








Efficacy of Acupuncture Treatment in the Treatment of Female Myofascial Pelvic Pain Syndrome: A Protocol for a Dual-Center Randomized Controlled Trial

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Introduction: Myofascial pelvic pain syndrome (MPPS) is a form of chronic pelvic pain (CPP) and pelvic floor dysfunction (PFD), significantly affecting women's physical and mental health. To date, high-quality evidence regarding the efficacy of acupuncture for treating MPPS is lacking. This dual-center randomized controlled trial aims to investigate whether acupuncture is effective for MPPS.

Methods and Analysis: A dual-center, parallel, randomized, controlled trial will recruit 180 participants diagnosed with MPPS, who will be randomly allocated (1:1) via computer-generated block randomization to receive either acupuncture treatment or combined electromyographic biofeedback with neuromuscular electrical stimulation (EMG-BF+NMES) for 3 weeks. Primary outcomes include pain intensity (Visual Analog Scale, VAS), myofascial tenderness, pelvic floor muscle function (Modified Oxford Scale), and ultrasound-guided VAS of myofascial trigger points. Secondary outcomes encompass pelvic floor neuromuscular activity (surface electromyography using the Glazer Protocol), Pelvic Floor Distress Inventory-Short Form 20 (PFDI-20), Pelvic Floor Impact Questionnaire-7 (PFIQ-7), Patient Assessment of Constipation Symptoms (PAC-SYM), Self-Rating Anxiety Scale (SAS), Self-Rating Depression Scale (SDS), the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), and the Pittsburgh Sleep Quality Index (PSQI). Assessments are scheduled at baseline (T0), immediately after the initial intervention (T1), at 1, 2, 3 weeks post-intervention (T2–T4), and at 3-month post-treatment follow-up (T5). Adverse events will be collected and recorded throughout the treatment period.

Conclusion: This trial will evaluate the efficacy and safety of acupuncture for MPPS, compare its therapeutic effects with EMG-BF+NMES, and provide evidence to support the clinical application of acupuncture.

Ethics and Dissemination: This study protocol was reviewed and approved by the Ethics Committee of Hangzhou Hospital of Traditional Chinese Medicine (Approval No. 2025LL003). Findings will be disseminated through peer-reviewed publications and academic conferences.

Trial Registration Number: ITMCTR2025000458.

Keywords: acupuncture, myofascial pelvic pain syndrome, electromyographic biofeedback, neuromuscular electrical stimulation, randomized controlled trial

Introduction

MPPS is a subtype of CPP and PFD that results from muscular and fascial injuries, leading to adhesions, spasms, and subsequent pain and pelvic floor symptoms. CPP is a highly prevalent condition, afflicting an estimated 26% of the global female population.¹ In Western countries, the prevalence of CPP among women aged 18–50 years ranges from 15% to 40%, within which MPPS constitutes a significant proportion.² Bedaiwy et al reported an MPPS incidence of 13.2%, with approximately 75% of affected participants experiencing severe pain (VAS score ≥ 7).³ It is well known that MPPS in women after childbirth is common in China, where the incidence is reported to range from 21.1% to 39.5%, with symptoms usually starting within 1–2 months after delivery.^{4,5}

On the contrary, MPPS is an under-recognized condition, and its actual prevalence may be higher due to the inherently private nature of symptoms, clinical heterogeneity, and lack of standardized diagnostic and therapeutic guidelines.⁶ With trends toward delayed childbearing and population aging, the incidence of MPPS is anticipated to rise in the coming years. As a first-line therapy for MPPS, pelvic floor physical therapy (PFPT) utilizes multimodal techniques including manual therapy, biofeedback, and neuromuscular electrical stimulation to restore normal pelvic floor muscle function.^{6–9} Although neuromuscular electrical stimulation and biofeedback therapy can alleviate pelvic floor pain, they pose challenges such as difficult probe insertion, lengthy treatment cycles, high recurrence rates, and contraindications. While manual therapy can relieve muscle spasms and improve local circulation, its analgesic efficacy is limited and contingent upon patient compliance, practitioner expertise, and individual pain thresholds. Current management strategies for MPPS remain constrained, often adversely affecting participants' physical and psychological health. The resulting chronic pain burden may perpetuate negative emotional states, which can further exacerbate pelvic floor dysfunction. Effective PFPT aims to interrupt this cycle.

Among various treatment methods, acupuncture is recognized as a promising therapeutic option for postpartum stress urinary incontinence (SUI).¹⁰ Its mechanisms involve the precise stimulation of defined acupoints to modulate neuraxial pathways linked to pelvic floor muscles thus improving urethral sphincter control.¹¹ Additionally, acupuncture enhances local blood circulation and nutrient supply to the pelvic floor, promoting the restoration of muscle elasticity and strength, while also facilitating tissue repair and reducing inflammatory responses. Clinical evidence further supports the therapeutic value of acupuncture in pelvic floor disorders.¹⁰ For instance, a multicenter randomized controlled trial demonstrated that electroacupuncture applied to lumbosacral acupoints for six weeks significantly reduced urinary leakage in women with SUI compared to sham electroacupuncture.¹² Equally, a randomized trial showed that the incorporation of acupuncture with biofeedback electrical stimulation was more effective in lessening urinary leakage, improving pelvic floor muscle strength, and enhancing the quality of life in women with SUI than either treatment alone.¹³ The impressive results may be due to direct stimulation of the pudendal nerve and modulation of local muscular rhythmic contractions. Taken together, these studies not only demonstrate that acupuncture alleviates postpartum pelvic floor myofascial pain and promotes muscle function but also effectively improves urinary incontinence symptoms, which, in turn, implies its potential as a multimodal intervention for pelvic floor dysfunction. Although acupuncture has demonstrated efficacy in treating PFD, its application for MPPS is still in the early stages of investigation, and a consensus on standardized treatment protocols has yet to be established. This raises significant concerns in clinical practice, particularly regarding the selection of acupuncture points, which can affect the efficacy and safety of the treatment. To address these concerns, this dual-center randomized controlled trial (RCT) aims to evaluate the efficacy and safety of acupuncture treatment for treating MPPS.

