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# **Is Acupuncture An Effective Treatment For Alleviating Fibromyalgia?**

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies  
Philadelphia College of Osteopathic Medicine  
Suwanee, Georgia

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## ABSTRACT

**OBJECTIVE:** The objective of this selective EBM review is to determine whether or not acupuncture is an effective treatment for alleviating fibromyalgia.

**STUDY DESIGN:** Systematic review of three randomized controlled trials published in 2014, 2016, and 2017.

**DATA SOURCES:** Data sources for this review were articles published in peer-reviewed journals using PubMed Database.

**OUTCOME(S) MEASURED:** The outcome measured was the patients decrease in pain intensity through the use of the visual analog scale.

**RESULTS:** Stival et al. (2014) found that the change in pain for patients who received true acupuncture to be statistically significant with a p-value of 0.0001. Ugurle et al. (2017) also found that the group who received true acupuncture to have a statistically significant p-value of < 0.001. Vas et al. (2016) found that participants who received true acupuncture over the course of the study also had a significant p-value of <0.01.

**CONCLUSIONS:** The results of these three trials were all promising, but further research is warranted to assess the long-term benefits of using acupuncture for alleviating fibromyalgia.

**KEY WORDS:** fibromyalgia, acupuncture

## INTRODUCTION

Fibromyalgia is a chronic widespread musculoskeletal pain disorder that is often accompanied by changes in mood, sleep, fatigue, irritable bowel syndrome and memory.<sup>1</sup> While the disorder affects both men and women worldwide, women, especially those with a family history of the disorder, have a higher risk of developing it.<sup>1</sup> Currently, pharmacological treatment is commonly used to alleviate the symptoms, but holistic alternatives are being examined for efficacy.<sup>1</sup> This paper evaluates three randomized controlled trials that compares the efficacy of acupuncture in alleviating pain in various parts of the body due to fibromyalgia.

Fibromyalgia affects over 4 million Americans and 5% of the world's population.<sup>2</sup> It is believed that 75% of people living with fibromyalgia remain undiagnosed.<sup>2</sup> On average, a patient suffering from fibromyalgia sees a medical provider between 12-18 times each year.<sup>3</sup> For those patients that have been diagnosed, 10,000 dollars a year is spent to treat each patient.<sup>2</sup> With statistics like these and the vast array of specialties that physician assistants work in, the chances of having a patient with fibromyalgia becomes more likely every year.

Fibromyalgia is known to be a complex chronic pain disorder that is associated with fatigue, anxiety, sleep disturbances, and GI motility issues.<sup>1</sup> While the true cause of fibromyalgia remains unknown, those who live with it have a decreased pain tolerance.<sup>3</sup> Current treatment of this condition consists of pain and sleep management.<sup>3</sup>

While there is no curative treatment or gold standard for fibromyalgia, there are several medications and therapies that are used to treat the symptoms.<sup>1</sup> Conventional treatments such as pregabalin, duloxetine HCL, and milnacipran HCL focus on alleviating some of the pain and depression associated with fibromyalgia.<sup>1</sup> Pregabalin, which is FDA approved for diabetic neuropathy, is one of the most commonly used drugs to treat fibromyalgia due to its positive

effects on pain, fatigue, sleep disturbances, and mood changes.<sup>4</sup> Non-pharmacological alternative treatments such as massages, yoga, and chiropractics, are gaining popularity among those living with fibromyalgia to help relieve some of the associated pain.<sup>1</sup>

The alternative option of acupuncture would allow patients to receive pain relief without the potential harms associated with putting various substances into their bodies. Despite the positive effects that current treatments yield, not all therapeutic options work for all patients due to drug interactions and unpleasant side effects.<sup>4</sup> Pregabalin, for example, may cause excessive drowsiness which may impede a patient's ability to be productive in their daily lives.<sup>4</sup> Serotonin and norepinephrine reuptake inhibitors (SNRIs), such as duloxetine HCL, are notorious for causing diaphoresis and headaches.<sup>4</sup> Acupuncture, if found to be efficacious, would allow patients to experience some pain relief without the worry of side effects or overall concern of introducing chemicals into the body.

## OBJECTIVE

The objective of this selective Evidence based medicine (EBM) review is to determine whether or not acupuncture is an effective treatment for alleviating fibromyalgia.

