

# Efficacy evaluation of Mongolian medical warm acupuncture for sciatica caused by lumbar disc herniation: a randomized, controlled, single-blind clinical trial

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**Abstract. – OBJECTIVE:** This study aimed to evaluate the short-term and long-term efficacy of Mongolian medical warm acupuncture for sciatica caused by lumbar disc herniation (LDH).

**PATIENTS AND METHODS:** The patients diagnosed with sciatica caused by LDH were randomly divided into the warm acupuncture of the Mongolian medicine group (n = 42, warm acupuncture treatment), the sham acupuncture group (n = 38, sham acupuncture using blunt-tipped needles) and the conventional drug group (n = 40, ibuprofen sustained release capsule). All patients were treated for 4 weeks and followed up for 8 weeks. The visual analog scale for leg pain (VAS-LP), Mongolian medicine indicators (efficacy indicators), VAS for waist pain (VAS-WP) and the Mos 36-item short form health survey (SF-36) score were analyzed at baseline, after two-week treatment, after four-week treatment, at four-week follow-up and at eight-week follow-up.

**RESULTS:** Warm acupuncture treatment significantly decreased the VAS-LP and VAS-WP scores of patients at treatment and follow-up ( $p < 0.05$ ), and pain was improved compared to the conventional drug group and sham acupuncture group. The total effective rate was markedly higher in the warm acupuncture of the Mongolian medicine group compared with the conventional drug group at 8-week follow-up ( $p < 0.05$ ), but sham acupuncture treatment resulted in no evident improvement in the Mongolian medicine indicators. Additionally, at treatment and follow-up, warm acupuncture of the Mongolian medicine group showed a significant increase in the physical function, physical role,

body pain, and emotional and mental health role scores of the SF-36 survey compared with the sham acupuncture groups.

**CONCLUSIONS:** Mongolian medical warm acupuncture effectively relieves leg and waist pain and improves the total therapeutic effect and the quality of daily life for patients with sciatica caused by LDH, with significant long-term efficacy. Our study provides a basis for warm acupuncture in the treatment of sciatica caused by LDH.

Chinese Clinical Trial Registry ID: ChiCTR-15007413.

*Key Words:*

Mongolian medical warm acupuncture, Sciatica, Visual analog score.

## Introduction

Sciatica, also called lumbosacral radicular syndrome, is a common clinical disease worldwide<sup>1</sup>. It is characterized by sciatic nerve pain that radiates from the low back to below the knee, paresthesia and muscle weakness in the affected leg or foot<sup>2</sup>. The incidence rate of sciatica has been increasing in recent years, with more than three-quarters of the population experiencing it<sup>3</sup>. This common disease has seriously affected the daily life and work of patients, causing economic and social burdens that cannot be ignored<sup>4</sup>. Herniated disc involving nerve root compression

is the cause of about 90% of sciatica cases, producing substantial pain<sup>5</sup>. For pain control, pain medication and physical therapy are commonly applied for sciatica<sup>5</sup>. However, the use of pain medication is associated with adverse effects such as dizziness, ataxia, and nausea, and long-time use can cause addiction and tolerance<sup>6</sup>. Surgery is a traumatic treatment with a risk of post-operative infection and cerebrospinal fluid leakage, and it only delays the pain of patients<sup>7</sup>. Therefore, it is particularly important to develop effective clinical treatment programs to improve pain in patients with sciatica caused by lumbar disc herniation.

With the changes in medical concepts and needs, many patients with sciatica are willing to accept non-pharmacological treatment, such as traction, acupuncture, massage, and physiotherapy<sup>8</sup>. However, the therapeutic effect of these treatments is not exact<sup>9,10</sup>. Mongolian medicine, a kind of traditional medicine, has a unique mechanism and good efficacy in the treatment of sciatica<sup>11</sup>. There is no disease name of sciatica in Mongolian medicine classics, but due to the similar pathogenesis and clinical symptoms, sciatica is classified as “lower limb’s Baimai disease” in Mongolian medicine<sup>12</sup>. According to the theory of Mongolian medicine, the environmental and dietary factors (cold diet and imbalance between cold and heat) and external factors (trauma and disease) result in the imbalance of three roots (Heyi, Badagan, Xila), thus damaging the Baimai of the lower limbs and causing the disease<sup>13</sup>. “Improving the blood circulation of Heyi, dredging Baimai, adjustment and pain relief” are the main principles of treatment of the lower limb’s Baimai disease, and Mongolian medical warm acupuncture can be a treatment option. Mongolian medical warm acupuncture is a traditional therapy in which acupuncture combined with heat stimulation is given to specific or other sites (acupoints) of the human body to achieve the purpose of prevention and treatment of diseases. Warm acupuncture contributes to unclogging meridians and regulating blood circulation<sup>14</sup>. Additionally, it has been reported<sup>11,15</sup> that warm acupuncture can effectively improve pain threshold, inhibit inflammation, and improve clinical symptoms, which has broad prospects in the treatment of sciatica<sup>16</sup>. Due to the defects of the research design and some limitations of other objective factors, the evaluation of the curative effect of warm acupuncture in the treatment of sciatica is inconsistent, leading to insufficient objectivity<sup>17,18</sup>. Therefore, it is vital to conduct

reasonable and standardized clinical trials to clarify the efficacy and safety of Mongolian medical warm acupuncture for the treatment of sciatica. The three-arm trial not only provides the absolute efficacy of the experimental group by comparison with the placebo but also observes efficacy and safety advantages through the comparison with the positive drugs<sup>19</sup>. In this study, we designed a randomized, single-blind, three-arm clinical trial to assess the short-term and long-term curative effects of warm acupuncture for sciatica caused by lumbar disc herniation. The patients who were diagnosed with sciatica and lower limb Baimai disease were treated with warm acupuncture, and we analyzed the changes in visual analog scale (VAS) for leg pain (VAS-LP), Mongolian medicine indicators (efficacy indicators), VAS for waist pain (VAS-WP) and the Mos 36-item short-form health survey (SF-36) at the treatment and follow-up. This study provided a basis for the clinical treatment of sciatica caused by lumbar disc herniation.

## Patients and Methods

### Patients

Patients were recruited via the publicity column of the Affiliated Hospital of Inner Mongolia Medical University from June 2017 to December 2017. Patients who have been diagnosed with sciatica caused by lumbar disc herniation in a Mongolian medical clinic were also recruited.

