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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 8 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 4-8 structured sessions providing information and peer support delivered by breast cancer survivors via telephone. 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 experienced breast cancer recurrence. The project utilizes a cost-effective approach with the potential for widescale dissemination.

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Enhancing Well-Being During Breast Cancer Recurrence

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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 will be 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 will be open to all Southwest Oncology Group institutions. A randomized, two group design will be 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.

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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 will involve 30 women meeting the eligibility criteria who all participate in the intervention and complete 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 will commence participation following a first recurrence of breast cancer. At that time, the participants will complete a battery of instruments, including baseline measures of well-being. Participants will be 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 will complete an intervention completed within a four-week period; the intervention will cover four discrete content areas and will be carried out in four (Pilot Study) or four to eight (Main Study) telephone calls. Assessments of well-being will be 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 will complete baseline questionnaires and will receive a questionnaire packet to complete and return by mail in six weeks. All women will be 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. Each participating institution will be required to compile materials about resources available in their catchment area. Project staff will compile 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 will receive the four session telephone intervention from Y-ME peer counselors.

Main Study: All women will complete the baseline questionnaires and will be provided with basic information (as above). Women in the *control group* will receive no additional intervention. They will mailed self-administered assessment questionnaires to complete 3 months and 6 months later. Patients in the *intervention group* will be 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 will be used, and calls should require no longer than 45 minutes to complete. Each call will focus on different problem areas from the group below. The modules reflect psychosocial, physical, and existential concerns. Each woman will be given a choice about the order in which the sessions are presented. Each call will provide basic information and the opportunity for the patients to discuss individual concerns. The general format is to provide information is 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 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 can contact the Southwest Oncology Group physician who enrolled her on the study. Following the first session, the patients will be 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 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 is 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 study was activated by the Southwest Oncology Group on June 1, 1997. Currently, 27 of the 30 patients targeted for the Pilot Study have been accrued. The Pilot Study will stay open until August 1, 1998 to enable the last three pilot patients to be registered. The Main Study will open Group-wide on July 15, 1998 for activation by all Southwest Oncology Group institutions. Given the time required for Institutional Review Board review, we anticipate that the first patients for the main study will be registered in September 1998.

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

1. Recruitment of additional staff, including Research Associate (University of Hawaii) (due to a position turnover) and peer counselors (Y-ME) (due to the need for additional counselors for the main study).

2. Recruitment of new Co-Investigator at Y-ME. Ms. Michelle Melin, the previous co-investigator, left Y-ME for another position. Bonnie Taylor, Ph.D., was selected to serve as the Y-ME Co-Investigator. Dr. Taylor is a clinical psychologist with extensive experience with cancer patients. She has served on the Y-ME Board of Directors (of which she is currently President) since 1990.

3. Development of continuing education and provision of feedback and reinforcement for Y-ME peer counselors by Dr. Taylor. These activities were implemented based on suggestions from the counselors from the Pilot Study and will be continued for the Main Study.

4. Development of new training protocols for the newly-recruited additional Y-ME counselors for the Main Study, based on feedback and experience of the current counselors (all of whom will continue into the Main Study phase).

5. Revision of the protocol document. Based on feedback from the institutions in the Pilot Study and from the patients who participated, we made the following modifications to the protocol:

   a. The restriction that patients participating in this protocol should not have any past experience on plans to enroll on Southwest Oncology Group treatment protocols was dropped as an eligibility criterion (due to clarification that all current Southwest Oncology Group breast cancer treatment protocols use disease-free survival as their primary outcome measure; thus any potential effects of the current study on survival would not affect the outcomes of these studies).

   b. Patients will be allowed to register for the protocol up to 56 days post-recurrence in the Main Study (due to institutional feedback that it was difficult to enroll patients within 42 days of their diagnosis of recurrence and that patients could benefit from beginning the intervention at a later period).

   c. The number of intervention sessions in the Main Study will be flexible between four and eight (rather than being specified as being four sessions of equal length as in the Pilot). This was based on consistent patient feedback indicating that more flexibility in scheduling and telephone call length was needed, a suggestion that was reinforced by the Y-ME counselors.

   d. Based on strong recommendations from the consultants, we instituted tape recording of the intervention telephone calls for quality control and to provide feedback to the counselors. The consent form was modified to reflect this procedure. The taping provided useful information and will be continued on a random basis in the Main Study.

   e. Revision of the protocol forms. Based on feedback from the institutions in the Pilot Study, we made small modifications to the newly-developed forms (Telephone Counseling Evaluation Form, Psychosocial Predictors Form, Current Cancer Treatment).

6. Approval was obtained for the participation of eight additional Southwest Oncology Group institutions to take part in the Pilot Study (to bring the total number of Pilot institutions to 12).

7. Periodic mailings from Dr. Gotay to the Project Team and Principal Investigators and Data Managers at the Pilot Institutions to encourage their participation, provide sample materials, and communicate new information. Three mailings were made during this project year. Dr. Gotay will continue such communications to all institutions which activate the Main Study throughout the period of accrual. As Study Coordinator, Dr. Gotay also responded to numerous telephone calls and e-mails from the Pilot Institutions and others regarding IRB issues, questions about eligibility, and other aspects of the protocol.

8. Regular communications were established between Dr. Gotay and Project Team (including the Southwest Oncology Group Statistical Center, Operations Office, Y-ME, and the consultants). Monthly telephone conferences have been scheduled between Dr. Taylor at Y-ME, and weekly or more frequent e-mail or telephone communication with the Southwest Oncology Group Statistical Center (Ms. Lovato and Dr. Moinpour).

9. Two project group meetings were held in conjunction with Southwest Oncology Group meetings in Seattle, Washington (October 1997) and Atlanta, Georgia (April 1998).

10. Presentations about the study were made by Dr. Gotay at the October 1997 Southwest Oncology Group Plenary Session, October 1997 and the April 1998 Breast Cancer Committee Meetings and Cancer Control Research Committee Meetings.

11. Analysis of the Telephone Counseling Evaluation Form for the first 10 patients on the Pilot Study was conducted by Dr. Gotay. Analysis indicated that almost all patients rated the evaluation highly, although a number of the women pointed out the need for the telephone calls to be more flexible, both in number and in length. This provided a basis for modifying the protocol for the Main Study, as described above.

Recommendations in Relation to Statement of Work Outlined in the Proposal

The project is currently completing 21 months of intensive activity and is just about to open for accrual to the Main Study. In the Statement of Work included in the proposal, the Main Study was to be midway through accrual by this time. The Statement of Work significantly underestimated the amount of time needed for the protocol development and approval and to complete accrual to the Pilot Study. Given the large number of Southwest Oncology Group institutions and the absence of other protocols currently available to this patient population, however, there is excellent potential for rapid accrual to the Main Study. We will make every effort to ensure that accrual proceeds as quickly as possible during the next year. The scope of activities is as specified in the Statement of Work.

CONCLUSIONS

None, project is not 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.

APPENDIX

Attached on the following pages is the Southwest Oncology Group protocol S9632, "Enhancing Well-Being During Breast Cancer Recurrence".

Southwest
Oncology Group
A National Clinical Research Group

June 1, 1998

TO: **PILOT INSTITUTIONS**: ALL SOUTHWEST ONCOLOGY GROUP MEDICAL ONCOLOGISTS AT: ARIZONA, ARKANSAS, LOYOLA AND PSOC; ALL CCOP MEDICAL ONCOLOGISTS AT: GREENVILLE, HAWAII, KANSAS CITY, OZARKS REGIONAL, SOUTH ALABAMA, SPARTANBURG, AND WICHITA; ALL CGOP MEDICAL ONCOLOGISTS AT: SIERRA-NEVADA HOSPITAL (CGOP OF UC-DAVIS)

FROM: Jennifer S. Gazvoda, Protocol Coordinator

RE: **S9632**, "Enhancing Well-Being During Breast Cancer Recurrence." Study Coordinators: C. Gotay, Ph.D., C. Moinpour, Ph.D., K.S. Albain, M.D. and B. Taylor, Ph.D.

REVISION #5

The study referenced above has been revised as follows:

Michelle E. Melin, M.A. is no longer with the Y-ME National Breast Cancer Organization. Bonnie Taylor, Ph.D., President of the Board, and Judy Perotti, Director of Patient Services, are now noted in the protocol as Study Coordinator and contact person respectively. This revision affects the face page and Section 7.1f. The fax number for Y-ME has also been revised.

