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Original Research

Effect of acupoint hot compress on relieving pain in primiparous women during the latent phase of the first stage of labor: A study protocol for a prospective, multi-center, randomized controlled clinical trial

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Abstract:

Introduction: Labor pain is an unavoidable feature of childbirth and is characterized by extreme intensity. Adequate pain management is thus essential not only from the aspect of physiological pain

but also due to the adverse effects of pain on the psychological well-being of parturients. Many studies have shown the benefits of acupoint hot compress. However, to date, little is known of its use for alleviating labor pain. The purpose is to evaluate the effect of acupoint hot compress on relieving pain in primiparous women during the latent phase of the first stage of labor, as well as its effects on perinatal outcomes.

Methods and analysis: A total of 1100 primiparous women from 18 institutions will be randomly allocated to two groups according to central stratified block randomization method. The controls will be treated only with obstetrical care, while those in the intervention group will be treated with four hours of acupoint hot compress at 42 ± 2 ◦C starting one hour following the onset of regular uterine contractions. The primary outcome will be the pain intensity measured at 1, 3, and 5 h after the onset of regular uterine contractions using a visual analog scale. An independent statistician will process the data using computer software (IBM SPSS Statistics 25.0).

Conclusion: The study will assess the effect of acupoint hot compress on pain reduction and perinatal outcomes in primiparous women during the latent phase of labor. The findings will have the potential to provide a non-pharmacological and non-invasive intervention with Traditional Chinese Medicine (TCM) for pain relief during labor and to improve the perinatal outcomes.

Ethics and dissemination: The study has been approved by the Ethics Committee of Women's Hospital, School of Medicine, Zhejiang University (No. IRB-20230379-R). The results of the main trial will be submitted for publication in a peer-reviewed journal.

Trial registration: ChiCTR2300079244

Keywords: Acupoint; Hot compress; Labor pain; Pain relief; Latent phase

Strengths and limitations of this study:

- This will be the first trial to investigate the effect of acupoint hot compress on relieving pain in primiparous women during the latent phase of the first stage of labor.
- The findings will have the potential to provide a non-pharmacological and non-invasive intervention with TCM for pain relief during labor and to improve the perinatal outcomes.
- Since there are no suitable hot compress placebo, the group randomization is not concealed from the subjects.
- We adopt an uniform treatment to evaluate the efficacy of acupoint hot compress on the pain relief for each participant without individualized treatment, which may lead to the bias.

1. Introduction

Pain is described as an unpleasant subjective sensation and represents one of the five vital signs [1]. Labor pain is an unavoidable feature of childbirth and is characterized by extreme intensity [2]. Adequate pain management is thus essential not only from the aspect of physiological pain but also due to the adverse effects of pain on the psychological well-being of parturients [3]. The presence of fear and anxiety may adversely affect the parturients' health, and may also influence the decision to request an elective caesarean section [4-6]. Hence, the discovery of an effective method for the alleviation of labor pain is needed.

The treatments for relieving labor pain are classified primarily into pharmaceutical and non-pharmacological approaches [7]. Medication is the most frequent form of pain relief used in mainstream medical practice [8,9]. However, the possible negative consequences of the drugs on both the mother and fetus have led to interest in non-pharmacological treatments to reduce labor pain during childbirth [10,11].

Acupoint hot compress is a non-pharmacological and non-invasive treatment based on the principles of TCM. Many studies have shown the benefits of acupoint hot compress; specifically, it is inexpensive, simple to use, safe, and effective, and can assist in reducing pain as well as preventing emotional disturbances and disorders [12-14]. However, to date, little is known of its use for alleviating labor pain. We thus plan to conduct a randomized controlled clinical trial to investigate the efficacy of acupoint hot compress in the reduction of labor pain in primiparous women.

2. Participants and study design

2.1 Objective

The objective is the evaluation of the effects of acupoint hot compress on the relief of pain in primiparous women during the latent phase of labor, as well as its effects on perinatal outcomes.

2.2 Design of the trial

The trial will be performed in China as a prospective, multi-center, open-label, controlled clinical trial with a 1:1 allocation. The protocol follows the the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [15] (**Table 1**) and will be undertaken in accordance with the Consolidated Standards of Reporting Trials (CONSORT) [16] guidelines (**Figure 1**).

2.3 Recruitment of participants

The study will be undertaken at 18 clinical centers in China: Women's Hospital, School of Medicine, Zhejiang University; Gansu Provincial Maternal and Child Health Care Hospital; Hangzhou First People's Hospital; Hangzhou Women's Hospital; Yiwu Maternity and Children Hospital; Jiaxing Maternity and Child Health Care Hospital; The Second Affiliated Hospital of Wenzhou Medical University; Lishui Central Hospital; Wenzhou Central Hospital; Hangzhou Fuyang Women and Children Hospital; Hangzhou Linping District Maternity and Child Health Care Hospital; The Fourth Affiliated Hospital, Zhejiang University School of Medicine; Tonglu Maternal and Child Health Hospital; The First People's Hospital of Jiashan; The First Affiliated Hospital of Ningbo University; The First People's Hospital of Xiaoshan District; Tongxiang Maternal and Child Health Hospital; Huzhou Maternity and Child Health Care Hospital. Recruitment will not discriminate against any particular cultural, racial, or socio-economic group.

2.4 Inclusion criteria

(1) Age ranging from 20 to 34 years;

(2) Gestational age ranging from 37 to 41 weeks;

(3) Primiparous parturient women with planned vaginal delivery;

(4) Singleton pregnancy;

(5) Meet the diagnostic criteria of the latent phase of the first stage of labor [17];

(6) Ability to communicate well with the researcher and comply with the test requirements;

(7) Provided written informed consent.

2.5 Exclusion criteria

(1) Prior uterine surgery or uterine abnormalities;

(2) Fetal anomalies, chromosomal abnormalities, or stillbirth;

(3) Prenatal diseases, including infectious, central nervous system, urogenital diseases, and internal and surgery-related diseases, as well as the use of long-term medication;

(4) A history of psychiatric or neuropsychological disorders, as well as impaired verbal communication;

(5) The presence of severe diabetes, skin diseases, sensory disorders, acute inflammation, high fever, and allergies to the material used in the study product;

(6) Patients with incomplete information.

2.6 Subject withdrawal

Subjects enrolled in the clinical trial will have the option to withdraw at any time.

2.7 Subject drop-out

(1) Change from vaginal delivery to cesarean section;

(2) Non-completion of the intervention;

(3) The principal researcher will have the authority to conclude the study at any time when the benefits are considered to outweigh the risks;

(4) Poor treatment compliance by the subject.

2.8 Calculation of sample size

The size of the sample will be determined in accordance with primary outcomes. The pilot study selected pain during the latent phase of labor, rated on a visual analog scale (VAS), as the primary outcome; the difference between the means of the control and intervention groups was found to be 0.61 with a standard deviation of 1.08. With 90% power, a two-sided threshold of 0.05, and a 20% dropout rate, the size of the sample was found to be 1100, with 550 participants in each group.

2.9 Randomization and blinding

The eligible subjects will be randomly allocated to the control and intervention groups in a 1:1 ratio according to central stratified block randomization method, which will be generated by an independent statistician using conventional statistical computer software (SPSS version 25.0; IBM Corp., USA). No blinding method will be used.

