

ORIGINAL RESEARCH

EFFECTIVENESS OF ACUPUNCTURE IN THE
TREATMENT OF FIBROMYALGIA

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Context • Fibromyalgia syndrome (FMS) is a prevalent musculoskeletal disorder associated with pain, mood state alteration, and disability. A structured and effective treatment plan for palliative care has not been established. The genesis of FMS is not clear. FMS occurs primarily in adult women.

Design • Using a quasi-experimental clinical design and following the criteria of the American College of Rheumatology (ACR), for FMS, 21 participants completed the study. The mean age was 53.6 years. The data were collected at baseline and at 1 and 2 months. Acupuncture treatments included 17 points for FMS symptoms, and 8 outcome measures were collected.

Results • The Fibromyalgia Impact Questionnaire (FIQ) showed significant differences at 1 and 2 months. For the SF-12, 3 subscales showed significant differences between baseline and 2 months. Four of 6 items were significantly changed. The mean number of general health symptoms was significantly decreased by 2 months. For the Catastrophe Index, sig-

nificant differences were found for baseline vs 2 months. Pain threshold scores were significantly different at end of treatment for 5 bilateral tender points. There was significant improvement in Beck Depression items for both 1- and 2-month periods. In a multivariate regression model, 5 covariates were included—age, number of weeks in treatment, number of doctors treating, number of general symptoms, and baseline FIQ score. The results indicated significant age effect. This analysis showed that the higher the FIQ score, the more positive the change experienced by study participants. Number of weeks in treatment, number of doctors who treated, and total number of general health symptoms did not have a significant effect on outcomes.

Conclusions • Significant improvement was experienced by participants at 8 weeks of treatment. Acupuncture treatment as delivered was effective at reducing FMS symptoms in this outcome study. (*Altern Ther Health Med.* 2006;12(2):34-41.)

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Fibromyalgia syndrome (FMS) is a chronic musculoskeletal disorder associated with a high degree of pain, significant mood state alteration, and disability, including high rates of unemployment.¹ The American College of Rheumatology (ACR), the National Fibromyalgia Association and other reliable sources estimate that approximately 2% to 6% of the adult United States population has FMS.² Although a higher percentage of women are affected, it does strike men, women and children of all ages and races.^{3,4} A variety of prevalence studies of fibromyalgia in both the United States and Europe have demonstrated that regardless of differences in diagnostic criteria used, fibromyalgia is common in the population, occurs primarily in older persons, and women are most frequently diagnosed with the disorder.⁵ Using the 1990 ACR criteria, in Wichita, Kan, Wolfe and colleagues found a prevalence of 2% for both sexes, 3.4% for women and 0.5% for men. Prevalence of the syndrome increased with age. The threshold as measured by dolorime-

ter/algometer and greater tender point counts as highest prevalence was between 60 and 79 years old.³ Women were found to have a lower pain threshold.^{6,7} Bennet reported in 1995 that 6 million Americans were affected by fibromyalgia, of whom 4 million were women.⁷

Patients with FMS are high consumers of both conventional and complementary and alternative medicine (CAM) services. In 2003, the total annual costs for individual FMS claimants were \$5,945. Hidden costs of disability and treatment of associated comorbidities greatly increase the burden of FMS and account for nearly 70% of the economic burden.^{8,9} A Health Maintenance Organization study found that the total claimant cost for FMS patients was more than double that for non-FMS claimants.⁸

A European study recently compared the cost of illness of 3 musculoskeletal conditions in relation to general well-being. The study found that total costs were high in fibromyalgia especially because of costs for formal and informal care, aids, adaptations and workdays lost. Well being of patients was lower in the fibromyalgia group compared to other musculoskeletal disorders.¹⁰ Additionally, it has been found that fibromyalgia patients are more likely to be unemployed and use chiropractic and other complementary therapies for which payment is likely to be out of pocket,¹¹ creating further disease related cost burden for the patient.

