

ORIGINAL RESEARCH

Outcomes of Acupuncture for Chronic Pain in Urban Primary Care

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Purpose: The purpose of this study was to describe outcomes of the Acupuncture to Decrease Disparities in Outcomes of Pain Treatment (ADDOPT) trial, testing acupuncture as an adjunct to usual treatment for chronic pain in urban health centers.

Method: We conducted a quasi-experimental trial. Primary care patients (>21 years old) with chronic pain caused by osteoarthritis or neck or back pain at 4 hospital-owned safety net health centers in the Bronx, New York, received weekly acupuncture treatments provided by supervised acupuncture students for up to 14 weeks. Pain and functional status were assessed during a 6-week run-in period before acupuncture, during treatment, and after treatment.

Results: Of 495 referred patients, 226 (47%) initiated acupuncture. Back pain was the most common referring diagnosis (59.5%) followed by osteoarthritis (16.3%). Patients were older (mean age, 54.3 years), mostly insured by Medicaid (60.4%), often receiving disability (38.3%), and often in poor or fair overall health (46.7%). They had high baseline levels of pain (mean severity per the Brief Pain Inventory, 6.8; mean days with pain, 12.3 of 14). The mean number of treatments was 9.7 (standard deviation, 7.3). Pain severity improved from baseline (6.8 vs. 5.6 at 12 weeks and 5.5 at 24 weeks), as did physical well-being (31.8 vs. 35.7 at 12 weeks and 35.3 at 24 weeks). Using hierarchical linear modeling methods, reduction in pain severity between baseline and the treatment phase was significant ($P < .001$). Improvements in physical well-being were significant at 12 and 24 weeks after baseline ($P < .001$).

Conclusions: Referred primary care patients experienced high levels of pain and pain-related disability. Weekly acupuncture was associated with short-term improvements in pain and quality of life. (J Am Board Fam Med 2013;26:692–700.)

Keywords: Acupuncture, Chronic Pain, Complementary Medicine, Underserved Populations

This article reports the outcomes of the Acupuncture to Decrease Disparities in Pain Treatment (ADDOPT) trial, a recent National Institutes of

Health–funded clinical trial of acupuncture for chronic back pain, neck pain, and osteoarthritis offered in the community health center setting to an ethnically diverse and medically underserved patient population in the Bronx, New York.

Chronic pain is a major problem in primary care practice, affecting an estimated 10% to 40% of the population.^{1–6} Minority populations experience disparities in both the prevalence and outcomes of chronic pain.^{7–10} There are strong positive associations between pain and impairment of physical and psychological functioning,^{11,12} lost productivity,¹³ and lower socioeconomic status.⁶ Particularly in light of recent concerns regarding the abuse of prescription analgesics and the consequent growing pressure to limit prescription of narcotic medica-

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tions, primary care physicians (PCPs) are in desperate need of more effective strategies for managing patients with chronic pain conditions.

A great deal of evidence now supports the use of acupuncture therapy in the treatment of chronic pain conditions, particularly for 3 common causes of chronic pain: osteoarthritis,^{14–16} neck pain,^{17,18} and low back pain.^{19–23} Although the mechanism of action remains unclear, and although many studies find both “sham” (needles in nonacupuncture points) and real acupuncture to be effective, it is clear that 40% to 50% of patients experience a reduction in pain with acupuncture treatment.

For the most part, patients from lower socioeconomic groups have not had access to acupuncture treatment in the United States because the services are not generally reimbursed by insurers. To examine the effectiveness of acupuncture for chronic pain, we developed a new delivery model that offers care inside the community health center primary care setting using student acupuncturists so that services could be provided at no cost to patients.

The ADDOPT trial sought to demonstrate both the feasibility and acceptability of offering acupuncture in the primary care setting and the effect of this treatment on pain and functional outcomes. The feasibility findings have been reported elsewhere²⁴; here we report the effect of acupuncture on pain and functional status.

