Intervention to Improve Psychological Functioning for Newly Diagnosed Patients With Cancer

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Purpose/Objectives: To test the effects of a computer-based nursing intervention designed to provide patients and family caregivers with concrete, objective information on symptom management; provide education about disease and treatment; coordinate medical resources; and provide emotional support and counseling.

Design: Two-site, randomized clinical trial.

Settings: A large, urban, midwestern, tertiary-cancer center and a community-based cancer center in a medium-sized midwestern city.

Sample: 109 patients newly diagnosed with breast, colon, or lung cancer who were receiving chemotherapy; 54 received standard care, and 55 participated in the intervention group.

Methods: Outcome data were collected via structured telephone interviews at three time points: baseline, midway through the intervention, and one month postintervention. The intervention consisting of nine visits, five in person and four by telephone, was conducted over 18 weeks by advanced practice oncology nurses.

Main Research Variables: Psychosocial functioning, anxiety, and depression.

Findings: Patients who received the intervention had significantly less depression between baseline and the midway point, as well as less anxiety and greater improvement in the role-emotional and mental health subscales of the Medical Outcomes Study 36 Short Form.

Conclusions: Cancer-care nursing interventions can decrease psychosocial morbidity and improve quality of life for newly diagnosed patients with cancer undergoing treatment. Additional research is needed to understand who benefited most from the intervention.

Implications for Nursing: This nurse-directed intervention resulted in improved mental health for patients; however, physical subscales were not changed. Further work is needed to determine why depression and mental health were affected yet physical health and symptoms did not differ between groups. Results support the important role of nurses in addressing mental health issues in patients and families experiencing cancer.

Key Points . . .

- Newly diagnosed patients with cancer exhibit psychosocial distress, including anxiety and depression.
- A computer-based nursing intervention can be used to document and standardize cancer-care delivery.
- A computer-based nursing intervention may improve psychosocial functioning, depression, and anxiety for newly diagnosed patients with cancer undergoing chemotherapy.
- Patients with cancer who are most in need of psychosocial interventions may be more likely to drop out of intervention studies.

Newly diagnosed patients with cancer frequently struggle to cope with diagnosis, treatment, and survival, often with limited resources, creating physical, psychological, and financial burdens. Hospital stays have been shortened, limiting the time patients and caregivers have to learn care tasks (e.g., administering medications and treatments, managing and monitoring symptoms). Coping at home with cancer-treatment-related symptoms, such as fatigue and pain, presents tremendous challenges for patients and their families and may contribute to psychological dysfunction, such as depression and anxiety (Schag & Heinrich, 1989).

The purpose of this pilot study was to test a computer-based nursing intervention that provided assistance with symptom management, information about disease and treatment, emotional counseling and support, and coordination of services to newly diagnosed patients and their families who are dealing with cancer and chemotherapy treatment. Providing patients

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and families with concrete, objective information about symptoms, symptom management, emotional support, and counseling was hypothesized to reduce the psychological impact of cancer treatment, including depression and anxiety.

Background

Lung, breast, and colorectal cancers account for 55% of all female cancers and 25% of all male cancers that occur during adulthood (Jemal, Thomas, Murray, & Thun, 2002). Although these cancers may differ in terms of surgical or chemotherapeutic treatments, most require intensive treatment with chemotherapy. The physical and psychological impact of diagnosis and treatment can be significant for both patients and their caregivers.

Many studies have found significant emotional distress in patients with cancer following diagnosis. Ferrell, Grant, Funk, Otis-Green, and Garcia (1997) conducted focus groups to identify quality-of-life issues for breast cancer survivors. Psychological stressors related to the cancer experience included awareness of death, fear of recurrence, anxiety after the initial diagnosis, delayed diagnosis, and altered priorities. Stress also has been related to side effects of chemotherapy. Researchers found that significantly more women receiving chemotherapy experienced anxiety or depressive mood compared with those receiving surgery alone or in combination with hormone treatment (Maguire et al., 1980).

Research results have provided insight regarding the relationship between symptoms, losses in function and mobility, and patients' levels of depression (Kurtz, Given, Kurtz, & Given, 1994). These researchers found significant relationships between patient depression, physical discomfort related to symptoms, and dependency with activities of daily living and caregiver problems, such as depression, impact on health, impact on schedule, and caregiver assistance. Gender differences in depression also have been observed (Given, Given, & Stommel, 1994). Among men, changes in symptoms at baseline corresponded with changes in depression, whereas women who had an increase or decrease in symptom experience had no change in depression over time. For many women, depression was significantly less likely to improve over time.

Depression has been shown to be a major consequence in new and recurrent breast cancer (Given & Given, 1992). Over the six months following diagnosis, depression tended to decrease somewhat yet remained high for patients with recurrent disease. Depression and anxiety are common, as is fear of reoccurrence (Ferrell et al., 1998).

Several intervention studies have tested the impact of psychological treatment on patients with cancer. Intervention studies that stressed psychological counseling and support have found significant improvements in patients with cancer. McCorkle et al. (1989) randomized patients with metastatic disease to one of three conditions: home care provided by oncology nurses, home care from regular nurses, or standard health care. Patients in the two homecare conditions had greater independence and less distress. Researchers tested an intervention with patients with metastatic breast cancer (Spiegel, Bloom, Kraemer, & Gottheil, 1989). Patients in the experimental group met weekly in psychological support groups for one year. By the final session, patients in the experimental group demonstrated significantly less tension, fatigue, and confusion. Cella, Sarafian, Snider, Yellen, and Winicour (1993) led an eight-week support group for 77 patients with cancer. A control group was not used, but self-reported quality of life improved significantly by the final session, compared with reports from the beginning of the study.

