Pain and Fatigue Management: Results of a Nursing Randomized Clinical Trial

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Purpose/Objectives: Through a randomized clinical trial, to compare patients undergoing an initial course of chemotherapy who report pain and fatigue at baseline and who are receiving conventional care alone with those receiving conventional care plus a nursing intervention on outcomes reported at 20 weeks.

Setting: Chemotherapy clinics of two comprehensive and two community cancer centers.

Methods: Interviews were conducted at baseline and 10 and 20 weeks. An 18-week, 10-contact nursing intervention utilizing problem-solving approaches to symptom management and improving physical functioning and emotional health was implemented.

Sample: The sample consisted of 53 patients in the experimental arm and 60 in the control arm who reported pain and fatigue at baseline.

Variables: Pain and fatigue, numbers of other symptoms, and physical role impact and social-functioning subscales from the Medical Outcomes Study 36 Short Form.

Findings: Patients who received the intervention reported a significant reduction in the number of symptoms experienced and improved physical and social functioning. Fewer patients in the experimental arm reported both pain and fatigue at 20 weeks.

Conclusions: Behavioral interventions targeted to patients with pain and fatigue can reduce symptom burden, improve the quality of the daily life of patients, and demonstrate the "value-added" role of nursing care for patients undergoing chemotherapy.

Implications for Nursing: These data support the "value-added" role of nursing interventions for symptom management and improved quality of life during the course of cancer treatment.

Key Points . . .

- Pain and fatigue are prevalent symptoms among patients with cancer.
- When behavioral interventions were targeted toward patients with both pain and fatigue, their overall symptom burden was reduced and quality of life improved.
- Behavioral interventions have an important role in symptom management, over and above pharmacologic treatments.

Symptom distress in patients with cancer has been reported in the literature for more than 25 years (Ferrell & Schneider, 1988; Ganz, Golant, Rivera, Dean, & Benjamin, 2000; McCorkle & Young, 1978; Weisman & Worden, 1976). High symptom distress has been associated with specific cancer sites (e.g., lung), women compared to men, younger patients compared to older, and combination cancer therapies compared to a single modality (Given, Given, Azzouz, Kozachik, & Stommel, 2001; Sarna, 1993).

Universally, fatigue has been reported as the most prevalent symptom but not necessarily the most bothersome (Jacobsen et al., 1999; Richardson, 1995; Tishelman, Degner, & Mueller, 2000). Although a great deal of research has been conducted to describe the symptom experience of patients with cancer and cancer treatment, information on how best to manage symptoms has lagged far behind.

Symptom management has become an integral component of cancer care for patients receiving chemotherapy and

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radiation. Researchers who study symptom management often focus on a single symptom and have not examined the symptom experience of patients who have multiple symptoms (Dodd, Miaskowski, & Paul, 2001; Ferrell & Rivera, 1997; Given et al., 2001; Graydon, Bubela, Irvine, & Vincent, 1995; Miaskowski, Kragness, Dibble, & Wallhagen, 1997; Miaskowski, Zimmer, Barrett, Dibble, & Wallhagen, 1997; Sarna, 1993).

Pain and fatigue are common symptoms that occur throughout the course of cancer and treatment. Pain and fatigue are prevalent particularly during chemotherapy and often are considered sentinel to the complexity of patients' symptom experience (Irvine, Vincent, Graydon, Bubela, & Thompson, 1994; Jacobsen et al., 1999). Researchers suggest that pain and fatigue may add to the severity and number of "other" symptoms and increase the complexity of symptom management (Given et al., 2001; Irvine et al.; Miaskowski & Lee, 1999).

Sarna (1993) was one of the first researchers to examine the effect of concurrent symptoms. In a study of 69 women with lung cancer, she found that 41% of women with fatigue concurrently experienced frequent pain and that the severity of fatigue and pain were highly correlated. Symptom distress was associated strongly with decreased quality of life and functional status.

