

## Improvement in Fibromyalgia Symptoms With Acupuncture: Results of a Randomized Controlled Trial

DAVID P. MARTIN, MD, PhD; CHRISTOPHER D. SLETTEN, PhD; BRENT A. WILLIAMS, MS;  
AND INES H. BERGER, MD

**OBJECTIVE:** To test the hypothesis that acupuncture improves symptoms of fibromyalgia.

**PATIENTS AND METHODS:** We conducted a prospective, partially blinded, controlled, randomized clinical trial of patients receiving true acupuncture compared with a control group of patients who received simulated acupuncture. All patients met American College of Rheumatology criteria for fibromyalgia and had tried conservative symptomatic treatments other than acupuncture. We measured symptoms with the Fibromyalgia Impact Questionnaire (FIQ) and the Multidimensional Pain Inventory at baseline, immediately after treatment, and at 1 month and 7 months after treatment. The trial was conducted from May 28, 2002, to August 18, 2003.

**RESULTS:** Fifty patients participated in the study: 25 in the acupuncture group and 25 in the control group. Total fibromyalgia symptoms, as measured by the FIQ, were significantly improved in the acupuncture group compared with the control group during the study period ( $P=.01$ ). The largest difference in mean FIQ total scores was observed at 1 month (42.2 vs 34.8 in the control and acupuncture groups, respectively;  $P=.007$ ). Fatigue and anxiety were the most significantly improved symptoms during the follow-up period. However, activity and physical function levels did not change. Acupuncture was well tolerated, with minimal adverse effects.

**CONCLUSION:** This study paradigm allows for controlled and blinded clinical trials of acupuncture. We found that acupuncture significantly improved symptoms of fibromyalgia. Symptomatic improvement was not restricted to pain relief and was most significant for fatigue and anxiety.

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FIQ = Fibromyalgia Impact Questionnaire; MPI = Multidimensional Pain Inventory

Fibromyalgia is characterized by chronic widespread musculoskeletal pain and associated symptoms, such as fatigue, joint stiffness, and sleep disturbance.<sup>1</sup> The disorder is thought to represent an alteration in pain threshold or sensory processing at the level of the spinal cord or higher cortical levels. No cure is known, and available treatments are only partially effective. Fibromyalgia affects 2% of the general population: 3.4% women and 0.5% men.<sup>2</sup> The prevalence of women with the condition increases with age and is greater than 7% in women older than 60 years. Fibromyalgia is also perceived by many to be a disabling condition. Although it is not a progressive or degenerative disease process, it can severely affect quality of life.

Acupuncture is a complementary medical technique used for the treatment of painful disorders, among other

conditions. More than 90% of patients with fibromyalgia have tried complementary techniques, including dietary and herbal supplements, indicating their openness to complementary medicine and/or inadequate response to allopathic therapies.<sup>3</sup> The National Institutes of Health has issued a consensus statement that concludes that acupuncture may be of adjunctive help in the treatment of fibromyalgia, although a lack of controlled studies weakened the conclusion.<sup>4</sup>

Of the many trials of acupuncture for fibromyalgia, only 2 were randomized and controlled.<sup>5</sup> The first, by Deluze et al,<sup>6</sup> concluded that acupuncture was effective therapy. The second, more recent study by Assefi et al<sup>7</sup> concluded that acupuncture was not effective for fibromyalgia. Hence, further research is required to define the possible role of acupuncture in the treatment of fibromyalgia.

The current study was designed to test the hypothesis that acupuncture improves symptoms of fibromyalgia with validated syndrome-specific measurement tools and long-term follow-up. Also, we sought to test the feasibility of conducting prospective, randomized studies of acupuncture with a control group exposed to simulated acupuncture.

### PATIENTS AND METHODS

The protocol was approved by the Mayo Foundation Institutional Review Board, and written consent was obtained from all participants before treatment. Our study population was recruited from patients who were referred to the Mayo Fibromyalgia Treatment Program in Rochester, Minn, by their physician, usually after a trial of conservative management. This program includes confirmation of

From the Department of Anesthesiology (D.P.M., I.H.B.) and Department of Health Sciences Research (B.A.W.), Mayo Clinic College of Medicine, Rochester, Minn; and Division of Psychology and Department of Pain Medicine, Mayo Clinic College of Medicine, Jacksonville, Fla (C.D.S.). Dr Berger is now with the Medical College of Georgia, Augusta.

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Address reprint requests and correspondence to David P. Martin, MD, PhD, Department of Anesthesiology, Mayo Clinic College of Medicine, 200 First St SW, Rochester, MN 55905 (e-mail: martin.david@mayo.edu).

