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Award Number: DAMD17-96-1-6009

TITLE: Enhancing Well-Being During Breast Cancer Recurrence

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REPORT DATE: June 2000

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	June 2000	Annual (1 Jul 99 - 31 May 00)

4. TITLE AND SUBTITLE
Enhancing Well-Being During Breast Cancer Recurrence

5. FUNDING NUMBERS
DAMD17-96-1-6009

6. AUTHOR(S)
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT ***(Maximum 200 Words)***

Significant numbers of breast cancer patients will experience a recurrence of their disease. Breast cancer recurrence is a time of enormous crisis, with significant distress, depression, and symptomatology, and few effective coping strategies. Targeted support services are currently unavailable.

This study tests the hypothesis that patients experience greater well-being by participating in an intervention designed for breast cancer patients experiencing a first recurrence. Following a pilot study phase, 300 breast cancer patients will be enrolled within 6 weeks post-recurrence. All participants are Southwest Oncology Group (SWOG) institutions. The women will be randomly assigned to a control group or an intervention to be carried out by Y-Me, a national breast cancer support and advocacy organization. The intervention consists of 4 to 8 structured sessions providing information and peer support delivered by breast cancer survivors via telephone over a 4 week period. Endpoints are assessed at baseline and 3 and 6 months later through validated quality of life and depression questionnaires.

This study provides information about improving well-being during a little studied portion of the breast cancer trajectory. The intervention is delivered by individuals who are well-qualified to provide support: women who themselves have experience breast cancer recurrence. The project utilizes a cost-effective approach with the potential for widescale dissemination.

14. SUBJECT TERMS
Breast Cancer

15. NUMBER OF PAGES
63

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

FOREWORD

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

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

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

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

06/28/00

PI - Signature Date

ANNUAL REPORT TABLE OF CONTENTS

SOUTHWEST ONCOLOGY GROUP
DAMD17-96-1-6009 ANNUAL REPORT

Enhancing Well-Being During Breast Cancer Recurrence

INTRODUCTION

A. Subject and Purpose of the Research

This project uses a two phase implementation process to determine whether patients will experience greater levels of well-being as a function of participating in an intervention designed for breast cancer patients experiencing a first recurrence.

A Pilot Study was conducted in selected Southwest Oncology Group institutions to: refine intervention protocol materials; develop operating procedures to ensure coordination and communication between the Principal Investigator, Southwest Oncology Group Operations Office, the Study Coordinator, the Southwest Oncology Group Statistical Center, Y-ME, and the institutions accruing patients; develop a training program for the breast cancer survivors who will provide the intervention; finalize assessment questionnaires and examine length and ease of administration by telephone, especially with respect to burden for institution staff; and examine participation and attrition.

The Main Study is currently open to all Southwest Oncology Group institutions. A randomized, two group design is used to evaluate the impact of a telephone intervention delivered by breast cancer survivors on well-being in patients experiencing a first recurrence of breast cancer versus written information. The primary objective of the main study is: to assess the effectiveness of a telephone intervention delivered by breast cancer survivors on well-being in patients experiencing a first recurrence of breast cancer versus written information delivered by mail.

The secondary research objectives of the full trial are: to examine the impact of sociodemographic, clinical, and psychosocial predictors of well-being in patients experiencing a first recurrence of breast cancer; and to examine changes in well-being over time since recurrence.

B. Background of Previous Work

<u>The Psychosocial Impact of Breast Cancer Recurrence</u>

Despite significant increases in five-year breast cancer survival rates, mortality curves for these patients have remained largely unchanged for many years. While many breast cancer patients, especially women diagnosed with Stage I disease, can realistically expect to be cured of their disease, significant numbers of patients will experience a recurrence of their breast cancer at some point following diagnosis, treatment, or a disease-free period. Although this statistic is not generally emphasized, when all stages of breast cancer are considered, as many as 50% of patients will experience recurrence.

Recurrence marks a significant change in the breast cancer care continuum, since it brings home the limits of current knowledge in oncology. The cancer care team must acknowledge that the treatment did not work: that all of the optimism, faith in medicine, and careful compliance with treatment were not enough to forestall disease progression. The patient and family may question whether all of the suffering that they have gone through was really worth it, and they may have a sense of failure: not only about treatment, but about themselves. They must deal with a new reality: that the patient is experiencing pain and other symptoms of her recurrence, that chances for cure have been reduced, and that once again, treatment decisions need to be made.

What is a woman's experience when the worst happens – that is, when breast cancer returns? Surprisingly, very little attention has been given to this issue in the literature: only nine studies have been reported about recurrence of any cancer during the past 15 years (1). We do know that the patients identify the threat of recurrence as one of the most feared possible outcomes of cancer. The fear of recurrence repeatedly emerges as an important psychosocial theme in breast cancer patients who are newly-diagnosed (2, 3), attending follow-up visits (4), and among long-term survivors (5).

The largest study based on data from patients actually experiencing a recurrence is Worden's cross-sectional study of 102 individuals with recurrences of various cancers (6, 7). Worden found that distress levels of the patients with recurrence were high and equivalent to levels in newly-diagnosed patients. Compared to newly-diagnosed patients, the individuals in this study were less willing to participate in interventions focused solely on psychosocial counseling and more concerned about their medical problems and existential concerns. Among the factors that predicted higher distress were more symptoms, lack of social support, less hope, and being younger. Cella, Mahon, and colleagues (8, 9) also assessed adjustment in 40 patients within one month of recurrence; the patients represented a variety of cancer sites, and 27 were experiencing a first recurrence. Patients in this study experienced high levels of distress: they "almost universally agree that recurrence is more upsetting than initial diagnosis" (8, p. 20). There was a suggestion that having anticipated the possibility of recurrence aided adjustment: patients who reported that they were "completely surprised" by the recurrence fared the worst.

Several studies have focused on breast cancer recurrence. Silberfarb et al. (10) compared psychosocial status in groups of breast cancer patients during initial diagnosis (N=50), first recurrence (N=52), and metastatic disease (N=44). The findings indicated that the stage of first recurrence clearly was the most emotionally stressful time in their samples (10, p. 454). Significantly, only one woman out of the 52 could identify a single coping strategy she had found helpful, in marked contrast to the other two groups. In addition, the findings of this study illustrate how recurrence is often marked by physical impairment as well: 81% of the women in the recurrence group reported pain, the highest percentage of any group. Jenkins et al. (11) evaluated 22 women with newly-diagnosed breast cancer recurrence, and found that 45% experienced depression and anxiety at the level of psychiatric diagnosis; previous psychiatric illness was a significant predictor of recurrence distress. A recent study by Lewis and Deal (1) further described problems in 15 married couples in which the wife was diagnosed with a recurrence of breast cancer. A number of problems in marital adjustment were reported, as well as depression experienced by 40% of the women; the recurrence had been diagnosed a median of 10 months previously, indicating the long-lasting psychosocial impact of breast cancer recurrence and the potential that intervention could provide a real benefit for these patients.

Interventions to Reduce Psychosocial Distress

No intervention directed at the needs of patients experiencing a recurrence of breast cancer (or any other cancer) has been reported. However, several reviews (12-14), including a recent meta-analysis (15), have concluded that psychosocial interventions have a positive impact on the well-being of patients across the spectrum of disease stages and sites. To date, research has not established whether one kind of intervention is more effective than another, or more appropriate for certain patients. A variety of intervention types (e.g., informational, psychological, behavioral, social support) and formats (e.g., group, individual, telephone) have demonstrated beneficial effects. Effects have been demonstrated for quality of life, symptom management, and psychological functioning. The optimal point to evaluate the impact of psychosocial interventions has not been firmly established; most studies assess outcomes at one or more intervals during the first year post-intervention (12-14), although impacts may be long-lasting, even extending to ultimate survival (e.g., 16).

This study draws on an approach which has been found effective by a number of investigators: a brief, time-limited intervention combining information and support delivered by telephone. The telephone is

frequently used in providing information regarding cancer treatment and counseling (17-22). In particular, the telephone may make services available to individuals for whom traveling would pose difficulties because of geography, health, or access to transportation. The telephone-directed intervention approach is especially well-suited to the Southwest Oncology Group setting, given the potential of providing standardized assessment across participating institutions at a relatively low cost. Other cooperative groups, including the Eastern Cooperative Oncology Group and the Cancer and Leukemia Group B, are currently conducting research protocols utilizing telephone-delivered interventions, although no other group has focused on patients with recurrence. In fact, patients with recurrence appear to have recourse to few specialized resources; although resource and support programs frequently offer assistance to newly diagnosed patients, hospice patients, and (increasingly) to survivors, patients going through a recurrence seem to "fall between the cracks."

The Use of Lay Organizations to Provide Support to Breast Cancer Patients

The intervention will be provided by women who are particularly well-qualified to provide support and information: breast cancer survivors who have themselves experienced recurrence. A distinctive feature of this study is its delivery of the intervention through an established national breast cancer advocacy and support organization, Y-ME. Although Y-ME has provided telephone hotline services (using a toll-free 800 number) since 1987, the impact of the service has not been systematically assessed. This is also true for other lay programs for breast cancer patients, such as the American Cancer Society's Reach-to-Recovery program (23). This study will utilize breast cancer survivors within the context of a structured protocol, as well as standardized and validated outcome measures. If the program proves effective, it can become part of Y-ME's program and be delivered on a standard basis. The use of a voluntary organization staffed with non-health professionals represents a cost-effective approach to providing support. Y-ME has participated in a Southwest Oncology Group Lay Advisors/Advocates Steering Committee for the past two years. The lay advisors (who include representatives of national organizations and volunteers selected through a nationwide search) are special members of the Group, serve as members of Disease and other Committees (including the Committee on Women and Special Populations and the Breast Cancer Committee), and attend semi-annual Group meetings. The lay advisors contributed to the development and design of this protocol.

This study will provide information about how to improve well-being during a portion of the breast cancer trajectory where little attention has been focused. The project utilizes a cost-effective approach to intervention with demonstrated usefulness in cancer patients. The intervention will be delivered by individuals who are especially well-qualified to provide support: women who themselves have experienced breast cancer recurrence. This project represents one of the first formal research collaborations between a clinical cooperative research group and a lay breast cancer organization. The project reflects the overriding motivation of both groups: to provide the best possible care and support to cancer patients.

BODY

A. Experimental Methods

Overview

The Pilot Study involved 30 women meeting the eligibility criteria who all participated in the intervention and completed the outcome assessment questionnaires. The Main Study utilizes a two arm randomized design with repeated measures at three time points. Three hundred breast cancer patients commence participation following a first recurrence of breast cancer. At that time, the participants complete a battery of instruments, including baseline measures of well-being. Participants are stratified by age (< 50 years vs. ≥ 50 years), time since diagnosis (< 2 years vs. ≥ 2 years), and recurrence site (soft tissue/bone vs.

visceral) and randomly assigned to intervention group (intervention vs. control). Participants in the intervention group complete an intervention completed within a four-week period; the intervention will cover four discrete content areas and will be carried out in four to eight telephone calls. Assessments of well-being are collected at approximately three months post-baseline, and again 6 months post-baseline. The primary outcome is well-being, including quality of life (as measured by the Cancer Rehabilitation Evaluation System-Short Form (CARES-SF) [24-30]) and depression (as measured by the Center for Epidemiologic Studies-Depression scale (CES-D) [31-32]).

Eligibility Criteria

Eligibility criteria include: having received definitive surgical treatment for Stage I, II, or IIIa breast cancer and being diagnosed with a first recurrence of breast cancer in the past 42 days (pilot study) or 56 days (main study); being female; no current psychiatric diagnosis affecting ability to participate in the intervention; ability to read and understand English. In the first eight months the pilot study was open, patients must have had no previous enrollment or plans to enroll on a Southwest Oncology Group treatment protocol; this restriction was eliminated for the last portion of the pilot study and for the main study. All patients must complete baseline questionnaires to participate. Institutional Review Board approval must have been received prior to patient registration.

Procedures

Pilot Study: All women completed baseline questionnaires and received a questionnaire packet to complete and return by mail in six weeks. All women were provided with a basic information packet including a copy of the Y-ME booklet "I Still Buy Green Bananas" and a list of agencies which provide cancer-related information. All participating institutions compiled materials about resources available in their catchment area. Project staff compiled information on national organizations such as Y-ME, the Cancer Information Service (1-800-4-CANCER), and the American Cancer Society as part of the information packet. All women in the pilot study received the four session telephone intervention from Y-ME peer counselors.

Main Study: All women complete the baseline questionnaires and are provided with basic information (as above). Women in the *control group* receive no additional intervention. They are mailed self-administered assessment questionnaires to complete 3 months and 6 months later. After completing the final assessment, they are given the same packet of materials provided earlier to the women in the intervention group. Patients in the *intervention group* are provided with an intervention consisting of four to eight counseling/information sessions delivered by Y-ME counselors by telephone over a one-month period.

A standardized intervention protocol is used, and calls should require no longer than 45 minutes to complete. Each call focuses on different problem areas from the group below. The modules reflect psychosocial, physical, and existential concerns. Each woman is given a choice about the order in which the sessions are presented. Each call provides basic information and the opportunity for the patients to discuss individual concerns. The general format is to provide information in specified areas, active listening when the women discuss their concerns, assistance in problem-solving, and information about resources that may be helpful.

The intervention is not designed to provide psychotherapy. Instead, the Y-ME peer counselors provide information, peer support, and referrals to community organizations. Procedures currently in place at Y-ME are used if serious psychological disturbance is detected during a telephone session. In such cases, patients are asked if the Y-ME peer counselor can contact the Southwest Oncology Group physician who enrolled her on the study. Following the first session, the patients are sent a packet of written materials.

Study Endpoints

The primary endpoint in this study is well-being (CARES-SF psychosocial functioning and depression) three months post-enrollment in the study. A CARES-SF Psychosocial score of .615 or greater will designate impaired psychosocial functioning. This cut-off has been found to correctly classify breast cancer patients "at risk" for psychosocial distress, as identified in a comprehensive clinical interview by a social worker; the estimated probability of classifying women in the high risk group was .81 in a recursive partitioning model (30). Depression will be indicated by a score of 16 or above on the Center for Epidemiological Studies – Depression (CES-D) scale (31-32).

Longer-term well-being will also be examined at 6 months post-study entry. The intervention will also be evaluated through a standardized "Telephone Counseling Evaluation Form." A "Psychosocial Predictors Form" will be used to examine possible predictors of well-being. These include: social support (measured by Reynolds et al.'s four-item scale [33]); optimism-pessimism (measured using the total score on the Life Orientation Test (LOT) [34-35]); surprisingness of the recurrence (8); and, Sense of Coherence Scale (SOC) (36-38). A "Current Cancer Treatment" form will ascertain treatments being received at baseline, 3 and 6 months.

