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Original Research Article

Randomized Controlled Trial of Acupuncture for Women with Fibromyalgia: Group Acupuncture with Traditional Chinese Medicine Diagnosis-Based Point Selection

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Abstract

Background. Group acupuncture is a growing and cost-effective method for delivering acupuncture in the United States and is the practice model in China. However, group acupuncture has not been tested in a research setting.

Objective. To test the treatment effect of group acupuncture vs group education in persons with fibromyalgia.

Design. Random allocation two-group study with repeated measures.

Setting. Group clinic in an academic health center in Portland, Oregon.

Subjects. Women with confirmed diagnosis of fibromyalgia (American College of Radiology 1990 criteria) and moderate to severe pain levels.

Methods. Twenty treatments of a manualized acupuncture treatment based on Traditional Chinese Medicine diagnosis or group education over 10 weeks (both 900 minutes total). Weekly Revised Fibromyalgia Impact Questionnaire (FIQR) and Global Fatigue Index at baseline, five weeks, and 10 weeks and a four-week follow-up were assessed.

Results. Thirty women were recruited, with 78% reporting symptoms for longer than 10 years. The mean attendance was 810 minutes for acupuncture and 861 minutes for education. FIQR total, FIQR pain, and Global Fatigue Index all had clinically and statistically significant improvement in the group receiving acupuncture at end of treatment and four weeks post-treatment but not in participants receiving group education between groups.

Conclusions. Compared with education, group acupuncture improved global symptom impact, pain, and fatigue. Furthermore, it was a safe and well-tolerated treatment option, improving a broader proportion of patients than current pharmaceutical options.

Key Words. Fibromyalgia; Group Acupuncture; Traditional Chinese Medicine; Pain; Fatigue; Randomized Controlled Trial

Fibromyalgia is a multisymptomatic disorder characterized by chronic widespread pain, fatigue, and sleep and balance issues, as well as cognitive impairment,

depression and anxiety [1] [2]. It affects nearly 4 million people in the United States [3] and has been largely underdiagnosed by primary care physicians [4]. Further, fibromyalgia is associated with a high level of health care utilization and productivity loss [5,6].

Many patients with fibromyalgia, like many patients with chronic pain, utilize complementary and alternative medicine as adjunct therapy. It has been estimated that almost 40% use at least one complementary and alternative medicine modality [7]. The same report indicated that nearly 7% use acupuncture. Major consensus documents recommend education for patients with fibromyalgia [8] but have been more cautious with acupuncture.

Despite this, the research literature indicates mixed efficacy. In a recent review of reviews, Lauche et al. [9] found that acupuncture may be effective for the treatment of fibromyalgia. However, among the four reviews, two indicated that there was insufficient evidence [10,11] and two indicated positive results for pain and reduction of symptom impacts [12,13]. Interestingly, among the 11 trials found among all of these reviews, none of the acupuncture protocols have used Traditional Chinese Medicine diagnosis or group treatments.

Traditional Chinese Medicine (TCM) is one of the most common styles of acupuncture treatment. Its diagnoses are orthogonal to biomedical diagnosis [14]. From a TCM point of view, fibromyalgia is a disease that is mainly comprised of one of three main diagnoses but includes as many as 12 different diagnoses based on signs and symptoms [15]. Each diagnosis has different points that are prescribed. Given this, it is possible that the variability in results is due to treatments that do not match the presentation (from a TCM point of view). Indeed, a review of the literature indicates that all of the reported protocols were fixed point protocols, giving further credence to this possibility.

In this manuscript, we report outcomes from a two-group randomized allocation clinical trial of Traditional Chinese Medicine diagnosis-based group acupuncture protocol vs group education (see the Supplementary Data for acupuncture protocol). The study design was appropriate for evaluating both the acceptability and feasibility of conducting such a trial and the possible impact of of acupuncture among women who failed to get relief from their fibromyalgia symptoms from standard pharmacological treatments. The primary hypothesis was that the study would be both feasible and acceptable among study participants. The secondary hypothesis was that participants in group acupuncture would have more improvement on the Fibromyalgia Impact Questionnaire–Revised (FIQR) total score. Finally, there was an exploratory hypothesis that fatigue would be improved in the group acupuncture arm but not in the group education arm.