Effective 3/26/98, patients who have previously enrolled or who plan to enroll on other Southwest Oncology Group treatment protocols are eligible for this study. A statement to this effect has been added to Section 5.7.

Page 5 of the CARES-SF Form has been revised to correct an incomplete question which now reads, "Have you had radiation therapy treatments in the last month?"

Please append this notice and replacement pages 1, 7, 8, and page 5 of the CARES-SF Form to your copy of the protocol.

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

cc: DCPC
Carol Moinpour, Ph.D.
Laura Lovato, M.S.
Polly Feigl, Ph.D.
Dona Marrah
Catherine Smith, Department of Defense

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14980 Omicron Drive•San Antonio, TX 78245-3217 • Telephone 210-677-8808 • FAX 210-677-0006 • http://www.oo.saci.org

Southwest
Oncology Group
A National Clinical Research Group

March 1, 1998

TO: **PILOT INSTITUTIONS**: ALL SOUTHWEST ONCOLOGY GROUP MEDICAL ONCOLOGISTS AT: ARIZONA, ARKANSAS, LOYOLA AND PSOC; ALL CCOP MEDICAL ONCOLOGISTS AT: GREENVILLE, HAWAII, KANSAS CITY, OZARKS REGIONAL, SOUTH ALABAMA, SPARTANBURG, AND WICHITA; ALL CGOP MEDICAL ONCOLOGISTS AT: SIERRA-NEVADA HOSPITAL (CGOP OF UC-DAVIS)

FROM: Diana R. Schissel, Protocol Coordinator

RE: **S9632**, "Enhancing Well-Being During Breast Cancer Recurrence." Study Coordinators: C. Gotay, Ph.D., C. Moinpour, Ph.D., K.S. Albain, M.D. and M.E. Melin, M.A.

REVISION #4

The study referenced above has been revised as follows:

1. Section 5.1 (sentences 1 - 3) has been modified as follows for clarification.

   "A 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. She must have been informed of her first recurrence of breast cancer within the past 42 days. "First recurrence" is defined as any distant metastatic site, or chest wall recurrence, or scar recurrence, or nodal recurrence."

2. Section 7.1e has been revised as follows.

   "Each institution will provide patients with basic information at study entry. This information should include a copy of the National Cancer Institute (NCI) booklet, "When Cancer Recurs: Meeting the Challenge Again" (call 1-800-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 distributed to study participants; addresses and/or phone numbers should be provided. The baseline questionnaires should be completed before a study patient is given the pamphlet(s) and list of resources."

3. Section 7.1f has been modified removing reference to the Southwest Oncology Group ID number and replacing it with "patient number". Also, reference to site of metastases has been deleted, however, site of recurrence remains.

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4. Section 7.2c has been revised as follows.

   "Each institution will provide patients with basic information at study entry. This information should include a copy of the National Cancer Institute (NCI) booklet, "When Cancer Recurs: Meeting the Challenge Again" (call 1-800-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 distributed to study participants; addresses and/or phone numbers should be provided. The baseline questionnaires should be completed before a study patient is given the pamphlet(s) and list of resources. Women in the control group will receive the standard level of interaction and support provided by their medical team."

5. Section 7.3, Session 2 - 4: "Decision- making" has been changed to "issues".

6. Section 13.1: The parenthetical remark in the last sentence of this section has been modified as follows: "(no more than one working day prior to submitting the **fax to Y-ME - see Section 7.1f**)".

7. Section VI, Pilot and Main Model Consent Forms: Reference to the Food and Drug Administration has been removed.

Please append this notice and replacement pages 7 - 10, 17, 28 and 31 to your copy of the protocol.

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

cc: DCPC
Carol Moinpour, Ph.D.
Laura Lovato, M.S.
Polly Feigl, Ph.D.
Dona Marrah
Catherine Smith, Department of Defense

Southwest
Oncology Group
A National Clinical Research Group

December 15, 1997

TO: **PILOT INSTITUTIONS**: ALL SOUTHWEST ONCOLOGY GROUP MEDICAL ONCOLOGISTS AT: ARIZONA, ARKANSAS, LOYOLA AND PSOC; ALL CCOP MEDICAL ONCOLOGISTS AT: GREENVILLE, HAWAII, KANSAS CITY, OZARKS REGIONAL, SOUTH ALABAMA, SPARTANBURG, AND WICHITA; ALL CGOP MEDICAL ONCOLOGISTS AT: SIERRA-NEVADA HOSPITAL (CGOP OF UC-DAVIS)

FROM: Diana R. Schissel, Protocol Coordinator

RE: **S9632**, "Enhancing Well-Being During Breast Cancer Recurrence." Study Coordinators: C. Gotay, Ph.D., C. Moinpour, Ph.D., K.S. Albain, M.D. and M.E. Melin, M.A.

REVISION #3

The study referenced above has been revised as follows:

The face page and Section 7.1f have been modified for consistency. Michelle Melin's phone number has been revised on the face page to match Section 7.1f. The fax number listed in Section 7.1f has been modified to correspond with the face page. Also, Section 7.1f has been revised to include a request for the patient's Southwest Oncology Group ID number, age, address and site of metastases/recurrence.

Please append this notice, the revised face page, and replacement page 8 to your copy of the protocol.

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

cc: DCPC
Carol Moinpour, Ph.D.
Laura Lovato, M.S.
Polly Feigl, Ph.D.
Dona Marrah
Monica Yee
Catherine Smith, Department of Defense

Operations Office
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Southwest
Oncology Group
A National Clinical Research Group

December 1, 1997

TO: **PILOT INSTITUTIONS**: ALL SOUTHWEST ONCOLOGY GROUP MEDICAL ONCOLOGISTS AT: ARIZONA, ARKANSAS, LOYOLA AND PSOC; ALL CCOP MEDICAL ONCOLOGISTS AT: GREENVILLE, HAWAII, KANSAS CITY, OZARKS REGIONAL, SOUTH ALABAMA, SPARTANBURG, AND WICHITA; ALL CGOP MEDICAL ONCOLOGISTS AT: SIERRA-NEVADA HOSPITAL (CGOP OF UC-DAVIS)

FROM: Diana R. Schissel, Protocol Coordinator

RE: **S9632**, "Enhancing Well-Being During Breast Cancer Recurrence." Study Coordinators: C. Gotay, Ph.D., C. Moinpour, Ph.D., K.S. Albain, M.D. and M.E. Melin, M.A.

REVISION #2

The study referenced above has been revised as follows:

1. The list of institutions has been modified to clarify that the CGOPs of the participating Member institutions will not be allowed to participate unless specifically listed. The face page has been updated accordingly.

2. Section V of both Model Consent Forms has been modified. The word "local" has been added to the second sentence in order to clarify that the local institutions will be responsible for any necessary medical care for physical injury or disease which is determined to be the proximate (or direct) result of participation in this study.

NOTE: Once your IRB review has been received in the Operations Office and approved, the database will be updated to allow patient registration.

Please append this notice, the revised face page, and replacement pages 28 and 31 to your copy of the protocol.

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

cc: DCPC
Carol Moinpour, Ph.D.
Laura Lovato, M.S.
Polly Feigl, Ph.D.
Dona Marrah
Monica Yee
Catherine Smith, Department of Defense

Operations Office
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Southwest
Oncology Group
A National Clinical Research Group

October 15, 1997

TO: **PILOT INSTITUTIONS**: ALL SOUTHWEST ONCOLOGY GROUP, CGOP AND CCOP MEDICAL ONCOLOGISTS AT: GREENVILLE CCOP, HAWAII CCOP, KANSAS CITY CCOP, OZARKS REGIONAL CCOP, SOUTH ALABAMA CCOP, SPARTANBURG CCOP, WICHITA CCOP, SIERRA NEVADA HOSPITAL (CGOP OF UC-DAVIS), ARIZONA, ARKANSAS, LOYOLA AND PSOC

FROM: Diana R. Schissel, Protocol Coordinator

RE: **S9632**, "Enhancing Well-Being During Breast Cancer Recurrence." Study Coordinators: C. Gotay, Ph.D., C. Moinpour, Ph.D., K.S. Albain, M.D. and M.E. Melin, M.A.

