Original Investigation

Evaluation of Stepped Care for Chronic Pain (ESCAPE) in Veterans of the Iraq and Afghanistan Conflicts
A Randomized Clinical Trial

Matthew J. Bair, MD, MS; Dennis Ang, MD; Jingwei Wu, MS; Samantha D. Outcalt, PhD; Christy Sargent, BS; Carol Kempf, RN; Amanda Froman, BS; Arlene A. Schmid, PhD, OTR; Teresa M. Damush, PhD; Zhangsheng Yu, PhD; Louanne W. Davis, PsyD; Kurt Kroenke, MD

IMPORTANCE Despite the prevalence and the functional, psychological, and economic impact of chronic pain, few intervention studies of treatment of chronic pain in veterans have been performed.

OBJECTIVE To determine whether a stepped-care intervention is more effective than usual care, as hypothesized, in reducing pain-related disability, pain interference, and pain severity.

DESIGN, SETTING, AND PARTICIPANTS We performed a randomized clinical trial comparing stepped care with usual care for chronic pain. We enrolled 241 veterans from Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn with chronic (>3 months) and disabling (Roland Morris Disability Scale score, ≥7) musculoskeletal pain of the cervical or lumbar spine or extremities (shoulders, knees, and hips) in the Evaluation of Stepped Care for Chronic Pain (ESCAPE) trial from December 20, 2007, through June 30, 2011. The 9-month follow-up was completed by April 2012. Patients received treatment at a postdeployment clinic and 5 general medicine clinics at a Veterans Affairs medical center.

INTERVENTIONS Step 1 included 12 weeks of analgesic treatment and optimization according to an algorithm coupled with pain self-management strategies; step 2, 12 weeks of cognitive behavioral therapy. All intervention aspects were delivered by nurse care managers.

MAIN OUTCOMES AND MEASURES Pain-related disability (Roland Morris Disability Scale), pain interference (Brief Pain Inventory), and pain severity (Graded Chronic Pain Scale).

RESULTS The primary analysis included 121 patients receiving the stepped-care intervention and 120 patients receiving usual care. At 9 months, the mean decrease from baseline in the Roland Morris Disability Scale score was 1.7 (95% CI, −2.6 to −0.9) points in the usual care group and 3.7 (95% CI, −4.5 to −2.8) points in the intervention group (between-group difference, −1.9 [95% CI, −3.2 to −0.7] points; $P = .002$). The mean decrease from baseline in the Pain Interference subscale score of the Brief Pain Inventory was 0.9 points in the usual care group and 1.7 points in the intervention group (between-group difference, −0.8 [95% CI, −1.3 to −0.3] points; $P = .003$). The Graded Chronic Pain Scale severity score was reduced by 4.5 points in the usual care group and 11.1 points in the intervention group (between-group difference, −6.6 [95% CI, −10.5 to −2.7] points; $P = .001$).

CONCLUSIONS AND RELEVANCE A stepped-care intervention that combined analgesics, self-management strategies, and brief cognitive behavioral therapy resulted in statistically significant reductions in pain-related disability, pain interference, and pain severity in veterans with chronic musculoskeletal pain.

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Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Matthew J. Bair, MD, MS, Veterans Affairs Health Services Research and Development, Center for Health Information and Communication, Richard L. Roudebush Veterans Affairs Medical Center (Mail Code 11-H), 1481 W 10th St, Indianapolis, IN 46202 (mbair@iupui.edu or Matthew.Bair@va.gov).

Chronic pain is a critical health problem that affects approximately 100 million US adults.[1] Chronic pain costs the United States an estimated $635 billion each year in medical treatment and lost productivity[1] and is the most common cause of disability.[2] Chronic pain is frequently accompanied by mental health disorders that complicate treatment.[3] The deleterious effects of chronic pain on quality of life and function are well known.[4]

Chronic pain is a critical health problem among veterans. Pain was the most frequently reported symptom in veterans of the Persian Gulf War[5] and ranged in prevalence from 40% to 50% among veterans of Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn (OEF/OIF/OND).[6,7] The Veterans Affairs (VA) pain management strategy[8] was initiated in 1998 and established pain management as a national priority. Despite this effort, no intervention studies to treat chronic pain in veterans of the Iraq and Afghanistan conflicts have been reported, to our knowledge.

