Warm acupuncture for fibromyalgia with increased cold sensitivity: a cross-over randomised controlled trial

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Abstract

Objective

Although approximately 85% of fibromyalgia patients exhibit increased sensitivity to cold, no therapy is available for this particular subgroup. This exploratory clinical trial to evaluate the effect of warm acupuncture, a traditional and common used acupuncture therapy, in treating fibromyalgia patients with high cold sensitivity.

Methods

This randomised, single-blinded, cross-over preliminary study involved an 8-weeks observation and 8-weeks intervention. Thirty-eight patients were assigned to either warm acupuncture group or observation group for 8 weeks randomly, then the assignment switched. The primary outcome was the change in Visual Analogue Scale (VAS) score for cold sensitivity. Secondary outcomes included changes in sensitivity to pain, wind, noise, bright light, and odor assessed by VAS, and series of specialised scales regarding other common fibromyalgia symptoms. A modified intention-to-treat analysis was used to compare differences.

Results

The VAS for cold sensitivity decreased by 2.31-cm in the treatment period and by 0.83-cm in the observation period at week 8 (MD, 1.48; 95% CI, 0.28 to 2.67; p=0.019), and the between-group difference became apparent starting at week 4 (MD, 1.16; 95% CI, −0.03 to 2.36; p=0.015). The secondary efficacy measures, including the VAS for pain, wind, and the Polysymptomatic Distress Scale scores, showed greater improvement during the treatment period compared with that in the observation period at week 8. Adverse events were infrequent and minor.

Conclusions

Warm acupuncture may reduce the heightened sensitivity to cold, pain and wind, as well as the severity of the fibromyalgia in those patients with cold intolerance.

Key words

fibromyalgia, cold temperature, acupuncture, moxibustion, complementary therapies

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Introduction

Fibromyalgia (FM), characterised by generalised chronic pain, is often accompanied by fatigue, sleep disturbances, emotional abnormalities, temperature sensitivity, and cognitive dysfunction (1). The global prevalence of FM is 0.7 to 9.3%, and it is more prevalent in women than in men, especially in the 30 - 50 age group (2), The pathogenesis of FM remains elusive. Current research often associates it with central sensitisation, an abnormality in the central nervous system that results in an increased response to stimuli such as pain, temperature, odour, sound and light (3).

The symptoms of FM are not only diverse but also vary from person to person. For instance, each patient is highly possible to have various properties of pain, involving but not limited to pressure pain (58%), prickling (33%), burning (30%) and allodynia pain (20%)(4). Furthermore, it is worth noting that their responses to therapies also vary. In fact, currently, there is no treatment that can simultaneously improve all symptoms in FM. Even the recognized first-line drugs, such as pregabalin, can only bring about a 30% improvement in pain for 27% of the patients and have limited improvement in symptoms such as fatigue and depression (5). As a result, the therapeutic approach for managing patients with FM is typically characterised by integrated and multidisciplinary interventions (6). The well-known variability in clinical presentation and treatment response making it necessary to personalise the treatment to the specific needs of patients and to investigate treatment options for different subtypes (1, 2).

Clinical observation have found that high sensitivity to cold is a common phenomenon presented in patients with FM that there were four out of five patients develop the symptom of cold intolerance (7). FM-related symptoms are likely to worsen when the ambient temperature drops or in winter and get better when the weather warms or in summer (8, 9). A systematic study (17 RCT) evaluated the relationship between FM and temperature, and showed the cold-pain threshold decreased evaluated by low-temperature sensitivity tests in all patients (9). The physical symptoms (pain, sleep, fatigue) are different between heat and cold sensitivity in FM, and the potential to increase life satisfaction may exist by dividing patients into subgroups for nursing care (10). Although high cold sensitivity is quite common, however, there has not any intervention research on this type of FM patients.