2.10 Interventions

2.10.1 Control group

The participants will receive only obstetrical care, involving the monitoring of maternal vital signs, fetal position and heart rate, uterine contractions, and the amount of vaginal bleeding, as well as monitoring the progress of labor, managing pain, and providing psychological and social support [18].

2.10.2 Intervention group

Participants in this group will receive obstetrical care together with acupoint hot compress at 42 ± 2 ◦C for four hours, starting one hour after the onset of regular uterine contractions. This will be

applied using a Hu-Chao-Nuan-Gong-Bao, a licensed Class II item of medical equipment (license No. 20192090292) manufactured by Jiangxi Shenghe Industrial Development Co., Ltd. (Nanchang, China). Acupoint hot compress includes two sizes(**Figure 2**), model A (measuring 16x9 cm) and model B(measuring 13x10 cm). These comprises four hot cores, each measuring 8x7 cm (Model A), as well as one hot core measuring 11.5x8 cm (Model B). Agents such as inorganic salts and activated carbon can be placed within the hot cores in specific proportions in a sealed inner bag. The temperature can be maintained at a constant level due to the specific rates of oxygen and water vapor transmission within the breathable layer (**Figure 3**).

The selection of acupoints will be determined according to our hospital's clinical experience and in consultation with 10 experts. The Nomenclature and Location of Acupuncture Points (National Standard of the People's Republic of China, 2006 [GB/T 12346-2006]) describes the acupoint locations [19]. As shown in **Figure 4**, two of the hot cores shown in Model A will be applied separately on Bilateral Yongquan (KI1) 1 h after the onset of regular uterine contractions, while two of the other hot cores in Model A will be applied separately on Bilateral Sanyinjiao (SP6) and one hot core from Model B will be applied on Baliao (BL31-34).

2.11 Primary outcome

2.11.1 Labor pain

Pain during the latent phase of the first labor stage will be assessed using a VAS in which, on a scale of 0 to 10, "0" represents "no discomfort" and "10" indicates "terrible pain". Pain intensity will be assessed using the VAS at 1, 3, and 5 h following the onset of regular uterine contractions.

2.12 Secondary outcomes

2.12.1 Labor duration

The labor duration will be measured from the start of labor until birth. The durations of all labor stages (first, second, third), as well as the overall duration, will be recorded.

2.12.2 Blood loss

Blood loss estimation after the delivery and at 2 h postpartum will be recorded. The method of measuring blood loss is the quantitative measurements of the blood volume and weight [20].

2.12.3 Symptoms of depression

The symptoms of depression may cover physical, emotional, and cognitive abnormalities. Depressed mood and a loss of interest or pleasure are the primary symptoms of depression. The Edinburgh Postnatal Depression Scale (EPDS) will be administered to identify depression symptoms 48 h after delivery [21].

2.12.4 Apgar scores

The Apgar score is utilized to access the five physical signs of the newborn, including pulse, respiration, appearance, muscle tone and reflex irritability. The Apgar scores will be documented at 1 and 5 min after delivery.

2.13 Safety

The medical device to be used is a hot compress, which has been authorized by the Medical Products Administration under license number 20192090292.

The pilot study did not find any adverse events (AEs). The potential AEs will be described to the participants in this study, and people with sensory abnormalities will be excluded.

2.14 Data collection and management

Standardized training for conducting the study and the procedures involved will be provided to all researchers. The raw data will be assembled and documented in case-report forms at the participating site and will be entered directly into the electronic database with a double data-entry system. All data will be kept under secure conditions. Incomplete information with missing data will be discarded.

2.15 Statistical methods

Independent analysts will conduct the statistical analysis using SPSS 25.0. All analyses will be undertaken using the intention-to-treat approach. For continuous data, t-tests, covariance analysis, or Wilcoxon-Mann-Whitney tests will be used for analysis, while for categorical data, chi square tests or Fisher's exact tests will be utilized. In addition, a logistic regression analysis will be undertaken to determine associations between the independent variables.

3. Discussion

The World Health Organization (WHO) describes the promotion of maternal and newborn healthcare as a key objective in their Sustainable Development Goals [22]. Achievement of these goals necessitates reducing complications resulting from pregnancy which contribute significantly to maternal deaths throughout the world [23]. This requires the application of effective strategies at different times to improve maternity care. One of the primary objectives of maternity care is the

control of labor pain, which can contribute greatly to childbirth outcomes [24-25]. Currently used methods for the relief of labor pain include both pharmacological methods, such as epidural analgesia, narcotics, and intravenous opioid administration [26-27], and non-pharmacological applications, including acupuncture, hot compress, and massage and music therapy [28-30].

Most pharmacological methods used for the management of labor pain are expensive can have negative effects on both the mother and newborn [31]. This has led to an increased exploration of non-pharmacological techniques which may also improve the experience of the delivery process.

The hot compress is a non-pharmacological method for pain management that is economical, safe, and non-invasive, and also does not require specialized training for administration [31]. According to the gate control theory, the hot compress can inhibit the transfer of pain signals to the brain by stimulating endorphin release to reduce pain [33]. The hot compress also dilates the blood vessels, thus enhancing blood circulation [34].

Acupoint hot compress, integrating acupoint with natural heat physical agent, is well-received by patients and their families both physiologically and psychologically compared to other therapies due to its noninvasive and inexpensive feature [13].

In summary, the goals of the trial are the evaluation of the therapeutic effects of acupoint hot compress on pain relief in primiparous women during the latent phase of labor and assessment of the effects of the use of acupoint hot compress on perinatal outcomes. It is hoped that the trial will provide a novel non-pharmacological and non-invasive intervention for pain relief during labor.

There remain some limitations in the this protocol. First, since there are no suitable hot compress placebo, the group randomization is not concealed from the subjects. Second, it is widely recognized that TCM should be treated based on the syndrome differentiation to reach the best result, however, we adopt an uniform treatment to evaluate the efficacy of acupoint hot compress on the pain relief for each participant without individualized treatment, which may lead to the bias. Third, each participant has different skin surface area, however the hot compress sizes are fixed, and it may cover other acupoints in the area, so it is necessary to include active control individuals who employ these acupoints in future research.

Trial status

This trial is registered at Chinese Clinical Trial Registry, ChiCTR2300079244. This report is based on protocol version 2.1, date 16 May 2024. Recruiting started in January 2024 and the estimated end date is August 2025.

Patient and public involvement

No patient and public involvement.

Data Sharing Statement

The data obtained in the study will be made available by the corresponding author on reasonable request.

Ethics Approval and Informed Consent

The study has been approved by the Ethics Committee of Women's Hospital, School of Medicine, Zhejiang University (No. IRB-20230379-R). Any modifications to the protocol will be submitted for ethics approval, and updated in the ChiCTR. All participants will receive a comprehensive explanation of the purpose, procedures, and potential risks associated with the trial and will be required to provide informed consent before taking part.

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Authors'contributions

FQ conceived and formulated the trial, reviewed and revised the manuscript. XYL and YQP wrote the manuscript. NL, TYZ, YJL, YHZ, FFW, DX contributed to revision of the manuscript. All authors read and approved the final manuscript.

