A Cognitive Behavioral Intervention for Symptom Management in Patients With Advanced Cancer

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Purpose/Objectives: To evaluate the effectiveness of a cognitive behavioral intervention in decreasing symptom severity in patients with advanced cancer undergoing chemotherapy.

Design: Prospective, randomized clinical trial based on cognitive behavioral theory.

Setting: Six urban cancer centers in the midwestern United States.

Sample: 124 patients 21 years of age or older were recruited and randomized to receive conventional care or conventional care and an intervention. Participants were newly diagnosed with stage III, stage IV, or recurrent cancer (solid tumor or non-Hodgkin lymphoma), undergoing chemotherapy, cognitively intact, and able to read and speak English.

Methods: Data were gathered via telephone interviews at baseline and 10 and 20 weeks after randomization. Nurses with experience in oncology delivered a five-contact, eight-week intervention aimed at teaching patients problem-solving techniques to affect symptom severity.

Main Research Variables: Gender, site of cancer, age, symptom severity and depressive symptoms at baseline, group (i.e., experimental versus control), and total symptom severity.

Findings: Patients in the experimental group and those with lower symptom severity at baseline had significantly lower symptom severity at 10 and 20 weeks; the experimental difference at 20 weeks occurred primarily in those 60 years of age and younger. Depressive symptoms at baseline predicted symptom severity at 20 weeks; however, age, gender, and site of cancer did not affect symptom severity at either time point.

Conclusions: A cognitive behavioral intervention to teach problem-solving skills can be effective for patient symptom self-management during and following an intervention.

Implications for Nursing: Problem-solving strategies should be included in educational programs for patients with advanced cancer, particularly those 60 years of age and younger.

Key Points . . .

- Conventional symptom management may not adequately meet the needs of patients with advanced cancer.
- Cognitive behavioral interventions using problem-solving techniques have affected symptoms in patients with early-stage disease.
- The effectiveness of cognitive behavioral interventions using problem-solving techniques is not well established in patients with late-stage disease or across multiple symptoms.

As the number of people living with cancer continues to increase, more patients are being diagnosed with recurrent and advanced stage (i.e., III or IV) disease. Treatment for patients with advanced cancer may be aggressive, resulting in severe symptoms that persist after treatment has ended (Hwang, Chang, Fairclough, Cogswell, & Kasimis, 2003; Kornblith et al., 2003). Patients have indicated that symptom management is an essential component of their cancer care, yet authors have reported that current methods to assist patients with symptom management may be ineffective (Morasso et al., 1999). Although assisting patients with managing symptoms has become a national priority (Patrick et al., 2003), the effectiveness of interventions aimed at decreasing the presence and severity of cancer- and treatment-related symptoms has not been well established for patients with advanced disease.

Cognitive behavioral interventions (CBIs) use a multimodal approach toward symptom management and are particularly effective in decreasing symptom severity for patients with cancer (Antoni et al., 2001; Dodd & Miaskowski, 2000; Given et al., 2002; Quesnel, Savard, Simard, Ivers, & Morin,

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2003; Sheard & Maguire, 1999). However, most studies have been limited to testing the effectiveness of CBIs in reducing the severity of a particular symptom, such as fatigue or pain (Oliver, Kravitz, Kaplan, & Meyers, 2001; Quesnel et al.), or in patients who present with a particular site of cancer, such as breast cancer, regardless of the stage of disease (Antoni et al.; Cruess et al., 2000). The goal of this study was to evaluate the effectiveness of a CBI in decreasing overall symptom severity in patients with advanced cancer undergoing chemotherapy. The study was designed to answer the following question: After controlling for gender, site of cancer, age, and symptom severity and depressive symptoms at baseline, does a CBI decrease symptom severity at 10 and 20 weeks following entry into the study for patients with advanced cancer completing a course of chemotherapy?

Background

Symptom Distress and Patients With Advanced Cancer

Among patients with varying stages of disease, 14%–100% report pain, 1%–42% report depression, and 4%–91% report fatigue (Patrick et al., 2003). The large discrepancies in reported symptoms are the result, in part, of the timing of measurement, measurement strategies, and related methodologic issues. The presence and severity of cancer- and treatment-related symptoms can affect a patient's mood, ability to perform activities of daily living, and overall quality of life (Dodd, Miaskowski, & Paul, 2001; Given, Given, Azzouz, Kozachik, & Stommel, 2001; McMillan & Small, 2002). As a patient's disease progresses to an advanced stage, symptoms and side effects from the tumor and related treatment can intensify (Vainio & Auvinen, 1996; Walsh, Donnelly, & Rybicki, 2000). Symptoms in patients with advanced cancer change over time, and subsequent distress from these symptoms accelerates as patients approach death (Hwang et al., 2003).

Despite the impact of cancer- and treatment-related symptoms on patients' lives, current interventions aimed at symptom management may not be adequate to meet the needs of those with advanced cancer. Morasso et al. (1999) found that nearly two-thirds of patients with advanced cancer reported unmet needs regarding symptom management that were associated with psychological and symptom distress. Inadequate symptom management may be the result of patients' and healthcare practitioners' beliefs that more severe and bothersome symptoms are a normal and expected part of having advanced disease. Such beliefs may be caused by providers' (and general practitioners in particular) lack of in-depth knowledge regarding symptom management techniques (Barclay, Todd, Grande, & Lipscombe, 2002). Regardless of the underlying cause, reports of ineffective symptom management in patients with advanced cancer underscore the need to evaluate new interventions in this patient population (Brescia, 2004; Given et al., 2002; Oncology Nursing Society, 2003).

