

Acupuncture for Treatment of Persistent Arm Pain Due to Repetitive Use

A Randomized Controlled Clinical Trial

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Objective: To compare true and sham acupuncture in their abilities to relieve arm pain and improve arm function in individuals with arm pain due to repetitive use.

Methods: Participants with persistent arm pain (N = 123) were randomly assigned to true or sham acupuncture groups and received 8 treatments over 4 weeks. The primary outcome was intensity of pain (10-point scale) and secondary outcomes were arm symptoms, arm function, and grip strength. Outcomes were measured during treatment (at 2 and 4 wk) and 1 month after treatment ended.

Results: Arm pain scores improved in both groups during the treatment period, but improvements were significantly greater in the sham group than in the true acupuncture group. This difference disappeared by 1 month after treatment ended. The true acupuncture group experienced more side effects, predominantly mild pain at time of treatments.

Discussion: Sham acupuncture reduced arm pain more than true acupuncture during treatment, but the difference did not persist after 1 month. Mild side effects from true acupuncture may have blunted any positive treatment effects. Overall, this study did not find evidence to support the effectiveness of true acupuncture in treatment of persistent arm pain due to repetitive use.

Key Words: arm pain, acupuncture, randomized controlled trial
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Pain due to musculoskeletal disorders of the upper extremity, also called repetitive strain injuries (RSI), is a frequent and increasing cause of disability in US workplaces^{1–7} and has resulted in the longest absences listed by the US Bureau of Labor Statistics for leading events and exposures in 2001.⁸ Ergonomic risk factors include force, awkward and static postures, repetition, dynamic factors, compression, and vibration.^{9,10} Like “low back pain,” RSI arm pain may derive from tendons, nerves, or muscles and encompass a variety of diagnoses, including lateral and medial epicondylitis, tendonitis, carpal tunnel syndrome, and “nonspecific arm pain.”^{3,6} Nonsurgical treatments include work place redesign, rest, splints, nonsteroidal anti-inflammatory drugs, and physical therapy. However, there have been few well-designed randomized controlled clinical trials (RCTs) to provide evidence of efficacy of these conservative treatments.^{11,12}

Some people with RSI arm pain have turned to acupuncture treatment, and some reports suggest it may be helpful.^{13–18} However, evidence from controlled clinical trials is limited. One small study suggested that laser acupuncture reduced pain from carpal tunnel syndrome.¹⁹ A Cochrane Database of Systematic Reviews of acupuncture treatment for lateral epicondylitis found 3 RCT studies in English that compared acupuncture with placebo, but each was criticized for serious flaws.^{20–23}

Our study provides evidence from a large and well-designed trial testing the hypothesis that true acupuncture provides greater relief of symptoms than sham acupuncture in people with persistent arm pain due to repetitive use.

METHODS

Study Design

This study followed a 2-week placebo run-in that compared sham acupuncture with a placebo pill.^{24,25} A parallel RCT, which will be reported separately, compared amitriptyline with a placebo pill. The participants who were assigned to sham acupuncture during the run-in were seamlessly rerandomized at its end to either true acupuncture or continued sham acupuncture. Study participants received twice-weekly treatments during the

placebo run-in phase (total of 4) and during the subsequent 4-week treatment phase (total of 8). A posttreatment visit was scheduled 4 weeks after completion of treatment. Participants received acupuncture treatments from experienced community-based acupuncturists. Study assessments were performed at an academically affiliated community hospital.

Study Participants

From June 2001 to April 2003, we recruited men and women from the greater Boston and Cambridge communities through advertisements and referrals from health professionals. Research assistants performed telephone-screening interviews to determine eligibility and willingness to participate. Because participants were initially randomly assigned to either the acupuncture or pill arms, they had to fulfill requirements for both trials. To be eligible, a person had to be at least 18 years old, have distal upper extremity pain associated with repetitive use that had persisted for at least 3 months, had received prior treatment for the arm pain, and reported pain intensity of 3 or more on the 10-point pain scale. Exclusions included persons with systemic connective tissue or muscular diseases, neurologic disorders (eg, cerebrovascular accidents, cervical disc disease), pregnancy, acute trauma to the affected arm, use of medications that interact with amitriptyline, and previous treatment with acupuncture for arm pain or prior use of acupuncture within 1 year for any problem. Participants were allowed to continue taking anti-inflammatory medications and other nonacupuncture current treatment, such as physical therapy that was in progress, but were discouraged from starting new treatments for arm pain during the study.

