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STUDY PROTOCOL

Clinical Efficacy of Acupuncture in the Treatment of Uterine Contraction Pain Post-Cesarean Section: Protocol of a Randomized Controlled Trial

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Purpose: Uterine contraction pain post-cesarean section (UCPCS) is one of the main complaints for mothers in the early stages of the puerperium. Acupuncture, a non-pharmacological therapy, has shown sound analgesic effects with almost no toxic side effects. This study uses acupuncture as an intervention and aimed to provide strong evidence for the clinical efficacy of acupuncture in treating UCPCS.

Patients and Methods: This single-blind, randomized controlled trial (RCT) was conducted at the Ludian County Hospital of Traditional Chinese Medicine, China. Participants (138) are randomly assigned in a 1:1 ratio to either an observation or control group following cesarean section. Both groups receive routine postpartum care, the control group with sham acupuncture and the observation group with conventional acupuncture for 3 days. The primary outcome is the mean Visual Analogue Scale (VAS) score of the UCPCS. Secondary outcomes include the mean of UCPCS intensity, frequency, total duration, number of days to disappear, amount of vaginal bleeding and lactation, time to first lactation, and the Edinburgh Postnatal Depression Scale (EPDS) score. The final results will be analyzed in accordance with the intention-to-treat (ITT) principle using SPSS V.28.0.

Discussion: This is the first RCT using non-penetrating sham acupuncture as a control to validate the clinical efficacy of acupuncture for UCPCS. The results of this study are expected to provide an effective therapeutic option for UCPCS, as well as offer clinicians and researchers strong evidence regarding non-pharmacological interventions.

Keywords: uterine contraction pain post-cesarean section, acupuncture, protocol, randomized controlled trial

Introduction

The global cesarean section rate has continuously increased over the years, particularly in Asian countries.[1] China's cesarean section rate reached 43.4% in 2019, significantly exceeding the World Health Organization's recommended level.[2] As this rate climbs, postoperative pain is drawing increasing attention. Uterine contraction pain is a non-negligible component of pain in the early postoperative period. Uterine contraction pain post-cesarean section (UCPCS) is characterized by intermittency, uncertainty of position, and short duration.[3] Postpartum lactation stimulation and the use of contraction-type medications can further exacerbate uterine contraction pain.[4,5] When UCPCS occurs, it not only

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disturbs the mother's daily activities and quality of sleep, but also causes the mother to resist breastfeeding due to the pain, which directly affects the newborn's nutritional intake. In the long term, if not effectively dealt with, in addition to slowing the uterine recovery process, it may induce chronic pain, postpartum anxiety or depression, posing an ongoing threat to the health of mother and child.[3,6,7]

Both non-pharmacological and pharmacological approaches serve as vital elements in the management of UCPCS.[8,9] Local hot compress is the most widely used non-pharmacological therapy in clinical practice and is effective in relieving uterine cramping, but its efficacy of analgesia is relatively mild. Non-steroidal anti-inflammatory drugs (NSAIDs) are the most widely used pharmacologic therapy for postpartum analgesia. However, evidence does not support it as the safest and most effective oral analgesic option.[10] Although diclofenac sodium suppositories, a commonly used type of NSAIDs, could reduce the risk of gastrointestinal adverse effects, they can still cause nausea and vomiting.[11] Therefore, finding safe and effective therapies is also significant.

Acupuncture is a safe, non-pharmacological therapy that has been shown to reduce or eliminate various types of pain.[12,13] Studies have shown that acupuncture can alleviate the severity of UCPCS, reduce the frequency of episodes, shorten pain duration, and promote postpartum recovery.[14,15] However, many studies did not blind participants, making it difficult to rule out a placebo effect. The clinical efficacy of acupuncture for treating UCPCS still requires further validation. We thus designed a randomized controlled trial (RCT) to validate the clinical efficacy of acupuncture in UCPCS using non-penetrating sham acupuncture as a control.