The inclusion criteria were as follows: 1) patients who conformed to the North American Spine Society guidelines for diagnosis and treatment of lumbar disc herniation<sup>20</sup> and diagnostic criteria of sciatica<sup>21</sup>; 2) patients conformed to the clinical diagnostic criteria of “lower limb’s Baimai disease” in Mongolian medicine<sup>22</sup>; 3) the VAS of pain foot  $\geq$  40 mm; 4) patients’ age ranging from 18 to 65, males or females; 5) course of sciatica was 1-24 months; 6) patients had no mental disorders and serious disease of heart, liver, kidney, hematopoietic and digestive system; 7) patients had good compliance with the therapy; 8) patients were willing to sign informed consent and participate in this study.

Patients who met any of the following criteria were excluded: 1) Patients who needed surgical treatment for severe lumbar disc herniation, equine cauda syndrome, or foot drop; 2) patients who failed to respond to conservative treatment for three months. 3) patients who were pregnant or lactating; 4) patients with severe osteoporosis or

signs of a potentially serious condition; 5) patients with poor compliance or not meeting the related provisions of the Medical Ethics Committee.

The trial was terminated early for patients who met any of the following criteria during the trial: 1) patients did not meet the inclusion criteria; 2) subjects voluntarily withdrew; 3) Patients received other therapies or voluntarily changed the course of treatment during the trial; 4) patients developed serious adverse reactions or complications that made them unfit to continue the trial.

### **Sample Size Calculation**

According to a previous study<sup>23</sup>, the changes in VAS-LP during the treatment period were 30 mm in patients receiving conventional acupuncture. Considering the significance of the therapeutic value, the expected changes in VAS-LP score in warm acupuncture and conventional drug groups were 40 mm. Subsequently, the required number in each group was calculated with a desired  $\alpha$  level = 0.05 and inspection efficiency  $1-\beta = 0.09$  according to multiple mean comparing sample's number formulas. The required number of patients was 34 in each group. Finally, considering a 10% dropout rate, the sample size was 38 patients in each group.

### **Study Design**

This study was a single-center, single-blind, and randomized controlled clinical trial at the Affiliated Hospital of Inner Mongolia Medical University, Inner Mongolia, China. In this study, the researchers, operators, and statisticians were separated. The researchers did not know the patients' treatment programs. Operators treated the patients according to a randomly selected treatment program. Patients were blinded to group assignment and received the treatment provided by operators. Third-party statisticians were unaware of the overall design of the trial. All researchers received the related training on the blind method principle before the clinical trial and strictly observed it.

This study was performed under the supervision of the Affiliated Hospital of Inner Mongolia Medical University. The Ombudsman is a traditional Chinese medicine doctor who has relevant expertise, professional training and at least five years of practical experience in clinical research work. The Ombudsman conducted the flying visit about trial process and supplement, including the verification of test data, program compliance, adverse effects, management of trail and the safety of patients, which ensure the quality and safety of this study to a large extent.

### **Trial Registration and Ethics Approval**

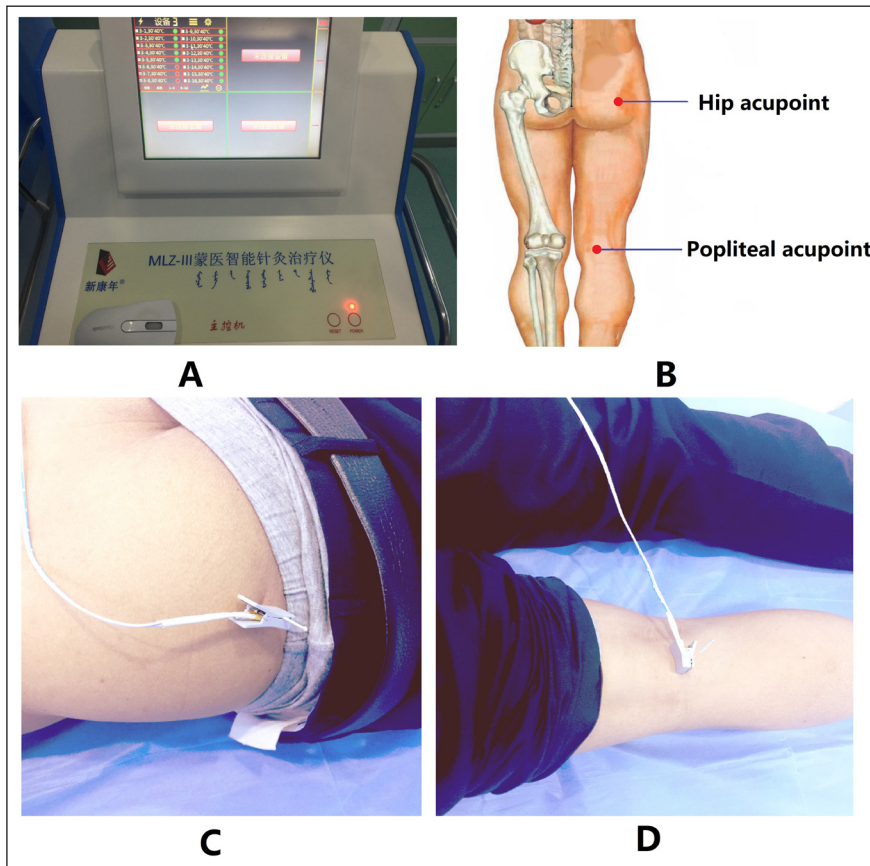
This trial was approved by the Ethics Committee of the Affiliated Hospital of Inner Mongolia Medical University (No. KY2018005). Research purpose, content, requirements, and others complied with the basic requirements of medical ethics. The study was registered on the Chinese Clinical Trial Registry (ChiCTR-INR-15007413).