REVISION #1

The study referenced above has been revised as follows:

1. The following Pilot Institutions have been added: Greenville CCOP, Kansas City CCOP, South Alabama CCOP, Spartanburg CCOP, Wichita CCOP, Sierra Nevada Hospital (CGOP of UC-Davis), Arizona and PSOC. The face page has been modified accordingly. Entire copies of the protocol have been enclosed for these additional institutions.

2. Michelle Melin's fax number has been updated on the face page. Also, Section 7.1f has been revised to include new phone and fax numbers.

3. Section 5.6 has been revised. "Clinical Update Form" has been replaced with "Support Services Form" for protocol consistency. The following sentence has also been added: "The CRA must complete a Prestudy Form and a Cover Sheet for the patient questionnaires within 7 days prior to registration in order to be eligible for the Pilot Study or to be randomized to the Main Study."

4. "Must" has been added to the statement in Section 13.2 to complete the sentence. "At the time of registration, the caller **must** have completed the Registration form."

All Pilot Institutions must submit a copy of their IRB approval to the Southwest Oncology Group Operations Office (Attention: Diana R. Schissel) for submission to the Department of Defense as soon as possible. (NOTE: Hawaii CCOP, Ozarks Regional CCOP, and Arkansas have already submitted copies of their IRB approval and do not need to re-submit.)

Please note that 0.7 Cancer Control credits have been assigned to this study. Also, there will be $500.00 available for each eligible registration for all non-CCOP institutions.

Please append this notice, the revised face page, and replacement pages 7, 8 and 17 to your copy of the protocol.

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

cc: DCPC
Carol Moinpour, Ph.D.
Laura Lovato, M.S.
Polly Feigl, Ph.D.
Dona Marrah
Monica Yee
Catherine Smith, Department of Defense

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Southwest
Oncology Group
A National Clinical Research Group

June 1, 1997

TO: **PILOT INSTITUTIONS**: ALL SOUTHWEST ONCOLOGY GROUP AND CCOP MEDICAL ONCOLOGISTS AT: HAWAII CCOP, OZARKS REGIONAL CCOP, ARKANSAS AND LOYOLA

FROM: Diana R. Schissel, Protocol Coordinator

RE: **S9632**, "Enhancing Well-Being During Breast Cancer Recurrence." Study Coordinators: C. Gotay, Ph.D., C. Moinpour, Ph.D., K.S. Albain, M.D. and M.E. Melin, M.A.

ACTIVATION

The study referenced above is now open for limited institution participation (Pilot Institutions only). Entire copies have been enclosed for your use.

All Pilot Institutions must submit a copy of their IRB approval to the Southwest Oncology Group Operations Office (Attention: Diana R. Schissel) for submission to the Department of Defense as soon as possible.

Please note that 0.7 Cancer Control credits have been assigned to this study. Also, there will be $500.00 available for each eligible registration for all non-CCOP institutions.

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

cc: DCPC
Carol Moinpour, Ph.D.
Laura Lovato, M.S.
Polly Feigl, Ph.D.
Dona Marrah
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Catherine Smith, Department of Defense

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PRIVILEGED COMMUNICATION
FOR INVESTIGATIONAL USE ONLY
Revised 10/15/97
Revised 12/1/97

S9632
Activated 6/1/97
Revised 12/15/97
Revised 6/1/98

SOUTHWEST ONCOLOGY GROUP

ENHANCING WELL-BEING DURING BREAST CANCER RECURRENCE

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PARTICIPANTS: PILOT INSTITUTIONS: ALL SOUTHWEST ONCOLOGY GROUP MEDICAL ONCOLOGISTS AT: ARIZONA, ARKANSAS, LOYOLA AND PSOC; ALL CCOP MEDICAL ONCOLOGISTS AT: GREENVILLE, HAWAII, KANSAS CITY, OZARKS REGIONAL, SOUTH ALABAMA, SPARTANBURG, AND WICHITA; ALL CGOP MEDICAL ONCOLOGISTS AT: SIERRA-NEVADA HOSPITAL (CGOP OF UC-DAVIS)
MAIN STUDY: ALL SOUTHWEST ONCOLOGY GROUP, CCOP AND CGOP MEDICAL ONCOLOGISTS

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mb

SCHEMA

Pilot Study

Study Entry (Pre-registration Assessments)

1. Patient completes baseline questionnaires

2. Nurse/CRA completes baseline

   a. S9632 Prestudy Form
   b. Quality of Life Cover Sheet

3. Nurse/CRA gives patient

   a. S9632 Clinical Update Form
   b. Questionnaire packet for 6-week assessment

4. Nurse/CRA faxes patient name/phone number to Y-ME

Telephone Intervention

1. All patients

2. Y-ME contacts patient and conducts intervention

3. Four telephone counseling sessions

4. Y-ME sends written materials after each telephone session

6-Week Assessment (Post-registration Assessment = 1)

1. Patient completes and mails questionnaires

2. Nurse/CRA calls patient and administers Telephone Counseling Evaluation Form

3. Nurse/CRA completes

   a. S9632 Clinical Update Form
   b. Quality of Life Cover sheet

SCHEMA

MAIN STUDY

Study Entry (Pre-registration Assessments)

1. Patient completes baseline questionnaires
2. Nurse/CRA completes baseline
   a. **S9632** Prestudy Form
   b. Quality of Life Cover Sheet
3. Nurse/CRA gives patient information packet

Randomization

Control Arm

1. Standard level of support
2. Nurse/CRA mails questionnaires 2 weeks prior to the 3 & 6 month assessments

Telephone Counseling Intervention Arm

1. Nurse/CRA faxes name/phone number to Y-ME
2. Y-ME contacts patient and conducts intervention
3. Four telephone counseling sessions
4. Y-ME sends patient written materials after session
5. Nurse/CRA mails questionnaires 2 weeks prior to the 3 and 6 month assessments

3 Month Assessment (Post-registration Assessment = 1)

Control Arm

1. Patient mails questionnaire packet
2. Nurse/CRA:
   a. **S9632** Clinical Update Form
   b. Quality of Life Cover Sheet

Telephone Counseling Intervention Arm

1. Patient mails questionnaire packet (including Telephone Counseling Intervention Form)
2. Nurse/CRA:
   a. **S9632** Clinical Update Form
   b. Quality of Life Cover Sheet
3. Y-ME conducts telephone counseling sessions
4. Y-ME sends patient written materials after session

6 Month Assessment (Post-registration Assessment = 2)

Control Arm

1. Patient mails questionnaire packet
2. Nurse/CRA:
   a. **S9632** Clinical Update Form
   b. Quality of Life Cover Sheet
3. Nurse/CRA sends patients written materials at 6 months randomization (end of study)

Telephone Counseling Intervention Arm

1. Patient mails questionnaire packet (including Telephone Counseling Intervention Form)
2. Nurse/CRA:
   a. **S9632** Clinical Update Form
   b. Quality of Life Cover Sheet
3. Y-ME conducts telephone counseling sessions
4. Y-ME sends patient written materials after session

1.0 OBJECTIVES

A two phase implementation process will be used 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.

Pilot Study

The specific objectives of the limited institution Pilot Study are:

1.1 To refine intervention protocol materials.

1.2 To develop operating procedures to ensure coordination and communication between the Principal Investigator, the Southwest Oncology Group Operations Office, the Study Coordinator, the Southwest Oncology Group Statistical Center, Y-ME, and the institutions accruing patients.

1.3 To develop a training program for the breast cancer survivors who will provide the intervention.

1.4 To finalize questionnaires and examine length and ease of administration by telephone, especially with respect to burden for institution staff.

1.5 To examine participation and attrition.

Main Study

The Main Study will be open to all Southwest Oncology Group institutions. A randomized, two group design will be 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 full trial is:

1.6 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.

The secondary research objectives of the full trial are:

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

1.8 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. This section does not need to be submitted as a part of the initial forms set.

_____5.1 A 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. She must have been informed of her first recurrence of breast cancer within the past 42 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, or isolated contralateral new primary breast cancers are excluded. NOTE: Patients may be receiving or plan to receive their FIRST treatment for this recurrence. No prior treatment for recurrent/metastatic disease is allowed, with the exception of surgical treatment for in-breast relapse following lumpectomy.

_____5.2 Patients must be female.

_____5.3 Patients will be eligible regardless of treatment received for this recurrence, including no treatment.

_____5.4. Patients must not present with a current psychiatric diagnosis that would interfere with their ability to participate in the intervention.

