1-1-2010

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Citation Details

Dickinson KC, Sharma R, Duckart JP, Corson K, Gerrity MS, Dobscha SK. VA Healthcare costs of a collaborative intervention for chronic pain in primary care. Medical Care 48, 38-44, 2010.

VA Healthcare Costs of a Collaborative Intervention for Chronic Pain in Primary Care

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Background: Chronic pain is costly to individuals and the healthcare system, and is often undertreated. Collaborative care models show promise for improving treatment of patients with chronic pain. The objectives of this article are to report the incremental benefit and incremental health services costs of a collaborative intervention for chronic pain from a veterans affairs (VA) healthcare perspective.

Methods: Data on VA treatment costs incurred by participants were obtained from the VA's Decision Support System for all utilization except certain intervention activities which were tracked in a separate database. Outcome data were from a cluster-randomized trial of a collaborative intervention for chronic pain among 401 primary care patients at a VA medical center. Intervention group participants received assessments and care management; stepped-care components were offered to patients requiring more specialized care. The main outcome measure was pain disability-free days (PDFDs), calculated from Roland-Morris Disability Questionnaire scores.

Results: Participants in the intervention group experienced an average of 16 additional PDFDs over the 12-month follow-up window as compared with usual care participants; this came at an adjusted incremental cost of $364 per PDFD for a typical participant. Important predictors of costs were baseline medical comorbidities, depression severity, and prior year's treatment costs.

Conclusions: This collaborative intervention resulted in more pain disability-free days and was more expensive than usual care. Further research is necessary to identify if the intervention is more cost-effective for some patient subgroups and to learn whether pain improvements and higher costs persist after the intervention has ended.

Key Words: chronic pain, collaborative care, pain improvement, cost, primary care

(*Med Care* 2010;48: 38–44)

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Supported by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development Service Projects PMI 03–195 and REA 06–174.

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ISSN: 0025-7079/10/4801-0038

Chronic, noncancer pain is associated with considerable physical and psychosocial impairment, and increased healthcare utilization and costs.[1–4] Chronic pain results not only in direct costs for treatment but also in increased disability compensation, decreased productivity, and lost tax revenue.[3] It is estimated that common pain conditions cost the United States $61.2 billion per year in lost productive time alone.[5] There are many approaches to treating chronic pain, including medications, surgery, physical therapy, anesthesiology interventions, multidisciplinary pain centers, behavioral interventions, and alternative therapies such as chiropractic manipulation and acupuncture; many are expensive and rarely offer a complete cure.[3] Chronic pain patients are frequently managed with medications such as opioids, and medication costs can easily exceed $4000 per year.[3] Providers and patients often search for a satisfactory combination of treatments to ease suffering and increase functional status, while minimizing costs to the individual and the healthcare system.

Collaborative care interventions based in primary care have emerged as one successful approach to supporting guideline-concordant care and improving outcomes for chronic conditions.[6–8] These interventions are based on the chronic care model developed by Wagner et al[9]; they seek to optimize patient-clinician interactions while providing system support, typically in the form of patient activation, clinician feedback, and care management. The "Study of the Effectiveness of A Collaborative Approach to Pain" (SEACAP) sought to assess whether a novel collaborative care intervention would result in improvements in chronic pain and depression outcomes compared with treatment as usual (TAU) among patients treated in a veterans affairs (VA) primary care setting.[10,11] SEACAP showed modest effects, with intervention patients showing greater improvements in self-reported pain-related disability, pain interference, pain intensity, global impression of change, and depression over 12 months compared with TAU patients. The differences in scores between baseline and 12 months for the intervention group and the TAU group, respectively, were −1.4 versus −0.2 for the Roland-Morris Disability Questionnaire (RMDQ)[12,13] (pain-related disability, SEACAP's primary outcome), −4.7 versus −0.6 for the Chronic Pain Grade Pain Intensity subscale,[14] and −3.7 versus −1.2 for the Patient Health Questionnaire-9[15] (depression). The objectives of this manuscript are to report the incremental benefit (described in pain disability-free days)

and incremental health services costs of the SEACAP intervention from a VA healthcare perspective.

METHODS

Design

SEACAP was a cluster-randomized trial of a collaborative intervention entitled "Assistance with Pain Treatment" (APT). APT was designed to educate and activate patients and clinicians, and to facilitate care. APT and SEACAP design and results have been described in detail elsewhere.[10,11] The VA Medical Center (VAMC) institutional review board approved the study and all patients and participating primary care clinicians gave written informed consent.