A Canadian study on women with FMS estimated high direct costs (70%), exceeding those from most other studies. These costs were mainly associated with number of comorbidities and indices of the effect of FMS, psychological distress, and pain intensity.⁹

Acupuncture, a holistic therapy and a component of traditional Chinese medicine (TCM), has a long-standing history of at least 2,500 years and incorporates medical traditions of China and other Asian countries.^{12,13} Many studies have detailed the use of acupuncture as treatment for chronic pain^{12,14-19} and as a treatment for FMS.^{12,18,20-24} Acupuncture is a complex intervention that involves stimulation of anatomical location by penetration of skin using thin, solid metallic needles, which are manipulated manually or electronically. Needle stimulation is believed to balance energy flow known as *qi* through the body that is essential in maintaining physical and mental health.^{12,25,26} Evidence suggests that acupuncture maybe an effective therapy in treating FMS.^{12,27}

ETIOPATHOGENESIS

The genesis of fibromyalgia is not clear,^{28,29} though many epidemiological and clinical studies have focused on uncovering the causal links to development of this disorder.³⁰⁻³⁷ Many of the studies used chemical and physical markers associated with the concomitant disorders that co-vary with fibromyalgia to uncover precursors to development of the syndrome.³⁸⁻⁴² Some evidence suggests that both biological and psychosocial stress play a pathogenesis role in triggering FMS.⁴³ Even so, a systematic review of the pathophysiology of fibromyalgia syndrome did not produce clarity on the matter. The study found that neither

infections, trauma, nor psychiatric abnormalities consistently precede the onset of pain in patients with this syndrome; but, it was found that central pain processing abnormalities were exhibited in most fibromyalgia patients in the study.⁴⁴

According to TCM, fibromyalgia can be included under the category of internal medical and painful obstruction patterns. Etiological factors such as trauma, stress, poor dietary habits, and emotional imbalance could have a negative impact on organ function (eg, liver, spleen, kidney) and might cause depletion of true *qi* and blood and body fluids. These changes ultimately result in stagnation of *qi* and blood and/or promote formation of damp and phlegm and/or deficiency of *yin*, which are basically responsible for all the signs and symptoms of fibromyalgia.

DIAGNOSIS AND CLASSIFICATION

Though ACR criteria for diagnosis of fibromyalgia are primarily used in the currently reported research data, there has been controversy in the literature about whether the ACR criteria may be too broad compared to other criteria. The controversy revolves around what constitutes pain.^{45,46} The ACR criterion requires pain distributed across the 4 quadrants of the body and for tender point count to be 11 or more of 18 points.⁴⁷ The 18 bilateral tenderpoints sites are occiput, low cervical, trapezius, supraspinatus, second rib, lateral epicondyle, gluteal, greater trochanter, and knee.

In order for the ACR criteria to be met, patients are required to demonstrate pain response through overt pain-signaling behavior when tender points are palpated. Interestingly, such a response is not required when the Prescott study diagnostic criteria is used.^{45,46} Additionally, manual palpations of tender points and manual dolorimetry have been questioned due to potential for low reliability across examiners.⁴⁸⁻⁵¹ Also, other criteria have allowed for fewer tender points, 3 to 5, with collateral symptoms part of the defining characteristics.^{38,52,53} Muller and Laudersch criteria also require fewer tender points than the ACR criteria and therefore identify more patients as having fibromyalgia.^{52,53} Additionally, the label of primary fibromyalgia, which indicates fibromyalgia as the patient's primary diagnosis and secondary fibromyalgia (concomitant diagnosis), has been abandoned as a result of studies that indicated that the 2 groups were not statistically different in any major study parameter and therefore, the classification did not provide a discriminating factor for the disorder.^{54,55} Thus, it is important to consider the evaluation criteria that were used to determine a diagnosis of fibromyalgia when reviewing clinical or epidemiological data and to be precise in the diagnostic parameters of proposed research. Current ACR criteria were used in this study.

According to the ACR criteria, for a tender point to be considered active the participant must state that the palpation was painful; "tender" is not to be considered "painful." Digital palpation should be performed with an approximate force of 4 kg on each tender point mentioned above. Widespread pain must have been present for at least 3 months. The presence of a second clin-

ical disorder does not exclude the diagnosis of FMS.⁴⁷ In this study, an algometer was used for greater precision in measurement and a single assessor was used for all patients and measurement periods to increase reliability of the measure.

