Meta-Analysis of the Effect of Psychoeducational Interventions on Pain in Adults With Cancer

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Purpose/Objectives: To determine the effect of psychoeducational interventions on pain in adults with cancer.

Data Sources: 25 intervention studies published from 1978–2001.

Data Synthesis: When analyzed across all studies, a statistically significant, beneficial effect on pain was found. However, threats to validity were present in some studies. The most serious of these involved a lack of random assignment to treatment condition and a floor effect on pain. When limited to the studies with the best methodologic quality, the effect on pain continued to be statistically significant. Effect on pain by type of treatment was examined and found to be somewhat variable and limited by the small number of studies testing each type of treatment.

Conclusions: Methodologic quality was variable. Reasonably strong evidence exists for relaxation-based cognitive-behavioral interventions, education about analgesic usage, and supportive counseling. Minimal data were available about the relative effectiveness of different types of psychoeducational interventions because few studies included withinstudy contrasts of different experimental interventions and usual care was not well documented.

Implications for Nursing: Psychoeducational interventions are not a substitute for analgesics, but they may serve as adjuvant therapy. Assessment and clinical judgment are critical. The intervention must be acceptable to patients and not too burdensome for patients in pain to

illions of people are diagnosed with cancer every year, and studies have estimated that the majority of individuals with cancer, at some point, will experience pain from their disease (Agency for Healthcare Research and Quality, 2002; Bonica, 1990). However, many researchers have found that pain management is lacking and must be improved (Cleeland et al., 1994; Coyle, Adelhardt, Foley, & Portenoy, 1990; Wells, 2000). In response, efforts have been made to improve pain management for individuals with cancer (Jacox, Carr, & Payne, 1994; Jadad & Browman, 1995; Zech, Grond, Lynch, Hertel, & Lehmann, 1995).

Although analgesics are a mainstay of pain management, they may cause undesired effects such as sedation, nausea, constipation, and renal or liver toxicity. Researchers have examined the effect of adjunctive pain therapy in adults with cancer using educational, psychosocial, and cognitive-behavioral interventions (hereafter referred to as psychoeducational interventions). If practice is to be evidence based, the strength of the research basis for these psychoeducational interventions must be examined and communicated to clinicians. Although relevant systematic reviews of this topic have been conducted (Carroll & Seers, 1998; Devine & Westlake, 1995; Pan, Morrison, Ness, Fugh-Berman, & Leipzig, 2000; Smith, Holcombe, & Stullenbarger, 1994; Thomas & Weiss, 2000;

Key Points...

- ➤ Inadequately controlled pain is a problem for adults with cancer.
- ➤ Adjunctive treatment of pain with some forms of psychoeducational interventions for pain is promising.
- ➤ Additional high-quality research is needed to determine the relative effectiveness of different types of treatment, the duration of treatment effect, and the frequency with which the treatment should be administered to achieve maximum effect.
- ➤ Quality of life is a key outcome variable that should be measured in future research on the effect of psychoeducational interventions on pain.

Trijsburg, van Knippenberg, & Rijpma, 1992; van Fleet, 2000; Wallace, 1997), most of these reviews do not include recent studies, some lack critical information about the review methodology used (e.g., search strategies, inclusion criteria), some include studies with both adults and children without separate analysis, some include studies with a wide range of painful chronic conditions, and most provide narrative summaries of the statistical analyses in individual studies rather than quantitative analysis of effect size values (i.e., the quantitative estimate of a treatment's effect on pain).

Standard terminology does not exist for the class of interventions that is the focus of this review: education, relaxation, guided imagery, music, hypnosis, cognitive reappraisal, coping strategies, and supportive counseling. Conducting separate systematic reviews on each of these intervention classes is problematic because many studies have incorporated more than one of these types of interventions in the experimental treatment. The terms used to classify most or all of these interventions have included cognitive-behavioral (Kwekkeboom, 1999), psychoeducational (Devine & Westlake, 1995), complementary (Loitman, 2000), complementary and alternative (Pan

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et al., 2000), nontraditional (Newell & Sanson-Fisher, 2000), psychological (Trijsburg et al., 1992), and nonpharmacologic (Sellick & Zaza, 1998).

The amount of patient education varies substantially across the various types of treatments; however, virtually all of the interventions included some health-, disease-, or intervention-related information or teaching as a rationale for treatment, as instruction in using pharmacologic interventions for pain, and as instruction in using one or more nonpharmacologic coping strategy for pain. Because of this, use of the more global term "psychoeducational" seems appropriate. Nonetheless, to increase the usefulness of the review, the various types of treatment will be analyzed at the finest possible level of specificity. To avoid the complexity associated with assessing the developmental appropriateness of interventions across the lifespan, this review has been limited to studies of adults.

Purpose

The primary purpose of this meta-analysis was to obtain more stable and interpretable estimates than previously were available about the effect of selected psychoeducational interventions on pain in adults with cancer. Secondary purposes were to determine whether some types of psychoeducational interventions have a stronger research base than others and whether publication bias, a Hawthorne effect, measurement reactivity, a floor effect on pain, or lack of internal validity offered plausible alternative explanations for the findings.

Method

Meta-analysis is a quantitative approach for reviewing literature through statistical analysis of findings from individual studies (Glass, 1976). In this review, meta-analytic methods (Hedges & Olkin, 1985) were used to summarize and analyze the effect of psychoeducational interventions on pain in adult patients with cancer.

Sample

Literature identification strategies included searches of the following computerized databases: Cumulative Index to Nursing and Allied Health Literature, PubMed®, Dissertation Abstracts International, PsycLIT®, and the Cochrane Database of Systematic Reviews. Computerized searches of the following key words were conducted: cancer/neoplasms, patient/client education, counseling, behavioral therapy, guided imagery, hypnosis, relaxation therapy, music, and pain. Reference lists of relevant studies and reviews also were examined.

Three selection and three exclusion criteria for studies were used. Studies were selected if they (a) involved provision of a psychoeducational intervention to adults with cancer; (b) used an experimental, quasi-experimental, or prepost single group study design; and (c) included an outcome measure of pain for which an effect size value was discernable. Studies were excluded if (a) they examined other hypotheses (e.g., comparing the effectiveness of psychoeducational interventions and pharmacotherapy), (b) they had fewer than five subjects in each treatment condition (i.e., treatment and control groups), or (c) all treatment and control groups were not selected from the same setting(s).

Three exclusion criteria existed for outcomes. Effect size values were excluded from analysis if they were derived from

treatment and control groups that were apparently nonequivalent or from measures that were inappropriate. The criteria indicative of treatment and control group nonequivalence determined that effect size values were not used if the difference between treatment and control groups on pretest scores was an effect size value of 1 or more or if the ratio of treatment to control group standard deviations was less than 0.25 or greater than 4. In addition, because pain is a highly personal, subjective experience, measures of provider-rated pain were judged to be inappropriate.

Twenty-five studies met all selection criteria and were included in the review, whereas another 25 relevant intervention studies could not be included in the meta-analysis because no effect size values on pain could be calculated. Most of the 25 studies that did not meet selection criteria included only narrative comments on treatment effect (e.g., from case study data) and suggested a beneficial effect of psychoeducational interventions on pain. Information on these studies is available from the researcher or will be available from a longer version of this review that will be published and updated in the *Cochrane Database of Systematic Reviews*.