SEACAP was conducted in 3 urban and 2 rural primary care clinics of 1 VAMC. All staff primary care clinicians were eligible to participate (N = 54). Of the 46 who agreed to participate, 2 left their VA primary care practices before patient enrollment began and 2 had no patients enroll. The remaining clinicians were randomly assigned to intervention (n = 20) or TAU (n = 22) prior to patient recruitment using stratified random assignment. Randomization was stratified by professional training (nurse practitioner or physician assistant vs. physician), the proportion of their patients currently receiving opioid prescriptions, and distance from the main VAMC site (>15 vs. ≤15 miles). We detected no differences between participating and nonparticipating clinicians in terms of professional training, distance from the main hospital, proportion of patients receiving prescriptions for opioids, or panel size. Patients enrolled in the trial were assigned to the same group as their primary care clinicians, yielding 187 in the intervention group and 214 in TAU.

Inclusion criteria were medical record documentation of a musculoskeletal pain diagnosis, pain of at least 12 weeks duration, Chronic Pain Grade[14] intensity and interference item scores each ≥4 (indicating moderate or greater severity), and regular access to a telephone. Exclusion criteria included previously documented diagnoses of fibromyalgia, chronic fatigue syndrome, or somatization disorder. We also excluded patients with bipolar disorder, psychotic disorder, dementia, terminal illness, suicidal ideation requiring urgent attention, and patients whose medical records contained special flags indicating a history of disruptive behavior.

Treatment

APT is based on Wagner's chronic care model,[9] previous collaborative interventions[7,16–20] and multidisciplinary pain approaches,[21–24] chronic pain treatment guideline criteria having at least fair to moderate evidence supporting their impact on pain outcomes,[25–27] and brief activating interventions for back pain.[28] The 2 key members of the APT team were a full-time clinical psychologist care manager and a VAMC internist who spent up to 1 day per week on APT team activities. A physical therapist also participated in some group educational meetings. Clinicians in the intervention group received an initial educational program followed by ongoing contacts with the APT team for feedback and recommendations. All intervention group patients received assessments and care management, while stepped-care components such as APT internist or mental health consultation were offered to those patients requiring more intensive or specialized care approaches. During initial assessments, the care manager sought to identify fear-avoidance beliefs, such as fear of movement or of pain exacerbations, explored for treatment barriers, screened for comorbid psychiatric disorders (including depression and substance misuse), and developed individualized functional goals. The care manager and intervention internist then developed treatment recommendations that were communicated to the patient's primary care clinician. In some cases, the internist also interacted directly with patients to discuss symptoms or provide additional support. Patients were contacted by the care manager every 2 months after the initial assessment for follow-up, goal modification, encouragement, and administration of pain, depression, and alcohol measures. Additionally, intervention participants were encouraged to attend a 4-session workshop co-led by the care manager and internist or physical therapist; sessions included education, skill practice, and support for goal setting and attainment. The TAU group received routine pain care from their primary care clinicians. Both TAU and intervention clinicians had access to the specialty pain clinic, ancillary services including physical, occupational, and recreational therapies, and co-located mental health services.

Outcome Measures

For SEACAP main analyses, the primary outcome measure was the RMDQ.[12,13] The RMDQ has content and construct validity, internal consistency, and responsiveness to pain among patients with chronic pain.[13,29] For the cost effectiveness analysis, the primary outcome was the number of pain disability-free days (PDFDs) that patients experienced during the 12-month study period. We had considered also analyzing EQ-5D quality of life scores but there were no differences between TAU and intervention patients, perhaps because the EQ-5D may not be sensitive enough to detect small to moderate changes.[30,31] The number of PDFDs was computed from 3, 6, and 12 month RMDQ scores following methods similar to those employed by Lave et al[32] to compute depression-free days.[33,34] RMDQ scores at the beginning and end of each time interval were used to estimate pain disability for each day in that interval; we regarded patients with scores of 5 or lower as fully pain disability free and those with scores of 19 or higher as fully pain disabled.[35,36] For patients with RMDQ scores from 6 to 18, the proportion of days spent in pain disability was assumed to increase linearly with the score. The total number of PDFDs over the study period was obtained by summing PDFDs across time intervals.

