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Patient training in cancer pain management using integrated print and video materials: a multisite randomized controlled trial

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Abstract

Standard guidelines for cancer pain treatment routinely recommend training patients to reduce barriers to pain relief, use medications appropriately, and communicate their pain-related needs. Methods are needed to reduce professional time required while achieving sustained intervention effectiveness. In a multisite, randomized controlled trial, this study tested a pain training method versus a nutrition control. At six oncology clinics, physicians (N=22) and nurses (N=23) enrolled patients (N=93) who were over 18, with cancer diagnoses, pain, and a life expectancy of at least six months. Pain training and control interventions were matched for materials and method. Patients watched a video followed by about 20 minutes of manual-standardized training with an oncology nurse focused on reviewing the printed material and adapted to individual concerns of patients. A follow-up phone call after 72 hours addressed individualized treatment content and pain

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communication. Assessments at baseline, one, three, and six months included barriers, the Brief Pain Inventory, opioid use, and physician and nurse ratings of their patients' pain. Trained versus control patients reported reduced barriers to pain relief ($P<.001$), lower usual pain ($P=.03$), and greater opioid use ($P<.001$). No pain training patients reported severe pain (>6 on a 0–10 scale) at one-month outcomes ($P=.03$). Physician and nurse ratings were closer to patients' ratings of pain for trained versus nutrition groups ($P=.04$, $P<.001$ respectively). Training efficacy was not modified by patient characteristics. Using video and print materials, with brief individualized training, effectively improved pain management over time for cancer patients of varying diagnostic and demographic groups.

1. INTRODUCTION

All cancer pain guidelines include a mandate for patient education within standard practice (Agency for Health Care Policy and Research 1994; DuPen et al 1999; Grossman et al 1999; Miaskowski et al 2005). Studies argue convincingly that improved cancer pain treatment depends in part on training patients, as well as physicians and nurses, to understand treatment options (Cleeland et al 1994a; DuPen et al 2000; Miaskowski et al 2001), to communicate effectively about pain and its treatment (Kimberlin et al 2004; Von Roenn et al 1993), and to use opioids appropriately (Ersek et al 1999; Schumacher et al 2002; Von Roenn et al 1993; Ward et al 1993).

Patient pain training is neither new nor unproven. However, effective strategies are needed that have sustained impact while requiring feasible amounts of professional time. Clinical trials document the efficacy of patient education in improving cancer pain knowledge (Chang et al 2002; deWit et al 1997; Lin et al 2006; Wells et al 2003) and outcomes (Devine 2003; Miaskowski et al, 2004; Oliver et al, 2001), although these efforts are not universally successful in reducing pain (deWit et al 1997; Ward et al 2000). Nearly all clinical trials have had relatively brief endpoints of two to six weeks, whereas cancer pain often continues for much longer.

A barrier to the adoption of routine patient pain training is the professional time required. Furthermore, it is difficult for educators to consistently repeat the same core information that all patients require. While changing content helps to maintain the involvement of trainers, variations can lead to patients receiving incomplete information. Alternatively, repetition results in disinterested trainers 'going through the motions' without ensuring that learning and not just teaching has occurred. Print materials reinforce face-to-face training, sometimes with audiotapes and sometimes including caregivers in training (Clotfelter 1999; Ferrell et al 1993; Ferrell et al 1995; Lin et al 2006). Videos or DVDs help both providers and patients by presenting information in a standardized yet engaging manner, allowing face-to-face time to be individualized. Videos have been used in clinical trials with varying, modest success (Anderson et al 2004; Clotfelter 1999; Keefe et al 2005; Wells et al 2003). The challenge is to determine methods and materials that optimize professional time while achieving sustained, effective cancer pain control.

This study tested a training procedure designed to ensure that content and presentation were standardized, while professional time was conserved for addressing individual patient needs, based on psycho-educational principles (Devine 2003). Administration was targeted to 'learnable moments', when patients had cancer-related pain, but were healthy enough to learn and apply new information. We hypothesized that, compared with the active control, patients who watched the pain video and received the handbook, followed by individualized training, would 1) have fewer barriers to treatment, 2) report lower pain, and 3) be more likely to take prescribed opioids over the six-month follow-up than patients who received similar training

on a non-pain topic. We also hypothesized that trained patients would communicate their pain levels more directly to their physicians and nurses, thereby improving the professionals' knowledge of their patients' pain levels, leading to improved pain treatment.

2. METHODS

2.1 Participants

2.1.1 Sites—Twenty-two oncologists and the 23 nurses who work with them at six urban and rural regional oncology clinics consented to participate and to enroll eligible patients in the randomized clinical trial of pain or nutrition training. The six sites included oncology clinics in 1) an urban private medical center, 2) an urban public university medical center, 3) an urban HMO, 4) a small urban private practice clinic, 5) a small suburban private practice clinic, and 6) a mid-sized rural medical center. Each site included at least two oncologists and nurses, and each oncologist had at least two patients who participated.

