THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 16, Number 4, 2010, pp. 397–409

DOI: 10.1089/acm.2009.0599

Traditional Chinese Medicine for Treatment of Fibromyalgia: A Systematic Review of Randomized Controlled Trials

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Abstract

Background: Traditional Chinese Medicine (TCM) is popular for treatment of fibromyalgia (FM) although there is a lack of comprehensive evaluation of current clinical evidence for TCM's therapeutic effect and safety.
Objective: To review systematically the beneficial and harmful effects of TCM therapies for FM.
Methods: We searched six English and Chinese electronic databases for randomized clinical trials (RCTs) on TCM for treatment of FM. Two authors extracted data and assessed the trial quality independently. RevMan 5 software was used for data analyses with an effect estimate presented as mean difference (MD) with a 95% confidence interval (CI).
Results: Twenty-five RCTs were identified with 1516 participants for this review. Seven trials (28%) were evaluated as having a low risk of bias and the remaining trials were identified as being as unclear or having a high risk of bias. Overall, ten trials were eligible for the meta-analysis, and data from remaining 15 trials were synthesized qualitatively. Acupuncture reduced the number of tender points (MD, –3.21; 95% CI –4.23 to –2.11; $p < 0.00001$, $I^2 = 0\%$), and pain scores compared with conventional medications (MD, –1.78; 95% CI, –2.24 to –1.32; $p < 0.00001$; $I^2 = 0\%$). Acupuncture showed no significant effect, with a random-effect model, compared with sham acupuncture (MD, –0.55; 95% CI, –1.35–0.24; $p = 0.17$; $I^2 = 69\%$), on pain reduction. A combination of acupuncture and cupping therapy was better than conventional medications for reducing pain (MD, –1.66; 95% CI, –2.14 to –1.19; $p < 0.00001$; $I^2 = 0\%$), and for improving depression scores with related to FM (MD, –4.92; 95% CI, –6.49 to –3.34; $p < 0.00001$; $I^2 = 32\%$). Other individual trials demonstrated positive effects of Chinese herbal medicine on pain reduction compared with conventional medications. There were no serious adverse effects reported that were related to TCM therapies in these trials.
Conclusions: TCM therapies appear to be effective for treating FM. However, further large, rigorously designed trials are warranted because of insufficient methodological rigor in the included trials.

Introduction

Fibromyalgia (FM) is nonspecific rheumatism in which typical symptoms are chronic widespread musculoskeletal pain and stiffness with accompanying fatigue, anxiety, sleep disorder; and/or irritable bowel syndrome.[1] Experts in the United States and Canada have developed diagnostic criteria for identifying this disease for the American College of Rheumatology (ACR),[2] which are also commonly used in China. This disease appears to affect increasing numbers of people, with a disabling outcome on their quality of life (QoL).[3]

As the cause of FM is unknown, it is characterized and diagnosed by its symptoms of chronic widespread pain and multiple tender points associated to some degree of facilitation by the central nervous system.[4] There are two important goals for treating these symptoms.[4] The first goal is reduction of pain, and the second goal is restoring functionality. Many peer-reviewed articles about the treatment of FM have been published involving different pharmacologic agents including nonsteroidal anti-inflammatory drugs (NSAIDs), opioid and nonopioid analgesics, anticonvulsants, antidepressants, α-adrenergic agonists, muscle relaxants, topical agents, local anesthetics, N-methyl-D-aspartate (NMDA) receptor antagonists, and botulinum toxin. None of these medications have proven to be effective for the entire scope of symptoms and disabilities associated with FM.[4] One recent systematic review[5] concluded that antidepressants are associated with

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This is a full-text article of a presentation for the 5th International Congress on Complementary Medicine Research, Tromsø, Norway, May 19–21, 2010.

improvements in pain, depression, fatigue, sleep disturbances, and health-related QoL in people with FM, with large effect sizes for tricyclic and tetracyclic antidepressants (TCAs; standard mean difference [SMD] = –1.64; 95% confidence interval [CI], –2.57 to –0.71). Uceyler et al.[6] came to similar conclusions about amitriptyline. Tofferi et al.[7] suggested that cyclobenzaprine offered some benefit to patients with FM, with 1 of 5 patients experiencing improvements, while Moore et al.[8] showed that pregabalin had proven efficacy for relieving neuropathic pain and FM, although many patients experienced trivial benefit or discontinued treatment because of adverse effects.

Antidepressants have been shown to have some effect, whereas NSAIDs, steroids, and calcitonin have not. Cyclobenzaprine, alprazolam, tramadol, and SAM-e have shown some benefit to patients in small studies.[7] Many medications produce significant sedation and physical dependence as well as causing psychologic dependence.[4]

A systematic review[9] of randomized clinical trials (RCTs) of nonpharmacologic interventions concluded that, although significant differences between groups occurred, the varying combinations of intervention in the studies studies and the wide range of outcome measures used made it hard to form clear conclusions across studies. The interventions included education, relaxation therapy, cognitive–behavioral therapy, acupuncture, and hydrotherapy, and there was some preliminary support for aerobic exercise.

In Traditional Chinese Medicine (TCM) theory, FM is mainly caused by emotional upsets, which affect the Liver. Stagnation of *qi* activity leads to the stasis of Blood, which causes pain. The principle of treatment is regulating the *qi* and Blood, combined with dispelling Cold and removing Damp.[10] TCM is a whole system that uses a range of therapies to treat FM; these include acupuncture, moxibustion, herbal medicine, and massage. Two systematic reviews have suggested that acupuncture alone is effective for treating FM; one analysis involved three RCTs and four cohort studies and the other analysis included three positive RCTs and two negative RCTs.[11,12] No systematic review reported the effect of herbal medicine or other TCM therapies for FM, but a review published in 2005[13] suggested that "many of the herbs and other dietary supplements used by our patients are known to have potential adverse effects and may pose a risk to the patient." This current systematic review aims to update the evidence from RCTs to evaluate the therapeutic effect and safety of TCM, including Chinese herbal medicine for FM.

