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# Efficacy and safety of transcutaneous electrical acupoint stimulation for the management of primary dysmenorrhoea: protocol for a randomised controlled trial in China

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## ABSTRACT

**Introduction** Primary dysmenorrhoea (PD) is a common menstrual concern with significant physical and psychosocial impacts. The effectiveness and safety of transcutaneous electrical acupoint stimulation (TEAS) in alleviating PD symptoms remain uncertain due to insufficient evidence. This single-centre, parallel, randomised controlled study intends to evaluate the efficacy and safety of TEAS for PD management.

**Methods and analysis** 60 participants aged 18–40 years diagnosed with moderate to severe PD will be recruited from Tai'an Hospital of Traditional Chinese Medicine (TCM) and randomly assigned to either a TEAS group or a TEAS-sham group (1:1). The TEAS group will undergo 12 sessions of TEAS treatment over two menstrual cycles, with 30 min per session, three sessions weekly. Participants in the TEAS-sham group will receive TEAS stimulation using identical devices and protocols but without current output. The primary outcome is the Visual Analogue Scale (VAS) for pain assessment. Secondary outcomes are Short-Form McGill Pain Questionnaire, total effective rate, uterine artery haemodynamics, prostaglandin and β-endorphin level, mental well-being and quality of life. Adverse events and their potential reasons and the use of analgesics will also be recorded.

**Ethics and dissemination** This study was approved by the Medical Ethics Committee of Tai'an Hospital of TCM. Written informed consent will be obtained from each participant. The results will be submitted for publication in a peer-reviewed journal.

**Trial registration number** ChiCTR2300071686.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A registered randomised controlled trial will be conducted to assess the efficacy and safety of transcutaneous electrical acupoint stimulation (TEAS) in managing primary dysmenorrhoea.
⇒ The comparator is TEAS-sham, which has been conducted in previous studies to blind the participants.
⇒ TEAS treatment will begin 7 days before menstruation, which could lead to different commencement times for each participant.

## INTRODUCTION

Primary dysmenorrhoea (PD) is a painful period without pelvic pathology, with recurrent lower abdominal crampy pain and associated symptoms of back pain, nausea, headaches and poor quality of sleep.[1 2] Its global prevalence ranges from 50% to 90%.[3 4] PD is common and has significant detrimental impacts on finances, work and daily activities, quality of life[4 5] and mental well-being.[6 7] Non-steroidal anti-inflammatory drugs (NSAIDs) are the first-line approaches to PD management.[8 9] However, more and more people tend to seek complementary therapies[10] due to the commonly reported side effects of NSAIDs as they are not well tolerated.[11]

Transcutaneous electrical acupoint stimulation (TEAS), a contemporary adaptation of traditional acupuncture, offers a non-invasive treatment employing surface electrodes instead of needles, thereby mitigating discomfort associated with acupuncture needle insertion.[12 13] Compared with traditional acupuncture, TEAS presents distinct advantages, including its non-trauma nature, reduced risk of infection and enhanced acceptability.[14] Previous studies[15–17] have demonstrated TEAS as a viable modality for pain management, widely implemented in clinical settings. However, the absence of randomised controlled trials (RCTs) investigating TEAS for PD leaves a gap in clinical evidence regarding its efficacy and safety. Therefore, this study aims to explore the efficacy and safety of TEAS on PD management.

## METHODS AND ANALYSIS

### Trial design and setting

This study is designed as a single-centre, participant-blind, parallel, RCT on the efficacy

and safety of a TEAS treatment for PD over two menstrual cycles in Tai'an Hospital of Traditional Chinese Medicine (TCM). This trial has been registered with the Chinese Clinical Trial Registry (ChiCTR2300071686) and approved by the Medical Ethics Committee of Tai'an Hospital of TCM, whereby the protocol is conducted based on the Standard Protocol Items: Recommendations for Interventional Trials reporting template.[18] Moreover, the intervention description followed the Template for Intervention Description and Replication checklist and guide,[19] where Consolidated Standards of Reporting Trials guidelines[20] will guide the final report of the trial.