Interventions aimed at improving symptom management in patients with cancer can be targeted toward practitioners (National Comprehensive Cancer Network, 2004) or patients. Because patients with cancer often are treated by multiple providers or may not have regular and reliable access to providers for assistance with symptom management, interventions targeted toward patients and their families are vital. Cognitive behavioral theory, which guided the framework for this study, has shown promise in improving symptom management in patients with cancer (Nezu, Nezu, Friedman, Faddis, & Houts, 1998), although the application of the interventions in patients with advanced disease is unknown.

Theoretical Framework

Cognitive behavioral theory is based on three principles: The manner in which patients perceive a situation affects their behavior and beliefs regarding their ability to control it, patients can change the way they perceive a situation (i.e., cognitive reframing), and patients' ability to control a situation effectively can be improved by changing their perspective (Dobson, 2001). Patients' attitudes regarding symptoms (i.e., patients' belief in their ability to manage symptoms or their knowledge of which factors are causing specific symptoms) will affect their ability to manage symptoms effectively. If cognitive reframing can occur, patients can alter their misconceptions regarding symptoms and symptom management and realize that steps can be taken to manage symptoms effectively (Kwekkeboom, 1999). Of the different types of CBIs, problem-solving therapy can be particularly advantageous for patients with cancer- and treatment-related symptoms (Nezu et al., 1998). Problem-solving skills help patients identify which symptoms pose problems, teach patients to generate strategies to manage symptoms, and assist patients with developing, implementing, and evaluating the efficacy of the strategies so that they can be retained and employed independently in the future (D'Zurilla & Goldfried, 1971; Kwekkeboom). For example, problem-solving skills for patients experiencing pain might include helping patients determine pain levels that are unacceptable, encouraging patients to generate interventions to control pain given available resources (e.g., engaging family caregivers to remind patients to take pain medication around the clock), and helping patients evaluate interventions (e.g., keeping a pain diary in which patients record when pain medication is taken as well as pain levels before and after taking medication).

CBIs using problem-solving techniques operate under the assumption that if patients are taught to implement self-care behaviors successfully, they will manage their symptoms effectively by forming a positive or adaptive orientation to symptom management, identifying realistic goals and objectives for managing symptoms, implementing strategies to decrease the severity or impact of symptoms, and verifying the effectiveness of the strategies (D'Zurilla & Nezu, 2001). Patients gain a sense of control over their cancer care, which empowers them to collaborate with family caregivers and healthcare practitioners to manage symptoms. Teaching problem-solving skills is particularly useful for patients undergoing cancer treatment because symptoms may persist after active treatment ends.

Cognitive Behavioral Interventions

CBIs have been associated with improved symptom management outcomes for patients with cancer, particularly when patients initially exhibit high levels of distress (Baider, Peretz, Hadani, & Koch, 2001; Trask, Paterson, Griffith, Riba, & Schwartz, 2003). In patients with breast cancer, for example, CBIs have been shown to decrease symptom severity and depression (Antoni et al., 2001; Ganz et al., 2000; Lev et al., 2001), improve immune response after surgery (McGregor

et al., 2004), and increase sleep efficiency (Quesnel et al., 2003).

CBIs that focus on problem-solving skills also have been associated with lower anxiety and improved health perceptions in patients with melanoma (Trask et al., 2003), decreases in the quantity of symptoms in Caucasian men with prostate cancer (Mishel et al., 2003), fewer depressive symptoms and less anxiety in patients with stage II cancer who were clinically depressed (Evans & Connis, 1995), and improved knowledge, more independence in managing symptoms, and better perceptions of familial support in patients with stages I–III cancer undergoing radiation (Benor, Delbar, & Krulik, 1998). Patients with multiple sites of cancer undergoing active treatment also have demonstrated benefits from CBIs using problem-solving techniques (Given et al., 2002; Larson, Dodd, & Aksamit, 1998; Rawl et al., 2002).

Despite the breadth of the research, most studies have focused on patients with one type of cancer (e.g., breast, prostate) and excluded patients with advanced-stage or recurrent disease. The few studies that have been conducted in patients with advanced-stage disease reported that CBIs show promise in affecting various aspects of patients' lives. CBIs using problem-solving skills have been shown to increase patient satisfaction with symptom control in women with recurrent and advanced breast cancer (Classen et al., 2001; Northouse et al., 2002). In addition, Bucher et al. (2001) found that patients with advanced cancer in a nonrandomized clinical trial were able to improve their problem-solving ability after an educational session. Whether CBIs with a problem-solving approach affect symptom severity in patients with varying sites of cancer is unknown, however, as well as whether patients are able to maintain the skills after the intervention has ended.