Methods

Inclusion Criteria

We included parallel-group RCTs of any kind of TCM treatment, including acupuncture, herbal medicine, massage, and/or cupping compared with no treatment, placebo, and/or conventional medication in patients with FM. We also included combined therapy with TCM and other interventions compared with other interventions in RCTs, or combined therapy of two kinds of TCM compared with medication or other interventions. FM was diagnosed according to recognized criteria. Outcome measures included reduction in severity of pain or depression, improvement of QoL, and reduction of relapse rate. When multiple publications reported the same groups of participants, we only included the primary publication and excluded the duplicated publications. There was no limitation on language and publication type.

Identification and selection of studies

We searched the China Network Knowledge Infrastructure (CNKI; 1979–2009), Chinese Scientific Journal Database VIP (1989–2009), Wan Fang Database (1985–2009), Chinese Biomedicine (CBM) database (1978–2009), PubMed (1966–2009) and Cochrane Library (Issue 3, 2009). All searches ended at August 2009. The search terms included fibromyalgia, fibrosis, fibrositis, myofascitis, ormyofibrositis, combined with traditional Chinese medicine, TCM, herbal, acupuncture, massage, cupping, or Tui Na. Two authors (Cao H and Liu JP) selected studies for eligibility and checked against the inclusion criteria independently.

Data extraction and quality assessment

Two authors (Cao H and Liu JP) extracted the data from the included trials independently. The methodological quality for RCTs was assessed, using criteria from the *Cochrane Handbook for Systematic Reviews of Interventions, Version 5.0.1*.[14] The quality of trials was categorized into low risk of bias, unclear risk of bias, or high risk of bias according to the risk for each important outcome within included trials, including adequacy of generation of the allocation sequence, allocation concealment, blinding, whether there were incomplete outcome data ("Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group [compared with total randomized participants], reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors"),[14] or selective outcome, or other sources of bias.

Data analysis

Data were summarized using risk ratio (*RR*) with 95% CIs for binary outcomes or mean difference (MD) with a 95% CI for continuous outcomes. We used Revman 5.0.2 software from the Cochrane Collaboration for data analyses. Meta-analysis was used if the trials had acceptable homogeneity of study design, participants, interventions, controls, and outcome measures. Statistical heterogeneity was tested by examining I^2square[15] or p-value; an $I^2 > 50\%$ or a p-value < 0.1 indicates the possibility of statistical heterogeneity. Both a fixed-effect model and a random-effects model were used if there was a possibility of statistical heterogeneity among the trials. If the I^2 was $<50\%$, or the p-value was >0.1, only a fixed-effect model was used for meta-analysis. Publication bias was explored via a funnel-plot analysis.

Results

Description of studies

After primary searches in six databases, 883 citations were identified.The majority was excluded because of obvious ineligibility, and full-text papers of 35 studies were retrieved. Finally, 25[16–38] randomized trials were included in this review, two trials[39,40] were excluded as duplicated publications, and eight trials[41–48] were excluded because the

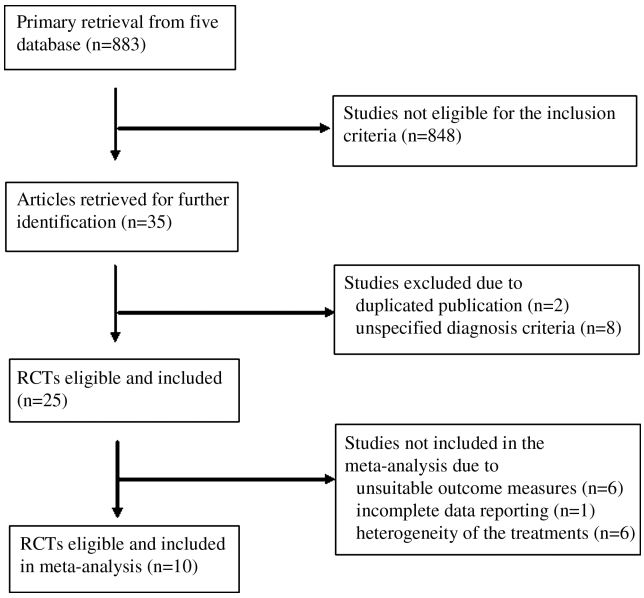

FIG. 1. Study enrollment process. RCTs, randomized controlled trials.

diagnosis criteria were not specified (Fig. 1). The characteristics of included trials are listed in Table 1. Of the included trials, two were unpublished postgraduate student dissertations.*,†

The twenty-five RCTs involved a total of 1516 patients with FM. The participants were ages 17–77, and the disease duration was from 3 months to 20 years. Twenty-three trials used ACR 1990 as the diagnostic criteria, one trial[31] used the International Academy of Soreness Research (IASR)[53] for diagnosing FM, and one trial[26] made diagnoses according to the subjects' symptoms. The interventions included acupuncture (electroacupuncture, auricular acupuncture), cupping, herbal medicine (decoctions, capsules, and external preparations), massage, moxibustion, and combinations of acupuncture and cupping, or acupuncture and herbal medicine. The controls included no treatment, sham acupuncture, or conventional medications. The treatment duration ranged from 12 days to 12 weeks. Changes in visual analogue scale (VAS) scores as the major outcome measurement were reported in 15 trials. Seven trials[18,23,27,31,33,34,†] calculated the change of number of tender points, and used the McGill Pain Questionnaire (MPQ), Present Pain Intensity (PPI), or Fibromyalgia Impact Questionnaire (FIQ) for assessing intensity of pain. Four trials[20,25,28,*] used the Hamilton Depression Scale (HAMD) or Hamilton Anxiety Scale (HAMA) to assess depression or anxiety. Three trials[16,24,34] used the Short-Form–36 (SF-36) and QoL scale (QoLS) for measuring QoL. Six trials used four categories to evaluate treatment effects including cure (symptoms disappeared and no tender points existed), markedly effective (symptoms reduced more than >50%), effective/reduced (symptoms reduced between 25% and 50%), and ineffective (symptoms reduced <25%). The combined rates of the markedly effective and effective treatments were used to calculate a total effective rate, which was the main outcome measure in some trials.