Methods

The overall goal of the ADDOPT study was to introduce and evaluate the addition of acupuncture to the management of chronic pain for ethnically diverse, low-income primary care patients. The Albert Einstein College of Medicine Institutional Review Board approved the study.

Setting and Participants

The study was conducted in 4 hospital-owned primary care health centers serving low-income families in the Bronx. Practices serve a mostly minority population (29% to 69% black, 23% to 58% Hispanic) who are mostly insured by Medicaid (43% to 59%) or uninsured (5% to 15%). All practices were part of the New York City Research and Improvement Networking Group, a practice-based research network dedicated to decreasing health disparities through primary care research and quality improvement in the urban safety net setting.

Recruitment

Medical staff at each participating practice received a brief (60 minutes) orientation to the study, including an overview of acupuncture procedures and a summary of the evidence of effectiveness in chronic pain conditions. Enrollment occurred between March 2009 and July 2011. PCPs referred interested and eligible patients (>21 years old, suffering from ≥ 3 months of chronic pain [osteoarthritis or neck or back pain], fluent in English or Spanish, able to provide home phone numbers to facilitate scheduling, and available for up to 14 weekly treatments). Patients taking anticoagulants were not eligible. Once referred, the study coordinator contacted patients by telephone to confirm eligibility and describe study procedures.

Design

The study employed a repeated measures quasi-experimental design,²⁵ with each participant having multiple measures before and after treatment, allowing assessment of what may be variable patterns of pain before the intervention.²⁶ Although a randomized design with usual care control would have been ideal, because this was primarily a feasibility and acceptability trial with limited funding resources, we chose this pragmatic nonrandomized design to maximize our recruiting ability and the acceptability of the trial to staff and patients. This pragmatic design allowed us to offer the intervention without randomization to all patients with target diagnoses who met eligibility criteria, maximizing both limited resources and feasibility and acceptability to patients and staff. Assessments of pain before acupuncture were collected biweekly during a 6-week run-in period before the initial acupuncture session. A priori power analyses indicated that adequate power (90%) to detect small effects (0.25) could be achieved by recruiting 43 participants per site, assuming correlations between measures ($r = 0.10$; $\alpha = 0.05$).

Intervention

Treatment (up to 14 sessions) was provided during weekly sessions at each practice by faculty-student acupuncture teams (third-year interns from the Pacific College of Oriental Medicine and the Swedish Institute and their licensed acupuncturist supervisors) at no cost to patients. Trainees saw the same patient for repeated visits, although in some cases the student changed at the end of an academic term;

faculty supervisors tended to be consistent for each patient. Acupuncturists evaluated patients based on medical history, examination of the tongue (tongue diagnosis) and pulse (pulse diagnosis), and palpation of the meridians then made an assessment and formulated a treatment plan. This approach to acupuncture is an extremely broad-based and flexible approach, incorporating both the recently popularized principles of traditional Chinese medicine as well as techniques of classic Chinese medicine, which includes sinew and primary and divergent meridian treatments as well.²⁷ The acupuncture team was free to adapt and change the treatment approach from week to week based on the condition of the patient and response to treatment. Usual care from the PCP continued while the patients were receiving acupuncture.

Data Collection

During the run-in period before acupuncture, participants completed biweekly pain assessments during brief phone calls. A baseline interview was conducted in person before the first acupuncture treatment; this interview included detailed demographics, functional status, and multiple pain measures. Pain was reassessed approximately every 2 weeks (to capture variations in pain) either in person during visits or by phone; functional status was collected at 12 and 24 weeks from the start of treatment. Pain was assessed using (1) the Brief Pain Inventory (BPI),²⁸ which includes subscales measuring pain severity and the extent to which pain interferes with function, and (2) the Chronic Pain Grading Scale, which assesses pain intensity and pain-related disability at present and over the preceding 4 weeks,²⁹ and the patient's reported pain-free days during the previous 2 weeks.³⁰ A change of 30% on the BPI is generally accepted as clinically significant change.^{31,32} After the intervention, patients completed a single-question, validated measure of global impression of change. Health-related quality of life was assessed using the SF-12, a 12-item generic inventory that assesses 8 dimensions of physical and mental health-related quality of life and provides 2 composite scores, the physical component scale and the mental health scale.³³ No minimum clinically meaningful difference was established in our population for the SF-12. A change of 4 to 5 on the 36-item Short