### **Interventions**

Patients were randomly assigned to warm acupuncture of the Mongolian medicine group, sham acupuncture group and conventional drug group in a 1:1:1 ratio ( $n = 43$ ) using an allocation sequence from a computer-generated random number table. Patients in the former two groups, warm acupuncture of the Mongolian medicine group and the sham acupuncture group attended therapy sessions three times per week for 4 weeks. In the warm acupuncture of the Mongolian medicine group, warm acupuncture treatment was provided by physicians who have physician qualifications and at least three years of clinical acupuncture experience. Special silver needles (Kangnian Medical Instrument Co., Ltd, Shanghai, China) used for warm acupuncture were 50 mm or 70 mm in length and 0.5 mm in diameter, respectively. The MLZ-III Mongolian medicine intelligent acupuncture therapy instrument (produced by Inner Mongolia Medical University, Patent No. ZL 2011 2 0058078.0) was adopted to heat the silver needles at 40°C for 30 min (Figure 1A). After the silver needles were cooled, the physicians used the needles to perform warm acupuncture treatment<sup>24</sup>.

The acupoints, including hip acupoint, popliteal acupoint, and the evident pain point, were selected based on Mongolian medicine classics combined with expert opinion and clinical experience. The hip acupoint was located three inches from the flat tailbone of the gluteus maximus, and the popliteal acupoint was in the middle of the transverse lines of the popliteal line (Figure 1B). The specific acupuncture procedures were as follows: first, the patients were placed in a prone position, and the skin was routinely sterilized with 75% alcohol. Then, the 70 mm needle was inserted into the hip acupoint at a depth of 33-66 mm until patients produced tactile sensation (Figure 1C). Additionally, the 50 mm needle was inserted into the popliteal acupoint at a depth of 20-40 mm (Figure 1D). The evident pain point was treated dialectically according to the individual condition of the patients.

A special placebo needle without a needle tip (0.5 mm\*50 mm, Kangnian Medical Instrument



**Figure 1.** Apparatus and acupoints for Mongolian medical warm acupuncture. **A**, MLZ-III Mongolian medicine intelligent acupuncture therapy instrument. **B**, position diagram for Hip acupoint, Popliteal acupoint. **C**, Warm acupuncture diagram for Hip acupoint. **D**, Warm acupuncture diagram for Popliteal acupoint.

Co., Ltd, Shanghai, China) was used in the sham acupuncture group. The placebo needle includes a needle and needle pad. The needle is a blunt point silver needle, and the needle pad is an aseptic polyethylene cylindrical foam pad. The needle pad is used for fixing the needles, whose bottom diameter is 1 cm and height is 5 mm, and its bottom bonds double-sided adhesive. During the treatment, the needle pad was fixed first, and then the acupuncture procedures were the same as the warm acupuncture of the Mongolian medicine group. However, the placebo needle only touched the skin surface. After treatment, pressing the acupoints slightly made patients feel like pulling out the needle.

In the conventional drug group, ibuprofen sustained release capsule (Fenbid, H10900089, Sino-American Schwebbes Co., Ltd., Tianjin, China) was adopted: one oral capsule at a time for adults was administrated twice daily (once in the morning and once in the evening). The treatment course lasted for 7 days, with a total of 4 courses.

### Outcome Measures

The primary outcomes were VAS-LP value and Mongolian medicine indicators. VAS-LP,

formulated by the Chinese Association for the Study of Pain (CASP)<sup>25</sup>, has high sensitivity in the evaluation of pain and has been commonly used to measure lower limb pain, with 0 indicating no pain and 100 indicating the worst possible pain. The total effective rate served as the indicator assessing the curative effect of Mongolian medicine. The criteria for efficacy evaluation were formulated with reference to the “lower limb’s Baimai disease” described in the Internal Medicine of Mongolian medicine<sup>26</sup>: 1) Cure: disappearance of back and leg pain and other related symptoms, normal functional activities, no recurrence at six-month follow-up; 2) Significant effect: basic disappearance of back and leg pain and other related symptoms, no restriction of functional activities; 3) Improvement: relief or improvement of back and leg pain and other related symptoms, restored partial functional activities, but the condition is unstable and often recurs; 4) Invalid: the symptoms have no obvious change, or even worsen.

The second outcomes were the VAS-WP value and SF-36 score. VAS-WP was similar to VAS-LP. SF-36 evaluates the physical state and mental state of patients considering 8 dimensions

containing physical functioning, physical role, body pain, general health, emotional role, vitality, mental health, and social functioning<sup>27</sup>. A higher SF-36 score indicates a higher quality of life.

Baseline information of patients was collected in the week when patients were enrolled in the trial: sex, age, education, smoking, drinking, work, course of disease, lumbar disc herniation segment, VAS-LP, VAS-WP, and SF-36. VAS-LP, VAS-WP, SF-36 and Mongolian medical indicators were collected after 2 weeks and 4 weeks of treatment. After treatment, the patients were followed up at weeks 8 and 12 of enrollment.

### **Follow-up**

Outpatient or telephone follow-up was carried out. Patients who could not attend outpatient appointments were followed up by phone, while other patients attended the clinic. The 4-week and 8-week follow-up were performed at weeks 8 and 12 after enrollment, respectively. The contents of the follow-up included VAS-LP, VAS-WP, and SF-36 scores and Mongolian medicine symptoms and indicators.

### **Statistical Analysis**

SPSS 22.0 (IBM Corp., Inc., Armonk, NY, USA) was adopted for statistical analysis. The paired *t*-test was used to analyze the changes before and after treatment. Data passing normality tests were compared using a one-way analysis of variance (ANOVA) followed by an LSD post hoc test. The intergroup comparison of enumeration data used the Chi-square test ( $\alpha = 0.05$ ). The data was expressed as mean  $\pm$  standard deviations (SD). No adjustment for multiplicity was made during statistical analysis.  $p < 0.05$  was considered to be statistically significant.

## **Results**

### **Overall Conditions of Clinical Trial**

We recruited a total of 165 patients, 138 of whom were recruited via the publicity column and 27 patients via the Mongolian medical clinic. In the early period of recruitment, 31 patients were excluded by preliminary telephone screening, including 12 patients whose course of disease was  $> 20$  years, 10 patients who suffered from other chronic diseases, and 9 patients who refused to participate for other reasons. The remaining 134 patients were further examined in a Mongolian medical clinic. Subsequently, 5 patients were excluded by clinical diagnosis,

including 3 patients with VAS-LP  $< 40$  mm and 2 patients with lumbar disc herniation but without sciatica symptoms. Finally, 129 patients participated in the clinical trial, and they were randomized into three groups. During the study period, 9 patients dropped out, including 4 patients who used other treatments, 3 patients who gave up due to poor compliance, and 2 patients who gave up treatment due to job transfer. The remaining 120 patients completed this research, and their data were completed (Figure 2). There were no adverse reactions during this trial.