Measures

The major variables included characteristics of the study, sample, treatment, setting, and outcomes. Study characteristics included publication form and date, professional preparation of the first author, manner of assignment of subjects to treatment condition, and type of control group. Sample characteristics of age, gender, ethnicity, and type of cancer were coded. Treatment characteristics included the content, timing, duration, frequency, and mode of delivery of the experimental intervention. Setting characteristics included the country and site (e.g., hospital, clinic, community) where the intervention occurred. Outcomes were coded according to the actual measure, timing and manner of data collection, sample size, and direction and magnitude of treatment effect. The outcome selected for analysis was self-reported pain. Use of analysis was not included in analysis because the direction of "beneficial" effect is unclear. For example, in some instances, decreased pain might be indicated by lower analgesic usage; however, in other instances, encouraging subjects to use prescribed medications appropriately could result in their increased use of analgesics. Reliability of coding information from the research reports, based on percent agreement, was acceptable (87%).

Procedures

The scale-free, size-of-effect statistic used in this meta-analysis was based on Cohen's (1969) population statistic delta (d), which represents the standardized mean difference between treatment and control groups measured in standard deviation units. The effect size statistic provides information about both the direction and magnitude of treatment effect. The basic formula for the effect size statistic is $g = [(M_c - M_e)SD]$. When control group mean (M_c) and experimental group mean (M_e) and the pooled within-group standard deviation (SD) were not available in the research report, g was calculated from selected statistics (e.g., t values or exact p values) or from proportions using formulas and tables described by Glass, McGraw, and Smith (1981) and Rosenthal (1994). Hedges and Olkin (1985) demonstrated that small studies overestimate the population effect size value (d). Using

procedures described by Hedges and Olkin, the effect of small sample size bias was removed by multiplying effect size statistic g by a coefficient that includes information on the sample sizes of the experimental and control groups, resulting in the statistically unbiased effect size statistic d. Studies with large sample size provide more stable estimates of d than studies with small sample size (Hedges & Olkin). To give greater weight to studies with larger sample sizes, each effect size value (d) then was weighted by the inverse of its variance before averaging the effect size values across studies (Hedges & Becker, 1986; Hedges & Olkin). Because d values calculated from proportions have a different sampling distribution than d values calculated from means or t values, their variances were calculated using a procedure derived by L.V. Hedges (personal communication, June 14, 1991). In this article, d₁ was used to represent the average, weighted, unbiased estimate of effect. According to Cohen, d values of 0.2, 0.5, and 0.8 correspond with small, medium, and large effects, respectively.

For all effect size values, the convention was adopted to ascribe them a positive sign when the experimental group did better on the outcome than the control group (e.g., reported less pain) and a negative sign when the control group had less pain. Whenever pre- and post-treatment scores were reported on the same outcome, a pretreatment d value was calculated and the observed post-test effect size value was adjusted for any pretreatment difference between groups by subtracting the d value estimated from pretest data from the d value estimated from post-test data.

Unit of statistical analysis: Studies were allowed to contribute only one effect size value (d) to any estimate of effect obtained by averaging effect size values across multiple studies (i.e., d.) (hereafter called a sample of studies). Because some studies had multiple outcomes, control groups, or experimental treatment groups, several procedures were needed to obtain the single effect size value for self-reported pain for each study; these are described in detail elsewhere (Devine, 1992; Devine & Reifschneider, 1995). For example, when two or more measures of self-reported pain were found in a study, all effect size values for these measures of pain calculated for the comparison between the experimental treatment and control groups were averaged to provide a single estimate of effect. When multiple experimental treatment groups were used, several decision rules were applied. If the primary researcher made a prediction about which experimental treatment group would have the largest effect on pain, the effect size value calculated for that treatment group was selected to represent the study. If no prediction was made, in most instances, the effect size values for pain were averaged across all experimental treatment groups. However, if the design was factorial, the effect size value for the experimental group that received the largest number of treatments (i.e., factors) was selected to represent the study.

A modified sample of studies was used for subgroup analyses (i.e., analysis of the effect of each type of treatment on pain). A study could be represented by more than one effect size value as long as only one effect size value (d) from the study was used in the calculation of any average, weighted, unbiased estimate of effect (d_{+}). For example, in a study with two experimental treatment groups (e.g., education only and relaxation only), the effect size value for each of those treatments was included in the appropriate type-of-treatment subgroup. If a study had two

experimental treatment groups that received the same treatment content (i.e., only the mode of treatment delivery varied), the effect size values for the two experimental groups in that study would be averaged to obtain a single effect size value for the appropriate type-of-treatment subgroup.

Results

Twenty-five studies were included in the meta-analysis (see Table 1). When multiple reports of the same research were available, they were reviewed for relevant information and included in the reference list. However, for analysis, all research reports based on a single sample of subjects were considered a single study.

Study Characteristics

The studies were published from 1978–2001. Seventy-two percent of studies (n = 18) were published in a journal or book. The rest were primarily theses (16%) or doctoral dissertations (8%) that were not identified as being published in a journal, and one (4%) was available only as an abstract in a conference proceeding. Of the 21 studies for which professional preparation of the first author was discernable, 71% were nurses, 24% were physicians, and 5% were psychologists. With regard to design, 88% of the studies (n = 22) included a control group. The other three studies involved preand post-test analysis of a single group or a single group crossover design. Of the studies with a control group, most (n = 15)of the control treatments involved usual care for the setting, whereas the other seven included usual care for the setting plus a placebo or an alternate treatment. Individual subjects were randomly assigned to treatment groups in 80% of the studies (n = 20). Sample sizes in the studies ranged from 6-313, and the median sample size was 38.

Many of the studies examined only the short-term effect of a treatment on pain. In eight studies (32%), post-treatment pain was measured within about an hour of providing treatment. In the other studies, the length was quite variable. Post-treatment pain was measured one to two weeks after the initial treatment in six studies, four to five weeks after the initial treatment in two studies, at multiple points in time in five studies, and more than 52 weeks after the treatment began in three studies. One study did not report timing.

Subject Characteristics

The 25 studies included data from 1,723 adults with cancer. As reported in 20 studies, the average age of subjects ranged from 33–77 years. Sixty-eight percent of the studies had more women than men, and in seven studies (28%), only women were included. Only 11 studies reported the race or ethnicity of subjects. One study's subjects were Lebanese (Ali, 1990); in four studies, all subjects were described as Caucasian or Anglo Saxon. The other six studies' subjects ranged from 73%–98% Caucasian. In most studies, non-Caucasians were described as nonwhite. Only one study had a substantial proportion of African American subjects (27%) (Dalton, 1984). In no instances were separate analyses of treatment effect by age, gender, or race or ethnicity reported.

In 21 studies, the type of malignancy was reported. In five studies, all subjects had breast cancer, and in the other 16 studies, adults with various cancers were included in the sample. Frequently, no single type of cancer was in the majority.