Form is considered meaningful and is thought to apply to the SF-12 as well.³⁴

Analysis

Before analysis, all data were reviewed for accuracy, and descriptive summaries (means, standard deviations, frequencies, and proportions) were generated for sample sociodemographic, baseline pain, disability, and health measures. Spearman's ρ was used to evaluate the relationship between patient and clinician assessments of change and observed improvements in self-rated pain severity and physical health. Hierarchical linear modeling (HLM)³⁵ was used to evaluate change in outcomes over time while accounting for the correlations among the repeated measures and the variability attributable to individual and site characteristics. Unlike repeated-measures analysis of variance or traditional ordinary least squares regression, which drop cases when all data points are not assessed or do not occur at fixed intervals, HLM models do not require fixed data collection points nor require that all patients have measures at all time points, allowing HLM to make use of all available data.

Before modeling, covariance estimates and intraclass correlations were calculated to determine the variability in outcomes attributable to site and individual characteristics. Significant variability in outcomes was found between individuals (SF-12 intraclass correlation [ICC], 0.47; BPI ICC, 0.58), and a smaller, nonsignificant amount of variability in outcomes was attributable to site characteristics (SF12 ICC, 0.013; BPI ICC, 0.019). On the basis of these findings, random effects terms representing individuals were used in the model, and site was treated as a fixed effect. Preliminary HLM models were run to determine which random effects components (slopes, intercepts) were necessary to model individual variability in outcomes. All potential predictors were examined to assess their relationship to pain severity and physical health. During the model building stage, predictors were considered significant at $P = .10$; in the final model, predictors that were significant at $P = 0.05$ were retained. Fixed effects representing site, time, and treatment period were retained in the model regardless of significance level to ensure proper specification. Two self-reported outcomes were analyzed. Functional status, measured with the SF-12 physical health composite score, was recorded at 3 points during the study (at baseline, 12 weeks after baseline [treatment pe-

riod], and 24 weeks after baseline [after treatment]). The pain severity scale of the BPI was measured at 10 points during the study (4 assessments during the run-in period including baseline, 4 assessments during the treatment period, and 2 assessments after treatment). All analyses were conducted using PASW Statistics (version 18.0.0; SPSS, Inc., Chicago, IL).

Results

Figure 1 provides details of study recruitment. PCPs referred 495 patients, of whom 291 were reached and confirmed to be eligible. Of these, 226 (78%) initiated acupuncture. The most common reason for not initiating acupuncture was an inability to attend the scheduled acupuncture session because of scheduling conflicts. As expected, back pain was the most common diagnosis among those enrolled ($n = 133$; 58.8%), followed by osteoarthritis ($n = 39$; 17.3%) and multiple conditions ($n = 36$, 15.9%). Patients who did not initiate treatment did not differ significantly from those who initiated treatment for pain condition; demographics (age, race/ethnicity, US born, education, insurance, Medicaid); pain severity; physical health; or disability.

The average age was 54.3 years (standard deviation [SD], 14 years; median, 53.9 years); 70.8% of participants described themselves as English-speaking and 27% as primarily Spanish-speaking, and more than half (53.5%) were Hispanic (Table 1). Many participants (38.5%) described themselves as disabled;

Figure 1. Recruitment and study participation. PCP, primary care physician.