This clinical trial sought to test the effectiveness of a problem-solving CBI in reducing symptom severity among patients undergoing chemotherapy for advanced cancer from a variety of solid tumors and non-Hodgkin lymphoma. The study results extend the science of symptom management by testing the impact of a CBI among patients undergoing chemotherapy for late-stage disease, which has been underresearched. In addition, the researchers in this study chose to measure symptom severity as a cumulative score. Previous studies have demonstrated the effectiveness of CBIs on individual symptoms (e.g., sleep disturbance, pain); however, symptoms rarely occur in isolation (Dodd et al., 2001), particularly in patients with advanced-stage disease. By using symptom severity as a cumulative score across multiple symptoms, this study was able to examine how the intervention affected patients' total symptom severity experience.

Methods

Sample

Patients 21 years of age or older with a diagnosis of advanced disease for a solid tumor or non-Hodgkin lymphoma were screened at six cancer centers in Michigan, Indiana, and Ohio during a 20-month period. Inclusion criteria for the study were patients who were newly diagnosed with advanced (i.e., stage III or IV) or recurrent cancer and undergoing chemotherapy. Exclusion criteria were patients who were not cognitively intact, could not read and speak English, and did not have regular access to a telephone. Power analysis demonstrated that two covariates in the model and a sample size of 113 would produce an 85% power for a two-sided partial t test to detect an R-square increase of 0.06 as a result of the addition of the group effect to the linear regression model. The researchers assumed an alpha of 0.05 and that the model with the two covariates alone accounted for at least 20% of the variance in the dependent variable (Cohen, 1988).

Procedure

Recruiters employed by the study approached potential participants and explained the study, and, if interested, patients signed consent forms. Once consent was obtained, a baseline interview was completed to collect sociodemographic, treatment, and symptom-related information. Following baseline data collection, a stratified randomization schema was used to randomly assign patients from each recruitment site to the conventional care group or the conventional care plus a five-contact, eight-week, nurse-delivered intervention group. Follow-up interviews for patients in both arms of the study were completed by non-nurses 10 and 20 weeks after entry into the study to collect data regarding symptom severity and potential confounding variables, such as depressive symptoms, age, gender, and site of cancer. The first interview was conducted 10 weeks after recruitment into the study because of the likelihood that most patients would have completed one to two cycles of chemotherapy in that time; the second interview was conducted after 20 weeks because of the likelihood that most patients would have completed one course of chemotherapy. Interviewers were not nurses and were not aware of which arm of the study patients were in. Approval from the institutional review board of each participating site as well as the investigators' institutions was obtained before the study was implemented.

Intervention

The symptom management intervention delivered to patients in the experimental group consisted of five contacts during an eight-week period with an RN who was experienced in oncology. The intervention was based on cognitive behavioral theory and was designed to help patients understand the nature of symptoms, improve patients' belief in their ability to control symptoms, and teach patients problem-solving skills. The first and last contacts occurred in person; the second, third, and fourth contacts were conducted by telephone. The purpose of the first in-person contact was to establish a rapport with patients, and the last contact was meant to facilitate closure to the intervention. Telephone contacts were used at other times to minimize patient burden that might result from participating in the study. Contacts with nurse interventionists were scheduled at two-week intervals to allow patients enough time to implement and assess the effectiveness of symptom management strategies. During each contact, nurses assessed patients' pain, fatigue, nausea, vomiting, insomnia, dyspnea, weakness, anorexia, fever, dry mouth, constipation, mouth sores, and depressive symptoms. Patients rated the severity of each symptom and its impact on four dimensions of their quality of life: appetite and eating, daily activities, emotions and mood, and sleep. Once patients identified which symptoms were severe or affecting their quality of life, nurse interventionists helped patients reframe their attitudes and beliefs with regard to controlling individual symptoms. Nurses proposed cognitive

and behavioral self-care strategies and assisted patients with plans to carry them out.

A customized computer documentation program was used to lead nurses through the patient encounter from symptom assessment to selecting intervention strategies that were incorporated into patients' plan of care. The computer documentation program was developed by the principal investigators during a previous study and has been used with more than 300 patients with cancer. Any symptom that patients gave a severity score of 5 or higher on a 0–10 scale or 3 or higher on the quality-of-life scale, which was rated 0–5, automatically posted to patients' plan of care. Nurses and patients reviewed symptoms that reached the thresholds. Patients then selected which symptoms they would focus on during the following two weeks. Together with each patient, nurses tailored a list of interventions, which patients agreed to implement, to decrease the severity or impact of the symptom. Interventions were grouped according to the following domains: prescribe, teach-assess-evaluate, communicate, and counsel. For a patient with pain, for example, a nurse might suggest recording pain levels throughout the day, using distraction, or enhancing communication with physicians and family caregivers regarding current and acceptable pain levels (see Table 1). Although nurses suggested strategies, patients ultimately were responsible for choosing and implementing them.

Quality Assurance

Four nurse interventionists were employed for the study, and each attended an initial two-day training session during which the study's goals, procedures, and objectives were discussed. On completion of the initial training, nurse interventionists performed two mock interviews that were recorded and reviewed by the principal investigators and a quality assurance coordinator for protocol compliance and appropriateness of interventions. After the mock interviews were considered acceptable, interventionists recorded one intervention per month for the duration of the study, which was reviewed by the quality assurance coordinator. In addition, the quality assurance coordinator reviewed the computer record of every intervention session that was completed during the study for protocol compliance, appropriateness of interventions, and completeness of data. Finally, all nurses participated in monthly telephone conference calls during which strategies were reviewed by the group to ensure uniformity in the delivery of the intervention.