Other studies combined specific portions of therapy encompassing health education, stress management, coping skills, and supportive group psychotherapy (Fawzy et al., 1990; Fawzy & Fawzy, 1994). Patients were taught stress management strategies such as relaxation exercises, problem solving, and group support. Six months following the intervention, the experimental group reported significantly less depression, fatigue, and confusion. Additionally, the vigor scale on the Profile of Mood States was significantly higher for these patients. The long-lasting effects particularly were important.

In a recent review of psychosocial interventions for patients with cancer, Fawzy (1999) noted that effective interventions were those that combined three major components: (a) education tailored to the type and phase of cancer treatment, (b) coping skills, and (c) emotional support and counseling. Prior research demonstrated that these interventions have improved outcomes when used individually but are even more powerful and enduring when used in combination (Fawzy).

Theoretical Framework

Self-regulation theory (Johnson, Fieler, Jones, Wlasowicz, & Mitchell, 1997) was used to direct development of the nursing intervention used in this study. Self-regulation theory is based on the parallel response model of coping with threatening events that incorporates two pathways of information processing. Figure 1 illustrates the conditions under which patients can be expected to benefit from psychoeducational interventions. Interventions that support effective problem solving should result in improved outcomes. Alternately, emotionally based responses to an event actually may increase the distress experienced.

Johnson (1996) demonstrated that information that helped patients regulate their negative emotional responses improved outcomes. Johnson, Fieler, Wlasowicz, Mitchell, and Jones (1997) suggested that nurses could help patients reduce their emotional responses and direct patients' attention to the objective features of the experience. Self-regulation theory suggests that concrete, objective information in combination with appropriate emotional support and counseling may minimize disruption of patients' usual activities, resulting in decreased emotional and psychological distress.

The intervention tested in the current study was a computer-based nursing intervention designed to provide concrete, objective information to patients and their families about disease-related problems (e.g., symptom management), emotional distress (e.g., anxiety, depression), and use of community resources. Patients with cancer who received the intervention were hypothesized to have higher psychological functioning scores and lower depression and anxiety scores than those receiving standard care.

Methods

This randomized clinical trial of a computer-based nursing intervention for patients and their family caregivers was implemented at two midwestern sites. Patients newly diagnosed with breast, colorectal, or lung cancer who were undergoing