Table 1. Study Characteristics and Outcomes

Study	Allocation to Treatment Condition	Subjects, Sample Size, Attrition, Analgesic Use, Baseline Pain ^a	Interventions	Pain Measures, Effect Size Values ^b , Timing of Post-Test Measure	
Ali, 1990 Alternate assignmen dropouts replaced		Adults with various cancers having pain Treatment: n = 15; Control: n = 15 Attrition: Six were lost from the treatment group, and eight were lost from the control group. MPQ total at pretest: 66.3 on a 2–100 scale	Treatment: Hypnosis (relaxation, comforting, and pain reduction suggestions, plus similar posthypnotic suggestions) Control: Usual care	MPQ: Total d = 1.44° Immediately after treatment	
Arathuzik, 1994	Random assignment	Women with metastatic breast cancer having pain Treatment 1: n = 8; Treatment 2: n = 8; Control: n = 8 Attrition: None was reported. Average pain sensation at pretest: 4.6 on a 0–10 scale	Treatment 1: Relaxation, visualization, cognitive-coping skills training (e.g., distraction, positive affirmation) (two hours, administered once) Treatment 2: Relaxation and visualization (1.25 hours, administered once) Control: Routine care and pain medications on an as-needed basis	Treatment 1 VAS (sensation) d = 0.756° VAS (distress) d = -0.05° Treatment 2 VAS (sensation) d = 0.893° VAS (distress) d = -0.041° Immediately after treatment	
Beck, 1988, 1991 ^d	Crossover design with random assignment	Adults experiencing cancer pain; most had breast cancer or multiple myeloma. N = 15, one day wash out between treatments Attrition: Six were lost from the study. Average pain intensity at pretest: 1.5 on a 0-5 scale	Treatment: Self-selected audiotaped music for 45 minutes twice daily for three days Control 1: Usual care (baseline) Control 2: Audiotaped, low-frequency 60-cycle hum for 45 minutes twice daily for three days	Usual care control VAS (pain intensity) d = 0.79 Noise control VAS (pain intensity) d = 0.248 Immediately after treatment No effect size value could be calculated for MPQ present pain intensity.	
Benor et al., 1998	First in treatment group, matched pair assigned to control	Adults with breast, colon, genital, prostatic, or lymphatic cancer receiving chemotherapy or radiation Treatment: n = 48; Control: n = 46 Attrition: Nine were lost from the study. Average pain intensity at pretest: 3.3 on a 1–7 scale	Treatment: Ten structured home visits over three months provided problem solving and coaching (including guidance, education, and support). Control: Usual care	Symptom control assess- ment (pain subscale) d = 0.887° Approximately three months after treatment initiated	
Clotfelter, 1999	Random assignment	Adults with cancer; most had breast, lung, prostatic, or lymphatic cancer. Treatment: n = 18; Control: n = 18 Attrition: 17 were excluded from data analysis because they had 0 pain at pre- and post-test. Average pain intensity at pretest: 16 on a 0–100 mm scale	Treatment: 14-minute videotape, booklet, and 1:1 summary about patient concerns, communication related to pain, importance of pain management, and pharmacologic and nonpharmacologic methods of pain management Control: Usual care	VAS (pain intensity) d = 0.55 Two weeks after treatment	
			(0	Continued on next page)	

^a Pain intensity rating at the pretest (across all groups). This information is not available for all studies.

^b d = the standardized mean difference measured in standard deviation units

 $^{^{\}text{c}}$ Adjusted for pretest differences between groups (d $_{\text{post-test}}-$ d $_{\text{pretest}})$

^d Duplicate report of the same research

^e Multiple effect size values for the same outcome measure over time are averaged.

Table 1. Study Characteristics and Outcomes (Continued)

Study	Allocation to Treatment Condition	Subjects, Sample Size, Attrition, Analgesic Use, Baseline Pain ^a	Interventions	Pain Measures, Effect Size Values ^b , Timing of Post-Test Measure	
Cuenot, 1994 Random assignment		Adults with cancer experiencing pain; most had lung or breast cancer. Treatment: n = 20; Control: n = 20 Attrition: None was reported. Average pain intensity at pretest: 5.9 on a 0–10 scale	Treatment: 45 minutes of self-se- lected music. Patients were instructed to assume a comfortable position in subdued lighting. Control: 45 minutes of self-selected activity. Patients were encouraged to assume a comfortable position in sub- dued lighting and use accustomed ways to manage pain (other than mu- sic).	VAS (pain intensity) d = 0.394° Immediately after treatment	
Dalton, 1984, 1987 ^d	Random assignment	Adults with cancer experiencing pain; most had breast or colon cancer or multiple myeloma. Treatment: n = 15; Control: n = 15 Attrition: None was reported. Average pain intensity at pretest: 33 on a 0–100 scale	Treatment: 60 minutes or less of education on the theory of pain using drawings of pain pathways and the role of self-control modalities (e.g., distraction, relaxation, self-massage). Verbal and written directions as well as practice opportunities were provided. Home practice was encouraged. Control: Usual care	MPQ Present pain intensity $d = -0.386^{\circ}$ Words chosen $d = -0.333^{\circ}$ VAS (pain intensity) $d = -0.158^{\circ}$ Pain during activities $d = -0.092^{\circ}$ 7-10 days after the pretest	
Darraugh, 1978	Pre- and post-test	Adults with metastatic cancer experiencing pain; most had breast, bone, or lung cancer. Single group: N = 6 Attrition: None was reported at post-treatment data collection point 1. Pain intensity at pretest: 3.3 on a 0–5 scale	Treatment: 20-minute tape on differential relaxation (i.e., a form of progressive relaxation) intended to be used twice a day No control group	MPQ Rank value of words d = 0.503 Scale value of words d = 0.25 Present pain intensity d = 0.276 Immediately after treatment, week 1 and week 2 data were not reported.	
e Wit et al., 1997 Stratified random assignment by age, gender, and number of metastatic sites Wi Tre Wi Tre Att Av		Adults with cancer experiencing pain; most had breast or genitourinary cancer. Without home care (HC) Treatment: n = 106; Control: n = 103 With HC Treatment: n = 53; Control: n = 51 Attrition: 78 were lost from the study. Average present pain intensity at pretest: 3.3 on a 0–10 scale	Treatment: 30–60 minutes of education (plus audiotape and booklet) with two 5–15 minute follow-up phone calls. Topics included pain, medication, side effects, myths, nonpharmacologic interventions for pain, and what to do if pain control is inadequate. Topics were tailored for prior knowledge and relevance for each patient. Control: Usual care	Subgroups with and without HC were reported separately. Pain subscale from EOERC® d = 0.345° (without HC) d = -0.188° (with HC) VAS (present pain intensity)® d = 0.618° (without HC) d = -0.343° (with HC) VAS (average pain intensity)® d = 0.578° (without HC) d = -0.262° (with HC) VAS (worst pain intensity)® d = 0.446° (without HC) d = 0.061° (with HC) No effect size value could be calculated for MPQ at two four, and eight weeks after pretest.	
Farzanegan, 1989	Random assignment of matched pairs	Adults were referred to a pain clinic for cancer-related pain and started on scheduled	Treatment: Four sessions of individualized patient therapy were spaced one to two weeks apart. Topics included	MPQ Sensory d = -0.436° Affective d = 1.313°	
			(0	Continued on next page,	

^a Pain intensity rating at the pretest (across all groups). This information is not available for all studies.

^b d = the standardized mean difference measured in standard deviation units

 $^{^{\}text{c}}$ Adjusted for pretest differences between groups (d_{post-test}-d_{pretest})

^d Duplicate report of the same research

^e Multiple effect size values for the same outcome measure over time are averaged.