Analysis

Anticipated total accrual for the Pilot Study was 30 patients. Sample size for the Main Study is 300 patients, with 255 patients expected to be available at the three-month assessment point. Power calculations indicate that a sample size of 255 is sufficient to test intervention vs. control group differences for the two primary endpoints (CARES-SF Psychosocial cutoff score and CES-D cut-off score); with a power of .90 and a one-tailed alpha-level of .025, the study will be able to detect differences in proportions of women who score "at risk" of 20% between the intervention and control groups. Secondary analyses will utilize logistic and least squares regression analyses.

B. Results/Progress to Date

Current Status. The protocol for the pilot study was activated by the Southwest Oncology Group on June 1, 1997. The target sample size of 30 patients was reached in July 1998. The Main Study opened Group-wide on July 15, 1998 for activation by all Southwest Oncology Group institutions. The first patient was accrued to the protocol in September 1998. As of June 15, 2000, 137 patients had been entered on the study. Accrual has been steady over the 2000 calendar year. The accrual has been stable at approximately 7-10 per month for the past year.

During the past year, the following activities have been completed:

1. Recruitment and training of additional peer counselors (Y-ME) (due to disease progression and death in one of the original counselors, and desire to take a break from counseling by another counselor).

2. Continuation of continuing education and provision of feedback and reinforcement for Y-ME peer counselors by Dr. Taylor and Ms. Perotti.

3. Periodic communications from Dr. Gotay to the Project Team, Principal Investigators and Data Managers at participating institutions to encourage their participation, and communicate new information. The Southwest Oncology Group Operations Office is setting up a listserve to enable communication with all institutions that have activated the study to facilitate regular e-mail messages. We plan to send reminder e-mails every three months.

4. As Study Coordinator, Dr. Gotay continues to respond to numerous telephone calls and e-mails regarding eligibility and other aspects of the protocol. These calls have come primarily from individuals at Southwest Oncology Group institutions and women across the country who learn about the study from the Y-ME newsletter or internet home page, where the study is listed. The first self-referred patient who learned about the project from the Y-ME newsletter was entered onto the study in May 2000. Despite many other queries from women across the country, this was the first woman who met eligibility criteria and took part in the study.

5. Regular communications were maintained between Dr. Gotay and the Project Team (including the Southwest Oncology Group Statistical Center, Southwest Oncology Group Operations Office, Y-ME, and the consultants). Monthly telephone conferences are scheduled between Dr. Taylor at Y-ME, and weekly or more frequent e-mail or telephone communication with the Southwest Oncology Group Statistical Center (Drs. Green and Moinpour).

6. Two project group meetings were held in conjunction with Southwest Oncology Group meetings in San Diego, CA (October 1999) and Seattle, WA (April 2000).

7. Presentations about the study were made at the April 2000 Southwest Oncology Group Nurse Oncologist Plenary Session (C. Gotay), and the October 1999 and April 2000 Breast Cancer Committee and Cancer Control Research Committee Meetings (C. Gotay).

8. The Southwest Oncology Group Statistical Center has continued to send reminders to let institutional personnel know about upcoming questionnaire completion dates for women registered at their institutions. This information is computer-generated and is transmitted to each institution on a monthly basis in the same way as is done for treatment studies.

9. The Southwest Oncology Group Statistical Center analyzed numbers of cases of missing questionnaires (either baseline, 3 month, or 6 months) by institution. There were few missing questionnaires overall, and one institution accounted for the majority of forms that had not been submitted. That institution received counseling by the Statistical Center.

10. Dr. Gotay and her staff continue to send mailed materials to institutions who have women who are in the control condition. The institutions distribute these materials to the women after they complete their final questionnaires. They also send materials to women who inquire about the study but do not meet eligibility criteria. These breast cancer survivors seem to appreciate receiving the materials a great deal.

11. Dr. Gotay presented a poster based on the pilot study results at the Department of Defense Era of Hope meeting on June 8-11, 2000 in Atlanta, GA. The extended abstract is included as an Appendix.

12. Dr. Gotay is the lead author on a manuscript in press at the Journal of the National Cancer Institute which discusses the role of cooperative groups such as the Southwest Oncology Group in behavioral research. This project is discussed in the manuscript.

KEY RESEARCH ACCOMPLISHMENTS

None, the project is not completed.

REPORTABLE OUTCOMES

None, the project is not completed.

CONCLUSIONS

After a slower-than-expected start, the protocol continues to accrue at a steady rate. There is considerable enthusiasm for the research in the Group among behavioral scientists and clinicians alike, and women participating in the protocol have been highly supportive. Continued vigilance is needed to keep the protocol salient in the minds of physicians, nurses, and data managers so that referrals will be maintained until study completion. Dr. Gotay and the project team will maintain efforts at publicizing the study, providing communications with Southwest Oncology Group institutions, and making presentations at the Group meetings to ensure that the study continues to have a high profile within the Group. We recognize that sustained effort is needed to make certain that this study meets its accrual goals. Since there are still no studies elsewhere in the country that we are aware of addressing the needs of this population of breast cancer patients, we are convinced that our project will make a significant contribution when it is completed.

REFERENCES

1. Lewis FM, Deal LWE. Balancing our lives: A study of the married couple's experience with breast cancer recurrence. Oncology Nursing Forum 22:943-953, 1995.

2. Lasry J-C, Margolese RG. Fear of recurrence, breast-conserving surgery, and the trade-off hypothesis. Cancer 69:2111-2115, 1992.

3. Noguchi M, Saito Y, Nishijima H, et al. The psychological and cosmetic aspects of breast conserving therapy compared with radical mastectomy. Surgery Today 23: 598-602, 1993.

4. Lampic C, Wennberg A, Schill JE, et al. Anxiety and cancer-related worry of cancer patients at routine follow-up visits. Acta Oncologica 33:119-125, 1994.

5. Haltutten A, Hietanen P, Jallinoja P, et al. Getting free of breast cancer: An eight-year perspective of the relapse-free patients. Acta Oncologica 31:307-310, 1992.

6. Worden JW. The experience of recurrent cancer. Journal of Psychosocial Oncology 3:5-16, 1986.

7. Worden JW. The experience of recurrent cancer. CA-A Cancer Journal for Clinicians 39:305-310, 1989.

8. Cella DF, Mahon SM, Donovan MI. Cancer recurrence as a traumatic event. Behavioral Medicine 16:15-22, 1990.

9. Mahon SM, Cella DF, Donovan MI. Psychosocial adjustment to recurrent cancer. Oncology Nursing Forum 17:47-52, 1990.

10. Silberfarb PM, Maurer H, Crouthamel CS. Psychosocial aspects of neoplastic disease: I. Functional status of breast cancer patients during different treatment regimens. American Journal of Psychiatry 137:450-455, 1980.

11. Jenkins PL, May VE, Hughes LE. Psychological morbidity associated with local recurrence of breast cancer. International Journal of Psychiatry in Medicine 21:149-155, 1991.

12. Andersen BL. Psychological interventions for cancer patients to enhance quality of life. Journal of Consulting and Clinical Psychology 60:552-568, 1992.

13. Trijsburg RW, van Knippenberg FCE, Rijpma SE. Effects of psychological treatment on cancer patients: A critical review. Psychosomatic Medicine 54:489-517, 1992.

14. Fawzy FI, Fawzy NW, Arndt LA, Pasnau RO. Critical review of psychosocial interventions in cancer care. Archives of General Psychiatry 52:100-113, 1995.

15. Meyer TJ, Mark MM. Effects of psychosocial interventions with adult cancer patients: A meta-analysis of randomized experiments. Health Psychology 14:101-108, 1995.

16. Spiegel D, Kraemer HC, Bloom JR, et al. Effects of psychosocial treatment on survival of patients with metastatic breast cancer. Lancet 2:888-891, 1989.

17. Alter CL, Fleishman SB, Kornblith AB, et al. Supportive telephone intervention for patients receiving chemotherapy: A pilot study. Psychosomatics , in press.

18. Anderson DM, Duffy K, Hallett CD, Marcus AC. Cancer prevention counseling on telephone hotlines. Public Health Reports 107:278-283, 1992.

19. Hagopian GA, Rubenstein JH. Effects of telephone call interventions on patients' well-being in a radiation therapy department. Cancer Nursing 13:339-344, 1990.

20. Mermelstein HT, Holland JC. Psychotherapy by telephone: A therapeutic tool for cancer patients. Psychosomatics 32:407-412, 1991.

21. Nail LM, Greene D, Jones LS, Flannery M. Nursing care by telephone: Describing practice in an ambulatory oncology center. Oncology Nursing Forum 16:387-395, 1989.

22. Rainey LC. Cancer counseling by telephone help-line: the UCLA psychosocial cancer counseling line. Public Health Reports 100:308-315, 1985.

23. Willits M-J. Role of "Reach to Recovery" in breast cancer. Cancer 74:2172-2173, 1994.

24. Ganz PA, Hirji K, Sim M-S, et al. Predicting psychosocial risk in patients with breast cancer. Medical Care 31:419-431, 1993.

25. Schag CAC, Ganz PA, Polinsky ML, et al. Characteristics of women at risk for psychosocial distress in the year after breast cancer. Journal of Clinical Oncology 11:783-793, 1993.

26. Ganz PA, Coscarelli A, Fred C, et al. Breast cancer survivors: Psychosocial concerns and quality of life. Breast Cancer Research & Treatment, in press.

27. Ganz PA, Schag CA, Lee JJ, Sim MS. The CARES: A generic measure of health-related quality of life for patients with cancer. Quality of Life Research 1:19-29, 1992.

28. Schag CAC, Heinrich RL, Aadland RL, Ganz PA. Assessing problems of cancer patients: Psychometric properties of the Cancer Inventory of Problem Situations. Health Psychology 9:83-102, 1990.

29. Schag CC, Heinrich RL, Ganz PA. The Cancer Inventory of Problem Situations: An instrument for assessing cancer patients' rehabilitation needs. Journal of Psychosocial Oncology 1:11-24, 1983.

30. Ganz PA, Schag CC, Cheng H. Assessing the quality of life: A study in newly diagnosed breast cancer patients. Journal of Clinical Epidemiology 43:75-86, 1990.

31. Comstock CW, Helsing KJ. Symptoms of depression in two communities. Psychological Medicine 6:551-563, 1976.

32. Weissman MM, Sholomskas D, Pottenger M, et al. Assessing depressive symptoms in five psychiatric populations: A validation study. American Journal of Epidemiology 106:203-214, 1977.

33. Reynolds P, Boyd PT, Blacklow RS, et al. The relationship between social ties and survival among black and white cancer patients. Cancer Epidemiology, Biomarkers, and Prevention 3:253-259, 1994.

34. Scheier MF, Carver CS. Optimism, coping, and health: Assessment and implications of generalized outcome expectancies. Health Psychology 4:219-247, 1985.

35. Carver CS, Pozo-Kaderman C, Haris SD, et al. Optimism vs. pessimism predicts the quality of women's adjustment to early stage breast cancer. Cancer 73:1213-1220, 1994.

36. Antonovsky A. Health, stress, and coping. San Francisco: Jossey-Bass, 1979.

37. Antonovsky A. The structure and properties of the Sense of Coherence scale. Social Science & Medicine 36:725-733, 1993.

38. Chamberlain K, Petrie K, Azariah R. The role of optimism and sense of coherence in predicting recovery following surgery. Psychology and Health 1, 1992.

APPENDICES

Attached on the following pages are the Southwest Oncology Group protocol S9832, "Enhancing Well-Being During Breast Cancer Recurrence" and the Era of Hope Meeting Extended Abstract.

Southwest
Oncology Group
A National Clinical Research Group

May 1, 1999

TO: ALL SOUTHWEST ONCOLOGY GROUP, CCOP AND CGOP MEDICAL ONCOLOGISTS

FROM: Jennifer S. Gazvoda, Protocol Coordinator

RE: **S9832**, "Enhancing Well-Being During Breast Cancer Recurrence." Study Coordinators: C. Gotay, Ph.D., C. Moinpour, Ph.D., K.S. Albain, M.D., S. Martino, D.O., B. Taylor, Ph.D.

REVISION #5

The Clinical Update Form has been revised to include space to indicate whether the assessment is obtained at Month 3 or Month 6 and the date of the assessment. The revised Clinical Update Form is now numbered as Form #49100 and replaces the 7/15/98 version (Form #4338). The form number change is reflected in Sections 14.5, 14.6 and 18.9.

Please append this notice to your copy of the protocol and replace pages 16, 23 and the Clinical Update Form.

This memorandum serves to notify the NCI and Southwest Oncology Group Statistical Center.

cc: DCP
Laura Lovato, M.S.
Stephanie J. Green, Ph.D.
Carol Moinpour, Ph.D.
Dona Marrah
Catherine Smith, Department of Defense
Bonnie Taylor, Ph.D. - Y-ME National Breast Cancer Organization
Judy Perotti - Y-ME National Breast Cancer Organization

Southwest
Oncology Group
A National Clinical Research Group

March 1, 1999

TO: ALL SOUTHWEST ONCOLOGY GROUP, CCOP AND CGOP MEDICAL ONCOLOGISTS

FROM: Jennifer S. Gazvoda, Protocol Coordinator

RE: **S9832**, "Enhancing Well-Being During Breast Cancer Recurrence." Study Coordinators: C. Gotay, Ph.D., C. Moinpour, Ph.D., K.S. Albain, M.D., S. Martino, D.O., B. Taylor, Ph.D.

REVISION #4

Section 5.0 of the above-noted study has been revised to include space to indicate (1) the date the patient was informed of her first recurrence and (2) the date the patient is planning to begin her FIRST treatment for this recurrence. As a reminder, Section 5.0 must be completed and submitted to the Statistical Center within 14 days of registration. Sections 14 and 18 have been revised to include form numbers.

Please append this notice to your copy of the protocol and replace pages 6, 15, 16 and 23.

This memorandum serves to notify the NCI and Southwest Oncology Group Statistical Center.

cc: DCP
Laura Lovato, M.S.
Stephanie J. Green, Ph.D.
Carol Moinpour, Ph.D.
Dona Marrah
Catherine Smith, Department of Defense
Bonnie Taylor, Ph.D. - Y-ME National Breast Cancer Organization
Judy Perotti - Y-ME National Breast Cancer Organization

Southwest
Oncology Group
A National Clinical Research Group

December 1, 1998

TO: ALL SOUTHWEST ONCOLOGY GROUP, CCOP AND CGOP MEDICAL ONCOLOGISTS

FROM: Jennifer S. Gazvoda, Protocol Coordinator

RE: **S9832**, "Enhancing Well-Being During Breast Cancer Recurrence" Study Coordinators: C. Gotay, Ph.D., C. Moinpour, Ph.D., K.S. Albain, M.D., S. Martino, D.O., B. Taylor, Ph.D.