Costs

Data on VA treatment costs incurred by intervention and TAU group patients were obtained directly from the VA's Decision Support System (DSS) for all utilization except certain APT team activities that were not recorded in this system. DSS contains comprehensive information on fixed, variable, and indirect costs incurred by the VA on all inpatient, outpatient, surgical, and pharmaceutical utilization, but does not include all costs related to outside healthcare

providers or financing of capital expenses.[37] DSS employs a microcosting approach whereby treatment costs are computed by cumulating the costs of individual components of the treatment.[38,39] The DSS system has been used for other VA cost analyses.[34,40]

The intervention team used a Microsoft Access database to keep track of activities not recorded in DSS; this included time spent on telephone and in-person contacts with participants which they estimated on a daily or weekly basis depending on the frequency of the activity. DSS costs for comparable activities were used to approximate costs of APT team patient care activities that were not recorded in the DSS system. Contact duration (time), contact type (in-person or telephone), and clinician profession were used to identify comparable activities. Including all fixed and indirect costs, in-person consultations with the team care manager, internist, and physical therapist were assigned hourly costs of $271.30, $313.60, and $145.78, respectively. DSS costs for telephone consultations unrelated to the APT intervention by the team internist were, on average, 90% of the costs of in-person encounters of similar duration. Based on this observation, team internist and care manager telephone encounters with intervention group patients were assigned 90% of the costs of in-person encounters of similar duration. Additional patient care-related activities (eg, weekly case conferences and group educational meetings) by the team care manager and internist that exceeded the indirect care-related work associated with normal clinical practice were assigned costs based on in-person patient encounter rates. For intervention team, patient care activities that could not be ascribed to individual patients, costs were assigned to patients in proportion to the amount of time that the intervention team spent on care directly attributable to those patients.

Costs of training time for the team care manager, internist, and physical therapist were calculated using their hourly salary plus benefits rates. Primary care clinicians' training time costs were calculated using the hourly salary plus benefits rate of the team internist for all physicians and the main VAMC site's average nurse practitioner hourly salary plus benefits rate was used for all nurse practitioners. Other costs, divided equally among intervention group patients, included a video/DVD provided to intervention group patients ($327.50) and travel expenses related to APT team training ($2,321.84).

A regression model of the natural logarithm of total VA costs was used to analyze adjusted differences in costs between TAU and intervention group patients; such semi-log models are commonly used for skewed cost data.[41] We also compute the incremental effect of the intervention and other key predictors of costs in this nonlinear regression, for selected patient profiles.[42]

RESULTS

Unadjusted Patient Characteristics, Outcomes, and Costs

Table 1 summarizes baseline characteristics, quality of life, and pain outcomes, PDFDs, as well as VA treatment costs for intervention and TAU group patients. There were no statistically significant differences between the 2 groups on baseline health and demographic characteristics. Mean VA treatment costs in the 12 months prior to study enrollment were $6079 and $7445 for intervention and TAU patients, respectively. Based on RMDQ scores at 3, 6, and 12 month intervals, intervention and TAU group patients were computed to have been pain disability free on average for 142 and 124 days, respectively, during the 12-month study period. APT team activities added $1192 in costs for intervention patients so that total VA costs were $11,263 for intervention group patients and $8920 for TAU group patients. Figure 1 shows the distribution of log total costs for TAU and intervention group patients.

TABLE 1. Patient Characteristics, Outcomes, and Costs*

Variable	Intervention Group (n = 187) Mean (SD) or %	Treatment as Usual Group (n = 214) Mean (SD) or %
Demographics		
Age	62.1 (11.3)	61.3 (12.3)
Sex, male	92	92
Baseline health		
PHQ-9 score†	8.1 (5.7)	8.4 (6.0)
Opioid prescription 6 mo prior to enrollment	44	42
Chronic disease score‡	5.0 (3.1)	4.9 (3.0)
EQ-5D score§	0.6 (0.2)	0.6 (0.2)
Roland-Morris score¶	14.9 (4.4)	14.5 (4.4)
Outcomes		
12-mo EQ-5D score	0.6 (0.2)	0.6 (0.2)
12-mo Roland-Morris score	13.3 (5.7)	14.2 (5.6)
Pain disability-free days‖ 0–3 mo	31.3 (25.3)	30.0 (26.6)
Pain disability-free days 3–6 mo	34.4 (28.5)	30.2 (28.3)
Pain disability-free days 6–12 mo	74.1 (59.1)	63.0 (57.7)
Pain disability-free days 0–12 mo	141.8 (108.3)	124.1 (107.5)
Costs		
VA treatment costs in year prior to enrollment, $	6079 (7068)	7445 (10,899)
VA treatment costs while enrolled in study excluding intervention team activities, $	10,071 (14,504)	8920 (13,131)
Costs of intervention team activities, $	1192 (405)	—
Total VA costs, $	11,263 (14,566)	8920 (13,131)

*None of the univariate differences between the intervention and treatment as usual groups were statistically significant at the $P < 0.05$ level.
†Patient Health Questionnaire-9 score, range 0 to 27.
‡Chronic disease score is the RxRisk-V score which uses prescription data to determine medical comorbidities, range 0 to 45.
§EQ-5D score, range −0.109 to 1.
¶Roland-Morris Disability Questionnaire score, range 0 to 24.
‖Computed from Roland-Morris Disability Questionnaire scores.