Table 1. Study Characteristics and Outcomes (Continued)

Study	Allocation to Treatment Condition	Subjects, Sample Size, Attrition, Analgesic Use, Baseline Pain ^a	Interventions	Pain Measures, Effect Size Values ^b , Timing of Post-Test Measure	
		analgesics. Treatment: n = 15; Control: n = 14 Attrition: One was lost from the control group. Average pain intensity at pretest: 80 on a 0-100 scale	information about pain treatment, re- laxation techniques (e.g., progressive relaxation, controlled breathing, guided imagery), disease-related counseling, and home practice of re- laxation. Control: Usual care in a pain clinic	Evaluative d = 0.37° VAS (pain intensity) d = -0.276° Four to five weeks after pretest	
Fulmer, 1983	Random assignment	Adults with terminal cancer in hospice experiencing pain Treatment: n = 6; Control: n = 6 Attrition: 24 subjects were lost to study primarily because of disease progression. Average pain intensity at pretest: 2.1 on a 0–5 scale	Treatment: 15 minutes of instruction on the use of guided imagery (i.e., Ball of Healing Energy technique). An audiotape was provided with instructions to use it twice a day for two weeks. Control: 15 minutes spent with researcher in general conversation	MPQ Total d = 0.371° Number of words d = 0.108° Present pain intensity d = -0.272° Two weeks after pretest	
Gaston-Johansson et al., 2000	Random assignment	Hospitalized adults with breast cancer having an autologous bone marrow transplant (BMT) Treatment: n = 52; Control: n = 58 Attrition: 15 were subjects lost to the study. Average pain intensity at pretest: 5.98 on a 0–100 scale. After BMT, 47% reported pain and only two reported mouth or throat pain. The average pain intensity in the control group was less than 20 on a 0–100 scale at all three times.	Treatment: Two weeks before hospital admission, the clinical social worker provided information about pain management, coping strategies (e.g., cognitive restructuring with 15 positive self-statements to use), brief muscle relaxation, and cue-controlled relaxation. An audiotape recorder, audiotape, and earphones were provided. Patients were encouraged to listen to the five-minute relaxation/imagery tape daily and before stressful events. Content was reinforced three times during hospitalization. Control: Usual care	GJ-POM ^e Affective d = -0.085 ^c Sensory d = -0.058 ^c VAS (pain intensity) ^e d = -0.317 ^c Two days before BMT and seven days after	
Goodwin et al., 2001	Random assignment with 2:1 allocation of treatment to control group	Adults with metastatic breast cancer Treatment: n = 99; Control: n = 44 Attrition: 90 were lost to the study. Mortality at one year was approximately 65%. Average pain intensity at pretest: 1.83 on a 0–10 scale	Treatment: Weekly group meetings lasted 90 minutes for one year or longer if beneficial. The goals of therapy were to foster support and encourage expression of emotions about cancer and its effects on patients' lives. Coping strategies were discussed. Monthly sessions were provided for family and friends. Control: Usual care; also, every four to six months, study participants were sent educational materials about breast cancer and its treatment as well as relaxation and nutrition.	VAS (pain experience) d = 0.356 VAS (suffering/hurt) d = 0.223 Interaction with baseline pain was noted with minimal effect in those with low pain. One year after pretest	
Graffam & Johnson, 1987	Crossover design with ran- dom assignment of the or- der of treatments	Hospitalized adults with cancer N = 30 subjects served as their own control. Attrition: None was reported.	Treatment 1: 15-minute audiotape, including five minutes of music, guided progressive muscle relaxation Treatment 2: 15-minute audiotape,	Treatment 1 VAS (pain sensation) d = 0.949 VAS (pain distress) Continued on next page)	

^a Pain intensity rating at the pretest (across all groups). This information is not available for all studies.

^b d = the standardized mean difference measured in standard deviation units

 $^{^{\}rm c}$ Adjusted for pretest differences between groups (d_{post-test}-d_{pretest})

^d Duplicate report of the same research

^e Multiple effect size values for the same outcome measure over time are averaged.

Table 1. Study Characteristics and Outcomes (Continued)

Kusek, 1982	Pre- and post-test	Average pain intensity at pre- test: 3.8 on a 0–5 scale	including five minutes of music, with guided imagery	d = 0.972 Treatment 2 VAS (pain sensation) d = 0.972
Kusek, 1982	Pre- and post-test			VAS (pain distress) d = 1.006 Immediately after treatment
		Adults with bone metastases in pain; most had breast, prostate, or lung cancer. Single group: N = 7 Pain intensity at pretest: 3 on a 0–5 scale	Treatment: One 20-minute home visit was provided to educate patients about pain management. A teaching packet was provided. Topics included factors affecting pain, use of pain medications, recognizing and treating side effects of analgesics, and issues of dependence and tolerance. No control group	MPQ Sensory d = 0.686 Affective d = 0.661 Evaluative d = 0.532 Miscellaneous d = 0.435 Pain rating index d = 1.106 Present pain intensity d = 0.93 One week after treatment
Maguire et al., 1983	Random assignment by week of admission	Adults having modified radical mastectomy for breast cancer Treatment: n = 75; Control: n = 77 Attrition: 20 were lost to the study. Pain at pretest was not reported. At post-test, 61% in the control group had pain.	Treatment: A nurse specialist educated and counseled in the hospital, at discharge, and every two months to monitor progress until patients were well adapted. Topics included instruction in arm exercises, advise on prostheses, feelings related to the loss of a breast, and social adjustment. Control: Usual care	Percent with arm pain d = 0.259 12–18 months after surgery
Oliver et al., 2001	Random assignment	Adult patients with cancer in moderate pain (i.e., at least 30 on a 100-point scale), not in hospice, and not being treated by a pain management service Treatment: n = 34; Control: n = 30 Attrition: Nine consenting subjects were lost to the study. 177 declined screening, and 91 wanted enrollment deferred but never were enrolled. Pain at pretest average pain score: 52.5 on a 0–100 scale	Treatment: 20 minutes of individualized education and coaching by a health educator and a patient education booklet. Topics included addressing misconceptions about pain management and encouraging dialogue about pain control with their oncologists. Pain management goals were identified, and strategies to achieve goals were developed. Control: Equal time with a health educator receiving standardized education about pain	VAS (average pain) d = 0.524° MOS (pain frequency) d = 0.277° MOS (pain effects) d = 0.247° Two weeks after treatment
Rimer et al., 1987	Random assignment	Adults with cancer being treated with narcotics for nonsurgical pain; most had lung, colorectal, or breast cancer. Treatment: n = 127; Control: n = 103 Attrition: 35 were lost to the	Treatment: 15 minutes of education about pain management included printed materials about an analgesic regimen for pain, the rationale for compliance, debunking myths about tolerance and addiction, and aids to promote implementation of analgesic regimen.	Percent with no or mild pair d = 0.494 Four weeks after treatment

^a Pain intensity rating at the pretest (across all groups). This information is not available for all studies.

^b d = the standardized mean difference measured in standard deviation units

 $^{^{\}text{c}}$ Adjusted for pretest differences between groups (d $_{\text{post-test}}-$ d $_{\text{pretest}})$

^d Duplicate report of the same research

^e Multiple effect size values for the same outcome measure over time are averaged.