CONCOMITANT DISORDERS

FMS has been associated with a variety of other disorders of both musculoskeletal and nonmusculoskeletal origin.⁵ These disorders include myofascial pain, irritable bowel symptoms,⁵ migraine headache, chronic fatigue syndrome, carpal tunnel syndrome, sleep disorders, dysmenorrhea, urinary tract symptoms,⁵⁶ non-allergic rhinitis, nasal congestion, lower respiratory symptoms,⁵⁷ recurrent non-cardiac chest pain, heartburn, palpitations, and multiple chemical sensitivities (MCS).⁵⁸ Other diseases investigated for relevance to fibromyalgia include Chlamydia pneumonia,⁵⁹ and temporomandibular disorders.^{60,61} Since many disorders present concomitantly with fibromyalgia and since there is a high degree of individual differences in which these collateral disorders occur, investigations have focused on whether these disorders are precursors to or are secondary to fibromyalgia. For example, in an investigation of hepatitis C virus and fibromyalgia, there were no statistical differences in autoimmune markers between patients who met and those who did not meet the criteria for fibromyalgia.⁶² Nicolodi's study of migraine and fibromyalgia suggests that migraine may be a predictor for the development of fibromyalgia, however.⁶³ Similarly, Buchwald has indicated that MCS may be a precursor to the development of FMS.⁵⁸ In 2002, an Italian study was conducted to assess the prevalence of fibromyalgia in primary Sjogren's syndrome and to evaluate the clinical differences between patients affected with both primary fibromyalgia and primary Sjogren's syndrome and those affected only with fibromyalgia. The study reported a moderate increase of fibromyalgia prevalence in primary Sjogren's syndrome.⁶⁴

TREATMENT

There is no structured and effective treatment plan for FMS, which will provide significant palliative care as well as deter increased disability. Pharmacological therapies are reported as mildly effective for the short term, but, are not sufficient and may be responsible for mild to severe adverse effects. As a result, the current prognosis for fibromyalgia patients is considered poor. Though not curative, several non-pharmacological therapies, such as acupuncture, patient education, aerobic exercise, cognitive-behavioral therapy (CBT), stress management, relaxation response, acupuncture,³⁴ homeopathy, qi gong and other exercise modalities^{34,65-71} have provided some improvement in perception of pain, mood state, function, sleeplessness, and fatigue by introducing new mechanisms of coping with this chronic disorder. These therapies have been tested singly and in various combinations⁷² and are generally administered as adjunctive ones.

In general, evidence to date on acupuncture for most rheumatic diseases, including FMS, is encouraging. A randomized,

double-blind, controlled trial of real electroacupuncture vs sham with bi-weekly acupuncture sessions for 3 weeks (6 total treatments) produced significant improvement in pain threshold, analgesic support used, regional pain score, visual analog scale (VAS)-scored pain, sleep quality, and patient or physician global assessment. No improvement was found in morning stiffness, however. Differences between the groups were significant for 5 of the 8 outcome measures after treatment.⁶⁸

Acupuncture use in the treatment of fibromyalgia has been shown to be promising, but clinical trials have generally been methodologically weak and higher quality evidence is needed.^{18,27} Differences in the importance of needle placement continue to be noted in findings of various studies. For example, in a single-site, single-blind, randomized trial investigating (1) needle placement, (2) needle stimulation, and (3) treatment frequency, significant pain improvement was noted overall but it was not dependent upon needle location or stimulation.⁷³

Berman and colleagues' review of 3 randomized control trials and 4 cohort studies found somewhat positive results. Overall acupuncture was more effective than the sham, but the limited amount of positive evidence and insufficient number of studies indicated further investigation is required.^{18,27,74,75} Due to inconclusive results of previous data, the treatment pattern for the trial reported here was chosen from both existing Chinese literature^{25,76} and through pilot work (Table 1).²⁷

This study was conducted (1) to add to the body of knowledge about the relationship between acupuncture treatment and relief of fibromyalgia symptoms and (2) to assist in clarification of the literature due to differing previous findings. The specific goals of the study were to determine the effectiveness and safety of acupuncture needling at specific points for fibromyalgia symptoms when delivered 2 times per week for 8 weeks.

