A Randomized Clinical Trial of Acupuncture Compared with Sham Acupuncture in Fibromyalgia

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Background: **Fibromyalgia is a common chronic pain condition for which patients frequently use acupuncture.**

Objective: **To determine whether acupuncture relieves pain in fibromyalgia.**

Design: **Randomized, sham-controlled trial in which participants, data collection staff, and data analysts were blinded to treatment group.**

Setting: **Private acupuncture offices in the greater Seattle, Washington, metropolitan area.**

Patients: **100 adults with fibromyalgia.**

Intervention: **Twice-weekly treatment for 12 weeks with an acupuncture program that was specifically designed to treat fibromyalgia, or 1 of 3 sham acupuncture treatments: acupuncture for an unrelated condition, needle insertion at nonacupoint locations, or noninsertive simulated acupuncture.**

Measurements: **The primary outcome was subjective pain as measured by a 10-cm visual analogue scale ranging from 0 (no pain) to 10 (worst pain ever). Measurements were obtained at baseline; 1, 4, 8, and 12 weeks of treatment; and 3 and 6 months after completion of treatment. Participant blinding and adverse effects were ascertained by self-report. The primary outcomes were evaluated by pooling the 3 sham-control groups and comparing them with the group that received acupuncture to treat fibromyalgia.**

Results: **The mean subjective pain rating among patients who received acupuncture for fibromyalgia did not differ from that in the pooled sham acupuncture group (mean between-group difference, 0.5 cm [95% CI, −0.3 cm to 1.2 cm]). Participant blinding was adequate throughout the trial, and no serious adverse effects were noted.**

Limitations: **A prescription of acupuncture at fixed points may differ from acupuncture administered in clinical settings, in which therapy is individualized and often combined with herbal supplementation and other adjunctive measures. A usual-care comparison group was not studied.**

Conclusion: **Acupuncture was no better than sham acupuncture at relieving pain in fibromyalgia.**

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Fibromyalgia is a condition of unknown cause that is characterized by chronic, diffuse pain and tenderness to palpation at specific musculoskeletal sites (1). It is the second most common rheumatologic condition after osteoarthritis, afflicting 2% to 4% of the U.S. population (2). Most randomized, controlled trials of allopathic interventions have not demonstrated sustained benefit, and use of complementary and alternative medicine for fibromyalgia is common (3). For example, 60% to 90% of patients with fibromyalgia report using 1 or more complementary or alternative treatments (4, 5), and 22% of these patients have tried acupuncture (6). Despite skepticism in western cultures, the literature suggests that acupuncture may alleviate chronic pain (7).

Randomized, controlled trials of acupuncture face many methodologic challenges, including the identification of appropriate treatment and control groups, blinding of study participants, and the inability to blind practitioners (8). Needle placement and the extent to which needle insertion and stimulation is necessary are also controversial (7–9). In the only rigorous randomized, controlled trial of acupuncture for fibromyalgia, 7 of 8 outcome measures significantly improved after 3 weeks of treatment with electroacupuncture (10). However, because blinding was not assessed and electroacupuncture involves perceptible current, these promising results could reflect a lack of blinding to treatment condition. Moreover, the study followed patients only during treatment. Because fibromyalgia is a chronic condition, longer-term outcomes should be examined.

To address these methodologic problems, we performed a randomized, controlled trial of acupuncture to treat fibromyalgia that included 3 sham acupuncture treatments to account for the effects of needle insertion and placement. The adequacy of participant blinding was carefully evaluated. We sought to determine whether directed acupuncture that is designed to treat fibromyalgia relieves pain better than does sham acupuncture in adults with fibromyalgia. On the basis of the scant literature and our clinical experience, we hypothesized a priori that directed acupuncture would result in the greatest clinical improvement.

See also:

Print

Editors' Notes 11
Summary for Patients I-24

Web-Only

Conversion of figures and table into slides

METHODS

Participants

Participants were recruited from the greater Seattle, Washington, metropolitan area between January 2001 and September 2002. Recruitment strategies included dissemination of information on the study through newspapers, television, advertisements, signs posted at university-affiliated hospitals, and letters to local fibromyalgia support groups and health care providers with large caseloads of patients with fibromyalgia. Potential participants were told that they had an equal chance of being assigned to 1 of 4 acupuncture interventions, none of which have been proven but 1 of which was believed to have the most potential to improve the symptoms of fibromyalgia. The institutional review boards at the participating institutions approved the study, and participants provided written informed consent.

Eligible participants were English-speaking adults 18 years of age or older in whom fibromyalgia was diagnosed by a physician and who had a prerandomization global pain score of 4 or greater on a visual analogue scale (0 = no pain, 10 = worst pain ever). Participants agreed to undergo randomization and kept use of any fibromyalgia-related pharmacologic and nonpharmacologic therapies constant throughout the study. At the baseline evaluation before randomization, a research coordinator trained in tender-point examination confirmed the diagnosis of fibromyalgia by using the 1990 criteria of the American College of Rheumatology (1).

