

Review Article

A Systematic Evaluation of Content, Structure, and Efficacy of Interventions to Improve Patients' Self-Management of Cancer Pain

Antje Koller, MNS, RN, Christine Miaskowski, PhD, RN, FAAN, Sabina De Geest, PhD, RN, FAAN, FRCN, Oliver Opitz, MD, and Elisabeth Spichiger, PhD, RN

Institute of Nursing Science (A.K., S.D.G., E.S.), Faculty of Medicine, University of Basel, Basel, Switzerland; Department of Physiological Nursing, School of Nursing (C.M.), University of California, San Francisco, California, USA; Tumorzentrum Ludwig Heilmeyer—Comprehensive Cancer Center Freiburg (O.O.), Faculty of Medicine, University of Freiburg, Freiburg, Germany; and Inselspital Bern University Hospital (E.S.), Bern, Switzerland

Abstract

Context. Cancer pain continues to be extensively undertreated, despite established guidelines. Although the efficacy of interventions that support patients' self-management of cancer pain has been demonstrated in several studies, the most effective components of these interventions remain unknown.

Objectives. The purpose of this review of experimental and quasi-experimental studies was to systematically describe the structure and content components, as well as the efficacy of various components, of interventions designed to improve patients' self-management of cancer pain.

Methods. A systematic review of the literature was done that supplemented the 2009 meta-analysis of Bennett et al. Intervention components were categorized using content analysis. The intervention components were compared based on their calculated largest effect sizes (ESs) within each study (i.e., Hedges G_u for between-group differences in pain intensity scores).

Results. Based on 34 publications (i.e., 24 interventions), seven structure and 16 content components were identified. In 11 studies with statistically significant ESs, the largest ES within each study ranged from -1.87 to -0.44 , which represented clinically meaningful effects. No single component was found to have a discernable influence on ES.

Conclusion. This analysis provides researchers and clinicians with a detailed overview of the various structural and content components, as well as various combinations that were tested in intervention studies to improve cancer pain management. However, because of a variety of limitations, the most efficacious

Address correspondence to: Elisabeth Spichiger, PhD, RN, Institute of Nursing Science, University of Basel, Bernoullistrasse 28, CH-4056 Basel, Switzerland.
E-mail: Elisabeth.spichiger@unibas.ch

Accepted for publication: September 1, 2011.

intervention components or combination of components remain to be determined in future studies. *J Pain Symptom Manage* 2012;44:264–284. © 2012 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Pain, patient education, cancer, behavioral interventions, self-care, educational interventions, family caregiver, systematic review

Introduction

Despite the availability of analgesics and established guidelines to maximize treatment efficacy,^{1,2} cancer pain remains undertreated.^{3–5} An extensive portion of this undertreatment can be attributed to patient factors or barriers that hinder effective pain management.^{6,7} Although many interventions to support patients' self-management of cancer pain have been developed and tested, it remains unclear which intervention components are most effective.^{8–10} Therefore, the purpose of this review of experimental and quasi-experimental studies was to systematically describe the structure and content components, as well as the efficacy of various components, of interventions designed to improve patients' self-management of cancer pain.

Background

Pain is one of the most frequent symptoms experienced by oncology patients.^{1,11} Although effective treatments exist,^{3,5} more than 40% of cancer patients experience moderate-to-severe pain.^{2,12,13} Because of the deleterious effects of pain on mood, functional status, and quality of life, pain control is an essential component of cancer treatment.^{14,15} Established guidelines describe five steps that are crucial for optimal pain management by clinicians and patients: assessment, planning, implementation of actions, evaluation of these actions, and adaptations if pain management is inadequate.^{3,5,16} Clinicians diagnose and treat pain, whereas patients and their family caregivers (FCs) need to follow these five steps on a daily basis to achieve pain control. Cancer patients and their FCs need to apply complex self-management strategies, such as self-monitoring of pain and related symptoms, obtaining the prescribed pain medication, taking pain medication on a regular

schedule, and using nonpharmacologic pain management strategies. Finally, patients need to evaluate the effectiveness of these strategies and make adaptations if necessary by titrating as-needed medications and effectively communicating with their clinicians if their pain is not relieved.¹⁶

If applied correctly, pain management strategies can reduce pain in 95% of oncology patients.¹² However, a large part of undertreatment of cancer pain is attributed to patient barriers. For example, oncology patients take only 56% to 70% of their medication despite being in severe pain, even if analgesics were prescribed correctly.^{6,17} Patient barriers are multifactorial and often a consequence of a lack of knowledge about cancer pain and its self-management.^{6,18,19} As an example, opioids are associated with fears and misconceptions.^{6,20,21} In addition, practical problems, such as difficulty obtaining prescribed pain medication, difficulty tailoring medications to individual needs, or inadequate management of side effects, were found to inhibit optimal pain control.^{6,22}

Lorig²³ defines interventions that support patients' self-management as a "set of planned activities designed to improve patients' behaviors, health status, or both" (p. xiii) and describes self-management and its support as a complex process. It is no longer sufficient for patients with cancer pain to learn and practice distinct skills. They also need to manage their pain as a part of daily life using advanced problem-solving skills.^{23,24} Often, interventions that are designed to support patients' self-management are guided by theoretical frameworks that provide directions on how to change patients' cognitions (alterations in knowledge, beliefs, and attitudes)^{23,25} and behaviors (alterations in actions and skills).²⁵ In addition, affective aspects of an intervention have received more attention, particularly in terms of the identification

of specific factors that drive a person's actions.²⁵ It is increasingly important for patients to gain advanced skills in how to deal with the consequences of their disease within their social environment (e.g., problem-solving and decision-making skills, skills to form effective partnerships with clinicians, and the achievement of confidence in being able to deal with problems).²³ For this review, interventions were viewed as planned activities that support patients to achieve optimal pain control. Interventions that focused exclusively on the use of nonpharmacologic interventions (e.g., distraction and relaxation) were not included in this review.

Based on three systematic reviews,^{8–10} evidence on the efficacy of interventions to improve patients' self-management of cancer pain has increased. In a 2001 systematic review, only eight interventions were evaluated, and only two were randomized controlled trials (RCTs).^{8,26,27} Interventions varied greatly in type, duration, and content. Improvements in pain intensity were reported in five studies,^{20,26–29} but most studies did not have appropriate control groups. In addition, in one RCT,²⁷ effect sizes (ESs) were calculated; the ESs were small and not statistically significant ($d = 0.20–0.25$). However, Allard et al.⁸ concluded that interventions directed at patients and FCs may be effective in improving patients' attitudes toward self-management of pain. The authors emphasized the importance of using a pain diary to monitor pain. However, it is not clear how they reached this conclusion because none of the studies tested the effects of different components of the intervention.

In a second review of six studies of interventions for self-management of pain, Devine¹⁰ noted that the interventions varied greatly in terms of type, duration, and content. Larger ESs were noted when patients were not randomized; patients reported pain verbally to the person who conducted the intervention; and patients had average or present pain intensity scores of three or less (on a 0–10 numeric rating scale [NRS], with 0 = no pain and 10 = maximum pain) at the time of enrollment. A medium ES for pain intensity ($d = 0.4$) was found, while controlling for those three factors that had confounding effects on pain intensity. Devine concluded that interventions designed to support self-management of cancer pain frequently but not invariably reduced pain.

In 2009, Bennett et al.⁹ published a meta-analysis of 21 experimental studies on the efficacy of interventions that targeted patients' and/or FCs' management of cancer pain. The overall effect on pain intensity in 10 of 12 studies that used the same outcome measure (0–10 NRS with 0 = no pain and 10 = maximum pain) was a statistically significant 1.1-point reduction (95% confidence interval [CI] $-1.8, -0.41$) in average pain, a statistically significant 0.98-point reduction in least pain, a statistically significant 0.78-point reduction (95% CI $-1.21, -0.35$) in worst pain, and a statistically significant 0.65-point reduction (95% CI $-1.21, -0.09$) in current pain. In addition, the overall effect on pain management knowledge and attitudes was statistically significant. Despite these findings, the authors concluded that the relationships between the interventions—improved knowledge and attitudes, medication adherence, decreased pain scores, and decreased pain interference with daily life—remain unclear. Significant heterogeneity, arising from differences in study designs, as well as methods and types of interventions, were present, which may have weakened the results. The authors hypothesized that other factors, including the specific components of the interventions, could have influenced their findings.

In summary, over the past 15 years, the number of studies and the proportion of RCTs have increased, whereas outcome criteria have shifted from an improvement in patients' knowledge about cancer pain management to a clinically significant decrease in pain intensity. Although statistically significant decreases in pain intensity were found across studies, the effects in terms of being clinically meaningful were in the moderate range ($d = 0.2–0.4$, weighted mean differences 0.65–1.1). All systematic reviews^{8–10} concluded that interventions varied greatly in terms of type, duration, and content. In addition, it was not possible to determine which types of interventions were most effective. To improve the efficacy of interventions for cancer pain management, it is essential to determine which structure and content components contribute to the best outcomes. A comprehensive evaluation of the efficacy of the components of interventions studied to date is a critical first step to optimize oncology patients' ability to effectively manage

pain. Therefore, in this systematic review, structure and content components of interventions tested to date to support adult oncology patients' self-management of cancer pain were categorized, and their efficacy was evaluated.

Methods

Review of the Literature

Studies included in the meta-analysis of Bennett et al. (2009) served as the foundation for this review.⁹ This literature search was updated in Medline, CINAHL, and the Cochrane Library from December 2007 to November 2010 using the same search terms as Bennett et al. An additional search was performed within references of identified studies.

