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Feasibility of a Patient-Controlled Cognitive-Behavioral Intervention for Pain, Fatigue, and Sleep Disturbance in Cancer

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Purpose/Objectives: To evaluate the feasibility of a patient-controlled cognitive-behavioral intervention for pain, fatigue, and sleep disturbance during treatment for advanced cancer and to assess initial efficacy of the intervention.

Design: One group pre- and post-test design.

Setting: Outpatient oncology clinics at a comprehensive cancer center in the midwestern United States.

Sample: 30 adults with advanced (recurrent or metastatic) colorectal, lung, prostate, or gynecologic cancer receiving chemotherapy or radiotherapy.

Methods: Participants completed baseline measures (e.g., demographics, symptom inventory) and received education and training to use an MP3 player loaded with 12 cognitive-behavioral strategies (e.g., relaxation exercises, guided imagery, nature sound recordings). Participants used the strategies as needed for symptom management for two weeks, keeping a log of symptom ratings with each use. Following the two-week intervention, participants completed a second symptom inventory and an evaluation of the intervention.

Main Research Variables: Feasibility, patient-controlled cognitive-behavioral intervention, pain, fatigue, and sleep disturbance.

Findings: Thirty of 43 eligible patients (73%) agreed to participate; of them, 27 (90%) completed the study. Most reported that they enjoyed the intervention, had learned useful skills, and perceived improvement in their symptoms. Symptom scores at two weeks did not differ significantly from baseline; however, significant reductions in pain, fatigue, and sleep disturbance severity were found in ratings made immediately before and after use of a cognitive-behavioral strategy.

Conclusions: The patient-controlled cognitive-behavioral intervention appears to be feasible for additional study and could reduce day-to-day severity of co-occurring pain, fatigue, and sleep disturbance.

Implications for Nursing: A randomized, controlled trial is needed to test efficacy of the intervention for co-occurring pain, fatigue, and sleep disturbance. Meanwhile, based on previous efficacy studies, cognitive-behavioral strategies can be recommended for certain individual symptoms.

Improvements in cancer treatment have allowed people diagnosed with advanced (recurrent or metastatic) disease to live longer; however, these patients experience a heavy symptom burden. Patients with advanced cancer often report experiencing up to five symptoms at a given time and significantly more when receiving chemotherapy or radiation therapy (Chang, Hwang, Feuerman, & Kasimis, 2000; Feyer, Kleeberg, Steingräber, Günther, & Behrens, 2008). Researchers have identified co-occurring pain, fatigue, and sleep disturbance as a common symptom cluster among people with advanced cancer (Beck, Dudley, & Barsevick, 2005; Hoffman, Given, von Eye, Gift, & Given, 2007). Because the science regarding symptom clusters is new, few treatments that target co-occurring symptoms have been investigated. One logical option is to test interventions that have been effective for each of the cluster component symptoms when experienced in isolation. Evidence supports cognitive and behavioral strategies such as relaxation, distraction, and imagery for each of the three component symptoms (Kwekkeboom, Cherwin, Lee, & Wanta, 2009). The purpose of this study was to evaluate the feasibility and initial efficacy of a patient-controlled cognitive-behavioral intervention for managing pain, fatigue, and sleep disturbance during treatment for advanced cancer.

Background

Symptom Clusters

Patients with cancer often experience multiple symptoms (Potter, Hami, Bryan, & Quigley, 2003; Saini et al., 2006; Teunissen, de Graeff, Voest, & de Haes, 2007), and as oncology specialists working with particular groups of patients may notice, certain symptoms tend to occur together. Symptoms such as nausea and vomiting have

been found to occur concurrently, or "cluster," as do hot flashes and pain as well as altered taste, poor appetite, and weight loss (Chen & Lin, 2007; Gift, Jablonski, Stommel, & Given, 2004; Honea, Brant, & Beck, 2007). The concept of symptom clusters in cancer is relatively new, but scholars have outlined some basic hallmarks. A symptom cluster is a group of two or more symptoms that occur concurrently, are related to one another, and are independent of other symptoms (Kim, McGuire, Tulman, & Barsevick, 2005). The symptoms may share a common causal mechanism, or they may be linked in some other manner, such as through effects of medication used in treating a component symptom. Although the disease itself may cause the symptoms, symptom clusters frequently have been reported among people receiving cytotoxic therapy (Fan, Filipczak, & Chow, 2007).