REVISION #3

The above-noted protocol has been revised to distinguish between the two packets of information that patients receive. The first is a packet compiled locally at the institution and includes: a copy of the National Cancer Institute (NCI) booklet, "When Cancer Recurs: Meeting the Challenge Again" and/or the Y-ME booklet, "I Still Buy Green Bananas" and a list of local and national agencies that provide cancer-related information and support. This basic information packet is given to all patients at baseline. The second packet is compiled by the Y-ME National Breast Cancer Organization and is distributed by Y-ME to patients on the intervention arm after the first telephone session rather than following each session. This standardized Y-ME packet is distributed by the Study Coordinator to patients on the control arm after the six month assessment has been received. The above-noted protocol has also been corrected to indicate that the Additional Concerns Form is completed by the patient rather than the nurse/CRA. These revisions are reflected in the Schema, Sections 7.2, 7.3, 9.0 and the Model Informed Consent form.

Section 7.1d has been revised to reflect that "the counselor will discuss a list of issues....where the patient has concerns." The last sentence of Section 10.3 has been deleted since it was redundant.

The CARES-SF Form was revised to indicate the Southwest Oncology Group Patient Number rather than the Southwest Oncology Group Study Number. The Quality of Life Cover Sheet was revised to specify that the Telephone Counseling Evaluation Form is to be completed at months three and six only. The section capturing reasons why the questionnaires may not have been completed has been revised.

Stephanie Green, Ph.D. has replaced Polly Feigl, Ph.D. as Secondary Statistician for this study. This change is reflected on the face page of the protocol.

Please append this notice to your copy of the protocol and replace pages 2, 7 - 9, 11, 13, 24, the face page, the CARES-SF Form and the Quality of Life Cover Sheet.

This memorandum serves to notify the NCI and Southwest Oncology Group Statistical Center.

cc: DCP
Laura Lovato, M.S.
Stephanie J. Green, Ph.D.
Carol Moinpour, Ph.D.
Dona Marrah
Catherine Smith, Department of Defense
Bonnie Taylor, Ph.D. - Y-ME National Breast Cancer Organization
Judy Perotti - Y-ME National Breast Cancer Organization

Southwest
Oncology Group
A National Clinical Research Group

October 15, 1998

TO: ALL SOUTHWEST ONCOLOGY GROUP, CCOP AND CGOP MEDICAL ONCOLOGISTS

FROM: Jennifer S. Gazvoda, Protocol Coordinator

RE: **S9832**, "Enhancing Well-Being During Breast Cancer Recurrence" Study Coordinators: C. Gotay, Ph.D., C. Moinpour, Ph.D., K.S. Albain, M.D., S. Martino, D.O., B. Taylor, Ph.D.

REVISION #2

The following revisions have been made to the above noted protocol:

Sections 5.3 and 5.5 have been combined into Section 5.3 to clarify eligibility with regard to prior treatment.

The NCI Cancer Information Service (CIS) phone number has been corrected in Section 7.2c and on the Support Services Form.

A statement has been added to Section II of the Model Informed Consent to indicate that the Study Coordinators and supervisors at Y-ME are the only people who will listen to the tapes and all tapes will be destroyed after they have been reviewed.

Question #32 on the CARES-SF Form has been corrected to read, "I have insurance problems" rather than "I have financial problems".

Please append this notice to your copy of the protocol and replace pages 6, 8, 24, the CARES-SF Form and the Support Services Form.

This memorandum serves to notify the NCI and Southwest Oncology Group Statistical Center.

cc: DCP
Laura Lovato, M.S.
Polly Feigl, Ph.D.
Carol Moinpour, Ph.D.
Dona Marrah
Catherine Smith, Department of Defense
Bonnie Taylor, Ph.D. - Y-ME National Breast Cancer Organization
Judy Perotti - Y-ME National Breast Cancer Organization

Southwest
Oncology Group
A National Clinical Research Group

September 1, 1998

TO: ALL SOUTHWEST ONCOLOGY GROUP, CCOP AND CGOP MEDICAL ONCOLOGISTS

FROM: Jennifer S. Gazvoda, Protocol Coordinator

RE: **S9832**, "Enhancing Well-Being During Breast Cancer Recurrence" Study Coordinators: C. Gotay, Ph.D., C. Moinpour, Ph.D., K.S. Albain, M.D., S. Martino, D.O., B. Taylor, Ph.D.

REVISION #1

The Study Calendar for the above-noted protocol has been revised to correctly reference Section 7.2c (rather than Section 7.1c) in the "π" notation. The CARES-SF Form has been revised to correct typographical errors in questions #45 and 46.

Please append this notice to your copy of the protocol and replace page 11 and the CARES-SF Form.

This memorandum serves to notify the NCI and Southwest Oncology Group Statistical Center.

cc: DCP
Laura Lovato, M.S.
Polly Feigl, Ph.D.
Carol Moinpour, Ph.D.
Dona Marrah
Catherine Smith, Department of Defense
Bonnie Taylor, Ph.D. - Y-ME National Breast Cancer Organization
Judy Perotti - Y-ME National Breast Cancer Organization

Southwest
Oncology Group
A National Clinical Research Group

July 15, 1998

TO: ALL SOUTHWEST ONCOLOGY GROUP, CCOP AND CGOP MEDICAL ONCOLOGISTS

FROM: Jennifer S. Gazvoda, Protocol Coordinator

RE: **S9832**, "Enhancing Well-Being During Breast Cancer Recurrence" Study Coordinators: C. Gotay, Ph.D., C. Moinpour, Ph.D., K.S. Albain, M.D., S. Martino, D.O., B. Taylor, Ph.D.

ACTIVATION

S9632, the Pilot Study, is anticipated to reach its accrual goal and will be permanently closed effective 8/1/98. **S9832**, the Main Study referenced above, is now **open for registration**. Entire copies of the protocol are enclosed for your use.

This memorandum serves to notify the NCI and Southwest Oncology Group Statistical Center.

cc: DCPC
Laura Lovato, M.S.
Polly Feigl, Ph.D.
Carol Moinpour, Ph.D.
Dona Marrah
Catherine Smith, Department of Defense
Bonnie Taylor, Ph.D. - Y-ME National Breast Cancer Organization
Judy Perotti - Y-ME National Breast Cancer Organization

SOUTHWEST ONCOLOGY GROUP

ENHANCING WELL-BEING DURING BREAST CANCER RECURRENCE

PARTICIPANTS: ALL SOUTHWEST ONCOLOGY GROUP, CCOP AND CGOP MEDICAL ONCOLOGISTS

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mb

SCHEMA

Study Entry

Patient signs informed consent and completes baseline questionnaires (CARES-SF, CES-D, Psychosocial Questionnaire, Support Services Form and the Additional Concerns Form)

Nurse/CRA completes baseline

a. S9832 Prestudy Form
b. Quality of Life Cover Sheet

Nurse/CRA gives all patients basic information packet to include booklets and a list of support services

Randomization

Control

Standard level of support

Nurse/CRA mails questionnaires 2 weeks prior to the 3 & 6 month assessments

Upon return of 3 & 6 month questionnaires, Nurse/CRA completes:

a. S9832 Clinical Update Form
b. Quality of Life Cover Sheet

Study Coordinator distributes standardized Y-ME packet of information to patient.

Intervention

Nurse/CRA faxes patient information to Y-ME

Y-ME contacts patient and conducts intervention [4 - 8 sessions over 4 weeks]

Y-ME sends standardized packet to patient

Nurse/CRA mails questionnaires (including Telephone Counseling Intervention Form) two weeks prior to the 3 & 6month assessments

Upon return of 3 & 6 month questionnaires, Nurse/CRA completes:

a. S9832 Clinical Update Form
b. Quality of Life Cover Sheet

1.0 OBJECTIVES

1.1 To assess the effectiveness of a telephone intervention delivered by breast cancer survivors on well-being of patients experiencing a first recurrence of breast cancer.

1.2 To examine the impact of sociodemographic, clinical, and psychosocial predictors of well-being in patients experiencing a first recurrence of breast cancer.

1.3 To examine changes in well-being over time since recurrence.

2.0 BACKGROUND

The Psychosocial Impact of Breast Cancer Recurrence.

Despite significant increases in five-year breast cancer survival rates, mortality curves for these patients have remained largely unchanged for many years. While many breast cancer patients, especially women diagnosed with Stage I disease, can realistically expect to be cured of their disease, significant numbers of patients will experience a recurrence of their breast cancer at some point following diagnosis, treatment, or a disease-free period. Although this statistic is not generally emphasized, when all stages of breast cancer are considered, as many as 50% of patients will experience recurrence.

Recurrence marks a significant change in the breast cancer care continuum, since it brings home the limits of current knowledge in oncology. The cancer care team must acknowledge that the treatment did not work: that all of the optimism, faith in medicine, and careful compliance with treatment were not enough to forestall disease progression. The patient and family may question whether all of the suffering that they have gone through was really worth it, and they may have a sense of failure: not only about treatment, but about themselves. They must deal with a new reality: that the patient is experiencing pain and other symptoms of her recurrence, that chances for cure have been reduced, and that once again, treatment decisions need to be made.

What is a woman's experience when the worst happens—that is, when breast cancer returns? Surprisingly, very little attention has been given to this issue in the literature: only nine studies have been reported about recurrence of any cancer during the past 15 years. *(1)* We do know that the patients identify the threat of recurrence as one of the most feared possible outcomes of cancer. The fear of recurrence repeatedly emerges as an important psychosocial theme in breast cancer patients who are newly-diagnosed, attending follow-up visits, and among long-term survivors. *(2 - 5)*

The largest study based on data from patients actually experiencing a recurrence is Worden's cross-sectional study of 102 individuals with recurrences of various cancers. *(6 - 7)* Worden found that distress levels of the patients with recurrence were high and equivalent to levels in newly-diagnosed patients. Compared to newly-diagnosed patients, the individuals in this study were less willing to participate in interventions focused solely on psychosocial counseling and more concerned about their medical problems and existential concerns. Among the factors that predicted higher distress were more symptoms, lack of social support, less hope, and being younger. Cella, Mahon, and colleagues also assessed adjustment in 40 patients within one month of recurrence; the patients represented a variety of cancer sites, and 27 were experiencing a first recurrence. *(8 - 9)* Patients in this study experienced high levels of distress: they "almost universally agree that recurrence is more upsetting than initial diagnosis". *(8)* There was a suggestion that having anticipated the possibility of recurrence aided adjustment: patients who reported that they were "completely surprised" by the recurrence fared the worst.

Several studies have focused on breast cancer recurrence. Silberfarb et al. compared psychosocial status in groups of breast cancer patients during initial diagnosis (N=50), first

recurrence (N=52), and metastatic disease (N=44). The findings indicated that the stage of first recurrence clearly was the most emotionally stressful time in their samples. *(10)* Significantly, only one woman out of the 52 could identify a single coping strategy she had found helpful, in marked contrast to the other two groups. In addition, the findings of this study illustrate how recurrence is often marked by physical impairment as well: 81% of the women in the recurrence group reported pain, the highest percentage of any group. Jenkins et al. evaluated 22 women with newly-diagnosed breast cancer recurrence, and found that 45% experienced depression and anxiety at the level of psychiatric diagnosis; previous psychiatric illness was a significant predictor of recurrence distress. *(11)* A recent study by Lewis and Deal further described problems in 15 married couples in which the wife was diagnosed with a recurrence of breast cancer. *(1)* A number of problems in marital adjustment were reported, as well as depression experienced by 40% of the women. The recurrence had been diagnosed a median of 10 months previously, indicating the long-lasting psychosocial impact of breast cancer recurrence and the potential that intervention could provide a real benefit for these patients.

Interventions to Reduce Psychosocial Distress.

No intervention directed at the needs of patients experiencing a recurrence of breast cancer (or any other cancer) has been reported. However, several reviews, including a recent meta-analysis, have concluded that psychosocial interventions have a positive impact on the well-being of patients across the spectrum of other disease sites and stages. *(12 - 15)* To date, research has not established whether one kind of intervention is more effective than another, or more appropriate for certain patients. A variety of intervention types (e.g., informational, psychological, behavioral, social support) and formats (e.g., group, individual, telephone) have demonstrated beneficial effects. Effects have been demonstrated for quality of life, symptom management, and psychological functioning. The optimal point to evaluate the impact of psychosocial interventions has not been firmly established. Most studies assess outcomes at one or more intervals during the first year post-intervention, although impacts may be long-lasting, even extending to ultimate survival. *(12 - 14, 16)*

This study will draw on an approach that has been found effective by a number of investigators: a brief, time-limited intervention combining information and support delivered by telephone. The telephone is frequently used in providing information regarding cancer treatment and counseling. *(17)* In particular, the telephone may make services available to individuals for whom traveling would pose difficulties because of geography, health, or access to transportation. Other cooperative groups, including the Eastern Cooperative Oncology Group and the Cancer and Leukemia Group B, are currently conducting research protocols utilizing telephone-delivered interventions. However, no other group has focused on patients with recurrence. In fact, patients with recurrence appear to have recourse to few specialized resources. Resource and support programs frequently offer assistance to newly diagnosed patients, hospice patients, and (increasingly) to survivors. Patients going through a recurrence seem to "fall between the cracks."

The Use of Lay Organizations to Provide Support to Breast Cancer Patients.

The intervention will be delivered by women who are particularly well-qualified to provide support and information: breast cancer survivors who have themselves experienced recurrence. A distinctive feature of this study is its delivery of the intervention through an established national breast cancer advocacy and support organization, Y-ME. Although Y-ME has provided telephone hotline services (using a toll-free 800 number) since 1987, the impact of the service has not been systematically assessed. This is also true for other lay programs for breast cancer patients, such as the American Cancer Society's Reach-to-Recovery program. *(23)* This study will utilize breast cancer survivors within the context of a structured protocol, as well as standardized and validated outcome measures. If the program proves effective, it can become part of Y-ME's program and be delivered on a standard basis. The use of a voluntary organization staffed with non-health professionals represents a cost-effective approach to providing support. Y-ME has participated in a Southwest Oncology Group Lay Advisors/Advocates Steering Committee for the past two

years. The lay advisors (who include representatives of national organizations and volunteers selected through a nationwide search) are special members of the Group, serve as members of Disease and other Committees (including the Committee on Women's Health and the Breast Cancer Committee), and attend semi-annual Group meetings. The lay advisors contributed to the development and design of this protocol.

This study will provide information about how to improve well-being during a portion of the breast cancer trajectory where little attention has been focused. The project utilizes a cost-effective approach to intervention with demonstrated usefulness in cancer patients. The intervention will be delivered by individuals who are especially well-qualified to provide support: women who themselves have experienced breast cancer recurrence. This project represents one of the first formal research collaborations between a clinical cooperative research group and a lay breast cancer organization. Southwest Oncology Group staff will be responsible for having patients complete the baseline assessment package in the clinic, for mailing follow-up questionnaires, and for monitoring the return of questionnaires from patients. The project reflects the overriding motivation of both groups: to provide the best possible care and support to cancer patients.

This study was designed to include minorities, but was not designed to measure differences of intervention effects.

3.0 DRUG INFORMATION

There is no drug information for this study.

4.0 STAGING CRITERIA

There are no staging criteria for this study.