Participants were excluded if they reported other pain-related medical conditions or potential contraindications to acupuncture treatment (such as bleeding disorders or severe needle phobia), were pregnant or breastfeeding, used narcotics (which could blunt the effects of acupuncture), were involved in litigation related to fibromyalgia (which might reduce their incentive for improvement), or had previously received acupuncture (to maximize blinding).

Randomization Procedure

A research coordinator screened and enrolled participants at an academic research center. After participants completed a baseline evaluation, another research coordinator who was uninvolved with data collection randomly assigned them to 1 of 4 treatment groups by using a computer-generated, blocked random-allocation sequence with a block size of 4. This research coordinator informed the acupuncture clinic of the treatment assignment.

Intervention

Eight U.S.-trained and licensed acupuncturists with a median of 10 years of experience (range, 4 to 18 years) provided study treatments in their private offices. One investigator trained the acupuncturists in the study procedures to increase their comfort with delivering all 4 treatments and monitored compliance with the protocol throughout the study. Participants were assigned an acupuncturist according to geographic convenience and schedule availability, and every effort was made to have them treated by the same acupuncturist for the entire 12 weeks. The primary acupuncturist was defined as the practitioner from whom a participant received the most treatments. In all groups, participants were asked to attend treatment sessions twice weekly for 12 weeks (24 treatments). We considered participants who attended 80% or more (≥19 of 24) of acupuncture appointments to have completed a full course of treatment. Outcome measures were collected at regularly scheduled time points from participants who discontinued treatment.

Participants received directed acupuncture designed to treat fibromyalgia according to the practice of Traditional Chinese Medicine or 1 of 3 sham acupuncture treatments. One sham intervention, a control for acupoint specificity, involved acupuncture typically used to treat irregular menses or "early menses due to Blood Heat" (an unrelated condition) according to Traditional Chinese Medicine. Another sham intervention, which was also a control for acupoint specificity, used body locations not recognized as true acupoints or meridians for needling (sham needling). The third sham treatment, a control for needle insertion, consisted of noninsertive simulated acupuncture at the same acupoints used in directed acupuncture (simulated acupuncture). This technique, in which a toothpick in a needle guide-tube is used to mimic needle insertion and withdrawal, has been shown to be indistinguishable from true acupuncture in acupuncture-naïve patients with back pain (9). Simulated acupuncture more closely duplicates the needle insertion experience than do techniques using placebo needles that require placing adhesive or plastic foam on the skin (11, 12).

Acupoints and sham points (**Appendix Figure**, avail-

Context

A substantial number of patients use acupuncture to treat the symptoms of fibromyalgia, but previous randomized trials of this intervention are inconclusive, in part because of control groups that did not permit adequate blinding of the patients.

Contribution

This study randomly assigned 100 patients with fibromyalgia to 12 weeks of either true acupuncture treatment or one of 3 types of sham acupuncture. No differences in pain were identified between acupuncture and sham acupuncture.

Cautions

The study had too few patients to detect small differences between the groups. Patients could use other fibromyalgia therapies, so this study evaluates acupuncture as adjunctive treatment.

–The Editors

able at www.annals.org) were chosen by a study acupuncturist with 15 years of experience in treating fibromyalgia and were approved by 3 other senior acupuncturists. In all groups that underwent needle insertion, needles were retained at standard depths (13) for 30 minutes at each acupoint. Disposable Chinese, Japanese, or Korean needles (34 to 40 gauge) were used, depending on the practitioner's preference. In the simulated acupuncture group, participants remained on the table for 30 minutes after simulated insertion and then underwent simulated needle withdrawal. Efforts were made to imitate the sounds of opening needle packs and needle disposal.

Acupuncturists were not blinded to the treatments they delivered. To maximize participant blinding, we included only acupuncture-naïve persons who could not compare their treatment with previous experiences with acupuncture, limited contact among study participants, restricted conversation between acupuncturists and participants, and blindfolded participants during treatment. All research personnel who collected or analyzed data were unaware of treatment group. At the end of 12 weeks, we collected data to assess the adequacy of blinding.

Outcome Measures

Demographic measures collected at the baseline evaluation included age, sex, race, education, marital status, and duration of pain and diagnosis of fibromyalgia. Participants also listed the types of therapies they had previously tried for their pain. We grouped this information into manual therapies (physical, ergonometric, chiropractic, or massage therapy), mental health therapies (psychotherapy or cognitive behavioral therapy), dietary changes, or other therapies (nerve blocks, hypnosis, or biofeedback).

Outcome measures were collected at baseline; after 1, 4, 8, and 12 weeks of acupuncture treatment; and 3 and 6 months after completion of treatment (weeks 24 and 36). The primary outcome was subjective pain, as measured by a standard 10-cm visual analogue scale (0 = no pain, 10 = worst pain ever). Other outcomes measured by using a visual analogue scale were intensity of fatigue (0 = none, 10 = worst ever), sleep quality (0 = worst ever, 10 = best ever), and overall well-being (0 = worst ever, 10 = best ever). We assessed physical and mental functioning by using the Medical Outcomes Study 36-item Short-Form Health Survey (14), which has high reliability and validity in many patient groups, including those with chronic pain and fatigue (15, 16). The Short Form-36 Physical and Mental Component Summary scores are standardized in the U.S. population to have a mean of 50 and standard deviation of 10, with higher scores indicating better functioning (17).