_____5.5 Patients must be able to read and understand English.

_____5.6 Patients must have completed the baseline packet of questionnaires (CARES-SF, CES-D, Psychosocial Predictors Form, and Support Services Form) within 7 days prior to registration in order to be eligible for the Pilot Study or to be randomized to the Main Study. The CRA must complete a Prestudy Form and a Cover Sheet for the patient questionnaires within 7 days prior to registration in order to be eligible for the Pilot Study or to be randomized to the Main Study.

_____ date questionnaires completed

_____5.7 Patients must have no previous enrollment or plans to enroll on another Southwest Oncology Group treatment protocol. NOTE: **Effective 3/26/98**, patients who have enrolled or who plan to enroll on other Southwest Oncology Group treatment protocols are eligible for this study.

_____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. (There is no randomization in the Pilot Study.) 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)

7.0 TREATMENT PLAN

7.1 Pilot Study

a. There is no randomization in the Pilot Study. All women receive the intervention.

b. All patients will complete a baseline questionnaire packet (see Section 18.0) prior to registration: CARES-SF, CES-D, Psychosocial Predictors Form, and the Support Services Form.

c. The nurse or CRA will complete the **S9632** Prestudy Form and the Quality of Life Cover Sheet for the patient questionnaires.

d. A second packet (with a stamped envelope addressed to the Southwest Oncology Group institution) should be given to the woman for completion in six weeks (Post-registration Assessment = 1): CARES-SF; CES-D; Support Services Form; Telephone Counseling Evaluation Form. The CRA or nurse will inform patients that they will complete the questionnaires six weeks after beginning the intervention.

e. Each institution will provide patients with basic information at study entry. This information should include a copy of the National Cancer Institute (NCI) booklet, "When Cancer Recurs: Meeting the Challenge Again" (call 1-800-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 distributed to study participants; addresses and/or phone numbers should be provided. The baseline questionnaires should be completed before a study patient is given the pamphlet(s) and list of resources.

f. The CRA will fax the name, address, telephone number, age, site(s) of recurrence and patient number to Y-ME, attention Judy Perotti, Director of Patient Services, (Phone: 312/294-8513; Fax: 312/294-8597), 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.

g. The CRA or nurse should call the patient six weeks after study entry (Post-registration Assessment = 1) to determine if the four telephone intervention sessions have occurred. The CRA or nurse should ask if the patient still has the questionnaire packet given her at study entry. If the patient has the packet, a time for a telephone interview should be arranged; ask the woman to complete the questionnaires prior to the date. If the patient no longer has the follow-up packet, arrange the telephone interview and mail a new packet to the patient. 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 and encourage 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.

h. If the patient has not completed the four session intervention, ask her when she is scheduled to do so. Recontact the patient at that time, and follow the instructions in Section 7.1g. If the patient indicates that she does not wish to complete the four sessions, ask her to complete the forms at that time (follow instructions in Section 7.1g).

i. The Clinical Update Form and Quality of Life Cover Sheet will be completed by the CRA or nurse after the patient packet is returned. It may be necessary to call the patient if the follow-up questionnaire packet is not received in a reasonable amount of time. If the patient cannot or does not return the packet, the CRA or nurse should still complete and submit the **S9632** Clinical Update Form and the Quality of Life Cover Sheet.

7.2 Main Study

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

b. The nurse or CRA will complete the **S9632** Prestudy Form and the Quality of Life Cover Sheet for the patient questionnaires.

c. Each institution will provide patients with basic information at study entry. This information should include a copy of the National Cancer Institute (NCI) booklet, "When Cancer Recurs: Meeting the Challenge Again" (call 1-800-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 distributed to study participants; addresses and/or phone numbers should be provided. The baseline questionnaires should be completed before a study patient is given the pamphlet(s) and list of resources. Women in the control group will receive the standard level of interaction and support provided by their medical team.

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 questionnaire packets at two follow-up points after randomization: three months (Post-registration Assessment = 1) and six months (Post-registration Assessment = 2); a self-addressed, stamped envelope will be included for return to the treating institution. The follow-up packet includes the CARES-SF, the CES-D, the Support Services Form, and the Telephone Counseling Evaluation Form (for patients on the intervention arm). Follow-up packets should be mailed two weeks prior to the scheduled assessment.

f. The **S9632** 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 questionnaire packet is not received within one week after the scheduled assessment, the nurse or CRA should call and remind the patient to submit the packet 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 (Post-registration Assessment = 1) and at Month 6 (Post-registration Assessment = 2). At Month 3, determine if the four telephone intervention sessions have occurred. The CRA or nurse should ask if the patient still has the questionnaire packet given her at study entry. If the patient has the packet, a time for a telephone interview should be arranged; ask the woman to complete the questionnaires prior to the date. If the patient no longer has the follow-up packet, arrange the telephone interview and mail the packet to the patient. 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.

h. If the patient has not completed the four session intervention, ask her when she is scheduled to do so. Recontact the patient at that time, and follow the instructions in Section 7.2g. If the patient indicates that she does not wish to complete the four sessions, ask her to complete the forms at that time (follow instructions in Section 7.2g).

i. The Clinical Update Form and Quality of Life Cover Sheet will be completed by the CRA or nurse after the patient packet is returned. It may be necessary to call the patient if the follow-up questionnaire packet is not received in a reasonable amount of time. If the patient cannot or does not return the packet, the CRA or nurse should still complete and submit the **S9632** Clinical Update Form and the Quality of Life Cover Sheet.

7.3 The Telephone Intervention

Patients in the intervention group will receive four counseling/information sessions delivered by telephone at weekly intervals. A standardized intervention protocol will be used, and sessions should require no longer than 45 minutes to complete. 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:

Session 1 Get acquainted; provide overview of sessions; set priorities and order for the topics to be discussed.

Session 2 - 4 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.

Following each 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. Women in the Control arm will be sent the standardized 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 1 (PILOT STUDY)

REQUIRED STUDIES	PRE STUDY	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	¥ Wk 6
ASSESSMENTS Ω							
CARES-SF	X						X
CES-D	X						X
Support Services Form	X						X
Psychosocial Predictors Form	X						
Telephone Counseling Evaluation Form							X
S9632 Prestudy Form	X						
S9632 Clinical Update Form							X
Quality of Life Cover Sheet	X						X
THERAPY							
Basic Information Packet	Xπ						
Telephone Counseling Sessions		Xf	Xf	Xf	Xf		

Ω Forms are found in Section 18.0. (See Section 14.0 for data submission guidelines and Section 15.0 for QOL Assessment instructions.)

f All patients on the Pilot Study will receive intervention.

π See Section 7.1e.

¥ Post-registration Assessment = 1

9.0 STUDY CALENDAR 2 (MAIN STUDY)

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 Predictors Form	X						
Telephone Counseling Evaluation Form						X	X
S9632 Prestudy Form	X						
S9632 Clinical Update Form						X	X
Quality of Life Cover Sheet	X					X	X
THERAPY							
Basic Information Packet	Xπ						
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.)

¥ Post-registration Assessment = 1

\# Post-registration Assessment = 2

f Intervention arm patients only

π See Section 7.2c.

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. Patients will be asked to check all services listed on the Support Services Form that they have used during the time period covered by assessment.

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

a. Social support

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 (**S9632** Prestudy Form), and at 3 and 6 months (**S9632** 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 Anticipated total accrual (Pilot Study): The Pilot Study will involve a total of 30 patients from four Group institutions (the University of Hawaii Minority-Based CCOP, Loyola University, Ozark Regional CCOP, and the University of Arkansas Cancer Center). Investigators estimates of the number of patients available at their institutions documented the feasibility of enrolling 30 patients over a six-month period.

11.2 Sample size (Main Study): 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)*

11.3 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)

11.4 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)*

11.5 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 7.1f).

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 (PILOT AND MAIN STUDIES):

Submit a copy of the following:

a. Registration Form

b. Pre-registration CARES-SF, CES-D, Support Services Form, Psychosocial Predictors Form, **S9632** Prestudy Form and Quality fo Life Cover Sheet (Pre-Registration Assessment)

14.5 PILOT STUDY - AFTER THE 6 WEEK ASSESSMENT:

Submit the Quality of Life Cover Sheet, **S9632** Clinical Update Form, CARES-SF, CES-D, Support Services Form and Telephone Counseling Evaluation Form.