To date, no dual-center randomized controlled trial (RCT) has specifically compared the efficacy of acupuncture therapy with that of combined electromyography-biofeedback and neuromuscular electrical stimulation (EMG-BF + NMES) for the treatment of myofascial pelvic pain syndrome (MPPS). Importantly, this study is the first to employ pelvic floor ultrasound-guided trigger point pain assessment, comprehensive hemodynamic measurements, and acoustic characteristics of pelvic floor muscles as primary outcome measures, thereby providing novel evidence for mechanistic research into MPPS.

Given the relatively high prevalence of MPPS among women of different ages and physiological states (eg, postpartum), the present study focused on a well-defined clinical population: women aged 20–70 years who were

married or had a history of sexual intercourse, met the established clinical diagnostic criteria for MPPS (see the Participant Characteristics section), and were neither pregnant nor menstruating at the time of enrollment. This age range covers the majority of women affected by MPPS, including nulliparous and parous women. The requirement of being married or having a history of sexual intercourse is based on the clinical necessity of pelvic floor assessment and treatment procedures.

Methods

Objective

The objective of this study is to test the hypothesis that acupuncture treatment demonstrates superior effectiveness compared to combined EMG-BF+NMES, particularly in alleviating pain and improving clinical symptoms associated with pelvic floor myofascial hypertonia in female participants. This approach offers the additional benefits of being more cost-effective and potentially providing more sustainable therapeutic outcomes.

Study Design and Setting

This dual-center, randomized, parallel-group controlled trial will be conducted at two tertiary care hospitals in China: Hangzhou Hospital of Traditional Chinese Medicine (Hangzhou TCM Hospital Affiliated to Zhejiang Chinese Medical University) and First Teaching Hospital of Tianjin University of Traditional Chinese Medicine with a planned study period from March 18, 2025, to November 30, 2026. Using a computer-generated block randomization scheme with 1:1 allocation, eligible participants will be assigned to either (1) acupuncture treatment or (2) combined EMG-BF+NMES. The complete study protocol, including randomization procedures and treatment schedules, is shown in [Figure 1](#) and [Table 1](#). This study will be conducted in full compliance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement.¹⁴

Ethical Standards and Registration

This study protocol was reviewed and approved by the Ethics Committee of Hangzhou Hospital of Traditional Chinese Medicine on January 27, 2025 (Approval No. 2025LL003). The trial protocol was registered with the International Traditional Medicine Clinical Registry (identification code ITMCTR2025000458 Date of Registration: March 4, 2025, website: itmctr.ccebtc.org.cn). All procedures will be conducted in accordance with the Declaration of Helsinki and relevant guidelines.

Informed Consent

Written informed consent will be obtained from all participants by a qualified researcher before any study-related procedures, including baseline assessments and randomization. Participants will be informed of their right to withdraw at any time without consequence.

Study Procedure

This trial consists of six phases: baseline (T0), immediately post-intervention (T1), and at 1 week (T2), 2 weeks (T3), 3 weeks (T4), and 3 months (T5) post-treatment. Eligibility assessments will be performed by independent researchers not involved in intervention or outcome evaluation to minimize bias. During screening, participants will receive detailed verbal and written information about the study procedures, risks, and expectations. Efficacy outcomes will be assessed at multiple time points as specified in the Outcome Measures section, including T1, T2, T3, T4, and T5. Safety outcomes will be monitored throughout the treatment period. Secondary outcomes include pelvic floor neuromuscular activity (surface electromyography using the Glazer Protocol), PFDI-20, PFIQ-7, PAC-SYM, SAS, SDS, SF-36, and PSQI. Additional assessments include treatment expectancy, blinding integrity, intervention compliance, and adverse events. Throughout the trial, participants may not use medications or receive other pelvic floor therapies (eg, manual massage) that could interfere with outcomes. Those requiring such therapies due to disease progression or other medical needs will

