

# World Journal of *Clinical Cases*

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Clinical Trials Study

# Clinical efficacy of electromagnetic field therapy combined with traditional Chinese pain-reducing paste in myofascial pain syndrome

Jing Xiao, Bing-Yan Cao, Zeng Xie, Yu-Xuan Ji, Xing-Li Zhao, Hong-Jie Yang, Wei Zhuang, Hai-Hua Sun, Wen-Ming Liang

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## Abstract

### BACKGROUND

Pulsed electromagnetic field (PEMF) therapy is widely used to treat myofascial pain syndrome (MPS). Damp-clearing and pain-reducing paste (DPP) comprises medical herbs and has been a traditional method of reducing myofascial pain in China for a long time, and it is usually administered with heating. However, the synergistic effect of PEMF therapy on heating-DPP in patients with MPS is unclear.

### AIM

To investigate the synergistic effect of PEMF therapy plus heating-DPP in lumbar MPS.

### METHODS

This double-blind, randomized, placebo-controlled trial was conducted on 120 patients with lumbar MPS who were randomly divided into an experimental group (EG,  $n = 60$ ) and a control group (CG,  $n = 60$ ). Patients in both groups were treated with heating-DPP combined with PEMF therapy; however, the electromagnetic function of the therapeutic apparatus used in the CG was disabled. Each treatment lasted for 20 min and was applied five times a week for two weeks. The short-form McGill Pain Questionnaire was applied at five time points: pretest, end of the first and second weeks of treatment, and end of the first and fourth week after completing treatment. Visual analog scale (VAS), present pain intensity index (PPI), and pain rating index (PRI; total, affective pain, and sensory pain scores) scores were then analyzed.

### RESULTS

Compared with the CG, the VAS, PPI and PRI scores (total, affective pain and sensory pain scores) in the EG were significantly lower after treatment and during follow-up.

# CONCLUSION

PEMF therapy combined with heating-DPP showed better efficacy than heating-DPP alone in reducing the overall intensity of pain and sensory and affective pain.

**Key Words:** Traditional Chinese pain-reducing paste; Damp-clearing and pain-reducing paste; Pulsed electromagnetic field; Myofascial pain; Myofascial pain syndrome

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**Core Tip:** The present study was a double-blind, randomized, placebo-controlled trial designed to compare the clinical efficacy of pulsed electromagnetic field (PEMF) therapy combined with heating-damp-clearing and pain-reducing paste (DPP) to that of heating-DPP alone for lower back myofascial pain syndromes. The main finding was that PEMF therapy combined with heating-DPP had better efficacy than heating-DPP alone in reducing the intensity of pain.

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# INTRODUCTION

Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage”[1]. Myofascial pain syndrome (MPS) is a musculoskeletal disorder in which tension (called the myofascial trigger point (MTrP)) is felt in local areas of muscle and fascia. Pain is felt when contact pressure is applied on MTrP, and snapping palpation or needle insertion causes a local twitching reaction[2]. MPS can result from muscle overuse and trauma; psychological stress; or ergonomic, structural, or systemic factors[3]. MPS often has a referred neuropathic component and affects more than three-quarters of the world's population[4]. Although MPS is a disease with no standard management and surveillance protocol[5], effective therapeutic methods are available for its treatment. Electromagnetic field (EMF) therapy is used clinically to treat myofascial pain. Generally, EMFs can be classified as static, low, or high-frequency fields. Extremely low frequencies between 1 and 300 Hz occur[6] and are associated with a minimal level of harm, beneficial clinical results, and a relatively small financial outlay[7]. In a randomized controlled trial, Elshawi *et al* [8] found that adding a pulsed EMF (PEMF) to a conventional physical therapy protocol yields superior clinical improvement in pain. PEMF is recommended by the United States Food and Drug Administration for the treatment of musculoskeletal diseases[9]. In an expert consensus study, Cao *et al* [10] recommended using EMF to treat MPS; and in a review study, Paolucci *et al* [11] concluded that EMF is well tolerated and effective with no negative side effects and that it can be integrated with rehabilitation for the treatment of pain in chronic and acute musculoskeletal diseases. In our study, the participants were given a PEMF therapy device, which generates the PEMF and heat.

In addition to PEMF therapy, a traditional Chinese herbal formula - damp-clearing and pain-reducing paste (DPP) - has been used to treat MPS for decades at Xiyuan Hospital of the China Academy of Chinese Medical Sciences. The application of this traditional Chinese medicine topical paste has a long history. After use, the topical paste quickly exerts its effect at the site of administration but can also exert its effect systemically *via* the systemic circulation. The paste has a long-lasting effect and a wide treatment range[12]. Because the EMF alters ion channels and accelerates blood circulation[13,14], this therapy may increase the penetration of the DPP molecules into target tissues. To the best of our knowledge, this is the first study to investigate the synergistic effects of PEMF therapy and DPP in patients with MPS. We hypothesized that PEMF therapy combined with heating-DPP has better efficacy than heating-DPP alone in pain reduction.



## MATERIALS AND METHODS

### Patient recruitment

A total of 120 participants diagnosed with lower back MPS according to the China National Diagnostic Criteria were recruited and divided into the experimental (EG) and control (CG) groups using the block randomization method. Seven patients dropped out, while 113 (EG = 58, CG = 55) completed all the tests, as shown in Figure 1.