Warm acupuncture is a distinctive acupuncture therapy technique combining acupuncture and moxibustion. Acupuncture refers to 'needle insertion', and moxibustion refers to the burning of mugwort (Artemisia argyi, a traditional Chinese medicinal herb known for its ability to dispel cold and dampness). The mugwort is shaped into a conical or cylindrical form and is placed at the end of the needle handle. While the needle is inserted, the mugwort is burned to stimulate the body's acupuncture points. On the basis of Chinese medicine theory, the warming energy of moxibustion can dispel cold and wind, which helps acupuncture unblock the flow of qi and blood in the meridians, therefore, warm acupuncture therapy is suitable for pain-related conditions that are highly sensitive to wind or cold, such as knee osteoarthritis and ankylosing spondylitis (11, 12). Hence, this study applied warm acupuncture therapy to the treatment of FM patients with high cold sensitivity, aiming to explore its therapeutic effects, safety and curative effect characteristics and to provide more precise treatment options for patients with FM.

Materials and methods

Study design and participants

This was a randomised, prospective, single-blinded (evaluator), cross-over clinical trial. All participants received the treatment but in different orders. Every patient acted as his or her own control. The study protocol was approved by the ethics committee of Guang'anmen Hospital (a tertiary-level hospital in Beijing, China) with approval number 2022-008-ky.

Recruitment was from February 2022 to February 2024 using advertisements

on posters in Guang'anmen Hospital. The inclusion criteria included: i) The 2011 American College of Rheumatology Research Classification Criteria for fibromyalgia (13); ii) Age >18 years; iii) The type and dose of drugs used for FM had been stable for at least 2 weeks; iv) The Visual Analogue Scale (VAS) score of sensitivity to the cold scale had been no less than 4; v) Signed informed consent form. Patients were excluded if they had acute systemic or localised infectious diseases, severe visceral diseases, or were too frail to undergo acupuncture treatment. Additionally, pregnant women were not included in the study.

Randomisation and blinding

A list of consecutive numbers ranging from 1 to 38 was generated by computer with the help of the SPSS Statistics® v.10.0 software. Subsequently, each of these numbers was randomly assigned to the two groups in a precisely 1 to 1 ratio. The resulting randomisation scheme was then carefully placed in sequentially-numbered, opaque envelopes and stored in the scientific research office of the hospital to ensure its security and proper management.

The responsibility for assessing outcomes, collecting data, and conducting statistical analyses of each research staff was blinded to group allocation. The acupuncturist were the only study personnel with access to the group information.

Intervention

All participants either underwent an 8-week warm acupuncture treatment and then had an 8-week observational phase without any intervention or vice versa. During the treatment period, warm acupuncture therapy was administered twice weekly.

Certified acupuncturist who had a minimum of 1 years of professional experience performed acupuncture. Standardised operating procedures and locations of acupoints were provided for acupuncturist. Location of acupoints followed the World Health Organization's Standard Acupuncture Locations (14). The acupoints included bilateral Hegu (LI04), Houxi (SI3), Zusanli (ST36), Taichong (LR3), Taixi (KI3), Zulinqi (GB41). The treatment process was as follows: a) Acupuncturist used disposable stainless steel needles with a diameter of 30 mm and a length of 40 mm (manufactured by Suzhou Hwato Medical Instrument) placed on the skin at acupoints. For ST36, needles were inserted to a depth of approximately 30 mm, and for LI04, SI3, ST36, LR3, KI3, GB41, to approximately 15-20 mm. b) Acupuncturist twisted, lifted and thrust the needle for 10 seconds to obtain the sensation of "Deqi" (soreness, numbness, distension, or heaviness); c) After the needle got 'qi', burning moxibustion was placed on the tail of the needles at least 3 cm from the skin at Zusanli (ST36) and Taixi (KI3); d) A thin cardboard was placed between the moxibustion and the skin to prevent burning senseation. The needles and moxibustion were retained for 20 minutes.

Outcomes

Demographic characteristics were collected including age, gender, height, weight, duration of FM symptoms, and medical history at the baseline evaluation.

The primary outcome was the change in Visual Analogue Scale (VAS) score for cold sensitivity after 8 weeks of observation or treatment. Cold VAS consists of a 10-cm horizontal line, where 0 means 'not afraid of the cold' and 10 means 'very afraid of the cold', with higher scores indicating greater sensitivity to cold.

The secondary outcomes consisted of changes in the scores of nine assessment scales after 8 weeks of observation or treatment:

- *Pain severity*

The pain severity was evaluated by the VAS. In the VAS score, 0 represents no pain and 10 represents very painful pain.