Table 1. Study Characteristics and Outcomes (Continued)

Study	Allocation to Treatment Condition	Subjects, Sample Size, Attrition, Analgesic Use, Baseline Pain ^a	Interventions	Pain Measures, Effect Size Values ^b , Timing of Post-Test Measure	
		study. At post-test, 76% of the con- trol group had more than mild pain.	Control: Usual care		
Scallion, 1981	Random assignment	Adults with bone metastases in pain; most had breast, prostate, or lung cancer. Treatment: n = 12; Control: n = 9 Attrition: None was reported.	Treatment: 15-minute taped instruction on progressive mental and muscle relaxation as well as controlled breathing Control: Usual care Subjects reported post-test pain to	Present pain intensity d = 0.909 Unable to determine timing of measurement No effect size value could be determined for average	
		Pain at pretest was not reported.	the researcher. Timing was not clearly stated.	pain or constant pain.	
Sloman, 1995; Sloman et al., 1994 ^d	Random assignment	Hospitalized adults with cancer pain; many types of cancer were found in the sample. Treatment 1: n = 20; Treatment 2: n = 20; Control: n = 20 Attrition: Seven were lost from the study. Additional subjects were randomly assigned to balance groups. Pain intensity at pretest: 2.5 on a 0–5 scale	Treatment 1: Twice weekly sessions with nurse-administered relaxation and guided imagery. Patients were encouraged to practice on their own twice a day and whenever they experienced pain. Treatment 2: Twice weekly sessions with audiotape-guided relaxation and guided imagery. Patients were encouraged to practice twice a day using the audiotape and whenever they experienced pain. Control: Usual care	Treatment 1 MPQ Sensory d = 0.658° Affective d = 0.069° Present pain intensity d = 0.862° VAS (worst pain) d = 1.083° Treatment 2 MPQ Sensory d = 0.511° Affective d = 0.279° Present pain intensity d = 0.985° VAS (worst pain) d = 0.708° Three weeks after pretest	
Spiegel & Bloom, 1983	Random assignment	Adults with metastatic breast cancer Treatment: n = 30; Control: n = 24 Attrition: 23 were lost to the study. Analyses were conducted on 54 patients who completed data collection at two points in time. Individual regression was used to interpolate missing data. Average pain sensation at baseline: 2.5 on a 0–10 scale	Treatment: Weekly 90-minute group therapy sessions were held for one year. One of the two treatment groups participated in self-hypnosis exercises. Results for the two treatment groups were not reported separately in detail. Both had less pain than control subjects, and hypnosis was reported to have an additive analgesic effect. Control: Usual care	VAS (sensation) d = 0.676 VAS (suffering/pain) d = 0.587 Pain frequency d = 0.014 Pain duration d = 0.352 12 months after pretest	
Syrjala et al., 1992	Random assignment	Adults receiving BMT for a hematologic malignancy Treatment 1: n = 12; Treatment 2: n = 11; Control: n = 12 Attrition: 22 were lost to the study. Usual care control group not used in meta-analysis because gender distribution	Treatment 1: Hypnosis was explained, and concern was elicited. Hypnosis was induced with relaxation and imagery. Additional phrases related to health, well-being, self-control, and enhanced coping. Inductions were taped and provided for daily self-administration. Treatment 2: Progressive muscle relaxation and brief autogenic relaxation	Treatment 1 VAS° (intensity of mouth or throat pain) d = 0.823° Treatment 2 VAS° (intensity of mouth or throat pain) d = 0.228° Pain was recorded daily and averaged for each of three weeks. Interaction was noted for Continued on next page)	

^a Pain intensity rating at the pretest (across all groups). This information is not available for all studies.

^b d = the standardized mean difference measured in standard deviation units

 $^{^{\}circ}$ Adjusted for pretest differences between groups (d $_{post\text{-test}} - d_{pretest})$

^d Duplicate report of the same research

^e Multiple effect size values for the same outcome measure over time are averaged.

Table 1. Study Characteristics and Outcomes (Continued)

Study	Allocation to Treatment Condition	Subjects, Sample Size, Attrition, Analgesic Use, Baseline Pain ^a	Interventions	Pain Measures, Effect Size Values ^b , Timing of Post-Test Measure
		was significantly different. Pain in the control group averaged across weeks 1–3: 46 on a 0–100 scale	(a tape was provided for daily self-administration), cognitive restructuring of uncomfortable experiences, procedural and sensation information, short-term goal setting for self-care with monitoring progress, and meaning of illness and treatment explored Control: Equal time was spent with the therapist. Conversation was dictated by the patient, and coping skills were not introduced. All treatments were administered for 90 minutes twice before admission and then for 30 minutes twice a week for four weeks.	Treatment 2's effect; week 1: d = -0.062°; week 2: d = 0.244°; week 3: d = 0.501°
Syrjala et al., 1995	Random assignment	Adults receiving BMT for a hematologic malignancy Treatment 1: n = 24; Treatment 2: n = 23; Treatment 3: n = 24; Control: n = 22 Attrition: 67 were lost to the study. Pain in the control group averaged across weeks 1–3: 39.4 on a 0–100 scale	Treatment 1: Relaxation and imagery (as in Treatment 2), cognitive restructuring self-defeating cognitions, distracting attention from noxious physical sensations, short-term goal setting for self-care with monitoring progress, incorporating visions of favorite places and people into imagery, discouraging goal setting that could not be controlled, and problem solving. Written and one-on-one instructions plus audiotapes were provided for daily self-administration. Treatment 2: Information was provided about pain and nausea. Deep breathing, progressive muscle relaxation and imagery with brief autogenic relaxation, and additional phrases/images about well-being, strength, competence, and comfort were provided. Written and one-on-one instructions plus audiotapes were provided for daily self-administration. Treatment 3: Psychotherapeutic support related to affective status and current situation, positive reframing, and information about the normal course of pain and medical treatment Control: Usual care All three experimental treatments were administered for 90 minutes twice before admission and then for 30 minutes twice a week for five weeks.	Treatment 1 VASe (intensity of mouth or throat pain) d = 0.504c Treatment 2 VASe (intensity of mouth or throat pain) d = 0.268c Treatment 3 VASe (pain intensity) d = 0.354c Pain was recorded daily and averaged for each of three weeks. Interaction was noted for Treatment 3's effect; week 1: d = 0.164c; week 2: d = 0.405c; week 3: d = 0.494c
Ward et al., 2000	Random assignment	Adults with progressive or metastatic gynecologic cancer experiencing pain in	Treatment: Individually tailored information was given about barriers to and side effects from pain manage-	Brief Pain Inventory ^e Worst pain d = -0.593 ^c Interferes with life
			· · · · · · · · · · · · · · · · · · ·	Continued on next page

^a Pain intensity rating at the pretest (across all groups). This information is not available for all studies.

^b d = the standardized mean difference measured in standard deviation units

 $^{^{\}text{c}}$ Adjusted for pretest differences between groups (d $_{\text{post-test}}-$ d $_{\text{pretest}})$

^d Duplicate report of the same research

^e Multiple effect size values for the same outcome measure over time are averaged.

