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Cancer Health Empowerment for Living without Pain (Ca-HELP): Effects of a tailored education and coaching intervention on pain and impairment

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ABSTRACT

We aimed to determine the effectiveness of a lay-administered tailored education and coaching (TEC) intervention (aimed at reducing pain misconceptions and enhancing self-efficacy for communicating with physicians) on cancer pain severity, pain-related impairment, and quality of life. Cancer patients with baseline "worst pain" of $\geqslant 4$ on a 0–10 scale or at least moderate functional impairment due to pain were randomly assigned to TEC or enhanced usual care (EUC) during a telephone interview conducted in advance of a planned oncology office visit (265 patients randomized to TEC or EUC; 258 completed at least one follow-up). Patients completed questionnaires before and after the visit and were interviewed by telephone at 2, 6, and 12 weeks. Mixed effects regressions were used to evaluate the intervention adjusting for patient, practice, and site characteristics. Compared to EUC, TEC was associated with increased pain communication self-efficacy after the intervention ($P < .001$); both groups showed significant ($P < .0001$), similar, reductions in pain misconceptions. At 2 weeks, assignment to TEC was associated with improvement in pain-related impairment (−0.25 points on a 5-point scale, 95% confidence interval −0.43 to −0.06, $P = .01$) but not in pain severity (−0.21 points on an 11-point scale, −0.60 to 0.17, $P = .27$). The improvement in pain-related impairment was not sustained at 6 and 12 weeks. There were no significant intervention by subgroup interactions ($P > .10$). We conclude that TEC, compared with EUC, resulted in improved pain communication self-efficacy and temporary improvement in pain-related impairment, but no improvement in pain severity.

1. Introduction

Inadequate control of cancer-related pain causes suffering, impairs quality of life, and may contribute to depression, suicide, and premature death [3,15,28,29,52,67,68]. Barriers to effective pain control have been identified at the level of systems, providers, and patients and their families [8,10,53,72]. Addressing barriers at the patient level is attractive for 4 reasons. First, patients and their families are directly motivated to achieve better pain control [32]. Second, patients wield substantial influence over what physicians do [34]. Third, prior studies in both cancer [54] and other chronic diseases [20,31] suggest that expanding patient involvement in care can improve patient outcomes. Fourth, numerous randomized trials [4,11–14,19,37,39,49,57,66,69–71,73,76,78,79] and 2 systematic reviews [5,16] suggest that psychoeducational interventions may be effective in reducing perceived barriers (pain misconceptions) and improving outcomes.

Unfortunately, the magnitude of benefit derived from many psychoeducational interventions for cancer pain has been modest [5]. Most such interventions have emphasized pain control education (aimed at overcoming pain-related misconceptions),

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sometimes but not always tailored to patients' individual needs [13,73]. Few (eg, [76,78]) have focused on patient–physician communication. Extensive research has demonstrated the critical importance of patient–physician communication in achieving desired health-related outcomes [38,55,59]. Although much of this literature focuses on physician communication skills, some emphasizes the importance of patient communication skills and self-efficacy [20,31,44,45,62,63].

On the basis of this prior work, we reasoned that patients' capacity and self-efficacy for asking questions, making requests, and signaling distress to their physicians might be important in achieving better pain control. In addition, we posited that improving patients' self-efficacy for pain control would itself be associated with better outcomes. We therefore developed and piloted [54] a brief, patient-centered, tailored education and coaching intervention designed to enhance skills and self-efficacy for communicating with the cancer physician while also correcting common pain-related misconceptions. Salient aspects of the intervention included brevity, ease of delivery by trained lay health educators, tailoring to patients' specific needs and concerns, and a focus on how to communicate with the cancer physician about pain. In the current randomized controlled trial, we hypothesized that the intervention would improve pain severity, pain-related impairment, and functional status.

2. Methods

2.1. Design overview

This randomized controlled trial compared tailored education and coaching (TEC) to enhanced usual care (EUC). Methodological details have been published elsewhere [35] and are only summarized here. Patients with at least moderate baseline pain or significant functional impairment due to pain (see below) were randomly assigned to TEC or EUC during a telephone enrollment interview conducted days in advance of a planned oncology office visit (the index visit). The intervention was delivered in a private space just before the index visit. Patients were surveyed at enrollment (by phone), before and after the index visit (using self-administered questionnaires, with assistance from the research assistant as needed), and again at 2, 6, and 12 weeks (by phone). Two features of the design merit further explanation. First, we randomized patients rather than physicians or clinics because the TEC intervention is posited to act through changes in individual-level knowledge, attitudes, and behaviors, and because prior research suggests that spillover effects (resulting from a single physician caring for patients assigned to both arms of the study) are likely to be modest [21,54]. Second, we used EUC instead of usual care as the control in order to estimate the effects of activation-coaching over and above the effects of nonspecific, empathetic attention absent any coaching. The research protocol was approved by human subjects protection committees at all participating institutions.

2.2. Recruitment of study sites, physicians, and patients

Cancer care physicians practicing medical oncology ($n = 46$) or radiation oncology ($n = 3$) were recruited from 3 health systems and one private practice in metropolitan Sacramento, California. Ethics approval was granted by institutional review boards affiliated with UC Davis/Northern California Department of Veterans Affairs and with Kaiser-Permanente. Eligible patients were cognitively intact, English-speaking adults (age 18–80) with 1 of 8 cancer types (lung, breast, prostate, head and neck, esophageal, colorectal, bladder, gynecologic) who reported a score of 4 or greater (on a scale of 0–10) for "worst pain during the past 2 weeks" or pain during the same period that interfered at least "moderately" with functioning. Exclusions included a major surgical procedure scheduled within 6 weeks, enrollment in hospice, followed by a pain management specialist beyond a single consultation, and inability to receive and/or complete mailed enrollment materials. Potentially eligible patients were identified by computer-generated lists and were sent a study invitation letter along with a postage-paid opt-out postcard. Patients not returning the postcard were contacted by phone, screened for eligibility, and invited to participate. Verbally consenting patients were mailed an enrollment packet and scheduled to participate in the enrollment interview. Patients were promised a total of $80 compensation for completing the trial.

