach focused on helping patients make better use of their existing support network. Past interventions have focused on providing support within the intervention or encouraging patients to incorporate other group members into their support networks (see Appendix B, Table 13). These strategies have had little success. Our data suggest that future interventions should provide patients with strategies for improving use of their existing support resources.

SIBCP focused on improving the social environment by changing the patient’s behavior. The intervention included assertive communication training (e.g., how to ask for support or give feedback) to provide women with strategies for getting support. Assertive communication skills were used to help women seek support from individuals capable of meeting their identified needs. Women who frequently (five or more times per week) used assertive communication techniques experienced the greatest improvements in perceptions of family support. Most cancer patients acknowledge the importance of communicating needs and concerns (Kilpatrick, Kristjanson, Tataryn, & Fraser, 1998), but report that this dialogue is often infrequent and difficult (Fried, Bradley, O’Leary, & Byers, 2005; Hilton, 1994). Barriers for discussing cancer-related needs or concerns include a fear of burdening others, concerns about worrying others, and the belief that it is harmful to acknowledge negative feelings or experiences (Peters-Golden, 1982). Improving assertive communication may yield multiple benefits for
patients. Cancer patients who are able to express their needs report better emotional
adjustment (Giese-Davis, Mermanson, Koopman, Weiber, & Spiegel, 2000; Spiegel et
al., 1983), fewer physical complaints (Mesters, Van Den Borne, McCormick, Pruyn, &
DeBoer, 1997), and higher levels of self-esteem and perceived control (Mesters et al.,
1997).
For cancer patients, increased fat intake and weight gain are associated with
recurrence and poorer survival (Holm, Nordevang, Hjalmar et al., 1993; Saxe, Rock,
Wicha, & Schottenfeld, 1999; Willett, 1999; Zhang, Folsom, Sellers, Kushi, & Porter,
1999). Yet, many cancer patients experience dietary changes (e.g., food restrictions,
austerity or taste aversions from chemotherapy; Broeckel et al., 2000; Jacobsen, Bovbjerg,
Schwartz et al., 1995) and weight gain (e.g., weight and metabolic changes due to
chemotherapy; Camoriano, Loprinzi, & Ingle, 1990; Denmark-Wahnefried, Hars,
Conaway et al., 1997) related to cancer treatments. The SIBCP intervention included
strategies for eating less fat and increasing fiber intake. Women reported using these
strategies regularly (almost daily) and rated the dietary intervention components as very
helpful. Moreover, women in the intervention reported improved dietary habits. Using
strategies for eating less fat was associated with improved dietary habits during the
intervention and women maintained these changes at 12-month follow-up. Our data
indicate that patients can participate in dietary interventions during adjuvant treatment
and show improvements in dietary habits during this vulnerable time. Helping patients
reduce the impact of treatment on nutrition and weight could lead to improved quality of
life, reduced rates of infection, and increased disease free survival (Galban et al., 2000).
Reductions in chemotherapy can compromise survival (Budman et al., 1998; Bonadonna & Valagussa, 1981). Studies suggest that treatment side effects (Demissie, Silliman, & Lash, 2000) and emotional distress (Lebovitz, Srain, Schleifer et al., 1990; McDonough, Boyd, Varvares, & Maves, 1996) reduce compliance with recommended chemotherapy regimens. SIBCP included intervention components that specifically targeted treatment compliance (i.e., disease and treatment information, relaxation and distraction techniques, and strategies to enhance communication with medical providers). We found that women who used techniques for communicating with medical providers were more likely to complete recommended Doxorubicin (Adriamycin) regimens. This widely used chemotherapy agent has multiple side effects including nausea and vomiting, loss of appetite, diarrhea, difficulty swallowing, thinned or brittle hair, skin irritation, and swelling, pain, redness, or peeling of skin on the palms and soles of the feet (Spratto & Woods, 2005). Many of these side effects can be reduced or managed with medical treatment. Improved communication with medical providers may have led to better management of treatment side effects and greater tolerance of chemotherapy regimens. Communication between patients and healthcare providers has been cited as one of the most important predictors of treatment compliance (Dimatteo & DiNicola, 1982; DiMatteo, Linn, Chang, & Cope, 1993; Taylor, 2003). Improving patient-provider communication could yield multiple benefits including better compliance with recommended cancer treatments and increases in important health behaviors (e.g., diet, exercise, smoking cessation). Future interventions could provide communication skills training to patients and healthcare providers.
Women who reported frequent use of exercise techniques (four or more times per week) were more likely to complete recommended Paclitaxel (Taxol) regimens. Paclitaxel has multiple side effects including nausea and vomiting, loss of appetite, thinned or brittle hair, myalgia, arthralgia, and paresthesia (Spratto & Woods, 2005). Side effects such as myalgia/arthralgia and paresthesia are extremely debilitating and difficult to manage with medical treatment. Exercise may help patients better manage these treatment side effects. Regular use of SIBCP exercise strategies (four or more times per week) was associated with fewer treatment side effects. MacVicar and colleagues’ (1989) reported similar findings for an exercise intervention with Stage II breast cancer patients who were undergoing chemotherapy. Exercise on stationary bicycles (20-30 minutes three times per week for 10 weeks) resulted in improved functional status, reductions in nausea, and fewer physical symptoms. Providing exercise interventions for cancer patients may be especially relevant, as cancer patients often discontinue exercise and reduce physical activity while undergoing treatment (Andersen, 2002). For example, our data suggest that women undergoing chemotherapy were less likely to use exercise strategies. Helping patients maintain or increase physical activity during treatment may improve the management of treatment side effects and increase treatment compliance.

While the SIBCP intervention had positive effects on immune functioning (T-cell blastogenesis), we found no association between use of intervention techniques and immune outcomes. We expected a positive association between use of progressive muscle relaxation and immune outcomes. Past studies of relaxation training with cancer patients have reported positive intervention effects for cell counts and cell activity (e.g.,
NK cell cytotoxicity, T-cell blastogenesis; Gruber et al., 1993; Walker, Walker, Ogston et al., 1999). We also expected a positive association between use of exercise strategies and immune outcomes, as evidence suggests that physical activity has positive consequences for immune functioning (Fairey, Courneya, Field, & Mackey, 2002; Woods, Davis, Smith, & Nieman, 1999). Additional studies are needed to determine the relationship between intervention strategies and immune outcomes. It is possible that the SIBCP intervention produced benefits for immune functioning through a combination of intervention techniques including stress management, relaxation, exercise, dietary changes, and/or social support and communication.

Attendance

Session attendance impacts intervention outcomes for psychotherapy (Choi & Medalia, 2005) and health behavior interventions (Clifford, Tan, & Gorsuch, 1991). To increase the likelihood that patients will benefit from treatment, we must identify the factors that contribute to poor attendance and develop strategies to overcome these obstacles. Women with fewer socio-economic and social support resources were less likely to attend SIBCP intervention sessions. These data suggest that women with the most needs and the greatest disease burden (e.g., less access to treatment and higher mortality rates; ACS, 2004; Bradley et al., 2002; NCI, 2000) were less likely to participate in the intervention. Our findings highlight the need for intervention strategies and delivery methods that facilitate participation among patients with limited resources. SIBCP used telephone make-up sessions for women who were unable to attend group. This strategy increased participation among all participants and may have especially benefited women with fewer socio-economic resources. We also found that
concentrating efforts to increase participation at the beginning of the intervention may have improved overall attendance. Women tended to continue in the SIBCP intervention if they completed the first three sessions either in person or by telephone. Combining in person and telephone delivery increased access to the SIBCP intervention, but a sub-group of women remained difficult to reach. Future efforts should focus on novel strategies for reaching patients with the greatest treatment needs and the fewest socio-economic resources.

While women with fewer socio-economic resources had lower intervention attendance, these women benefited most from treatment. SIBCP participants with less formal education showed the greatest improvement on anxiety and physical functioning outcomes. Similarly, past studies report greater treatment benefits for cancer patients with fewer educational or economic resources (Lepore et al., 1999, 2003; Helgeson et al., 2000). These findings highlight the importance of increasing access to treatment for patients with limited resources. If given the opportunity to participate, these patients will benefit from psychological and behavioral interventions. Increasing access to interventions may reduce disparities in cancer outcomes related to socio-economic status. Psychological and behavioral interventions may help patients with fewer resources obtain information about cancer and develop strategies for coping with the disease.

Attendance was not associated with SIBCP intervention outcomes. Because SIBCP was designed to examine disease outcomes (recurrence), we made every effort (e.g., telephone sessions) to increase intervention attendance and limit the impact of attendance on intervention outcomes. These efforts were successful, as 70% (n= 80) of
SIBCP participants attended 90% of the intervention sessions (23 of the 26 sessions), and only 11% \((n=13)\) attended fewer than five sessions. Because the majority of participants received most of the intervention, attendance did not impact intervention outcomes.

**Strengths and Limitations**

Several characteristics of SIBCP increased the advantages of using data from this trial. First, SIBCP is the first intervention study with cancer patients to assess intervention processes (e.g., intervention evaluations, utilization of intervention techniques) that may contribute to positive outcomes. Second, the intervention demonstrated benefits for multiple outcomes, which allowed us to test the relationships between intervention outcomes and relevant treatment components (e.g., the relationship between assertive communication techniques and family support outcomes). The availability of data for patient satisfaction, important group experiences, and feelings of group cohesion made it possible to test for relationships between these variables and patient characteristics. Third, the intervention was delivered in a group format, which is consistent with previous intervention studies and interventions offered in the clinical setting. The ability to generalize to group interventions is increasingly important. Rising costs and limited resources make group interventions more feasible than individual treatment in many clinical settings. Fourth, we recruited patients who were at a specific point in cancer treatment. All patients began the study after surgical treatment and prior to the start of adjuvant therapy, which placed all participants at the same point in the disease trajectory. Because cancer patients’ needs or concerns change over the course of illness, we used this recruitment strategy to reduce the threat of confounding variables. Finally, the sample is homogeneous for disease, treatment, and prognostic variables.
Sample homogeneity increases our ability to interpret findings by decreasing variability in treatment side effects, physical functioning problems, mortality threat, and patient needs.

Several characteristics of the SIBCP trial may limit the generalizability of our findings. First, sample homogeneity for ethnicity, gender, and socio-economic status limit our ability to generalize findings to some clinical populations. Gender and/or cultural background may influence treatment efficacy and the factors that are associated with positive treatment outcomes. In addition, intervention participants’ personal resources may impact treatment outcomes. Second, we conducted a large number of repeated measures ANOVAs to identify potential moderators of the intervention. While this strategy allowed us to systematically test for important patterns, it resulted in an increased family wise error rate for tests of intervention x time x potential moderator interactions. Third, we dichotomized (median splits) variables for moderators, utilization of intervention techniques, feelings of group cohesion, and attendance for inclusion in repeated measures ANOVAs. Using median splits can result in the loss of information due to reduced variability, decreased power to detect effect sizes or decreases in effect size, and sampling error (MacCallum, Zhang, Preacher, & Rucker, 2002). Other correlational methods would have been preferred, but these methods require a larger sample size, normally distributed variables, and/or more data points. We also considered using change scores, but this strategy increases measurement error and limits options for examining change over multiple time points. Future studies should consider using correlational methods such as structural equation modeling, latent curve modeling, or multi-level modeling.
Future studies are needed to test for mediators. We could not test whether use of techniques mediated intervention effects because utilization data was not collected in the assessment-only group. Tests of mediation require data from intervention and control group participants (Kraemer et al., 2002). Our findings suggest that future studies should conduct tests of mediation for relaxation, increasing social support, assertive communication, communicating with medical providers, dietary strategies, and exercise. Future studies could obtain valuable information by testing for mediated moderation and moderated mediation. For example, an interaction between patient characteristics and intervention effects could be mediated by use of a specific intervention technique within a subgroup of patients. Likewise, patient characteristics could moderate the relationship between use of particular intervention techniques and intervention outcomes. A better understanding of these relationships would allow us design and deliver more effective interventions.

*Future Directions*

The long-term effects of cancer diagnosis and treatment highlight the need for extended follow-up. Long-term cancer-related sequelae include somatic complaints (e.g., pain), loss of stamina or fatigue, financial difficulties, narrowed employment options, disruptions in social support, and emotional distress (Michael et al., 2000; Broeckel, Jacobsen, et al., 2000; Hewitt et al., 1999; Ey, Compas, Epping-Jordan, Worsham, 1998; Spencer, Lehman, Wynings et al., 1999; Steginga et al., 2001). Few intervention studies assess long-term outcomes. Only 19% of the studies we reviewed provided follow-up data for 12 months or longer, with the longest follow-up conducted 36 months post intervention. Most (76%) of these studies reported long-term maintenance of
intervention effects, but these studies only examined psychological adjustment, quality of life, or survival outcomes. Long-term data for health behaviors or biologic (immune or endocrine data) outcomes remain unavailable. Additional studies with long-term follow-up are needed.

The long-term impact of cancer makes the need for long-lasting intervention effects clear. Studies of psychotherapy suggest that intervention effect sizes increase with the duration of treatment (Hansen, Lambert, & Forman, 2002). Rehse and Pukrop (2003) conducted a meta-analysis of cancer interventions and found that intervention length (number of sessions) was the most powerful moderator of effect size. Interventions with 12 or more sessions had an effect size of .51 vs. .23 for shorter interventions. Sheard and Maguire (1999) found similar results in their meta-analysis of cancer interventions. Lengthening treatment may increase the size and durability of intervention effects (Kadera, Lambert, & Andrews, 1996; Maling et al., 1995), but extending interventions is not financially feasible in most clinical settings and many cancer patients have difficulty attending long interventions. Other options should be considered. Building a maintenance component into interventions might be a feasible strategy. For example, SIBCP included maintenance sessions focused on managing setbacks and relapse prevention techniques. The frequency of sessions was reduced from weekly to monthly as a way to transition to the end of treatment. Finally, we may be able to increase intervention effect sizes and the duration of effects by identifying and including the intervention strategies most responsible for change. Our data suggest that these intervention strategies include relaxation training, assertive communication and social support, communicating with medical providers, diet, and exercise.
Given the limited resources available for psychological and behavioral interventions, we must develop cost efficient and time efficient interventions. First, dismantling studies could build on our findings by providing randomized tests of intervention components. We could gather more information about the processes that contribute to positive intervention outcomes by having participants complete more frequent (e.g., daily diary) measures of technique use. Frequent data collection has become more feasible with the use of handheld devices (PDA’s), the internet, cell phones, and automated telephone systems. Second, we need to develop intervention delivery methods (e.g., internet or telephone) that reduce costs and make interventions available to a larger number of patients. For example, Cimprich and colleagues (2005) have combined delivery methods for a cognitive behavioral intervention with breast cancer patients. Women attend two group sessions in person, two individual telephone sessions, and all women receive an intervention workbook. This blended approach provides individually tailored information as well as peer support, and reduces the cost and time burdens associated with using all in person or individual sessions.

Providing interventions in a group format could reduce costs and increase the feasibility of delivering interventions in the clinical setting. Data also suggest that patients may benefit most from group interventions. Sheard and Maguire (1999) conducted a meta-analysis of depression and anxiety outcomes for interventions with cancer patients. Results showed that interventions delivered in an individual format had effect sizes approximately 50% lower than those found for group interventions (.27 vs. .69 for anxiety and .30 vs. .54 for depression). Group formats may provide unique benefits such as feelings of group cohesion, information obtained from group discussions,
and models of successful coping by other group members. Importantly, data indicate that patients find group experiences important and many patients prefer group formats to individual sessions (Cimprich et al., 2005).

Psychosocial and behavioral interventions have demonstrated the ability to reduce cancer-related burdens, but the majority of interventions have focused on psychological or quality of life outcomes. Treatment compliance is an important area in need of study. Data suggest that dosage reductions for chemotherapy compromise survival (Budman et al., 1998; Bonadonna & Valagussa, 1981) and noncompliance with radiation therapy can compromise control of local disease (Li, Brown, Ampil, Burton, Yu, & McDonald, 2000). Our data indicate that strategies for improving communication with medical providers and increasing exercise positively impact compliance with recommended chemotherapy regimens. Additional studies are needed to test for intervention strategies that can reduce treatment refusals, premature termination of treatment, or receipt of less treatment than recommended.

Interventions for improving health behaviors represent an important area of study. If we can reduce negative health behaviors and increase positive health behaviors, patients may experience improvements in quality of life, greater treatment tolerance, reduced risk for future health problems, and important biological changes (e.g., sympathetic, adrenocortical, and immune). Health behaviors that should be targeted include smoking, diet/weight management, and physical activity. First, continued cigarette smoking has been associated with increased risk for recurrence and lowered survival (Browman et al., 1993; Chang, Orav, McNamara, Tong, & Antin, 2004; Steven et al., 1983). Brief education-focused interventions may be insufficient for increasing
quit rates (Andersen, 2002). Additional studies are needed to test smoking cessation strategies such as nicotine replacement. Second, obesity at diagnosis, increased fat intake, and weight gain may be related to recurrence and poorer survival in breast cancer patients (Rock & Denmark-Wahnefried, 2002; Saxe et al., 1999; Zhang et al., 1995). Interventions have focused on improving dietary habits and increasing physical activity, but these interventions report mixed findings for weight loss. Future research efforts should focus on developing weight loss and weight maintenance strategies for cancer patients. Finally, physical activity may have positive benefits for treatment side effects, stress, quality of life, physical functioning, and immune and endocrine responses (Dimeo, Fetscher, Lange, Mertelsmann, & Keul, 1997; Fairey et al., 2002; Nieman, 2003, Smith & Weidemann, 1990). Past exercise interventions report promising results that suggest increasing physical activity can reduce treatment side effects and improve treatment compliance. Additional studies are needed to test methods for increasing physical activity among cancer patients.