The absence of studies is concerning because chronic pain may prove even more disabling in veterans of recent conflicts than in veterans of previous eras owing to the high combat intensity of the OEF/OIF/OND conflicts and an increased prevalence of comorbidities, such as anxiety and depression.[9] Given the prevalence of pain, associated morbidity, and related costs, enormous challenges lie ahead for the VA. Other health care systems also will be challenged as veterans return from military service and seek care.

Numerous studies have documented inadequate pain management.[10,11] Although several guidelines exist,[12-14] evidence suggests modest effectiveness of the current pain treatments. Pain management is complex owing to the interplay of multiple biological, psychological, and social factors that contribute to chronic pain. This complexity often leads to a failure to respond well to single treatments, requiring a multimodal, multidisciplinary treatment approach.[15] Although multidisciplinary pain clinics have been shown to improve pain outcomes,[16] these clinics are not widely available because of fiscal constraints and reimbursement issues.[17]

For patients with chronic pain, self-management programs have proved effective. A systematic review by Newman et al[18] found strong evidence that self-management strategies are effective for low back and osteoarthritis pain. Furthermore, pain outcomes may depend more on effective self-management than on other treatments.[19]

Cognitive behavioral therapy (CBT) is a skills-based treatment that teaches patients to identify and change maladaptive thoughts and behaviors and to replace them with more helpful thoughts and behaviors. Strong evidence from numerous studies supports the benefits of CBT for several pain conditions,[20] including chronic pain.[21]

The stepped-care model, which is validated for the management of low back pain in primary care,[22] guided the Evaluation of Stepped Care for Chronic Pain (ESCAPE) trial. The ESCAPE trial tested an intervention involving 12 weeks of analgesic therapy optimization according to an algorithm coupled with pain self-management strategies (step 1) followed by 12 weeks of CBT (step 2). The primary aim was to estimate the effectiveness of the intervention during a 9-month period in veterans of the Afghanistan (OEF) and Iraq (OIF/OND) conflicts who had chronic and disabling musculoskeletal pain.

Methods

Study Setting and Sample

From December 20, 2007, through June 30, 2011, we recruited participants from patients at a postdeployment clinic and 5 general medicine clinics at the same VA medical center. Potential participants were identified through the VA's electronic medical record to create a master list of veterans who, within the preceding 6 months, reported at least moderate pain (pain score, ≥4), according to the scale routinely used in VA clinics (0 indicates no pain; 10, worst pain imaginable).[8] The institutional review board of Indiana University and the research committee of the Richard L. Roudebush Veterans Affairs Medical Center, Indianapolis, approved this study, and the trial was monitored by an independent data and safety monitoring board. The full study protocol can be found in the trial protocol in Supplement 1.

Patients were included if they were OEF/OIF/OND veterans, if they self-reported chronic pain (>3 months' duration) of the cervical or lumbar spine or an extremity (hip, knee, or shoulder), and if pain was at least moderately disabling (defined as a Roland Morris Disability Scale [RMDS] score of ≥7)[23,24] at the initial visit. Individuals were excluded if they had severe medical conditions that might limit study participation, active psychosis, schizophrenia, current alcohol or substance dependence, active suicidal ideation, prior or pending back surgery, or pregnancy. All enrolled patients gave written informed consent.

Randomization and Blinded Outcome Assessments

After the baseline interview, eligible participants were block randomized in groups of 8 to the stepped-care intervention or to the usual care arm. Randomization lists were generated by computer, and treatment assignments were supplied in sealed opaque envelopes. After obtaining patient consent and completion of a baseline assessment, the project manager (C.S.) revealed the randomization assignment for each patient by opening the next envelope in sequence. All baseline and follow-up assessments were conducted by a trained research assistant (A.F.) who was blinded to the treatment allocation.

Outcome Assessments

Data were collected at baseline and 3, 6, and 9 months after randomization. The assessment interviews were conducted in person, by telephone, or via mail. The assessments were informed by recommendations of the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT).[25] The primary study outcome was pain-related disability as assessed by the 24-item RMDS,[23,24] which has been validated in patients with low back pain and other chronic pain conditions. This scale is scored from 0 to 24; higher scores represent more severe pain-related disability. In low back pain trials, Patrick et al[26] and Bombardier et al[27] suggested a minimum clinically significant difference in RMDS scores of 2 to 3 points. Furthermore, Jordan et al[28] identified a 30% decrease as a clinically meaningful improvement.

