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ORIGINAL RESEARCH

Evaluation of Tuina Combined with Medicated Oil in Non-Specific Low Back Pain Treatment: A Randomized Clinical Trial

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Purpose: Non-specific low back pain (NSLBP) causes functional impairments and reduced quality of life. Evidence for non-pharmacological approaches, such as Tuina and Flying Eagle Wood Lok Medicated Oil (TNO), remains limited. This study compares the efficacy of TNO and Tuina with water (TNW).

Patients and Methods: This single-center, open-label, evaluator-blinded randomized controlled trial (June 2023 - June 2025) was conducted at Shanghai Municipal Hospital of Traditional Chinese Medicine with 100 participants aged 20–59 years, diagnosed with NSLBP based on the North American Spine Society criteria. The Ethics Committee (2023SHL-KY-96-01) approves the study, and assessors are blinded to group assignments for objective evaluations. All participants provided informed consent and completed the study. The trial group received TNO treatment thrice weekly for 4 weeks, with 20-minute follow-up sessions, compared to TNW. The primary outcome was the Visual Analog Scale (VAS) score, with secondary outcomes (JOA scores, Infrared Thermography, muscle tension, and tenderness scores). Adverse reactions were recorded for safety assessment.

Results: This trial recruited 100 patients (mean [SD] age, 35.0 [5.2] years; 57 [57%] female) who were randomized into two groups. One hundred percent of patients completed all outcome measurements. The mean difference in VAS scores from baseline at week 8 for the TNO group was −4.48 (95% CI, −4.89 to −4.07). At week 8, the difference in JOA scores for the TNO groups was 10.8 (95% CI, 10.12 to 11.48; P <0.001). The effectiveness remained at the follow-up. LC-MS analysis identified 621 compounds (Negative: 258, Positive: 363).

Conclusion: This study found that TNO was more effective than Tuina alone, with improved pain, muscle tension, tenderness, and thermal imaging at 8 weeks. Thus, this combination should be considered for the treatment of non-specific low back pain. The short follow-up period (8 weeks), the single-center design, and the absence of a placebo oil group are significant limitations that may restrict generalizability.

Trial Registration Chinese Clinical Trial Registry: : ChiCTR2300076144.

Keywords: non-specific low back pain, Tuina, medicated oil, back pain, clinical trial

Introduction

Low back pain is a symptom of a serious musculoskeletal problem that causes functional impairments and reduces quality of life across all age groups.[1] Low back pain with non-specific low back pain (NSLBP) is the most prevalent type.[2]

NSLBP is a leading cause of disability worldwide, affecting 1.71 billion people. Its prevalence increases annually in developed and developing countries.[2–4] NSLBP has led to substantial financial burdens worldwide.[2,5] In the US, indirect

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costs of low back pain, including lost productivity and income, are estimated at 18.5 to 28.2 billion USD. In China, low back pain is a significant issue, particularly among middle-aged and elderly populations, with women more affected than men across all age groups.[6] Low back pain also affects personal finances, hindering asset accumulation, especially among older adults, leading to early retirement and reduced income.[2,7]

Regarding the patient's condition, most (80%) reported moderate to severe pain levels, significantly affecting their daily activities (76%).[5,7] NSLBP includes different nociceptive, neuropathic, neoplastic, or nonspecific pain types, often overlapping.[1,5,8,9] Acute NSLBP can be caused by physical, psychological, or social factors or a combination of these.[2] It typically has no clear pathoanatomical cause, and individuals with pain often score above 85% on most pain scales.[2]

Diagnostic tests are unnecessary for managing NSLBP, as clinical tests lack accuracy.[2,5] The North American Spine Society Instrument (NASS) has developed evidence-based clinical guidelines to diagnose and treat NSLBP.[10,11] While the criteria of NASS were developed in Western populations, previous studies have confirmed their applicability and reliability in Asian patients, which supports their use in our research.[12,13] Treatment methods for NSLBP include pharmacological approaches, including NSAIDs, opioids, and corticosteroid injections. However, these treatments may not effectively manage long-term pain and can cause side effects like gastrointestinal issues, addiction, and increased cardiovascular risk.[5,14–17]

Nonpharmacologic treatments are typically recommended for most individuals with low back pain.[5,14,18,19] Treatment methods for NSLBP vary based on the patient's condition, with the primary goal being pain reduction and addressing related disabilities.[7] Tuina, a form of traditional Chinese manual therapy, is a popular non-drug treatment for musculoskeletal pain, offering distinct clinical benefits, and has been employed for centuries in China to alleviate pain and promote healing.[17,20,21] These non-invasive methods are cost-effective, easy to apply, and generally well-accepted by patients.[21–23] Tuina uses manual techniques to relieve pain, improve circulation, and enhance mobility. Evidence supports its effectiveness in managing NSLBP by improving lumbar mobility, reducing pain, and easing muscle stiffness;[7,23–27] the application of Tuina in combination with other therapies and medicated oils remains underexplored in randomized controlled trials (RCTs).[20,28,29]

Studies related to using herbal extract oils combined with their effects on the skin have demonstrated the ability to reduce inflammatory markers and decrease pain.[30–35] These effects include reduced M1 macrophage polarization, lower levels of TNF-α, IL-6, and iNOS in skin and muscle tissue, and increased β-EP concentration.[30] Piperitone, Linalool, and β-Ionone are the main active compounds in medicated oil, known for their antimicrobial and anti-inflammatory properties. Linalool and Piperitone help combat free radicals and are commonly used to promote relaxation and reduce stress.[36,37] The fragrance of medicated oil, Linalool, β-Ionone may help enhance mood and alleviate anxiety.[38,39] Medicated oils have been traditionally used in Chinese medicine to enhance the effects of manual therapies.[35,40,41] These oils are believed to have anti-inflammatory, analgesic, and blood-circulating properties, aiding in managing pain and muscle tension.[41] Clinical trials on medicated oils in Tuina for NSLBP are limited, with no conclusive evidence of their combined efficacy, and few randomized controlled trials directly addressing this approach. This gap highlights the need for rigorous studies investigating the clinical effectiveness and the underlying mechanisms of such combined therapies. Flying Eagle Wood Lok Medicated Oil (FEMO) ingredients include *Panax notoginseng* (Burk) F.H. Chen, *Aconitum carmichaelii* Debx., *Arisaema erubescens* (Wall). Schott, *Pinellia ternata* (Thunb). Breit, *Carthamus tinctorius* L., is safe in various trials and is widely used. Moreover, the sensory characteristics of medicated oils (eg, fragrance, warmth) may introduce potential placebo effects, reinforcing the importance of appropriate control groups in clinical trial design.[42,43] In this study, Liquid Chromatography–Mass Spectrometry (LC-MS) was used to identify and characterize the major active compounds in FEMO.[44–46] Integrating LC-MS findings with clinical outcomes allows for a deeper understanding of how FEMO may contribute to therapeutic effects when combined with Tuina. This study aims to evaluate their effectiveness, hypothesizing that combining FEMO with Tuina will offer a more effective and affordable alternative to invasive and pharmacological treatments.