STUDY METHODS

Twenty-four participants were recruited from the greater Los Angeles and Orange County area. For 80% power, the sample size required was estimated at 22 participants total. Inclusion criteria were as follows: (1) prior diagnosis of FMS by physician; (2) meet ACR-FMS diagnosis criteria at clinical screening; (3) a response of moderate or greater to the question, "Currently, how severe is your FMS?"; (4) understand and provide a signed informed consent form approved by university IRB. Exclusion criteria were as follows: (1) any immunodeficiency state, whether past or current, due to either a disease or immunosuppressive medications; (2) pregnant; (3) diagnosed and/or undergoing treatment for acute depression and/or psychological illness; (4) previous acupuncture intervention; (5) silicon breast implants; (6) use of narcotics or prescription analgesics; (7) refusal to or inability to sign or understand an informed consent; (8) bleeding disorder; and (9) unwilling to discontinue possible intervention or disclose current therapy for non-exclusionary diagnosis.

Community-wide recruitment (eg, mailings, ads, support groups) in the greater Los Angeles and Orange County area

was used to generate the study sample. Participants were either referred by attending physicians or through self-report as having met the criteria for inclusion in the study. Community recruitment was used to supplement the participant resource of university clinic patients in the main and satellite clinics. The participants who were successfully recruited were admitted into the study once they had been clinically screened and found to meet ACR criteria for FMS and as well as all inclusion and exclusion criteria. They then signed an informed consent document and Human Subjects Bill of Rights. Human Subject Approval was received from the university's Institutional Review Board before participants were recruited.

Demographic data including outcome measures were collected at baseline. A single clinician conducted all algometer readings to promote consistency and reliability of these data. Participants began treatment for FMS following a baseline assessment and completed outcome measures at the midpoint (4 weeks) and end of study (8 weeks).

ACUPUNCTURE POINTS

A consistent set of acupuncture points for optimum FMS and FMS comorbidity relief were used. Acupoints were based on traditional literature, clinical experience, and data from previous clinical trials (Table 1).⁷⁴ A within-group design was intentionally used for the trial, as definitive points and frequency of delivery have not been determined.

Two acupuncture treatments were administered per week, with 3- to 4-day intervals between each treatment, for 16 total treatments over 8 weeks. The study alternated standardized posterior and anterior points. Each week one session treated anterior points and another session treated posterior points.

Skin was sterilized with prepackaged alcohol-preparation pads before and after acupuncture treatments (per acupuncture point) according to the standard procedures of the National Certification for Acupuncture and Oriental Medicine and California Acupuncture Board. Acupuncture needles measuring 1 inch (2.54 cm), 34-gauge, 0.22 mm in diameter were inserted to standard depths of 0.4 to 0.6 in (1.0-1.5 cm).⁷⁷

OUTCOME MEASURES

The primary outcome measure was the Fibromyalgia Impact Questionnaire (FIQ), which is a disease-specific instrument.⁷⁸ The secondary outcome measures included a Medical Outcomes Study Short Form General Health Survey (SF-12),^{79,80} a double-anchored 100-mm visual analog scale (VAS),⁸¹ the Southern California University of Health Sciences Health Assessment Questionnaire (HAQ, a self reported functional disability instrument), the Beck Depression Inventory,^{82,83} the Coping Strategies Questionnaire (a 50-item instrument with 10 subscales that assess cognitive and behavioral pain coping mechanisms used and their effectiveness),⁸⁴ the Helplessness subscale of the Rheumatology Attitudes Index (RAI),⁸⁵ and tender point count with pain threshold measured by algometer.⁸⁶ Data collection instruments were standardized for this disorder

and have been successfully used by these investigators in a previous study on FMS during which they were confirmed to be sensitive enough to detect changes in outcome.

SIDE EFFECTS AND WITHDRAWAL

No side effects were reported. One participant was diagnosed with lupus during the study period and was withdrawn from the study. Another participant had severe pain in the upper back and was diagnosed with cancer; she was also withdrawn from study. One participant withdrew for a family emergency that required relocation.

RESULTS

Within-group analyses (paired samples *t*-test) were conducted to determine whether the intervention produced a significant mean change in the primary outcome measure (FIQ) from baseline to 1 month and from baseline to 2 months. Descriptive data, disease history, and other variables collected at baseline were used for control purposes or in the construction of a model determining those factors which may facilitate or mediate effectiveness of the therapy. Secondary outcome measures were used to establish reliability of the findings from the primary outcome measure, for model building, and for determination of measures appropriate for use in subsequent trials.

Twenty-one participants (19 females, 2 males) completed the study. Participants served as their own control in this 8-week pilot study. The average age was 53.6 years, with a range of 44 to 71 years and a standard deviation of 7.98. Forty-seven percent of the participants were employed during the study. The mean number of years of education was 14.48, with a range from 12 to 20 and a standard deviation of 2.67.

