# Collaborative Care for Chronic Pain in Primary Care

## A Cluster Randomized Trial

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**Context** Chronic pain is common in primary care patients and is associated with distress, disability, and increased health care use.

**Objective** To assess whether a collaborative intervention can improve chronic pain–related outcomes, including comorbid depression severity, in a Department of Veterans Affairs primary care setting.

**Design, Setting, and Participants** Cluster randomized controlled trial of a collaborative care assistance with pain treatment intervention vs treatment as usual at 5 primary care clinics of 1 Department of Veterans Affairs Medical Center. Forty-two primary care clinicians were randomized to the assistance with pain treatment intervention group or the treatment as usual group. The 401 patients had musculoskeletal pain diagnoses, moderate or greater pain intensity, and disability lasting 12 weeks or longer and were assigned to the same treatment groups as their clinicians. Recruitment occurred from January 2006 to January 2007 and follow-up concluded in January 2008.

**Intervention** Assistance with pain treatment included a 2-session clinician education program, patient assessment, education and activation, symptom monitoring, feedback and recommendations to clinicians, and facilitation of specialty care.

**Main Outcome Measures** Changes over 12 months in pain-related disability (Roland-Morris Disability Questionnaire, range of 0-24), pain intensity (Chronic Pain Grade [CPG] Pain Intensity subscale, range of 0-100), and depression (Patient Health Questionnaire 9 [PHQ-9], range of 0-27), measured as β coefficients (difference in slopes in points per month).

**Results** Intervention patients had a mean (SD) of 10.6 (4.5) contacts with the assistance with pain treatment team. Compared with the patients receiving treatment as usual, intervention patients showed greater improvements in pain-related disability (Roland-Morris Disability Questionnaire β, –0.101 [95% confidence interval {CI}, –0.163 to –0.040]; $P = .004$ and CPG Pain Intensity subscale β, –0.270 [95% CI, –0.480 to –0.061]; $P = .01$). Among patients with baseline depression (PHQ-9 score ≥10), there was greater improvement in depression severity in patients receiving the intervention compared with patients receiving treatment as usual (PHQ-9 β, –0.177 [95% CI, –0.295 to –0.060]; $P = .003$). The differences in scores between baseline and 12 months for the assistance with pain treatment intervention group and the treatment as usual group, respectively, were –1.4 vs –0.2 for the Roland-Morris Disability Questionnaire, –4.7 vs –0.6 for the CPG Pain Intensity subscale, and –3.7 vs –1.2 for PHQ-9.

**Conclusion** The assistance with pain treatment collaborative intervention resulted in modest but statistically significant improvement in a variety of outcome measures.

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CHRONIC NONCANCER PAIN IS associated with considerable physical and psychosocial impairment, distress, comorbid depression, and increased health care use and costs.[1-4] Many primary care patients report chronic pain,[2,5,6] most commonly musculoskeletal pain.[2,7] Guidelines for chronic pain treatment have been developed.[8,9] However, implementation has been problematic, especially in busy primary care practices in which access to recommended treatment components may be limited.

Multifaceted, collaborative interventions can promote guideline-concordant care and improve outcomes for chronic conditions in primary care.[10,11] These interventions, based on the chronic care model,[10] attempt to optimize patient and clinician interactions via education and activation while providing system support, including care management and clinician feedback. Several investigators have demonstrated improvements in pain intensity and pain-related function in studies of interventions using collaborative approaches.[12-14] However, one of these studies used a pre-post design,[14] and the

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intervention in another study was designed to target depression rather than pain.[12] Aside from these initial investigations, we are not aware of any rigorous published studies of collaborative approaches to chronic pain in primary care.

The Study of the Effectiveness of a Collaborative Approach to Pain (SEACAP) assessed whether a collaborative care intervention would result in improvements in chronic pain–related outcomes, including depression, compared with treatment as usual among patients treated in a Department of Veterans Affairs (VA) primary care setting.

## METHODS

A cluster randomized trial of a collaborative intervention for chronic pain, SEACAP was conducted in 5 primary care clinics of 1 VA Medical Center. The local institutional review board approved the study and all enrolled patients and participating primary care clinicians gave written informed consent. The design and baseline findings from SEACAP were previously reported.[15]

### Setting

The study took place in 3 urban and 2 rural primary care clinics that collectively treated 42 000 patients. Most patients with chronic pain at the VA Medical Center are treated for pain by their primary care clinicians. A specialty pain clinic at the main hospital provides multidisciplinary consultation, an introductory pain education class, and in some cases intervention by an anesthesiologist. However, the clinic is not staffed to provide ongoing care and typically refers patients back to clinicians for ongoing pain management. A system-wide electronic medical record includes inpatient and outpatient progress notes, laboratory data, and consultation reports.

### Sample and Recruitment

Sample size calculations showed that using an intracluster correlation coefficient of 0.02 and an $\alpha$ level of .05, a sample size of 320 (20 clinicians per group and 8 patients per clinician) would allow for detection of a mean (SD) difference of 2.0 (5.6) points (effect size of 0.36) on the Roland-Morris Disability Questionnaire (RMDQ)[16,17] with 83% power. To compensate for participant attrition and other potential threats to effect size, including clinician-to-clinician contamination, the target patient sample size was increased by 25% to 400. Statistical power may be greater than 83% because the analyses were based on longitudinal methods using data at baseline, 3, 6, and 12 months.

All full-time and part-time staff physicians (n=33), an internal medicine fellow (n=1), physician assistants (n=2), and nurse practitioners (n=18) who treated patients in the primary care clinics were eligible to participate. Clinician recruitment methods included e-mails, mailings, and presentations at practice meetings. Participating clinicians gave investigators permission to recruit their patients.

All patients enrolled in primary care assigned to participating clinicians were potentially eligible to participate. Patients were recruited over 12 months, from January 2006 to January 2007, using 2 approaches. First, patients due for an appointment with a participating clinician within 6 weeks were mailed a letter describing the study and inviting them to contact the study office (by telephone or mail) for screening. Second, flyers asking patients to contact the study office for screening were posted in primary care clinics and at prominent locations around the VA Medical Center. To increase the number of female participants, patients of 2 women's health clinics were mailed flyers along with annual reminder letters for clinical care.