Interventions to support oncology patients' self-management of pain were defined by Bennett et al. as "information, behavioral instructions, and advice in relation to management of cancer pain by means of verbal, written, audio- or video-taped or computer-aided modalities, which are given by a health-care provider or peer, for example expert patients" (p. 193).⁹ Trials were included if they met the following criteria: "experimental design with a comparison group (randomized controlled trials (RCTs) or controlled trials), where the control group received usual care or attention only; included adults with pain from active cancer and not pain from cancer treatment such as surgery or chemotherapy; used a patient-based educational intervention on an individual basis; assessed pain-related outcomes" (p. 193). Bennett et al.⁹ excluded studies that included psychobehavioral methods in the intervention. For the present review, the same inclusion and exclusion criteria were used. However, in this review, two studies that were included in the meta-analysis of Bennett et al. were excluded because they only evaluated interventions on relaxation, distraction, and massage but not on pharmacologic interventions,³⁰ or they did not report pain outcomes for a control group.³¹

Bennett et al.⁹ assessed the studies' validity using the following criteria: randomization method, groups' baseline differences, groups treated similarly apart from the intervention, blinding of outcome assessors, reporting of outcomes for both groups, and the use of intent-to-treat analysis. These criteria were

used to judge the additional studies included in this review.

Categorization of Intervention Components

Based on the work of Mayring,³² content analysis was used to categorize the structure and content components of the interventions. For each study, the first author categorized each of its intervention components. In the second step, the first and last authors collapsed these categories and refined them based on discussions with the third author. Finally, the last author read all the publications and categorized the components of the intervention. Results were compared with the first author's categorizations, and disagreements were discussed until consensus was reached. Based on these analytical steps, components of interventions were categorized into seven structure components (Table 1) and 16 content components (Table 2).

Calculation of ESs

When possible, Hedges's G_u , a unit-free ES, was calculated for between-group effects for each pain intensity measure at each time point.³³ If information was not sufficient in study publications, additional online information from Bennett et al.⁹ was used. Hedges's G_u is a standardized mean difference parameter that differs from other commonly used ES calculations in that it contains a sample bias corrector, which results in an unbiased estimation of effects, especially for small studies.³⁴ The greater a negative ES differs from zero, the larger the difference in pain reduction is between the two groups in favor of the intervention group. A G_u of less than -0.3 was considered a clinically meaningful ES in accordance with health outcomes research in oncology patients.^{35,36} Furthermore, we defined a large ES as G_u less than -0.8 and a medium ES as G_u -0.3 to -0.8 .³⁷ The largest ES within each study was used for evaluation.

Because of the small number of studies, it was not possible to use quantitative methods (e.g., moderator analysis) to analyze the efficacy of single intervention components. Instead, by way of example, as shown in Table 3 for the structure component of FC involvement, smaller tables that included only statistically significant studies were developed to evaluate patterns or trends associated with a specific

Table 1
Structure Components of Interventions to Support Oncology Patients' Pain Self-Management

Author, Year ^a	Mode of Delivery ^b	Materials Given to Patient	Receiver of Intervention	Provider of Intervention	Interaction Provider/Receiver ^c	Structured or Tailored ^d
Aubin et al., 2006 ^{18,i}	Face-to-face Video	Booklet	Patient or patient and FC	Specially trained homecare nurses Video: nr	Questions	Structured and tailored
Yildirim et al., 2009 ⁴²	Face-to-face Slide presentation	Booklet	Patient	Two PhD-prepared registered nurses and one physician	Questions	Structured and tailored
Lai et al., 2004 ⁵⁸	Face-to-face	Booklet	Patient	Master's-prepared oncology nurse	Questions	Structured and tailored
Oliver et al., 2001 ^{46,54}	Face-to-face	Booklet	Patient	Master's-level psychology student or four-year medical student	Interaction	Structured and tailored
Vallières et al., 2006 ¹⁹	nr	Booklet	Patient	nr	nr	Structured
Lin et al., 2006 ⁵²	Face-to-face	Booklet	Patient and FC	Research assistant	Questions	Structured and tailored
Miaskowski, 2004 ^{49,59}	Face-to-face Phone call	Booklet Pillbox	Patient or patient and FC	Specially trained oncology nurses	Interaction	Structured and tailored
Keefe et al., 2005 ⁵¹	Face-to-face Video Audiotapes	Booklet Videotape Audiotapes	Patient and FC	Registered nurse-level nurse educator knowledgeable about cancer pain and skilled in coping skills training interventions Video: nr	Interaction	Structured and tailored
Ward et al., 2009b ^{39,44,50}	Face-to-face	nr	Patient or patient and FC	Five Master's-prepared nurses and two psychologists	Interaction	Structured and tailored

Intensity of Intervention ^f	Brief Description of Intervention ^f	Pain Measurement Method	Time Points of Measurement ^g	Effect Size G _u (95% CI) ^h	
One session: duration nr Video: duration 15 minutes	Interactive cognitive behavioral session at patients' homes. HCPs were contacted directly by homecare nurses if patients had contacted them with problems	- Average and worst pain intensity (time frame not specified) • NRS: 0 (no pain) to 10 (worst imaginable pain)	- Two weeks T1/2 - Four weeks T2/2	- Average pain* - Worst pain* - Average pain - Worst pain*	-1.18 (-1.75, -0.62) -1.87 (-2.50, -1.25) -0.57 (-1.21, 0.07) -1.25 (-1.93, -0.56)
First session: duration 30–40 minutes Second session after three days: 5–15 minutes (*as required*) Third session after seven days: 5–15 minutes (*as required*)	Interactive cognitive sessions in patient's room in hospital	- Present, worst, and least pain intensity (time frame not specified) • NRS: 0 (no pain) to 10 (worst imaginable pain)	- Two weeks T1/3 - Four weeks T2/3 - Eight weeks T3/3	- Present pain* - Worst pain - Least pain* - Present pain* - Worst pain - Least pain* - Present pain* - Worst pain - Least pain*	-1.29 (-1.97, -0.61) -0.49 (-1.12, 0.14) -0.82 (-1.47, -0.18) -1.56 (-2.27, -0.85) -0.48 (-1.11, 0.15) -0.82 (-1.47, -0.18) -1.48 (-2.18, -0.78) -0.37 (-1.00, 0.25) -0.96 (-1.62, -0.31)
Five sessions over five days: duration 10–15 minutes each	Interactive cognitive session performed during hospitalization	- Average, least current, and worst pain intensity (time frame not specified) • NRS: 0 (no pain) to 10 (worst imaginable pain)	- Two weeks T1/1	- Average pain - Least pain* - Current pain* - Worst pain	-0.52 (-1.25, 0.20) -0.94 (-1.70, -0.19) -0.87 (-1.62, -0.12) -0.08 (-0.79, 0.64)
One session: duration 20 minutes	Interactive cognitive behavioral session	- Average pain in past two weeks • NRS: 0 (no pain) to 10 (worst imaginable pain) converted into 0–100 scale	- Two weeks T1/1	- Average change prepost compared between groups*	-0.61 (-1.01, -0.21)
One session: duration nr	Cognitive behavioral session	- Average and worst pain intensity in past 48 hours • NRS: 0 (no pain) to 10 (worst pain)	- One week T1/2 - Three weeks T2/2	- nr - Average pain* - Worst pain	nr -0.59 (-1.09, -0.09) -0.46 (-0.95, 0.04)
One session: duration 30–40 minutes Two follow-up sessions after two and four weeks: duration nr Phone number to call if questions arose	Interactive cognitive session in private room at routine visits at outpatient clinic and two follow-up sessions to reinforce information	- Worst pain intensity in past 24 hours • NRS: 0 (no pain) to 10 (worst imaginable pain)	- Two weeks T1/2 - Four weeks T2/2	- Worst pain - Worst pain*	-0.16 (-0.67, 0.34) -0.53 (-1.05, -0.02)
Three sessions over six weeks (Weeks 1, 3, and 6); First session: mean duration 107 minutes (including ~20 minutes for study questionnaire); second session: mean duration 48 minutes; third session: mean duration 69 minutes (including ~20–30 minutes for study questionnaire and exit interview)	Interactive cognitive behavioral sessions at patient's home or clinic and three phone calls	- Average, worst, and least pain intensity in past 24 hours • NRS: 0 (no pain) to 10 (excruciating pain)	- One week T1/1	- Worst pain* - Average pain* - Least pain*	-0.47 (-0.78, -0.16) -0.51 (-0.82, -0.21) -0.43 (-0.74, -0.12)
Three phone calls over six weeks (Weeks 2, 4, and 5); mean duration 13–16 minutes	Interactive cognitive behavioral sessions at patients' homes	- Usual and worst pain intensity (last week) • NRS: 0 (no pain) to 10 (worst imaginable pain)	- One week T1/1	- Usual pain unadjusted* - Worst pain unadjusted	-0.49 (-0.95, -0.04) -0.38 (-0.83, 0.06)
Three sessions over approximately one to two weeks: duration 45–60 minutes each (average length of sessions: 56 minutes [range 20–90 minutes]; average number of days from first to last session: 14 days [range 8–32 days]) Videotape: duration nr ("brief")	Interactive cognitive behavioral session at a location that was convenient for the patient, usually at patients' homes. Phone call for evaluation of strategies and revise plans	- Pain severity: composite T-score of Z-scores of five values - Pain duration during the past week • VRS (never, sometimes, often, almost always, and always) - and of worst, least pain intensity during the past week and pain now • NRS: 0 (no pain) to 10 (worst imaginable pain)	- Five weeks T1/2 - Nine weeks T2/2	- Pain severity: solo vs. dyad - Pain severity: dyad vs. control - Pain severity: solo vs. control*	0.38 (-0.05, 0.82) -0.02 (-0.45, 0.41) -0.44 (-0.88, -0.01)
One session: duration 20–80 minutes Two phone calls two and four weeks after the session: duration 5–10 minutes	Interactive cognitive behavioral session at a location that was convenient for the patient, usually at patients' homes. Phone call for evaluation of strategies and revise plans	- Pain severity: composite T-score of Z-scores of five values - Pain duration during the past week • VRS (never, sometimes, often, almost always, and always) - and of worst, least pain intensity during the past week and pain now • NRS: 0 (no pain) to 10 (worst imaginable pain)	- Five weeks T1/2 - Nine weeks T2/2	- Pain severity: solo vs. dyad - Pain severity: dyad vs. control - Pain severity: solo vs. control	-0.29 (-0.75, 0.16) -0.14 (-0.60, 0.32) 0.12 (-0.35, 0.59)