Materials and Methods

Trial Design and Setting

This single-blind RCT is being conducted at the Ludian County Hospital of Traditional Chinese Medicine in China. A total of 138 participants are being recruited and randomly assigned in a 1:1 ratio to either an observation or control group. Each participant receives six acupuncture treatments over three consecutive days and follow-up for 2 weeks. The study protocol is designed in strict accordance with the Standard Protocol Items: Recommendations for Interventional Trials 2013 (SPIRIT 2013) (Supplementary Material 1) and adheres to the principles of the Declaration of Helsinki.[16] This study was approved by the Medical Ethics Committee of Ludian County Hospital of Traditional Chinese Medicine (LD2024-002) and registered with the China Clinical Trial Registry (ChiCTR2400086062). The study design flow chart is presented in Figure 1, and the registration, intervention, and evaluation timeline is shown in Table 1.

Participants

Recruitment and Informed Consent

All participants will be recruited via posters displayed in the obstetrics department. A senior obstetrician will initially screen enrollees before a scheduled cesarean section and provide a detailed introduction to the study process, the rules to follow, and the benefits and potential risks of participation. After a cesarean section, the team will conduct further screening, and eligible participants will sign an informed consent form (Supplementary Material 2) for formal enrollment. Participants can withdraw from the study at any time, for any reason, with no risk of losing benefits.

Inclusion Criteria

Participants must meet the following criteria: (1) cesarean section; (2) age ≥18 years; (3) pregnancy duration between 37 and 42 weeks; (4) single and live birth; (5) intent to breastfeed; (6) American Society of Anesthesiologists (ASA) Classification I or II; and (7) ability to participate in the clinical study and actively provide informed consent.

Exclusion Criteria

Participants who met any of the following criteria will be excluded: (1) severe complications during pregnancy or childbirth; (2) history of uterine or pelvic pain; (3) psychological disorders or mental illnesses, emotional abnormalities, inability to understand and express research-related issues adequately; (4) long-term use of analgesic medications; (5) allergic to acupuncture or skin abnormality at the site of needling; (6) allergic to or contraindications for use of NSAIDs; or (7) participation in other studies.