2.1.2 Physicians and Nurses—Participating physicians and nurses completed descriptive information after consenting to study participation.

2.1.3 Patients—Inclusion criteria for patient entry to the study were: 1) cancer diagnosis with disease-related persistent pain; 2) life expectancy of at least six months; 2) ambulatory functional status; 3) cancer treatment expected to be stable over the next six months; 4) age over 18; and 5) English reading and writing proficiency adequate to participate in the intervention and assessments. Exclusion criteria included active alcohol or other substance abuse and major psychiatric diagnosis for which treatment was being received. Of 226 patients screened, 93 met eligibility and consented to participate, 15 declined consent (Figure 1).

2.2 Procedure

2.2.1 Overview—Materials were developed specifically for this randomized controlled trial targeting ambulatory cancer patients with disease-related pain who were expected to live at least for six months. The Institutional Board (IRB) of the Fred Hutchinson Cancer Research Center and each IRB for the participating institutions approved the study protocol and human subject consents. After physicians and nurses consented to the study and provided baseline information, the investigators briefly reviewed the rationale for the study with each clinic site and the physicians and nurses viewed the patient materials and reviewed how the material would be used with patients. These sessions lasted 30 to 60 minutes. All physician/nurse partners were given a set of pain and nutrition materials.

Oncology research nurses for the study traveled from the coordinating center to the sites to work with each institution's participating nurses and physicians to identify eligible patients. Patients were contacted by phone by the research nurse to set up an appointment for consenting. At that time patients were told that the study was "about training doctors, nurses, patients and their families about ways to help cancer patients feel more comfortable." To reduce potential demand characteristics, patients were told that they would be randomly assigned to receive information and materials either about nutrition or about managing physical problems. Following consent and baseline assessment by a study research nurse at either the clinic site or the patient's home, patients were stratified by institution and ethnicity, and were randomly assigned in blocks based on stratifications to one of the two intervention groups. The intervention was provided in a second session within a week of the baseline assessment by a second research nurse. Surviving patients completed outcome assessments at one, three and six months after the intervention with the research nurse who did the patient consenting and baseline assessment. MD/RN pairs completed pain and medical status reports on their patients at the same time points.

For blinding, physicians and nurses were not informed of patient randomizations, but patients potentially could reveal their randomization by bringing study materials to medical appointments. This occurred infrequently. The five research nurses on the study all provided patient training and assessments. However, the assessment nurse assigned to a patient was not told the randomization. Patients were asked not to inform the assessing nurse of their group assignment.

2.2.2 Material Development—Contents of the print materials and video were determined through consensus meetings of an expert advisory panel of cancer clinicians in the community including: medical oncology, radiation oncology, anesthesiology, neurology, hospice/palliative care oncology, nursing, social work, and psychology. After content was outlined, materials were written and the video produced. Print materials were sent to 32 national leaders in the field of cancer pain management for review, editing and any other recommendations, with appropriate revisions made in response to these extensive reviews.

The materials and method were designed for routine use in ambulatory practice by nurses and physicians. The 15 minute videotape provided basic information applicable to all patients, primarily through a vehicle of cancer patients with pain talking about their experiences with treatment (Syrjala et al 1997b). An accompanying handbook reiterated the video content, but with more detailed information (Syrjala et al 1997a). The reading level was targeted to sixth grade, although it was necessary to use some medical terms beyond that level. The handbook was intended as a resource for pain and related symptom questions or needs that might arise over the course of cancer care, and as a quick source for information that might have been forgotten or that the patient wanted others in their family to see. The handbook was organized into 4 sections: “What You Want to Know” addressed common barriers to pain relief, awareness of the wide variety of treatment options available, and essential components of communication with physicians, “Side Effects” described prominent pain treatment-related symptoms that can disrupt treatment and what to do about them, “Things to Tell Your Doctor” provided a one-page symptom checklist for rapid screening of issues for the nurse/physician to focus on during an appointment, “Treatments” provided a chart and cards for each of 26 common medications and other pain treatments. The treatment section was designed with removable cards and a box provided to each nurse/physician pair to hand out cards to patients as they prescribed a medication. The removable cards were designed to reduce the volume of paperwork given to patients to those materials pertinent to their care. Since nurse/physician pairs were blinded to randomization assignments, we allowed them to give cards to any patients on the study without discriminating whether the patient had received pain or nutrition content.

Nutrition materials were designed to match the pain materials in that there were print and video contents, and the study nurses individualized the focus to the expressed needs of each patient.