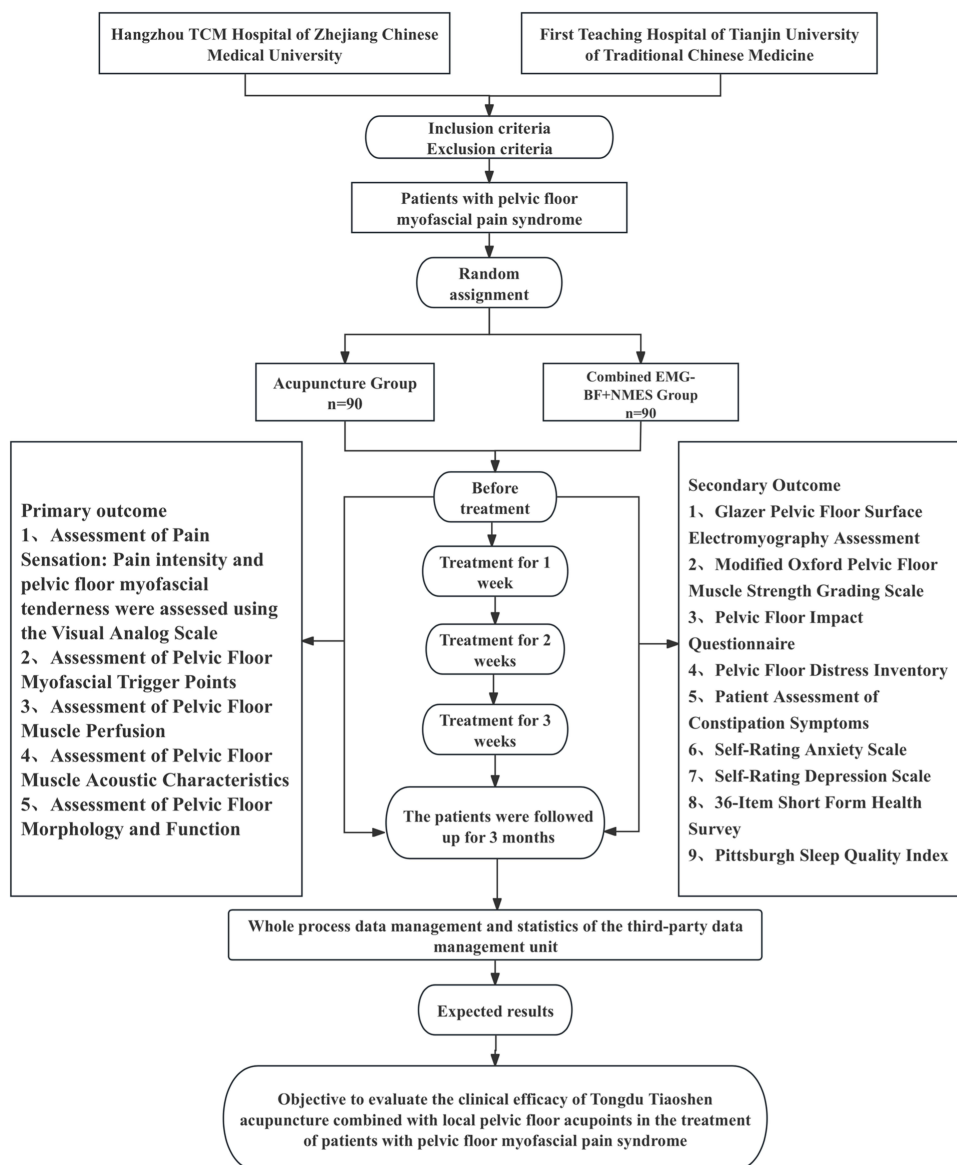


Figure 1 Flow chart of the study design.

be withdrawn and classified as dropouts. To support recruitment, all study-related interventions and outcome measurements will be provided free of charge.

Participant Characteristics

Diagnosis of MPPS was established according to European Association of Urology guidelines,¹⁵ requiring fulfillment of both clinical and physical examination criteria:

Clinical Symptoms

Participants must have experienced pelvic pain as one of the chronic symptoms, with a minimum duration of 6 months and must not be pregnant or menstruating at the time of enrollment. Additionally, they must exhibit ≥ 1 of the following chronic symptoms (duration > 6 months): (a) Persistent pelvic pain; (b) Lower urinary tract symptoms (frequency, urgency, dysuria, or retention); (c) Sexual dysfunction (dyspareunia or vaginismus); (d) Defecatory disorders (constipation, dyschezia, or incomplete evacuation).

Table 1 Schedule of Enrollment, Interventions, and Assessments

Time Point	T0	T1	T2	T3	T4	T5
Enrollment						
Eligibility screen	✓					
Informed consent	✓					
Demographic data	✓					
Randomization	✓					
Interventions						
Acupuncture group		✓	✓	✓	✓	✓
EMG-BF+NMES group		✓	✓	✓	✓	✓
Primary Outcomes						
Pelvic pain VAS (self-reported)	✓	✓	✓	✓	✓	✓
Pelvic floor tenderness VAS	✓	✓	✓	✓	✓	✓
Trigger point tenderness (ultrasound)	✓				✓	✓
Pelvic floor muscle blood supply (Doppler)	✓				✓	✓
Acoustic characteristics of PFM (2D ultrasound)	✓				✓	✓
Pelvic floor function (3D/2D ultrasound)	✓				✓	✓
Secondary Outcomes						
Glazer sEMG assessment	✓				✓	✓
MOS	✓				✓	✓
PFIQ-7	✓				✓	✓
PFDI-20	✓				✓	✓
PAC-SYM	✓				✓	✓
SAS	✓				✓	✓
SDS	✓				✓	✓
SF-36	✓				✓	✓
PSQI	✓				✓	✓
Other						
Adverse events monitoring		✓	✓	✓	✓	✓
Adherence assessment					✓	✓

Notes: "✓" indicates that the procedure or assessment is performed at that time point. Time point: T0, baseline; T1, immediately after the initial intervention; T2, at 1 week post-intervention; T3, at 2 weeks post-intervention; T4, at 3 weeks post-intervention; T5, at 3-month post-treatment follow-up.

Abbreviations: PFM, Pelvic Floor Muscles; VAS, Visual Analog Scale; sEMG, surface Electromyography; MOS, Modified Oxford Scale; PFIQ-7, Pelvic Floor Impact Questionnaire-7; PFDI-20, Pelvic Floor Distress Inventory-20; PAC-SYM, Patient Assessment of Constipation Symptoms; SF-36, 36-Item Short Form Health Survey; PSQI, Pittsburgh Sleep Quality Index.

Pelvic Floor Palpation

Transvaginal palpation of the pelvic floor musculature (including the pubococcygeus, iliococcygeus, coccygeus, and obturator internus muscles) should reveal the following diagnostic characteristics: (a) Presence of palpable taut bands within the muscle fibers; (b) Identification of tender nodules along these taut bands; (c) Reproduction of referred pain upon digital compression of these hyperirritable trigger points; (d) Demonstrable restriction in passive muscle stretch range due to pain provocation. The detailed inclusion and exclusion criteria for study participation are shown in [Table 2](#).

Randomization, Allocation Concealment and Blinding Procedures

The randomization process was conducted by Nanjing White Tower Clinical Medical Research Co., Ltd. using a secure, web-based centralized randomization system. The computer-generated dynamic block randomization scheme with 1:1 allocation ensured balanced assignment to either the acupuncture intervention or the combined EMG-BF+NMES treatment arm. This advanced methodology prevented investigators from predicting patient allocation, thereby maintaining allocation concealment and minimizing selection bias. Eligible participants were randomized through either a dedicated computer terminal or WeChat-based application interface following successful system authentication. Upon randomization, the central system automatically generated and assigned unique identification numbers along

Table 2 Inclusion Criteria, Exclusion Criteria and Withdrawal Criteria

Inclusion Criteria	<ul style="list-style-type: none"> • Meet the diagnostic criteria listed above; • Aged 20–70 years, married women, or women with a history of sexual intercourse; • Conscious or pressing pain VAS score ≥ 3; • Are neither pregnant nor menstruating at the time of enrollment; • Provide written informed consent.
Exclusion Criteria	<ul style="list-style-type: none"> • Chronic pelvic pain attributable to other pathologies (eg, reproductive, urinary, or gastrointestinal system disorders); • Receipt of any relevant treatment within 1 month prior to study enrollment, including acupuncture, EMG-BF+NMES, and any drugs that may change the symptoms of MPPS; • Local infections at potential acupuncture sites, contraindications to acupuncture treatment, or skin lesions/infections in the pelvic region; • History of major pelvic trauma, surgical interventions, or space-occupying pelvic lesions; • Cognitive or psychiatric impairments precluding protocol compliance.
Withdrawal Criteria	<ul style="list-style-type: none"> • Poor adherence to trial protocols or voluntary withdrawal; • Development of severe adverse events, complications, or disease progression warranting discontinuation; • Incomplete outcome data compromising efficacy assessments; • Concurrent use of additional therapies or unauthorized modification of the assigned treatment regimen.

