

Efficacy of Myofascial Trigger Point Dry Needling in Treatment of Primary Dysmenorrhea: A Study Protocol for a Three-Arm Randomized Controlled Trial

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Background and Objective: Primary dysmenorrhea carries substantial medical, social, and economic burdens, leading many patients to seek low-risk complementary and alternative therapies, such as acupuncture. Myofascial trigger point dry needling (MTrP-DN) has recently gained attention as a potential treatment, though evidence remains limited and its distinction from acupuncture is debated. Therefore, this study aims to evaluate the therapeutic efficacy of MTrP-DN for primary dysmenorrhea, using traditional acupuncture as an active control and sham needling as a passive control.

Methods and Analysis: This is a randomized, subject-blind, sham-controlled trial. A total of 150 subjects with primary dysmenorrhea will be randomly assigned in a 1:1:1 ratio to the MTrP-DN, acupuncture, or sham group, receiving consecutive 3-week treatments with follow-up for 12 months. The primary outcome is pain intensity, measured by the visual analogue scale (VAS). Secondary outcomes include quality of life, non-steroidal anti-inflammatory drug (NSAID) usage, self-reported improvement using the Global Rate of Change (GROC) scale, serum inflammatory markers, and uterine blood flow assessed by Doppler. Outcomes will be evaluated at baseline, 1st month, 2nd months, and 12th months post-treatment during menstruation. Multivariate analysis of variance will be used to analyze the interactions between different groups, different time periods, and the interaction of group and time.

Discussion: This study is the first to compare the efficacy of MTrP-DN with acupuncture in the treatment of primary dysmenorrhea, focusing on their effects on pain intensity, uterine blood flow, and inflammatory markers. Including a sham control group helps address blinding issues and accurately assess MTrP-DN's effects on pain and quality of life.

Trial Registration Number: Clinicaltrial.gov (NCT06316583).

Keywords: myofascial trigger point, dry needling, primary dysmenorrhea, acupuncture

Introduction

Primary dysmenorrhea, defined as menstrual pain without pelvic organic lesions, is characterized by recurrent lower abdominal cramps during menstruation.¹ It is the leading cause of gynecologic consultations, affecting 50% to 90% of women. More than half of these women experience moderate to severe pain.^{2,3} Alongside abdominal discomfort, symptoms such as nausea, vomiting, diarrhea, headache, fatigue, and dizziness may also occur. In severe cases, additional symptoms such as cold extremities, pale complexion, profuse sweating, and fainting may manifest.⁴ This condition imposes a significant societal and economic burden, as 30–50% of affected women miss school or work at least once per cycle.^{2,5,6}

Primary dysmenorrhea primarily results from elevated prostaglandin levels in menstrual fluid, which heighten uterine muscle contraction, causing periodic ischemia. This often leads to patients exhibiting elevated uterine blood flow indices.^{1,7,8} Conventional treatments, such as non-steroidal anti-inflammatory drugs (NSAIDs) and the oral contraceptive pill, are commonly employed.^{9–11} However, approximately 20–25% of women find these treatments ineffective, and there's a concern that long-term NSAID use may increase the risk of cardiovascular side effects.^{9,12}

Given the increasing burden of primary dysmenorrhea and concerns about the side effects of conventional medications, patients are turning to complementary and alternative therapies, with acupuncture being a popular choice.^{13,14} Systematic reviews and meta-analyses have indicated that acupuncture may be an effective non-pharmacological treatment for primary dysmenorrhea, offering benefits such as pain relief and enhanced quality of life.^{15,16} However, acupuncture based on Traditional Chinese Medicine (TCM) requires extensive training and expertise, limiting its widespread implementation among practitioners. Additionally, the complexity of the treatment and the limited, often low-quality evidence from current studies¹⁷—due in part to the lack of replication in acupuncture research—highlight the need for further investigation and other potential non-pharmacologic treatment.