Dodd, Miaskowski, and Paul (2001) first identified the co-occurrence of pain, fatigue, and sleep disturbance among patients with cancer receiving chemotherapy. Recent investigations have suggested that 40%–80% of patients with cancer experience co-occurring pain, fatigue, and sleep disturbance (Beck et al., 2005; Francoeur, 2005; Hickok, Morrow, Roscoe, Mustian, & Okunieff, 2005; Miaskowski et al., 2006; Miaskowski & Lee, 1999). Pain, fatigue, and sleep disturbance appear to be related to one another, and the experience of any one of the symptoms may cause or exacerbate the others. In theory, pain may wake the individual from usual sleep, prevent falling asleep, and contribute to loss of energy. Similarly, fatigue may lead to daytime napping and interruptions in night-time sleep. Both fatigue and sleep disturbance can increase sensitivity to pain. The presence of these co-occurring symptoms may significantly affect physical and psychological functioning, more so than any one of the symptoms experienced in isolation, and may contribute to greater suffering among patients affected by the symptom cluster (Dodd et al., 2001; Miaskowski et al., 2006).

Cognitive-Behavioral Strategies

Nurses have used many strategies to facilitate management of physical and psychological symptoms. Strategies such as relaxation, guided imagery, and distraction have been identified by a variety of names. The strategies have been called *nonpharmacologic* or *nondrug* treatments in nursing and medical literature (American Pain Society, 2005; McCaffery & Pasero, 1999) and *mind-body* therapies by people working in integrative or complementary medicine (National Center for Complementary and Alternative Medicine, 2009). Although used by a variety of disciplines, the theory and practice of such strategies grew largely from psychology literature, where they are identified as *cognitive* or *behavioral* techniques (Turk, Meichenbaum, & Genest, 1983).

Cognitive-behavioral theory provides the rationale for using relaxation, imagery, and distraction as treatment strategies for cancer-related symptoms. The theory suggests that the event or bodily experience (i.e., symptom) one perceives is shaped, at least in part, by what one believes and how one thinks about the symptom (e.g., its meaning, implications, controllability) (Breitbart & Holland, 1993; Turk et al., 1983). Cognitive-behavioral interventions are believed to affect symptoms by changing symptom-related thoughts, diminishing those beliefs that exacerbate symptoms, and increasing personal perceptions of control over symptoms. Pain, fatigue, and sleep disturbance are more than purely physiologic symptoms; they also have cognitive, affective, and behavioral components (Keefe, 1996). Strategies such as relaxation or imagery can be used to help redirect attention away from the symptom sensation, change maladaptive thoughts and beliefs about symptoms, reduce sympathetic arousal, and provide skills to facilitate coping with associated distress.

Cognitive-behavioral strategies have been recommended to facilitate coping among individuals with isolated symptoms, particularly pain (American Pain Society, 2005; Breitbart & Holland, 1993; McCaffery & Pasero, 1998). Numerous investigators have demonstrated that strategies such as relaxation, distraction, and imagery can effectively diminish the negative physical and emotional reaction to cancer pain, as well as diminish pain intensity (Anderson et al., 2006; Kwekkeboom, Kneip, & Pearson, 2003; Luebbert, Dahme, & Hasenbring, 2001; Sloman, Brown, Aldana, & Chee, 1994; Syrjala, Donaldson, Davis, Kippes, & Carr, 1995). Cancer researchers have demonstrated similar findings in people with other disease and treatment-related side effects such as nausea, vomiting, and distress (Mundy, DuHamel, & Montgomery, 2003; Redd, Montgomery, & DuHamel, 2001; Roffe, Schmidt, & Ernst, 2005). Investigators have applied the same strategies to the treatment of insomnia (Davidson, Waisberg, Brundage, & MacLean, 2001; Rumble, Keefe, Edinger, Porter, & Garst, 2005; Simeit, Deck, & Conta-Marx, 2004) and fatigue (Dimeo, Thomas, Raabe-Menssen, Propper, & Mathias, 2004; Jereczek-Fossa, Marsiglia, & Orecchia, 2001; Schulz, 2001) with beneficial effects. Although some evidence suggests that cognitive-behavioral strategies are useful in treating pain, fatigue, and sleep disturbance as isolated symptoms, no research has tested their effects on co-occurring symptoms (i.e., symptom clusters).