## Sample size

Sample size calculation was based on the primary outcome of Visual Analogue Scale (VAS) pain assessment post-intervention. In our previous unpublished pilot study, the mean value of VAS scores of the TEAS group and TEAS-sham group decreased by 2.5 and 1.2; and the test SD was 2.46 and 2.32, respectively. A recent study[21] suggested a minimal clinically important difference (MCID) should be considered as 2 (comparable with VAS 20 mm) when VAS >4. Where n is the sample size, Z is the Z value for 95% confidence limits (which is 1.96 when $\alpha$=0.05), 1–$\beta$=0.90 and MCID is $\Delta$=2. The required sample size was 25 and increased by 20% for possible dropout and incomplete responses. Therefore, we will recruit a total of 60 individuals with 30 in each group with a 1:1 randomisation ratio.

$$N = 2\,[Z_{1-\alpha} + Z_{1-\beta}(s/\Delta)]^2$$

## Randomisation and blinding

An independent and blinded statistician will use computer-generated sequence numbers to allocate participants to either the treatment or control group employing a randomised block approach. Maintaining the blind allocation process, the statistician, devoid of contact with acupuncturists or participants, will ensure concealment by preserving blind block sizes. Allocation assignments will be conveyed directly to the acupuncturist tasked with implementing the intervention via sealed envelopes upon determination. The acupuncturist will remain blinded to the allocation until the commencement of treatment for either the intervention or control group. Furthermore, personnel involved in data management, analysis and outcome assessment will be blinded.

Randomisation will encompass two arms: (1) participants will receive TEAS intervention led by a licensed acupuncturist at the Tai'an Hospital of TCM, involving a TEAS treatment over two menstrual cycles (12 sessions in total), with 30 min per session, three sessions weekly; or (2) the TEAS-sham group will receive the same protocol as the TEAS treatment, but the device will be inactivated.

## Study procedures

A total of 60 participants with PD will be recruited from the hospital. All participants will give voluntary, informed consent (online supplemental file) to enter the study and will be free to leave the study at any stage. All participants will be randomly allocated to the TEAS group or TEAS-sham group and complete a set of study-specific online questionnaires at baseline (T0), post-intervention (T1) and follow-up (T2). Venous blood samples will be collected at both pre-intervention and post-intervention to detect levels of prostaglandin E2 (PGE2), prostaglandin F2$\alpha$ (PGF2$\alpha$) and $\beta$-endorphin (EP), and the samples will be discarded after use. Colour Doppler ultrasonography will be employed to assess changes in uterine artery blood flow, including pulsatility index (PI), resistance index (RI) values and ratio of systolic peak and diastolic peak (S/D ratio) at both T0 and T1. The acupuncturist will record any adverse events (AEs) during the whole trial. The schedule detailing participant enrolment, intervention administration and outcome assessments is summarised in figure 1, while a flow diagram of the trial design is presented in figure 2.

## Participants

### Inclusion criteria

Participants with PD will be included if the following criteria are met: (1) ultrasound examination shows no organic lesions in the reproductive organs; (2) aged 18–40 years old; (3) menstrual cycle is 28±7 days; (4) VAS score ≥4 cm at baseline; (5) willing to complete the surveys and sign the informed consent form.

### Exclusion criteria

Participants will be excluded if one of the following criteria is met: (1) secondary dysmenorrhoea; (2) sensitive or allergic reactions to TEAS; (3) uncontrolled physical or psychiatric abnormalities; (4) women who are in lactation or planning to conceive.

## Recruitment and withdrawal

Participant recruitment will be conducted through public advertisements on social media channels and distribution of flyers within the hospital. Additionally, snowballing methods will be used to promote recruitment. A brief introduction of the trial will be released, where all interested individuals can contact the researcher for the suitability check. In addition, eligible individuals will be issued the written informed consent, detailing the aim, procedure, benefits, possible risks of the study and voluntary participation. Participants are required to provide signed confirmation and consent to proceed with the study. Following this, participants will be randomly assigned to either the TEAS group or the TEAS-sham group. The recruitment began on 1 August 2023, and the trial will continue until a sample size of 60 has been reached. However, the trial will end on 31 December 2024, regardless of the sample size.