2.3. Enrollment and randomization

During the enrollment interview, patients gave verbal consent and provided information on baseline pain and health-related quality of life. They were then randomized to the TEC or EUC groups by a computer-generated blocked-randomization scheme to assure balanced assignment within physicians and encoded 3-digit treatment assignment sequences to preserve concealment.

2.4. Visit procedures

Patients were asked to arrive 1 h before their scheduled oncology appointment. Upon arrival, they were greeted by a trained health educator (HE), escorted to a quiet space, and assisted in completing written informed consent, withholding details of the assigned intervention until after written consent was obtained, to protect against differential nonparticipation bias. The HE assisted consenting patients in completing the previsit/preintervention questionnaire and then administered the assigned intervention (TEC or EUC). The TEC intervention consisted of 6 components summarized by "ACT-PReP": (1) *assess* current knowledge, attitudes, and preferences; (2) *correct* misconceptions; (3) *teach* in 2 domains (pain control and patient–physician communication); (4) *plan* by identifying goals and brainstorming about suitable patient–physician communication strategies; (5) *rehearse* using role-playing exercises; and (6) *portray* learned skills. On the basis of a model developed by Oliver et al. [54], the TEC approach uses a specific assessment of each patient's learning needs (using the Short Barriers Questionnaire, SBQ) [75] and goals/values (employing open-ended questioning as guided by training and the ACT-PReP manual) [35], to develop a set of individualized messages and skill-building exercises designed to increase self-efficacy and enhance patient–physician communication. (The ACT-PReP manual is available on request from the authors.)

As an initial step in the TEC intervention, the HE reviews information supplied by the patient as part of the baseline questionnaire, focusing on current symptoms, pain related knowledge and attitudes, and self-efficacy. In the EUC intervention, the HE verbally reviewed selected aspects of a National Cancer Institute (NCI) booklet on pain control [51], emphasizing that pain is controllable with modern treatments, pain medicines have controllable side effects, and cancer patients rarely experience addiction. The NCI booklet was also provided to TEC patients. Thus, both interventions supplied knowledge, but TEC corrected specific misconceptions, taught in the communication domain, facilitated planning, and encouraged rehearsal of new skills. HE fidelity to the assigned intervention was maintained through extensive initial training (30–40 h, until mastery was attained), regular reinforcement (several hours every 3–6 months), and structured review of audio recordings of each patient encounter using a standard checklist of 12 behaviors (eg, "asks the patient open-ended questions about misconceptions noted on previsit questionnaire," "helps patient identify primary goal for

pain management and frame the goal so it is achievable"; complete list available from the authors on request). Per session adherence to the 12 key TEC intervention elements averaged 88% (standard deviation, 16%; full range 46% to 100%; interquartile range, 77% to 100%), and adherence to the 4 EUC elements averaged 99.5%, both over 7 quarters of data collection. The most common reasons for incomplete fidelity to the ACT-PReP protocol were patient failure to identify a specific question to ask the doctor and patient reluctance to engage in role-play. After the intervention, patients completed the previsit/postintervention questionnaire, had their doctor visit, and filled out the postvisit questionnaire.

2.5. Measures

Demographic characteristics were assessed using administrative records, the screening interview, and the enrollment interview. Cancer type and stage were obtained by chart review using a standardized abstraction form. Item analysis was used to assess the internal consistency (Cronbach's alpha) of previously validated scale measures adopted for use in this study and to suggest appropriate scale modifications. To address relatively infrequent intermittent item missingness, all scale measures except for the 2 SF-12 subscales were computed as the patient's mean nonmissing response to the items for the scale for that time point, provided that at least half of those items were nonmissing [23]. This imputation was used for 6% of observations of the pain impairment scale (primarily due to nonresponse to the 2 items assessing impairment "at work" and with "recreational activities") and for less than 1% of observations of the other scales. Nonresponse was not associated with intervention assignment.

Pain severity was assessed as the mean of average and worst pain, with 0 on each of the 2 component scales representing no pain over the past 2 weeks and 10 representing the worst pain imaginable. Time point–specific Cronbach's alpha values for the pain severity scale ranged from 0.81 to 0.93.

Pain impairment was measured using the mean response to 5 of the 6 items from the Medical Outcomes Study (MOS) Pain Impairment Scale: the sleep item was omitted as a result of its low correlation with the other items and consequent deleterious impact on internal consistency reliability [61]. Time point–specific Cronbach alpha values for the pain impairment scale ranged from 0.84 to 0.91. *Functional status and well-being* was assessed with the Physical and Mental Health Component Scores of the SF-12 [74].

Pain misconceptions were assessed using the mean response to 11 five-point Likert scale items based on the SBQ [75] before the intervention and at the 2-week telephone interview. Cronbach's alphas for the SBQ were 0.73 and 0.74 at baseline and at 2 weeks, respectively.

Self-efficacy for communicating about pain with the cancer doctor was assessed using the mean response to the 5 items in the Perceived Efficacy in Patient–Physician Interactions scale, with the wording of the items modified to refer to communication with cancer doctors specifically [45]. Time point–specific Cronbach alpha values for the communication self-efficacy scale ranged from 0.84 to 0.91.