When patients contacted the study office, a research assistant reviewed the patient's medical records and administered a brief telephone questionnaire. Eligible patients were offered subsequent in-person enrollment appointments, often matching primary care clinician appointments. Patients at remote locations could complete enrollment interviews by telephone or videoconferencing. Participants were offered $10 in compensation for participation in the enrollment interview.

Inclusion criteria were medical record documentation of an *International Classification of Diseases, Ninth Revision, Clinical Modification* musculoskeletal pain diagnosis (back, arthritic, or neck or joint pain), pain of at least 12 weeks duration, scores of 4 or higher (indicating moderate or greater severity) on each of 2 subscales from the Chronic Pain Grade (CPG)[18] assessing pain intensity and interference in the prior 3 months, and RMDQ score of 6 or greater at the time of the enrollment interview[16,17] (because persons with scores $\geq$6 are generally dissatisfied with their back pain status[19,20]). Exclusion criteria included documented diagnoses of fibromyalgia, chronic fatigue syndrome, somatization disorder, bipolar disorder, psychotic disorder, dementia, or terminal illness. Patients were also excluded if they had active suicidal ideation requiring urgent attention or flags in the medical record indicating a history of disruptive behavior. For patients aged 65 years or older, or if concerns about cognitive problems arose during screening, the short Orientation-Memory-Concentration Test[21] was administered; a score of 10 or greater was exclusionary. Patients with alcohol or substance use disorders were included in the study.

### Randomization

The statistician, who did not know the clinicians, randomized the clinicians to the assistance with pain treatment intervention or treatment as usual using stratified random assignment. Randomization by clinician enabled efficient clinician education, interactions between the intervention clinicians, and minimization of clinician-patient and clinician-to-clinician contamination effects. Intervention effects do not tend to generalize (spillover) to nonintervention participants in multifaceted intervention trials, even when patients receive care from the same clinician.[22,23]

Random assignment was stratified by professional training (nurse practitioner or physician assistant vs physician), distance from main hospital (>15 miles vs ≤15 miles), and proportion of patients in clinician panels currently receiving prescriptions for opioids. These variables were selected to minimize potential imbalances due to clinician training, attitudes toward pain treatment, and access to specialty pain resources. Forty-six of 54 eligible clinicians (85%) agreed to participate. Of these 46, 2 left their practices before patient enrollment and 2 had no patients enrolled due to small caseloads. There were no differences between participating and nonparticipating clinicians in terms of professional training, distance from main hospital, proportion of patients receiving prescriptions for opioids, or panel size. Of the 42 remaining clinicians, 20 were randomized to the assistance with pain treatment intervention group and 22 were randomized to the treatment as usual group. Patients enrolled in the study were assigned to the same group as their clinicians. Neither clinicians nor patients were informed of their randomization status prior to agreeing to participate in the study.

### Intervention

The assistance with pain treatment intervention is based on the chronic care model,[10] previous collaborative interventions,[10,24-26] multidisciplinary pain approaches,[27,28] chronic pain treatment guideline criteria,[9,29,30] and brief activating interventions for back pain.[20] The key members of the intervention team were a full-time psychologist care manager and an internist who spent up to 1 day per week on intervention activities; these team members did not have prior extensive training in pain management. The specifics of their training for this project and other details about the intervention are reported elsewhere.[15] Before patient recruitment, clinicians assigned to the intervention group participated in two 90-minute workshops led by the intervention team. These sessions introduced the intervention, included education about chronic pain and abbreviated training in shared decision-making skills,[31] and surveyed clinicians' communication preferences.[32]

After enrolling in the study, intervention patients received an initial telephone contact, were mailed written materials, and received an assessment visit with the care manager. Assessments were usually performed face-to-face in primary care clinics but occasionally by telephone or videoconferencing. Assessment goals included identification of fear-avoidance beliefs (eg, fear of movement or pain exacerbations), exploration of treatment barriers, screening for comorbid psychiatric disorders (including depression and alcohol or substance misuse), and development of individualized functional goals. The care manager and intervention internist then jointly reviewed assessment results and developed treatment recommendations that were communicated to clinicians, usually through medical record electronic alerts or e-mail. In straightforward situations, the intervention team drafted orders for clinicians to sign if they agreed with the treatment recommendations. Patients requiring more intensive assessment or specialized care received stepped-care components (eg, assistance with pain treatment internist or mental health consultation). In some cases, the intervention internist telephoned patients to discuss symptoms or provide additional education.

Patients were encouraged to attend a 4-session workshop at the main hospital within 4 months of enrollment. This workshop was adapted primarily from a brief activating approach[20,33] and primary care group visit models.[34] It was led by the care manager and co-led by the intervention internist or a physical therapist. Workshop participants received additional educational materials[35] and a list of community resources.

The care manager attempted to contact patients by telephone every 2 months over a 12-month period to readminister pain, depression, and substance use disorder screenings; assess goals and activities; and provide support. The care manager and intervention internist re-reviewed cases to determine whether additional recommendations or stepped care were indicated. Feedback and recommendations were communicated to clinicians.

### Treatment as Usual

All treatment as usual and assistance with pain treatment intervention clinicians had access to the specialty pain clinic; ancillary services including physical, occupational, and recreational therapy; and collocated mental health services. All clinicians were notified when patient recruitment began. When a patient enrolled in the study, a note was placed in the patient's medical record.

### Data Collection

Research assistants, blinded to the study group status, collected patient data at baseline, 3, 6, and 12 months. Baseline measures were usually obtained in person; telephone or videoconferencing was used occasionally (n=40). Follow-up measures were usually obtained by mail, but research assistants telephoned patients to administer measures, complete missing items, or resolve discrepancies in 13% of follow-up assessments. Follow-up concluded in January 2008.