Measures

To test the impact of the intervention, age, gender, and cancer site and stage were identified during the baseline interview, and symptom severity and depressive affect were assessed at baseline, 10 weeks, and 20 weeks. The site of cancer was grouped according to breast, lung, and other (e.g., colorectal, gastrointestinal-pancreatic, genitourinary-gynecologic). The stage of cancer was identified during the medical record audit at recruitment as stage III or IV according to tumor, node, metastasis guidelines (National Cancer Institute, 2004).

Symptom severity was measured during each interview observation by asking patients to rate the severity of each symptom on a scale of 0 (not present) to 10 (as severe as it possibly could be) and then summing severity ratings for each symptom, with higher scores indicating higher levels of severity (possible range = 0–120). The symptoms that were included in the severity index included pain, fatigue, nausea, vomiting, insomnia, dyspnea, weakness, anorexia, fever, dry mouth, constipation, and mouth sores.

Patients' reports of depressive symptoms were evaluated by the **Center for Epidemiologic Studies–Depression (CES-D) scale** (Radloff, 1977). The 20-item CES-D scale assesses a respondent's level of depressive symptoms on a four-point Likert-type scale (i.e., 1 = almost all of the time, 2 = most of the time, 3 = some of the time, 4 = rarely or none of the time). Scoring for the CES-D scale consists of reverse-coding negative items and summing individual items so that higher scores indicate higher levels of depressive symptoms. Reliability analysis of the CES-D scale revealed a Cronbach's alpha of 0.89.

Statistical Analyses

Univariate analyses were conducted for all continuous variables to study their underlying distribution. Comparisons of continuous variables between groups (i.e., experimental versus

Table 1. Examples of Interventions Used to Assist Patients With Symptom Management

Symptom	Prescribe	Teach-Assess-Evaluate	Communicate	Counsel
Fatigue	Listen to a guided imagery tape daily. Eat calorie- and protein-dense foods. Engage in low-impact exercise daily. Take brief naps early in the day. Establish a bedtime routine: Go to bed and get up at the same time each day.	Assess your family and social resources and ask for help with daily tasks if you need it. Teach about chemotherapy side effects and when to anticipate nadir. Prioritize daily activities and space them out so you do not tire yourself.	Tell your doctor if you • Have no energy • Feel so exhausted that you cannot move • Are unable to perform your usual daily activities.	Verbalize how your fatigue has altered your lifestyle.
Pain	Take your pain medication as prescribed around the clock. Keep track of your pain levels through a pain diary. Distract yourself with music, hobbies, or television.	Begin a constipation management program when you begin taking narcotic analgesics; take a stool softener twice a day and increase your fluid and fiber intake. Try positioning yourself with pillows to relieve some pain. Have additional pain medication on hand in case you have breakthrough pain.	Tell your doctor if • Around-the-clock pain medication does not relieve or lower your pain. • Your pain prevents you from getting a good night's sleep. • Your pain affects your ability to perform your usual daily activities.	Verbalize how your pain affects your emotions. Verbalize how you want your pain to be managed; then, plan how to communicate this to your doctor.

control, those lost to attrition versus those who completed the study) were made by t tests or regression models and adjusted for potentially confounding variables. For variables that did not satisfy the t test assumption of equal variances, the p value from the t test was based on the Satterthwaite method for correcting the degrees of freedom. Furthermore, any violation of normality was primarily in terms of skewness; therefore, t tests were employed to compare means for all variables.

To compare categorical variables between the levels of the group variable or attrition variable, the contingency-table Pearson chi-square test for general association was used. When 20% or more of the cells of the contingency table had expected counts less than five, the two-sided Fisher's exact test for the overall cross-classification table was used. Linear regression models were used to answer the research question.

Results

Sample

A total of 124 patients agreed to participate in the study; 62 were randomized to the control arm and 62 to the experimental arm (see Table 2). Attrition for the study equaled 40, so attrition analysis was performed to detect any significant differences between those who did not complete the study and those who remained. As the results in Table 3 illustrate, patients who did not complete the study were significantly more likely to be male ($p < 0.05$) and report much higher symptom severity ($p = 0.05$, $\bar{X} = 35.9$, SD = 18.7) than those who did not ($\bar{X} = 29.0$, SD = 17.8), which suggested that those who did not complete the study were too ill to continue participation. Further analysis revealed that the primary causes for attrition were death (43%, n = 17) and advancing disease (33%, n = 13). No other significant differences existed between groups.

