Published in final edited form as:

Oncol Nurs Forum. 2010 May ; 37(3): E151–E159. doi:10.1188/10.ONF.E151-E159.

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

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Abstract

Purpose—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 in controlling symptoms.

Design—One-group pretest-posttest 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 GYN cancer receiving chemotherapy or radiotherapy.

Methods—Participants completed baseline measures (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 over the following 2-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, sleep disturbance.

Findings—73% of the 43 eligible patients agreed to participate (N=30) and of these, 90% (n=27) completed the study. The majority of participants reported that they enjoyed the intervention, had learned useful skills, and perceived improvement in their symptoms. Symptom scores at 2-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 feasible for further study and could reduce day-to-day severity of co-occurring pain, fatigue, and sleep disturbance.

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

Feasibility of a Patient-Controlled Cognitive Behavioral Intervention for Symptom Management in Cancer

More than 500,000 people in the U.S. develop recurrent or metastatic cancer each year (American Cancer Society, 2007). Improvements in cancer treatment have allowed persons diagnosed with advanced disease to live longer, however, these patients experience a heavy symptom burden. Patients with advanced cancer often report experiencing up to 5 symptoms at any given time, and significantly more when receiving chemo- or radiation therapy (Chang, Hwang, Feuerman, & Kasimis, 2000; Feyer, Kleeberg, Steingraber, Gunther, & Behrens, 2008). Recently, researchers have identified co-occurring pain, fatigue, and sleep disturbance as a common symptom cluster among persons with advanced cancer (Beck, Dudley, & Barsevick, 2005; Hoffman, Given, von Eye, Gift & Given, 2007). Because the science regarding symptom clusters is quite new, few treatments that target these 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, 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, or 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. While the disease itself may cause the symptoms, symptom clusters have frequently been reported among persons receiving cytotoxic therapy (Fan, Filipczak & Chow, 2007).

Dodd and colleagues first identified the co-occurrence of pain, fatigue, and sleep disturbance among cancer patients receiving chemotherapy in 2001. More recent investigations have suggested that 40–80% of patients with cancer experience co-occurring pain, fatigue and sleep disturbance (Beck, Dudley & Barsevick, 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 nighttime 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, Miaskowski & Paul, 2001; Miaskowski et al., 2006).

Cognitive-behavioral strategies—Nurses have used a number of 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 “non-drug” treatments in nursing and medical literature (American Pain Society, 2005; McCaffery & Pasero, 1999), and “mind-body” therapies by persons 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 the 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, Meichenbaum & Genest, 1983). Cognitive-behavioral interventions are thought to effect 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 long 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 persons 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 these same strategies to the treatment of insomnia (Davidson, Waisberg, Brundage, & MacLean, 2001; Simeit, Deck, & Conta-Marx, 2004; Rumble, Keefe, Edinger, Porter, & Garst, 2005) and fatigue (Dimeo, Thomas, Raabe-Menssen, Propper, & Mathias, 2004; Jereczek-Fossa, Marsiglia, & Orecchia, 2001; Schulz, 2001) with beneficial effects. While there is evidence to suggest that cognitive-behavioral strategies are useful in treating pain, fatigue, and sleep disturbance as isolated symptoms, there has been no research to test their impact 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 to say, 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 targeting the intervention to only those persons with particular characteristics, or tailoring the treatment based on an individual’s particular needs and interests. The patient-centered approach is advantageous in that allows for individual differences in patient’s 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, while the same strategies are ineffective for other patients (Donovan & Laack, 1998; Kwekkeboom, Wanta & Bumpus, 2008). Thus, clinicians cannot provide a single therapy and assume that it will be effective for all patients. This is particularly true if patients are dealing with multiple symptoms of varying intensity, duration, and timing. It would be optimal if patients were provided with a variety of strategies from which they could choose those most appealing and effective 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 or not it is possible to successfully carry out the study (e.g., recruitment/retention, acceptability of the study procedures and intervention). As a secondary aim, we evaluated initial efficacy of the intervention in controlling symptoms. The research questions were:

1. Will patients with symptoms related to advanced cancer agree to participate in and complete the 2-week study?
2. Will participants find the study procedures and the patient-controlled cognitive-behavioral intervention acceptable?
3. What effect does the intervention have on participants' symptom intensity?