2.2.3 Patient Intervention—Pain or nutrition training occurred at the patient’s medical clinic, during a scheduled oncologist appointment, or at the patient’s home if the patient was not planning to be at the clinic in the required time frame of a week after baseline. Over half of the trainings (57%) occurred at the oncology clinics. Materials needed were a VCR, the video, the printed material, and paper and pencil for any questions the patient might wish to remember. Duration of the training was 30 to 45 minutes, including the patient’s viewing of the 15 minute video.

2.2.3.1 Pain training: The pain training included watching the videotape and reviewing the content of the handbook with the nurse while focusing on individual patient concerns. At the start of the training, the patient completed a checklist specifying which of 8 common barriers to pain relief the patient had ‘wondered about.’ The patient then viewed the videotape. The nurse next paged through the handbook to familiarize the patient with what material was

available in this resource. During this brief review, the nurse pointed out the information that the patient had ‘wondered about’ on the checklist, and helped the patient apply the information to his or her own situation. The nurse then had the patient complete the ‘Things to Tell Your Doctor’ assessment checklist and demonstrated that copies of this sheet in the handbook could be used to provide rapid communication related to pain and symptoms that the doctor would need to know. The nurse encouraged the patient take the checklist to the next doctors’ appointments, and to take in a new checklist whenever a new pain occurred, when pain was not well controlled, or when other symptoms occurred. All specific treatment questions were referred back to the patient’s physician or nurse by saying “that is an important question to ask your doctor; will you be able to call him/her today or will you be able to ask the doctor at your next appointment?”

2.2.3.2 Nutrition training: The nutrition materials were matched to the pain training in materials, procedure, and time frame. The video was approximately the same length (15 minutes) as the pain video, the nutrition print materials were somewhat longer, the face-to-face time had the same procedure for identifying individual concerns and required the same duration of face-to-face professional time. Patients watched a video developed for cancer patients by the Fred Hutchinson Cancer Research Center Nutrition Department, and received printed materials on nutrition prepared by the National Cancer Institute (U.S. Department of Health and Human Services 1992) and by oncology nurses who participated in the study. After the patient viewed the nutrition video, the nurse reviewed the nutrition print materials with the patient and identified nutrition issues important to the individual. These issues included how to get adequate nutrition without an appetite, how to select easy nutritious foods to prepare when fatigue is a barrier, or even how to microwave a potato. As with the pain training, specific treatment questions were referred back to the patient’s physician or nurse.

2.2.3.3 Follow-up Training: After 72 hours, patients in both the pain and nutrition groups were contacted by phone as a follow-up to the training. The goal of the follow-up was to reinforce the learning from the training. Content included having the patient rate pain, nausea and eating symptoms again, checking whether the patient had looked at any of the training material, asking whether the patient had any questions, and checking whether treatment questions had been called in or taken to the patient’s physician or nurse. This call lasted about 10 minutes.

2.2.4 Measures—Patients completed a baseline assessment prior to randomization and intervention. Survivors whose health status was adequate to continue participation completed outcome assessments at one, three and six months either in their homes or at their oncology clinic, depending on patient preference. An assessment research nurse remained with patients during the assessments to assure that patients were able to complete forms, and that family did not assist patients with their assessments. While all forms were in paper and pencil format, if necessary because of fatigue, the nurse read questions while the patients looked at a large-print set of response options. At the start of the study, nurses were trained to administer the forms using standardized introductions, procedures and responses to patient questions.

Outcome variables included self-report measures and medication use. The *Barriers Questionnaire (BQ)* assessed beliefs that can be barriers to adequate treatment for cancer pain (Ward et al 2000; Ward et al 1993; Ward et al 1994). The BQ is a validated and reliable measure with 24 items which are answered on a scale from 0 = ‘disagree very much’ to 5 = ‘agree very much’, with a mean score calculated. Internal reliability with this sample of patients was $\alpha = 0.81$. The *Brief Pain Inventory (BPI)* assessed usual pain, worst pain and interference with function caused by pain, each responded to on numerical rating scales from 0–10 (Cleeland et al 1994b; Cleeland 1989; Serlin et al 1995). The BPI is a widely used, well-standardized instrument for evaluating multiple dimensions of pain. The *Memorial Symptom Assessment*

Scale (MSAS) assessed general symptom severity. This measure has established reliability and validity and assesses common symptoms in cancer patients using a scale from 0 = 'not at all' to 4 = 'extremely' (Portenoy et al 1994). To be certain that side effects specific to analgesic treatment were adequately assessed, we added questions on the side effects of interest including constipation, nausea and vomiting, sedation, and eating (to assess possible effect of the nutrition intervention and for face validity in the control intervention). The added questions assessed intensity, bothersomeness, frequency and duration of the symptom. A symptom severity mean score was calculated from the combined original and added items on this modified MSAS, with possible range from 0-4. Reliability for the overall modified MSAS was $\alpha = 0.89$. The eating problems subscale included six items specific to issues commonly faced by cancer patients and had an internal reliability of $\alpha = 0.82$. Through patient interview and viewing medications when possible, research nurses recorded medications and other treatments taken for pain or symptoms including drug name, dose, route, and schedule. For opioids, these data were transformed to total daily morphine equivalent dose with equivalencies calculated from tables in *Cancer Pain Guidelines* (Agency for Health Care Policy and Research 1994).