Adjusted PDFDs

Table 2 shows regression models for PDFDs that patients experienced during the study period as well as for the

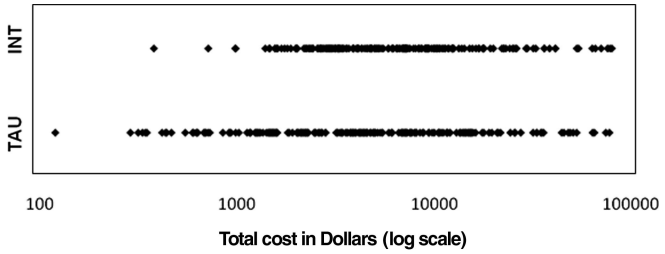

FIGURE 1. Distribution of costs for TAU and intervention group patients.

natural logarithm of total VA costs. Independent variables included in both regression models were intervention status, sex, age, depression severity, opioid prescription in the 6 months prior to enrollment, and baseline chronic disease burden (RxRisk-V score[44]). In addition, baseline RMDQ score was included in the PDFDs model, while VA treatment costs in the year prior to enrollment were included in the costs model. An alternative analysis that included baseline RMDQ and prior-year VA treatment costs in both models yielded results very similar to those presented below.

Baseline pain disability accounted for most of the explanatory power of the pain disability model ($\delta R^2 > 0.38$)—each unit increase in pain as measured by the baseline RMDQ score predicted 18.7 fewer PDFDs ($P < 0.001$). A unit increase in disease burden as measured by the chronic disease score (RxRisk-V score) predicted 3.2 fewer PDFDs ($P = 0.016$). Patients in the intervention group experienced an average of 16.6 more PDFDs than those in the TAU group over the study year ($P = 0.016$).

Adjusted Costs

Patients in the APT intervention group incurred 71.5% higher adjusted costs than those in the TAU group ($P < 0.001$). Among SEACAP patients, each one-year increase in age was associated with a 0.9% increase in costs ($P = 0.03$). A one-unit increase in severity of depression measured by the Patient Health Questionnaire-9 score (PHQ-9) was associated with a 2.1% increase ($P = 0.012$), while a one-unit increase in the baseline chronic disease burden (RxRisk-V score) resulted in a 7.9% increase ($P < 0.001$) in costs. A 1% increase in VA treatment costs in the year prior to study enrollment was associated with a 0.45% increase ($P < 0.001$) in costs incurred during the study period.

Adjusted Incremental Effects of the Intervention and Patient Characteristics on Costs

Table 3 presents the predicted 12-month mean TAU and intervention group VA costs for patients with 3 different profiles. To further illustrate the variation in these costs, Table 3 provides estimates of the incremental dollar effects of selected changes in patient baseline characteristics, and shows how changes in patient attributes can alter the cost of a PDFD produced by the intervention. The sizes of changes in baseline continuous variables were chosen to approximate 1 standard deviation. A smearing estimator was used in all retransformations[45]; an analysis of error terms from the cost regression found no evidence of heteroscedasticity.

TABLE 2. Regression Models for Pain Disability-Free Days and Total Costs

	Pain Disability-Free Days (n = 346; R^2 = 0.66)		Log Total Costs* (n = 398; R^2 = 0.46)	
Variable	**Regression Coefficient (95% CI)**	***P***	**Regression Coefficient (95% CI)**	***P***
Intercept	409.9 (364.5, 455.4)	<0.001	3.4 (2.6, 4.3)	<0.001
Intervention (reference category-treatment as usual group)	16.6 (3.1, 30.1)	0.016	0.5 (0.4, 0.7)	<0.001
Demographics				
Female	−12.3 (−38.5, 13.8)	0.355	0.2 (−0.1, 0.6)	0.147
Age	0.2 (−0.4, 0.8)	0.558	0.0 (0.0, 0.0)	0.03
Baseline health				
PHQ-9 score†	−0.5 (−1.9, 0.9)	0.468	0.0 (0.0, 0.0)	0.012
Opioid prescribed 6 mo prior to enrollment	−7.7 (−23.4, 8.0)	0.337	0.0 (−0.2, 0.3)	0.662
Chronic disease score‡	−3.2 (−5.8, −0.6)	0.016	0.1 (0.0, 0.1)	<0.001
RMDQ score§	−18.7 (−20.6, −16.9)	<0.001	—	—
Costs				
VA treatment costs in year prior to enrollment	—	—	0.4 (0.4, 0.5)	<0.001