with group allocation. To implement physical allocation concealment in parallel, the randomization results were printed and sealed in sequentially numbered, opaque envelopes by the randomization team. After a participant was enrolled, the envelope corresponding to the enrollment sequence was opened to determine the group assignment. Thus, both the electronic system (preventing real-time prediction) and the sealed envelopes (ensuring physical concealment) were used as complementary measures. For quality control, the randomization team conducted post-trial verification of all randomization records before printing and delivering the allocation documents to researchers for inclusion in the case report form binders. While participant blinding was not feasible due to the nature of the interventions, we implemented partial blinding by maintaining the data collection team, database managers, and statistical analysts unaware of group assignments throughout the study period to ensure objective outcome assessment. A major limitation of this trial is the inability to blind participants to their group allocation, as the two interventions differ substantially in their procedures. This may introduce psychological suggestion and expectation bias, particularly for subjective pain outcomes. Future studies should consider using sham acupuncture or other blinding methods when feasible.

Interventions

Acupuncture Group

A standardized acupuncture protocol will be administered by licensed practitioners using sterile, single-use stainless-steel needles (0.25×40 mm and 0.35×100 mm; Suzhou Medical Products Factory Co., Ltd., China). The treatment commenced with the patient in a supine position. The following acupoints were needed: bilateral PC6 (Neiguan), GV29 (Yintang), DU23 (Shangxing), and DU20 (Baihui). Upon completion of needling at these points, the patient was repositioned to a prone position. Subsequently, local pelvic floor acupoints, including bilateral BL54 (Zhibian), bilateral ST28 (Shuidao), and bilateral BL35 (Huiyang), were selected and stimulated.

The procedure will be conducted in sequential order:

PC6: Bilateral insertion with combined twisting, lifting, and thrusting techniques using a reducing manipulation for one minute, after which needles were immediately withdrawn.

GV29: The needle was subcutaneously inserted (depth: 7–12 mm) toward the nasal tip using a sparrow-pecking reducing manipulation for one minute, followed by needle retention for 30 minutes.

DU20 and DU23: A penetration technique was applied from DU23 to DU20 (depth: approximately 65 mm) using a balanced reinforcing–reducing manipulation for one minute, with subsequent needle retention for 30 minutes.

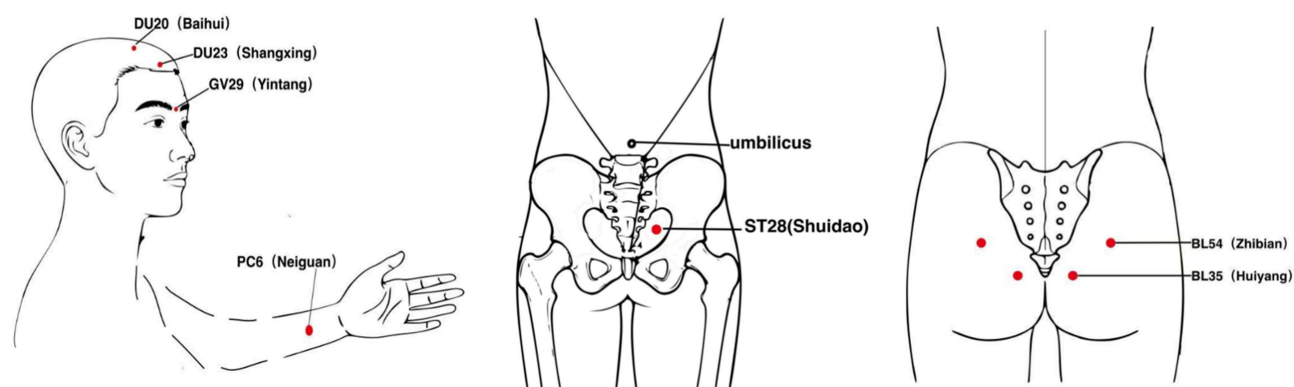


Figure 2 Acupuncture Point Diagram.

BL54 and ST28: A 0.35×100 mm needle was inserted at BL54 and penetrated to ST28 using a two-handed insertion technique (depth: 80–90 mm). Stimulation continued until the patient reported a *deqi* sensation, typically characterized by distension or an electric sensation.

BL35: The needle was obliquely inserted (depth: 80–90 mm) toward the sciatic rectal fossa until a *deqi* sensation was elicited in the pelvic floor region.

With the exception of the unilateral points GV29, DU23, and DU20, all acupoints were needled bilaterally. Stimulation intensity was carefully adjusted according to individual patient tolerance. Needles were retained for 30 minutes. Upon withdrawal, manual compression was applied to each point to prevent bleeding.

The treatment regimen consisted of sessions administered every other day over a period of three weeks, totaling 10 sessions (see Figure 2).

Combined EMG-BF+NMES Group

Pelvic floor rehabilitation was conducted using the AM1000B Pelvic Floor Biofeedback Neuromodulation System (Shenzhen Creative Industry Co., Ltd., China). The intervention was delivered by trained physical therapists in an outpatient setting on a one-to-one basis. Participants were placed in the dorsal lithotomy position. A sterilized, lubricated vaginal probe (25 mm in diameter) was inserted to a depth of 4–5 cm.

The following parameters were configured for electrical stimulation of the pelvic floor muscles: a 1-s ramp-up phase, a 1-s ramp-down phase, a stimulation frequency of 10 Hz, a pulse width of 200 μ s, with alternating 10-s stimulation and 10-s rest cycles. Stimulation intensity was adjusted individually according to each participant's tolerance and therapeutic response. For the biofeedback training protocol, the parameters were set to an 8-s active contraction phase followed by a 10-s relaxation phase.