Pain-control self-efficacy was assessed using mean responses to 2 items (confidence in ability to decrease pain, and to reduce pain using methods other than medication taking) from the pain management subscale of the Chronic Pain Self-Efficacy scale [1]. Time point–specific Cronbach alpha values for the pain control self-efficacy scale ranged from 0.78 to 0.88.

2.6. Patient accrual and study flow

Of 3720 patients sent a recruitment letter, 3413 were excluded (including 1011 who returned an opt-out postcard, 1015 who could not be reached by telephone despite repeated calls, and 1387 who were ineligible) (Fig. 1). The remaining 307 were randomized, and of these, 265 received the allocated treatments. A total of 258 patients (126 TEC, 132 EUC) completed at least one follow-up assessment and were eligible for analysis (Fig. 1). Follow-up interviews were conducted by research assistants and 2 study coordinators. Although these assessments were not strictly blinded because of study coordinators' hypothetical access to treatment assignment files, in practice, follow-up assessors were not aware of patients' group assignments. The number of analyzable subjects was 249 at 2 weeks, 246 at 6 weeks, and 232 at 12 weeks.

2.7. Statistical analysis

Unadjusted between-arm comparisons of the distribution of baseline characteristics in the analysis sample were performed by Fisher's exact test (for categorical variables) and Student's t test for (for continuous variables). Unadjusted within-patient comparisons were assessed by the paired t test. The adjusted effect of the intervention on primary and secondary outcomes was estimated by separate mixed-effects multiple linear regression models for each outcome at 2, 6, and 12 weeks, using a common specification. Fixed effects (independent variables) were specified for the binary variable indicating assignment to the experimental intervention, prespecified patient characteristics (gender, age, partnership status, cancer stage, baseline measure of the outcome), and practice type (health maintenance organization [HMO], Veterans Affairs (VA) hospital, or academic/private—academic faculty plus one busy private practitioner). Random intercepts for physicians were specified to control for between-physician heterogeneity in study outcomes. Between-physician and residual error variance components were estimated by restricted maximum likelihood. To assess heterogeneity in treatment effects on the primary outcomes (pain severity and pain-related impairment at 2 weeks), subgroup-specific between-arm adjusted mean differences were estimated by a series of interaction models that included the same basic specification as described above but with an additional fixed effect specified for the interaction of the experimental intervention with the categorical variable describing the patient subgroups of interest. A *difference in differences* approach was used to assess the immediate impact of the experimental intervention on the self-efficacy outcomes: mean changes in self-efficacy during the baseline visit were compared by 2-sample t tests. The sensitivity of our inferences to alternative missing data assumptions and analysis strategies was assessed by multiple imputation methods and by fitting alternative mixed effects models for longitudinal data [50]. All statistical analyses were conducted in Stata, release 11 (StataCorp, College Station, TX). Statistical significance was declared when (2-sided) P values were less than 0.05.

3. Results

More than three-fourths of study participants were women, the mean age was 58 years, and 71% were white. Breast and lung cancer were the dominant cancer types (Table 1). At baseline, patients randomized to the experimental intervention (TEC) were similar to those assigned to control (EUC), except that TEC patients were older (60 vs 57 years; Student's t test on 256 degrees of freedom, $t(256) = 2.49$, $P = .04$) and were less likely to be living with a spouse or partner (56% vs 68%, Fisher exact test $P = .04$) (Table 1). Baseline pain severity (mean of average and worst pain) was also slightly higher among the TEC group (6.8 vs 6.5 on a scale of 0–10; $t(256) = 1.59$, $P = .11$) (Table 1).