Myofascial Trigger Point Dry Needling (MTrP-DN) is gaining recognition as an effective treatment for muscle pain by targeting trigger points within muscles that contribute to discomfort.¹⁸ These points, often felt as palpable nodules or tense bands, are stimulated to induce muscle twitching, which helps relieve pain.¹⁹ MTrP-DN is straightforward to perform and does not require TCM training, making it widely used in pain clinics. While MTrP-DN is widely used for various musculoskeletal chronic pain conditions and has been effective for neck-shoulder pain and low back pain,^{20–22} limited evidence supports its use for primary dysmenorrhea.²³

Both MTrP-DN and acupuncture target specific points to relieve pain, though their mechanisms differ. MTrP-DN focuses on myofascial trigger points, promoting muscle relaxation, blood flow, and pain modulation. Acupuncture, targeting points along energy pathways (Qi), may work through similar mechanisms. While there is overlap between trigger points and acupuncture points,^{24–26} further research is needed to fully understand their relationship and clinical applications.

This study aims to evaluate the efficacy of MTrP-DN in treating primary dysmenorrhea compared to acupuncture and a sham group, focusing on pain relief, quality of life, inflammatory factors, local uterine blood flow, and long-term outcomes. It also explores the differences and similarities between MTrP-DN and acupuncture in terms of point selection, treatment effects, and their impact on inflammation and uterine circulation.

Methods and Analysis

We adhered to the guidelines outlined in the Standard Protocol Items: Recommendations for Interventional Trials, Reporting Interventions in Clinical Trials of Acupuncture,²⁷ the principles of the Consolidated Standards of Reporting Trials and the Standards for Reporting Interventions in Clinical Trial of Acupuncture²⁸ and How to design high-quality acupuncture trials—a consensus informed by evidence²⁹ when designing and reporting our trial protocol.

Study Design and Setting

This will be three-arm, randomized, subject-blind, sham-controlled trial carried out on Pain clinic, Department of Acupuncture and moxibustion and Department of Gynecology in Beijing Hospital. The trial protocol and informed consent ([Supplementary Material 1](#)) were approved by the Ethics Committee of Beijing Hospital (2024BJYYEC-KY012-02) and registered with ClinicalTrials.gov (NCT06316583). All procedures will rigorously adhere to the Declaration of Helsinki. The design of the trial is summarized in [Figure 1](#) and the schedule of treatment, assessments and data collection is shown in [Table 1](#).

Protocol Amendments

Substantial protocol amendments (changes to eligibility criteria, outcomes, or analyses) will be reported to investigators, ethics committees, trial registries, and journals as appropriate, and will be documented in updated protocol and registration records.