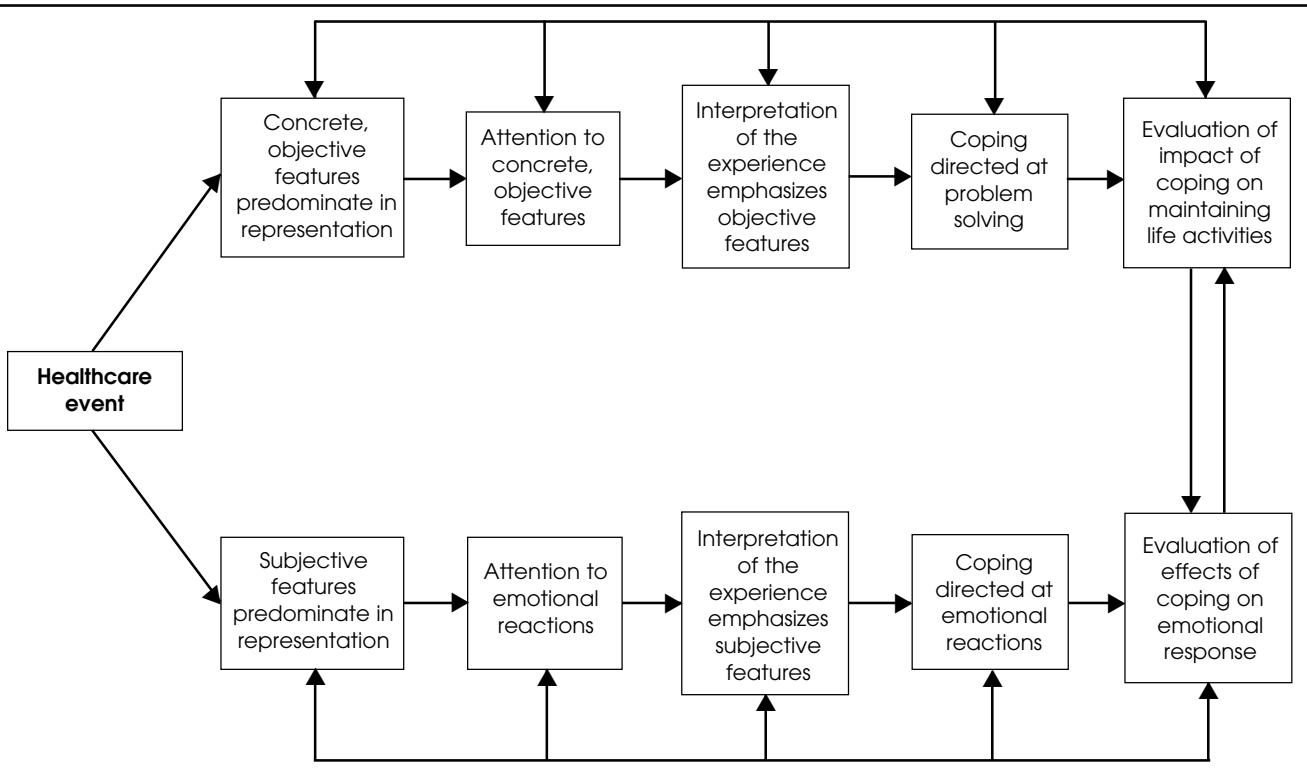

Figure 1. Self-Regulation Theory

Note. From *Self-Regulation Theory: Applying Theory to Your Practice* (p. 11), by J.E. Johnson, V.K. Fieler, L.S. Jones, G.S. Wlasowicz, and M.L. Mitchell, 1997, Pittsburgh, PA: Oncology Nursing Society. Copyright 1997 by Oncology Nursing Society. Reprinted with permission.

chemotherapy and had identified caregivers were approached within 56 days of initiating chemotherapy. Patients were eligible to participate if they were 18 or older and spoke English. Patients first were approached by a trained recruiter who explained the study. If patients expressed interest, they were asked about their caregivers' participation. If caregivers could be identified and both patients and caregivers were willing, the dyads were enrolled in the study. Approval to conduct this study was obtained from all university and clinical site institutional review boards.

Sample

After completion of a baseline telephone interview, patients were assigned randomly to receive the computer-based nursing intervention or conventional cancer care (control group). Group assignment was generated via computer and stratified according to (a) site of recruitment, (b) site of the patients' cancer, and (c) caregivers' employment status. Caregivers' employment status was believed to influence implementation of home interventions.

Researchers screened 557 patient-caregiver dyads to determine eligibility. Three hundred thirty-two patients were not eligible for the study, with the most frequent reason being that the patients were not receiving chemotherapy (n = 169, 51%). Two hundred twenty-five patient-caregiver dyads met the eligibility criteria. Of those, 100 refused to participate, most often indicating being "too busy" as the reason. One hundred twenty-five patient-caregiver dyads agreed to participate and signed consent forms. Of those, five dyads were not randomized because they refused to participate when contacted for initial data collection.

Thirty-one participants did not continue in the study for one of three reasons. Six patients in the intervention group and five in the standard care group died during the study period. Nine dyads from the intervention group and four from the standard care group withdrew because they felt that the intervention was too time consuming or that this was not a good time for them to participate in a research study. Seven dyads were dropped or withdrew for other reasons. About the same number of dyads dropped out at each site (15 and 16); however, attrition from the intervention group was twice that of the standard care group (21 versus 10).

Outcome Measures

Researchers used psychosocial and mental health subscales of the **Medical Outcomes Study 36 Short Form (SF-36)** to assess psychosocial functioning. The SF-36 is a generic health status scale for adults with chronic conditions. The psychometric properties of this multidimensional health assessment instrument were summarized by Stewart and Ware (1993), and Ware, Snow, Kosinski, and Gandek (1993), who found high internal consistency for the subscales, 100% scaling success, and substantial clinical validity. The SF-36 subscales that were used to measure mental health and psychosocial functioning were: vitality, social functioning, role-emotional functioning, and mental health. This instrument has been used widely in research on chronic diseases, such as cancer, and with patients of varying socioeconomic status.

The **Centers for Epidemiological Studies Depression-20 scale (CESD-20)** was used to assess depressive mood (Radloff, 1977). The CESD-20 has been used widely, especially in studies that focus on levels of depression within

nonpsychiatric populations. The **State-Trait Anxiety Inventory (STAI)** was used to measure state anxiety (Spielberger, Gorsuch, & Lushene, 1970; Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983). The STAI consists of 20 statements that assess feelings of apprehension, tension, nervousness, and worry.

Procedure

Outcome data collection: Outcome data were collected throughout the intervention using telephone interviews, which were chosen as a preferred data collection method to ease subject burden. Two trained interviewers collected outcome data at three points during the six-month study: initial entry into the study (baseline), midway through the intervention (time 2), and one month postintervention (time 3). Time 3 data collection was used to determine if the intervention effect persisted or increased following cessation of intervention. Detailed training was provided using interviewer manuals and training procedures developed by the Michigan State University research team (Collins, Given, Given, & King, 1988).

Quality assurance of the outcome data collected was conducted on a monthly basis and included critical reviews of taped interviews, as well as case file reviews. Interviews were taped so the quality assurance monitor could check for consistency of delivery. Each interview took approximately one hour to complete, and interviewers were blind to respondents' group assignments. Data were collected at 9 weeks to determine intervention effect on chemotherapy symptoms and at 24 weeks to assess intervention effect one month after cessation of the intervention. Timing of outcome data collection in relation to intervention sessions is presented in Table 1.