**Unique Contributions of the Present Study**

The current study provides the first systematic evaluation of the factors associated with positive intervention outcomes for cancer patients. SIBCP is the first intervention study with cancer patients to 1) assess intervention processes (e.g., intervention evaluations, utilization of intervention techniques) that may contribute to positive outcomes, 2) test the association between intervention processes and outcomes, and 3) match intervention techniques with outcomes. Our findings make several novel contributions to the literature. First, we found that satisfaction was not associated with the use of intervention techniques, and satisfaction did not indicate whether patients
would benefit from intervention components. Future studies should not use ratings of satisfaction as a proxy for utilization or efficacy of intervention strategies. Second, our data suggest that improvements in family support were associated with strategies (e.g., assertive communication, identifying who would be best to ask for particular types of support) for increasing patients’ use of existing social networks. Future interventions should focus on these strategies rather than efforts to provide new sources of support. Third, the SIBCP intervention represents the only randomized trial to target treatment compliance and examine which intervention strategies show a relationship with better compliance. Strategies for communicating with medical providers and exercise were associated with receipt of recommended chemotherapy regimens. Our data indicate that these strategies should be included in future interventions targeting treatment compliance. Finally, the SIBCP intervention included diet and exercise components, which encouraged women to make health behavior changes during adjuvant therapy. Our data show that women were able to improve dietary habits and increase physical activity during this vulnerable time. These findings indicate that patients can participate in and benefit from health behavior interventions during cancer treatment.

Findings from SIBCP suggest important directions for future research. Our data provide valuable and unique data for designing dismantling studies and developing future interventions. The intervention techniques associated with positive treatment outcomes in this study should be tested in future interventions. Future studies could benefit from including frequent assessments of intervention evaluations and utilization of intervention techniques. Assessing these variables frequently (e.g., daily) could yield more accurate information and richer data. In addition, future studies should assess utilization of
techniques in both the intervention and control arms. Data from all participants would allow us to test for mediators of treatment outcomes. Finally, we assessed important positive group experiences, but we did not collect information regarding negative group experiences. We must develop a better understanding of the negative experiences that contribute to poor treatment outcomes, low attendance, and intervention dropout.

Conclusions and Recommendations

Managing cancer-related sequelae has become increasingly important as individuals live longer with the burdens of cancer and its treatments (ACS, 2006). If unaddressed, these problems can contribute to a poorer recovery and long-term disruptions in quality of life (Gotay & Muraoka, 1998; Green et al., 2000). Studies show that psychosocial and behavioral interventions are effective for reducing cancer-related problems, but additional work is needed. Dismantling studies should be conducted to further test intervention strategies such as relaxation training, assertive communication training, communicating with healthcare professionals, diet, and exercise. Identifying the intervention strategies responsible for positive outcomes will help us design and implement treatments with larger effect sizes and longer lasting benefits. Future studies should give special attention to intervention designs and delivery methods that will increase treatment availability for patients with fewer socio-economic resources. These patients face the most barriers to intervention participation (e.g., lack of transportation, time, and financial resources) as well as the greatest disease burden (ACS, 2004; NCI, 2000). Finally, greater attention should be given to interventions that target treatment compliance, smoking, diet or weight management, and physical activity. Improving
treatment compliance and health behaviors among cancer patients could yield benefits for
treatment tolerance, quality of life, biological outcomes (e.g., immune functioning), and
future health.
LIST OF REFERENCES


APPENDIX A

TABLES AND FIGURES
<table>
<thead>
<tr>
<th>Intervention Target</th>
<th>Outcome measured</th>
<th>Number of studies (N=109)</th>
<th>Percent of studies showing a significant benefit (p&lt;.05) for intervention patients vs. control patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional distress (N=72)</td>
<td>Anxious symptoms</td>
<td>25</td>
<td>64%</td>
</tr>
<tr>
<td></td>
<td>Depressive symptoms</td>
<td>33</td>
<td>55%</td>
</tr>
<tr>
<td></td>
<td>Mood</td>
<td>45</td>
<td>60%</td>
</tr>
<tr>
<td>Cancer-specific stress (N=13)</td>
<td>Traumatic stress</td>
<td>13</td>
<td>31%</td>
</tr>
<tr>
<td>Quality of life (N=29)</td>
<td>Global quality of life</td>
<td>20</td>
<td>45%</td>
</tr>
<tr>
<td></td>
<td>Mental quality of life</td>
<td>7</td>
<td>57%</td>
</tr>
<tr>
<td></td>
<td>Physical quality of life</td>
<td>8</td>
<td>50%</td>
</tr>
<tr>
<td>Social adjustment (N=12)</td>
<td>Social support</td>
<td>6</td>
<td>17%</td>
</tr>
<tr>
<td></td>
<td>Social activities</td>
<td>3</td>
<td>67%</td>
</tr>
<tr>
<td></td>
<td>Relationship satisfaction</td>
<td>4</td>
<td>50%</td>
</tr>
<tr>
<td>Diet or nutrition (N=4)</td>
<td>Dietary change</td>
<td>4</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>Weight loss</td>
<td>4</td>
<td>50%</td>
</tr>
<tr>
<td>Exercise (N=6)</td>
<td>Physical functioning</td>
<td>5</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>Treatment side effects</td>
<td>4</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>Mood or quality of life</td>
<td>3</td>
<td>67%</td>
</tr>
</tbody>
</table>

Table 1. Summary of outcomes for randomized intervention studies with cancer patients.
Table 1 (continued)

<table>
<thead>
<tr>
<th>Intervention Target</th>
<th>Outcome measured</th>
<th>Number of studies (N=109)a</th>
<th>Percent of studies showing a significant benefit (p&lt;.05) for intervention patients vs. control patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking cessation (n=4)</td>
<td>Smoking status</td>
<td>4</td>
<td>50%</td>
</tr>
<tr>
<td>Biologic outcomes (N=9)</td>
<td>Cell counts</td>
<td>5</td>
<td>40%</td>
</tr>
<tr>
<td></td>
<td>Cell activity</td>
<td>7</td>
<td>57%</td>
</tr>
<tr>
<td></td>
<td>Cortisol</td>
<td>3</td>
<td>67%</td>
</tr>
<tr>
<td>Survival (N=10)</td>
<td>Length of survival</td>
<td>10</td>
<td>40%</td>
</tr>
</tbody>
</table>

a. The number of studies across intervention targets and outcome variables does not total N=109. Most intervention studies include multiple intervention targets and outcome measures, and thus, studies overlap across outcomes.
<table>
<thead>
<tr>
<th>Intervention Target</th>
<th>Sessions</th>
<th>Intervention Component</th>
<th>Measured Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress</td>
<td>1-18</td>
<td>▪ Understanding stress responses&lt;br&gt;▪ Progressive muscle relaxation training</td>
<td>Perceived Stress Scale</td>
</tr>
<tr>
<td>Quality of Life:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional distress</td>
<td>10-15</td>
<td>▪ Relaxation training, positive coping, problem solving.</td>
<td>Profile of Mood States</td>
</tr>
<tr>
<td>Social adjustment</td>
<td>4-9</td>
<td>▪ Identify social network&lt;br&gt;▪ Identify support needed and specific social contact&lt;br&gt;▪ Communication skills training</td>
<td>Social Network Index&lt;br&gt;PSS Family and Friends</td>
</tr>
<tr>
<td>Health Behaviors</td>
<td>13-16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diet</td>
<td></td>
<td>▪ Food intake diary&lt;br&gt;▪ Low fat/high fiber information, food substitution&lt;br&gt;▪ Intake and energy balance information</td>
<td>Food Habits Questionnaire</td>
</tr>
<tr>
<td>Exercise</td>
<td></td>
<td>▪ Stretching and walking protocol (20min/day x 3/wk)</td>
<td>7-Day exercise recall</td>
</tr>
</tbody>
</table>

Table 2. Intervention targets, sessions, components, and measured variables.
### Table 2 (continued)

<table>
<thead>
<tr>
<th>Intervention Target</th>
<th>Sessions</th>
<th>Intervention Component</th>
<th>Measured Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>2-3, 10</td>
<td>• Referral information, Group support for cessation.</td>
<td>Tobacco intake (cigs/day)</td>
</tr>
</tbody>
</table>
| Compliance          |          | • Disease/treatment information, Assertive communication skills  
|                     |          | • Monitoring of treatment/follow up appointments, Goal setting. | Dose intensity  
|                     |          |                                      | Chemo refusal/dropout  
|                     |          |                                      | Loss to follow up |
| Physical functioning| NA       | NA | KPS physical functioning  
<p>|                     |          |                                      | SWOG treatment toxicity |
| Immunity            | NA       | NA | Cellular immune assays |
| Disease endpoints   | NA       | NA | Event/time to recurrence |</p>
<table>
<thead>
<tr>
<th>Category</th>
<th>Total (N=227)</th>
<th>Assessment (n=113)</th>
<th>Intervention (n=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Sociodemographic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (Years)</td>
<td>50.82</td>
<td>(10.76)</td>
<td>51.07</td>
</tr>
<tr>
<td>Race (% Caucasian)</td>
<td>90</td>
<td></td>
<td>90</td>
</tr>
<tr>
<td>Education (Years)</td>
<td>14.75</td>
<td>(2.74)</td>
<td>14.34</td>
</tr>
<tr>
<td>Family Income (K/Year)</td>
<td>67.98</td>
<td>(71.41)</td>
<td>66.30</td>
</tr>
<tr>
<td>Significant Other (%Yes)</td>
<td>74</td>
<td></td>
<td>72</td>
</tr>
<tr>
<td>Prognostic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage (II vs. III %)</td>
<td>90</td>
<td></td>
<td>92</td>
</tr>
<tr>
<td>Nodes (number positive)</td>
<td>3.05</td>
<td>(5.45)</td>
<td>3.06</td>
</tr>
<tr>
<td>Tumor size (cm.)</td>
<td>3.02</td>
<td>(1.77)</td>
<td>2.91</td>
</tr>
<tr>
<td>ER/PR (% positive)</td>
<td>68</td>
<td></td>
<td>68</td>
</tr>
<tr>
<td>Menopausal status (% Pre)</td>
<td>54</td>
<td></td>
<td>52</td>
</tr>
<tr>
<td>Treatment Received/Recommended</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery (% Mastectomy)</td>
<td>43</td>
<td></td>
<td>43</td>
</tr>
<tr>
<td>Radiation therapy (% Yes)</td>
<td>54</td>
<td></td>
<td>51</td>
</tr>
<tr>
<td>Hormonal therapy (% Yes)</td>
<td>75</td>
<td></td>
<td>80</td>
</tr>
<tr>
<td>Chemotherapy (% Yes)</td>
<td>84</td>
<td></td>
<td>85</td>
</tr>
</tbody>
</table>

Table 3. Initial equivalence of study arms on sociodemographic, prognostic, and treatment variables. Percentages or means and standard deviations (in parentheses) are provided.
<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>Education</th>
<th>Income</th>
<th>Marital status</th>
<th>Social network</th>
<th>Cancer-related distress</th>
<th>Surgical treatment</th>
<th>Chemo-therapy</th>
<th>Radiation therapy</th>
<th>Neuroticism</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Emotional distress</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POMS TMD</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POMS Anxiety</td>
<td>ns</td>
<td></td>
<td></td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Social adjustment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSS Family</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diet</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FHQ</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FHQ substitution</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
</tbody>
</table>

Table 4. Repeated measures ANOVAs testing potential moderators of the intervention effect. F values and effect sizes (Eta squared in parentheses) are provided.
Table 4 (continued)

<table>
<thead>
<tr>
<th>Age</th>
<th>Education</th>
<th>Income</th>
<th>Marital status</th>
<th>Social network</th>
<th>Cancer-related distress</th>
<th>Surgical treatment</th>
<th>Chemotherapy</th>
<th>Radiation therapy</th>
<th>Neuroticism</th>
</tr>
</thead>
</table>

**Exercise**

| 7 Day Recall | ns | ns | ns | ns | ns | ns | ns | ns | ns | ns | ns |

**Physical functioning**

| KPS | ns | \( F=3.81^{*} \) \((\eta^2=.02)\) | ns | ns | ns | ns | ns | ns | ns | ns | ns |
| SWOG | ns | ns | ns | ns | ns | ns | ns | ns | ns | ns | ns |

**Immune functioning**

| PHA | ns | ns | ns | ns | ns | ns | ns | ns | ns | ns | ns |
| Con A | ns | ns | ns | ns | ns | ns | ns | ns | ns | ns | ns |

\*p≤.05  \*\*p≤.01

Note: Displayed F values are for the group x time x potential moderator interaction in repeated measures ANOVA. All F values with p > .05 are noted as ns in the table.
<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Satisfaction with intervention topics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stress management information</td>
<td>3.70</td>
<td>.60</td>
<td>4.00</td>
<td>1-4</td>
</tr>
<tr>
<td>Relaxation and relaxation practice</td>
<td>3.67</td>
<td>.58</td>
<td>4.00</td>
<td>2-4</td>
</tr>
<tr>
<td>Medical provider communication</td>
<td>3.31</td>
<td>.71</td>
<td>3.00</td>
<td>1-4</td>
</tr>
<tr>
<td>Social support</td>
<td>3.50</td>
<td>.63</td>
<td>4.00</td>
<td>1-4</td>
</tr>
<tr>
<td>Assertive communication</td>
<td>3.22</td>
<td>.71</td>
<td>3.00</td>
<td>1-4</td>
</tr>
<tr>
<td>Problem solving</td>
<td>3.40</td>
<td>.75</td>
<td>4.00</td>
<td>2-4</td>
</tr>
<tr>
<td>Diet information</td>
<td>3.88</td>
<td>.36</td>
<td>4.00</td>
<td>2-4</td>
</tr>
<tr>
<td>Exercise information</td>
<td>3.46</td>
<td>.77</td>
<td>4.00</td>
<td>1-4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>3.52</td>
<td>.36</td>
<td>3.63</td>
<td>2-4</td>
</tr>
<tr>
<td><strong>Group cohesion</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7.85</td>
<td>1.03</td>
<td>8.00</td>
<td>4-9</td>
</tr>
<tr>
<td><strong>Important group experiences</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feeling accepted/belonging</td>
<td>3.06</td>
<td>.78</td>
<td>3.00</td>
<td>1-5</td>
</tr>
<tr>
<td>Changing behaviors/attitudes</td>
<td>3.50</td>
<td>.76</td>
<td>3.50</td>
<td>1-5</td>
</tr>
<tr>
<td>Getting information/advice</td>
<td>4.14</td>
<td>.63</td>
<td>4.20</td>
<td>1-5</td>
</tr>
</tbody>
</table>

Table 5. Descriptive statistics for satisfaction with intervention topics, group cohesion, perceptions of important group experiences, utilization of intervention techniques, and attendance.
Table 5 (continued)

<table>
<thead>
<tr>
<th>Utilization of intervention techniques</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress management</td>
<td>5.25</td>
<td>1.67</td>
<td>5.33</td>
<td>1-8</td>
</tr>
<tr>
<td>Relaxation and relaxation practice</td>
<td>3.36</td>
<td>1.87</td>
<td>3.50</td>
<td>0-7</td>
</tr>
<tr>
<td>Medical provider communication</td>
<td>4.23</td>
<td>2.57</td>
<td>4.00</td>
<td>0-8</td>
</tr>
<tr>
<td>Social support</td>
<td>3.57</td>
<td>1.85</td>
<td>3.00</td>
<td>0-8</td>
</tr>
<tr>
<td>Assertive communication</td>
<td>4.90</td>
<td>1.90</td>
<td>5.00</td>
<td>1-8</td>
</tr>
<tr>
<td>Problem solving</td>
<td>3.99</td>
<td>1.79</td>
<td>4.00</td>
<td>0-8</td>
</tr>
<tr>
<td>Eating less fat</td>
<td>6.62</td>
<td>1.41</td>
<td>7.00</td>
<td>2-8</td>
</tr>
<tr>
<td>Increasing fiber</td>
<td>6.63</td>
<td>1.31</td>
<td>7.00</td>
<td>2-8</td>
</tr>
<tr>
<td>Exercise</td>
<td>4.35</td>
<td>1.76</td>
<td>4.00</td>
<td>0-8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Attendance</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensive phase (18 sessions)</td>
<td>14.24</td>
<td>5.75</td>
<td>17.00</td>
<td>0-18</td>
</tr>
<tr>
<td>Maintenance phase (8 sessions)</td>
<td>6.04</td>
<td>2.97</td>
<td>7.00</td>
<td>0-8</td>
</tr>
<tr>
<td>Total (26 sessions)</td>
<td>20.27</td>
<td>8.50</td>
<td>24.00</td>
<td>0-26</td>
</tr>
</tbody>
</table>
Table 6. Correlations between participant characteristics and satisfaction with intervention topics, group cohesion, perceptions of important group experiences, utilization of intervention techniques, and attendance.