## METHODS

The criteria used in the selection of the studies were based on specific populations, interventions, comparisons, outcomes measured, and type of study. The population included both female and male patients over the age of 17 who had a confirmed diagnosis of fibromyalgia. The interventions used were true acupuncture sessions. The comparisons used were sham acupuncture sessions, which is defined as using guide tubes with the needles removed.<sup>5</sup> The outcomes measured were the patients' fibromyalgia pain improvement based on the visual

analog pain scale. The studies used in this systematic review include a double-blind randomized controlled trial and two patient-blinded randomized controlled trials.

In order to find articles suitable for this review, PubMed was used. All articles were published in peer-reviewed journals within the last 10 years and had not been previously used in a systematic review or meta-analysis. The keywords “fibromyalgia”, “acupuncture”, and “randomized controlled trial” were used to search for articles. All articles were written in English and Stival et al was also written in Portuguese.<sup>6</sup> All studies selected were chosen based on patient-oriented outcomes (POEMS). The inclusion criteria consisted of studies that were randomized, controlled, and either participant or double blinded. Exclusion criteria consisted of studies investigating pain due to diseases other than fibromyalgia as well as patients under the age of 17. Statistics were reported using p-values, confidence intervals, and mean change from baseline.

**Table 1: Demographics & Characteristics of included studies**

Study	Type	#Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Vas <sup>5</sup> (2016)	Patient blind RCT	164	17-55	Women with a diagnosis of fibromyalgia who had not previously received acupuncture	Chronic pain due to any process other than fibromyalgia, anticoagulant or opioid use, pregnancy	2	Acupuncture to different parts of the body vs sham acupuncture
Stival <sup>6</sup> (2014)	Double blind RCT	36	48-59	Men and women with a diagnosis of fibromyalgia	Bleeding diathesis, pregnancy, fear of needles	0	Acupuncture to different parts of the body vs sham acupuncture
Ugurlu <sup>7</sup> (2017)	Patient blind RCT	50	43-58	Women with a diagnosis of fibromyalgia, normal neuro exam findings, and	Previously receiving acupuncture, having an autoimmune or	0	Acupuncture to 12 different parts of the body vs sham acupuncture

				failure of conventional treatment methods such as SSRIs and TCAs.	inflammatory disease, being pregnant, bleeding diathesis, or having other chronic diseases such as asthma, diabetes, kidney failure, or epilepsy		done on the same spots with non-penetrating needles and guide tubes
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**OUTCOMES MEASURED**

The outcome measured in all three studies looked at the alleviation of fibromyalgia pain based on patient pain improvement from the acupuncture. Vas et al looked at the change in pain intensity after 10 weeks of true acupuncture treatments.<sup>5</sup> Data was collected by self-applied questionnaires, and interviews at baseline, after 10 weeks of treatment, 6 months from baseline, and 12 months from baseline.<sup>5</sup> The primary outcome measured was the Visual Analog Scale (PainVAS) measured at 10 weeks.<sup>5</sup> The Mann-Whitney U test was utilized to assess the differences between the true acupuncture and sham acupuncture groups.<sup>5</sup> The patients were blinded in this randomized controlled trial.<sup>5</sup>

Stival et al looked at the alleviation of pain based on the visual analog scale for pain immediately before acupuncture treatment and right after.<sup>6</sup> The measurements consisted of using a ruler with a scale of 0 to 10 centimeters, with the number zero representing no pain and 10 representing the worst pain ever experienced by the patient.<sup>6</sup> Subjects then marked the position that correlated with their pain level at that time.<sup>6</sup> Both the patients and the examiners were blinded in this study<sup>6</sup>. Ugurlu et al also examined pain alleviation by measuring the changes in the patients pain levels after receiving twelve sessions of true acupuncture over the course of

eight weeks.<sup>7</sup> The visual analog scale was also used to assess the changes in pain level for this study.<sup>7</sup> The patients were blinded during the treatment in this study.<sup>7</sup> In all three studies, true acupuncture groups were compared to sham acupuncture.