Patient-Centered Interventions

A growing number of nurse researchers have focused their work on developing and testing patient-centered interventions, that is, interventions that take into account the needs and preferences of individual care recipients (Lauver et al., 2002). Interventions can be patient centered in many different ways, such as by targeting the intervention only to patients with particular characteristics or tailoring the treatment based on an individual's

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particular needs and interests. The patient-centered approach is advantageous in that it allows for individual differences in patients' values, beliefs, perceived needs, and treatment preferences. Providing such an approach to symptom-management interventions may increase the likelihood of achieving beneficial outcomes.

Using a patient-centered approach to cognitive-behavioral symptom management is particularly important. Individual success with cognitive-behavioral strategies has been shown to vary. That is, certain strategies may work well for some patients, whereas the same strategies are ineffective for others (Donovan & Laack, 1998; Kwekkeboom, Wanta, & Bumpus, 2008). Therefore, clinicians cannot provide a single therapy and assume that it will be effective for all patients, particularly if patients are dealing with multiple symptoms of varying intensity, duration, and timing. Optimally, patients would be provided with a variety of strategies from which they could choose the most appealing and effective ones for their individual symptom experience and use them where ever or whenever they are needed. A patient-centered approach to cognitive-behavioral symptom management could be implemented by giving patients the knowledge and skills to control and self-administer their choice of strategies.

The primary aim of this study was to assess the feasibility of a patient-controlled cognitive-behavioral intervention using an MP3 player to deliver cognitive-behavioral strategies for co-occurring pain, fatigue, and sleep disturbance during cancer treatment. Feasibility was assessed with respect to whether successfully carrying out the study (e.g., recruitment and retention, acceptability of the study procedures, intervention) is possible. As a secondary aim, the initial efficacy of the intervention in controlling symptoms was evaluated. The research questions were as follows.

- Will patients with symptoms related to advanced cancer agree to participate in and complete the two-week study?
- Will participants find the study procedures and the patient-controlled cognitive-behavioral intervention acceptable?
- What effect does the intervention have on participants' symptom intensity?

Methods

Design and Participants

The study used a one-group pre- and post-test design. A convenience sample of 30 adult patients (aged 21 years or older) receiving treatment for advanced (metastatic or recurrent) colorectal, lung, prostate, or gynecologic cancers was recruited from the outpatient oncology clinics at a university-affiliated comprehensive cancer center in the midwestern United States. Inclusion criteria were having at least two of the three symptoms, including pain rated 3 or higher on a 0–10 scale in the prior 48 hours and report of fatigue or sleep disturbance in the prior week. Patients were excluded if their pain was postoperative or neuropathic in etiology, as determined with the Neuropathic Pain Screening Questionnaire (Portenoy, 2006). Study procedures were reviewed and approved by the university's health sciences institutional review board.

Instruments

Demographic questionnaire and chart review form: A patient demographic form included items regarding age, gender, education, race, and ethnicity. A chart review form completed by study personnel included information regarding cancer diagnosis, current treatments, and supportive medications prescribed (e.g., analgesics, steroids, psychostimulants, hypnotics or sedatives).

Symptom inventory: Pain severity was measured with four 0–10 numeric rating scale items from the Brief Pain Inventory (Cleeland, 1989), including pain now, worst pain, least pain, and average pain in the prior 24 hours. Scores were averaged across the four items to create a single pain severity estimate, with higher scores indicating more severe pain. Cronbach alpha in this use was 0.81–0.9. Fatigue severity was measured with four 0–10 numeric rating scale items from the Brief Fatigue Inventory (Mendoza et al., 1999), including fatigue now, worst fatigue, least fatigue, and usual fatigue in the prior 24 hours. Scores were averaged across the four items to create a single fatigue severity index, with higher scores indicating more severe fatigue. Cronbach alpha was 0.8–0.9. Sleep disturbance was measured with two items: a 0–10 numeric rating scale measure of sleep disturbance in the prior 24 hours and a verbal rating of sleep quality from the Pittsburgh Sleep Quality Index (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). Because the items used different scales, a z score was created for each item and the two scores were averaged to create a single index of sleep severity. Z scores were then transformed to t scores for ease of interpretation ($\bar{X}$ = 50, SD = 10), with higher scores indicating greater sleep disturbance.