At each time point that a patient was assessed, the patient's physician and nurse were asked to rate the patient's usual and worst pain on the same 0-10 scale used by patients.

Covariates included the *Functional Assessment of Cancer Therapy-General (FACT-G)*, *ECOG Performance Status*, and basic demographic information. The FACT-G assessed 28 aspects of patient physical, social, emotional and functional status. This measure has established reliability and validity and is widely used in cancer clinical trials (Cella et al 2002; Cella et al 1993). The FACT-G provided a control for confounds from non-pain health-related quality of life factors. For instance patients with poorer FACT-G scores, whether or not they have greater pain or other symptoms, may have reduced ability to learn during pain training. Also important, the FACT-G permitted description of quality of life differences or similarities between the pain and nutrition groups as evidence of the success of randomization. The research nurses rated the ECOG Performance Status (Cleeland et al 1994a) after patient assessments and chart review. It assessed functional status from 0 = 'fully active' to 4 = 'completely disabled'. Research nurses collected from each patient's chart baseline information on diagnosis, stage of disease, and etiology of pain. At each assessment point, the research nurse attempted to determine from the chart which medications were prescribed at that time, concurrent medical diagnoses or problems.

2.3 Statistical Methods

Analyses were performed using SPSS 10.0 for Windows and STATA 6.0 for Windows. Distributions of scores were examined for normality. The total daily morphine equivalent dose was log-transformed because of its skewed distribution at all assessment times. For each post-baseline assessment the outcome variables were re-expressed as a difference from baseline (1 month, 3 month or 6 month outcome minus baseline). The patient's usual pain and worst pain scores were analyzed both as differences from baseline (continuous variables) and as dichotomous variables indicating severe pain (7-10 score) versus mild to moderate pain (0-6). In order to assess the main effect of the pain training versus control on outcome variables, the regression model included the intervention (pain training versus control, as a dichotomous variable), the baseline value of the dependent variable, and time (as a categorical variable). For the dichotomous dependent variables, severe usual pain and severe worst pain, the continuous form of their baseline variables was used as an independent variable. Analyses were carried out using generalized estimating equations (GEE) to take account of the statistical dependence of the multiple observations over time for each patient and varying duration of observations for patients (Diggle et al 1994). If group assignment was significantly associated with an

outcome variable, the interaction of the group variable and time was also tested to assess whether the effect of the pain training versus nutrition might vary over time.

The association of each outcome variable with patient characteristics was also determined. Characteristics evaluated were age, gender, education (years completed), ethnic group (white versus non-white), marital status (married versus all others), pain due to treatment (versus due only to disease), diagnosis (grouped as breast, colorectal, gynecologic, all others), stage (local, regional, metastatic/systemic), institution providing care (6 institutions), baseline performance status and overall quality of life (FACT-G). Each covariate was evaluated in either a linear or logistic regression model predicting each outcome including the specific covariate, time as a categorical variable, the baseline level of the outcome variable and the dichotomous intervention group variable. If a covariate was significantly associated with an outcome variable, the model was expanded to include a covariate by group interaction to determine if the effect of the intervention differed across levels of the covariate (simple model).

A final model for each outcome variable was calculated by a backward elimination process starting from a model that included intervention group, time, baseline value of the outcome variable, any covariates that had a significant association with the outcome variable in a simple model, and any interaction terms that had been significant in simple models. The time and intervention variables and the baseline value of outcome variables were retained in the final models along with any covariates and interactions that remained significant after the backward elimination process.

3. RESULTS

3.1 Participant Characteristics

Among referring and participating physicians, all but one specialized in oncology and all but four of the 45 physicians and nurses had been practicing in oncology for at least 5 years (Table 1). The number of enrolled patients per physician ranged from 2-11 with a median of 4.

From the original sample of 93 enrolled patients, 78 (84%) completed one month outcome assessments; 63 completed three month assessments, and 49 (53%) completed the six month assessment (Figure 1). All patients who did not complete the study were lost because of death or end stage illness leading to death, with the exception of three patients who requested to drop the study and one patient dropped because of cognitive impairment. All patients who did not finish the study, including voluntary dropouts, had expired by the next scheduled assessment. Six-month survival was similar in the two intervention groups with 54% surviving in the pain training and 51% in the nutrition control ($P = .58$, log rank test). Ten patients with no outcome data were in the nutrition control with five in the pain training (10 vs. 5; Chi-squared = 1.67, ns). The association between intervention group and outcome measures was analyzed using the 78 patients with at least a one-month assessment.