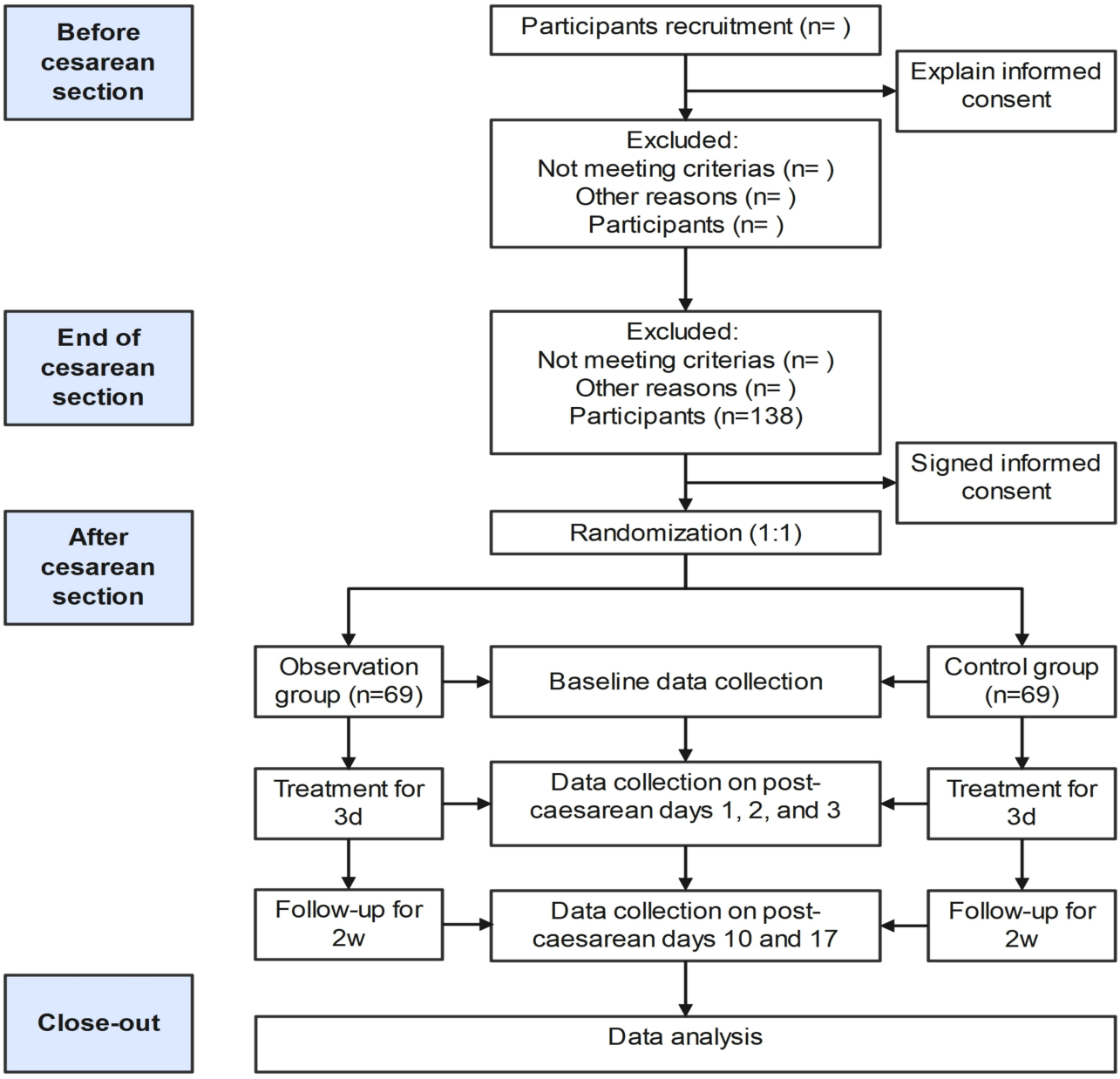

Figure 1 Flow chart of study design.

Other Criteria

Participants meeting any of the following criteria will be eliminated: (1) incorrect enrollment; or (2) poor compliance or voluntary withdrawal.

Participants meeting any of the following criteria will be removeded from the study: (1) experiencing intolerable pain during the study that can not be alleviated by medication; or (2) experiencing serious adverse events (AEs) or complications during the study period.

Randomization and Allocation

The trial uses SPSS V.28.0 (IBM, Chicago, IL) software to assign numbers 1–138 to all participants, allocating them to two groups in a 1:1 ratio through a random number generator. A third party not involved in the trial generates and stores the random numbers. Grouping information is placed in opaque envelopes and, when participants are included they are randomly assigned to different groups to receive specific interventions.

Table 1 Timeline for Enrolment, Intervention, and Evaluation

	Study period							
	Before CS	Post-CS	Post-CS					
Timepoint (day)	−1	0	0~0.5[a]	1	2	3	10	17
Enrolment								
Eligibility screen	×	×						
Informed consent	×	×						
Randomization		×						
Allocation		×						
Demographic data	×	×						
Interventions								
Observation group			×					
Control group								
Outcome indicators								
Primary indicator								
VAS			×					
Secondary indicators								
Intensity, frequency, total duration of pain, and number of days to disappear				×				
Vaginal bleeding volume				×				
First lactation time						×		
Lactation volume				×				
EPDS		×				×	×	×
Rescue analgesia								×
Supplementary indicators								
First time of exhaustion						×		
Urination and defecation frequency		×		×				
Treatment expectation				×				
AEs			×					
Compliance								×
Blinding						×		
Satisfaction						×		×

Note: [a]start time of first acupuncture intervention.
Abbreviations: CS, cesarean section; VAS, visual analogue scale; EPDS, edinburgh postnatal depression scale; AEs, adverse events.