Two other primary pain outcomes assessed included pain interference and pain severity. Pain interference was assessed by the Pain Interference subscale from the Brief Pain Inventory (BPI).[29] The BPI Pain Interference subscale has 7 items that rate how pain interferes with mood, physical activity, work, social activity, relations with others, sleep, and enjoyment of life (range, 0-10). Higher scores indicate greater pain interference. We calculated the mean of the 7 item scores for an overall Pain Interference score, and a 1- to 2-point change was considered clinically important, with a decrease considered improvement. Pain severity was measured by the 7-item Graded Chronic Pain Scale,[30] which rates patients' pain severity on a scale of 0 to 100, with higher scores representing more severe pain. Further research is needed to assess clinically meaningful cut points.

Intervention

The intervention was delivered by 2 nurse care managers (NCMs) (which included C.K.) trained in all treatment components, including optimization of analgesic treatment, self-management strategies, and CBT. The NCMs met weekly with physician investigators (M.J.B. and D.A.) and a supervising psychologist (L.W.D.) to review care of the intervention group, a model of case supervision implemented in previous trials.[31,32] The protocol called for biweekly telephone contacts between the patients and NCMs for a total of 12 contacts during the trial period. Several procedures were implemented to ensure treatment fidelity, including extensive training, observation, audiotaping, and feedback after treatment sessions. To enhance the reproducibility of the intervention, we used a manualized and algorithmic approach in the context of a care management delivery model.

Step 1

In clinical practice, analgesics are the most common and pragmatic approach to treating pain. Therefore, step 1 consisted of optimization of analgesic therapy for 12 weeks using an evidence-based algorithm[33] (outlined in **Table 1**). We operationally classified analgesics into the following 8 categories: (1) first-line analgesics; (2) other nonsteroidal anti-inflammatory drugs; (3) topical analgesics; (4) gabapentinoids; (5) tricyclic antidepressants and cyclobenzaprine hydrochloride; (6) tramadol hydrochloride; (7) short-acting opioids; and (8) long-acting opioids.

At the study baseline, the NCMs obtained a comprehensive history of previous pain treatments. This treatment history included previous use of analgesics, including duration and dosing, to determine whether an adequate treatment trial had been completed. If inadequate dosage, scheduling, or treatment adherence had been a problem, a trial of the previously tried analgesic with appropriate dosing and scheduling was recommended.

The NCMs followed an algorithm developed by the ESCAPE investigators[33] and conducted follow-up calls to assess changes in pain severity and interference, global improvement, patient desire for treatment change, and treatment adherence. If bothersome adverse effects emerged, patients received a different analgesic treatment. Treatment response was assessed every 2 weeks, and ongoing care was discussed during case management meetings. Prescriptions were entered by a physician-investigator (M.J.B.), and all study medications were dispensed through the medical center pharmacy. A research pharmacist oversaw medication dispensing.

Because analgesics may not relieve pain sufficiently when used alone, this intervention step also involved teaching patients pain self-management strategies. In conjunction with analgesic treatment, the intervention group received education about common treatments and the natural history of chronic pain. The NCMs encouraged all patients to minimize bed rest, return to normal activities as soon as possible, and perform recommended stretching and strengthening exercises, including walking.

Patients were also provided a menu of self-management strategies to learn and use to help to manage their pain. The menu of additional strategies included goal setting, problem solving, positive self-talk, relaxation techniques, behavioral plans, and communication with their primary care physicians. The NCMs delivered the self-management strategies using a standardized protocol.

Because we expected many study patients would have coexisting mental health conditions, the NCMs regularly assessed for depression and anxiety symptoms during each step. Patients found to have comorbid major depression, posttraumatic stress disorder, or severe anxiety received a referral to a mental health practitioner.

Step 2

All patients proceeded to step 2 immediately after completion of step 1. Analgesic therapy and self-management strategies started during step 1 were continued.