### **Baseline Characteristics of Patients**

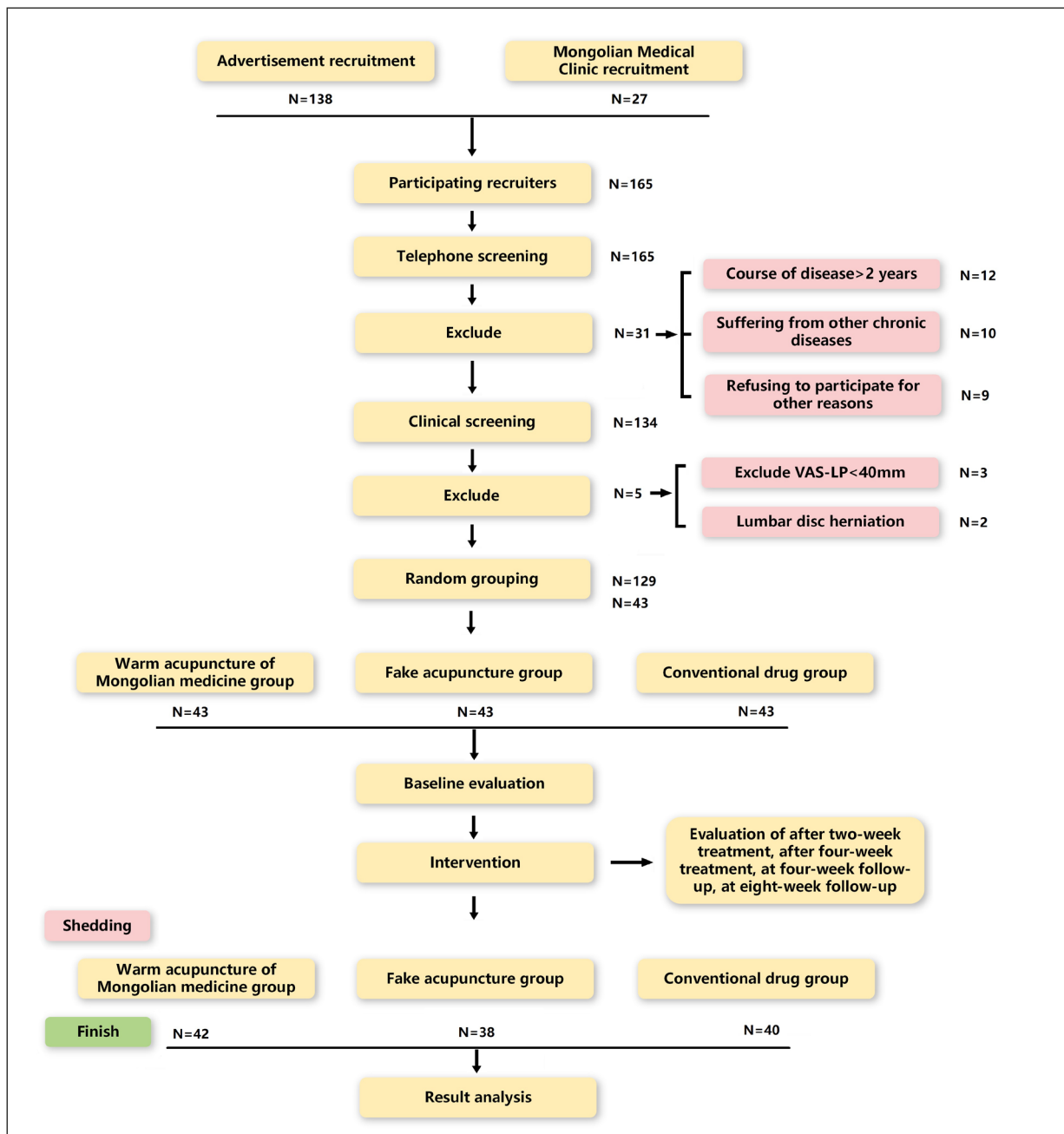
The differences in sociodemographic characteristics of the three groups of patients were analyzed using a Chi-square test and one-way analysis of variance. No significant difference in age, body mass index (BMI), smoking, drinking, work types, course of disease, lumbar disc herniation segment (L3-L4, L4-L5 and L5-S1) and straight leg raise test was found among three groups before treatment ( $p > 0.05$ ) (Table I).

VAS-LP, VAS-WP, and SF-36 were used to evaluate the disease degree of patients in each group. The VAS-LP value ranged from 58 to 74.5 in the warm acupuncture of the Mongolian medicine group, 53.5 to 68 in the sham acupuncture group, and 51.5 to 72.5 in the conventional drug group. The VAS-WP value ranged from 37.5 to 62 in the warm acupuncture of the Mongolian medicine group, 37 to 52.5 in the sham acupuncture group, and 33.5 to 55 in the conventional drug group. There was no significant difference in VAS-LP value, VAS-WP value, and eight-dimension scores of SF-36 between the three groups before treatment (Figure 3). The results above indicated that they were comparable.

### **Effect of Mongolian Medical Warm Acupuncture on VAS-LP and VAS-WP Scores**

The changes in VAS-LP and VAS-WP scores are displayed in Figure 4. In warm acupuncture of the Mongolian medicine group, the VAS-LP and VAS-WP scores were significantly decreased after 2-week treatment ( $p < 0.05$ ), and the VAS-LP and VAS-WP scores at 8-week follow-up were lower than those at 4-week follow-up. The results indicated that warm acupuncture effectively relieved the pain of patients and had a long-term curative effect.

In the sham acupuncture group and conventional drug group, the VAS-LP and VAS-WP scores



**Figure 2.** Flow diagram of enrollment and participation.

decreased after 2-week treatment, while the scores showed an upward trend with the extension of treatment. At the 4-week and 8-week follow-up, the VAS-LP and VAS-WP scores were lower than those at baseline and showed a decreasing trend at the 8-week follow-up. It indicated that conventional drugs and sham acupuncture relieved the pain of patients in the short term.