Baseline patient data obtained from VA medical records included age, sex, *International Classification of Diseases, Ninth Revision, Clinical Modification* musculoskeletal pain diagnoses, whether patients had received prescriptions for opioids within 6 months prior to enrollment, and global medical morbidity (number of RxRisk-V [chronic disease score] categories[36]). Baseline information obtained from patients included employment, marital and disability status, pain duration, pain-related functional interference and intensity (RMDQ[16,17] and CPG Pain Interference and Pain Intensity subscales[18]), health-related quality of life[37] (EQ-5D), depression severity

(Patient Health Questionnaire 9 [PHQ-9]),[38,39] posttraumatic stress disorder (PTSD; trauma stem plus PTSD Checklist 17),[40,41] alcohol misuse (Alcohol Use Disorders Identification Test on Consumption),[42] substance use disorder (Drug Abuse Screening Test 10),[43] anxiety disorders (Primary Care Evaluation of Mental Disorders [PRIME-MD] anxiety and panic modules),[44] global VA health care satisfaction,[45] receipt and rating of effectiveness of prior VA chronic pain treatment,[46] and use of non-VA care. Because previous investigations have identified variability in pain treatment and pain outcomes by race or ethnicity,[47] this characteristic also was included (race/ethnicity was identified by the patient from preselected options) as a demographic characteristic.

### Study Outcomes

The primary study outcome was self-reported pain-related disability over 12 months (RMDQ score was based on responses to 24 yes or no items and the score range was 0 [no disability] to 24 [extremely severe disability]).[16,17] Additional main outcomes were depression severity (based on responses to the PHQ-9 with a score range of 0 [no symptoms of depression] to 27 [extremely severe depression])[38,39] and pain intensity (based on the CPG Pain Intensity subscale with a score range of 0 [no pain] to 100 [worst pain imaginable]).[18] These measures were selected for their brevity and psychometric strength. The RMDQ has content and construct validity, internal consistency, and responsiveness to change among patients with chronic pain.[17,48] The CPG is valid and reliable for use in a general population, and valid for assessing change in pain severity over time.[49] The PHQ-9 has good sensitivity (88%) and specificity (88%) for major depression and demonstrates concurrent validity with measures of functional impairment.[38,50]

Secondary outcomes were the CPG Pain Interference subscale (score range of 0 [no interference] to 100 [extreme interference]),[18,49] and proportions of patients with 30% reductions in RMDQ scores over 12 months. Based on previous studies,[17,20,51,52] a 30% reduction in RMDQ score was defined as clinically meaningful to calculate the number needed to treat. Outcomes also included the patient-rated global impression of change,[53] global VA health care satisfaction,[45] health-related quality of life (EQ-5D),[37] and receipt and rating of effectiveness of VA chronic pain treatment.[46] A regional VA database was used to collect prescription and health care use data. A separate database was used to collect information on the timing and content of assistance with pain treatment intervention team activities.[15]

### Statistical Analysis

Baseline patient and clinician characteristics were compared between groups using the 2-tailed *t* test for continuous variables and the $\chi^2$ test for categorical variables. Follow-up data were collected on 389 enrollees (97%) at 3 months, 366 (91%) at 6 months, and 362 (90%) at 12 months. Seven patients (2%) completed measures at only 1 time point (baseline). Data missingness did not vary by study group or baseline RMDQ or PHQ-9 scores. The effects of the intervention on patient outcome variables were tested using intention-to-treat analyses with multilevel models.[54] For primary and secondary outcomes, time (baseline, 3, 6, and 12 months) formed the first level of the model, the patient formed the second level, and the clinician formed the third level. Patient-level covariates of age, sex, baseline depression severity, baseline opioid status (yes or no), and medical morbidity were included. These covariates were chosen because depression, opioid use, and medical morbidity may be important potential predictors of pain or depression treatment response.[4,55,56] Because randomization was at the clinician level, group assignment (treatment as usual or intervention) was included at the third level of the model. The group × time interaction term tests if the change over time in the dependent variable of interest is significantly different for the 2 study groups.

Two-level models were used for opioid prescription and VA health care use variables at 12 months, with patients at the first level, and clinician and intervention status at the second level. The same patient-level covariates were included. For most variables, distributions were positively skewed with a majority of zero values, so these variables (any or none) were dichotomized and a logistic model was used. Continuous models were used for clinician and ambulatory visits. In moderator analyses, 3-level models were used (time, patient, clinician) and included the same patient-level covariates as in the main analyses; an interaction term assessed treatment effect differences between groups over time. Depression status, distance from VA facility, and disability payment status were tested as potential moderators. Data on intervention costs were obtained from the VA Decision Support System and a separate database that tracked intervention team activities not captured by this system. Fixed and indirect costs of care as well as costs of training personnel were included.