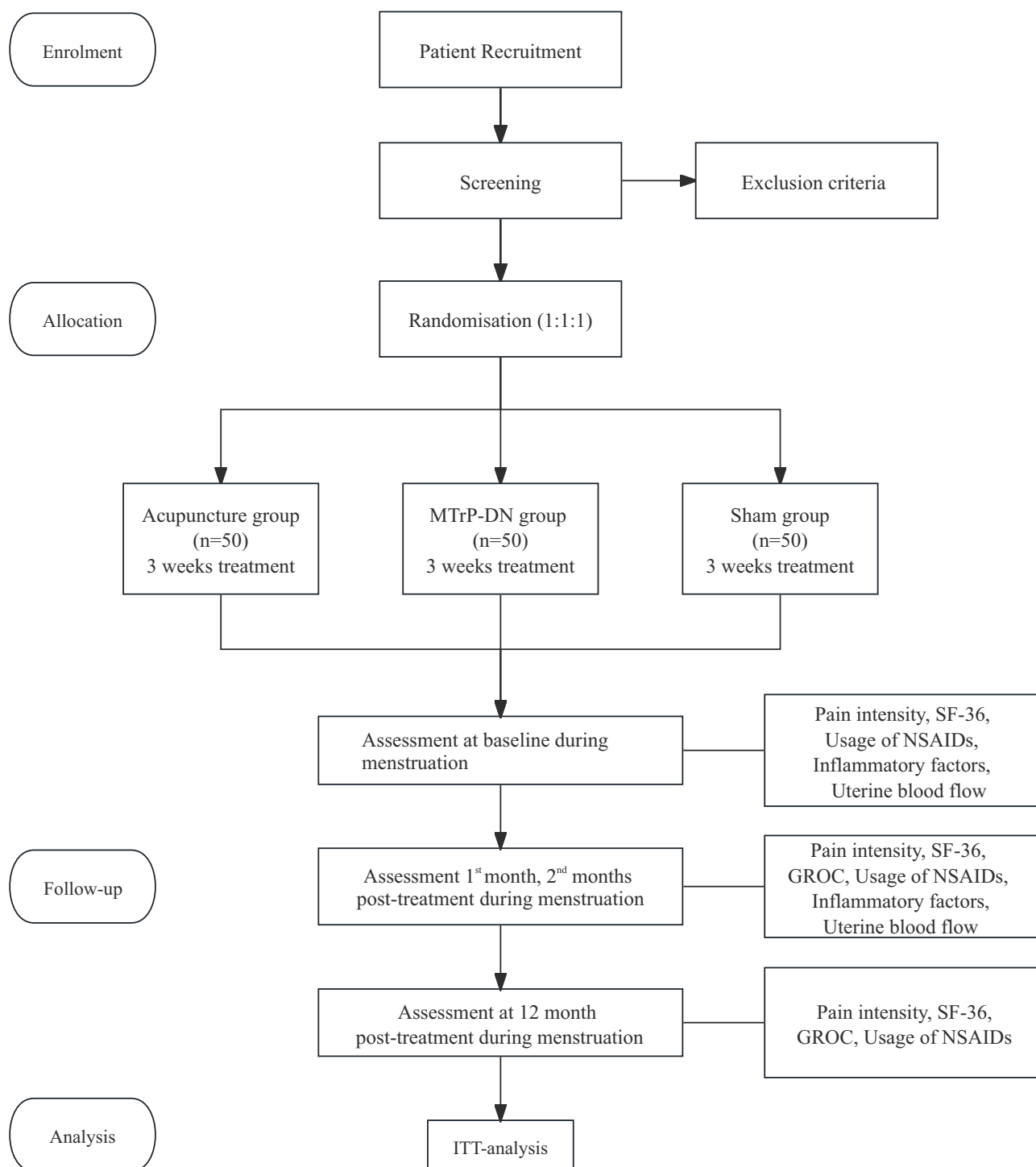


Figure 1 Flowchart of the trial.

Abbreviations: GROC, Global Rate of Change, NSAIDs, Non-steroid anti-inflammatory drugs; MTrP-DN, Myofascial trigger point dry needling.

Subjects Recruitment

Subjects recruitment started in April, 2024 and plan to finish the recruitment at the end of 2025, and the whole trial might be finished in December 2026. Subjects are recruited from the outpatient departments of Acupuncture and Moxibustion, Gynecology, and the Pain Clinic. We also post recruitment materials on official social media and display posters in hospitals and communities. Interested individuals can contact the researchers by telephone or in person. The study

Table 1 Schedule of Enrolment, Intervention and Assessments

	Baseline	Treatment Phase			Follow-Up Phase		
		Week1	Week2	Week3	1month	2month	12month
Subjects							
Enrolment	x						
Signed informed consent	x						
Medical history	x						
Gynecologic examination	x						
TCM diagnosis	x						
Intervention		x	x	x			
Outcomes measure							
Pain intensity	x				x	x	x
SF-36	x				x	x	x
GROC					x	x	x
Inflammatory factors	x				x	x	
Uterine Blood Flow	x				x	x	
NSAIDs usage	x				x	x	x
Acupuncture Treatment Expectation Scale	x						
Treatment Credibility Scale		x		x			
Adverse events		x	x	x	x	x	x

Abbreviations: GROC: Global Rate of Change, NSAIDs:Non-steroid anti-inflammatory drugs,TCM: Traditional Chinese Medicine,SF-36:36-Item Short Form Survey.

protocol will be explained to potential subjects, and written informed consent will be obtained before screening them according to the inclusion and exclusion criteria. Eligible and consented subjects will be randomly assigned, in a ratio of 1:1:1, to receive MTrP-DN treatment (n=50), acupuncture treatment (n=50), or sham treatment (n=50).