No significant difference was identified in VAS-LP and VAS-WP scores between the sham

acupuncture group and the conventional drug group at treatment and follow-up, suggesting the two groups had similar effects on pain relief. Furthermore, the VAS-LP and VAS-WP scores of warm acupuncture of the Mongolian medicine group were significantly higher than those of the conventional drug group during treatment and follow-up. These results showed that warm acupuncture was superior to conventional drugs in relieving the pain of patients.

**Table I.** Comparison of sociodemographic characteristics and baseline clinical characteristics of patients in three groups.

Characteristics	Warm acupuncture of the Mongolian medicine group (N = 42)	Sham acupuncture group (N = 38)	Conventional drug group (N = 40)	$\chi^2$	<i>P</i>
Gender (n, %)				6.525	0.038
Female	26 (61.9)	21 (55.3)	29 (72.5)		
male	16 (38.1)	17 (44.7)	11 (27.5)		
Median age (range)-yr	45.0 ± 11.8 (34-57)	42.0 ± 12.5 (31-62)	44.0 ± 16.8 (37-65)		0.620
Body mass index (range)	22.0 ± 2.0 (21-23)	22.0 ± 2.1 (21-23)	23.0 ± 2.2 (22-24)		0.052
Smoking (n, %)				2.72	0.257
Yes	9 (21.4)	11 (28.9)	8 (20.0)		
No	33 (78.6)	27 (71.1)	32 (80.0)		
Drinking (n, %)				5.707	0.058
Yes	11 (26.2)	16 (42.1)	14 (35.0)		
No	31 (73.8)	22 (57.9)	26 (65.0)		
Work types (n, %)				0.618	0.734
Physical labor	18 (42.9)	15 (39.5)	15 (37.5)		
Non-physical labor	24 (57.1)	23 (60.5)	25 (62.5)		
Course of disease (range)-mh	10.0 ± 3.9 (7-15)	9.0 ± 3.5 (5-13)	9.1 ± 3.6 (6-15)		0.403
L3-L4 protrude (n, %)				2.429	0.297
Yes	7 (16.7)	10 (26.3)	9 (22.5)		
No	35 (83.3)	28 (73.7)	31 (77.5)		
L4-L5 protrude (n, %)				2.752	0.253
Yes	34 (81.0)	27 (71.1)	30 (75.0)		
No	8 (19.0)	11 (28.9)	10 (25.0)		
L5-S1 protrude (n, %)				2.225	0.329
Yes	29 (69.1)	23 (60.5)	24 (60.0)		
No	13 (30.9)	15 (39.5)	16 (40.0)		
Pain site (n, %)				29.705	0.000
Left	19 (45.2)	25 (65.8)	11 (27.5)		
Right	23 (54.8)	13 (34.2)	29 (72.5)		
Straight leg raise test (n, %)				3.534	0.171
positive	31 (73.8)	30 (78.9)	27 (67.5)		
negative	11 (26.2)	8 (21.1)	13 (32.5)		

### ***The Effect of Mongolian Medical Warm Acupuncture on Mongolian Medicine Indicators***

Figure 5 and Table II display the therapeutic effects of different treatments in patients. Both at treatment and follow-up, the total effective rate of sham acupuncture group was significantly lower than that of the conventional drug group and the warm acupuncture of Mongolian medicine group ( $p < 0.05$ ), indicating that the sham acupuncture treatment has no evident therapeutic effect in the treatment of sciatica. The total effective rate showed no significant difference between the conventional drug group and the warm acupuncture of the Mongolian medicine group both at 2-week and 4-week treatment, but it was evidently higher in the latter group at 8-week follow-up ( $p < 0.05$ ). It indicated that the long-term efficacy of warm acupuncture in the treatment of sciatica is better than conventional drug therapy. The

patients in the conventional drug group did not have adverse reactions. The treatment sites of patients in the warm acupuncture of the Mongolian medicine group became red and swollen after treatment because the acupuncture needles were thick. The redness and swelling did not affect the activity of patients and subsided in approximately 2-3 days. There were no other adverse reactions in the warm acupuncture of the Mongolian medicine group.

In the conventional drug group, the total effective rate was as high as 87.5% at four-week treatment, while it decreased at 8-week treatment. It suggested that conventional drugs have some efficacy in the short term, but the long-term efficacy is not satisfactory. In the warm acupuncture of the Mongolian medicine group, the total effective rate of 4-week treatment (95.2%) was higher than that of 2-week treatment (90.9%), suggesting that the efficacy of warm acupuncture was increased with the prolonging of treatment.

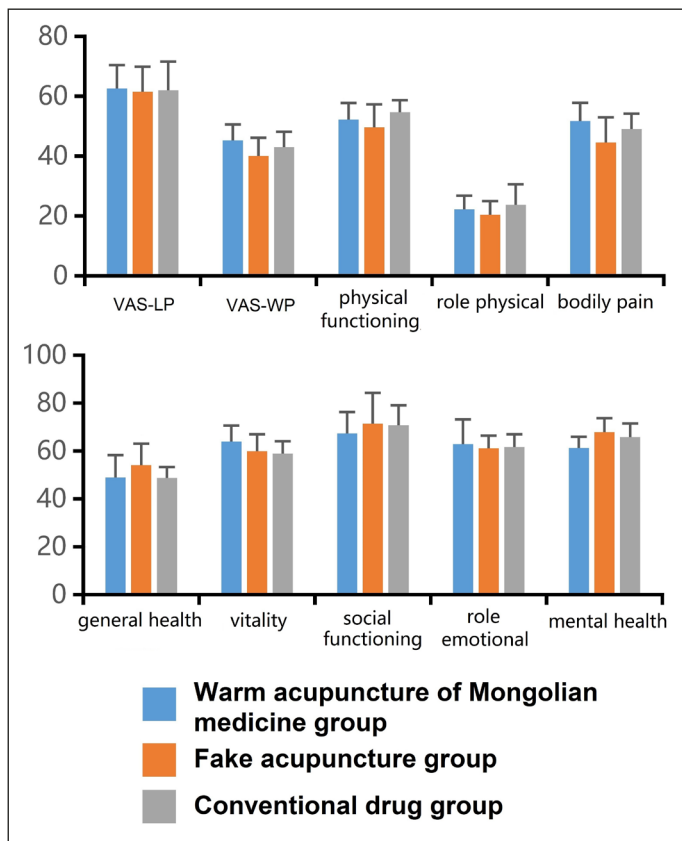


Figure 3. The VAS-LP, VAS-WP and eight-dimension scores of SF-36 of patients at baseline.