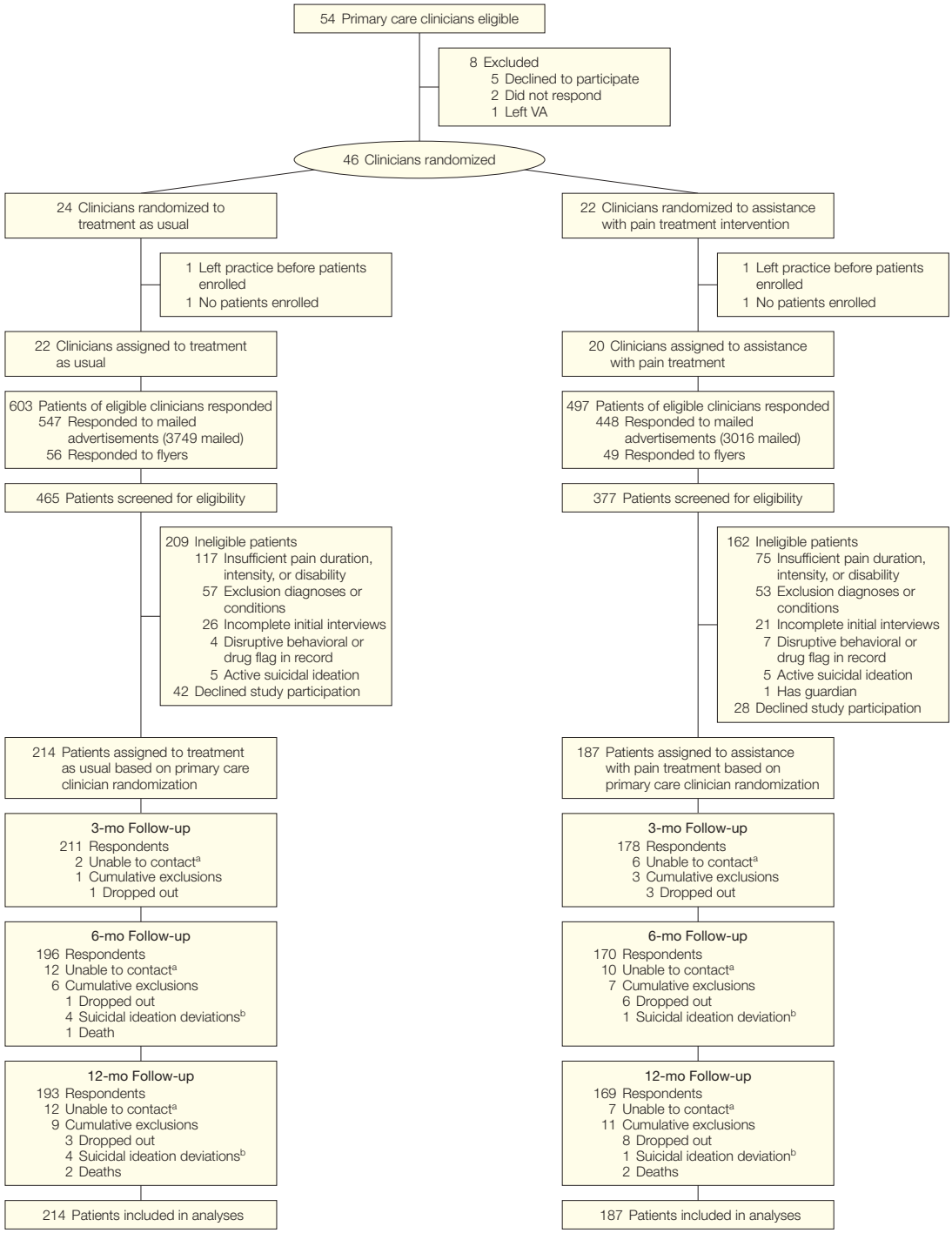
Unadjusted means and proportions are presented to describe baseline characteristics. Adjusted means, proportions, and corresponding *P* values are reported for all other models using the method described by Raudenbush and Bryk.[54] Descriptive patient, clinician, and intervention implementation data analyses were conducted using SPSS versions 13.0 and 16.0 (SPSS Inc, Chicago, Illinois). All multilevel analyses were conducted using HLM version 6.0 (Scientific Software International, Lincolnwood, Illinois).[57] All significance tests were 2-sided and the $\alpha$ level was set at .05. HLM incorporates all patients who have at least 1 time point in the first level of the model. Thus, patients were not excluded from the main analyses because of missing dependent follow-up variables.

## RESULTS

Of 6765 eligible primary care patients mailed advertisement letters, 995 re-

sponded by calling or returning a mailing to our research office (15%). Women had a higher rate of response (20%) than men (14%), and respondents were slightly older than nonrespondents (mean [SD] age of 64.0 [13.1] years vs 62.3 [14.6] years, respectively). Posted flyers drew another 176 respondents; of these, 105

**Figure.** Participant Flow




[a]Patients who could not be contacted remained in the study and were contacted for subsequent follow-ups.
[b]Deviation in protocol due to detection of active suicidal ideation requiring urgent clinical attention.
VA indicates Veterans Affairs.

were patients of eligible clinicians. There was no association between group assignment and method of recruitment. Of 842 patients completing the screening, 442 completed enrollment interviews (53%), and 401 subsequently enrolled (48%) in the study (FIGURE). Eight percent of enrollees were women and the mean (SD) age of enrollees was 61.1 (11.8) years. Patient sample demographics approximated local, regional, and national VA populations.[58,59]

There were no significant baseline differences between intervention and treatment as usual clinicians and patients (TABLE 1 and TABLE 2). Approximately one-third of patients were employed within the prior 12 months, and two-thirds reported receiving disability payments. Two-thirds of patients had more than 1 musculoskeletal pain diagnosis. The median duration of pain was 10 years. The mean (SD) RMDQ score was 14.7 (4.4), corresponding to moderate or greater levels of pain intensity and disability.[17,61] Depression, PTSD, and panic attacks were common, each occurring in approximately one-fifth of patients. Of the covariates included in the main analyses, baseline depression severity, opioid status, and medical morbidity had significant bivariate relationships (all $P < .001$) with RMDQ score.

In adjusted models, intervention patients showed significantly greater improvements in pain-related disability based on the RMDQ ([difference in slopes in points per month] β, –0.101 [95% confidence interval {CI}, –0.163 to –0.040]; $P = .004$) and pain intensity based on the CPG Pain Intensity subscale (β, –0.270 [95% CI, –0.480 to –0.061]; $P = .01$) compared with treatment as usual patients during a 12-month period. Compared with treatment as usual patients with depression (baseline PHQ-9 ≥ 10) over 12 months, intervention patients with depression showed significantly greater improvements in PHQ-9 scores (β, –0.177 [95% CI, –0.295 to –0.060]; $P = .003$).

The difference in scores between baseline and 12 months for patients in the intervention group and patients in the treatment as usual group, respectively, were –1.4 vs –0.2 for the RMDQ, –4.7 vs –0.6 for the CPG Pain Intensity subscale, and –3.7 vs –1.2 for the PHQ-9. At 12 months, 21.9% of intervention patients vs 14.0% of treatment as usual patients (adjusted $P = .04$) demonstrated 30% reductions in RMDQ score, resulting in a number needed to treat of 12.70 (95% CI, 12.48-12.74).