The inclusion criteria were as follows: Patients who (1) Were aged 18–75 years; (2) met the diagnostic criteria listed in the textbook of *Musculoskeletal Rehabilitation* (third edition, 2018)[15]; (3) underwent imaging (radiography, computed tomography, or magnetic resonance imaging) and biochemical examinations except in the case of myofascial pain caused by tumor, infection, fracture, or other reasons; and (4) provided written informed consent.

Exclusion criteria were as follows: (1) Hypertension, severe cardiovascular and cerebrovascular diseases, superficial open wounds on the skin, infectious diseases, or bleeding tendency; (2) suspected or confirmed vertebral or spinal tumors, tuberculosis, and severe osteoporosis; (3) history of lumbar surgery or severe congenital deformity of the lumbar spine; (4) administration of other treatment methods 48 h before seeing the doctor; (5) pregnant or lactating women; and (6) inability to comprehend the contents of the scale for judging degree of pain.

Drop-out criteria for patients included in this study were as follows: (1) Inability to attend meetings on time or receive treatment as required; (2) use of drug or treatment that influenced the efficacy of the study or performance of the behavior required for the index detection; (3) damage or discomfort during treatment; and (4) voluntary withdrawal.

### Study design

This study was a randomized, double-blind, placebo-controlled clinical trial. The research protocol was approved by the ethics committee of Xiyuan Hospital of the China Academy of Chinese Medical Sciences (ethical approval No. 2018XLA049-7) and registered in the Chinese Clinical Trial Registry (registration no. ChiCTR2000033700) <http://www.chictr.org.cn>.

### Interventions

PEMF therapy: An EMF was generated using a PEMF therapeutic instrument (CZ-02B, Xingchen Wanyou Technology Co., Ltd., Beijing, China), which generates a 50 Hz and 3 mT PEMF. The instrument contains a host and belt that not only generates an EMF but also generates heat. DPP, a topical prescription produced at Xiyuan Hospital of the China Academy of Chinese Medical Sciences, is composed of *Radix paeoniae rubra*, *Achyranthis bidentatae radix*, *Angelica sinensis radix*, *Cassia twig*, *Caulis spatholobi*, *Clubmoss herb*, *Semen persicae*, *Tougucao*, *Kusnezoff monkshood root*, *Radix aconiti*, *Frankincense*, and *Myrrh*. All herbs were ground to a fine powder and mixed with vinegar to make a paste. According to traditional Chinese medical theory, this paste can invigorate circulation, eliminate stagnation, and reduce pain.

DDP was applied to the skin of the lower back, and the belt of the electromagnetic and thermal generator was fastened around the lower back. Each treatment lasted for 20 min and was applied five times a week for two weeks. The same procedure and dose were applied in both groups. However, the electromagnetic function of the therapeutic apparatus used in the CG was disabled by technicians.

### Assessments

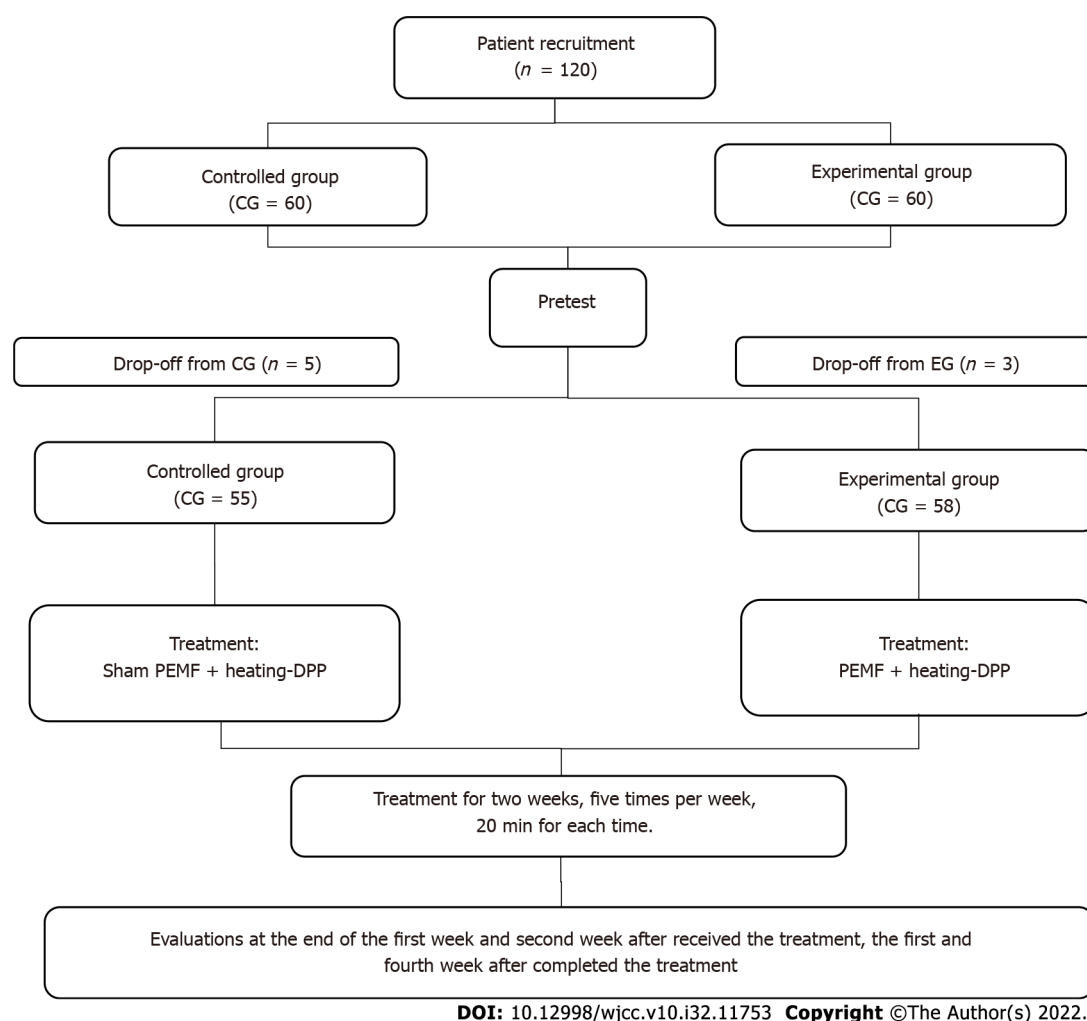
Pain is a symptom and not a sign, and its evaluation is dependent on the report or demonstration[16]. Questionnaires represent an appropriate reporting option, and in this study, the short-form McGill Pain Questionnaire (SF-MPQ) was used to evaluate patients' pain, and it is reportedly reliable and valid[17–19]. The SF-MPQ is sensitive to the effectiveness of pain therapies in different population settings[20,21] and measures the sensory and affective components of pain. The questionnaire included the visual analog scale (VAS), present pain intensity index (PPI), and pain rating index (PRI), to detect the intensity of pain, sensory pain, and affective pain.