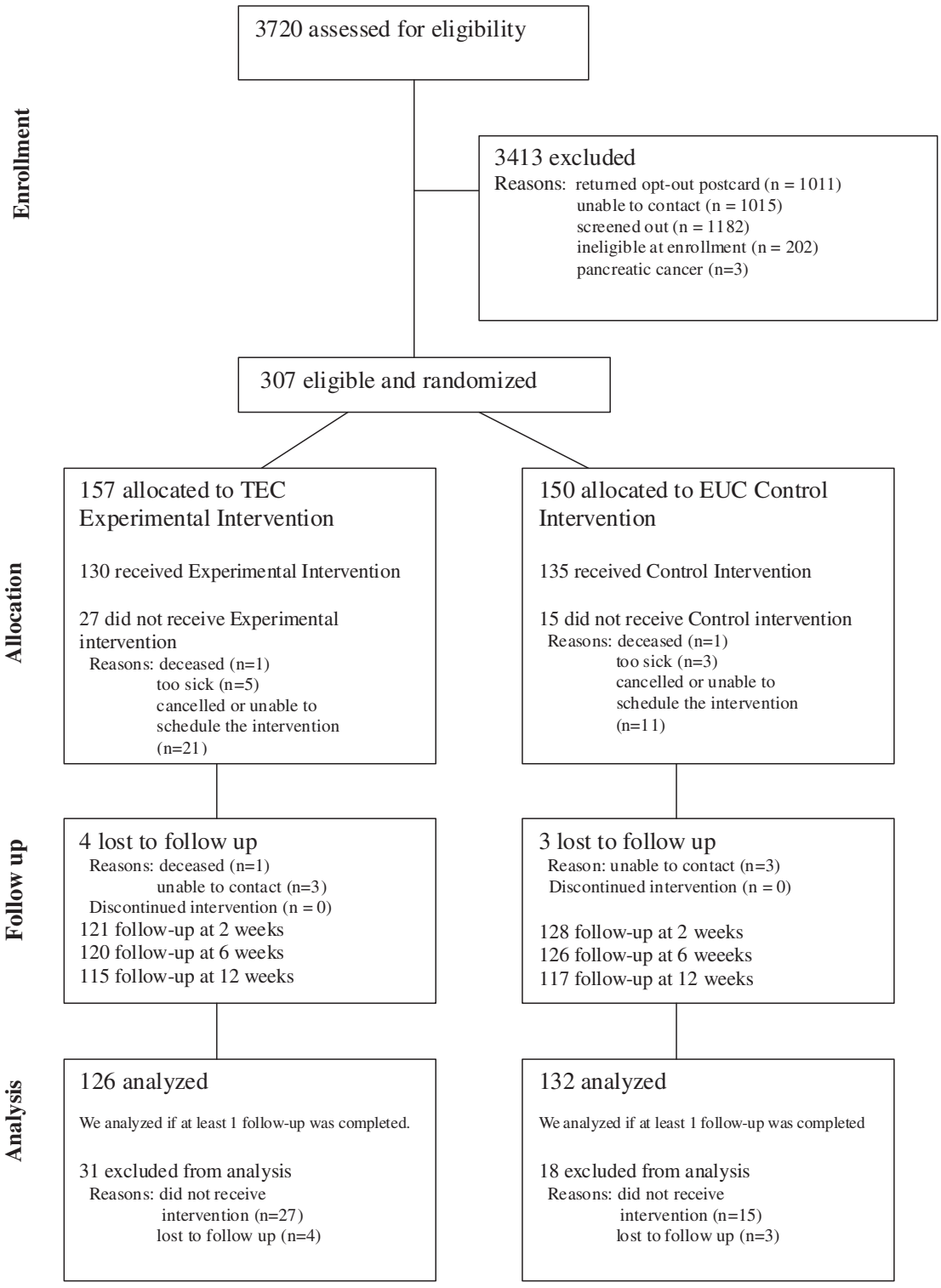

Fig. 1. CONSORT diagram showing flow of participants through trial.

3.1. Pain misconceptions

Pain misconceptions in both the intervention and control group decreased significantly between the baseline visit and the 2-week follow-up interview (mean decrease in both groups combined, 0.23 points along a 5-point scale; paired *t* test on 248 df = 6.55, $P < .001$), but there was no significant effect of the intervention on misconceptions at 2-week follow-up (difference between TEC and EUC = 0.02; Student's $t(247) = 0.28$, $P = .78$). To assess whether the intervention had the expected effects on *communication self-efficacy*, we measured this construct before and immediately after the intervention. Communication self-efficacy increased more among patients assigned to TEC (mean increase, 0.23 points; 95% confidence interval [CI] = 0.15 to 0.31) than control (mean increase, 0.02 units; 95% CI = −0.04 to 0.08) (Student's $t(256) = 4.28$, *P* value for change between groups <0.001). On the other hand, gains in

Table 1
Baseline characteristics of study participants who completed at least one follow-up assessment ($n = 258$)

Characteristic	Assigned to experimental intervention ($n = 126$)[a]	Assigned to control intervention ($n = 132$)[a]	*P* value for difference
Female sex,%	77.8	79.5	.76
Age, y, mean (SD)	59.8 (9.1)	57.3 (10.1)	.04
Race/ethnicity, n (%)			.17
White non-Hispanic	85 (68.0)	100 (76.3)	
Hispanic or Latino	13 (10.4)	8 (6.1)	
Black, not Hispanic	20 (16.0)	13 (9.9)	
Asian	6 (4.8)	5 (3.8)	
Other	1 (0.8)	5 (3.8)	
Education, n (%)			.93
<12 y	36 (28.6)	40 (30.3)	
12–15 y	40 (31.8)	39 (29.5)	
⩾16 y	50 (39.7)	53 (40.2)	
Living with spouse or partner,%	55.6	68.2	.04
Cancer type, n (%)			.90
Breast	71 (56.3)	77 (58.3)	
Lung	22 (17.5)	24 (18.2)	
Other	33 (26.2)	31 (23.5)	
Cancer treatment, n (%)			
Chemotherapy within 2 weeks	42 (33.3)	41 (31.1)	.12
Radiotherapy within 2 weeks	8 (6.3)	11 (8.3)	.73
Surgery within 3 months	0 (0)	1 (0.8)	.81
Site of care, n (%)			.92
Academic cancer center	56 (44.4)	56 (42.4)	
Health maintenance organization	63 (50.0)	66 (50.0)	
Veterans' Affairs hospital	2 (1.6)	4 (3.0)	
Private practice	5 (4.0)	6 (4.5)	
Pain severity (mean of average and worst pain) at enrollment, scale 0–10, mean (SD)	6.8 (1.7)	6.5 (1.9)	.11
MOS Pain Impairment Scale at enrollment, scale 1–5, mean (SD)	3.1 (0.9)	3.2 (0.9)	.94
SF-12 at enrollment, scale 0–100			
Mental Health Score, mean (SD)	44.5 (10.1)	44.6 (10.6)	.97
Physical Health Score, mean (SD)	32.3 (8.4)	32.6 (9.1)	.78
Pain misconceptions (Short Barriers Questionnaire) [75], scale 1–5, mean (SD)	2.4 (0.7)	2.3 (0.6)	.33
Communication self-efficacy, scale 1–5, mean (SD)	4.3 (0.7)	4.1 (.8)	.03
Pain control self-efficacy, scale 1–5, mean (SD)	3.1 (1.0)	2.9 (1.0)	.26

[a] Observations for some variables do not sum to the overall total as a result of missing values.

pain control self-efficacy were similar in patients assigned to TEC (mean increase, 0.16; 95% CI = 0.006 to 0.31) as in patients assigned to control (mean increase, 0.19; 95% CI = 0.07 to 0.31) (Student's $t(256) = 0.31$, *P* value for change between groups = .76).