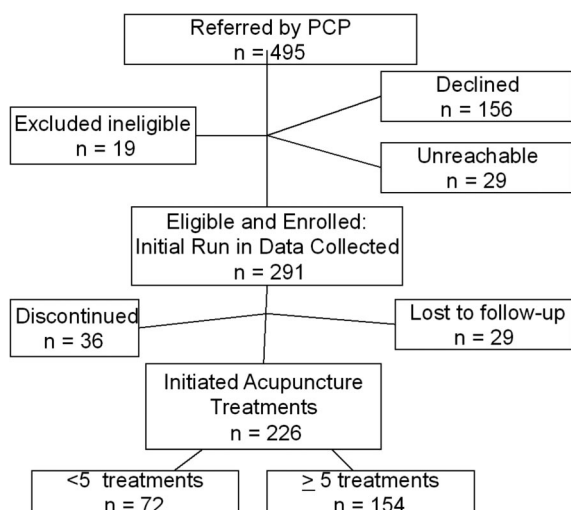


Table 1. Demographics of Participants Who Initiated Treatment (n = 226)

Demographics	
Mean age, years (SD)	54.3 (14)
Born in the United States	107 (47.3)
Language spoken most frequently	
English	160 (70.8)
Spanish	60 (26.5)
Other	6 (2.7)
Marital status	
Married	48 (21.2)
Living with a partner	12 (5.3)
Divorced	30 (13.3)
Widowed	30 (13.3)
Separated	27 (11.9)
Never married	1 (0.4)
Single	75 (33.2)
Other	1 (0.4)
Race/Ethnicity	
Hispanic	121 (53.5)
Non-Hispanic black	61 (27)
Non-Hispanic white	9 (4)
Non-Hispanic other	34 (15)
Working status	
Unemployed	23 (10.2)
Full time	52 (23)
Part time	13 (5.8)
Disabled	87 (38.5)
Insurance	
Fee-for-service Medicaid	7 (3.1)
Managed care Medicaid	129 (57.1)
Private insurance	52 (23)
No insurance	13 (5.8)
Household Income (\$)	
<20,000	95 (42)
20,000–29,000	27 (11.9)
30,000–39,000	18 (8)
40,000–49,000	6 (2.7)
>50,000	7 (3.1)
Don't know/refused to answer	67 (29.6)
Education	
Some HS or less	79 (34.9)
HS graduate	55 (24.3)
Some college	57 (25.2)
College graduate or more	31 (13.7)

Data are n (%) unless otherwise indicated. SD, standard deviation; HS, high school.

an additional 10.2% were unemployed, and the remaining participants were employed either full or part time. Almost half (42%) of participants were from households earning less than \$20,000 per year; 3.1% reported household incomes of \$50,000 or

greater. More than half (57.1%) were receiving Medicaid; 23% had private insurance, and 5.8% were uninsured.

Baseline pain and disability scores are included in Table 2. Patients reported an average baseline disability score of 66.7 (SD, 30.9; possible range, 0–100), an average baseline BPI pain severity score of 6.7 (SD, 2.1; possible range, 0–10), and a pain interference mean of 6.4 (SD, 2.9). Baseline scores on the SF-12 also reflected significant morbidity: 46.3% of the sample scored in the “poor” or “fair” range for overall health.

Of patients initiating treatment ($n = 226$), the mean number of treatments per patient was 9.7 (SD, 7.3), and 154 (68.1%) had ≥ 5 treatments (chosen to indicate a meaningful engagement with treatment, based on expert opinion). There were no statistically significant differences in the proportion of patients engaging in ≥ 5 treatments in regard to referring diagnosis, baseline level of pain and disability, baseline functional status as measured by the SF-12, and specific demographic factors (data not shown). A few participants ($n = 9$) reported an adverse event, all of which were related to a transient increase in pain or numbness. The most common reasons for discontinuing treatment were “no longer interested” (27%), poor health (23%), and lack of improvement (18%).

Multivariate Results

Table 2 and Figure 2 show the trend in mean scores before and after baseline for our primary outcomes, functional status, and pain severity. In assessing change over time using HLM, the covariates retained in the multivariate model for functional health status included treatment site, number of acupuncture treatments received, baseline disability, and age. In the adjusted model, functional status was significantly improved in the periods during and after treatment. Functional status did not differ by site, although site was retained in the model for complete specification. Number of treatments was significantly related to functional status; degree of disability and age were negatively related to functional health. The multivariate model for pain severity revealed a significant reduction in severity during the treatment period and a nonsignificant reduction (from baseline) during the period after treatment. Interaction terms representing time by treatment periods were nonsignificant, indicating the slope of pain severity did not change across treatment periods.