5.0 ELIGIBILITY CRITERIA

Each of the criteria in the following section must be met in order for a patient to be considered eligible for registration. Use the spaces provided to confirm a patient's eligibility. For each patient, this section must be photocopied, completed and submitted to the Statistical Center (see Section 14.4).

SWOG Patient No. _____

Patient's Name _____

_____ 5.1 Patient must have received definitive surgical treatment for Stage I, II or IIIa breast cancer, with or without adjuvant chemotherapy, hormonal therapy and/or radiation therapy.

_____ 5.2 Patient must have been informed of her first recurrence of breast cancer within the past 56 days. "First recurrence" is defined as any distant metastatic site, or chest wall recurrence, or scar recurrence, or nodal recurrence. Ipsilateral breast tumor recurrence following lumpectomy, and isolated contralateral new primary breast cancers are excluded. NOTE: We suggest not approaching the patient within the first three weeks post-diagnosis. See Section 7.1 for further suggestions about approaching the patient.

Date patient informed of her first recurrence _____

_____ 5.3 Patients may be receiving or planning to receive their FIRST treatment for this recurrence. Patients who have completed their first regimen for this recurrence are not eligible. Exceptions: Patients may have had prior surgical treatment for in-breast relapse following lumpectomy, and patients may have completed local palliative RT.

Date patient to begin her FIRST treatment for this recurrence _____

_____ 5.4 Patients must be female.

_____ 5.5 Patients must not have a current psychiatric diagnosis that would interfere with their ability to participate in the intervention.

_____ 5.6 Patients must be able to read and understand English.

_____ 5.7 Patients must have completed the baseline packet of questionnaires (CARES-SF, CES-D, Psychosocial Questionnaire, and Support Services Form) within 7 days prior to registration in order to be eligible.

Date questionnaires completed _____

5.8 If Day 7 falls on a weekend or holiday, the limit may be extended to the next working day.

In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test is done on a Monday, the Monday one week later would be considered Day 7. This allows for efficient patient scheduling without exceeding the guidelines.

_____ 5.9 All patients must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines.

_____ 5.10 At the time of patient registration, the date of institutional review board approval for this study must be provided to the Statistical Center.

6.0 STRATIFICATION/DESCRIPTIVE FACTORS/ RANDOMIZATION SCHEME

Participants will be randomly assigned to one of two arms: (a) intervention; or, (b) control. This randomization will be dynamically balanced with respect to the following stratification factors, using the method of Pocock and Simon: *(24)*

a. Age (< 50 vs. ≥ 50)

b. Time since initial diagnosis (< 2 years vs. ≥ 2 years)

c. Recurrence site (soft tissue without bone vs. soft tissue with bone vs. visceral)

NOTE: Visceral takes precedence. The first two categories are only applicable if there is no visceral involvement.

7.0 TREATMENT PLAN

7.1 Approaching Patients for This Study

a. We recommend that you do not approach women about participating in this study during the first three weeks after they have been informed about the recurrence. The patient may not be ready to consider an intervention at this time. If after three weeks, the patient still says no, wait a few weeks longer and ask her again.

b. Explain that this study is comparing the kind of support women seek on their own when informed about a recurrence versus a special program that both organizes existing support and tailors help to the needs of the individual woman.

c. Since we do not know if this special program really does help women more than what they do on their own, we need a "control" group. Women in the control group will continue to make use of existing sources of support. At the end of their study participation (in six months), these women will receive all materials developed for the special counseling group.

d. If randomized to the special counseling program, the patient will be called between four to eight times by a breast cancer survivor who volunteers at Y-ME. Some of these counselors have also had a recurrence. The counselor will discuss a list of issues and problems faced by other women diagnosed with a recurrence, including any area where the patient has concerns. Patients will select which topics they want to spend more time discussing. That is, patients decide to have shorter or longer sessions as long as no more than eight calls occur.

7.2 Main Study Procedures

a. Prior to randomization, all patients will complete baseline questionnaires: CARES-SF, CES-D, Psychosocial Questionnaire, the Support Services Form and the Additional Concerns Form (see Section 18.0).

b. The nurse or CRA will complete the S9832 Prestudy Form and the Quality of Life Cover Sheet for the patient questionnaires.

c. Each institution will provide all patients with a packet of basic information after the baseline questionnaires have been completed. This packet of basic information is compiled locally and should include a copy of the National Cancer Institute (NCI)

booklet, "When Cancer Recurs: Meeting the Challenge Again" (call 1-800-4-CANCER for copies) and/or the Y-ME booklet, "I Still Buy Green Bananas" (call Y-ME 312/986-8338). A list of local and national agencies [e.g., Y-ME, other advocacy groups, American Cancer Society, NCI Cancer Information Service (CIS)], that provide cancer-related information and support, should also be prepared and included in the basic information packet distributed to all study participants. Addresses and/or phone numbers should also be provided. The baseline questionnaires should be completed before a study patient is given the pamphlet(s) and list of resources.

d. The CRA or nurse will phone and fax the names and telephone numbers for patients randomized to the **intervention group only** to Y-ME, so that the Y-ME peer counselor can initiate the intervention. The patients will be informed that a Y-ME peer counselor will be calling in the next few days to begin the intervention.

e. The CRA will inform all patients that they will be mailed questionnaires at two follow-up points after randomization: three months and six months; a self-addressed, stamped envelope will be included for return to the treating institution. The follow-up questionnaires include the CARES-SF, the CES-D, the Support Services Form, the Telephone Counseling Evaluation Form (for patients on the intervention arm) and the Additional Concerns Form. Follow-up questionnaires should be mailed two weeks prior to the scheduled assessment.

f. The S9832 Clinical Update Form and the Quality of Life Cover Sheet for the patient-completed questionnaires should be completed by the nurse or CRA. If the questionnaires are not received within one week after the scheduled assessment, the nurse or CRA should call and remind the patient to submit the questionnaires to the institution. The nurse or CRA should still complete and submit the Cover Sheet for the questionnaires and the Clinical Update Form to the Statistical Center, even if the patient does not submit her questionnaires.

g. The CRA or nurse should call the patient at Month 3 and at Month 6. The CRA or nurse should ask if the patient has received the questionnaires. If the patient has the questionnaires, a time for a telephone interview should be arranged; ask the woman to complete the questionnaires prior to the date. At the time the telephone interview occurs, the CRA or nurse should go over each questionnaire, asking the patient if she has answered all questions. The CRA or nurse should ask each question on the Telephone Counseling Evaluation Form, encouraging the patient to note positive and negative views about the intervention. The patient should be directed to return the envelope with the questionnaires to the treating institution.

7.3 The Telephone Intervention

Patients in the intervention group will receive four to eight counseling/information sessions delivered by telephone at weekly intervals; at least one call and no more than two calls will occur per week. A standardized intervention protocol will be used, with the time of each session decided by the patient and counselor. Each session will focus on different problem areas from the group listed below. Each patient will be given a choice about the order in which the sessions are presented, allowing each woman to prioritize her own concerns.

The content of the intervention sessions is as follows:

Get acquainted; provide overview of sessions; set priorities and order for the topics to be discussed.

Physical problems: symptom control, treatment issues.

Social support: understanding reactions of other people, how to build a social support network.

Existential concerns: spiritual concerns, activities that may be helpful (e.g., recording one's own oral history), the importance of hope.

Stress management: approaches that may be helpful, including relaxation, visualization, exercise (with physician supervision), healthy eating.

Closure and debriefing.

Each session will provide basic information and an opportunity for the patients to discuss individual concerns. The general format for the intervention sessions will be to provide information in specified areas, active listening when the women discuss their concerns, assistance in problem-solving (particularly to help the women define and prioritize their own solutions to problems), and information about resources that may be helpful (books and other written or audiovisual materials, local resources). Patients will be provided with information about local or national resources, addressing areas of concern as appropriate.

The intervention is not designed to provide psychotherapy. Instead, the Y-ME peer counselors will provide information, peer support, and referrals to community organizations. Procedures currently in place at Y-ME will be used if serious psychological disturbance is detected during a telephone session. In such cases, patients will be asked if the Y-ME peer counselor may contact the Southwest Oncology Group physician who enrolled her on the study.

After the first session, the patients will be sent a standardized packet of written or audiovisual materials to reinforce what was discussed during the session and provide additional information. The Study Coordinator will send the women in the Control arm the standardized Y-ME packet of written materials after the six month assessment has been received.

7.4 Women may withdraw from this study at any time should they wish to do so. Please document the reason for withdrawal on the Quality of Life Cover Sheet submitted with each of the three sets of questionnaires.

7.5 Patients will go off study after six months (see Section 14.7). No further follow-up will be required.

8.0 DOSAGE MODIFICATIONS AND TOXICITIES TO BE MONITORED

There are no dose modifications or toxicities associated with this study.

9.0 STUDY CALENDAR "Enhancing Well-Being During Breast Cancer Recurence"

REQUIRED STUDIES	PRE STUDY	Wk 1	Wk 2	Wk 3	Wk 4	Mo 3	Mo 6
ASSESSMENTS Ω							
CARES-SF	X					X	X
CES-D	X					X	X
Support Services Form	X					X	X
Psychosocial Questionnaire Form	X						
Telephone Counseling Evaluation Form						X	X
S9832 Prestudy Form	X						
S9832 Clinical Update Form						X	X
Quality of Life Cover Sheet	X					X	X
Additional Concerns Form	X					X	X
THERAPY							
Basic Information Packet	Xπ						
Standardized Y-ME Packet ¥	X¥						X¥
Telephone Counseling Sessions		Xf	Xf	Xf	Xf		

Ω Forms are found in Section18.0. (See Section 14.0 for data submission guidelines and Section 15.0 for QOL Assessment instructions.)

f Intervention arm patients only. Four to eight sessions can occur during the four week period.

π See Section 7.2c.

¥ The standardized Y-ME packet will be sent by Y-ME to women on the intervention arm after the first session. This packet will be sent by the Study Coordinator to women on the Control arm after the six month assessment has been received.

10.0 MEASUREMENTS OF EFFICACY AND ENDPOINT DEFINITIONS

10.1 The primary outcome is well-being (CARES-SF psychosocial functioning and depression) three months post-enrollment on the study.

a. CARES-SF Psychosocial score of ≥ .615

The Cancer Rehabilitation Evaluation System - Short Form (CARES-SF) yields both a total score and five subscales: physical aspects, psychosocial concerns, medical interaction, marital problems, and sexual issues. It is a newly developed, brief form of the CARES. *(25 - 26)* Data supporting the measurement properties of this questionnaire are primarily documented for the long form (i.e., the CARES). However, the CARES-SF correlates well with the CARES. *(25)* In a number of studies, the full CARES has been shown to be valid and reliable. *(27 - 32)* It differs from other quality of life instruments by providing more concrete information about patient experiences. Normative information is available, including a recent study in breast cancer survivors one, two, and three years post-diagnosis, which demonstrates that the CARES is responsive to change. *(32)*

The CARES-SF contains a minimum of 38 and a maximum of 57 items. The exact number varies because of skip patterns related to patient-specific experiences. Respondents rate how great a problem they find in specified areas on five-point scales. *(25)* A CARES Psychosocial score of .615 or greater has been found to correctly classify breast cancer patients "at risk" for psychosocial distress, as identified in a comprehensive clinical interview by a social worker. The estimated probability of classifying women in the high risk group was .81 in a recursive partitioning model. *(30)* Given the correlation between the CARES and the CARES-SF, we will use a CARES-SF cutoff score of .615.

b. Depression. Depression will be assessed by a score above 16 on the Center for Epidemiological Studies - Depression (CES-D) scale. *(1, 33 - 38)*

The CES-D has been extensively used in both community and patient populations, including cancer patients. *(1, 33 - 38)* It includes 20 symptom-related items. Respondents rate the frequency of having experienced these symptoms during the past week on four point scales. In many studies, the scale has been shown to distinguish reliably among in-patient populations and to be sensitive to changes over time. The interpretation of scores is also facilitated by a score "cutoff" of 16 (which reflects that 6 of 20 symptoms are at least moderately persistent). Persons scoring above this cutoff are likely to be classified as clinically depressed when they receive a full clinical evaluation. In this study, the CES-D will be used to designate patients who score above (at risk of depression) or at or below the cutoff score (not at risk of depression).

10.2 Longer-term quality of life. Scores for the two quality of life endpoints described above will also be examined at 6 months post study entry. The CARES-SF total score will also be examined at 3 and 6 months.

10.3 Evaluation of Intervention. The intervention will be evaluated through scores on the Telephone Counseling Evaluation Form at 3 months.

The Telephone Counseling Evaluation Form will provide information about the patient's overall appraisal of the intervention, primarily to provide concrete information about what the participants found helpful, and what areas could be improved to aid in future interventions. At study entry, 3 months and 6 months, all patients will also complete the Support Services Form regarding their use of community services and other forms of assistance (e.g., support groups, church groups, counseling) during the previous six months, and whether they have used Y-ME resources. Since Y-ME has a national

hotline, it is possible that patients in either group could call Y-ME for (additional) assistance. Patients in the intervention group will not be able to access their peer counselor delivering the intervention except during the scheduled sessions.

10.4 Psychosocial Predictors. A Psychosocial Questionnaire will be used to examine possible predictors of well-being. These include:

a. Social support will be measured by the total score on Reynolds et al.'s four-item scale found to predict breast cancer survival. *(39)*

b. Optimism-pessimism

Optimism-pessimism will be measured by using the total score on the Life Orientation Test (LOT). This 8-item scale has been demonstrated to have high levels of internal consistency and test-retest validity in breast cancer patients. *(40)* In a recent study, Carver et al. found that scores on this scale predicted breast cancer survival. *(41)*

c. Surprisingness of the recurrence

How surprising the recurrence was will be measured by the score on a single question. Cella et al. found this question correlated with recurrence distress. *(8)*

d. Sense of Coherence

The meaning of their recurrence to the patients will be measured by the total score on Antonovsky's Sense of Coherence Scale (SOC); this is one of the few available scales to focus on existential concerns. *(42)* We will use the short form of this scale (13 items), which has demonstrated high internal consistency and construct validity. *(43 - 44)*

10.5 Current Cancer Treatment. A form will be used to ascertain current cancer treatments at study entry (**S9832** Prestudy Form), and at 3 and 6 months (**S9832** Clinical Update Form). This information may help to identify subgroups of interest (e.g., women who receive high dose chemotherapy with stem cell support).

11.0 STATISTICAL CONSIDERATIONS

11.1 Sample size: 300 patients will be randomly assigned to either the intervention or control group in order to yield 255 study participants at the 3-month evaluation point. This estimate is based on previous Southwest Oncology Group studies which include repeated quality of life questionnaires with a completion rate in excess of 85%. *(45)*

11.2 Power Calculations: Primary Analyses. Power calculations indicate that a sample size of 255 at three months is sufficient to test intervention versus control group differences outlined below for the two primary endpoints: 3-month CARES-SF Psychosocial Summary cut-off score and 3-month CES-D cut-off score. All estimates use one-tailed tests. An alpha level of .025 (.05 divided by 2) will be used to adjust for the two planned comparisons.