During their enrollment visits, candidates provided written informed consent, completed questionnaires, and underwent grip strength testing with a Jamar dynamometer and pinch meter. The study's occupational medicine physicians (R.G. and S.M.) performed targeted physical examinations to identify reasons for exclusion and to assign clinical diagnosis(es) for the arm pain using previously defined criteria.^{3,26}

During the informed consent process, potential participants were told that they would be randomly assigned to either the acupuncture or amitriptyline trial, and that they had a 50% chance of receiving active treatment at some time during the study. We offered participants courtesy treatment with true acupuncture or amitriptyline after their participation if they had received only placebo treatment during the study. They also received information about possible side effects of treatment. The Institutional Review Boards of the Cambridge Health Alliance, Beth Israel Deaconess Medical Center, Harvard Medical School, and Harvard School of Public Health approved the study protocol.

Randomization used a permuted block randomization with blocks of variable size (2, 4, or 6) and sealed sequentially numbered, opaque envelopes containing the treatment assignments. Randomization was stratified by

the individual's level of pain (< 3 or ≥ 3) at the end of the placebo run-in phase. An administrative assistant not involved in patient recruitment or data collection selected the envelopes and kept a confidential log of assignments.

Intervention: Acupuncture and Sham Acupuncture

Acupuncture treatments focus on relaxing the muscles and opening channels to the circulation of what acupuncturists call "qi." Point selection in our study was based on the location of the pain, limitations to the range of arm motion, and local sensitivity to palpation. Local channel points proximal to the area of pain were combined with distal points that control the area of pain. Nonmeridian local "trigger" points ("ah shi" points) were included. To incorporate the acupuncture theory of "opening the gates" in pain conditions, all participants received needling on Liver 3 (a point near the big toe) on the contralateral side of the affected arm, which was paired with Large Intestine 4, a point on the hand of the affected arm.¹⁴ If both arms were affected, the latter point was needled bilaterally.

A consensus team of senior acupuncturists selected 20 allowable acupuncture points based on the acupuncture literature.^{13,14,16} We used a "manualized" approach²⁷ that allowed some flexibility to vary the location of points according to the specific location and nature of the pain, while providing standardization of treatment. Besides the required points, practitioners could select between 5 and 8 additional points at each session and could include local area points traditionally used to affect specific regions (ie, LI 5, P5, P6, P7, and TW5) and local and distal sensitive "ah shi" points.

During true acupuncture treatments, single use disposable sterile needles (32 gauge, or 0.25-mm diameter) were inserted to standard depth and needled with neutral to moderate stimulation. After obtaining "de qi"²⁸ needles were retained for 20 minutes.

The placebo intervention was identical to the true intervention, except that a validated acupuncture sham needle device was used.²⁹⁻³¹ Both interventions began with disinfection with alcohol and application of a plastic ring fixed with sterile surgical adhesive tape. The sham needle looks and feels like a real acupuncture needle but has a blunt tip that only touches the skin before retracting up into a hollow shaft handle. Sham needles were applied to the same acupuncture points as real needles but without skin penetration. Participants remained with the same acupuncturist throughout entire study. Practitioners were instructed to maintain the exact same procedures and interactions with participants whether administering placebo or true treatment.

All acupuncturists were graduates of a master's program in acupuncture, licensed by the state Board of Medicine, and certified by the National Commission for the Certification of Acupuncture. Eight acupuncturists provided the bulk of the treatments ($> 95\%$). Five of these had previously performed acupuncture in other RCTs. Their experience ranged from 2 to 26 years with an

average of 10 years. All acupuncturists were thoroughly trained in the study protocol, agreed that the protocol was efficacious, and were monitored monthly.

Blinding

Throughout the study, participants were blinded to whether they were receiving placebo or true treatment. Research assistants involved in data collection were also blind to treatment assignment. Acupuncturists could not be blinded but were trained to maintain “neutral” communications with participants. To test the success of blinding, participants were asked at each data collection point whether they believed they were receiving active or placebo treatment.

