# The effects of acupuncture versus sham acupuncture in the treatment of fibromyalgia: a randomized controlled clinical trial

Uğurlu FG[1], Sezer N[1], Aktekin L[1], Fidan F[1], Tok F[2], Akkuş S[1]

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## ABSTRACT

**Objective**: The aim of this manuscript is to determine and to compare the efficacy of real acupuncture with sham acupuncture on fibromyalgia (FM) treatment.
**Methods**: 50 women with FM were randomized into 2 groups to receive either true acupuncture or sham acupuncture. Subjects were evaluated with Visual Analogic Scale (VAS), at night, at rest and during activity; SF-36, Fibromyalgia Impact Questionnaire (FIQ), Beck Depression scale (BDI), Fatigue Severity Scale (FSS) at baseline, 1 month and 2 months after the 1st session. Patients in both groups received 3 sessions in the 1st week, 2 sessions/week during 2 weeks and 1 session/week in the following 5 weeks (totally 12 sessions).
**Results**: 25 subjects with a mean age of 47.28±7.86 years were enrolled in true acupuncture group and 25 subjects with a mean age of 43.60±8.18 years were enrolled in sham acupuncture group. Both groups improved significantly in all parameters 1 month after the 1st session and this improvement persisted 2 months after the 1st session ($p<0.05$). However, real acupuncture group had better scores than sham acupuncture score in terms of all VAS scores, BDI and FIQ scores either 1 or 2 months after the 1st session (all $p<0.05$).
**Conclusion:** Acupuncture significantly improved pain and symptoms of FM. Although sham effect was important, real acupuncture treatment seems to be effective in treatment of FM.


**Keywords:** Fibromyalgia; Acupuncture; Sham acupuncture.

1. Physical Medicine and Rehabilitation, Yıldırım Beyazıt University Medical School
2. Physical Medicine and Rehabilitation, Gülhane Military Medical Academy

## INTRODUCTION

Fibromyalgia (FM) is characterized by chronic widespread musculoskeletal pain that is often associated to other manifestations such as fatigue, sleep disturbances, anxiety and depression. Not only did the diagnostic criteria for FM change over time but also they are heterogeneous according to the classification system used. While a diagnosis according to the earlier criteria of the American College of Rheumatology (ACR) required the presence of a specific number of tender points, more recent guidelines did not define tender points but focused on the presence of widespread pain locations[1,2]. Affecting 2-4% of the populations in industrialized countries, FM is the second most common rheumatologic disorder in the world, with the majority of patients in clinical settings being female[3]. The etiology of FM remains unknown[4].

Treatment of FM is symptomatic, aiming at the alleviation of pain, fatigue and sleep disturbances, and the improvement of physical and psychological symptoms, as well as social functioning. Treatment strategies for the management of FM include a variety of pharmacological and non-pharmacological therapies including complementary and alternative medicine (CAM) treatments. Acupuncture is one of the most frequently used CAM intervention, which has been used as a treatment option in China for over 2000 years[5,6] and is increasingly accepted in the West, where its use has become considerably more common in recent decades, especially for pathologies producing high levels of pain[7,8], and thus it has been suggested as a treatment for FM[9,10].

Previously, it has been reported that acupuncture treatment was an useful method for FM treatment[11]. However, the findings of acupuncture studies compared with sham acupuncture are conflicting[12-15]. There is a moderate evidence that acupuncture is more

effective than sham acupuncture in improving symptoms of FM[12-14]. However, Assefi et al.[15], in a randomized, controlled, double-blind study, evaluated the efficacy of acupuncture in relieving pain in 100 FM patients and reported that acupuncture treatment was not superior to sham treatment for pain relief. Additionally, these previous studies were focused on pain and fibromyalgia impact questionnaire (FIQ) scale[11-15]. To the best knowledge of authors, in the literature, effects of acupuncture treatment on pain, fatigue, depression and quality of life have not been assessed in FM patients. Accordingly, the aim of this study is; (1) to compare the efficacy of acupuncture with sham acupuncture in management of FM; (2) to determine the efficacy of acupuncture on pain, fatigue, depression and quality of life in patients with FM.