FINDINGS FROM OUTCOME MEASURES

The primary outcome measure was the FIQ. The total score provides an estimation of FMS impact ranging from 0 to 100. The higher the total scores, the greater the impact. The results showed an improvement over time (Table 2). The mean total score decreased significantly from 53.6 to 38.9 between baseline and 1 month ($P = .0001$) and continued to drop in the second month to 30.5, statistically significant ($P = .0001$) for both comparisons.

The SF-12 scale, an abbreviated version of the SF-36, is a health status instrument used to assess general participant outcomes. It generates a physical and mental component summary of participant health status. For the baseline-vs-second-month comparison, the SF-12 subscales showed significant differences in 3 subscales (Table 2)—ACC, the accomplishment subscale; REG, the extent to which emotional problems affect work or regular daily activities; and EM, the emotional well-being subscale. There were no significant differences between baseline and 1 month.

The VAS is an outcome measure used to assess pain. For the baseline-vs-second-month comparison, 4 of 6 VAS items

TABLE 1 The Point Selection for Acupuncture Treatment of Fibromyalgia Based on Pathogenesis and Tender Points

a) Posterior Side

Point	Specialty	Point location	Therapeutic function	
1	GB 20	Tender point	Below the occiput and at the depression between trapezius and steinocleidomastoid m	Eliminate internal wind, relieve headaches, and relieve local pain
2	GV 14	Tender point	At the depression below the spinal process of the 7th cervical vertebra	Remove qi and blood stagnation, eliminate internal wind, and relieve local pain
3	GB 21	Tender point	At the highest point of the shoulder and at midpoint between C7 and acromion	Promote qi circulation at gallbladder channel and relieve local pain
4	SI 12	Tender point	At the depression on the superior border of the scapular spine	Remove wind from the muscles, relieve muscle spasm of the back, and relieve local pain
5	GB 30	Tender point	At the lateral 1/3 between sacral hiatus and greater trochanter	Relieve local pain and promote qi circulation on the Shaoyang channel
6	BL 25	Tender point, Back-Shu point of the largest intestine	1.5" lateral to the lower border of spinal process of the 4th lumbar vertebra	Relieve local pain, tonify large intestine, and relieve symptoms of irritable bowel syndrome
7	BL 23	Back-Shu point of the kidney	1.5" lateral to the lower border of spinal process of the 2nd lumbar vertebra	Tonify kidney-yang, nourish kidney-yin, strengthen the back, and balance liver and kidney
8	BL 40	Principal point of the back	At the midpoint of the popliteal crease	Promote qi flow on the back channel, relax the back muscles, and relieve low back pain

b) Anterior Side

1	LR 3	Yuan-Primary point of the liver	1.5" above the web between 1st and 2nd toes, at the depression between 1st and 2nd metatarsals	Open the Four Gates to soothe qi flow of all channels, tonify liver, and strengthen tendons
2	GB 34	Influential point of the tendon	At the depression anterior and inferior to the fibular head	Strengthen tendons and relieve pain of the muscles, tendon, and the soft tissues
3	KI 25	Tender point	In the 2nd intercostal space, 2" lateral to the anterior midline	Relieve local pain, stimulate heart to house mind, and relieve anxiety, depression, or stress
4	LI 4	Yuan-Primary point of the large intestine	In the space between 1st and 2nd metacarpal bones, at the midpoint of the radial border of the 2nd metacarpal	Open the Four Gates to soothe qi of all channels, remove wind, and treat irritable bowel syndrome
5	ST 36	Qi-generating point	3" below the knee and 1 finger breadth lateral to the anterior border of the tibia	Generate qi in general, promote qi circulation in all channels, and enhance immune function
6	LI 11	He-Sea point of the large intestine	In the depression at the lateral end of the cubital crease with the elbow flexed	Relieve local pain, clear damp-heat from large intestine, and treat irritable bowel syndrome
7	ST 40	Luo-Connecting point of the stomach	8" below the knee and 2 finger breadths lateral to the anterior border of the tibia	Resolve damp-phlegm and promote qi circulation at the lower extremities
8	SP 6	Intersection point of 3 foot-yin channels	3" above the tip of medial malleolus and at the posterior border of the tibia	Nourish yin/blood to muscles, relieve muscle aches, and harmonize spleen, liver, kidney
9	LR 8	Tender point, He-Sea point of the liver	At the depression above the insertion of semimembrinosus tendon on medial side of knee	Relieve local pain, promote liver qi, and relieve pain of the soft tissues, and harmonize liver and kidney