Outcome Measures

We compared true with sham acupuncture on changes in each outcome measure between the end of the 2-week run-in period (which serves as the baseline for the treatment phase), the end of treatment (4 wk later), and 1 month after treatment ended. Longitudinal trends also included values obtained at the midpoint of treatment (2 wk). The primary outcome was self-reported intensity of pain with movement in the more severely affected arm during the preceding week, measured on a 10-point numerical rating scale, that went from 1 (no pain or discomfort) to 10 (pain or discomfort as intense as you can imagine).³²

Secondary outcome measures were: arm symptoms using the Levine Symptom Severity Scale³³; Upper Extremity Function Scale³⁴; and grip strength measured by a Jamar hand dynamometer (Sammons Preston Inc, Bolingbrook, IL).

In addition, we assessed depression and mood states using the Center for Epidemiologic Studies-Depression Scale (CES-D)^{35,36}; general well-being using an abbreviated General Well Being Schedule,^{36,37} and problems with sleeping (10-point scale).³⁴ Self-reported treatment side effects were assessed using check lists, and adherence to acupuncture treatments by counting number of kept office visits.

Statistical Analysis

Sample size estimates for the treatment phase were based on changes in the primary outcome pain score and findings from previous pain studies.³⁸⁻⁴⁰ We estimated that 60 patients in each treatment group would provide 80% power to detect a difference of 1.45 points on the 10-point pain scale.

Changes on each outcome measure were calculated by subtracting baseline values (end of run-in) from end-of-treatment results. We compared true acupuncture with the placebo device in intention-to-treat analyses. For the participants who dropped out during treatment, we imputed missing data with a last value carried forward approach. All reported *P* values are 2-sided. *t* tests were used to test for statistical differences of means and the χ^2 test (or Fisher exact test) for proportions.

To examine longitudinal trends in outcome scores, we fit regression models using generalized estimating equations using the SAS program.^{41,42} Independent variables included study week, treatment group, and the interaction between these 2 variables. We also examined the effect of different covariates in these regression models using multivariate analyses.

RESULTS

Study Population (Fig. 1)

A total of 1110 people completed telephone screening. Of these, 817 were not eligible or refused to participate. At enrollment, 23 were found to be ineligible or refused to enroll. Two hundred and seventy people were randomized into the placebo run-in phase: 135 to sham acupuncture and 135 to placebo pill. During the 2-week placebo run-in, 2 participants were found to be ineligible and 10 withdrew, leaving 123 participants to be randomized to the true (*n* = 63) or sham (*n* = 60) acupuncture groups. Of these, 61 and 57 respectively completed the 4-week treatment period, and 56 and 55 returned for posttreatment assessment, respectively.

At the time of enrollment, there were no statistical significant differences in baseline intensity of pain, levels of secondary outcome measures, or other current treatments for arm pain between those who were ultimately randomized to true and sham acupuncture. During the placebo run-in period, the intensity of pain decreased from a mean of 5.8 (\pm 1.4) to 4.9 (\pm 1.9) (confidence interval: -1.5, -0.3, *P* = 0.0035) in those subsequently randomized to true acupuncture, and from 5.4 (\pm 1.4) to 4.8 (\pm 2.0) (confidence interval: -1.2, 0.01, *P* = 0.05) in those who remained on sham acupuncture.

At the start of the treatment for acupuncture trial, there were no statistically significant differences in baseline characteristics of participants in the true and sham acupuncture groups (Table 1). Two thirds of participants had symptoms for 1 year or more, and almost equal numbers were males and females. This was a highly educated population with over 3 quarters having finished at least 4 years of college. Sleep disturbance did not seem to be a problem in these participants.

The participants reported up to 3 repetitive tasks that they felt contributed to the onset of their arm symptoms (Table 2). The single most frequent task was computer keyboarding/mousing (70% in each group). Twenty-five (40%) of participants in acupuncture and 20 (33%) in sham reported changing jobs or stopping work since first developing discomfort in their upper extremity (*P* = 0.42). Seventy-four percent of participants had service-related jobs (business, computers, education, personal care, health care), and about 6% had job titles in construction, maintenance/repair, production, or material moving. Nineteen participants were full-time or part-time students. Only 1 person in each group was receiving worker compensation, and none was receiving disability payments.