Intervention patients also reported significantly greater reductions in the alternate measure (CPG Pain Interference subscale) of pain-related disability (β, –0.578 [95% CI, –1.071 to –0.084]; $P = .03$) over 12 months (TABLE 3) and significantly improved ratings of global impression of change at 6 months (3.6 vs 4.5; $P < .001$) and 12 months (3.7 vs 4.4; $P < .001$) compared with treatment as usual patients. However, there were no significant differences in health-related quality of life (EQ-5D) scores, ratings of global health care treatment satisfaction, or ratings of pain treatment effectiveness over 12 months when comparing intervention patients with treatment as usual patients.

In moderator analyses, group × time changes for the RMDQ score, CPG Pain Intensity subscale, and CPG Pain Interference subscale did not significantly vary by baseline depression status ($P = .25$, $P = .20$, and $P = .22$, respectively), distance from nearest VA facility ($P = .08$, $P = .17$, and $P = .18$, respectively), or total number of intervention team contacts ($P = .28$, $P = .87$, and $P = .58$, respectively). However, the effect of group assignment on RMDQ scores differed by disability payment status ($P = .03$). For the treatment as usual patients, the RMDQ scores were generally greater over 12 months for those who were currently receiving disability or had a disability claim in progress compared with those who were not receiving or anticipating disability payments.

Intervention patients were more often prescribed adjunctive medications including antidepressants, nonsteroidal anti-inflammatory drugs, and capsaicin (TABLE 4). Intervention patients were not more likely to receive opioids, but when prescribed opioids, were more likely to receive long-acting opioids. There were no significant group differences in proportions with inpatient admissions, emergency department visits, or mental health or pain consultation service appointments; or in numbers of primary care or total ambulatory visits (Table 4). In-

**Table 1.** Participating Clinician Characteristics

| Characteristic | Treatment as Usual (n = 22) | Assistance With Pain Treatment Intervention (n = 20) | Group Test *P* Value |
|---|---|---|---|
| Physicians, No. (%) | 16 (73) | 14 (70) | .85 |
| Nurse practitioners or physician assistants, No. (%) | 6 (27) | 6 (30) | .85 |
| Female sex, No. (%) | 9 (41) | 12 (60) | .22 |
| Period since training, mean (SD), y[a] | 16.1 (9.7) | 18.7 (8.8) | .38 |
| Work full-time, No. (%)[b] | 15 (68) | 12 (60) | .58 |
| No. of patients in panel, mean (SD)[c] | 696 (367) | 640 (425) | .66 |
| No. of patients in panel prescribed opioids, mean % (SD)[c] | 15.5 (4.7) | 17.3 (8.1) | .41 |
| Job satisfaction subscale score, mean (SD)[d] | 4.3 (0.9) | 4.3 (0.9) | .83 |
| Satisfaction with pain resources, mean (SD)[e] | 2.6 (0.8) | 2.4 (1.1) | .38 |

[a] There were 39 clinicians who responded.
[b] Defined as spending more than 60% of their time in the clinic.
[c] Panel refers to the number of active patients that the clinician was responsible for treating. There were 38 clinicians who responded.
[d] Average of 5 items (Likert scales, range 1-6); a higher score represents greater satisfaction. There were 41 clinicians who responded.
[e] Average of 3 items (Likert scales, range 1-6); a higher score represents greater satisfaction. There were 41 clinicians who responded.

**Table 2.** Baseline Patient Characteristics[a]

| Characteristic | Treatment as Usual (n = 214) | Assistance With Pain Treatment Intervention (n = 187) | Group Test *P* Value |
|---|---|---|---|
| Age, mean (SD), y | 61.3 (12.3) | 62.1 (11.2) | .48 |
| Male sex | 196 (92) | 172 (92) | .89 |
| Self-reported race/ethnicity | | | |
| White | 189 (88) | 168 (90) | .72 |
| Black | 5 (2) | 2 (1) | |
| American Indian/Alaska Native | 6 (3) | 7 (4) | |
| Married | 122 (57) | 114 (61) | .42 |
| Education beyond high school | 164 (77) | 137 (73) | .44 |
| Worked during past 12 mo | 69 (32) | 58 (31) | .82 |
| Live > 1 h from a VA facility | 61 (29) | 54 (29) | .93 |
| Currently receiving disability payment | 134 (63) | 125 (67) | .38 |
| Report non-VA health care in prior 6 mo | 123 (57) | 100 (53) | .33 |
| Duration of pain, y | | | |
| Mean (SD) | 14.9 (13.1) | 14.7 (12.3) | .90 |
| Median (range) | 10 (0.2-61) | 10 (0.3-64) | |
| Musculoskeletal pain diagnoses | | | |
| Back pain | 145 (68) | 123 (66) | .67 |
| Neck or joint pain | 140 (65) | 120 (64) | .79 |
| Rheumatism, osteoarthritis, or arthritis | 101 (47) | 97 (52) | .35 |
| Roland-Morris Disability Questionnaire for pain, mean (SD)[b] | 14.5 (4.4) | 14.9 (4.4) | .43 |
| Current pain intensity, mean (SD)[c] | 5.1 (2.1) | 5.3 (2.2) | .34 |
| Health-related quality of life (EQ-5D), mean (SD)[d] | 0.64 (0.18) | 0.64 (0.17) | .86 |
| RxRisk-V medical morbidity, mean (SD)[e] | 4.8 (3.0) | 5.0 (3.1) | .60 |
| Patient Health Questionnaire 9[38,f] | | | |
| Major depression diagnosis | 42 (20) | 29 (16) | .28 |
| Depression severity, mean (SD) | 8.4 (6.0) | 8.1 (5.7) | .64 |
| Posttraumatic stress disorder[g] | 40 (19) | 26 (14) | .21 |
| PRIME-MD[49] | | | |
| Anxiety syndrome | 27 (13) | 25 (13) | .82 |
| Panic attack within past 4 wk | 36 (17) | 31 (17) | .97 |
| Positive AUDIT-C alcohol misuse screening[h] | 31 (14) | 34 (18) | .32 |
| Endorses drug misuse in past 6 mo[i] | 8 (4) | 4 (2) | .35 |
| Reports prior substance use treatment | 39 (18) | 25 (13) | .19 |
| Taking antidepressant at study entry | 80 (37) | 66 (35) | .66 |
| Taking opioid in 6 mo prior to study entry | 90 (42) | 83 (44) | .64 |
| Global care satisfaction, mean (SD)[j] | 2.9 (0.8) | 2.9 (0.9) | .61 |
| Reports good or better pain treatment effectiveness[k] | 60 (28) | 59 (32) | .88 |

Abbreviations: AUDIT-C, Alcohol Use Disorders Identification Test on consumption; PRIME-MD, Primary Care Evaluation of Mental Disorders; VA, Department of Veterans Affairs.