VAS was used to evaluate pain intensity. A 10 cm ruler was included on the form, with anchor statements on the left (no pain) and right (extreme pain). The patient was asked to mark their current pain level on the ruler. The PPI measures the magnitude of pain experienced by an individual and represents a numeric-verbal combination to assess overall pain intensity[22]. The PPI was scored from 1 to 5, with 1 = mild pain, 2 = discomfort, 3 = distressing pain, 4 = horrible pain, and 5 = excruciating pain. The PRI has 15 descriptors - descriptors 1–11 for sensory pain and 12–15 for affective pain. Each descriptor was ranked on an intensity scale (0 = none, 1 = mild, 2 = moderate, and 3 = severe)[23]. To clarify the effect of the interventions on sensory and affective pain, the scores from these two pain types were analyzed individually.

For all pain scores, a higher value means worse pain.

### Outcomes

The main outcomes were changes in the overall pain intensity (VAS and PPI scores) and in sensory and



**Figure 1 Flow schematic of the study.** CG: Control group; EG: Experimental group; EMFP: Pulsed electromagnetic field; DPP: Damp-clearing and pain-reducing paste.

ffective pain (PRI scores) at the end of the first and second weeks of receiving treatment and at the end of the first and fourth weeks after completing treatment. The secondary outcome, which specified the effectiveness of the intervention on biological and psychological pain, was the change in sensory and affective pain scores.

### Sample size

The long power package was used to estimate the sample size for analysis by the generalized estimating equation (GEE)[24]. Based on Chang's estimation,  $\alpha$  was set to 0.5 (two-sided) and  $\beta$  to 0.2, and a sample size of 43 was obtained for each group. Owing to the estimated 30% dropout rate, 56 participants were required for each group[25]. 60 participants were enrolled in each group.

### Randomization and blinding

The Good Clinical Practice Statistical Office at Xiyuan Hospital was entrusted with generating random envelopes using the block randomization method. 120 cases were numbered and split into 30-case groups: A1-A30, B1-B30, C1-C30, and D1-D30. Before joining the group, an instrument technician adjusted and numbered the instruments according to the envelopes. The number was reflected on the instruments, whereas the grouping result was not. During enrollment, the participants were assigned numbers from small to large according to the sequence of enrollment.

Blinding was executed by special personnel who took charge of blind editing and implementation. The number of envelopes was the same as that of the PEMF instruments and remained unchanged throughout the experiment. Patients and physicians were not informed of the differences in equipment and grouping. Blinding was removed by the time data collection was completed.

### Statistical analysis

The difference in age between the EG and CG was calculated using an independent sample *t*-test, while that in sex was calculated using the  $\chi^2$  test. The pretest pain scores were calculated using the

Mann-Whitney *U* test. The pain scores from the pretest were then set as covariates to calculate the posttest outcomes using GEE. The ordinal logistic model was used in the GEE analysis to calculate the ordinal data - VAS and PPI scores. The linear with a link function of log was used to analyze the continuous data - PRI total, sensory, and affective scores. The main effects of time and group, interactions between time and group, and simple effects between the two groups at each time point were tested. All calculations were performed using SPSS version 20 (IBM Corp., Armonk, NY, USA).

## RESULTS

### Baseline characteristics

A total of 120 patients with MPS were enrolled; however, seven of them were dropped. Finally, 113 patients were included for statistical analysis (EG:  $n = 58$ , men = 16, women = 42, mean age =  $50.7 \pm 13.3$  years; CG:  $n = 55$ , men = 15, women = 40, mean age =  $52.6 \pm 13.6$  years). The basic characteristics of the patients and the pretest results in each group are listed in Table 1. The chi-square test was used to test for sex equality between the groups, while an independent t-test was used to test for age; VAS; PPI, PRI, and RRI sensory pain scores; and PRI affective pain scores. All tests showed no significant differences between the EG and CG (Table 1).