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Consent for publication

The results will be published in international scientific journals.

Disclosure

The author(s) report no conflicts of interest in this work.

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Table

Table 1 Schedule of Enrollment, Intervention and Assessments

Figure Legend

Figure 1 Flow chart of study procedures;

Figure 2 Two style of acupoint hot compress;

Figure 3 Structure diagram of hot core;

Figure 4 Locations of acupoint hot compress;

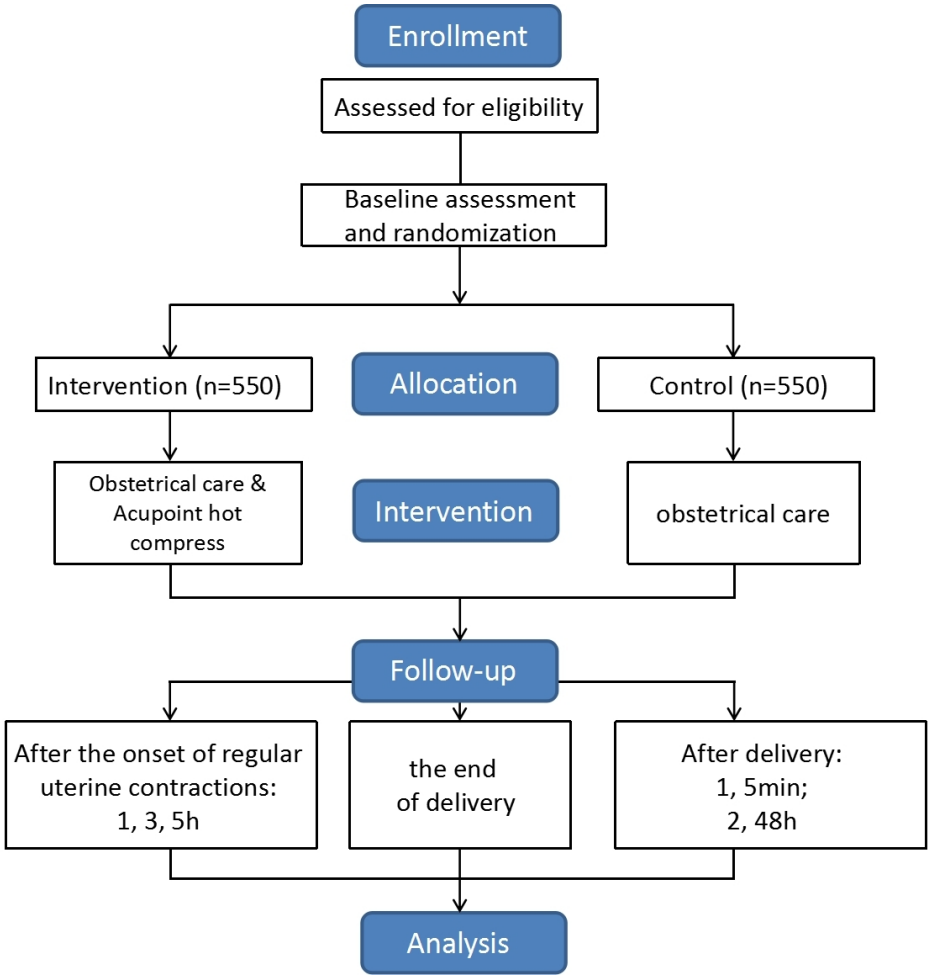

Figure 1 Flow chart of study procedures

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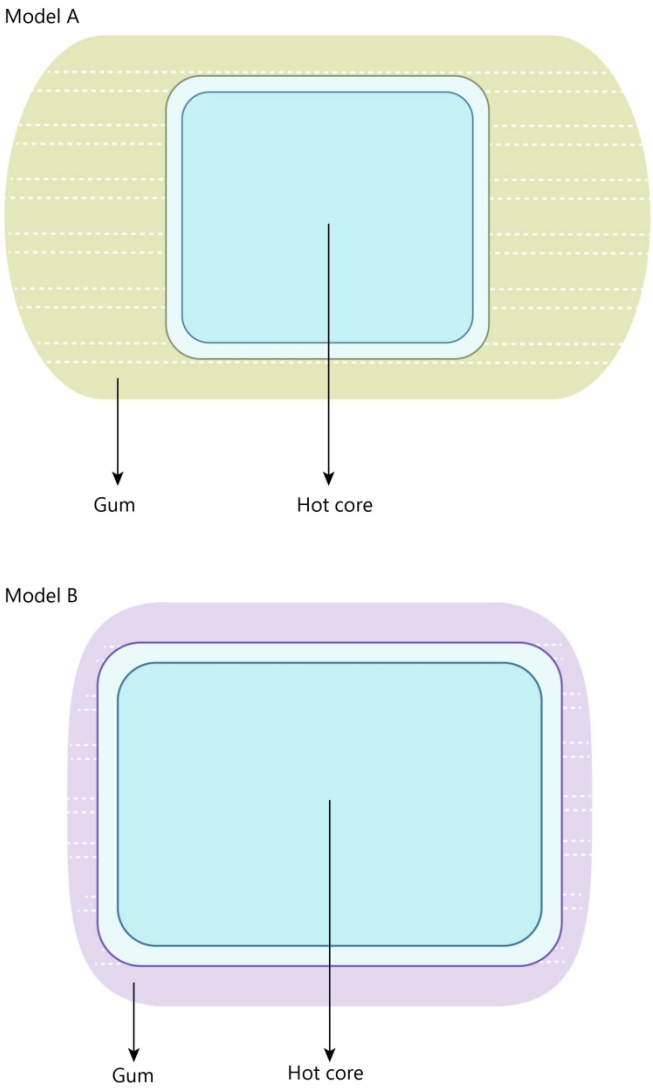

Figure 2 Two style of acupoint hot compress

210x297mm (300 x 300 DPI)