Blinding and Unblinding

Given the specific nature of acupuncture manipulation, achieving double blinding is challenging, so participants are only blinded using non-penetrating sham needling.[17,18] At the end of the treatment, participants will be asked to guess whether

they have received genuine acupuncture. Meanwhile, care providers, data collectors, and data analysts are unclear about the groupings and interventions. Typically, unblinding occurs following data analysis but may be done earlier to ensure participant safety under certain necessary circumstances, such as severe AEs. Emergencies are first treated by the acupuncturist in conjunction with the professional staff, trying to maintain blinding from other researchers. Details are reported on the appropriate case report form (CRF) page.

Interventions

All participants will receive two routine treatments: local hot compress and massage. Licensed acupuncturists with at least 3 years of experience carry out acupuncture treatments for both groups. Acupuncturists are trained in advance on standardized practices. Acupuncture interventions are initiated on the first postpartum day following the initial oxytocin administration and continued for three consecutive days. Considering the painful characteristics of contractions, to enhance the analgesic effect, the treatment is performed twice a day, more than 6 hours apart, for 30 minutes each time, and stimulation occurs at 15 minutes.[19,20]

Observation Group

Treatment is performed using conventional acupuncture (Figure 2A). Based on Chinese medicine meridian theory, long-term clinical experience and references, bilateral Zusanli (ST36), Diji (SP8), Taichong (LR3), and Zulinqi (GB41) are selected,[21–24] and follow World Health Organization localization criteria[25] (Figure 3 and Table 2). The acupuncturist uses 0.30×40 mm Huatuo brand disposable acupuncture needles (Suzhou Medical Supplies Factory Limited, license number: Su Food and Drug Administration of Machinery Production 20010020; registration