### Evaluation of the outcomes of overall pain intensity

The VAS scores in the EG were significantly lesser than those in the CG after the intervention (Wald  $\chi^2 = 4.198$ ,  $P = 0.040$ ); the time effect (Wald  $\chi^2 = 3.806$ ,  $P = 0.283$ ) and interaction effect of time and interventions (Wald  $\chi^2 = 14.736$ ,  $P = 0.002$ ) were also significant (Figure 2A). At each testing point, the VAS scores of the EG were lesser than those of the CG (T1: Wald  $\chi^2 = 22.231$ ,  $P = 0.000$ ; T2: Wald  $\chi^2 = 33.434$ ,  $P = 0.000$ ; T3: Wald  $\chi^2 = 28.782$ ,  $P = 0.000$ ; T4: Wald  $\chi^2 = 60.137$ ,  $P = 0.000$ ) (Table 2). As shown in Table 2, the VAS scores of both groups were significantly reduced (EG: Wald  $\chi^2 = 109.567$ ,  $P = 0.000$ ; CG: Wald  $\chi^2 = 48.753$ ,  $P = 0.000$ ) (Table 2). These results indicated that overall pain in EG was reduced more than that in CG, and the difference in efficacy increased over time.

Similar results were observed for the PPI scores, as its decrease in the EG was significantly larger than that in the CG after the intervention (Wald  $\chi^2 = 30.545$ ,  $P = 0.000$ ); the time effect (Wald  $\chi^2 = 39.539$ ,  $P = 0.000$ ). However, and interaction effect of time and interventions (Wald  $\chi^2 = 3.237$ ,  $P = 0.356$ ) was not statistically significant (Figure 2B). Compared with the CG, the PPI scores of the EG were lesser at each testing point (T1: Wald  $\chi^2 = 16.402$ ,  $P = 0.000$ ; T2: Wald  $\chi^2 = 25.200$ ,  $P = 0.000$ ; T3: Wald  $\chi^2 = 17.110$ ,  $P = 0.002$ ; T4: Wald  $\chi^2 = 16.577$ ,  $P = 0.000$ ) (Table 3). The reduction in PPI scores was also significant in both groups (EG: Wald  $\chi^2 = 93.582$ ,  $P = 0.000$ ; CG: Wald  $\chi^2 = 38.414$ ,  $P = 0.000$ ) (Table 3). These results suggest that the overall pain tested from PPI was also decreased more in EG relative to that in CG. However, the difference in efficacy between the two groups was not changed significantly over time.

### Evaluation of the outcomes of sensory pain and affective pain

We analyzed the PRI scores in three ways: Total pain, sensory pain, and affective pain scores.

The total PRI scores of the EG were significantly lesser than those of the CG after the intervention (Wald  $\chi^2 = 47.934$ ,  $P = 0.000$ ). The time (Wald  $\chi^2 = 49.423$ ,  $P = 0.000$ ) and interaction effect of time and interventions (Wald  $\chi^2 = 11.180$ ,  $P = 0.000$ ) were also significant (Figure 3A). There was a statistically significant difference in total PRI scores between the EG and CG at each testing point (T1: Wald  $\chi^2 = 13.836$ ,  $P = 0.001$ ; T2: Wald  $\chi^2 = 15.177$ ,  $P = 0.000$ ; T3: Wald  $\chi^2 = 26.756$ ,  $P = 0.002$ ; T4: Wald  $\chi^2 = 61.454$ ,  $P = 0.000$ ) (Table 4). A significant decrease in total PRI scores was also found in both groups (EG: Wald  $\chi^2 = 238.185$ ,  $P = 0.000$ ; CG: Wald  $\chi^2 = 65.551$ ,  $P = 0.000$ ) (Table 4).

The PRI sensory pain scores of the EG were significantly lesser than those of the CG after the intervention (Wald  $\chi^2 = 46.196$ ,  $P = 0.000$ ). The time effect (Wald  $\chi^2 = 39.984$ ,  $P = 0.000$ ) and interaction effect of time and interventions (Wald  $\chi^2 = 12.986$ ,  $P = 0.005$ ) were also significant (Figure 3B). There was a statistically significant difference in PRI sensory pain scores between the EG and CG at each testing point (T1: Wald  $\chi^2 = 10.353$ ,  $P = 0.001$ ; T2: Wald  $\chi^2 = 13.305$ ,  $P = 0.000$ ; T3: Wald  $\chi^2 = 28.271$ ,  $P = 0.000$ ; T4: Wald  $\chi^2 = 63.510$ ,  $P = 0.000$ ) (Table 5). A significant decrease in PRI sensory pain scores was found in both EG and CG (Wald  $\chi^2 = 197.864$ ,  $P = 0.000$ ; Wald  $\chi^2 = 45.488$ ,  $P = 0.000$ ) (Table 5).