Additional symptoms and their effect on daily functioning were assessed with the M.D. Anderson Symptom Inventory (Cleeland et al., 2000). The symptom inventory includes items measuring 13 common cancer-related symptoms and their effect on general activity, mood, work, relations with other people, walking, and enjoyment of life. All items are rated on a 0–10 numeric rating scale. The authors calculated a concurrent symptom score by averaging scores on 10 symptom ratings (excluding pain, fatigue, and sleep disturbance) with higher scores indicating greater concurrent symptoms. Scores on the seven items rating how much symptoms interfered with daily activities were averaged to create an overall symptom-interference score, with higher scores indicating greater interference. Reliability and validity of the M.D.

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Anderson Symptom Inventory has been demonstrated in patients with cancer (Cleeland et al., 2000). Cronbach alpha for the two subscales in the sample were 0.81–0.83 and 0.9–0.93, respectively.

Treatment log book: Participants kept a log each time a cognitive-behavioral strategy was used. They recorded the time of day and strategy used and made immediate pre- and post-treatment recordings of the severity of pain, fatigue, and sleep disturbance using a 0–10 scale.

Post-study evaluation: A 12-item survey was created for the current study to assess participants' perceptions of acceptability of the study procedures (e.g., time commitment, equipment, questionnaires) and the patient-controlled cognitive-behavioral intervention itself (e.g., length, variety, usefulness of recordings).

Patient-Controlled Cognitive-Behavioral Intervention

Because cancer-related symptoms are temporal, ranging from minutes to days, and intermittent with periods of exacerbation and relief, the authors chose a brief intervention (two weeks) provided during chemotherapy or radiation treatment when symptom exacerbations were likely to occur (Braud et al., 2003; Cleeland, 2000; Given et al., 2004). The intervention included recordings of 12 brief cognitive-behavioral strategies provided on an MP3 player (iPod Nano™, Apple, Inc.) with earbud-style headphones. All spoken recordings were made specifically for the current study and used the same female voice with no musical background. Cognitive-behavioral strategies included relaxation, distraction, and imagery exercises in four categories.

Relaxation exercises: Three relaxation exercises were offered to stimulate the release of muscle tension and anxiety that can exacerbate pain, produce fatigue, and prevent sleep. Progressive muscle relaxation (19:51 minutes) guided participants in tensing and relaxing various muscle groups in succession from hands and arms, up to the head, and down to the feet. Jaw relaxation (4:46) involved relaxing muscles of the mouth, throat, and face to stimulate a yawn and release tension throughout the body. Rhythmic breathing (8:50) instructed participants in focusing attention on breathing, slowing the pace of breathing, passively relaxing muscles, and silently repeating a calming word or phrase.

Nature imagery: Three guided imagery scripts were offered to distract attention and provide relaxation through focus on images of a pleasant nature scene. Meadow imagery (21:19) guided participants in imagining themselves on a peaceful walk through a meadow, sitting amongst wildflowers, and observing a stream. Beach imagery (21:49) instructed participants in imagining themselves walking onto a sandy beach, observing the water, and resting in the sun. Mountain imagery (19:28) led participants in imagining themselves taking a hike through a wooded mountain path, resting along a rock ledge at a clearing, and viewing a valley below.

Symptom-focused imagery: Three symptom-focused guided imagery scripts were offered to focus attention on manipulating mental images of a specific symptom and reducing its intensity. Pain-focused imagery (24:08) guided participants in creating mental images of their pain, allowing pain to flow out of the body, and eliminating any remaining pain with images of a pain-numbing anesthetic solution. Fatigue-focused imagery (21:07) involved creating mental images of energy drawn from the universe, circulating a ball of energy throughout the body, and re-energizing the body's cells. Sleep-focused imagery (18:22) instructed participants in imagining themselves floating on a cloud through the night sky and being blanketed in deep sleep.