In the regression with 2-week *pain severity* as the outcome, assignment to the TEC intervention was associated with a statistically nonsignificant improvement (adjusted TEC vs EUC difference in mean pain severity = −0.21; Wald *z* test = −1.10, *P* = .27, Table 2). The strongest predictor of 2-week pain severity in this model was baseline pain severity (*P* < .01). Living with a partner was associated with significantly less pain (*P* = .01). In the regression with 2-week *pain-related impairment* as the outcome, baseline pain impairment was similarly a significant predictor. Assignment to the TEC group was associated with a statistically significant 0.25 point decline in impairment along a 5-point scale (*P* = .01, Table 3). This represents an improvement of about ¼ of a standard

Table 2
Effect of TEC intervention on pain severity at 2-week follow-up.[a]

Characteristic	Coefficient	95% CI	Wald *z* statistic	*P* value
Treatment (0 = control, 1 = experimental intervention)	−0.21	−0.60 to 0.17	−1.10	.27
Preintervention pain severity	0.72	0.63 to 0.81	15.06	<.01
Age (10 y)	0.01	−0.20 to 0.21	0.05	.96
Lives with partner (vs lives alone)	−0.55	−0.95 to −0.15	−2.71	.01
Site (academic center combined with private practice is reference)[b]				
HMO	−0.14 −0.77	−0.53 to 0.24	−0.73	.46
VA		−2.04 to 0.51	−1.18	.24
Cancer stage (0 = local/regional, 1 = metastatic)	−0.06	−0.46 to 0.34	−0.28	.78
Female sex	−0.13	−0.63 to 0.37	−0.51	.61

[a] Coefficients for fixed effects estimated in a mixed-effects multiple linear regression model of the pain severity outcome, estimated in the sample of patients with nonmissing data on model variables (complete-case analysis $n = 249$), with random physician intercepts to account for the nesting of patients (the unit of randomization and analysis) within 39 physicians. Restricted maximum likelihood estimates of the variance components: between-physician variance = 0.00; residual error variance = 2.23.
[b] Private practice patients ($n = 11$) were included as part of the reference group because of small numbers.

Table 3
Effect of TEC intervention on pain-related impairment at 2-week follow-up.[a]

Characteristic	Coefficient	95% CI	Wald *z* statistic	*P* value
Treatment (0 = control, 1 = experimental intervention)	−0.25	−0.43 to −0.06	−2.59	.01
Preintervention pain impairment	0.74	0.64 to 0.84	14.38	<.01
Age (10 y)	−0.02	−0.12 to 0.07	−0.49	.63
Lives with partner (vs lives alone)	−0.23	−0.42 to −0.03	−2.28	.02
Site (academic center is reference)				
HMO	−0.09	−0.28 to 0.11	−0.87	.38
VA	−0.36	−0.98 to 0.27	−1.12	.26
Cancer stage (0 = local/regional, 1 = metastatic)	−0.07	−0.26 to 0.13	−0.66	.51
Female	−0.14	−0.39 to 0.11	−1.10	.27

[a] Coefficients for fixed effects estimated in a mixed-effects multiple linear regression model of the pain severity outcome, estimated in the sample of patients with nonmissing data on model variables (complete-case analysis $n = 249$), with random physician intercepts to account for the nesting of patients (the unit of randomization and analysis) within 39 physicians. Restricted maximum likelihood estimates of the variance components: between-physician variance = 0.002; residual error variance = 0.533.

deviation, generally considered a small but potentially clinically important effect [24]. Nearly identical results were obtained in additional analyses that included fixed effects for HEs to assess whether primary outcomes varied according to which of the 11 HEs delivered the intervention. The overall test of the HE factor was statistically insignificant for 2-week pain severity (Wald χ^2 test on 10 df = 16.7; $P = .08$) and for 2-week pain-related impairment (Wald $\chi^2 = 4.17$, $P = .94$).

Examination of subgroup effects revealed no significant interaction between intervention assignment and baseline pain severity, pain impairment, gender, marital status (living with partner vs not), ethnicity (white vs minority), cancer type (breast vs other), cancer stage (local/regional vs metastatic), or clinical site (academic, HMO, or VA) (Forrest plot, Fig. 2).

There were no significant effects of the intervention on other clinical outcomes (Table 4). In particular, the effect on pain-related impairment noted at 2 weeks was not sustained at 6 and 12 weeks ($P > .20$, Table 3). In addition, SF-12 Physical and Mental Health Component scores measured at 6 weeks were not affected by group assignment (Table 4). However, inspection of Fig. 3 (which includes only patients with complete data—that is, follow-up information at 2, 6, and 12 weeks) shows that both pain severity and pain-related impairment tended to improve over time among patients assigned to both groups. Sensitivity analyses that used all available longitudinal data in mixed-model random missingness models, a mixed-effects model for longitudinal outcomes that yields valid inferences under ignorable missingess assumptions [50], produced similar estimates and inferences as reported above for pain severity and pain-related impairment. In addition, multiple imputation analyses under both ignorable and nonignorable missing data assumptions yielded similar findings for these outcomes at 2 weeks. Given the larger amount of missing data at 6 and 12 weeks, point estimates at these latter time points were more sensitive to the ignorable missingness assumption, but *P* values remained nonsignificant under a variety of nonignorable imputation patterns.

4. Discussion

The results of this randomized controlled trial suggest that although a brief, lay-administered TEC intervention emphasizing patient–physician communication is feasible and is associated with meaningful changes in communication self-efficacy, it conveys no significant benefits on pain severity and only small, temporary benefits on pain-related impairment. Though short-lived, the observed improvements in pain-related impairment may be clinically significant, translating, for example, to roughly 1 in 4 patients experiencing a reduction in pain-related interference with ambulation and work (or recreation and mood) from "quite a bit" to "slightly."