Each treatment session lasted 40 minutes and was administered every other day (48-h intervals) over a 3-week period, for a total of 10 sessions.

Outcome Measures

Primary Outcome

Assessment of Pain Sensation

Pain intensity and pelvic floor myofascial tenderness will be assessed using the Visual Analog Scale (VAS). Assessments were conducted at the following time points: before the first treatment, immediately after the first treatment, and at 1, 2, 3 weeks and 3 months after the commencement of treatment.

Assessment of Pelvic Floor Myofascial Trigger Points

Myofascial trigger point tenderness was assessed before and after the 3-week treatment period, and at the 3-month post-treatment follow-up. Using transvaginal two-dimensional ultrasound, key pelvic floor and pelvic wall muscles (including the puborectalis, pubococcygeus, iliopsoas, coccygeus, piriformis, and obturator internus) were identified. After

observing their echogenicity and muscle fiber continuity, direct pressure was applied to each muscle. Identified trigger points were then scored for tenderness intensity using the VAS.

Assessment of Pelvic Floor Muscle Perfusion

Hemodynamic parameters of the pelvic floor muscles were quantitatively assessed before and after treatment using color and spectral Doppler ultrasound. With the patient in a standardized position, the left and right longitudinal sections of the puborectalis muscle were clearly visualized via real-time two-dimensional ultrasound and centered in the image. Participants were instructed to briefly hold their breath to minimize motion artifact. After the dissipation of any transient flow artifacts, the dominant supplying blood vessel was identified. The peak systolic velocity (PSV), end-diastolic velocity (EDV), resistance index (RI), and systolic-to-diastolic (S/D) ratio were measured.

Assessment of Pelvic Floor Muscle Acoustic Characteristics

Using two-dimensional ultrasound, the echogenicity, fiber continuity, dynamic movement (including contraction and relaxation), and contraction duration of the pelvic floor muscles were evaluated before and after the 3-week treatment and at the 3-month post-treatment follow-up. Acoustic characteristics specific to participants with MPPS were analyzed.

Assessment of Pelvic Floor Morphology and Function

Overall pelvic floor morphology and function were evaluated using three-dimensional and two-dimensional ultrasound before and 3 weeks after the completion of treatment, and at the 3-month post-treatment follow-up.

Secondary Outcomes

The following secondary outcomes were assessed at baseline and after the 3-week treatment period, and at the 3-month post-treatment follow-up:

Glazer Pelvic Floor Surface Electromyography (sEMG) Assessment

Pelvic floor muscle function was objectively quantified using sEMG in accordance with the standardized Glazer protocol. A vaginal surface electrode was positioned to record bioelectrical activity during a standardized sequence: (1) baseline resting tone, (2) phasic (fast-twitch) contractions, (3) tonic (sustained) contractions, (4) post-contraction relaxation, and (5) an endurance test. This assessment quantifies neuromuscular activity to provide an objective basis for diagnosing dysfunctions (eg, urinary incontinence and pelvic floor pain) and for guiding individualized treatment strategies, such as biofeedback training.^{16,17}

Modified Oxford Pelvic Floor Muscle Strength Grading Scale (MOS)

The MOS demonstrates strong correlations with sEMG parameters measured via the Glazer protocol. Its stability and validity across diverse clinical populations support its utility as a reliable and practical tool for assessing pelvic floor muscle function in women, with particular relevance during the perinatal period.¹⁸

Pelvic Floor Impact Questionnaire (PFIQ-7)

The Chinese version of the PFIQ-7 demonstrated robust psychometric properties and is a reliable instrument for assessing the impact of pelvic floor disorders, including urinary incontinence, pelvic organ prolapse, and fecal incontinence, on women's lives. Specifically, it exhibited excellent internal consistency (Cronbach's $\alpha = 0.98$) and acceptable test-retest reliability (intraclass correlation coefficient = 0.79).

Pelvic Floor Distress Inventory (PFDI-20)

Similarly, the Chinese version of the PFDI-20 showed strong psychometric performance. It demonstrated excellent internal consistency (Cronbach's $\alpha = 0.92$) and acceptable test-retest reliability (intraclass correlation coefficient = 0.77) for evaluating symptom distress in women with the aforementioned conditions.¹⁹

Patient Assessment of Constipation Symptoms (PAC-SYM)

This scale has demonstrated excellent internal consistency (Cronbach's $\alpha = 0.89$) and good criterion validity in the assessment of constipation across three symptom domains (stool, rectal, and abdominal). Its validity is supported by strong correlations with severity ratings from both participants and investigators ($r = 0.68$ and 0.72 , respectively; $P < 0.0001$), in addition to moderate correlations with quality of life measures.²⁰

Self-Rating Anxiety Scale (SAS)

A pregnancy-specific modification of the SAS demonstrated excellent criterion validity, with AUC values above 0.985 across all trimesters, suggesting that such tailored versions may offer superior validity over the original instrument in specific populations.²¹

Self-Rating Depression Scale (SDS)

The SDS, adapted into a 12-item version for Chinese pregnant women, exhibited good overall reliability, with a Cronbach's α of 0.811 and a split-half reliability of 0.770, along with acceptable construct validity.²²

36-Item Short Form Health Survey (SF-36)

The SF-36 provides a comprehensive assessment of quality of life, with higher scores indicating better overall health status. It demonstrated satisfactory reliability and validity in this study, with a Cronbach's α coefficient of 0.838 and a Spearman-Brown coefficient of 0.828.²³

Pittsburgh Sleep Quality Index (PSQI)

The PSQI is a validated self-report questionnaire that retrospectively assesses sleep quality and disturbances over a one-month interval. It demonstrates high diagnostic accuracy, with a reported sensitivity of 89.6% and specificity of 86.5% for identifying individuals with poor sleep quality.²⁴

Safety Evaluation

During the treatment period of this study, all patients are not permitted to take any medications that may alter the symptoms of MPPS. And regularly inquire about medication use during the research process. Each patient is required to undergo safety assessment before and after treatment, which includes the following two aspects: (1) Vital signs: body temperature, heart rate/rhythm, respiration, and blood pressure measured before treatment and 10 minutes after treatment; (2) Adverse events/reactions: documentation of acupuncture-related adverse events such as bleeding, pain, hematoma, allergy at the needling site, as well as needling syncope. Researchers will provide detailed explanations to all participants regarding the importance of accurately reporting any changes in their condition and any medical events occurring after treatment. Investigators must avoid using leading or suggestive questioning when eliciting information about adverse events. Throughout the treatment period, participants will be closely monitored for any adverse events. When an adverse event occurs, the following information will be comprehensively documented: (a) The nature and cause of the event; (b) Date and time of onset; (c) Severity and duration; (d) Any interventions or treatments provided; (e) The final outcome and resolution status. The causal relationship between the adverse event and the study intervention will be promptly assessed and recorded in the designated "Adverse Event Form".