Of the patients who are in active treatment, 30%–50% experience pain on a daily basis (Ahles, Ruckdeschel, & Blanchard, 1984; Miaskowski & Lee, 1999; Miaskowski, Zimmer, et al., 1997; Portenoy & Miaskowski, 1998). Fatigue often presents during active treatment and often is described by patients as their most frequent and distressing symptom (Miaskowski & Lee; Mock et al., 2001; Schwartz, 1998, 2000; Schwartz et al., 2000).

In a sample of patients with cancer who had completed adjuvant therapy, Gaston-Johansson, Fall-Dickson, Bakos, and Kennedy (1999) found that 91% reported fatigue and 47% reported pain. In chart audits of patients with lung cancer receiving radiation, 19% had fatigue and 80% had pain (Hickok, Morrow, McDonald, & Bellg, 1996). Others have found the opposite (i.e., a higher percentage of patients with fatigue) (Given et al., 2001). Despite variations related to the prevalence of pain and fatigue in the literature, researchers agree on the pervasive nature of the problems posed by these two symptoms (Given et al.; Miaskowski & Lee, 1999). Beck and Schwartz (2000) examined pain and fatigue in a cross-sectional study of 84 patients and found a significant difference in fatigue based on pain intensity. They concluded that pain contributed negatively to the fatigue experience of the patients.

Given et al. (2001) examined the symptom experience of patients who had both pain and fatigue. Patients who experienced pain and fatigue reported an average of 6.3 "other" symptoms, whereas those reporting fatigue alone reported 4.5 other symptoms. Those with pain alone reported 3.8 other symptoms, and those reporting neither pain nor fatigue reported only 2.5 other symptoms, on average. This relationship between the presence of pain and fatigue and other symptoms persisted at each of the four observations during the 12 months following diagnosis (Given et al.).

A number of other researchers have shown the effect of pain and fatigue on overall functional and emotional status (Andrykowski, Curran, & Lightner, 1998; Demetri, Kris, Wade, Degos, & Cella, 1998; Given et al., 2001; Kassa, Loge, Knowbel, Jordboy, & Brenne, 1999; Mock et al., 1997; Richardson, 1995). This work suggests that effective management of pain and fatigue may be key to the overall management of symptoms.

Dodd, Janson, et al. (2001) commented on the lack of knowledge of concurrent symptoms and their consequences. Even though pain and fatigue may be related, they may not share the same etiology. Thus, different mechanisms may be needed for the management of each symptom. The extent to which synergistic influence affects symptom management when multiple symptoms occur is unknown. Therefore, understanding the pattern of the symptom experience and not examining one symptom in isolation when multiple symptoms are present is critical.

Few systematic studies, few inception cohort studies, and even fewer examinations of management strategies have been conducted targeting patients experiencing multiple symptoms. As a result, information is not available to establish how patients who present with both pain and fatigue describe their symptom experience and the impact on patient care outcomes. Clearly, further exploration is needed to understand the complexity of multiple symptoms and determine effective management approaches that address multiple symptoms (Cella, Peterman, Passik, Jacobsen, & Breitbart, 1998; Dimeo, Stieglitz, Bovell-Fischer, Fetscher, & Kaul, 1999). Research also must be conducted to explore whether pain and fatigue have an independent effect on the presence of other symptoms and how management of pain and fatigue is related to overall symptom control. This article begins to address these issues.

The purpose of this study was to compare data from a 20-week, randomized, clinical trial of a supportive nursing intervention plus conventional care versus conventional care alone among patients undergoing an initial course of chemotherapy who reported pain and fatigue at baseline. The number of symptoms, a reduction in physical role impact, and improved social function were the outcomes of interest and were assessed at 10 and 20 weeks. This study was part of a larger symptom management trial.