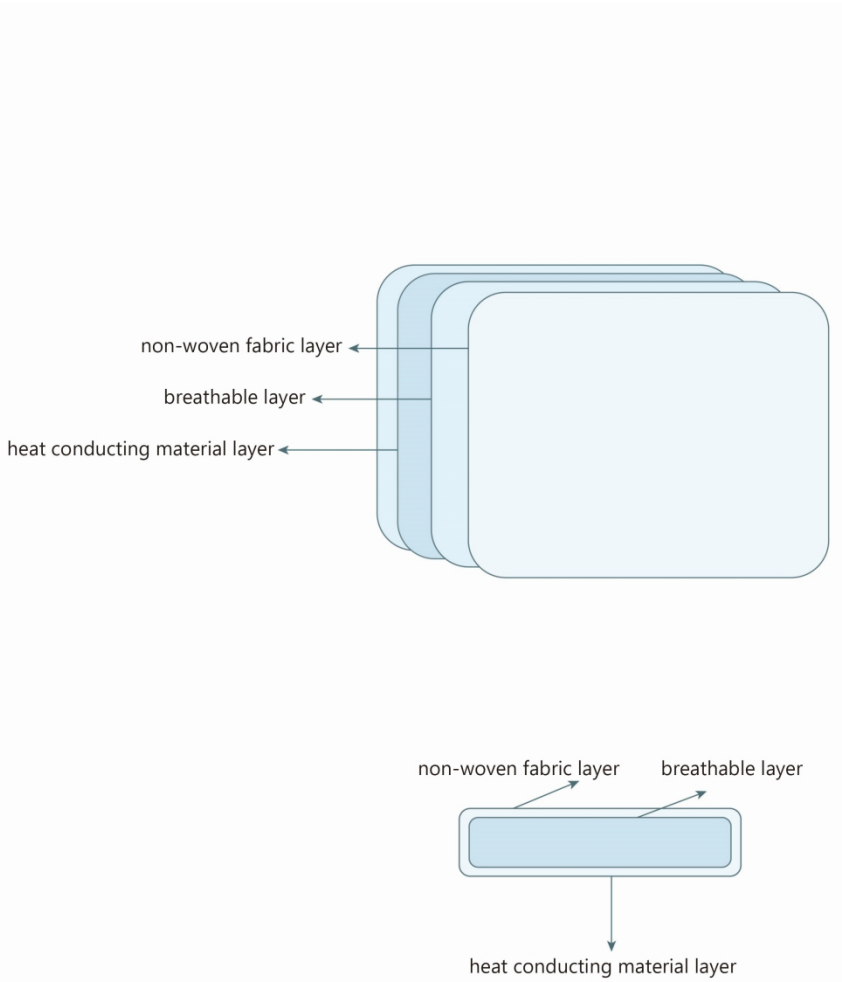

Figure 3 Structure diagram of hot core

656x928mm (96 x 96 DPI)

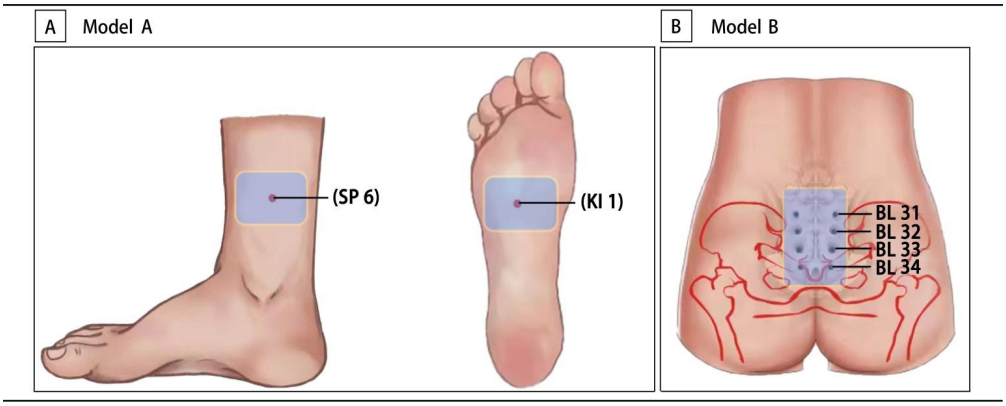

Figure 4 Locations of acupoint hot compress

406x177mm (96 x 96 DPI)

		Enrollment	Allocation	Post-allocation	Follow-up							
Time point		$-t_1$	0	t_1	t_1 1h	t_2 3h	t_3 3h	t_4	t_5 1min	t_6 5min	t_7 2h	t_8 48h
					After the onset of regular uterine contractions			the end of delivery	After delivery			
Enrollment	Eligibility screen	X										
	Informed consent	X										
	Randomization	X										
	Allocation		X									
Interventions	Obstetrical care & Acupoint hot compress			X								
	Obstetrical care			X								
Assessments	pain (VAS)				X	X	X					
	The duration of labor							X				
	Bleeding loss							X			X	
	Emotion symptoms (EPDS)											X
	Apgar scores								X	X		

Table 1 Schedule of Enrollment, Intervention and Assessments

Abbreviations: VAS, visual analogue scale; EPDS, edinburgh postnatal depression scale.

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Original Research

Effect of acupoint hot compress on relieving pain in primiparous women during the latent phase of the first stage of labor: A study protocol for a prospective, multi-center, randomized controlled clinical trial

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Abstract:

Introduction: Labor pain is an unavoidable feature of childbirth and is characterized by extreme intensity. Adequate pain management is thus essential not only from the aspect of physiological pain but also due to the adverse effects of pain on the psychological well-being of parturients. Many studies have shown the benefits of acupoint hot compress. However, to date, little is known of its use for alleviating labor pain. The purpose is to evaluate the effect of acupoint hot compress on relieving pain

in primiparous women during the latent phase of the first stage of labor, as well as its effects on key maternal and neonatal outcomes.

Methods and analysis: This prospective, multi-center, randomized controlled trial will be conducted across 18 institutions in China from January 2024 to August 2025. A total of 1100 primiparous women aged 20-34 years, with singleton pregnancies at 37-41 weeks of gestation. will be enrolled and randomly allocated to two groups using a central stratified block randomization method. The controls will be treated only with obstetrical care, while those in the intervention group will receive the same obstetrical care as the control group, with the addition of acupoint hot compress therapy at 42 ± 2 °C for four hours, starting one hour after the onset of regular uterine contractions during the latent phase of labor. The primary outcome will be the pain intensity measured at 1, 3, and 5 h after the onset of regular uterine contractions using a visual analog scale.

Ethics and dissemination: The study has been approved by the Ethics Committee of Women's Hospital, School of Medicine, Zhejiang University (No. IRB-20230379-R). The results of the main trial will be submitted for publication in a peer-reviewed journal.

Trial registration: This trial is registered at Chinese Clinical Trial Registry, ChiCTR2300079244.

Strengths and limitations of this study:

- The study will employ a multi-center, prospective, randomized controlled design across 18 institutions.
- Central stratified block randomization with stratification by clinical center will be implemented to minimize selection bias.

- No blinding method will be used due to the lack of a feasible placebo for the hot compress intervention.
- A standardized, non-individualized treatment protocol will be applied, potentially limiting personalization of acupoint therapy.
- Fixed-size hot compress devices may unintentionally stimulate adjacent acupoints, confounding intervention specificity.

1. Introduction

Pain is described as an unpleasant subjective sensation and represents one of the five vital signs [1]. Labor pain is an unavoidable feature of childbirth and is characterized by extreme intensity [2]. Adequate pain management is thus essential, not only for addressing physiological pain but also for mitigating the negative effects of pain on the psychological well-being of parturients [3]. The presence of fear and anxiety may adversely affect the parturients' health, and may also influence the decision to request an elective caesarean section [4-6]. Hence, the discovery of an effective method for the alleviation of labor pain is needed.

The treatments for relieving labor pain are classified primarily into pharmacological and non-pharmacological approaches [7]. Medication is the most frequent form of pain relief used in mainstream medical practice [8,9]. However, the possible negative consequences of the drugs on both the mother and fetus have led to interest in non-pharmacological treatments to reduce labor pain during childbirth [10,11].