Nature sounds: Three recordings of nature sounds were included to provide a peaceful source of distraction and relaxation without recommendations for creating specific imagery. Recordings included forest sounds (7:12), surf and waves (7:46), and sounds of a rainstorm (7:37). The nature sound recordings were commercial recordings purchased for the study (Grout, 1996).

Procedure

Clinic staff identified patients who met study eligibility criteria based on diagnosis and treatment, then briefly introduced the study and asked if a research nurse could visit to provide more information. The research nurse met with interested patients, assessed symptoms, and completed eligibility screening. The nurse then explained the study purpose and procedures and obtained written informed consent from patients who were willing to participate.

Participants completed the demographic survey and a baseline symptom inventory. The research nurse provided the intervention training, including (a) a brief review of the physiology of cancer-related pain, fatigue, and sleep disturbance; (b) an explanation of how cognitive-behavioral strategies were expected to affect symptoms; (c) a description of the 12 strategies provided on the MP3 player; and (d) personalized recommendations for using the strategies based on participants' typical daily symptom experience. The research nurse guided participants in selecting the specific strategies perceived to be useful for each target symptom and recommended use shortly before the symptom typically occurred in an attempt to preempt symptom exacerbation. Participants were provided with all training information in an educational booklet. Next, the research nurse demonstrated how to use the MP3 player by reviewing how to turn the player on, locate a recording, start and stop the recording, and control volume. Participants practiced and provided a repeat demonstration, locating and playing a particular recording. Finally, the research nurse provided participants with a treatment log book and taught

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them how to record each use of a cognitive-behavioral strategy and make 0–10 numeric ratings of symptom severity before and after each use.

Follow-up phone calls were made within the first 48 hours and at one week to resolve any questions or concerns about operating the MP3 player, using the cognitive-behavioral strategies, or completing the log book. A phone call also was made near the end of the two-week period to arrange a final meeting at the participant's next oncology clinic visit. At the final meeting, a data collector (someone other than the research nurse who provided the intervention training) retrieved the MP3 player and log and administered a second symptom inventory and the post-study evaluation. Participants were reimbursed $70 ($5 per day) as compensation for their time and effort.

Data Analysis

Descriptive and inferential statistics were computed with SPSS® version 16.0. Feasibility of study participation and completion was assessed by calculating recruitment and retention rates, identifying reasons for refusal, assessing completeness of the data, and describing frequency with which cognitive-behavioral strategies were used. Participants' perceptions of acceptability of the study procedures and of the intervention itself were evaluated by calculating descriptive statistics to summarize responses to the post-study evaluation items. To explore effects on symptom intensity, nonparametric tests (Wilcoxon signed rank) were used to compare baseline and two-week symptom inventory scores and to compare average pre- and post-treatment symptom ratings from the treatment log books.

Results

Sample Characteristics

Demographic characteristics of the sample are reported in Table 1. Participants' ages ranged from 36–79 years ($\bar{X}$ = 56.27, SD = 11.23). Most were Caucasian, women, and well educated with a bachelor's degree or higher. Fifteen participants had gynecologic cancers, and almost all (n = 27) were receiving chemotherapy alone or in combination with radiation therapy. Concurrent symptom mean scores were 6.41 (SD = 2.28) at baseline and 6.52 (SD = 2.52) at two weeks. Almost all (n = 27) participants had two or more supportive medications prescribed for their symptoms.