In addition to the initial recruitment efforts, we will utilize snowball recruitment, where enrolled subjects will be encouraged to refer others who meet the inclusion criteria. This method will help expand the sample size. A 12-month follow-up will be conducted for further observation.

Eligibility

Inclusion Criteria

1. All primary dysmenorrhea diagnosed clearly by gynecologists without evidence of pelvic organic lesions shall be diagnosed according to the diagnostic criteria for primary dysmenorrhea outlined in the Clinical Practice Guidelines of the Society of Obstetricians and Gynaecologists of Canada in 2017 (No.345)³⁰ and will be further verified by Doppler examination.
2. Aged between 18 and 30 years old.
3. A history of recurrent dysmenorrhea for more than 2 years.
4. Abdominal pain intensity >30mm on the Visual Analog Scale (VAS, 0–100mm).
5. Subjects must sign an informed consent form and be willing to undergo treatment and cooperate to complete the relevant procedures of this trial.

Exclusion Criteria

1. Suffering from secondary dysmenorrhea or any other reproductive and urinary system diseases, such as endometriosis, etc.
2. History of pregnancy or miscarriage, or during the preconception period.
3. Those with skin infections in the abdomen and waist.
4. Those who have previously used acupuncture related-treatments.
5. Subjects with a history of mental illness and severe diseases such as heart, liver, brain, kidney, and hematopoietic system diseases.
6. Referred to pain clinics or used analgesics such as morphine or pentazocine in the past 6 months; or currently taking oral or injectable anticoagulants; or allergic to NSAIDs.
7. Those who have adverse reactions to needling therapy (such as needle fainting).

Randomization and Blinding

Eligible subjects will be randomly assigned to one of three groups—the acupuncture group, MTrP-DN group, or sham group—in equal proportions using a central randomization system. The randomization sequence will be generated by third-party personnel not involved in the trial, utilizing SAS V.9.4. Numbered, sealed, opaque envelopes containing the group assignments will be provided to the research assistant, who is not involved in outcomes assessment. Blinding will be maintained for subjects, examiners, data collectors, and statisticians, with only acupuncturists and MTrP-DN practitioners having access to this information. The researchers will unblind the assignments only in the event of a serious adverse event.

To verify subjects' blinding to the treatment modalities, the Treatment Credibility Scale³¹ will be administered after the first and last treatment. Subjects will be asked to assess the logicity and perceived success of the treatment, along with their confidence in its ability to alleviate primary dysmenorrhea. Similar expectations of efficacy across all three groups suggest that any differences in outcomes are not solely attributable to psychological placebo effects. Conversely, if there are discrepancies in expectations, caution should be exercised when interpreting the results, as these differences may influence the observed outcomes beyond the specific therapeutic effects of the treatments.

Intervention

Treatment will be administered by pain specialists and acupuncturists with a minimum of 5 years of relevant experience. Each subject will then receive their assigned treatment for 30–40 minutes weekly over a span of 3 weeks, followed by a treatment-free week coinciding with the expected onset of menses. Additionally, all subjects will be instructed to perform self-stretching exercises of the external and internal obliques and rectus abdominis muscles³² (Figure S1) starting from the treatment day, 3–5 times daily for approximately 2 minutes each time, throughout the course of one month to help alleviate pain. These exercises are included as they are known to promote muscle relaxation, improve blood flow, and reduce menstrual discomfort, supporting the overall effectiveness of the treatment protocol.³³ In the event of significant menstrual pain (VAS over 60mm or they could not tolerate) during the treatment period, subjects are permitted to orally take NSAIDs for symptomatic relief.