Patients and Methods

The treatment protocol was developed based on a model used in temporomandibular joint disorders [16]. The focus was to have a manualized acupuncture treatment based on TCM diagnosis as it is practiced in clinics and taught in many acupuncture schools. It reduces treatment variability while providing realistic treatments.

Participants

This study included women, aged 18–75, with a confirmed diagnosis of fibromyalgia using the 1990 American College of Radiology definition. The newer 2010 criteria were not used, following Wolfe et al.'s recommendation that the 2010 criteria were not intended to replace the 1990 criteria but rather to address issues with poor physician training in diagnosis. [2] All participants reported an average pain of 5 or higher on a visual analog scale (VAS) over the last week and agreed to not change any medication or treatment for the duration of the study. This was confirmed weekly with the individuals by study staff who were not associated with treatment. We limited the population to those with a score of less than 29 on the Beck Depression Inventory [17] and those who had not used acupuncture or Oriental medicine in the previous six months. We excluded those with a routine daily use of narcotics or a history of substance abuse, pregnant or nursing mothers, those with a known coagulation abnormality that might have precluded the safe use of acupuncture such as thrombocytopenia, those with a concurrent autoimmune disease such as rheumatoid arthritis that could potentially confound the analysis, and those undergoing disability determination or who were involved in litigation related to fibromyalgia. Further, they had to have a Traditional Chinese Medicine diagnosis that included either Liver Qi Stagnation, Qi and Blood Stagnation, or Qi and Blood Deficiency. These were all confirmed by the treating acupuncturists. The goal was to recruit moderately symptomatic fibromyalgia patients who could safely receive the treatments.

Randomization

For this study, participant assignments were made using a random allocation process using a minimum likelihood allocation process [18–20] to either a 10-week group acupuncture or group education with a one-month follow-up post-treatment. The allocation program determined which group the individual would be assigned by weighing the randomization in an effort to eliminate variance between the two groups on key characteristics. Allocation was balanced on baseline Fibromyalgia Impact Questionnaire–Revised total score, acupuncture treatment expectancy (How much do you expect group acupuncture to improve your fibromyalgia symptoms? 0 is no change and 7 is no more symptoms), body mass index (BMI), and age. The individuals were told their group assignment after the baseline measurements

were obtained. Masking of the intervention groups was not possible.

Blinding

As it was impossible to blind the interventionists or patients in this study, the data were collected and entered by blinded individuals. The statistics were analyzed (SM) without knowledge of the intervention received by each group. The blinding was only removed once the preliminary analysis was completed.

Interventions

Group acupuncture, sometimes referred as community acupuncture, participants received twice-weekly group acupuncture session using the Traditional Chinese Medicine style of diagnosis, each lasting approximately 40 minutes. Traditional Chinese Medicine diagnosis included traditional pulse and tongue examination and in-depth patient interviews. The practitioners had prior experience diagnosing this population and had participated in a calibration exercise prior to starting the participant treatment [15,21]. The treatments took place in a room where eight acupuncture tables were set up. Patients were allowed to talk to each other but tended to rest quietly once the needles were in place. Each treatment was limited to a total of 25 (Tempo brand 0.16 mm × 40 mm or 0.20 mm × 40 mm) single-use needles with standard depth and no requirement of de qi response (see C.1.e in the Supplementary Data for explanation). Needles were manipulated manually if required and were retained for a maximum of 20 minutes. While the protocol required a minimum of five years of practice, all acupuncturists had more than 10 years of experience treating chronic pain. The technical details of the acupuncture protocol are provided in the Supplementary Data.

The group education protocol involved a facilitated education process. Participants who were allocated to this arm had group discussion on chapters from a fibromyalgia book focusing on current understanding of fibromyalgia etiology, demographics, and pharmacologic and nonpharmacologic treatment options [21]. The discussions were facilitated but led primarily by the participants. Group education was selected, as it is a commonly offered treatment, and it accounted for both the practitioner-patient interaction in group acupuncture and total treatment time.