- *Wind, noise, bright light and odor sensitivity.*

The sensitivity was evaluated by VAS, with 0 being insensitive and 10 being very sensitive. These questions actually originated from items in the Revised Fibromyalgia Impact Questionnaire scale (FIQR)(15).

- *Overall FM severity evaluation*.

The Polysymptomatic Distress Scale scores (PDS)(13) from the 2011 FM Diagnostic Criteria and the FIQR scores(15) were used to assess the severity of FM. The PDS focuses on the comprehensive assessment of the distress degree of multiple symptoms, while the FIQR emphasizes more on the impact of the disease on daily life functions and quality of life. The scoring range of the PDS is from 0 to 31, and that of the FIQR scale is from 0 to 100.

- *Anxiety and depression*. The Hamilton Anxiety Scale (HAMA) was used to assess the severity of the patient's anxiety symptoms, including cognitive and somatic symptoms, with 14 questions and a total score of 0-56(16). The Beck Depression Inventory-II (BDI-II) assesses the degree of depression with 13 questions and a total score of 0-39(17).

- *Fatigue*. The Multidimensional Fatigue Scale (MFI) was used to evaluate the fatigue of patients in the past one week, with 20 questions and a total score of 20-100 (18).

- *Sleep quality*. The Pittsburgh Sleepiness Scale (PSQI) was used to assess the sleep quality with 19 questions and a total score of 0-19 (19).

- *Quality of life*. The 36-item Short-Form Health Survey (SF-36) was used to assess the patients' quality of life over the past 4 weeks. It is categorised into two main dimensions, physical health and mental health, each with a score of 100(20).

All those measures were evaluated at weeks 0, 4, 8, 12, and 16 for a total of 5 times. For the VAS, TPC, PDS, FIQR, HAMA, BDI-II, MFI and PSQI, higher scores indicate greater severity of the assessed symptom(s). While for the SF-36, higher scores indicate a better quality of life.

Additionly, after 8-week warm acupuncture treatment, the participants were self-assessed using the Patient Global Impression of Change (PGIC) questionnaire (21) to document any perceived change in overall health status (score range, 1 (very much improved), 2 (much improved), 3 (minimally improved), 4 (no change) , 5 (minimally