Materials and Methods

Liquid Chromatograph-Mass Spectrometry

20 mL FEMO was used for LC-MS analysis with a UHPLC system (ACQUITY UPLC I-Class HF, Waters, USA; ACQUITY UPLC HSS T3 (100 mm × 2.1 mm, 1.8 μm), Waters, USA; PDA, Waters, USA), Mass Spectra (Thermo-Obitrap-QE), and the raw data were analyzed by Oebiotech (Oebiotech, China).

Study Design

A single-center, open-label, assessor-blinded randomized clinical study was conducted from June 16, 2023, to February 28, 2025, at the Shanghai Municipal Hospital of Traditional Chinese Medicine. Approved by the hospital's Ethics Committee (2023SHL-KY-96-01), patients were recruited through digital media, advertisements, and healthcare posters, with written consent obtained. The study was conducted in accordance with the Declaration of Helsinki, as authorized by the Regional Ethics Review Committee, and adhered to the CONSORT guidelines. The experimental protocol is available in Figure 1.

Eligibility Criteria

Patients with validated NSLBP were eligible for this study. The eligibility criteria were as follows: 1) Diagnosis of NSLBP according to the criteria set by the North American Spine Society and the Chinese expert consensus;[47,48] 2) Age between 20 and 59; 3) Discontinue any therapies affecting research effectiveness during the trial; 4) Voluntarily participate, cooperate with the doctor, and sign informed consent.

Sample Size Calculation

Based on preliminary results, the sample size for each group was calculated using G*Power 3.1 software with $\alpha = 0.05$ and $1\text{-}\beta = 0.95$, accounting for a 10% dropout rate. The VAS means and standard deviations for the two pre-experimental

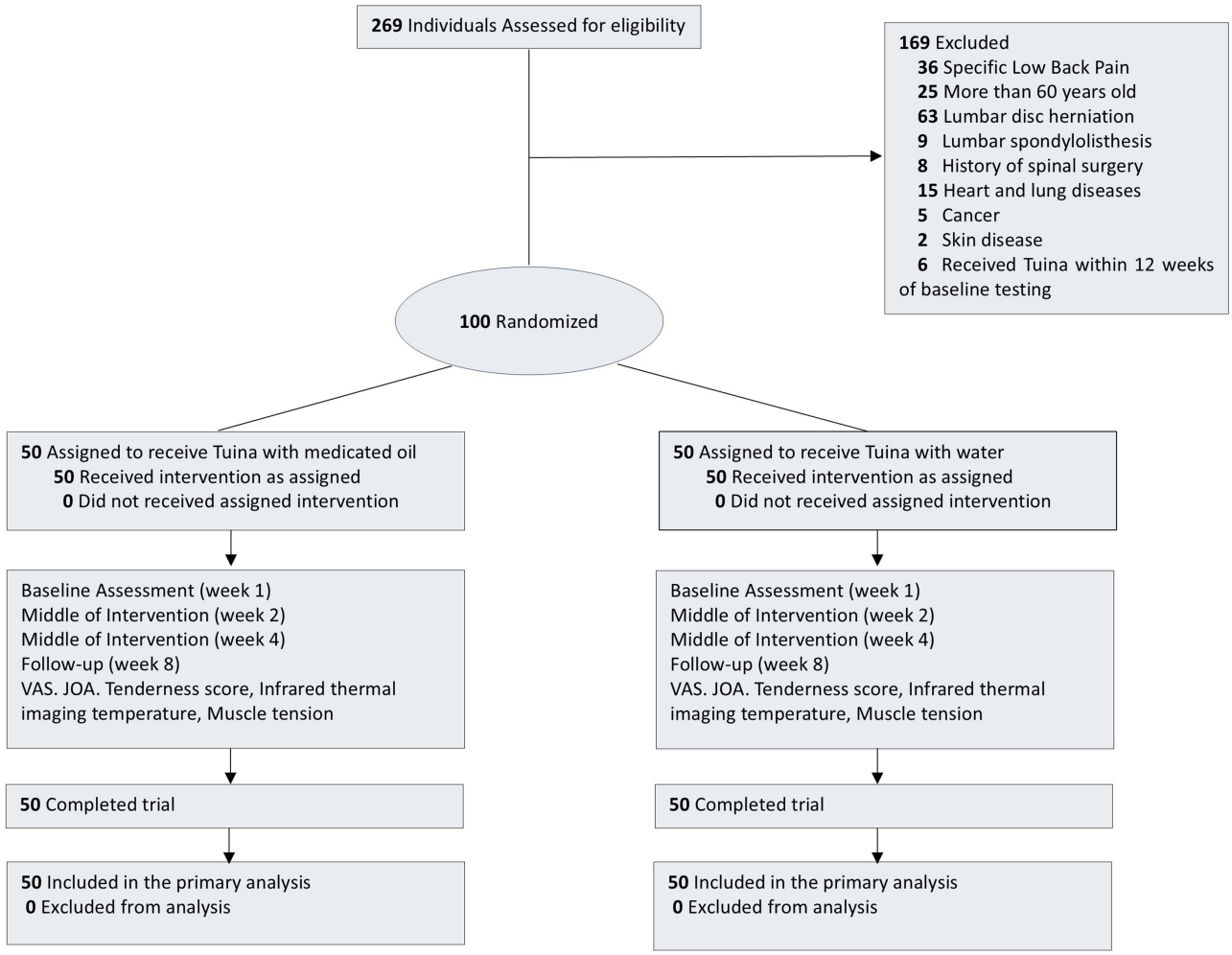

Figure 1 Flow diagram of study participants.
Abbreviations: TNO, Tuina with oil; TNW, Tuina with water; VAS, Visual Analog Scale score; JOA, Japanese Orthopedic Association's evaluation of treatment scores.

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groups were 3.57 ± 1.35 and 2.61 ± 1.39, respectively, with a 1:1 parallel grouping.[24,49] Based on the above parameters, 50 NSLBP patients must be included in the two groups.

Randomization, Allocation Concealment, and Blinding

Before treatment, a self-employed office worker created the random assignment list using a random number generator (Strategic Applications Software, version 9.1.3; SAS Institute Inc). The data was placed in sealed envelopes, which doctors opened in front of participants to assign patients equally to two groups. To strengthen the blinding procedure, outcome assessors were not involved in treatment delivery and were kept unaware of patient group assignments through separate scheduling and coded data sheets. This ensured that blinding was preserved during data collection and analysis. All researchers, except Tuina doctors, were blinded to group assignments, and Tuina doctors were not involved in the evaluation of results or data analysis.

Statistical Analysis

Data analysis was performed using SPSS 27.0 with $\alpha = 0.05$ and $P<0.05$, indicating a significant difference. 1) Normal distribution data is presented as Mean ± SD, while non-normal data is described using median or interquartile range. Count data is presented by frequency or rate. 2) A *t*-test is used for normally distributed data with equal variances, and a corrected *t*-test is used for uneven variances. The rank sum test is used for non-normal data, and the chi-square test is used for comparing rates. Given the multiple comparisons across different spinal sites for muscle tension and tenderness, we have now applied a Bonferroni correction to reduce the risk of Type I error, as suggested.