MTrP-DN Treatment Group

Trigger points were diagnosed when there was a palpable taut band, local pain on palpation of the spot and referred pain reproducing the symptoms of the patient (pain recognition). The procedure entails disinfecting the treatment points and utilizing traditional acupuncture needles (0.35×50mm, Hwato brand, Suzhou Medical Supplies Factory Co., China) to stimulate the points repeatedly until muscle soreness and local twitch responses are induced.³⁴ With the patient lying supine, the needle is inserted through the skin and advanced horizontally into the trigger point at the lateral edge of the rectus abdominis muscle, until the first local twitch response is triggered. According to Hong,³⁴ eliciting local twitch responses is a key element of an effective MTrP-DN technique, though there is ongoing debate regarding their necessity for a positive outcome.³⁵ After the first local twitch response is achieved, the needle is moved in and out of the rectus abdominis muscle in 3–5mm horizontal motions (without rotation) for 25–30 seconds. This duration typically induces

2–3 local twitch responses. Additionally, if subjects report lower back pain, trigger points in the back can also be targeted. These back trigger points are situated bilaterally from the twelfth thoracic vertebra to the third lumbar vertebra.

Traditional Acupuncture Treatment Group

Two experienced acupuncturists will use acupuncture point needling therapy. The most common TCM diagnoses arising for primary dysmenorrhea are: stagnation of Qi and blood, stagnation of cold, damp heat attacking the lower jiao, deficiency of Qi and blood and deficiency of kidney and liver. Primary acupuncture points include GongSun (SP4), Guilai (ST29), Zhongji Ren-3, Ciliao (BL32), Diji (SP8), Sanyinjiao (SP6), Uterus Point and additional points used according to the individual diagnoses. Acupuncture points will be used based on diagnosis of TCM ([Table S1](#)). Seirin 0.2×30 mm acupuncture needles (Hwato brand, Suzhou Medical Supplies Factory Co., China) are inserted bilaterally to a depth of ≤ 2 cm, and the needles are retained for 30 min. All subjects receive the de qi sensation (which is the needling sensation of soreness, numbness or heaviness).

Sham Group

Subjects in the sham group will be administered a sham needle procedure utilizing a “Dong Bang” placebo needle, closely resembling the Park needle ([Figure S2](#), Hwato brand, Suzhou Medical Supplies Factory Co., China). This type of needle has demonstrated efficacy as a placebo technique in acupuncture studies involving the majority of subjects. The pain specialist employed the same procedure on the sham points as used with sham needles in the MTrP-DN group to maintain blinding among the subjects. Sham points are positioned 2cm away from trigger points or meridians. These sham needles apply mechanical stimulus to the tissue without penetrating the skin, generating a pressure sensation akin to that of a normal needle for the subjects.

Assessments and Outcomes

All endpoints will be assessed by research personnel who are blinded to the group assignments. Both primary and secondary endpoints will be evaluated at baseline, and at the 1st, 2nd, and 12th months post-treatment, during menstruation.

Primary Outcomes Measurement

The primary outcomes measure the average abdominal pain intensity assessed by the VAS at baseline, and at the 1st, 2nd, and 12th months post-treatment, during menstruation. Subjects indicate their abdominal pain intensity by marking a 100mm horizontal line, where the endpoints represent the extremes of pain expression (from no pain to maximum pain). The mean intensity of all days with menstrual pain (VAS >30mm) are calculated for the analysis.

Secondary Outcomes Measurement

Questionnaire

The health-related quality of life of subjects will be evaluated before treatment and at 1st, 2nd, and 12th months post-treatment using the Short Form Health Survey (SF-36)³⁶ ([Supplementary Material 2](#)). Additionally, self-perceived improvement will be assessed using a 4-point Global Rate of Change (GROC) scale at the same intervals. The Chinese version of the SF-36 questionnaire will be employed to assess changes in health-related quality of life, comprising eight domains that gauge the impact of pain on overall well-being. Scores range from 0 (indicating the lowest quality of life) to 100 (indicating the highest quality of life). In this study, the domains will be combined into physical component scores (PCS) and mental component scores (MCS). Although specific minimal clinically important differences (MCID) for the PCS and MCS of the SF-36 questionnaire are not available, changes between 3 and 5 points will be considered clinically relevant.³⁷ The GROC scale, categorized into four levels—significantly improved, improved, no change, and worsened—will measure the degree of perceived change.