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the diagnosis of fibromyalgia by a rheumatologist and 1.5 days of education, counseling, and group discussion about symptom management. At the conclusion of this program, patients were given an additional informational presentation about the current study and were invited to participate. To determine the sample size, we estimated that acupuncture would yield at least a 2-point reduction in the Fibromyalgia Impact Questionnaire (FIQ). On the basis of previous studies using the FIQ, 25 patients were required in each group. The trial was conducted from May 28, 2002, to August 18, 2003.

Patients were excluded if they had prior experience with acupuncture or a bleeding diathesis. They were required to have sufficient cognitive ability to read the consent form and to complete the survey instruments. Patients had to be within a geographic range that allowed for participation in 6 treatment sessions during a 2- to 3-week period. No monetary compensation was provided, but parking expenses were reimbursed.

#### MEASUREMENT TOOLS

The FIQ is a standardized and validated tool that is commonly used in fibromyalgia research.<sup>8</sup> The FIQ is a 20-item questionnaire used to assess the current health status of patients with fibromyalgia. Specifically, it evaluates physical functioning, work status, depression, anxiety, sleep, pain, stiffness, fatigue, and well-being, each on a 0- to 10-point scale. Individual item scores, not including the scores that deal with work status, are combined into a total fibromyalgia impact score that ranges from 0 to 80. Higher scores indicate a patient is more adversely affected by fibromyalgia. The FIQ has proven construct validity, test-retest reliability, and content relevance and is a widely recommended tool to use in fibromyalgia research.<sup>8</sup>

We also used the Multidisciplinary Pain Inventory (MPI), a more generalized measure of chronic pain and its impact.<sup>9</sup> The MPI is a 61-item questionnaire developed to evaluate patients with chronic pain. It is composed of 13 scales that measure different pain-related aspects of patients' lives. Five of these scales were chosen as useful outcome measures for this study: pain severity, interference (patients' perceptions about how pain interferes with their daily lives), life control (patients' perceptions about control over pain and life events), affective distress (mood, irritability, tension), and general activity level (composite activity score based on 4 other MPI scales that were not used: household chores, outdoor work, activities away from home, and social activities). The 5 scales represent areas that the Mayo Fibromyalgia Treatment Program attempts to improve. The 4 other scales not used involved support from a spouse or significant other. We excluded these scales because our program does not address these

issues and not all participants had significant others. The MPI has proven reliability and validity for both chronic pain and fibromyalgia.<sup>10</sup>

Patients were required to wait at least 4 weeks after completing the Fibromyalgia Treatment Program before beginning study treatments. We conducted FIQ and MPI measurements at baseline before treatment began, immediately after completion of all treatments, and 1 month and 7 months after completion of treatment.

#### RANDOMIZATION

After a 4-week period to adopt principles learned in the Fibromyalgia Treatment Program, patients completed baseline FIQ and MPI measurements. Patients were randomized immediately before the first treatment session to either the acupuncture or control group. Randomization was done in blocks of 4 to prevent imbalances in treatment allocation. There was no crossover between groups, and patients were scheduled to avoid any overlap during which they could compare experiences. Patients received treatments every 2 to 4 days during 2 to 3 weeks for a total of 6 sessions. All treatments were performed at 1 facility by 2 acupuncturists (D.P.M., I.H.B.).

#### ACUPUNCTURE GROUP

Patients in the acupuncture group were positioned in the sitting position with a screen placed so that they could not observe placement of the treatments yet were allowed eye contact with the acupuncturist (Figure 1). Acupuncture points were standardized for all patients and not modified for the specific symptoms of the patient. We picked strong regulatory points that commonly recur in the acupuncture literature. Specifically, we used bilateral points at large intestine 4, stomach 36, liver 2, spleen 6, pericardium 6, and heart 7. We also used axial paramedian points along the bladder meridian at the cervical spine during the first 3 sessions and at the lumbar spine during the last 3 sessions. Figure 2 illustrates the acupuncture points, totaling 18 needles during the first 3 sessions and 20 needles during the final 3 sessions.

At each point, the skin was wiped with alcohol, and an adhesive bandage was placed over the point. The needle was inserted through the bandage to the acupuncture point. The sensation of de Qi or "needle grab" was not specifically elicited. Electrical stimulation was applied at 2 Hz between large intestine 4 and stomach 36, bilaterally, and at 10 Hz over the axial circuits. All stimulator wires were taped to skin to avoid moving the needles. The pulse generator (IC-1107+, ITO Co Ltd, Tokyo, Japan) produced short, bipolar current spikes at an amplitude typically tolerable to most patients. Patients were asked, "Is the stimulation uncomfortable?" If it was uncomfortable, the current

was reduced appropriately. After placement of all needles and initiation of electrical stimulation, patients were allowed to rest quietly in a darkened room while relaxing music played in the background for 20 minutes.