Methodological quality

According to our predefined quality assessment criteria, seven [16,19,24,28,32,34,†] of the 25 trials (28%) were evaluated as having a low risk of bias, and another 18 included trials were evaluated as having an unclear risk of bias (Table 2). The sample size varied from 10 to 38 participants, with an average of 25 patients per group. None of the trials reported prior sample-size calculation, 11 trials[16,19,21,24,25,28,32,34,35,37] described randomization procedures (using a random number table, computer generation of random numbers, or a drawing), but only two trials[19,24] reported adequate allocation concealment. Four trials[19,24,32,34] blinded both patients and outcome assessors, one trial[16] only blinded patients, and three trials[28,33,*] blinded the outcome assessors. Nine trials[16,17,19,21,24,28,32,34,*] reported the number of dropouts, and three trials[16,32,34] used intention-to-treat analysis.

Effect estimates (Table 3)

Therapeutic effect of acupuncture. Twelve trials[16,19,22–24,26,31–34,38,†] tested acupuncture for treating FM. Six trials [16,19,24,26,32,33] compared acupuncture or electroacupuncture with sham acupuncture or sham electroacupuncture, and another six trials[22,23,31,34,38,†] compared acupuncture with conventional medications.

A pooling analysis of four trials[16,19,24,32] showed a significant effect of acupuncture compared to sham acupuncture for reducing pain according to VAS scores after treatment (MD, –1.24; 95% CI, –1.47 to –1.01; $p < 0.00001$). However, this effect became nonsignificant (MD, –0.55; 95% CI, –1.35–0.24, $p = 0.17$) when using a random-effects model because of significant heterogeneity ($I^2 = 69\%$). Three trials[23,31,†] compared acupuncture with conventional medications, and the pooling results showed that acupuncture was significantly better than conventional medications for reducing pain (MD, –1.78; 95% CI –2.24 to –1.32, $p < 0.00001$; $I^2 = 0\%$) and number of tender points (MD, –3.21; 95% CI, –4.23 to –2.11; $p < 0.00001$; $I^2 = 0$ %).

Two trials[22,23] reported the relapse rate after 6 months, suggesting that acupuncture (including transcutaneous electrical nerve stimulation [TENS] and electroacupuncture) was significantly better than amitriptyline for preventing relapse (*RR* 0.28; 95% CI, 0.11–0.67; $p = 0.005$; $I^2 = 0\%$).

Data from four trials[26,33,34,38] were not included in the meta-analysis because of poor reporting. The main findings of those trials are presented in Table 4.

As a result of the insufficient number of included trials in one meta-analysis, a meaningful funnel plot analysis was not feasible.

Therapeutic effect of herbal medicine. Six trials[20,21,25,30,36,37] tested herbal medicine against Western medicine for FM. Three trials[20,36,37] tested herbal decoctions, two trials[25,30] tested a Chinese patent medicine, and one trial[21]

*Fu XY, Li CD. Clinical randomized controlled trial on combination of acupuncture, cupping and medicine for treatment of fibromyalgia syndrome [dissertation for Master's degree from Chengdu University of Traditional Chinese Medicine, Chengdu, China]. 2004.

†Guo Y, Sun YZ. Clinical observation of therapeutic effect of penetration needling at the back in treating with fibromyalgia syndrome [dissertation for Master's degree from Heilongjiang University of Traditional Chinese Medicine, Heilongjiang, China]. 2005.

Table 1. Characteristics of Included Studies

Lead author, year, & Ref. #	*Diagnostic criteria*	*Sample Size (Rx/C)*	*Age (yr, Rx/C)*	*Duration of disease (m, Rx/C)*	*Experimental intervention*	*Control intervention*	*Duration of treatments*	*Outcomes*
Assefi NP 2005[16]	ACR 1990	25/24	46 ± 11/49 ± 14	72/84	Acupuncture, 2X/week	Sham acupuncture (false acupoints) 2X/week	12 weeks	VAS, SF-36
		25/23	46 ± 11/48 ± 10	72/84		Sham acupuncture (not insertion) 2X week		
Brattberg G 1999[17]	ACR 1990	11/12	48 ± 12.4	Unclear	Connective tissue massage 15X during 10 weeks	No treatment	10 weeks	VAS, DRI, HAD, FIQ, QoLS, mean value for 10 questions about sleep
		16/13			Connective tissue massage 15X during 10 weeks	Discussion 1X/week		
Cao JY 2003[18]	ACR 1990	28/28	42.1 ± 14.5	19.3 ± 15.1	Acupuncture + cupping therapy 3X/day, seroxat, 20 mg/day	Seroxat, 20 mg/day	4 weeks	HAMD, VAS, number of tender points
Deluze C 1992[19]	ACR 1990	36/34	46.8 ± 2.3/49 ± 2	172.8 ± 40.8/ 82.8 ± 15.6	Electroacupuncture 1X/day for 6 sessions	Sham electroacupuncture (false acupoints) 1X/day for 6 sessions	3 weeks	VAS, Sleep Quality
Fu HW 2006[20]	ACR 1990	21/21	36.2 ± 7.82/ 35.92 ± 10.28	7–36	Herbal medicine, (decoction) 200 mL 2X/day	Amitriptyline hydrochloride, 25–50 mg/night	12 weeks	HAMA, HAMD, scores for reduction of symptoms
Fu XY 2004[a]	ACR 1990	33/33	39.16/39.1	Unclear	Acupuncture 30 min, 1X/daiy + cupping therapy 5 min, 1X every 2 days	Amitriptyline, 25mg 2X/day	2 weeks	MPQ, PPI, HAMD
Gao GM 2007[21]	ACR 1990	30/28	32 ± 13/31 ± 12	2.5 ± 1.9/2.3 ± 1.8	Flavone of *Rhizoma Drynariae*, 0.25 g 3X/day	Meloxicam, 7.5mg 1X/day	12 weeks	FIQ, Zung Self-rating Depression Scale, Scores of Index of Pain
		30/29	32 ± 13/ 33 ± 14	2.5 ± 1.9/2.4 ± 1.6	Flavone of *Rhizoma Drynariae*, 0.25g 3 X/day	Meloxicam, 7.5 mg + amitriptyline 12.5–50mg 1X/day		
		28/29	30 ± 11/33 ± 14	2.3 ± 2.1/2.4 ± 1.6	Flavone of *Rhizoma Drynariae*, 0.25 g 3X/day + amitriptyline, 12.5—50 mg 1X/day	Meloxicam, 7.5 mg + amitriptyline, 12.5–50 mg 1X/day		
		27/29	32 ± 10/33 ± 14	2.4 ± 1.9/2.4 ± 1.6	Flavone of *Rhizoma Drynariae*, 0.25g 3X/day, meloxicam, 7.5 mg + amitriptyline, 12.5–50 mg 1 X/day	Meloxicam, 7.5mg + amitriptyline 12.5–50 mg 1X/day		
Guo XJ 2003[22]	ACR 1990	22/22	50 ± 3.1/51 ± 1.9	10 ± 3.6/ 11 ± 1.9	TENS[c] 30 min 1X/day	Oryzanol, 30 mg, vitamin B_1, 30 mg 3X/day + amitriptyline, 10–30 mg/night	45 days	Reduction of symptoms, effectiveness rate
		22/22	49 ± 6.7/51 ± 1.9	11 ± 2.4/ 11 ± 1.9	Electroacupuncture,[c] 30 min 1 X/day	Oryzanol, 30 mg, vitamin B_1, 30 mg 3 X/day + amitriptyline, 10–30 mg/night		
Guo Y 2005[23]	ACR 1990	19/19	50 ± 2.9/ 49 ± 3.4	11 ± 2.3/10 ± 3.6	Acupuncture 30 min 1X/day	Amitriptyline 10–30 mg 2X/day	30 days	VAS, number of tender points
Guo Y 2005[b]	ACR 1990	20/20	50 ± 7.1/ 49 ± 7.3	11 ± 2.5/10 ± 2.1	Acupuncture 30 min 1X/day	Amitriptyline, 10-30mg twice daily	30 days	VAS, number of tender points