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>Education</th>
<th>Income</th>
<th>Marital status</th>
<th>Social network</th>
<th>Cancer-related distress</th>
<th>Surgical treatment</th>
<th>Chemo-therapy</th>
<th>Radiation therapy</th>
<th>Neuroticism</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Satisfaction with topics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stress management information</td>
<td>-.02</td>
<td>-.08</td>
<td>-.08</td>
<td>.05</td>
<td>-.02</td>
<td>-.11</td>
<td>.11</td>
<td>.06</td>
<td>.01</td>
<td>-.01</td>
</tr>
<tr>
<td>Relaxation and relaxation practice</td>
<td>.07</td>
<td>.05</td>
<td>.09</td>
<td>.07</td>
<td>-.03</td>
<td>-.04</td>
<td>-.04</td>
<td>.21*</td>
<td>-.11</td>
<td>.01</td>
</tr>
<tr>
<td>Medical provider communication</td>
<td>-.05</td>
<td>-.16</td>
<td>.08</td>
<td>.04</td>
<td>-.04</td>
<td>-.04</td>
<td>-.12</td>
<td>.09</td>
<td>.16</td>
<td>.08</td>
</tr>
<tr>
<td>Social support</td>
<td>-.06</td>
<td>-.16</td>
<td>.04</td>
<td>.15</td>
<td>.13</td>
<td>.03</td>
<td>-.17</td>
<td>.13</td>
<td>.04</td>
<td>-.01</td>
</tr>
<tr>
<td>Assertive communication</td>
<td>-.03</td>
<td>-.07</td>
<td>.05</td>
<td>.04</td>
<td>.05</td>
<td>.07</td>
<td>.04</td>
<td>.03</td>
<td>.07</td>
<td>.07</td>
</tr>
<tr>
<td>Problem solving</td>
<td>.08</td>
<td>-.18</td>
<td>-.08</td>
<td>.06</td>
<td>.01</td>
<td>.11</td>
<td>.01</td>
<td>-.14</td>
<td>.14</td>
<td>.18</td>
</tr>
<tr>
<td>Diet information</td>
<td>-.02</td>
<td>.01</td>
<td>-.01</td>
<td>-.13</td>
<td>.07</td>
<td>-.01</td>
<td>-.09</td>
<td>-.05</td>
<td>.12</td>
<td>-.02</td>
</tr>
<tr>
<td>Exercise information</td>
<td>-.08</td>
<td>-.11</td>
<td>-.10</td>
<td>-.01</td>
<td>-.01</td>
<td>.08</td>
<td>-.01</td>
<td>-.04</td>
<td>.02</td>
<td>.04</td>
</tr>
<tr>
<td>Total</td>
<td>-.04</td>
<td>-.14</td>
<td>.03</td>
<td>.06</td>
<td>.05</td>
<td>.02</td>
<td>-.04</td>
<td>.06</td>
<td>.08</td>
<td>.07</td>
</tr>
<tr>
<td><strong>Group cohesion</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-.08</td>
<td>-.08</td>
<td>.04</td>
<td>.15</td>
<td>.30**</td>
<td>.03</td>
<td>-.08</td>
<td>-.08</td>
<td>.16</td>
<td>-.15</td>
</tr>
</tbody>
</table>

continued
### Table 6 (continued)

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>Education</th>
<th>Income</th>
<th>Marital status</th>
<th>Social network</th>
<th>Cancer-related distress</th>
<th>Surgical treatment</th>
<th>Chemotherapy</th>
<th>Radiation therapy</th>
<th>Neuroticism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important group experiences</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feeling accepted/belonging</td>
<td>.18*</td>
<td>-.16</td>
<td>-.14</td>
<td>-.04</td>
<td>-.01</td>
<td>.10</td>
<td>.22*</td>
<td>-.12</td>
<td>-.11</td>
<td>-.03</td>
</tr>
<tr>
<td>Changing behaviors/attitudes</td>
<td>-.05</td>
<td>-.10</td>
<td>.05</td>
<td>.04</td>
<td>.01</td>
<td>.24*</td>
<td>.19*</td>
<td>.09</td>
<td>-.06</td>
<td>.07</td>
</tr>
<tr>
<td>Getting information/advice</td>
<td>.14</td>
<td>-.02</td>
<td>-.04</td>
<td>-.14</td>
<td>-.09</td>
<td>-.08</td>
<td>.04</td>
<td>-.07</td>
<td>-.07</td>
<td>-.13</td>
</tr>
<tr>
<td>Utilization of techniques</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stress management</td>
<td>.10</td>
<td>.11</td>
<td>.02</td>
<td>-.11</td>
<td>.02</td>
<td>.15</td>
<td>.03</td>
<td>.01</td>
<td>.03</td>
<td>-.11</td>
</tr>
<tr>
<td>Relaxation and relaxation practice</td>
<td>.21*</td>
<td>.08</td>
<td>.06</td>
<td>-.03</td>
<td>-.15</td>
<td>.11</td>
<td>.01</td>
<td>-.17</td>
<td>.01</td>
<td>.03</td>
</tr>
<tr>
<td>Medical provider communication</td>
<td>.13</td>
<td>-.21*</td>
<td>-.07</td>
<td>-.08</td>
<td>-.03</td>
<td>.15</td>
<td>.18</td>
<td>-.09</td>
<td>.05</td>
<td>.01</td>
</tr>
<tr>
<td>Social support</td>
<td>.04</td>
<td>.01</td>
<td>-.04</td>
<td>.13</td>
<td>.04</td>
<td>.13</td>
<td>.18</td>
<td>.15</td>
<td>-.05</td>
<td>.03</td>
</tr>
<tr>
<td>Assertive communication</td>
<td>-.20*</td>
<td>.19</td>
<td>.01</td>
<td>.02</td>
<td>.01</td>
<td>-.01</td>
<td>-.06</td>
<td>.24*</td>
<td>-.03</td>
<td>.01</td>
</tr>
<tr>
<td>Problem solving</td>
<td>-.11</td>
<td>-.13</td>
<td>-.20</td>
<td>.04</td>
<td>.02</td>
<td>.04</td>
<td>-.07</td>
<td>.17</td>
<td>-.01</td>
<td>.02</td>
</tr>
<tr>
<td>Activity</td>
<td>Age</td>
<td>Education</td>
<td>Income</td>
<td>Marital status</td>
<td>Social network</td>
<td>Cancer-related distress</td>
<td>Surgical treatment</td>
<td>Chemotherapy</td>
<td>Radiation therapy</td>
<td>Neuroticism</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-----</td>
<td>-----------</td>
<td>--------</td>
<td>----------------</td>
<td>----------------</td>
<td>------------------------</td>
<td>-------------------</td>
<td>--------------</td>
<td>-------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Eating less fat</td>
<td>.20*</td>
<td>.25*</td>
<td>.11</td>
<td>-.07</td>
<td>.04</td>
<td>.06</td>
<td>-.14</td>
<td>.04</td>
<td>-.05</td>
<td>-.13</td>
</tr>
<tr>
<td>Increasing fiber</td>
<td>.27*</td>
<td>.17</td>
<td>-.01</td>
<td>-.05</td>
<td>-.01</td>
<td>.11</td>
<td>.03</td>
<td>-.03</td>
<td>.02</td>
<td>-.24*</td>
</tr>
<tr>
<td>Exercise</td>
<td>.26*</td>
<td>.05</td>
<td>-.07</td>
<td>-.10</td>
<td>-.12</td>
<td>-.02</td>
<td>.05</td>
<td>-.25*</td>
<td>.03</td>
<td>-.11</td>
</tr>
</tbody>
</table>

**Attendance**

<table>
<thead>
<tr>
<th>Intensive phase (18 sessions)</th>
<th>-.11</th>
<th>.28**</th>
<th>.26**</th>
<th>.29**</th>
<th>.26**</th>
<th>.08</th>
<th>-.07</th>
<th>.06</th>
<th>.12</th>
<th>-.22*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance phase (8 sessions)</td>
<td>-.10</td>
<td>.23*</td>
<td>.18*</td>
<td>.25**</td>
<td>.25**</td>
<td>.03</td>
<td>-.03</td>
<td>-.02</td>
<td>.04</td>
<td>-.28**</td>
</tr>
<tr>
<td>Total (26 sessions)</td>
<td>-.11</td>
<td>.27**</td>
<td>.24*</td>
<td>.28**</td>
<td>.26**</td>
<td>.07</td>
<td>-.06</td>
<td>.04</td>
<td>.09</td>
<td>-.25**</td>
</tr>
</tbody>
</table>

*p<.10     *p≤.05     **p≤.01
Table 7. Inter-correlations for satisfaction with intervention topics, group cohesion, perceptions of important group experiences, utilization of intervention techniques, and attendance.

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Satisfaction total</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Group cohesion</td>
<td></td>
<td>.45*</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Important group experiences**

3. Feeling accepted/ belonging | .30* | .22* | 1.00 |      |      |      |      |      |      |      |      |      |      |      |      |

4. Changing behaviors/attitudes | .26* | .01  | .37* | 1.00 |      |      |      |      |      |      |      |      |      |      |      |

5. Getting information/advice | .28* | .10  | .25* | .43* | 1.00 |      |      |      |      |      |      |      |      |      |      |

**Utilization of techniques**

6. Stress and immunity information | -.01 | .17  | -.06 | .13  | .10  | 1.00 |      |      |      |      |      |      |      |      |      |

7. Relaxation practice | .14  | .02  | -.05 | .09  | .06  | .33* | 1.00 |      |      |      |      |      |      |      |      |

8. Medical provider communication | -.21# | -.11 | -.01 | .09  | -.16 | .23* | -.02 | 1.00 |      |      |      |      |      |      |      |

9. Social support | .30* | .05  | .22# | .15  | .21# | .35* | .32* | .26* | 1.00 |      |      |      |      |      |      |

10. Assertive communication | .04  | -.01 | -.10 | .01  | -.06 | .44* | .35* | .08  | .42* | 1.00 |      |      |      |      |      |

*continued*
Table 7 (continued)

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Problem solving</td>
<td>.01</td>
<td>-.10</td>
<td>-.01</td>
<td>.11</td>
<td>-.07</td>
<td><strong>.28</strong>*</td>
<td>-.09</td>
<td><strong>.22</strong>#</td>
<td>* .35*</td>
<td>* .47*</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Eating less fat</td>
<td>.16</td>
<td>.16</td>
<td>-.10</td>
<td>-.06</td>
<td>.10</td>
<td><strong>.36</strong>*</td>
<td><strong>.28</strong>*</td>
<td>.10</td>
<td>.12</td>
<td>.18</td>
<td>-.16</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Increasing fiber</td>
<td>.16</td>
<td>.13</td>
<td>.01</td>
<td>.05</td>
<td>.06</td>
<td><strong>.26</strong>*</td>
<td>-.01</td>
<td>.04</td>
<td>.16</td>
<td>-.14</td>
<td><strong>.70</strong>*</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Exercise</td>
<td>.02</td>
<td>.09</td>
<td>.06</td>
<td>-.13</td>
<td>.03</td>
<td>.16</td>
<td><strong>.21</strong>#</td>
<td>-.01</td>
<td>.10</td>
<td>.06</td>
<td>-.07</td>
<td><strong>.39</strong>*</td>
<td><strong>.39</strong>*</td>
<td>1.00</td>
<td></td>
</tr>
</tbody>
</table>

**Attendance**

| 15. Total attendance    | .05 | **.34***| .17 | -.06| .16 | .17 | -.04| .16 | **.24***| -.01| .14 | .04 | -.02| 1.00|

# p<.10   *p<.05
<table>
<thead>
<tr>
<th>Intervention Techniques</th>
<th>Problem solving</th>
<th>Stress manage.</th>
<th>Relaxation</th>
<th>Social support</th>
<th>Assertive comm.</th>
<th>Eating less fat</th>
<th>Increasing fiber</th>
<th>Exercise</th>
<th>Medical provider comm.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Life:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Emotional distress</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POMS TMD</td>
<td>ns</td>
<td>ns</td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>POMS Anxiety</td>
<td>ns</td>
<td>ns</td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Social adjustment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSS Family</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td></td>
<td>F=2.60*</td>
<td>(η²=.04)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Table 8. Repeated measures ANOVAs testing the association between intervention outcomes and utilization of intervention techniques. F values and effect sizes (Eta squared in parentheses) are provided.
Table 8 (continued)

<table>
<thead>
<tr>
<th>Problem solving</th>
<th>Stress manage.</th>
<th>Relaxation</th>
<th>Social support</th>
<th>Assertive comm.</th>
<th>Eating less fat</th>
<th>Increasing fiber</th>
<th>Exercise</th>
<th>Medical provider comm.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Behaviors:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dietary patterns</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FHQ</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>F=2.72*</td>
<td>N/A</td>
<td>F=3.16* (η²=.04)</td>
</tr>
<tr>
<td>FHQ substitution</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>Exercise</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 Day Recall</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>ns</td>
<td>ns</td>
<td></td>
</tr>
<tr>
<td>Compliance:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>N/A</td>
<td>N/A</td>
<td>ns</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>ns</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>N/A</td>
<td>N/A</td>
<td>ns</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>ns</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>N/A</td>
<td>N/A</td>
<td>ns</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>T=6.10* ns</td>
</tr>
</tbody>
</table>

continued
Table 8 (continued)

<table>
<thead>
<tr>
<th>Problem solving</th>
<th>Stress manage.</th>
<th>Relaxation</th>
<th>Social support</th>
<th>Assertive comm.</th>
<th>Eating less fat</th>
<th>Increasing fiber</th>
<th>Exercise</th>
<th>Medical provider comm.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Functioning:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KPS</td>
<td>N/A</td>
<td>ns</td>
<td>ns</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>ns</td>
</tr>
<tr>
<td>SWOG</td>
<td>N/A</td>
<td>ns</td>
<td>ns</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>F=3.71* (η²=.04)</td>
</tr>
<tr>
<td>Immunity:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHA</td>
<td>N/A</td>
<td>ns</td>
<td>ns</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>ns</td>
</tr>
<tr>
<td>Con A</td>
<td>N/A</td>
<td>ns</td>
<td>ns</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>ns</td>
</tr>
</tbody>
</table>

*p ≤ .05

Note: Displayed F values are for the time x utilization interaction in repeated measures ANOVA. Displayed T values are for permutation one-way ANOVA with general scores. All F and T values with p ≥ .10 are noted as “ns” in the table. N/A indicates no test conducted because technique did not target that outcome.
Patient characteristics as moderators of the intervention

- For POMS TMD, there was a significant group x time x initial cancer-related distress interaction. Intervention participants with high initial cancer-related distress showed the greatest decrease in POMS TMD.

- For POMS Anxiety, there was a significant group x time x education interaction. Intervention participants with less formal education showed the greatest decreases in POMS Anxiety.

- For PSS-Family, there was a significant group x time x type of surgery interaction. Intervention participants who underwent a mastectomy showed the greatest increases in perceptions of family support.

- For KPS, there was a significant group x time x education interaction. Intervention participants with less formal education showed the greatest improvements in KPS scores at 12-month follow-up.

Associations with patient characteristics

Satisfaction:
- Receiving adjuvant chemotherapy was significantly associated with rating relaxation and relaxation practice with tapes as more helpful.

Feelings of group cohesion:
- Having a larger social network (SNI) was significantly associated greater feelings of group cohesion.

Important group experiences:
- Higher initial cancer-related distress was significantly associated with rating experiences of changing behavior/attitudes as more important.
- Having a mastectomy was significantly correlated with rating experiences of feeling accepted/belonging in the group as more important.
Table 9 (continued)

Associations with patient characteristics

Use of techniques:
- Older women were more likely to use strategies for improving health behaviors including increasing fiber in their diet and exercise.
- More formal education was significantly associated with using more strategies to reduce dietary fat.
- Women who received adjuvant chemotherapy were less likely to use strategies for exercise, but they were more likely to use assertive communication techniques.

Attendance
- Greater attendance was associated with more formal education, higher income, being married, and having a larger social network.
- Neuroticism was negatively associated with attendance.

Correlations between intervention evaluations, use of techniques, and attendance
- Satisfaction, feelings of group cohesion, and important group experiences were positively associated.
- Use of social support techniques was positively associated with satisfaction, feeling accepted/belonging in group, and getting information/advice.
- Use of strategies for managing stress was positively associated with use of all other intervention techniques.
- Use of relaxation, eating less fat, increasing fiber, and exercise were significantly correlated.
- Use of techniques for assertive communication, increasing social support, and problem solving were associated.
- Greater feelings of group cohesion and more use of assertive communication were positively associated with intervention attendance.

continued
Table 9 (continued)

Utilization of intervention techniques and intervention outcomes

Emotional distress:

- For POMS TMD, there was a significant relaxation use x time interaction. Women with higher use of progressive muscle relaxation showed a significant decrease in POMS TMD.

- For POMS Anxiety, there was a significant relaxation use x time interaction. Women with higher use of progressive muscle relaxation showed a significant decrease in POMS Anxiety.

Social adjustment:

- For PSS Family, there was a significant assertive communication x time interaction. Participants with higher use of assertive communication techniques showed a significant increase in PSS Family.

- For PSS Family, there was a trend for a social support technique x time interaction. Participants with higher use of techniques for increasing social support showed a significant increase in PSS Family.

Dietary patterns:

- For FHQ total scores, there was a significant communicating with medical providers x time interaction. Higher use of techniques for communicating with medical providers was associated with improved dietary patterns.

- For the FHQ total score, there was a trend for a techniques for an eating less fat x time interaction. Women with higher use of these techniques showed a significant increase in the FHQ total score.

Physical functioning:

- For SWOG, there was a significant exercise technique x time interaction. Intervention participants with lower exercise use reported an increase in SWOG scores that was greater than women who reported higher utilization of exercise techniques.

Compliance:

- Analysis revealed a trend for greater compliance with the recommended Doxorubicin (Adriamycin) regimen among women who frequently used intervention techniques for communicating with medical providers.

- Women with high use of exercise techniques were more likely to receive their recommended Paclitaxel (Taxol) regimen.
Figure 1. The biobehavioral model of stress and disease course.

Note. CNS = central nervous system

Figure 2. Experimental design and study flow diagram
Figure 3. Intervention participants with higher cancer-related distress demonstrate the greatest decrease in POMS Total Mood Disturbance

POMS Total Mood Disturbance: group x time x cancer-related distress $F = 3.75, p = .02$, $\eta^2 = .02$
Figure 4. Intervention participants with lower levels of formal education demonstrate greater decreases in POMS Anxiety compared to assessment-only participants with lower levels of education.

POMS Anxiety: group x time x education $F = 3.07, p = .05, \eta^2 = .02$

Note: The scale for POMS Anxiety was truncated to more clearly display the group x time x education interaction.
Figure 5. Intervention participants treated with mastectomy demonstrate the greatest increase in perceptions of family support.

PSS Family: group x time x type of surgery $F = 3.20, p = .04, \eta^2 = .02$

Note: The scale for PSS Family was truncated to more clearly display the group x time x type of surgery interaction.
Figure 6. Intervention participants with lower levels of formal education demonstrate greater increases in KPS compared to intervention participants with lower levels of education.