14.6 MAIN STUDY-AFTER THE MONTH 3 AND MONTH 6 ASSESSMENTS:

Submit the Quality of Life Cover Sheet, **S9632** Clinical Update Form, CARES-SF, CES-D, Support Services Form and Telephone Counseling Evaluation Form.

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

Submit a copy of the Off Treatment Notice

15.0 QUALITY OF LIFE ASSESSMENTS: 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

a. Pilot Study.

The QOL questionnaires (CARES-SF, CES-D and Support Services Form) will be administered at study entry (Pre-registration Assessment) and at six weeks post-study entry (Post-registration Assessment =1). The Psychosocial Predictors Form will only be administered at study entry. Study entry forms should be administered in the clinic, so that the nurse or CRA can be certain that the patient understands how to complete the questionnaires. The Telephone Counseling Intervention Form is administered by phone interview only at six weeks (Post-registration Assessment = 1).

b. Main Study.

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

1. within seven days prior to randomization (Pre-registration Assessment),
2. month 3 (Post-registration Assessment = 1)
3. month 6 (Post-registration Assessment = 2)

The Psychosocial Predictors Form 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 Maintaining the QOL Follow-up Assessment Schedule

a. Pilot Study

1. At study entry, give all patients a packet of questionnaires (CARES-SF, CES-D, Support Services Form, and Telephone Counseling Evaluation Form) in the event that a clinic appointment does not occur six weeks

later when the forms are due. Note on the forms the actual calendar date of the follow-up assessment in 6 weeks.

2. The nurse or CRA should call the patient six weeks after study entry to determine if the four telephone counseling sessions have occurred. If so, the nurse/CRA should ask if the patient still has the questionnaire packet given her at study entry. If the patient has the packet, she should be reminded to mail the questionnaires to the Southwest Oncology Group institution. The nurse/CRA should emphasize the importance of answering all items on each questionnaire. If the patient no longer has the packet, mail the packet to the patient.

3. If the patient has not completed the counseling intervention, follow instructions as outlined in Section 7.1h.

4. During the call at six weeks, the nurse or CRA should administer the Telephone Counseling Evaluation Form on the phone with the patient, encouraging the patient to provide any information that could help improve the intervention content and its method of delivery. This information will be used to revise and improve the telephone counseling intervention for the Main Study. If the patient cannot go over the Telephone Counseling Intervention Evaluation Form at that time, another phone interview should be scheduled at the patient's convenience.

5. If the patient does not submit the questionnaire packet, and you have contacted her to remind her that it is due, submit both a Quality of Life Cover Sheet indicating why the data are missing and the **S9632** Clinical Update Form to the Statistical Center.

b. Main Study

1. When a patient is randomized to the Main Study of **S9632**, 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.

2. 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.

3. 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.

4. 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.

5. 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.

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

15.3 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.

15.4 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 **S9632** 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.

15.5 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.

15.6 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).

15.7 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 M-j. 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 Forms (Pilot & Main Study). The consent forms must be reviewed and approved by the Institutional Review Board prior to registration of patients on this study.

18.2 Registration Form

18.3 CARES-SF

18.4 CES-D

18.5 Support Services Form

18.6 Psychosocial Predictors Form

18.7 Quality of Life Cover Sheet

18.8 **S9632** Prestudy Form

18.9 **S9632** Clinical Update Form

18.10 Telephone Counseling Evaluation Form

18.11 Off Treatment Notice

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.

Please note that the Department of Defense (funding source for this study) requires some sections of the consent form to be worded exactly as stated in bold-faced type. It is important to alert your local Institutional Review Board to the requirement for these bolded sections.

CONSENT FORM AND INFORMATION ABOUT

S9632 "Enhancing Well-Being During Breast Cancer Recurrence"
PILOT STUDY

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.**

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.

After this, you will be asked to take part in a program to help you cope with stress. This program gives you a chance to talk with a "peer counselor." A peer counselor is a woman who, like you, has experienced a recurrence of breast cancer. Your peer counselor will call you on the telephone for four weekly sessions. Some of these sessions may be taped to help train peer counselors. 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. Each session will take about 45 minutes and will be at a time that is convenient for you. 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 each session.

We'll ask you to fill out a survey two weeks after the last session of the program. The survey asks what you thought of the program and how you are doing. This information will help us to learn whether the program is helpful. 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.

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

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

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. ***You are authorized all necessary medical care for physical injury or disease which is determined to be the proximate (or direct) result of your participation in this research study. The U.S. Army, which funds this study, requires that such medical care is provided by the local research institute when conducting research with private citizens. (12/1/97) Other than medical care that is provided for physical injuries or disease determined to be a direct result of your participation on this trial, you will not receive any compensation for participating in this research study; however, this is not a release or waiver of your legal rights.***

VI. 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. *(3/1/98)* 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.

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, understand that you may refuse to continue on this study at any time, without fear of prejudice to additional treatment that may be needed.

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.

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

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

XI. 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

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.

Please note that the Department of Defense (funding source for this study) requires some sections of the consent form to be worded exactly as stated in bold-faced type. It is important to alert your local Institutional Review Board to the requirement for these bolded sections.

CONSENT FORM AND INFORMATION ABOUT

S9632 "Enhancing Well-Being During Breast Cancer Recurrence"
MAIN STUDY

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.**

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.

After this, you will be asked to take part in a program designed to help you cope with stress or you will receive standard care. By standard care, we mean whatever support is available in your hospital and hometown. Random assignment will determine whether you receive the program or standard care. This is similar to flipping a coin. You have equal chances of being in either group. We are trying to find out whether the program is helpful to patients, since similar programs have not included women such as yourself before. This program gives you a chance to talk with a "peer counselor." A peer counselor is a woman who, like you, has experienced a recurrence of breast cancer. Your peer counselor will call you on the telephone for four weekly sessions. Some of these sessions may be taped to help train peer counselors. 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. Each session will take about 45 minutes and will be at a time that is convenient for you. 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 each session.

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. ***You are authorized all necessary medical care for physical injury or disease which is determined to be the proximate (or direct) result of your participation in this research study. The U.S. Army, which funds this study, requires that such medical care is provided by the local research institute when conducting research with private citizens. (12/1/97) Other than medical care that is provided for physical injuries or disease determined to be a direct result of your participation on this trial, you will not receive any compensation for participating in this research study; however, this is not a release or waiver of your legal rights.***

VI. 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. *(3/1/98)* 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.

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.

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

XI. 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 6 3 2

Registration Step 1

Activation Date: June 1, 1997

Last Amended Date:

Enhancing Well-Being During Breast Cancer Recurrence

(Pilot Study Phase Registration Form)

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. Use **black ink** to complete this form. All date fields are Month/Day/Year. A copy of this form must be submitted to the Statistical Center. The following will serve as an example:

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

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 Gender: ☐ 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 without bone ☐ Soft tissue with bone ☐ Visceral

28536

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	

CARES-SF

CAncer Rehabilitation Evaluation System

Short Form

For Research

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

PATIENT NAME _____ AGE _____

INSTITUTION/MEMBER _____

0-☐ Pre-registration

☐ Post-registration Assessment Number

Date: ☐☐-☐☐-☐☐ (M,D,Y)

Instructions

Below is a list of Problem Statements that describe situations and experiences of individuals who have or have had cancer. Read each statement and circle the number 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 this apply to you?					
1. I have difficulty walking	0	(1)	2	3	4
2. I find that food tastes bad	0	1	2	3	(4)

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SWOG Patient #: _____

Pre-registration
Post-registration Assessment #

How much does it apply to you?	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
1. I have difficulty bending or lifting	0	1	2	3	4
2. I do not have the energy I used to	0	1	2	3	4
3. I have difficulty doing household chores	0	1	2	3	4
4. I have difficulty bathing, brushing my teeth, or grooming myself	0	1	2	3	4
5. I have difficulty planning activities because of the cancer or its treatments	0	1	2	3	4
6. I cannot gain weight	0	1	2	3	4
7. I find food unappealing	0	1	2	3	4
8. I find that cancer or its treatments interfere with my ability to work	0	1	2	3	4
9. I frequently have pain	0	1	2	3	4
10. I find that my clothes do not fit	0	1	2	3	4
11. I find that doctors don't explain what they are doing to me	0	1	2	3	4
12. I have difficulty asking doctors questions	0	1	2	3	4
13. I have difficulty understanding what the doctors tell me about the cancer or its treatments	0	1	2	3	4
14. I would like to have more control over what the doctors do to me	0	1	2	3	4
15. I am uncomfortable with the changes in my body	0	1	2	3	4
16. I frequently feel anxious	0	1	2	3	4
17. I have difficulty sleeping	0	1	2	3	4
18. I have difficulty concentrating	0	1	2	3	4
19. I have difficulty asking friends or relatives to do things for me	0	1	2	3	4
20. I have difficulty telling my friends or relatives about this cancer	0	1	2	3	4