Examination of putative mediators suggest that the TEC intervention achieved its immediate aims of reducing pain-related misconceptions and increasing communication self-efficacy. However, misconceptions were abated to an equal degree in the control group that received pain management education only, and improvements in communication self-efficacy did not lead to consistent or sustained improvements in pain outcomes.

The observed point estimates are at the lower end of those reported in a meta-analysis by Bennett et al. [5], which found that patient-based educational interventions reduced average pain by approximately half a standard deviation. However, in Bennett et al., effect sizes were smaller in studies that used placebo or attention controls as opposed to usual care [2,11,66] and larger in studies employing multiple contacts between educator and patient [30,35].

Larger intervention effects would likely have been observed had the control condition been usual care or placebo rather than EUC [5]. Using a robust control afforded us the opportunity to isolate the effects of TEC. However, the marginal reductions in pain severity were too small to be detected in our sample. Another reason for the paucity of significant results may be the heterogeneity of the study population with respect to disease status and baseline pain. In using broad eligibility criteria, we knowingly traded off rigor for potentially greater relevance and transportability [60]. Although we did not detect a significant interaction between baseline pain severity and effect of the intervention, it is possible that restricting study entry to patients with greater baseline pain might have resulted in larger effect sizes and greater stochastic significance. Finally, given the inability or reluctance of some TEC group patients to identify and rehearse specific pain-related questions during the coaching, future studies might use question prompt lists (such as those developed by Butow et al. [7]) to their advantage.

Pain at baseline was the most consistent predictor of pain at follow-up. In subgroup analysis, the intervention was similarly ineffective (with respect to pain severity) or effective (with respect to pain-related impairment) among patients with higher and lower levels of pain at baseline. Among other covariates, only living with a spouse or partner was related to reduced pain severity and pain-related impairment at 2 weeks. Marital status has been associated with less cancer pain and better quality of life in prior studies [6,28], perhaps because greater social support attenuates suffering directly and also encourages more effective interactions with medical providers. This suggests that clinicians should explore the patient's social context when addressing cancer pain management concerns [17].

In contrast to effects on pain, TEC had substantial, persistent effects on communication self-efficacy [45]. In a visit audiotape analysis, we found that TEC patients discussed their pain concerns more often than controls [65]. This suggests that patient involvement per se may not lead to improved pain management. Instead,