(Continued)

Table 1
Continued

Author, Year ^a	Mode of Delivery ^b	Materials Given to Patient	Receiver of Intervention	Provider of Intervention	Interaction Provider/Receiver ^c	Structured or Tailored ^d
Clotfelter, 1999 ^{26,47}	Video	Booklet	Patient or patient and FC	nr	No interaction	Structured
Lovell et al., 2010 ^{40,51}	Video	Booklet Videotape	Patient or patient and FC	Video: patients, caregivers, and health professionals	No interaction	Structured
Wells et al., 2003 ^{56,j}	Face-to-face Phone call	Written information	Patients and FC	Session: not specified Video: experts (physician and nurse) and patients Weekly telephone calls: oncology nurse specialist	Questions (interaction in Group 3)	Structured and tailored
van der Peet, 2008 ^{27,38,43}	Face-to-face	Booklet	Patient or patient and FC	Palliative care nurses	Interaction	Structured and tailored
Yates et al., 2004 ⁶⁰	Face-to-face Phone call	Booklet	Patient	Two experienced registered nurses	Interaction	Structured and tailored
Ward et al., 2008 ^{44,50,65}	Face-to-face Phone call	Booklet	Patient	Master's-prepared oncology nurse	Interaction	Structured and tailored
De Wit et al., 1997 ^{27,43}	Face-to-face Phone call	Booklet Audiotapes	Patient	Three nurses trained as pain counselors	Interaction	Structured and tailored
Chang et al., 2002 ⁵⁵	Face-to-face	Booklet	Patient	Research assistant	Questions	Structured and tailored
Wilkie et al., 2010 ^{41,52}	Face to face Phone call Video	Booklet Laminated pain diary Grease pencil Note card	Patient	Four research assistants with at least high school diploma, Bachelor's, Master's degree, or one of the authors Video: trained actress with white coat	Interaction	Structured and tailored
Ward et al., 2000 ^{15,44,48,53}	Face-to-face Phone call	Booklet	Patient	Research nurse	Interaction	Structured and tailored

Intensity of Intervention ^f	Brief Description of Intervention ^f	Pain Measurement Method	Time Points of Measurement ^g	Effect Size C _u (95% CI) ^h	
Video: duration 14 minutes	Cognitive behavioral video presentation in office in private oncology practice	- Present pain intensity • VAS: 0 (no pain) to 100 mm (worst imaginable pain)	- Two weeks T1/1	- Present pain intensity* - Not calculated	
Video: duration nr	Cognitive behavioral booklet and video presentation at home	- Worst and average pain intensity • NRS: 0 (no pain) to 10 (worst imaginable pain)	- Two weeks T1/2 (Four weeks T2/2 nr: effects of the treatment groups were averaged across both postrandomization time points)	- Worst pain video and booklet vs. control* - Worst pain booklet vs. control - Worst pain video vs. control - Average pain video and booklet vs. control* - Average pain booklet vs. control - Average pain video vs. control	- Not calculated
One session: duration 20–30 minutes Group 2: access to a pain hotline: duration nr (only 18% of all patients in this group used the hotline) Group 3: Four weekly phone calls over the month after the educational session	All groups: interactive cognitive intervention session after a video presentation of 15 minutes Group 2: patients were encouraged to call a toll-free hotline if they had questions or concerns about pain control Group 3: patients received phone calls to reinforce information of intervention	- Worst pain and average pain intensity in past 24 hours • NRS: 0 (no pain) to 10 (worst imaginable pain)	- One month T1/6 (T2–T5 nr) Data from Bennett - Six months T6/6 Data from Bennett	- Average pain hotline vs. control - Average pain phone calls vs. control - Worst pain hotline vs. control - Worst pain phone calls vs. control - Average pain hotline vs. control - Average pain phone calls vs. control - Worst pain hotline vs. control - Worst pain phone calls vs. control	-0.08 (–0.76, 0.61) -0.28 (–0.99, 0.43) -0.39 (–1.08, 0.30) -0.41 (–1.12, 0.30) 0.71 (–0.27, 1.69) 0.30 (–0.59, 1.18) 0.46 (–0.51, 1.42) 0.40 (–0.49, 1.29)
Three sessions over six weeks (Weeks 1, 3, and 6): duration 60–90 minutes each	Interactive cognitive behavioral sessions at patient's home. Research staff contacted HCP to report findings and give advice if applicable	- Present pain intensity (time frame not specified) • NRS: 0 (no pain) to 10 (worst imaginable pain)	- Four weeks T1/2 - Eight weeks T2/2	- Present pain - Present pain	–0.40 (–0.83, 0.03) –0.28 (–0.71, 0.16)
One session: duration ~30 minutes Phone call seven days after intervention session: duration ~15 minutes One session: duration 20–60 minutes Phone call after two to three days: duration nr	Interactive cognitive behavioral session at clinic visit at outpatient department. Phone call was made so that the patient could clarify questions and make comments Interactive cognitive session in a private room at clinic visit. Phone call to give patients the opportunity to clarify questions and make comments	- Average pain intensity (time frame not specified) • NRS: 0 (no pain) to 10 (worst imaginable pain) - Pain severity score (mean of least, and worst pain in past week and pain now) • NRS: 0 (no pain) to 10 (worst imaginable pain) - Usual pain (time frame not specified) • VRS: 0 (none), 1 (mild), 2 (moderate), and 3 (severe pain) in the past week	- One week T1/2 - 13 weeks T2/2 - One month T1/2 - Two months T2/2	- Average pain - Average pain - Pain severity score - Usual pain - Pain severity score - Usual pain	–0.30 (–0.60, 0.01) –0.06 (–0.39, 0.27) 0.00 (–0.32, 0.33) –0.28 (–0.60, 0.05) –0.24 (–0.58, 0.10) –0.10 (–0.44, 0.23)
One session: duration 30–60 minutes Phone call three and seven days postdischarge: duration 5–15 minutes	Interactive, cognitive behavioral intervention session provided in the hospital at the day before discharge. Two phone calls to reinforce information of session	- Average and current pain intensity in the past week • NRS: 0 (no pain), 10 (pain as bad as you can imagine)	- Eight weeks T3/3 - Eight weeks T3/3 Data from Bennett (T1–T7 nr)	- Average pain - Current pain	–0.25 (–0.51, 0.01) –0.20 (–0.46, 0.05)
One session: duration 30–40 minutes	Interactive cognitive intervention session held at day of discharge in the patient's room in hospital	- Pain intensity in the past 24 hours • NRS: 0 (no pain) to 10 (worst imaginable pain)	- Two weeks T1/1	- Pain intensity not specified	–0.24 (–0.89, 0.41)
Video: duration 12 minutes One session Week 2: duration 5–10 minutes Two phone calls Weeks 1 and 3: duration 5–10 minutes each One session: duration ~25 minutes Phone call one week postintervention: duration 5–10 minutes	Interactive cognitive behavioral sessions and phone calls Interactive cognitive intervention session; 10 minutes giving information, up to 15 minutes discussion about questions and concerns. Phone call was made so that the patient could clarify questions	- Present pain intensity • VAS: 0 (no pain) to 100 mm (worst imaginable pain) - Worst pain in the past week • NRS: 0 (no pain) to 10 (worst imaginable pain)	- One week T1/1 - One month T1/2 - Two months T2/2	- Present pain - Worst pain - Worst pain	0.24 (–0.08, 0.56) –0.19 (–0.89, 0.51) 0.06 (–0.69, 0.82)

(Continued)

Table 1
Continued

Author, Year ^a	Mode of Delivery ^b	Materials Given to Patient	Receiver of Intervention	Provider of Intervention	Interaction Provider/Receiver ^c	Structured or Tailored ^d
Syrjala et al., 2008 ⁶⁴	Face-to-face Video Phone call	Booklet Individualized cards Paper and pencil	Patient	Research nurse Video: cancer patients with pain	Interaction	Structured and tailored
Ward et al., 2009b ⁶⁶	Phone call	Booklet	Patient	43 Bachelor's-prepared nurses and health educators	No interaction	Structured and tailored
Rimer et al., 1987 ²⁸	Face-to-face	Booklet Wallet-sized cards	Patient	Oncology nurse	Interaction	Structured and tailored
Anderson et al., 2004 ⁵⁷	Face-to-face Video Phone call	Booklet Video	Patient or patient and FC	Session: research nurse Video: cancer patients representing targeted minority group (males/females, Hispanic/African American patient)	Questions	Structured
McMillan, 2007 ^{45,63}	Face-to-face	Booklet Assessment tools Symptom diary	FC	Experienced registered nurse	Interaction	Structured and tailored

95% CI = 95% confidence interval; FC = family caregiver; nr = not reported; HCPs = health care providers; NRS = numeric rating scale; VRS = verbal rating scale; VAS = visual analogue scale; T = time point of measurement; vs. = versus.