### CONTROL GROUP

Patients in the control group were positioned identically to patients in the acupuncture group so that they could not observe the treatments. Identical points were used. Each point was wiped with alcohol, the skin was indented with a dull surgical instrument, and a small circular adhesive bandage was applied that had previously been rigged with an acupuncture needle such that the needle handle stuck out of the bandage but did not pierce the skin. Instead, the needle was bent to form a tripod so that it was supported on the skin surface and appeared as if it were anchored within the skin. Patients in the control group felt the wipe with alcohol, a mild pricking sensation, and placement of an adhesive bandage (Figure 3). All the while they were not able to see the procedure.

Electrical stimulation was applied to the same points as the acupuncture group. Even though the lights flashed on the pulse generator, the resistance of the skin prevented any perceptible current flow. Just as in the acupuncture group, patients were asked, "Is the stimulation uncomfortable?" After placement of the placebo treatment, patients relaxed for 20 minutes in a darkened room while quiet music played in the background. Once the treatment was completed, both the acupuncture and control groups looked the same. In preliminary trials, volunteers could not tell the difference between the 2 procedures.

### BLINDING

Conversation was controlled and neutral in both groups. During placement of the treatment, neutral conversation was used (family, sports, the weather, and so on). Any reference to specific treatment or symptoms was deflected or referred to the blinded study coordinator. At the end of the treatments, all materials were removed from the room so patients could not observe the needles or other equipment.

### STATISTICAL ANALYSES

On completion of the treatment sessions, patients filled out 3 additional FIQ and MPI surveys. This was done by mail at the end of the treatments and at 1 month and 7 months after the end of the treatments. All evaluations were obtained by the study coordinator, who was blinded to the group assignment. If patients had concerns about adverse effects or needed to consult with a physician for any other reason, they were referred to a clinician not associated with the study. If patients were unable to com-



FIGURE 1. Experimental setup. Patients were seated with a tray and blanket placed as a headrest such that their view of the treatment was obscured. Both acupuncture and control treatments looked identical. Some acupuncture needles were attached to an electrical stimulator, whereas others were not. For clarity, not all acupuncture points are shown in this illustration.

plete all 6 sessions, they still remained in their respective groups for follow-up measurements of pain and quality of life. Data were analyzed based on the intention-to-treat principle.

Figure 4 shows the sequence of events for each patient in the study. Patients were enrolled after they completed the Fibromyalgia Treatment Program. Randomization occurred at least 4 weeks later, when the baseline assessment was made. Then patients received 6 treatments for 2 to 3 weeks. Assessments were made immediately after completion of the treatments and at 1 month and 7 months later.

The primary end point was the FIQ total score, measured as the sum of the 8 FIQ subscales (each on a 0- to 10-point scale). The primary analysis involved comparing the FIQ total score between the acupuncture and control group

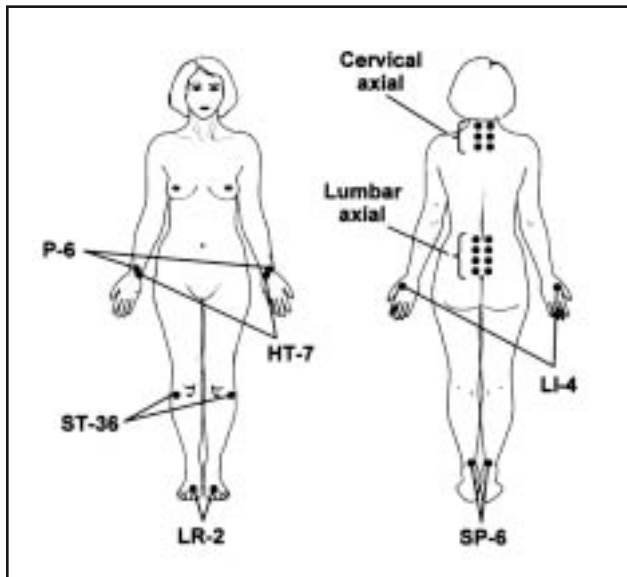


FIGURE 2. Acupuncture points. Needles were placed at the large intestine 4 (LI-4), stomach 36 (ST-36), liver 2 (LR-2), spleen 6 (SP-6), pericardium 6 (P-6), and heart 7 (HT-7). Electrical stimulation was provided between LI-4 and ST-36 at 2 Hz. Axial points were placed along the bladder meridian and stimulated at 10 Hz. The cervical axial circuit was used only during the first 3 sessions, and the lumbar axial circuit was used only during the last 3 sessions.

over time using a repeated-measures analysis of variance model. An overall treatment effect was estimated after adjusting for time and baseline FIQ total score. Examining

treatment effects at individual time points using analysis of covariance complemented this analysis. Secondary analyses involved analyzing the FIQ and MPI subscales individually using similar techniques as described herein.