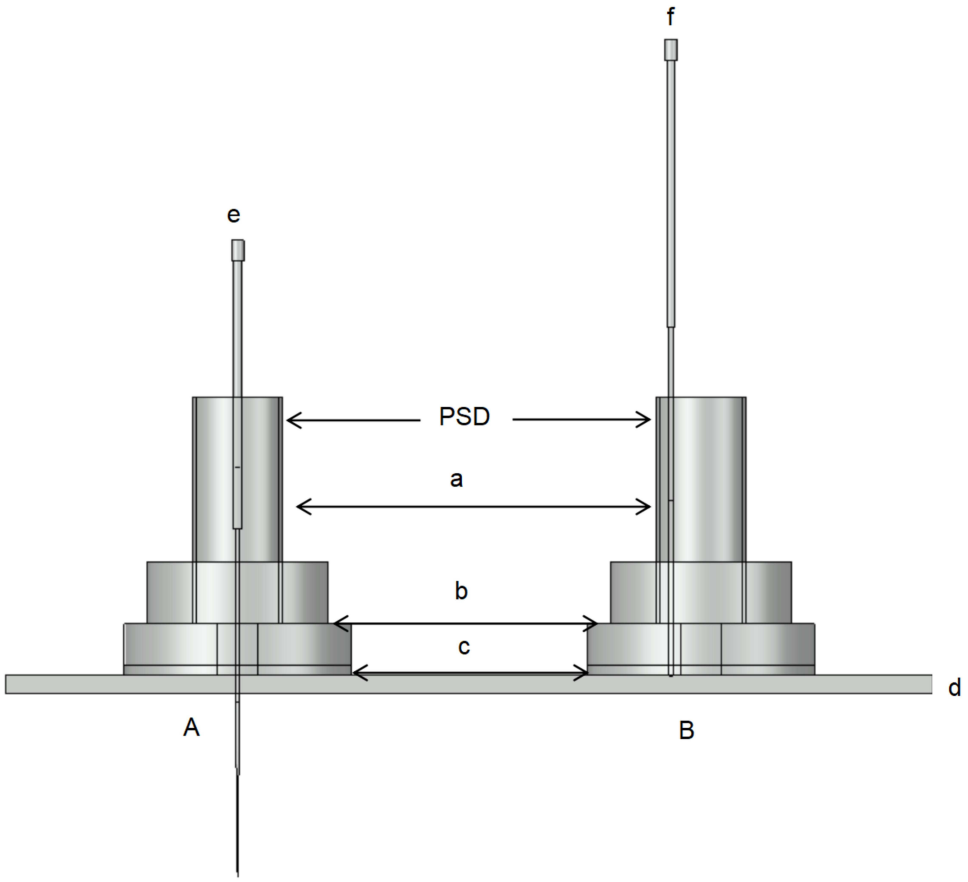

Figure 2 Illustration of intervention and appliance. (**A**) Observation group; (**B**) Control group; a, transparent catheter; b, opaque base; c, double-sided foam tape; d, skin; e, conventional acupuncture needle; f, blunt needle.
Abbreviation: PSD, park sham acupuncture device.

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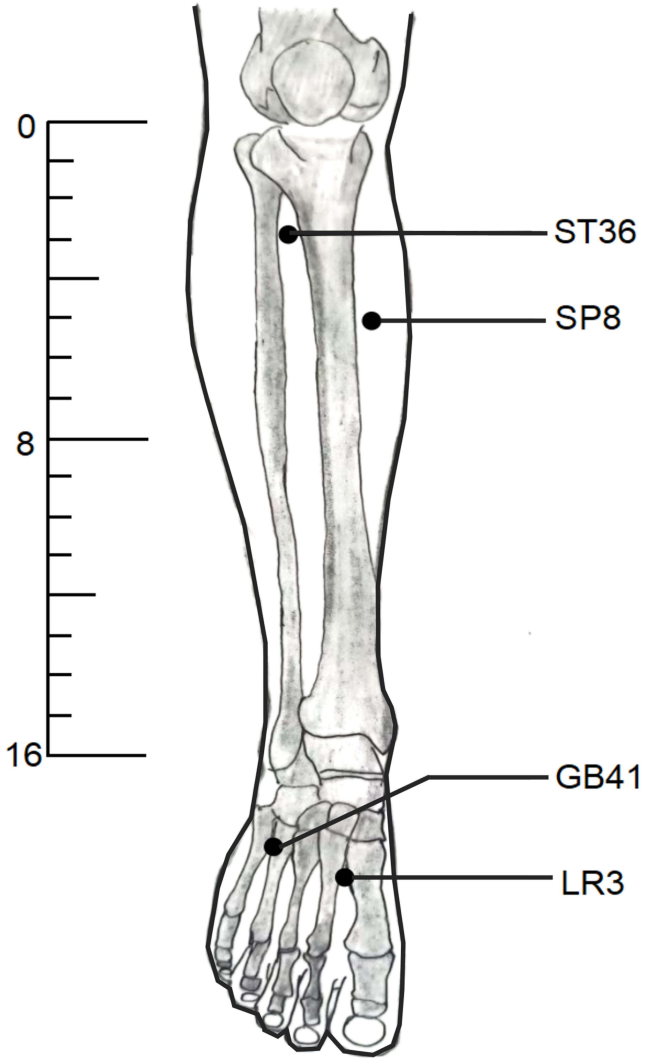

Figure 3 Acupoints selected in this study.

certificate number: 201622770970) and the Park Sham Acupuncture Devices (PSDs). The PSD (Figure 2) includes a transparent catheter (Φ 4×20 mm), two opaque bases (Φ 4×15 mm, Φ 5×10 mm), and double-sided foam tape (Φ 1×15 mm) (produced by Suzhou Medical Supplies Factory, China, batch number: 210401). The acupuncturist assists the participant in a comfortable supine position, exposed the skin below both knees and sterilizes the acupuncture site with 75% alcohol. The needles are placed into PSDs, exposing the tip, and the needle is secured at the acupuncture point with the help of foam tape. Vertical puncture occurs at SP36 and SP8 to 10–15 mm, LR3, and at GB4