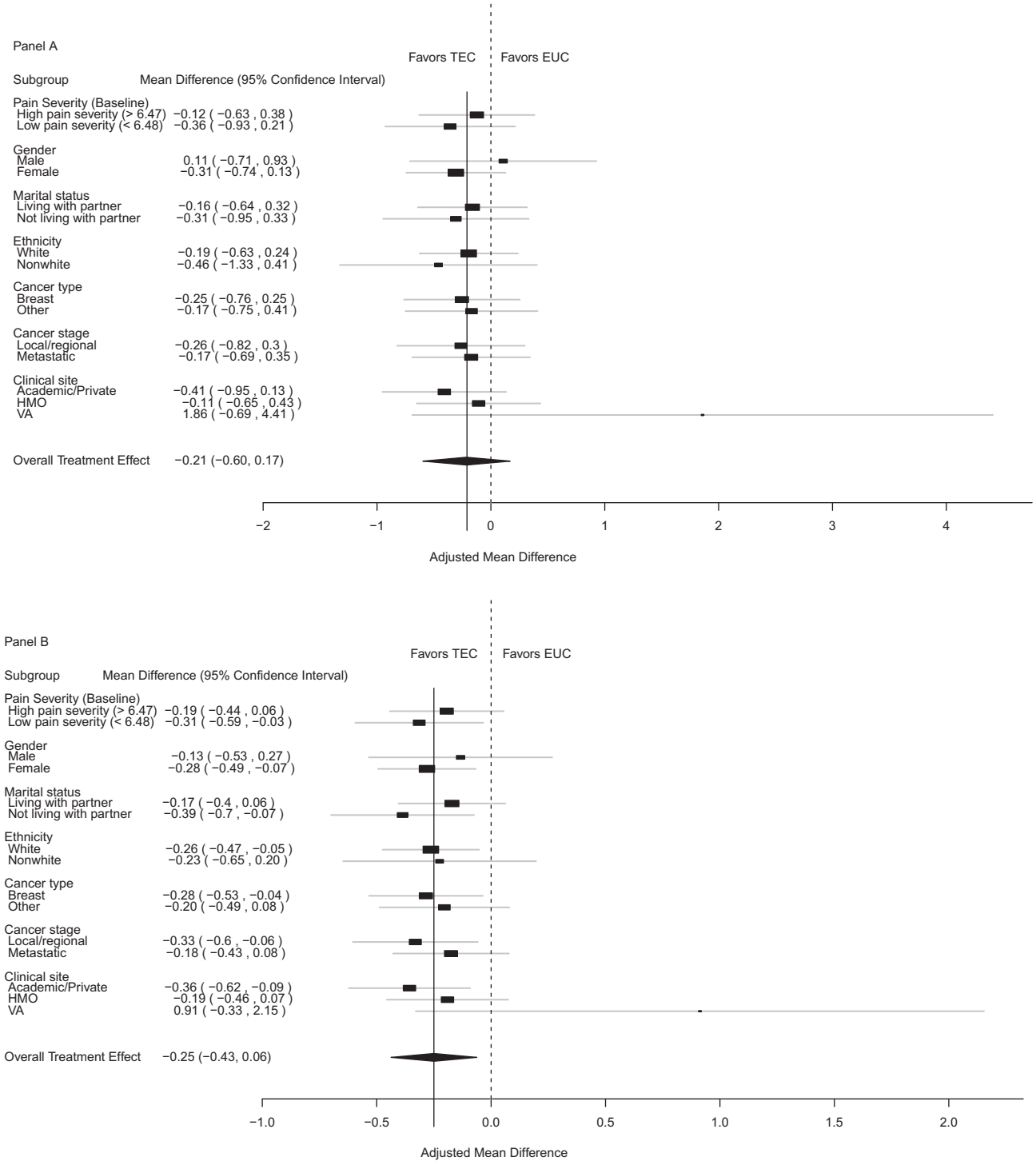

Fig. 2. Forrest plot showing subgroup effects with respect to pain severity (A) and pain-related impairment (B). The *x*-axis shows coefficients derived from mixed effects multiple linear regression adjusted for age, gender, marital status, study site, and cancer stage. The null value (no intervention effect) is 0.

future research should examine both the quality of problem solving and clinician's receptivity to increased patient participation in decision making.

Certain limitations of this study arise from its design and execution. Randomization occurred at the patient level, so physicians may have "borrowed" what they learned from one patient and applied it to the next. The study employed a limited number of lay HEs. Although mixed effects models showed no significant fixed effect of the individual HEs, the results might have been different had we selected a different group of HEs. Patients (but not physicians or study personnel) were aware of their assigned intervention; social desirability response bias may have muted the measured intervention effects if patients in both groups reported diminished pain in an effort to please the investigators. In addition, physicians could have inferred the group assignment (eg, by attending to the kinds of questions patients asked) and treated their patients differently. Multiple patient outcomes were investigated with no correction for multiple comparisons. Although this approach is defensible [18], it is less conservative and may lead to false-positive results. Finally, the study was conducted at 4 sites

Table 4
Effect of intervention on pain severity, pain-related impairment, and SF-12 functional status and well being at 2-, 6-, and 12-week follow-up.

Model[a]	Complete-case sample size (*N*)	Treatment effect (coefficient)	Standard error	Wald *z* statistic	*P* value
Pain severity					
2-wk follow-up	249	−0.21	0.20	−1.10	.27
6-wk follow-up	246	−0.02	0.24	−0.07	.94
12-wk follow-up	232	0.17	0.28	0.62	.54
Pain-related impairment					
2-wk follow-up	249	−0.25	0.10	−2.59	.01
6-wk follow-up	246	−0.07	0.10	−0.70	.49
12-wk follow-up	232	0.07	0.13	0.57	.57
SF-12[b]					
MCS 6-wk follow-up	238	0.08	1.24	0.06	.95
PCS 6-wk follow-up	238	0.92	1.06	0.87	.39

[a] Treatment effects are regression coefficients from separate mixed effects multiple linear regression model for each outcome for each follow-up time point. All models include fixed effects of age, gender, study site, cancer stage, marital status (living with partner), preintervention outcome score, and random effect of physician. Complete-case sample size describes number of patient observations used to estimate each regression model.

[b] MCS indicates Mental Health Component Score; PCS, Physical Health Component Score. Both components are scaled from 0 to 100, with higher scores representing better health.

in a single metropolitan area. We cannot directly generalize the results to other settings, although the consistency of the results with prior research provides assurance that the overall conclusions extend beyond Sacramento.

Although the practical appeal of one time psychoeducational interventions for cancer pain is obvious, some experts have concluded that more sustained, multi-faceted interventions are necessary to deliver more robust effects. For example, Miaskowski