## RESULTS

Vas et al utilized continuous data that was unable to be converted into dichotomous data.<sup>5</sup> The study began with 164 female participants, however, two withdrew before the start of treatment due to a comorbidity of an acute myocardial infarction and a change of address, respectively.<sup>5</sup> Of the participants that remained, 80 made up the experimental group and 82 were in the control group.<sup>5</sup> Any patient with a chronic pain disorder other than fibromyalgia, pregnant patients, or anyone who was using anticoagulants were excluded from the study to avoid confounders from skewing results.<sup>5</sup> The trials were held at clinical practices under the supervision of physicians.<sup>5</sup> The participants of both the experimental and control groups were similar in demographics and pain levels as well as in regards to what pharmacological treatment they were receiving. The experimental group received one session of acupuncture for 20 minutes per week on the dorsal and lumbar regions of their bodies for a total of 9 weeks.<sup>5</sup> The control group went through the same process; however, guide tubes with the needles removed were utilized for their treatment.<sup>5</sup> The visual analog pain scale was analyzed using the Mann-Whitney U test before and after the treatments to establish a p-value.<sup>5</sup> Data revealed that there was a mean change in baseline of 41.2 % in the experimental group and a mean change of 27% in the control group from baseline to week 10.<sup>5</sup> These numbers revealed that although both groups saw a statistically significant decrease in pain after treatments, the group that received true acupuncture had a greater reduction in pain as signified by a p-value of 0.001.<sup>5</sup> The difference between the means indicates a large treatment effect size. No adverse events were noted from this study.

**Table 2: Visual analog pain scale at baseline and 10 weeks post-treatment<sup>5</sup>**

<b>Mean change of experimental group from baseline</b>	<b>Mean change of control group from baseline</b>	<b>95% CI of Experimental group</b>	<b>95% CI of Control group</b>	<b>p-value</b>
41.2%	27%	47.6 to 34.9	33.2 to 20.8	0.001

Stival et al also utilized continuous data that was unable to be converted into dichotomous data.<sup>6</sup> This study was comprised of 36 participants, both men and women, with none being excluded from the study.<sup>6</sup> Twenty-one patients were a part of the experimental group and 15 patients were involved in the control.<sup>6</sup> When selecting individuals for the study, those who were pregnant or had bleeding diathesis were excluded from participating due to potential safety concerns (Table 1).<sup>6</sup> Treatments for both groups took place at a local hospital under physician supervision.<sup>6</sup> As seen in the previous study, both the experimental group and control group were matched by similar demographics and current pharmacological treatment.<sup>6</sup> The experimental group underwent a 20 minute acupuncture session during which 0.20 x 40 mm needles were perpendicularly placed over the heart, pericardium, spleen, large intestine, liver, and stomach as recommended by traditional Chinese medicine.<sup>6</sup> The control group received the same treatment with the exception of needles that measured 0.18 x 8mm and were placed to the left of the true acupuncture points.<sup>6</sup> Immediately before and after the intervention, patients completed a visual analog pain scale for pain.<sup>6</sup> The results of the visual analog pain scale were analyzed by the Mann-Whitney U test.<sup>6</sup> Data for this study was presented as mean  $\pm$  standard deviation.<sup>6</sup> In the treatment group, there was a change of  $-4.36 \pm 3.23$  between the initial and final visual analog pain scales, which resulted in a statistically significant p-value of 0.001.<sup>6</sup> In the control group, a change of  $-1.70 \pm 1.55$  was seen between the initial and final visual analog scales, however, with

a p-value of 0.06, it was not deemed to be statistically significant.<sup>6</sup> Based on Cohen's d coefficient, this study was shown to have a large effect, despite the small size.<sup>6</sup> Overall, pain alleviation was improved for the patients who received true acupuncture. No adverse events were noted from this study.

**Table 3: VAS changes in mean  $\pm$  standard deviation and p-values of both groups<sup>6</sup>**

	<b>True acupuncture n=21</b>	<b>Sham acupuncture n=15</b>	<b>p-value</b>
<b>VAS initial</b>	7.27 $\pm$ 2.66	5.27 $\pm$ 2.50	
<b>VAS final</b>	2.91 $\pm$ 2.38	4.01 $\pm$ 2.43	
<b>Change</b>	-4.36 $\pm$ 3.23	-1.70 $\pm$ 1.55	0.005

The use of continuous data was extended to Ugurlu et al.<sup>7</sup> This study was comprised of 25 participants in the experimental group and 25 participants in the control group and none were lost during the two months of the trial.<sup>7</sup> Any patient with any other pain disorders, chronic medical condition, bleeding diathesis, or who were currently pregnant, were excluded from taking part in the study for their own safety and avoid any potential confounding factors (Table 1).<sup>7</sup> The trials took place at an outpatient clinic affiliated with a local hospital and was overseen by a physician.<sup>7</sup> Both the treatment group and control group were matched characteristically.<sup>7</sup> Participants in both groups received 3 sessions of acupuncture in the first week, 2 sessions per week for the following 2 weeks, and 1 session per week in the following 5 weeks, totaling 12 sessions.<sup>7</sup> Each session lasted approximately 30 minutes.<sup>7</sup> The acupuncture sites chosen were LI 4, ST 36, LV 3, GB 41, GB 34, GB 20, SI 3, SI 4, UB 62, UB 10, SP 6, HT 7, DU 20, DU 14, Kd 27, Ren 6, and PC 6 ; all of which correspond to various parts of the body.<sup>7</sup> In the group that