To evaluate the adequacy of blinding, we asked participants to rate how certain they were that they had received directed acupuncture or simulated acupuncture on a 7-point scale (1 = very sure, 7 = very uncertain) after 12 weeks of treatment. For both questions, we defined certainty as an answer of 1 (very sure) or 2 (moderately sure). Participants also rated their acupuncturists' skill level (1 = high, 7 = low) and reported adverse events they experienced, including discomfort or bruising at the sites of needle insertion, nausea, or feeling faint, at weeks 1, 4, 8, and 12. To assess adherence to the eligibility requirement of keeping other fibromyalgia-related therapies constant throughout the study, participants answered questions at week 1 and after active treatment ended at week 12 about medications they were using to manage their pain. We calculated the total number of medications that each participant reported using, the percentage of participants in each treatment group who were using 1 or more medications, and the 3 most commonly reported medications at both time points.

Statistical Analysis

Descriptive Statistics

We described demographic, clinical, and outcome variables at baseline by using means and standard deviations for continuous variables and percentages for categorical variables, separately by treatment group.

Adverse Effects

We used generalized estimating equations (18) with the logit link to test the overall association of the 4 treatment groups with the odds of experiencing bruising at needle insertion sites, discomfort at needle insertion sites, and nausea during active treatment (weeks 1 to 12). Because feeling faint was reported only once during the study, we did not formally analyze this adverse effect. In these generalized estimating equation models, we assumed an unstructured working correlation matrix with the robust variance estimator to account for correlation created by nesting multiple patients within acupuncturist. These analyses adjusted for time (weeks 1, 4, 8, and 12) and primary acupuncturist as categorical covariates.

Missing Data

Participants with missing data were included in the generalized estimating equation models of the visual analogue scale and Short Form-36 outcomes unless no valid observations after baseline were available. Generalized estimating equation models can accommodate missing data but assume that data are missing completely at random, for reasons unrelated to any variables in the model. This assumption could be violated if participants dropped out of the study or missed a treatment because their pain had improved or worsened.

Clinical Response

We tested the association of treatment with each primary outcome (visual analogue scale for pain, fatigue, sleep quality, and overall well-being, and Short Form-36 Physical and Mental Component Summary scores) by using generalized estimating equation models with the identity

link for continuous outcomes. In these models, we assumed an unstructured working correlation with the robust variance estimator to accommodate the correlated data. This modeling adjusted for the baseline values of each outcome, with time (weeks 1, 4, 8, 12, 24, and 36) and acupuncturist as categorical factors.

The analysis compared clinical response in the directed acupuncture group with a pooled sham acupuncture control group. We combined all 3 sham acupuncture treatments into a single control group because none of the omnibus Wald tests from the generalized estimating equation models for the primary outcomes comparing the 3 groups was statistically significant (visual analogue scale for pain, $P > 0.2$, intensity of fatigue, $P = 0.12$, sleep quality, $P > 0.2$, and overall well-being, $P = 0.06$; Short Form-36 Physical and Mental Component Summary scores, $P > 0.2$). After combining the 3 control groups, we calculated the adjusted least-square mean difference between the directed acupuncture and the pooled sham-control group for each outcome. Because a treatment-by-time interaction was not suspected a priori, it was not included in the models.

Secondary Analyses

We evaluated the success of blinding by using chi-square tests to compare the percentage of participants in the directed acupuncture and pooled sham acupuncture control groups who were certain that they had received directed and simulated acupuncture at week 12. Chi-square tests were also used to compare participants' rating of the acupuncturists' skill level and the percentage of participants who received a full course of treatment. We calculated the range and the median number of pain medications reported by participants in the directed acupuncture and pooled sham-control groups. The total number of pain medications reported by participants in these 2 groups was compared by using generalized estimating equation models with an unstructured correlation matrix and the robust variance estimator at week 1 and after week 12. These models used a log link assuming a Poisson distribution for the number of medications. We used chi-square tests to compare the proportion of participants reporting use of at least 1 pain medication at week 1 and after week 12.

Power

In the original protocol, the sample size of 25 participants per group was calculated to yield 80% power to detect a difference of 3.0 cm between the directed acupuncture group and each of the 3 sham acupuncture groups on the visual analogue scale for pain. After peer review and additional statistical consultation, we modified our analytic plan to compare directed acupuncture with the pooled sham acupuncture group. All analyses were performed by using SAS software, version 9.0 (SAS Institute Inc., Cary, North Carolina). We set an α error threshold of 0.05 for statistical significance, and inferential point estimates are presented with 95% CIs.