Intervention Protocol

Table 1 outlines the intervention protocol, including each session's timing, type, and focus. The intervention occurred over 18 weeks and consisted of nine visits (five in person and four via telephone) with a master's-prepared oncology nurse specialist. Pilot studies indicated that 18 weeks was an appropriate time period to provide support when it was needed most (during the chemotherapy treatment period) and was sufficient time to help most patients and families stabilize and implement interventions. A single nurse specialist delivered interventions at one site, whereas the other site had two nurse specialists to accommodate the clinic schedule. During the visits, patients' physical, mental, and resource needs were assessed using the computer-based nursing intervention. Telephone visits were alternated with in-person clinic visits to decrease burden on the participants who had to travel monthly to the clinic site. Theoretically, all interventions were related to focusing patients' attention on the objective sequence of coping.

Development of the computer-based nursing intervention: The computer-based nursing intervention program was developed specifically for this study by the research team at Michigan State University. The computer-based nursing intervention was a menu-driven computer program that guided clinical assessment, problem identification, selection of interventions, and measurement of outcomes. It was designed based on current literature, oncology nursing practice standards, and practice guidelines for cancer symptom management. For each symptom or problem, exhaustive problem-specific lists of appropriate interventions were programmed into the computer-based nursing intervention. For example, nurses were able to select interventions for fatigue such as prescribing an exercise regimen; structuring sleep, rest, and activity time; or soliciting assistance from family members, depending on patient circumstances and preferences.

The computer-based nursing-intervention program was loaded on laptop computers, which allowed nurse specialists to input quantified assessments of patients' physical and psychosocial functioning (including anxiety and depression) and symptom experiences. Nurses asked patients to rate on a four-point scale the frequency, intensity, limitations, and degree of bother or distress caused by each symptom or problem. As a result of these detailed, quantified assessments, nurses and patients were able to prioritize problems that reached predetermined thresholds on frequency, severity, distress, or limitations ratings. Nurses were prompted to select appropriate interventions from standardized menus in designing the care plan. All interventions were saved on the computer for the next visit. Interventions and outcomes were evaluated at each visit and documented. Through this computerized nursing intervention system, the intervention was clearly documented

Table 1. Intervention Protocol: Timing, Type, and Focus of Intervention Visits in Relation to Outcome Data Collections

Focus of Visit	Session 1[a] Clinic Visit	Session 2 2 weeks Phone Visit	Session 3 4 weeks Clinic Visit	Session 4 6 weeks Phone Visit	Session 5 8 weeks Clinic Visit	Session 6 10 weeks Phone Visit	Session 7 12 weeks Clinic Visit	Session 8 14 weeks Phone Visit	Session 9 16 weeks Clinic Visit
Symptom management/monitor	X	X	X	X	X	X	X	X	X
Information on disease and treatment	X	X	X	–	X	X	X	–	X
Emotional support and counseling	X	X	X	X	X	X	X	X	X
Coordination of resources	X	–	X	–	X	–	X	–	X
Outcome data collection	↑ Baseline				↑ Time 2 (nine weeks)				↑ Time 3 (one month postintervention)

[a] Intervention started within 56 days of initiating chemotherapy.

and standardized across sites and allowed for individual tailoring of care plans that were designed specifically to meet each patient's unique needs. In addition, the computer-based nursing intervention enabled processes of care to be linked to patient and caregiver outcomes and allowed monitoring of intervention delivery to ensure consistency and adherence to protocol.

Intervention nurse training: Nurse specialists were trained intensively, focusing on delivery of the intervention protocol and use of the computer-based nursing intervention system. Researchers developed an intervention manual that outlined policies and procedures and detailed all elements of the protocol to be delivered. A clinical nurse manager conducted training sessions onsite and prepared simulated cases to facilitate development of skills in problem assessment, implementation of appropriate interventions, and evaluation of intervention outcomes.

Intervention visits: At the initial intervention visit, nurse specialists completed a brief history with the patient, including assessment of cancer history and other comorbid conditions. Social, demographic, and employment data were entered into the computer-based nursing intervention, and emotional health status (e.g., depression, anxiety), social role functioning, and current cancer- and treatment-related symptoms were assessed. From the symptom assessment protocol, a computerized plan of care was developed in collaboration with the patient and caregiver, tailored specifically to address the identified patient needs. In all subsequent encounters, whether in person or via telephone, nurses evaluated the effectiveness of interventions, assessed new problems, and provided concrete, objective information about disease and treatment, symptom management, and availability of community resources. In addition, nurses provided emotional support and counseling to patients and caregivers at each visit.

Symptom experience was assessed for 38 symptoms that may occur during chemotherapy. For each symptom that a patient reported experiencing, the nurse conducted detailed symptom assessments including frequency, severity, limitations, and level of distress. Interventions were tailored individually to address a maximum of four symptoms that were prioritized as problems by the patient. Nurses selected evidence-based interventions that could be directed toward each symptom or problem from a symptom-specific menu. They evaluated the effectiveness of each intervention at each subsequent visit. For example, if a patient complained of constipation, nurses provided interventions regarding fluid intake, dietary intervention, and laxative use. At the subsequent visit, nurses assessed current constipation symptom experience and evaluated previously prescribed interventions for their effectiveness. If constipation was not resolved, nurses adjusted intervention dosages or prescribed alternative interventions. If constipation was resolved, they documented the resolution and that problem was closed.