Table 2 describes the patient participants who did and did not participate in at least one outcome assessment for the clinical trial. No baseline differences distinguished the participants randomized to the two groups or for whom there was no outcome data, with the exception that patients with no outcome data were older than nutrition patients with outcome data. Patient diagnoses were diverse. Breast cancer was most common, followed by colorectal, lung, gynecologic cancers, and multiple myeloma. Other diseases included leukemia, sarcoma, prostate, bladder and pancreatic cancer, lymphoma, and melanoma. Most patients had metastatic or advanced disease, but about a quarter did not. All had pain as a result of cancer, with some also having pain from treatment (26%). Patients in the two randomized groups did not differ across time on ECOG performance status or FACT-G scores.

3.2 Intervention Outcomes

Among the ten outcome variables considered (two of which were dichotomous versions of the two pain scores, worst and usual pain) six had statistically significant associations with the intervention group (Table 3). All six associations between intervention and the outcome variables were significant both in the simple models including only time, intervention and the baseline value of the outcome variable, as well as in the final models, including covariates, indicated in Table 3.

The pain training group had a greater average decrease from baseline in barrier beliefs about cancer pain than the nutrition group, by 0.3 points ($P < .001$; Figure 2) and a greater average decrease in usual pain, by 0.8 (SD 1.7) points ($P = .03$; Figure 3). This difference exceeded the ‘minimum important difference’ marker of 0.2 SD (Guyatt et al 2002;Cohen 1988). At one month, the mean difference between groups of 1.0 (SD 2.0) on the 0-10 scale, met the ‘clinically meaningful difference’ of 0.5 indicating a moderate effect size (Norman et al 2003). While the two groups began with equivalent levels of pain, at one month after training, the group randomized to pain training reported 25% lower mean pain than the nutrition control. As seen descriptively in Figure 3, mean usual pain differences between groups were greatest at one month and declined gradually thereafter. While significantly different at one month and in the overall GEE analysis, group comparisons were not significant at six month time point. The nutrition group had no significant effect on reports of eating problems.

The pain training, compared to the control, had a greater narrowing of the gap between the physician’s assessment of usual pain and the patient’s self-assessment of usual pain compared to baseline by 0.9 points ($P = .04$; Figure 4a). Similarly, the pain training group had a greater narrowing of the gap between the nurses’ assessment of usual pain and the patient’s self-assessment compared to baseline by 1.5 points ($P = .001$; Figure 4b). Finally, the pain group used higher doses of opioids than the nutrition group ($P = .001$; Figure 5), as indicated by a model-based mean difference of 0.3 on the log scale. The log scale ratio of opioid dose between the pain training and nutrition groups increased over time, relative to the ratio at baseline, with ratios of 1.1, 2.0 and 3.1, for months 1, 3 and 6, respectively. The pain training effect on opioid use differed significantly, also, between those whose pain was due to treatment versus those whose pain was due to other etiology, primarily due to disease ($P = .009$). In the nutrition group, post-baseline opioid use dropped among those whose pain was due to treatment compared to those whose pain was due primarily to disease, with a ratio of opioid dose in these two pain-source groups of 0.28 of the ratio at baseline. In the pain training group, however, the corresponding ratio was 0.76, closer to unity.

When usual pain was cast in the dichotomous form of severe versus mild to moderate pain, the difference between the pain training and nutrition groups was again statistically significant ($P = .03$) with the odds of having severe usual pain in the control group 6 times greater than the odds in the pain training group, though with a wide 95% confidence interval for this odds ratio (1.2 to 32.7). No patients in the pain training group reported usual pain above a 6 on the 0-10 scale at one month outcome vs. 6 patients (17%) in the control group. This distinction was not maintained at 3 and 6 months. There were not significant associations between the groups on the outcomes of worst pain (continuous, $P = .5$, or dichotomous, $P = .6$), pain interference with function ($P = .1$) or overall symptom severity ($P = .5$).

3.3 Interactions with Outcomes

Among analyses of covariate relationships with outcomes, only the log opioid dose demonstrated a significant interaction between intervention and a covariate (described above for pain due to treatment). No other covariate significantly modified the intervention effect. However, other outcomes did show some significant associations with covariates across the

intervention groups. The institution providing care was significantly associated with the change in barriers to pain treatment from baseline, with a range of 0.75 points among the six institutions ($P < .001$). No pattern in this institution change could be discerned. The change in worst pain from baseline was two points higher (toward greater pain) for non-whites than for whites ($P < .001$). The change in the pain interference score was two points larger for non-whites than whites ($P = .02$) and varied by a range of two points across institutions ($P < .001$). When worst pain was classified as severe versus mild to moderate pain, non-whites were much more likely to report severe pain than whites, with an odds ratio of 18.4 ($P = .009$, 95% C. I. for the odds ratio: 2.1 to 56.3). There were no significant associations between any of the covariates considered and the outcomes of usual pain, patient-minus-physician evaluation of usual pain compared to baseline, or usual pain classified as severe versus less than severe. Decline in barriers, absolute barrier score, opioid dose, and change in opioid dose did not directly correlate with any pain levels ($P > .10$ for all tests).