TABLE 2 Fibromyalgia Impact Questionnaire and SF-12 Subscales

a) Fibromyalgia Impact Questionnaire

	Mean	N	SD	SE	P value
Baseline	53.62	19	10.61	2.43	.0001
1 month	38.93	19	13.66	3.13	
Baseline	54.01	20	10.47	2.34	.0001
2 month	30.46	20	15.38	3.44	

b) SF-12 Subscales

ACC	Baseline	1.95	20	.68	.15	
	2 month	1.40	20	.82	.18	.037
ACT	Baseline	3.20	20	1.05	.24	
	2 month	2.75	20	1.33	.30	.095
REG	Baseline	1.25	20	.91	.20	
	2 month	.70	20	.86	.19	.037
EM	Baseline	6.50	20	2.48	.55	
	2 month	9.50	20	2.98	.67	.000
General health	Baseline	1.55	20	.89	.20	
	2 month	1.80	20	.83	.19	.204
Normal work	Baseline	1.70	20	1.26	.28	
	2 month	2.05	20	.99	.22	.330
Social activity	Baseline	1.50	20	1.24	.28	
	2 month	1.15	20	1.23	.27	.246

ACC=accomplished less at work or regular daily activities

ACT=limitations in activities during a typical day such as climbing flight of stairs or moving a table

REG=emotional problems affecting work or regular activities

EM=how you have felt in past 4 weeks

were significantly improved (Table 3): severity of pain ($P = .002$), least severe pain ($P = .007$), pain interfering with activities ($P = .044$), and mood state ($P = .002$).

The Health Assessment Questionnaire (HAQ), a self-report functional (disability) status measure, was the fourth outcome measure employed. For the mean number of general health items between baseline vs second month, there was an improvement in self-reported health items from a mean of 4.6 to 3.7, ($P = .022$) (Table 3).

The fifth outcome measure was the Beck Depression Scale. The scores report baseline vs first month and baseline vs second month. At baseline, the mean score was 14.1, which indicates a mild or moderate level of depression. But at 1 month, the mean score dropped to 8.9. The difference was significant ($P = .007$) (Table 4). No single score was high enough to require exclusion from the study and/or referral for treatment. The cutoff for having no depression is 5 (or lower). At second month, the mean score dropped even more, to 6.3. This difference was statistically significant ($P = .0001$).

The sixth measure, the 6-item Catastrophe Index of the Coping Strategy Questionnaire (CSQ), is a pain coping assessment instrument conceived to measure the extent to which participants used 6 different cognitive coping strategies and 2 behavioral coping strategies.⁸⁷ The CSQ showed a significant dif-

TABLE 3 Visual Analog Scale and Health Assessment Questionnaire

a) Visual Analog Scale (VAS)

	Mean	N	SD	SE	P value
How severe is your pain now?	Baseline 5.45	20	1.959	.438	
	2 month 3.85	20	2.254	.504	.002
What is the LEAST severe that your pain has been in the last week?	Baseline 3.65	20	2.183	.488	
	2 month 2.45	20	1.986	.444	.007
What is the MOST severe that your pain has been in the last week?	Baseline 7.45	20	1.731	.387	
	2 month 6.40	20	2.303	.515	.069
How much is pain interfering with your activities?	Baseline 5.70	20	2.494	.558	
	2 month 4.20	20	2.707	.605	.044
How is your mood presently?	Baseline 4.90	20	2.382	.533	
	2 month 3.20	20	2.042	.457	.002
How confident are you that the treatment you'll be receiving will be successful at reducing the pain?	Baseline 7.50	20	1.878	.420	
	2 month 7.35	20	2.368	.530	.691

b) Health Assessment Questionnaire

Baseline	4.61	18	2.4767	.5838
2 month	3.66	18	3.1249	.7365 .022
Baseline	2.27	18	1.7424	.4107
2 month	2.50	18	1.6539	.3898 .532

ference between baseline and second month ($P = .006$) (Table 4), but no significant differences between baseline and 1 month.