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SWOG Patient #: _____

____ Pre-registration
____ Post-registration Assessment # ____

How much does it apply to you?					
21. I find that my friends or relatives tell me I'm looking well when I'm not ..	0	1	2	3	4
22. I find that my friends or relatives do not visit often enough	0	1	2	3	4
23. I find that my friends or relatives have difficulty talking with me about my illness	0	1	2	3	4
24. I become nervous when I am waiting to see the doctor	0	1	2	3	4
25. I become nervous whem I get my blood drawn	0	1	2	3	4
26. I worry about whether the cancer is progressing	0	1	2	3	4
27. I worry about not being able to care for myself	0	1	2	3	4
28. I do not feel sexually attractive	0	1	2	3	4
29. I am not interested in having sex	0	1	2	3	4
30. I sometimes don't follow my doctor's instructions	0	1	2	3	4
31. I have financial problems	0	1	2	3	4
32. I have insurance problems	0	1	2	3	4
33. I have difficulty with transportation to and from my medical appointments and/or other places	0	1	2	3	4
34. I am gaining too much weight	0	1	2	3	4
35. I have frequent episodes of diarrhea	0	1	2	3	4
36. I have times when I do not have control of my bladder	0	1	2	3	4

Do you have children?					
37. I have difficulty helping my children cope with my illness	0	1	2	3	4

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SWOG Patient #: _____

____ Pre-registration

____ Post-registration Assessment # ____

[redacted]

38. I have difficulty talking to the people who work with me about the cancer	0	1	2	3	4
39. I have difficulty asking for time off from work for medical treatments.	0	1	2	3	4
40. I am worried about being fired	0	1	2	3	4

[redacted]

41. I have difficulty finding a new job since I have had cancer	0	1	2	3	4

[redacted]

42. I find that the frequency of sexual intercourse has decreased	0	1	2	3	4

[redacted]

43. My partner and I have difficulty talking about our feelings	0	1	2	3	4
44. My partner and I have difficulty talking about wills and financial arrangements	0	1	2	3	4
45. I do not feel like embracing, kissing, or caressing my partner	0	1	2	3	4
46. My partner and I are not getting along as well as we usually do	0	1	2	3	4
47. My partner spends too much time taking care of me	0	1	2	3	4
48. I have difficulty asking my partner to take care of me	0	1	2	3	4

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SWOG Patient #: _____ ____Pre-registration ____Post-registration Assessment #____

[redacted]

[redacted]

49. I have difficulty initiating contact with potential dates 0 1 2 3 4

50. I have difficulty telling a date about the cancer or its treatment 0 1 2 3 4

[redacted]

51. I become nervous when I get chemotherapy 0 1 2 3 4

52. I become nauseated during and/or before chemotherapy 0 1 2 3 4

53. I feel nauseated after I receive chemotherapy 0 1 2 3 4

54. I vomit after chemotherapy 0 1 2 3 4

55. I have other side effects after chemotherapy 0 1 2 3 4

[redacted]

56. I get nervous when I get radiation treatments 0 1 2 3 4

57. I feel nauseous or vomit after my radiation treatments 0 1 2 3 4

[redacted]

58. I have problems with ostomy care and maintenance 0 1 2 3 4

[redacted]

59. I have difficulty with my prosthetic device (artificial limb, breast prosthesis, etc.) 0 1 2 3 4

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Southwest Oncology Group

Your Feelings (CES-D)

SWOG Study No. ☐☐☐☐☐ Protocol Step ☐

SWOG Patient No. ☐☐☐☐☐☐ Patient's Name _____ (L) (F) (M)

Institution / Member _____ Physician _____

Scheduled time to obtain CES-D:

0-☐ Pre-registration

☐ Post-registration Assessment Number

Date: ☐☐-☐☐-☐☐ (M,D,Y)

Circle the number 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	0	1	2	3
2. I did not feel like eating: my appetite was poor	0	1	2	3
3. I felt that I could not shake off the blues even with help from my family or friends	0	1	2	3
4. I felt that I was just as good as other people	0	1	2	3
5. I had trouble keeping my mind on what I was doing	0	1	2	3
6. I felt depressed	0	1	2	3
7. I felt that everything I was doing was an effort	0	1	2	3
8. I felt hopeful about the future	0	1	2	3
9. I thought my life had been a failure	0	1	2	3
10. I felt fearful	0	1	2	3
11. My sleep was restless	0	1	2	3
12. I was happy	0	1	2	3
13. I talked less than usual	0	1	2	3
14. I felt lonely	0	1	2	3
15. People were unfriendly	0	1	2	3
16. I enjoyed life	0	1	2	3
17. I had crying spells	0	1	2	3
18. I felt sad	0	1	2	3
19. I felt that people disliked me	0	1	2	3
20. I could not get "going"	0	1	2	3

Southwest Oncology Group

SUPPORT SERVICES

SWOG Study No. S 9 6 3 2 Protocol Step ☐

SWOG Patient No. ☐☐☐☐☐☐ Patient's Name _____ (L) (F) (M)

Institution / Member _____ Physician _____

Scheduled time to obtain Support Services Questionnaire:

0-☐ Pre-registration

☐ Post-registration Assessment Number

Date: ☐☐-☐☐-☐☐ (M,D,Y)

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

RESOURCE	USED		If Yes, HOW HELPFUL				
	No	Yes	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							
Called Cancer Information Service (1-800-CANCER)							
American Cancer Society							
Other advocacy or cancer-related organization, specify: _____							
Print materials for cancer patients							
Internet							
Other resource, specify: _____							
Other resource, specify: _____							

SWOG 02-28-97 SW358

Southwest Oncology Group

PSYCHOSOCIAL PREDICTORS

SWOG Study No. ☐☐☐☐☐ Protocol Step ☐

SWOG Patient No. ☐☐☐☐☐☐ Patient's Name _____ (L,F,M)

Institution / Member _____ Physician _____

Date: ☐☐-☐☐-☐☐ (M,D,Y)

Please indicate the extent to which you agree with each of the following items, using the following response format. Circle One Number for each item.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. In uncertain times, I usually expect the best	0	1	2	3	4
2. It's easy for me to relax	0	1	2	3	4
3. If something can go wrong for me, it will	0	1	2	3	4
4. I always look on the bright side of things	0	1	2	3	4
5. I'm always optimistic about my future	0	1	2	3	4
6. I enjoy my friends a lot	0	1	2	3	4
7. It's important for me to keep busy	0	1	2	3	4
8 I hardly never expect things to go my way	0	1	2	3	4
9. Things never work out the way I want them to	0	1	2	3	4
10. I don't get upset too easily	0	1	2	3	4
11. I'm a believer in the idea that "every cloud has a silver lining"	0	1	2	3	4
12. I rarely count on good things happening to me	0	1	2	3	4

13. How surprised were you by the recurrence?

1-☐ Completely surprised
2-☐ Knew it would happen
3-☐ 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 to 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

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

19. Has it happened in the past that you were surprised by the behavior of people you thought you knew well?

1 never happened — 2 — 3 — 4 — 5 — 6 — 7 always happened

Southwest Oncology Group

PSYCHOSOCIAL PREDICTORS

SWOG Study No. ☐☐☐☐☐ Protocol Step ☐

SWOG Patient No. ☐☐☐☐☐☐ Patient's Name _____ (L,F,M)

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

SWOG 02-28-97 SW357

Southwest Oncology Group

QUALITY OF LIFE Cover Sheet

SWOG Study No. S 9 6 3 2 Protocol Step ☐

SWOG Patient No. ☐☐☐☐☐☐ Patient's Name _____ (L) (F) (M)

Institution / Member _____ Physician _____

Amended data: ☐ Yes, mark amended items in red.

Instructions: Submit two copies of this cover sheet to the SWOG Statistical Center each time the patient is scheduled to complete the QUALITY OF LIFE Questionnaires, whether the Questionnaires are actually completed or not. Other cooperative groups: see protocol for mailing instructions.