A cognitive-behavioral framework that focused on problem solving, information acquisition, self-care management for symptoms, and emotional and social support for patients guided this nursing intervention. Cognitive-behavioral intervention studies have shown that patients can participate actively in symptom control strategies with positive outcomes (Ahles et al., 1984; Breitbart & Payne, 1998; Compas, Haaga, Keefe, Leitenberg, & Williams, 1998; Du Pen, Niles, Hansberry, Kraybill, & Stillman, 1997; Ferrell, Ferrell, Ahn, & Tran, 1994; Ferrell, Rhiner, & Ferrell, 1993; Wellisch, 1981). Cognitive-behavioral strategies assist patients in recognizing and modifying factors that contribute to physical and emotional distress by changing thoughts and behaviors in a positive manner and assisting patients in solving problems related to implementing strategies for self-care. Supportive counseling can assist patients in managing stressors by encouraging communication with family and professionals (Mock et al., 1997; Nail, Jones, Greene, Schipper, & Jensen, 1991). Pain and fatigue were sentinel symptoms, and the nursing intervention was directed toward these symptoms, as well as 12 other common symptoms experienced by patients undergoing chemotherapy in the current study. Using this cognitive-behavioral model, nurses worked directly with patients to assist them in acquiring the knowledge, skills, behavioral reframing, and support necessary to manage the problems they were experiencing.

Table 1. Baseline Scores for Patients Reporting Pain and Fatigue: Experimental and Control Groups

	Experimental (n = 53)		Control (n = 60)		
Demographic Characteristic	**n**	**%**	**n**	**%**	**p**
Age					
Mean	59	–	57	–	0.46
SD	10	–	11	–	
Gender					
Male	15	28	17	28	1.00
Female	38	72	43	72	
Education					
Less than high school	2	3	4	7	0.10
High school graduate	12	23	13	21	
Some college	14	26	22	37	
College graduate	13	25	4	7	
Postcollege graduate	12	23	17	28	
Marital status					
Married	41	77	46	77	0.93
Not married	12	23	14	23	
Employment status					
Employed	11	21	14	23	0.69
Retired	6	11	5	7	
Not employed	36	68	38	63	
Unknown	-	-	4	7	
Site of cancer					
Breast	17	32	22	37	0.79
Colon	8	15	8	13	
Lung	20	15	6	10	
Gynecologic	8	38	23	38	
Lymphoma	0	-	1	2	
Stage of cancer					
Early—I or II	14	26	18	30	0.63
Late—III or IV	38	72	40	66	
Unknown	1	2	2	4	
Scale scores	**$\bar{x}$**	**SD**	**$\bar{x}$**	**SD**	**p**
Symptom count	7.3	2.8	6.8	1.5	0.25
Medical Outcomes Study 36 Short Form physical role impact	11.0	21.0	11.0	22.0	0.92
Medical Outcomes Study 36 Short Form social functioning	51.0	26.0	52.0	28.0	0.78

Methods

A randomized clinical trial was designed to test the effectiveness of a supportive nursing intervention on patients' symptom management, the physical role impact, and social functioning. The outcome variables to be assessed included reduction in the numbers of symptoms reported and the level of social and physical role functioning reported between the baseline and the 20-week observation immediately following the end of the trial.

Setting

Four outpatient cancer treatment sites were used for this study. Two sites were affiliated with comprehensive cancer centers, and two were community cancer treatment clinics.

Sample

Eligible patients were within 56 days of initiating their first cycle of chemotherapy following a new cancer diagnosis. Patients were at least 40 years old and receiving chemotherapy for a new diagnosis of colon, breast, or lung cancer, non-Hodgkin's lymphoma, or other solid tumors. All patients had to have reported both pain and fatigue at their baseline interview. Patients had to be cognitively intact, able to read English to comprehend the consent forms, and willing to participate in the 10-session nursing intervention that covered 20 weeks. Patients had to have caregivers who were willing to participate in this study. Patients were excluded if they were not expected to survive the 20-week intervention and the 12-week follow-up data collection period.

Instruments

All data were collected through telephone interviews. Patients' age, education, employment, gender, income, and living arrangements were collected at baseline. Type of cancer, stage of disease, as well as treatment received were obtained from medical records after patients signed the consent forms. The following measures were collected at each wave or interview period.

Symptoms: The **Symptom Experience Scale** developed by the current study's researchers asked patients if they had

experienced any of the following symptoms associated with cancer or cancer treatment in the previous two weeks: nausea, vomiting, pain, fatigue, insomnia, difficulty breathing, coordination problems, fever, cough, dry mouth, constipation, anorexia, diarrhea, or mouth sores. A sum of the number of symptoms reported by each patient formed the count of symptoms for this study (Given et al., 2001; McCorkle, 1987).