A participant may be discontinued from the study for the following reasons: (1) confirmation of pregnancy during the trial; (2) discovery of a disease that may affect the trial; (3) problems with the medical or trial procedures; (4) other reasons determined by the research

| | Screening & Enrolment | Baseline & Allocation (T0) | Post-intervention (T1) | | Follow-up (T2) |
|---|---|---|---|---|---|
| **Time point** | Cycle -1 | Cycle 0 | Cycle 1 | Cycle 2 | Two more cycles post intervention |
| **Enrolment** | | | | | |
| ✓ Eligibility screen | X | | | | |
| ✓ Informed consent | X | | | | |
| ✓ Baseline | | X | | | |
| ✓ Allocation | | X | | | |
| **Intervention:** TEAS | | | ⟷ | ⟷ | |
| **Control**: TEAS-sham | | | ⟷ | ⟷ | |
| **Assessments** | | | | | |
| **Primary outcome** | | | | | |
| Pain (VAS, SF-MPQ) | | X | | X | X |
| **Secondary outcomes** | | | | | |
| Total effect rate | | | | X | X |
| RI, PI, S/D | | X | | X | |
| PGE2, PGF2, β-EP | | X | | X | |
| Mental wellbeing (SAS, SDS) | | X | | X | X |
| Quality of life (SF-12) | | X | | X | X |

**Figure 1** Schedule of enrolment, interventions and assessments. PI, pulsatility index; RI, resistance index; SAS, Self-rating Anxiety Scale; S/D, ratio of systolic peak and diastolic peak; SDS, Self-rating Depression Scale; SF-12, 12-item Short-Form Health Survey; SF-MPQ, Short-Form McGill Pain Questionnaire; TEAS, transcutaneous electrical acupoint stimulation; VAS, Visual Analogue Scale.

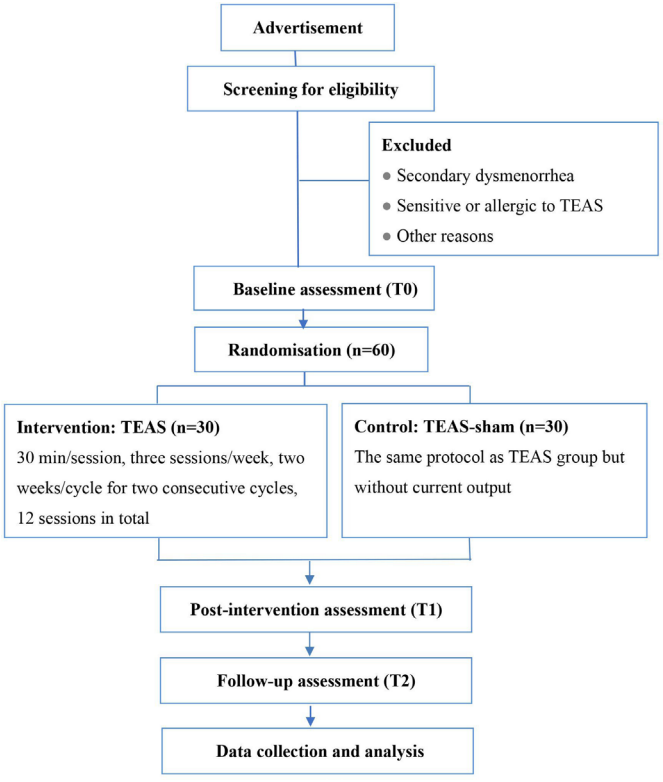


**Figure 2** Trial design flow chart. TEAS, transcutaneous electrical acupoint stimulation.

team. Besides this, participants can withdraw at any time during the trial, with or without reasons being provided.

## Intervention group

Based on previous studies[22 23] and the Delphi consensus,[24] nine acupoints are selected for the intervention, namely Sanyinjiao (SP6), Diji (SP8), Hegu (LI4), Ciliao (BL32), Guilai (ST29) and Taichong (LR3); Guanyuan (CV4); Qihai (CV6) and Zigong (EX-CA1). In accordance with the WHO standard acupuncture point locations,[25] the details of identified acupoints are shown in table 1. This study will be conducted in the Department of Massage of Tai'an Hospital of TCM, with all manipulations performed by the same acupuncturist to ensure procedural consistency.