Quality Control

Full-time attending physicians in the Tuina department handle treatments. They are graduates of Shanghai University of Traditional Chinese Medicine, specializing in acupuncture, moxibustion, and Tuina manipulation, with 5–8 years of clinical experience. They had completed standardized training and passed practical assessments before participating in this study. This ensured consistency and reproducibility of techniques across patients. After completing standardized training and passing an evaluation, they use expert-formulated Tuina techniques for treatment based on diagnosis and treatment standards.

Intervention

Complete standardized training on Tuina techniques before treatment, allowing patients to be treated after passing the assessment. Tuina techniques formulated by the expert group are used in accordance with diagnostic standards. The plan includes: 1) Rubbing tendons on the lumbar spine with palm kneading for 3 minutes. Apply thumb Tuina on the iliac crest, affected buttocks, popliteal fossa, and calf for 3 minutes. 2) Use the thumb folding flicking technique on the lumbar quadratus and Ashi acupoint for 2 minutes. 3) Grab the affected muscles for 2 minutes. 4) Advise the patient to perform stretching movements for 2 minutes. 5) In the TNO group, apply 8–10 drops of FEMO on the affected area and rub for 8 minutes; in the TNW group, the same procedure was performed using water—intervention: Three sessions per week, 20-minute intervals, for 4 weeks (12 sessions), presented in detail in Supplementary 1.

Outcome Measurement

By combining the VAS, JOA, Tenderness score, infrared thermal imaging, and muscle tension test, the study comprehensively evaluates the intervention's effectiveness, capturing both subjective (patient-reported) and objective (physiological) outcomes. This dual approach ensures that the survey can robustly assess both the symptomatic relief and underlying physiological changes, offering a well-rounded understanding of the intervention's impact on NSLBP.

Results

Main Components of FEMO Detected by LC-MS

FEMO analysis using LC-MS under positive and negative ion modes (Figure 2). LC-MS analysis identified 621 compounds (Negative: 258, Positive: 363), classified into: Alkaloids (12), Amino Acids/Peptides (3), Carbohydrates/

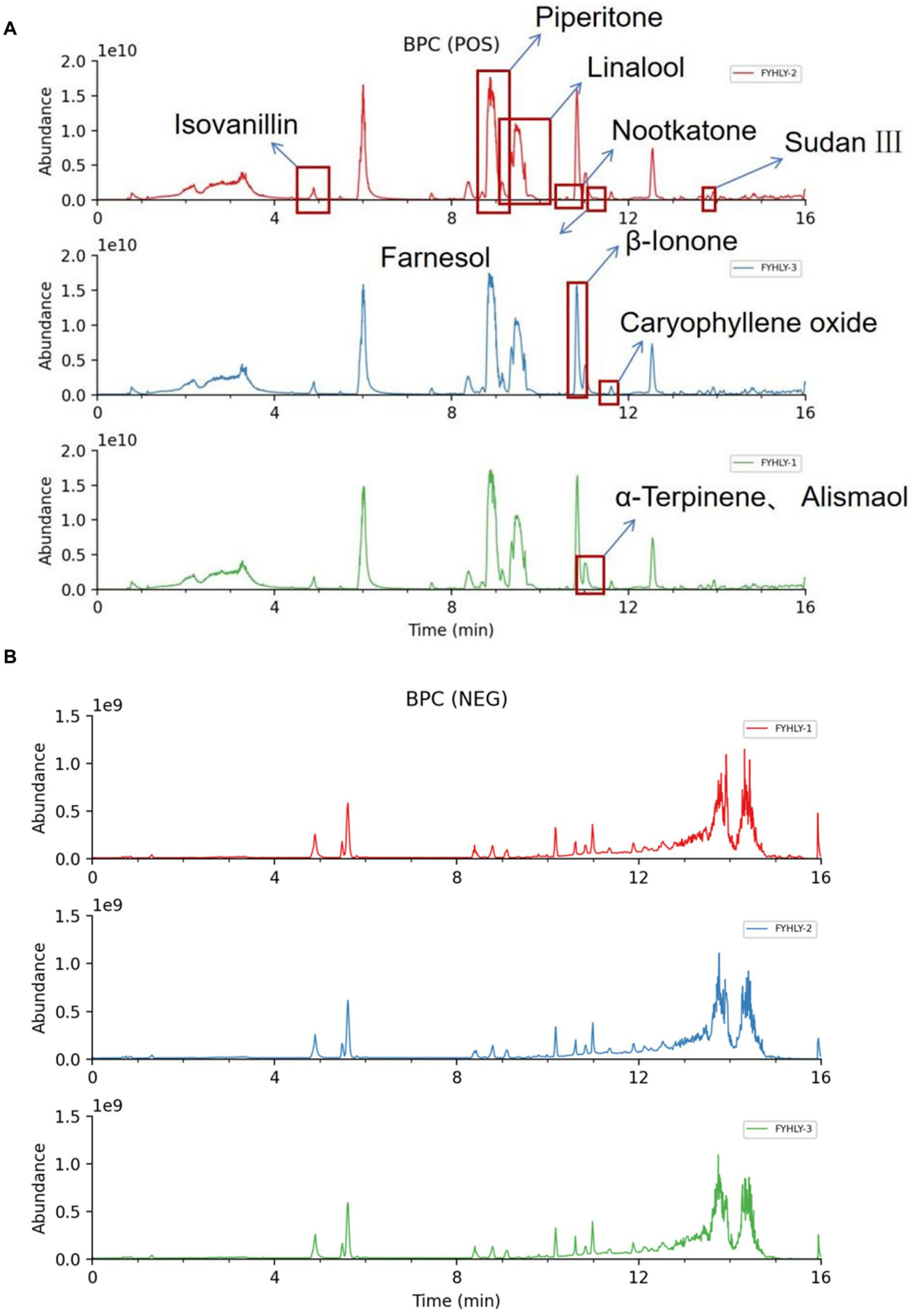

Figure 2 LC-MS Analysis in Positive Mode (**A**) and Negative Mode (**B**).

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Glycosides (6), Carboxylic Acids (15), Fatty Acyls (9), Flavonoids (19), Organic Acids (3), Phenols (25), Phenylpropanoids (54), Quinones (8), Steroids (14), Terpenes (114), and Others (339). Among them, Piperitone, Sudan III, β-Lonone, Isovanillin, Nootkatone, Linalool, α-Terpinene, Farnesol, Alismol, and Caryophyllene Oxide showed a stronger response in positive mode in Figure 3 and Table 1.