Role of the Funding Source

The National Center for Complementary and Alternative Medicine funded the study but had no role in study design, data collection, analysis, interpretation, manuscript preparation, or decisions regarding publication.

RESULTS

Participants and Randomization

One hundred persons underwent random assignment; of these, 96 received the allocated intervention (**Figure 1**). Of the 4 participants who underwent allocation but did not start treatment, 1 dropped out because of a medical emergency, 2 dropped out for personal reasons (moved away or too busy to participate), and 1 was assigned to receive simulated acupuncture but accidentally received directed acupuncture. This participant was included in the originally assigned simulated acupuncture group for all analyses. After randomization, 2 participants in each of the 4 treatment groups could not complete the study for personal reasons, and 2 additional participants receiving simulated acupuncture discontinued the study (1 could not tolerate blindfolding, and 1 experienced exacerbation of preexisting migraine headaches).

Patients were assigned to 1 of 8 acupuncturists according to scheduling convenience. Acupuncturist A had 33 patients who underwent 607 total treatments, acupuncturist B had 20 patients who underwent 473 total treatments, acupuncturist C had 16 patients who underwent 354 total treatments, acupuncturist D had 13 patients who underwent 289 total treatments, acupuncturist E had 7 patients who underwent 162 total treatments, acupuncturist F had 4 patients who underwent 104 total treatments, acupuncturist G had 4 patients who underwent 102 total treatments, and acupuncturist H had 3 patients who underwent 72 total treatments. Treatment group was randomly distributed within acupuncturist.

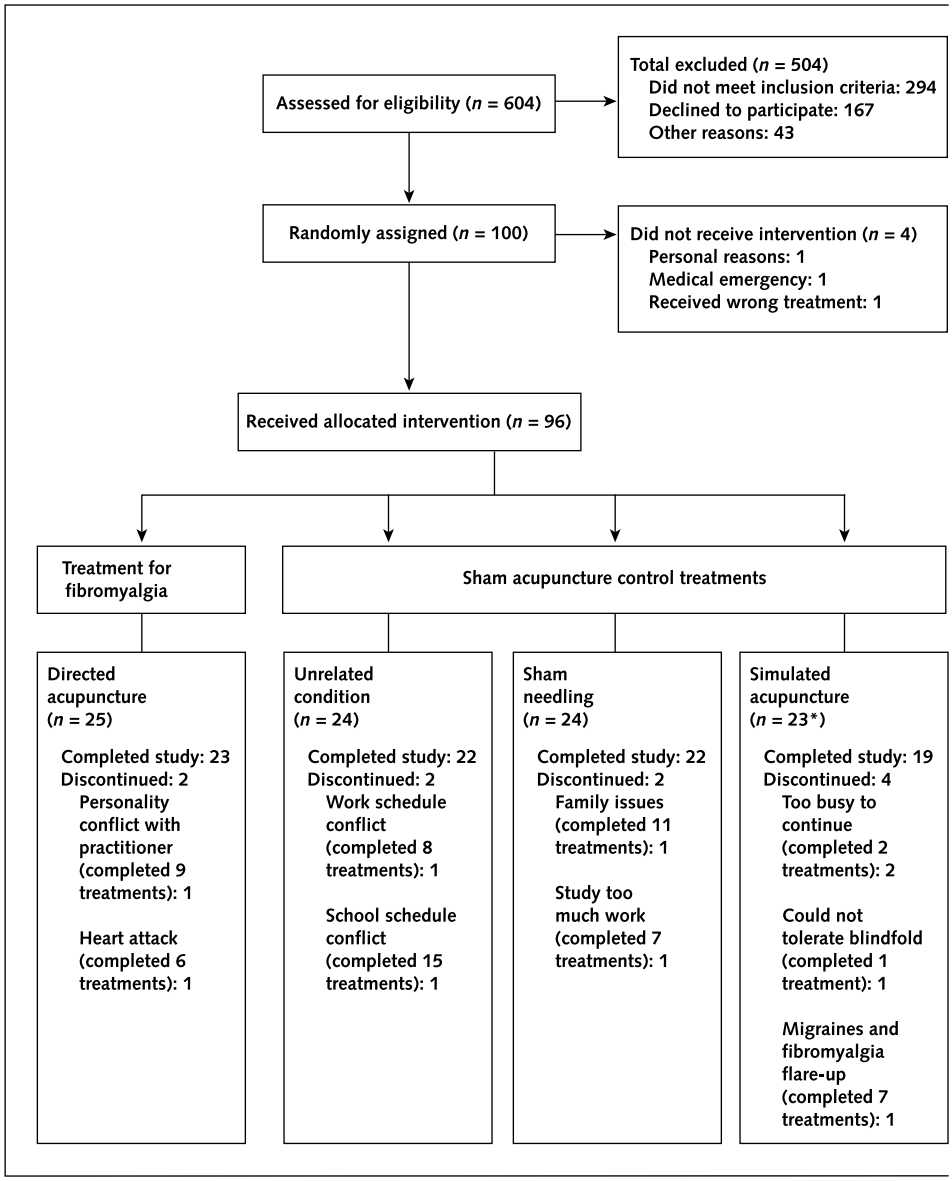
Participant Characteristics

Most participants were white, married women. On average, participants were 47 years of age and had experienced pain for about 10 years. The average baseline score on the visual analogue scale was 7.0 cm for pain intensity, 7.7 cm for fatigue intensity, 3.3 cm for sleep quality, and 4.0 cm for overall well-being. Demographic and clinical features at baseline did not differ across the 4 treatment groups (**Table**).