## METHODS

### SUBJECTS

This randomized controlled clinical trial include 50 female patients diagnosed with FM according to the 1990 ACR classification criteria, and all patients completed the study[16]. Patients were numbered in order of admittance to our out-patient clinic and randomly separated in two groups (numbers were chosen via computer programme). Inclusion criteria were: (1) widespread pain for six months or more and to be diagnosed with FM according to the 1990 ACR classification criteria; (2) normal neurological examination findings, including deep tendon reflexes, voluntary muscle action and sensory function; 3) having failed to achieve improvement following other treatments including nonsteroidal anti-inflammatory drugs, major opioids, tricyclic antidepressants (amitriptyline or cyclobenzaprine), selective serotonin re-uptake inhibitors, serotonin-norepinephrine re-uptake inhibitors, anticonvulsant drugs such as gabapentine, pregabalin and some other multidisciplinary therapies. Exclusion criteria were: (1) sufficient knowledge of acupuncture which may prevent blinding (e.g. having received acupuncture previously); (2) known bleeding diathesis; (3) autoimmune or inflammatory diseases; (4) participation in other clinical trials; (5) pregnancy or lactation; or (6) diabetes mellitus, multiple sclerosis, alcoholism, polyneuropathy, kidney failure, asthma, emphysema, bronchitis, epilepsy, schizophrenia, or psychosis.

Patients consenting to participate in the study were recruited and randomly assigned to either real acupuncture or sham acupuncture. The study was approved by the local ethical committee and performed between January and July 2015.

### INTERVENTION

Patients in both groups received 3 sessions in the first week, 2 sessions/week in the following 2 weeks and 1 session/week in the following 5 weeks (totally 12 sessions) lasting for 30 minutes each session, always performed by the same experienced physician (F.G.U). The acupuncturist used disposable, sterilized, flexible stainless steel 0.25 × 40 millimeter needles. The acupuncture points employed 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, PC 6.

In acupuncture group; needle penetration was 10–30 millimeter without extra rotational or manual stimulation after needle insertion and the depth of needle penetration was determined by the patient's sensitivity until "chi" sensation was obtained. Needles were placed on the acu-points while the patients were supine or prone position. The inclination of the needle was 90° in all points.

In the sham acupuncture intervention, Park sham devices were used. It is a non-penetrating needle device with a blunt and retractable needle and a guide tube. A pre-cut guide tube which is fixed by a self-adhesive pad was slightly depressed down onto the selected point. And then, the blunt sham needle is carefully placed into the guide tube. When pressed, it telescopes into the handle and induces a pricking sensation rather than penetrates the skin. During this process, no twirling lifting and thrusting manipulation is conducted.

### OUTCOME ASSESSMENT

Baseline demographic findings, pain intensity during activity, rest and at night, quantified with a 10 cm visual analog scale (VAS), FIQ, Medical Outcomes Survey Short Form-36 (SF-36), Beck Depression Inventory (BDI) and Fatigue Severity Scale (FSS) were obtained. Patients were evaluated by the same physician (not blinded)for these parameters before treatment, 1 month and 2 months after the first session treatment.

FIQ is a functional and symptom based questionnaire specific to FM assessing FM-related consequences including the ability to perform routine physical tasks as well as pain, sleep, fatigue, stiffness and psy-

chological variables such as anxiety and depression. Total score ranges between 0-80 with a higher score indicating a more negative impact[17].

In addition to these pain-related outcomes, patients' quality of life was assessed by SF-36 scale. This scale quantifies patients' quality of life in 8 multi-item scales measuring physical functioning, role limitations owing to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations owing to emotional problems and mental health[18]. Higher values indicate better quality of life.

Additionally, symptoms of depression were assessed using the BDI, an instrument that has been widely used as a measure both in patients with mental disorders and in the general population[19]. Scores from 0–13 indicate minimal depression, scores from 14–19 indicate mild depression, scores from 20–28 indicate moderate depression, and scores from 29–63 indicate severe depression.

Moreover, we used FSS, a 9-item scale that reflects how fatigue influences motivation, exercise, physical functioning, and daily activities, and interferes with work, family, and social life. The final score is the average of all item scores, ranging from 1 to 7. A higher score indicates more fatigue severity.

### STATISTICAL ANALYSIS

Data were analyzed using SPSS v.15.0 for Windows. Descriptive statistics are given as mean±standard deviation (SD). Kolmogorov-Smirnov Test was used to determine whether data followed a normal distribution. Paired sample t test was used in comparing parameters of 1 and 2 months after the 1st session according to the baseline. Differences between the groups were investigated using the independent sample t test. The level of significance was set at $p < 0.05$.

## RESULTS

The procedure was well tolerated by all patients, and all of them completed the study. None of the subjects in both groups declared adverse events or complications of applications. The mean age of in acupuncture group was 47,28±7,86 years. The mean age of in sham group was 43,60±8,18 years. Groups were similar with regards to demographic and baseline clinical data (except for FIQ score which was significantly higher in the sham group, p=0.034) (other p values>0.05) (Table I and Table II).

Both groups improved significantly 1 month after the 1st session in terms of pain intensity during activity, rest and at night, scores of FIQ, SF-36, BDI and FSS, and this improvement persisted for 2 months after the 1st session (all p<0.05) (Table II).