4. DISCUSSION

Patient pain training significantly reduced usual pain and barriers to pain relief in cancer patients as predicted. Efficacy was achieved in part it seemed through improved patient-physician and patient-nurse communication about pain intensity, as well as increased use of opioids in the pain training group. Compared with patients who received nutrition training, those receiving pain training reported 25% lower usual pain ratings on average at one month. No patients in the pain training reported severe pain (above a 6 on a 0-10 scale) one month after the intervention, unlike the control group. Relevant to generalizability, the training was equally effective for patients regardless of age, gender, diagnosis, stage of disease, etiology of pain, health status of the patient, or site of clinical care. No difference in effect based on race was found either, but the sample was largely Caucasian, non-Hispanic. Other studies have found it more difficult to meet the pain management training needs of African American and Hispanic cancer patients using similar methods (Anderson et al 2004). Also important, training effectiveness decayed somewhat by six months suggesting that clinical follow-up and assistance with adaptation to changes as disease progresses may be essential to durability of the training. Other studies have documented a requirement of at least a month for 'maturation' of treatment efficacy (Lin et al 2006), but we noted only one study that followed patients for six months to document maintenance or erosion in effects with time (Wells et al 2003).

The efficacy of this study, as reflected in reduction of both barriers and pain level, has not been seen in some other studies that used similar methods. Success with this procedure may be attributable to the extensive tailoring of the video and handbook to specific training targets and then individualizing training to patient needs using a manualized procedure. Other studies have used videos to standardize pain training. They have reported improved knowledge and self-efficacy, but less success in reducing pain (Clotfelter 1999; Keefe et al 2005; Wells et al 2003).

Our results are consistent with other studies, using different methods, that have found that usual pain and barriers could be reduced with educational efforts, but worst pain and interference of pain with activities have been more difficult to impact (Agency for Health Care Policy and Research 1994; Chang et al 2002; DuPen et al 2000). Some studies have reported success in reducing worst pain when using longer training periods and more extended professional time in training (Lin et al 2006; Miaskowski et al 2004). Worst pain may be more difficult to treat because of its fluctuating and sometimes very brief nature. On the other hand, opioids are the mainstay of analgesics for moderate to severe pain and consequently are the focus for many guidelines and training efforts, including the pain training in this study. Opioids target primarily usual pain and longer duration breakthrough pain. More specifically targeted intervention may be needed to reduce worst pain, interference and side effects of pain treatment. Overall, our

results suggest that brief patient training is highly specific and does not generalize to seemingly related outcomes.

Several difficulties in use of the study materials and in clinical management of cancer pain problems became evident in evaluating these patients over time. We did not see chart evidence that participants used the symptom checklist or the treatment record designed for tracking medications. Similarly, physicians and nurses rarely handed out medication cards as treatments changed. Reinforcement for routine tracking of medications and symptoms may need to come from patients' personal physicians or nurses or may require more training. Patients and physicians not only need to learn how to communicate about pain, but also need to communicate more effectively about analgesics, analgesia-related side effects and pain interference with sleep or activities. We found that many patients were placed on appropriate sustained release analgesics and given immediate release breakthrough medications, but the doses of sustained release medication were not re-evaluated as pain changed. Thus patients might continue indefinitely on the same dose and schedule of sustained release medication, while breakthrough doses increased several fold. Side effects were a common reason for discontinuing analgesics according to patients. Yet they frequently had not told their physicians about the side effects or that they had stopped analgesics, consistent with findings of other adherence research (Ersek et al 1999; Miaskowski et al 2001). In sum, communication can be improved through patient training, but patients will still depend on their physicians and nurses to determine which tools are useful and to reinforce utilization of communication strategies.

Future efforts that combine patient and provider targeted methods may improve these broader long term outcomes (Allard et al 2001; DuPen et al 2000). The methods tested in this study may be more effective and the outcomes more sustained if provided by, and reinforced by, the clinic nurses and physicians where patients receive treatment. This clinic integrated approach could assist patients in applying the training information when disease progresses and as treatment or side effects change. While we believe that the opportunity for reinforcement and follow-up from patients' health care providers might help to maintain the effectiveness of training, we also note that intensity and repetition of educational content has not, in itself, ensured improved outcomes. Other pain education studies of longer intervention duration or covering more targeted areas than our training have found less consistent pain relief effects (deWit et al 1997; Ferrell et al 1995; Keefe et al 2005). This may be a case where fewer targets for training result in better outcomes, although more extensive training has, in some cases, shown broadly improved pain outcomes although over a shorter follow-up period (Miaskowski et al 2004).