Outcome Measures

The primary outcome of the study was the Fibromyalgia Impact Questionnaire–Revised total score [22]. The FIQR is a well-validated questionnaire with known psychometric properties. The total score combines subscales in three domains: function, overall impact, and symptoms. Participants completed the FIQR weekly for 10 weeks and at four weeks following the final class of each intervention. Secondary outcomes included the pain VAS and multisensory sensitivity, embedded in the FIQR, and the global fatigue index (GFI), measured within the Multidimensional Assessment of Fatigue (MAF) questionnaire. The MAF [23,24] is an American College of Rheumatology–recommended scale for the measure of fatigue in rheumatic conditions [25]. The MAF was administered at baseline, five weeks, and 10 weeks, and at four weeks post-treatment. All assessments were conducted electronically via REDCap.

Adverse events were monitored and reported using weekly inquiries by staff not involved in either of the treatment interventions. These reports were then screened by an independent physician who had no other study involvement. Participants were encouraged to report all events regardless of their potential relationship to the intervention. The research team (CE) categorized adverse events as serious or nonserious.

Statistical Analysis

Sample Size

This study was a proof of concept study, for which sample size is not normally calculated. However, sample size was calculated using simulations based on the known characteristics of this population and the repeated-measures protocol. The design was calculated to achieve greater than 80% power to detect an effect size of 0.09 ($P = 0.05$) with a dropout rate of 9% and controlling for two covariates (baseline pain and group) [26].

Primary and Secondary Outcome Analysis

All analyses were conducted on an intent-to-treat basis. To account for participants who dropped out of the study, we modeled the missing data based on a curvilinear approach of the current data, truncating the scores to the highest and lowest pain scores reported over the previous six months (collected at baseline). We performed a random-effects GLS regression with baseline pain and baseline treatment expectation as fixed effects and *time x group* allocation as a random effect. The random effect is the between-group variable of interest. In order to control for heteroskedasticity and within-panel serial correlation, we will perform a robust analysis. The Breusch-Pagan-LaGrange Multiplier for random effects was calculated for each model. All secondary analyses were Holm-Bonferroni-corrected to account for family-wise error [26]. The analysis was conducted by SM, who was blinded to group assignment. Statistical analysis was completed using Stata software, version 13.1 (College Station, TX, USA).

Role of the Funding Source

The study (K23AT006392) was funded by the National Center for Complementary and Integrative Health,

National Institutes of Health. The protocol was developed by the author but reviewed by the Office of Clinical Research Affairs. They had no other function in conducting the research or the preparation of the manuscript.

The study was approved by the Oregon Health and Science University Institutional Review Board and registered (NCT02053090) on ClinicalTrials.gov.

Results

Baseline Characteristics and Flow of Participants

A total of 30 participants were randomized to the two groups, with 16 in the group acupuncture arm and 14 in the group education arm. The first subject was recruited in September 2014, and the final follow-up was conducted in July 2015. The women were primarily non-Hispanic Caucasian (87.1%) with a mean age of 54 years. The baseline FIQR total score (SD) was 51.4 (15.5), indicating a high level of negative impact. The global fatigue index was 36.1 (6.7). Baseline pain (question 12) scores were 6.2 (1.8) and 6.3 (1.4) for the education and acupuncture groups, respectively. The allocation process was successful in that both groups had nonsignificant differences in age, acupuncture expectancy, BMI, and baseline FIQR total scores. All participants had a TCM diagnosis of either Qi and Blood Stagnation, Qi and Blood Deficiency, or Liver Qi Stagnation. This was determined by two acupuncturists (SM and CW) at the screening visit. No participants were excluded due to this criterion (Table 1).

Intervention, Attendance, and Adherence

Those in the group acupuncture arm completed 83.3% of the treatment visits and 98.1% of the assessments. In the group education arm, they had a similar completion rate of 96% of the treatments and 91% of the assessments. This demonstrates that the protocol was acceptable among the participants.

There were no unexpected adverse events related to the treatment protocols or study participation in either group. One individual in the acupuncture group reported bruising (<1% of treatments), and there was one case of dizziness that resolved by sitting for three minutes. The CONSORT diagram shows the participant flow (Figure 1).