CARES-SF Psychosocial Summary Cut-off Score. Patients with a 3 month CARES-SF psychosocial summary score greater than or equal to .615 will be considered at risk for

psychosocial distress, whereas patients with a psychosocial score less than .615 will be considered not at risk. Fifty percent of patients on the control arm are expected to have subscale scores above .615, whereas a smaller proportion of intervention arm patients should score above .615 on this subscale. Table 1 shows the power the study has to detect group differences based on varying percentages of patients at risk.

CES-D Score. Patients with a 3 month CES-D score greater than 16 will be considered at risk for depression, whereas patients with a CES-D score less than or equal to 16 will be considered not at risk. A recent study by Lewis and Deal found that 40% of 15 women with a breast cancer recurrence had CES-D scores above 16. *(1)* The patients in this study were a median of 10 months post-recurrence diagnosis. Given that the women in this study will be newly diagnosed with recurrence, we expect that at least 40% of the control group to score "at risk," with the proportion at risk more likely to be 50 or 60%. We expect patients in the intervention arm to be significantly more likely to have scores below the cutoff. Table 1 provides power to detect group differences.

Table 1:

Power to Detect Group Differences Based on Varying percentages of Patients

Percentage of Patients:* Intervention Group	Percentage of Patients:* Control Group	Power
.20	.40	.90
.29	.50	.90
.39	.60	.90
.44	.65	.90

*Percentages represent patients who score above the cutoff (.615 for the CARES-SF Psychosocial Summary score, 16 for the CES-D)

11.3 Secondary Analyses. The CARES-SF Mean Score (total score) will be used to explore whether patients receiving the telephone intervention show mean improvement in overall quality of life than patients not receiving the intervention. Descriptive statistics for patients' sociodemographic and clinical information and psychosocial predictors will also be reported along with the 3 and 6 month descriptive results for the primary endpoints. The three well-being scales will be used as dependent variables in regression analyses to explore the effect of sociodemographic, clinical, and baseline psychosocial predictors on the efficacy of the intervention. Logistic regression will be used to examine the predictors for scoring above or below the cutoffs on the CARES-SF psychosocial summary score and the CES-D scores. Least-squares regression will be used to examine the predictors for the CARES-SF total score. Independent predictors considered will include sociodemographics (age, education, marital status, ethnicity), clinical variables (stage of disease, time since diagnosis, site of recurrence, treatments received, history of psychiatric dysfunction) and psychosocial predictors (social support, optimism-pessimism, how surprising the recurrence was, sense of coherence). Both univariate analyses and stepwise regression will be used to investigate the relationships among the predictors and the endpoints in order to identify a more parsimonious group of predictors. In addition, statistical methods for the exploration of longitudinal data will be applied to model within-patient changes in scores over time. *(46 - 49)*

11.4 Study Duration. Accrual for this study is 30 months, with an expected accrual rate of 10 patients per month.

12.0 DISCIPLINE REVIEW

There is no discipline review in conjunction with this study.

13.0 REGISTRATION GUIDELINES

13.1 All patients will be registered with the Southwest Oncology Group Statistical Center by telephoning 206/667-4623, 6:30 a.m. to 5:00 p.m. Pacific time, Monday through Friday, excluding holidays. Patients must be registered prior to the initiation of treatment (no more than one working day prior to submitting the fax to Y-ME - see Section 7.0).

13.2 At the time of registration, the caller must have completed the Registration Form.

13.3 The caller must also be prepared to provide the date of institutional review board approval for this study. Patients will not be registered if the IRB approval date is not provided or is > 1 year prior to the date of registration. The caller must also confirm that a list of local resources to provide support to breast cancer patients is available at the institution.

13.4 Exceptions to the current registration policies will not be permitted. Therefore, exceptions to eligibility requirements, participation by an institution/member not identified as eligible AND/OR cancellations will not be allowed.

14.0 DATA SUBMISSION SCHEDULE

14.1 Data must be submitted according to protocol requirements for **ALL** patients registered, whether or not intervention sessions are completed, including patients deemed to be ineligible.

14.2 Master forms are included in Section 18.0 and (with the exception of the sample consent form) must be photocopied for data submission to the Statistical Center.

14.3 Group members and CCOPs must submit one copy of all data forms directly to the Statistical Center in Seattle. CGOPs must submit (number of copies to be determined by the Group member) copies of all forms to their Group institution for forwarding to the Statistical Center.

14.4 WITHIN 14 DAYS OF REGISTRATION:

Submit a copy of the following:

a. Registration Form (Form # 32379).

b. Completed copy of Section 5.0 including patient identifiers.

c. Pre-registration CARES-SF (Form # 2836), CES-D (Form # 55532), Support Services Form (Form # 48909), Psychosocial Questionnaire (Form # 19092), S9832 Prestudy Form (Form # 45674), Quality of Life Cover Sheet (Form # 40404) and Additional Concerns Form (Form # 609).

14.5 AFTER THE MONTH 3 ASSESSMENT:

For all patients: submit the Quality of Life Cover Sheet (Form # 40404), Additional Concerns Form (Form # 609), S9832 Clinical Update Form (Form # 49100), CARES-SF (Form # 2836), CES-D (Form # 55532), and Support Services Form (Form # 48909).

For patients on the intervention arm only: submit the Telephone Counseling Evaluation Form (Form # 57890).

14.6 AFTER THE MONTH 6 ASSESSMENT:

For all patients: submit the Quality of Life Cover Sheet (Form # 40404), the Additional Concerns Form (Form # 609), S9832 Clinical Update Form (Form # 49100), CARES-SF (Form # 2836), CES-D (Form # 55532), and Support Services Form (Form # 48909).

For patients on the intervention arm only: submit the Telephone Counseling Evaluation Form (Form # 57890).

14.7 WITHIN 14 DAYS AFTER THE MONTH 6 ASSESSMENT OR OFF STUDY FOR ANY REASON:

Submit a copy of the Off Treatment Notice (Form # 25524).

15.0 SPECIAL INSTRUCTIONS FOR SOUTHWEST ONCOLOGY GROUP NURSES OR CRAs

[Note: Southwest Oncology Group nurses and CRAs have responsibility for collecting outcome data for this study. The psychosocial intervention will be delivered by Y-ME, a national breast cancer advocacy and support organization.]

15.1 Assessment Schedule

For both arms, the QOL questionnaires must be completed as follows:

a. within seven days prior to randomization (Pre-registration Assessment),

b. month 3,

c. month 6.

The Psychosocial Questionnaire is administered only at study entry. Follow-up questionnaires must be completed at home and returned by mail. Only patients in the intervention arm must complete a Telephone Counseling Evaluation Form at 3 and 6 months.

15.2 General Instructions

a. Remind patients to answer the questions with their first impression and not to spend a lot of time thinking about each question. Remind patients that there are no right or wrong answers for questions addressing patient quality of life. We are interested in their idea or sense about how they are doing.

b. Stress the importance of the quality of life questionnaires for learning more about the problems women face when they have a recurrence. This information can help us design better support programs for future patients.

15.3 Maintaining the QOL Follow-up Assessment Schedule

a. When a patient is randomized to **S9832**, a confirmation of registration with all follow-up QOL assessment dates will be sent to the investigator under whose name the patient was registered. The nurse or CRA should put a copy of these scheduled dates in the patient's folder as a reminder of when to have the patient complete QOL questionnaires.

b. Pre-registration assessments are obtained in the clinic. Make certain that the patient understands how to complete all forms before she leaves the clinic since follow-up questionnaires will be completed at home and mailed to the Southwest Oncology Group institution.

c. Two weeks prior to the 3 and 6 month assessments, mail the questionnaire packets to the patient, and call to remind her of the scheduled assessment. Only patients in the intervention arm should receive the Telephone Counseling Evaluation Form.

d. If a patient refuses or cannot complete the QOL questionnaires for some reason, then this must be documented on the Quality of Life Cover Sheet and mailed to the Statistical Center as soon as this information is known.

e. If a patient refuses or cannot complete the QOL questionnaire at one time point, she should be asked to do so at the next scheduled administration time.

f. Questionnaires should be completed even if an intervention arm patient does not complete the intervention, if the patient is willing.

15.4 Standardizing the Administration of Questionnaires

a. Please read all instructions to the patient that are part of the QOL Questionnaires. Make certain that the patient understands the different sections of the questionnaire, as the format for providing answers varies. For example, in the CARES-SF, ensure that the patient understands the concept of skip patterns (if the answer to a question is no, skip to item ---). Explain the specific administration times for this protocol. It should take approximately 20 minutes for the patient to complete the questionnaire.

b. Patients should be directed to report all symptoms and limitations whether or not related to the cancer or its treatment.

c. When questionnaires are completed in your presence, it is permissible to assist the patient with completing the questionnaire, being careful not to influence the patient's response. Note on the Cover Sheet what assistance was required and indicate the reason (e.g., forgot glasses, too sick, etc.). Discourage family members from 1) being present while the patient completes the questionnaire and/or 2) influencing patient responses. The Southwest Oncology Group QOL Assessment Training Video available to all Southwest Oncology Group institutions provides guidance in this area.

15.5 Additional Quality Control Issues

a. It is very important to review the questionnaire after the patient has completed the form to be sure all of the questions have been answered, and that only one answer has been marked. For mailed follow-up questionnaires, it is important to review the mailed questionnaires as soon as they arrive.

b. If the patient has marked more than one answer per question, ask the patient which answer best reflects how she is feeling. For mailed questionnaires, a

phone call can be made to the patient to clarify the multiple response. Once the patient has selected one response, mark this clearly on the questionnaire and put your initials and the date.

c. If the patient has skipped a question, inform the patient that the question was not answered, and ask if she would like to answer it. Always give the patient the option to refuse. Make a note in the margin by the particular item that the patient did not want to answer this question. This issue can also be clarified by phone if the questionnaire was mailed.

d. For each scheduled QOL assessment, complete a cover sheet, attach it to the QOL questionnaires, sign it, and mail it on the day the data are obtained from the patient (or the day you receive the data by mail). See Section 14.0 for data submission guidelines. The person signing the Cover Sheet (or the person who registered the patient) may be called if there are questions regarding QOL questionnaires or cover sheets. For mailed questionnaires, attach a cover sheet to the questionnaires and check the "Other" category under where the questionnaires were administered. If questionnaires were not completed, return the Cover Sheet, indicating the reason for the missing questionnaires.

e. The QOL liaison or one oncology nurse or CRA from any institution registering patients on **S9832** must attend one QOL assessment training session held at each of the biannual Southwest Oncology Group meetings. Most data management institutions have received a copy of the QOL Assessment Training Video. If your institution does not have a copy, please contact the data management institution to which you submit data to and borrow their copy, or contact the Operations Office to request a copy. The training video helps standardize instructions for obtaining the QOL data and handles staff turnover training needs between Southwest Oncology Group meetings.

15.6 When the patient's questionnaires are received, the CRA or nurse should note in the forms any questions that the patient did not want to answer.

15.7 Questions regarding QOL assessments can be directed to the Study Coordinator, Carolyn Gotay, Ph.D. (808/586-2975) or Carol M. Moinpour, Ph.D. at the Statistical Center (206/667-4623).

15.8 Identification and Training of Women to Deliver the Intervention:

a. Women will be recruited to be peer counselors through Y-ME's current screening, interview, and assessment procedures. Additional criteria for peer counselors are one or more breast cancer recurrences and a score less than 16 on the CES-D.

b. The peer counselors will attend a training course in how to deliver the intervention.

c. The training program for the individuals delivering the intervention will be based on Y-ME's current training model, which covers counseling skills, Y-ME Hotline volunteer regulations, and related medical information (glossary of medical terms, supplemental readings such as the PDQ for breast cancer) and a take-home exam.

d. The Y-ME quality assurance program includes a test scenario (where the peer counselor conducts a sample interview in the presence of the supervisor) and an evaluation of actual performance (through a simulated breast cancer patient

telephone call made by a supervisor). These procedures will be maintained, with the quality assurance testing occurring annually.

e. The trainees will be provided with National Cancer Institute materials regarding recurrence and clinical trials.

f. The trainees will be required to pass an exam before they can provide the intervention.

g. The peer counselors will be required to complete 6 hours of continuing education per year.

16.0 ETHICAL AND REGULATORY CONSIDERATIONS

The following must be observed to comply with Food and Drug Administration regulations for the conduct and monitoring of clinical investigations. They also represent sound research practice:

Informed Consent

The principles of informed consent are described by Federal Regulatory Guidelines (Federal Register Vol. 46, No. 17, January 27, 1981, part 50) and the Office for Protection from Research Risks Reports: Protection of Human Subjects (Code of Federal Regulations 45 CFR 46). They must be followed to comply with FDA regulations for the conduct and monitoring of clinical investigations.

Institutional Review

This study must be approved by an appropriate institutional review committee as defined by Federal Regulatory Guidelines (Ref. Federal Register Vol. 46, No. 17, January 27, 1981, part 56) and the Office for Protection from Research Risks Reports: Protection of Human Subjects (Code of Federal Regulations 45 CFR 46).

Adverse Experiences

There are no commercial or investigational agents used in conjunction with this study.

17.0 BIBLIOGRAPHY

1. Lewis FM, Deal LWE. Balancing our lives: A study of the married couple's experience with breast cancer recurrence. Oncology Nursing Forum 22;943-953, 1995.

2. Lasry J-C, Margolese RG. Fear of recurrence, breast-conserving surgery, and the trade-off hypothesis. Cancer 69;2111-2115, 1992.

3. Noguchi M, Saito Y, Nishijima H, et al. The psychological and cosmetic aspects of breast conserving therapy compared with radical mastectomy. Surgery Today 23;598-602, 1993.

4. Lampic C, Wennberg A, Schill JE, et al. Anxiety and cancer-related worry of cancer patients at routine follow-up visits. Acta Onc 33;119-125, 1994.

5. Haltutten A, Hietane, P, Jallinoja P, et al. Getting free of breast cancer: An eight-year perspective of the relapse-free patients. Acta Onc 31;307-310, 1992.

6. Worden JW. The experience of recurrent cancer. Journal of Psychosocial Oncology 3;5-16, 1986.

7. Worden JW. The experience of recurrent cancer. CA-A Cancer Journal for Clinicians 39;305-310, 1989.

8. Cella DF, Mahon SM, Donovan MI. Cancer recurrence as a traumatic event. Behavioral Medicine 16;15-22, 1990.

9. Mahon SM, Cella DF, Donovan MI. Psychosocial adjustment to recurrent cancer. Oncology Nursing Forum 17;47-52, 1990.

10. Silberfarb PM, Maurer H, Crouthamel CS. Psychosocial aspects of neoplastic disease: I. Functional status of breast cancer patients during different treatment regimens. American Journal of Psychiatry 137;450-455, 1980.