Similar to the PRI sensory pain scores, the PRI affective pain scores decrease in the EG was significantly larger than that in the CG after the intervention (Wald  $\chi^2 = 16.057$ ,  $P = 0.000$ ); the time effect (Wald  $\chi^2 = 23.546$ ,  $P = 0.000$ ) and interaction effect (Wald  $\chi^2 = 8.325$ ,  $P = 0.040$ ) were also significant (Figure 3C). Compared to the CG, the PRI affective pain scores of the EG were lesser at each testing point (T1: Wald  $\chi^2 = 3.227$ ,  $P = 0.072$ ; T2: Wald  $\chi^2 = 5.489$ ,  $P = 0.019$ ; T3: Wald  $\chi^2 = 5.588$ ,  $P = 0.018$ ; T4: Wald  $\chi^2 = 23.485$ ,  $P = 0.000$ ) (Table 6). The reduction in PRI affective pain scores was also significant in both groups (EG: Wald  $\chi^2 = 128.366$ ,  $P = 0.000$ ; CG: Wald  $\chi^2 = 78.635$ ,  $P = 0.000$ ) (Table 6).

In general, total pain, sensory pain and affective pain from PRI scores were reduced in two groups, while the reduction in EG was more than that in CG. Interestingly, the significant difference in affective pain between the two groups was observed after two week's treatment.

**Table 1 Basic characteristics of the patients and pretest results**

Group	Sex		Age	Pretest				
	Men	Women		VAS	PPI	PRI	PRI sensory	PRI affective
CG ( <i>n</i> = 55)	15	40	52.62 ± 13.62	5 (4-7)	3 (1-3)	7 (4-11)	4 (3-7)	2 (1-4)
EG ( <i>n</i> = 58)	16	42	50.74 ± 13.33	5 (4-7)	3 (1-3)	7 (4.75-10.25)	5.5 (3.75-8.25)	2 (1-3)
Test statistic	$\chi^2 = 0.001$		$t = 0.740$	$Z = 0.911$	$Z = 0.800$	$Z = 0.823$	$Z = 1.199$	$Z = 0.049$
<i>P</i> value	0.97		0.46	0.36	0.42	0.411	0.231	0.961

CG: Control group; EG: Experimental group; VAS: Visual analog scale; PPI: Present pain intensity index; PRI: Pain rating index.

**Table 2 Changes in visual analog scale scores after treatment**

Group	T1	T2	T3	T4	Wald $\chi^2$	<i>P</i> value
CG ( <i>n</i> = 55)	4 (3-5)	3 (2-4)	4 (3-4)	4 (3-5)	48.753	0.000
EG ( <i>n</i> = 58)	3 (2-4)	2 (1-3)	2 (1-3)	2 (1-3)	109.567	0.000
Wald $\chi^2$	22.231	33.434	28.782	60.137		
<i>P</i> value	0.000	0.000	0.000	0.000		

CG: Control group; EG: Experimental group.

**Table 3 Changes in present pain intensity index scores after treatment**

Group	T1	T2	T3	T4	Wald $\chi^2$	<i>P</i> value
CG ( <i>n</i> = 55)	2 (1-2)	1 (1-2)	1 (1-2)	1 (1-2)	38.414	0.000
EG ( <i>n</i> = 58)	1 (1-2)	1 (0-1)	1 (0-1)	1 (0-1)	93.582	0.000
Wald $\chi^2$	16.402	25.200	17.110	16.577		
<i>P</i> value	0.000	0.000	0.002	0.000		

CG: Control group; EG: Experimental group.

**Table 4 Changes in pain rating index total scores after treatment**

Group	T1	T2	T3	T4	Wald $\chi^2$	<i>P</i> value
CG ( <i>n</i> = 55)	5 (3-7)	4 (2-5)	5 (3-6)	6 (4-7)	65.551	0.000
EG ( <i>n</i> = 58)	4 (2-6)	2 (1-4)	3 (1-5)	3 (1-5)	238.185	0.000
Wald $\chi^2$	13.836	15.177	26.756	61.454		
<i>P</i> value	0.001	0.000	0.002	0.000		

CG: Control group; EG: Experimental group.

## DISCUSSION

The present study was designed as a double-blind, randomized, placebo-controlled trial to control bias. The experiment was performed to compare the clinical efficacies of PEMF therapy combined with heating-DPP and heating-DPP alone for lower back MPS. The main finding of our study was that PEMF therapy combined with heating-DPP had better efficacy than heating-DPP alone in reducing the intensity of pain as well as sensory and affective pain. heating-DPP also had a positive effect on pain reduction.

**Table 5** Changes in pain rating index sensory pain scores after treatment

Group	T1	T2	T3	T4	Wald $\chi^2$	P value
CG (n = 55)	4 (2-5)	3 (1-4)	4 (2-5)	4 (3-5)	45.488	0.000
EG (n = 58)	3 (2-4)	3 (2-4)	2 (1-3)	2 (1-4)	197.864	0.000
Wald $\chi^2$	10.353	13.305	28.271	63.510		
P value	0.001	0.000	0.000	0.000		

CG: Control group; EG: Experimental group.