Table 2 Location of Acupoints

Acupoints	Location
Zusanli (ST36)	On the anterior aspect of the leg, on the line connecting ST35 with ST41, 3 B-cun inferior to ST35
Diji (SP8)	On the tibial aspect of the leg, posterior to the medial border of the tibia, 3 B-cun inferior to SP9
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 dorsal pedis artery
Zulinqi (GB41)	On the dorsum of the foot, distal to the junction of the bases of the fourth and fifth metatarsal bones, in the depression lateral to the fifth extensor digitorum longus tendon

to 15–10 mm (depth adjusted to patient muscle thickness). For each acupoint, lifting, inserting, and rotating movements of the needle to stimulate the De-qi sensation are gently performed, and maneuvers are repeated after 15 minutes. Women are kept warm during interventions. After 30 minutes, the acupuncturist removes the acupuncture needles and PSDs and, lightly presses the skin with a sterile dry cotton ball for a few seconds.

Control Group

The control group uses the exact specifications of sterile blunt-tipped needles (Suzhou Medical Supplies Factory, lot number: 9018390000, China) and PSDs for non-insertion interventions at the same acupoints (Figure 2B). The acupuncturist fixes blunt needles at the acupuncture points and slowly lifts, inserts and rotates them vertically downward, with the needles forming a depression with the plane of the skin but not piercing it. Participants will experience a pinprick sensation during this process, at which point the needle will be returned to the foam tape. The process is repeated after 15 minutes. Other operations are the same as those performed in the observation group.

Remedial Measures

When a participant needs analgesia, diclofenac sodium suppositories (Hubei Tongshun Pharmaceutical Co., Ltd) will be provided if the participant's UCPCS lasts >30 minutes in a single session, or ≤30 minutes but occurring at a frequency of ≤30 minutes per session and with a Visual Analogue Scale (VAS) score of ≥4.[26] This is because the duration of UCPCS varies from a few seconds to several hours per episode, and the onset time of diclofenac sodium suppositories is approximately 30 minutes. It is also used to treat other types of pain with a VAS ≥4. The kind of pain, VAS score, and time to remission are recorded in detail on the pain record sheet (Supplementary Material 3) and the CRF.

Follow-Up

In general, UCPCS disappeared around 7 days after delivery. However, Zheng's study showed that the average duration of UCPCS was 16.48 days.[27] That study was the longest we could find on the duration of uterine contraction pain and, bearing its results in mind, we set our study period at 17 days, with 2-week follow-up post-acupuncture treatment to fully observe UCPCS.

Outcomes and Assessment

Primary Outcome

Mean UCPCS degree at different time points: the assessment uses a 10 cm VAS, where 0–10 indicated no pain to the most severe pain (Supplementary Material 3).

Secondary Outcomes

These outcomes are closely related to UCPCS. First, the intensity, frequency, duration, and number of days until disappearance of UCPCS are recorded in detail using the pain record sheet (Supplementary Material 3), completed each time pain occurs, and averages when analyzing data. Second, the amount of vaginal bleeding and lactation are measured at different time points using the weighing method and lactation score (Supplementary Material 4).[28,29] Time of first breastfeeding is also recorded. Meanwhile, the Edinburgh Postnatal Depression Scale (EPDS) score is used to assess the impact of UCPCS on participants' mood.[30] The EPDS has a total score of 30, with a score of more than 13 suggesting a risk of postpartum depression and higher scores indicating more severe depressive symptoms. Finally, the use of analgesic medication is documented.

Other Secondary Outcomes

Before the intervention, acupuncture treatment expectation levels are quantified using a 4-point scale (0=none; 1=1–30%; 2=31–70%; and 3=71–100% improvement). Following the intervention, the following are recorded: first time of exhaustion, frequency of urination and defecation, blinding, treatment satisfaction, adherence, and AEs.