## RESULTS

Figure 5 illustrates patient enrollment and allotment to study groups. Sixty patients were enrolled in the study on completion of the Fibromyalgia Treatment Program. Ten of these patients withdrew from the study during the 4-week period of stabilization before treatments started and before randomization. Eight of those patients had difficulty in scheduling the 6 treatment sessions. One patient had received acupuncture in the past but had forgotten this during the initial screening process. The final patient elected to withdraw because of apprehension about needles and a history of vasovagal syncope. Therefore, 50 patients completed the baseline assessment and were randomly allocated to the acupuncture and control groups. There were no significant differences between the groups with respect to age, sex, or race. All patients were women except for 1 (in the control group), even though the study was equally open to both men and women. All patients were white except for 1 (in the acupuncture group), reflecting the racial composition of the geographic area where the study was conducted. The mean  $\pm$  SD age of the patients was

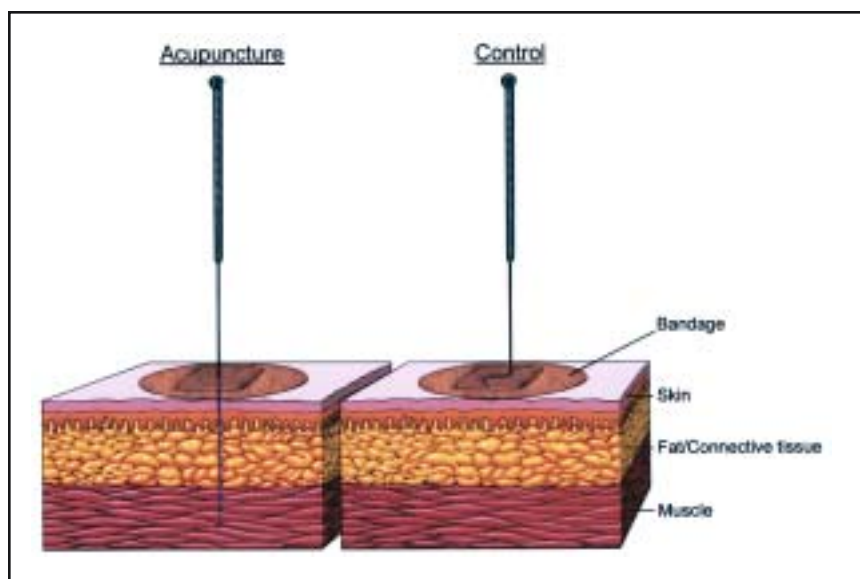


FIGURE 3. Comparison of acupuncture and control needle configurations. In the acupuncture group, the skin is wiped with alcohol, a sterile bandage is applied, and the needle is inserted through the bandage to the acupuncture point. In the control group, the skin is wiped with alcohol, the skin is briefly "poked" but not cut, and then a bandage is affixed that contains a modified acupuncture needle that looks identical to the acupuncture treatment.

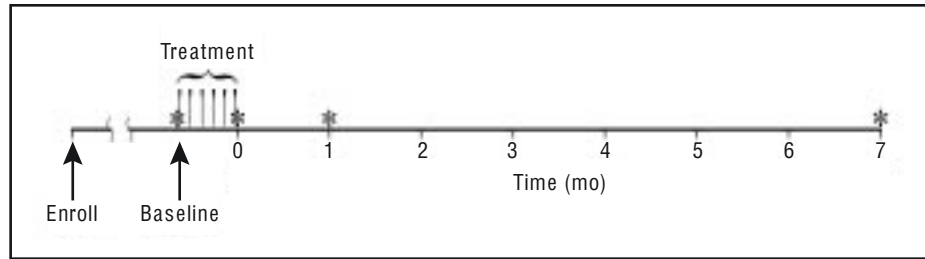


FIGURE 4. Timeline for each patient. At least 4 weeks elapsed between enrollment and baseline assessment. Patients were then randomized to receive 6 acupuncture or 6 control treatments during a 2- to 3-week period. Assessments (indicated by asterisks) were made at baseline, treatment completion (0 months), and 1 and 7 months after treatment.

51.7±14.1 years for the control group and 47.9±11.2 years for the acupuncture group ( $P=.30$ ).

All patients completed at least 5 treatment sessions. Two patients in the acupuncture group and 1 in the control group were not able to complete the last session because of scheduling conflicts. They remained in their respective groups for data collection and analysis, as required by the intention-to-treat principle. The number of questionnaires returned was 100% at baseline and 96% to 98% through the remainder of the study. One patient in the control

group did not complete any questionnaires after conclusion of the treatment sessions and was considered lost to follow-up.