Adverse Effects

Eighty-nine participants reported on adverse events at weeks 1, 4, 8, and 12. Overall, 37% experienced discomfort at the sites of needle insertion or simulated needle insertion, 30% had bruising, 3% reported nausea, and 0.3% felt faint at some point during the study. Patients assigned to simulated acupuncture (29%) had significantly

Figure 1. **Participant flow.**



* One participant assigned to the simulated acupuncture group was mistakenly administered directed acupuncture. This person was included in the originally assigned simulated acupuncture group for all analyses, yielding 24 total participants in that group.

less discomfort than did those assigned to directed acupuncture (61%), acupuncture for an unrelated condition (70%), or sham needling (64%) ($P = 0.02$). Similarly, less bruising was reported by patients in the simulated acupuncture group (10%) than in the directed acupuncture (52%), acupuncture for an unrelated condition (74%), or sham needling (68%) groups ($P = 0.001$). Treatment group was not significantly associated with nausea ($P > 0.2$).

Missing Data

All longitudinal visual analogue scale outcomes were missing for 7 participants (1 in the directed acupuncture group, 1 in the unrelated condition group, 3 in the sham needling group, and 2 in the simulated acupuncture group). All longitudinal Short Form-36 data were also missing for these 7 participants, and for 1 other participant receiving directed acupuncture and 1 other participant receiving simulated acupuncture. Thus, the generalized estimating equation analyses included 93 participants for the visual analogue scale outcomes and 91 participants for the Short Form-36 outcomes.

Clinical Response

Figures 2 and **3** show the mean values for the visual analogue scale and Short Form-36 outcomes, by week. Values are graphed separately for the directed acupuncture and pooled sham acupuncture control groups. For all outcomes, improvement occurred most rapidly from weeks 0 to 1, became attenuated during weeks 1 to 8, plateaued between weeks 8 to 12, and decreased slightly 3 and 6

months after treatment cessation. No significant differences were detected between the directed acupuncture and the pooled control group for any of the study outcomes. Participants in the directed acupuncture group had slightly higher mean values for pain and fatigue and slightly lower mean values for sleep quality and overall well-being than did participants in the pooled sham-intervention control group. None of these differences were statistically significant. The least-square mean differences derived from the generalized estimating equation models that compared the directed acupuncture group with the pooled sham-intervention group were 0.5 cm (95% CI, −0.3 to 1.2 cm) for pain ($P > 0.2$), 0.5 cm (CI, −0.2 to 1.2 cm) for fatigue ($P = 0.19$), −0.5 cm (CI, −1.3 to 0.2 cm) for sleep quality ($P = 0.18$), −0.3 cm (CI, −1.0 to 0.3 cm) for overall well-being ($P > 0.2$), −0.4 (CI, −2.3 to 1.5) for the Short Form-36 Physical Component Summary score ($P > 0.2$), and −1.5 (CI, −4.0 to 1.0) for the Short Form-36 Mental Component Summary score ($P > 0.2$). The main effect by acupuncturist was not significant for any outcome.

Secondary Analyses

At week 12, 75 participants rated the success of our blinding procedures. Overall, 32% of participants believed they were receiving acupuncture specifically designed for fibromyalgia; no significant difference was observed between the directed acupuncture and pooled sham acupuncture control groups ($P > 0.2$). Likewise, 4% of all participants believed that they were receiving simulated acupuncture, with no difference between the 2 groups ($P > 0.2$). The directed acupuncture and pooled sham-control groups did not significantly differ in the rating of the skill level of the acupuncturist ($P > 0.2$). Overall, 77% of participants rated their acupuncturists' skills as high and 5% as medium; 17% did not know; and none rated their acupuncturists' skills as low. On average, patients completed 21 of 24 scheduled treatments (84% of the directed acupuncture group and 79% of the pooled sham acupuncture control groups completed a full course of treatment; $P > 0.2$).