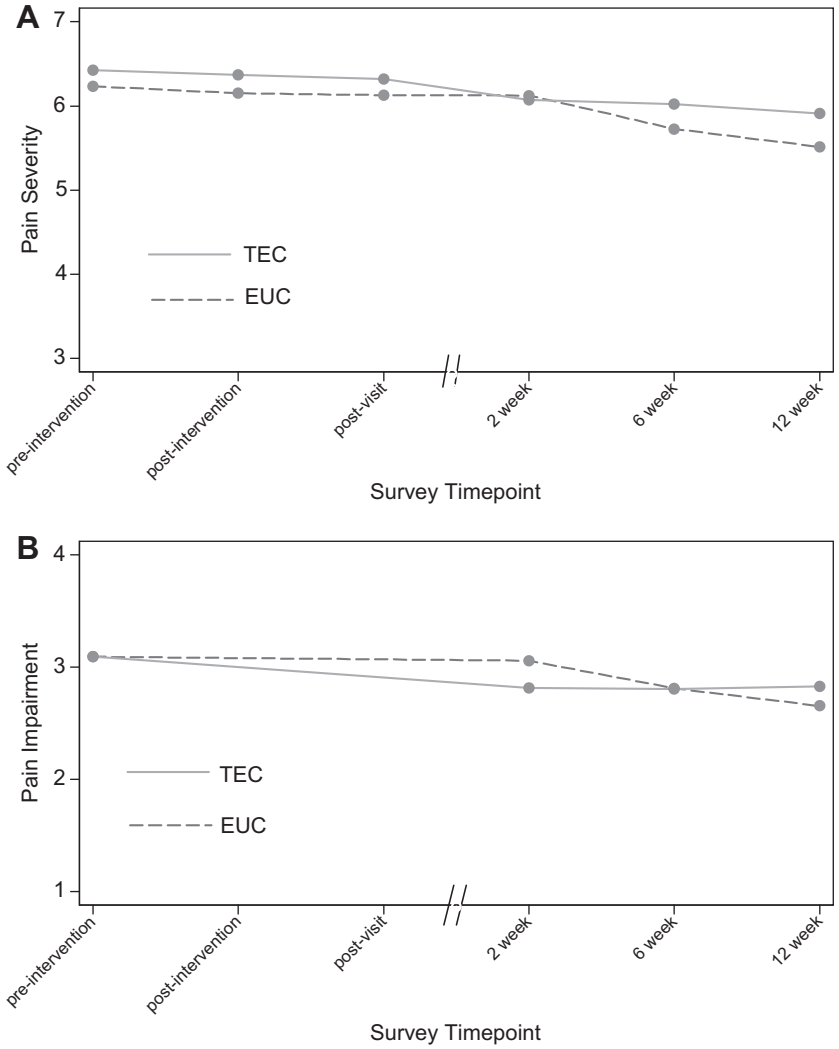

Fig. 3. Mean pain severity (A) and impairment (B) among intervention (TEC) and control (EUC) patients over time. *Preintervention* measures were obtained in the cancer doctor's office just before the intervention, *postintervention* measures right after the intervention but before the visit, *postvisit* measures just after the visit, and other measures at 2, 6, and 12 weeks after the visit. Only the 222 subjects completing all 3 follow-up interviews are included. Alternative graphical presentations using all available data at each time point, with and without imputation for intermittently missing values, were nearly identical.

argues that "too little consideration has been given to what constitutes an effective dose of an educational intervention to improve cancer pain management" [48]. The goal should be to develop more theoretically grounded, engaging, and potent interventions [70] that are reinforced over time as needed. One promising direction is to focus more intensively on health self-efficacy [27], which has been shown in several studies to correlate with health outcomes [40–43,46,56]. In addition, the need for cost-effective reinforcement could be addressed by combining in-person coaching with interactive multimedia computer programs [26]. Particularly when tailored to key attitudes and psychological predispositions, such programs have been shown to increase knowledge, boost self-efficacy, and/or change health behaviors in a variety of clinical contexts [22,26,77].

The relatively small benefit derived from many psychoeducational interventions for cancer pain (including ours) suggests that patient- and family-centered programs alone are insufficient to produce robust, sustained improvements in pain outcomes. One reason is that *physician* behaviors such as prescribing, referring, and counseling are critical to achieving better pain control. Studies in primary care show that patients' expectations and requests have a marked influence on physician behavior. For example, asking for a medical test, medication, or referral increases the likelihood that a patient will receive it by 25% to 50% regardless of clinical appropriateness [33,34].

However, cancer pain differs from other medical conditions in several ways. First, the terrifying nature of the disease shifts control over the content and direction of clinical discourse away from the patient and toward the physician. Therefore, in addition to teaching patients how to engage with physicians, physicians need to be taught to yield conversational control to patients [36,64].

Second, the complex side-effect profile of narcotic analgesics places special demands on communication about risks and benefits. As a consequence of well-orchestrated public information campaigns, physicians and the public are keenly aware of the adverse personal and public health effects of opiates [47]. In addition, societal ambivalence about opiates introduces unspoken tensions into oncologist-patient discussions about pain management [47].

Third, competing demands weigh heavily on oncologists as they struggle to reassure themselves and their patients that escalating pain medication needs do not signal disease progression requiring disease-specific therapy—a constant threat in cancer care. Physicians need sufficient clinical agility to treat symptoms and investigate causes at the same time.

Finally, prior studies suggest that patient activation may increase tension in the patient–physician relationship [9,25,58]. Therefore, combined patient and physician interventions, particularly if supported by systems changes, may be more effective than either alone [17].

Two decades of research on psychoeducational interventions for cancer pain underscore the difficulties of this work. Sustained, multilevel interventions are likely to be more effective but also more costly. For this reason, more research is needed to identify subgroups that have the greatest need and are most likely to benefit. In light of past research suggesting that activation/coaching may produce the biggest gains for the most vulnerable populations [30], more work is needed on how to most effectively deliver such interventions to racial, ethnic, and linguistic minorities as well as patients with severe, undertreated pain.

Conflict of interest statement

The authors report no conflicts of interest pertaining to the topic of this article.

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Appendix Table

Primary and secondary outcomes at follow-up.

Characteristic	Assigned to experimental intervention (n = 126)		Assigned to control intervention (n = 132)	
	N	Mean (SD)	*N*	Mean (SD)
Pain severity, scale 0–10				
Follow-up week 2	121	6.2 (2.1)	128	6.2 (2.1)
Follow-up week 6	120	6.1 (2.2)	126	5.8 (2.2)
Follow-up week 12	115	5.9 (2.3)	117	5.6 (2.5)
MOS Pain Impairment Scale, scale 1–5				
Follow-up week 2	121	2.9 (1.0)	128	3.1 (1.0)
Follow-up week 6	120	2.8 (1.0)	126	2.8 (1.0)
Follow-up week 12	115	2.8 (1.0)	117	2.7 (1.1)
SF-12 subscales, scale 0–100				
Follow-up week 6				
Mental Health Score	115	45.9 (10.9)	123	46.3 (11.0)
Physical Health Score	115	33.2 (9.9)	123	32.4 (10.3)
Pain misconceptions (Short Barriers Questionnaire)				
Follow-up week 2	121	2.1 (0.7)	128	2.1 (0.6)
Communication self-efficacy, scale 1–5				
Follow-up week 2	121	4.5 (0.6)	128	4.2 (0.7)
Follow-up week 6	119	4.5 (0.6)	125	4.2 (0.8)
Follow-up week 12	115	4.5 (0.6)	114	4.2 (0.8)
Pain control self-efficacy, scale 1–5				
Follow-up week 2	121	3.7 (1.1)	128	3.6 (1.0)
Follow-up week 6	120	3.4 (1.1)	124	3.4 (1.1)
Follow-up week 12	114	3.4 (1.2)	116	3.5 (1.2)

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