11. Jenkins PL, May VE, Hughes LE. Psychological morbidity associated with local recurrence of breast cancer. International Journal of Psychiatry in Medicine 21;149-155, 1991.

12. Andersen BL. Psychological interventions for cancer patients to enhance quality of life. Journal of Consulting and Clinical Psychology 60;552-568, 1992.

13. Trijsburg RW, van Knippenberg FCE, Rijpma SE. Effects of psychological treatment on cancer patients: A critical review. Psychosomatic Medicine 54;489-517, 1992.

14. Fawzy FI, Fawzy NW, Arndt LA, Pasnau RO. Critical review of psychosocial interventions in cancer care. Archives of General Psychiatry 52;100-113, 1995.

15. Meyer TJ, Mark MM. Effects of psychosocial interventions with adult cancer patients: A meta-analysis of randomized experiments. Health Psychology 14;101-108, 1995.

16. Spiegel D, Kraemer HC, Bloom JR, et al. Effects of psychosocial treatment on survival of patients with metastatic breast cancer. Lancet 2;888-891, 1989.

17. Alter CL, Fleishman SB, Kornblith AB, et al. Supportive telephone intervention for patients receiving chemotherapy: A pilot study. Psychosomatics (in press).

18. Anderson DM, Duffy K, Hallett CD, Marcus AC. Cancer prevention counseling on telephone hotlines. Public Health Reports 107;278-283, 1992.

19. Hagopian GA, Rubenstein J. Effects of telephone call interventions on patients' well-being in a radiation therapy department. Cancer Nursing 13;339-344, 1990.

20. Mermelstein HT, Holland JC. Psychotherapy by telephone: A therapeutic tool for cancer patients. Psychosomatics 32;407-412, 1991.

21. Nail LM, Greene D, Jones LS, Flannery M. Nursing care by telephone: Describing practice in an ambulatory oncology center. Oncology Nursing Forum 16;387-395, 1989.

22. Rainey LC. Cancer counseling by telephone help-line: the UCLA psychosocial cancer counseling line. Public Health Reports 100;308-315, 1985.

23. Willits MJ. Role of "Reach to Recovery" in breast cancer. Cancer 74;2172-2173, 1994.

24. Pocock SJ, Simon R. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. Biometrics 31;103-115, 1975.

25. Schag CAC, Ganz PA, Heinrich RL. Cancer Rehabilitation Evaluation System - Short Form (CARES-SF): A cancer specific rehabilitation and quality of life instrument. Cancer 68;1406-1413, 1991.

26. Ganz P.A., Schag CA, Lee JJ, Sim MS. The CARES: A generic measure of health-related quality of life for patients with cancer. Quality of Life Research 1;19-29, 1992.

27. Schag CAC, Heinrich RL, Aadland RL, Ganz, PA. Assessing problems of cancer patients: Psychometric properties of the Cancer Inventory of Problem Situations. Health Psychology 9;83-102, 1990.

28. Schag CC, Heinrich RL, Ganz PA. The Cancer Inventory of Problem Situations: An instrument for assessing cancer patients' rehabilitation needs. Journal of Psychosocial Oncology 1;11-24, 1983.

29. Ganz PA, Schag CC, Cheng H. Assessing the quality of life: A study in newly diagnosed breast cancer patients. Journal of Clinical Epidemiology 43;75-86, 1990.

30. Ganz PA, Hirji K, Sim M-S, et al. Predicting psychosocial risk in patients with breast cancer. Medical Care 31;419-431, 1993.

31. Schag CAC, Ganz PA., Polinsky ML, et al. Characteristics of women at risk for psychosocial distress in the year after breast cancer. Journal of Clinical Oncology 11;783-793, 1993.

32. Ganz PA, Coscarelli A, Fred C, et al. Breast cancer survivors: Psychosocial concerns and quality of life. Breast Cancer Research & Treatment 38;183-199, 1996.

33. Comstock CW, Helsing KJ. Symptoms of depression in two communities, Psychological Medicine 6;551-563, 1976.

34. Weissman MM, Sholomskas D, Pottenger M, et al. Assessing depressive symptoms in five psychiatric populations: A validation study. American Journal of Epidemiology 106;203-214, 1977.

35. Challis G B, Stam HJ. A longitudinal study of the development of anticipatory nausea and vomiting in cancer chemotherapy patients: The role of absorption and autonomic perception. Health Psychology 11;181-189, 1992.

36. Edgar L, Rosberger Z, Nowlis D. Coping with cancer during the first year after diagnosis. Cancer 69;817-828, 1992.

37. Fobair P, Hoppe RT, Bloom JR. Psychosocial problems among survivors of Hodgkin's disease. Journal of Clinical Oncology 4;805-814, 1986.

38. Gritz ER, Wellisch DK, Landsverk JA. Psychosocial sequalae in long-term survivors of testicular cancer. Journal of Psychosocial Oncology 6;41-63, 1988.

39. Reynolds P, Boyd PT, Blacklow RS, et al. The relationship between social ties and survival among black and white cancer patients. Cancer Epidemiology, Biomarkers, and Prevention 3;253-259, 1994.

40. Scheier MF, Carver CS. Optimism, coping, and health: Assessment and implications of generalized outcome expectancies. Health Psychology 4;219-247, 1985.

41. Carver CS, Pozo-Kaderman C, Haris SD, et al. Optimism vs. pessimism predicts the quality of women's adjustment to early stage breast cancer. Cancer 73;1213-1220, 1994.

42. Antonovsky A. Health, stress, and coping. San Francisco: Jossey-Bass, 1979.

43. Antonovsky A. The structure and properties of the Sense of Coherence scale. Social Science & Medicine 36;725-733, 1993.

44. Chamberlain K, Petrie K, Azariah R. The role of optimism and sense of coherence in predicting recovery following surgery. Psychology and Health 1;1992.

45. Hayden KA, Moinpour CM, Metch B, et al. Pitfalls in quality-of-life assessment: Lessons from a Southwest Oncology Group breast cancer clinical trial. Oncology Nursing Forum 20;1415-1419, 1993.

46. NM, Ware JH. Random effects models for longitudinal data. Biometrics 38;963-974, 1982.

47. Ware JH. Linear models for the analysis of longitudinal data. The American Statistician 41;95-101, 1985.

48. Diggle PJ, Liang KY, Zeger SL. Analysis of Longitudinal Data. Oxford: Oxford Science Publications, 1994.

49. Little RJA, Rubin DB. Statistical Analysis with Missing Data. New York: John Wiley & Sons, 1987.

18.0 MASTER FORMS SET

18.1 This section contains the Model Informed Consent Form. The consent form must be reviewed and approved by the Institutional Review Board prior to registration of patients on this study.

18.2 Southwest Oncology Group Registration Form (Form # 32379)

18.3 CARES-SF (Form # 2836)

18.4 CES-D (Form # 55532)

18.5 Support Services Form (Form # 48909)

18.6 Psychosocial Questionnaire (Form # 19092)

18.7 Quality of Life Cover Sheet (Form # 40404)

18.8 S9832 Prestudy Form (Form # 45674)

18.9 S9832 Clinical Update Form (Form # 49100)

18.10 Telephone Counseling Evaluation Form (Form # 57890)

18.11 Additional Concerns Form (Form # 609)

18.12 Off Treatment Notice (Form # 25524)

This model informed consent form has been reviewed by the DCT/NCI and is the official consent document for this study. Local IRB changes to this document are allowed. (Institutions should attempt to use sections of this document which are in bold type in their entirety.) Editorial changes to these sections may be made as long as they do not change information or intent. If the institutional IRB insists on making deletions or more substantive modifications to the risks or alternatives sections, they may be justified in writing by the investigator and approved by the IRB. Under these circumstances, the revised language, justification and a copy of the IRB minutes must be forwarded to the Southwest Oncology Group Operations Office for approval before a patient may be registered to this study.

CONSENT FORM AND INFORMATION ABOUT

S9832 "Enhancing Well-Being During Breast Cancer Recurrence"

TO BE CONDUCTED AT

_____

_____

I. **You are invited to take part in this research study because you have breast cancer that has come back after previous treatment. The purpose of this study is to learn how to help breast cancer patients to deal with the stresses of recurrence. This study is comparing whether a special program that offers assistance by phone from a breast cancer survivor is more helpful than what women do on their own.**

We cannot and do not guarantee you will benefit if you take part in this study. If you take part in this study, the program may help you better cope with the stress of this time.

II. First, you will be asked to complete several questionnaires. The questions ask about how you are feeling and problems you may have experienced related to your cancer. They will take about 45 minutes to complete.

You will be randomly assigned to "standard care" or the telephone counseling program. Random assignment is similar to flipping a coin. You will have a equal chance of being in either group. By "standard care", we mean the support you seek on your own thorugh your hospital, home health care providers, family, and friends. If you are in the telephone counseling group, you will have the opportunity to talk with a "peer counselor". A peer counselor is a woman who, like you, has had breast cancer and may also have had a recurrence of her breast cancer. Your peer counselor will call you on the telephone for four to eight sessions over a four-week period. The number of sessions will be decided by you and the counselor, but at least one session will occur each week. Some of these sessions may be taped to help train the peer counselors. The Study Coordinators and supervisors at Y-ME are the only people who will listen to the tapes. All tapes will be destroyed after they have been reviewed. Your counselor will discuss concerns that women with breast cancer recurrence often have. You will have a chance to ask questions and talk with her. These sessions could cover any of the following: physical problems, social support, spiritual concerns and/or stress management. She will be calling from the Y-ME national offices. Y-ME is a national organization that gives support to breast cancer patients. The length of the sessions will be your decision, depending on which topics you wish to discuss in more detail. That is, you can have four longer calls or six shorter calls or some combination. Your peer counselor has received special training so that she can offer up-to-date information. She will mail you a packet of materials after the first session. *(12/1/98)*

Initial of Witness: _____ Date : _____
Initial of Subject : _____ Date: _____

We'll ask you to fill out a survey two and five months after the last session of the program. The survey asks how you are doing. This information will help us to learn whether the program is helpful and would be useful for future patients. For women who took part in the program, we will also ask what you thought of it. A Clinical Research Associate at your hospital will contact you to give you the survey. Filling it out should take half an hour or less. After the last questionnaire, the women who received standard care will receive the same packets of materials that the women in the program received earlier.

This study and these materials will be provided at no cost to you.

III. **You may be asked to answer questions about private matters, which could cause you to feel a loss of privacy. It is possible that the program, or answering questions about how you are doing could make you feel uncomfortable, and you are encouraged to talk about this with the peer counselor and Clinical Research Associate. You may also skip any questions you prefer not to answer and you are free to stop your participation at any time.**

IV. **There may be other solutions for your stress, such as participating in other counseling programs or support groups. It is not known if the support you receive will offer any increased benefit than that currently available outside of participation in this research. If you feel you need additional support, please contact the physician or Clinical Research Associate who referred you to this study for a list of local resources. The costs of participating in other counseling programs or support groups will be your responsibility.**

V. We will keep any information we learn from this study confidential and disclose it only with your permission. By signing this form, however, you allow us to make your records available to the National Cancer Institute, the U.S. Army Medical Research and Materiel Command and the Southwest Oncology Group. If we publish the information we learn from this study in a medical journal, you will not be identified by name. You may request a copy of the study results after the study is finished.

VI. In the event of injury or illness resulting from the research procedures, emergency medical treatment will (or will not) be provided without cost. Continuing medical care and/or hospitalization will not be provided free of charge but must be paid for in the same way your regular medical care is paid. The Quality of Life Questionnaire and routine follow-up by the nurse will be provided to you free of charge. We cannot pay you to take part in these studies. The parts of the research consisting of keeping research records will be paid by those organizing and conducting the research.

VII. Whether or not you take part in this study will not affect your future relations with your doctors (there will be no loss of benefit or change in attitude) or _____ (hospital name). If significant new findings are developed during the course of this study which may relate to your willingness to continue, this information will be provided to you. In addition, you understand that you may refuse to continue on this study at any time, without fear of prejudice to additional treatment that may be needed.

Initial of Witness: _____ Date : _____
Initial of Subject : _____ Date: _____

VIII. The doctor(s) involved with your care can answer any questions you may have about this study. In case of a problem or emergency, you can call the doctors listed below day or night.

	Office	Home
Dr.		
Dr.		
Dr.		

You can also call the Institutional Review Board (#_____) if you have any questions, comments or concerns about the study or your rights as a research subject.

IX. We will give you a copy of this form to keep.

X. You are deciding whether or not to take part in this study. If you sign below, it means that you have decided to volunteer for this study after reading and understanding all the information on this form.

Date	Signature of Subject *Subject's Name:
Time	Signature of Investigator *Investigator's Name:
Subject's Address (type/print)	Signature of Witness *Witness' Name:

*Type or Print Full Name

Southwest Oncology Group Statistical Center
1100 Fairview Avenue North, MP557
PO Box 19024
Seattle, WA 98109-1024
Patient Registration (206) 667-4623

Southwest Oncology Group Operations Office
14980 Omicron Drive
San Antonio, TX 78245-3217
(210) 677-8808

Southwest Oncology Group Registration Form

SWOG Protocol Number S 9 8 3 2 | **Registration Step** 1 | **Tx Assignment** ☐ | **Activation Date:** July 15, 1998 | **Last Amended Date:**

Enhancing Well-Being During Breast Cancer Recurrence

Affix Patient Label Here OR

Patient Name _____

Patient Number _____

INSTRUCTIONS: All of the information on this Registration Form and Protocol Eligibility Section 5.0 must be answered appropriately for a patient to be considered eligible for registration. The registration form must be entirely filled out and referred to during the registration. A copy must be submitted with the prestudy form and pathology report(s). For optimum accuracy, use black ink, print in CAPITAL LETTERS, and avoid contact with the edges of the boxes. The following will serve as a numeric example:

0 1 2 3 4 5 6 7 8 9

Caller's SWOG Roster ID ☐☐☐☐☐

SWOG Investigator Number ☐☐☐☐☐

SWOG Institution Number ☐☐☐☐☐

IRB Approval Date ☐☐ / ☐☐ / ☐☐☐☐

Date of Informed Consent ☐☐ / ☐☐ / ☐☐☐☐

Projected Start Date of Treatment ☐☐ / ☐☐ / ☐☐☐☐

Patient Name (last, first, middle):

Patient's Date of Birth: ☐☐ / ☐☐ / ☐☐☐☐ **Patient's Race / Ethnicity:** ☐☐ / ☐☐

Patient's Sex: ☐ Female ☐ Male **Method of Payment:** ☐☐

Patient's Social Security Number: ☐☐☐ - ☐☐ - ☐☐☐☐

Patient's Zip Code (USA): ☐☐☐☐☐ **Country of Residence (if not USA):**

Height (cm): ☐☐☐ **Weight (kg):** ☐☐☐.☐ **BSA (m2):** ☐.☐☐ **Performance Status:** ☐