Harris RE 2005[24]	ACR 1990	29/28	46 ± 10.1/ 51.3 ± 10.0	66 ± 44.52/ 62.04 ± 50.88	Acupuncture on traditional site with stimulation 20 min 1–3X/week	Acupuncture on nontraditional site with stimulation, 20 min 1–3X/week	9 weeks	Numeric Rating Scale NRS, Multi-Dimensional Fatigue Inventory questionnaire, RC, SF-36
		30/27	44.5 ± 10.9/ 48.1 ± 10.9	63.12 ± 57.96/ 69.24 ± 49.2	Acupuncture on traditional site without stimulation, 20 min 1–3X/week	Acupuncture on nontraditional site without stimulation, 20 min 1–3X /week		
Jiang F 2004[25]	ACR 1990	10/10	38 ± 11/35 ± 11	48 ± 36/48 ± 48	*Baishao Zongdai* capsule, 0.6 g 3X/day, amitriptyline hydrochloride 25–50 mg/night + usual care	Amitriptyline hydrochloride 25–50 mg/night + usual care	12 weeks	VAS, HAMA, HAMD, SCL-90
		10/10	40 ± 9/37 ± 10	60 ± 60/60 ± 48	*Baishao Zongdai* capsule, 0.6 g 3X/day, mirtazapine 7.5–15mg, amitriptyline hydrochloride, 25–50 mg/ night + usual care	Mirtazapine, 7.5–15 mg, amitriptyline hydrochloride, 25–50 mg/night + usual care		
Lautenschlager J 1989[26]	Clinical symptoms	25/25	Unclear	Unclear	Electroacupuncture	Sham acupuncture with disconnected laser equipment	Unclear	VAS
Li AL 2004[27]	ACR 1990	28/30	46.8	27.6	Herbal decoction 150 mL 2X/day plus acupuncture 20 min 1X/day	Amitriptyline 50 mg, 2X/day	15 days	Self-rating scores of pain, sleep disorder, fatigue, etc., scores of product of number of tender points and pain intensity
Li CD 2006[28]	ACR 1990	33/33	38.26/39.10	Unclear	Acupuncture 30 min + cupping therapy 5 min 1X/day, amitriptyline 25mg twice daily	Amitriptyline, 25 mg 2X/day	12 days	MPQ, HAMD
Li J 2005[29]	ACR 1990	23/23	40 ± 2/40 ± 1.8	36 ± 6/36 ± 5.4	Acupuncture[c] 30 min + computerized intermediate frequency (electromagnetic wave) treatment 20 min 1X/day	Amitriptyline, 25 mg/night	30 days	Effective rate calculated according to VAS and reduction of symptoms
Liu JZ 2002[30]	ACR 1990	34/30	31 ± 4.3/30 ± 4.5	24 ± 6/24 ± 9.6	*Zheng Qing Feng Tong Ning* Tablet 40–60 mg 3 X/day + usual care	Doxepin 25 mg/ night + usual care	8 weeks	Effective rate calculated according to product of number of tender points and pain intensity andreduction of symptoms
Liu Q 2002[31]	IASR	30/30	29–68/31–69	45.6 ± 16.8/ 46.8 ± 14.4	Acupuncture with heavy manual stimulation 6 min 1X/day	Ibuprofen, 0.3 g 3X/day	2 weeks	VAS, number of tender points
Martin DP 2006[32]	ACR 1990	25/25	51.7 ± 14.1/ 47.9 ± 11.2	Unclear	Electroacupuncture, 20 min 1X every 2–4 days	Sham electroacupuncture (not insertion) 20 min 1X every 2 –4 days	2–3 weeks	FIQ, MPI

(*continued*)

Table 1. (Continued)