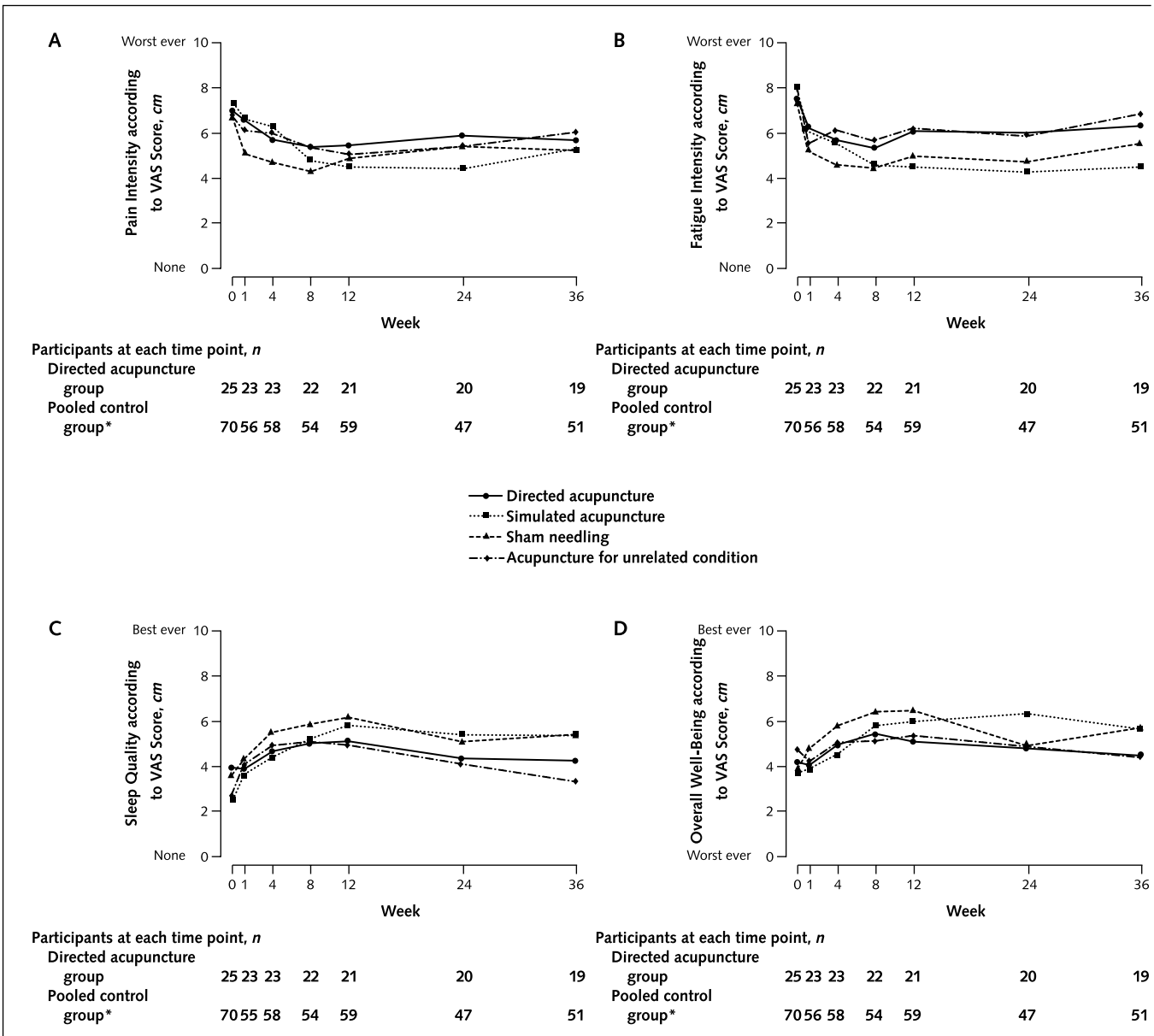
The total number of pain medications that participants in the directed acupuncture group reported using ranged from 0 to 4 (median, 1.2), whereas the range for participants in the pooled sham-control group was 0 to 5 (median, 0.8). One outlier in the latter group reported use of 9 medications. The generalized estimating equation models showed no significant difference between the directed acupuncture and pooled sham acupuncture control groups in the total number of pain medications used during active treatment ($P > 0.2$). The 2 groups did not differ in the percentage of participants who reported use of at

Table. **Descriptive Information for Demographic Characteristics and Pain Variables, by Treatment Group at Baseline**

Variables	Directed Acupuncture for Fibromyalgia ($n = 25$)	Sham Acupuncture Control Treatments		
		Needling for an Unrelated Condition ($n = 25$)	Sham Needling ($n = 24$)*	Simulated Acupuncture ($n = 25$)
Demographic and clinical features				
Mean age, *y*	46, SD 11	46, SD 11	49, SD 14	48, SD 10
Women, %	88	96	100	96
White ethnicity, %	96	88	96	92
College graduate, %	40	44	40	48
Marital status, %				
Single, never married	12	28	28	16
Married or living with partner	76	48	60	56
Divorced, separated, or widowed	12	24	12	28
Mean duration of pain, *y*	12, SD 18	9, SD 7	9, SD 7	10, SD 16
Mean time since fibromyalgia diagnosis, *y*	6, SD 5	5, SD 3	7, SD 6	7, SD 4
Previous therapies, %				
Manual†	83	71	88	92
Mental health‡	33	35	17	22
Dietary changes	50	46	33	35
Other§	29	17	16	25
Outcomes				
Mean score on visual analogue scales				
Pain intensity	7.0, SD 2	6.9, SD 2	6.8, SD 2	7.3, SD 2
Fatigue intensity	7.5, SD 2	8.1, SD 1	7.3, SD 2	7.9, SD 2
Sleep quality	4.0, SD 2	2.8, SD 2	3.7, SD 2	2.6, SD 2
Overall well-being	4.2, SD 2	4.7, SD 2	3.9, SD 2	3.7, SD 2
Mean summary score on Short Form-36				
Physical Component	28, SD 8	31, SD 9	31, SD 8	32, SD 9
Mental Component	42, SD 11	41, SD 12	42, SD 8	42, SD 9