The treatments were tolerated well by the patients, and most reported enjoying the experience. Many of the patients in both groups reported feeling tired and/or relaxed after the treatments. Mild bruising and soreness were more common in the acupuncture group. Two patients experienced mild vasovagal symptoms, which were managed conservatively. One patient (in the control group) experienced a pulmonary

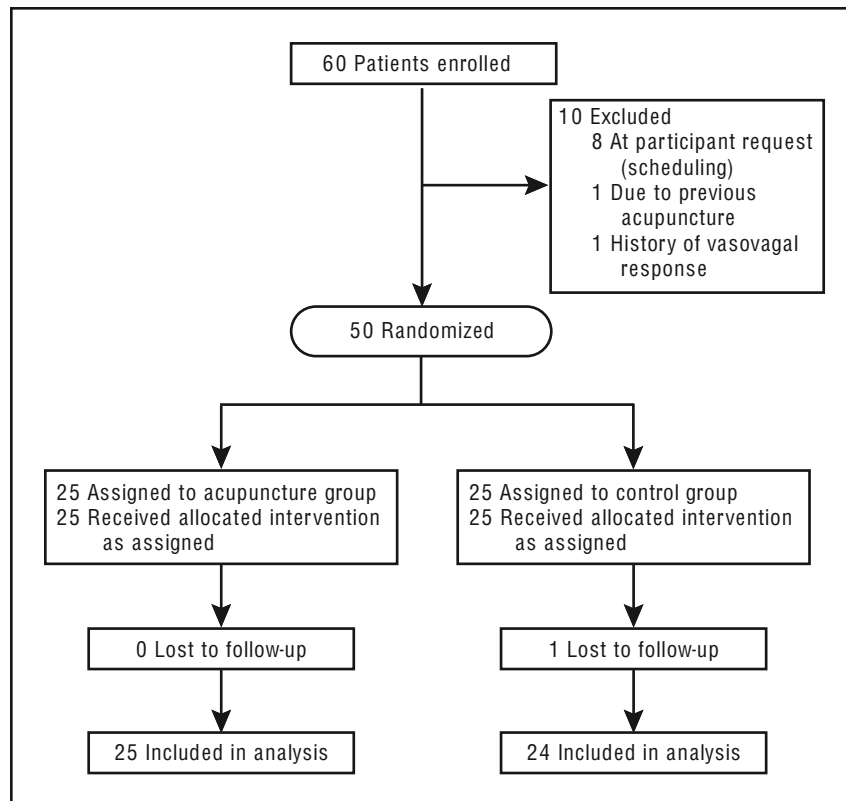


FIGURE 5. Patient enrollment.

TABLE 1. Analysis of Variance for the Fibromyalgia Impact Questionnaire (FIQ)\*

FIQ scale	Group effect up to 7 mo		Group effect up to 1 mo	
	Acupuncture-control mean estimate (95% CI)	P value	Acupuncture-control mean estimate (95% CI)	P value
Total	-4.3 (-7.7 to -0.9)	.02	-4.9 (-8.7 to -1.2)	.01
Physical function	-0.3 (-0.9 to 0.3)	.27	-0.4 (-1.1 to 0.3)	.28
Well-being	+0.4 (-0.6 to 1.4)	.41	+0.8 (-0.4 to 2.0)	.18
Pain	-0.7 (-1.5 to 0.3)	.07	-0.8 (-1.8 to 0.2)	.14
Fatigue	-0.9 (-1.6 to -0.2)	.02	-1.2 (-2.1 to -0.4)	.007
Sleep	-0.3 (-1.3 to 0.6)	.49	-0.7 (-1.8 to 0.5)	.25
Stiffness	-0.6 (-1.6 to 0.4)	.26	-1.0 (-2.3 to 0.3)	.16
Anxiety	-1.1 (-1.9 to -0.2)	.02	-1.1 (-2.0 to -0.2)	.02
Depression	-0.7 (-1.6 to 0.2)	.14	-0.7 (-1.6 to 0.3)	.18

\*Acupuncture-control mean estimate is derived from a repeated-measures analysis of variance model. This value is the mean expected difference between active and placebo with respect to the particular FIQ subscale, adjusted for time (days since baseline measurement) and baseline subscale value. Negative values for this estimate indicate that values for the active arm are lower than the placebo arm. Positive values indicate that values for the active arm are higher. The *P* values test whether the group effect is significantly different from 0. *P* < .05 suggests a difference between treatment groups with respect to the particular FIQ subscale. CI = confidence interval.

embolism. She had had a history of thromboembolic problems, and her complication was believed to be unrelated to the study.