Lead author, year, & Ref. #	*Diagnostic criteria*	*Sample Size (Rx/C)*	*Age (yr, Rx/C)*	*Duration of disease (m, Rx/C)*	*Experimental intervention*	*Control intervention*	*Duration of treatments*	*Outcomes*
Sprott H 1998[33]	ACR 1990	10/10	55	Unclear	Electroacupuncture on points according to TCM 2X/week + basic therapy	Sham acupuncture disconnected laser equipment plus basic therapy	3 weeks	Number of tender points, VAS
		10/10			Basic therapy with no puncture treatment			
Targino RA 2008[34]	ACR 1990	34/24	52.09 ± 10.97/ 51.17 ± 11.20	118.8 ± 117.3/ 93 ± 75.25	Acupuncture 20 min 2X/week + tricyclic antidepressants 12.5–75 mg 1X/day, exercise 2X/week	Tricyclic antidepressants, 12.5–75 mg 1X/day + exercise 2X/week	10 weeks	VAS, number of tender points below 4 kg/cm^2, mean PPT, SF-36
Wang CM 2008[35]	ACR 1990	28/28	44.3	Unclear	Acupuncture 20 min + laser radiation on tender points 3 min 1X/day	Amitriptyline, 10 mg 2X/day	20 days	VAS
Yang HB 2008[36]	ACR 1990	38/38	46.8	27.6	Herbal decoction, 20 mL 2X/daydaily + psychologic treatment	Indometacin, 75 mg 1X/day + carbamazepine, 0.2 mg 3X/day	8 weeks	Effective rate calculated according to reduction of symptoms
Yang TG 2007[37]	ACR 1990	33/17	38.2 ± 8.29/ 36.7 ± 10.13	39.36 ± 16.32/ 47.64 ± 17.76	Herbal decoction (*Jiawei Xiaoyao* powder), 100 mL 2X/day	Amitriptyline, 25 mg, and ibuprofen sustained release capsules, 1 grain 2X/day	4 weeks	VAS, effective rate calculated according to reduction of symptoms
Zhang YG 2001[38]	ACR 1990	34/30	36	30	Acupuncture 30 min 1X/day	Amitriptyline, 25 mg/night	30 days	Effective rate calculated according to reduction of symptoms

[a]Fu XY, Li CD. Clinical randomized controlled trial on combination of acupuncture, cupping and medicine for treatment of fibromyalgia syndrome [dissertation for Master's degree from Chengdu University of Traditional Chinese Medicine, Chengdu, China]. 2004.

[b]Guo Y, Sun YZ. Clinical observation of therapeutic effect of penetration needling at the back in treating with fibromyalgia syndrome [dissertation for Master's degree from Heilongjiang University of Traditional Chinese Medicine, Heilongjiang, China]. 2005.

[c]Selection of the acupoints according to Syndrome Differentiation.

±represents plus/minus standard deviation (for age and duration of disease).

m/f, male /female; Rx/C, experimental group/control group; m, months; ACR 1990, American College of Rheumatology 1990 criteria for classifying fibromyalgia; VAS, visual analogue scale; SF-36, Short Form–36; DRI, Disability Rating Index; HAD, Hospital Anxiety and Depression Scale; FIQ, Fibromyalgia Impact Questionnaire; QoLS, Quality of Life Scale; HAMD, Hamilton Depression Scale; HAMA, Hamilton Anxiety Scale; MPQ, McGill PainQuestionnaire; PPI, present pain intensity; TENS, transcutaneous electrical nerve stimulation; NRS, Numeric Rating Scale; SCL-90,RC, reliability of change; IASR, International Academy of Soreness Research; SCL-90, symptom checklist 90; TCM, Traditional Chinese Medicine; MPI, Multidimensional Pain Inventory; PPT, pain pressure threshold.

Table 2. Assessing Risk of Bias of Included Trials

Lead author, year & ref. #	*Sequence generation*	*Allocation concealment*	*Blinding of participants, personnel, and outcome assessors*	*Incomplete outcome data*	*Selective outcome reporting*	*Other sources of bias*	*Risk of bias*
Assefi NP 2005[16]	Computer-generated, blocked random-allocation sequence with a block size of 4	Unclear	Blinded to patients	No	No	No	Low risk of bias
Brattberg G 1999[17]	Unclear	Unclear	Not mentioned	No	No	No	Unclear risk of bias
Cao JY 2003[18]]	Unclear	Unclear	Unclear	No	No	No	Unclear risk of bias
Deluze C 1992[19]	Electronic numbers generator	Closed envelopes	Blinded to patients and outcome assessors	No	No	No	Low risk of bias
Fu HW 2006[20]	Unclear	Unclear	Unclear	No	No	No	Unclear risk of bias
Fu XY 2004[a]	Table of random numbers	Unclear	Blinded to outcome assessors	No	No	No	Low risk of bias
Gao GM 2007[21]	Table of random numbers	Unclear	Unclear	No	No	No	Unclear risk of bias
Guo XJ 2003[22]	Unclear	Unclear	Unclear	No	No	No	Unclear risk of bias
Guo Y 2005[23]	Unclear	Unclear	Unclear	No	No	No	Unclear risk of bias
Guo Y 2005[b]	Unclear	Unclear	Unclear	No	No	No	Unclear risk of bias
Harris RE 2005[24]	Computer-generated random numbers in a four-block design	Closed envelope	Blinded to patients and outcome assessors	No	No	No	Low risk of bias
Jiang F 2004[25]	Draw cast	Unclear	unclear	Yes (SD_{final})	No	No	Unclear risk of bias
Lautenschlage 1989[26]	Unclear	Unclear	Blinded to patients	Yes (SD)	No	No	Unclear risk of bias
Li AL 2004[27]	Unclear	Unclear	Unclear	No	No	No	Unclear risk of bias
Li CD 2006[28]	Table of random number	Unclear	Blinded to outcome assessors	No	No	No	Low risk of bias
Li J 200529	Unclear	Unclear	Unclear	Yes (VAS scores)	No	No	Unclear risk of bias
Liu JZ 2002[30]	Unclear	Unclear	Unclear	Yes (continuous data)	No	No	Unclear risk of bias
Liu Q 2002[31]	Unclear	Unclear	Unclear	No	No	No	Unclear risk of bias
Martin DP 2006[32]	In blocks of 4	Unclear	Blinded to patients and outcome assessors	No	No	No	Low risk of bias
Sprott H 1998[33]	Unclear	Unclear	Blinded to outcome assessors	Yes (SD of number of tender points)	No	No	Unclear risk of bias
Targino RA 2008[34]	Computer-generated	Unclear	Blinded to patients and outcome assessors	No	No	No	Low risk of bias
Wang CM 2008[35]	Draw cast	Unclear	Unclear	No	No	No	Unclear risk of bias
Yang HB 2008[36]	Unclear	unclear	Unclear	No	No	No	Unclear risk of bias
Yang TG 2007[37]	Table of random number	unclear	Unclear	No	No	No	Unclear risk of bias
Zhang YG 2001[38]	Unclear	Unclear	Unclear	No	No	No	Unclear risk of bias

[a]Fu XY, Li CD. Clinical randomized controlled trial on combination of acupuncture, cupping and medicine for treatment of fibromyalgia syndrome [dissertation for Master's degree from Chengdu University of Traditional Chinese Medicine, Chengdu, China]. 2004.