Table 1. Study Characteristics and Outcomes (Continued)

Study	Allocation to Treatment Condition	Subjects, Sample Size, Attrition, Analgesic Use, Baseline Pain ^a	Interventions	Pain Measures, Effect Size Values ^b , Timing of Post-Test Measure	
		last two weeks Treatment: n = 13; Control: n = 14 Attrition: 17 were lost to the study. Worst pain intensity at base- line: 3.96 on a 0–10 scale	ment with analgesics. Content was prompted by data from questionnaires about barriers to pain management and side effects from analgesics. A booklet was provided, questions were answered, and a follow-up phone call was made for clarification. Control: Usual care	d = -0.279° No effect size values could be calculated for two subscales: "least pain in last week" and "pain now" Four to eight weeks after treatment	
Zimmerman et al., 1989	Random assignment	Adults with chronic pain from cancer receiving scheduled pain medications; most had breast, bone, lung, or prostate cancer. Treatment: n = 20; Control: n = 20 Attrition: None was reported. Pain at pretest was not reported.	Treatment: Lying quietly in a darkened room for 30 minutes while listening to self-selected, audiotaped music. It was suggested that it would help them relax and reduce their pain. Control: Lying quietly in a darkened room for 30 minutes. It was suggested that it would help them relax and reduce their pain.	MPQ Sensory d = 0.813 Evaluative d = 0.982 Present pain intensity d = 0.611 Words chosen d = 0.982 VAS (pain intensity) d = 0.627 Immediately after treatment	

^a Pain intensity rating at the pretest (across all groups). This information is not available for all studies.

However, in two of these studies, more than half of the subjects had breast cancer. Subjects in two studies had various forms of hematologic malignancies, and in one study, subjects had various forms of gynecologic malignancies.

Documented pain was an identified selection criterion in 17 of the 25 studies (68%). In three other studies (12%), pain was expected to occur in the weeks following bone marrow transplant. In the other five studies, the presence of pain presumably was assumed. For short-term studies of chronic pain, one can obtain a crude estimate of expected pain level in the absence of treatment (baseline pain) by examining pretreatment pain level. This is very important because when the expected level of pain is relatively mild in the absence of an experimental intervention, the intervention is less likely to be found to reduce pain because little room exists for change on the variable. Typically, this phenomena is called the floor effect.

In 21 studies, pain prior to treatment was reported for present or usual pain intensity. To provide a single estimate of baseline pain for each study, in most instances, pain level prior to the treatment was averaged across treatment and control groups. In a few instances, pretest scores on pain were not relevant because they were measured prior to ablative chemotherapy given in anticipation of a bone marrow transplant. In those cases, the post-test pain intensity in the control group was used to estimate anticipated pain level in the absence of treatment (i.e., baseline pain). In the studies reviewed, various measures of present or usual pain were employed, but a 0–10 numeric scale was the most common. To analyze values across studies, results from other scales (e.g., 0–5, 0–100) were converted using linear interpolation to the correspond-

ing value on a 0-10 scale. Once all scores were on a 0-10 scale, baseline pain varied from 1.6-8. Baseline pain was 3 or less in six studies (24%). These studies, in addition to one that did not report present or usual pain but reported usual worst pain, which was less than 4 on a 0-10 scale, were judged to have a floor effect on the outcome pain.

Setting Characteristics

Seventy-six percent of the studies (n = 19) were conducted in the United States. The other six studies were fairly evenly distributed among the United Kingdom, Canada, Australia, and the Middle East (i.e., Lebanon and Israel). Of the 21 studies reporting the setting of the experimental treatment setting, eight (38%) were conducted exclusively in an inpatient hospital setting, seven (33%) were conducted exclusively in some type of outpatient treatment facility, and three (14%) were conducted exclusively in the home. The remaining three studies involved a combination of settings, such as initial instruction in an intervention (e.g., relaxation training) in the outpatient oncology clinic with a subsequent practice component conducted in the subjects' homes.

Treatment Characteristics

At least one effect size value could be coded for 29 experimental treatment groups identified in the 25 studies in the sample. Analysis of the narrative descriptions of treatments revealed that experimental interventions included one or more general categories of content: education (e.g., use of analgesics), cognitive-behavioral counseling (e.g., instruction in the use of a cognitive-behavioral coping strategy such

^b d = the standardized mean difference measured in standard deviation units

 $^{^{\}rm c}$ Adjusted for pretest differences between groups (d_{post-test}-d_{pretest})

^d Duplicate report of the same research

^e Multiple effect size values for the same outcome measure over time are averaged.

as relaxation, guided imagery, hypnosis, distraction, or music), and nonbehavioral-noncognitive support or counseling (e.g., emotional support, group support, expressive counseling).

The most prevalent interventions studied were cognitive-behavioral interventions focused on promoting relaxation. These included 12 experimental treatment groups involving one or more of the following: progressive muscle relaxation, guided imagery, self-selected music, or hypnotherapy. In only 5 of these 12 treatments was a single type of treatment used (e.g., self-selected music only, guided imagery only). In the others, multiple types of relaxation-based interventions were combined (e.g., relaxation and guided imagery, self-selected music and hypnosis).

Experimental treatments involving only education (n = 6) typically provided information about pain and pain treatment. Myths about analgesic medications and appropriate use of medications often were discussed. Some included a general description of nonpharmacologic interventions for pain (e.g., relaxation, distraction).

Eleven experimental treatments were administered that included various combinations of educational, cognitive-behavioral, and supportive interventions. In six of these experimental treatments, a relaxation-based cognitive-behavioral intervention was combined with some other intervention, such as other cognitive-behavioral interventions (e.g., self-massage, cognitive restructuring, problem solving, goal setting), education, or supportive counseling. In five experimental treatments, supportive counseling was included and often combined with other interventions, such as education, coping strategies, or cognitive restructuring.

Threats to Validity

Before determining average treatment effects, threats to validity based on publication bias, low internal validity, the floor effect, measurement reactivity, and the Hawthorne effect (Cook & Campbell, 1979; Rosenthal, 1979) were examined using weighted regression procedures based on a fixed effects model (Hedges & Olkin, 1985) to estimate the relationship between threats to validity and size of effect. This was performed to determine whether the magnitude or direction of treatment effect differed among studies that were and were not affected by threats to validity. For some of these threats (e.g., low internal validity, publication bias, Hawthorne effect, high measurement reactivity), concern existed that studies with this threat could inflate estimates of treatment effectiveness, whereas with other threats (i.e., a floor effect), concern existed that studies with a threat could deflate estimates of effect. In other words, were beneficial treatment effects absent or greatly diminished among studies that did not include a threat that might inflate estimates of treatment effectiveness: studies that were unpublished, had random assignment of subjects to treatment condition, had lower measurement reactivity (i.e., subjects reported their pain in a manner other than verbally to the researcher who provided the experimental intervention), or had a placebo or alternate treatment control group? Or, were beneficial treatment effects absent or greatly diminished among studies that did include a threat that might deflate estimates of treatment effectiveness, such as studies that had a documented floor effect on pain (e.g., baseline present or average pain of 3 or less on a 0–10 scale)? Significant relationships were found with effect size values for manner of assignment to treatment condition (Z = 2.72, p < 0.05), measurement reactivity (Z = 2.99, p < 0.05), and presence of a floor effect on pain (Z = 2.42, p < 0.05) but not for publication form or presence of a placebo or alternate treatment. Studies with random assignment to treatment group and lower measurement subjectivity had lower effect size values. Studies with a floor effect on pain had lower effect size values. No statistical interactions were found in the relationships among threats to validity and effect size values. However, measurement reactivity was confounded with manner of assignment to treatment condition; 83% of the studies without random assignment of subjects to treatment condition had higher measurement reactivity, whereas only 26% of the studies with random assignment had higher measurement reactivity ($C^2 = 6.1$, p < 0.05). No other confounding relationships were noted among threats to validity. To control for the three identified threats to validity in subsequent analyses, aggregate results were reported for all studies as well as for the higher quality studies (those with random assignment to treatment condition and without a documented floor effect on pain).