Functioning: Two subscales from the Medical Outcomes Study 36 Short Form (SF-36) (Ware, 1993) were used to measure the impact of the intervention on patients' social and physical role performance. The physical role function subscale contains four items that ask whether the person was limited in a kind of work or any other activity, cut down the amount of time spent on work or other activities, accomplished less than he or she would have liked, and had difficulty performing work or other activities. "Yes" or "no" categories were used to record responses (internal consistencies exceeded 0.80 on all occasions). The social function subscale contains two items: the extent to which physical health or emotional problems interfered with normal social situations with family, friends, neighbors, or groups, and how much of the time and physical health or emotional problems interfered with social activities. Responses to the former item were recorded on a four-point scale and ranged from "not at all" to "quite a bit." Responses to the latter item were recorded on a six-point scale: "all of the time," "most," "a good bit," "some," "a little," and "none of the time." Internal consistency for this subscale exceeded 0.80 for all administrations. The scores for the subscales of the SF-36 were standardized to range from 0–100 with the higher scores indicating better function. Information in the SF-36 scoring manual revealed the scoring method. The scores, in turn, were used to analyze the study data.

Cancer stage: Stage of disease was classified according to the TNM staging system of the American Joint Committee on Cancer, which classifies tumors on a scale of 0–IV. The study's researchers collapsed stages 0–II into the early stage and stages III and IV as late stage. These data were collected from patients' medical records at the time of their enrollment.

Table 2. Number of Symptoms and Impact of Cancer Treatment on Physical Role Impact and Social Functioning by Group and Time

		Observation I		Observation II		Observation III	
	n	$\bar{x}$	SD	$\bar{x}$	SD	$\bar{x}$	SD
Symptom count							
Exp	53	7.3	2.8	5.2	2.9	3.3	2.6
Ctrl	60	6.8	2.1	6.1	3.2	4.4	2.7
• Breast							
Exp	17	6.5	2.5	4.6	2.9	3.1	2.3
Ctrl	22	7.1	1.8	6.4	3.6	4.7	2.4
• Lung							
Exp	20	8.7	2.8	6.5	2.7	4.8	2.9
Ctrl	23	6.6	2.6	6.9	2.7	4.5	3.1
• Other							
Exp	16	6.4	2.7	4.5	2.8	1.8	1.9
Ctrl	15	6.5	1.5	4.5	2.6	3.8	2.7
Physical role impact							
Exp	53	11	22	23	38	50	41
Ctrl	59	11	22	16	28	31	36
• Breast							
Exp	17	13	18	29	44	49	38
Ctrl	22	3	9	15	35	22	37
• Lung							
Exp	20	5	14	7	20	36	39
Ctrl	23	22	31	12	22	29	35
• Other							
Exp	16	16	31	33	44	65	45
Ctrl	14	18	7	22	26	47	33
Social functioning							
Exp	53	51	26	56	30	76	30
Ctrl	59	52	28	56	27	63	32
• Breast							
Exp	17	48	29	56	35	73	32
Ctrl	22	53	22	53	19	58	27
• Lung							
Exp	20	48	25	44	28	69	34
Ctrl	23	58	33	57	32	61	37
• Other							
Exp	16	56	23	68	22	88	16
Ctrl	14	39	24	60	32	72	32

Ctrl—control group; Exp–experimental group

Recruitment Procedure

Nurse recruiters specially trained for this study at each site identified patients (and their caregivers) who were eligible for the study, explained the study, and obtained signed informed consents for those willing to participate. The institutional review boards for the protection of human subjects at each participating university and agency approved the study.

Telephone interviews were conducted from a central location. Each interviewer was trained and followed an explicit quality assurance protocol. Baseline interviews were conducted within eight weeks of the patients initiating chemotherapy. Follow-up interviews were conducted at 10 and 20 weeks following the baseline interview. Medical record audits were completed at the end of the study. The contents of the medical record audit included treatment protocols, toxicity, and complications for each patient. The project coordinator at each site informed the intervention nurses of each patient-caregiver dyad that was randomized into the experimental group. The intervention nurse then contacted the dyad by telephone to introduce him- or herself and review the consent and the patient's role in the study. The nurse scheduled a meeting with the patient to conduct the baseline intervention session.