During each session, nurses provided concrete, objective information about the management and monitoring of each symptom that reached threshold, indicating the symptom needed to be addressed. Similarly, nurses addressed problems related to coordination of resources and other disease- and treatment-specific problems if the patient judged them to be concerns. Nurses also provided emotional support and counseling during each session. For instance, nurses listened to patients' concerns about symptoms or other issues (e.g., fear of recurrence) and taught active communication techniques to patients and their caregivers to enhance communication between patients, caregivers, family, and healthcare providers. Participants were encouraged to telephone the intervention nurses between scheduled encounters if questions or concerns arose. Only occasionally did a patient or family member call outside the scheduled session.

Researchers programmed detailed protocols into the computer-based nursing intervention, which guided delivery of the intervention and the circumstances under which patients' or caregivers' problems would be managed or referred. For instance, if patients had anxiety, nurses could choose from a menu of interventions: teach relaxation techniques, counsel regarding thought-stopping, prescribe exercise, or refer to another healthcare professional if indicated. In-person encounters were designed to have patients and their caregivers present and last approximately one hour, whereas telephone encounters were designed to last approximately 20 minutes. Having both people present allowed nurses to observe interactions between patients and their caregivers and have the caregivers reinforce interventions.

Standard care or control group patients received any education normally delivered during chemotherapy but no attention outside of medical visits. Standard care consisted of verbally telling the patients about what they might expect from chemotherapy and symptoms that should be reported to the doctor.

Intervention quality assurance: A master's-prepared clinical nurse coordinator, who was a member of the research team, developed and implemented a quality assurance plan for the intervention protocol. The nurse generated monthly reports from the aggregate computer-based nursing intervention data and reviewed the reports to ascertain the accuracy and completeness of the intervention data and adherence to the intervention protocol.

Statistical Analyses

Baseline measures for the standard care and intervention groups were compared using t tests. Repeated measures analyses of variance (ANOVA) were used to analyze the effect of the treatment over time on each of the following outcomes: (a) SF-36 psychosocial functioning subscales of vitality, social functioning, role emotional, and mental health, (b) depression, and (c) anxiety.

Gender, cancer stage, age, group, time, and the group-by-time interaction were included in the model. Researchers assessed changes over time from two perspectives. First, analyses of the first two time points identified possible effects immediately following acute treatment. Second, analysis of baseline and times 2 and 3 assessed variables after time had elapsed from acute treatment. Reliability was assessed on all scales. Cronbach's alpha ranged from 0.76–0.93 (see Table 2).

Results

Sample

One hundred nine patients with breast, colon, or lung cancer who were undergoing chemotherapy treatment provided data for the analyses presented here. The typical participant was Caucasian, female, and married (see Table 3). The average age was 55.7 years (SD = 11.9). Of the 109 patient participants, 99 (91%) were Caucasian, and 84 (77%) were female. The sample was distributed evenly between early (stage

Table 2. Reliability Analyses: Cronbach's Alpha for Scales at Each Time

Scale (No. of items)	Baseline (N = 109)	Time 2 (N = 94)	Time 3 (N = 77)
STAI (20)	0.90	0.91	0.92
CESD-20 (20)	0.85	0.88	0.89
SF-36 Scales			
Vitality (4)	0.90	0.90	0.93
Social function (2)	0.80	0.83	0.89
Role emotional (3)	0.79	0.86	0.76
Mental health (5)	0.84	0.89	0.85

STAI—State-Trait Anxiety Inventory

CESD-20—Centers for Epidemiological Studies Depression-20 Scale

SF-36—Medical Outcomes Study 36 Short Form

I or II) and late (stage III or IV) cancers. Education levels were fairly heterogeneous. Researchers compared demographic characteristics of the standard care (n = 54) and intervention groups (n = 55) using t tests and chi-square analyses and found no significant differences.

Because the attrition or dropout rate was higher in the intervention group than in the control group, baseline differences between patients who dropped out and those who completed the study were examined. Attrition status was defined as those who left the study for whatever reason at time 2 and time 3. Two-way ANOVA were run to compare baseline SF-36 subscale scores, anxiety, and depression scores. Significant main effects were found for attrition on depression scores ($F = 5.34$, $p = 0.02$), the SF-36 vitality subscale scores ($F = 10.64$, $p = 0.001$), and SF-36 social functioning subscale scores ($F = 4.13$, $p = 0.04$). Patients who left the study had significantly higher depression scores at baseline ($\overline{X} = 14.3$) than those who completed the study ($\overline{X} = 10.6$). Similarly, those who left the study had lower SF-36 vitality scores ($\overline{X} = 36.9$) than those who completed the study ($\overline{X} = 51.5$), and lower SF-36 social functioning scores ($\overline{X} = 61.5$) than those who completed the study ($\overline{X} = 73.0$), indicating that those who left the study had worse functioning at baseline. Researchers observed no main effects for group, and although more patients were lost from the intervention group, researchers found no group-by-attrition status interactions.