Participant Characteristics

Of 269 screened candidates, 100 NSLBP patients (37%) met the inclusion criteria and were assigned to either the TNO (Tuina with Flying Eagle Wood Lok Medicated Oil) group (n = 50, median age 36.0 years; 29 females, 21 males) or the TNW (Tuina with water) group (n = 50, median age 34.0 years; 28 females, 22 males). All 100 participants completed all outcome assessments at each time point; these are shown in Table 2 and Figure 1

Efficacy

Table 3 shows the VAS scores for both groups. At 4 weeks post-treatment, the TNO group had a mean decrease of −4.46 (95% CI, −4.88 to −4.04), while the TNW group saw a reduction of −2.32 (95% CI, −2.58 to −2.06). The TNO group showed a significant inter-group difference of −2.14 (95% CI, −2.58 to −1.70; $p<0.001$). At follow-up, the TNO group had a mean decrease of −2.36 (95% CI, −2.88 to −1.84; $p<0.001$) compared to the TNW group. VAS scores for both groups are shown in Figure 4.

Table 3 shows the JOA scores for both groups. At 4 weeks post-treatment, the TNO group significantly increased by 10.92 (95% CI, 10.35 to 11.49), while the TNW group had a mean increase of 7.12 (95% CI, 6.37 to 7.87). The TNO group showed a substantial difference of 3.80 (95% CI, 2.87 to 4.73; $p<0.001$) compared to the TNW group. At follow-up, the TNO group had a mean increase of 3.80 (95% CI, 2.79 to 4.81; $p<0.001$) over the TNW group. JOA scores are shown in Figure 4.

Table 3 shows the infrared thermal imaging temperatures for both groups. At 4 weeks post-treatment, the TNO group had a significant reduction of −3.27 (95% CI, −3.60 to −2.93), while the TNW group had a decrease of −1.60 (95% CI, −2.13 to −1.07). The TNO group showed a substantial difference of −1.67 (95% CI, −2.26 to −1.08; P<0.001) compared to the TNW group. Infrared thermal imaging results are shown in Figure 4.

Table 3 gives the muscle tension of the 2 study groups. At the 4-week post-treatment assessment, the TNO group recorded a mean increase of 2.44 (95% CI, 2.09 to 2.80) at 1.5 cun to the right of the L2 spinous process; 4.14 (95% CI, 3.53 to 4.75) at 3 cun to the right of the L2 spinous process; 4.27 (95% CI, 3.54 to 4.99) at 1.5 cun to the left of the L2 spinous process; 4.48 (95% CI, 3.89 to 5.07) at 3 cun to the left of the L2 spinous process; 4.00 (95% CI, 3.34 to 4.63) at 1.5 cun on the right of the L4 spinous process; 3.30 (95% CI, 2.59 to 4.00) at 3 cun to the right of the L4 spinous process; 4.58 (95% CI, 4.00 to 5.17) at 1.5 cun to the left of the L4 spinous process; 3.94 (95% CI, 3.21 to 4.67) at 3 cun to the left of the L4 spinous process. Compared with the baseline, the TNW group recorded a mean increase of 2.70 (95% CI, 2.31 to 3.09) at 1.5 cun to the right of the L2 spinous process, 2.14 (95% CI, 1.77 to 2.51) at 3 cun to the right of the L2 spinous process, 2.10 (95% CI, 1.76 to 2.44) at 1.5 cun to the left of the L2 spinous process, 2.48 (95% CI, 2.10 to 2.85) at 3 cun to the left of the L2 spinous process, 2.07 (95% CI, 1.71 to 2.44) at 1.5 cun to the right of the L4 spinous process, 2.34 (95% CI, 1.82 to 2.85) at 3 cun to the right of the L4 spinous process, 2.26 (95% CI, 1.87 to 2.65) at 1.5 cun to the left of the L4 spinous process and 2.36 (95% CI, 1.48 to 3.24) at 3 cun to the left of the L4 spinous process in muscle tension.

The TNO group shows a substantial difference between the groups in muscle tension of 2.03 (95% CI, 1.46 to 2.60; $P<0.001$) at 1.5 cun to the right of the L2 spinous process, 2.00 (95% CI, 1.32 to 2.68; $P<0.001$) at 3 cun to the right of the L2 spinous process, 2.16 (95% CI, 1.43 to 2.90; $P<0.001$) at 1.5 cun to the left of the L2 spinous process, 2.01 (95% CI, 1.34 to 2.67; $P<0.001$) at 3 cun to the left of the L2 spinous process, 1.92 (95% CI, 1.23 to 2.60; $P<0.001$) at 1.5 cun to the right of the L4 spinous process, 0.96 (95% CI, 0.22 to 1.70; $P=0.004$) at 3 cun to the right of the L4 spinous process, 2.33 (95% CI, 1.66 to 3.00; $P<0.001$) at 1.5 cun to the left of the L4 spinous process and 1.58 (95% CI, 0.56 to 2.60; $P<0.001$) at 3 cun to the left of the L4 spinous process. An analysis of the muscle tension in the two groups is presented in Table 3.

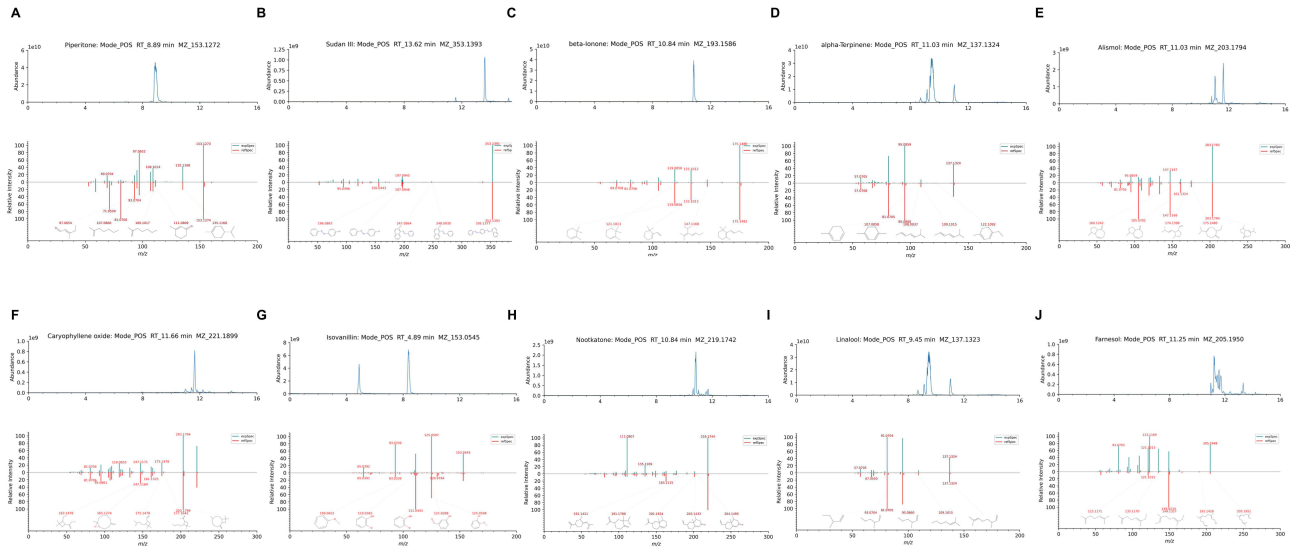

Figure 3 Mass Spectra of the Top 10; (**A**) Mass Spectra of Piperitone; (**B**) Mass Spectra of Sudan III; (**C**) Mass Spectra of β-Ionone; (**D**) Mass Spectra of α-Terpinene; (**E**) Mass Spectra of Alismaol; (**F**) Mass Spectra of Caryophyllene Oxide; (**G**) Mass Spectra of Isovanillin; (**H**) Mass Spectra of Nootkatone; (**I**) Mass Spectra of Linalool; (**J**) Mass Spectra of Farnesol.