NSAIDs Usage

The amount and frequency of NSAIDs usage during menstruation at baseline and at 1st menstruation, 2nd menstruation and 12th menstruation after treatment.

Inflammatory Factors

Inflammatory factors levels will be assessed via enzyme-linked immunosorbent assay (ELISA) at baseline, 1st month, and 2nd months post-treatment, specifically on the second day of menstruation, as recommended. The selected inflammatory factors, namely Prostaglandin F₂ alpha (PGF₂-α), C-reactive protein (CRP), interleukin-6 (IL-6), and interleukin-8 (IL-8), will be determined based on previous research findings.⁷

Uterine Blood Flow

Abdominal color Doppler ultrasound will be utilized to measure uterine artery blood flow at the level of the uterine artery isthmus at baseline, 1st month, and 2nd months post-treatment, preferably on the second day of menstruation in the morning. Doppler systolic/diastolic ratio (S/D), pulsatility index (PI), and resistance index (RI) values will be documented. All ultrasound scans will be conducted using a 5mhz abdominal pulse Doppler probe to ascertain uterine artery blood flow indices. The measurements will be carried out by the same individual, and three consecutive measurements will be obtained. The measurement techniques will be based on previous research findings and will be performed by gynecologists blinded to the subjects' group assignments.³⁸

Assessment of Treatment

After all eligible subjects complete the screening process, they will fill out the Acupuncture Treatment Expectation Scale³⁹ (Table S2) to assess their expectations of acupuncture treatment. Subjects will be also asked to assess the logicity and perceived success of the treatment after one session and last session using the Treatment Credibility Scale, along with their confidence in its ability to alleviate primary dysmenorrhea.

Safety Assessment Indicators

All subjects can report adverse events (AEs) during the treatment period, such as unexpected physical reactions or discomfort symptoms, through outpatient visits or phone calls, with particular attention to acupuncture-related complications. All adverse events reported by subjects will be described in the Case Report Form (CRF). If adverse events are severe and related to the trial, subjects will be withdrawn from the study and provided with appropriate medical care.

Trigger Points and Traditional Acupuncture Points Comparison

Photographic records of the acupuncture points and trigger points of each subject will be maintained. When the study is completed, a senior acupuncturist will analyze the trigger points of the MTrP-DN group alongside the TCM diagnosis. The aim is to ascertain whether they align with recognized acupuncture points and to specify their specific names accordingly.

Data Monitoring and Management

The research follow-up personnel will promptly, thoroughly, and accurately input the data from the subjects' original observation records into the CRF and upload them to the electronic data management system. Subsequently, upon signing the CRF, they will promptly submit it to the clinical trial data custodian. Once data entry and verification are completed as necessary, the CRFs will be archived and stored in numerical order. Researchers and sponsors are responsible for appropriately preserving the documents and materials of the clinical trial in accordance with GCP requirements, maintaining them for a retention period of 5 years.

In addition, an independent Data Safety Monitoring Committee (DSMC) consisting of four experts with backgrounds in pain clinic, acupuncture, gynecology and statistics will be established prior to the trial. The DSMC will hold an online conference every 6 months to oversee the trial progress and review the safety and quality of the data. At the stage of 1/2 enrollment, an interim analysis will be conducted, and the DSMC will decide whether it is necessary to terminate the trial in advance. Information involving personal privacy (name, age, telephone number) will be concealed within DSMC reports.