^aFirst author of main study is named; publications of the main study and studies on the same intervention in which additional information was found are referenced, main publication is printed bold.

^bFace-to-face, phone calls, video presentation, slide presentation, and audiotapes.

^cActive participation in discussion was possible for patients during intervention (interaction), only questions could be asked by the patients (questions), or content was only presented to patients without any possibility for questions or discussion (no interaction).

^dSame for every patient (structured) and/or individualized for each patient (tailored).

^eNumber and duration of each session and phone call over which time period.

^fCognitive means information only and behavioral means also instructions on how to do things (see Table 2).

^gTime points are indicated as T "number of actual time points of follow-up measurement"/"number of performed time points of follow-up measurement;" printed in bold are the time points at which the biggest effect size (ES) in each study occurred; "data from Bennett": data were extracted from online information by Bennett et al.¹⁰

^hPrinted in bold are the largest ESs in each study; statistically significant ESs ($P < 0.05$) are marked with an asterisk (*).

ⁱQuasi-experimental design with nonequivalent groups.

^jOne group pretest post-test design for intervention, randomized controlled trial evaluated only telephone follow-up of intervention.

structure or content component of an intervention. For each of these analyses, the statistically significant studies were first grouped according to ES and then examined visually for patterns for each of the defined intervention components based on their ES.

Finally, components of studies with large ESs were summarized. Studies were categorized as statistically significant if the P -value was less than 0.05 at any time point for any pain intensity measure.

Results

Nineteen studies were included from the meta-analysis of Bennett et al.⁹ Although an additional 12 studies were identified through the literature search, only five met the inclusion criteria. Four studies were found within databases,^{38–41} and one study was found by hand search.⁴² Another 10 articles were identified that contained additional information on seven of these studies.^{43–52} Therefore, a total

Intensity of Intervention ^a	Brief Description of Intervention ^b	Pain Measurement Method	Time Points of Measurement ^c	Effect Size C _u (95% CI) ^d
One session: duration 30–45 minutes Phone call after three days: duration 10 minutes Video: duration 15 minutes	Interactive cognitive behavioral session at oncology clinic or patient's home after watching a videotape; a phone call was made to reinforce learning from session. Patients were given paper and pencil for questions they wanted to remember	- Average and worst pain intensity (time frame not specified) • NRS: 0 (no pain) to 10 (worst imaginable pain)	- Six months T3/3 (T1 and T2 nr) - Worst pain "Significant at T1" Data from Bennett	- Average pain - Worst pain -0.18 (-0.59, 0.23) 0.15 (-0.27, 0.56)
One phone call: mean duration seven minutes	Cognitive phone call by health educators of cancer information service call center	- Pain severity: average of worst, least pain intensity during past week and pain now • NRS: 0 (no pain) to 10 (worst imaginable pain) - Pain duration during the past week • VRS (never, sometimes, often, almost always, and always)	- Four weeks T1/1	- Pain severity intervention - Pain severity item assessment -0.05 (-0.20, 0.11) -0.07 (-0.22, 0.08)
One session: duration 15 minutes	Interactive cognitive intervention session at clinic visit	- Present pain intensity (time frame not specified) • VRS: six-point (no, mild, discomforting, distressing, horrible, excruciating)	- Four weeks T1/1	- Not calculated - Not calculated
One session: duration ~30 minutes Video: duration 20 minutes Phone call 48–72 hours after intervention: duration not specified	Interactive cognitive session after patients had been shown a videotape targeted at their specific minority group and gender at a scheduled clinic visit. Phone call to review patients' pain control	- Worst pain intensity (time frame not specified) • NRS: 0 (no pain) to 10 (worst imaginable pain)	- Two to four weeks T1/3 - Six to seven weeks T2/3 - Eight to 10 weeks T3/3	- Not calculated - Not calculated
Three sessions over nine days: first session duration: 45 minutes, second and third sessions: 30 minutes each	Interactive cognitive behavioral sessions for FCs at patients' homes	- Present pain intensity • NRS: 0 (no pain) to 10 (worst pain)	- Two weeks T1/2 - Four weeks T2/2	- Not calculated - Not calculated

of 24 studies (i.e., 24 interventions) and 10 additional articles were included in this review.

Study Characteristics

Designs. Of the 24 studies, 23 were RCTs.^{19,26–28,38–42,53–66} In one study,¹⁸ a quasi-experimental design was used. Four studies were pilot RCTs^{53–55,61} in preparation for larger studies.^{39,62,65} In two of these pilot studies,^{54,61} statistically significant effects were found.

Participants. A total of 4139 patients were included across the 24 studies and 1041 in the 11 statistically significant studies. Sample sizes ranged from 30 to 1256 (median 109). In the four pilot studies, sample sizes ranged from 37 to 82. Studies with larger samples were not more likely to show statistically significant or larger effects than studies with smaller samples. In fact, statistically significant differences were found in three small studies (i.e., $n = 30–40$).^{26,42,58} In two of these studies,

Table 2
Content Components of Interventions to Support Oncology Patients' Pain Self-Management

Author, Year ^c	Cognitive: Information and Recommendations ^a										Behavioral: Instructions on How to Perform Desired Behavior ^b		Goal Setting	Contact	Sum of Components	ESs ^u		
	Information on Pain ^d	Pain Tx Medication ^e	Pain Tx, Alternative Methods ^f	Cognitive Barriers ^g	Side Effects ^h	Behavioral Recs, Medication ⁱ	Behavioral Recs, Communication ^j	Behavioral Recs, Miscellaneous ^k	Behavioral Recs, FCs ^l	Pain Monitoring, Regularly ^m	Managing Pain ⁿ	Applying Alternative Methods ^o	Managing Side Effects ^p	Communication With Clinicians ^q			Set Goals and Plan Strategies to Reach Goals ^r	Evaluate Efficacy of Strategies ^s
Aubin et al., 2006 ^{18,v}	✓	✓		✓					✓				✓				6	-1.87*
Yildirim et al., 2009 ⁴²	✓	✓		✓		✓											7	-1.56*
Lai et al., 2004 ⁵⁸	✓	✓	✓	✓	✓												6	-0.94*
Oliver et al., 2001 ^{46,54}		✓		✓										✓			5	-0.61*
Vallières et al., 2006 ¹⁹		✓		✓					✓				✓				5	-0.59*
Lin et al., 2006 ⁶²		✓		✓													2	-0.53*
Miaskowski et al., 2004 ^{49,59}		✓		✓	✓	✓			✓	✓		✓	✓				9	-0.51*
Keefe et al., 2005 ⁶¹	✓	✓	✓	✓	✓	✓				✓	✓		✓				9	-0.49*
Ward et al., 2009b ^{39,44,50}	✓	✓		✓	✓	✓				✓				✓			7	-0.44*
Clotfelter et al., 1999 ^{26,47}	✓	✓	✓	✓	✓	✓				✓		✓			✓		10	np*
Lovell et al., 2010 ^{40,51}	✓	✓	✓	✓	✓	✓	✓	✓				✓					10	np*
Wells et al., 2003 ^{56,w}	✓	✓		✓	✓	✓											5	-0.41
van der Peet et al., 2009 ^{26,38,43}	✓	✓	✓	✓	✓	✓			✓		✓		✓			✓	11	-0.40
Yates et al., 2004 ⁶⁰	✓	✓		✓	✓	✓				✓			✓				7	-0.30
Ward et al., 2008 ^{44,50,65}	✓	✓		✓	✓	✓							✓				3	-0.28
De Wit et al., 1997 ^{27,43}	✓	✓	✓	✓	✓	✓			✓		✓		✓		✓		11	-0.25
Chang et al., 2002 ⁵⁵		✓		✓							✓		✓				2	-0.24
Wilkie et al., 2010 ^{41,52}		✓		✓					✓				✓				3	-0.24
Ward et al., 2000 ^{44,48,50,53}		✓		✓									✓				3	-0.19
Syrjala et al., 2008 ⁶⁴		✓		✓	✓	✓	✓						✓				7	-0.18
Ward et al., 2009a ⁶⁶		✓		✓	✓	✓							✓				3	-0.07

Rimer et al., 1987 ²⁸	✓	✓	✓	✓	✓														4	np
Anderson et al., 2004 ⁵⁷	✓	✓	✓	✓	✓	✓													3	np
McMillan et al., 2007 ^{45,63}	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓				13	np
Total	12	20	7	23	16	12	18	3	2	7	5	4	4	10	3	2	3			

Tx = treatment; Recs = recommendations; np = not possible to calculate; FCs = family caregivers; ESs = effect sizes.

^aInformation and advice so that a lay person could improve his/her knowledge of pain management.

^bBehavioral instructions on how to perform desired behavior means skill building via instructions so that a lay person could actually perform desired pain management.

^cFirst author of main study is named; publications of the main study and studies on the same intervention in which additional information was found are referenced, main publication is printed bold.