Table 3 shows the tenderness scores for both groups. At 4 weeks post-treatment, the TNO group had a mean reduction of −1.74 (95% CI, −2.16 to −1.32), while the TNW group showed a decrease of −1.22 (95% CI, −1.54 to −0.90). A significant difference of −0.52 (95% CI, −0.99 to −0.05; P=0.017) was observed between the groups. At follow-up, the TNO group had a mean reduction of −0.50 (95% CI, −0.94 to −0.04; P=0.024) compared to TNW. Tenderness scores are shown in Figure 4.

Discussion

NSLBP is a clinical condition characterized by significant morbidity and a recurrence rate of 33%, with complementary and alternative medicine being advised for effective management.[50,51] Tuina is commonly utilized for treating back pain, which could account for firm adherence to the treatment in this randomized clinical trial, where no participants dropped out.[23,25]

Table 1 Top 10 Ingredients by Content

No	Name	Content (%)	Adducts	Formula	m/z	Type
1	**Piperitone**	48.97	M + H, M + Na, M + H - H_2O	$C_{10}H_{16}O$	153.1272	Terpene
2	**Linalool**	23.70	M + H - H_2O, M + H	$C_{10}H_{18}O$	137.1323	Terpene
3	**β-Ionone**	15.46	M + H - H_2O, M + H	$C_{13}H_{20}O$	193.1586	Terpene
4	**α-Terpinene**	1.42	M + H	$C_{10}H_{16}$	137.1324	Terpene
5	**Nootkatone**	0.95	M + H	$C_{15}H_{22}O$	219.1742	Terpene
6	**Isovanillin**	0.87	M + H	$C_8H_8O_3$	153.0545	Phenol
7	**Farnesol**	0.60	M + H - H_2O	$C_{15}H_{26}O$	205.1950	Terpene
8	**Sudan III**	0.51	M + H	$C_{22}H_{16}N_4O$	353.1393	Other
9	**Alismaol**	0.48	M + H - H_2O	$C_{15}H_{24}O$	203.1794	Terpene
10	**Caryophyllene Oxide**	0.27	M + H	$C_{15}H_{24}O$	221.1899	Terpene

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Table 2 Comparison of Clinical Baseline Data Between the Two Groups of Patients

Baseline	TNO Group (n = 50)	TNW Group (n = 50)	Z/χ^2	P
Age (year), M (IQR)	36.0 (28.0 to 43.0)	34.0 (30.0 to 42.0)	−0.494	0.622
BMI (kg/m^2), M (IQR)	23.2 (21.5 to 24.1)	23.4 (22.2 to 24.1)	−1.055	0.291
Gender, n (%)			0.041	0.840
Man	21 (42)	22 (44)		
Woman	29 (58)	28 (56)		
Duration of illness (months), M (IQR)	34.5 (30.0 to 43.0)	24 (30.0 to 43.0)	−0.073	0.942

Abbreviations: TNO, Tuina with oil; TNW, Tuina with water; IQR, Interquartile Range.

The analysis of FEMO combined with Tuina using LC-MS in positive and negative ion modes identified terpenes, such as Piperitone and Linalool, as the dominant components. These terpenes may contribute to the oil's therapeutic properties, particularly its anti-inflammatory effects.[52,53] TNO led to a lower VAS score after 8 weeks than TNW. The chemical components profiling supports a plausible biological basis for the observed clinical benefits.

A systematic review of 47 randomized controlled studies on spinal manipulation therapy, with 9,211 participants aged 35–60, found moderate evidence suggesting it has a similar effect to alternative treatments in alleviating pain (mean difference −3.17, 95% CI −7.85 to 1.51). It also showed minor improvements in functionality and better clinical outcomes (SMD −0.25, 95% CI −0.41 to −0.09).[54]

In this study, FEMO can effectively reduce pain intensity and improve functional outcomes in patients with NSLBP. Importantly, beyond statistical significance, the observed changes in pain outcomes should also be considered in terms of their clinical importance. The mean reduction in VAS scores in the FEMO group was approximately 4, well above the commonly reported MCID threshold of roughly 1.5–2.0 points for low back pain.[55,56] Similarly, the mean increase of 10.8 points in JOA scores substantially exceeds the MCID for functional improvement (estimated at 4–6 points),[57,58] indicating that the improvements were statistically significant to patients' daily lives. Another potential mechanism underlying the effects of FEMO could be the placebo effect associated with its physiologically positive qualities (warmth, comfort, and patient-perceived therapeutic value). While not easily quantifiable, these factors may have contributed to the observed improvements and deserve consideration as part of the treatment's holistic impact.

A literature review revealed that Swedish massage with ginger oil and Thai massage provided improved short-term (6 weeks) and long-term (15 weeks) relief from lower back pain, thereby enhancing quality of life.[59] This indicates that combining manual techniques and oil agents has a specific therapeutic effect on NSLBP.

This study showed improved lumbar function in NSLBP patients, including walking, bending, and daily activities. A separate survey of 120 women with pregnancy-related back pain found that topical rose oil significantly reduced pain intensity, but its effect on function was similar to the placebo. Rose oil was found to reduce pregnancy-related lower back pain without adverse effects.[60]

Adding FEMO to Tuina more effectively reduces short-term and long-term NSLBP than Tuina alone, enhancing its benefits. This is the first clinical study to utilize FEMO in conjunction with Tuina for musculoskeletal pain. Previous research supports these findings, demonstrating the analgesic and anti-inflammatory effects of medicated oil. However, most studies have employed oral tablets or decoctions rather than oil formulations. The components in Huoluo oil are also used to treat neurological diseases,[61,62] basic experiments for dermatological diseases, and otolaryngological diseases.[63,64]

Both treatment plans significantly improved lumbar spine function, reducing activity dysfunction after 4 weeks. However, the TNO group showed more significant improvement in functional impairment. The magnitude of VAS reduction (−4.48) exceeded the Minimal Clinically Important Difference for low back pain, suggesting that the improvements are statistically significant and meaningful for patients' daily lives. The TNO group exhibited a more substantial decrease in the JOA score, as well as improvements in infrared thermal imaging, muscle tension, and

Table 3 VAS Scores and JOA Scores, Infrared Thermal Imaging Temperature, Muscle Tension, and Tenderness Score Among Study Participants