[b]Guo Y, Sun YZ. Clinical observation of therapeutic effect of penetration needling at the back in treating with fibromyalgia syndrome [dissertation for Master's degree from Heilongjiang University of Traditional Chinese Medicine, Heilongjiang, China]. 2005.

SD_{final}, standard deviation at the end of the treatment SD, standard deviation; VAS, visual analogue score SD, standard deviation.

Table 3. Estimated Effect of Included Trials in Meta-Analyses

Lead author, year and ref. #	*Interventions*	*Estimate effects*	*Weight*	*p-value*
1. VAS scores after treatment				
1.1 Therapeutic effect of acupuncture				
1.1.1 Acupuncture versus sham acupuncture				
Assefi NP 2005[16]	Acupuncture versus sham acupuncture on false acupoints	0.10 [–1.19, 1.59]	13.67%	
Assefi NP 2005[16]	Acupuncture versus sham acupuncture without insertion	–0.30 [–1.64, 1.04]	13.18%	
Deluze C 1992[19]	Electroacupuncture versus sham electroacupuncture on false acupoints	–1.39 [–1.64, –1.14]	35.09%	
Harris RE 2005[24]	Acupuncture on traditional site versus acupuncture on nontraditional site	–1.30 [–2.07, 0.10]	13.01%	
Harris RE 2005[24]	Acupuncture on traditional site with stimulation versus acupuncture on nontraditional site with stimulation	0.92 [–0.59, 2.43]	11.70%	
Martin DP 2006[32]	Electroacupuncture versus sham electroacupuncture without insertion	–0.70 [-2.06, 0.66]	13.34%	
	Overall (FEM, $I^2 = 69\%$)	**MD –1.24 [–1.47, –1.01]**	**100%**	**<0.00001**
	Overall (REM, $I^2 = 69\%$)	**MD –0.55 [–1.35, 0.24]**	**100%**	**0.17**
1.1.2 Acupuncture versus conventional medications				
Guo Y 2005[23]	Acupuncture versus amitriptyline	–1.71 –2.39, –1.03]	39.69%	
Guo Y 2005[a]	Acupuncture versus amitriptyline	–1.66 [–2.97, –0.35]	21.63%	
Liu Q 2002[31]	Acupuncture versus ibuprofen	–1.90 [–2.61, –1.19]	38.68%	
	Overall (FEM, $I^2 = 0\%$)	**MD –1.78 [–2.24, –1.32]**	**100%**	**<0.00001**
1.2 Combination of acupuncture and cupping therapy + conventional medications versus medications alone				
Cao JY 2003[18]	Acupuncture + cupping therapy and seroxat versus seroxat alone	–1.63 [–2.18, –1.08]	44.62%	
Li CD 2006[28]	Acupuncture + cupping therapy and amitriptyline versus amitriptyline	–1.77 [-2.74, 0.80]	55.38%	
	Overall (FEM, $I^2 = 0\%$)	**MD –1.66 [–2.14, 1.19]**	**100%**	**<0.00001**
2. # of tender points after treatment				
Therapeutic effect of acupuncture				
Guo Y 2005[23]	Acupuncture versus amitriptyline	–4.00 [–6.73, –1.27]	16.4%	
Guo Y 2005[a]	Acupuncture versus amitriptyline	–3.30 [–6.02, –0.58]	16.5%	
Liu Q 2002[31]	Acupuncture versus ibuprofen	–3.00 [–4.35, –1.65]	67.1%	
	Overall (FEM, $I^2 = 0\%$)	**MD –3.21 [–4.23, –2.11]**	**100%**	**<0.00001**
3. HAMD scores after treatment				
Combination of acupuncture and cupping therapy + conventional medications versus conventional medications alone				
Cao JY 2003[18]	Acupuncture plus cupping therapy and seroxat versus seroxat alone	–6.00 [–8.36, –3.64]	44.62%	
Li CD 2006[28]	Acupuncture plus cupping therapy and amitriptyline versus amitriptyline	–4.04 [–6.16, –1.92]	55.38%	
	Overall (FEM, $I^2 = 32\%$)	**MD –4.92 [−6.49, –3.34]**	**100%**	**<0.00001**
4. Relapse rate after 6 months of treatment				
Acupuncture versus conventional medications				
Guo XJ 2003[22]	TENS versus oryzanol, vitamin B_1, and amitriptyline	0.30 [0.06, 1.44]	32.6%	
Guo XJ 2003[22]	Electroacupuncture versus oryzanol, vitamin B_1 and amitriptyline	0.30 [0.06, 1.44]	32.6%	
Guo Y 2005[23]	Acupuncture versus amitriptyline	0.24 [0.05, 1.03]	34.7%	
	Overall (FEM, $I^2 = 0\%$)	***RR* 0.28 [0.11, 0.67]**	**100%**	**0.005**

[a]Guo Y, Sun YZ. Clinical observation of therapeutic effect of penetration needling at the back in treating with fibromyalgia syndrome [dissertation for Master's degree from Heilongjiang University of Traditional Chinese Medicine, Heilongjiang, China]. 2005.

VAS, visual analogue scale; FEM, fixed effect model; MD, mean difference; REM, random effect model; HAMD; Hamilton Depression Scale; TENS, transcutaneous electrical nerve stimulation; *RR*, risk ratio.

tested active components of an herbal medicine. As a result of the variation of herbal medicines, the data were not combined. The main findings of the six trials are presented in Table 4.

Therapeutic effect of massage. Only one small trial[17] tested massage for treatment of FM and showed no significant difference between "connective tissue" massage and no treatment for reducing pain according to VAS scores after treatment (MD, –0.58; 95% CI, –1.76–0.60; $p = 0.34$).

Therapeutic effect of combination therapies of TCM. Six trials[17,27–29,35,*] tested the therapeutic effect of combination TCM therapies for treating FM. Three trials[18,28,*] compared acupuncture plus cupping therapy with medications, one trial[29] compared acupuncture plus computerized intermediate frequency treatment with amitriptyline, one trial[35] compared acupuncture plus laser treatment with amitriptyline, and one trial[27] compared acupuncture plus herbal medicine with Western medications.