For the purposes of this analysis, 113 patients who reported pain and fatigue at the baseline interview were examined; 53 patients were assigned to the experimental group and 60 to the control group.

Intervention

The intervention was comprised of evidence-based intervention strategies that were delivered only to the experimental group. All study participants, regardless of random assignment, completed the observation interviews. Trained personnel who were not nurses conducted all of the telephone interviews. All patients received conventional care as prescribed by their oncology care team. The experimental group received additional assistance, above and beyond what was received from the formal healthcare system. The experimental group reported the current intensity of each symptom on a 1–10 scale and then reported the symptom's impact on a variety of quality-of-life indicators on a 0–5 scale. Any current intensity rated 5 or higher or quality-of-life impact self-reported at 3 or higher was considered the threshold for problem status. Each intervention nurse had the same cancer-nursing intervention software loaded onto a laptop computer. This software housed problem-specific, evidence-based intervention strategies that the nurse and patient could mutually select for the patient to implement on his or her own behalf to move the problem toward resolution.

The supportive care intervention consisted of 10 contacts, 6 in person and 4 via telephone, occurring at two-week intervals over a 20-week period. This cognitive-behavioral intervention focused on both patients and caregivers; however, this report is limited to patient data. The intervention was targeted to assess and intervene with previously identified symptoms. At each visit, the nurse assessed all symptoms. Any symptom that reached a level of 5 or higher on a 10-point scale or a reported severity of 3 or higher on a 5-point scale with respect to the impact on patients' quality of life were posted to the problem list. These patient assessments were part of the cancer-nursing intervention. Patient responses were selected from the options available in the intervention program and related to the impact that a particular symptom had on quality-of-life indicators (e.g., sleep, mobility, emotions, appetite). Patients were asked to rate their responses from 0 (no impact) to 5 (a great impact). For example, pain would be assessed according to its onset, duration, maximum severity, impact on daily activities, and other associated problems, such as fatigue or insomnia. All symptoms and functional health indicators that reached a threshold (i.e., either the current intensity self-rating of 5 or higher or quality-of-life indicators self-rating 3 or higher) were posted to the plan of care. Once a symptom was posted, the nurse and patient addressed it until the symptom was controlled or the intervention ended. At each intervention encounter, the nurse would ask the patient to evaluate the efficacy of the intervention strategies identified previously and the status of the problem resolution. Intervention strategies then were modified, changed, or deleted depending on the result. Revisions to the plan of care were made as necessary to resolve the problem. Interventions were tailored to the patients' problems and categorized as teaching, counseling and support, coordination, and communication. Using a computer-assisted protocol, the intervention nurse was able to document in real time the interventions for each patient problem at each encounter in which the nurse and patient focused on the problem. Nurses with certification in oncology were trained to use the intervention software with a paper case, as well as a live demonstration of an intervention encounter, with patient-caregiver dyad models. Every screen for each patient-caregiver dyad was reviewed by the nurse coordinator on a monthly basis. In-person meetings with the patient-caregiver dyad lasted approximately one hour; telephone encounters lasted 20 minutes, on average, and were conducted independently for the patient and caregiver.

To demonstrate the effectiveness of the intervention, the control group did not receive the experimental intervention. Patient-caregiver dyads were randomly assigned to one of two groups: conventional care plus the telephone interviews or conventional care, telephone interviews, and the nursing intervention.

Analysis

Data analysis included several analytic approaches. One-way analysis of variance (ANOVA) and chi-square tests were used to assess the equivalences at baseline between the experimental and control groups on all independent and dependent variables.