In the intervention group, participants will receive TEAS treatment from a licensed acupuncturist, 30 min per session. Before treatment, the acupuncturist will disinfect the local skin of the participant's acupoints with ethyl alcohol, then place the square-shaped electrode patch (3×3 cm) on the nominated skin surface of acupoints, connect the electrode patch to electronic acupuncture treatment instrument (SDZ-II Nerve and Muscle Stimulator, Suzhou Medical Appliance Factory, China) and then turn on the power switch to stimulate acupoints. The pair of electrode pieces will be placed on two acupoints located on the same side or the anterior median line, where connection crossing the anterior

Table 1 Locations of acupuncture points used in both groups

| Acupoint | Location |
|---|---|
| Sanyinjiao (SP6) | On the tibial aspect of the leg, posterior to the medial border of the tibia, 3 B-cun superior to the prominence of the medial malleolus |
| Diji (SP8) | On the tibial aspect of the leg, posterior to the medial border of the tibia, 3 B-cun inferior to Yinlingquan (SP9) |
| Guanyuan (CV4) | On the lower abdomen, 3 B-cun inferior to the centre of the umbilicus, on the anterior median line |
| Qihai (CV6) | On the lower abdomen, 1.5 B-cun inferior to the centre of the umbilicus, on the anterior median line |
| Hegu (LI4) | On the dorsum of the hand, radial to the midpoint of the second metacarpal bone |
| Ciliao (BL32) | In the sacral region, in the second posterior sacral foramen |
| Guilai (ST29) | On the lower abdomen, 4 B-cun inferior to the centre of the umbilicus, 2 B-cun lateral to the anterior median line |
| Taichong (LR3) | On the dorsum of the foot, between the first and second metatarsal bones, in the depression distal to the junction of the bases of the two bones, over the dorsalis pedis artery |
| Zigong (EX-CA1) | On the lower abdomen, 4 B-cun inferior to the centre of the umbilicus, 3 B-cun lateral to the anterior median line |

median line is not allowed. The selected acupoint combinations are as follows: ipsilateral SP6 and SP8, ipsilateral LI4 and LR3, ipsilateral ST29 and EX-CA1, left BL32 and CV4, and right BL32 and CV6.

TEAS stimulus parameters will be set as follows: 'disperse-dense' wave with frequency of 2 Hz and 100 Hz alternative, the current intensity will be 5–12 mA. Each point will receive stimulation for a total of 30 min. The treatment runs three times weekly, where the treatment starts 7 days before the participants' period and until the end of the cycle, with two consecutive cycles administered for 12 sessions in total.

## Control group

In the control group, the identical stimulators will be used following the same protocol as the intervention group, but without the application of stimulus. Participants will be informed of this message: 'due to the different TEAS setting, you will receive intervention that you may feel or not the electric stimulation', to achieve blinding. This method has been conducted in previous studies to blind the participants.[26 27] Moreover, data on the trial procedures and period will be collected as well. The participants in this group will receive two cycles of complimentary acupuncture treatment upon completion of the study.

## Follow-up

Follow-up is designed to evaluate the further effects of TEAS for PD, whereby the assessments will be performed after post-intervention, lasting two menstrual cycles. Data collection for participants from both groups will occur at T2, as detailed in figure 1.

## Outcomes

### Primary outcome

#### *VAS pain*

VAS is a self-reported scale for assessing pain intensity,[28] where the degree of pain gradually increases from painless on the far left to the worst pain on the far right.[29] As previously reported, VAS is the most used instrument to evaluate the analgesic effects of various therapies.[30–32] In this study, participants will be asked to select a number that best represents the pain they experienced during the last period via an online survey at T0, T1 and T2.