Quality Control

The trial will be conducted in accordance with strict quality control measures. A team of professional inspectors will be established, and all relevant personnel—including investigators, Clinical Research Coordinators (CRC), and Clinical Research Associates (CRA)—will undergo rigorous training to ensure compliance with Good Clinical Practice (GCP) standards regarding operational standardization, data authenticity, and reliability of conclusions. The trial protocol has been registered (see Trial registration section). Prior to enrollment, written informed consent will be obtained from all participants. All participant data will be stored securely to ensure confidentiality. All the information will be stored in a password-protected electronic document and secured through encryption services. The device is used for electronic storage. The questionnaire can be filled out in paper form.

Statistical Methods

Sample Size

This superiority study will randomize participants into two groups: (1) the acupuncture group receiving the study intervention, and (2) the control group receiving combined EMG-BF+NMES. The primary outcomes were the change from baseline in VAS scores for both pelvic floor myofascial tenderness and pelvic pain after 3 weeks of treatment. Sample size calculation was based on the between-group difference in VAS scores of pelvic floor trigger points at 3 weeks, derived from a pilot study and existing literature.²⁵ Using G*Power 3.1.9.7 for a two-sample *t*-test with $\alpha = 0.05$ (two-tailed) and 90% power ($1 - \beta = 0.90$), and assuming post-treatment means of 3.96 (SD = 0.82) for the acupuncture group and 4.61 (SD = 0.86) for the control group (effect size $\Delta = 0.77$), a minimum of 37 participants per group was required. Factoring in a 20% dropout rate, we planned to enroll 45 participants per group, for a total of 180 participants across two centers.

Statistical Analysis

Data will be entered into the Electronic Data Capture (EDC) system to ensure integrity. All modifications to the electronic Case Report Forms (eCRFs) will be stored in the study database. Statistical analyses will be performed according to a pre-specified statistical analysis plan using SPSS software (version 25.0; IBM SPSS Statistics). Descriptive statistics will be generated for all variables.

Normality and homogeneity of variance will be tested for within-group comparisons (pre- vs. post-treatment). A paired *t*-test will be used if assumptions are met; otherwise, the Wilcoxon signed-rank test will be applied. For between-group comparisons, normality and homogeneity of variance will be tested. An independent samples *t*-test will be used if assumptions are met; otherwise, the Mann–Whitney *U*-test will be applied. For continuous data meeting normality and homogeneity of variance assumptions, results will be presented as mean \pm standard deviation. For non-normally distributed data, results will be presented as median with interquartile range (IQR). Categorical data will be analyzed using the chi-square test or Fisher's exact test, as appropriate. For the primary outcome, the between-group comparison will be assessed at a two-tailed significance level of $P < 0.05$ without adjustment. For exploratory analyses of secondary outcomes and multiple time points, multiple comparisons will be adjusted using the Benjamini–Hochberg (BH) method to control the false discovery rate, and an adjusted $P < 0.05$ will be considered statistically significant.

Missing Data Handling

Multiple imputation will handle missing data under the missing at random (MAR) assumption, meaning missingness depends only on observed variables. The imputation model will include outcomes, group allocation, covariates, and auxiliary variables related to missingness (eg, age, BMI). Continuous and categorical variables will be imputed using linear and logistic regression, respectively, with five imputations performed. Parameter estimates from each imputed dataset will be combined using Rubin's rules, incorporating within- and between-imputation variance. For sensitivity analyses, we will: (1) re-analyze using a pattern mixture model (PMM) under the missing not at random (MNAR) assumption; and (2) increase imputations to 20 and compare primary effect estimates to verify stability.

Interim Analyses and Stopping Guidelines

The Data Safety Monitoring Board (DSMB) may recommend early termination of the trial if safety concerns arise (eg, SAE incidence $> 10\%$ or unexpected treatment-related SAE), if clear evidence of futility emerges, or if external evidence renders continuation unethical. The DSMB will have access to unblinded data when necessary, but interim results will not be disclosed to investigators or participants unless early termination is required. The final decision to terminate the trial will be made jointly by the DSMB, principal investigator, and sponsor, in consultation with the Ethics Committee if required.

Discussion

Electrical stimulation therapy can alleviate pelvic floor pain and associated symptoms by inhibiting nociceptive signal transmission, whereas biofeedback aids in the identification and relaxation of pelvic floor muscles.¹⁵ Nevertheless, this therapeutic approach has limitations: participants with MPPS and pelvic floor muscle spasms often experience difficulties with vaginal probe insertion and demonstrate poor adherence to treatment. Other challenges include delayed efficacy, contraindications, and practical barriers such as a narrow indication spectrum, prolonged treatment duration, and high recurrence rates.²⁶ Although manual massage may alleviate MPPS symptoms, it presents certain challenges, including incomplete pain relief, low patient compliance, strong reliance on practitioner skill, treatment resistance, and limited therapeutic efficacy.^{15,27} Therefore, safer and more effective therapies are needed. Acupuncture is a promising candidate for MPPS, given its generally acceptable safety profile and few absolute contraindications. Studies suggest that electroacupuncture at the Baliao points (BL31–BL34), in conjunction with vaginal manipulation, can alleviate pain and improve pelvic floor muscle strength.²⁶ Furthermore, deep needling at the four sacral points can stimulate the pudendal nerve, inhibit central pain sensitization, and induce rhythmic contraction of pelvic floor muscles, thereby providing both analgesic and functional regulatory benefits.²⁸

Clinical experience at the First Teaching Hospital of Tianjin University of Traditional Chinese Medicine suggests that specific acupuncture techniques can alleviate urinary retention and incontinence. The underlying mechanism involves regulation of central nervous system feedback related to urinary control and the enhancement of detrusor–sphincter coordination, thereby reducing the volume and frequency of stress urinary incontinence.²⁹ Research indicates that individuals with chronic pain often exhibit both central and peripheral pain sensitization, presenting with symptoms such as spontaneous pain and hyperalgesia. Psychological factors, including anxiety and depression can exacerbate sensitization.^{30,31} Acupuncture may inhibit pain sensitization and help regulate emotion through the “Tiaoshen” (mind-regulating) approach, potentially providing an additional strategy for chronic pain management.