Table 2. Sociodemographic and Disease-Related Characteristics of the Sample

Characteristic	n	%
Age (years)		
Range = 36–91	–	–
$\bar{X}$ = 62	–	–
SD = 12	–	–
Symptom severity		
Range = 0–76	–	–
$\bar{X}$ = 31	–	–
SD = 18	–	–
Gender		
Male	52	42
Female	72	58
Recruitment site		
A	45	36
B	26	21
C	24	19
D	18	15
E	11	9
Ethnicity		
Caucasian	117	94
African American	6	5
Native American	1	1
Site of cancer		
Breast	41	33
Lung	22	18
Other	61	49
Stage of cancer		
III	31	25
IV	35	28
Recurrent[a]	58	47

N = 124

[a] Indicates the written diagnosis at recruitment sites where no restaging of the cancer occurred

Table 3. Comparison of Sociodemographic Characteristics, Outcome Variables, and Other Measures Between Those Lost to Attrition and Those Who Completed the Study

	Lost to Attrition (n = 40)		Completed Study (n = 84)	
Characteristic	**n**	**%**	**n**	**%**
Gender (female)*	17	43	55	66
Ethnicity (Caucasian)	36	90	81	96
Cancer site (breast)	9	23	33	39
Characteristic	**$\bar{X}$**	**SD**	**$\bar{X}$**	**SD**
Age (years)	62.8	13.1	58.8	11.9
Symptom severity*	35.9	18.7	29.0	17.8
Depressive symptoms	15.4	10.5	13.7	7.6

N = 124

* $p \leq 0.05$

Symptom Occurrence and Severity

Table 4 lists the percentage of patients reporting each symptom as well as the mean severity of symptoms. Total symptom severity for the sample at baseline ranged from 0–76 ($\bar{X}$ = 31.2, SD = 18.3). The most common symptoms were fatigue, insomnia, weakness, and pain, which were reported by more than 60% of the sample. Average severity scores for each of these symptoms were 5 or higher on the 0–10 scale.

Baseline equivalencies were evaluated between participants in the experimental and control groups regarding age, gender, site of cancer, depressive symptoms, and symptom severity. No significant differences existed at baseline between the two groups on any variable.

Effects of the Intervention

Linear regression analyses were performed using symptom severity at 10 weeks (i.e., immediately following the end of the intervention) as the outcome variable and gender, site of cancer, age, and depressive symptoms and symptom severity at baseline as potentially confounding variables; all possible interactions were explored. Symptom severity at baseline ($p = 0.01$) and group assignment ($p = 0.04$) were significant predictors of symptom severity at 10 weeks after adjusting for other covariates (see Table 5). Patients in the experimental group reported a mean symptom severity of 19.1 at 10 weeks (SD = 13.1), compared with 27.7 (SD = 18.9) in the control group. As expected, patients with higher symptom severity at enrollment reported higher symptom severity scores at 10 weeks. Gender, site of cancer, depressive symptoms at baseline, and age did not affect symptom severity at 10 weeks.

Analysis was repeated at 20 weeks to determine whether the effects observed at 10 weeks were sustained at 20

Table 4. Frequency and Average Severity of Patient Symptoms at Baseline

Symptom	n[a]	%	$\bar{X}$ Severity	SD
Fatigue	109	88	5.7	2.3
Insomnia	91	73	5.6	2.3
Weakness	87	70	5.6	2.4
Pain	82	66	5.0	2.6
Constipation	60	48	5.4	2.7
Anorexia	58	47	5.7	2.6
Dry mouth	57	46	5.7	2.3
Nausea	56	45	5.4	2.6
Dyspnea	53	43	4.4	2.3
Vomiting	26	21	7.5	2.6
Mouth sores	25	20	3.5	2.5
Fever	14	11	4.9	2.7

N = 124

[a] Patients were considered to have a symptom if they reported experiencing the symptom at least once during the week before the interview and rated its severity higher than 1 on a scale of 0–10.

weeks. Significant predictors of symptom severity at 20 weeks included participating in the intervention (p = 0.02), reporting higher levels of depressive symptoms (p = 0.04) and higher symptom severity (p = 0.01) at baseline, and the interaction of age and group (p = 0.03), as seen in Table 6. No other interactions were found to be significant. Patients in the experimental group had a mean symptom severity of 22.1 (SD = 15.2) at 20 weeks versus 28.2 (SD = 19.6) in the control group.

To assess the interaction between age and group, patients in each arm of the trial were dichotomized according to the median age into groups of those 60 years of age and younger and those older than 60 years of age (see Table 7). Separate models were run for each group with symptom severity and depressive symptoms at baseline, age, gender, and group (i.e., experimental versus control) as predictor variables of symptom severity at 20 weeks. Among those who were older than age 60, the regression model revealed no significant difference (p = 0.99) in mean symptom severity scores at 20 weeks between patients in the experimental and control groups. However, for patients 60 years of age and younger, those in the experimental group had a mean symptom severity score of 16.1, compared to 28.0 in the control group. The differential effect of the intervention by age approached significance (p = 0.057).

Discussion

Patients with advanced cancer are at an increased risk for developing multiple and severe symptoms secondary to aggressive treatment and advancing disease, and conventional care may not be sufficient to assist them with symptom management needs (Morasso et al., 1999). This trial was conducted to evaluate the effectiveness of a problem-solving CBI on symptom severity for patients with advanced disease undergoing chemotherapy.

The eight-week, five-contact intervention was designed to assist patients with identifying troublesome symptoms, generating intervention strategies to decrease symptom severity, and evaluating the effectiveness of the strategies. Although age, gender, site of cancer, and depressive symptoms at baseline did not significantly affect symptom severity at 10 weeks, participants in the control group and those with higher symptom severity at baseline reported significantly higher symptom severity at 10 weeks. Data suggest that patients with advanced disease undergoing chemotherapy are able to successfully implement problem-solving strategies that reduce the severity of symptoms. The results of this study extend the work of other investigators who have reported on the effectiveness of CBIs in decreasing the severity of specific symptoms (Oliver et al., 2001) and for patients with a single cancer site (Antoni et al., 2001; Cruess et al., 2000). The results of this study extend support for using CBIs to affect multiple symptoms in patients with advanced disease across tumor types.