Sample Size

This study hypothesizes that the observation group will be more effective than the control group in treating UCPCS, with a minimum clinically significant difference of 1.6 cm based on VAS score.[31] One study showed that, after 2 days of UCPCS treatment, the acupuncture group experienced a change in VAS scores of 5.28±0.6, while the control group showed a shift of 2.24±0.63.[14] Considering the pain characteristics, we predict a VAS score reduction of 5.28±0.6 in the observation group and 3.33±0.6 in the control group after 3 days of treatment; that is, α=0.025, β=0.1, Δ=1.6, K=1, according to the formula:[32]

$$n_c = \frac{\left(Z_{1-\alpha} + Z_{1-\beta}\right)^2 \sigma^2 \left(1 + \frac{1}{K}\right)}{\left(\mu_T - \mu_C - \Delta\right)^2}$$

This trial requires 62 participants per group, with a 10% dropout rate, totaling 69. In total, 138 participants are planned.

Data Collection, Management, and Quality Control

Demographic data are collected from the e-case system, and data collectors gather other data through direct interaction with participants via different means (see Outcomes section). Both paper and online CRF will be used to manage data efficiently. One researcher records raw data promptly, using the paper CRF, and two cross-enter data into the online CRF. Finally, two statistical analysts analyze the data. Participants' data will be retained for 5 years after completion of the study.

To control data quality and ensure rigor and consistency, rigorous training of the personnel involved in the study (including acupuncturists, nursing operations, data collectors, entrants, analysts, etc) was carried out before recruiting participants. All personnel are required to work strictly according to the study protocol. Data collectors are immediately contacted for verification if data anomalies or missing information are found during entry. Analysts process the data promptly and report any issues to the collectors. Any changes to the paper CRF are noted next to the original data, including the person responsible, date, reason, and modified data. The study leader and the ethics committee regularly review the data collection and processing procedures.

Statistical Methods

All data will be processed and analyzed using SPSS software. Variables conforming to a normal distribution will be expressed as mean±standard deviation, whereas non-normally distributed variables will be presented as median and interquartile range. Normality will be assessed using the Shapiro–Wilk test (P>0.05). Ordinal variables and count variables will be expressed using percentages. Paired-sample t-tests will be used when variables conform to a normal distribution and the variances are congruent, and Welch's t-tests will be used when the variances are not congruent. If neither is satisfied, the Wilcoxon signed-rank test will be used. Nonparametric tests will be applied for categorical variables. Ordinal variables will be analyzed using either chi-square tests or rank sum tests. The data from multiple observation time points will be analyzed using repeated measures analysis of variance (ANOVA) or a generalized linear mixed model (GLMM), depending on the data's distribution. P<0.05 is considered a statistically significant difference. The study will adhere to the intention-to-treat (ITT) principle and employ multiple imputations for handling missing data.

Adverse Events

Adverse events in this study are defined as a participant experiencing any adverse medical event. Collection of AE data begins after participant enrollment. If AEs occur before treatment, they are not related to the intervention. All AEs throughout the study will be recorded and detailed on the CRF. These AEs may include acupuncture-related events such as prolonged pain at the needle site, ecchymosis, hematoma, infection, etc., or drowsiness, dysuria, nausea, and vomiting due to NSAIDs. If AEs occur, they will be treated promptly by a medical professional. If the criteria for serious AEs are met, they will be reported to the ethics committee as serious AEs.

Confidentiality

This trial assigns numbers to conceal the true identities of participants. Any information about the participant is kept strictly confidential and will not be disclosed without authorization to any individual or organization other than the involved physician. Only data entry and analysis personnel have access to the CRF, and the final publicized results of the study will not include any personal information relating to participants. Participants' medical records are stored at the hospital, and access is granted to researchers and the ethics committee only if they have signed an informed consent form.

Protocol Modification

The study protocol, informed consent form, recruitment materials, and other documents will be approved by the Medical Ethics Committee of Ludian County Hospital of Traditional Chinese Medicine. The ethical review body will review and approve any subsequent modifications, including changes in study objectives, study design, patient population, sample size, study procedures, etc.