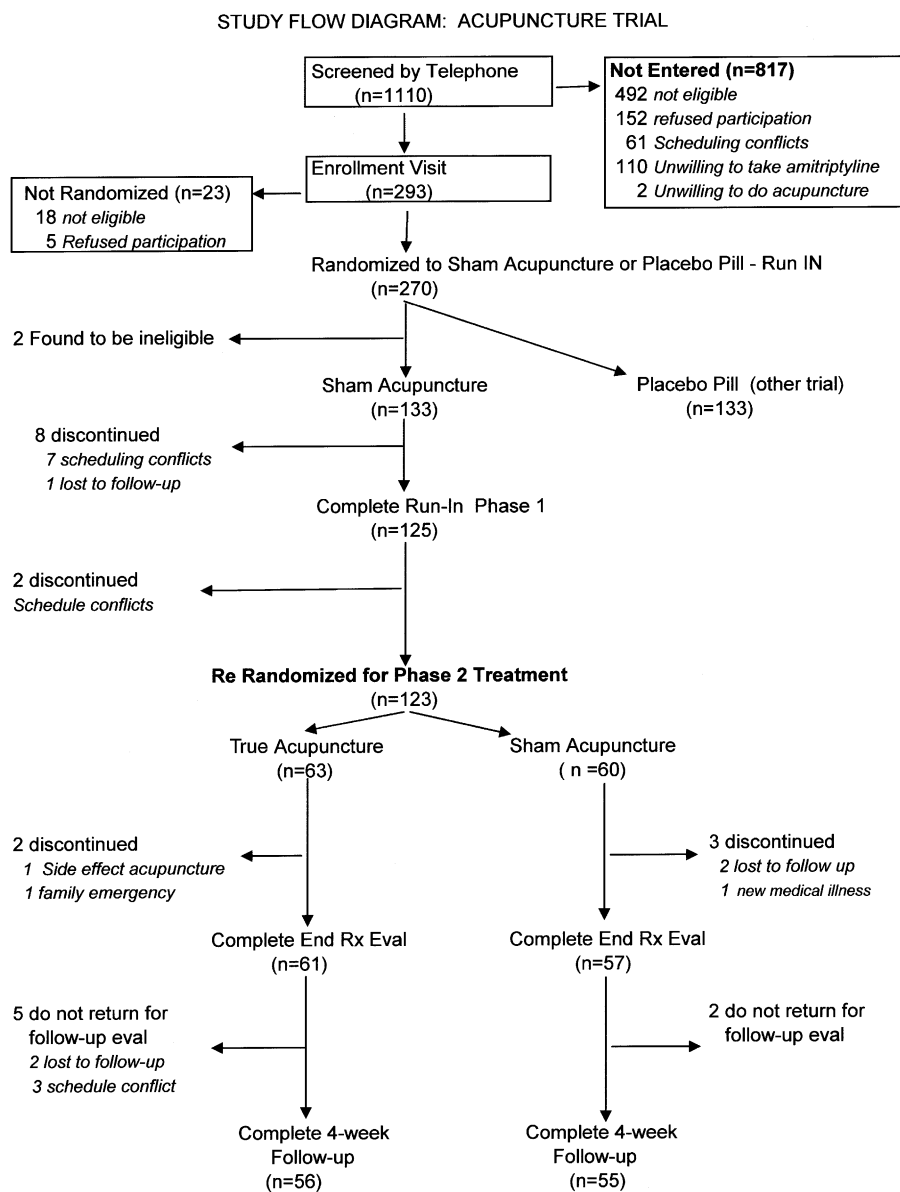


FIGURE 1. Study flow diagram.

During the enrollment visit, the examining physician assigned clinical diagnoses for the arm pain. Frequencies of the single “most important” diagnosis are summarized in Table 3. The majority fell into the categories of tendonitis or epicondylitis. No one had fibromyalgia.

Outcomes

Both treatment groups experienced decreases in the intensity of arm pain, arm symptoms, and improved arm function (Table 4). The sham acupuncture group improved more than the true acupuncture group in the intensity of arm pain ($P = 0.033$) and on the arm symptom severity scale ($P = 0.006$). Changes in arm

function and grip strength were not statistically significant. Differences between groups were not sustained at the follow-up visit 1 month after treatment ended (Fig. 2), although the arm pain levels remained statistically significantly lower than baseline levels.