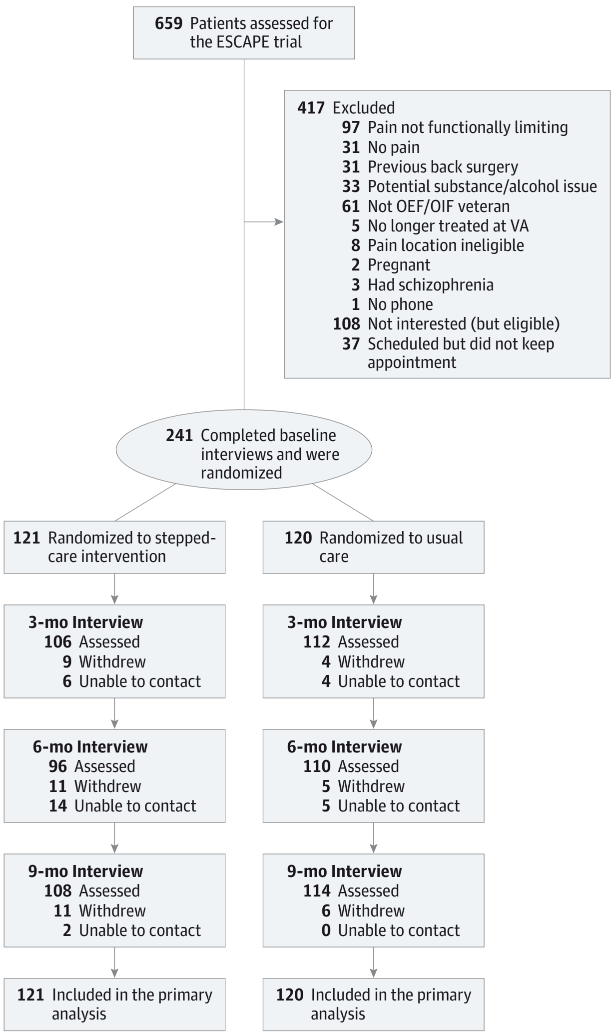
Table 1. ESCAPE Trial Step 1 Analgesic Algorithm

Category	Analgesic
First line	Acetaminophen and naproxen
Other NSAIDs	Ibuprofen, meloxicam, etodolac, diclofenac, and salsalate
Topical analgesics	For example, capsaicin cream, 0.025% or 0.075%
Gabapentinoids	Gabapentin and pregabalin
Tricyclic antidepressants and cyclobenzaprine hydrochloride	Nortriptyline hydrochloride and amitriptyline hydrochloride
Tramadol hydrochloride[a]	Tramadol
Short-acting opioids	Combined hydrocodone bitartrate and acetaminophen, combined oxycodone hydrochloride and acetaminophen, and immediate-release oxycodone and morphine
Long-acting opioids	Sustained-release morphine and methadone hydrochloride

Abbreviations: ESCAPE, Evaluation of Stepped Care for Chronic Pain; NSAIDs, nonsteroidal anti-inflammatory drugs.

[a] Included in its own class as a weak opioid or a combination opioid and norepinephrine reuptake inhibitor.

Figure 1. Flowchart of Participants in the Evaluation of Stepped Care for Chronic Pain (ESCAPE) Trial in Veterans of the Afghanistan and Iraq Conflicts



OEF/OIF indicates Operation Enduring Freedom/Operation Iraqi Freedom; VA, Veterans Affairs.

To complement the behavioral focus of pain self-management in step 1, we adapted a CBT program.[34] This program was based on the CBT concept that thoughts affect feelings that, in turn, affect behaviors. The CBT step consisted of 6 individual sessions delivered by telephone. Biweekly sessions lasted approximately 45 minutes and involved discussions of thoughts and feelings about pain, past treatments for pain, identification of barriers to reducing functional limitations and pain severity, and cognitive restructuring after coaching from a psychologist. The NCMs helped veterans to identify maladaptive thoughts, including inaccurate interpretations of pain and its impact. Patients were taught to examine the accuracy and usefulness of these thoughts and to develop more adaptive cognitions. At the end of each session, home practice was assigned to apply the lessons learned.

Usual Care

Patients randomized to usual care received educational handouts on musculoskeletal pain. During the trial, patients were followed up by their treating physician for all medical care. This care included continuation of medications, clinic visits, specialty referrals, and other care as usual. Therefore, use of pharmacologic and nonpharmacologic treatments for pain was permitted.

Statistical Analysis

The goal of the analysis was to detect a moderate treatment effect size. We defined a moderate effect size as an SD of 0.4 or 1.8 change points on the RMDS score at 9 months. With a 1:1 treatment allocation and allowance for more than 15% loss to follow-up, we enrolled 121 patients per group to ensure at least 100 patients per group for the desired power of 80% and significance of .05 (2-tailed) for the analyses.