Method

Design and Participants

The study used a one-group pretest posttest design. A convenience sample of 30 adult patients (≥ 21 y.o.) receiving treatment for advanced (metastatic or recurrent) colorectal, lung, prostate, or GYN cancers was recruited from the outpatient oncology clinics at a University-affiliated Comprehensive Cancer Center in the Midwestern United States. To be eligible, patients needed to have at least 2 of the 3 symptoms including pain rated ≥ 3 on a 0–10 scale in the past 48 hours, and report of fatigue and/or sleep disturbance in the past week. Patients were excluded if their pain was post-operative or neuropathic in etiology (as determined using 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 & 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 (i.e., analgesics, steroids, psychostimulants, hypnotics/sedatives).

Symptom Inventory—Pain severity was measured with four 0–10 numeric rating scale (NRS) items from the Brief Pain Inventory (Cleeland, 1989) including pain now, worst pain, least pain, and average pain in the past 24 hours. Scores were averaged across the four items to create a single pain severity estimate with higher scores indicating more severe pain. Cronbach's alpha in this use was $\alpha = .81-.90$. Fatigue severity was measured with four 0–10 NRS items from the Brief Fatigue Inventory (Mendoza et al., 1999) including fatigue now,

worst fatigue, least fatigue, and usual fatigue in the past 24 hours. Scores were averaged across the four items to create a single fatigue severity index with higher scores indicating more severe fatigue. Cronbach's alpha in this use was $\alpha = .80-.90$. Sleep disturbance was measured with two items: (1) a 0–10 NRS measure of sleep disturbance in the last 24 hours, and (2) 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 ($M=50$, $SD=10$), with higher scores indicating greater sleep disturbance.

Additional symptoms and their impact on daily functioning were assessed with the MD 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 NRS. We 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 MD Anderson Symptom Inventory has been demonstrated in persons with cancer (Cleeland et al.). Cronbach's alpha for the two subscales in this sample were $\alpha = .81-.83$ and $\alpha = .90-.93$, respectively.

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

Post-Study Evaluation—A 12-item survey was created for this 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, we chose a brief intervention (2-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. Cupertino, CA), with earbud style headphones. All spoken recordings were made specifically for this 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.

1. Progressive Muscle Relaxation (19:51) guided participants in tensing and relaxing various muscle groups in succession from hands and arms, up to the head, and down to the feet.
2. Jaw Relaxation (4:46) guided participants in relaxing muscles of the mouth, throat, and face to stimulate a yawn and release tension throughout the body.

3. Rhythmic breathing (8:50) guided 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.

1. Meadow Imagery (21:19) guided participants in imagining themselves on a peaceful walk through a meadow, sitting amongst wildflowers, and observing a stream.
2. Beach Imagery (21:49) guided participants in imagining themselves walking onto a sandy beach, observing the water, and resting in the sun.
3. Mountain Imagery (19:28) guided 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 symptoms and reducing its intensity.

1. 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.
2. Fatigue-focused Imagery (21:07) guided participants in creating mental images of energy drawn from the universe, circulating a ball of energy throughout the body, and re-energizing the body's cells.
3. Sleep-focused Imagery (18:22) guided 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. She then explained the study purpose and procedures, and obtained written informed consent from those patients willing to participate.

Participants completed the demographic survey and a baseline symptom inventory. The research nurse provided the intervention training including: (1) a brief review of the physiology of cancer-related pain, fatigue, and sleep disturbance, (2) an explanation of how cognitive-behavioral strategies were expected to impact symptoms, (3) a description of the 12 strategies provided on the MP3 player, and (4) 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 pre-empt symptom exacerbation. Participants were provided with all training information in an educational booklet. Next the research nurse demonstrated how to use the MP3 player,

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 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 1 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 was also made near the end of the 2-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/day) as compensation for their time and effort.

Data Analysis

Descriptive and inferential statistics were computed using SPSS 16.0 (SPSS, Inc.). 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 2-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 ranged in age from 36 to 79 ($M=56.27$, $SD = 11.23$). Most were Caucasian, female, and well educated with a bachelor's degree or higher. Half of all participants had GYN cancers, and nearly all ($n=27$) were receiving chemotherapy, alone or in combination with radiation therapy. Concurrent symptom scores were $M = 6.41$ ($SD = 2.28$) at baseline and $M = 6.52$, ($SD = 2.52$) at 2-weeks. Nearly all ($n=27$) participants had two or more supportive medications prescribed for their symptoms.