The seventh outcome measure, the Helplessness Index, a subscale of the RAI that is used to measure participants' helplessness showed no significant differences for any of the comparisons.

The final outcome measure was the tender point count with pain threshold measured by algometer. The level of pain for the 18 tender points also was measured to determine the overall pattern of (1) level of pressure and (2) level of pain experienced. An algorithm was created to categorize these into 4 levels. For each tender point, the most frequent patterns are reported for baseline and second month. By the second month of the study, there was an improvement in which study participants felt less pain when greater pressure was applied at the knee, occiput, trapezius, gluteal, and supraspinatus bilaterally (Table 5).

MULTIVARIATE REGRESSION MODEL

A linear multivariate regression model predicting change in FIQ for female participants was created. The 2 male participants were eliminated for this analysis. The dependent variable was

TABLE 4 Beck Depression Scale and Catastrophe Index

a) Beck Depression Scale

	Mean	N	SD	SE	P value
Baseline	14.11	18	9.50	2.24	
1 month	8.89	18	8.92	2.10	.007
Baseline	13.50	20	9.19	2.05	
2 month	6.25	20	7.89	1.76	.0001

b) Coping Strategy—Catastrophe Index

	Mean	N	SD	SE	P value
Baseline	10.67	21	9.4833	2.07	
2 month	7.14	21	7.9264	1.73	.006

“change in the total FIQ score” between baseline and second month. Five covariates were included in the regression model: age, number of weeks in treatment, number of treating clinicians, number of general symptoms and baseline FIQ score.

The results indicate significant age effect ($P = .040$). The older study participants experienced more positive change following treatment. The baseline FIQ total score was used as a control variable and it was significant ($P = .012$), indicating the higher the FIQ score, the more positive change experienced by study participants. Number of weeks, number of doctors, and total number of general symptoms did not affect results significantly.

CONCLUSIONS

These data indicate that acupuncture treatment at the points chosen and at the frequency used in this study produced significant improvement in the primary measure without side effects. After 2 months of treatment, an assessment of perceptible pain at tender points showed that participants were able to tolerate more pressure at tender points with less pain. These changes occurred at the knee, occiput, trapezius, gluteal, and supraspinatus bilaterally. This finding and the algorithm used to produce these data should be investigated for reliability and validity in subsequent studies.

The multivariate analysis indicated that there was a significant age effect. Older study participants had a more positive reaction to treatment. And additional findings from this analysis indicated that the higher the FIQ baseline score, the more positive the change experienced by the study participants. Though somewhat counterintuitive, similar findings have been reported in other musculoskeletal studies as well. For example, in a study of osteoarthritis patients, those with greater disability duration, younger age, and higher scores on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) were most likely to drop out, and older participants were more likely to complete the intervention. Additionally, it was found that those with the least disability and pain rebounded to original levels to a greater degree after treatment than did those who initially were more disabled.⁷⁴

The possible confounds of number of weeks treated, num-

TABLE 5 Tender Point Measures—Pressure/Pain Pattern*

Bilateral tender points	Baseline patterns	Third period patterns
Lower cervical (lc)	2	2
Second rib (sr)	4, 1	4, 1
Lateral epicondyle (le)	3	3
knee (kn)	1, 3	3, 1
Occiput (oc)	1, 3	3, 1
Trapezius (tra)	1, 3	3, 1
Gluteal (glu)	1, 3	3, 1
Greater trochanter (gtr)	1, 4	1, 4
Supraspinatus (su)	1, 3	3, 1

*Explanation of pressure/pain patterns:

- 1=more pressure, more pain
- 2=less pressure, more pain
- 3= more pressure, less pain (+)
- 4=moderate pressure, more pain

ber of doctors, and total number of general health symptoms did not affect results significantly.

Though much more research needs to be done regarding acupuncture treatment for fibromyalgia, the elimination of a variety of alternate explanations for findings, the significant improvement in the primary measure across all participants, and the finding of many subscales of the secondary measures indicating significant improvement by the end of treatment suggest that acupuncture should be considered as a treatment option for fibromyalgia patients.

With continued sound research in this area, primary care physicians and specialists in musculoskeletal disorders may begin to recognize the potential benefit of acupuncture to their patients and refer their patients to licensed, experienced acupuncturists who may offer some symptom relief to fibromyalgia sufferers.

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