Table 1. Demographic Characteristics of Sample at Baseline

Characteristic	n
Gender	
Female	24
Male	6
Race	
Caucasian	26
African American	2
Missing	2
Education	
12th grade, GED, or less	5
Some college	8
Bachelor's degree	7
Master's degree	10
Cancer diagnosis	
Gynecologic	15
Lung	8
Colorectal	6
Prostate	1
Current treatment	
Chemotherapy	25
Radiation therapy	2
Chemotherapy plus radiation	2
Missing	1
Eastern Cooperative Oncology Group performance status	
0 (fully active)	3
1 (ambulatory, light work)	13
2 (ambulatory, self-care)	3
3 (limited self-care)	5
Missing	6
Supportive medications	
Analgesics	21
Steroids	20
Psychostimulants	2
Hypnotics or sedatives	28
Number of supportive medications described	
1	3
2	13
3	14

N = 30

Feasibility, Participation, and Study Completion

A flow diagram depicting recruitment and retention of participants through the study is provided in Figure 1. Eighty patients over 36 weeks were referred to research staff to learn more about the study and complete screening; 30 patients met criteria and agreed to participate. Thirteen were eligible but were not interested in participating; of them, four stated that they were not interested, four gave no reason, two did not want to work with the MP3 player, one was bothered by questionnaires, one indicated that the study period was not a good time, and one felt too overwhelmed. Three participants did not complete the full two-week study; one dropped at the end of the first week because of frustration with the MP3 player, and two dropped during the second week because of hospitalization for complications or disease progression.

Among the 27 patients who completed the study, two had missing questionnaire data; one person missed two scales at the baseline assessment, and one person missed four scales at the two-week post-test assessment.

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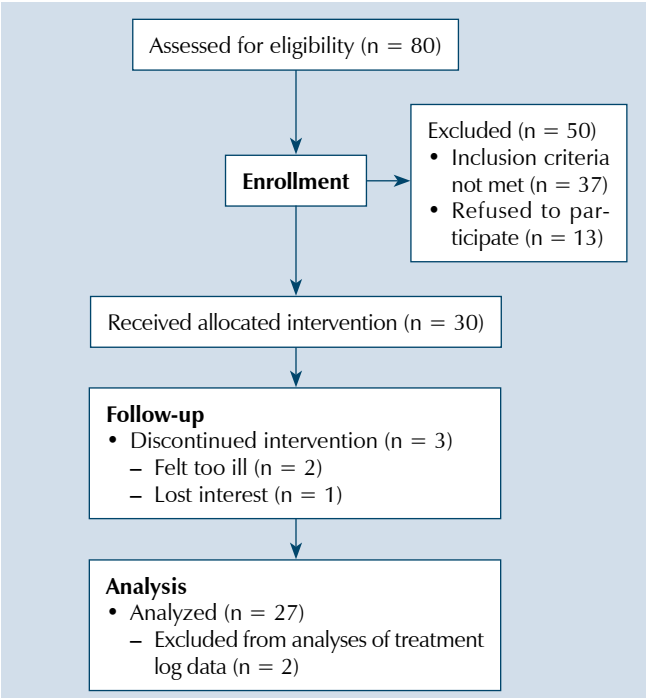

Figure 1. Flow Diagram of Study Recruitment and Retention

In addition, two patients completed the study but failed to return their treatment log books.

Data from the treatment log books indicated that participants used the cognitive-behavioral strategies 2–22 times during the two weeks ($\bar{X}$ = 12, SD = 5). A total of 293 uses were reported across the 25 completed logs. Cognitive-behavioral strategies were most frequently used during the evening hours (5 pm–11 pm; n = 132, 45%), followed by daytime hours (7 am–5 pm; n = 97, 33%) and night-time hours (11 pm–7 am; n = 64, 22%). All 12 strategies were used by at least some participants. The strategies used most frequently were focused breathing, beach imagery, sleep-focused imagery, and rainstorm nature sounds.

Feasibility and Acceptability of Study Procedures and Intervention

Data from post-study evaluations indicated that 11 participants (37%) had an issue with the MP3 player and headphones. Three had difficulty using the controls (e.g., click wheel) to navigate the menu or to turn the MP3 player on and off. Two noted that the ear-bud headphones fell out during use. Two ran out of battery power and had difficulty recharging the player. One participant accidentally locked the controls and was unable to operate the player. Despite these difficulties, most (n = 26, 87%) reported that the instructions for using the MP3 player were clear. Few had problems completing the questionnaires or treatment log books (n = 5, 17%). Overall, the study procedures (n = 26, 87%) and time commitment (n = 24, 80%) were acceptable to most participants, and 20 (67%) indicated that they would have agreed to participate if the study had been of longer duration (i.e., from four to six weeks).