Some strengths of this randomized trial include the diversity of oncology clinic sites participating, along with the varied disease and demographic characteristics of patients enrolled. The study design included integrated video, print and training content, as well as multiple time points over a long duration of follow-up and a high rate of survivor data completion. Our ability to blind study staff and to use a manualized treatment with a method-matched active control also strengthened the treatment design.

Several study limitations should be considered. The randomized cohort may not equally generalize to all types of cancer patients. In particular, there were few non-white or Hispanic participants and the study was targeted to patients with advanced disease. The study implementation could not assure complete blinding to randomized assignment within the clinic settings. Some contamination across the two groups was suggested by slight (non-significant) improvements on all outcomes in the nutrition group at one month. Based on control patient comments, assessment in itself may have provided communication teaching for some attentive control patients. Also, physician and nurse site training and exposure to the study materials could have temporarily changed practice. However, the limited clinic use of the provided study

materials suggests that busy oncology clinics, without symptom case managers, may have difficulty applying the intervention with consistency. The large number of hypotheses tested for associations of patient characteristics with outcomes has not been adjusted for multiple testing, because adjustments such as the Bonferroni method are too conservative when there are repeated measures with numerous analysis steps. Power to detect real associations would be decreased with these adjustments. In particular, with the multiple outcomes tested, those above $P=.01$ are especially important to replicate or determine methodologies to strengthen. It is possible that some of the less significant covariate associations with outcomes are due to chance given the number of analyses.

These data document positive outcomes from including a patient training component in standard practice guidelines for cancer pain. Patient training using integrated video and print materials conserve health care professional time, while providing assurance that all cancer patients with pain receive necessary core information. This allows face-to-face time to be individualized to cancer patient needs and can have sustained benefits on pain relief.

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Figure 1.
 Flow diagram of patient progress through the study.

Figure 2. Mean barriers to pain relief scores, with standard errors, by intervention group over time from baseline, pre-randomization, to six-month outcome evaluation.

Figure 3. Mean usual pain rating, with standard errors, by intervention group over time from baseline, pre-randomization, to six-month outcome evaluation.

Figure 4.

Mean difference between patient rating of pain vs. (4a) physician rating of the patient's pain, and (4b) nurse rating of the patient's pain, by intervention group over time with standard errors. Possible score range is -10 to 10.

Figure 5.
Mean daily opioid use, in morphine equivalent doses with log transformation and standard errors, by intervention group over time from baseline to six-month outcomes.

Table 1

Participating Oncology Physician and Nurse Characteristics

	RN	MD
N	23	22
Age, mean (SD)	43 (7.40)	45 (8.70)
Gender, n (%)		
Male		18 (82%)
Female	23 (100%)	4 (18%)
Race/Ethnicity, n (%)		
Caucasian	21 (91%)	20 (91%)
Hispanic	1 (4%)	
Asian		2 (9%)
Other	1 (4%)	
Degree/Training Specialty, n (%)		
BSN/BA	12 (52%)	
RN	4 (17%)	
Associate Degree/Other	7 (30%)	
Medical Oncologist		19 (86%)
Radiation Oncologist		2 (9%)
Other		1 (5%)
Years in Oncology Practice, mean (SD)	11.43 (3.90)	14.18 (9.40)