One month after the first session real acupuncture group had better scores than sham acupuncture group in terms of pain intensity (during activity, rest and at night) and BDI, FSS and FIQ scores 1 month after the 1st session (all p<0.05) (Table II). However, mental and physical component summaries of SF-36 were similar between the groups (all p>0.05) (Table II).

Two months after the first session real acupuncture group had better scores than sham acupuncture group in terms of pain intensity during activity, rest and at night and BDI, mental and physical component summaries of SF-36 and FIQ scores (all p<0.05) (Table II). However, FSS score was similar between the two groups (p=0.09) (Table II).

## DISCUSSION

The present study's findings indicate immediate improvement after both real acupuncture and sham acupuncture application in all pain outcome measures (VAS activity, VAS rest, VAS night), functions, symptoms, quality of life, fatigue and depression in FM patients. However, real acupuncture had additional effects, as compared with sham acupuncture.

The inhibition of trigger points with acupuncture may decrease or remove their nociceptive input, normalize the synaptic efficacy, and reduce peripheral and central sensitization. However, acupuncture points may be far away from the related trigger points according to the meridian theory. After eliciting a local twitch response with a needle, substance P and calcitonin gene

**TABLE I. DEMOGRAPHIC DATA OF THE PATIENTS**

| | Real Acupuncture Group (n=25) | Sham Acupuncture Group (n=25) | P |
|---|---|---|---|
| Age (years) | 47.28 ±7.86 | 43.60 ± 8.18 | 0.089 |
| Disease duration (years) | 6.28 ± 4.97 | 6.32 ± 2.21 | 0.143 |
| Employee (n) | 6 | 4 | 0.490 |
| Nonemployee (n) | 19 | 21 | |

Independent sample t-test, *P<0.05

**TABLE II. BASELINE AND POST-TREATMENT CLINICAL DATA OF THE PATIENTS.**

| | Real Acupuncture Group | | Sham Acupuncture Group | | Real Acupuncture Group vs. Sham Acupuncture Group |
|---|---|---|---|---|---|
| | Mean ± SD | P[a] | Mean ± SD | P[a] | P |
| VAS activity | | | | | |
| Baseline | 8.28 ±1.45 | | 8.60 ± 1.25 | | 0.471 |
| 1 month after 1st session | 5.44 ± 1.41 | <0.001* | 6.84 ± 1.10 | <0.001* | 0.001* |
| 2 months after 1st session | 2.52 ± 1.44 | <0.001* | 5.36 ± 2.04 | <0.001* | <0.001* |
| VAS rest | | | | | |
| Baseline | 8.12 ±1.42 | | 8.76 ± .96 | | 0.097 |
| 1 month after 1st session | 5.20 ± 1.22 | <0.001* | 6.96 ± 1.13 | <0.001* | <0.001* |
| 2 months after 1st session | 2.58 ± 1.32 | <0.001* | 5.60 ± 2.04 | <0.001* | <0.001* |
| VAS night | | | | | |
| Baseline | 8.88 ±1.23 | | 8.72 ± 1.10 | <0.001* | |
| 1 month after 1st session | 5.92 ± 1.15 | <0.001* | 7.08 ± .91 | <0.001* | 0.001* |
| 2 months after 1st session | 2.84 ± 1.21 | <0.001* | 5.64 ± 1.80 | 0.467 | <0.001* |
| FIQ score | | | | | |
| Baseline | 60.75 ± 10.88 | | 63.92 ± 5.43 | | 0.034* |
| 1 month after 1st session | 38.98 ± 11.46 | <0.001* | 54.79 ± 7.84 | <0.001* | <0.001* |
| 2 months after 1st session | 26.24 ± 10.95 | <0.001* | 47.11 ± 9.25 | <0.001* | <0.001* |
| PCS (SF-36) | | | | | |
| Baseline | 30.17 ± 5.27 | | 28.65 ± 7.28 | | 0.086 |
| 1 month after 1st session | 38.88 ± 6.32 | <0.001* | 36.04 ± 7.30 | <0.001* | 0.079 |
| 2 months after 1st session | 42.93 ± 6.77 | <0.001 | 38.84 ± 7.75 | <0.001* | 0.034* |
| MCS (SF-36) | | | | | |
| Baseline | 33.77 ± 8.03 | | 30.31 ± 7.24 | | 0.148 |
| 1 month after 1st session | 41.18 ± 8.70 | <0.001* | 37.78 ± 5.85 | <0.001* | 0.177 |
| 2 months after 1st session | 48.67 ± 8.29 | <0.001* | 41.10 ± 5.88 | <0.001* | 0.034* |
| FSS | | | | | |
| Baseline | 55.28 ± 4.17 | | 57.28 ± 6.27 | | 0.078 |
| 1 month after 1st session | 47.12 ± 6.65 | <0.001* | 50.88 ± 7.97 | <0.001* | 0.019* |
| 2 months after treatment | 39.24 ± 9.21 | <0.001* | 44.12 ± 10.53 | <0.001* | 0.098 |
| BDI | | | | | |
| Baseline | 28.24 ± 8.87 | | 28.44 ± 9.30 | | 0.899 |
| 1 month after 1st session | 15.64 ± 9.21 | <0.001* | 21.80 ± 9.88 | <0.001* | 0.020* |
| 2 months after 1st session | 9.48 ± 7.68 | <0.001* | 18.76 ± 8.31 | <0.001* | <0.001* |