One of the primary goals of CBIs that include a problem-solving component is for patients to continue implementing problem-solving skills after the intervention is complete. To evaluate the effectiveness of the intervention in assisting patients with managing symptoms in the absence of direct contact with a nurse interventionist, symptom severity was evaluated at 20 weeks, approximately two-and-a-half months after the intervention was completed for patients in the experimental

Table 5. Predictors of Symptom Severity at 10 Weeks

Variable	β	df	Type III SS	F	p
Group	6.66	1	1,003.31	4.39	0.04
Control	–	–	–	–	–
Intervention	–	–	–	–	–
Symptom severity at baseline	0.30	1	1,591.71	6.96	0.01
Gender	–1.95	1	51.07	0.22	0.64
Female	–	–	–	–	–
Male	–	–	–	–	–
Age	–0.01	1	1.14	–	0.94
Depressive symptoms at baseline	0.41	1	585.54	2.56	0.11
Site of cancer	–	3	1,302.40	1.90	0.14
Breast	3.28	–	–	–	–
Other	9.33	–	–	–	–
Lung	3.47	–	–	–	–

N = 113

Note. All possible interactions were tested.

Table 6. Predictors of Symptom Severity at 20 Weeks

Variable	β	df	Type III SS	F	p
Group	46.67	1	1,607.89	6.06	0.02
Control	–	–	–	–	–
Intervention	–	–	–	–	–
Symptom severity at baseline	0.35	1	1,843.16	6.95	0.01
Gender	1.49	1	22.54	0.08	0.77
Female	–	–	–	–	–
Male	–	–	–	–	–
Age	0.15	1	342.31	1.29	0.26
Depressive symptoms at baseline	0.64	1	1,188.53	4.48	0.04
Site of cancer	–	3	547.58	0.69	0.56
Breast	–3.46	–	–	–	–
Other	–7.04	–	–	–	–
Lung	–	–	–	–	–
Age times group interaction	–0.70	1	1,323.14	4.99	0.03

N = 84

Note. All possible interactions were tested. Only significant interactions were included in the final model.

group. Although mean symptom severity for patients in the experimental group increased after the intervention ended, symptom severity was still significantly lower for patients in the experimental group than the control group at 20 weeks. Therefore, patients who received the intervention were able to integrate problem-solving skills into their lives and continue to use them to manage symptoms after the completion of the intervention. Other authors have not found a sustained effect of CBIs on patients' symptoms (Mishel et al., 2003; Trask et al., 2003); however, patients with advanced cancer were not targeted in the studies. One possible explanation is that once patients reach advanced-stage disease, the symptom experience plays a larger role in their lives and they have a greater need to continue to use symptom management techniques over time. Another possibility is that symptom burden in patients with earlier-stage disease is not as great; therefore, more opportunity existed for patients in this sample to learn and retain symptom management techniques.

Data also revealed an interaction between age and group for predicting symptom severity at 20 weeks. Patients in the experimental group who were 60 years of age and younger had lower symptom severity scores than those in the control group, and this difference approached statistical significance. No significant differences were found in symptom severity at 20 weeks between patients in the experimental and control groups who were older than age 60. The data suggest that patients 60 years of age and younger may be more amenable to a CBI.

Table 7. Effect of Group by Age on Symptom Severity at 20 Weeks

Age (years)	$\bar{X}$[a]	β	F	p
Older than 60	–	7.50	–	0.99
Control	19.2	–	–	–
Experimental	19.3	–	–	–
60 and younger	–	2.97	3.87	0.06
Control	28.0	–	–	–
Experimental	16.1	–	–	–

[a] Means were adjusted for gender, age, site of cancer, depression at baseline, and symptom severity at baseline.

Overall, the study demonstrated that a problem-solving CBI can be effective at decreasing symptom severity across multiple tumor types in patients with advanced cancer and that these effects can be sustained after an intervention is completed, particularly in younger patients. Although nurses may use a problem-solving approach intuitively when helping patients with symptom management, data from this study suggest that teaching patients problem-solving strategies can lower symptom severity and that these strategies are retained following the intervention.

Limitations

Because of the limited research regarding the effectiveness of CBIs in patients with advanced cancer, this study used symptom severity as an aggregate score across symptoms to begin to investigate the potential for CBIs to affect overall symptom severity in patients with advanced cancer. Although choosing to measure symptom severity as a cumulative score allowed the researchers to determine the effectiveness of the intervention on overall symptom severity, this approach did not provide information regarding the differential effectiveness of the intervention on individual symptoms. How symptoms are "weighted" in patients with advanced cancer also is unclear; using a cumulative symptom severity score assumes equality among symptoms. Some symptoms, such as pain or fatigue, may concern patients more than others, such as dry mouth. Based on sample size, the researchers were unable to test the effectiveness of the intervention on individual symptoms and compare those results to a cumulative score.