Location/Index	Time	Score Median (IQR)		Mean Change in Score from Baseline (95% CI)		TNO Group vs TNW Group		Group × Time Interaction	Time	Group
		TNO Group (n = 50)	TNW Group (n = 50)	TNO Group	TNW Group	Difference (95% CI)	*P* Value			
VAS scores										
	Baseline	6.00 (6.00 to 7.00)	6.00 (5.00 to 6.00)	NA	NA	NA	NA	χ^2=324.45	χ^2=2469.75	χ^2=56.26
	W-1	5.00 (4.00 to 5.00)	5.00 (4.00 to 5.00)	−1.26 (−1.59 to −0.93)	−1.10 (−1.29 to −0.91)	−0.16 (−0.45 to 0.13)	0.549			
	W-2	3.00 (3.00 to 4.00)	4.00 (3.00 to 4.00)	−2.64 (−3.01 to −2.27)	−2.00 (−2.19 to −1.81	−0.64 (−0.99 to −0.29)	<0.001			
	W-4	2.00 (1.00 to 2.00)	3.00 (3.00 to 4.00)	−4.46 (−4.88 to −4.04)	−2.32 (−2.58 to −2.06)	−2.14 (−2.58 to −1.70)	<0.001	*P*<0.001	*P*<0.001	*P*<0.001
	W-8	1.50 (1.00 to 2.00)	4.00 (3.00 to 4.00)	−4.48 (−4.89 to −4.07)	−2.12 (−2.48 to −1.76)	−2.36 (−2.88 to −1.84)	<0.001			
JOA scores										
	Baseline	15.00 (13.00 to 15.00)	14.50 (13.00 to 15.00)	NA	NA	NA	NA	χ^2=153.96	χ^2=1,183,019.11	χ^2=28.64
	W-1	19.00 (17.00 to 19.00)	18.50 (17.00 to 19.00)	3.98 (3.92 to 4.04)	4.00 (4.00 to 4.00)	−0.02 (−0.07 to −0.03)	0.937			
	W-2	21.00 (19.00 to 21.00)	20.50 (19.00 to 21.00)	6.04 (5.95 to 6.13)	6.00 (6.00 to 6.00)	0.04 (−0.03 to 0.11)	0.745			
	W-4	25.00 (24.00 to 26.00)	22.00 (20.00 to 23.00)	10.92 (10.35 to 11.49)	7.12 (6.37 to 7.87)	3.80 (2.87 to 4.73)	<0.001	*P*<0.001	*P*<0.001	*P*<0.001
	W-8	25.00 (24.00 to 25.00)	22.00 (20.00 to 23.00)	10.80 (10.12 to 11.48)	7.00 (6.20 to 7.80)	3.80 (2.79 to 4.81)	<0.001			
Infrared Thermal Imaging Temperature (°C)										
	Baseline	35.35 (34.70 to 35.60)	35.40 (34.77 to 35.55)	NA	NA	NA	NA	χ^2=450,625.35	χ^2=565.28	χ^2=55.01
	W-1	34.46 (33.90 to 34.84)	34.45 (34.20 to 35.20)	−0.86 (−1.23 to −0.50)	−0.69 (−1.13 to −0.25)	−0.17 (−0.63 to 0.30)	>0.999			
	W-2	33.12 (32.59 to 33.67)	34.60 (34.40 to 34.82)	−2.06 (−2.50 to −1.61)	−0.86 (−1.31 to −0.41)	−1.19 (−1.77 to - 0.61)	<0.001	*P*<0.001	*P*<0.001	*P*<0.001
	W-4	31.69 (31.50 to 32.46)	33.62 (33.25 to 34.26)	−3.27 (−3.60 to −2.93)	−1.6 (−2.13 to −1.07)	−1.67 (−2.26 to −1.08)	<0.001			
Muscle tension										
1.5 cun right of the L2 spinous										
	Baseline	8.00 (7.87 to 8.31)	7.90 (7.30 to 8.31)	NA	NA	NA	NA	χ^2=134.64	χ^2=2124.83	χ^2=67.14
	W-1	8.47 (7.85 to 8.82)	8.45 (8.32 to 8.80)	0.28 (−0.12 to 0.67)	0.73 (0.48 to 0.98)	−0.46 (−0.90 to −0.01)	0.042			
	W-2	10.79 (10.18 to 11.44)	10.46 (10.11 to 10.74)	2.62 (2.12 to 3.12)	2.68 (2.28 to 3.09)	−0.06 (−0.51 to −0.38)	<0.001	*P*<0.001	*P*<0.001	*P*<0.001
	W-4	12.90 (12.37 to 13.50)	10.42 (10.04 to 11.25)	2.44 (2.09 to 2.80)	2.70 (2.31 to 3.09)	2.03 (1.46 to 2.60)	<0.001			
3 cun right of the L2 spinous										
	Baseline	8.33 (7.96 to 8.74)	8.43 (7.96 to 8.64)	NA	NA	NA	NA	χ^2=93.59	χ^2=852.43	χ^2=83.20
	W-1	9.66 (9.15 to 10.76)	8.62 (7.23 to 8.90)	1.45 (0.87 to 2.03)	−0.14 (−0.58 to 0.29)	1.59 (0.87 to 2.31)	<0.001			

(*Continued*)

Table 3 (Continued).