Age: ☐ <50 ☐ ≥50 **Time Since Initial Diagnosis:** ☐ <2 years ☐ ≥2 years

Recurrence Site: ☐ Soft tissue only ☐ Bone ± soft tissue ☐ Visceral ± soft tissue ± bone

32379

Southwest Oncology Group Registration Form Code Sheet

Patient's race:

0 - Unknown	1 -Caucasian	2 - African American	3 - Native American
4 - Eskimo	5 -Aleut	6 - Chinese	7 - Filipino
8 - Hawaiian	9 - Korean	10 - Vietnamese	11 - Japanese
12 - Asian Indian	13 - Samoan	14 - Guamanian	15 - Hmong
16 - Fijian	17 - Laotian	18 - Thai	19 - Tongan
20 - Pakistani	21 - Cambodian	22 - Other API	23 - Other race

Patient's Ethnicity (Spanish/Hispanic Origin):

0 - Unknown	1 - No (not Spanish)	2 - Yes, Mexican	3 - Yes, Puerto Rican
4 - Yes, Cuban	5 - Yes, Central American		6 - Yes, South American
7 - Yes, Other	8 - Yes, NOS		

Method of Payment:

1 - Private	2 - Medicare	3 - Medicare and Private	4 - Medicaid
5 - Medicaid and Medicare		7 - No insurance (self-pay)	
8 - No insurance (no means)		9 - Other-specify_____	
10 - Unknown		11 - Veterans Admin	12 - Military

Other Group Registration Code:

9981 - NCIC	9982 - CALGB	9984 - GOG	9987 - MDACC
9995 - ECOG	9996 - NCCTG	9997 - RTOG	

SOUTHWEST ONCOLOGY GROUP

CARES-SF (CAncer Rehabilitation Evaluation System Short Form For Research)

SWOG Patient No. ☐☐☐☐☐☐ SWOG Study No. S 9 8 3 2 Protocol Step: 1

Patient's Name _____

Institution/Member _____ Physician _____

ASSESSMENT: ☐ PreStudy ☐ Month 3 ☐ Month 6

Date: ☐☐ / ☐☐ / ☐☐☐☐

INSTRUCTIONS:

The following is a list of Problem Statements that describe situations and experiences of individuals who have or have had cancer. Read each statement and mark an X in the box that best describes **HOW MUCH EACH STATEMENT APPLIES TO YOU** during the **PAST MONTH, INCLUDING TODAY**. Some sections will not apply to you. Please skip these sections and proceed to the next one as directed.

EXAMPLE:

How much does it apply to you?	Not at all	A Little	A Fair Amount	Much	Very Much
1. I have difficulty walking	☐	☒	☐	☐	☐
2. I find that food tastes bad	☐	☐	☐	☒	☐

Questionnaire begins here

How much does it apply to you?	Not at all	A Little	A Fair Amount	Much	Very Much
1. I have difficulty bending or lifting	☐	☐	☐	☐	☐
2. I do not have the energy I used to	☐	☐	☐	☐	☐
3. I have difficulty doing household chores	☐	☐	☐	☐	☐
4. I have difficulty bathing, brushing teeth, or grooming myself	☐	☐	☐	☐	☐
5. I have difficulty planning activities because of the cancer or its treatments	☐	☐	☐	☐	☐
6. I cannot gain weight	☐	☐	☐	☐	☐
7. I find food unappealing	☐	☐	☐	☐	☐
8. I find that cancer or its treatments interfere with my ability to work	☐	☐	☐	☐	☐
9. I frequently have pain	☐	☐	☐	☐	☐
10. I find that my clothes do not fit	☐	☐	☐	☐	☐

Continued on next page

SOUTHWEST ONCOLOGY GROUP
CARES-SF

SWOG Patient No. [ ][ ][ ][ ][ ][ ] SWOG Study No. S 9 8 3 2 Protocol Step 1

Patient's Name _____

ASSESSMENT: ☐ PreStudy ☐ Month 3 ☐ Month 6

continued from page 1

How much does it apply to you?	Not at all	A Little	A Fair Amount	Much	Very Much
11. I find that doctors don't explain what they are doing to me	☐	☐	☐	☐	☐
12. I have difficulty asking doctors questions	☐	☐	☐	☐	☐
13. I have difficulty understanding what the doctors tell me about the cancer or its treatments	☐	☐	☐	☐	☐
14. I'd like to have more control over what the doctors do to me	☐	☐	☐	☐	☐
15. I am uncomfortable with the changes in my body	☐	☐	☐	☐	☐
16. I frequently feel anxious	☐	☐	☐	☐	☐
17. I have difficulty sleeping	☐	☐	☐	☐	☐
18. I have difficulty concentrating	☐	☐	☐	☐	☐
19. I have difficulty asking friends or relatives to do things for me	☐	☐	☐	☐	☐
20. I have difficulty telling my friends or relatives about this cancer	☐	☐	☐	☐	☐
21. I find that my friends or relatives tell me I'm looking well when I'm not	☐	☐	☐	☐	☐
22. I find that my friends or relatives don't visit often enough	☐	☐	☐	☐	☐
23. I find that my friends or relatives have difficulty talking with me about my illness	☐	☐	☐	☐	☐
24. I become nervous when I am waiting to see the doctor	☐	☐	☐	☐	☐
25. I become nervous when I get my blood drawn	☐	☐	☐	☐	☐
26. I worry about whether the cancer is progressing	☐	☐	☐	☐	☐
27. I worry about not being able to care for myself	☐	☐	☐	☐	☐
28. I do not feel sexually attractive	☐	☐	☐	☐	☐
29. I am not interested in having sex	☐	☐	☐	☐	☐
30. I sometimes don't follow my doctor's instructions	☐	☐	☐	☐	☐

Continued on next page

SOUTHWEST ONCOLOGY GROUP
CARES-SF

SWOG Patient No. ☐☐☐☐☐☐ SWOG Study No. S 9 8 3 2 Protocol Step 1

Patient's Name _____

ASSESSMENT: ☐ PreStudy ☐ Month 3 ☐ Month 6

continued from page 2

How much does it apply to you?	Not at all	A Little	A Fair Amount	Much	Very Much
31. I have financial problems	☐	☐	☐	☐	☐
32. I have insurance problems	☐	☐	☐	☐	☐
33. I have difficulty with transportation to and from my medical appointments and/or other places	☐	☐	☐	☐	☐
34. I am gaining too much weight	☐	☐	☐	☐	☐
35. I have frequent episodes of diarrhea	☐	☐	☐	☐	☐
36. I have times when I do not have control of my bladder	☐	☐	☐	☐	☐

Do you have children? ☐ Yes ☐ No
If No, skip to next section.

37. I have difficulty helping my children cope with my illness	☐	☐	☐	☐	☐

Are you working or have you been employed during the last month? ☐ Yes ☐ No
If No, skip to next section.

38. I have difficulty talking to the people who work with me about the cancer	☐	☐	☐	☐	☐
39. I have difficulty asking for time off from work for medical treatments	☐	☐	☐	☐	☐
40. I am worried about being fired	☐	☐	☐	☐	☐

Did you look for work during the past month? ☐ Yes ☐ No
If No, skip to next section.

41. I have difficulty finding a new job since I have had cancer	☐	☐	☐	☐	☐

Have you attempted sexual intercourse since your cancer diagnosis? ☐ Yes ☐ No
If No, skip to next section.

42. I find that the frequency of sexual intercourse has decreased	☐	☐	☐	☐	☐

Continued on next page

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SOUTHWEST ONCOLOGY GROUP
CARES-SF

SWOG Patient No. ☐☐☐☐☐☐ SWOG Study No. S 9 8 3 2 Protocol Step 1

Patient's Name _____

ASSESSMENT: ☐ PreStudy ☐ Month 3 ☐ Month 6

continued from page 3

How much does it apply to you?	Not at all	A Little	A Fair Amount	Much	Very Much
Are you married or in a significant relationship? ☐ Yes ☐ No *If No, skip to next section.*					
43. My partner and I have difficulty talking about our feelings	☐	☐	☐	☐	☐
44. My partner and I have difficulty talking about wills and financial arrangements	☐	☐	☐	☐	☐
45. I do not feel like embracing, kissing, or caressing my partner	☐	☐	☐	☐	☐
46. My partner and I are not getting along as well as usual	☐	☐	☐	☐	☐
47. My partner spends too much time taking care of me	☐	☐	☐	☐	☐
48. I have difficulty asking my partner to take care of me	☐	☐	☐	☐	☐
Are you single and not in a significant relationship? ☐ Yes ☐ No *If No, skip to next section.*					
49. I have difficulty initiating contact with potential dates	☐	☐	☐	☐	☐
50. I have difficulty telling a date about the cancer or its treatment	☐	☐	☐	☐	☐
Have you had chemotherapy treatments in the last month? ☐ Yes ☐ No *If No, skip to next section.*					
51. I become nervous when I get chemotherapy	☐	☐	☐	☐	☐
52. I become nauseated during and/or before chemotherapy	☐	☐	☐	☐	☐
53. I feel nauseated after I receive chemotherapy	☐	☐	☐	☐	☐
54. I vomit after chemotherapy	☐	☐	☐	☐	☐
55. I have other side effects after chemotherapy	☐	☐	☐	☐	☐

(care9832)

12/1/98 2836

SOUTHWEST ONCOLOGY GROUP
CARES-SF

SWOG Patient No. | | | | | | | **SWOG Study No.** S 9832 **Protocol Step** 1

Patient's Name _____

ASSESSMENT: ☐ PreStudy ☐ Month 3 ☐ Month 6

continued from page 4

How much does it apply to you?	Not at all	A Little	A Fair Amount	Much	Very Much
Have you had radiation therapy treatments in the last month? ☐ Yes ☐ No *If No, skip to next section.*					
56. I get nervous when I get radiation treatments	☐	☐	☐	☐	☐
57. I feel nauseous or vomit after my radiation treatments	☐	☐	☐	☐	☐
Do you have an ostomy? ☐ Yes ☐ No *If No, skip to next section.*					
58. I have problems with ostomy care and maintenance	☐	☐	☐	☐	☐
Do you have a prosthesis? ☐ Yes ☐ No *If No, skip to next section.*					
59. I have difficulty with my prosthetic device (artificial limb, breast prosthesis, etc.)	☐	☐	☐	☐	☐

SOUTHWEST ONCOLOGY GROUP
YOUR FEELINGS (CES-D)

SWOG Patient No. ☐☐☐☐☐☐ SWOG Study No. S 9 8 3 2 Protocol Step 1

Patient's Name _____

Institution/Member _____ **Physician**_____

ASSESSMENT: ☐ PreStudy ☐ 3 Month ☐ 6 Month

DATE: ☐☐/☐☐/☐☐☐☐

Instructions: Mark an X in the appropriate box for each statement which best describes how often you felt or behaved this way - DURING THE PAST WEEK.

DURING THE PAST WEEK:	Rarely or None of the time (Less than 1 day)	Some or a Little of the Time (1-2 Days)	Occasionally or a Moderate Amount of the Time (3-4 Days)	Most or All of the Time (5-7 Days
1. I was bothered by things that usually don't bother me	☐	☐	☐	☐
2. I did not feel like eating; my appetite was poor	☐	☐	☐	☐
3. I felt that I could not shake off the blues even with help from my family or friends	☐	☐	☐	☐
4. I felt that I was just as good as other people	☐	☐	☐	☐
5. I had trouble keeping my mind on what I was doing	☐	☐	☐	☐
6. I felt depressed	☐	☐	☐	☐
7. I felt that everything I was doing was an effort	☐	☐	☐	☐
8. I felt hopeful about the future	☐	☐	☐	☐
9. I thought my life had been a failure	☐	☐	☐	☐
10. I felt fearful	☐	☐	☐	☐
11. My sleep was restless	☐	☐	☐	☐
12. I was happy	☐	☐	☐	☐
13. I talked less than usual	☐	☐	☐	☐
14. I felt lonely	☐	☐	☐	☐
15. People were unfriendly	☐	☐	☐	☐
16. I enjoyed life	☐	☐	☐	☐
17. I had crying spells	☐	☐	☐	☐
18. I felt sad	☐	☐	☐	☐
19. I felt that people disliked me	☐	☐	☐	☐
20. I could not get "going"	☐	☐	☐	☐

(sw356) ***7/15/98*** 55532

SOUTHWEST ONCOLOGY GROUP
SUPPORT SERVICES

SWOG Patient No. ☐☐☐☐☐☐ SWOG Study No. S 9 8 3 2 Protocol Step 1

Patient's Name _____

Institution/Member _____ **Physician**_____

ASSESSMENT: ☐ PreStudy ☐ 3 Month ☐ 6 Month

DATE: ☐☐/☐☐/☐☐☐☐

Instructions: Please check whether or not you used any of the following resources during the last month. If used, please rate the helpfulness of that resource on a scale from **1 (Very Helpful)** to **5 (Not Helpful At All).**

RESOURCE	Used	Not Used	If Used, HOW HELPFUL 1 (Very Helpful)	2	3	4	5 (Not Helpful)
Office visit: mental health counselor	☐	☐	☐	☐	☐	☐	☐
Office visit: physician	☐	☐	☐	☐	☐	☐	☐
Office visit, other, specify: _____	☐	☐	☐	☐	☐	☐	☐
Telephone counseling (other than this study)	☐	☐	☐	☐	☐	☐	☐
Family	☐	☐	☐	☐	☐	☐	☐
Friends	☐	☐	☐	☐	☐	☐	☐
Religious group	☐	☐	☐	☐	☐	☐	☐
Women's group	☐	☐	☐	☐	☐	☐	☐
Other group contact, specify: _____	☐	☐	☐	☐	☐	☐	☐
Breast cancer advocacy organization	☐	☐	☐	☐	☐	☐	☐
Cancer Information Service (1-800-4-CANCER)	☐	☐	☐	☐	☐	☐	☐
American Cancer Society	☐	☐	☐	☐	☐	☐	☐
Other advocacy/cancer-related organization, specify: _____	☐	☐	☐	☐	☐	☐	☐
Print materials for cancer patients	☐	☐	☐	☐	☐	☐	☐
Internet	☐	☐	☐	☐	☐	☐	☐
Other resource, specify: _____	☐	☐	☐	☐	☐	☐	☐
Other resource, specify: _____	☐	☐	☐	☐	☐	☐	☐

(sw358)

10/15/98 48909

SOUTHWEST ONCOLOGY GROUP
PSYCHOSOCIAL QUESTIONNAIRE

SWOG Patient No. ☐☐☐☐☐☐ SWOG Study No. S☐☐☐☐ Protocol Step 1

Patient's Name _____

Institution/Member _____ **Physician**_____

Date: ☐☐/☐☐/☐☐☐☐ (mm,dd,yyyy)