Three participants did not complete treatment—two in the group education arm and one in the group acupuncture arm. A conservative approach was used to model their data. Each provided data at baseline and a single follow-up. The dropouts were related to scheduling difficulty due to new employment (acupuncture and education) and surgery unrelated to the study (education). For each of these cases, the two points were used to determine a trajectory for FIQR total scores and global fatigue inventory scores truncated by their historic high (for individuals in the acupuncture group) and the historic low (in the education group). For the individuals in the education group, the FIQR total scores remained relatively stable, with nonsignificant reduction at end of treatment and the four-week follow-up. The model for the individual in the group acupuncture arm reported increased FIQR total score at the second visit, which extrapolated to clinically significantly higher FIQR total scores (~20% increase) and was truncated at the historic high reported at baseline.

Primary Outcome Analysis—FIQR Total

The original model included the covariates baseline pain, BMI, age, and acupuncture expectancy. Only baseline pain and BMI were significant in the final model. The parsimonious model explained 70.4% of the variation between groups and 17.7% of the within-group variation. Individuals in the group education arm had a nonsignificant improvement ($P = 0.50$) at end of treatment and at the four-week follow-up. Individuals in the group acupuncture arm received a clinically and statistically significant improvement ($P < 0.001$) in FIQR total scores, with a modeled average improvement at the end of treatment (10 weeks) of 17.3, which continued to improve at the four-week follow-up, with an average improvement of 22.3. These represent 34% and 43% improvements in overall fibromyalgia impact, respectively. The Breusch-Pagan-LaGrange Multiplier for random effects was significant ($P < 0.001$) for all models, indicating that the random effect model was appropriate (Table 2A).

Secondary Outcome Measures

Global Fatigue Index

As with the previous analysis, the original model included baseline Global Fatigue Index (GFI), BMI, age, and acupuncture expectancy. The results of this were adjusted using Holms-Bonferroni correction (N = 2) [27]. Only baseline GFI was significant in the final model. The reduced model explained 73.5% of the variation between groups and 39.8% of the variation within $P < 0.001$. Individuals in the group education arm had a nonsignificant worsening on the GFI ($P = 0.30$). Individuals in the group acupuncture arm reported a clinically and statistically significant improvement ($P < 0.001$) in the GFI. They reported a 25% improvement at the end of treatment and a 33% improvement at four weeks post-treatment (Table 2B and Figure 2). Figure 2 shows the raw data with a fitted line and standard deviations.

Pain VAS

The pain VAS is an item within the FIQR. The model ($P < 0.0001$) was Holms-Bonferroni adjusted (N = 3) and included baseline pain. By the end of treatment,

Table 1 Demographics indicate a population with a high amount of disease impact with high BMI and fatigue

	Group acupuncture (N = 16)	Group education (N = 14)	Significance
Age, y	52.3 (12.9)	56 (12.0)	0.42
BMI, kg/m^2	33.2 (10.2)	32.7 (7.7)	0.88
Acupuncture expectancy	4.4 (1.8)	4.3 (1.8)	0.92
Education expectancy	4.0 (1.7)	3.8 (1.0)	0.32
FIQR total	51.1 (15.9)	52.8 (14.0)	0.70
Pain VAS (Q12 from FIQR)	6.2 (1.8)	6.3 (1.4)	0.52
Global fatigue impact	36.7 (6.5)	35.6 (7.2)	0.36

BMI = body mass index; FIQR = Fibromyalgia Impact Questionnaire–Revised; VAS = visual analog scale.