In this study, seven acupoints—PC6 (Neiguan), GV29 (Yintang), DU23 (Shangxing), DU20 (Baihui), BL54 (Zhibian), ST28 (Shuidao), and BL35 (Huiyang)—are selected to synergistically intervene in MPPS through three levels: local pelvic regulation, systemic anti-inflammation, and central mind-regulation (Tiaoshen). The “Zhibian penetrating Shuidao” needling technique, developed by Professor Ji Laixi’s team at Shanxi University of Chinese Medicine, involves a single needle piercing from BL54 to ST28. It has been widely used for reproductive and urinary system disorders, including voiding dysfunction, sexual dysfunction, and dysmenorrhea.²⁹ A study demonstrated that this technique inhibits the NOD1/RIP2/NF- κ B signaling pathway, downregulating pro-inflammatory mediators such as IL-1 β , IL-18, TNF- α , COX-2, and PGF2 α , thereby alleviating pelvic inflammation and smooth muscle spasm.³² Given that MPPS shares the core pathology of chronic pelvic inflammation and myofascial hypertonicity, this needling method is likely to exert its analgesic effect through the same pathway. Huiyang (BL35) lies deep to the pudendal nerve trunk. Needling this point directly stimulates afferent fibers of the pudendal nerve, activates the endogenous analgesic system at the spinal level, and synergistically relieves pain by regulating pelvic autonomic nerve function and improving pelvic floor muscle spasm.³³ Neiguan (PC6) activates the vagus–macrophage axis via the α 7nAChR-JAK2/STAT3 pathway, suppressing the release of pro-inflammatory cytokines such as TNF- α , IL-1 β , and IL-6. Through its systemic anti-inflammatory effect, it reduces inflammatory stimulation of pelvic nerve endings, inhibits central sensitization, and modulates autonomic balance, thereby alleviating pain and associated mood disorders.³⁴ Regarding the head acupoints, a randomized controlled trial by Li et al demonstrated that electroacupuncture at Baihui (GV20) and Yintang (GV29) combined with transcutaneous auricular vagus nerve stimulation significantly improved both depressive and pain symptoms in patients with comorbid depression and chronic pain, with effects lasting for at least 8 weeks.³⁵ Animal experiments further indicated that electroacupuncture at Baihui exerts anxiolytic effects by promoting oxytocin release from the paraventricular nucleus of the hypothalamus.³⁶ Yintang is one of the most commonly used acupoints for anxiety. Clinical evidence shows that acupuncture at Yintang significantly relieves terminal restlessness and psychological distress in 86.9% of palliative care patients.³⁷

From the perspective of traditional Chinese medicine (TCM), Zhibian (BL54) belongs to the Bladder Meridian and unblocks the lumbosacral meridian Qi, promoting blood circulation; Shuidao (ST28) belongs to the Stomach Meridian,

located in the lower abdomen, which facilitates diuresis, reduces edema, and regulates Qi movement. The penetrating needling of these two points together invigorates Qi and blood, relieves spasm, and stops pain. Baihui (GV20) and Shangxing (DU23) belong to the Governor Vessel, and both are considered to lift yang Qi, nourish the brain, and calm the spirit (Anshen). Yintang (GV29) directly relieves anxiety and stress, while Neiguan (PC6) calms the mind, regulates Qi, and alleviates pain. In response to the anxiety and depression frequently accompanying MPPS, these four acupoints collectively embody the TCM strategy of “regulating the spirit (Tiaoshen)”, targeting both the sensory and psycho-emotional components of pain. An earlier study by Yang et al³⁸ further showed that acupuncture can assuage the emotional response to painful stimulation, supporting the role of these acupoints in addressing the psycho-emotional dimension of MPPS. Based on the above mechanisms, the MPPS patients enrolled in this study are identified by TCM pattern differentiation as having Qi stagnation and blood stasis combined with restless mind (Shen disturbance). The therapeutic principles are to move Qi and invigorate blood, unblock meridians and relieve pain, and calm the mind. The acupoint combination—Zhibian penetrating Shuidao to move Qi and blood and thereby treat “stasis”, and Neiguan, Baihui, Shangxing, and Yintang to calm the mind and treat “stagnation”—directly addresses the intertwined pathogenesis of “stasis, stagnation, and pain”, forming an integrated “local–systemic–central” three-dimensional therapeutic strategy of “mind-regulation, anti-inflammation, and pain relief”. Although the effectiveness of acupuncture for MPPS symptoms has been reported, certain limitations persist in its clinical application. It has not yet been extensively adopted as a treatment for MPPS. This study further integrates pain with psycho-emotional factors. Few randomized controlled trials have been reported on the use of acupuncture therapy for pelvic pain. To our knowledge, this trial is one of the first to adopt a two-center, parallel-group, randomized controlled design to comprehensively evaluate clinical outcomes before and after treatment and at follow-up, as well as the safety of the intervention. Furthermore, it aims to explore the differences between acupuncture and pelvic floor electrical stimulation combined with biofeedback in improving pain symptoms and other aspects in patients with MPPS. Importantly, this study also employs pelvic floor ultrasound-guided trigger point pain assessment, comprehensive hemodynamic measurements, and acoustic characteristics of pelvic floor muscles as primary outcome measures, thereby providing novel evidence for mechanistic research into MPPS.