**Table 6** Changes in pain rating index affective pain scores after receiving treatment

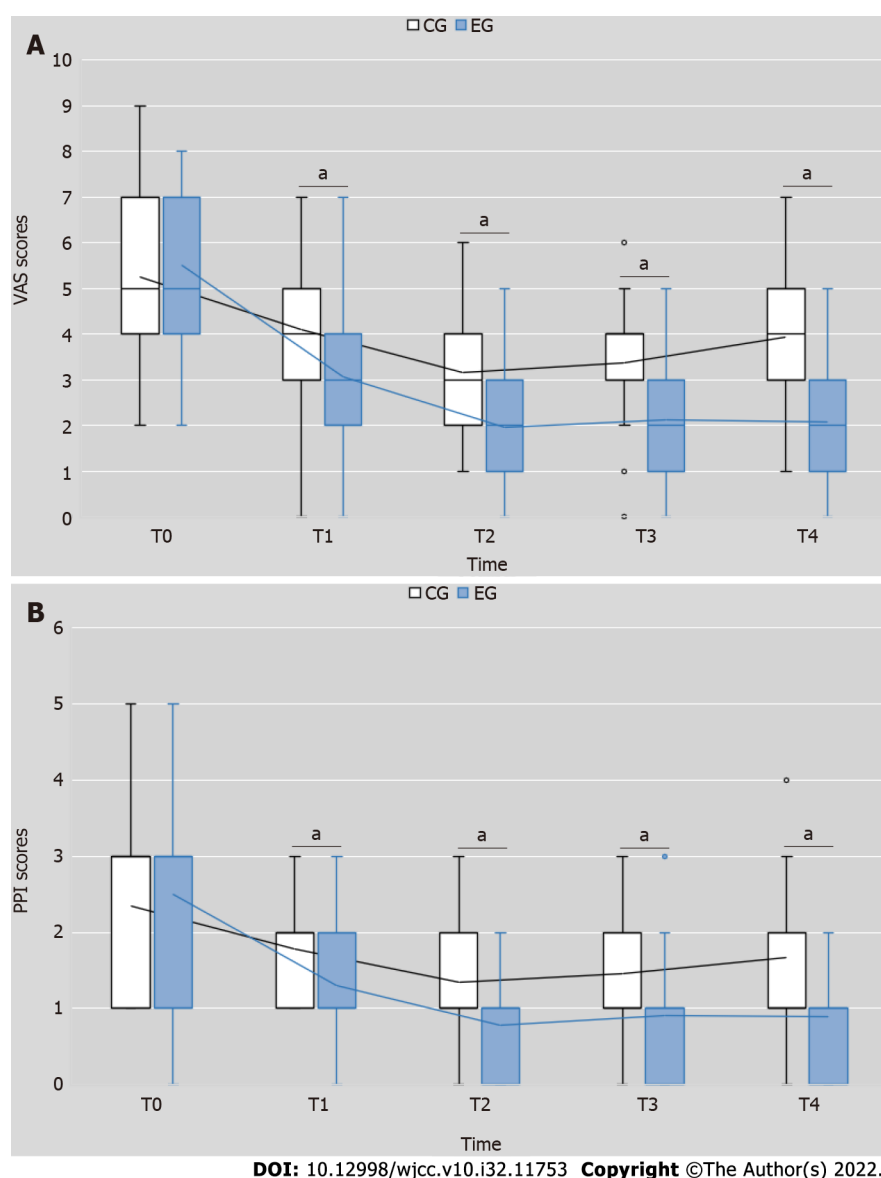
Group	T1	T2	T3	T4	Wald $\chi^2$	P value
CG (n = 55)	1 (0-2)	1 (0-2)	1 (0-2)	1 (1-2)	78.635	0.000
EG (n = 58)	1 (0-2)	0 (0-1)	1 (0-1)	1 (0-1)	128.366	0.000
Wald $\chi^2$	3.227	5.489	5.588	23.485		
P value	0.072	0.019	0.018	0.000		

CG: Control group; EG: Experimental group.

The VAS is a commonly used visual scale for evaluating the general intensity of pain, whereas the PPI is a numeric-verbal scale[18]. Both VAS and PPI provide data on overall pain intensity[26]. Regarding the significant reduction in overall pain intensity observed after PEMF therapy, our findings were consistent with another study conducted by Elshiwi *et al*[8] that PEMF therapy combined with physiotherapy (Transcutaneous Electrical Nerve Stimulation(TENS) therapy and exercise) decreased overall pain intensity better than physiotherapy alone[26]. To explain these results and biological mechanisms, the MTrP should be discussed. The MTrP is a typical indicator and evaluation factor for MPS. The incidence of MPS with associated MTrPs varies between 30% and 85% in patients presenting to pain clinics[27]. Latent ischemia at MTrPs is believed to be a cause of pain. Ischemia creates an acidic environment that lowers acetylcholinesterase levels, enhances the effects of acetylcholine (ACH), and prolongs muscular contraction[5]. Following an acidified environment and prolonged muscle contraction, nociceptive substances (*e.g.*, calcitonin gene-related peptide) are released, causing an increase in the number of ACH receptors and in ACH release[28]. This vicious cycle depletes adenosine triphosphate at trigger points, inhibiting the withdrawal of  $\text{Ca}^{2+}$  from muscle fibers. The accumulation of  $\text{Ca}^{2+}$  within myocytes is cytotoxic and stimulates inflammatory mediators, increases nociceptive sensitization, and results in severe pain[28,29]. Ion balance is maintained through the exchange of sodium, potassium, calcium, and chloride ions. By directing the movement of ions, the EMF can modify the charge distribution within cells and influence the opening and closing of some voltage-gated calcium channels[13]. Since the accumulation of  $\text{Ca}^{2+}$  in MTrPs causes MSP, the stimulation of calcium channels could lead to calcium withdrawal, relaxation of taut muscles, improved blood circulation, and consequently, reduced pain. Sun *et al*[14] found that PEMF could increase vein blood flow velocity in patients with diabetes, which supports the abovementioned theories. A review article summarized that low-frequency EMF downregulated pro-inflammatory proteins such as nuclear factor kappa B, tumor necrosis factor- $\alpha$ , interleukin (IL)-6, and interferon- $\gamma$  and upregulated anti-inflammatory cytokines such as IL-4, IL-10, and IL-13, meaning it can eliminate inflammation in MPS[30]. The elimination of inflammation relieves pain[31].