At the conclusion of the treatments, patients were asked their opinion regarding group assignment. Approximately half of the patients in each group reported that they did not know their assignment (13 [52%] in the control group and 10 [40%] in the acupuncture group). Of the 12 in the control group who had an opinion, 7 (58%) were correct and 5 (42%) were incorrect. Of the 15 in the acupuncture group who had an opinion, only 5 (33%) were correct and 10 (67%) were incorrect. Hence, the ability of the patients to accurately determine the treatment they received did not exceed chance.

Table 1 presents the results of the repeated-measures analysis of variance for the FIQ. This analysis revealed a positive group effect of acupuncture that was statistically

superior to the control group (*P* = .01). Subscale analysis revealed significant group effects for symptoms of fatigue and anxiety. The remainder of the subscales also showed trends toward improvement of symptoms, although they were not statistically significant individually. Repeated-measures analysis of the MPI data is presented in Table 2. The group effect showed significant improvement in pain (*P* = .03) up to 1 month after treatment, but the effect was not statistically significant when the 7-month data were included (*P* = .05).

Figure 6 shows the difference in FIQ score between the acupuncture and control groups at each time point, with the greatest difference at 1 month (*P* = .007). More detailed comparisons of both the FIQ and MPI measurements at each time point are given in Table 3. The total FIQ score in the acupuncture group was improved 7.4 points over the

TABLE 2. Analysis of Variance for the Multidimensional Pain Inventory (MPI)\*

MPI scale	Group effect up to 7 mo		Group effect up to 1 mo	
	Acupuncture-control mean estimate (95% CI)	P value	Acupuncture-control mean estimate (95% CI)	P value
Pain severity	-3.8 (-7.5 to -0.2)	.05	-4.6 (-8.7 to -0.5)	.03
Interference	+0.1 (-3.2 to 3.4)	.95	+0.1 (-3.4 to 3.6)	.97
Life control	0.0 (-2.1 to 2.1)	.98	+1.2 (-1.3 to 3.8)	.34
Affective distress	-1.1 (-3.9 to 1.7)	.44	-2.2 (-5.2 to 0.9)	.17
General activity level	-0.6 (-3.1 to 1.8)	.61	-1.2 (-3.8 to 1.4)	.38

\*Acupuncture-control mean estimate is derived from a repeated-measures analysis of variance model. This value is the mean expected difference between active and placebo with respect to the particular MPI subscale, adjusted for time (days since baseline measurement) and baseline subscale value. Negative values for this estimate indicate that values for the active arm are lower than the placebo arm. Positive values indicate that values for the active arm are higher. The *P* values test whether the group effect is significantly different from 0. *P* < .05 suggests a difference between treatment groups with respect to the particular MPI subscale. CI = confidence interval.

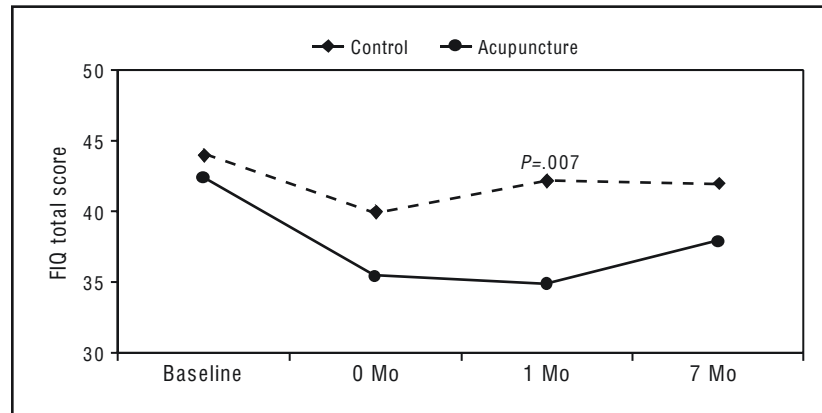


FIGURE 6. Effect of acupuncture and control on the Fibromyalgia Impact Questionnaire (FIQ) total score.

control group at 1 month after treatment ( $P=.007$ ). At this time point, pain severity as measured by the MPI was also significantly decreased ( $P=.03$ ). Other symptoms that showed statistically significant improvement included fatigue, anxiety, and affective distress. All symptom subscales showed some improvement, although not all were statistically significant.