Scheduled time to obtain Quality of Life Questionnaires:

0-☐ Pre-registration

☐ Post-registration Assessment Number

Was the CARES-SF Questionnaire completed? ☐ No ☐ Yes

If Yes, Date Questionnaire was completed: ☐☐-☐☐-☐☐ (M,D,Y)

Was the CES-D completed? ☐ No ☐ Yes

If Yes, Date completed: ☐☐-☐☐-☐☐ (M,D,Y)

Was the Psychosocial Predictors Scale completed (Baseline only)? ☐ No ☐ Yes

If Yes, Date completed: ☐☐-☐☐-☐☐ (M,D,Y)

Was the Support Services Form completed? ☐ No ☐ Yes

If Yes, Date completed: ☐☐-☐☐-☐☐ (M,D,Y)

Was the Telephone Counseling Evaluation Form completed? ☐ No ☐ Yes

If Yes, Date completed: ☐☐-☐☐-☐☐ (M,D,Y)

If Completed, In general did the patient require assistance? ☐ No ☐ Yes

Describe: _____

If Completed, Questionnaires administered:
0-☐ in the clinic
1-☐ by telephone
2-☐ by mail

If Not completed, Please give reason (check one)

1-☐ Patient kept appointment for examination, but could not complete Questionnaires due to illness.

2-☐ Patient kept appointment for examination, but refused to complete Questionnaires for reason other than illness.
Specify reason: _____

3-☐ Patient refused to complete Questionnaires by telephone interview.
Specify reason: _____

4-☐ Patient could not be contacted.

5-☐ Questionnaire not administered due to institution error.

6-☐ Patient off treatment, but cannot be contacted for follow-up

7-☐ Patient died

8-☐ Other reason, specify: _____

BY: _____ **Date:** _____ **SWOG 02-28-97 SW361**

Southwest Oncology Group

S9632 PRESTUDY

SWOG Study No. S 9 6 3 2 Step 1

SWOG Patient No. ☐☐☐☐☐☐ Patient's Name _____ (L,F,M)

Institution / Member _____

Physician _____

Date: ☐☐ - ☐☐ - ☐☐ (M,D,Y)

Amended data: ☐ Yes, mark amended items in red.

Instructions: All dates are MONTH, DAY, YEAR. Indicate an unknown part of a date with a horizontal line drawn across the appropriate boxes.

PATIENT CHARACTERISTICS

Current Pain Medication Index

0-☐ Nothing

1-☐ Non-Opioid Analgesics

2-☐ Non-Opioids plus Weak Opioids (e.g., Tylenol3, Percocet)

3-☐ Strong Opioids (e.g., morphine, Dilaudid, methadone)

Psychotropic Medications ☐ No ☐ Yes

Menopausal Status

1-☐ Pre (regular menses or < 6 months since LMP and **not** on estrogen replacement and **no** prior bilateral ovariectomy)

2-☐ Post (prior bilateral ovariectomy OR > 12 months since LMP with **no** prior hysterectomy)

3-☐ Other (pre/post will be defined by age at the Statistical Center)

TUMOR STAGE NODE STAGE AT DIAGNOSIS OF PRIMARY

Tumor stage

T-status: (check one)

T0 ☐ T1 ☐ T2 ☐ T3 ☐

Node stage

N-status: (check one)

N0 ☐ N1 ☐ N2 ☐ N3 ☐

TREATMENT FOR PRIMARY

RT ☐ No ☐ Yes

Chemotherapy ☐ No ☐ Yes

Hormonal Therapy ☐ No ☐ Yes

Surgery

0-☐ None

1-☐ Less than total mastectomy

2-☐ Total, modified radical or radical mastectomy

DISEASE HISTORY

Date of:	(M)	(D)	(Y)
Histologic Diagnosis of **Primary**	☐☐ -	☐☐ -	☐☐
Diagnosis of **Recurrence**	☐☐ -	☐☐ -	☐☐
Diagnosis of **Contralateral** breast malignancy	☐☐ -	☐☐ -	☐☐

TREATMENT FOR RECURRENCE

RT ☐ No ☐ Yes

Chemotherapy ☐ No ☐ Yes

Hormonal Therapy ☐ No ☐ Yes

Surgery ☐ No ☐ Yes

Notes:

By: _____ **Date:** _____ SWOG 05-08-97 SW355

S9632 PRESTUDY Instructions

Patient Characteristics

This section is designed to record descriptive information regarding the patient. The information recorded here is based on that available at the time of registration to the protocol.

Current Pain Medication Index: Record the appropriate category of pain medications taken by the patient at the time of registration to the protocol.

0 - Nothing
1 - Non-Opioid Analgesics
2 - Non-Opioids plus Weak Opioids (e.g., Tylenol 3, Percocet, etc.)
3 - Strong Opioids (e.g., morphine, Dilaudid, methadone, etc.)

Psychotropic Medications: Record whether the patient is currently taking any psychotropic medications. For the purposes of this study, consider only drugs with known psychotropic effects. For example:

- Antidepressants (e.g., Prozac, Elavil)
- Antianxiety medications (e.g., Valium, Ativan, Xanax)
- Sleeping medications (e.g., Restoril, Dalmane, Ambien)
- Antipsychotics (e.g., Haldol)
- Antimanic medications (e.g., Lithium, Depakote)
- Other psychotropic medications (e.g., Klonopin)

Menopausal Status: Record the patient's menopausal status at the time of registration to the protocol.

1 - Pre if the patient has regular menses or is within 4 months of last menstrual period and premenopausal FSH and not on estrogen replacement.
2 - Post if the patient had a prior bilateral ovarictomy or is more than 12 months from last menstrual period with no prior hysterectomy.
3 - Other if menopausal status cannot be determined.

Disease History

Date of histologic diagnosis of primary disease: Please record the date the patient was first diagnosed with breast cancer.

Date of diagnosis of recurrence: Please record the date the patient was diagnosed with a first recurrence of breast cancer. First recurrence is defined as the first diagnosis after primary surgery of any distant metastatic site, or chest wall recurrence, or scar recurrence.

Date of diagnosis of contralateral breast malignancy: Please record the date the patient was diagnosed with a contralateral breast malignancy.

T,N Stage at Diagnosis of Primary
Stage is coded according to the International Coding System of the AJCC.

Primary Tumor (T)

T0	No evidence of primary tumor
T1	Tumor 2 cm or less in greatest dimension
T2	Tumor more than 2 cm, but not more than 5 cm in greatest dimension
T3	Tumor more than 5 cm in greatest dimension

Regional Lymph Nodes (N)

N0	No regional lymph node metastasis
N1	Metastasis to movable ipsilateral axillary lymph node(s)
N2	Metastasis to ipsilateral axillary lymph nodes that are fixed to one another or to other structures

Treatment for Primary

Prior treatment refers to any disease-related treatment that the patient received for their primary breast cancer.

Radiation Therapy: Please indicate whether this patient had any radiation therapy **related to her breast primary.**

Chemotherapy: Please indicate whether the patient had any adjuvant hemotherapy **related to her breast primary**. The therapy must have been administered with the intent of affecting, destroying, controlling or changing malignant tissue.

Hormonal Therapy: Please indicate whether the patient had any adjuvant hormonal therapy **related to her breast primary**. The therapy must have been administered with the intent of affecting, destroying, controlling or changing malignant tissue. Hormonal therapy includes: hormones, antihormones, endocrine surgery/ablation.

Surgery: Please indicate whether the patient had any surgery **related to her breast primary.** Surgery **excludes** any biopsy done only for diagnostic purposes, e.g., incisional biopsies and needle biopsies are excluded.

0 - None if no surgery was performed.
1 - Less than total mastectomy
2 - Total, modified radical or radical mastectomy

Treatment for Recurrence

Treatment refers to any disease-related treatment that the patient is receiving for her breast recurrence. Treatment pertains only to the breast cancer recurrence, not other diseases or malignancies the patient may have had.

Radiation Therapy: Please indicate whether the patient had any radiation therapy **related to her breast cancer recurrence** since the diagnosis of recurrence.

Chemotherapy: Please indicate whether the patient is currently receiving chemotherapy **related to her breast cancer recurrence.** The therapy must be administered with the intent of affecting, destroying, controlling or changing malignant tissue.