KPS: group x time x education $F = 3.81, p = .02, \eta^2 = .02$

Note: The scale for KPS was truncated to more clearly display the group x time x education interaction.
Greater utilization of relaxation techniques is associated with decreases in POMS Total Mood Disturbance.

POMS Total Mood Disturbance: utilization of relaxation x time $F = 3.29, p = .04, \eta^2 = .04$
Figure 8. Greater utilization of relaxation techniques is associated with greater decreases in POMS Anxiety.

POMS Anxiety: utilization of relaxation x time $F = 3.66, p = .03, \eta^2 = .04$
Figure 9. Greater utilization of assertive communication techniques is associated with increases in perceptions of family support.

PSS Family: utilization of assertive communication techniques x time $F = 3.53, p = .03, \eta^2 = .05$

Note: The scale for PSS Family was truncated to more clearly display the assertive communication techniques x time interaction.
Figure 10. Greater utilization of social support techniques is associated with increases in perceptions of family support.

PSS Family: utilization of social support techniques x time $F = 2.60, p = .08, \eta^2 = .04$

Note: The scale for PSS Family was truncated to more clearly display the social support techniques x time interaction.
Figure 11. Greater utilization of techniques for communicating with medical providers is associated with improved dietary habits.

Food Habits Questionnaire: utilization of techniques for communicating with medical providers x time  \( F = 3.16, \ p = .05, \ \eta^2 = .04 \)

Note: The scale for the Food Habits Questionnaire was truncated to more clearly display the communicating with medical providers x time interaction.
Figure 12. Greater utilization of techniques for reducing fat intake is associated with improved dietary habits.

Food Habits Questionnaire: utilization of reducing fat intake techniques x time $F = 2.72$, $p = .07$, $\eta^2 = .03$

Note: The scale for the Food Habits Questionnaire was truncated to more clearly display the reducing fat intake techniques x time interaction.
Figure 13. Greater utilization of exercise techniques is associated with fewer treatment side effects.

SWOG: utilization of exercise techniques x time $F = 3.71, p = .03, \eta^2 = .04$

Note: The scale for SWOG was truncated to more clearly display the utilization of exercise techniques x time interaction.
APPENDIX B

TABLES OF INTERVENTION STUDIES WITH CANCER PATIENTS
Table 10. Intervention studies with cancer patients targeting emotional distress (N=72)

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Intervention Approach</th>
<th>Anxious symptoms</th>
<th>Depressive symptoms</th>
<th>Mood or emotional distress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allen et al., 2001</td>
<td>149 early stage breast cancer patients</td>
<td>SC</td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Antoni et al., 2001</td>
<td>100 early stage breast cancer patients</td>
<td>CBT</td>
<td>+</td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Arakawa et al., 1997</td>
<td>60 hospitalized cancer patients (various sites)</td>
<td>B</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bailey et al., 2001</td>
<td>90 cancer patients (various sites)</td>
<td>B</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Berglund et al., 1994</td>
<td>199 cancer patients (various sites)</td>
<td>SC</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Bindeman et al., 1991</td>
<td>80 cancer patients (various sites)</td>
<td>B</td>
<td>+</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Bordeleau et al., 2003</td>
<td>215 metastatic breast cancer patients</td>
<td>SE</td>
<td></td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Brandberg et al., 1994</td>
<td>149 Stage I malignant melanoma patients</td>
<td>ED</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Burns et al., 2001</td>
<td>8 breast and ovarian cancer patients</td>
<td>B</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Burton et al., 1995</td>
<td>200 breast cancer patients</td>
<td>SC</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Cain et al., 1986</td>
<td>80 gynecologic cancer patients</td>
<td>SC</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Capone et al., 1980</td>
<td>97 gynecologic cancer patients</td>
<td>SC</td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Chan et al., 2005</td>
<td>155 gynecologic cancer patients</td>
<td>SC</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clacey et al., 1985</td>
<td>50 breast cancer patients with mastectomies</td>
<td>SC</td>
<td>N</td>
<td>+</td>
<td>N</td>
</tr>
<tr>
<td>Classen et al., 2001</td>
<td>102 metastatic breast cancer patients</td>
<td>SE</td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Cruess et al., 2000</td>
<td>34 early stage breast cancer patients</td>
<td>CBT</td>
<td></td>
<td></td>
<td>N</td>
</tr>
</tbody>
</table>

continued
Table 10 (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Intervention Approach</th>
<th>Anxious symptoms</th>
<th>Depressive symptoms</th>
<th>Mood or emotional distress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cunningham and Tocco, 1989</td>
<td>53 cancer patients (various sites)</td>
<td>ED</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Dodd, 1987</td>
<td>60 patients receiving radiation (various sites)</td>
<td>ED</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dodd, 1988</td>
<td>60 patients receiving chemotherapy (various sites)</td>
<td>ED</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edelman et al., 1999a</td>
<td>124 metastatic breast cancer patients</td>
<td>CBT</td>
<td></td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Edelman et al., 1999b</td>
<td>47 breast cancer patients</td>
<td>CBT</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Edgar et al., 1992</td>
<td>205 cancer patients (various sites)</td>
<td>CBT</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Edgar et al., 2001</td>
<td>225 breast and colorectal cancer patients</td>
<td>SC</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Edmonds et al., 1999</td>
<td>66 metastatic breast cancer patients</td>
<td>CBT</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Elsesser et al., 1994</td>
<td>20 cancer patients (various sites)</td>
<td>CBT</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Evans &amp; Connis, 1995</td>
<td>72 cancer patients with depressive symptoms</td>
<td>CBT</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Fawzy et al., 1990</td>
<td>66 malignant melanoma patients</td>
<td>CBT</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Fawzy, 1995</td>
<td>61 malignant melanoma patients</td>
<td>CBT</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Fertle et al., 1979</td>
<td>60 advanced cancer patients (various sites)</td>
<td>SC</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Fukui et al., 2000</td>
<td>50 breast cancer patients</td>
<td>CBT</td>
<td>N</td>
<td>N</td>
<td>+</td>
</tr>
<tr>
<td>Giesler et al., 2005</td>
<td>99 prostate cancer patients</td>
<td>SC</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Given et al., 2004a</td>
<td>237 cancer patients (various sites)</td>
<td>CBT</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Goodwin et al., 2001</td>
<td>235 metastatic breast cancer patients</td>
<td>SE</td>
<td></td>
<td>+</td>
<td></td>
</tr>
</tbody>
</table>

continued
<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Intervention Approach</th>
<th>Anxious symptoms</th>
<th>Depressive symptoms</th>
<th>Mood or emotional distress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greer et al., 1992</td>
<td>156 cancer patients (various sites)</td>
<td>CBT</td>
<td>+</td>
<td>N</td>
<td>+</td>
</tr>
<tr>
<td>Heinrich &amp; Schag, 1985</td>
<td>51 cancer patients (various sites)</td>
<td>CBT</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Helgeson et al., 1999</td>
<td>312 Stage I to III breast cancer patients</td>
<td>ED</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Hellbom et al., 1998</td>
<td>527 cancer patients (various sites)</td>
<td>SC</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Jacobsen et al., 2002</td>
<td>411 cancer patients beginning chemotherapy</td>
<td>CBT</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Johnson et al., 1998</td>
<td>84 prostate cancer patients receiving radiation</td>
<td>ED</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Kissane et al., 2003</td>
<td>303 breast cancer patients</td>
<td>CBT</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kolcaba &amp; Fox, 1999</td>
<td>53 breast cancer patients beginning radiation</td>
<td>B</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Larson et al., 2000</td>
<td>41 breast cancer patients</td>
<td>SC</td>
<td>N</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Larsson &amp; Starrin, 1992</td>
<td>64 breast cancer patients</td>
<td>B</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Lepore et al., 2003</td>
<td>250 prostate cancer patients</td>
<td>ED</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Lerman et al., 1990</td>
<td>48 cancer patients (various sites)</td>
<td>B</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Linn et al., 1982</td>
<td>114 men with end stage cancer (various sites)</td>
<td>SC</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Lyles et al., 1982</td>
<td>50 cancer patients (various cancer sites)</td>
<td>B</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maguire et al., 1980</td>
<td>152 breast cancer patients</td>
<td>SC</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Manne et al., 2005</td>
<td>258 breast cancer patients and their partners</td>
<td>CBT</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Marchioro et al., 1996</td>
<td>36 non-metastatic breast cancer patients</td>
<td>CBT</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Mc Ardle et al., 1996</td>
<td>272 breast cancer patients</td>
<td>SC</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
</tbody>
</table>

166
Table 10 (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Intervention Approach</th>
<th>Anxious symptoms</th>
<th>Depressive symptoms</th>
<th>Mood or emotional distress</th>
</tr>
</thead>
<tbody>
<tr>
<td>McGregor et al., 2004</td>
<td>29 early stage breast cancer patients</td>
<td>CBT</td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>McQuellon et al., 1998</td>
<td>150 cancer patients (various sites)</td>
<td>ED</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Mishel et al., 2005</td>
<td>509 breast cancer patients</td>
<td>CBT</td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Moorey et al., 1998</td>
<td>57 cancer patients with adjustment reactions</td>
<td>CBT</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Nezu et al., 2003</td>
<td>132 cancer patients (various sites)</td>
<td>SC</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Pruitt et al., 1993</td>
<td>31 distressed cancer patients</td>
<td>ED</td>
<td>+</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Richardson et al., 1997</td>
<td>47 breast cancer patients</td>
<td>SC</td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Rutter et al., 1996</td>
<td>36 cancer patients (various sites)</td>
<td>Other&lt;sup&gt;a&lt;/sup&gt;</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Samarel et al., 1997</td>
<td>181 breast cancer patients</td>
<td>SC</td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Sandgren et al., 2000</td>
<td>53 breast cancer patients</td>
<td>CBT</td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Sandgren &amp; McCaul, 2003</td>
<td>222 breast cancer patients</td>
<td>ED</td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Savard et al., 2005</td>
<td>57 breast cancer patients with insomnia</td>
<td>CBT</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Scott et al., 2004</td>
<td>94 early stage breast cancer patients</td>
<td>CBT</td>
<td></td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Simpson et al., 2001</td>
<td>89 breast cancer patients</td>
<td>SC</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Spiegel et al., 1981</td>
<td>58 metastatic breast cancer patients</td>
<td>SE</td>
<td></td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Stanton et al., 2002</td>
<td>60 breast cancer patients</td>
<td>Other&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Taylor et al., 2003</td>
<td>73 African-American breast cancer patients</td>
<td>CBT</td>
<td></td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Trask et al., 2003</td>
<td>26 bone marrow transplant patients</td>
<td>ED</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Walker et al., 1999</td>
<td>96 advanced breast cancer patients</td>
<td>B</td>
<td>N</td>
<td>N</td>
<td>+</td>
</tr>
</tbody>
</table>

continued
Table 10 (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Intervention Approach</th>
<th>Anxious symptoms</th>
<th>Depressive symptoms</th>
<th>Mood or emotional distress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weber et al., 2004</td>
<td>30 prostate cancer patients</td>
<td>SC</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Yates et al., 2005</td>
<td>109 breast cancer patients</td>
<td>ED</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
</tbody>
</table>

Note: For intervention outcomes, + = improvements for intervention patients and N=no significant difference between study arms. For intervention approach, CBT=cognitive-behavioral therapy, B=behavioral therapy, ED=psycho-educational intervention, SE=supportive-expressive therapy, and SC=supportive counseling.

a. Rutter et al. (1996) conducted a communication training intervention with doctors.

b. Stanton et al. (2002) conducted a writing/journaling intervention.
<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Intervention approach</th>
<th>Traumatic stress symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allen et al., 2001</td>
<td>149 early stage breast cancer patients</td>
<td>SC</td>
<td>N</td>
</tr>
<tr>
<td>Antoni et al., 2001</td>
<td>100 early stage breast cancer patients</td>
<td>CBT</td>
<td>N</td>
</tr>
<tr>
<td>Baider et al., 2001</td>
<td>90 cancer patients (various sites)</td>
<td>B</td>
<td>N</td>
</tr>
<tr>
<td>Chan et al., 2005</td>
<td>155 gynecologic cancer patients</td>
<td>SC</td>
<td>N</td>
</tr>
<tr>
<td>Classen et al., 2001</td>
<td>102 metastatic breast cancer patients</td>
<td>SE</td>
<td>+</td>
</tr>
<tr>
<td>Edgar et al., 1992</td>
<td>205 cancer patients (various sites)</td>
<td>CBT</td>
<td>N</td>
</tr>
<tr>
<td>Helgeson et al., 1999</td>
<td>312 Stage I to III breast cancer patients</td>
<td>ED</td>
<td>+</td>
</tr>
<tr>
<td>Larson et al., 2000</td>
<td>41 breast cancer patients</td>
<td>SC</td>
<td>N</td>
</tr>
<tr>
<td>Levine et al., 2005</td>
<td>181 breast cancer patients</td>
<td>Other(^b)</td>
<td>+</td>
</tr>
<tr>
<td>Manne et al., 2005</td>
<td>258 breast cancer patients and their partners</td>
<td>CBT</td>
<td>N</td>
</tr>
<tr>
<td>Stanton et al., 2005</td>
<td>558 breast cancer patients</td>
<td>ED</td>
<td>N</td>
</tr>
<tr>
<td>Taylor et al., 2003</td>
<td>73 African-American breast cancer patients</td>
<td>CBT</td>
<td>N(^a)</td>
</tr>
<tr>
<td>Wengstrom et al., 1999</td>
<td>134 breast cancer patients receiving radiation</td>
<td>ED</td>
<td>+</td>
</tr>
</tbody>
</table>

**Table 11. Intervention studies with cancer patients targeting cancer-specific traumatic stress (N=13)**

Note: For intervention outcomes, + = improvements for intervention patients and N=no significant difference between study arms. For intervention approach, CBT=cognitive-behavioral therapy, B=behavioral therapy, ED=psycho-educational intervention, SE=supportive-expressive therapy, and SC=supportive counseling.

a. Taylor et al. (2003) reported that the intervention did not have a main effect for the IES, but the intervention reduced traumatic stress among women with high initial psychosocial distress.

b. Levine et al. (2005) conducted a supportive counseling intervention combined with imagery, yoga, and relaxation techniques.
<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Intervention approach</th>
<th>Global QOL</th>
<th>Mental QOL</th>
<th>Physical QOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allen et al., 2001</td>
<td>149 early stage breast cancer patients</td>
<td>SC</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bordeleau et al., 2003</td>
<td>215 metastatic breast cancer patients</td>
<td>SE</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burns et al., 2001</td>
<td>8 breast and ovarian cancer patients</td>
<td>B</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chan et al., 2005</td>
<td>155 gynecologic cancer patients</td>
<td>SC</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DeWit et al., 1997</td>
<td>313 chronic pain patients</td>
<td>SC</td>
<td>N</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Edelman et al., 1999b</td>
<td>47 breast cancer patients</td>
<td>CBT</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edgar et al., 2001</td>
<td>225 breast and colon cancer patients</td>
<td>SC</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edmonds et al., 1999</td>
<td>66 metastatic breast cancer patients</td>
<td>CBT</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elsesser et al., 1994</td>
<td>20 cancer patients (various sites)</td>
<td>CBT</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Giesler et al., 2005</td>
<td>99 prostate cancer patients</td>
<td>SC</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Given et al., 2004a</td>
<td>237 cancer patients (various sites)</td>
<td>CBT</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Given et al., 2004b</td>
<td>165 cancer patients (various sites)</td>
<td>CBT</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heinrich &amp; Schag, 1985</td>
<td>51 cancer patients (various sites)</td>
<td>CBT</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Helgeson et al., 1999</td>
<td>312 Stage I to III breast cancer patients</td>
<td>ED</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Jacobsen et al., 2002</td>
<td>411 cancer patients beginning chemotherapy</td>
<td>CBT</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
</tbody>
</table>

Table 12. Intervention studies with cancer patients targeting quality of life (N=29)

170
<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Intervention approach</th>
<th>Global QOL</th>
<th>Mental QOL</th>
<th>Physical QOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lepore et al., 2003</td>
<td>250 prostate cancer patients</td>
<td>ED</td>
<td>N</td>
<td>N</td>
<td>N&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Lev et al., 2001</td>
<td>18 early stage breast cancer patients</td>
<td>SC</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marchioro et al., 1996</td>
<td>36 breast cancer patients</td>
<td>CBT</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Nezu et al., 2003</td>
<td>132 cancer patients (various sites)</td>
<td>SC</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Penedo et al., 2004</td>
<td>92 prostate cancer patients</td>
<td>CBT</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Richardson et al., 1997</td>
<td>47 breast cancer patients</td>
<td>SC</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sandgren &amp; McCaul, 2003</td>
<td>222 breast cancer patients</td>
<td>ED</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sandgren et al., 2000</td>
<td>53 breast cancer patients</td>
<td>CBT</td>
<td>+</td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Savard et al., 2005</td>
<td>57 breast cancer patients with insomnia</td>
<td>CBT</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simpson et al., 2001</td>
<td>89 breast cancer patients</td>
<td>SC</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stanton et al., 2002</td>
<td>60 breast cancer patients</td>
<td>Other&lt;sup&gt;a&lt;/sup&gt;</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trask et al., 2003</td>
<td>26 bone marrow transplant patients</td>
<td>ED</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walker et al., 1999</td>
<td>96 breast cancer patients</td>
<td>B</td>
<td>+</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Other interventions not specified.