*The estimate of the percentage impact of an independent variable on costs is related to the variable's regression coefficient (B) as follows: $100 \times B$ for a unit change in a continuous predictor, and $100 \times (\exp(B) - 1)$ for a dichotomous predictor (43). When the predictor variable is also expressed as a natural logarithm (costs in 12 months preceding study enrollment in the model in Table 2), then the variable's regression coefficient is interpreted as the predicted percentage change for a 1% change in the value of the predictor.

†Patient Health Questionnaire-9 score, range 0 to 27.

‡Chronic disease score is the RxRisk-V score which uses prescription data to determine medical comorbidities, range 0 to 45.

§Roland-Morris Disability Questionnaire score, range 0 to 24.

TABLE 3. Predicted Mean Costs and Incremental Effects of Predictors

				Incremental Effects on 12 mo Costs ($) (Factors)						
Patient Type	Group	12-mo Predicted Mean Costs ($)	Cost of a Pain Disability-Free Day	Intervention	Female	10-yr Increase in Age	6-Point Increase in Severity of Depression	Opioid Prescription 6 mo Prior to Enrollment	3-Point Increase in Chronic Disease Score	$10,000 Increase in Treatment Costs in yr Prior to Enrollment
Profile 1*	TAU	8447	364	6035	2332	817	1146	398	2252	5183
Profile 1*	INT	14,482		—	3998	1400	1963	684	3860	5765
Profile 2†	TAU	3780	162	2701	—	366	512	178	1008	4179
Profile 2†	INT	6479		—	—	626	878	307	1727	4863
Profile 3‡	TAU	25,967	1117	18,554	7168	2510	3521	1226	6922	6268
Profile 3‡	INT	44,521		—	12,291	4305	6036	2103	11,867	6605

*Profile 1: 62-yr-old male veteran with depression severity of 8 on PHQ-9 scale, no opioid prescription in the 6 mo prior to enrollment, with a chronic disease score of 5 and treatment costs of $7444 in the year preceding enrollment in the study.

†Profile 2: 35-yr-old female veteran with depression severity of 2 on PHQ-9 scale, no opioid prescription in the 6 mo prior to enrollment, chronic disease score of 2, and $2000 in treatment costs in the year prior to study enrollment.

‡Profile 3: 75-yr-old male veteran with depression severity of 16 on PHQ-9 scale, an opioid prescription in the 6 mo prior to enrollment, chronic disease score of 8, and $25,000 in treatment costs in the year prior to study enrollment.

TAU refers to treatment as usual group.

INT refers to APT intervention group.

Profile 1 depicts a patient with baseline characteristics close to the mean for those enrolled in SEACAP. Profiles 2 and 3 depict patients with characteristics typically associated with lower and higher costs, respectively. For the patient in Profile 1, the APT intervention predicts a $6035 increase in costs; the cost per PDFD produced by the APT intervention is $364. Profile 2 reflects a younger, female veteran with a relatively low burden of chronic disease and depression, and relatively low costs in the year preceding enrollment in SEACAP. For such a patient, the predicted increase in costs due to the APT intervention is $2701, and $162 is the predicted cost of a PDFD produced by the intervention. Profile 3 represents an older male veteran with high burdens of chronic disease and depression, as well as high costs in the year prior to enrollment. The predicted increase in costs due to APT is $18,554 for such a patient, and the predicted cost per PDFD produced is $1117.

DISCUSSION

We previously found that a collaborative approach to treating chronic pain in a primary care setting was moderately effective in decreasing pain-related disability, pain interference, pain intensity, and depression severity scores compared with usual care over a 12-month period. We report here that the intervention resulted in more PDFDs compared with usual care. The intervention group had significantly higher costs than the usual care group, likely attributable to the cost of the intervention as well as changes in treatment as a result of the intervention.