Feasibility - Participation and Study Completion

A flow diagram, depicting recruitment and retention of participants through the study is provided in Figure 1. A total of 80 patients over 36 weeks were referred to research staff to learn more about the study and complete screening. Thirty-seven were determined to not meet diagnostic or symptom eligibility criteria. Thirteen were eligible but not interested in participating. Four simply stated 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 it was not a good time, and one reported feeling too overwhelmed. Thirty patients (70% of those eligible) met criteria and agreed to participate. Three participants did not complete the full 2-week study; one dropped at the end of the first week due to frustration with the MP3 player, and two dropped during the second week due to hospitalization for complications or disease progression.

Among the 27 persons 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

2-week posttest assessment. In addition, two persons 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 from 2 to 22 times during the two weeks ($M=12$, $SD=5$). A total of 293 uses were reported across the 25 completed logs. Cognitive-behavioral strategies were most frequently used during the evening hours (5pm – 11pm), ($n=132$, 45%), followed by daytime hours (7am – 5pm), ($n=97$, 33%), and nighttime hours (11pm – 7am) ($n=64$, 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 – Acceptability of Study Procedures and the Patient-Controlled Cognitive-Behavioral Intervention

Data from post-study evaluations indicated that eleven participants (37%) had a problem 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/off. Two noted that the earbud 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 book ($n=5$, 17%). Overall, the study procedures ($n=26$, 87%) and time commitment ($n=24$, 80%) were acceptable to most participants; and over half indicated that they would have agreed to participate if the study had been of longer duration, from 4–6 weeks ($n=20$, 67%).

With regard to the cognitive-behavioral strategies themselves. Twenty-three (77%) participants 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 2-week intervention did not differ from each other nor did scores on symptom interference with daily activities (Table 2). However, the immediate changes in symptom ratings from pre- to post-treatment with a cognitive-behavioral strategy were significant. Average pain scores decreased from $M=4.54$ ($SD=2.27$) pre-treatment to $M=2.77$ ($SD=2.06$) post-treatment ($Z = -4.20$, $p < .01$). Average fatigue scores decreased from $M=4.90$ ($SD=1.86$) pre-treatment to $M=3.44$ ($SD=2.11$) post-treatment ($Z = -4.03$, $p < .01$). And average sleep disturbance scores decreased from $M=5.05$ ($SD=2.12$) pre-treatment to $M=2.81$ ($SD=2.07$) post-treatment ($Z = -4.11$, $p < .01$).

Discussion

Results of this study indicate that it is feasible for patients with advanced cancer to use the patient-controlled cognitive-behavioral intervention and feasible to 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 for symptom clusters, and the ideal selection criteria with regard to baseline symptom status have not yet been determined. In this study, we 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 2-week period of data collection. The remaining two participants dropped out of the study, thus we were unable to determine if they also developed all three symptoms.

Our finding that patients with advanced cancer were willing to use a cognitive-behavioral intervention for symptom management is consistent with recent research. Recent studies have shown that one third of patients with advanced cancer choose to use complementary therapies, and that 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 greater number of physically debilitating symptoms (Egilsdatter, Kristoffersen, Fonnebo, & Norheim, 2009; Wyatt, Sikorskii, Siddiqi, & Given, 2007). Thus, patients with advanced cancer experiencing symptom clusters are a particularly appropriate population in 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 this study. This confirms that offering a variety of cognitive-behavioral strategies is advantageous, as strategies that are appealing and effective for some participants are not appealing or effective for others. Recent investigations allowing study participants to self-select strategies from a “menu” of possibilities clearly demonstrates the presence of individual preferences for treatment (Kozachik, Wyatt, Given, & Given, 2006; Wyatt, Sikorskii, Siddiqi, & Given, 2007). When patients are able to try a variety of strategies, it increases the likelihood that they can hone in on and identify the treatments that are most effective for them. Although the delivery of the patient-controlled cognitive-behavioral intervention occurs over a brief 2-week period, participants are able to use the strategies as often as needed. Kroenke and Swindle (2000) found that as few as 5 treatment sessions were effective in producing symptom relief, even among persons with complete multi-symptom syndromes like 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 could potentially produce stronger treatment effects at later follow-up points. Despite the lack of improvement at 2-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 a 2-week follow-up. Similarly, Berman, Iris, Bode and Dregenberg (2009) reported significant reductions in chronic non-cancer 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 between baseline pain intensity and a 6-week follow-up assessment.