The high rate of attrition in the study is another potential limitation. Attrition analyses demonstrated that patients who did not complete the study were more likely to have higher levels of symptom severity. These findings could affect the study's clinical applicability. Patients whose disease state is progressing and who have severe symptoms may not be amenable to CBIs or may not have the stamina to undergo such an intervention.

Because the majority of the sample was Caucasian, generalizability of the results to other ethnic groups is not possible. Mishel et al. (2003) reported on the differential effectiveness of CBIs based on ethnicity. The current study should

be replicated with patients of various ethnic backgrounds to determine whether CBIs are similarly effective for patients with advanced-stage disease in other ethnic groups.

Conclusion and Implications for Practice and Research

By examining the effectiveness of an intervention that seeks to decrease the severity of symptoms in patients with advanced cancer, this study expands the current level of knowledge regarding symptom management. Study results suggest that, regardless of the site of solid tumor, a CBI that focuses on problem-solving skills can be an effective intervention for a patient's symptom self-management during an intervention as well as in the following months. Future research replicating these findings would be helpful for increasing the generalizability of the results, further examining how the intervention affects specific symptoms, and gauging the effectiveness of the intervention in the presence of varying treatment protocols. Furthermore, defining the target and specific effectiveness of interventions will allow healthcare practitioners to meet individual patients' needs and contribute to the comfort of patients with advanced cancer.

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References

Antoni, M.H., Lehman, J.M., Kilbourn, K.M., Boyers, A.E., Culver, J.L., Alferi, S.M., et al. (2001). Cognitive-behavioral stress management intervention decreases the prevalence of depression and enhances benefit finding among women under treatment for early-stage breast cancer. *Health Psychology, 20,* 20–32.

Baider, L., Peretz, T., Hadani, P.E., & Koch, U. (2001). Psychological intervention in cancer patients: A randomized study. *General Hospital Psychiatry, 23,* 272–277.

Barclay, S., Todd, C., Grande, G., & Lipscombe, J. (2002). Controlling cancer pain in primary care: The prescribing habits and knowledge base of general practitioners. *Journal of Pain and Symptom Management, 23,* 383–392.

Benor, D.E., Delbar, V., & Krulik, T. (1998). Measuring impact of nursing intervention on cancer patients' ability to control symptoms. *Cancer Nursing, 21,* 320–334.

Brescia, F.J. (2004). Palliative care in pancreatic cancer. *Cancer Control, 11,* 39–45.

Bucher, J.A., Loscalzo, M., Zabora, J., Houtz, P.S., Hooker, C., & Brintzenhofe-Szoc, K. (2001). Problem-solving cancer care education for patients and caregivers. *Cancer Practice, 9,* 66–70.

Classen, C., Butler, L.D., Koopman, C., Miller, E., DiMiceli, S., Giese-Davis, J., et al. (2001). Supportive-expressive group therapy and distress in patients with metastatic breast cancer: A randomized clinical intervention trial. *Archives of General Psychiatry, 58,* 494–501.

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences* (2nd ed.). Hillsdale, NJ: Lawrence Erlbaum Associates.

Cruess, D.G., Antoni, M.H., McGregor, B.A., Kilbourn, K.M., Boyers, A.E., Alferi, S.M., et al. (2000). Cognitive-behavioral stress management reduces serum cortisol by enhancing benefit finding among women being treated for early stage breast cancer. *Psychosomatic Medicine, 62,* 304–308.

Dobson, K.S. (Ed.). (2001). *Handbook of cognitive-behavioral therapies* (2nd ed.). New York: Guilford Press.

Dodd, M.J., & Miaskowski, C. (2000). The PRO-SELF program: A self-care intervention program for patients receiving cancer treatment. *Seminars in Oncology Nursing, 16,* 300–308.

Dodd, M.J., Miaskowski, C., & Paul, S.M. (2001). Symptom clusters and their effect on the functional status of patients with cancer. *Oncology Nursing Forum, 28,* 465–470.

D'Zurilla, T.J., & Goldfried, M.R. (1971). Problem solving and behavior modification. *Journal of Abnormal Psychology, 78,* 107–126.

D'Zurilla, T.J., & Nezu, A.M. (2001). Problem solving therapies. In K.S. Dobson (Ed.), *Handbook of cognitive-behavioral therapies* (2nd ed., pp. 211–245). New York: Guilford Press.

Evans, R.L., & Connis, R.T. (1995). Comparison of brief group therapies for depressed cancer patients receiving radiation treatment. *Public Health Reports, 110,* 306–311.

Ganz, P.A., Greendale, G.A, Petersen, L., Zibecchi, L., Kahn, B., & Belin, T.R. (2000). Managing menopausal symptoms in breast cancer survivors: Results of a randomized controlled trial. *Journal of the National Cancer Institute, 92,* 1054–1064.

Given, B., Given, C.W., McCorkle, R., Kozachik, S., Cimprich, B., Rahbar, M., et al. (2002). Pain and fatigue management: Results of a nursing randomized clinical trial. *Oncology Nursing Forum, 29,* 949–956.

Given, C.W., Given, B., Azzouz, F., Kozachik, S., & Stommel, M. (2001). Predictors of pain and fatigue in the year following diagnosis among elderly cancer patients. *Journal of Pain and Symptom Management, 21,* 456–466.