### Secondary outcomes

#### *Short-Form McGill Pain Questionnaire*

The Short-Form McGill Pain Questionnaire (SF-MPQ) is a multidimensional assessment of perceived pain (quality of pain) in adults,[33] where SF-MPQ comprises a Pain Rating Index (PRI), VAS and present pain intensity (PPI). Accordingly, PRI consists of 15 descriptors (11 sensory and 4 affective) which are rated on an intensity scale as 0=none, 1=mild, 2=moderate or 3=severe, with scores on the VAS from 0 to 10 and PPI from 0 to 5. The total score of subclasses constitutes the intensity value of pain. Similarly, the SF-MPQ will be assessed at T0, T1 and T2 via the online survey.

#### *Total effective rate*

The total effective rate (TER) will be used to measure the symptom improvement of TEAS on PD. Participants will rate their pain using VAS at T0, T1 and T2 via an online survey. According to the clinical guiding principles of new TCM of the Ministry of Health of China,[34] clinical efficacy is divided into 'cure', 'remarkable effect', 'improvement' and 'failure' as shown in table 2. The statistician will evaluate TER at T1 and T2, which is marked as the ratio of the sum of the first three to the total number of participants.

#### Uterine artery haemodynamics (RI, PI, S/D)

The colour Doppler ultrasound diagnostic instrument will be used by an experienced iconography physician at the hospital to assess the uterine artery haemodynamic indicators, including PI, RI and S/D ratio, at T0 and T1.

Table 2 Clinical efficacy evaluation criteria on total score of dysmenorrhoea symptoms

| Improvement level | After-treatment score |
|---|---|
| Cure | 0 |
| Remarkable effect | 1/2 of baseline score |
| Improvement | 1/2–3/4 of baseline score |
| Failure | The same as baseline or higher |

Total effective rate=(numbers of 'cure', 'remarkable effect' and 'improvement')/total numbers×100%.

### Prostaglandin and β-EP level (PGE2, PGF2α, β-EP)

After 8–9 hours of fasting, participants' blood samples will be drawn by a registered nurse and centrifuged to a 2 mL aliquot of serum. Following this, ELISA will be used to detect PGE2 and PGF2α and β-EP levels. The biochemical analysis will be performed in a clinical laboratory at the hospital, at T0 and T1.

### Mental well-being

The Self-rating Anxiety Scale (SAS) and Self-rating Depression Scale (SDS), as self-reporting questionnaires, have been widely used for the assessment of anxiety and depression. They comprise of 20 items with a total score of 80, separately. A higher score shows a greater correlation between anxiety and depression, whereas a score of more than 40 indicates the association of clinical disorders.[35] The SAS and SDS will be measured at T0, T1 and T2 via an online survey.

### Quality of life

The 12-item Short-Form Health Survey (SF-12) will be used to assess the general physical health status, consisting of 12 questions covering 8 health domains.[36] The questions will be combined, scored and weighted to develop the physical component score and mental component score, ranging from 0 to 100. This outcome will be measured using the online surveys at T0, T1 and T2.

## Safety assessment

The occurrence, nature, severity and potential causes of any AEs during the intervention will be recorded using an observational sheet. Additionally, prior to commencing each intervention session, the acupuncturist will inquire about any delayed AEs from the preceding session. Immediate management of AEs will be conducted by the acupuncturist, and the affected participants with severe AEs will be withdrawn from the trial.

## Use of analgesics

In this study, participants in both groups with unbearable pain will be allowed to use analgesics, where the dosage and frequency of any analgesics and the time of use are requested to be documented in the observational sheet.

## Data collection and management

Researchers, including the data collector, data manager, statistician and outcome assessor, will be independent and blinded within the procedure. Participants' demographic data, baseline pain intensity, disease history, history of PD, menstrual cycle, pain management situation, mental well-being and quality of life will be collected at the baseline (T0). Data will be collected via study-specific questionnaires across the different scales, including VAS, SF-MPQ, SAS, SDS and SF-12 at T1 and T2. Moreover, AEs and the use of analgesics will be collected through an observational sheet and open-ended questions during the trial and follow-up. Uterine artery haemodynamic indexes and prostaglandin (PG) and β-EP levels will be obtained by Doppler ultrasound diagnosis and blood sampling, respectively, at T0 and T1.

Data will be stored in a secure network managed by an independent manager, whereby all data will be recorded during the trial period using the original questionnaires and online surveys. Additionally, all data will be downloaded and exported by two researchers independently, and they will cross-check the data to ensure accuracy and completeness. If there is any inconsistency, a third researcher will resolve the conflict based on the original surveys and report sheets.