<sup>b</sup> Data not available.

continued
Table 12 (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Intervention approach</th>
<th>Global QOL</th>
<th>Mental QOL</th>
<th>Physical QOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wengstrom et al., 1999</td>
<td>134 breast cancer receiving radiation</td>
<td>ED</td>
<td>N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: For intervention outcomes, + = improvements for intervention patients and N = no significant difference between study arms. For intervention approach, CBT = cognitive-behavioral therapy, B = behavioral therapy, ED = psycho-educational intervention, SE = supportive-expressive therapy, and SC = supportive counseling.


b. Lepore et al., (2003) reported that the intervention had no main effect for physical QOL, but analysis revealed an interaction between group and education level. For men with no college degree, intervention patients had improved physical QOL compared to control patients.
<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Intervention approach</th>
<th>Social support</th>
<th>Social activities</th>
<th>Relationship satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cain et al., 1986</td>
<td>80 gynecologic cancer patients</td>
<td>SC</td>
<td></td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Edelman et al., 1999b</td>
<td>47 breast cancer patients</td>
<td>CBT</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edmonds et al., 1999</td>
<td>66 metastatic breast cancer patients</td>
<td>CBT</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evans &amp; Connis, 1992</td>
<td>72 cancer patients (various sites)</td>
<td>CBT</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ferlic et al., 1979</td>
<td>60 advanced cancer patients (various sites)</td>
<td>SC</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maguire et al., 1983</td>
<td>152 breast cancer patients</td>
<td>SC</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maunsell et al., 1996</td>
<td>250 non-metastatic breast cancer patients</td>
<td>SC</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Mishel et al., 2005</td>
<td>509 breast cancer patients</td>
<td>CBT</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Richardson et al., 1997</td>
<td>47 breast cancer patients</td>
<td>SC</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Samarel et al., 1997</td>
<td>181 early stage breast cancer patients</td>
<td>SC</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Scott et al., 2005</td>
<td>94 early stage breast cancer patients</td>
<td>CBT</td>
<td></td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Weber et al., 2004</td>
<td>30 prostate cancer patients</td>
<td>SC</td>
<td>N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 13. Intervention studies with cancer patients targeting social adjustment (N=12)

Note: For intervention outcomes, + = improvements for intervention patients and N=no significant difference between study arms. For intervention approach, CBT=cognitive-behavioral therapy and SC=supportive counseling.
Cheblowski et al., 1993  
209 breast cancer patients  
Individualized dietary intervention with a nutritionist  
+  
+

Kristal et al., 1997  
144 overweight breast cancer patients  
Individual and group dietary intervention with a health professional  
+  
+

Nordevang et al., 1992  
169 early stage breast cancer patients  
Individualized dietary intervention with a nutritionist  
+  
N

Pierce et al., 1997  
93 Stage I to III breast cancer patients  
Dietary intervention delivered via telephone  
+  
N

**Table 14. Intervention studies with cancer patients targeting diet or nutrition (N=4).**

Note: For intervention outcomes, + = improvements for intervention patients and N=no significant difference between study arms.
<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Setting</th>
<th>Approach</th>
<th>Physical functioning</th>
<th>Treatment side effects/symptoms</th>
<th>Mood or quality of life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cunningham et al., 1986</td>
<td>30 bone marrow transplant patients</td>
<td>Inpatient</td>
<td>Resistive exercises</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dimeo et al., 1997</td>
<td>72 bone marrow transplant patients</td>
<td>Inpatient</td>
<td>In-hospital-bed biking</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Dimeo et al., 1999</td>
<td>63 bone marrow transplant patients</td>
<td>Inpatient</td>
<td>In-hospital-bed biking</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>MacVicar et al., 1989</td>
<td>45 Stage II breast cancer patients</td>
<td>Outpatient</td>
<td>Stationary biking</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Mock et al., 1997</td>
<td>50 Stage I or II breast cancer patients</td>
<td>Outpatient</td>
<td>Walking</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Segal et al., 2001</td>
<td>123 Stage II or III breast cancer patients</td>
<td>Outpatient</td>
<td>Walking and stretching</td>
<td>+</td>
<td>N</td>
<td></td>
</tr>
</tbody>
</table>

**Table 15. Intervention studies with cancer patients targeting exercise (N=6).**

Note: For intervention outcomes, + = improvements for intervention patients and N=no significant difference between study arms.
<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Approach</th>
<th>Smoking status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Griebel et al., 1998</td>
<td>28 cancer patients (various sites)</td>
<td>One individual smoking cessation session (20 minutes) with a nurse and 5 weekly telephone sessions</td>
<td>N</td>
</tr>
<tr>
<td>Gritz et al., 1993</td>
<td>186 head and neck cancer patients</td>
<td>Discussion of readiness to quit, 3 informational booklets, and physician’s expressions of confidence in the patient’s ability to quit</td>
<td>N</td>
</tr>
<tr>
<td>Stanislaw &amp; Wewers, 1994</td>
<td>26 cancer patients (various sites)</td>
<td>Individual smoking cessation intervention with a nurse including 3 20-minute in-person sessions and 5 weekly telephone sessions</td>
<td>+</td>
</tr>
<tr>
<td>Wewers et al., 1994</td>
<td>30 cancer patients (various sites)</td>
<td>Individual smoking cessation intervention with a nurse including 3 20-minute in-person sessions and 5 weekly telephone sessions</td>
<td>+&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Table 16. Intervention studies with cancer patients targeting smoking (N=4).

Note: For intervention outcomes, + = improvements for intervention patients and N=no significant difference between study arms.

a. In this study (Wewers et al., 1994), cancer patients represented a subset of participants from an intervention for post-operative patients with various diseases: cardiovascular (n=22), oncology (n=30), and general surgery (n=28).

b. Wewers et al. (1994) reported no differences in smoking status between study arms when collapsing across diseases. For cancer and cardiovascular patients, the intervention group had higher abstinence rates compared to the control group.
### Table 17. Intervention studies with cancer patients targeting biologic outcomes (N=9).

Note: For intervention outcomes, + = improvements for intervention patients and N=no significant difference between study arms. For intervention approach, CBT=cognitive-behavioral therapy, B=behavioral therapy, and SC=supportive counseling.

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Intervention approach</th>
<th>Cell counts&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Cell activity&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Cortisol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cruess et al., 2000</td>
<td>34 Stage I or II breast cancer patients</td>
<td>CBT</td>
<td>+&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elsesser et al., 1994</td>
<td>20 cancer patients (various sites)</td>
<td>CBT</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fawzy et al., 1990</td>
<td>66 Stage I or II malignant melanoma patients</td>
<td>CBT</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Gruber et al., 1993</td>
<td>13 Stage I breast cancer patients</td>
<td>B</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Larson et al., 2000</td>
<td>41 Stage I to IV breast cancer patients</td>
<td>SC</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>McGregor et al., 2004</td>
<td>29 early stage breast cancer patients</td>
<td>CBT</td>
<td>N</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Richardson et al., 1997</td>
<td>47 Stage I to III breast cancer patients</td>
<td>SC</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Van der Pompe et al., 1997</td>
<td>23 Stage II, III or recurrent breast cancer patients</td>
<td>SC</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Walker et al., 1999</td>
<td>96 breast cancer patients</td>
<td>B</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
</tbody>
</table>

#### a. Cell counts include measures of T4 cells, T8 cells, B-cells, and T4 cells/T8 cells ratio.

#### b. Cell activity includes measures of NK lysis and blastogenesis.

#### c. Cruess and colleagues (2001) published data with the same sample of women and reported that intervention patients experienced decreased free testosterone and total testosterone compared to control participants.
<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Approach</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cunningham et al., 1998</td>
<td>66 metastatic breast cancer patients</td>
<td>SE</td>
<td>N</td>
</tr>
<tr>
<td>Edelman et al., 1999c</td>
<td>121 metastatic breast cancer patients</td>
<td>CBT</td>
<td>N</td>
</tr>
<tr>
<td>Fawzy et al., 1993</td>
<td>66 malignant melanoma patients</td>
<td>CBT</td>
<td>+</td>
</tr>
<tr>
<td>Goodwin et al., 2001</td>
<td>235 metastatic breast cancer patients</td>
<td>SE</td>
<td>N</td>
</tr>
<tr>
<td>Ilnyckyj et al., 1994</td>
<td>127 cancer patients (various sites)</td>
<td>SC</td>
<td>N</td>
</tr>
<tr>
<td>Kissane et al., 2004</td>
<td>303 breast cancer patients</td>
<td>CBT</td>
<td>N</td>
</tr>
<tr>
<td>Kuchler et al., 1999</td>
<td>271 gastrointestinal cancer patients (various sites)</td>
<td>SC</td>
<td>+</td>
</tr>
<tr>
<td>Linn et al., 1982</td>
<td>120 advanced cancer patients (men with various sites)</td>
<td>SC</td>
<td>N</td>
</tr>
<tr>
<td>Richardson et al., 1990</td>
<td>92 hematologic cancer patients</td>
<td>SC</td>
<td>+</td>
</tr>
<tr>
<td>Spiegel et al., 1989</td>
<td>86 metastatic breast cancer patients</td>
<td>SE</td>
<td>+</td>
</tr>
</tbody>
</table>

**Table 18. Intervention studies with cancer patients examining length of survival (N=10).**

Note: For intervention outcomes, + = improvements for intervention patients and N=no significant difference between study arms. For intervention approach, CBT=cognitive-behavioral therapy, B=behavioral therapy, SE=supportive-expressive therapy, and SC=supportive counseling.
REFERENCES


APPENDIX C

SIBCP INTERVENTION DESCRIPTION
DESCRIPTION OF THE SIBCP INTERVENTION

Conceptualization and content of intervention

The biobehavioral model has been used for targeting the areas of change. Specifically, the intervention is designed to reduce stress, enhance quality of life (i.e. emotional adjustment, social adjustment and support and breast specific concerns--body image and sexuality), increase positive health behaviors, decrease negative health behaviors, and improve compliance. Each construct in the model has been operationalized to correspond to intervention components and assessment measures. Selection of specific therapeutic techniques and content was guided by the literature on psychosocial intervention research with cancer patients (see Andersen, 1992), intervention studies with immunity outcomes (see Kiecolt-Glaser & Glaser, 1992 for a review), and our experience in running pilot groups.

We hypothesize that it will be especially important that the psychological intervention produce long term behavioral and psychological changes if immune responses and/or disease endpoints are to be effected. Therefore, we include a maintenance intervention, and the Transtheoretical Model of Behavior Change (Prochaska & DiClemente, 1984, 1986) is used as the guiding theoretical framework for it. Despite its relevance to long term behavioral change, this model has not been used in
the cancer rehabilitation area, but it has been widely used in cancer prevention and screening studies (e.g. smoking cessation, high-fat diets, fruit and vegetable consumption, exercise acquisition, mammography screening; Prochaska et al., 1994). Longitudinal studies of change have found that people pass through five stages of change---precontemplation (no intention to change), contemplation (seriously considering change), preparation (taking steps to change), action (actively involved in meaningful change), and maintenance (maintaining meaningful change)---and further, data suggest that there is a pattern of change in the decisional balance as individuals move through the stages (Prochaska et al., 1994). The model integrates constructs from alternative theories, such as self-efficacy (Bandura, 1982) and Janis and Mann's (1977) decisional balance model. This model has direct implications for the design of interventions, i.e. interventions for behavior change should be matched to the individual's stage of change. In fact, stage matched materials have been more effective than traditional interventions for important health behaviors, e.g. helping people quit smoking (Prochaska, DiClemente, Velicer, & Rossi, 1993) and reducing fat intake (Greene, Rossi, Reed, Willey, & Prochaska, in press). In short, we have adopted this clinically useful and conceptually strong model in the design of the maintenance component of the intervention.

**Intensive phase**

*Part 1.* Stress reduction and enhancing QoL (emotional adjustment) (Sessions 1, 10-12, 17). There are four components. (a) A simplified version of Gatchel, Baum, and Krantz's (1989) model of stress as a psychophysiological process will be offered as a way to conceptualize the cancer stressor. Adaptive coping strategies (e.g. seeking information, positive appraisal) will be introduced as skills that can be learned and
applied generically. (b) Progressive muscle relaxation (PMR) training (ala Bernstein and Borkovec, 1973 and as modified as a skills training effort with group instruction, Carlson & Bernstein, in press) will be used as a method for lowering overall body tension. Women will be provided with cassette tapes for home use. Instruction will begin with 16 muscle group and move through the steps to relaxation by recall. (c) Cognitive restructuring (Hawton & Kirk, 1989) will be used to identify current manifestations of the cancer stressor (e.g. low mood, low energy/fatigue, disrupted relationship with spouse). The A (Activity/Event)--B (Beliefs/Automatic thoughts)--C (Consequences/Feelings and Behaviors) model will be offered with examples. (d) Problem solving will follow the principles of Goldfried and Davison (1976) and Hawton and Kirk (1989). It will consist of five stages: overview of the principles; how to define and formulate target problems, generation of problem solutions; decision making; and, verification of solutions. To learn the principles, women will have "hands" on experience by working on solutions for two target problems: fatigue and time management. This section will conclude with women targeting 1-2 other areas for problem solving to enhance generalization.

Part 2. Compliance (Sessions 2-3, Portions of Session 10). Of the very few studies focused on compliance, the data suggest information about the disease and treatment (Richardson et al., 1987; Robinson, 1990), and enlistment of help of significant others, i.e. social support (Richardson et al., 1987). There will be three components. (a) Disease and treatment information will be offered to reduce uncertainty and aid in medical decision making and compliance. Existing educational materials (e.g. the NCI's Breast Cancer Digest and American Cancer Society materials) will be used. (b) The use of relaxation and distraction in coping with treatments (e.g. chemotherapy side effects)
and anxiety vis-a-vis follow up medical examinations will be discussed. (c) Assertive communication exercises will be conducted to enhance communication with physicians and other health care professionals (see below under Part 3).

**Part 3.** Improving QoL (social adjustment) (Sessions 4-7). There are three components. (a) The supportive context of the group intervention will be used to direct social comparisons among the group members; as women learn that many of their reactions to the cancer "crisis" are normal and shared by others, problem solving strategies and ways of adaptive coping will be fostered (e.g. Taylor's conceptualization of adjustment to threatening events; Taylor, Lichtman, & Wood, 1984). (b) Women's social network will be identified using a concentric circle model (with the patient at the center). We will systematically cover five levels of social relationships (e.g. coworkers and friends; physicians; parents/in laws and siblings; children of all ages; and spouse/spouse equivalent) and identify sources of satisfaction and clarify areas of difficulty (Cohen & Wills, 1985). (c) Assertive communication skills, modeled after the work of Jakubowski and Lange (1978) will be taught to assist women in expressing their thoughts, feelings, and needs in a manner which facilitates support from and communication with members of their social networks. Four techniques are used: specificity and clarity of one's message; direct communication; "owning" one's message (use of "I," "my" etc. in statements); and, asking for feedback. These skills will be practiced across the five levels of social relationships identified in (b) above.

**Part 4.** Improving QoL (breast specific component) (Sessions 8-9). Specific breast cancer sequelae of body changes, menopausal changes, hormonal changes with Tomoxifen therapy, hair loss, and impact on sexual self schema (esteem) will be
discussed as well as coping with body sexual changes as discussed in Andersen and Elliot (1993). This session will be prefaced by a session focused on social support from the partner.

**Part 5. Health behaviors, (Sessions 14-16).** There are three components: diet, exercise, and negative health behaviors. (a) Information on a low fat eating plan will be offered to achieve dietary change (dietary fat < 25% of energy intake and dietary fiber of 20-30 grams/day from fruits, vegetables, and grains; these are NCI fat and fiber guideline levels). The intervention will provide participants with the skills and knowledge to gradually lower their fat and increase their fiber intake, and was adapted from the procedures from the WINS study. The guidelines emphasize the influence of discriminative stimuli for eating, the substitution of low-fat food items for high fat foods, and the setting of step-wise goals for lowering fat intake. The guiding conceptualization will be that of health behavior change rather than dieting. We will begin and end the dietary intervention with individualized, stage matched reports for dietary change (i.e. fat reduction and specific fiber recommendations based on current eating pattern). Such reports are generated by incorporating the data from the stages of change (Prochaska et al., 1994), Decisional Balance (Janis & Mann, 1977), and the Food Frequency Questionnaire (Kristal, SeLett, Henry, & Fowler, 1990; see below). Consultant Geoffrey Greene has developed these procedures and will provide the computer software for generating the reports. Finally, we note that if the dietary data indicate deficiencies in RDA nutrients based on 2/3 of the 1989 RDAs (Food and Nutrition Board, 1989), women in either group (intervention or control) will be provided with appropriate educational materials to increase intake of the deficient nutrient(s). Study subjects will be monitored
by project dietary research assistant supervised by co PI Bossetti. We will monitor women with significant weight loss, a low albumin, or other indicators of compromised nutritional status to ensure that there is appropriate medical and dietary coverage, and to ensure that the dietary intervention is complimentary to any other needed dietary care.

(b) According to the American College of Sports Medicine’s (1991) Guidelines for Exercise Testing and Prescription, “exercise therapy is becoming an accepted aspect of rehabilitation in patients with cancer. Regular exercise counteracts the detrimental effects of bed rest and provides psychological benefits” (pg. 178). Available data suggest that resuming or maintaining regular exercise would provide positive health benefits, as recent controlled trials suggest that even moderate levels of aerobic exercise performed 3-5 times per week for 20-30 minute intervals improve aerobic fitness in middle aged women (King, Haskell, Taylor, Kraemer, & DeBusk, 1991). In the only study that assessed the effect of aerobic activity in breast cancer patients, MacVicar et al (1989) reported that exercising on a stationary bicycle three times per week was associated with a 40% increase in aerobic efficiency and fewer reports of nausea than in non-exercise controls. The exercise intervention is modeled on the home walking protocol of King (1991) et al. which was found effective for older women. An exercise program of this magnitude (producing 50-60% of maximum heart rate) is sufficient to produce positive psychological benefits (King, Taylor, & Haskell, 1993), and low-intensity exercise appears to be beneficial for the immune system in terms of increasing the numbers of natural killer cells and the number of circulating lymphocytes (Newsholme & Parry-Billings, 1994). Didactic information will include how to set realistic goals, schedules for rest, techniques for increasing energy expenditure during
activities of daily living, and coping strategies for setbacks. Women who are unable to perform the walking protocol due to treatment complications will be provided with alternative activity/rest goals. Co-PI Emery will provide guidance on the specific procedures for implementing and monitoring the exercise program. Prior to participation in the exercise component, subjects will complete the Physical Activity Readiness Questionnaire (British Columbia Department of Health, 1975). This instrument was developed as a screening instrument and tested with over 1 million Canadians for the Canadian Home Fitness Test. It is 100% sensitive for the detection of medical contraindications and approximately 80% specific. In addition, co-PI Farrar will provide medical clearance for all subject’s, and will provide medical consultation during the course of the study for any concerns regarding exercise participation of subjects.

