

# Fibromyalgia (2023)

## Overview

### Introduction

**Fibromyalgia, also called fibromyalgia syndrome (FMS), is a long-term condition that causes pain all over the body.**

As well as widespread pain, other symptoms of fibromyalgia include:

- increased sensitivity to pain
- muscle stiffness
- difficulty getting to sleep or staying asleep, which can make you feel very tired (fatigue)
- problems with mental processes (known as “fibro-fog”), such as difficulty concentrating or remembering things
- headaches
- irritable bowel syndrome (IBS), a digestive condition that causes stomach pain and bloating
- feelings of frustration, worry or low mood

Fibromyalgia falls into the category of chronic primary pain. Chronic pain refers to pain that persists or recurs for more than 3 months. Chronic primary pain has no underlying condition to adequately account for the pain or its impact.

The definitions of fibromyalgia and chronic primary pain are both from a biomedical understanding of illness. Members of the British Acupuncture Council (BAcC) have trained in one or more traditionally-based systems of acupuncture (TBSA). This means they use the traditional theory to assess all signs and symptoms and develop a treatment strategy. Individuals with a diagnosis of fibromyalgia are likely to receive different treatments: in terms of the acupuncture points used and the auxiliary techniques such as moxibustion and cupping. However, tailoring treatments for individuals can be problematic when it comes to researching the benefits of acupuncture for fibromyalgia.

At present, clinical research indicates that acupuncture reduces pain and improves well-being for those with a diagnosis of fibromyalgia when compared to sham procedures. However, more research is required to establish whether acupuncture is also beneficial for fatigue, sleep, physical function and stiffness. Further research should also be conducted to investigate the benefits of acupuncture compared to other treatment options (See Commentary).

Acupuncture is safe when provided by a properly trained practitioner who adheres to professional codes of conduct and safety. The British Acupuncture Council is an Accredited Register of the [Professional Standards Authority \(PSA\)](#). The PSA protects the public by overseeing the regulation and registration of healthcare professionals. The PSA is accountable to the U.K. parliament.

## Systematic reviews

### **Effect of Acupuncture on Pain, Fatigue, Sleep, Physical Function, Stiffness, Well-Being, and Safety in Fibromyalgia: A Systematic Review and Meta-Analysis (Zheng and Zhou 2022)[1]**

This review analysed the data from 12 studies. All these studies, a total of 715 patients, measured the treatment effect on pain. Four studies, with 357 patients, examined well-being. In these studies, acupuncture was compared to sham acupuncture.

The authors concluded that “Moderate quality of evidence supports acupuncture in reducing pain in patients with fibromyalgia. Therefore, acupuncture is recommended as a treatment for fibromyalgia”.

When compared to sham:

- Acupuncture alleviated pain SMD: -0.42, CI, -0.66, -0.17, P< 0.001
- Improved well-being SMD: -0.86, CI, -1.49, -0.24, P< 0.007

Standardised Mean Difference (SMD) is a way of estimating the effect of a treatment compared to a control or comparison group. By convention, 0.2 is considered a small effect, 0.5 medium and 0.8 large. To give some perspective in the National Institute of Health Care Excellence (NICE) analysis of the evidence of pharmacological management for chronic primary pain (including fibromyalgia), when compared to placebo < 3 months the SMDs were as follows: anti-depressants -0.45; SSRI -0.41; tricyclic antidepressants -0.99, benzodiazepines -0.38 and NSAIDs -0.28 [2].

The Zheng and Zhou 2022 review also analysed the data measuring fatigue, sleep, physical function, and stiffness. Fewer studies measured these outcomes, in each comparison there were fewer than 300 patients. Although acupuncture was superior to sham in most of these comparisons the results were not statistically significant. This means the results could have been due to chance. More research will need to be done before definitive conclusions can be drawn

### **Acupuncture therapy for fibromyalgia: a systematic review and meta-analysis of randomized controlled trials (Zhang et al 2019)[3]**

Like the Zheng and Zhou 2022 study above this review also included 12 studies. There is considerable crossover in the clinical trials analysed in both of these reviews. Zhang et al also showed that acupuncture was better at relieving pain than sham acupuncture.

Similarly, Zhang et al indicates the acupuncture improves the quality of life when compared to sham.

Two of the studies included within this review compared acupuncture to amitriptyline, which is a tricyclic anti-depressant. Both of these studies reported data on pain changes using a visual analogue scale (VAS) 0-10cm. This means that participants mark their pain at a point on a 10 centimetre line, where zero is 'no pain' and the 10 centimetre mark is 'pain as bad as it could possibly be'.

- Acupuncture was superior to amitriptyline by a mean difference -1.81 (-2.43,-1.18).

So a person whose pain reduced by 2 in the amitriptyline group on average would have their pain reduced by 3.81 if they were in the acupuncture group.