As noted in ACOG Committee Opinion No. 766, non-pharmacologic pain management techniques may be beneficial for women experiencing pain during the latent phase of labor [12]. Several studies have indicated that non-pharmacological interventions have shown promising results in alleviating labor pain during the latent phase of labor. A systematic review of relaxation techniques for labor pain management has suggested that methods such as relaxation and music therapy could reduce pain and improve satisfaction with pain relief during the latent phase [13]. Another research has revealed that massage therapy can effectively alleviate labor pain during the latent phase [14].

Acupoint hot compress, as a non-pharmacological intervention, is a non-invasive treatment based on the principles of Traditional Chinese Medicine (TCM). Many studies have shown the benefits of acupoint hot compress; specifically, it is inexpensive, simple to use, safe, and effective, and can assist in reducing pain as well as preventing emotional disturbances and disorders [15-17]. However, to date, little is known of its use for alleviating labor pain, particularly during the latent phase of the first stage of labor. We thus plan to conduct a randomized controlled clinical trial to investigate the efficacy of acupoint hot compress in the reduction of labor pain in primiparous women during the latent phase.

2. Methods and analysis

2.1 Objective

This study aims to evaluate the effect of acupoint hot compress on pain relief in primiparous women during the latent phase of labor, as well as its impact on key maternal and neonatal outcomes, including labor duration, intrapartum and postpartum bleeding, maternal depression symptoms, and neonatal Apgar scores.

2.2 Hypothesis

We hypothesise that using acupoint hot compress during the latent phase of labor will effectively alleviate labor pain, reduce labor duration, lower intrapartum and postpartum blood loss, ease the maternal depression symptoms and improved neonatal Apgar scores.

2.3 Design of the trial

This study is a prospective, multi-center, open-label, randomized controlled trial. It will enroll 1100 primiparous women across 18 clinical centers in China. Participants will be allocated 1:1 to either the control (standard obstetric care) or intervention group (standard care plus acupoint hot compress). Participants may withdraw voluntarily at any time, with the reasons documented to assess potential bias. The trial may be terminated early if significant safety concerns (e.g., severe intervention-related adverse events) arise. The protocol follows the the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [18] (**Supplementary material 1**) and will be undertaken in accordance with the Consolidated Standards of Reporting Trials (CONSORT) [19] guidelines (**Figure 1**).

2.4 Recruitment of participants

Recruitment will take place from January 2024 to August 2025. Eligible primiparous women will be identified upon hospital admission for labor, with obstetricians, midwives and nurses screening participants based on inclusion and exclusion criteria. After receiving a comprehensive explanation of the purpose, procedures, risks, and benefits regarding the study, eligible women will provide written informed consent. Consented participants will be enrolled and randomized into the control or

intervention group using a central stratified block randomization method. To ensure adequate enrollment, regular training sessions will be conducted for obstetricians, midwives, and nurses at each center to familiarize them with the study protocol and recruitment process. The study will be undertaken at 18 clinical centers in China: Women's Hospital, School of Medicine, Zhejiang University; Gansu Provincial Maternal and Child Health Care Hospital; Hangzhou First People's Hospital; Hangzhou Women's Hospital; Yiwu Maternity and Children Hospital; Jiaxing Maternity and Child Health Care Hospital; The Second Affiliated Hospital of Wenzhou Medical University; Lishui Central Hospital; Wenzhou Central Hospital; Hangzhou Fuyang Women and Children Hospital; Hangzhou Linping District Maternity and Child Health Care Hospital; The Fourth Affiliated Hospital, Zhejiang University School of Medicine; Tonglu Maternal and Child Health Hospital; The First People's Hospital of Jiashan; The First Affiliated Hospital of Ningbo University; The First People's Hospital of Xiaoshan District; Tongxiang Maternal and Child Health Hospital; Huzhou Maternity and Child Health Care Hospital. Recruitment will not discriminate against any particular cultural, racial, or socio-economic group.

2.5 Inclusion criteria

The inclusion criteria are: Age ranging from 20 to 34 years; gestational age ranging from 37 to 41 weeks; primiparous parturient women with planned vaginal delivery; singleton pregnancy; meet the diagnostic criteria of the latent phase of the first stage of labor [20]; ability to communicate well with the researcher and comply with the test requirements; and provided written informed consent.

2.6 Exclusion criteria

(1) Prior uterine surgery or uterine abnormalities;

(2) Fetal anomalies, chromosomal abnormalities, or stillbirth;

(3) Prenatal diseases, including infectious, central nervous system, urogenital diseases, and internal and surgery-related diseases, as well as the use of long-term medication;

(4) A history of psychiatric or neuropsychological disorders, as well as impaired verbal communication;

(5) The presence of severe diabetes, skin diseases, sensory disorders, acute inflammation, high fever, and allergies to the material used in the study product;

(6) Patients with incomplete information.

2.7 Withdrawal criteria

(1) Adverse events (AEs) related to the intervention (e.g., skin burns, severe allergic reactions) occur;

(2) Participants fail to comply with the study protocol;

(3) Participants will have the option to voluntarily withdrawal at any time and for any reason.

2.8 Drop-out criteria

(1) Change from vaginal delivery to cesarean section;

(2) Non-completion of the intervention;

(3) The principal researcher will have the authority to conclude the study at any time when the benefits are considered to outweigh the risks;

(4) Poor treatment compliance by the subject.

2.9 Calculation of sample size

The sample size calculation will be based on the primary outcome of pain intensity during the latent phase of labor, rated on a visual analog scale (VAS). The pilot study was conducted with 50 participants (25 in the control group and 25 in the intervention group). The difference between the means of the two groups was found to be 0.61 with a standard deviation of 1.08. With 90% power, a two-sided threshold of 0.05, and a 20% dropout rate, the size of the sample was found to be 1100, with 550 participants in each group. The pilot study sample was representative of the main study population in terms of demographic characteristics and clinical setting, ensuring the generalizability of the findings.

2.10 Randomization and blinding

The eligible subjects will be randomly allocated to the control and intervention groups in a 1:1 ratio using central stratified block randomization method, which will be generated by an independent statistician using conventional statistical computer software (SPSS version 25.0; IBM Corp., USA). □ No blinding method will be used due to the lack of a feasible placebo for the hot compress intervention.

2.11 Interventions

2.11.1 Control group

The participants will receive only obstetrical care, including monitoring of maternal vital signs, fetal position and heart rate, uterine contractions, vaginal bleeding, and labor progress, as well as

conventional pain management (breathing techniques and massage), and psychological and social support [21].

2.11.2 Intervention group

Participants in the intervention group will receive the same obstetrical care as the control group (detailed in Section 2.11.1), including the conventional pain management. Additionally, they will receive acupoint hot compress therapy at 42 ± 2 °C for four hours, starting one hour after the onset of regular uterine contractions during the latent phase of labor. This will be applied using a Hu-Chao-Nuan-Gong-Bao, a licensed Class II item of medical equipment (license No. 20192090292) manufactured by Jiangxi Shenghe Industrial Development Co., Ltd. (Nanchang, China). Acupoint hot compress includes two sizes (**Figure 2**), model A (measuring 16x9 cm) and model B (measuring 13x10 cm). These comprises four hot cores, each measuring 8x7 cm (Model A), as well as one hot core measuring 11.5x8 cm (Model B). Agents such as inorganic salts and activated carbon can be placed within the hot cores in specific proportions in a sealed inner bag. The temperature can be maintained at a constant level due to the specific rates of oxygen and water vapor transmission within the breathable layer (**Figure 3**).