^dIncludes pain definition, pain causes, pain timeline, pain consequences, pain cure/control, breakthrough pain, and how medication works.

^eIncludes name and kind of medication, routes of administration, around the clock/as needed, schedule, and dosing.

^fIncludes physical (heat, cold, and massage), cognitive (relaxation, distraction, imagery, deep breathing exercise, and active pacing method), and other interventions (transcutaneous electrical nerve stimulation and nerve block).

^gIncludes concerns about tolerance, addiction, fatalism, religious fatalism, being a good patient, side effects of medication are inevitable and unmanageable, masking signs of disease progression, distracting the clinicians from treating the disease, harming the immune system, injections, and respiratory depression.

^hIncludes constipation, vomiting, nausea, sedation, drowsiness, confusion, urinary retention, pruritus, postural hypotension, and suggestions for side effect management.

ⁱIncludes information about compliance, medication intake, and not to stop medication abruptly.

^jIncludes explanation of pain measurement such as the visual analogue scale, stressing the importance of communication with the clinicians.

^kIncludes information about not driving a car, that occasional alcohol is OK with medication, that support groups and peer support can be helpful; support group addresses, recommendations on how to apply given information to one's own situation, that it might take more than one health care professional to manage pain.

^lIncludes recommendations about when and who to call for help.

^mIncludes assessment in a pain diary on pain intensity, location, quality, pattern, number of hours per day in pain, notes of any differences in pain, pain treatment (name, intake of medication, and use of alternative methods), and other information (symptoms or problems, effect of pain on sleep, family life, relationships with others, hours of sleep, and unusual activities or exercise).

ⁿIncludes skill building for pain management tasks (such as an individualized pain management plan with specific instructions when and how to take medication).

^oIncludes skill building on how to apply alternative pain control methods, such as deep breathing exercises, relaxation, massage.

^pIncludes skill building on how to manage side effects of pain medication, such as constipation and nausea.

^qIncludes skill building on when, how, and with which wording and arguments to communicate with clinicians, feedback on observed behavior during clinic visits.

^rFor example: "I want to sleep one night without waking up from my pain."

^sEvaluation during a follow-up contact with intervention staff as to whether goals were reached.

^tIntervention staff giving advice on pain medication or reporting effectiveness of current regimen.

^uESs marked with an asterisk are statistically significant at a level of 0.05.

^vQuasi-experimental design with nonequivalent groups.

^wOne group pretest post-test design for intervention, randomized controlled trial evaluated only telephone follow-up of intervention.

Table 3
 Example of the Method Used to Determine Pattern for Structure Component “FC Involvement”

Author/Year	ES	Patient Only	Patient and FC	Patient or Patient and FC
Aubin et al., 2006 ¹⁸	-1.87			✓
Yildirim et al., 2009 ⁴²	-1.56	✓		
Lai et al., 2004 ⁵⁸	-0.94	✓		
Oliver et al., 2001 ^{46,54}	-0.61	✓		
Vallières et al., 2006 ¹⁹	-0.59	✓		
Lin et al., 2006 ⁶²	-0.53		✓	
Miaskowski et al., 2004 ^{49,59}	-0.51			✓
Keefe et al., 2005 ⁶¹	-0.49		✓	
Ward et al., 2009b ^{39,44,50}	-0.44	✓		

FC = family caregiver; ES = effect size.

the ESs were large (-1.56 and -0.94).^{42,58} The effect in the nonrandomized study ($n = 80$) was even larger (-1.87).¹⁸

Across the 24 studies, the proportion of women (57%) was slightly higher than that of men (43%). Various cancer diagnoses were included (e.g., lung, breast, prostate, gastrointestinal, gynecological, hematological, head and neck, and other cancers). Most studies (14) were conducted in the U.S.,^{26,28,39,41,53,54,56,57,59,61,63-66} two were conducted in Canada,^{18,19} three in Taiwan,^{55,58,62} two in The Netherlands,^{27,38} two in Australia,^{40,60} and one in Turkey.⁴² The mean age of participants ranged from 48 to 77 years. Attrition rates in the 17 studies that reported them ranged from 15% to 69%.^{18,27,28,38-40,53,54,56-61,63-66}

Time of Follow-Up. Time points from completion of the intervention to final evaluation (follow-up) ranged from one week^{59,61} to six months,⁵⁶ with one to six assessments. Mean duration of follow-up, across the 24 studies, was 6.5 weeks, and it was 3.5 weeks for the 11 statistically significant studies. Statistically significant effects were found within two weeks of follow-up in eight of the 11 studies^{18,26,40,54,58,59,61,62} and within five weeks of follow-up in three studies.^{19,39,42} The three largest ESs were found after two^{18,58} and four weeks.⁴²

Pain Measurement. In 21 of 24 studies, a 0 (no pain) to 10 (worst imaginable pain) NRS was used to measure pain. In the remaining three studies, a 0 (no pain) to 100 (worst imaginable pain) NRS^{26,41} or a four-point Likert scale was used.⁶⁵ Four different types of pain intensity measures were used within the studies, although in one study the type of pain measurement was not specified.⁵⁵ Across all studies, average pain

was used in 12 studies,^{18,19,27,40,54,56,58-61,64,65} worst pain in 12 studies,^{18,19,40,42,53,56-59,61,62,64} present pain in eight studies,^{26-28,38,41,42,58,63} and least pain in three studies.^{42,58,59} Composite scores for pain intensity measures were used in three studies.^{39,65,66} More than one pain intensity measure was used in 11 studies.^{18,19,27,40,42,56,58,59,61,64,65} In seven of these studies, statistically significant effects were found.^{18,19,40,42,58,59,61} In four studies, the largest effects were found for average pain intensity,^{19,54,59,61} in two studies for worst pain intensity,^{18,62} in one study for present pain intensity,⁴² in one study for least pain,⁵⁸ and in one study for a composite score.³⁹

Calculation of ESs. ES calculations could not be done for five of the 24 studies.^{26,28,40,57,63} According to the calculated Hedges's G_u , clinically meaningful effects (i.e., less than -0.3) were found in nine studies, with statistically significant results.^{18,19,39,42,54,58,59,61,62} In two statistically significant studies,^{26,40} published information was insufficient to calculate an ES. Across all studies, one to nine ESs were calculated. The largest ES within each study ranged from -1.87¹⁸ to -0.07.⁶⁶ In all statistically significant studies, ESs were clinically meaningful and ranged from -1.87 to -0.44, with large ESs in three studies^{18,42,58} and medium ESs in six studies.^{19,39,54,59,61,62} In Tables 1 and 2, the studies are ordered from largest to smallest ES.

Structure Components

Structure components of the intervention included how the intervention was delivered (mode of delivery); what materials were given to patients; receiver and provider of the intervention; whether interactions took place between providers and receivers; the level of

individualization for each patient (“structured or tailored”); and contact time between clinicians and patients/FCs and timing of the intervention (i.e., “intensity of the intervention;” for details, see Table 1). “Total dose of the intervention” was defined as the total contact time of the receivers with the intervention over all sessions and phone calls.

Mode of Delivery. In 20 of the 24 studies, the intervention was delivered face to face^{18,27,28,38,39,41,42,53–65} with or without the combination of phone calls and/or slide, audio, or video presentations. In two studies,^{26,40} the mode of delivery was a video presentation, and in one study, it was a single phone call.⁶⁶ The mode of delivery was not reported in one study.¹⁹ In eight of the statistically significant studies, the intervention was delivered face to face,^{18,39,42,54,58,59,61,62} combined with phone calls in one study,⁵⁹ and with video/audiotapes or slide presentations in three studies.^{18,42,61} In both statistically significant studies in which the intervention was delivered via video presentation only,^{26,40} the information provided was not sufficient to calculate an ES. In terms of the optimal mode of delivery, no discernable pattern was found.

Material Provided to Patients. In all but one study,³⁹ written materials were given to patients and FCs. In addition, patients were given audiotapes of the intervention sessions,^{27,61} copies of prepared videotapes,^{40,57,61} a pillbox,⁵⁹ paper and pencil to write down things patients wanted to remember,⁶⁴ or a laminated card with a grease pencil to mark pain intensity measures.⁴¹ In the three statistically significant studies with large ESs^{18,42,58} and in four of the statistically significant studies with medium ESs,^{19,26,54,62} patients were provided only with booklets. In two of the statistically significant studies with medium ESs, in addition to the booklet, patients were provided with a pillbox⁵⁹ or videotapes and audiotapes.⁶¹ In one of the statistically significant studies with a medium ES, the type of educational material was not reported.³⁹ In terms of the optimal material, no discernable pattern was found.

Receiver of the Intervention. In one study, the intervention was directed at elderly patients,²⁶ and in one study patients from minority

groups were recruited.⁵⁷ In 13 studies, only patients participated,^{19,27,28,41,42,53–55,58,60,64–66} whereas in six studies, FCs could participate.^{18,26,38,40,57,59} In four studies, FCs were included as an integral part of the intervention.^{39,56,61,62} In one nonsignificant study, the intervention was solely for FCs.⁶³ In five of the statistically significant studies,^{19,39,42,54,58} only patients were included, two yielding a large ES.^{42,58} In two of the statistically significant studies with a medium ES,^{61,62} patients and FCs were included. In four of the statistically significant studies in which FCs had the option to participate with patients, one yielded a large ES,¹⁸ one yielded a medium ES,⁵⁹ and in two studies the ESs could not be calculated.^{26,40} In one study that attempted to evaluate “FC involvement” specifically (i.e., patient alone, patient and FC, vs. standard care),³⁹ no significant differences were found between the three groups. In terms of the optimal receiver of the intervention, no discernable pattern was found.