Effect on Pain

Pain was measured using self-report. In many instances, this involved a verbal report to the researcher who also provided the experimental intervention. In 15 studies (60%), subjects completed a written questionnaire on pain or provided a verbal report of pain to someone other than the researcher who provided the treatment. Researchers most frequently used the McGill Pain Questionnaire and various visual analog-type scales to assess pain. In 21 (84%) studies, a positive treatment effect on pain was d = 0.25 or larger. Across all studies, a moderate-sized, statistically significant, beneficial effect on pain was found ($d_1 = 0.41$; 95% confidence interval = 0.29, 0.52; O = 35.9; df = 24). When analyses were restricted to the nine studies with random assignment to treatment condition, no documented floor effect on pain, and data collection by a method other than verbal report of pain to the researcher who provided the experimental intervention, the effect size value was somewhat smaller. Nonetheless, the effect on pain remained statistically significant ($d_{\perp} = 0.36$; 95% confidence interval = 0.15, 0.58; Q = 5.7; df = 8). Effect size values also were analyzed by type of treatment to probe the evidence basis for each of the prevalent types of treatment.

Relaxation-promoting cognitive-behavioral interventions: Relaxation-based interventions (e.g., relaxation alone or with guided imagery, self-selected music therapy, or hypnosis) were the most prevalent types of treatments tested. Across all 12 studies with this type of intervention, a statistically significant, homogeneous, moderate-to-large beneficial effect on pain was found (see Table 2). When analyses were limited to the seven studies with random assignment to treatment condition and no documented floor effect on pain, the effect was somewhat smaller, but still moderately sized and statistically significant. Of these seven studies, the treatments tested included relaxation exercises plus guided imagery (n = 3, d_{+} = 0.49), relaxation exercises plus guided imagery and hypnosis (n = 2, d_{\perp} = 0.46), relaxation only (n = 1, d = 0.91), and self-selected music (n = 1, d_+ = 0.39). The studies testing relaxation only and self-selected music asked participants to report pain to the researcher who provided the treatment; all other studies asked subjects to complete a written questionnaire on pain or report pain to someone other than the researcher who provided the treatment.

Table 2. Average Effect Size Values on Pain by Type of Intervention

	All Studies		Higher Quality Studies Only			
Type of Treatment Content	d.	n	d₊	n	95% Confidence Interval	Q
Relaxation, guided imagery, music, or hypnosis	0.65*	12	0.49*	7	0.21, 0.77	3.2a
Education	0.36*	6	0.40*	3	0.16, 0.64	0.6^{a}
Support plus other content	0.44*	5	0.35	1 ^b		
Relaxation plus other content	0.07	6	0.24	5	-0.09, 0.57	2.7^{a}

d₊ = average, unbiased, weighted effect size

Confidence intervals that do not include zero indicate that the d_{\star} value is statistically significant (p < 0.05).

Q = homogeneity statistic

Note. Higher quality studies are those with random assignment of subjects to treatment group and no documented floor effect on the outcome pain.

Education: The effect of education was tested in six studies. Across all six studies with this type of intervention, a statistically significant and homogeneous small-to-moderate beneficial effect on pain was found. When analyses were limited to the studies with random assignment and no documented floor effect on pain, the effect was somewhat larger and statistically significant.

Relaxation plus other content: Relaxation-based cognitive-behavioral interventions were combined with other types of treatment content (e.g., distraction, self-massage or stroking the skin, problem solving, positive affirmation about ability to cope with pain, cognitive reappraisal, goal setting, education, supportive counseling) in six studies, all of which used random assignment of subjects to the treatment group. Given the variability in both the types of treatments and the effect size values in this subset (d values ranged from -0.24 to 0.51), aggregating effect size values may obscure important differences by type of treatment. When aggregated, no effect on pain was found (p > 0.05). To identify promising treatments that combine relaxation with other types of content, individually considering the five studies that did not have a documented floor effect on pain perhaps is more informative. Arathuzik (1994) tested the effect of relaxation, guided imagery, distraction, and positive affirmation about the ability to deal with pain and measured the effect on pain immediately after treatment (d = 0.38). In two studies, education about pain was combined with relaxation, distraction, and cutaneous stimulation (d = -0.24 [Dalton, 1984]) or with relaxation, guided imagery, deep breathing and counseling (d = 0.24[Farzanegan, 1989]). In two studies, relaxation exercises, imagery, cognitive reappraisal, and goal setting were combined with information about sensations, procedure, and supportive counseling (d = 0.23 [Syrjala, Cummings, & Donaldson, 1992]) or combined with distraction, incorporating self-selected visions into imagery, and problem solving (d = 0.51[Syrjala, Donaldson, Davis, Kippes, & Carr, 1995]).

Supportive counseling plus other content: The effect of supportive counseling was tested in five studies. All five studies yielded a positive effect size value larger than d=0.25 and, on average, had a statistically significant and homogeneous small-to-moderate beneficial effect on pain. Only one study (Syrjala et al., 1995) had both random assignment and no documented floor effect on pain. Treatment included psy-

chotherapeutic support related to affective status and current situation, positive reframing, and information about pain and medical treatment and had a small-to-moderate effect on pain (d = 0.35). This subset of studies included the only studies in this review that followed subjects for a year or more (Goodwin et al., 2001; Maguire, Brooke, Tait, Thomas, & Sellwood, 1983; Spiegel & Bloom, 1983). A floor effect on pain at admission to the study could be less relevant for studies of such long duration. When analysis was limited to the three studies using random assignment of individuals to treatment condition, the effect on pain was statistically significant and homogeneous (d_+ = 0.33; Q = 0.14; 95% confidence interval = 0.07, 0.59).

Discussion

Many of the effective educational interventions specifically promoted the use of prescribed analgesics based on the rationale that patients often decline analgesics because of concern related to addiction or side effects. Education about analgesic use was frequently, but not invariably, found to reduce pain. In several studies that found a minimal or even a negative effect of education on pain, a floor effect on pain commonly existed. Given the widely accepted mandate to educate patients, the possibility exists that, in some of these studies, the experimental and control treatments did not differ much in content and when education is adequate, additional education about analgesics is not helpful. The study by de Wit et al. (1997) is particularly interesting in this regard. The experimental educational intervention was provided predominately during hospitalization. Upon discharge, 104 of the subjects received home care and 209 did not. The effect on pain averaged across measures taken at two, four, and eight weeks after discharge differed dramatically depending on whether the subjects received home care (d = -0.18) or not (d = 0.5). This difference could be the result of many factors (e.g., the group receiving home care was older and had more complex pain problems, randomization in the subgroup could have been inadequate, the nurses providing home care could have provided similar education to subjects in the control group thus minimizing the difference between the experimental and control treatments). Unfortunately, the actual content of usual care was not described.

^{*} p < 0.05

^a Effect size value is homogeneous.

^b With only one study, a confidence interval or test for homogeneity cannot be calculated.