This study has 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, which may not be representative of the larger patient population. Previous studies have shown that females tend to be more inclined to use “complementary” therapies like relaxation and imagery than males (Verhoef, Balneaves, Boon & Vroegindewey, 2005), however, there does not appear to be any difference in the symptom relief achieved with such interventions (Kwekkeboom, Kneip & Pearson, 2003; Kwekkeboom, Wanta & Bumpus, 2008). Future recruitment efforts will need to target male participants to achieve equal representation. Similarly, efforts should be made to include persons with a wider range of educational levels. Second, the study used a one-group pretest-posttest design. Without a

control group, we cannot evaluate the relative impact of nonspecific effects such as novelty effects of using an MP3 player or effects of the therapeutic relationship between research nurse and study participant. Third, a number of uncontrolled extraneous variables could have influenced symptom outcomes. Although we collected information about supportive medications to determine if this was a feasible study procedure, the sample size was not sufficient to use the information in this initial assessment of efficacy. In our next study, we will ask participants to keep a daily log of any steps they took to control symptoms (drug and non-drug) and will collect a large enough sample size to use this information as a covariate in data analyses.

We encountered additional challenges in this feasibility study that helped us to prepare for future work. We had planned for participants to complete post-test measures at a 2-week follow-up clinic appointment. In most cases, patients were scheduled for return clinic visit at or around day 14, but in some cases, appointments were delayed due to inclement weather, altered lab values pre-empting chemotherapy, or other cancelations. In future studies, we plan to mail the 2-week questionnaires in advance and will call to remind participants on the day they need to be completed. While most participants did not have difficulty with the MP3 player, a few had minor challenges. The greatest problem had to do with operating the click wheel control device. For future research, we have selected a different MP3 player with simple controls, a larger screen, and no click wheel. The earbud headphones were problematic for a few participants and could not be used by persons with hearing aides. Standard over-the-ear style headphones will be offered in these cases.

Conclusions

The patient-controlled cognitive-behavioral intervention appears feasible and worthy of further study in managing in co-occurring pain, fatigue, and sleep disturbance. While it is too early to know if the specific cognitive-behavioral strategies are effective for this symptom cluster, based on past research, practicing nurses can confidently recommend 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 treatment-as-usual in a larger sample. This study will further evaluate the efficacy of the intervention in controlling the pain, fatigue, sleep disturbance symptom cluster in persons with advanced cancer. The larger trial will correct a number of weaknesses identified in this feasibility study. It will also allow us 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.

Acknowledgments

This work was supported by research grants from the University of Wisconsin-Madison Graduate School and the Center for Patient-Centered Interventions (Grant Number P20 NR008987 from the National Institute of Nursing Research, [PI: Sandra Ward, UW-Madison School of Nursing]). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Nursing Research or the National Institutes of Health.

References

American Cancer Society. Overview: Advanced Cancer. 2007 [Accessed February 4 2009]. Available at: http://www.cancer.org/docroot/CRI/CRI_2_1x.asp?rnav=criv&dt=79