Two trials[18,28] showed that a combination of acupuncture and cupping therapy plus medications was significantly better than conventional medications alone for reducing pain (MD, –1.66, 95% CI, 2.14 to –1.19, $p < 0.00001$, $I^2 = 0\%$) and HAMD scores (MD, –4.92, 95% CI, –6.49 to –3.34, $p < 0.00001$, $I^2 = 32\%$).

Four trials[27,29,35,*] were not included in the meta-analysis as a result of the data being unavailable. The main findings of these trials are presented in Table 4.

Adverse effects. An outcome of adverse events was described in 11 trials.[16,20,21,25,27,29,30,34,36,*,†] Adverse effects from eight trials[16,21,25,29,30,34,*,†] were related to TCM therapies, including four[16,29,34,†]related to acupuncture, three to herbal medicine, and one* to cupping therapy. The adverse effects of acupuncture were bruising, nausea, fainting, discomfort at the sites of needle insertions or simulated needle insertions, and temporary edema of the hand. Nausea, fainting, dry mouth, bimalleolar edema, and skin rash were reported as adverse effects of herbal medicines. One trial* reported that 1 patient had mild scalding on the skin after being included in a cupping group ($n = 33$).

Lethargy, nausea, fainting, dry mouth, fatigue, blurred vision, hyperhydrosis, and constipation were reported adverse effects of conventional medications.

No serious adverse event was reported in any of the included trials.

Discussion

The data from the 25 RCTs that were analyzed demonstrate that, acupuncture, acupuncture combined with cupping therapy, or acupuncture combined with cupping and conventional medication were significantly more effective than conventional medication alone for reducing pain and number of tender points in subjects with FM. The therapeutic effect of acupuncture appears to be similar to sham acupuncture for pain reduction, but more data are needed to prove this finding. The therapeutic effects of herbal medicine and massage are uncertain due to limited numbers of clinical trials.

There are several limitations in this review. The quality of the included studies is generally poor, which indicates an unclear risk of bias resulting from insufficient reporting of methodological components in the trials. There were unclear descriptions of randomization procedures and lack of blinding in the majority of trials, which may have created potential performance biases and detection biases, as patients and researchers might have been aware of the therapeutic interventions. Intention-to-treat analysis was not applied in most of the included trials, and although it was not possible to perform a meaningful funnel-plot analysis because of the insufficient number of included trials in the meta-analysis, there remained the possible existence of publication bias. To the ability to perform meta-analysis was limited because of the heterogeneity of the interventions among the included trials and the variance of composite outcome measures used in 15 of the included trials. This was particularly relevant to the outcome classifications as *cure, markedly effective, effective or ineffective,* which were used in six trials and but was not validated; thus the findings were hard to interpret. Consequently, interpretation of these positive findings should be cautious, and the study methodology needs to be improved for future confirming studies.

The searches conducted in the present study identified four systematic reviews of acupuncture for treating FM. The latest one[50] published in 2009 included only six trials, which were all included in this systematic review. In this systematic review five high-quality trials compared acupuncture with sham acupuncture, which may not be appropriate as a placebo against which to evaluate the therapeutic effect of real acupuncture.[51] There were 12 trials evaluating acupuncture for FM in this review, but only two of them used syndrome-differentiation for acupuncture-point selection. The data suggesting that acupuncture is effective for FM should be taken as being tentative and further randomized trials are warranted. Control interventions in such trials should be carefully selected, as, at the present time, there is not a proper "acupuncture placebo."

Nine of the included trials[16,17,22,23,25,32–34,38] reported the results of follow-up. One trial[34] followed all the patients for 2 years, reporting that the acupuncture group was significantly better than the control group with respect to numbers of tender points after 6 months, but, at 2 years, noting that there was no significant difference in any outcomes. One trial[32] followed all patients for 7 months and showed no difference between acupuncture and sham acupuncture for pain reduction. Assefi et al.[16] followed all patients for 6 months, suggesting that the observed effect was probably driven by the higher mean score in the simulated-acupuncture group compared with the sham-needling group. Another trial[17] followed patients for up to6 months and showed no statistically significant differences between massage and no treatment for the tested parameters at 3 and 6 months. Two trials[22,23] followed the patients for 6 months, suggesting that acupuncture was significantly better than amitriptyline for preventing relapse after treatment, although the number of patients who were followed was too small for substantial statistical analysis. There is no evidence for a long-term effect of herbal medicine or cupping therapy.

Most of the existing trials are of small size and have an unclear risk of bias or a high risk of bias. Further rigorously designed trials are needed to confirm the effectiveness of TCM therapy for treating FM. Randomization methods need to be described clearly and reported fully. Although blinding of patients and practitioners might be very difficult for

Table 4. Characteristics of Randomized Controlled Trials outside Meta-Analysis

Lead author, year & ref. #	*Comparisons*	*Main findings*
Acupuncture versus sham acupuncture		
Lautenschlager J 1989[26]	Acupuncture versus sham laser acupuncture	Significant difference between acupuncture and sham treatment in pain reduction measured by all 3 methods by end of treatment. At follow-up of 3 months after last treatment, no significant changes were observed ($p > 0.05$).
Sprott H 1998[33]	Acupuncture versus sham laser acupuncture	Data for pain reduction by tender points were not completely reported, but # of tender points was not significantly decreased after acupuncture treatment, compared to sham treatment ($p > 0.05$). Intensity of pain, measured by VAS, was not significantly reduced, neither immediately at end of treatment or 2 months after treatment ($p > 0.05$).
Acupuncture versus no treatment		
Sprott H 1998[33]	Acupuncture versus no treatment	# of tender points was significantly decreased after acupuncture treatment, compared to no treatment ($p > 0.05$).
Acupuncture versusconventional medication		
Zhang YG 2001[38]	Acupuncture versus amitriptyline	No significant difference in total effective rate between the two groups (88.2% versus 83.3%; $p > 0.05$), but at follow-up at 6 months after end of the treatment, the total effective rate in the acupuncture group was higher than in the amitriptyline group (67.6% versus 40.0%; $p < 0.05$).
Acupuncture + other interventions versus other interventions		
Targino RA 2008[34]	Acupuncture plus tricyclic antidepressants and exercise with tricyclic antidepressants and exercise	Patients in acupuncture group were significantly better than the control group in terms of VAS scores ($p < 0.001$), PPT ($p < 0.001$), # of tender points below 4 kg/cm^2 ($p < 0.001$), and in 5 subscales of the SF-36 ($p < 0.05$).
Massage versus no treatment		
Brattberg G 1999[17]	Connective tissue massage versus no treatment or discussion	No significant difference between connective tissue massage and no treatment for reducing pain according to VAS scores after treatment (MD, –0.58; 95% CI, –1.76 to 0.60; $p = 0.34$).
Herbal medicine versus conventional medications		
Fu HW 2006[20]	*Shugan Jieyu Huoxue Tongluo* decoction versus amitriptyline	Herbal decoction superior to amitriptyline for reducing depression according to HAMD after treatment (MD, –3.70; 95% CI, –6.09 to –1.31; $p = 0.002$)
Guo GM 2007[21]	Total flavones of *Rhizoma Drynariae* versus meloxicam	No difference between two groups in pain reduction according to VAS scores after treatment (MD, –0.80; 95% CI, –1.66 to 0.06; $p > 0.05$).
	Total flavones of *Rhizoma Drynariae* versus meloxicam and amitriptyline	No difference between two groups on pain reduction according to VAS scores after treatment (MD, –0.10; 95% CI, –0.87 to 0.64; $p > 0.05$).