Baseline characteristics of patients were reported, with categorical variables as frequencies (percentages) and continuous variables as means (SDs). The primary end point compared the change from baseline to 9 months between study groups. We used the intention-to-treat principle and included all randomized patients in the analysis. Mixed-effect models with repeated measurements were used as the primary analysis. Change from baseline to each follow-up visit constituted the response variable, and treatment groups, visit, and their interaction were the main predictors and were adjusted for the baseline value of the outcome measure. A random intercept was included to model within-participant correlation. The intervention effect was evaluated based on the mixed-effect models with repeated measurements analysis. In addition, we present summary statistics (mean [SD]) of outcome measurements at baseline and at the 9-month assessment by treatment group. A 2-sample *t* test was used to compare the difference of change from baseline to 9 months.

We evaluated the sensitivity of our analysis to missing data. We found no difference in the magnitude of missing data between study arms, and none of the outcome variables at baseline was associated with the probability of missing. We used complete cases and the last observation carried forward and obtained similar results. Therefore, we report results of the primary analysis based on the mixed-effect models with repeated measurements. The profiles of outcome measurements during the 9-month follow-up were also summarized by means and 95% CIs at each visit. A clinically important response for RMDS scores (>30% decrease) at 9 months was analyzed using a log-binomial model (SAS GENMOD procedure with log link function)[35] for calculating relative risk. Analyses were conducted using commercially available software (SAS, version 9.3; SAS Institute Inc).

Results

Participant Flow

Figure 1 details participant enrollment and follow-up in the trial. Of the 659 patients initially undergoing assessment, 272 were ineligible, most often because they did not report pain or have at least moderately limiting pain (ie, RMDS score <7 [n = 128]). Of the 387 eligible patients, 242 (62.5%) enrolled. One participant consented, enrolled, and completed a baseline assessment. However, after being randomized to usual care, the participant immediately withdrew and requested that the assessment be destroyed and not included in the study, leaving 241 patients with baseline data.

Baseline Characteristics of Study Sample

Baseline characteristics are shown in **Table 2**. The mean age of patients was 36.7 (range, 21-73) years, and 88.4% were men. In terms of racial mix, 77.7% were white, 13.0% were black, and 9.2% classified as other (3 patients refused to answer). The primary site of pain was the low back (57.3%) followed by the knee (21.6%), neck (7.5%), shoulder (7.1%), and hip (6.6%). More than two-thirds of the patients (66.4%) had served in the Army, 74.9% had been deployed to Iraq, 8.8% had been deployed to Afghanistan, and 16.3% had been deployed to both conflicts (information was missing for 2 patients).

As shown in **Table 3**, the stepped-care intervention and usual care groups had similar baseline pain measures. The mean RMDS score of 13.9 (range, 0-24) represents moderately severe pain-related disability. Likewise, the mean BPI Pain Interference subscale score of 5.4 (range, 0-10) represents moderately severe interference with activities because of pain, and a mean Graded Chronic Pain Scale severity score of 66.2 (range, 0-100) signifies moderate pain intensity.

At 9 months, overall follow-up completion was 91.7% (89.3% for the intervention group and 94.2% for the usual care group), with no significant differences between groups. Patients lost to or unavailable for follow-up did not differ on baseline characteristics from those who provided data at 9 months. The most frequently cited reason for withdrawal from the study was lack of time.

Primary Study Outcomes

The primary analysis included 121 patients in the intervention group and 120 in the usual care group. Compared with usual care, the intervention led to significant improvements in all pain outcomes at 9 months (Table 3 and **Figure 2**). The RMDS score decreased by 1.7 (95% CI, −2.6 to −0.9) points from baseline to 9 months in the usual care group and by 3.7 (95% CI, −4.5 to −2.8) points in the intervention group (between-group difference, −1.9 [95% CI, −3.2 to −0.7] points; $P = .002$). Patients in the intervention group were more likely to demonstrate at least a 30% improvement in RMDS scores by 9 months (relative risk, 1.52 [95% CI, 1.22-1.99]; $P < .001$), with a number needed to treat of 7.5 for 30% improvement.

The mean decrease in the BPI Pain Interference subscale score was 0.9 (95% CI, −1.2 to −0.5) points in the usual care group and 1.7 (95% CI, −2.1 to −1.3) points in the intervention group (between-group difference, −0.8 [95% CI, −1.3 to −0.3] points; $P = .003$). The Graded Chronic Pain Scale severity score was reduced by 4.5 (95% CI, −7.3 to −1.8) points in the usual care group and 11.1 (95% CI, −13.9 to −8.3) points in the intervention group (between-group difference, −6.6 [95% CI, −10.5 to −2.7] points; $P = .001$). Figure 2 illustrates the significant intervention effect on pain-related disability (RMDS score), BPI Pain Interference subscale score, and Graded Chronic Pain Scale severity score throughout the 9-month trial. Although all 3 pain outcomes significantly improved, the reduction in pain severity was more modest than those for pain-related disability and pain interference.