With an increased average cost of about $2300 per patient for the intervention over TAU during the study year, our findings fall on the low end of costs for commonly-used chronic pain interventions. The average number of direct patient contacts (in-person or telephone) with the APT intervention team was approximately 11, which corresponds to $209 per contact. In comparison, the costs of visits to physical therapists and chiropractors were $221 and $185 in 1995 dollars, respectively, per month in a randomized back pain study,[46] which translates to about $2600 and $2200 per year. Management of pain with medication often exceeds $4000 per year while the minimum cost of lumbar surgery is estimated at $15,000.[3]

Previous studies of other collaborative care interventions, in particular for depression and panic disorder, have shown much lower intervention costs than we found.[47–49] APT participants experienced an average of 16 more PDFDs over 12 months than those in usual care, resulting in a cost of $364 per PDFD for a typical participant. Yet, in a collaborative care intervention aimed at reducing depression among older adults, intervention patients had 107 more depression-free days over 24 months than usual care patients, corresponding to an incremental outpatient cost per depression-free day of $2.76.[47] In another study aimed at increasing anxiety-free days among people with panic disorder, a collaborative approach helped people in the intervention group have about 75 more anxiety-free days over 12 months at a cost savings of $4 per anxiety-free day.[48] Our use of micro cost data to identify comparable activities for patient care-related work by the intervention team contributed to our high estimates of intervention costs. Prior studies have used provider salary and benefits plus a markup (typically 30%) for overhead (eg, Katon et al[47]), which would produce lower cost estimates. While salary, benefits, and overhead may provide an accurate measure of incremental costs in clinical trial settings, using microcosts for comparable activities provides a better estimate of costs if interventions were incorporated into standard care.

In addition, while our primary outcome measure of PDFDs was modeled on Lave et al's[32] method of calculating depression-free days, psychometric differences in the measures used for depression (Hamilton Depression Rating Scale) and pain (RMDQ), as well as differences in the

disorders themselves, may contribute to differences in the numbers of disorder-free days calculated. Overall, these methodological differences in calculation of costs and disorder-free days limit our ability to compare the cost-effectiveness of APT to previous collaborative interventions.

Given the relatively high cost per PDFD, it would be helpful to identify subgroups for which APT is more cost-effective. For example, preliminary SEACAP analyses show a relationship between baseline RMDQ score and likelihood of 12 month response (defined as a 30% reduction in RMDQ): for every unit increase in baseline RMDQ score, the odds of response decrease by 9% ($P = 0.002$). Additional responder analyses are in progress. In addition, in Table 3, we presented statistical estimates of costs for 3 types of patients, which show that younger, female veterans with a low chronic disease burden have predicted costs of $162 per PDFD. Taken together, these findings suggest that APT may be more cost effective for younger and overall healthier veterans who have lower baseline pain-related disability. For veterans with greater baseline pain-related disability or more chronic conditions, other types of pain care (eg, referral based approaches) might be more cost effective.

Another potential approach to improving the cost-effectiveness of APT would be through economies of scale, by treating more patients using the same resources. However, because much of the intervention focused on individualized care (goal-setting, treatment regimen review), we would not expect to see much economy of scale if implemented in a larger population. Furthermore, one-time costs such as clinician and intervention team training were small contributors to the overall cost of the intervention. In an analysis taking out all intervention team costs, intervention group patients continued to have 26% higher adjusted costs than the TAU group. We are currently conducting a 30-month assessment to see if intervention treatment effects persist. If so, the intervention may become cost-effective over time.

This study has several limitations. The treatment setting of the VA system differs in many respects, including patient demographics, from other US healthcare systems. Our study sample was comprised largely of older white men and results may not generalize to other populations. We had to estimate the costs of the intervention, which were not captured in the VA costing system; our use of costs of comparable services may have led to overestimates relative to many other studies that have relied on provider salary and benefits information. For example, we assigned costs to most intervention team activities at the same rates used for direct patient encounters. Finally, our study looked at incremental costs from a VA health system perspective, which does not take into account effects of the intervention on healthcare received elsewhere. We do note that intervention and TAU patients reported similar numbers of contacts with outside providers.

The APT collaborative care intervention of the SEACAP study resulted in more PDFDs and higher costs than usual care over the 12-month follow-up period. The wide range in cost to obtain an additional PDFD suggests that the intervention may be quite costly for older people with many comorbidities and long-standing pain, perhaps suggesting that the intervention in its current form be targeted to certain groups of patients. We are currently conducting a 30-month follow-up to ascertain whether the benefits experienced by the intervention group are maintaining or changing over time, which may affect the cost-benefit ratio.

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