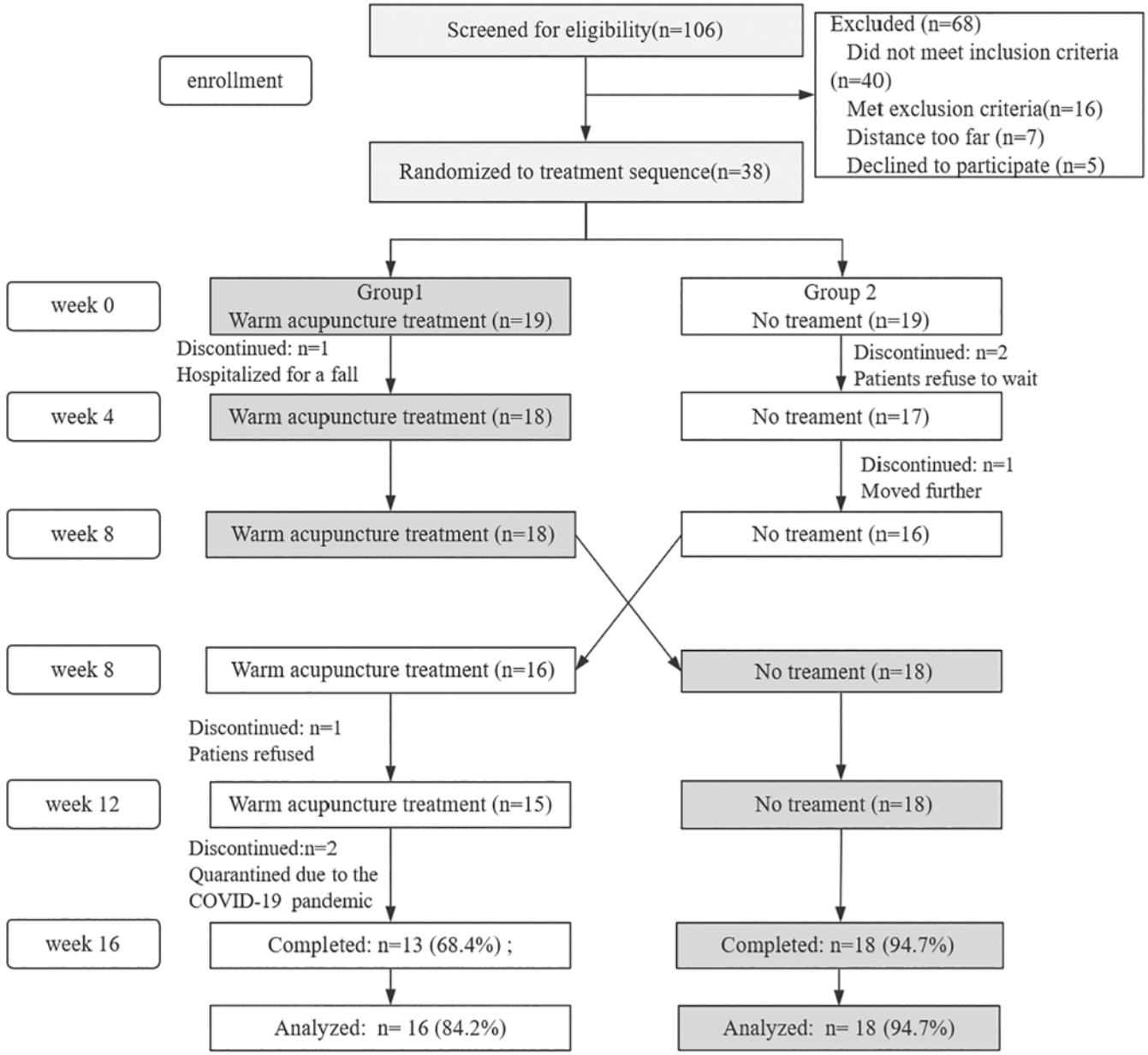

Fig. 1. Flow chart.

worsened), 6 (much worse), 7 (very much worse)).

Liver and kidney function were monitored at the baseline, week 8 and 16. Adverse events and medications taken by participants for comorbid conditions during the study period were recorded.

Statistics

This was an exploratory, crossover trial. Each group had 15 participants, and the sample size was determined based on the regulations for exploratory studies in Chinese medicine (22). Considering a 20% dropout rate, 38 patients were recruited.

Statistical analyses were conducted with the SPSS Statistics® v.10.0 software. The analyses were performed based on the modified intention-to-treat principle with all patients who had received at least one treatment. For patients who did not complete the entire treatment or had missing data, the data recorded at the last time were used for endpoint analysis. Measurement data were described by mean (standard deviation) or quartile, while count data were described by frequency (component ratio). Efficacy evaluation was analyzed using multivariate analysis of variance (ANOVA), with sequence and treatment as fixed variables and subjects within-sequence as random factors. Statistical tests were 2-sided and $P < 0.05$ was to be considered statistically.

Results

The flow chart is shown in Figure 1.

Demographics and baseline characteristics. The average age of the whole cohort was 45.29 (SD 12.29) years, of whom 88.2% were female, and the median disease duration was 27 months. Four patients maintained their original medication during the trial; one patient

Table I. Demographics and baseline characteristics.

Variables	fibromyalgia (n=34)
Age, years	45.29 (12.29)
Sex, female, no. (%)	30 (88.2%)
BMI, kg/m^2	22.58 (2.45)
Disease duration, month, Md (P25,P75)	27 (13, 84)
Number of concomitant medications, no. (%)	4 (11.76%)
VAS score for cold sensitivity¶	7.85 (2.02)
VAS score for Pain¶	6.90 (2.08)
VAS score for wind sensitivity¶	6.71 (1.90)
VAS score for noise sensitivity¶	5.68 (2.29)
VAS score for bright light sensitivity¶	5.65 (2.72)
VAS score for odor sensitivity¶	7.36 (2.19)
FIQR total score¶	51.64 (18.52)
PDS score ¶	19.38 (5.85)
HAMA score¶	25.60 (11.50)
BDI-II score¶	11.80 (6.60)
MFI-20 score¶	66.60 (10.60)
PSQI score¶	12.90 (3.00)
SF-36 score§	
Physical component score	35.0 (19.60)
Mental component score	35.90 (20.90)