## Statistical analysis

Data analysis will be performed by an independent statistician blinded to the entire allocation and intervention process using SPSS v.27 software. All statistical analyses will be based on the intention-to-treat population of all randomly assigned patients, with a two-sided significance level of less than 0.05. Independent Student's t-tests will be employed for between-group analysis to examine differences in anthropometric characteristics (ie, body mass index (BMI), waist and hip ratio (WHR), menstrual and obstetric history), scores of questionnaires (ie, VAS, SF-MPQ, SAS, SDS and SF-12) and pain-related biomarkers (ie, RI, PI, S/D, PGE2, PGF2 and β-EP). Within-group differences will be analysed using paired t-tests. Data from measurements will be analysed by a generalised estimated equation (GEE) model using group and time as the main effects and baseline as a covariate. Missing values will not be imputed, as GEE can accommodate missing data and provides a natural way to deal with missing values.[37] Treatment effective rate will be examined by multinomial logistic regression, followed by linear contrast for pairwise comparison analysis. A subgroup analysis will be conducted on participants taking analgesics to examine changes in analgesics usage. Correlation between PD and mental health will be realised through Sperman's correlation analysis of scores of PD measurements (ie, VAS and SF-MPQ) and mental health measurements (ie, SAS, SDS and SF-12). Gender, age, BMI, WHR and menstrual and obstetric history will be adjusted for all models. The characteristics of participants, AEs and their potential causes and reasons for withdrawals will be recorded and analysed qualitatively to provide insights into the future study design.

### Patient and public involvement

None.

### Deviations from the original protocol

The sample size calculation underwent revision after reviewer feedback. Initially, the calculation was predicated upon the mean and SD of VAS scores across two groups post-intervention. However, to address reviewer comments and informed by a prior study,[21] a revised approach has been adopted. This updated methodology is founded on the mean and SD of the difference values of VAS scores between the two groups, with due consideration given to the MCID.

Two primary outcomes initially designated for this study have been reclassified as secondary outcomes in view of the importance for RCTs to maintain a single primary outcome and reviewer feedback. Consequently, VAS pain assessment was retained as the primary outcome, with other metrics relegated to secondary outcomes.

The modifications underwent rigorous evaluation and received approval from the Ethics Committee. The revised details are presented in the clinical trial registry record (ChiCTR2300071686) for transparency.

## ETHICS AND DISSEMINATION

This study adhere to the principles outlined in the Declaration of Helsinki.[38] Ethics approval was granted by the Medical Ethics Committee of Tai'an Hospital of TCM, and the trial has been registered with the Chinese Clinical Trial Registry (ChiCTR2300071686). Written informed consent will be obtained from each participant to enter the study, presenting the study aims and procedure, participant's privacy, benefits, potential risks and voluntary participation. Further, participants will not be identified by their responses to the surveys because all data are automatically de-identified, and all data will be kept in a secure location. The Ethics Committee will be in charge of experiment monitoring, and the trial conduct will be subject to periodical audits by the registration platform per year.

The study's findings will undergo peer review for journal publication and will be presented at both national and international conferences. Participants will be informed of the results through email or telephone communication.

## DISCUSSION

This protocol describes a randomised, sham-controlled, parallel-group, single-centre trial with a separation of the participant, practitioner, assessor and statistician. We aim to investigate the efficacy and safety of TEAS for PD compared with a TEAS-sham group by validated evaluation tools.