**The Effect of Mongolian Medical Warm Acupuncture on SF-36 Score**

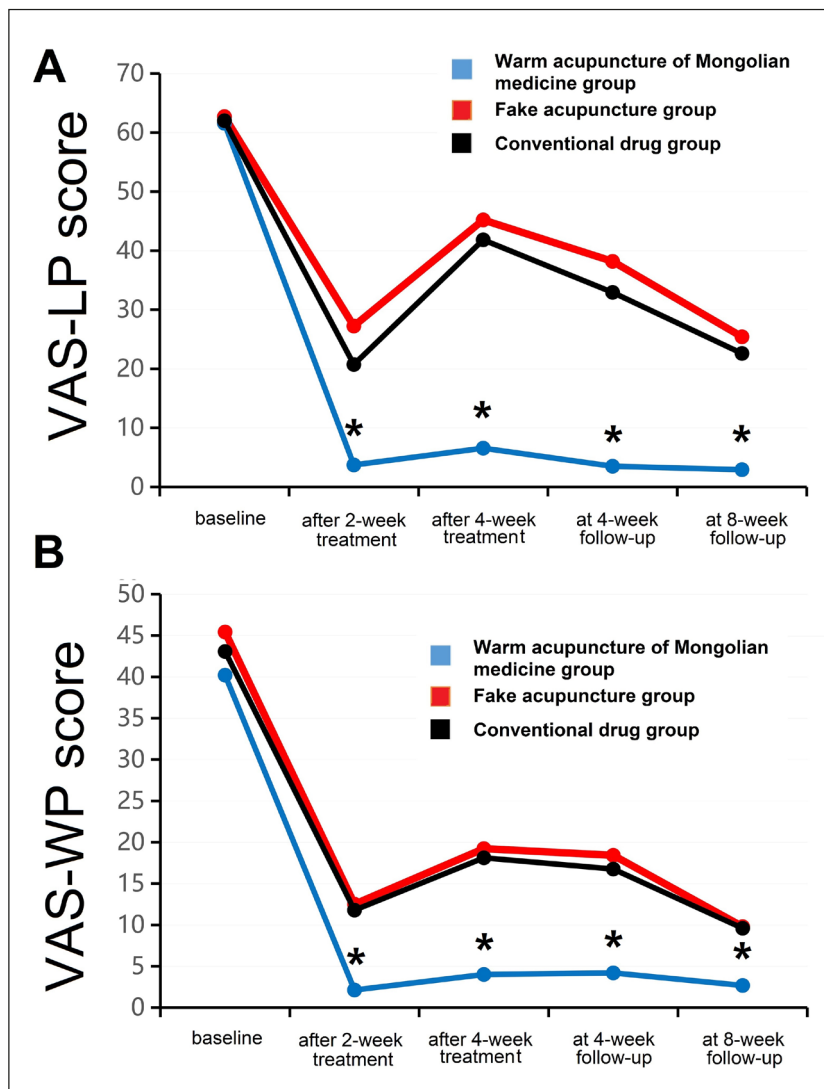
The changes in SF-36 scores in the three groups are displayed in Figure 6. In the warm acupuncture of the Mongolian medicine group, the physical role, general health, vitality, social functioning, and

mental health scores were increased in the treatment and follow-up compared with baseline. Compared with the sham acupuncture group, the physical function, physical role, body pain, emotional role, and mental health scores of the SF-36 survey in the warm acupuncture of the Mongolian medicine

Table II. The comparison of the Mongolian medicine indicators during the treatment and follow-up among the three groups.

		Warm acupuncture of the Mongolian medicine group (N = 42)	Sham acupuncture group (N = 38)	Conventional drug group (N = 40)
After 2-week treatment	Cure	/	/	/
	Significant effect	12 (28.6%)	/	9 (22.5%)
	Improvement	22 (52.4%)	5 (13.2%)	21 (52.5%)
After 4-week treatment	Invalid	8 (19.0%)	33 (86.8%)	10 (25.0%)
	Cure	18 (42.9%)	/	15 (37.5%)
	Significant effect	17 (40.4%)	1 (2.6%)	14 (35.0%)
At 4-week follow-up	Improvement	5 (11.9%)	7 (18.4%)	6 (15.0%)
	Invalid	2 (4.8%)	30 (79.0%)	5 (12.5%)
	Cure	14 (33.3%)	/	12 (30.0%)
At 8-week follow-up	Significant effect	18 (42.9%)	/	15 (37.5%)
	Improvement	7 (16.7%)	4 (10.5%)	6 (15.0%)
	Invalid	3 (7.1%)	34 (89.5%)	7 (17.5%)
At 8-week follow-up	Cure	10 (23.8%)	/	10 (25.0%)
	Significant effect	22 (52.4%)	/	14 (35.0%)
	Improvement	5 (11.9%)	2 (5.3%)	6 (15.0%)
	Invalid	5 (11.9%)	36 (94.7%)	10 (25.0%)