Provider of the Intervention. Interventions were performed by specifically trained clinicians who had a Master’s or PhD level education in four studies,^{39,42,58,65} Bachelor’s-prepared nurses in 11 studies,^{18,27,28,38,53,57,59–61,63,66} research assistants whose educational level was not described in two studies,^{55,62} or a medical or a psychology student in one study.⁵⁴ In one study, a trained actress in a white coat presented the information in the video.⁴¹ In five studies, the provider of the intervention was not described.^{19,26,40,56,64} In the three studies with large ESs, the intervention was provided by Master’s- or PhD-prepared nurses^{42,58} or by specially trained home care nurses.¹⁸ In one study with a medium ES, the intervention was provided by a Master’s-prepared nurse.³⁹ In the other statistically significant studies, the providers were Bachelor’s-prepared nurses,^{59,61} a medical or a psychology student,⁵⁴ or the educational level of the provider was not reported.^{19,26,40,62} In terms of the optimal educational level of the provider of the intervention, no discernable pattern was found.

Interaction Between Provider and Receiver. Active participation of patients in the intervention session was reported in 13 studies.^{27,28,38,41,53,54,59–61,63–66} In seven studies, patients were

only allowed to ask questions,^{18,42,55–58,62} and no interaction took place in three studies.^{26,40,66} Whether interaction was part of the intervention was not reported in one study.¹⁹ In the three studies with large ESs^{18,42,58} and in one study with a medium ES,⁶² patients were allowed to ask questions. In four statistically significant studies, interactions were possible,^{39,54,59,61} whereas in two statistically significant studies, no interaction was possible (ES not reported),^{26,40} and in one statistically significant study, interaction was not reported.¹⁹ A discernable pattern for the component “interaction” was not observed.

Structured vs. Tailored Interventions. Four of the 24 interventions contained only structured components.^{19,26,40,57} The remaining 20 interventions contained structured and tailored components. Tailored components included questions during and after the intervention, individualized information, and skill building. All but three of the statistically significant studies^{19,26,40} used structured and tailored components including the statistically significant studies with large ESs.^{18,42,58} A discernable pattern for the component “structured or tailored” was not seen.

Intensity of the Interventions. Interventions consisted of single or multiple sessions (single or multiple exposures) with or without phone calls. The total dose across interventions, calculated as total contact time between patients/FCs and the provider of the intervention, in the 17 studies with sufficient details^{26–28,38,39,41,42,53–55,57–61,64,66} ranged from seven to 270 minutes. Doses of interventions with single sessions ranged from 14 to 40 minutes;^{18,19,26,28,54,55} the dose of the single phone call in one study was seven minutes,⁶⁶ whereas doses in those studies in which a combination of sessions and phone calls was used ranged from 30 to 270 minutes.^{27,38,39,41,42,53,56–61,63–65} One of the three statistically significant studies with a large ES had only a single session (dose not reported),¹⁸ one comprised three sessions (dose 50–75 minutes),⁴² and one comprised five sessions (dose 40–70 minutes).⁵⁸ The number of sessions in the other statistically significant interventions ranged from one to six, and doses ranged from 14 to 270 minutes.^{19,26,39,54,59,61,62} The longest statistically significant intervention

(260–270 minutes)⁵⁹ had an ES of -0.51 . In terms of the optimal timing or duration, no discernable pattern was observed.

Content Components

The content components of the interventions were divided into four elements: cognitive, behavioral, goal setting, and direct contact between research staff and clinicians. “Cognitive” refers to addressing patients’ and FCs’ knowledge, beliefs, and attitudes about pain and its management. Auditory or visual information on desired behaviors was evaluated here. “Behavioral” refers to behavioral suggestions in combination with active skill building and skill rehearsal. Pain monitoring was included in “behavioral” whenever patients were taught how to perform it as a regular part of their self-management. “Goal setting” means that reachable individual aims were set as part of the intervention. “Contact” means that pain-related information or advice about pain management was given to patients’ clinicians by research staff (for details, see Table 2).

Single vs. Combined Content Components. Ten studies involved only cognitive components,^{28,39,53,55–58,62,65,66} whereas 14 studies included both cognitive and behavioral components.^{18,19,26,27,38–41,54,59–61,63,64} Of these 14 studies, three contained goal setting,^{39,54,63} and in three studies, research staff contacted the patients’ clinicians.^{18,27,38} None of the studies combined all four content components. Three of the statistically significant studies contained only cognitive components,^{42,58,62} with two yielding large ESs.^{42,58} One of the statistically significant studies with a large ES included cognitive and behavioral components and “contact with clinicians by research staff”.¹⁸ The other statistically significant studies contained cognitive and behavioral components,^{19,26,39,40,54,59,61} and two of these included goal setting.^{39,54}

Cognitive Content Components. Across all studies, the number of cognitive components ranged from two to nine. In all but one study, “cognitive barriers” were addressed.⁴¹ Other frequently addressed components were information about “pain medications” (20 studies),^{18,19,26–28,38,40,42,53–64} “behavioral suggestions about communication with clinicians” (18 studies),^{18,19,26,27,38,40–42,54,56–61,63,64,66} and “side effects” (16

studies).^{26–28,38–40,42,53,56,58,59,61,63–66} In one of the statistically significant studies,⁴⁰ the intervention contained all the nine predefined cognitive content components (ES calculation not possible). In one of the statistically significant studies with medium ESs,⁶² only two cognitive components were included. Statistically significant studies with large ESs contained three to seven cognitive components.^{18,42,58} In terms of cognitive components, no discernable pattern was observed.

Behavioral Content Components. In 14 studies, behavioral components were included.^{18,19,26,27,38–41,54,59–61,63,64} The most frequently included behavior was “communication with clinicians.”^{18,19,27,38,41,54,59,60,63,64} Across these 14 studies, one to four behavioral components were included. No study included all five predefined behavioral components. Eight studies that contained behavioral components yielded statistically significant results.^{18,19,26,39,40,54,59,61} Across these eight statistically significant studies, the number of behavioral components ranged from one to four. The study with a large ES that contained behavioral components included both “communication with clinicians” and “pain monitoring.”¹⁸ In terms of behavioral components, no discernable pattern was observed.

Goal Setting. The first study to use goal setting was published in 2001.⁵⁴ This component was not integrated in any other intervention until 2007⁶³ and 2009,³⁹ when it was added to an already existing program. Two of the statistically significant studies with medium ESs contained goal setting.^{39,54} However, the three studies with large ESs did not contain goal setting.^{18,42,58} The number of studies that contained “goal setting” was too small to detect any pattern.

Contact Between Research Staff and Patients’ Clinicians. Clinicians were contacted directly by research staff to report findings or give advice about medication regimens in three studies.^{18,38,43} One study yielded statistically significant results, with a large ES of -1.87 .¹⁸ The number of studies that contained “contact between research staff and patients’ clinicians” was too small to detect any pattern.

Discussion

To our knowledge, this systematic review is the first to provide a detailed description of structure and content components of interventions aimed at improving patients’ self-management of cancer pain, as well as an evaluation of the efficacy of various components of these interventions. Across the 24 studies, nine demonstrated not only statistically significant but clinically meaningful ESs in the moderate^{19,39,54,59,61,62} to large^{18,42,58} range.

Patterns Associated With Structure and Content Components and ES

Across the seven structure and 16 content components, no discernable patterns for any single component or for any combination of components was observed within studies that demonstrated statistically significant and clinically meaningful effects. The lack of discernable patterns may be related to the heterogeneity in study designs (e.g., heterogeneous patient populations or time of follow-up) as well as variability in the number of structure and content components included as part of the intervention. In addition, other factors may have influenced the interventions’ efficacy such as empathy of the provider⁶⁷ or setting of the intervention (e.g., clinic or home).^{68,69}

Dose of Intervention and Comparison of Single vs. Multiple Exposure Interventions

The two longest interventions, although comparable in terms of total dose (180–270 minutes vs. 263–272 minutes) and timing (three sessions over six weeks),^{38,59} did not result in the largest ESS. This finding suggests that spending more time with patients does not automatically result in increased knowledge or changes in patients’ behaviors. However, the smallest ESs was found for the shortest intervention that was provided via telephone,⁶⁶ which suggests that a minimum amount of time needs to be spent with the patient to increase patients’ knowledge and change behavior. This hypothesis is strengthened by several studies of smoking cessation⁷⁰ and exercise promotion.^{71,72} However, to date, the optimal dose and timing of an intervention to improve cancer pain management are not

known. Considering the financial benefit of short vs. long interventions, we agree with Bennett et al.⁹ that the implementation of more cost-effective interventions that use standardized material need to be explored in future clinical trials.

Consistent with the meta-analysis of Bennett et al.,⁹ multiple exposure interventions were not associated with larger ESs than single exposure interventions. This finding is confirmed in a systematic review of 20 tailored interventions that were designed to change health behaviors related to nutrition, smoking cessation, obtaining mammograms, and exercise, which were compared with structured interventions.⁷³ Although Ryan and Lauver⁷³ did not give any explanation for this finding, we agree with Bennett et al.,⁹ who stated that this finding may be related to other factors that were not incorporated into the interventions.