Plus-minus values are mean (SD) unless otherwise noted.
SD: standard deviation; Md (P25, P75): quartile; BMI: body mass index; VAS: Visual Analogue Scale (with scores ranging from 0 to 10); FIQR: Revised Fibromyalgia Impact Questionnaire (with scores ranging from 0 to 100; function scores ranging from 0 to 30; overall impact scores ranging from 0 to 20; symptoms scores ranging from 0 to 50); PDS: Polysymptomatic Distress Scale scores (with scores ranging from 0 to 31); HAMA: Hamilton Anxiety Scale(with scores ranging from 0 to 21); BDI: Beck Depression Inventory (with scores ranging from 0 to 63); MFI-20: Multidimensional Fatigue Inventory-20 (with scores ranging from 20 to 100); PSQI: Pittsburgh Sleep Quality Index (with scores ranging from 0 to 56); SF-36: 36-item Short-Form Health Survey (with scores ranging from 0 to 100).
¶Higher scores reflect more severe symptoms.
§Higher scores indicate better status.

Table II. Changes from baseline in VAS scores.

Outcome	Mean change from baseline (95% CI)		Paired difference (95% CI)	
	Warm acupuncture (n=34)	Observation (n=34)	Warm acupuncture *vs.* observation	*p*
Cold sensitivity VAS				
Week 4	1.81 (0.61, 3.01)	0.65 (-0.55, 1.84)	1.16 (-0.03, 2.36)	0.015
Week 8	2.31 (1.11, 3.51)	0.83 (-0.36, 2.03)	1.48 (0.28, 2.67)	0.019
Pain VAS				
Week 4	1.71 (0.65, 2.77)	0.32 (-0.90, 1.54)	1.39 (0.48, 2.30)	0.016
Week 8	2.51 (1.46, 3.56)	0.58 (-0.64, 1.82)	1.93 (0.75, 3.11)	0.013
Noise sensitivity VAS				
Week 4	1.75 (1.01, 2.48)	0.62 (0.00, 1.23)	1.13 (0.16, 2.09)	0.036
Week 8	1.62 (0.81, 2.42)	0.68 (0.02, 1.34)	0.94 (-0.09, 1.97)	0.15
Wind sensitivity VAS				
Week 4	1.37 (0.17, 2.57)	0.50 (-0.70, 1.70)	0.87 (-0.33, 2.07)	0.08
Week 8	2.68 (1.47, 3.87)	0.64 (-0.56, 1.84)	2.04 (0.84, 3.23)	0.004
Bright light sensitivity VAS				
Week 4	0.84 (0.07, 1.60)	-0.15 (-1.16, 0.85)	0.99 (-0.27, 2.25)	0.21
Week 8	-0.06 (-2.22, 2.10)	0.14 (-0.82, 1.10)	-0.20 (-2.56, 2.16)	0.85
Odor sensitivity VAS				
Week 4	0.54 (-0.33, 1.41)	0.79 (0.23, 1.34)	-0.25 (-1.28, 0.78)	0.64
Week 8	0.32 (-0.53, 1.17)	0.91 (0.31, 1.50)	-0.59 (-1.63, 0.45)	0.37

VAS: visual analogue scale (with scores ranging from 0 to 10).

took pregabalin 150 mg/day, one took lorazepam 2mg/day, and two took duloxetine 60 mg/day and 120 mg/day respectively (Table I).

Order effects. After applying analysis of variance to all indicators, no significant effects were detected for the sequence (as a fixed factor) or the subject (as a random factor), indicating that the study outcomes were not influenced by the order of interventions or by subject variability within the sequence.

Efficacy analyse results. Primary end points: The VAS for cold sensitivity decreased by 2.31 in the treatment period and by 0.83 in the observation period at week 8 (mean difference, 1.48; 95% CI, 0.28 to 2.67; p=0.019), and the between-group difference became apparent starting in week 4 (mean difference, 1.16; 95% CI, –0.03 to 2.36; p=0.015) (Table II).