The present study has several limitations. First, in clinical practice, both acupuncture treatment and electrical stimulation combined with biofeedback therapy may cause pain or discomfort, potentially leading to treatment refusal and reduced compliance. Second, blinding of participants was not feasible in this trial. Participants were fully aware of their group allocation, which may introduce psychological suggestion and expectation bias. The primary outcome measures include subjective pain assessment tools such as the Visual Analog Scale (VAS). Participants’ subjective feelings and expectations may directly influence their scores, potentially biasing the effect estimates. Third, we have refined the enrollment criteria to exclude women who were pregnant or menstruating at the time of enrollment, as these physiological conditions may affect treatment outcomes and introduce bias. Consequently, the findings of this study may not be generalizable to pregnant or menstruating women. Finally, the trial requires ten treatment sessions. If a participant experiences menstruation during the treatment period, therapy must be temporarily suspended, which may also influence the outcomes. We will accurately document the time of menstrual onset for each participant. Future studies should consider strategies to improve treatment adherence, systematically document concomitant therapies, and further explore the applicability of the intervention in broader populations.

This study aims to evaluate the efficacy of acupuncture, including both systemic and local pelvic floor acupoints, for the treatment of MPPS. The findings will provide scientific evidence for the application of acupuncture in MPPS treatment and offer a potentially useful therapeutic option for participants with MPPS.

Conclusion

This protocol describes the design of a two-center, parallel-group, randomized controlled trial that will be the first to compare the clinical efficacy and safety of acupuncture versus pelvic floor electrical stimulation combined with biofeedback in patients with myofascial pelvic pain syndrome (MPPS). A key novelty of this study lies in the use of outcome measures that combine objective and subjective assessments, including pelvic floor ultrasound-guided trigger point pain evaluation, ultrasound-based hemodynamic measurements, acoustic characteristics of the pelvic floor muscles, and patient-reported psycho-emotional assessments. It should be noted that this manuscript is a study protocol; therefore,

no conclusions on the trial outcomes can be drawn at this stage. Upon completion of the trial, the results will be reported in a separate publication, which may provide preliminary evidence regarding the potential effectiveness of acupuncture for MPPS and possible differences between the two active interventions. These findings, if observed, may offer insights for future clinical decision-making and mechanistic research.

Ancillary and Post-Trial Care

After the 3-week intervention and 3-month follow-up, participants in both groups will return to the care of their regular healthcare providers. Participants in the acupuncture group who benefited from the treatment may, if clinically indicated and willing, continue acupuncture at their own expense. For participants in the control group who do not achieve adequate pain relief with EMG-BF+NMES, a complimentary course of acupuncture (up to 10 sessions) will be offered after trial completion. This is provided as a gesture of gratitude and to ensure equitable access to the investigational treatment. For subjects who are unable to cooperate with the trial due to pain or adverse events, we will provide them with the option to suspend or terminate their participation in the trial.

Protocol Amendments

Any amendments to the protocol that may impact the conduct of the study, potential benefits to participants, or patient safety—including changes in study objectives, study design, patient population, sample size, or study procedures—will be submitted as a formal modification to the Ethics Committee of Hangzhou Hospital of Traditional Chinese Medicine. No such changes will be implemented until written approval from the ethics committee has been obtained.

Abbreviations

MPPS, Myofascial Pelvic Pain Syndrome; CPP, Chronic Pelvic Pain; PFD, Pelvic Floor Dysfunction; VAS, Visual Analog Scale; EMG-BF+NMES, Combined Electromyographic Biofeedback with Neuromuscular Electrical Stimulation; PFDI-20, Pelvic Floor Distress Inventory-Short Form 20; PFIQ-7, Pelvic Floor Impact Questionnaire-7; PAC-SYM, Patient Assessment of Constipation Symptoms; SAS, Self-Rating Anxiety Scale; SDS, Self-Rating Depression Scale; SF-36, Medical Outcomes Study 36-Item Short-Form Health Survey; PSQI, Pittsburgh Sleep Quality Index; PFPT, Pelvic Floor Physical Therapy; SUI, Stress Urinary Incontinence; RCT, Randomized Controlled Trial; CRC, Clinical Research Coordinator; CRA, Clinical Research Associate; GCP, Good Clinical Practice; sEMG, Surface Electromyography; MOS, Modified Oxford Pelvic Floor Muscle Strength Grading Scale; DSMB, Data Safety Monitoring Board; EDC, Electronic Data Capture; eCRF, Electronic Case Report Form; PSV, Peak Systolic Velocity; EDV, End-Diastolic Velocity; RI, Resistance Index; S/D, Systolic-to-Diastolic Ratio; IQR, Interquartile Range; BH, Benjamini–Hochberg; MAR, missing at random; PMM, pattern mixture model; MNAR, missing not at random; TCM, traditional Chinese medicine.

Data Sharing Statement

No datasets were generated or analysed during the current study.

Ethics Approval and Consent to Participate

This study protocol was reviewed and approved by the Ethics Committee of Hangzhou Hospital of Traditional Chinese Medicine (Approval No. 2025LL003). All procedures will be conducted in accordance with the Declaration of Helsinki and relevant guidelines. Written informed consent will be obtained from all participants by a qualified researcher before any study-related procedures, including baseline assessments and randomization. Participants will be informed of their right to withdraw at any time without consequence.

Consent for Publication

Not applicable, as no patient data or images will be published in this article.

Acknowledgments

The authors would like to express gratitude to all the participants.

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.

Funding

This RCT was funded by Open Project of the National Clinical Research Center for Chinese Medicine Acupuncture and Moxibustion (Grant No. NRCOP2024019). The funder had no role in study design, writing of the report and decision to submit for publication. The sponsor (Hangzhou Hospital of Traditional Chinese Medicine) was responsible for the study design, protocol development, and overall coordination of the trial. The collaborating site (First Teaching Hospital of Tianjin University of Traditional Chinese Medicine) will participate in participant recruitment and data collection under the coordination of the sponsor. An independent Data Monitoring Committee, with no competing interests and independent from the sponsor and funder, will have access to interim data and oversee the safety of participants.

Disclosure

Dr Liyuan Jiang reports Support for the manuscript from the Open Project of the National Clinical Research Center for Chinese Medicine Acupuncture and Moxibustion (Grant No. NRCOP2024019), during the conduct of the study, outside the submitted work. The authors declare that they have no competing interests.

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