Baseline degree of disability and receiving Medicaid were both positively related with reported pain severity. Adjusted regression coefficients for pain severity and functional status are reported in Table 3.

Almost one third of participants (30.3%) experienced a 30% or greater improvement in pain, and 39.9% experienced 2a 0% or greater improvement between the baseline run-in period and the last measurement; the overall sample experienced 11.5% improvement. Patient assessment of change was significantly related to change in pain severity and physical health following treatment (Table 4). Clinical global ratings (reported by acupuncturists) were not related to change in either outcome or patient impression of change.

Discussion

The goals of this study were 2-fold. First, we sought to evaluate the feasibility and acceptability to patients and clinicians of offering acupuncture for chronic pain in the urban community health center setting, where it has rarely been available in the past. As we report elsewhere, we identified many patients with substantial chronic pain and related disability, as well as great enthusiasm among clinicians and patients for acupuncture.²⁴ We also have demonstrated a high level of engagement with treatment among this patient population, with more than two thirds of our participants attending ≥ 5 acupuncture treatment sessions. This suggests that, despite a lack of familiarity with the discipline and the many barriers to regular attendance experienced by patients in this setting, patients are motivated to incorporate acupuncture into their care in a serious and committed fashion.

Our second goal, and the focus of this report, was to evaluate the effectiveness of acupuncture in treating chronic pain in this setting. Here we were able to reach 2 important conclusions new to the literature on this subject. First, acupuncture offered in the primary care community health center setting to an ethnically and racially diverse and socioeconomically underprivileged population with moderate to severe chronic pain is associated with a clinically and statistically significant reduction of pain in more than 30% of subjects. Most clinical trials of acupuncture to date have not delivered the service in the primary care setting, and to our knowledge none have focused exclusively on a medically underserved, community health center–based population. Given the chal-

Table 2. Pain, Disability, and Functional Status

	Brief Pain Inventory*		12-Item Short Form†			CPGS		PFD: Days With Pain in the Past 2 Weeks (0–14)	PIQ-6 (40–78)
	Pain Severity (0–10)	Pain Interference (0–10)	Physical Health (0–100)	Mental Health (0–100)	Fair/Poor General Health, n (%)	Disability Score (0–100%)	Characteristic Pain Intensity (0–100%)		
Before baseline									
6 weeks	6.9 (6.6–7.1)	6.9 (6.6–7.3)	—	—	—	72.6 (69.1–76.1)	78.6 (76.8–80.3)	13.0 (12.6–13.3)	68.4 (67.5–69.2)
4 weeks	6.9 (6.6–7.2)	6.6 (6.2–7)	—	—	—	—	—	12.5 (12–12.9)	—
2 weeks	7.0 (6.6–7.4)	6.5 (6–7)	—	—	—	—	—	12.5 (11.9–13)	—
Baseline	6.7 (6.5–7)	6.4 (6–6.8)	31.7 (30.4–33.1)	38.2 (36.2–40.1)	107 (46.7)	66.8 (62.8–70.8)	77.3 (75.2–79.3)	12.3 (11.9–12.8)	67.4 (66.4–68.3)
Follow-up									
2 weeks	6.2 (5.8–6.5)	5.5 (5–5.9)	—	—	—	—	—	11.1 (10.5–11.8)	63.9 (62.7–65.2)
4 weeks	5.7 (5.3–6.1)	5.0 (4.5–5.6)	—	—	—	—	—	10.7 (10–11.4)	62.3 (60.9–63.7)
8 weeks	5.6 (5.2–6)	5.0 (4.4–5.6)	—	—	—	—	—	10.7 (9.9–11.4)	61.5 (59.9–63.1)
12 weeks	5.6 (5.2–6.1)	4.9 (4.3–5.5)	35.7 (33.8–37.6)	43.7 (41–46.4)	52 (40.63)	43.7 (37.7–49.8)	65.1 (61.2–69.1)	10.1 (9.3–10.9)	60.8 (60–61.9)
16 weeks	5.7 (5.2–6.3)	5.0 (4.4–5.7)	—	—	—	—	—	10.6 (9.7–11.5)	61.7 (59.9–63.5)
24 weeks	5.5 (4.9–6.1)	5.0 (4.4–5.7)	35.3 (33–37.5)	45.2 (42.5–47.8)	36 (33.64)	45.2 (38.2–52.2)	64.7 (59.9–69.5)	10.9 (10–11.7)	62.2 (60.2–64.1)