With regard to the cognitive-behavioral strategies themselves, 23 participants (77%) indicated that they enjoyed using the strategies, 1 (3%) did not enjoy them, and 3 (10%) were unsure. Twenty-five (83%) indicated that they had learned useful skills by participating, and 23 (77%) reported that their symptoms improved as a result of using the strategies. Participants largely indicated that they were offered enough strategies to find one that they liked (n = 23, 77%) and that the length of the recordings was "about right" (n = 20, 67%).

Effect on Symptom Intensity

Symptom ratings made before and after the two-week intervention did not differ from each other, nor did scores on symptom interference with daily activities (see Table 2). However, the immediate changes in symptom ratings from pre- to post-treatment with a cognitive-behavioral strategy were significant. Mean pain scores decreased from 4.54 (SD = 2.27) pretreatment to 2.77 (SD = 2.06) post-treatment ($Z = -4.2$, $p < 0.01$). Mean fatigue scores decreased from 4.9 (SD = 1.86) pretreatment to 3.44 (SD = 2.11) post-treatment ($Z = -4.03$, $p < 0.01$). Average sleep disturbance scores decreased from 5.05 (SD = 2.12) pretreatment to 2.81 (SD = 2.07) post-treatment ($Z = -4.11$, $p < 0.01$).

Discussion

The current study's results indicate that patients with advanced cancer can feasibly use the patient-controlled cognitive-behavioral intervention and researchers can conduct future studies of the intervention's effects on pain, fatigue, and sleep disturbance in adult patients with advanced cancer. Recruitment and retention statistics were good. Very few studies have tested interventions

Table 2. Symptom Severity and Symptom Interference With Daily Activities at Baseline (Pretest) and After Two Weeks (Post-Test)

	Pretest (N = 30)		Post-Test (N = 27)	
Symptom	$\bar{X}$	SD	$\bar{X}$	SD
Pain severity	1.89	1.54	2.52	2.21
Fatigue severity	3.74	1.76	3.89	1.89
Sleep disturbance severity	50.25	8.85	50	7.98
Symptom interference	4.03	2.33	4.56	2.67

Note. None was significant at $p < 0.05$.

Note. Symptom interference is related to all symptoms, not just pain, fatigue, and sleep disturbance.

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for symptom clusters, and the ideal selection criteria with regard to baseline symptom status have not been determined. In the current study, the authors included patients who were experiencing at least two of the three symptoms that make up the cluster at baseline, with the expectation that the third symptom would be likely to develop as well. Of the 14 patients entered on study with only two qualifying symptoms at baseline, 12 (86%) had indicators of all three symptoms during the two-week period of data collection. The remaining two participants dropped out of the study; therefore, the authors were unable to determine whether they also developed all three symptoms.

The finding that patients with advanced cancer were willing to use a cognitive-behavioral intervention for symptom management is consistent with recent research. Studies have shown that 33% of patients with advanced cancer choose to use complementary therapies, and the number is higher when such services are offered as part of routine care (Corbin, Mellis, Beaty, & Kutner, 2009). Patients who choose complementary therapies tend to have more advanced disease and a higher number of physically debilitating symptoms (Egilsdatter Kristoffersen, Fønnebø, & Norheim, 2009; Wyatt, Sikorskii, Siddiqi, & Given, 2007). Therefore, patients with advanced cancer experiencing symptom clusters are a particularly appropriate population on which to continue testing the patient-controlled cognitive-behavioral intervention.

Although certain cognitive-behavioral strategies were used more frequently than others, all 12 strategies were used in the current study. The finding confirms that offering a variety of cognitive-behavioral strategies is advantageous because strategies that are appealing and effective for some participants are not for others. Investigations that allow participants to self-select strategies from a menu of possibilities clearly demonstrate the presence of individual preferences for treatment (Kozachik, Wyatt, Given, & Given, 2006; Wyatt et al., 2007). When patients are able to try a variety of strategies, the likelihood that they can hone in on and identify the treatments that are most effective for them increases. Although the delivery of the patient-controlled cognitive-behavioral intervention occurred over a brief two-week period, participants were able to use the strategies as often as needed. Kroenke and Swindle (2000) found that as few as five treatment sessions were effective in producing symptom relief, even among patients with complete multisymptom syndromes such as chronic fatigue and irritable bowel syndrome.