received true acupuncture, 0.25 x 40 mm needles were placed at 90 degree angles within each part of the body.<sup>7</sup> In the control group, non-penetrating needle devices that contained blunt and retractable needles were used.<sup>7</sup> The blunt needles were deployed in the guide tube, creating a pricking sensation without any actual penetration taking place.<sup>7</sup> Patients filled out a visual analog pain scale questionnaire prior to receiving the first session of acupuncture and came back one month later to fill out another one.<sup>7</sup> The results were analyzed using SPSS v.15.0 for Windows.<sup>7</sup> Data for this study was presented as mean  $\pm$  standard deviation.<sup>7</sup> In the treatment group, the mean and standard deviation of  $5.20 \pm 1.22$  proved to show a great reduction in pain from the  $8.12 \pm 1.42$  baseline.<sup>7</sup> This change in mean resulted in a p-value of 0.001, thus making it statistically significant.<sup>7</sup> In the control group, the baseline mean and standard deviation was  $8.76 \pm .96$  and one month after the initial session was  $6.96 \pm 1.13$ .<sup>7</sup> Although the change seen in the control group was still statistically significant with a p-value of 0.001, the change in the treatment group showed a greater change, which is likely to have a more positive effect on the pain alleviation of a larger population.<sup>7</sup>

**Table 4: Changes in mean  $\pm$  standard deviation and p-values of both groups at baseline and one month later<sup>7</sup>**

	<b>True acupuncture n=25</b>	<b>Sham acupuncture n=25</b>	<b>p-value</b>
<b>VAS initial</b>	$8.12 \pm 1.42$	$8.76 \pm .96$	0.001
<b>VAS final</b>	$5.20 \pm 1.22$	$6.96 \pm 1.13$	0.001

## DISCUSSION

Fibromyalgia is a mysterious disorder that still has much to be learned about it and many hurdles to overcome before patients can be properly treated. One of those hurdles is insurance. Because acupuncture is an alternative procedure, most insurance companies are not willing to cover it, thus leading to a smaller population having access to this treatment.<sup>3</sup>

Acupuncture needles are regulated as class II medical devices by the FDA and are currently used to treat several medical conditions such as osteoarthritis, menstrual cramps, migraines, and chemotherapy-induced nausea and vomiting.<sup>8,9</sup> Due to the relatively low risk associated with acupuncture, most people are able to have it done without any complications, thus leading to an improved quality of life attributed to an alleviation of pain. Those who should be cautioned to use this treatment include pregnant women, since the stimulation yields the possibility of inducing labor, and anyone living with a bleeding disorder, as the procedure may increase their bleeding risk.<sup>8</sup>

The limitations of the studies utilized in this review must also be considered. There have been very few studies done on the effects of acupuncture on chronic pain disorders such as fibromyalgia, therefore limiting the selection of studies for this review. In all three studies, the sample population was small. Vas et al had the largest sample size with only 162 participants.<sup>5</sup> Additionally, the studies done by Vas et al and Ugurlu et al were only comprised of female participants.<sup>5,7</sup> Furthermore, because the physicians who oversaw the studies by Ugurlu et al and Vas et al were not blinded, there was the potential for bias.<sup>5,7</sup> In Vas et al participants in the true acupuncture group were on higher doses of pain medication than those in the control group, thus leading to potentially skewed results.<sup>5</sup>

## CONCLUSIONS

After evaluating all three randomized controlled trials, it is evident that all three of the studies showed improvement in the alleviation of fibromyalgia as a result of receiving acupuncture. Although improvement was shown, the exact number of acupuncture sessions needed to alleviate fibromyalgia remains unclear since all three studies had varied amounts. In future studies, the inclusion of more male participants would further strengthen the evidence to support the use of acupuncture for fibromyalgia. Additionally, future studies are warranted to determine if acupuncture is more effective in certain ethnicities or age groups over others. This research could greatly mold the way in which patients with fibromyalgia are treated in the near future.

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