The selection of acupoints will be determined according to our hospital's clinical experience and in consultation with 10 experts. The Nomenclature and Location of Acupuncture Points (National Standard of the People's Republic of China, 2006 [GB/T 12346-2006]) describes the acupoint locations [22]. As shown in **Figure 4**, two of the hot cores shown in Model A will be applied separately on Bilateral Yongquan (KI1) 1 h after the onset of regular uterine contractions, while two

of the other hot cores in Model A will be applied separately on Bilateral Sanyinjiao (SP6) and one hot core from Model B will be applied on Baliao (BL31-34).

2.12 Primary outcome

2.12.1 Labor pain

Pain during the latent phase of labor will be assessed using a VAS in which, on a scale of 0 to 10, "0" represents "no discomfort" and "10" indicates "terrible pain". Pain intensity will be assessed using the VAS at 1, 3, and 5 h following the onset of regular uterine contractions. The VAS is a widely validated and reliable tool for pain assessment, demonstrating high sensitivity in detecting pain intensity variations[23]. To reduce potential confounding effects, participants will be allocated using a central stratified block randomization method to ensure balanced group allocation. Moreover, all clinical centers will follow the same standardized protocols for labor monitoring and pain assessment to minimize variability.

2.13 Secondary outcomes

2.13.1 Labor duration

The labor duration will be measured from the start of labor until birth. The durations of all labor stages (first, second, third), as well as the overall duration, will be recorded.

2.13.2 Blood loss

Blood loss estimation after the delivery and at 2 h postpartum will be recorded. The method of measuring blood loss is the quantitative measurements of the blood volume and weight [24]. The quantification of the blood loss is as follows: A calibrated under-buttocks drape will collect all fluids

immediately after delivery. The total volume of collected fluid will be recorded, and pre-placental fluids (e.g., amniotic fluid, urine) will be subtracted to isolate blood loss. Blood-soaked materials (e.g., gauze, pads) will be weighed, and blood volume calculated as: Blood Volume (mL)=Wet Weight (g)-Dry Weight (g). Cumulative blood loss will be determined by combining the volumes from the drapes, and weighed materials.

2.13.3 Symptoms of depression

The symptoms of depression may cover physical, emotional, and cognitive abnormalities. Depressed mood and a loss of interest or pleasure are the primary symptoms of depression. The Edinburgh Postnatal Depression Scale (EPDS) will be administered within 48 hours postpartum to identify depression symptoms. The EPDS is a well-validated instrument widely used to assess depression and anxiety symptoms in perinatal populations [25,26]. Participants will complete the EPDS questionnaire independently, as it is a self-reported tool. The completed questionnaires will be collected and recorded by trained researchers.

2.13.4 Apgar scores

The Apgar score is utilized to access the five physical signs of the newborn, including pulse, respiration, appearance, muscle tone and reflex irritability. The Apgar scores will be documented at 1 and 5 min after delivery. The Apgar score serves as a predictive indicator for neonatal mortality, morbidity, and long-term neurodevelopmental outcomes [27,28].

2.14 Safety

The medical device to be used is a hot compress, which has been authorized by the Medical Products Administration under license number 20192090292.

The pilot study did not find any AEs. The potential AEs will be described to the participants in this study, and people with sensory abnormalities will be excluded.

2.15 Data collection and management

Standardized training for conducting the study and the involved procedures will be provided to all researchers. All data will be collected using standardized case report forms (CRFs) and entered into a secure electronic database with a double data-entry system to minimize errors. Regular audits conducted by the research team will ensure data accuracy and completeness. Access to the database will be restricted to authorized personnel only, and all data will be anonymized to protect participant confidentiality. Incomplete or missing data will be documented and addressed through follow-up with the participating clinical centers.

2.16 Statistical methods

Independent analysts will conduct the statistical analysis using SPSS 25.0. All analyses will be undertaken using the intention-to-treat approach. For continuous data, t-tests, covariance analysis, or Wilcoxon-Mann-Whitney tests will be used for analysis, while for categorical data, chi square tests or Fisher's exact tests will be utilized. In addition, a logistic regression analysis will be undertaken to determine associations between the independent variables.

3. Ethics and dissemination

The study has been approved by the Ethics Committee of Women's Hospital, School of Medicine, Zhejiang University (No. IRB-20230379-R). This report is based on protocol version 2.1, date 16 May 2024. Any modifications to the protocol will be submitted for ethics approval, and updated in the ChiCTR. All participants will receive a comprehensive explanation of the purpose, procedures, and potential risks associated with the trial and will be required to provide informed consent before taking part. The data obtained in the study will be made available by the corresponding author on reasonable request. The results will be published in international scientific journals.

4. Discussion

In our study, we aim to address labor pain relief, a critical aspect of maternity care that aligns with the WHO Sustainable Development Goals prioritizing maternal and newborn healthcare [29]. These goals emphasize reducing pregnancy-related complications, a leading cause of global maternal mortality [30]. Effective interventions across all stages of maternity care are essential to achieve these objectives. Our focus on labor pain management during the latent phase reflects a key priority in maternal health, given its significant impact on childbirth outcomes [31,32].

Currently used methods for labor pain relief include pharmacological approaches, such as epidural analgesia, narcotics, and intravenous opioid administration [33,34], as well as non-pharmacological interventions, including acupuncture, hot compress, massage, and music therapy [35-37]. Most pharmacological methods are expensive and can have negative effects on both the mother and newborn [38]. This has led to increased exploration of non-pharmacological techniques, which may enhance the delivery experience.

The hot compress is an economical, safe, and non-invasive non-pharmacological method for pain management [39]. According to the gate control theory, the hot compress can stimulate endorphin release, thereby reducing pain perception by inhibiting the transmission of pain signals to the brain [40]. Additionally, the hot compress dilates blood vessels, enhancing local blood circulation and further contributing to pain relief [41].

Building on these physiological mechanisms, acupoint hot compress integrates the benefits of heat therapy with TCM by targeting specific acupoints. Compared to other therapies, acupoint hot compress is particularly well-received by patients and their families due to its non-invasive nature, low cost, and psychological comfort [16]. The combination of physiological and psychological benefits makes acupoint hot compress a promising intervention for labor pain management.

There remain some limitations in this protocol. First, since there is no suitable placebo for the hot compress intervention, the group randomization is not concealed from the subjects. This lack of blinding may introduce performance bias, since subjects' awareness of group allocation may bias pain perception and reporting, potentially overestimating the efficacy of the intervention. Second, while it is widely recognized that TCM should be tailored based on syndrome differentiation, our study adopts a uniform treatment protocol for all participants. This approach may limit the generalizability of the findings, as the lack of individualized treatment could reduce the effectiveness of intervention for certain participants, leading to variability in outcomes. Third, the fixed sizes of the hot compress devices may not fit all participants' body shapes and acupoint locations. This could cause either inadequate stimulation of the target acupoints or unwanted stimulation of nearby ones, possibly introducing bias in measurements.