### Timing and acupoints

Treatment timing plays a pivotal role in PD management. We anticipate that pre-menstrual TEAS treatment may yield a superior effect for PD compared with treatment initiated at menstruation onset, based on the following rationale: (1) the strong effect of temporal influences on therapeutic outcomes of PD has been extensively recorded in TCM literature and suggested the concept of 'preventive treatment before disease' in the Inner Canon of Huangdi (黄帝内经); (2) the recognised pathogenesis of PD posits an elevation in PG levels, with the peak manifestation of PD occurring approximately 48 hours before menstruation[39]; (3) previous studies indicate that pre-menstrual treatment is more effective than menstrual onset for managing PD.[40 41]

A Delphi consensus, known as the Delphi study, is a commonly used method to obtain input from a group of experts.[24 42] A Delphi process can be performed to create a consensus on issues subject to uncertainty. In this way, opinions are constantly evolving and improved among expert groups, achieving a consensus through combined expertise and professional expertise finally.[43] Previous studies[44 45] have suggested that Delphi can be used to develop an acupuncture clinical trial protocol by experts' consensus on the best practice treatment regimen, offering evidence-based guidance for clinical practice. In our study, we have conducted a Delphi process with a panel of five clinical experts, which remains anonymous to encourage experts to express themselves openly. The experts were asked to suggest the treatment regimen they would expect to be used with PD. Besides, a previous study reported[22] on acupuncture treatment for dysmenorrhoea, suggesting the most frequently used points to manage dysmenorrhoea were SP6, CV4, SP8, LR3 and BL32. Finally, our treatment protocol was developed by the consensus of the Delphi method, existing literature and classic acupuncture points from the TCM literature. This process makes our study replicable, consistent and as scientifically rigorous as possible.

### Combination of subjective and objective assessments

Pain, a complex, subjective and multifaceted experience,[46] poses many challenges in its assessment.[47]

As previously reported,[47 48] not exactly reliable and validated methods can objectively quantify an individual's experience of pain. Therefore, using accurate and sensitive tools is crucial to ensure the reliability of pain outcomes. In our study, we will use VAS and SF-MPQ as the outcome measures to evaluate the participant's pain. Besides subjective measurements, colour Doppler ultrasonography and blood samples will be conducted to assess the uterine artery blood flow changes and PG and β-EP level, respectively.

The mechanisms of PD remain unclear, and the most widely accepted explanation for the pathogenesis of PD is the overproduction of uterine PGs. Enhanced release of PGs, allegedly from disintegrating cells during endometrial sloughing, is considered to be myometrial hypercontractility, resulting in ischaemia and hypoxia of the uterine muscle, ultimately pain.[8] Therefore, more and more studies tend to investigate uterine blood flow by

Doppler ultrasonography, which can reflect the severity of symptoms of PD and the immediate analgesia effects using index values in vivo.[49] In this study, uterine artery blood flow indicators of PI and RI values and S/D ratio will be detected before and after intervention to explain the effects of TEAS in the future.

In summary, a combination of subjective and objective measures will be performed to evaluate the painful periods in the current study. The strengths of the ultrasonography will especially guarantee the quality of this study and improve the stability and repeatability as well.

## Relationship between PD and mental health

PD is a common gynaecological disorder closely related to changes in hormonal secretions during periods. Psychological factors are recognised as significant contributors to dysmenorrhoea and therefore should be factored into treatment approaches.[50 51] Existing literature suggests a bidirectional association between dysmenorrhoea and anxiety and depression, whereby recurrent painful periods increase the risk of anxiety and depression, and in return, anxiety and depression intensify pain severity.[52 53] Therefore, this study aims to comprehensively evaluate the relationship between dysmenorrhoea and anxiety and depression through self-reported scales. Additionally, we seek to investigate whether TEAS therapy can ameliorate anxiety and depression in women experiencing PD.

## Study limitations

However, there are potential limitations in this trial. As TEAS treatment will begin 7 days before menstruation, this therapy may interfere with the menstrual periods or the different treatment times for each participant due to the slightly fluctuating menstrual cycle. Besides, the characteristics of our participants from the single-centre setting are representative of the local population with PD but may limit its generalisability.

## Relevance to clinical practice

Despite its prevalence and significant impact on physical and mental well-being, PD often remains undertreated. Some women perceive painful periods as a normal part of life rather than a health concern, leading to neglect of treatment options.[54] We expect that this study will raise awareness of PD as a health issue, prompting women and health professionals to seek non-pharmacological methods as a resource in PD management. If TEAS is proven as a safe and effective therapy for PD management, the results of this study will be beneficial to provide an important approach for the clinical guidelines for the best TEAS practice in managing PD, which is beneficial to improving women's health.

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