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

[b] The score range is 0 to 24.

[c] Item is the VA pain as a fifth vital sign (numeric rating scale)[50] screening item. Based on patient response to "How would you rate your pain at the present time?" The score range is 1 to 10.

[d] Based on US time tradeoff scoring criteria.[37] The score range is –1 to 1.

[e] The score range is 0 to 45.

[f] The score range is 0 to 27. A diagnosis of major depression is given if either of the first 2 items (depressed mood or anhedonia) plus a total of 5 of all 9 items are endorsed at more than half the days (the ninth item regarding thoughts of death counts if present at all).

[g] Based on the [posttraumatic stress disorder] PTSD Checklist Score 17 plus endorsement of trauma stem. A score of 50 or greater was used as the cutoff and has been shown to be optimal for diagnosing this disorder in veterans.[41]

[h] The cutoff for alcohol misuse is 4 drinks/d or greater, which has a sensitivity of 86% and a specificity of 72% for heavy drinking and/or active alcohol abuse or dependence.[42]

[i] Based on the Drug Abuse Screening Test 10. A score of 2 or greater is recommended as a cutoff for screening for substance misuse.[43]

[j] Among the 365 patients (91%) indicating receipt of VA health care in the 6 months prior to baseline and who completed the treatment satisfaction survey. The score range is 0 to 4.

[k] Of 401 patients, 220 (55%) indicated receipt of and rated VA care (ever) for chronic pain; the difference between treatment as usual and intervention patients was nonsignificant (*P*=.19). Among the 220 reporting care, 119 (54%) reported good or better pain treatment effectiveness.

tervention patients were more likely to have physical therapy appointments. Unadjusted mean costs (including fixed and indirect costs) for assistance with pain treatment personnel and their training, training sessions for primary care clinicians, and materials were $1192 per intervention patient.

The assistance with pain treatment intervention was generally implemented as intended (TABLE 5). Almost all patients received initial assessments. Fewer than half attended at least 1 group workshop; patients often reported travel difficulties, including distance to the hospital. The mean (SD) number of completed follow-up telephone contacts was 5.4 (1.7) compared with a target of 7; however, there was a median of 10 (range, 1-26 contacts) intervention team contacts per patient over 12 months when combining all types of direct contact (initial telephone call, assessment, group workshops, and follow-up calls). During the 6 months of peak patient enrollment, the intervention internist spent a mean (SD) of 3.3 (1.3) hours per week on assistance with pain treatment activities.

## COMMENT

In this cluster randomized controlled trial, a collaborative intervention resulted in significant improvements in pain disability and intensity and patient-rated global impression of change. Depression severity and pain disability and intensity improved among the patients with depression. Process measures including greater use of adjunctive pain medications and long-term opioids suggest that the intervention contributed to delivery of guideline-concordant care. While intervention patients had more physical therapy visits than usual care patients, there were no significant differences between the 2 groups in total ambulatory visits.

Although there were significant differences in a variety of outcomes, improvements were generally modest. The mean treatment effect by RMDQ change scores was less than a difference of 2

points, and only 22% of intervention patients achieved a 30% reduction in RMDQ score. The minimal clinically important difference for RMDQ score ranges from 2 to 8 and is dependent on baseline score.[17,51,52] The minimal clinically important difference for RMDQ score may be as low as 2 for subpopulations with high rates of chronicity,[52] as would be the case with our patient population.

While previous chronic pain interventions have resulted in more substantive improvements, the samples studied have often been demographically, medically, and functionally dissimilar to the patients in our study. For example, in one study,[20] 42% of primary care patients receiving a brief activating intervention demonstrated a one-third reduction in RMDQ score at 6 months compared with 24% of control patients. The majority of patients were younger, female, and working full-time. In contrast, the patients in our study represent a complex population because the patients were older, two-