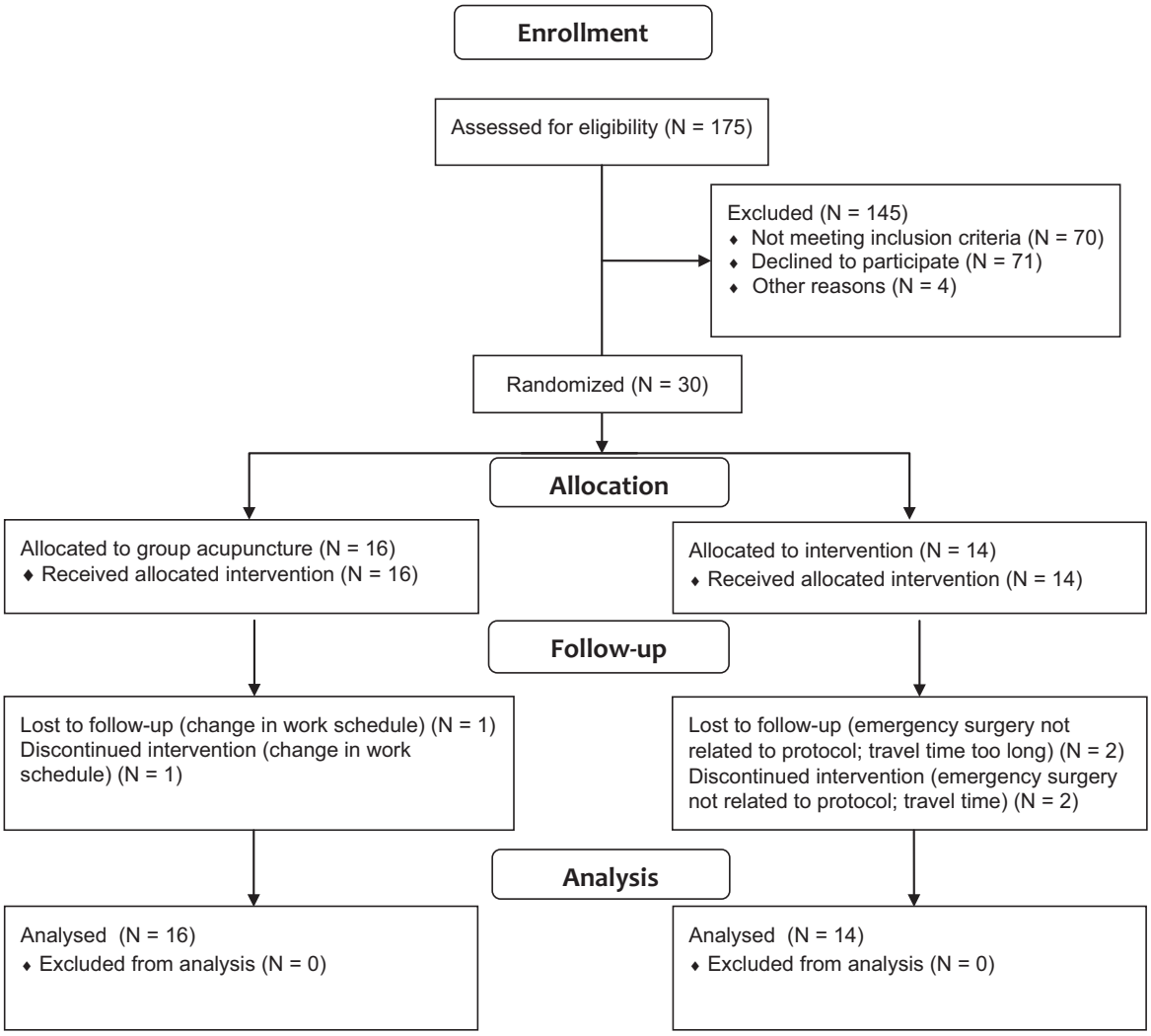

Figure 1 CONSORT flow diagram.

Table 2A Fibromyalgia impact questionnaire—revised total score

FIQR total score				95% CI	
	β	Standard error	*P*	Lower limit	Upper limit
Baseline BMI	−0.560	0.152	0.000	−0.858	−0.262
Baseline FIQR total	0.788	0.087	0.000	0.616	0.960
Group educationxdays	−0.029	0.042	0.498	−0.111	0.054
Group acupuncturexdays	−0.225	0.045	0.000	−0.313	−0.137
Constant	29.33				

BMI = body mass index; CI = confidence interval; FIQR = Fibromyalgia Impact Questionnaire–Revised.

Table 2B Global fatigue index

Global fatigue index				95% CI	
	β	Standard error	*P*	Lower limit	Upper limit
Baseline GFI total	0.708	0.146	0.000	0.421	0.994
Group educationxdays	0.010	0.010	0.296	−0.009	0.029
Group acupuncturexdays	−0.117	0.027	0.000	−0.129	−0.645
Constant	10.29				

CI = confidence interval; GFI = global fatigue index.