Psychological Functioning

SF-36 subscales scores are calculated so that higher scores indicate higher functioning. Overall, trends in SF-36 subscales indicated that participants' psychosocial functioning improved over time, regardless of group assignment (see Table 4). None of the functional outcomes showed a significant intervention

Table 3. Sample Demographics

	Standard Care Group (N = 54)		Intervention Group (N = 55)		Total Sample (N = 109)	
Characteristic	**n**	**%**	**n**	**%**	**n**	**%**
Cancer site						
Breast	28	26	27	25	55	51
Colon	13	12	12	11	25	23
Lung	13	12	16	15	29	27
Cancer stage						
I	8	7	6	6	14	13
II	21	19	19	17	40	37
III	14	13	20	18	34	31
IV	11	10	10	9	21	19
Employment						
Full-time	20	19	14	13	34	32
Part-time	4	4	6	6	10	9
Not employed	30	28	34	32	64	59
Marital status						
Married	40	37	40	37	80	73
Not married	14	13	14	13	28	26
Education						
Grade school or less	8	7	7	6	15	14
Completed high school	19	17	20	18	39	36
Attended college	11	10	12	11	23	21
Completed college	2	2	9	8	11	10
Completed graduate/ professional degree	14	13	7	6	21	19
Race						
Caucasian/White	50	46	49	45	99	91
African American	2	2	2	2	4	4
Mexican American	–	–	1	1	1	1
Native American	1	1	2	2	3	3
Asian/Pacific Islander	1	1	–	–	1	1
Gender						
Male	10	9	15	14	25	23
Female	47	40	40	37	84	77

Table 4. Repeated Measures Analyses of SF-36 Scales Using All Three Time Points

Outcome	Group	Baseline	Time 2	Time 3	F (Group x Time)	p
Vitality	Intervention	47.7	50.6	49.6	1.75	0.18
	Standard care	51.7	47.8	54.3		
Social function	Intervention	69.4	73.2	79.3	0.63	0.53
	Standard care	72.3	70.7	83.1		
Role emotional	Intervention	72.6	82.9	72.8	2.17	0.12
	Standard care	78.9	72.3	78.5		
Mental health	Intervention	76.3	81.2	79.9	1.56	0.21
	Standard care	77.3	76.5	80.5		
Mental component score	Intervention	50.5	53.9	52.5	2.08	0.13
	Standard care	51.6	50.6	52.9		

Note. Means were adjusted for age, gender, and cancer stage.

effect (group-by-time interaction) when using data from all three time points. Gender differences were not significant.

Because time 3 data were collected approximately four weeks after the nursing intervention was completed (24 weeks following enrollment), researchers hypothesized that any effect the intervention had may have been lost by time 3. That is, time 3 data analysis did not demonstrate statistical significance. Thus, further analyses were performed on baseline and time 2 data only (see Table 5). Role-emotional, mental health, and mental component scores were significant for the group-by-time interaction, at $p = 0.10$ level. The adjusted means showed that, for each of these scales, the intervention group improved from baseline to time 2, whereas the standard care group declined. These results suggest that the intervention had a more significant impact on psychological functioning immediately following intervention.

Depression Scores

Results for depression are presented in Tables 6 and 7. The group-by-time effect showed a trend toward significance when using data from the three time points ($p = 0.07$) and reached statistical significance when using data from baseline and time 2 only ($p = 0.05$). Pair-wise comparisons of the means showed that the intervention group significantly improved (i.e., had lower depression scores) from baseline to time 2.

Anxiety

Anxiety outcome data also are presented in Tables 6 and 7. The intervention did not appear to have a significant effect on anxiety when examining the data from the three time points. However, a trend toward a group-by-time interaction ($p = 0.09$) occurred between baseline and time 2 favoring the intervention group. Pair-wise comparisons of the means showed that the intervention group improved (had lower anxiety scores) from baseline to time 2 ($p = 0.09$) whereas the standard care group remained unchanged.

Discussion

Patients who received the experimental computer-based nursing intervention had significantly less depression than patients in the standard care group. Also, trends favoring improvement occurred in other measures of psychological health of patients in the experimental group. Intervention effects demonstrated trends toward significance on measures of role-emotional function, mental health, and anxiety at time 2. Intervention effects did not appear to last beyond the intervention period, as indicated by nonsignificant differences between the groups at time 3. An additional data collection point at completion of the intervention may have provided some insight into the duration of the intervention effects. Other studies, however, have demonstrated longer intervention effects. The current study's results stand in contrast to Fawzy et al. (1990) and Fawzy and Fawzy (1994), who found lasting effects six months after intervention.

General questions remain unanswered about the efficacy of the intervention and, specifically, for whom it was most effective. Further analysis is ongoing and may aid the understanding

Table 5. Repeated Measures Analyses of SF-36 Scales Using Baseline and Time 2 Only

Outcome	Group	Baseline	Time 2	F (Group x Time)	p
Vitality	Intervention	47.4	50.7	2.61	0.11
	Standard care	51.3	47.7		
Social function	Intervention	69.9	74.0	0.78	0.38
	Standard care	72.8	71.6		
Role emotional	Intervention	71.3	80.5	3.67	0.06
	Standard care	77.3	70.8		
Mental health	Intervention	76.2	81.0	2.96	0.09
	Standard care	76.9	76.2		
Mental component score	Intervention	50.3	53.5	3.67	0.06
	Standard care	51.3	50.4		

Note. Means were adjusted for age, gender, and cancer stage.