* One person in the sham needling group did not complete the baseline questionnaire.
† Includes physical, ergonometric, chiropractic, and massage therapy.
‡ Includes psychotherapy and cognitive behavioral therapy.
§ Includes nerve blocks, hypnosis, and biofeedback.

Figure 2. **Mean values for the visual analogue scale (*VAS*) outcomes and total number of participants for whom valid data were available at weeks 0 (baseline); 1, 4, 8, and 12 (duration of treatment); and 24 and 36 (3 and 6 months of follow-up), by treatment group, by week.**



A. Pain intensity. $P > 0.2$. **B.** Fatigue intensity. $P = 0.19$. **C.** Sleep quality. $P = 0.18$. **D.** Overall well-being. $P > 0.2$. All P values are from the generalized estimating equation model comparing the directed acupuncture group with the pooled sham-intervention control group. *The pooled sham-intervention control group includes acupuncture for an unrelated condition, sham needling, and simulated acupuncture.

least 1 pain medication at week 1 (82% of the directed acupuncture group and 86% of the pooled sham-control group; $P > 0.2$) or after week 12 (68% and 72%, respectively; $P > 0.2$). The 3 most commonly used drugs at both time points were, in descending order, ibuprofen, acetaminophen, and naproxen.

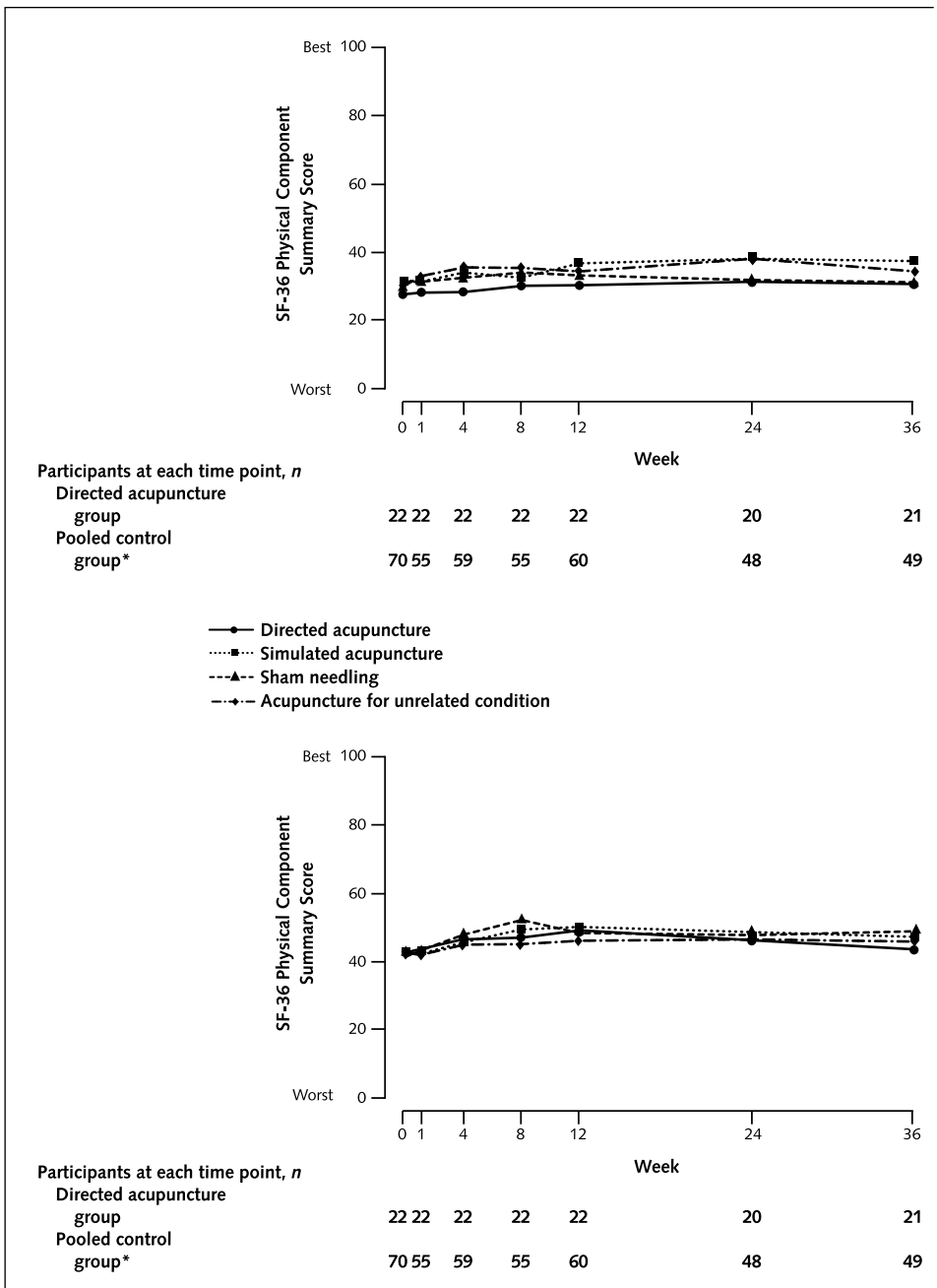
Discussion

Acupuncture has been used for more than 2 millennia in China. Since its reintroduction in the United States in the early 1970s, acupuncture has become a widely used form of complementary and alternative medicine, particularly to treat chronic pain (7). We found that directed acupuncture for fibromyalgia was no better than sham acupuncture at relieving pain. Possible explanations include a nonspecific response to the acupuncturist's healing presence or the relaxing environment of the acupuncture clinic, a psychological response to participation in a clinical trial, or fluctuations in the natural history of disease. A usual-care control group would have helped to differentiate among these 3 possibilities.

Previous well-designed randomized, controlled trials of acupuncture to treat chronic pain have been largely inconclusive but suggest that sham needling is as effective as real acupuncture (7, 19–21). Few guidelines exist, however, for identifying appropriate sham point locations; the depth, direction, and duration of needle insertion; or the need for needle stimulation. Needle insertion at traditional and control locations can elicit similar physiologic responses (22–25), including release of endorphins that can be blocked by opioid antagonists (26). Furthermore, functional magnetic resonance imaging has demonstrated that stimulation of both acupoint and sham points reduces activation in cortical areas of the brain believed to be involved with processing of pain signals (27).

A blinded study of acupuncture is challenging to conduct because it is almost impossible to blind acupuncturists

Figure 3. **Mean values for the Short Form-36 (*SF-36*) outcomes and total number of participants for whom valid data were available at weeks 0 (baseline); 1, 4, 8, and 12 (duration of treatment); and 24 and 36 (3 and 4 months of follow-up), by treatment group.**



Top. Physical Component Summary score. **Bottom.** Mental Component Summary score. For both panels, $P > 0.2$ (from generalized estimating equation model comparing the directed acupuncture group with the pooled sham-intervention control group). *The pooled sham-intervention control group includes acupuncture for an unrelated condition, sham needling, and simulated acupuncture.