In the initial longitudinal analysis, arm pain and arm symptoms scores declined faster (0.19 points per wk, $P = 0.03$) in the sham compared with the true acupuncture group. Variables were then tested in a multiple regression model, and the most important factors were age, sex, expectancy, and baseline pain. After adjusting for these variables in a longitudinal multiple regression analysis, arm pain still decreased faster in the sham group than in the true acupuncture group by 0.14 points per

TABLE 1. Baseline Characteristics [Mean ± SD or n (%)]

Variables	True Acupuncture (n = 63)	Sham Acupuncture (n = 60)
Age, y	34.9 ± 10.0	37.5 ± 11.0
Female	29 (46.0)	32 (53.3)
Non-white	15 (23.8)	10 (16.7)
At least 4 y of college	49 (77.8)	49 (81.7)
Symptom duration < 1 y	19 (30.2)	20 (33.3)
Current NSAID use	19 (30.6)	25 (41.7)
Current antidepressant use	2 (3.2)	2 (3.3)
Past acupuncture	9 (14.3)	9 (15.0)
Expected pain in 2 wk		
No additional treatment	5.8 ± 1.7	5.6 ± 1.6
With acupuncture	4.0 ± 1.8	3.6 ± 1.4
Current stress at work*	3.2 ± 1.0	2.8 ± 1.2
Satisfaction with current job†	2.4 ± 1.0	2.5 ± 1.2
CES-Depression Scale score	9.7 ± 7.1	9.6 ± 7.1
CES-No. with score ≥ 16	13 (20.6)	11 (18.3)
General Well-Being Score	65.3 ± 9.6	64.8 ± 8.7
Clinical Diagnostic Groups		
Tendonitis/epicondylitis	40 (63.5)	40 (66.7)
Neuropathic/neuralgia	6 (9.5)	8 (13.3)
Nonspecific	5 (7.9)	5 (8.3)
Other diagnosis	12 (19.1)	7 (11.7)
Intensity of pain‡	4.87 ± 1.93	4.82 ± 1.97
Severity of symptoms§	2.06 ± 0.46	2.12 ± 0.51
Upper extremity function scale	24.05 ± 12.22	22.73 ± 12.05
Grip strength	67.76 ± 23.12	65.67 ± 26.52
Sleep¶	1.46 ± 1.01	1.98 ± 1.94

*Degree of stress at work or school (5-point scale: 1 = "little or no stress" to 5 "severe stress").

†Degree of satisfaction with current job (5-point scale: 1 = "very satisfied" to 5 "not satisfied at all").

‡Intensity of pain (10-point scale: 1 = no pain to 10 most intense pain imaginable).

§Severity of arm symptoms: mean score of 11 items, each assessed on 5-point scale, higher scores indicate more symptoms.

||Sum of impact on 8 types of arm function, each measured on 10-point scale, total score ranges from 8 = no functional impairment to 80 = maximal amount of functional impairment.

¶Problem with sleeping (10-point scale: 1 = no problem to 10 = cannot sleep at all).

NSAID indicates nonsteroidal anti-inflammatory drug.

week ($P = 0.01$), and arm symptoms (Levine symptom severity score) also improved slightly faster by 0.04 points per week ($P < 0.001$).

A "marked clinical response" defined as improvement in the pain score by $\geq 50\%$ occurred in 28% of the sham group and 19% of the true acupuncture during treatment, but this difference was not statistically significant ($P = 0.23$). Each acupuncturist had a balanced number of placebo and true assignments, and acupuncturist assignment did not influence outcome.