Structured or Tailored Interventions

In this review, differences in the efficacy of tailored vs. structured interventions were not observed. To date, findings on the benefits of tailored vs. structured interventions in supporting self-management are inconsistent; for example, one systematic review⁷³ did not show a benefit of tailored vs. structured interventions, whereas a second review in cancer patients⁷² did. We agree with Ryan and Lauver⁷³ that these inconsistent findings may relate to moderating effects of sociodemographic or clinical characteristics of patients and providers.

Evaluating Single Components of Interventions

Some authors investigated the effect of a single component within a complex intervention, such as telephone contact after the intervention,⁵⁶ coaching patients to report their pain,⁴¹ or the effect of FC involvement.³⁹ None of these studies yielded a statistically significant effect for the single intervention component. The explanation for this lack of effect remains unclear. It may be that the “whole” is greater than “the sum of the parts” (i.e., effects of interventions are based on the combination of components). Alternatively, the lack of statistically significant results may be the result of insufficient power. Researchers who

want to test single components within complex interventions need to base power calculations on potentially smaller ESs for the single components.

Comparison of the Three Studies With the Largest ESs

The largest ES (-1.87) was found for worst pain intensity at four weeks after the intervention in a nonrandomized trial ($n = 80$) in Canada.¹⁸ The cognitive-behavioral intervention for oncology pain patients and FCs was provided by home care nurses who had direct contact with patients' clinicians. The structured and tailored single exposure intervention of 15 minutes entailed a video and a booklet that was given to patients. Patients were allowed to ask questions.

The second largest ES (-1.56) was found for present pain intensity at four weeks after the intervention in a small RCT ($n = 40$) in Turkey.⁴² The intervention contained only cognitive components and was delivered in three sessions of five to 40 minutes' duration over seven days by PhD-prepared nurses or a physician to oncology pain inpatients who were due to be discharged from the hospital. The structured and tailored intervention entailed a slide presentation and a booklet that was given to patients. Patients were allowed to ask questions.

The third largest ES of -0.94 was found for least pain intensity at two weeks after the intervention in a small RCT ($n = 30$) conducted in Taiwan.⁵⁸ This cognitive, structured, and tailored intervention included five sessions of 10 to 15 minutes' duration provided by Master's-prepared clinicians to oncology inpatients who were to be discharged from the hospital. A booklet was given to patients, and patients were allowed to ask questions.

Findings from these three studies need to be interpreted with caution because of several methodological limitations. In the study of Aubin et al.,¹⁸ a nonrandomized and nonequivalent control group was used. In addition, patients in the intervention group showed a tendency to have higher baseline pain intensity scores and a shorter pain treatment history than patients in the standard care group. Subsequently, effects may have been overestimated.¹⁰ The other two studies^{42,58} investigated relatively small quite homogeneous samples in Turkey and Taiwan, contained only cognitive components, and were

both performed within an inpatient setting as part of the patients' preparation for self-management of pain at home.^{42,58} As health care systems and standard care approaches to pain management may differ substantially among countries, system factors may have contributed to the large ESs in these studies. Furthermore, the interventions in these small studies may have been tailored specifically to these patients' cultural backgrounds. For example, previous research found that Taiwanese patients tend to think fatalistically about pain.^{18,74} Finally, the fact that these studies were conducted with inpatients suggests that this transition (from hospital to home) may be an optimal time to begin an intervention.

Limitations

Four limitations of this review need to be acknowledged. First, it was based on published descriptions of the interventions. Therefore, unpublished details may have influenced the efficacy of the interventions. Second, a quantitative analysis of the intervention components' efficacy was not possible because of the number of studies in relation to the amount of intervention components. However, findings from this review provide specific details on ESs associated with structure and content components of various interventions tested to date. Third, other factors (e.g., environmental and cultural factors) not included in publications may have influenced the efficacy of interventions. Finally, our analyses may represent an overestimation of ESs. Of note, in more than half of the evaluated studies, more than one pain outcome was assessed at more than one time point, whereas no corrections for multiple testing were reported in any of these studies.

Conclusions

We agree with Bennett et al.⁹ that clinicians should integrate interventions to support oncology patients' and FCs' self-management of pain into routine practice. This systematic review provides researchers and clinicians with a detailed overview of the various structural and content components as well as various combinations that were tested in intervention studies to improve cancer pain management.

Because it was not possible to clearly discriminate the efficacy of various intervention components, only a limited number of recommendations can be made to clinicians and researchers. Based on the findings from this review, clinicians and researchers need to balance the costs with the benefits when designing an intervention to improve cancer pain management. Culturally appropriate interventions need to include, at a minimum, the provision of written material and a face-to-face educational session of not less than 15 minutes that includes three cognitive components: information on pain treatment, cognitive barriers toward pain management, and information on how to implement self-management of pain strategies. Interventions may be implemented for inpatients and outpatients. However, because of a variety of limitations, the most efficacious intervention components or combination of components remain to be determined in future studies. Additional research is needed that evaluates critical components and the optimal intervention doses. Finally, patient, provider, and system factors, such as variations between different health care systems or empathy between patients and providers, need to be evaluated to provide clinicians with the optimal approaches to improve the care of oncology patients with pain.

Disclosures and Acknowledgments

This research was supported by unrestricted grants from the Ebnet Foundation, Parrotia Foundation, Stiftung zur Krebsbekämpfung, and Hans-H. Hasbargen GmbH & Co. KG. Dr. Miaskowski is supported by grants from the National Cancer Institute, National Institute of Nursing Research, and American Cancer Society. The authors declare no conflicts of interest.

References

1. Breivik H, Cherny N, Collett B, et al. Cancer-related pain: a pan-European survey of prevalence, treatment, and patient attitudes. *Ann Oncol* 2009; 20:1420–1433.
2. Mercadante S. Pain treatment and outcomes for patients with advanced cancer who receive follow-up care at home. *Cancer* 1999;85:1849–1858.

3. Jacox A, Carr DB, Payne R, et al. Management of cancer pain. Clinical Practice Guideline Number 9. AHCPR Publication No. 94-0592. Rockville, MD: Agency for Health Care Policy and Research, US Department of Health and Human Services, Public Health Service, 1994.
4. Kirou-Mauro AM, Hird A, Wong J, et al. Has pain management in cancer patients with bone metastases improved? A seven-year review at an outpatient palliative radiotherapy clinic. *J Pain Symptom Manage* 2009;37:77-84.
5. World Health Organization. Cancer pain relief. Geneva, Switzerland: World Health Organization, 1986.
6. Ward SE, Goldberg N, Miller-McCauley V, et al. Patient-related barriers to management of cancer pain. *Pain* 1993;52:319-324.
7. Berry PE, Ward SE. Barriers to pain management in hospice: a study of family caregivers. *Hosp J* 1995;10:19-33.
8. Allard P, Maunsell E, Labbe J, Dorval M. Educational interventions to improve cancer pain control: a systematic review. *J Palliat Med* 2001;4:191-203.
9. Bennett MI, Bagnall AM, Closs SJ. How effective are patient-based educational interventions in the management of cancer pain? Systematic review and meta-analysis. *Pain* 2009;143:192-199.
10. Devine EC. Meta-analysis of the effect of psycho-educational interventions on pain in adults with cancer. *Oncol Nurs Forum* 2003;30:75-89.
11. Spichiger E, Muller-Frohlich C, Denhaerynck K, Stoll H, Hantikainen V, Dodd M. Prevalence of symptoms, with a focus on fatigue, and changes of symptoms over three months in outpatients receiving cancer chemotherapy. *Swiss Med Wkly* 2011. [Epub ahead of print].
12. Mercadante S. Why are our patients still suffering pain? *Nat Clin Pract Oncol* 2007;4:138-139.
13. Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in outpatients with metastatic cancer. *N Engl J Med* 1994;330:592-596.
14. Glover J, Dibble SL, Dodd MJ, Miaskowski C. Mood states of oncology outpatients: does pain make a difference? *J Pain Symptom Manage* 1995;10:120-128.
15. Ferreira KA, Kimura M, Teixeira MJ, et al. Impact of cancer-related symptom synergisms on health-related quality of life and performance status. *J Pain Symptom Manage* 2008;35:604-616.
16. McCaffery M, Pasero C. Pain: Clinical manual, 2nd ed. St. Louis, MO: C.V. Mosby Co., 1999.
17. Miaskowski C, Dodd MJ, West C, et al. Lack of adherence with the analgesic regimen: a significant barrier to effective cancer pain management. *J Clin Oncol* 2001;19:4275-4279.
18. Aubin M, Vezina L, Parent R, et al. Impact of an educational program on pain management in patients with cancer living at home. *Oncol Nurs Forum* 2006;33:1183-1188.
19. Vallières I, Aubin M, Blondeau L, Simard S, Giguere A. Effectiveness of a clinical intervention in improving pain control in outpatients with cancer treated by radiation therapy. *Int J Radiat Oncol Biol Phys* 2006;66:234-237.
20. Ferrell BR, Ferrell BA, Ahn C, Tran K. Pain management for elderly patients with cancer at home. *Cancer* 1994;74:2139-2146.
21. Jacobsen R, Liubarskiene Z, Moldrup C, et al. Barriers to cancer pain management: a review of empirical research. *Medicina (Kaunas)* 2009;45:427-433.
22. Schumacher KL, Koresawa S, West C, et al. Putting cancer pain management regimens into practice at home. *J Pain Symptom Manage* 2002;23:369-382.
23. Lorig K. Patient education: A practical approach, 3rd ed. Thousand Oaks, CA: Sage, 2001.
24. Lorig KR, Holman H. Self-management education: history, definition, outcomes, and mechanisms. *Ann Behav Med* 2003;26:1-7.
25. Glanz K, Rimer B, Lewis F. Health behavior and health education: theory, research, and practice. *Educ for Health* 2004;17:399-402.
26. Clotfelter CE. The effect of an educational intervention on decreasing pain intensity in elderly people with cancer. *Oncol Nurs Forum* 1999;26:27-33.
27. De Wit R, van Dam F, Zandbelt L, et al. A pain education program for chronic cancer pain patients: follow-up results from a randomized controlled trial. *Pain* 1997;73:55-69.
28. Rimer B, Levy MH, Keintz MK, et al. Enhancing cancer pain control regimens through patient education. *Patient Educ Couns* 1987;10:267-277.
29. Walker JR. A study to develop and assess the value of a leaflet on pain control for patients taking MST in the community. *Palliat Med* 1992;6:65-73.
30. Dalton J. Education for pain management: a pilot study. *Patient Educ Couns* 1987;9:155-165.
31. Barlesi F, Duffaud F, Doddoli C, et al. Impact d'un livret d'information sur la douleur destiné aux patients en oncologie thoracique. [Impact of a brochure on pain destined for thoracic oncology patients]. *Presse Med* 2004;33:1313-1318.
32. Mayring P. Qualitative Inhaltsanalyse: Grundlagen und Techniken, 8th ed. [Qualitative content analysis: Basic principles and techniques]. Weinheim, Germany: Beltz, 2003.
33. Hedges L. Distribution theory for Glass's estimator of effect size and related estimators. *J Educ Stat* 1981;6:107-128.
34. Wang M, Bushman B. Integrating results through meta-analytic review using SAS software. Cary, NC: SAS Publishing, 1999.