to the treatments they are delivering and it may be difficult to convince study participants that sham acupuncture is a credible treatment (6). As a consequence, different expectations may be inadvertently communicated to participants in the control groups (28) that can strongly influence treatment results (29). This critical issue was not addressed in a previous high-quality randomized, controlled trial of acupuncture for fibromyalgia (10). Our results cannot be explained by differing expectations across groups because participants in all interventions were successfully blinded to treatment group and expressed similarly positive views of their acupuncturists.

A few comments about our method of administering acupuncture and our study limitations deserve mention. First, acupuncture treatments are typically individualized and may be combined with dietary, herbal, and massage therapy for coexisting problems. Our directed acupuncture treatment was uniformly applied and did not use adjunctive therapies. Although no article has suggested that individualized acupuncture is superior to fixed-point prescriptions, some experts have argued that the latter is suboptimal. Second, acupuncturists with different philosophies, backgrounds, training, and clinical experiences might have chosen different points for the directed acupuncture intervention. No gold standard exists for the selection of acupoints for treatment of fibromyalgia. In the absence of data, we therefore designed a protocol based on our extensive clinical experience, which may differ from that of others. Third, our statistical analysis made assumptions about missing values, specifically that the values were missing completely at random. Although this assumption is difficult to formally test, we found no evidence that patient dropout was treatment related. Finally, our statistical analyses evaluated multiple outcomes, thereby increasing the risk for a type I error. Even with this caveat, however, we found no significant influence of treatment on any of the outcomes. A marginally significant difference was found among the 3 sham acupuncture control groups for the visual analogue scale of overall well-being. This effect is probably driven by the higher mean score in the simulated acupuncture group compared with the sham needling group at a single time point (week 24). Across all intervals, no consistent pattern of differences for overall well-being were observed among the sham-control groups. This finding suggests that the marginally significant difference is due to chance.

In conclusion, we did not find that acupuncture reduced pain in patients with fibromyalgia. Strengths of our study include the use of sham acupuncture control groups and standard outcome measures, rigorous blinding of participants to treatment assignment, a relatively low rate of attrition, and long-term follow-up. Future research should examine individualized acupuncture regimens to treat chronic widespread pain and other complementary and alternative medicine techniques that are popular among patients with fibromyalgia.

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Appendix Figure. **Acupoint and sham needling regimens used in each treatment group.**