### DISCUSSION

In this controlled, randomized, and blinded assessment of acupuncture, our study patients were unable to determine in which group they had participated. Such blinding is

necessary for quality research in acupuncture because the control group displayed the expected placebo response that is typical of pain studies.<sup>11</sup> An alternative choice for control treatments in studying acupuncture is to place needles at incorrect or “sham” points. Although it would have been easier to use this as a control, we agree with others who have argued that needling at sham locations is also likely to provide neuromodulatory inputs to the sensory nervous system. Sham needling may in fact produce physiologic changes indistinguishable from “true” acupuncture points. We believe that the simulated acupuncture configuration described herein provides an inexpensive and effective method of providing realistic placebo acupuncture treat-

TABLE 3. Results of the Fibromyalgia Impact Questionnaire (FIQ) and Multidimensional Pain Inventory (MPI)\*

Symptoms	Baseline			Immediately after treatment			1 mo after treatment			7 mo after treatment		
	Acu-puncture	Control	P value	Acu-puncture	Control	P value	Acu-puncture	Control	P value	Acu-puncture	Control	P value
<b>FIQ</b>												
Total score	42.4±11.0	44.0±9.8	.60	35.7±12.3	40.0±11.9	.28	34.8±12.1	42.2±10.2	.007	38.1±12.1	42.7±9.6	.24
Physical impairment	4.1±2.4	3.6±2.5	.45	3.2±2.2	3.6±2.5	.11	3.7±2.5	3.3±2.3	.96	3.5±2.5	3.3±2.2	.85
Feel good	3.3±2.7	2.7±2.0	.40	4.3±2.9	3.6±2.9	.58	4.6±2.9	3.1±2.4	.10	3.8±2.9	3.6±2.3	.99
Pain	6.2±2.2	6.5±1.8	.63	4.9±2.6	5.6±2.3	.42	4.7±2.4	5.9±2.3	.09	5.5±2.3	6.4±2.1	.25
Fatigue	7.6±2.1	7.6±1.8	>.99	6.5±2.6	7.1±2.5	.39	5.6±2.7	7.7±2.1	.001	7.0±2.4	7.6±1.9	.35
Rest	6.9±2.1	7.3±2.4	.53	5.6±2.9	6.4±3.0	.39	5.9±3.1	6.8±2.2	.28	6.1±2.9	6.3±2.5	.89
Stiffness	7.2±1.9	6.8±2.0	.52	5.6±3.0	6.0±2.8	.49	5.8±2.7	6.6±2.9	.11	6.5±2.7	6.8±1.9	.61
Anxiety	4.2±2.9	5.5±2.2	.09	3.3±2.7	4.3±2.8	.79	2.6±2.3	5.1±2.6	.003	3.3±2.7	4.8±3.0	.31
Depression	2.9±3.0	4.0±3.1	.21	2.4±2.8	3.4±3.1	.90	2.0±2.4	3.7±2.7	.06	2.2±2.6	3.6±3.1	.29
<b>MPI</b>												
Pain severity	40.4±10.3	43.0±7.7	.32	36.0±9.7	40.9±8.5	.14	34.2±11.4	41.6±9.1	.03	37.3±13.1	41.4±8.4	.37
Interference	42.6±11.5	36.9±11.7	.09	39.0±11.3	34.9±11.9	.96	38.3±11.9	34.9±10.6	.96	37.7±12.2	35.5±12.1	.78
Life control	51.4±5.4	49.5±7.3	.31	52.9±5.5	51.3±8.6	.73	52.8±5.7	50.7±6.1	.30	52.8±6.4	53.6±5.0	.37
Affective distress	42.6±7.7	46.1±8.1	.13	40.7±9.6	43.5±9.4	.95	38.9±8.6	45.9±9.3	.03	41.7±9.9	43.0±8.4	.73
General activity level	55.7±8.1	56.6±8.2	.69	58.2±7.7	57.5±8.7	.72	55.4±9.2	58.3±8.4	.12	58.1±9.1	59.5±8.7	.53

\*Data are presented as mean ± 1 SD from analysis of covariance, adjusted for baseline values.

ments to patients who have not previously experienced genuine acupuncture.

Acupuncture treatments were well tolerated by our patients. Most patients found participation in the study to be pleasant and rewarding. Bruising and soreness were more common in the acupuncture group than in the control group, but these were mild and did not affect treatment. Acupuncture rarely causes adverse effects that might limit cognition or functional rehabilitation. Vasovagal symptoms (in both the acupuncture group and the control group) were the most troubling adverse effects for a few of our patients. Placing patients in the supine position would likely make them more comfortable.

We found that acupuncture improved symptoms of fibromyalgia significantly more than placebo. All symptom subscales were improved with acupuncture, but only fatigue and anxiety were statistically significant on their own. Pain trended closely toward statistical significance in the FIQ ( $P=.07$ ) and MPI ( $P=.05$ ). However, fibromyalgia is a syndrome of symptoms not just pain.

Our patients were homogenous in diagnosis and severity of symptoms. The Fibromyalgia Treatment Program has been shown to reduce the mean FIQ total score from 51.3 to 44.7.<sup>12</sup> The average FIQ total score of our patients at baseline after the Fibromyalgia Treatment Program was 42.5, which is close to the expected value. The improvement observed in our study was additive to the benefits obtained with the Fibromyalgia Treatment Program (ie, educational and behavioral interventions).