35. Guyatt GH, Osoba D, Wu AW, Wyrwich KW, Norman GR. Methods to explain the clinical significance of health status measures. *Mayo Clin Proc* 2002;77:371–383.
36. Osoba D, Rodrigues G, Myles J, Zee B, Pater J. Interpreting the significance of changes in health-related quality-of-life scores. *J Clin Oncol* 1998;16:139–144.
37. Cohen J. *Statistical power analysis for the behavioral sciences*, 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates, 1988.
38. van der Peet EH, van den Beuken-van Everdingen MH, Patijn J, et al. Randomized clinical trial of an intensive nursing-based pain education program for cancer outpatients suffering from pain. *Support Care Cancer* 2009;17:1089–1099.
39. Ward SE, Serlin RC, Donovan HS, et al. A randomized trial of a representational intervention for cancer pain: does targeting the dyad make a difference? *Health Psychol* 2009a;28:588–597.
40. Lovell MR, Forder PM, Stockler MR, et al. A randomized controlled trial of a standardized educational intervention for patients with cancer pain. *J Pain Symptom Manage* 2010;40:49–59.
41. Wilkie D, Berry D, Cain K, et al. Effects of coaching patients with lung cancer to report cancer pain. *West J Nurs Res* 2010;32:23–46.
42. Yildirim YK, Cicek F, Uyar M. Effects of pain education program on pain intensity, pain treatment satisfaction, and barriers in Turkish cancer patients. *Pain Manag Nurs* 2009;10:220–228.
43. De Wit R, van Dam F. From hospital to home care: a randomized controlled trial of a pain education programme for cancer patients with chronic pain. *J Adv Nurs* 2001;36:742–754.
44. Donovan HS, Ward SE, Song MK, et al. An update on the representational approach to patient education. *J Nurs Scholarsh* 2007;39:259–265.
45. Houts PS, ed. *The American College of Physicians home care guide for advanced cancer*. Philadelphia, PA: American College of Physicians, 1997.
46. Kalauokalani D, Franks P, Oliver JW, Meyers FJ, Kravitz RL. Can patient coaching reduce racial/ethnic disparities in cancer pain control? Secondary analysis of a randomized controlled trial. *Pain Med* 2007;8:17–24.
47. U.S. Department of Health and Human Services. *Managing cancer pain: Patient guide*. Clinical Practice Guideline No. 9, Consumer version. AHCPR Publication No. 94–0595. Rockville, MD: Agency for Health Care Policy and Research, US Department of Health and Human Services, Public Health Service, 1994.
48. Ward S, Hughes S, Donovan H, Serlin RC. Patient education in pain control. *Support Care Cancer* 2001;9:148–155.
49. West CM, Dodd MJ, Paul SM, et al. The PRO-SELF(c): Pain Control Program—an effective approach for cancer pain management. *Oncol Nurs Forum* 2003;30:65–73.
50. Donovan HS, Ward S. A representational approach to patient education. *J Nurs Scholarsh* 2001;33:211–216.
51. Lovell MR, Boyle FM. *Overcoming cancer pain: A guide for people with cancer, their families and friends*. Woolloomooloo, NSW: The Cancer Council NSW, 2010.
52. Wilkie DJ, Williams AR, Grevstad P, Mekwa J. Coaching persons with lung cancer to report sensory pain. Literature review and pilot study findings. *Cancer Nurs* 1995;18:7–15.
53. Ward S, Donovan HS, Owen B, Grosen E, Serlin R. An individualized intervention to overcome patient-related barriers to pain management in women with gynecologic cancers. *Res Nurs Health* 2000;23:393–405.
54. Oliver JW, Kravitz RL, Kaplan SH, Meyers FJ. Individualized patient education and coaching to improve pain control among cancer outpatients. *J Clin Oncol* 2001;19:2206–2212.
55. Chang MC, Chang YC, Chiou JF, Tsou TS, Lin CC. Overcoming patient-related barriers to cancer pain management for home care patients. A pilot study. *Cancer Nurs* 2002;25:470–476.
56. Wells N, Hepworth JT, Murphy BA, Wujcik D, Johnson R. Improving cancer pain management through patient and family education. *J Pain Symptom Manage* 2003;25:344–356.
57. Anderson KO, Mendoza TR, Payne R, et al. Pain education for underserved minority cancer patients: a randomized controlled trial. *J Clin Oncol* 2004;22:4918–4925.
58. Lai YH, Guo SL, Keefe FJ, et al. Effects of brief pain education on hospitalized cancer patients with moderate to severe pain. *Support Care Cancer* 2004;12:645–652.
59. Miaskowski C, Dodd M, West C, et al. Randomized clinical trial of the effectiveness of a self-care intervention to improve cancer pain management. *J Clin Oncol* 2004;22:1713–1720.
60. Yates P, Edwards H, Nash R, et al. A randomized controlled trial of a nurse-administered educational intervention for improving cancer pain management in ambulatory settings. *Patient Educ Couns* 2004;53:227–237.
61. Keefe FJ, Ahles TA, Sutton L, et al. Partner-guided cancer pain management at the end of life: a preliminary study. *J Pain Symptom Manage* 2005;29:263–272.
62. Lin CC, Chou PL, Wu SL, Chang YC, Lai YL. Long-term effectiveness of a patient and family pain education program on overcoming barriers to management of cancer pain. *Pain* 2006;122:271–281.

63. McMillan SC, Small BJ. Using the COPE intervention for family caregivers to improve symptoms of hospice homecare patients: a clinical trial. *Oncol Nurs Forum* 2007;34:313–321.
64. Syrjala KL, Abrams JR, Polissar NL, et al. Patient training in cancer pain management using integrated print and video materials: a multisite randomized controlled trial. *Pain* 2008;135:175–186.
65. Ward S, Donovan H, Gunnarsdottir S, et al. A randomized trial of a representational intervention to decrease cancer pain (RIDcancerPain). *Health Psychol* 2008;27:59–67.
66. Ward SE, Wang KK, Serlin RC, Peterson SL, Murray ME. A randomized trial of a tailored barriers intervention for Cancer Information Service (CIS) callers in pain. *Pain* 2009b;144:49–56.
67. Neumann M, Wirtz M, Bollschweiler E, et al. Determinants and patient-reported long-term outcomes of physician empathy in oncology: a structural equation modelling approach. *Patient Educ Counsel* 2007;69:63–75.
68. Krieger J, Takaro TK, Song L, Beaudet N, Edwards K. A randomized controlled trial of asthma self-management support comparing clinic-based nurses and in-home community health workers: the Seattle-King County Healthy Homes II Project. *Arch Pediatr Adolesc Med* 2009;163:141–149.
69. Ramsdell JW, Jackson JE, Guy HJ, Renvall MJ. Comparison of clinic-based home assessment to a home visit in demented elderly patients. *Alzheimer Dis Assoc Disord* 2004;18:145–153.
70. Lai DT, Cahill K, Qin Y, Tang JL. Motivational interviewing for smoking cessation. *Cochrane Database Syst Rev* 2010;(1):CD006936.
71. Yeom HA, Keller C, Fleury J. Interventions for promoting mobility in community-dwelling older adults. *J Am Acad Nurse Pract* 2009;21:95–100.
72. McPherson CJ, Higginson IJ, Hearn J. Effective methods of giving information in cancer: a systematic literature review of randomized controlled trials. *J Public Health Med* 2001;23:227–234.
73. Ryan P, Lauver DR. The efficacy of tailored interventions. *J Nurs Scholarsh* 2002;34:331–337.
74. Lai YH, Keefe FJ, Sun WZ, et al. Relationship between pain-specific beliefs and adherence to analgesic regimens in Taiwanese cancer patients: a preliminary study. *J Pain Symptom Manage* 2002;24:415–423.