The mechanism underlying the effect of DPP is difficult to explain since its pharmacology has not yet been fully studied. However, the functions of some of the herbs used in DPP have been tested. *Radix paeoniae rubra* can substantially improve the function of vascular endothelial cells and promote microcirculation[32]. *Achyranthis bidentate radix* has antioxidant and anti-inflammatory properties and promotes wound healing and angiogenesis[33]. *Angelica sinensis radix* contains ligustilide, which has a positive effect in chronic inflammatory pain. Many components of *Caulis spatholobi* exert an analgesic effect through multiple pathways with multiple targets[34], whereas its active ingredients mainly regulate inflammation-related pathways through targets such as PRKCA, IL6, and AKT1 to exert anti-inflammatory effects[35,36].

Since DPP is usually administered with heat to improve efficacy, the thermal effect was maintained in both groups, and symptom relief might be contributed to the thermal effect. When tissue temperature is higher than 41.5°C, heat causes localized blood flow, increasing the availability of nutrients and oxygen,



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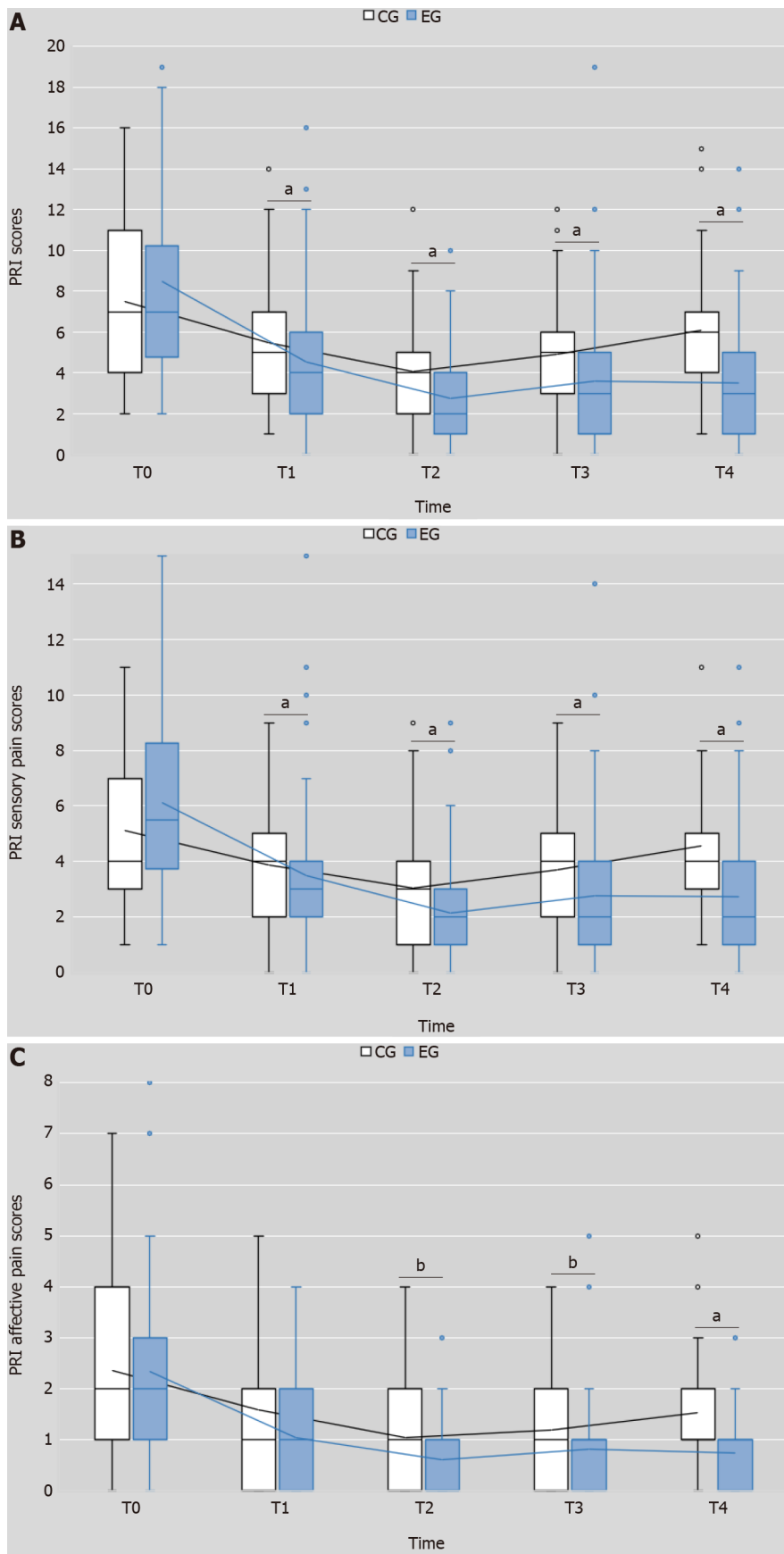
**Figure 2** Changes in visual analog scale and present pain intensity index scores after treatment. A: Visual analog scale scores; B: Present pain intensity index scores. T0 = pretest, T1 = end of the first week after receiving treatment, T2 = end of the second week after receiving treatment, T3 = end of the first week after completing treatment, T4 = end of the fourth week after completing treatment. <sup>a</sup> $P < 0.01$ , experimental group vs control group. CG: Control group; EG: Experimental group; VAS: Visual analog scale; PPI: Present pain intensity index.