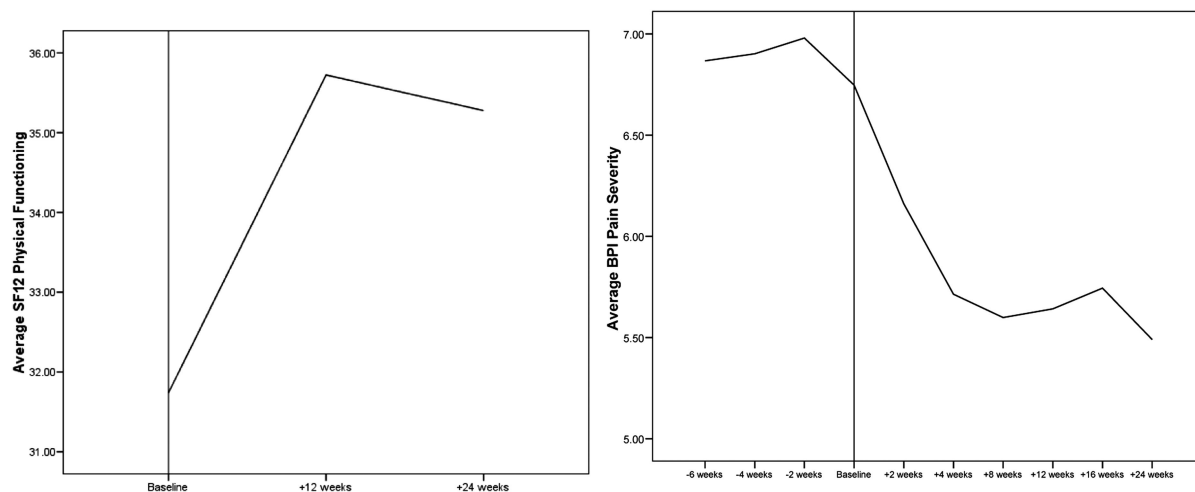
Data are mean (standard deviation) unless otherwise indicated.

*Higher Brief Pain Inventory score indicates more severe pain.

†Higher 12-item Short Form score indicates better function.

—, Not measured; CPGS, Chronic Pain Grading Scale; PFD, pain-free days; PIQ-6, 6-item Pain Impact Questionnaire.

Figure 2. Average physical function using the 12-item Short Form (SF12; left) and pain severity using the Brief Pain Inventory (BPI; right) over time.



lenges primary care doctors face in the treatment of chronic pain, particularly with new concerns being raised regarding the use of narcotic medications, and the overall safety of acupuncture as a treatment, this finding has potentially great importance in the management of pain in this setting. Acupuncture also is significantly associated with improved functional status among patients with a high degree of baseline disability.