Location/Index	Time	Score Median (IQR)		Mean Change in Score from Baseline (95% CI)		TNO Group vs TNW Group		Group × Time Interaction	Time	Group
		TNO Group (n = 50)	TNW Group (n = 50)	TNO Group	TNW Group	Difference (95% CI)	*P* Value			
	W-2	10.84 (10.28 to 11.46)	10.54 (9.70 to 11.34)	2.58 (2.06 to 3.10)	2.24 (1.77 to 2.72)	0.34 (−0.18 to 0.86)	0.288	*P*<0.001	*P*<0.001	*P*<0.001
	W-4	12.82 (11.77 to 13.37)	10.71 (10.04 to 11.11)	4.14 (3.53 to 4.75)	2.14 (1.77 to 2.51)	2.00 (1.32 to 2.68)	<0.001			
1.5 cun left of the L2 spinous										
	Baseline	8.25 (7.91 to 8.54)	8.42 (8.02 to 8.66)	NA	NA	NA	NA	χ^2=74.08	χ^2=1076.88	χ^2=14.475
	W-1	8.37 (7.28 to 9.00)	8.45 (8.22 to 8.52)	−0.02 (−0.35 to 0.30)	0.06 (−0.11 to 0.23)	−0.08 (−0.46 to 0.30)	>0.999			
	W-2	10.57 (10.20 to 11.32)	10.42 (9.96 to 11.24)	2.25 (1.80 to 2.69)	2.13 (1.76 to 2.49)	0.12 (−0.30 to 0.54)	>0.999	*P*<0.001	*P*<0.001	*P*<0.001
	W-4	12.52 (10.90 to 14.17)	10.53 (9.96 to 11.04)	4.27 (3.54 to 4.99)	2.10 (1.76 to 2.44)	2.16 (1.43 to 2.90)	<0.001			
3 cun left of the L2 spinous										
	Baseline	8.44 (7.92 to 8.90)	8.04 (7.71 to 8.40)	NA	NA	NA	NA	χ^2=73.06	χ^2=1514.23	χ^2=95.58
	W-1	9.56 (8.18 to 10.51)	8.85 (8.11 to 9.03)	1.01 (0.41 to 1.60)	0.50 (0.14 to 0.86)	0.51 (−0.13 to 1.14)	0.18			
	W-2	10.94 (10.30 to 11.34)	10.24 (10.04 to 10.82)	2.59 (2.19 to 2.99)	2.37 (2.02 to 2.71)	0.23 (−0.19 to 0.64)	0.677	*P*<0.001	*P*<0.001	*P*<0.001
	W-4	13.12 (11.97 to 13.60)	10.56 (10.11 to 11.15)	4.48 (3.89 to 5.07)	2.48 (2.10 to 2.85)	2.01 (1.34 to 2.67)	<0.001			
1.5 cun right of the L4 spinous										
	Baseline	8.15 (7.46 to 8.93)	8.21 (7.97 to 8.98)	NA	NA	NA	NA	χ^2=114.95	χ^2=719.37	χ^2=37.20
	W-1	11.24 (10.26 to 12.12)	8.89 (8.11 to 9.15)	2.76 (1.88 to 3.65)	0.25 (−0.14 to 0.64)	2.51 (1.61 to 3.41)	<0001			
	W-2	10.16 (9.04 to 10.84)	10.09 (9.64 to 10.90)	1.89 (1.31 to 2.46)	2.08 (1.45 to 2.71)	−0.19 (−0.82 to 0.44)	<0.001	*P*<0.001	*P*<0.001	*P*<0.001
	W-4	12.12 (10.93 to 13.23)	10.36 (9.79 to 11.15)	4.00 (3.34 to 4.63)	2.07 (1.71 to 2.44)	1.92 (1.23 to 2.60)	<0.001			
3 cun right of the L4 spinous										
	Baseline	9.02 (8.49 to 9.92)	8.43 (7.61 to 9.04)	NA	NA	NA	NA	χ^2=11.501	χ^2=519.83	χ^2=64.65
	W-1	9.32 (8.35 to 10.31)	8.43 (8.10 to 9.23)	0.29 (−0.27 to 0.84)	0.16 (−0.17 to 0.50)	0.12 (−0.5 to 0.74)	>0.999			
	W-2	11.10 (10.18 to 11.66)	10.31 (9.10 to 10.96)	1.89 (1.40 to 2.39)	1.78 (1.26 to 2.30)	0.11 (−0.42 to 0.64)	>0.999	*P*<0.001	*P*<0.001	*P*=0.009
	W-4	12.25 (11.17 to 13.6)	10.66 (10.26 to 11.06)	3.30 (2.59 to 4.00)	2.34 (1.82 to 2.85)	0.96 (0.22 to 1.70)	0.004			
1.5 cun left of the L4 spinous										
	Baseline	8.00 (7.86 to 8.33)	8.40 (8.15 to 8.91)	NA	NA	NA	NA	χ^2=165.98	χ^2=1279.27	χ^2=64.64
	W-1	10.25 (9.24 to 11.30)	8.63 (8.11 to 9.03)	2.15 (1.36 to 2.95)	−0.13 (−0.48 to 0.22)	2.28 (1.46 to 3.10)	<0.001			

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	W-2	10.71 (10.08 to 11.44)	10.89 (10.28 to 11.44)	2.57 (2.11 to 3.03)	2.10 (1.65 to 2.56)	0.46 (−0.1 to 1.02)	0.183	*P*<0.001	*P*<0.001	*P*<0.001
	W-4	13.17 (11.77 to 13.57)	10.90 (10.32 to 11.44)	4.58 (4.00 to 5.17)	2.26 (1.87 to 2.65)	2.33 (1.66 to 3.00)	<0.001			
3 cun left of the L4 spinous										
	Baseline	8.02 (7.81 to 8.27)	8.30 (7.91 to 8.71)	NA	NA	NA	NA	χ^2=42.07	χ^2=392.67	χ^2=44.77
	W-1	10.17 (9.55 to 11.12)	8.75 (8.42 to 9.22)	2.04 (1.42 to 2.65)	0.57 (0.18 to 0.96)	1.47 (0.79 to 2.15)	<0.001			
	W-2	10.74 (10.16 to 11.72)	10.28 (9.10 to 11.24)	3.94 (3.21 to 4.67)	1.68 (0.97 to 2.40)	0.95 (0.16 to 1.74)	0.009	*P*<0.001	*P*<0.001	*P*<0.001
	W-4	11.23 (10.87 to 13.4)	10.15 (9.96 to 11.06)	3.94 (3.21 to 4.67)	2.36 (1.48 to 3.24)	1.58 (0.56 to 2.60)	<0.001			
Tenderness Score										
	Baseline	3.00 (2.00 to 3.00)	3.00 (2.00 to 3.00)	NA	NA	NA	NA	χ^2=15.02	χ^2=396.76	χ^2=8.25
	W-1	2.00 (2.00 to 3.00)	2.00 (2.00 to 3.00)	−0.38 (−0.59 to −0.17) ***	−0.46 (−0.69 to −0.23) ***	0.08 (−0.15 to 0.31)	0.869			
	W-2	2.00 (1.00 to 2.00)	2.00 (2.00 to 3.00)	−0.76 (−1.09 to −0.43) ***	−0.52 (−0.81 to −0.23) ***	−0.24 (−0.60 to 0.12)	0.379	*P*=0.005	*P*<0.001	*P*=0.004
	W-4	1.00 (0.00 to 1.00)	2.00 (1.00 to 2.00)	−1.74 (−2.16 to −1.32) ***	−1.22 (−1.54 to −0.90) ***	−0.52 (−0.99 to −0.05)	0.017			
	W-8	1.00 (1.00 to 2.00)	2.00 (1.00 to 2.00)	−1.56 (−1.99 to −1.13) ***	−1.06 (−1.38 to −0.74) ***	−0.50 (−0.94 to −0.04)	0.024			

Note: 1 cun = 3.33 cm.

Abbreviations: NA, not applicable; TNO, Tuina with oil; TNW, Tuina with water; JOA, Japanese Orthopedic Association; VAS, Visual Analog Scale.