Secondary end points: The pain VAS score had a reduction of 1.81 at week 4 and 2.31 at week 8 in warming acupuncture treatment which was greater than the 0.32 decrease observed at week 4 (p=0.015) and the 0.58 at week 8 in the observation period (p=0.019). Besides, the treatment period also had better results than the observation period on the VAS score for wind, TPC, PDS score after 8 weeks. No difference was found between the two periods in the VAS score for noise sensitivity/bright light sensitivity/odor sensitivity, FIQR total score, SF-36 score, HAMA score, BDI-II score, and PSQI score. (Table II and Table III).

Impression of overall improvement (PGIC). All 31 patients who completed the trial reported improvement of their health state, that 7 patients (22.6%) reported significant improvement, 16 patients (51.6%) reported moderate improvement, and 8 patients (25.8%) reported slight improvement.

Adverse events. Liver and kidney function evaluations revealed no abnormalities. Six patients (15.8%) experienced a sensation of burning discomfort at the acupuncture points, and 1 patient (2.6%) was accidentally burned by a moxibustion stick on the skin with a wound about 1 cm in size, but the wound healed within two weeks. No other adverse events were reported.

Table III. Changes from baseline in other efficacy measures related to fibromyalgia symptoms.

Outcome	Mean change from baseline (95% CI)		Paired difference (95% CI)	
	Warm acupuncture (n=34)	Observation (n=34)	Warm acupuncture *vs.* observation	*p*
FIQR total score[¶]				
Week 4	6.71 (2.31,11.10)	0.37 (-3.56,4.30)	6.34 (0.44,12.23)	0.070
Week 8	13.38 (6.39,20.36)	6.27 (1.16,11.37)	7.11 (-1.53,15.75)	0.051
PDS[¶]				
Week 4	4.00 (3.24, 5.64)	1.00 (-0.20,2.20)	3 (1.80, 4.20)	0.019
Week 8	5.71 (4.51,6.90)	1.88 (0.69,3.08)	3.83 (2.63, 5.03)	0.038
HAMA score[¶]				
Week 4	5.74 (0.04,10.65)	1.59 (-5.61,5.91)	4.15 (3.14,5.16)	0.23
Week 8	7.12 (0.51,11.97)	3.50 (-3.71,7.83)	3.62 (2.61,4.63)	0.34
BDI-II score[¶]				
Week 4	2.41 (1.41,3.43)	0.94 (-0.06,1.96)	1.47 (0.46,2.48)	0.20
Week 8	2.62 (1.61,3.63)	2.11 (1.11,3.13)	0.51 (-1.52,0.50)	0.69
MFI-20 score[¶]				
Week 4	-0.85 (-7.57,5.87)	-0.26 (-5.96,5.42)	0.59 (-6.61,5.43)	0.91
Week 8	1.59 (-5.55,8.73)	3.88 (-2.96,10.72)	-2.29 (-9.24,4.66)	0.66
PSQI score[¶]				
Week 4	1.09 (0.08,2.10)	0.20 (-0.80,1.22)	0.89 (-0.12,1.90)	0.178
Week 8	0.76 (-0.25,1.77)	0.94 (-0.37,1.65)	-0.18 (-1.19,0.83)	0.813
SF-36 score[§]				
Physical component				
Week 4	-6.18 (-7.19,-5.17)	-2.97 (-3.99,-1.97)	-3.21 (-4.22,-2.20)	0.38
Week 8	-11.18 (-12.19,-10.17)	-7.28 (-8.30,-6.28)	-3.90 (-4.91,-2.89)	0.45
Mental component				
Week 4	-8.30 (-9.30,-7.28)	-1.64 (-2.65,-0.63)	-6.66 (-7.67,-5.65)	0.10
Week 8	-14.08 (-15.09,-13.07)	-5.61 (-6.63,-4.61)	-8.47 (-9.48,-7.46)	0.07

FIQR: Revised Fibromyalgia Impact Questionnaire (with total scores ranging from 0 to 100); PDS: Polysymptomatic Distress Scale scores (with scores ranging from 0 to 31); HAMA: Hamilton Anxiety Scale (with scores ranging from 0 to 21); BDI: Beck Depression Inventory (with scores ranging from 0 to 63); MFI-20: Multidimensional Fatigue Inventory-20 (with scores ranging from 20 to 100); PSQI: Pittsburgh Sleep Quality Index (with scores ranging from 0 to 56); SF-36, The 36-item Short-Form Health Survey (with scores ranging from 0 to 100).
[¶]Higher scores reflect more severe symptoms.§Higher scores indicate better status.