### **Comparing Verum and Sham Acupuncture in Fibromyalgia Syndrome: A Systematic Review and Meta-Analysis (Kim et al, 2019)[4]**

This review analysed the data from eight randomised controlled trials. Many of the included studies are the same as those analysed in the systematic reviews described above. "Verum" means real acupuncture (see commentary). In this review, as well as effects on pain and well-being, acupuncture was also shown to improve sleep quality.

The reviewers concluded: Verum acupuncture is more effective than sham acupuncture for pain relief, improving sleep quality, and reforming general status in FMS post treatment. However, evidence that it reduces fatigue was not found.

### **Clinical guidelines**

**NICE: National Institute for Health and Care Excellence, U.K.**

[Chronic pain \(primary and secondary\) in over 16s: assessment of all chronic pain and management of chronic primary pain. NICE guideline \[NG193\], 2021](#) [2]

- Recommends acupuncture for chronic primary pain, this includes fibromyalgia.

**EULAR European Alliance of Associations for Rheumatology**

[EULAR revised recommendations for the management of fibromyalgia](#) [5]

- Recommends acupuncture for fibromyalgia.

**TSPMR: The Turkish Society of Physical Medicine and Rehabilitation**

[The Turkish Society of Physical Medicine and Rehabilitation](#) (TSPMR) guideline recommendations for the management of fibromyalgia syndrome [6]

- Recommends acupuncture for fibromyalgia.

## Other

- [American College of Rheumatology](#) (ACR) state that acupuncture may ease the symptoms of fibromyalgia.
- [John Hopkins Medicine](#) list fibromyalgia as one of the conditions for which studies have shown acupuncture is an effective treatment alone or in combination with conventional therapies to treat.
- An Egyptian [Consensus evidence-based clinical practice recommendations for the management of fibromyalgia](#) recommends acupuncture for fibromyalgia [7].

## Commentary

### Introduction

Acupuncture clinical research can be split into efficacy trials and effectiveness trials. Efficacy trials have a sham/ placebo control group. It is assumed that patients will feel better by going through the process of having a consultation and the 'ritual' of acupuncture. This is often described as the placebo effect. The objective of efficacy trials is to understand the clinical benefits of acupuncture beyond these psychological (placebo) effects. Effectiveness trials compare acupuncture to another form of treatment, for example medication.

### Real or verum acupuncture

In evaluating the evidence base for acupuncture, it is important to assess whether the acupuncture given within clinical trials is similar to that given in practice. If there are differences, this may impact on the conclusions that can be drawn. This is called external validity.

In clinical trials the 'real' acupuncture is often called verum. This is to differentiate it from sham or placebo acupuncture. Two important aspects can be different between acupuncture in practice and clinical trials. These are the points used (points prescription) and the number of treatments given.

### Point prescriptions

In clinical research, the standard approach is to provide the same treatment for each patient in the treatment group. This often means that the same acupuncture points are used for all of those in the acupuncture treatment group. These are known as fixed point protocols. Some clinical trials allow the acupuncturist to choose from a pool of pre-selected acupuncture points. These are semi-fixed protocols. Finally, some clinical trials allow the acupuncturist to select points as they would in normal practice. This is known as 'individualised' acupuncture. Therefore, clinical trials that use fixed point protocols are less like practice than those that use 'individualised' acupuncture; with semi-fixed protocols somewhere in the middle. This means, potentially, the acupuncture delivered in a clinical trial is not as effective as the acupuncture received in practice. Consequently, there may be an underestimation of the benefit of acupuncture.

Very little research has been done to examine whether using individualised acupuncture is more effective than fixed points protocols. The impact of not using individualised acupuncture might be greater when investigating some conditions compared to others. It is possible that clinical trials of acupuncture for fibromyalgia are especially affected by this problem because it is a complicated condition.

A traditional acupuncturist does not base the treatment on the diagnosis of 'fibromyalgia'. They will take a full case history and arrive at a diagnosis using the traditional theory. This diagnosis is called 証 zhèng. Zhèng is usually translated as pattern. Even for conditions where the signs and symptoms are fairly consistent, such as osteoarthritis of the knee, patients can be diagnosed with different zhèng patterns. This means that patients with osteoarthritis of the knee we will get slightly different treatments depending on their overall signs and symptoms.

Fibromyalgia is far more complicated, beside the widespread pain there maybe other significant symptoms such as headaches, tiredness, insomnia, IBS and brain fog. A standard Chinese medicine textbook lists 17 zhèng – patterns associated with headaches, 9 associated with insomnia, and 20 associated with tiredness[8]. Whilst there is some overlap, different acupuncture points will be selected depending on the pattern. In addition, some of these patterns may require the use of moxibustion not just needles. This is a complicated issue and probably can only be fully understood through studying the traditional theories. However, hopefully, the central point is clear:

A fixed-point protocol given to all patients in the acupuncture group of a clinical trial is different to the individualised treatments those patients would receive in practice from a traditional acupuncturist. Consequently, clinical trials may underestimate the clinical benefit of acupuncture.