We saw maximum benefit at 1 month (among time points we considered), and that benefit was less significant at 7 months. Unfortunately, the design of this clinical trial does not allow a more precise determination of acupuncture's duration. The time course of improvement after acupuncture should be better characterized in future studies.

Although patients receiving acupuncture reported improved symptoms, they did not report significantly increased levels of activity or physical functioning. However, we neither set this as a goal for our patients nor encouraged any changes in behavior, even if they mentioned symptomatic improvement during the study. Also, the Fibromyalgia Treatment Program had already encouraged exercise and activity to these patients, so they may have previously adopted these suggestions. Regardless, the lack of functional improvement after reduction of chronic pain is not an observation unique to this study. Symptom reduction may be necessary, but not sufficient, for functional rehabilitation.

Two other randomized controlled studies of acupuncture for fibromyalgia have been published.<sup>6,7</sup> Deluze et al<sup>6</sup> prospectively studied 70 patients with fibromyalgia who

were randomized to receive either acupuncture or control acupuncture (35 patients in each group). The control acupuncture arm consisted of needle insertion at points 20 mm away from the experimental points, with decreased intensity of electrical stimulation. Patients received 6 treatment sessions and were assessed immediately after the course of acupuncture with no long-term follow-up. Intention-to-treat analysis showed that patients in the experimental group improved significantly in all parameters except morning stiffness, whereas the controls had no change. Pain threshold was improved by 70% in the experimental group and 4% in the control group. Unfortunately, this study did not use standardized or validated measures of fibromyalgia symptoms or quality of life. Furthermore, there were no long-term follow-up measurements to determine the duration of the effect.

Assefi et al<sup>7</sup> studied 25 patients in the acupuncture group compared with 3 separate control groups, each consisting of 25 patients. Their patients were drawn from "all comers" in the community who had fibromyalgia. Our patients were drawn from the Mayo Fibromyalgia Treatment Program, and thus they may have been more homogenous and possibly more severely affected. It has been suggested that patients at tertiary care centers have more severe disease. Our population may represent patients who have recalcitrant symptoms or are more severely affected than the general population. Many had already used most of the basic treatments for fibromyalgia. Although this may be the case, most of our patients were from the local community, so such a referral bias may be less significant. The study by Assefi et al was performed at several sites by 8 different acupuncturists. Our study was done at 1 site by 2 acupuncturists. This may have reduced the variability in our data.

The study by Assefi et al looked primarily at pain. Their quality-of-life measurement, the Medical Outcomes Study 36-Item Short-Form Health Survey, is not designed specifically for patients with fibromyalgia. We looked at all symptoms of fibromyalgia with a disease-specific, validated measurement tool, the FIQ. In fact, the FIQ was more sensitive in detecting significant differences between groups in our study than the MPI.

Our study showed that acupuncture reduced the FIQ score by 7 points. This benefit was additive to the beneficial effect produced by the Fibromyalgia Treatment Program, which also produced a mean benefit of 7 points.<sup>12</sup> The magnitude of clinical benefit produced by acupuncture is similar to that reported with pharmacological interventions such as tricyclic antidepressants<sup>13</sup> (7 points), fluoxetine<sup>14</sup> (8 points), and tramadol and acetaminophen<sup>15</sup> (6 points). Therefore, the effect of acupuncture is both clinically and statistically significant.

Our study has certain limitations. Perhaps most significant is the relatively small size of the study population. Additionally, some will argue that the acupuncture therapy provided was not optimal with respect to point selection, elicitation of de Qi, and electrical stimulation. To preserve blinding, the design of the study did not allow customized point selection or specific elicitation of the de Qi sensation, sometimes referred to as “needle grab.” Some schools of acupuncture require this sensation as an indication of proper needle position. However, studies suggest that the sensation of de Qi occurs equally frequently at true and sham acupuncture points.<sup>16</sup> Nevertheless, these deficiencies would tend to minimize the treatment effect observed. Hence, our results may represent a minimum effectiveness of acupuncture.

Our patients were mostly women, which does not accurately reflect the male-female ratio of the incidence of fibromyalgia. This may represent scheduling difficulties on behalf of potential patients or other factors that limited enrollment by men. Our population was also predominantly white, which reflects the community population in Olmsted County, Minnesota, where this study was conducted. Future research should extend these observations to men and to other ethnic and racial groups.

## CONCLUSION

This study represents a prospective, blinded, randomized trial of acupuncture for patients with fibromyalgia. Acupuncture was well tolerated with minimal adverse effects. Symptoms of fibromyalgia improved in the acupuncture group to a greater extent than in the control group. Specific symptoms that showed the most significant improvements included fatigue and anxiety. The improvement was both clinically and statistically significant. Therefore, acupuncture may have a role in the symptomatic treatment of patients with fibromyalgia.

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