ANOVA and chi-square tests also were used to compare patients lost from each arm of the trial with patients retained

Table 3. Effect of Group and Cancer Site and Their Interactions on Numbers of Symptoms at 20 Weeks

Source	SS	df	F	p
Intercept	5.05	1	0.85	0.360
Intake symptom count	72.28	1	12.12	0.001
Group	23.46	1	3.93	0.051
Site of cancer[a]				
• Lung	3.07	1	0.52	0.475
• Other	7.79	1	1.31	0.275
• Group X lung[b]	2.94	1	0.49	0.485
• Group X other	2.03	1	0.34	0.582

[a] Breast was the reference category.

[b] Interaction terms

Table 4. Effect of Group and Cancer Site and Their Interactions on the Impact on Physical Role at 20 Weeks

Source	SS	df	F	p
Intercept	71213.204	1	54.16	0.000
Intake physical role	9156	1	6.92	0.011
Group	5116	1	3.86	0.053
Site of cancer[a]				
• Lung	770	1	0.58	0.448
• Other	5899	1	4.46	0.038
• Group X lung[b]	7.4	1	0.01	0.941
• Group X other	144.84	1	0.01	0.742

[a] Breast cancer was the reference.

[b] Interaction terms

according to their baseline scores. Again, no differences were found. A general linear model (Statistical Package for Social Sciences, Version 10.1) was used to test each hypothesis. Independent variables entered into the model included group and sites of cancer. The baseline measure for each dependent variable was entered as a covariate, as was the site of cancer by group interaction term. Sites of cancer were collapsed into three groups—breast, lung, and other. The "other" category included colon and gynecologic cancers and lymphoma. Sites of cancer were entered into the model as dummy variables with breast cancer used as the reference. Because of the relatively small sample and the possibility that the study (which was a subproject of a larger, randomized, clinical trial) was powered inadequately to detect a significant difference, findings are reported at the $p < 0.10$ level of significance.

Findings

Testing for Baseline Equivalence

The sociodemographics of the sample are presented in Table 1. The mean age of the participants was 58 years (SD = 10.5), and about 72% were female. Seventy-three percent of the patients had at least some college education. Most patients were not currently employed. Breast and lung cancer were the most common diagnoses. About 70% of the sample had advanced stage disease (i.e., stages III or IV). Given the eligibility criteria that patients must be starting a new course of chemotherapy for solid tumors, this was an expected mix.

The tests for equivalency at baseline between the experimental and control groups regarding sociodemographic, independent, and dependent variables are presented in Table 1. No significant differences between the groups at baseline were found.

At baseline, patients entered the study with an average of seven or more symptoms (SD = 2.5). At intake, the mean physical role impact score was 11 for both the experimental and control groups, and the social mean role impact score was 51 for the experimental group and 52 for the control group. Given that these subscales were standardized on a 0–100 scale, the physical role impact score is very low. This indicates that at about seven to eight weeks into their treatment, patients were very compromised with respect to their ability to carry out their physical roles.

Testing for Intervention Effects

The univariate comparisons by group and by sites of cancer by group are presented in Table 2. Tables 3, 4, and 5 present the results of the models for testing the three hypotheses. In all models, the baseline scores for the dependent variables of interest had statistically significant effects on the variables at outcome. Thus, all outcomes are adjusted for patients' scores at baseline into the study. A main effect for the group was found on the count of symptoms. At the 20-week observation, patients in the experimental group, on average, reported 3.3 symptoms compared to the control group who reported 4.4 symptoms (see Table 2). A main effect for the group was found on patients' physical role impact score at 20 weeks ($\overline{X} = 50$ versus $\overline{X} = 31$) (see Table 2). Further, a main effect for cancer site was found. Compared with breast cancer ($\overline{X} = 49$), patients with other cancer sites ($\overline{X} = 65$) reported significant reductions in the impact on their physical roles at the 20-week observation (see Table 2). A main effect for the group was found on patients' social functioning at the 20-week observation ($\overline{X} = 76$ versus $\overline{X} = 63$) (see Tables 2 and 5). No effects were indicated for the cancer site or effects for interactions between group and site of cancer on patients' reports of social function at 20 weeks.