Blinding

At the end of the treatment period, similar proportions of participants in the true and sham

TABLE 2. Repetitive Tasks Contributing to Onset of Arm, Wrist, or Hand Symptoms

Types of Repetitive Tasks	True Acupuncture (n = 63)	Sham Acupuncture (n = 60)
	No. Tasks (%)	No. Tasks (%)
Keyboarding/mousing	44 (69.8)	42 (70.0)
Playing musical instrument	12 (19.1)	9 (15.0)
Arts/crafts work	7 (11.1)	3 (5.0)
Construction work-hammering	5 (7.9)	7 (11.7)
Home cleaning	5 (7.9)	7 (11.7)
Materials handling	5 (7.9)	9 (15.0)
Handwriting	4 (6.3)	2 (3.3)
Other	20 (31.7)	28 (46.7)
Total no. tasks	102	107

acupuncture groups believed they were receiving active treatment [71% vs. 81%, respectively ($P = 20$)].

Adherence

Ninety percent of participants in each study arm received all 8 treatments over the 4-week treatment period.

Influence of Treatment Side Effects on Study Outcomes

There were no serious adverse effects owing to acupuncture treatments. At each assessment, participants were asked if they had experienced any side effects that they attributed to acupuncture treatments in the past 2 weeks and, if so, to indicate their type(s) and severity(ies) on a check list. Prevalence of any side effects experienced during the 2-week placebo run-in period did not differ between the true (27%) and sham (28%) groups. During the treatment period, more of the true acupuncture group (54%) reported side effects at the midpoint or end-of-treatment assessments than the sham group (30%), ($P = 0.007$). "Pain during treatment" was the most

TABLE 3. Frequencies of Most Important Diagnoses

	True Acupuncture	Sham Acupuncture
Tendonitis/epicondylitis group		
Wrist/forearm extensor tendonitis or tenderness	14 (22.2)	15 (25.0)
Wrist/forearm flexor tendonitis or tenderness	8 (12.7)	11 (18.3)
Lateral epicondylitis	9 (14.3)	8 (13.3)
Medial epicondylitis	6 (9.5)	3 (5.0)
De quervain tendonitis	3 (4.8)	3 (5.0)
Neuropathic/neuralgia group		
Cubital tunnel syndrome	1 (1.6)	1 (1.7)
Ulnar entrapment at wrist	0 (0.0)	1 (1.7)
Carpal tunnel syndrome	5 (7.9)	6 (10.0)
Nonspecific arm pain	5 (7.9)	5 (8.3)
Other diagnoses	12 (19.1)	7 (11.7)
Total	63	60

TABLE 4. Changes in Outcome Measures at End of Treatment

	True Acupuncture	Sham Acupuncture	Difference	P (Based on <i>t</i> test)
	Mean (SD)	Mean (SD)	(95% CI)	
Primary outcome				
Pain (10-point scale)				
Baseline	4.9 (1.9)	4.8 (2.0)		
End Rx	4.4 (2.3)	3.6 (1.9)		
Change	-0.43 (2.1)	-1.2 (1.8)	0.75 (0.06, 1.45)	0.033
Secondary outcomes				
Severity of symptoms				
Baseline	2.1 (0.46)	2.1 (0.51)		
End Rx	1.9 (0.49)	1.8 (0.49)		
Change	-0.13 (0.40)	-0.34 (0.44)	0.21 (0.06, 0.36)	0.006
Upper Extremity Function Scale				
Baseline	24.1 (12.2)	22.7 (12.1)		
End Rx	21.4 (12.6)	18.5 (10.7)		
Change	-2.7 (8.3)	-4.2 (7.5)	1.49 (-1.33, 4.31)	0.298
Grip strength (lb)				
Baseline	67.8 (23.1)	65.7 (26.5)		
End Rx	67.9 (23.8)	66.5 (26.1)		
Change	0.17 (10.8)	0.87 (10.6)	-0.69 (-4.50, 3.12)	0.720

CI indicates confidence interval.

frequent side effect and occurred in 43% of the true versus 15% of the sham groups ($P = 0.0007$).

We also looked at those individuals who reported “new side effects” attributable to acupuncture only in the treatment period, and not during the placebo run-in and found 23 (50%) in true acupuncture group versus 9 (21%) in sham group ($P = 0.004$).

DISCUSSION

To our knowledge, this is the largest randomized controlled trial to examine acupuncture treatment for distal arm pain due to repetitive use. During 8 acupunc-

ture treatments administered over 4 weeks, both the true and sham acupuncture groups experienced improvements in arm pain, symptoms, and function, which persisted 1 month after completion of treatment. The sham group improved significantly more than the true acupuncture group during the treatment period, but this advantage was not sustained 1 month after treatment ended. The difference in pain between sham and true acupuncture groups at the end of treatment (0.75 points on 10-point scale), although statistically significant, probably does not represent a clinically discernible difference.