- American Pain Society. Guideline for the management of cancer pain in adults and children. Glenview, IL: American Pain Society; 2005.
- Anderson KO, Cohen MZ, Mendoza TR, Guo H, Harle MT, Cleeland CS. Brief cognitive-behavioral audiotape interventions for cancer-related pain. *Cancer* 2006;107(1):207–214. [PubMed: 16708359]
- Beck S, Dudley WN, Barsevick AM. Using a mediation model to test a symptom cluster: pain, sleep disturbance, and fatigue in cancer patients. *Oncology Nursing Forum* 2005;32(3):E48–E55.
- Berman RLH, Iris MA, Bode R, Drengenberg C. The effectiveness of an online mind-body intervention for older adults with chronic pain. *The Journal of Pain* 2009;10(1):68–79. [PubMed: 18774342]
- Braud A, Genre D, Leto C, Nemer V, Cailhol J, Macquart-Moulin G, et al. Nurses' repeat measurement of chemotherapy symptoms. *Cancer Nursing* 2003;26(6):468–475. [PubMed: 15022978]
- Breitbart, W.; Holland, J. Psychological aspects of symptom management in cancer patients. Washington DC: American Psychiatric Press, Inc; 1993.
- Buyse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. *Psychiatry Research* 1989;28(2):193–213. [PubMed: 2748771]
- Chang VT, Hwang SS, Feuerman M, Kasimis BS. Symptom and quality of life survey of medical oncology patients at a veteran affairs medical centre: A role for symptom assessment. *Cancer* 2000;88(5):1175–1183. [PubMed: 10699909]
- Chen ML, Lin CC. Cancer symptom clusters: A validation study. *Journal of Pain & Symptom Management* 2007;34(6):590–599. [PubMed: 17629670]
- Cleeland, C. Measurement of pain by subjective report. In: Chapman, CR.; Loeser, JD., editors. *Issues in pain management*. New York: Raven Press; 1989. p. 391-403.
- Cleeland CS. Cancer-related symptoms. *Seminars in Radiation Oncology* 2000;10(3):175–190. [PubMed: 11034629]
- Cleeland CS, Mendoza TR, Wang XS, Chou C, Harle M, Morrissey M, et al. Assessing symptom distress in cancer: The M. D. Anderson Symptom Inventory. *Cancer* 2000;89(7):1634–1646. [PubMed: 11013380]
- Corbin LW, Mellis BK, Beaty BL, Kutner JS. The use of complementary and alternative medicine therapies by patients with advanced cancer and pain in a hospice setting: A multicentered, descriptive study. *Journal of Palliative Medicine* 2009;12(1):7–8. [PubMed: 19284251]
- Davidson JR, Waisberg JL, Brundage MD, MacLean AW. Nonpharmacologic group treatment of insomnia: a preliminary study with cancer survivors. *Psycho-Oncology* 2001;10(5):389–397. [PubMed: 11536417]
- Dimeo FC, Thomas F, Raabe-Menssen C, Propper F, Mathias M. Effect of aerobic exercise and relaxation training on fatigue and physical performance of cancer patients after surgery. A randomized controlled trial. *Supportive Care in Cancer* 2004;12(11):774–779. [PubMed: 15338385]
- Dodd MJ, Miaskowski C, Paul SM. Symptom clusters and their effect on the functional status of patients with cancer. *Oncology Nursing Forum* 2001;28(3):465–470. [PubMed: 11338755]
- Donovan M, Laack KD. Individually reported effectiveness of therapy for chronic pain. *Clinical Nursing Research* 1998;7(4):423–439. [PubMed: 9919097]
- Egildsatter Kristoffersen A, Fonnebo V, Norheim AJ. Do cancer patients with a poor prognosis use complementary and alternative medicine more often than others? *The Journal of Alternative and Complementary Medicine* 2009;15(1):35–40. [PubMed: 19769474]
- Fan G, Filipczak L, Chow E. Symptom clusters in cancer patients: A review of the literature. *Current Oncology* 2007;14(5):173–179. [PubMed: 17938700]
- Feyer P, Kleeberg UR, Steingraber M, Gunther W, Behrens M. Frequency of side effects in outpatient cancer care and their influence on patient satisfaction a prospective survey using the PASQOCR questionnaire. *Supportive Care in Cancer* 2008;16(6):567–575. [PubMed: 18322707]
- Francoeur RB. The relationship of cancer symptom clusters to depressive affect in the initial phase of palliative radiation. *Journal of Pain & Symptom Management* 2005;29(2):130–155. [PubMed: 15733806]
- Gift AG, Jablonski A, Stommel M, Given CW. Symptom clusters in elderly patients with lung cancer. *Oncology Nursing Forum* 2004;31(2):202–212. [PubMed: 15017438]