Hormonal Therapy: Please indicate whether the patient is currently receiving hormonal therapy **related to her breast cancer recurrence**. The therapy must have been administered with the intent of affecting, destroying, controlling or changing malignant tissue. Hormonal therapy includes: hormones, antihormones, endocrine surgery/ablation.

Surgery: Please indicate whether the patient has had any surgery **related to her breast cancer recurrence** since diagnosis of recurrence. Surgery for recurrence **excludes** any biopsy done only for diagnostic purposes, (e.g., incisional biopsies and needle biopsies are excluded).

Southwest Oncology Group

S9632 CLINICAL UPDATE

SWOG Study No. S 9 6 3 2 Step 1

SWOG Patient No. ☐☐☐☐☐☐ Patient's Name _____ (L,F,M)

Institution / Member _____

Physician _____

Scheduled time to obtain Clinical Update Form:

☐☐ Post-registration Assessment number

Date: ☐☐ - ☐☐ - ☐☐ (M,D,Y)

Amended data: ☐ Yes, mark amended items in red.

Instructions: All dates are MONTH, DAY, YEAR. Indicate an unknown part of a date with a horizontal line drawn across the appropriate boxes.

PATIENT CHARACTERISTICS

Current Performance Status

0-☐ Fully active

1-☐ Symptoms but ambulatory and able to do light work

2-☐ No work but self care and active > 50% of waking hours

3-☐ Limited self care, confined to bed or chair > 50% of waking hours

4-☐ Completely disabled

Current Pain Medication Index

0-☐ Nothing

1-☐ Non-Opioid Analgesics

2-☐ Non-Opioids plus Weak Opioids (e.g., Tylenol3, Percocet)

3-☐ 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 S9632 Clinical Update form was completed?

☐ No ☐ Yes

If Yes, Date: ☐☐ - ☐☐ - ☐☐ (M,D,Y)

Site(s): _____

_____

Notes:

By: _____ **Date:** _____ **SWOG 05-08-97 SW364**

S9632 CLINICAL UPDATE FORM Instructions

Scheduled time to obtain Clinical Update Form: List the post-registration assessment number (for assessment number, please refer to Section 9.0 of the protocol).

Patient Characteristics

This section is designed to record descriptive information regarding the patient. The information recorded here is based on that available at the time of assessment.

Current Performance Status: Please refer to Patient Characteristics in Chapter 1 of Volume II of the Data Manager's (Clinical Research Associate's) Manual.

Current Pain Medication Index: Record the appropriate category of pain medications taken at any time since the last assessment.

0 - Nothing
1 - Non-Opioid Analgesics
2 - Non-Opioids plus Weak Opioids (e.g., Tylenol 3, Percocet, etc.)
3 - Strong Opioids (e.g., morphine, Dilaudid, methadone, etc.)

Psychotropic Medications: Record whether psychotropic medications were taken at any time since the last S9632 Clinical Update Form was completed. For the purposes of this study, consider only drugs with known psychotropic effects. For example:

- Antidepressants (e.g., Prozac, Elavil)
- Antianxiety medications (e.g., Valium, Ativan, Xanax)
- Sleeping medications (e.g., Restoril, Dalmane, Ambien)
- Antipsychotics (e.g., Haldol)
- Antimanic medications (e.g., Lithium, Depakote)
- Other psychotropic medications (e.g., Klonopin)

Current Treatment Status

Current treatment refers to any disease-related treatment that the patient is receiving (or has received since the last S9632 Clinical Update Form was completed) for their breast recurrence. Treatment pertains only to the breast cancer recurrence, not other diseases or malignancies the patient may have had.

Radiation Therapy: Please indicate whether the patient had any radiation therapy **related to her breast cancer recurrence** since the last S9632 Clinical Update Form was completed.

Chemotherapy: Please indicate whether the patient had any chemotherapy **related to her breast cancer recurrence** since the last S9632 Clinical Update Form was completed. The therapy must have been administered with the intent of affecting, destroying, controlling or changing malignant tissue.

Hormonal Therapy: Please indicate whether the patient had any hormonal therapy **related to her breast cancer recurrence** since the last S9632 Clinical Update Form was completed. The therapy must have been administered with the intent of affecting, destroying, controlling or changing malignant tissue. Hormonal therapy includes: hormones, antihormones, endocrine surgery/ablation.

Surgery: Please indicate whether the patient had any surgery **related to her breast cancer recurrence** since the last S9632 Clinical Update Form was completed. Surgery for recurrence **excludes** any biopsy done only for diagnostic purposes, (e.g., incisional biopsies and needle biopsies are excluded).

Disease Status

Progression of disease since last assessment: Record whether the patient had any disease progression since the last S9632 Clinical Update Form was completed. Please refer to Chapter 7 of Volume I of the Data Manager's (Clinical Research Associate's) Manual.

If *yes*, record the date and site(s) of progression.

Southwest Oncology Group

Telephone Counseling Evaluation Form

SWOG Study No. ☐☐☐☐☐ Protocol Step ☐

SWOG Patient No. ☐☐☐☐☐☐ Patient's Name _____ (L) (F) (M)

Institution / Member _____ Physician _____

Scheduled time to obtain Evaluation of the Telephone Counseling Program:

0-☐ Pre-registration

☐ Post-registration Assessment Number

Date: ☐☐-☐☐-☐☐ (M,D,Y)

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, or Poor (Please circle one number on each line).

	Excellent	Good	Satisfactory	Fair	Poor	Not/ Applicable
a. The **way** problems were discussed	1	2	3	4	5	
b. The **types** of problems/issues discussed	1	2	3	4	5	
c. Medical information provided	1	2	3	4	5	
d. Other information provided	1	2	3	4	5	
e. Knowledge and skill of Counselor	1	2	3	4	5	
f. Counselor caring about you and your concerns	1	2	3	4	5	
g. Use of telephone for counseling sessions instead of meeting with Counselor in-person	1	2	3	4	5	
h. Length of each session (45 min.)	1	2	3	4	5	
i. Number of sessions (4)	1	2	3	4	5	
j. Quality of educational materials	1	2	3	4	5	
k. Relevance of questionnaires to your experience	1	2	3	4	5	
l. Telephone Sessions: Overall program	1	2	3	4	5	
(a) Get acquainted and planning discussion	1	2	3	4	5	
(b) Physical problems	1	2	3	4	5	6
(c) Social support	1	2	3	4	5	6
(d) Existential concerns	1	2	3	4	5	6
(e) Handling stress	1	2	3	4	5	6
(f) Wrap-up	1	2	3	4	5	

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

1-☐ Not at all helpful
2-☐ A little helpful
3-☐ Somewhat helpful
4-☐ Very helpful
5-☐ Extremely helpful

Please explain why: _____

_____

SWOG 02-28-97 SW359

Southwest Oncology Group

Telephone Counseling Evaluation Form

SWOG Study No. ☐☐☐☐☐ Protocol Step ☐

___ Pre-registration

___ Post-registration Assessment Number ___

SWOG Patient No. ☐☐☐☐☐☐ Patient's Name _____
(L) (F) (M)

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!

SWOG 02-28-97 SW359

Southwest Oncology Group

OFF TREATMENT NOTICE

Amended data: ☐ Yes, mark amended items in red.

Disease Committee: _____ SWOG Study No. ☐☐☐☐☐ Protocol Step ☐

SWOG Pt. No. ☐☐☐☐☐☐ Patient's Name _____ (L,F,M)

Institution / Member _____ Physician _____

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

Reason OFF TREATMENT (Check one)

1-☐ Treatment completed per protocol
2-☐ Toxicity, medically required, specify: _____
3-☐ Patient refused, due to toxicity, specify: _____
4-☐ Patient refused, other than toxicity, specify: _____
5-☐ Progression or relapse (attach **Notice of Recurrence/Relapse** Form). Sites: _____
6-☐ Death (attach **Notice of Death** form)
7-☐ Other, specify: _____

Date OFF TREATMENT

Date of completion, progression, death or decision to discontinue therapy ☐☐-☐☐-☐☐ (M,D,Y)

Will patient receive **Further Treatment**?

☐ No ☐ Yes, specify: _____ ☐ Unknown

Date of **Last Contact** (or **death**): ☐☐-☐☐-☐☐ (M,D,Y)

VITAL STATUS: ☐ Alive ☐ Dead (attach **Notice of Death** form)

Notes:

By: _____ **Date:** _____

SWOG 02-24-97 SW060