Hwang, S.S., Chang, V.T., Fairclough, D.L., Cogswell, J., & Kasimis, B. (2003). Longitudinal quality of life in advanced cancer patients: Pilot study results from a VA medical cancer center. *Journal of Pain and Symptom Management, 25,* 225–235.

Kornblith, A.B., Herndon, J.E., III, Weiss, R.B., Zhang, C., Zuckerman, E.L., Rosenberg, S., et al. (2003). Long-term adjustment of survivors of early stage breast carcinoma, 20 years after adjuvant chemotherapy. *Cancer, 98,* 679–689.

Kwekkeboom, K. (1999). A model for cognitive-behavioral interventions in cancer pain management. *Image: Journal of Nursing Scholarship, 31,* 151–156.

Larson, P.J., Dodd, M.J., & Aksamit, I. (1998). A symptom-management program for patients undergoing cancer treatment: The Pro-Self program. *Journal of Cancer Education, 13,* 248–252.

Lev, E.L., Daley, K.M., Conner, N.E., Reith, M., Fernandez, C., & Owen, S.V. (2001). An intervention to increase quality of life and self-care self-efficacy and decrease symptoms in breast cancer patients. *Scholarly Inquiry for Nursing Practice, 15,* 277–294.

McGregor, B.A., Antoni, M.H., Boyers, A., Alferi, S.M., Blomberg, B.B., & Carver, C.S. (2004). Cognitive behavioral stress management increases benefit finding and immune function among women with early-stage breast cancer. *Journal of Psychosomatic Research, 56,* 1–8.

McMillan, S.C., & Small, B.J. (2002). Symptom distress and quality of life in patients with cancer newly admitted to hospice home care. *Oncology Nursing Forum, 29,* 1421–1428.

Mishel, M.H., Germino, B.B., Belyea, M., Stewart, J.L., Bailey, D.E., Jr., Mohler, J., et al. (2003). Moderators of an uncertainty management intervention: For men with localized prostate cancer. *Nursing Research, 52,* 89–97.

Morasso, G., Capelli, M., Viterbori, P., Di Leo, S., Alberisio, A., Costantini, M., et al. (1999). Psychological and symptom distress in terminal cancer patients with met and unmet needs. *Journal of Pain and Symptom Management, 17,* 402–409.

National Cancer Institute. (2004). Staging: Questions and answers. Retrieved March 3, 2004, from http://cis.nci.nih.gov/fact/5_32.htm

National Comprehensive Cancer Network. (2004). *Cancer pain.* Jenkintown, PA: Author.

Nezu, A.M., Nezu, C.M., Friedman, S., Faddis, S., & Houts, P. (1998). *Helping cancer patients cope: A problem-solving approach.* Washington, DC: American Psychological Association.

Northouse, L.L., Walker, J., Schafenacker, A., Mood, D., Mellon, S., Galvin, E., et al. (2002). A family-based program of care for women with recurrent breast cancer and their family members. *Oncology Nursing Forum, 29,* 1411–1419.

Oliver, J.W., Kravitz, R.L., Kaplan, S.H., & Meyers, F.J. (2001). Individualized patient education and coaching to improve pain control among cancer outpatients. *Journal of Clinical Oncology, 19,* 2206–2212.

Oncology Nursing Society. (2003). *Oncology Nursing Society research agenda, 2003–2005.* Retrieved November 12, 2003, from http://www.ons.org/research/information/documents/pdfs/2003Plan.pdf

Patrick, D.L., Ferketich, S.L., Frame, P.S., Harris, J.J., Hendricks, C.B., Levin, B., et al. (2003). National Institutes of Health state-of-the-science conference statement: Symptom management in cancer: Pain, depression, and fatigue, July 15–17, 2002. *Journal of the National Cancer Institute, 95,* 1110–1117.

Quesnel, C., Savard, J., Simard, S., Ivers, H., & Morin, C.M. (2003). Efficacy of cognitive behavioral therapy for insomnia in women treated for nonmetastatic breast cancer. *Journal of Consulting and Clinical Psychology, 71,* 189–200.

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.

Rawl, S.M., Given, B.A., Given, C.W., Champion, V.L., Kozachik, S.L., Barton, D., et al. (2002). Intervention to improve psychological functioning for newly diagnosed patients with cancer. *Oncology Nursing Forum, 29,* 967–975.

Sheard, T., & Maguire, P. (1999). The effect of psychological interventions on anxiety and depression in cancer patients: Results of two meta-analyses. *British Journal of Cancer, 80,* 1770–1780.

Trask, P.C., Paterson, A.G., Griffith, K.A., Riba, M.B., & Schwartz, J.L. (2003). Cognitive-behavioral intervention for distress in patients with melanoma: Comparison with standard medical care and impact on quality of life. *Cancer, 98,* 854–864.

Vainio, A., & Auvinen, A. (1996). Prevalence of symptoms among patients with advanced cancer: An international collaborative study. Symptom Prevalence Group. *Journal of Pain and Symptom Management, 12,* 3–10.

Walsh, D., Donnelly, S., & Rybicki, L. (2000). The symptoms of advanced cancer: Relationship to age, gender, and performance status in 1,000 patients. *Supportive Care in Cancer, 8,* 175–179.