Table 2. Baseline Characteristics of 241 Patients in the ESCAPE Study

Baseline Characteristic	Study Group[a] Stepped Care (n = 121)	Usual Care (n = 120)
Age, mean (SD), y	36.4 (10.1)	38.2 (10.5)
Men	109 (90.1)	104 (86.7)
Race[b]		
White	93 (78.2)	92 (77.3)
Black	16 (13.4)	15 (12.6)
Other	10 (8.4)	12 (10.1)
Educational level[c]		
High school	27 (22.5)	31 (25.8)
>High school	93 (77.5)	89 (74.2)
Married	72 (59.5)	65 (54.2)
Income "just enough" to make ends meet	55 (45.5)	53 (44.2)
Employment status[c]		
Employed	73 (60.3)	73 (61.3)
Student	20 (16.5)	10 (8.4)
Unemployed or unable to work	28 (23.1)	36 (30.3)
Pain location		
Back	64 (52.9)	74 (61.7)
Knee	28 (23.1)	24 (20.0)
Neck	10 (8.3)	8 (6.7)
Shoulder	10 (8.3)	7 (5.8)
Hip	9 (7.4)	7 (5.8)
Served in Army	83 (68.6)	77 (64.2)
Deployment		
Iraq	94 (77.7)	85 (72.0)
Afghanistan	8 (6.6)	13 (11.0)
Both	19 (15.7)	20 (16.9)
No. of medical diseases, mean (SD)	0.86 (0.95)	1.03 (1.01)
PTSD symptom score, mean (SD)[d]	27.6 (19.2)	25.2 (19.7)
Depression score, mean (SD)[e]	11.1 (6.2)	11.3 (5.6)

Abbreviation: ESCAPE, Evaluation of Stepped Care for Chronic Pain.

[a] Data are presented as number (percentage) unless otherwise indicated.

[b] Information was missing for 3 patients.

[c] Information was missing for 1 patient.

[d] Determined using the Posttraumatic Stress Disorder Check List–17.[36] Scores range from 0 to 68, with higher scores representing more severe posttraumatic stress disorder symptoms.

[e] Determined using Patient Health Questionnaire–9.[37] Scores range from 0 to 27, with higher scores representing more severe depression.

Analgesic Use and Self-management Strategies

We determined analgesic use during the trial by self-report and electronic health record query. Treatment groups were similar at baseline in analgesic use (eTable in Supplement 2). At the end of step 1 (3 months), patients in the intervention group received more agents in each analgesic class relative to what they were prescribed at baseline. However, at the study end

Table 3. Baseline, 9-Month Follow-up, and Change in Pain Outcomes in ESCAPE Trial Participants

Outcome	Pain Outcomes: Stepped-Care Group (n = 121)	Usual Care Group (n = 120)	Between-Group Difference (95% CI)	*P* Value
RMDS Score (Range, 0-24)				
Baseline[a]	14.0 (4.3)	13.7 (4.7)	NA	.62
9-mo Follow-up[a]	10.6 (6.3)	12.1 (6.4)	NA	.09
Change from baseline, mean (95% CI)[b]	−3.7 (−4.5 to −2.8)	−1.7 (−2.6 to −0.9)	−1.9 (−3.2 to −0.7)	.002
BPI Pain Interference Subscale Score (Range, 0-10)				
Baseline[a]	5.4 (2.1)	5.4 (2.4)	NA	.86
9-mo Follow-up[a]	3.8 (2.6)	4.5 (2.7)	NA	.03
Change from baseline, mean (95% CI)[b]	−1.7 (−2.1 to −1.3)	−0.9 (−1.2 to −0.05)	−0.8 (−1.3 to −0.3)	.003
GCPS Severity Score (Range, 0-100)[c]				
Baseline[a]	67.3 (12.1)	65.1 (15.2)	NA	.22
9-mo Follow-up[a]	56.9 (19.1)	61.0 (19.3)	NA	.09
Change from baseline, mean (95% CI)[b]	−11.1 (−13.9 to −8.3)	−4.5 (−7.3 to −1.8)	−6.6 (−10.5 to −2.7)	.001