Table 6. Repeated Measures Analyses for Anxiety and Depression Using All Three Time Points

Outcome	Group	Baseline	Time 2	Time 3	F (Group x Time)	p
Anxiety	Intervention	33.4	29.9	32.6	1.83	0.16
	Standard care	32.2	32.2	31.0		
Depression	Intervention	11.2	7.8	9.3	2.72	0.07
	Standard care	10.6	10.0	8.3		

Note. Means were adjusted for age, gender, and cancer stage.

of other factors that interact with the intervention. Braden, Mishel, and Longman (1998) tested self-help interventions for women undergoing breast cancer treatment and examined personality characteristics as factors that interact with treatment effects. Their findings were consistent with the current study's in that their intervention resulted in positive outcomes and the effect of the intervention was strongest immediately after completion of the intervention. The current study's results were collected halfway through the intervention. When Braden et al. took the personality factor of resourcefulness into account, positive effects of the intervention were observed long term (at three months after completion of the intervention) but only for women with high resourcefulness. Fawzy et al. (1990), Fawzy and Fawzy (1994), and Spiegel, Bloom, and Yalom (1981) suggested that people with high levels of resourcefulness engage in trial-and-error learning that can result in effective self-management that is totally independent of support programs and interventions. Also, individuals who agree to participate in or complete psychosocial intervention studies may have higher levels of resourcefulness than those who choose not to do so. Although personality characteristics, such as resourcefulness, were not measured in the current study, researchers have planned further analyses to examine the influence of other factors (e.g., baseline demographic, clinical characteristics) that may have influenced intervention effects.

Limitations

Recruitment and retention of patients with cancer in clinical trials is challenging. Reluctance to participate in an optional study at a time when patients and families are overwhelmed by a life-threatening illness is understandable. Other investigators have reported that substantial numbers of patients decline to participate in psychosocial interventions (Meyer & Mark, 1995). Accrual to this two-site, cancer-care intervention study was relatively high, with a 56% participation rate. Recruitment efforts were successful, in part, because eligibility criteria were sufficiently broad and allowed inclusion of patients with diverse cancer diagnoses. Researchers specifically targeted patientd who were undergoing a single-treatment modality (chemotherapy) with the goal of the intervention to improve functioning, symptom management, and psychological morbidity for both patients and their caregivers. The high dropout rate also may have implications for practice because of the acuity of the population—11 patients died. Additionally, 13 dyads withdrew because the intervention took too much time. The dropout rate also was different depending on group; the intervention group had twice the dropout rate of the standard care group. Perhaps the intervention was too long and patients who benefited from a shorter intervention dropped out early.

The study involved a relatively small sample size, with a wide variety of types and stages of cancer. Although this could be viewed as a strength of this study with regard to generalizability of the findings, this heterogeneity may have contributed to the inability to observe more significant intervention effects.

Another limitation of the study relates to the possibility of diffusion of the intervention to the standard care group. After the study had been completed, one resourceful participant who had been randomized to the standard care group confessed that she had actively sought information about the intervention from patients who were receiving it. After learning what the intervention entailed, she hired an oncology clinical nurse specialist to provide similar services. The researchers do not know how many other patients or caregivers in the standard care group may have been as resourceful.

Implications for Further Research and Practice

Investigators who study behavioral and psychosocial interventions in oncology face a dilemma. Such interventions are designed to assist those who are most vulnerable, yet these patients are most likely to be recruited into trials and then lost once they are entered. Fortunately, no group-by-attrition interaction occurred in this research. Two difficulties remain, however. First, the power to detect significant differences is lost. Second, if a group effect is found, it becomes very difficult to examine the within-group analysis because those patients, to whom the intervention was addressed, have been lost. This suggests very strongly that more research needs to be directed toward learning

Table 7. Repeated Measures Analyses for Anxiety and Depression Using Baseline and Time 2 Data Only

Outcome	Group	Baseline	Time 2	F (Group x Time)	p
Anxiety	Intervention	33.6	30.2	2.96	0.09
	Standard care	32.4	32.4		
Depression	Intervention	11.2	7.9	3.99	0.05
	Standard care	10.7	10.0		

Note. Means were adjusted for age, gender, and cancer stage.

why the patients who, ostensibly, would benefit more from interventions chose to withdraw. Is this because they found the intervention to be inadequate or too intrusive, or did they withdraw for reasons totally unrelated to the intervention? More work that focuses on this area of psychosocial interventions is needed. Until more is learned about why people who are the targets of studies choose not to participate, it will be difficult to demonstrate the value that they may add to health outcomes and possibly to the larger healthcare system.

Future research should be conducted with a more defined population to limit the heterogeneity experienced with various types and stages of cancer. The current study's interventions were tailored to individual needs, and with the wide variety of patient needs, intervention effect on any one outcome was limited. For instance, only patients who exhibited depressive symptoms received interventions targeted to this symptom. Thus, the power to detect an intervention effect was diminished. Future research also should take into consideration medications that may affect depression or anxiety. Because of the greater dropout rate of the intervention group, researchers should determine if interventions can be delivered in a more time-efficient manner. Perhaps only a portion of the population needed to be followed for 18 weeks. Possibly, dyads that dropped out earlier had their problems resolved. If the length of the intervention was tailored to the individual but outcome measures were collected on all participants, the study might havehad a stronger effect.

In summary, although this study was a good beginning at delivering a standardized nursing intervention, results indicate that much more needs to be done before practice implications are apparent. Future research must take into account the large variations in patients with cancer and tailor interventions to their needs. Researchers then need to test a smaller number of interventions for effect with an adequate sample size.

