

**Effectiveness of complementary and alternative medical external therapy in fibromyalgia syndrome: A network Meta-analysis**

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University of Chinese Medicine.**ADMINISTRATIVE INFORMATION****Support** - This work was supported by funding from National Administration of Traditional Chinese Medicine(Num:2019XZZX—JB004), and Beijing Hospitals Authority(Num:PZ2019007).**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202370002**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 July 2023 and was last updated on 01 July 2023.**INTRODUCTION**

**Review question / Objective**  
Participants: Patients with fibromyalgia syndrome  $\geq 18$  years old. Intervention: The treatment group was treated with supplementary and alternative medical external therapy. Comparisons: The control group was treated with oral medication or routine physiotherapy. Outcome measures: The primary study outcome should include VAS, Number of tenderness points, FIQ, PSQI and HAMD.

**Condition being studied** Fibromyalgia syndrome (FMS) is a kind of systemic chronic bone pain with a long time, and it is also a common chronic rheumatic disease at present. The common accompanying symptoms are insomnia, fatigue, cognition and anxiety, but pain is the most typical symptom. The incidence of FMS in the general

population is about 2%-4%, and its incidence rate is second only to low back pain and osteoarthritis in bone diseases at present. However, the prevalence of FMS is mainly female and the prevalence increases with age. Because of its complex and diverse symptoms, FMS has brought many troubles to patients, which seriously affected their lives and increased their economic burden. Studies have shown that 24.5% of FMS patients were forced to leave their jobs five years after illness, and FMS has become the second largest disease in rheumatology and immunology department at present. Supplementary and alternative medicine non-drug therapy shows unique charm in FMS. In 2017, the European Anti-Rheumatism Alliance Fibromyalgia Treatment Management Recommendation pointed out that non-drug treatment should be the first-line treatment. If the effect is not good, individualized treatment should be carried out according to the

needs of patients In this guideline, it can be used as a recommended treatment to improve patients' pain symptoms and improve their lives.

## METHODS

**Participant or population** The patient's clinical diagnosis conforms to the FMS diagnosis proposed by American Rheumatology Society (ACR) or the FMS diagnosis and treatment guidelines proposed by Rheumatology Branch of Chinese Medical Association or the Chinese expert consensus on clinical diagnosis and treatment of fibromyalgia written by the Chinese expert consensus on clinical diagnosis and treatment of fibromyalgia The patient's age needs  $\geq 18$ .

**Intervention** The treatment group was treated with supplementary and alternative medical external therapy such as moxibustion, dry acupuncture, massage, cupping, umbilical acupuncture, abdominal acupuncture, electroacupuncture, needle knife, catgut embedding, acupoint injection and so on. There is no specific requirement for the material, action site, course of treatment and time in the treatment group.

**Comparator** The control group was treated with oral medication or routine physiotherapy, including the single use or combination of Chinese and Western medicines. No specific requirements were made for the types of oral medication and routine physiotherapy. If both the treatment group and the control group use complementary and alternative medical external therapy, they must be different types of therapy such as electroacupuncture and acupuncture.

**Study designs to be included** Our study is mainly based on RCT, and some prospective studies were also included, even if they were not randomized some prospective study.

**Eligibility criteria** Exclusion criteria: ① Non-prospective controlled studies such as case reports, theoretical research of TCM, literature research, data mining, self-controlled studies and animal experiments, etc. Repeated publication of literature; ③ Non-Chinese or English literature; Non-periodical literature includes abstracts of conference papers and dissertations; ⑤ The judgment of curative effect is not clear, the above outcome indexes are lacking, there is no baseline data, and the basic treatment measures are different; ⑥ The diagnosis is unclear and complicated with other diseases; ⑦ Self-control study before and after, the research results are

unknown, the data is false, etc. ⑧ Data are not presented in the form of average and difference.

**Information sources** We searched and built the database by computer until April 15, 2022. The Cochrane Library, PubMed, EMBASE, Web of Science CNKI, Wanfang Academic Journal Full Text Database, VIP Chinese Sci-tech Periodical Database, Chinese Biomedical Literature Database and other databases. We have collected all RCT studies on FMS in complementary and alternative medicine external therapy and manually searched the review literature to supplement some studies.

**Main outcome(s)** The primary study outcome should include VAS, Number of tenderness points, FIQ, PSQI and HAMD.

**Quality assessment / Risk of bias analysis** We assessed the risk of bias in the included randomized controlled trials (RCTs) using the Cochrane "risk of bias" assessment tool, including the domains of allocation, blinding, incomplete outcome data, selective reporting, and other bias. Each study was scored according to the selection, comparability, and outcome.

**Strategy of data synthesis** We used the Stata 16.0 software mvmeta package to carry out network Meta. The measurement data used the mean and difference as the effect statistics, and used the RevMan5.3 software to evaluate the literature and the risk of bias. Each effect size provided its 95% confidence interval (95% CI). Prediction interval plots were used to judge whether there was heterogeneity among studies, and local inconsistencies were assessed by node splitting. The similarity test of the evidence network is evaluated by comparing the clinical and clinical characteristics of each study, and the comparison results of the outcome indicators of any two treatment techniques are displayed in a league table, and the Meta test level is  $\alpha=0.05$ . When a closed loop is formed between interventions, an inconsistency test is required to assess the degree of consistency between direct and indirect comparisons. We Use the surface under the cumulative ranking curve (SUCRA) to identify the best interventions. At the same time, Stata16.0 software was used to draw the publication bias funnel diagram (compare-calibration map).

**Subgroup analysis** Our study does not involve subgroup analysis.

**Sensitivity analysis** We will consider running sensitivity analysis to identify the robustness and

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stability of merged results by excluding studies with high risk of bias.

**Country(ies) involved** China.

**Keywords** Fibromyalgia syndrome; Complementary and alternative medicine; Efficacy; Safety; Network Meta-Analysis.

**Contributions of each author**

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