Liu JZ 2002[30]	*Zhengqing Fengtong Ning* tablet versus doxepin	According to category outcome measurement, herbal medicine was significantly better than doxepin (91.2% versus 76.7%; $p < 0.05$) in total effective rate (markedly effective plus effective rate).
Yang HB 2008[36]	*Xiaoyao Qianghuo Chushi* decoction versus indometacin and carbamazepine	In terms of total effective rate, herbal medicine produced a better effect than conventional medication (94.74% versus 86.84%; $p < 0.05$).
Yang TG 2007[37]	*Jiawei Xiaoyao* powder versus amitriptyline and ibuprofen sustained release capsules	Therapeutic effect (MD, –1.89; 95% CI, –2.62 to –1.16; $p < 0.05$) and reduction of symptoms (90.9% versus 64.7%; $p < 0.05$) in the treatment group were more marked than in the control group.
Herbal medicine + other interventions versus other interventions		
Guo GM 2007[21]	Total flavones of *Rhizoma Drynariae* and amitriptyline versus meloxicam and amitriptyline	Significant difference between two groups in pain reduction according to VAS scores after treatment (MD, –2.00; 95% CI, –2.69 to –1.31; $p < 0.05$).
	Meloxicam, total flavones of *Rhizoma Drynariae* and amitriptyline versus meloxicam and amitriptyline	Significant difference between two groups in pain reduction according to VAS scores after treatment (MD, –1.10; 95% CI, –1.83 to –0.37; $p < 0.01$).
Jiang F 2004[25]	QoL	According to change of VAS scores, HAMD, and SCL-90, herbal medicine combined with conventional medications was significantly better than conventional medications alone for reducing pain and improving QoL for patients with FM ($p < 0.05$).
Combination of acupuncture and other TCM therapies versus conventional medications		
Fu XY 2004[a]	Acupuncture + cupping therapy versus amitriptyline	Combination of acupuncture + cupping therapy was significantly better than conventional medications for reducing VAS scores (MD = –1.96; 95% CI, –2.91 to –1.01; $p < 0.0001$) and HAMD scores (MD, –3.99; 95% CI –5.47 to 2.51; $p < 0.00001$).
Li AL 2004[27]	*Ding Tong* decoction plus acupuncture and psychologic therapy with amitriptyline and psychologic therapy	According to the scores of self-rating evaluation of reduction of symptoms and calculation of pain intensive and # of tender points, there were no significant differences between two groups ($p > 0.05$).
Li J 2005[29]	Acupuncture and computer intermediate frequency (electromagnetic wave) treatment versus amitriptyline, with psychologic therapy in both groups.	No significant difference between two groups in total effective rate (<3 scores on a 10-point VAS scale, or symptoms disappeared or markedly relieved, or # of tender points decreased > 6 points; 95.65% versus 95.65%; $p > 0.05$).
Wang CM 2008[35]	Acupuncture plus laser radiation versus amitriptyline	According to VAS scores after treatment, acupuncture + laser radiation were significantly better than amitriptyline for pain reduction (MD = –2.27; 95% CI, –3.05 to –1.49; $p < 0.00001$).

[a]Fu XY, Li CD. Clinical randomized controlled trial on combination of acupuncture, cupping and medicine for treatment of fibromyalgia syndrome [dissertation for Master's degree from Chengdu University of Traditional Chinese Medicine, Chengdu, China]. 2004.

VAS, visual analogue scale; PPT, pressure pain threshold; SF-36, Short Form–36; MD, mean difference; CI, confidence interval; HAMD, Hamilton Depression Scale; SCL-90, symptom checklist 90; QoL, quality of life; FM, fibromyalgia; TCM, Traditional Chinese Medicine.

acupuncture or herbal medicine, blinding of outcome assessors should be attempted as far as possible to minimize performance and assessment biases. Choosing outcome measures should be based on an international consensus and should include continuous data and daily average pain scores from baseline to study completion. Analysis of outcomes based on the intention-to-treat principle is vital as is the application of well-defined diagnostic criteria, such as ACR 1990, thus, increasing comparability between trials. Reporting of trials should follow Consolidated Standards of Reporting Trials (CONSORT)[52] standards to explain the processes involved explicitly and in a transparent manner.

Conclusions

The preliminary conclusions of the current study suggest that patents with FM might benefit from TCM treatment. FM is a chronic disease and better, larger trials will be the basis for demonstrating the effectiveness and long-term effects of TCM therapies.

Disclosure Statement

No competing financial conflicts exist.

Acknowledgments

H.J .Cao and Liu JP were supported by a grant from the National Basic Research Program of China ("973" Program, No. 2006CB504602) and an international cooperation project from the Ministry of Science and Technology of China (2009DFA31460). Liu JP was in part supported by the Grant Number R24 AT001293 from the National Center for Complementary and Alternative Medicine (NCCAM) of the U.S. National Institutes of Health. Lewith GT was supported by the Rufford Maurice Laing Foundation.

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