Discussion

The randomised, cross-over study suggested that for patients with FM, warm acupuncture therapy shows a tendency towards efficacy in potentially reducing sensitivity to cold, wind, and pain, and may have a certain positive influence on alleviating overall symptom severity and improving the overall impression of the health state. while it was ineffective for other common central sensitivities, such as photophobia and phonophobia, as well as mood, fatigue, and sleep, and had mild adverse effects.

To our awareness, there was no other study to apply warm acupuncture in treatment for FM. Only Li *et al*. (23) combined acupuncture and moxibustion to treat FM. They chose acupuncture points based on the meridians where the pain sites were located and added moxibustion after acupuncture. After 4 weeks, the treatment improved disease severity (evaluated by FIQR) and pain severity, similar to the findings of our study. However,warm acupuncturehas been well-researched for treating other chronic pain disorders. A review involving 66 studies (5132 subjects) (11) on warm acupuncture for osteoarthritis treatment suggested better results in overall effectiveness, pain and function improvement, with no serious adverse events. Another review (24) of 30 studies (3196 subjects) concluded that manual acupuncture plus moxibustion is the most effective in reducing pain and disability in non-specific low back pain patients, and its adverse event rate was significantly lower than that of the control group. These studies reveal the prospective value of warm acupuncture in the treatment of chronic pain and prompts for further progress and application.

Studies have found association between temperature and pain regulation in FM patients. The distribution of brown adipose tissue, which can produce heat, is similar to that of the pressure points of FM patients (25). The thermoregulation and pain regulation share regions in the brain (insular cortex and anterior cingulate gyrus), and that they may influence each other (26). Some researchers have also proposed that the efficacy of aerobic exercise in FM is related to the increased thermogenesis of exercise (27). The results of our study showed that the patients' sensitivity to cold and wind was improved while their pain was alleviated as well, which might further suggest that there is a correlation between temperature and pain regulation in patients with FM. However, the patients' sense of smell, vision and hearing were not improved accordingly, which might be due to the fact that the brain regions where these senses are distributed (such as the frontal lobe, temporal lobe and occipital lobe) are different from those for pain regulation.

The diverse symptoms, the complex pathophysiology, and the uncertain treatment responses lead to the fact that FM is very difficult to treat. To date, no single therapy can comprehensively improve all the core symptoms of FM, even the most widely recommended dynamic therapy, aerobic exercise (28). Studies have revealed the heterogeneity of pain in FM patients. Owing to the diverse extents of small fiber lesions, the manifestations can be heat, cold, or mechanical pain (4) indicating that different mechanisms lead to different symptoms. Thus, diverse symptoms require more targeted treatments. Moreover, a review of 11 systematic reviews (29) on acupuncture for FM showed an average pain reduction score of 1.13 (95% CI, -2.09 to -0.17); In contrast, the patients in our study had an average

pain reduction of 2.51, suggesting that targeted treatments for different subtypes might yield better effects.

As a crossover study, every participants received treatment, and each participant served as its own control, thus the effects of selection bias, inter-individual differences and confounding factors were reduced. Furthermore, given that all participants were afforded the same treatment, a more effective blinding process could be achieved among the patients. However, there were still some shortcomings. Firstly, there is no appropriate placebo design for warm needling acupuncture, because participants can easily distinguish the differences in intervention methods by the red glow of burning moxa and the warm heat sensation. Secondly, the outcomes were assessed according to patients' self-reported data because there is a lack of objective evaluation methods for FM. Additionally, since it is an exploratory study, the sample size of this study is relatively small and no follow-up on the curative effect has been conducted.

Taken together, this study explored a novel therapeutic approach for FM and is the first study to adopt warm acupuncture in cold-intolerant patients. It is expected to provide more abundant treatment options for FM patients, especially those who are intolerant to cold.

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