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References

Braden, C.J., Mishel, M.H., & Longman, A.J. (1998). Self-help intervention project. Women receiving breast cancer treatment. *Cancer Practice, 6,* 87–98.

Cella, D.F., Sarafian, B., Snider, P.R., Yellen, S.B., & Winicour, P. (1993). Evaluation of a community-based cancer support group. *Psycho-Oncology, 2,* 123–132.

Collins, C., Given, B., Given, C.W., & King, S. (1988). Interviewer training and supervision. *Nursing Research, 37,* 122–124.

Fawzy, F.I. (1999). Psychosocial interventions for patients with cancer: What works and what doesn't. *European Journal of Cancer, 35,* 1559–1564.

Fawzy, F.I., Cousins, N., Fawzy, N.W., Kemeny, M.E., Elashoff, R., & Morton, D. (1990). A structured psychiatric intervention for cancer patients. I. Changes over time in methods of coping and affective disturbance. *Archives of General Psychiatry, 47,* 720–725.

Fawzy, F.I., & Fawzy, N.W. (1994). A structured psychoeducational intervention for cancer patients. *General Hospital Psychiatry, 16,* 149–192.

Ferrell, B.R., Grant, M., Funk, B., Otis-Green, S., & Garcia, N. (1998). Quality of life in breast cancer. Part II: Psychological and spiritual well-being. *Cancer Nursing, 21,* 1–9.

Ferrell, B.R., Grant, M.M., Funk, B., Otis-Green, S., & Garcia, N. (1997). Quality of life in breast cancer survivors as identified by focus groups. *Psycho-Oncology, 6,* 13–23.

Given, B., & Given, C.W. (1992). Patient and family caregiver reaction to new and recurrent breast cancer. *Journal of the American Medical Women's Association, 47,* 201–206.

Given, C.W., Given, B.A., & Stommel, M. (1994). The impact of age, treatment, and symptoms on the physical and mental health of cancer patients. A longitudinal perspective. *Cancer, 74*(Suppl. 7), 2128–2138.

Jemal, A., Thomas, A., Murray, T., & Thun, M. (2002). Cancer statistics—2002. *CA: A Cancer Journal for Clinicians, 52,* 23–47.

Johnson, J.E. (1996). Coping with radiation therapy: Optimism and the effect of preparatory interventions. *Research in Nursing and Health, 19,* 3–12.

Johnson, J.E., Fieler, V.K., Jones, L.S., Wlasowicz, G.S., & Mitchell, M.L. (1997). *Self-regulation theory: Applying theory to your practice*. Pittsburgh, PA: Oncology Nursing Society.

Johnson, J.E., Fieler, V.K., Wlasowicz, G.S., Mitchell, M.L., & Jones, L.S. (1997). The effects of nursing care guided by self-regulation theory on coping with radiation therapy. *Oncology Nursing Forum, 24,* 1041–1050.

Kurtz, M.E., Given, B., Kurtz, J.C., & Given, C.W. (1994). The interaction of age, symptoms, and survival status on physical and mental health of patients with cancer and their families. *Cancer, 74*(Suppl. 7), 2071–2078.

Maguire, G.P., Tait, A., Brooke, M., Thomas, C., Howat, J.M., Sellwood, R.A., et al. (1980). Psychiatric morbidity and physical toxicity associated with adjuvant chemotherapy after mastectomy. *BMJ, 281,* 1179–1180.

McCorkle, R., Benoliel, J.Q., Donaldson, G., Georgiadou, F., Moinpour, C., & Goodell, B. (1989). A randomized clinical trial of home nursing care for lung cancer patients. *Cancer, 64,* 1375–1382.

Meyer, T.J., & Mark, M.M. (1995). Effects of psychosocial interventions with adult cancer patients: A meta-analysis of randomized experiments. *Health Psychology, 14,* 101–108.

Radloff, L.S. (1977). The CES-D scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement, 1,* 385–401.

Schag, C.A., & Heinrich, R.L. (1989). Anxiety in medical situations: Adult cancer patients. *Journal of Clinical Psychology, 45*(1), 20–27.

Spiegel, D., Bloom, J.R., Kraemer, H.C., & Gottheil, E. (1989). Effect of psychosocial treatment on survival of patients with metastatic breast cancer. *Lancet, 2,* 888–891.

Spiegel, D., Bloom, J.R., & Yalom, I. (1981). Group support for patients with metastatic cancer. A randomized outcome study. *Archives of General Psychiatry, 38,* 527–533.

Spielberger, C., Gorsuch, A., & Lushene, R. (1970). *The state-trait anxiety inventory*. Palo Alto, CA: Consulting Psychologists Press.

Spielberger, C.D., Gorsuch, R., Lushene, R., Vagg, P., & Jacobs, G. (1983). *Manual for the state-trait anxiety inventory (Form Y)* (Vol. 4). Palo Alto, CA: Consulting Psychologists Press.

Stewart, A., & Ware, J. (1993). *Measuring functioning and well-being: The medical outcomes study approach*. Durham, NC: Duke University Press.

Ware, J.E., Snow, K.K., Kosinski, M., & Gandek, B. (1993). *SF-36 health survey: Manual and interpretation guide*. Boston: The Health Institute, New England Medical Center.

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