- Given C, Given B, Rahbar M, Jeon S, McCorkle R, Cimprich B, et al. Effect of a cognitive behavioral intervention on reducing symptom severity during chemotherapy. *Journal of Clinical Oncology* 2004;22(3):507–516. [PubMed: 14752074]
- Grout, J. *Relaxing Sounds of Nature* [CD]. Clearwater, FL: NatureScapes Music; 1996.
- Hickok JT, Morrow GR, Roscoe JA, Mustian K, Okunieff P. Occurrence, severity, and longitudinal course of twelve common symptoms in 1129 consecutive patients during radiotherapy for cancer. *Journal of Pain & Symptom Management* 2005;30(5):433–442. [PubMed: 16310617]
- Hoffman AJ, Given BA, von Eye A, Gift AG, Given CW. Relationships among pain, fatigue, and insomnia, and gender in persons with lung cancer. *Oncology Nursing Forum* 2007;34(4):785–792. [PubMed: 17723980]
- Honea N, Brant J, Beck S. Treatment-related symptom clusters. *Seminars in Oncology Nursing* 2007;23(2):142–151. [PubMed: 17512442]
- Jerezek-Fossa BA, Marsiglia HR, Orecchia R. Radiotherapy-related fatigue: How to assess and how to treat the symptom. *Tumori* 2001;87(3):147–151. [PubMed: 11504369]
- Keefe FJ. Cognitive behavioral therapy for managing pain. *The Clinical Psychologist* 1996;49(3):4–5.
- Kim H, McGuire DB, Tulman L, Barsevick AM. Symptom clusters: Concept analysis and clinical implications for cancer nursing. *Cancer Nursing* 2005;28(4):270–282. [PubMed: 16046888]
- Kozachik S, Wyatt G, Given CW, Given BA. Patterns of use of complementary therapies among cancer patients and their family caregivers. *Cancer Nursing* 2006;29(2):84–94. [PubMed: 16565617]
- Kroenke K, Swindle R. Cognitive-behavioral therapy for somatization and symptom syndromes: A critical review of controlled clinical trials. *Psychotherapy and Psychosomatics* 2000;69(4):205–215. [PubMed: 10867588]
- Kwekkeboom KL, Cherwin CH, Lee JW, Wanta B. Mind-body treatments for the pain-fatigue-sleep disturbance symptom cluster in persons with cancer. 2009 Manuscript submitted for publication.
- Kwekkeboom KL, Kneip J, Pearson L. A pilot study to predict success with guided imagery for cancer pain. *Pain Management Nursing* 2003;4(3):112–123. [PubMed: 14566709]
- Kwekkeboom KL, Wanta B, Bumpus M. Individual difference variables and the effects of progressive muscle relaxation and analgesic imagery interventions on cancer pain. *Journal of Pain & Symptom Management* 2008;36(6):604–615. [PubMed: 18504089]
- Lauver DR, Ward SE, Heidrich SM, Keller ML, Bowers BJ, Brennan PF, et al. Patient-centered interventions. *Research in Nursing & Health* 2002;25(4):246–255. [PubMed: 12124719]
- Luebbert K, Dahme B, Hasenbring M. The effectiveness of relaxation training in reducing treatment-related symptoms and improving emotional adjustment in acute non-surgical cancer treatment: A meta-analytic review. *Psycho-Oncology* 2001;10(6):490–502. [PubMed: 11747061]
- McCaffery, M.; Pasero, C. *Pain: Clinical manual*. 2. St. Louis, MO: Mosby; 1998.
- Mendoza TR, Wang XS, Cleeland CS, Morrissey M, Johnson BA, Wendt JK, et al. The rapid assessment of fatigue severity in cancer patients: Use of the Brief Fatigue Inventory. *Cancer* 1999;85(5):1186–1196. [PubMed: 10091805]
- Miaskowski C, Cooper BA, Paul SM, Dodd M, Lee K, Aouizerat BE, et al. Subgroups of patients with cancer with different symptom experiences and quality-of-life outcomes: a cluster analysis. *Oncology Nursing Forum* 2006;33(5):E79–E89. [PubMed: 16955115]
- Miaskowski C, Lee KA. Pain, fatigue, and sleep disturbance in oncology outpatients receiving radiation therapy for bone metastasis: A pilot study. *Journal of Pain & Symptom Management* 1999;17(5):320–332. [PubMed: 10355211]
- Mundy EA, DuHamel KN, Montgomery GH. The efficacy of behavioral interventions for cancer treatment-related side effects. *Seminars in Clinical Neuropsychiatry* 2003;8(4):253–275. [PubMed: 14613052]
- National Center for Complementary and Alternative Medicine. What is CAM?. 2009 [Accessed March 19, 2009]. Available at: <http://nccam.nih.gov/health/whatiscam/overview.htm>
- Portenoy R. Development and testing of a neuropathic pain screening questionnaire: ID pain. *Current Medical Research & Opinion* 2006;22(8):1555–1565. [PubMed: 16870080]
- Potter J, Hami F, Bryan T, Quigley C. Symptoms in 400 patients referred to palliative care services: Prevalence and patterns. *Palliative Medicine* 2003;17(4):310–314. [PubMed: 12822846]