Table 2

Patient Characteristics by Intervention Group

Covariate or Outcome Measure at Baseline	Pain Training ^a	Nutrition Control ^a	Patients with No Outcomes ^b
N at randomization	48	45	15
N with outcomes	43	35	0
Age, mean (SD)	57.77 (13.28)	53.37 (11.90)	62.53 (13.43)
Range	31 - 80	27 - 74	39 - 86
Gender, n (%)			
Male	18 (42%)	10 (29%)	6 (40%)
Female	25 (58%)	25 (71%)	9 (60%)
Race/Ethnicity, n (%)			
Caucasian	40 (93%)	31 (88%)	14 (93%)
African-American	2 (5%)		
Asian		2 (6%)	1 (7%)
Other	1 (2%)	2 (6%)	
Education, n (%)			
High School or Less	15 (35%)	15 (43%)	6 (40%)
Some College or College Degree	22 (51%)	16 (46%)	6 (40%)
Professional Degree	6 (14%)	4 (11%)	3 (20%)
Diagnosis, n (%)			
Breast	10 (23%)	11 (31%)	4 (27%)
Colon	3 (7%)	7 (20%)	2 (13%)
Lung	6 (14%)	3 (9%)	2 (13%)
GYN	6 (14%)	4 (11%)	2 (13%)
Multiple Myeloma	4 (9%)	3 (9%)	1 (7%)
Other	14 (33%)	7 (20%)	4 (27%)
Disease Stage ^c n (%)			
Local	4 (9%)	4 (11%)	—
Regional	5 (12%)	5 (14%)	—
Metastatic or Systemic (e.g. Leukemia)	34 (79%)	26 (75%)	—
Baseline ECOG Performance Status, mean (SD) ^c	1.30 (.77)	1.03 (.79)	—
Baseline Quality of Life: FACT-G, mean (SD)	2.24 (.32)	2.36 (.35)	2.43 (.37)
Barriers Beliefs about Cancer Pain, 0-5, mean (SD)	1.78 (.57)	1.71 (.58)	1.72 (.60)
Usual Pain on BPI, 0-10, mean (SD)	4.07 (1.62)	4.14 (1.97)	4.00 (1.56)
Worst Pain on BPI, 0-10, mean (SD)	5.74 (2.30)	5.97 (2.63)	6.47 (2.13)
BPI Pain Interference with Function, 0-10, mean (SD)	4.97 (2.33)	5.09 (2.33)	5.94 (2.08)
MSAS Symptom Severity, 0-4, mean (SD)	1.04 (.51)	1.20 (.42)	1.10 (.43)
Daily Morphine Equivalent Dose, mean (SD)	29.15 (44.10)	27.13 (60.02)	42.37 (43.28)

FACT-G, Functional Assessment of Cancer Therapy – General; BPI, Brief Pain Inventory; MSAS, Memorial Symptom Assessment Scale

^a Descriptive information for patients who completed at least one outcome assessment and so could be included in outcome analyses (pain n=43, nutrition n=35).

^b Patients with no outcomes included those from both pain (n=5) and nutrition (n=10) who did not have one month assessments and so could not be included in the outcome analyses.

^c This information not abstracted from charts for patients who had no outcome data.

Table 3Pain Training Effects,^a N=78

Outcome	Estimated Mean Difference, Pain Training minus Control Group, in Change from Baseline ($\pm$ SE) ^b	Intervention effect: <i>P</i> value	Covariates and Interactions Related to Outcomes ^a
Barriers Beliefs (BQ), 0-5	-0.32 ($\pm$.09)	< .001	Institution
BPI Usual Pain, 0-10	-0.81 ($\pm$.36)	.03	
BPI Worst Pain, 0-10	0.27 ($\pm$.38)	.5	Ethnicity, diagnosis
BPI Pain Interference with Function, 0-10	-0.62 ($\pm$.38)	.1	Ethnicity, diagnosis, institution
Total Daily Morphine Equivalent Dose (Log10) ^c	0.31 ($\pm$.09)	< .001	Intervention $\times$ time, pain-due-to-treatment, pain-due-to-treatment $\times$ time
1 month	0.06		
3 months	0.30		
6 months	0.49		
MSAS Symptom Severity, 0-4	0.05 ($\pm$.07)	.5	Disease Stage (local, regional, metastatic/systemic)
Pt – MD Difference in Usual Pain Rating, -10-10	-0.92 ($\pm$.44)	.04	
Pt – RN Difference in Usual Pain Rating, -10-10	-1.56 ($\pm$.47)	.001	Disease Stage

BQ, Barriers Questionnaire; BPI, Brief Pain Inventory; MSAS, Memorial Symptom Assessment Scale

^a Estimates of intervention effect and its statistical significance are based on the final model including intervention group (dichotomous), time after baseline (1, 3, 6 months, categorical), baseline value of the specific outcome variable, and any covariates or interaction terms significantly related to outcomes. Only for Total Daily Morphine Equivalent Dose did the covariates interact significantly with intervention effect ($P = .009$).

^b Estimated mean, example: The decrease in usual pain from baseline for the pain training group is .81 points more than the decrease in usual pain for the nutrition group, a model-based average across all times after baseline. The difference in usual pain between the pain training and nutrition control does not vary significantly over time as indicated by the absence of an intervention $\times$ time interaction term.

^c The statistical significance for the intervention effect on log opioid dose is based on the combination of terms related to intervention in the final model: intervention, intervention $\times$ time, and intervention $\times$ pain-due-to-treatment. The mean effect of pain training versus control on log opioid dose, 0.81, is based on a model including only intervention, time (categorical) and the baseline value of log opioid dose. On the natural scale of opioid dose, the log10 values correspond to a dose ratio (pain training/control) of 2.0 overall and, at times 1, 3, and 6 months, ratios of 1.1, 2.0, and 3.1, respectively.