Sample Size Calculation

Initially, employing an F-test analysis within a repeated measures design, we determined the MCID for the VAS in the treatment of primary dysmenorrhea. Based on previous research findings and preliminary experimental data from our institution, we established the intergroup difference MCID for VAS as 10mm.²³ The average baseline VAS score was

60 mm, with a standard deviation of 12 mm across measurements based on preliminary experimental data from our institution and an assumed autocorrelation coefficient of 0.7 between adjacent time points. With a two-tailed alpha level of 0.05 and a statistical power of 80%, we performed a sample size calculation using PASS software version 21.0. The required sample size was determined to be 120 participants. To account for an expected dropout rate of 20%, we plan to enroll a total of 150 participants ([Supplementary Material 3](#)).

Data Analysis

Before conducting data analysis, a detailed Statistical Analysis Plan (SAP) will be formulated in advance. Independent statisticians will utilize SPSS 19.0 statistical analysis software to perform statistical analysis based on the SAP. Analyses will be conducted on the intention-to-treat population, which included all subjects who received at least one treatment. Multiple imputation will be employed to supplement missing data. To assess the robustness of our findings, we will also perform sensitivity analyses by comparing results from the imputed dataset with those from a complete-case analysis. Continuous data will be expressed as mean \pm standard deviation or median (interquartile range), while categorical data will be presented as rates or proportions (%). Comparison of categorical data will be conducted using chi-square tests and pairwise comparisons between groups. Comparison of continuous data between groups will be performed using one-way analysis of variance or non-parametric rank sum tests. For repeated measurements at different time periods, multivariate analysis of variance will be used to analyze the interactions between different groups, different time periods, and the interaction of group and time. In order to compare the size of group effects, standardized mean differences (SMDs) will also be calculated by dividing the mean difference by the combined standard deviation.

Quality Control

Before starting the trial, we developed an investigator's manual to standardize the assessment procedure, performance of acupuncture and MTrP-DN, outcomes measurements and data collection and entry. All the involved researchers will receive centralized and unified training to ensure strict adherence to the trial protocol and the standardization and uniformity of the study. The true and sham interventions will be provided by licensed acupuncturists or pain practitioner with at least 5 years of clinical experience.

Discussion

This trial aims to demonstrate the efficacy of MTrP-DN for primary dysmenorrhea, offering practical treatment options. The potential mechanism by which MTrP-DN may relieve dysmenorrhoeic pain is based on the concept of somatovisceral convergence. Within lamina I of the spinal cord, somatic and visceral nociceptive pathways intersect, allowing nociceptive input from one structure (muscle) to influence pain perception in another (uterus).⁴⁰ Both the rectus abdominis muscle and the uterus are innervated by lower thoracic spinal nerves (T10-T12), indicating a shared neural pathway. As a result, nociceptive activity in the rectus abdominis could amplify visceral pain sensations in the uterus, and vice versa.⁴⁰ Applying MTrP-DN to the rectus abdominis may deactivate myofascial trigger points, thereby reducing local nociceptive input and, in turn, decreasing the overall nociceptive drive to the spinal cord. This reduction could raise the nociceptive threshold of the uterus, leading to diminished menstrual pain. Such a counter-irritant effect provides a plausible neurophysiological explanation for the potential benefits of MTrP-DN in managing primary dysmenorrhoea. Furthermore, Simons and colleagues¹⁸ proposed that trigger points in the rectus abdominis can refer pain to the hypogastric region, mimicking or intensifying menstrual pain symptoms. Addressing these trigger points may therefore directly alleviate symptoms commonly associated with dysmenorrhoea. Given this theoretical framework and anatomical rationale, it is reasonable to hypothesize that MTrP-DN could serve as an effective intervention for female suffering from primary dysmenorrhoea. To date, however, only one RCT²³ has investigated this approach, reporting that a single session of dry needling targeting active trigger points in the rectus abdominis—combined with stretching exercises—was more effective than placebo needling and stretching alone in reducing pain intensity and the need for NSAIDs. These preliminary findings highlight the necessity for further well-designed studies to evaluate whether MTrP-DN could serve as a complementary or alternative therapeutic strategy in the management of primary dysmenorrhea.