improving tissue elasticity, normalizing tissue pH value, and exerting an analgesic effect[37].

Pain has a sensory and affective dimension[38]; it persists despite blockade of peripheral nociceptive inputs, which represents an effective motivational aspect of pain[39,40]. An example of this is the phenomenon of phantom limb pain. The PRI consists of a sensory and an affective subscale and can discriminate among various pain syndromes[26,41] and evaluate the level of pain after treatment. As summarized by Main[16], quantitative sensory testing offers reliability and precision, which may help identify those likely to develop central pain and may inform on the relationship between psychological factors and pain perception. The PRI results indicated that PEMF therapy combined with heating-DPP treatment was superior to heating-DPP treatment alone in decreasing sensory and affective pain.

However, concluding on whether PEMF therapy and heating-DPP treatment reduce psychological pain (affective pain) based on the PRI score is difficult. Therefore, we analyzed the sensory and affective pain scores separately. As shown in Table 5 and Table 6, PEMF therapy combined with heating-DPP had better results than heating-DPP treatment alone in the treatment of affective and sensory pain. This could be because overall pain intensity, sensory pain, and affective pain interact with each other; therefore, once the overall pain intensity was reduced, sensory and affective pain decreased simultaneously.





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**Figure 3** Changes in the pain rating index, sensory pain and affective pain. A: Pain rating index (PRI) scores; B: PRI sensory pain scores; C: PRI affective pain scores. T0 = pretest, T1 = end of the first week after receiving treatment, T2 = end of the second week after receiving treatment, T3 = end of the first week after completing treatment, T4 = end of the fourth week after completing treatment. <sup>a</sup> $P < 0.01$ , experimental group (EG) vs control group (CG); <sup>b</sup> $P < 0.05$ , EG vs

CG: Control group; EG: Experimental group; PRI: Pain rating index.

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## CONCLUSION

PEMF therapy combined with heating-DPP showed better efficacy than heating-DPP alone in reducing overall pain intensity, sensory pain, and affective pain. Distinctively, for affective pain, two weeks of treatment were required for superior clinical efficacy to manifest.

## ARTICLE HIGHLIGHTS

### **Research background**

Myofascial pain syndrome (MPS) is a common musculoskeletal disorder. Pulsed electromagnetic field (PEMF) therapy is a modern treatment for MPS, while damp-clearing and pain-reducing paste (DPP) combined with a heating effect has been used as an herbal ointment in China for a very long time.

### **Research motivation**

Both heating-DPP and PEMF are effective in the treatment of MPS. However, their synergistic effects remain unclear.

### **Research objectives**

This manuscript aimed to study whether PEMF therapy combined with heating-DPP is better than heating-DPP alone in the treatment of lumbar MPS.

### **Research methods**

In total, 120 patients with MPS were randomly assigned to two groups: the experimental (EG) and control (CG) groups. Both groups were treated with heating-DPP combined with PEMF therapy; however, the electromagnetic function was disabled in the therapeutic apparatus used for patients in the CG. All patients received a two-week intervention, and the short-form McGill Pain Questionnaire, which comprises a visual analog scale (VAS), present pain intensity index (PPI), and pain rating index (PRI), was completed by participants at five time points: pre-test, end of the first and second week of receiving treatment, and end of the first and fourth week after completing treatment.

### **Research results**

The VAS, PPI, and PRI (total, affective pain, and sensory pain scores) scores of the EG were significantly lesser than those of the CG after treatment and follow-up tests.

### **Research conclusions**

PEMF therapy combined with heating-DPP had better efficacy than heating-DPP alone in reducing overall pain intensity, sensory pain, and affective pain.

### **Research perspectives**

PEMF therapy plus heating-DPP, with their tested synergistic effects, may be a better option for treating lumbar MPS than heating-DPP alone. Further research on the pharmacology of DPP is needed.

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## FOOTNOTES

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**Clinical trial registration statement:** This study was registered in the Chinese Clinical Trial Registry (<http://www.chictr.org.cn>). The registration number is ChiCTR2000033700. And this registration policy applies to randomized placebo-controlled clinical trials.

**Informed consent statement:** The authors declare that there are no conflicts of interest regarding the publication of this article.

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**CONSORT 2010 statement:** The authors have read the CONSORT 2010 statement, and the manuscript was prepared and revised according to the CONSORT 2010 statement.

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