In summary, the findings of our study will have important practical implications for the management of labor pain. Firstly, acupoint hot compress represents a cost-effective alternative to pharmacological methods for pain management during labor, which can be particularly beneficial in resource-limited settings. Secondly, the technique is safe and does not require specialized training, making it feasible for widespread use among healthcare providers. Thirdly, the use of acupoint hot compress may improve the experience of the latent phase for primiparous women, leading to psychological benefits and better perinatal outcomes. Furthermore, this study only includes short-term observation indicators, but lacks long-term outcomes, such as postpartum recovery and infant development, which may limit the evaluation of the effects. Future studies should incorporate long-term follow-up to assess the sustained benefits and potential risks of acupoint hot compress in labor pain management.

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Contributors

FQ conceived and formulated the trial, reviewed and revised the manuscript. XYL and YQP wrote the manuscript. NL, TYZ, YJL, YHZ, FFW, DX contributed to revision of the manuscript. All authors read and approved the final manuscript. FQ is the guarantor.

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Competing interests statement

The author(s) report no conflicts of interest in this work.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication

Not applicable.

Provenance and peer review

Not commissioned; externally peer reviewed.

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Figure Legend

Figure 1 Flow chart of study procedures;

Figure 2 Two style of acupoint hot compress;

Figure 3 Structure diagram of hot core;

Figure 4 Locations of acupoint hot compress

Supplementary material

Supplementary material 1 Schedule of Enrollment, Intervention and Assessments

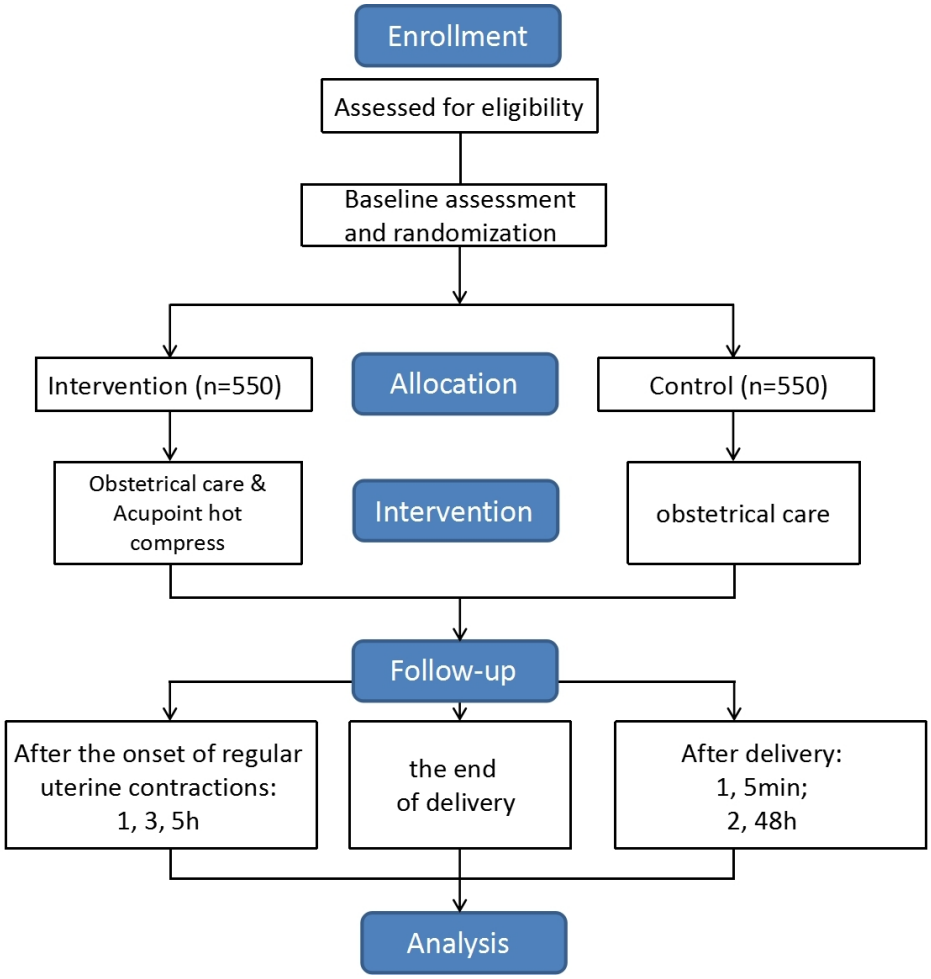

Figure 1 Flow chart of study procedures

314x305mm (96 x 96 DPI)

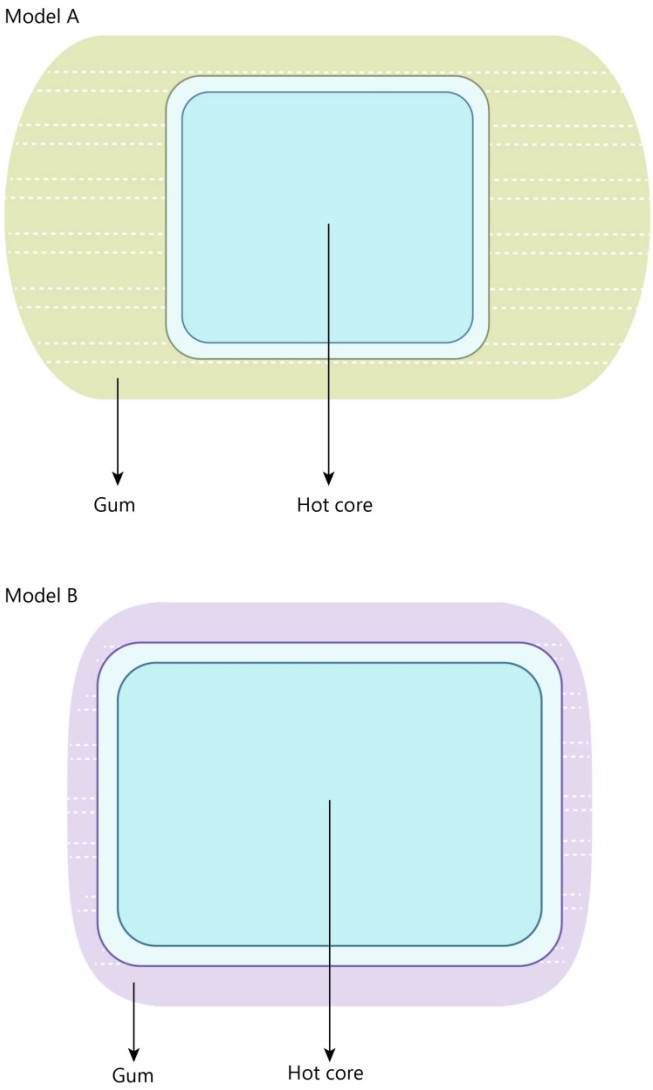

Figure 2 Two style of acupoint hot compress

210x297mm (300 x 300 DPI)