All interventions in this study are scheduled prior to the onset of menstruation. This timing is based on previous research that increased uterine PGF₂ α production in the weeks before menstruation could be transported in the blood and settle in rectus abdominis muscle taut bands, leading to irritation and activation, which typically revert to a latent state as prostaglandin levels decline post-menstruation.³² Additionally, it has been recommended that acupuncture be initiated before the menstrual cycle to maximize effectiveness by clearing stagnation and restoring balance.^{14,41} Furthermore, during the follicular phase (prior to ovulation), the body is generally in a more stable physiological state with higher estrogen levels, making it more responsive to acupuncture and needling. In light of these considerations, treatment sessions are strategically scheduled prior to menstruation rather than during the menstrual period to mitigate the potential exacerbation of menstrual symptoms due to post-needling soreness.

In this trial, a sham group is included as a control. Because this trial focuses on subjective outcomes such as pain, quality of life, and function, maintaining blinding is critical. The effectiveness of different sham types remains uncertain and may vary depending on the condition studied. Current consensus recommends that non-penetrating needle shams be used alongside the same device in the real treatment group to ensure effective blinding.²⁹ Therefore, in this study, participants in the sham group will receive a sham needling procedure at designated sham points. These sham needles create mechanical stimulation without skin penetration, producing a pressure sensation similar to real needling to maintain patient blinding.

The concept of myofascial trigger points was first introduced by Professor Janet Travell in 1942. Since then, the relationship between myofascial trigger points and traditional acupuncture points has been a topic of considerable debate. Substantial anatomical and functional overlap has been reported, with more than 92% of myofascial trigger points corresponding to classical acupuncture points.^{24,42} Both myofascial trigger points and acupuncture points can elicit similar referred sensations and modulate visceral symptoms.^{42,43} In the present study, we will explore the distinctions and commonalities between MTrP-DN and traditional acupuncture treatments concerning acupuncture point selection, treatment effectiveness, and their impact on inflammatory factors and local uterine circulation in primary dysmenorrhea, thus providing further insight into their correlation.

We must acknowledge several limitations in this protocol. Firstly, the acupuncturists and pain specialists cannot be blinded due to the nature of the intervention. Secondly, the sham control is not completely inert. Despite these limitations, the study is expected to yield high-quality evidence regarding the efficacy of MTrP-DN in treating primary dysmenorrhea, as well as uncovering potential intervention mechanisms. Lastly, considering subject adherence, this trial only includes a single session comprising three-week treatments.

In summary, this clinical trial aims to evaluate the efficacy of MTrP-DN in treating primary dysmenorrhoea by alleviating pain, modulating inflammatory markers and uterine blood flow, and improving quality of life. By systematically investigating the differences between trigger points and acupuncture points, as well as their respective effects, this study seeks to enhance the understanding of the relationship between acupuncture and MTrP-DN. Ultimately, the results are expected to provide robust scientific evidence supporting the clinical use of MTrP-DN as an effective treatment strategy for primary dysmenorrhoea.

Abbreviations

AEs, Adverse events; CRF, Case Report Form; CRP, C-reactive protein; DSMC, Data Safety Monitoring Committee; ELISA: Enzyme-linked immunosorbent assay; GROC, Global Rate of Change; IL-6, Interleukin-6; IL-8, Interleukin-8; MCID, Minimal clinically important difference; MCS, Mental component scores; MTrP-DN, Myofascial trigger point dry needling; NSAIDs, Non-steroidal anti-inflammatory drugs; PF₂ α , Prostaglandin F₂ α ; PCS, Physical component scores; PI, Pulsatility index; RI, Resistance index; SMDs, Standardized mean differences; SAP, Statistical analysis plan; TCM, Traditional Chinese Medicine; VAS, Visual Analog Scale.

Data Sharing Statement

The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

Ethics Approval and Informed Consent

The trial protocol and informed consent were approved by the Ethics Committee of Beijing Hospital (2024BJYYEC-KY012-02).

Consent for Publication

Consent obtained directly from subjects. All subjects and the public were not involved in the design of this study. The subjects will be informed of the result of this study during the follow-up visit.

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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