Instructions: Please indicate the extent to which you agree with each of the following items, using the following response format. Mark [X] only one box for each item.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. In uncertain times, I usually expect the best	☐	☐	☐	☐	☐
2. It's easy for me to relax	☐	☐	☐	☐	☐
3. If something can go wrong for me, it will	☐	☐	☐	☐	☐
4. I always look on the bright side of things	☐	☐	☐	☐	☐
5. I'm always optomistic about my future	☐	☐	☐	☐	☐
6. I enjoy my friends a lot	☐	☐	☐	☐	☐
7. It's important for me to keep busy	☐	☐	☐	☐	☐
8. I hardly ever expect things to go my way	☐	☐	☐	☐	☐
9. Things never work out the way I want them to	☐	☐	☐	☐	☐
10. I don't get upset too easily	☐	☐	☐	☐	☐
11. I'm a believer in the idea that "every cloud has a silver lining"	☐	☐	☐	☐	☐
12. I rarely count on good things happening to me	☐	☐	☐	☐	☐

13. How surprised were you by the recurrence?

☐ Completely surprised ☐ Knew it would happen ☐ Not at all surprised

14. Do you have a family member or friend you can talk to about your illness?

Family Member ☐ No ☐ Yes

Friend ☐ No ☐ Yes

15. Do you currently have anyone else to whom you can talk about your illness?

☐ No ☐ Yes If Yes, relationship? _____

16. Do you currently have a family member or friend to whom you can talk about other personal problems?

Family Member ☐ No ☐ Yes

Friend ☐ No ☐ Yes If Yes, relationship? _____

17. Do you currently have anyone else to whom you can talk about other personal problems?

☐ No ☐ Yes If Yes, relationship? _____

18. Do you have the feeling that you really don't care about what goes on around you?

☐1 very seldom or never ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 very often

continued on next page

(sw357)

7/15/98 19092

SOUTHWEST ONCOLOGY GROUP
PSYCHOSOCIAL QUESTIONNAIRE

SWOG Patient No. ☐☐☐☐☐☐ SWOG Study No. S☐☐☐ Protocol Step 1

Patient's Name _____

19. Has it happened in the past that you were surprised by the behavior of people you thought you knew well?
☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
never happened — always happened

20. Has it happened that people whom you counted on disappointed you?
☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
never happened — always happened

21. Until now your life has had:
☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
no clear goals or purpose at all — very clear goals and purpose

22. Do you have the feeling that you're being treated unfairly?
☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
very often — very seldom or never

23. Do you have the feeling that you are in an unfamiliar situation and don't know what to do?
☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
very often — very seldom or never

24. Doing the things you do every day is:
☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
a source of deep pleasure and satisfaction — a source of pain and boredom

25. Do you have very mixed-up feelings and ideas?
☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
very often — very seldom or never

26. Does it happen that you have feelings inside you would rather not feel?
☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
very often — very seldom or never

27. Many people, even those with a strong character, sometimes feel like sad sacks (losers) in certain situations How often have you felt this way in the past?
☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
never — very often

28. When something happened, have you generally found that:
☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
you overestimated or underestimated its importance — you saw things in the right proportion

29. How often do you have the feeling that there's little meaning in the things you do in your daily life?
☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
very often — very seldom or never

30. How often do you have feelings that you're not sure you can keep under control?
☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7
very often — very seldom or never

SOUTHWEST ONCOLOGY GROUP
QUALITY OF LIFE COVER SHEET

SWOG Patient No. ☐☐☐☐☐☐ **SWOG Study No.** S9832 **Protocol Step** 1

ASSESSMENT: ☐ PreStudy ☐ Month 3 ☐ Month 6

Patient's Name _____

Institution/Member _____ **Physician** _____

Was CARES-SF Questionnaire completed?	☐ No	☐ Yes
Was CES-D completed?	☐ No	☐ Yes
Was Psychosocial Predictors Scale completed (Prestudy only)?	☐ No	☐ Yes
Was the Support Services Form completed?	☐ No	☐ Yes
Was the Telephone Counseling Evaluation Form completed? (Month 3 and 6 only)	☐ No	☐ Yes
If Completed, In general did the patient require assistance?	☐ No	☐ Yes

Describe: _____

If Completed, Questionnaires administered:

☐ in the clinic
☐ by telephone
☐ by mail

If Not completed, Please give reason (check one):

☐ Illness/deteriorating health (e.g., at clinic but too ill/weak to complete, at home, hospital, hospice, but too ill/weak to complete, in coma or near death)
☐ Institution error (e.g., forgot to administer, did not continue schedule when patient went off treatment)
☐ Not illness related (e.g., unable to contact, patient refusal, patient failure to return questionnaire)
☐ Death
☐ Other

I have reviewed the Cover Sheet and Questionnaire(s). All forms are complete or an explanation is given for any missing data.

BY: _____ PHONE: (☐☐☐) ☐☐☐-☐☐☐☐

Notes:

(qlc9832) ***12/1/98*** 40404

SOUTHWEST ONCOLOGY GROUP
S9832 Prestudy Form

SWOG Patient No. [ ][ ][ ][ ][ ][ ] SWOG Study No. [S][9][8][3][2] Protocol Step [1]

Patient's Name _____

Institution/Member _____ **Physician**_____

Groups other than SWOG: Group Name/Study No./Pt. No. _____/_____/_____

Instructions: All dates are **MONTH, DAY, YEAR.** Explain any blank fields or blank dates in the **Notes** section at the bottom of the prestudy form. Place an [X] in appropriate boxes. Circle **AMENDED** items in red.

PATIENT CHARACTERISTICS

Current Pain Medication index:

- ☐ Nothing
- ☐ Non-Opioid Analgesics
- ☐ Non-Opioids plus Weak Opioids (e.g., Tylenol3, Percocet)
- ☐ Strong Opioids (e.g., morphine, Dilaudid, methadone)

Psychotropic Medications: ☐ No ☐ Yes

Menopausal Status

- ☐ Pre (regular menses or <6 months since LMP and NOT on estrogen replacement and NO prior bilateral ovariectomy)
- ☐ Post (prior bilateral ovariectomy OR >12 months since LMP with NO prior hysterectomy)
- ☐ Other (pre/post will be defined by age at the Statistical Center)

DISEASE HISTORY

Date of:

Histologic Diagnosis of Primary:
[ ][ ]/[ ][ ]/[ ][ ][ ][ ]

Diagnosis of Recurrence:
[ ][ ]/[ ][ ]/[ ][ ][ ][ ]

Diagnosis of Contralateral breast malignancy:
[ ][ ]/[ ][ ]/[ ][ ][ ][ ]

TUMOR AND NODE STAGE

Tumor status

T-status: (check one)

☐ T0 ☐ T1 ☐ T2 ☐ T3

Node status

N-status: (check one)

☐ N0 ☐ N1 ☐ N2 ☐ N3

TREATMENT FOR PRIMARY

RT	☐ No	☐ Yes
Chemotherapy	☐ No	☐ Yes
Hormonal Therapy	☐ No	☐ Yes

Surgery

- ☐ None
- ☐ Less than total mastectomy
- ☐ Total, modified radical or radical mastectomy

TREATMENT FOR RECURRENCE

RT	☐ No	☐ Yes
Chemotherapy	☐ No	☐ Yes
Hormonal Therapy	☐ No	☐ Yes
Surgery	☐ No	☐ Yes

Notes:

(sw355)

7/15/98 45674

SOUTHWEST ONCOLOGY GROUP
CLINICAL UPDATE

SWOG Patient No. ☐☐☐☐☐☐ SWOG Study No. S 9 8 3 2 Protocol Step 1

Patient Name _____ (L,F,M)

Institution / Member _____ Physician _____

Groups other than SWOG: Group Name/Study No./Pt. No. _____ / _____ / _____

Instructions: All dates are **MONTH, DAY, YEAR.** Explain any blank fields or blank dates in the **Notes** section at the bottom of the form. Place an [X] in appropriate boxes. Circle **AMENDED** items in red.

ASSESSMENT: ☐ Month 3 ☐ Month 6 **Date:** ☐☐ / ☐☐ / ☐☐☐☐

PATIENT CHARACTERISTICS

Current Performance Status:

- ☐ Fully active
- ☐ Symptoms but ambulatory and able to do light work
- ☐ No work but self care and active > 50% of waking hours
- ☐ Limited self-care, confined to bed or chair > 50% of waking hours
- ☐ Completely disabled

Current Pain Medication Index:

- ☐ Nothing
- ☐ Non-Opioid Analgesics
- ☐ Non-Opioids plus Weak Opioids (e.g., Tylenol3, Percocet)
- ☐ Strong Opioids (e.g., morphine, Dilaudid, methadone)

Psychotropic Medications: ☐ No ☐ Yes

CURRENT TREATMENT STATUS

RT	☐ No	☐ Yes
Chemotherapy	☐ No	☐ Yes
Hormonal Therapy	☐ No	☐ Yes
Surgery	☐ No	☐ Yes

DISEASE STATUS

Progression of disease since last S9832 Clinical Update form was completed?

☐ No ☐ Yes

If Yes, Date: (month, day, year) ☐☐ / ☐☐ / ☐☐☐☐

Site(s):

- ☐ bone
- ☐ liver
- ☐ lung
- ☐ brain
- ☐ other visceral
- ☐ local/chest wall
- ☐ nodes/soft tissue
- ☐ opposite breast
- ☐ other, specify: _____

Notes:

(clin9832) ***05/01/1999*** 49100

SOUTHWEST ONCOLOGY GROUP
TELEPHONE COUNSELING EVALUATION FORM

SWOG Patient No. ☐☐☐☐☐☐ SWOG Study No. S 9 8 3 2 Protocol Step 1

Patient's Name _____

Institution/Member _____ Physician_____

ASSESSMENT: ☐ 3 Month ☐ 6 Month

DATE: ☐☐/☐☐/☐☐☐☐

We are interested in knowing how satisfied you were with the telephone counseling program you have participated in these last few months - what you liked AND what you didn't like. Your comments will help us improve the counseling program.

1. Please rate each of the following aspects of the telephone counseling program: Excellent, Good Satisfactory, Fair, and Poor (Please mark an X in the appropriate box).

	Excellent	Good	Satisfactory	Fair	Poor	Not applicable
a. The way problems were discussed	☐	☐	☐	☐	☐	
b. The types of problems/issued discussed	☐	☐	☐	☐	☐	
c. Medical information provided	☐	☐	☐	☐	☐	
d. Other information provided	☐	☐	☐	☐	☐	
e. Knowledge and skill of Counselor	☐	☐	☐	☐	☐	
f. Counselor caring about you and your concerns	☐	☐	☐	☐	☐	
g. Use of telephone for counseling sessions instead of meeting with Counselor in person	☐	☐	☐	☐	☐	
h. Length of each session	☐	☐	☐	☐	☐	
i. Number of sessions	☐	☐	☐	☐	☐	
j. Quality of educational materials	☐	☐	☐	☐	☐	
k. Relevance of questionnaires to your experience	☐	☐	☐	☐	☐	
l. Telephone Sessions: Overall program	☐	☐	☐	☐	☐	
(a) Get acquainted and planning discussion	☐	☐	☐	☐	☐	
(b) Physical problems	☐	☐	☐	☐	☐	☐
(c) Social support	☐	☐	☐	☐	☐	☐
(d) Existential concerns	☐	☐	☐	☐	☐	☐
(e) Handling stress	☐	☐	☐	☐	☐	☐
(f) Wrap-up	☐	☐	☐	☐	☐	

(sw359)

7/15/98 57890

SOUTHWEST ONCOLOGY GROUP
TELEPHONE COUNSELING EVALUATION FORM

SWOG Patient No. ☐☐☐☐☐☐ SWOG Study No. S 9 8 3 2 Protocol Step 1

Patient's Name _____

ASSESSMENT: ☐ 3 Month ☐ 6 Month

2. In general, how much did the program help you with a problem or issue of importance to you?

☐ Not at all helpful ☐ Somewhat helpful ☐ Extremely helpful

☐ A little helpful ☐ Very helpful

Please explain why: _____

_____

3. What about the telephone counseling program did you find to be most helpful? Why?

_____

_____

_____

4. What about the program did you find to be not helpful at all? Why?

_____

_____

_____

5. What do you think could have been done to make this program better?

_____

_____

_____

6. Please note any comments you have about the telephone counseling program.

_____

_____

_____

_____

THANK YOU VERY MUCH! ***7/15/98*** 57890

SOUTHWEST ONCOLOGY GROUP
ADDITIONAL CONCERNS

SWOG Patient No. ☐☐☐☐☐☐ SWOG Study No. S 9 8 3 2 Protocol Step ☐

Patient's Name _____

Institution/Member _____ **Physician** _____

ASSESSMENT: ☐ PreStudy ☐ Month 3 ☐ Month 6

Please describe any concerns you have that haven't been covered in these questionnaires.

_____

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AN INTERVENTION TO ENHANCE WELL-BEING IN WOMEN EXPERIENCING A BREAST CANCER RECURRENCE

Carolyn Gotay, Ph.D., Carol Moinpour, Ph.D., Kathy Albain, M.D., Silvana Martino, M.D., Stephanie Green, Ph.D., Bonnie Taylor, Ph.D., Judy Perotti, Charles A. Coltman, Jr., M.D.

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This study, conducted in the Southwest Oncology Group (SWOG), tests the hypothesis that well-being will be enhanced by an intervention designed for breast cancer patients experiencing a first recurrence. Three hundred breast cancer patients within six weeks of recurrence are randomly assigned to a control group or an intervention carried out by Y-Me, a national breast cancer support and advocacy organization. The intervention consists of four to eight structured telephone sessions providing information and peer support delivered by breast cancer survivors over a four-week period. Endpoints are assessed at baseline and three and six months later through validated questionnaires of quality of life (Cancer Rehabilitation Evaluation System-Short Form [CARES-SF]) and depression (Center for Epidemiologic Studies-Depression scale [CES-D]).

A Pilot Study was conducted in 12 selected Southwest Oncology Group institutions to refine materials and procedures before implementing the randomized study. Thirty women participated in the intervention and completed assessment questionnaires at baseline and four weeks later. Fifty percent of participants were under 50 years of age, and 1/3 experienced a recurrence within two years of initial diagnosis. Seventy-nine percent of participants stated they were "completely surprised" about their recurrence. Seventy percent were clinically depressed (using the CES-D cutoff) at baseline and/or four weeks. Eighty-six percent found the intervention helpful (e.g., because of dissimilarity between patient and counselor and already having ample support). Women suggested more flexibility in scheduling telephone calls.

Based on Pilot Study experience, we modified the protocol to allow a larger window for enrollment and flexibility in number of intervention sessions, and instituted telephone call tape recording for quality control and counselor feedback. We also included more discussion on communication and establishing a relationship with callers as part of the Y-Me training, as well as instituted procedures to match patients facing bone marrow transplantation with a counselor who had undergone this procedure. The randomized protocol is actively accruing patients within the Southwest Oncology Group and should be completed within 18 months.

The U.S. Army Medical Research and Materiel Command under DAMD17-96-1-6009 supported this work