Discussion and Conclusion

Although UCPCS is a normal physiological phenomenon, it will disappear naturally after a few days. However, during early puerperium, women experience severe UCPCS, which has become one of their main complaints.[14,33] Therefore, early puerperal analgesic intervention in UCPCS is critical. Considering drug safety issues, this study uses acupuncture as an intervention, which is a safe and effective non-pharmacologic analgesic therapy.

After cesarean section, uterine contraction returns to the normal physiological state. The muscle layer compresses sensory nerve endings, releasing neurotransmitters, and compresses blood vessels, releasing inflammatory mediators that generate pain. Vascular compression leads to ischemia-reperfusion injury, causing uterine muscle contraction and worsening pain. The increased sensitivity to pain and the stimulation of endogenous oxytocin are also vital pathways contributing to uterine contraction pain.[34] Acupuncture exerts its analgesic effect by modulating multiple systems to reduce pain sensitivity, inhibit inflammation, and improve blood circulation.[13,35,36] Based on Chinese medicine meridian theory and long-term clinical experience, this study selected eight acupoints from the spleen, stomach, liver, and gallbladder meridian for intervention. The spleen and stomach meridians are commonly used in treating postpartum uterine contraction pain; the liver meridian regulates qi and blood flow to relieve pain; and the gallbladder meridian connects to the belt vessel, the pathway of which traverses the uterine region. Additionally, the analgesic effects of the selected acupoints have been validated in some studies.[21–24] Since uterine contraction pain is most intense during the first three days postpartum, this study administers acupuncture treatment for three days, twice a day, for 30 minutes each time, at six-hour intervals, aiming to achieve better therapeutic effects.[19,20]

The main objective of this study is to validate the clinical efficacy of acupuncture in treating UCPCS. Therefore, we use the reliable and widely used VAS to measure the UCPCS degree.[33] Pain intensity, frequency, duration, and number of days before disappearance of pain are also recorded in detail. Since uterine contractions are closely related to vaginal bleeding and lactation, measuring the amount of vaginal bleeding and lactation can indirectly reflect UCPCS.[4,5] Both are calculated using weighed and lactation scores to ensure data accuracy and objectivity.[28,29] Previous studies have shown that severe postpartum pain increases the risk of depression, so the EPDS is used to assess the effect of UCPCS on maternal mood.[37]

In contrast to previous studies of acupuncture for UCPCS, the present study is the first to use non-penetrating sham acupuncture as a control.[17] It is similar in appearance to regular acupuncture and is carried out with a needling sensation but does not penetrate the skin. This is advantageous in achieving participant blindness and reducing the placebo effect. However, this study also has some limitations. First, it is single-center, limiting the generalizability of the results. Second, acupuncturists must control the needling technique, making it challenging for blind acupuncturists. Third, this study only focuses on uterine contraction pain, excluding other pain types. Finally, the study is limited by a lack of biochemical assays to elucidate the underlying molecular mechanisms of acupuncture-induced analgesia.

In conclusion, this study's results are expected to provide an effective therapeutic option for UCPCS and strong evidence for clinicians and researchers who use non-pharmacological interventions.

Abbreviations

UCPCS, uterine contraction pain post-cesarean section; RCT, randomized control trial; VAS, visual analogue scale; EPDS, edinburgh postnatal depression scale; ITT, intention-to-treat; AEs, adverse events; CRF, case report form; PSD, park sham acupuncture device; ANOVA, repeated measures analysis of variance; GLMM, generalized linear mixed model.

Data Sharing Statement

The data produced in this trial will be available from the corresponding authors upon reasonable request after successful publication.

Ethics Approval and Consent to Participate

The ethical specifications for the study protocol and informed consent materials were approved by the Medical Ethics Committee of Ludian County Hospital of Traditional Chinese Medicine (LD2024-002) on 6 May 2024. All participants will be informed about the study in detail and will provide written informed consent before formal enrollment; they can withdraw from the study at any time.

Trial Status

The first participant was successfully enrolled on July 1, 2024. Participant recruitment is expected to conclude by January 2026, with study completion projected for April 2026.

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Author Contributions

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

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Disclosure

The authors report no conflicts of interest in this work.

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