VAS, Visual analog scale; FIQ, Fibromyalgia impact questionnaire; PCS, Physical component summary; MCS, Mental component summary; SF-36, Medical Outcomes Survey Short Form-36; FSS, Fatigue severity scale; BDI, Beck depression inventory.
a. Compared with baseline
Paired sample t test, *P<0,05

related peptide have been shown to significantly decrease at trigger points, which corresponds with the clinical observation of an immediate decrease in pain and local tenderness after the inhibition of a trigger point with acupuncture needling[20,21]. These effects are of great importance for the treatment of FM.

In a systematic review[22], it has been reported that effects of acupuncture treatment on pain (one month later) was not superior to sham acupuncture. Additionally, Assefi et al.[15] did not demonstrate any benefit of acupuncture in relieving pain compared with three different types of sham treatment. Nevertheless, in a

recent study, it has been shown that acupuncture was more effective than sham application on pain 10 weeks after initial treatment, and this effect persisted for 1 year[23]. Likewise, in our study, acupuncture was found to be superior to sham treatment on pain, one and two months after the 1st session.

We only found one study evaluating physical function (by SF 36 ) in FM patients treating with acupuncture in the literature[24]. This study indicated that sham acupuncture was more effective than real acupuncture in improving SF-36 physical function. Controversially, in our study, acupuncture treatment was more effective in SF-36 physical function than sham treatment; additionally we indicated that SF-36 mental function scores were more improved with real acupuncture at the 2nd month after initial treatment.

There are three studies comparing acupuncture and sham acupuncture effects on fatigue in these patients[11,15,24]. Fatigue was evaluated by VAS, multidimensional fatigue inventory and the correspondent domain of FIQ. One month after treatment, measurements were not significantly different between the two groups. In our study, fatigue was more alleviated in acupuncture group at the 1st month after treatment, but this effect did not persist.

In previous studies, acupuncture and sham acupuncture effects on global well-being were not different[11,15,25]. In our study, global well-being was evaluated by FIQ score. FIQ scores were higher in the sham group at baseline, which could indicate that sham group had a more severe form of FM. Nevertheless FIQ scores were significantly more improved in acupuncture group comparing to sham group. Additionally, we observed that depression was more relieved in acupuncture group comparing to the sham application. Our results demonstrated the effectiveness of acupuncture treatment on the patients; pain, fatigue, depression and quality of life comparing to sham acupuncture and in this regard, to the best knowledge of the authors, these results were the first in the literature.

While some of our findings were consistent with the literature, some of them were not. This contradiction may stem from the selected acupuncture points. Assefi also mentioned that there is no gold standard for the selection of acupuncture points for FM treatment[15]. Additionally, placement of the sham acupuncture devices at correct acupuncture points may provide neuromodulatory inputs to the sensory nervous system producing physiological changes. We believe that this effect may be responsible for favourable results in the sham acupuncture group. However, according to our results, this effect is lower than real acupuncture effect.

One advantage of acupuncture treatment is that it produces few adverse side-effects compared with many drugs used to treat FM. Generally, pain at site of needling and minor bleeding have been reported due to acupuncture[22]. However, acupuncture treatment is well tolerated by patients. Similarly, acupuncture treatments were also well tolerated by our patients and they did not report discomfort, soreness, vasovagal symptoms, bruising or hematomas during the treatment period, and also did not report any complaints during the follow-up evaluations.

The present study does have some limitations; primarily the small patient group with only female subjects, and the lack of follow-up, as well as the lack of double-blind design. Small patient group may cause a type 2 statistical error. Additionally, a potential bias would have ensued due to the fact that the physician who performed the assessments was not blinded. Nevertheless, our results are noteworthy.

In the light of these results, although sham effect was also important, real acupuncture treatment seems to be more effective in the treatment of FM. Acupuncture significantly improved symptoms of fibromyalgia (pain, depression, fatigue) and quality of life. Also, acupuncture did not have any side effect and was well tolerated. These results must be confirmed in future studies.

**CORRESPONDENCE TO**
Fatma Gülçin Uğurlu
Yıldırım Beyazıt University Medical School, Department of Physical Medicine and Rehabilitation, Bilkent/Ankara
E-mail: glcnrl@hotmail.com

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