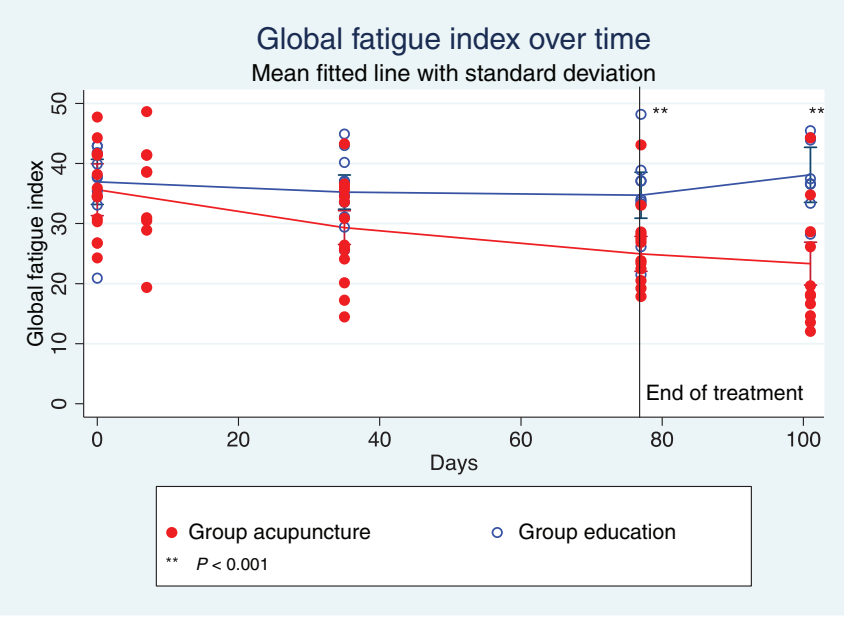

Figure 2 Global fatigue index over time. Individual measurements, means, and standard deviations are displayed. This does not take into account repeated measurements.

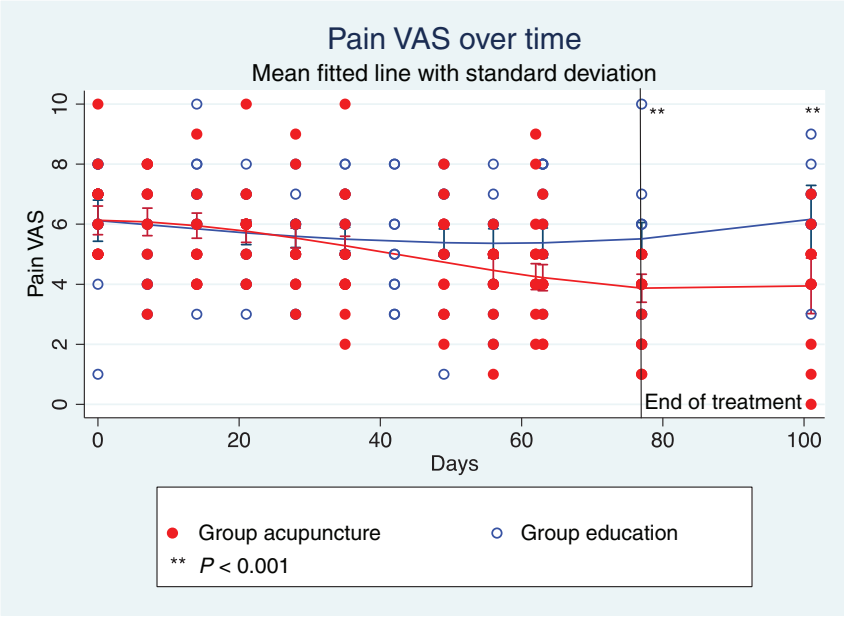

Figure 3 Pain visual analog scale over time. Individual measurements, means, and standard deviations are displayed. This does not take into account repeated measurements. VAS = visual analog scale.

participants in the group acupuncture arm reported an average reduction in pain of 2.8 from baseline, which was further reduced to 3.5 at the four-week follow-up. The model explained 73% of the variation between groups and 31% of the variation within groups (Figure 3).