**Table 3.** Adjusted Patient Outcomes Over Time[a]

| Measure | Mean (95% CI) Baseline | 3 mo | 6 mo | 12 mo | Δ From Baseline to 12 mo (95% CI) | *P* Value[b] |
|---|---|---|---|---|---|---|
| **Main Outcomes** | | | | | | |
| Roland-Morris Disability Questionnaire for pain | | | | | | |
| Assistance with pain treatment | 14.6 (14.3 to 14.9) | 14.0 (13.3 to 14.7) | 13.8 (13.4 to 14.2) | 13.3 (12.9 to 13.7) | –1.4 (–2.0 to –7.1) | .004 |
| Treatment as usual | 14.5 (14.0 to 15.0) | 14.4 (13.8 to 15.1) | 14.4 (13.7 to 15.1) | 14.3 (13.6 to 15.0) | –0.2 (–0.8 to 0.4) | |
| Chronic Pain Grade Intensity | | | | | | |
| Assistance with pain treatment | 67.4 (65.4 to 69.3) | 65.6 (63.5 to 67.7) | 63.3 (61.0 to 65.6) | 63.2 (60.7 to 65.7) | –4.7 (–6.9 to –2.5) | .01 |
| Treatment as usual | 66.0 (64.3 to 67.8) | 68.0 (66.1 to 70.0) | 66.3 (64.1 to 68.4) | 65.6 (63.3 to 67.9) | –0.6 (–2.6 to 1.5) | |
| PHQ-9 for depression (n = 148)[c] | | | | | | |
| Assistance with pain treatment | 14.4 (13.4 to 15.5) | 12.8 (11.3 to 14.3) | 12.0 (10.6 to 13.5) | 10.6 (9.1 to 12.1) | –3.7 (–4.9 to –0.24) | .003 |
| Treatment as usual | 14.4 (13.5 to 15.3) | 14.0 (12.8 to 15.3) | 13.2 (12.0 to 14.5) | 13.2 (11.9 to 14.5) | –1.2 (–4.9 to –2.4) | |
| **Secondary Outcomes** | | | | | | |
| Chronic Pain Grade Interference | | | | | | |
| Assistance with pain treatment | 49.3 (45.9 to 52.8) | 46.3 (42.8 to 49.7) | 44.8 (41.1 to 48.5) | 44.6 (40.7 to 48.4) | –5.7 (–9.8 to –1.7) | .03 |
| Treatment as usual | 48.7 (45.5 to 51.9) | 50.4 (47.3 to 53.6) | 50.0 (46.6 to 53.4) | 51.1 (47.6 to 54.6) | 2.3 (–1.6 to 6.1) | |
| Health-related quality of life (EQ-5D) | | | | | | |
| Assistance with pain treatment | 0.65 (0.63 to 0.68) | 0.61 (0.58 to 0.64) | 0.63 (0.60 to 0.66) | 0.64 (0.61 to 0.67) | –0.02 (–0.05 to 0.01) | .17 |
| Treatment as usual | 0.64 (0.62 to 0.67) | 0.62 (0.59 to 0.65) | 0.61 (0.58 to 0.63) | 0.60 (0.57 to 0.63) | –0.04 (–0.05 to –.02) | |
| Global treatment satisfaction | | | | | | |
| Assistance with pain treatment | 2.9 (2.8 to 3.0) | | 2.7 (2.6 to 2.9) | 2.7 (2.5 to 2.8) | –0.27 (–0.41 to –0.12) | .44 |
| Treatment as usual | 2.9 (2.8 to 3.1) | | 2.5 (2.3 to 2.6) | 2.6 (2.4 to 2.7) | –0.36 (–0.51 to –0.22) | |
| Effectiveness of pain treatment[d] | | | | | | |
| Assistance with pain treatment | 1.6 (1.4 to 1.9) | | 1.8 (1.6 to 2.0) | 1.9 (1.7 to 2.2) | 0.33 (0.04 to 0.61) | .64 |
| Treatment as usual | 1.8 (1.5 to 2.1) | | 1.7 (1.4 to 2.0) | 1.9 (1.6 to 2.2) | 0.20 (–0.13 to 0.52) | |
| Global impression of change in past 6 mo[e] | | | | | | |
| Assistance with pain treatment | | | 3.6 (3.4 to 3.8) | 3.7 (3.5 to 3.8) | | <.001 |
| Treatment as usual | | | 4.5 (4.3 to 4.6) | 4.4 (4.3 to 4.6) | | |

[a] Analyses of Patient Health Questionnaire 9 (PHQ-9) depression severity were adjusted for age, sex, RxRisk-V medical morbidity, and opioid prescription within 6 months prior to the enrollment date. All other outcomes were adjusted for age, sex, PHQ-9 score at baseline, RxRisk-V medical morbidity score, and opioid prescription at any point from 6 months before, up to, and including enrollment date (yes or no).

[b] All *P* values except for global impression of change reflect group difference in change in outcome (slope) over 12 months. The *P* value for global improvement of change reflects group differences at 6 months ($P < .001$) and at 12 months ($P < .001$).

[c] Among patients with baseline PHQ-9 depression scores of 10 or above at baseline.

[d] Among patients who reported receiving chronic pain treatment in the Department of Veterans Affairs during the prior 6 months, at baseline and at 6 months (n = 135), and at baseline and at 12 months (n = 123).

[e] Lower scores indicate improvement; the score range is 1 (very much improved) to 7 (very much worse).

thirds had more than 1 musculoskeletal pain diagnosis, the median duration of pain was 10 years, rates of disability were high, only one-third were employed, and comorbid mental and physical problems were common.

A strength of our study is that multiple measures showed improvements over time, including several well-validated measures of disability, depression, and patient-rated global impression of change. The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials has recommended that measures of patient ratings of global improvement be included in chronic pain clinical trials[62]; global impression of change was meaningfully different between our 2 groups. Depression severity also meaningfully improved among depressed patients in our sample, and our moderator analysis supports that improvements in pain intensity and disability can be achieved even among patients with depression. Although comorbid depression and pain have been shown to be associated with worse outcomes,[4] our findings add to those of another study suggesting that patients with comorbid depression and pain respond to primary care–based collaborative treatment.[12]

On the other hand, global treatment satisfaction did not improve for either group. This was not unexpected because our intervention focused specifically on pain and depression treatment. However, we did expect the assistance with pain treatment intervention to improve pain treatment effectiveness and quality of life, but neither was greatly improved in the intervention group. The EQ-5D (health-related quality of life) may be less sensitive to change than condition-specific instruments, perhaps due to limited response options.[63,64] Future studies should use qualitative methods to learn more about patient expectations and how ratings of global impression of change may be discordant from ratings of pain treatment effectiveness. Our study may have lacked power to detect differences in ratings of pain treatment effectiveness because only patients who reported receiving pain treatment were asked about effectiveness (n=215 at 6 months and n=182 at 12 months).