The improvement in both groups over time may reflect treatment effects, placebo effects, regression to the

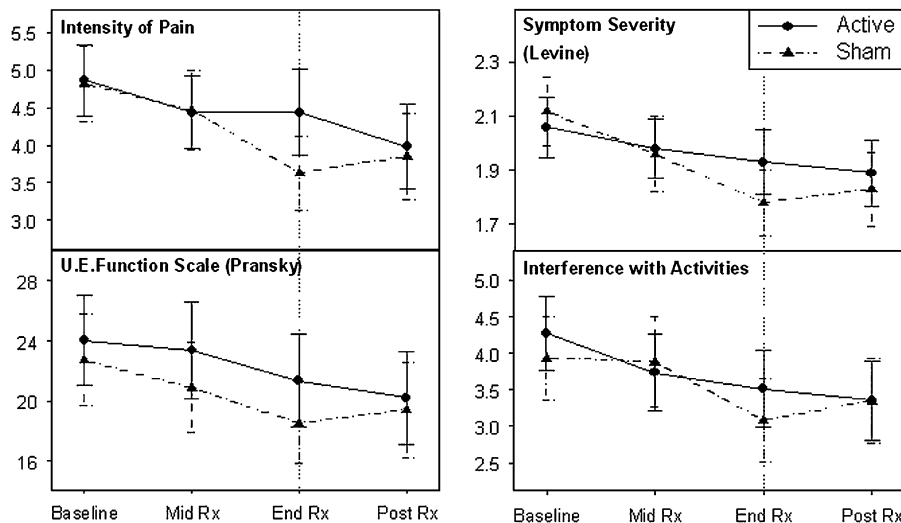


FIGURE 2. Longitudinal changes (mean ± 95% confidence interval) of outcome measures in acupuncture groups. Vertical line indicates end-of-treatment period.

mean, the natural history of the illness, or a combination of these factors. Because over half of participants had pain for 1 year or more, improvement due totally to natural history of the illness seems unlikely. Inclusion of a nontreatment control group would have been needed to address this issue.

Reasons for the superiority of the sham acupuncture device during treatment are not clear. One possibility is that treatment effects were blunted in the true acupuncture group because of the higher rates of side effects, and especially mild pain during treatment. We speculate that this discomfort may have been due to some of the needle placements in the arm, in close proximity to the painful areas. Another possibility might be that the sham device may have conferred genuine treatment effects, because it was applied to real acupuncture points (an "acupressure" effect). This seems less likely given the results of another RCT testing acupuncture in the treatment of fibromyalgia that found no significant differences between true acupuncture, noninsertive simulated acupuncture at true acupuncture points, and true acupuncture needling at nonacupoints.⁴³

At the end of the study and before results were known, some of our study's acupuncturists complained that the requirements that true and sham acupuncture be performed using identical methods involving a ring and sterile tape to "hold" the needles in place, and also limitations in selection of treatment points, may have decreased the effectiveness of true acupuncture. However, these issues were not reported as problems in another study using this technique.³⁰

One limitation of our study may have been that 8 treatments over 4 weeks were insufficient to achieve maximum benefits from true acupuncture, because other studies have demonstrated the need for longer treatment periods to demonstrate statistical differences between the treatment and control groups. For example, in patients treated with acupuncture for osteoarthritis of the knee, Berman et al⁴⁴ found no significant effects on pain scores until the 14th week of treatment, when pain had decreased by 40% in the true acupuncture group compared with 30% in the sham control. Even then, it is not clear whether the 10% difference would be clinically important.⁴⁵

In summary, our study found that sham acupuncture was, if anything, slightly superior to true acupuncture in relieving pain during treatment in persons with persistent arm pain due to repetitive use, but this difference would probably not be clinically discernible, and so the 2 treatments were essentially similar in clinical efficacy. Further studies of acupuncture for arm pain will be needed to verify our results. Future studies should examine the frequency and duration of treatment, compare different types of sham acupuncture, and test the value of methods aimed at increasing individualization of treatment methods.

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