Discussion

This study design has two unique strengths that differentiate it from the extant literature. Namely, the intervention was delivered to patients in a group setting, and the needle placement was based on TCM diagnosis. Group acupuncture is a treatment model that is frequently used in Asia and is increasingly being implemented here in the United States. This model is a useful treatment option for those with fibromyalgia. The treatment effect is larger than previously reported studies of acupuncture for fibromyalgia. This may be due to three contributing factors. First, the treatments were individualized using the diagnostic protocols of Traditional Chinese Medicine. While fibromyalgia is a single diagnosis within biomedicine, individuals with fibromyalgia have several different Traditional Chinese Medicine diagnoses [15], and fixed protocols do not take advantage of greater refinement of the population and the different treatment approaches used in treating each of these "subcategories."

The next contributing factor may be the group nature of the treatment. It is normalizing to see others with fibromyalgia, and often patients build relationships with the other participants. It is known that social networks are lacking in fibromyalgia populations and that it is generally thought of as protective. As such, increasing the network may provide benefit [28]. However, education was delivered in a group by an experienced fibromyalgia researcher using learner-led methodologies, yet the education group did not have similar improvements. This implies that if the group nature of the treatment is important, it is not sufficient for improvement and must be matched with the proper treatment.

Lastly, it may be that the study suffers from the limited number of participants and the early nature of the work. The reader is reminded that the preliminary hypothesis and design of the study were to determine the feasibility and acceptability of the treatment and measurement protocols. The secondary and exploratory hypotheses, disease impact, fatigue, and pain, were adjusted using conservative statistical methods for repeated hypotheses. However, in such cases, the effect size may be inflated [29]. As such, this needs to be confirmed by further research.

Other trials of acupuncture with fibromyalgia patients have reported smaller treatment effects [30–33]. In these trials, pain improved by 0.8–1.1 on a 10-point VAS, with no improvement in fatigue [30,10]. With the exception of a small trial in 1998 [34], each of these studies used fixed point protocols, which necessarily limits the efficacy of the treatments. Additionally, there have been no reported studies examining acupuncture delivered in a group setting for fibromyalgia.

There are two other limitations of this study: length of follow-up and limited number of acupuncturists. The follow-up for this study was only four weeks

postintervention. At the most recent Society for Acupuncture Research conference, several thought leaders suggested that all acupuncture studies should have a follow-up period of a minimum of six months, with one to two years being optimal [35,36]. It has been observed that in most pain studies the treatment effect continues to improve up to a year for those who respond to acupuncture [36].

While these results should be considered preliminary, given the lack of adverse events and the improvements in pain and fatigue, individualized acupuncture in a group setting should be considered in the treatment of fibromyalgia. The women in this study had a relatively high level of pain that was not being addressed using standard pharmaceutical approaches. Many reported functional improvements in their life, with a decrease of nearly half of the fatigue and pain they had 10 weeks prior. While larger and more diverse populations need to be studied, group acupuncture should be considered as a treatment option for those who are not otherwise controlling their symptoms.

There are three main directions in which future studies are warranted based upon our results. First, it is unclear whether the individualized treatments based on TCM diagnosis account for the increased efficacy of the treatments. Also, according to TCM, there are diagnoses that should respond quickly and those who would require a longer course of treatment. It is unclear if the participants in our study who did not improve were truly nonresponders or whether the treatment prognosis indicated that a longer course of treatment was warranted. Next, one needs to further examine the role of group treatments in a larger and more diverse population. Lastly, it is interesting that both pain and fatigue were addressed with our protocol. It may indicate that there is a common underlying mechanism (possibly also involving sleep disturbance and cognitive difficulties) that is addressed with acupuncture.

In conclusion, our study provides preliminary evidence that group TCM diagnosis–based acupuncture improves the negative impacts of fibromyalgia, pain, and fatigue. Given acupuncture's safety profile and relative lack of side effects and the body of research in which this is embedded, it should be considered as a treatment option for patients who are otherwise not obtaining relief from the most common symptoms of fibromyalgia: pain and fatigue.

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Supplementary Data

Supplementary Data may be found online at http://painmedicine.oxfordjournals.org.

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