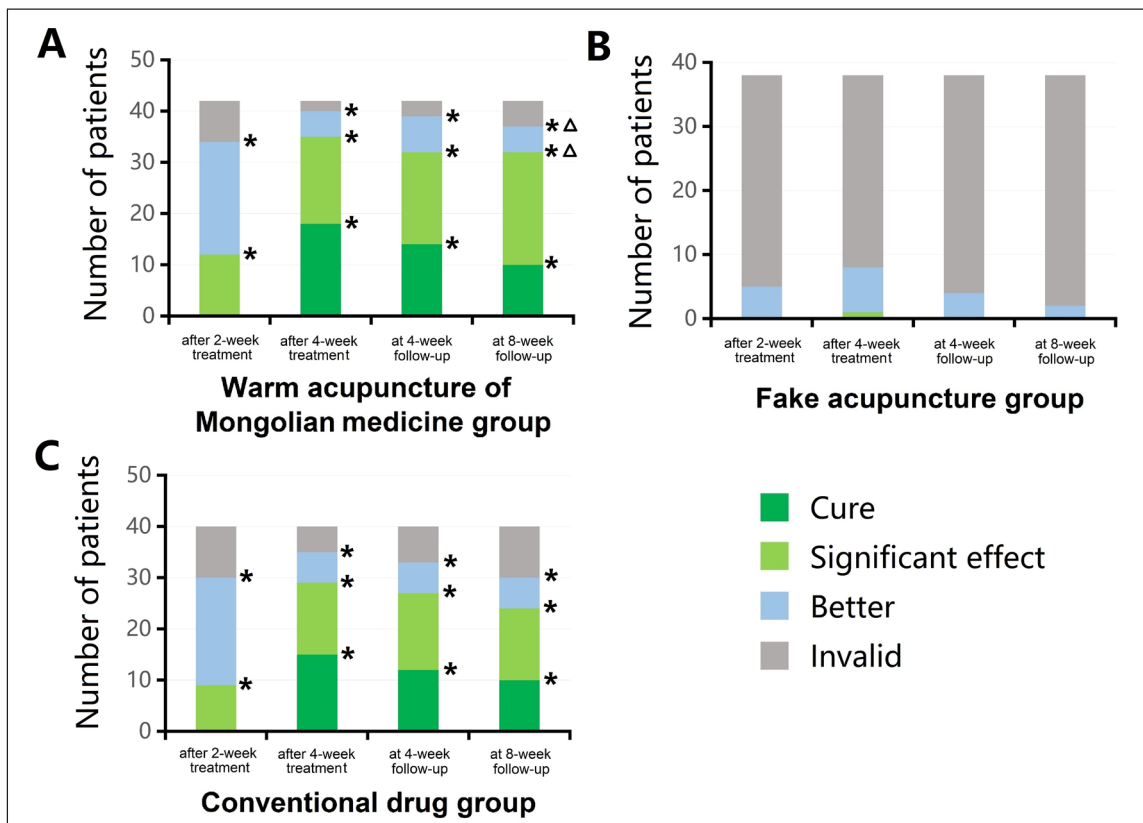
**Figure 4.** The changes of VAS-LP (A) and VAS-WP (B) scores in three groups during the treatment and follow-up. \* $p < 0.05$  vs. baseline.

group were significantly increased at treatment and follow-up. The bodily pain, general health, vitality, social functioning, and mental health scores in the warm acupuncture of the Mongolian medicine group were slightly higher than that in the conventional drug group, but there was no significant difference in general between the two groups during treatment and follow-up. The results meant that warm acupuncture was superior to the other two treatments in improving the quality of patients' lives.

## Discussion

The main clinical treatments of sciatica are drug treatment and surgery<sup>5</sup>. However, analgesics have some adverse effects, and surgery is a traumatic treatment with a risk of post-operative in-

fection and cerebrospinal fluid leakage<sup>6,7</sup>. Unlike those treatments, Mongolian medicine can adjust the balance of the whole by appropriate means to stimulate the auto-regulation function of the body in the treatment of sciatica<sup>28,29</sup>. Warm acupuncture has the functions of warming and unblocking meridians, enhancing immunity, and preventing and treating diseases. It exerts a therapeutic effect through the combination of acupuncture, hyperthermia and acupoint stimulation<sup>16</sup>. The special silver acupuncture needles used in warm acupuncture are effective heat-transferring medium. According to the theory of cold and warm balance, warm acupuncture (a hyperthermia therapy) has a good curative effect in treating cold diseases, such as the lower limb Baimai disease<sup>30</sup>. Needling into the acupoints can transmit the warming effect to the lesion and has the functions of eliminating



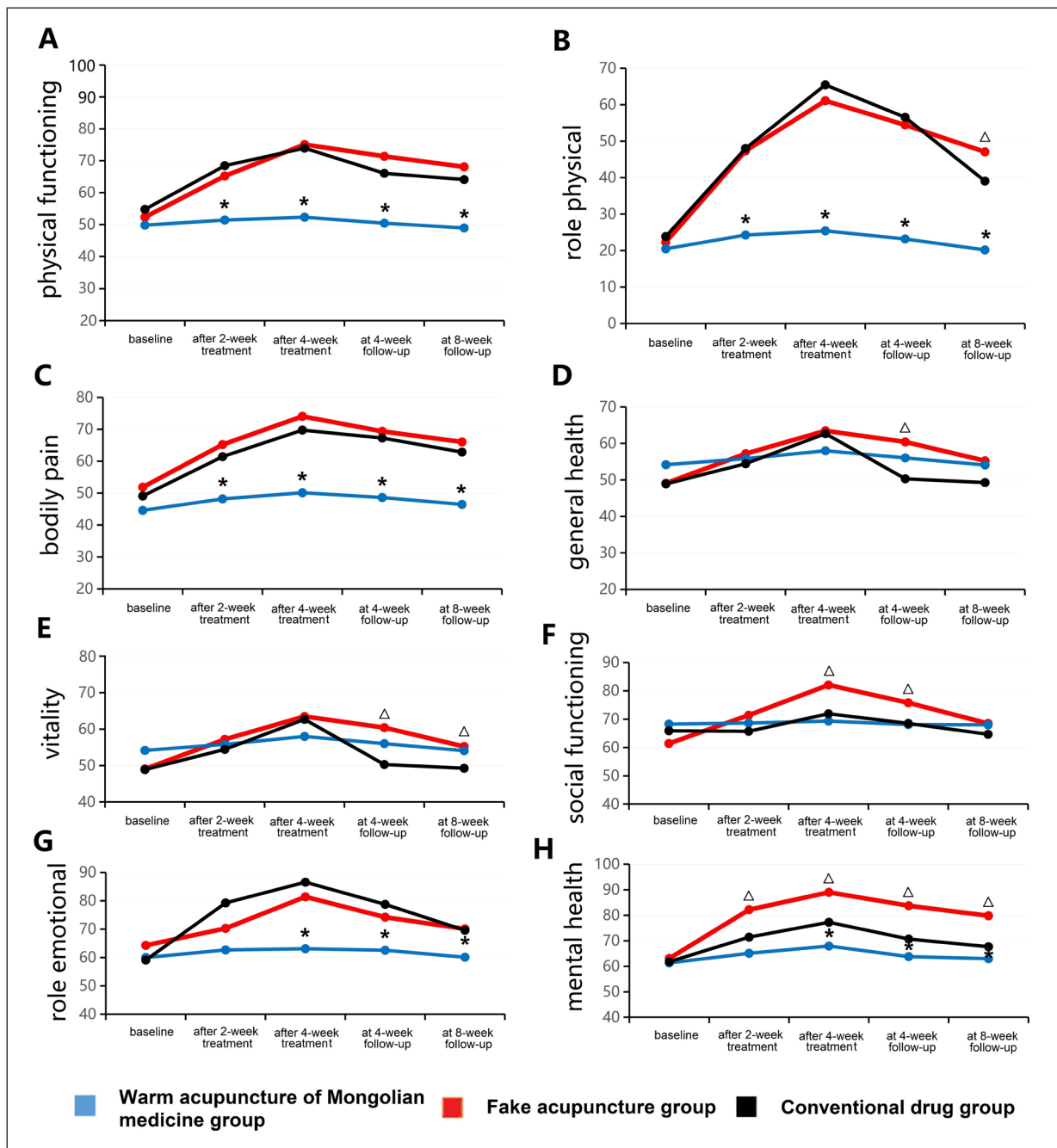
**Figure 5.** The changes of Mongolian medicine indicators during the treatment and follow-up in warm acupuncture of Mongolian medicine group (A), sham acupuncture group (B) and conventional drug group (C). \* $p < 0.05$  vs. sham acupuncture group at the corresponding time point.  $\Delta p < 0.05$  vs. conventional drug group at the corresponding time point.