(c) Information on controlling negative health behaviors (i.e. alcohol consumption and smoking) will be provided along with specific referral to community/self help group resources. Disturbed sleep patterns will be addressed with recommendations regarding activity programming, relaxation training, and sleep pattern monitoring.

Maintenance

Part 1. Preparation for maintenance (Session 18, Intensive). To implement the maintenance plan, immediately prior to the final session of the intensive intervention, each woman will complete two measures: 1) Stages of Change: Following the procedures of Prochaska et al. (1994), a 4- or 5- item algorithm for determining the stage of change for the seven target areas which have been the main foci of the intensive intervention: relaxation training, adherence to medical therapy, social support,
sexuality/body image, diet, exercise, and control of a negative/problematic health behaviors. For example, the first item on the algorithm will ask a woman if she has engaged in the desired positive behavior (e.g. practicing relaxation three times per week for 20 minutes; exercising 20 minutes three times per week; having one-two face to face interactions with a confidant per week). If a woman reports the undesired status or does not intend to change in the next 8 months (the length of the maintenance period), then she will be in the precontemplation stage. If she intends to change in the next 8 months, she will be in the contemplation stage. Women in the action stage will have reached a particular criterion (e.g. practicing relaxation three times per week) within the past 4 months (the length of the intensive intervention, or the relevant interval since the intervention was conducted during the intensive period). At this first assessment it is unlikely that any women will be in the maintenance phase (usually defined by maintaining the criterion behavior for six months).

2) Decisional Balance: Women will complete decisional balance measures (Janis & Mann, 1977) for each of seven specific target areas: relaxation training, adherence to medical therapy, social contact with an identified target, sexuality/body image, diet, exercise, and control of a negative/problematic health behavior. These measures will be brief (e.g. 8 item) measures which will tap the eight categories of decision making in the Janis and Mann model: gains or losses for self, gains or losses for significant others, self-approval or self-disapproval, and approval or disapproval of others. For each measure the item content will be specific to the target area. Following the method of Prochaska et al. (1994) a 5 point Likert scale will be used that ranges from not important (1) to extremely important (5) or strongly disagree (1) to strongly agree (5).
During the first portion of the last intensive therapy session the measures will be scored by research assistants. A brief, individualize report will be prepared for each woman which will summarize the level of the stage of change (i.e. precontemplation, contemplation, action, etc.) for each of the target areas. The report will be further individualized by providing stage-specific and target-specific intervention information for each women, modeled after the work on individualized self-help interventions of Prochaska et al (1993). The session will begin by delivery of the reports to the women, with discussion of the stages of change model and its applicability to the intervention targets. The session will end by establishing target goals in each area for each woman.

**Part II. (Sessions 19-26).** The same general format will be used for the eight maintenance sessions. Six primary components will be included. (a) We will review the goals for the month, with each woman rating goal attainment and updating her current progress, vis-a-vis stage of change (e.g. determine whether she has moved from contemplation to action). (b) We will emphasize problem solving, social support seeking, and increasing awareness of cues (including self talk) as these general strategies, along with duration of therapist contact in a maintenance program (e.g. Perri et al., 1988), have been important in the maintenance of change (e.g. Urban, White, et al., 1992). (c) Each session we will revisit intervention strategies for one of the seven target areas: relaxation training, adherence to medical therapy, social support, sexuality/body image, diet, exercise, and control of a negative/problematic health behavior. However, this additional coverage of target areas will be broken down into stage specific interventions, i.e. brief modules on relaxation for precontemplators, relaxation for contemplators;
relaxation for maintainers, etc. During the session the women will divide into small
groups based on their respective stage of change for the target behavior and the
interventions will be delivered within the small groups and stage appropriate exercises
and written material will be provided. Given the previous intensive intervention period,
it is likely that the women will fall into only 2 or 3 groups--contemplation, action or
maintenance. With two therapists it will be possible to assist all the subgroups during
this segment. (d) The session will close with goal setting for the next month. e) We
will prompt the group members to maintain contact with one another between the
monthly sessions. For example, women have been comfortable with sharing telephone
numbers or some members pair up as "buddies" for bi-weekly contacts. These contacts
are for social support and to facilitate maintenance of the behavior change goals. f)
Crisis management will be needed for particular difficult situations which arise (e.g. local
recurrence, death of a family member). The group will need to process such experiences
and provide support to one another as is appropriate.

Therapists and therapy reliability

A single cycle will be 26 sessions/39 therapy hours (18 intensive + 8
maintenance). There will be at least ten cycles of the intervention (i.e. 100 intervention
subjects/8-12 subjects per group). Several steps will be taken to insure reliability of the
treatment procedures. First, to maximize similarity across cycles, the therapists (two per
group) will follow a session-by-session written manual (see Appendix A). To insure
reliability within intervention cycles, therapist teams will meet weekly to review the
previous session, rate the topic coverage, and prepare for the next session. Then, all
sessions will be videotaped and independent ratings of 50% of the intensive and 100% of
the maintenance sessions will be done. The videotapes will be rated on coverage of the content scheduled for a particular session. If we determine that there is "drift" in the nature of the intervention we will take corrective action immediately. These data will also provide crude measures of intervention "dose" and involvement of the subjects in the intervention--both components of process research (Greenberg & Pinsof, 1986)--to generate testable hypotheses of intervention components.

Second, steps will be taken to standardize and document the treatment "dose" to the women. 1) Attendance [both in session and “at home,” see description below] will be monitored. 2) Each woman will be given a notebook which provides an easy to read written summary of each session. This facilitates the women keeping focused on the sequence and content of the intervention and, often, women use the outlines to prepare for the next week’s session. 3) There will be absences of women on occasion (e.g. women on chemotherapy often have low counts or feel ill) and we have devised procedures for them. When a session is missed, a woman is telephoned by the primary therapist. The therapist provides an update to the woman about the status of the other group members and then together they discuss the sessions content as provided in the notebook (The notebooks are written as if a therapist is talking to an individual person). Together they complete any of the session exercises as is appropriate. Of course, the therapist also discusses any special concerns the woman may indicate. When such procedures are followed, the telephone call is usually 15-20 minutes. This procedure not only keeps a woman up to date on the group progress but it also ensures that minimal group time is needed for "catch up." when a member returns. An important side benefit is that it also appears to reduce the likelihood of women dropping out of the groups as
they stay engaged in the group activities and process. The important practice of using the telephone with cancer patients was pioneered by Dr. Jimmie Holland and colleagues at Memorial (e.g. Mermelstein & Holland, 1991). We are currently pilot testing a checklist to document the content and process of these telephone calls (see Nail, Greene, Jones, & Flannery, 1989 or Hagopian & Rubenstein, 1990 for examples). 3) As described above, we will have the decisional balance and stages of change process data to document the women's progress during the maintenance phase. 4) We will assess the women's perceptions of the group experience with a modified version of the Participant Rating Form from the GROW Project (Roberts et al., 1991). It contains 30 Likert items and asks women to rate the most important aspect of the group experience.

Finally, for all subjects, both intervention and control, we will document participation in any therapeutic, counseling or related activities. This brief assessment will occur on an annual basis and will document any type of group involvement and all individual or family therapeutic contacts. We will obtain descriptive data on how involved the woman is/was in these experiences and how supportive she found them, attendance, and the type of group (e.g. breast cancer, cancer general, therapy group, social/recreational, religious group).
APPENDIX D

SIBCP INTERVENTION OUTCOMES: 0-4 MONTHS
PSYCHOLOGICAL, BEHAVIORAL, AND IMMUNE CHANGES FOLLOWING A PSYCHOLOGICAL INTERVENTION: A CLINICAL TRIAL

Barbara L. Andersen, Ph.D., 1 William B. Farrar, M.D., 2 Deanna M. Golden-Kreutz, Ph.D., 1
Ronald Glaser, Ph.D., 3 Charles F. Emery, Ph.D., 1 Timothy R. Crespin, Ph.D., 4
Charles L. Shapiro, M.D., 5 William E. Carson III, M.D. 2

1Department of Psychology and Comprehensive Cancer Center, The Ohio State University.
2Department of Surgery, College of Medicine; Comprehensive Cancer Center, The Ohio State University.
3Department of Molecular Virology, Immunology, and Medical Genetics, College of Medicine; Comprehensive Cancer Center; The Ohio State University.
4Primetrics, Inc; Columbus, OH.
5Division of Medical Oncology, Department of Internal Medicine, College of Medicine; Comprehensive Cancer Center, The Ohio State University.

Research support: American Cancer Society (PBR-89), the Longaberger Company-American Cancer Society Grant for Breast Cancer Research (PBR-89A), the U.S. Army Medical Research Acquisition Activity Grants (DAMD17-94-J-4165, DAMD17-96-1-6294, and DAMD17-97-1-7062), National Institute of Mental Health (RO1MH51487), National Cancer Institute (RO1CA92704, P30 CA16058), and General Clinical Research Center (MO1-RR0034).

Corresponding author/Reprint requests: Barbara L. Andersen, Ph.D.
Department of Psychology
1885 Neil Avenue
The Ohio State University
Columbus, OH 43210-1222
Telephone: (614)292-4236
Fax: (614)688-8261
E-mail: Andersen.1@osu.edu.
PURPOSE: A randomized clinical trial tests the hypothesis that a psychological intervention can reduce emotional distress, improve health behaviors and dose intensity, and enhance immune responses.

METHODS: We studied 227 women surgically treated for regional breast cancer. Prior to adjuvant therapy, women completed interviews and questionnaires assessing emotional distress, social adjustment, and health behaviors. A 60-ml blood sample was drawn for immune assays. Patients were randomized to either Intervention or Assessment only groups. The intervention was conducted in small patient groups, with one session per week for 4 months. The sessions included strategies to reduce stress, improve mood, alter health behaviors, and maintain adherence to cancer treatment and care. Re-assessment occurred following completion of the intervention.

RESULTS: As predicted, patients receiving the intervention showed significant lowering of anxiety, improvements in perceived social support, improved dietary habits, and reduction in smoking ($P$’s < .05). Analyses of adjuvant chemotherapy dose intensity revealed significantly more variability (i.e., more dispersion in the dose intensity values) for the Assessment arm ($P < .05$). Immune responses for the Intervention patients paralleled their psychological and behavioral improvements. T cell proliferation in
response to PHA and Con A remained stable or increased for the Intervention patients, whereas both responses declined for Assessment patients; this effect was replicated across three concentrations for each assay ($P$’s < .01).

CONCLUSION: These data show a convergence of significant psychological, health behavior, and biologic effects following a psychological intervention for cancer patients.
INTRODUCTION

There is ongoing debate about the impact of psychological interventions on cancer survival. Significant reductions in cancer patients’ emotional distress can be achieved with interventions (1, 2), particularly for those patients with high levels of distress (3, 4). Whether or not these changes in distress are related to improved survival rates is unknown. Of the eight prior randomized studies, four reported a survival benefit (5-8) whereas four others did not (4, 9-11). The majority were designed as psychotherapy studies to reduce stress or enhance coping, and not designed to test for survival effects.

If psychological interventions improve survival, the mechanism is unknown. Three have been proposed. One hypothesized mechanism is social support (5). Indeed, social isolation and low levels of perceived social support may confer increased risk for morbidity or death in coronary heart disease (12-14). Second, stress reduction from a psychosocial intervention might also lead to changed health behaviors [e.g., healthier diet, increased physical activity; (6)] or improved adherence to medical treatments (7), thus affecting survival. With two exceptions (6, 7), previous intervention studies have neither manipulated nor included intervention components to change health behaviors or...
adherence (1, 2). Finally, it is hypothesized that stress reduction interacts with
neuroendocrine and/or immune responses (15, 16) to yield improved illness or disease
outcomes. Designing trials to include multiple behavioral and biologic outcomes should
be the thrust for future behavioral intervention trials for many illnesses/conditions (17),
including cancer (2).

A clinical trial is underway, testing the hypothesis that a multi-component
biobehavioral intervention would impact the incidence of and time to recurrence for
women with regional breast cancer. As in previous trials (1), the intervention was
designed to reduce stress, lower emotional distress, and improve quality of life. Proposed
co-factors--social support, health behaviors, and adherence--were also included as
specific targets of the intervention. Another possible mechanism, immune function, was
assessed. Positive changes in the latter variables along with reductions in distress and
improvements in quality of life and health behaviors represent plausible hypotheses for
the direct or indirect effects of a psychological intervention on disease endpoints. Data
on the efficacy of the intervention on emotional distress, health behaviors, chemotherapy
dose intensity, and immune responses are reported here.
METHODS

Patient Eligibility

Women diagnosed with Stage II or III breast cancer, surgically treated, and awaiting adjuvant therapy were eligible. Exclusion criteria included prior cancer diagnosis; refusal of cancer treatment; age < 20 or > 85 years; residence > 90 miles from the research site; diagnoses of mental retardation, severe or untreated psychopathology (e.g., schizophrenia), neurological disorders, dementia, or any immunologic condition/disease.

Study Arms

Assessment Only. The baseline assessment occurred after breast surgery and prior to randomization and the start of adjuvant therapy. The initial assessment gathered psychological, behavioral, and medical/treatment information and data. Research assistants conducted individual, structured interviews that included questionnaire completion. A 60-mL blood sample was also drawn. Assessments were scheduled in the morning to maintain routine and minimize diurnal variability. Patients were paid $25.00 per assessment. At four months (corresponding to the end of the intervention), patients were similarly re-assessed.
**Intervention.** An identical baseline assessment protocol was used. The intervention was provided in small cohorts (n = 13), ranging from 8 to 12 patients. Each session was conducted by two clinical psychologists. Cohorts met weekly for 1.5 hours for 18 sessions (27 therapy hours during 4 months). For absences, a therapist telephoned the patient to provide support and discuss the session’s topic. The topics/techniques used are consistent with psychosocial interventions (1, 2) but also included diet, exercise, smoking, and adherence components (see Table 19).

**Measures**

**Individual Differences in Stress.** Evidence suggests that interventions may be differentially effective depending on characteristics of the patient (3, 4, 18). A measure of the most relevant type of stress, cancer-specific stress, is tested as an individual difference variable that may covary with the effectiveness of the intervention for reducing emotional distress (POMS, see below). The Impact of Events Scale (IES; 19) examines stress-related intrusive thoughts, denial of thoughts, and avoidant behaviors relevant to cancer diagnosis and treatment. For the present sample, coefficient alpha reliability is .87 and 4-month test-retest reliability is .78. Reliability data for the measures described below were calculated similarly.

**Emotional Distress.** The Profile of Mood States (POMS; 20) assesses negative mood. A Total Mood Disturbance score is the sum of five scales (Anxiety, Depression, Anger, Fatigue, and Confusion) minus the score of a Vigor scale. Cronbach’s alpha reliability is .92 and test-retest reliability is .78.
Social Adjustment. This construct is examined as a multivariate linear composite of four measures. (1) Social Network. The Social Network Index (SNI; 21, 22) documents an individual’s direct contact with family, friends, and the community. Test-retest reliability is .71. (2-3) Social Support. The Perceived Social Support Scales for Friends (PSS-Fr) and Family (PSS-Fa; 23) assesses need for and perception of receiving support from friends or family members. Alpha reliability is .82 and .88 and test-retest reliability is .79 and .80 for the PSS-Fr and PSS-Fa, respectively. (4) Dyadic Satisfaction. The satisfaction item (DS) from the Dyadic Adjustment Scale (DAS; 24) assesses relationship satisfaction among married or cohabiting couples. Test-retest reliability is .64.

Health Behaviors. Three measures assessed three behaviors. (1) Dietary Patterns. The Food Habits Questionnaire (FHQ; 25) assesses dietary choices and eating patterns with five scales: avoiding fat, food substitution with lower-fat alternatives, modification of food preparation, replacing high fat with low fat foods, and fruit and vegetable intake. Alpha reliability is .79 and test-retest reliability is .77. (2) Exercise. A 7-day report of moderate and vigorous physical activity, based on the Seven-Day Exercise Recall of the Stanford Heart Disease Prevention Program (26), provided a summary index of energy expenditure. Normative data are available (26). (3) Smoking. Patients were queried as to their smoking status and if smoking, daily intake (participants used cigarettes only), where 1 cigarette = 1 tobacco unit. Test-retest reliability is .93.

Adherence to Chemotherapy. Dose intensity for each drug was calculated (27, 28). As multiple chemotherapy agents often comprise a regimen, the value for each
patient was dose intensity averaged across the number of agents. The incidence of refusal, premature termination of chemotherapy, and the case lost to medical follow up was also recorded.

**Functional Status.** A research nurse, blind to randomization status, provided Karnofsky Performance Status (KPS; 29-31) ratings, based on a clinical interview and medical chart/records. Inter-rater reliability ranges from .70 to .97 (30,31).