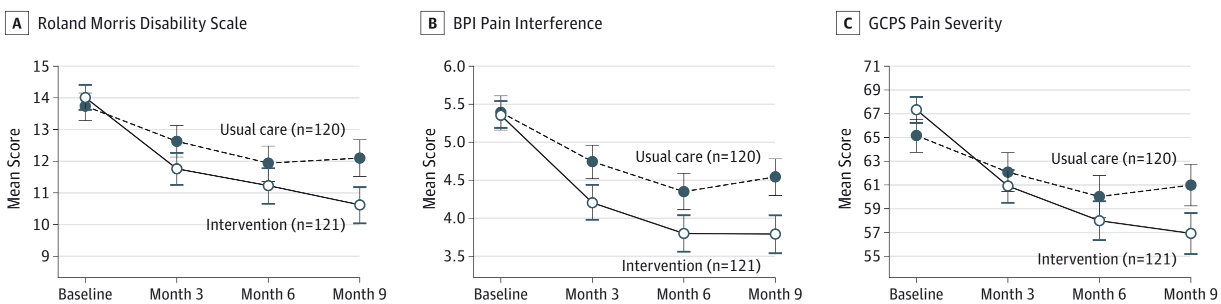
Abbreviations: BPI, Brief Pain Inventory; ESCAPE, Evaluation of Stepped Care for Chronic Pain; GCPS, Graded Chronic Pain Scale; NA, not applicable; RMDS, Roland Morris Disability Scale.

[a] Summary statistics by group and *P* value are based on the 2-sample *t* test.

[b] Estimates based on mixed-effect model with repeated measurements. Effect sizes are 0.24 for the RMDS, 0.26 for the BPI Pain Interference subscale, and 0.21 for GCPS severity.

[c] Denotes greater disability, pain interference, and pain severity scores.

Figure 2. Pain Outcomes



Outcomes were assessed at baseline and at months 3, 6, and 9 follow-up. A, Pain-related disability was measured by the Roland Morris Disability Scale. Scores range from 0 to 24, with higher scores representing more severe pain-related disability. B, Pain interference was measured by the Pain Interference subscale total score of the Brief Pain Inventory (BPI). Seven items are scored with a range from 0 to 10, with the mean calculated for the total score and a decrease considered improvement. C, Pain severity was measured by the Graded Chronic Pain Scale (GCPS). Scores range from 0 to 100, with higher scores representing more severe pain. Because we used the intention-to-treat principle, all randomized patients were included in the analysis. Substantial reduction was seen in all 3 measures during the 9-month trial among patients in the intervention group. A total of 11 patients withdrew from the intervention arm and 6 patients from the usual care arm. Error bars indicate 95% CIs.

(9 months), those patients were using more topical analgesics and patients in the usual care group received more tricyclic antidepressants.

Self-management Strategies, CBT, and Intervention Adherence

The intervention group had a mean of 5.6 (median, 6) telephone sessions with NCMs during step 1 to discuss analgesics and self-management strategies. Patients were taught several strategies, including tips about physical activity (96 patients [79.3%]), pain education (92 [76.0%]), alternative thinking (72 [59.5%]), stress management (66 [54.5%]), effective communication (32 [26.4%]), and community resources (21 [17.4%]). In step 2, the mean number of CBT sessions in which patients participated was 3.6 (median, 5). In total, patients received a mean of 9.2 (median, 12) NCM contacts during the 9-month study period.

Discussion

The stepped-care intervention targeted musculoskeletal pain because it is the most common, disabling, and costly of all pain conditions.[38,39] The functional and economic effect of musculoskeletal pain on military personnel[40] is substantial. We found that an intervention combining analgesics, self-management strategies, and CBT is effective in reducing pain-related disability, pain interference, and pain severity in OEF/OIF/OND veterans with chronic, disabling musculoskeletal pain of the spine and extremities.

The ESCAPE trial was designed and implemented within a large VA health care system. We believe that the ESCAPE intervention generalizes especially well to other VA medical centers and other large health care systems outside the VA. However, implementing the approach to smaller community settings or to private settings may be challenging.

Our study adds to the literature about multimodal approaches that combine pharmacologic and nonpharmacologic treatments that may be applied in nonspecialty settings. Study findings have implications for the patient-centered medical home environment, especially an emphasis on team-based care. This study also demonstrates a potential model of sequencing pain treatments involving analgesics, self-management strategies, and CBT.