The systematic reviews of acupuncture for fibromyalgia include many of the same randomised controlled trials (See Overview). Of the 13 studies included in the Zheng and Zhou 2022 review, 7 used standardised acupuncture treatment protocols past 5 used individualised treatments.

### **Number of treatments**

A more straightforward, but profoundly important, aspect of external validity is the number and frequency of treatments given. Clinical trials conducted in China often show acupuncture to be more effective. Some researchers feel that this may be attributed to differences in the cultural acceptance of acupuncture. In other words, Chinese people have a higher expectations therefore there is a stronger 'placebo effect' [9]. However, the reason might be much more mundane. Clinical trials in China generally provide more treatments at a higher frequency.

In the Zheng and Zhou 2022 review 3 of the clinical trials provided less than 10 treatments. A subgroup analysis was done to see if more treatments led to a greater reduction in pain. However, the result was not 'robust'. In other words, more high-quality trials need to be conducted before we can be confident in the results.

High-quality large-scale clinical trials have been conducted into acupuncture for lower back pain, neck pain, shoulder pain and osteoarthritis. Therefore, in this area the results

are more robust than for fibromyalgia. A high-quality systematic review of these four conditions has demonstrated that acupuncture is dose dependent: more treatments lead to a greater reduction in pain [10]. Similarly, a recent systematic review shows more treatments lead to a greater reduction in the severity of depression [11].

Surprisingly, little attention has been paid to the quality of acupuncture provided in clinical trials, even though poor-quality acupuncture may lead to misleading results. Fortunately, things are beginning to change. Relatively recently, a means to evaluate the quality of acupuncture has been developed: the NICMAN scale (National Institute for Complementary Medicine Acupuncture Network) [13]. Evaluating the quality of acupuncture is a complex problem and much more work will need to be done. [Is acupuncture dose dependent? Ramifications of acupuncture treatment dose within clinical practice and trials](#) by Bauer, McDonald and Saunders (2020) [12] provides a good explanation to the issue of number of treatments required.

## Sham acupuncture

Perhaps the most controversial part of acupuncture research is the interpretation of placebo-controlled trials. There is an underlying assumption that placebo sham procedures are inert. However, sham acupuncture procedures are most likely active. Please see [Should systematic reviews assess the risk of bias from sham-placebo acupuncture control procedures?](#) [13]. The active nature of sham procedures will reduce the estimated size of effect. In other words, clinical trials that use sham acupuncture will tend to underestimate the benefits of acupuncture.

## Summary

Zheng and Zhou 2022 concluded:

Moderate quality of evidence supports acupuncture in reducing pain in patients with fibromyalgia. Therefore, acupuncture is recommended as a treatment for fibromyalgia. They also found that acupuncture improved well-being.

but they also stated

No evidence that acupuncture works on fatigue, sleep quality, physical function, or stiffness was found.

In the first statement, 'moderate' refers to the quality of the evidence. If more high-quality large-scale clinical trials are conducted these conducted these could be included in a future systematic review. The evidence would then be stronger.

In the second statement, 'no evidence' does not mean: clinical trials demonstrate acupuncture is not beneficial for fatigue, sleep quality, physical function, or stiffness. It means that the clinical evidence did not produce a statistically significant result. It is harder to achieve a statistically significant result if there is less data available. The more trials and the larger these trials are the better. This is a bit like tossing a coin. If you toss a coin 10 times and it comes up heads seven times, this may be due to chance. However, if you toss a coin 100 times and it comes up head 70 times, we become suspicious that

the coin is fixed in some way. If we toss the coin 1000 times and it comes up heads 700 times, we will be more confident that the coin is fixed.

In the Zheng and Zhou 2022 review data was available for more than 300 participants for two of the six outcome measures: pain and well-being. Both produced statistically significant results in favour of acupuncture. For the other four outcomes data was available for fewer than 300 participants. These did not produce statistically significant results (Table 1).

**Table 1: Fibromyalgia Outcomes**

Outcome	Studies	N - participants	Statistically significant result
<b>Pain</b>	12	715	Yes
<b>Fatigue</b>	4	251	No
<b>Sleep</b>	2	151	No
<b>Physical function</b>	3	268	No
<b>Stiffness</b>	2	104	No
<b>Well-being</b>	4	357	Yes

A table that shows the number of trials and participants for each outcome in the Zheng and Zhou 2022 meta-analysis.

There are several possible explanations:

- absence of evidence – simply not enough clinical trials
- standardised treatments reduce the effectiveness of the acupuncture
- an insufficient number of treatment were given
- active sham procedures underestimate the efficacy of acupuncture
- all, or any combination, of the above
- acupuncture doesn't work for these outcomes

Therefore, it is important that more high-quality clinical trials are conducted to investigate the benefits of acupuncture for those with a diagnosis of fibromyalgia.

## References

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- 2 NICE, Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain, in NICE Guideline NG193. 2021,

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