**Immune Assays**

**Blood separation procedures.** Peripheral blood leukocytes (PBLs) were isolated from 60 mL of venous blood by using Ficoll density gradient centrifugation (Pharmacia Biotech, Inc., Piscataway, NJ). The isolated leukocytes were then washed in calcium- and magnesium-free phosphate-buffered saline and counted on a Coulter counter (Coulter Corp., Miami, FL). Aliquots of $6 \times 10^6$ isolated PBLs were suspended again in 0.6 mL of RPMI-1640 medium supplemented with 10% fetal bovine serum (HyClone, Logan, U.); 2-mercaptoethanol (BME: Sigma, St. Louis, MO); and 100X antibiotic-antimycotic stock, Hepes (N-2-hydroxyethyl-piperazine, N-2-ethane sulfonic acid), sodium bicarbonate, and L-glutamine (all from Gibco BRL, Grand Island, NY).

**Quantification of T lymphocytes, T-cell subsets, and NK cells.** PBLs were labeled with fluorescent-conjugated monoclonal antibodies (Mabs) specific for the following cell surface markers: total T-cells (CD3, fluorescein isothiocyanate), T4 subset (CD4, rhodamine), T8 subset (CD8, fluorescein isothiocyanate), and NK cells (CD56, rhodamine); MAbs were purchased from Coulter Corp. Briefly, an aliquot of PBLs was treated with Erythrocyte Lysis Buffer (Cytometry Protocols), resuspended in DPBS, and centrifuged for five minutes at 3300 rpm. $0.5 \times 10^6$ cells were incubated with the
appropriate MAb for 15 minutes in the dark, on ice. After the incubation, the cells were washed, and the labeled blood cells were fixed with DPBS containing 2% formaldehyde. Dual labeled immunoglobulin (IgG) was used to determine nonspecific immunofluorescence binding. Samples were analyzed with a Coulter EPICS XL-MCL flow cytometer.

**Blastogenic response to PHA and Con A.** The serial dilutions for PHA and Con A used were 2.5, 5.0, and 10.0 µg/mL. For the assays, isolated PBLs, resuspended in supplemented RPMI without phenol red, were seeded in triplicate at 0.5 x 10^5 per well and incubated for 68 hours at 37° C., with 5% CO₂, in sterile 96-well flat-bottomed plates. Wells were pulsed for the final 4 hours with MTS, i.e., 3-(4, 5-dimethylthiazol-2-yl)-5-(3-carboxymethoxyphenyl)-2-(4-sulfophenyl)-2H-tetrazolium, inner salt (Promega Corp., Madison, WI) and PMS (phenazine methosulfate), an electron-coupling reagent, to measure proliferative response. Briefly, the MTS assay is a nonradioactive calorimetric procedure that labels metabolically active cells via reduction of a colored substrate. The amount of proliferation was determined via optical density readings of the suspension in the well compared to cells and media alone, using an HTS7000 Bioassay micro plate reader (Perkin Elmer) at a determination wavelength of 492 nm and a reference wavelength of 690 nm, as has been noted (28, 32). No standard curves were employed in these assays. The average coefficient of variation (ACV) among replicate wells was 9.6% for the unstimulated cell control condition. For the PHA-stimulated condition, ACV was 4.6% for the 2.5 µg/mL dilution, 4.7% for 5 µg/mL, and 6% for 10 µg/mL. For the Con A-stimulated condition, ACV was 4% for the 2.5 µg/mL dilution, 4.7% for 5 µg/mL, and 5% for 10 µg/mL.
**NK cell cytotoxicity.** Briefly, PBLs were resuspended in complete medium at a density of 2.5 x 10^6 cells/ml and seeded into 96-well V-bottom microtiter plates in a volume sufficient to provide an effector to target (E:T) cell ratio of 100:1, 50:1, 25:1, 12.5:1, 6.25:1, and 3.13:1 (triplicate wells). Complete medium was added to each well to give a total volume of 200 µl. The NK-sensitive human myeloid K562 cell line was employed as the target in this assay (27). K562 cells were harvested from culture, labeled with ^51^Cr, and washed. 5 x 10^3 ^51^Cr-labeled K562 target cells were added to each well in a volume of 50 µl. Plates were centrifuged at 300 g for 5 min. and then incubated for 5 hours in 5% CO₂ at 37°C. After this incubation, the plates were again centrifuged at 300 g for 5 minutes and 100 µl of supernatant was harvested and counted using a Beckman 5500 gamma counter. Minimum and maximum ^51^Cr release was determined utilizing target cells that had been incubated in complete medium or 5% SDS detergent solution, respectively. Cytotoxicity was calculated using the following equation:

\[
\text{Cytotoxicity} = \frac{\text{Experimental } ^{51}\text{Cr release} - \text{Minimum release}}{\text{Maximum release} - \text{Minimum release}}
\]

**Statistics**

**Accrual and Randomization.** Power analyses suggested an N of 200 and 227 were accrued. Two sources were used: consecutive cases at a university-affiliated National Cancer Institute-designated Comprehensive Cancer Center (n = 189) and self- and physician-referred cases from the community (n = 38). Following the initial assessment, White and Freedman’s minimization method (33) was used for randomization. Prognostic and psychosocial strata were: 1) extent of disease/treatment [nodal status, tumor size, and anticipated bone marrow transplant (BMT) treatment], 4 levels: negative nodes but tumor > 2 cm, 1-3 positive nodes, >4 positive nodes with BMT, or, >4 positive nodes.
nodes without BMT; 2) hormone receptor status: positive vs. negative; 3) menopausal status: pre/peri vs. post-menopausal; and 4) partner status: spouse/partner vs. none. See Figure 14 for trial flow diagram.

Intervention Integrity and Attendance. To achieve reliability, therapists followed a session-by-session manual and patients received a companion manual. Equivalence of content was evaluated with session videotapes and patient ratings. Analyses of variance (ANOVAs) found no significant differences (all P’s > .40) between the 13 cohorts in the following: (1) frequency of use of the intervention components (e.g., relaxation); (2) rated helpfulness of each component; and, (3) rated importance of 20 group experiences (e.g., getting support).

Compliance with the intervention was excellent, with 81% of the women (92 of 114) participating. Of the 22 non-participants, 1 died, 4 dropped from the clinical trial, and 17 (15%) were intervention dropouts but continued in the trial. There was no difference between cohorts in attendance ($P > .20$). Participants completed 94% of the intervention sessions, either in person ($M = 13$ of 18 sessions, $SD = 2.96$) or combined with the telephone follow ups ($M = 17$ of 18 sessions, $SD = 1.88$). Absences were due to employment obligations or treatment toxicities requiring home stay.

Data Availability. Both study arms had excellent retention (see Figure 14). Excluding the 3 cases of recurrence/death (3 of 227), there was 94% (210 of 224) retention at 4 months. Notably, 43% (6 of 14) of the study dropouts also failed to return for their medical follow up, suggesting non-participation was not specific to the trial. Only 12 patients missed the 4-month assessment (5%; $n = 12$ of 224).
Data is analyzed according to intention to treat. Thus, findings include data from 15% of the intervention patients who did not participate but remained in the trial. Data for the four month assessment is as follows: Stress (IES), 87%; Emotional distress (POMS), 88%; Social adjustment, 88%; Health behaviors: Food Habits, 87%; Smoking 85%, Exercise 96%; and Compliance, 100%. Numbers are lower for the 4-month immune assays as 85% of the sample was undergoing chemotherapy; there were difficulties with poor venous access and low cell counts. When samples were insufficient, assays were prioritized. At 4 months, data were available for 83% of the NK cell assays and 75% of the Con A and PHA assays. Finally, data availability was equivalent between study arms for all measures.

**Analysis Plan.** The study arms are compared with respect to entry characteristics and outcome measures using chi-square or ANOVA models as appropriate. A repeated measures ANOVA model was used for the social, health behavior, and dose intensity variables. This was most appropriate due to the strong within-group pretreatment-post treatment correlations for the variables. The effect of primary interest was the two-way interaction, with Group (Intervention, Assessment) as the between subjects factor and Time (Initial, 4-month) as the within subjects factor. For emotional distress only, a mixed, three-factor repeated measures ANOVA was used, with Group and Initial Cancer Stress (Low, High, defined by an IES median split) as the between subjects factors and Time as the within-subjects factor. The three-way interaction tested whether the effectiveness of the intervention in reducing emotional distress was greater among patients with initially higher cancer stress. The likelihood of Type 1 errors was reduced by using a contingent, two-step analytic procedure. For measures containing subscales
(e.g., POMS), the total score was analyzed first, and only if significant, the analysis for the subscales followed. Four measures were used to assess the construct of social adjustment. For this, a multivariate analysis of variance (MANOVA) model was used to examine the effect of the intervention on the four measures simultaneously; if significant, ANOVA followed for each measure.

In contrast to the psychosocial variables, the immune outcomes exhibited low within-group pretreatment-post treatment correlations and the ANOVA model was not optimal. In this circumstance, an analysis of covariance (ANCOVA) model is best suited. Use of the initial (baseline) score as covariate reduces the error term and provides greater power (34). Again, steps were taken to reduce the likelihood of Type 1 errors. As a conservative strategy, a multivariate analysis of covariance (MANCOVA), with initial values as covariates, simultaneously tested all the dilutions/ratios within an assay (e.g., dilutions 2.5, 5.0, and 10.0 for Con A). Only if significant, follow up ANCOVAs tested for a Group effect at each dilution/ratio.
RESULTS

Description of the Sample

Accrual rate for the cancer center was 52%, higher than similar trials (4, 9, 18). Accrual from the community was essentially 100%, as all non-participants fell into excluded categories, such as diagnosis of stage I disease. In combination, overall accrual was 57%. Contrasts between cancer center and community accruals on demographics, disease and prognostic characteristics, or cancer treatment variables were not significant ($P$'s $> .09$). Analyses contrasting participants versus non-participants also found no significant differences between study arms ($P$'s $> .10$). Reasons for refusal were “too far” (25%, > 60 miles), “insufficient time” (20%), “not interested” (17%), “too stressed” (10%), and miscellaneous/not specified (28%).

Table 20 provides descriptive data. The data are similar to those of the Ohio Cancer Incidence Surveillance System (35) and SEER (36) database. Analyses of sociodemographic variables revealed no significant differences between study arms ($P$'s $> .27$). Further, there were no significant differences on disease/prognostic factors or treatments received/planned ($P$'s $> .23$). Groups were equivalent on most of the outcome variables, and the few differences were small in magnitude (see Table 21).
Emotional Distress and Individual Differences

The two-way interaction for Total Mood Disturbance was not significant. A significant three-way interaction was found, $F(1, 192) = 4.55, P = .03$, such that Total Mood Disturbance decreased more in the Intervention arm than the Assessment arm, $F(1, 93) = 4.13, P = .04$, for subjects with high initial cancer stress. Follow up analysis of the POMS scales was conducted for general clarification of the intervention effect. Of particular relevance is the Anxiety scale, as the intervention focused upon reducing stress and anxiety. The two-way interaction was significant, $F(1, 193) = 4.15, P = .04$, such that there was a greater reduction of anxious moods for the Intervention arm than for the Assessment arm. The three-way interaction was not significant; the intervention was equally effective in reducing anxiety for patients with low or high cancer stress. For the Fatigue scale, the two-way interaction was not significant, but a significant three-way interaction was found, $F(1, 193) = 5.14, P = .02$. The intervention lowered fatigue for patients with high cancer stress, rather than low. Interaction effects for the remaining scales were marginal ($0.05 < P's < 0.08$), though changes were in the hypothesized direction (i.e., greater reductions in distress for the Intervention arm).

Social Adjustment, Health Behaviors, and Adherence

As noted, analyses focused exclusively on the two-way interaction. A significant two-way interaction for social adjustment, $F(4, 140) = 2.41, P = .048$, was found. Follow up univariate analyses revealed a significant two-way interaction for PSS-Family, $F(1, 143) = 5.36, P = .02$. Perceived support from the family significantly increased in the Intervention arm, yet decreased in the Assessment arm.
Analyses of the overall dietary habits measure indicated a significant two-way interaction, $F (1, 194) = 5.01, P = .03$, in which only the Intervention arm significantly increased healthy food habits by 4 months. Follow up ANOVAs revealed significant interactions for Avoiding Fat, $F (1, 194) = 3.92, P = .049$ and Food Substitution scales, $F (1, 193) = 4.41, P = .04$. Analyses of the exercise recall measure approached significance for the interaction ($P = .08$), with a greater increase in physical activity in the Intervention arm than in the Assessment arm.

Analyses for smoking also showed a significant interaction, $F (1, 195) = 4.52, P = .03$, indicating the number of cigarettes smoked daily decreased for the Intervention participants, yet increased for the Assessment participants. When restricted to only active smokers, the interaction was again significant, $F (1, 15) = 4.94, P = .04$. Descriptively, there were changes in smoking status from 12 months prior to diagnosis to the 4-month assessment. Ninety per cent (90%) of the Assessment smokers either resumed or continued smoking in contrast to 30% of the Intervention smokers.

Regarding dose intensity of chemotherapy, the distribution of values was too skewed for parametric statistics because 67% of the patients received over 90% of their recommended regimen dose. Dose intensity between the Intervention and Assessment arms did not differ significantly for either means (90.2% vs. 87.7%, respectively) or medians (95.7% vs. 94.0%, respectively). However, the variance of dose intensity in the Assessment arm was significantly greater [$P = .03$; Conover’s squared rank test (37)], indicating more individual variability in dose intensity values for the Assessment patients compared to those for the Intervention patients.
Regarding adherence from the initial to the four-month assessment, seven women (7 of 227) discontinued chemotherapy against medical advice, five of which were from the Assessment arm. Six of 227 patients were lost to medical follow up, five of whom were from the Assessment arm. These descriptive data likely underestimate the incidence of non-compliant behaviors as both the clinical trial and the treating institutions were aggressive in maintaining follow up (e.g., providing transportation funds to the clinic, if needed).

**Immune Analyses**

**T lymphocyte Counts.** ANCOVAs revealed no significant Group effect on CD3, CD4, or CD8 counts.

**T cell Blastogenesis.** The MANCOVA revealed a significant effect for Con A-induced T cell blastogenesis, F (3, 154) = 6.37, P = .0004. Follow up ANCOVAs were significant for all Con A dilutions (P’s < .01). For each, there was an identical pattern of increased proliferation for the Intervention arm and decreased proliferation for the Assessment arm from the initial to the 4-month assessments. For illustration, data for the 5.0 µg/ml dilution, F (1, 158) =14.80, P = .0002, are provided (see Figure 15). For interested readers, when this data was analyzed using a repeated measures MANOVA model, results were similar F (3, 157) = 8.67, P = .00002.

There were similar, significant findings for PHA. The MANCOVA, F (3, 154) = 3.85, P = .01, and follow up ANCOVAs for each dilution were significant (P’s < .05). Across dilutions, the pattern is the same; proliferation remains constant for the Intervention arm but significantly declines for the Assessment only arm. Data for the 5.0
µg/mL dilution, $F(1, 158) = 8.64$, $P = .004$, are provided (see Figure 16). Again, for interested readers, when this data was analyzed using a repeated measures MANOVA model, results were similar $F(3, 157) = 2.35$, $P = .075$.

NK cell count and cell lysis. The findings for cell count were not significant. Findings for NK lysis, using either the MANCOVA or repeated measures MANOVA model, were not significant.
DISCUSSION

The present trial is part of the ongoing effort to test for changes in biobehavioral outcomes and disease endpoints following a psychological intervention. Lowering stress is the main goal for interventions (1, 2), and the most successful interventions reduce patients’ anxiety (38,39). When untreated, anxieties are common and arise from many sources (40): diagnosis (41), diagnostic tests (42), surgery (43), radiation (44), chemotherapy (45), bone marrow transplant (46), and cancer symptoms (47, 48). Here, anxiety was significantly reduced in the Intervention arm. Analyses also contrasted patients who differed in the magnitude of cancer-specific stress. For women with high stress, the intervention provided a 36% reduction in total mood disturbance compared to the 12% reduction found for the Assessment arm. Parallel effects emerged for feelings of fatigue. This may be important as fatigue can affect every aspect of a patient’s life (49), yet it is often not recognized. Oncologists attest that pain, for example, is routinely treated (95%), whereas fatigue receives little to no attention (5%; 50).

Many, if not all, interventions attempt to provide social support to patients, but it is rare that specific therapeutic techniques are used to improve a patient’s social adjustment in the “real world” to enable or facilitate social support from specific others (1,2). We are aware of only four intervention studies having noted strategies to help
patients to use social support (18), enhance interpersonal relationships (51), or address relationship difficulties (52, 53). In two other studies patients were ‘encouraged’ to return to prior social activities and maintain relationships (54, 55). Even so, studies have not included social adjustment or social support from others as an intervention outcome (1, 2) as was done here.

The patients’ initial assessment occurred shortly after illness onset and early treatment, as it is regarded as providing a more realistic reflection of how a patient’s family and friends actually respond in a crisis (56). The group format may have provided, in general, social support, but more importantly, the intervention components assisted patients to make their established network of relationships function more effectively for them. Maintaining existing relationship is important as data indicate that quality of life is poorer for breast cancer patients who are socially isolated (57). We do not know if the intervention patients received, or only perceived, more support from their family. When compared, it is perceived support that may actually be more important for adjustment (58-60) and health effects (12).

Some interventions with cancer patients focus only upon dietary (61-64), exercise (65,66), or smoking cessation change (67,68). The intervention model for these studies has been to have a professional (e.g., dietician) meet with a patient for one to several sessions. To our knowledge, psychological interventions for cancer patients have not previously included health behaviors as intervention targets or outcomes. The single exception offered skin protection information to melanoma patients receiving a psycho-educational intervention (69).
Despite the brevity of the health behavior component (4 of 18 sessions), significant changes in both positive and negative behaviors occurred. The dietary sessions provided information, sampling of low fat snacks, food intake diaries, and others. Reductions in fat intake were readily achieved, consistent with lengthier dietary interventions (25, 61,62). There were no differential changes in activity or exercise, likely due to the minimal time spent. However, even large randomized trials offering lengthy exercise interventions (e.g., 26 weeks) have reported significant change on some measures but not on others (66). Finally, the smoking reductions in the Intervention arm were significant, despite the low number of smokers in the trial. Recent research indicates that individuals who continue to smoke following a cancer diagnosis endorse reasons such as “I am more relaxed when I smoke” and “smoking relieves tension” (70). Our intervention was generally focused on stress reduction, and the specific aspects for smoking were similar to those in the National Cancer Institute’s “4 A’s” program used by physicians (i.e., Ask, Advise to quit, Assist the patient to stop, and Arrange follow up monitoring; 71) which has been effective in increasing cessation rates (72,73).