Initial assessment of efficacy indicated immediate improvement in symptom intensity, although longer-term improvement was not achieved. Longer periods of practice may allow patients to achieve effects more quickly and potentially produce stronger treatment effects at later follow-up points. Despite the lack of improvement at two weeks, immediate reductions in symptoms were significant at the time the cognitive-behavioral strategies were used. Severity scores for all three symptoms were significantly reduced immediately after using a cognitive-behavioral strategy. Such findings are not unusual with brief cognitive-behavioral interventions. Anderson et al. (2006) demonstrated immediate reductions in cancer pain intensity with recorded relaxation, distraction, and positive mood strategies, but effects were not significant at two-week follow-up. Similarly, Berman, Iris, Bode, and Dregenberg (2009) reported significant reductions in chronic noncancer pain immediately pre- to post-treatment using Web-based training in self-care pain management strategies (e.g., relaxation, positive thinking, emotional expression), but no significant differences were found between baseline pain intensity and a six-week follow-up assessment.

Limitations

The current study had notable limitations, particularly with regard to the preliminary evaluation of efficacy. First, the study used a convenience sample comprised of well-educated, primarily female participants that may not be representative of the larger patient population. Previous studies have shown that women tend to be more inclined to use complementary therapies such as relaxation and imagery than men (Verhoef, Balneaves, Boon, & Vroegindewey, 2005); however, the symptom relief achieved with such interventions does not appear to be different (Kwekkeboom et al., 2003, 2008). Future recruitment efforts should target men to achieve equal representation. Similarly, efforts should be made to include people with a wider range of educational levels. Second, the study used a one-group pre- and post-test design. Without a control group, the authors could not evaluate the relative effect of nonspecific effects such as novelty effects of using an MP3 player or effects of the therapeutic relationship between the research nurse and study participants. Third, a number of uncontrolled extraneous variables could have influenced symptom outcomes. Although the authors collected information about supportive medications to determine whether the study procedure was feasible, the sample size was not sufficient to use the information in this initial assessment of efficacy. In a future study, the authors will ask participants to keep a daily log of any steps they took to control symptoms (drug and nondrug) and will collect a large enough sample size to use the information as a covariate in data analyses.

The authors encountered additional challenges in the current feasibility study that helped them to prepare for future work. The authors had planned for participants to complete post-test measures at a two-week follow-up clinic appointment. Most patients were scheduled for return clinic visits at or around day 14, but in some cases, appointments were delayed because of inclement weather, altered laboratory values pre-empting chemotherapy, or other cancellations. In future studies, the authors plan to mail the two-week questionnaires in advance and will call

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to remind participants on the day they need to be completed. Although most participants did not have difficulty with the MP3 player, a few had minor challenges. The greatest issue involved operating the click wheel control device. For future research, the authors have selected a different MP3 player with simple controls, a larger screen, and no click wheel. The ear-bud headphones were problematic for a few participants and could not be used by patients with hearing aids. Standard over-the-ear–style headphones will be offered in such cases.

Conclusions

The patient-controlled cognitive-behavioral intervention appears feasible and worthy of additional study in managing co-occurring pain, fatigue, and sleep disturbance. Whether the specific cognitive-behavioral strategies are effective for this symptom cluster is not yet known, but based on past research, practicing nurses can be confident in recommending such treatments for the individual symptoms of pain, fatigue, or sleep disturbance.

A randomized, controlled trial is underway comparing the patient-controlled cognitive-behavioral intervention to usual treatment in a larger sample. That study will further evaluate the efficacy of the intervention in controlling the symptom cluster of pain, fatigue, and sleep disturbance in people with advanced cancer. The larger trial will correct a number of weaknesses identified in the current feasibility study. It also will allow the authors to investigate how individual difference variables such as outcome expectancy, perceived control, concurrent symptoms, use of supportive medications, and specific cognitive skills (e.g., imaging ability) influence how the cognitive-behavioral strategies work and for whom. If effective, the intervention could be implemented relatively easily, treating a large number of patients without significantly increasing nurse workload.

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