Second, we were able to demonstrate this level of effectiveness in a population with difficult-to-

treat pain using student acupuncturists who were available at no cost to the clinical sites or the patients. Because the one-on-one delivery model most common in the United States is extremely expensive to deliver, cost has been a major barrier to providing acupuncture to uninsured or underinsured patients without private financial resources. The model developed and tested in ADDOPT—using student acupuncture teams under the supervision of acupuncture faculty as part of their clinical training—has potential as a means to provide this

Table 3. Adjusted Regression Coefficients (Hierarchical Linear Modeling) for Pain Severity and Physical Function

	SF-12 Physical Functioning			BPI Pain Severity				
	Estimate	95% Confidence Interval	P Value	Estimate	95% Confidence Interval	P Value		
Treatment period	3.03	4.81	1.24	<.001	-0.71	-0.40	-1.03	<.001
Posttreatment period	2.61	4.47	0.77	.006	-0.41	0.77	-1.59	.496
Time (weeks centered around baseline)	—	—	—	—	-0.04	-0.13	0.04	.117
Time × treatment period	—	—	—	—	-0.02	0.04	-0.08	.554
Time × after treatment period	—	—	—	—	-0.01	0.07	-0.08	.854
Site			.44					.744
Site A	-0.55	-3.68	2.58	0.12	-0.36	0.60		
Site B	2.00	-1.50	5.50	-0.20	-0.74	0.35		
Site C	-0.66	-3.45	2.13	0.00	-0.43	0.43		
Site D	Reference	Reference	Reference	Reference	Reference	Reference		
CPGS disability score	-0.14	-0.18	-0.10	<.001	0.04	0.03	0.04	<.001
Treatments received	0.23	0.08	0.38	.003	—	—	—	—
Age	-0.18	-0.26	-0.10	<.001	—	—	—	—
Medicaid	—	—	—	—	0.50	0.85	0.15	.005

BPI, Brief Pain Inventory; CPGS, Chronic Pain Grading Scale; SF12, 12-item Short Form.

Table 4. Correlation Between Global Assessment of Change and Observed Change in Outcomes

	CGIC	ΔBPI	ΔSF12
Patient global impression of change*	0.132	0.293 [†]	-0.249 [‡]
CGIC*		0.166	0.001
Change in BPI (4 month after baseline)			-0.277 [‡]

*Lower scores indicate greater improvement.

[†]<.01.

[‡]<.05.

BPI, Brief Pain Inventory; CGIC, clinical global assessment of change; SF12, 12-item Short Form.

clinical service to underserved patients. Almost every major urban area in the United States has at least one acupuncture training program, and many of these schools seek clinical training sites within conventional health care settings where their students can gain experience. Critics may argue that the acupuncture care provided by students is of slightly lower quality than that provided by more experienced practitioners. This could explain why only 32% of our participants experienced 30% or greater reduction in pain score (compared with the 40% to 50% response rate seen in many studies). Yet the fact that this delivery model makes acupuncture available where it would otherwise not be feasible makes it an important approach to consider for community health centers interested in adding acupuncture to their options for chronic pain treatment.

Limitations

Several limitations related to intervention delivery and study design should be acknowledged. Our delivery model involved supervised students, with related consequences. Constraints of the academic calendar resulted in more turnover of clinicians and breaks in treatment course not typical of care in other settings. Although the preceptors were highly experienced, the varying skill levels of student acupuncturists could have influenced outcomes. However, our design did allow for an individualized approach to treatment that more accurately reflects real-world acupuncture treatment than the fixed point protocols often used in clinical trials.

With regard to study design, in the absence of a randomized trial, we cannot say that the improvements we saw were specifically due to acupuncture.

For example, it is possible that omitted variables, such as other concurrent treatment for pain, differential use of medications (both prescribed and over the counter) could have contributed to the differences seen. There was also substantial variation in “dosage”: the number of acupuncture treatments varied widely between patients. The exclusion of variables such as these, and because not all patients received the planned dosage, may result in misestimating the magnitude of the effect.

Conclusion

Referred primary care patients experience high levels of pain and pain-related disability. In this setting, weekly acupuncture was associated with statistically significant improvements in pain and quality of life. The model developed here—bringing acupuncturists-in-training directly into the primary care setting for an underserved population—is effective and viable as a way to deliver a nonpharmacological approach to the management of chronic pain in this setting.

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