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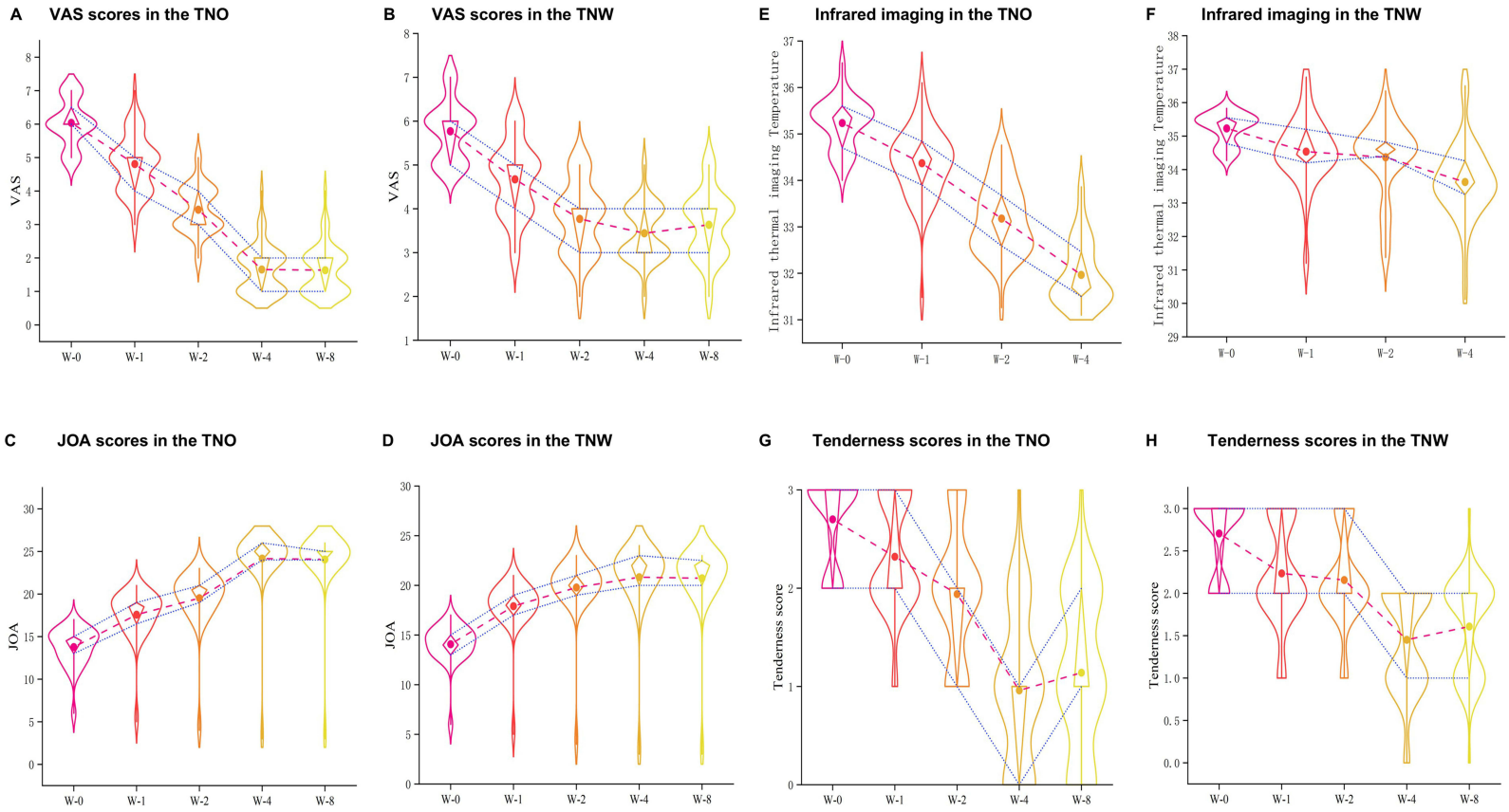

Figure 4 Outcomes Among Study Participants: (**A**) VAS scores in the TNO; (**B**) VAS scores in the TNW; (**C**) JOA scores in the TNO; (**D**) JOA scores in the TNW; (**E**) Infrared thermal imaging temperature in TNO; (**F**) Infrared thermal imaging temperature in TNW; (**G**) Tenderness score in the TNO; (**H**) Tenderness score in the TNW.

Abbreviations: TNO, Tuina with oil; TNW, Tuina with water; and JOA, Japanese Orthopedic Association's evaluation of treatment scores.

tenderness, particularly at the L2 and L4 spinous processes. A previous study found that medicated oil alleviates chronic pain, improves sleep, and reduces oxidative stress markers.[41] Our observations show that the improvements in pain and other indicators in the TNO groups are statistically significant and clinically meaningful.

Previous studies have examined Tuina therapy combined with external herbal Chinese medicine for pain and muscle-related conditions.[65,66] Medicated oil, with its aromatic essential oils, positively impacts anxiety levels and alleviates stress, improving the quality of life for patients with chronic conditions.[31,41,67,68] Unlike prior observational reports, this is the first RCT to rigorously test Tuina with FEMO, strengthening the evidence base for this traditional therapy. It is cost-effective, provides a comforting sensation, and is popular among patients, encouraging treatment adherence and recommendations. Tuina and medicated oil have been used for many years to treat pain.[24,27,34,40,69–72] This randomized controlled study is the first to examine Tuina combined with medicated oil for lower back pain. It found significant reductions in pain, functional impairment, and anxiety. While the mechanism is unclear, medicated oil likely enhances anti-inflammatory capacity through the skin. This study supports Tuina and medicated oil as a potential alternative therapy for back pain, with further research needed.

Limitations

This study has several limitations. First, therapist and patient awareness of the Tuina treatment could introduce performance bias. Second, the trial was conducted at a single site and limited to Chinese patients, which may have affected its generalizability. Third, the higher number of female participants may introduce gender bias. Future trials should aim for balanced gender distribution. Fourth, although measures were taken to conceal the test drug's characteristics, the distinction between the test drug and water was not completely masked. A neutral oil group should be considered in future research. Fifth, the lack of stratified randomization or subgroup analysis may affect sample representation. Sixth, the study's 8-week duration limits long-term data, and follow-ups beyond 12 weeks are needed. Finally, no control group was included, and further research on medicated oil for lower back pain is required.

Conclusion

In this randomized controlled study, individuals with NSLBP treated with Tuina and medicated oil showed significantly greater reductions in pain, muscle tension, tenderness, and infrared thermal temperature compared to those treated with Tuina alone. Thus, Tuina, with FEMO, could be a valuable supplementary therapy for pain relief in NSLBP patients. While the results are encouraging, they should be interpreted with caution due to the open-label design.

Abbreviations

CI, Confidence Interval; CONSORT, Consolidated Standards of Reporting Trials; FEMO, Flying Eagle Wood Lok Medicated Oil; IQR, Interquartile Range; JOA, Japanese Orthopedic Association; LC-MS, Liquid Chromatograph-Mass Spectrometry; NSLBP, Non-Specific Low Back Pain; PDA, Photodiode Array; RCT, Randomized Controlled Trial; SAS, Statistical Analysis System; SPSS, Statistical Package for the Social Sciences; TMC, Traditional Chinese Medicine; TNO, Tuina with Oil (Flying Eagle Wood Lok Medicated Oil); TNW, Tuina with Water; UHPLC, Ultra High-Performance Liquid Chromatography; VAS, Visual Analog Scale.

Data Sharing Statement

We have chosen not to share the research data to prevent it from being used for purposes outside the scope of the study. This ensures that the data is only utilized per the original research objectives.

Ethics Approval and Informed Consent

All experimental procedures were approved by the ethical application of the Shanghai Municipal Hospital of Traditional Chinese Medicine Ethics Committee (2023SHL-KY-96-01).

Chinese Clinical Trial Registry: ChiCTR2300076144.

All participants were adults (≥18 years). Written informed consent was obtained from every participant before enrollment, in accordance with the Declaration of Helsinki and local regulations.

Consent for Publication

All authors give full consent for this publication.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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