Relaxation-based cognitive-behavioral interventions usually were effective in reducing pain shortly after treatment. Because long-term effects of these relaxation-based interventions have not been well tested, the longer-term effects of these interventions are unknown. Patient motivation may be a critical factor, particularly if repeated self-administration of relaxation-based therapies is needed to achieve a longer-term effect on pain. The various relaxation-based interventions have been found to vary in acceptability to patients. In a study of adults with metastatic cancer who were in moderate to severe pain, even though pain was lower after their initial treatment, none of the six subjects was able to perform the progressive muscle relaxation twice a day for two weeks as recommended because it was too burdensome (Darraugh, 1978). Rhiner, Ferrell, Ferrell, and Grant (1993) found that only 8% of their sample of elderly patients selected relaxation as an intervention for pain compared with 50% selecting distraction; however, music was included with distraction. When relaxation was selected, it was not rated as effective for pain (rated 1 on a 0-4 scale), whereas distraction was rated 3.9. In other studies, relaxation was preferred. In their studies, Arathuzik (1994) and Graffam and Johnson (1987) taught their subjects both relaxation and visualization. In both instances, relaxation was preferred by more of the subjects. Self-selected music was tested in several studies and may hold particular promise for more debilitated or acutely ill patients because it requires less effort and attention than progressive muscle relaxation exercises or guided imagery.

Most of the studies reviewed demonstrated that psychoeducational interventions had at least a small beneficial effect on pain in adults with cancer (d = 0.2). Although this is very encouraging, conclusions drawn from this research must be tempered by concerns about the methodologic and reporting quality of studies, which are not merely of academic concern. The gold standard for judging treatment effectiveness typically involves reviewing the outcomes of many large, randomized, double-blind placebo trials; however, when few such studies exist in a research base, consumers must judge the merits of the studies available. When evaluating the study design and research report, some factors tend to limit the generalizability of study results (e.g., small sample size, poor description of subject characteristics), whereas other factors tend to increase or decrease estimates of treatment effectiveness (e.g., failing to have a concurrent, randomly assigned control group; having a floor effect on pain). The variety of such factors must be considered when deciding how much confidence to have in each study's results.

Research Implications

Concern about the methodologic and reporting quality of clinical research is neither new nor unique to nursing. This concern is evidenced in the Consolidated Standards of Reporting Trials (CONSORT) statement (www.consort-statement .org). Initially issued in 1996 and revised in 1999, the CONSORT statement includes a checklist of 22 items that were selected because they have been associated with biased estimates of treatment effect. Tools of this nature can help researchers design better studies as well as report them in a more interpretable manner; as a result, they will be able to provide research consumers with the framework in which to assess reported research.

Beyond the obvious methodologic issues of sampling and measurement, the practical difficulties involved in conducting pain research in adults with cancer are well acknowledged (Kerr, 1995). Cancer is not a single disease, and pain associated with it often is complex in nature. Pain in patients with cancer may be caused by a tumor, the cancer treatment, or a comorbid condition. Patients with cancer frequently experience pain from two or more sources. For example, among 200 patients in a cancer pain clinic, Banning, Sjogren, and Henriksen (1991) found that 75% of patients had pain from two or more causes. Twycross and Fairfield (1983) reported that 80 of 100 patients with cancer in hospice had pain in two or more anatomically distinct sites. This level of complexity in the pain phenomena is difficult to control or account for in research. The optimal intervention could vary with the type of pain (e.g., nociceptive versus neuropathic), and certainly it is not reasonable to assess only one level of pain intensity when multiple pains are present. Other difficulties can arise when a study's duration must be shortened because individuals with advanced disease become too ill to continue participation, when elements of the experimental treatment are included in usual care, or when an effective alternate treatment (e.g., a change in analgesics) is provided to subjects, thus leading to a floor effect on the outcome pain. Alternate treatments are to be expected because individuals in clinical trials have pain and need treatment for it. Usual care for the setting cannot be withheld and is likely to include some psychoeducational interventions (e.g., education about analgesics, coping strategies, booklets on distraction or relaxation), as well as an analgesic regimen that would be modified if patients' pain remained high. Research also suggests that many patients treat their own pain with psychoeducational interventions without having been taught these interventions. Dalton (1987) reported that 50% of subjects used nonpharmacologic interventions (including massage and distraction) to control their pain. Gaston-Johansson et al. (2000) found that prior to the experimental intervention, 35% of subjects reported using relaxation. Arathuzik (1991) reported that 20 coping strategies were used by 20% or more in a sample of 80 women. These strategies included remaining calm (69%), relaxing muscles (50%), visualization (48%), and putting pain out of their thoughts (41%). When various uncontrolled and undocumented interventions are used concurrently, they can obscure an experimental treatment's effect. Given this context, it is perhaps more understandable why some weaknesses (e.g., using small samples, having high attrition, using within-subject study designs, measuring only short-term effects) were so prevalent in this research. Despite the challenges inherent in research on pain, if researchers are to maximize their studies' usefulness, they must address the complex nature of the pain phenomena, as well as other therapy being used for pain, and describe both in their research.

Clinical Implications

Clinicians must make decisions about pain management based on the best available knowledge. First and foremost, psychoeducational interventions tested in this research were designed as an adjunct to analgesics and not as a substitute for them. Many psychoeducational interventions are wellknown to clinicians even if they are not always systematically implemented in all healthcare settings. Clinicians should examine the usual care in their settings, patient outcomes related to current pain management, and the research that is most relevant for their clinical practice. In reviewing the relevant research, clinicians must consider both the methodologic quality of the research as well as the study results. This information will help clinicians identify areas of clinical practice in need of improvement and relevant interventions that have a sufficiently strong research basis to make them worth including in clinical practice.

When examining interventions, healthcare providers must read treatment descriptions carefully because consistent relationships do not always exist between the treatment label and the treatment content. For example, Syrjala et al. relabeled the same content from hypnosis in their 1992 study to relaxation and imagery in their 1995 study to promote patient acceptance. The researchers suggested that hypnosis is not substantially different from relaxation and imagery. Similarly, notable differences were found in the various treatments labeled guided imagery. Most of the cognitive-behavioral interventions were audiotaped. Issues related to matching the intervention strategy to patients' preferences and beliefs are well discussed elsewhere (van Fleet, 2000). Although no adverse consequences from relaxation or imagery were reported in the studies reviewed, concern about using these interventions with individuals who have a history of psychiatric disorders has been discussed elsewhere (van Fleet).

Some interventions tested included only a single type of content (e.g., a relaxation audiotape), and some were multidimensional treatment packages (e.g., education plus coping strategies, goal setting, relaxation, and imagery). Typically, multidimensional treatments were provided over several weeks or were provided prior to hospitalization for bone marrow transplant (e.g., prior to the time when pain was anticipated). This difference points out the importance of considering the amount of pain patients are experiencing when selecting psychoeducational interventions to recommend. If the treatment is too burdensome, patients may not be able to comply with it.

Given the subjective and changing nature of pain and the fact that some psychoeducational interventions may be more acceptable to patients than others, clinical judgment is key. Clinicians must select which intervention(s) to recommend to patients. Research should inform, but it never can replace clinical judgment. No matter how much evidence exists that a treatment is usually effective, if it is not acceptable to patients or is not effective in reducing patients' pain, clinicians should change or modify the intervention until a satisfactory response is obtained. Appropriate use of analgesics is critical, and a reasonable research basis exists for several psychoeducational interventions; therefore, clinicians have many options. A thorough assessment including the current pain management plan as it is being implemented, the nature of the pain experienced, and what patients have found to be effective in the past may help clinicians decide how pain management might be improved.

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For more information \dots

- ➤ American Alliance of Cancer Pain Initiatives www.aacpi.org
- ➤ Cancer-Pain.org www.cancer-pain.org
- ➤ Talaria www.talaria.org
- ➤ World Health Organization www.whocancerpain.wisc.edu

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