Consistent with the current researchers' arguments regarding the impact of pain and fatigue on reports of other symptoms, patients in the experimental and control groups who reported pain and fatigue at 20 weeks experienced an average of 4.9 and 5.3 "other" symptoms, respectively. For those in both groups reporting neither pain nor fatigue at 20 weeks, the average number of "other" symptoms reported per patient was less than one symptom.

Table 6 documents the reduction in pain and fatigue achieved through the experimental intervention compared with reports by patients in the control group. A logistic regression model comparing the effect of group on the proportion of patients reporting pain and fatigue examined with those reporting either or neither symptoms at 20 weeks was run, and no significant difference was found by group. This lack of significance may be the result of relatively small numbers of patients distributed among the pain and fatigue, either pain or fatigue, or neither categories. This forced the researchers to compare only two groups at the 20-week observation. However, the trends were very encouraging. Substantially more patients in the experimental group (n = 10) reported neither

Table 5. Effect of Group and Cancer Site and Their Interactions on the Impact on Social Function at 20 Weeks

Source	SS	df	F	p
Intercept	51089	1	60.87	0.000
Intake social function	8684	1	10.34	0.002
Group	2850	1	3.39	0.070
Site of cancer[a]				
• Lung	26.46	1	0.032	0.860
• Other	2091.92	1	2.49	0.119
• Group X lung[b]	195	1	0.233	0.631
• Group X other	0.32	1	0.000	0.984

[a] Breast cancer was the reference.

[b] Interaction terms

Table 6. Pain and Fatigue Status at Observations II and III by Group Assignment for Patients With Pain and Fatigue at Baseline

	Experimental (n = 53)				Control (n = 60)			
	Observation II		Observation III		Observation II		Observation III	
Categories	n	%	n	%	n	%	n	%
Pain and fatigue	29	69	19	54	30	63	25	58
Pain only	–	–	1	3	1	2	2	5
Fatigue only	8	19	5	14	15	31	13	30
Neither pain nor fatigue	5	12	10	29	2	4	3	7
Total	42	100	35	100	48	100	43	100

Note. Only information regarding patients who experienced pain and fatigue at Observation I is included.

pain nor fatigue at the 20-week observation compared with only three patients in the control group.

Limitations

Although no differences were found between the experimental and control groups by age or gender, the sample was inadequately powered and not all covariates that could affect the outcomes were entered into the analysis. The disproportionately large number of patients with breast cancer in the sample may limit generaliziability. In addition, further exploration is needed to determine why such a large number of participants were unemployed. The researchers recognize these limitations in the interpretations made in this research.

Discussion

The findings from this study indicate that patients who reported pain and fatigue at baseline and who received the supportive nursing care intervention reported fewer numbers of symptoms and improved impact on their physical role and social role functioning. In addition, the total resolution of both pain and fatigue over time was in the expected direction (i.e., that the specialized intervention improved reports of both pain and fatigue over time) although it was not statistically significant. This trend suggests that management and control of pain and fatigue is an important route through which other symptoms can be reduced or eliminated.

The reduction in the count of symptoms, although significant, may be overshadowed by the impact of the intervention on improving physical and social functioning (Mock et al., 2001). Patients' abilities to perform their major roles, remain independent, and return to work or their major role responsibilities represents the "value-added" role of a nursing intervention to the care of patients undergoing a new course of chemotherapy.

When assessed according to site of cancer, the intervention had the least effect on patients with lung cancer. This was true for all the dependent variables. Patients receiving chemotherapy for lung cancer may have more advanced and complex disease, which makes their problems more refractory to behavioral interventions.

This research drew on cognitive-behavioral theory to guide the delivery of a behavioral intervention for the management of patient symptoms during chemotherapy. Unlike past work that focused on a single symptom, this research underscored the sentinel role of pain and fatigue as risk factors for the inclusion of patients in behavioral interventions. As Cooley, Short, and Moriarty (in press) noted, behavioral interventions have an important role in symptom management, over and above pharmacologic approaches. This research confirms this argument. Behavioral interventions targeted to patients with pain and fatigue can reduce the symptom burden, improve the quality of the daily lives of patients, and demonstrate the "value-added" role of nursing care for patients undergoing chemotherapy.

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