Patients in the ESCAPE intervention experienced a 3.7-point reduction in RMDS scores, which is clinically significant for individual patients.[41] Although between-group differences for the intervention and usual care did not meet a 2-point difference, this metric to define minimally important change is more appropriately applied to individual differences rather than group differences.[41] Findings from the ESCAPE trial are consistent with those in 3 previous trials[31,42,43] using a care management–based approach. Kroenke et al[31] combined antidepressants with a pain self-management program in patients with comorbid musculoskeletal pain and depression. Patients receiving the intervention showed substantial improvements in depression and a significant decrease of 3.3 points in the RMDS score compared with usual care. Dobscha and colleagues[42] evaluated a collaborative care intervention in veterans with chronic pain. The intervention was delivered by a clinical psychologist rather than nurses and showed that patients improved on pain disability (the RMDS score decreased by 1.4 points).[42] A recent trial by Kroenke et al[43] found that significantly more primary care patients with chronic pain improved because of an intervention that used automated symptom monitoring and NCMs to optimize use of nonopioid analgesics.[43]

The ESCAPE trial has some limitations. First, participants were all recent veterans with chronic musculoskeletal pain; our results may not apply to veterans from other eras or to nonveterans. Second, the trial was conducted at a single medical center. Single-center, randomized clinical trials have shown larger treatment effects than multicenter trials.[44] However, the intervention effects observed were comparable to other interventions tested at more than 1 site. Third, the ESCAPE trial tested a multimodal intervention and used a bundled approach to delivery. As a result, we were not able to determine the relative efficacy of intervention components and were unable to separate out attentional effects. However, to help disentangle these effects, we gathered in-depth, qualitative data from patients in the intervention group (n = 26) to determine their experiences with and perceptions of the intervention. The patients spoke about their evolving understanding of their pain experience during the trial and how this new understanding helped them manage their pain more effectively.[45,46] Fourth, study patients were not blinded. The major strengths of our trial include (1) a high-priority patient population (OEF/OIF/OND veterans) with complex pain care needs, (2) an innovative approach that challenges existing treatment paradigms for chronic pain, and (3) a telephone-based intervention delivered by NCMs that may be applied across multiple geographically dispersed clinical settings.

Conclusions

A stepped-care intervention that combined analgesics, self-management strategies, and CBT benefited OEF/OIF/OND veterans with chronic musculoskeletal pain in terms of pain-related disability, pain interference, and pain severity. Additional pain treatments will need to be combined in a stepped-care model to produce even greater improvements in pain.

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Author Affiliations: Research Service, Veterans Affairs Health Services Research and Development, Center for Health Information and Communication, Richard L. Roudebush Veterans Affairs Medical Center, Indianapolis, Indiana (Bair, Outcalt, Kempf, Froman, Damush, Kroenke); Department of Medicine, Indiana University School of Medicine, Indianapolis (Bair, Damush, Kroenke); Health Services Research, Regenstrief Institute, Inc, Indianapolis, Indiana (Bair, Damush, Kroenke); Rheumatology and Immunology, Wake Forest School of Medicine, Winston-Salem, North Carolina (Ang); Department of Biostatistics, Indiana University School of Medicine, Indianapolis (Wu, Yu); Department of Psychiatry, Indiana University School of Medicine, Indianapolis (Outcalt); Department of Physical Medicine and Rehabilitation, Indiana University School of Medicine, Indianapolis (Sargent); Department of Occupational Therapy, Colorado State University, Fort Collins (Schmid); Research Service, Richard L. Roudebush Veterans Affairs Medical Center, Indianapolis, Indiana (Davis).

Author Contributions: Dr Bair had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Bair, Ang, Schmid, Damush, Davis, Kroenke.
Acquisition, analysis, or interpretation of data: Bair, Ang, Wu, Outcalt, Sargent, Kempf, Froman, Schmid, Yu, Davis.
Drafting of the manuscript: Bair, Ang, Sargent, Froman, Yu.
Critical revision of the manuscript for important intellectual content: Bair, Ang, Wu, Outcalt, Kempf, Schmid, Damush, Yu, Davis, Kroenke.
Statistical analysis: Bair, Wu, Yu.
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Study supervision: Bair, Ang, Sargent, Kempf, Froman, Schmid, Yu.

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