- Redd WH, Montgomery GH, DuHamel KN. Behavioral intervention for cancer treatment side effects. *Journal of the National Cancer Institute* 2001;93(11):810–823. [PubMed: 11390531]
- Roffe L, Schmidt K, Ernst E. A systematic review of guided imagery as an adjuvant cancer therapy. *Psycho-Oncology* 2005;14(8):607–617. [PubMed: 15651053]
- Rumble ME, Keefe FJ, Edinger JD, Porter LS, Garst JL. A pilot study investigating the utility of the cognitive-behavioral model of insomnia in early stage lung cancer patients. *Journal of Pain & Symptom Management* 2005;30(2):160–169. [PubMed: 16125031]
- Saini T, Murtagh FE, Dupont PJ, McKinnon PM, Hatfield P, Saunders Y. Comparative pilot study of symptoms and quality of life in cancer patients and patients with end stage renal disease. *Palliative Medicine* 2006;20(6):631–636. [PubMed: 17060257]
- Schulz K. A comprehensive coping strategy programme reduced nausea and fatigue after autologous bone marrow transplantation for breast cancer. *Evidence-Based Mental Health* 2001;4(1):14–15.
- Simeit R, Deck R, Conta-Marx B. Sleep management training for cancer patients with insomnia. *Supportive Care in Cancer* 2004;12(3):176–183. [PubMed: 14760542]
- Slooman R, Brown P, Aldana E, Chee E. The use of relaxation for the promotion of comfort and pain relief in persons with advanced cancer. *Contemporary Nurse: A Journal for the Australian Nursing Profession* 1994;3(1):6–12. [PubMed: 8136641]
- Syrjala KL, Donaldson GW, Davis MW, Kippes ME, Carr JE. Relaxation and imagery and cognitive-behavioral training reduce pain during cancer treatment: a controlled clinical trial. *Pain* 1995;63(2):189–198. [PubMed: 8628584]
- Teunissen SC, de Graeff A, Voest EE, de Haes JC. Are anxiety and depressed mood related to physical symptom burden? A study in hospitalized advanced cancer patients. *Palliative Medicine* 2007;21(4):341–346. [PubMed: 17656411]
- Turk, DC.; Meichenbaum, D.; Genest, M. *Pain and Behavioral Medicine: A Cognitive-Behavioral Perspective*. New York: Guilford Press; 1983.
- Verhoef MJ, Balneaves LG, Boon HS, Vroegindewey A. Reasons for and characteristics associated with complementary and alternative medicine use among adult cancer patients: A systematic review. *Integrative Cancer Therapies* 2005;4(4):274–286. [PubMed: 16282504]
- Wyatt G, Sikorskii A, Siddiqi A, Given C. Feasibility of a reflexology and guided imagery intervention during chemotherapy: Results of a quasi-experimental study. *Oncology Nursing Forum* 2007;34(3):635–642. [PubMed: 17573322]

Figure 1.
CONSORT Flow Diagram

Figure 2.
Average symptom ratings pre- and post-treatment with a cognitive-behavioral strategy
All differences significant at $p < .01$

Table 1

Demographic Characteristics of Sample at Baseline (N=30)

Characteristic	n (%)
Gender	
Female	24 (80)
Male	6 (20)
Race	
Caucasian	26 (87)
African American	2 (7)
Missing	2 (7)
Education	
≤ 12 th grade or GED	5 (17)
Some college	8 (27)
Bachelor's degree	7 (23)
Master's degree	10 (33)
Diagnosis	
GYN cancer	15 (50)
Lung cancer	8 (27)
Colorectal cancer	6 (20)
Prostate cancer	1 (3)
Current Treatment	
Chemotherapy	25 (83)
Radiation Therapy	2 (7)
Chemotherapy + Radiation	2 (7)
Missing	1 (3)
ECOG Performance Status	
0 (Fully active)	3 (10)
1 (Ambulatory, light work)	13 (43)
2 (Ambulatory, self-care)	3 (10)
3 (Limited self-care)	5 (17)
Missing	6 (20)
Supportive Medications	
Analgesics	21 (70)
Steroids	20 (67)
Psychostimulants	2 (7)
Hypnotics/Sedatives	28 (93)
Number of Supportive Medications Prescribed	
One	3 (10)
Two	13 (43)
Three	14 (47)

Table 2

Symptom Severity and Symptom Interference with Daily Activities at Baseline (Pretest) and After 2-weeks (Posttest)

Symptom	Pretest	Posttest
	M (SD) (n=30)	M (SD) (n=27)
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)	50.00 (7.98)
Symptom Interference	4.03 (2.33)	4.56 (2.67)

None were significant at $p < .05$

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