It is possible that a more intensive intervention would have resulted in more substantive effects, especially consid-

**Table 4.** Adjusted Values for Use of Pain Medications and VA Health Care

| Characteristic | Treatment as Usual (n = 212)[a] | Assistance With Pain Treatment Intervention (n = 185)[a] | *P* Value |
|---|---|---|---|
| **Medication Prescriptions for 12-mo Period** | | | |
| Opioids | | | |
| Any opioid prescribed | 129 (61) | 120 (65) | .56 |
| If opioid prescribed, any that is long acting | 23 (18) | 37 (31) | .03 |
| Highest morphine equivalent dose >30 mg/d | 40 (31) | 47 (39) | .26 |
| If received opioids, ≥1 urine toxicology test | 10 (8) | 14 (12) | .27 |
| Antidepressant, any prescribed | 83 (39) | 99 (53) | .04 |
| NSAID, any prescribed | 83 (39) | 115 (62) | .001 |
| Capsaicin, any prescribed | 11 (5) | 81 (44) | <.001 |
| **Appointment Attendance for 12-mo Period** | | | |
| No. of primary care appointments, mean (SD) | 2.2 (1.7) | 2.0 (1.7) | .60 |
| No. of total ambulatory visits, mean (SD) | 13.8 (14.0) | 13.7 (14.0) | .94 |
| Any physical therapy appointment | 34 (16) | 87 (48) | <.001 |
| Any mental health appointment | 59 (28) | 83 (45) | .05 |
| Any substance use disorder appointment | <1 (0.3) | <1 (0.5) | .20 |
| Any pain specialty consultation service appointment | 6 (3) | 13 (7) | .07 |
| Any orthopedics or neurosurgery appointment | 28 (13) | 30 (16) | .32 |
| Any emergency department visit | 64 (30) | 56 (30) | .97 |
| Any inpatient admission | 28 (13) | 22 (12) | .85 |

Abbreviations: NSAID, nonsteroidal anti-inflammatory drug; VA, Department of Veterans Affairs.
[a]Data are presented as adjusted number (percentage) unless otherwise indicated. The numbers are adjusted for age, sex, Patient Health Questionnaire 9 score at baseline, RxRisk-V medical morbidity, and baseline opioid prescription status (prescribed opioid between 6 months prior to and including enrollment date); n=397 (analyses excluded 2 treatment as usual and 2 intervention patients who died during the study year).

**Table 5.** Implementation Characteristics for Patients Receiving the Assistance With Pain Treatment Intervention

| Characteristic | Intervention Patients (n = 187) |
|---|---|
| Time between initial telephone contact and Study enrollment, mean (SD), d | 27 (17) |
| Assessment visit, mean (SD), d | 26 (23) |
| Assessment visit Received visit, No. (%) | 183 (98) |
| In-person visit, No. (%) | 176 (94) |
| Length of visit, mean (SD), min | 65 (12) |
| No. of completed care management telephone calls after assessment visit, mean (SD) | 5.4 (1.7) |
| Met in person with physician pain specialist, No. (%) | 39 (21) |
| No. of visits, mean (SD) | 1.2 (0.5) |
| Had telephone contacts with physician pain specialist, No. (%) | 120 (64) |
| No. of telephone contacts, median (IQR) | 2 (2-3) |
| Attended at least 1 group workshop, No. (%) | 74 (40) |
| No. of group workshops attended, mean (SD) | 2.8 (1.1) |
| Total No. of contacts with intervention team, mean (SD) [median] | 10.6 (4.5) [10] |
| Direct contact with intervention team, mean (SD), h/patient | 2.7 (0.9) |

Abbreviation: IQR, interquartile range.

ering the complexity of our patient population. However, we specifically designed the assistance with pain treatment intervention so that it could be implemented in actual primary care settings at a reasonable cost. At the peak of enrollment in our study, the care manager's caseload was approximately 180 patients. Two recent VA collaborative intervention implementation studies documented a maximum panel size per depression care manager per quarter of 143 to 165 patients.[65] To further improve portability to other primary care settings, we provided supplemental pain management training to our intervention team rather than recruiting clinicians who already had substantial pain expertise.

Our study has several limitations. Veterans volunteered to participate in the study by responding to letters or advertisements offering screening. These participants may have been particularly motivated; outcomes for less motivated patients might be less favorable. However, 15% of patients responded to our mailed materials, indicating a substantial interest in treatment for chronic pain among VA patients.

In addition, we do not know if specific components of the assistance with pain treatment intervention contributed more to outcomes improvements than others. This is a common problem for studies of multifaceted interventions[11] and further research is needed to identify the most critical care components. As with previous collaborative intervention trials, the intervention patients had more contact with clinicians than the treatment as usual patients (mean of 2.7 hours per patient), raising the possibility that some intervention effects may be attributable to nonspecific attention. Additionally, although clinician-to-clinician contamination has the potential to attenuate effect size, based on previous research such effects are likely to be negligible. In our analyses, we did not adjust for multiple comparisons. While this would not have negated the significance of the findings among our 3 main outcomes, our findings for secondary outcomes should be considered exploratory due to the potential for type I error.

Finally, our results were obtained from a single VA medical center, potentially limiting generalizability. The assistance with pain treatment intervention was designed to work within the context of a large care system including primary care, specialty services, and ancillary services, and which relies on an electronic medical record. While we believe that the intervention would translate well to larger group practices, exporting the approach to smaller community or private settings might be challenging.

Overall, this study showed that a collaborative care intervention for chronic pain was significantly more effective than treatment as usual across a variety of outcome measures. Although many of the improvements were modest, they may be especially meaningful because patients in our sample were older, had long-standing pain, multiple medical problems, and reported high baseline rates of disability. Our results add to the growing body of literature suggesting that the collaborative care model is effective in improving clinical outcomes and adherence to treatment guidelines across a variety of chronic conditions. Patients in many health care systems and private group practices have limited access to specialty chronic pain services. A primary care–based intervention can have positive effects on pain disability and intensity, and on depressive symptoms.

**Author Contributions:** Dr Dobscha had full access to all of 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:* Dobscha, Corson, Perrin, Leibowitz, Doak, Sullivan, Gerrity.
*Acquisition of data:* Corson, Leibowitz, Doak, Dickinson.
*Analysis and interpretation of data:* Dobscha, Corson, Perrin, Hanson, Dickinson, Sullivan, Gerrity.
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*Study supervision:* Dobscha, Corson, Dickinson.
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