inflammation, loosening nerve root adhesion, and relieving local spasm<sup>31</sup>. In our study, the results displayed that the total effective rate of warm acupuncture treatment was increased with the prolonging of treatment, and the long-term curative effect was significantly better than that of conventional drug treatment. However, there was no evident improvement in the total effective rate after sham acupuncture treatment. Overall, warm acupuncture improved the clinical symptoms of patients with sciatica caused by lumbar disc herniation. Here, we have found that Mongolian medical warm acupuncture effectively relieves leg and waist pain and improves the total therapeutic effect and the quality of daily life for patients with sciatica caused by LDH, with significant long-term efficacy. Our study provides a basis for warm acupuncture in the treatment of sciatica caused by LDH.

The acupuncture points used in our study were selected with reference to the Mongolian medicine classics combined with long-term clinical practice. The warm acupuncture follows the principles of dialectical point selection in Mongolian medicine

and has a specific effect on the treatment of low back pain and leg pain<sup>16</sup>. We used the VAS-LP and VAS-WP scores to evaluate the degree of pain in patients. VAS-LP and VAS-WP are widely used to detect the pain in legs and waist<sup>32</sup>. Warm acupuncture reduced the VAS-LP and VAS-WP scores, suggesting effective relief of the pain of waist and leg for patients. Furthermore, we found that warm acupuncture was superior to conventional drugs and sham acupuncture in relieving the pain of patients, especially in terms of long-term efficacy. The effect of warm acupuncture on pain improvement is consistent with a previous study<sup>33</sup>.

Sciatica greatly reduces the life quality of patients<sup>1</sup>. Improving the life quality of patients is also an important task in clinical treatment. SF-36 is widely used as a generic measure of quality of life. This self-reported outcome measure calculates eight-dimension scores according to the patient responses to 36 questions<sup>27</sup>. In our study, we found that the physical function, physical role, body pain, emotional role, and mental health scores of the SF-36 survey in the warm acupuncture of the Mongolian medi-



**Figure 6.** The changes of SF-36 scores in eight dimensions in three groups during the treatment and follow-up, including physical function (A), role physical (B), bodily pain (C), general healthy (D), vitality (E), social function (F), role emotional (G), and mental health (H). \* $p < 0.05$  vs. warm acupuncture of the Mongolian medicine group at the corresponding time point.  $\Delta p < 0.05$  vs. baseline.

cine group were significantly higher than those in the sham acupuncture group. It indicated that warm acupuncture improved the quality of patients' lives, and the effects were better than sham acupuncture.

It is difficult to implement the placebo treatment in the clinical research of acupuncture due to its particularity and complexity. Positive drugs were

set as a control group in most of the clinical trials of acupuncture treatment for sciatica in the previous study<sup>34</sup>. However, a lack of high-quality placebo control or blank control group will affect the evaluation of clinical efficacy. Therefore, we applied sham acupuncture as the placebo control in this study. The placebo needles used in sham acupuncture

cture were similar in appearance to the needles used in warm acupuncture, and they were difficult for patients to distinguish. We found that sham acupuncture reduced VAS-LP and VAS-WP scores after two weeks of treatment. These results showed that sham acupuncture relieved the pain of patients and improved the patients' life quality. Sham acupuncture has some "efficacy" as a specific treatment, but its mechanism needs further investigation.

### Limitations

This study still has some limitations. First, we used two randomized control groups, but the small sample size and the short treatment and follow-up time in the control groups may lead to potential statistical bias in the baseline and efficacy evaluations<sup>35</sup>. Given this, larger clinical trials with an increased number of patients are required to eliminate experimental bias. Secondly, sciatica is a subjective sensory disease. The evaluation of pain is an extremely complex physiological and psychological process that is affected by many influencing factors. Therefore, a more objective evaluation method besides VAS-LP and VAS-WP should be adopted to quantify pain, which will be more beneficial to confirm the clinical value of warm acupuncture in the treatment of sciatica caused by lumbar disc herniation.

### Conclusions

Overall, Mongolian medical warm acupuncture significantly relieved the pain of leg and waist and improved total effective rate and the quality of daily life in patients with sciatica caused by lumbar disc herniation, with significant long-term efficacy. Our study provides the basis of warm acupuncture in the treatment of sciatica caused by lumbar disc herniation.

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### Availability of Data and Materials

We have uploaded the data to the Chinese Clinical Trial Registration Platform; all the data and materials are available on this platform.

### Ethics Approval

This study was approved by Ethics Committee of Affiliated Hospital of Inner Mongolia Medical University (No. KY2018005). All methods were carried out in accordance with relevant guidelines and regulations.

### Informed Consent

The patients signed the informed consent to participate in this study.

### Conflict of Interest

The authors declare no competing financial interests.

### Authors' Contributions

Lengge Si and Latai Ga: study concept and design; Runa A and Gula A: drafting the paper; Jiya Murigen and Rigatai A: data collection; Qizhu Wu and Lidao Bao: analysis and interpretation of data; Long Bai: performed figures; all authors have read and approved the final manuscript.

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