Poor adherence to treatment is a behavioral problem, and one that has received minimal investigation despite its importance (74). Within the Assessment group, there was a greater dispersion of chemotherapy dosages, more premature terminations of treatment, and lost to follow up cases. The data are consistent and in the predicted direction. However, in future research a larger sample size and disease sites yielding more variability in dose intensity values and/or higher rates of non-adherence are needed.
Finally, the oft-proposed mechanism for survival effects is improved emotions and/or lowered stress modulating the immune system, which, in turn, alters disease progression. Several intervention studies have tested for changes in NK cell lysis, and with one exception (75), null effects have been reported (76-80). We too observed no change in NK cell lysis yet found significant, reliable effects with blastogenesis; a pattern reported by others (81).

Blastogenesis remained stable or increased across time for Intervention patients, whereas responses declined for Assessment only patients. These experimental data extend our correlational report showing a negative relationship between high stress and low immune responses as women entered the trial (32). It is notable that the intervention effects on blastogenesis were reliable within and across the Con A and PHA assays. Even so, some might suggest that these intervention effects could be explained by other factors. We do not believe this is the case, a viewpoint bolstered by the successful randomization equating the groups, the reliability of blastogenesis findings, and their predicted consistency with the psychological and behavioral changes.

We also tested competing explanations for the intervention effect on immunity, testing for effects due to cell counts, chemotherapy, or radiation. When CD3, CD4, and CD8 cell counts were statistically controlled in MANCOVAs, study arm effects remained ($P$’s < .05). Thus, the changes in blastogenesis were functional and not due to cell trafficking. Regarding chemotherapy, patients from both study arms were equally likely to have completed chemotherapy at four months, and the study arms did not differ significantly in the number of patients receiving chemotherapy (see Table 20) or the dosages prescribed (see Table 21; all $P$’s > .05). Nevertheless, MANCOVA’s controlling
for the types of chemotherapy received (e.g., doxorubicin, paclitaxel) were conducted. They showed the same positive intervention effects on both Con A and PHA ($P$’s < .05). Regarding radiation, the study arms did not differ significantly in the number of patients receiving this treatment. By four months, more patients in the Intervention arm (n = 25) were still receiving radiation compared to the Assessment arm (n = 9; $P = .005$). When radiation status was controlled however, the positive effect of the intervention on PHA and Con A blastogenesis remained. Taken together, these analyses rule out competing explanations and provide evidence for a robust effect of the intervention on T cell blastogenesis.

The immune changes observed in the assessment arm (i.e., reduced proliferation in response to T cell mitogens) may indicate the presence of a functional defect in T cell immunity, although the precise immune implications of this phenomena cannot be discerned at this point in the study. Indeed it is possible that the observed alterations in lectin-induced blastogenesis do not represent a distinct immune deficiency. Any reduction in T cell effector function might theoretically lead to increased rates of breast cancer recurrence in surgically-treated stage II and III breast cancer patients because of the role the T cells appear to play in the process of tumor surveillance (82). However, it is important to note that alterations in polyclonal T cell proliferation in response to ex vivo stimulation of patient PBMCs with Con A or PHA are of uncertain significance with respect to subsequent cancer progression. Our follow up of the study participants will continue and we will be better able to determine if these immune effects or others relate to breast cancer recurrence rates.
If psychological interventions impact cancer survival, the process is likely to be multi-factorial, including psychological, behavioral, biologic responses, and others (16). This trial includes tests for the expected reductions in emotional distress, plus the additional intervention targets--health behaviors, adherence, and immunity--which may represent plausible routes to improved survival. In previous trials, the intervention effects have been strong (e.g., 10, 52, 69, 75, 83-86), moderate (87), and null (87, 88). It is important to note that positive intervention effects are a necessary condition for testing for recurrence or survival effects. Here, the predicted effects for emotional distress, social support, health behaviors, and immunity were observed, with some stronger than others. In combination, they provide the context for a meaningful test of disease endpoint hypotheses and a strategy to examine multiple routes by which psychological interventions may affect disease course.


35. Ohio Department of Health: Community health assessments and the center for public health data and statistics, 2002

36. SEER (Surveillance, Epidemiology, and End Results Program): Division of Cancer Control and Population Sciences, National Cancer Institute, 2000


42. Melendez JC, McCrank E: Anxiety-related reactions associated with magnetic resonance imaging examinations. JAMA 270: 745-747, 1993


232


ACKNOWLEDGMENTS

We thank the following individuals: Project coordinators Vicki DiLillo and Laura Peterson; research assistants Susan Aarestad, Elizabeth Bromet, Nicole Chaput, Andrew Christiansen, Angie Collier-Crespin, Larisa Demshuk, Melissa Douglas, Sarah Grimes, Leigh Ann Kutz, Melissa Petri, Kathryn Pingel, Beth Putz, Elizabeth Rayl, Lori Richardson, Teresa Styer, Samer Suleiman, Jan Varga-Spangler, Jessica Walker, Laura Wielonski, Marilyn Welt, and Deborah Yurek.
<table>
<thead>
<tr>
<th>Intervention Target</th>
<th>Sessions</th>
<th>Intervention Component</th>
<th>Measured Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress</td>
<td>1-18</td>
<td>Understanding stress responses, Progressive muscle relaxation training.</td>
<td>Impact of Events Scale</td>
</tr>
<tr>
<td>Quality of Life:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional distress</td>
<td>10-15</td>
<td>Relaxation training, Positive coping, Problem solving.</td>
<td>Profile of Mood States</td>
</tr>
<tr>
<td>Social adjustment</td>
<td>4-9</td>
<td>Identify social network, Identify support needed and specific social contact, Communication skills training.</td>
<td>Social Network Index Family and Friends</td>
</tr>
<tr>
<td>Health Behaviors</td>
<td>13-16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diet</td>
<td></td>
<td>Food intake diary, Low fat/high fiber information, Food substitution, Intake and energy balance information.</td>
<td>Food Frequency Questionnaire</td>
</tr>
<tr>
<td>Exercise</td>
<td></td>
<td>Stretching and walking protocol (20min/day x 3/wk).</td>
<td>7-Day exercise recall</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td>Referral information, Group support for cessation.</td>
<td>Tobacco intake (cigs/day)</td>
</tr>
<tr>
<td>Adherence</td>
<td>2-3, 10</td>
<td>Disease/treatment information, Assertive communication skills, Monitoring of treatment/follow up appointments, Goal setting.</td>
<td>Dose intensity Chemo refusal/dropout Loss to follow up</td>
</tr>
<tr>
<td>Immunity</td>
<td>NA</td>
<td>NA</td>
<td>Cellular immune assays</td>
</tr>
<tr>
<td>Disease endpoints</td>
<td>NA</td>
<td>NA</td>
<td>Event/time to recurrence</td>
</tr>
</tbody>
</table>

Table 19. Intervention targets, sessions, components, and measured variables.
<table>
<thead>
<tr>
<th>Category</th>
<th>Total (N=227)</th>
<th>Assessment (n=113)</th>
<th>Intervention (n=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td><strong>Sociodemographic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (Years)</td>
<td>50.82</td>
<td>(10.76)</td>
<td>51.07</td>
</tr>
<tr>
<td>Race (% Caucasian)</td>
<td>90</td>
<td></td>
<td>90</td>
</tr>
<tr>
<td>Education (Years)</td>
<td>14.75</td>
<td>(2.74)</td>
<td>14.34</td>
</tr>
<tr>
<td>Family Income (K/Year)</td>
<td>67.98</td>
<td>(71.41)</td>
<td>66.30</td>
</tr>
<tr>
<td>Marital Status (% Married)</td>
<td>67</td>
<td></td>
<td>67</td>
</tr>
<tr>
<td>Significant Other (%Yes)</td>
<td>74</td>
<td></td>
<td>72</td>
</tr>
<tr>
<td><strong>Prognostic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage (II vs. III %)</td>
<td>90</td>
<td></td>
<td>92</td>
</tr>
<tr>
<td>Nodes (number positive)</td>
<td>3.05</td>
<td>(5.45)</td>
<td>3.06</td>
</tr>
<tr>
<td>Tumor size (cm.)</td>
<td>3.02</td>
<td>(1.77)</td>
<td>2.91</td>
</tr>
<tr>
<td>ER/PR (% positive)</td>
<td>68</td>
<td></td>
<td>68</td>
</tr>
<tr>
<td>Menopausal status (% Pre)</td>
<td>54</td>
<td></td>
<td>52</td>
</tr>
<tr>
<td><strong>Treatment Received/Recommended</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery (% Segmental mastectomy)</td>
<td>43</td>
<td></td>
<td>43</td>
</tr>
<tr>
<td>Radiation therapy (% Yes)</td>
<td>54</td>
<td></td>
<td>51</td>
</tr>
<tr>
<td>Hormonal therapy (% Yes)</td>
<td>75</td>
<td></td>
<td>80</td>
</tr>
</tbody>
</table>

Table 20. Initial equivalence of study arms on sociodemographic, prognostic, treatment and performance status variables. Percentages or means and standard deviations (in parentheses) are provided.
Table 20 (continued)

<table>
<thead>
<tr>
<th>Category</th>
<th>Total (N=227)</th>
<th>Assessment (n=113)</th>
<th>Intervention (n=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>Mean SD</td>
<td>Mean SD</td>
<td>Mean SD</td>
</tr>
<tr>
<td>Chemotherapy (% Yes)</td>
<td>84 85 83</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>74 73 75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>82 86 79</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methotrexate</td>
<td>12 14 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-fluorouracil</td>
<td>18 19 17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>21 20 21</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Performance Status</strong></td>
<td>85.11 (7.95)</td>
<td>86.55 (6.91)</td>
<td>83.68 (8.65)</td>
</tr>
</tbody>
</table>

* Significant group difference, $P < .05.$
<table>
<thead>
<tr>
<th>Category</th>
<th>Total (N=227)</th>
<th>Assessment (n=113)</th>
<th>Intervention (n=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td><strong>Individual Difference: Stress</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Emotional Distress</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Profile of Mood States*</td>
<td>36.32 (34.26)</td>
<td>31.38 (32.11)</td>
<td>41.42 (35.67)</td>
</tr>
<tr>
<td>Anxiety*</td>
<td>13.10 (7.39)</td>
<td>12.02 (6.91)</td>
<td>14.17 (7.72)</td>
</tr>
<tr>
<td>Depression</td>
<td>11.76 (10.37)</td>
<td>10.83 (9.32)</td>
<td>12.68 (11.28)</td>
</tr>
<tr>
<td>Anger</td>
<td>7.85 (6.44)</td>
<td>7.49 (6.70)</td>
<td>8.22 (6.19)</td>
</tr>
<tr>
<td>Confusion</td>
<td>8.97 (5.49)</td>
<td>8.19 (5.37)</td>
<td>9.75 (5.53)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>9.58 (6.29)</td>
<td>8.65 (5.97)</td>
<td>10.49 (6.49)</td>
</tr>
<tr>
<td>Vigor</td>
<td>14.94 (6.36)</td>
<td>16.00 (6.43)</td>
<td>13.89 (6.13)</td>
</tr>
<tr>
<td><strong>Social Adjustment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Network Index</td>
<td>6.05 (2.91)</td>
<td>5.98 (2.85)</td>
<td>6.12 (2.98)</td>
</tr>
<tr>
<td><strong>Perceived Social Support</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Friends*</td>
<td>16.83 (3.49)</td>
<td>16.23 (3.79)</td>
<td>17.42 (3.07)</td>
</tr>
<tr>
<td>Dyadic Satisfaction Scale *</td>
<td>3.69 (1.38)</td>
<td>3.94 (1.28)</td>
<td>3.46 (1.43)</td>
</tr>
<tr>
<td><strong>Health Behaviors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Habits Questionnaire</td>
<td>43.13 (9.14)</td>
<td>42.91 (9.20)</td>
<td>43.35 (9.12)</td>
</tr>
<tr>
<td>Avoiding Fat</td>
<td>7.30 (2.82)</td>
<td>7.29 (2.76)</td>
<td>7.30 (2.90)</td>
</tr>
</tbody>
</table>

Table 21. Initial equivalence of study arms on individual differences in stress and outcome variables. Means and standard deviations (in parentheses) are provided.
Table 21 (continued)

<table>
<thead>
<tr>
<th>Category</th>
<th>Total (N=227)</th>
<th>Assessment (n=113)</th>
<th>Intervention (n=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Food Substitution</td>
<td>12.17 (3.54)</td>
<td>12.15 (3.70)</td>
<td>12.19 (3.39)</td>
</tr>
<tr>
<td>Meat Modification</td>
<td>11.60 (3.33)</td>
<td>11.30 (3.37)</td>
<td>11.89 (3.27)</td>
</tr>
<tr>
<td>Food Replacement</td>
<td>5.72 (2.12)</td>
<td>5.85 (2.20)</td>
<td>5.58 (2.03)</td>
</tr>
<tr>
<td>Fruit/Vegetable</td>
<td>6.34 (2.00)</td>
<td>6.32 (1.81)</td>
<td>6.37 (2.19)</td>
</tr>
<tr>
<td>Exercise (7 Day Recall)</td>
<td>17.50 (27.55)</td>
<td>19.15 (29.88)</td>
<td>15.64 (24.76)</td>
</tr>
<tr>
<td>Smoking (Cigs/day/person)</td>
<td>10.36 (9.52)</td>
<td>9.00 (8.56)</td>
<td>12.78 (11.13)</td>
</tr>
</tbody>
</table>

**Chemotherapy: Recommended (mg/m²/wk)**

- **Doxorubicin, n=168**: 37.49 (8.39) 36.27 (7.27) 38.67 (9.22)
- **Cyclophosphamide, n=187**: 516.28 (427.24) 483.02 (357.08) 552.14 (491.36)
- **Methotrexate, n=28**: 40.14 (25.73) 39.61 (29.94) 40.96 (18.76)
- **5-fluorouracil, n=41**: 444.64 (118.31) 441.35 (118.38) 448.45 (121.36)
- **Paclitaxel, n=48**: 121.38 (29.18) 123.03 (30.18) 119.86 (28.77)

**Immune Measures**

- **T Lymphocyte Counts (K/µL)**
  - T3: 1.28 (.59) 1.25 (.51) 1.32 (.66)
  - T4: .90 (.43) .86 (.39) .93 (.47)
  - T8: .43 (.22) .42 (.19) .43 (.25)

Blastogenic Response (optical density readings)

- Unstimulated cells (control): .21 (.14) .23 (.15) .18 (.13)

continued
Table 21 (continued)

<table>
<thead>
<tr>
<th>Category</th>
<th>Total (N=227)</th>
<th>Assessment (n=113)</th>
<th>Intervention (n=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Con A (µg/mL, with control values subtracted)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.0</td>
<td>.12 (.10)</td>
<td>.11 (.09)</td>
<td>.12 (.10)</td>
</tr>
<tr>
<td>5.0</td>
<td>.19 (.13)</td>
<td>.18 (.12)</td>
<td>.20 (.14)</td>
</tr>
<tr>
<td>2.5</td>
<td>.19 (.14)</td>
<td>.18 (.12)</td>
<td>.21 (.16)</td>
</tr>
<tr>
<td>PHA (µg/mL, with control values subtracted)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.0</td>
<td>.31 (.15)</td>
<td>.30 (.16)</td>
<td>.32 (.15)</td>
</tr>
<tr>
<td>5.0</td>
<td>.30 (.15)</td>
<td>.28 (.15)</td>
<td>.31 (.15)</td>
</tr>
<tr>
<td>2.5</td>
<td>.28 (.15)</td>
<td>.27 (.15)</td>
<td>.29 (.15)</td>
</tr>
<tr>
<td>Natural killer cell</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count (K/µL)</td>
<td>216.7 (137.2)</td>
<td>219.9 (130.7)</td>
<td>213.5 (143.8)</td>
</tr>
<tr>
<td>% Lysis at Effector to Target (E:T) ratios</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100:1</td>
<td>56.38 (19.33)</td>
<td>57.12 (19.45)</td>
<td>55.63 (19.27)</td>
</tr>
<tr>
<td>50:1</td>
<td>47.95 (18.98)</td>
<td>48.06 (18.99)</td>
<td>47.84 (19.06)</td>
</tr>
<tr>
<td>25:1</td>
<td>34.76 (15.39)</td>
<td>34.57 (15.31)</td>
<td>34.95 (15.55)</td>
</tr>
<tr>
<td>12.5:1</td>
<td>23.48 (12.20)</td>
<td>23.34 (12.56)</td>
<td>23.61 (11.90)</td>
</tr>
<tr>
<td>6.25:1</td>
<td>14.32 (8.37)</td>
<td>14.41 (8.74)</td>
<td>14.23 (8.04)</td>
</tr>
<tr>
<td>3.125:1</td>
<td>7.29 (4.85)</td>
<td>7.23 (4.82)</td>
<td>7.35 (4.89)</td>
</tr>
</tbody>
</table>

* Significant group difference, $P < .05$.
† Means based on the 25 smokers in the sample.
‡ Means based on the number of patients receiving the treatment.
Con A = Concanavalin A; PHA = Phytohemagglutinin.
Figure 14. Experimental design and flow diagram.
Figure 15. Example of significant effects for Con A induced proliferation. Optical density readings for 5.0 µg/mL dilution are displayed with error bars representing one standard error.
Figure 16. Example of significant effects for PHA induced proliferation. Optical density readings for 5.0 µg/mL dilution are displayed with error bars representing one standard error.