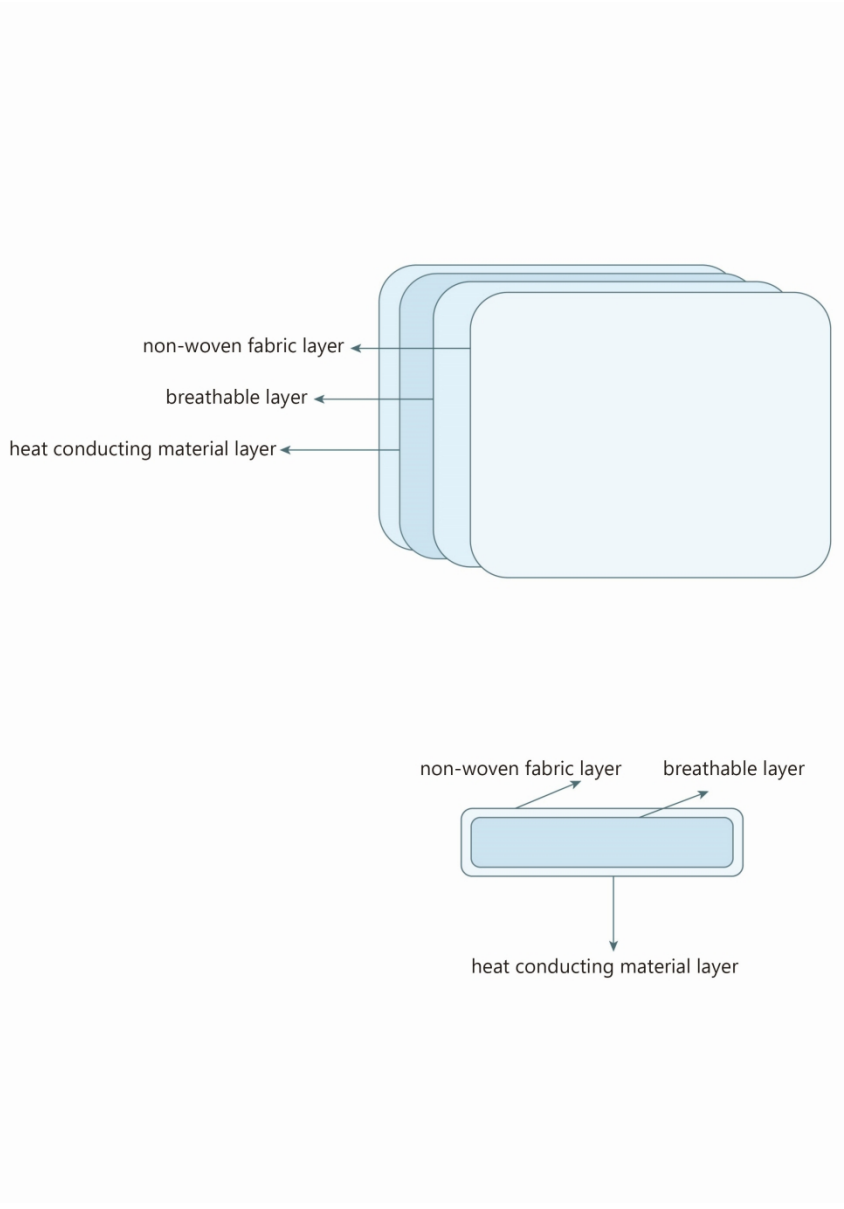

Figure 3 Structure diagram of hot core

656x928mm (96 x 96 DPI)

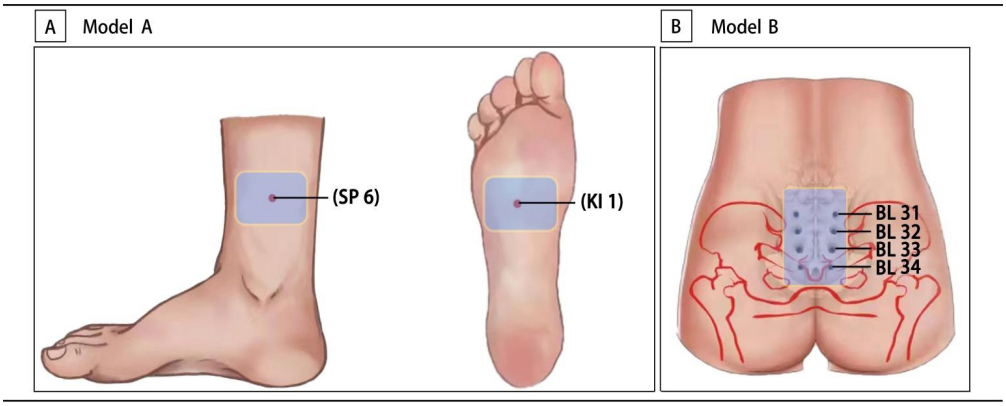

Figure 4 Locations of acupoint hot compress

406x177mm (96 x 96 DPI)

		Enrollment	Allocation	Post-allocation	Follow-up							
Time point		$-t_1$	0	t_1	t_1 1h	t_2 3h	t_3 3h	t_4	t_5 1min	t_6 5min	t_7 2h	t_8 48h
					After the onset of regular uterine contractions			the end of delivery	After delivery			
Enrollment	Eligibility screen	X										
	Informed consent	X										
	Randomization	X										
	Allocation		X									
Interventions	Obstetrical care & Acupoint hot compress			X								
	Obstetrical care			X								
Assessments	pain (VAS)				X	X	X					
	The duration of labor							X				
	Bleeding loss							X			X	
	Emotion symptoms (EPDS)											X
	Apgar scores								X	X		

Table 1 Schedule of Enrollment, Intervention and Assessments

Abbreviations: VAS, visual analogue scale; EPDS, edinburgh postnatal depression scale.

BMJ Open

Effect of acupoint hot compress on relieving pain in primiparous women during the latent phase of the first stage of labor: A study protocol for a prospective, multi-center, randomized controlled clinical trial

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Original Research

Effect of acupoint hot compress on relieving pain in primiparous women during the latent phase of the first stage of labor: A study protocol for a prospective, multi-center, randomized controlled clinical trial

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Abstract:

Introduction: Labor pain is an unavoidable feature of childbirth and is characterized by extreme intensity. Adequate pain management is thus essential not only from the aspect of physiological pain but also due to the adverse effects of pain on the psychological well-being of parturients. Many studies have shown the benefits of acupoint hot compress. However, to date, little is known of its use for alleviating labor pain. The purpose is to evaluate the effect of acupoint hot compress on relieving pain

in primiparous women during the latent phase of the first stage of labor, as well as its effects on key maternal and neonatal outcomes.

Methods and analysis: This prospective, multi-center, randomized controlled trial will be conducted across 18 institutions in China from January 2024 to August 2025. A total of 1100 primiparous women aged 20 to 34 years, with singleton pregnancies at 37 to 41 weeks of gestation, will be enrolled and randomly allocated to two groups using a central stratified block randomization method. The controls will be treated only with obstetrical care, while those in the intervention group will receive the same obstetrical care as the control group, with the addition of acupoint hot compress therapy at 42 ± 2 °C for four hours, starting one hour after the onset of regular uterine contractions during the latent phase of labor. The primary outcome will be the pain intensity measured at 1, 3, and 5 h after the onset of regular uterine contractions using a visual analog scale (VAS).

Ethics and dissemination: The study has been approved by the Ethics Committee of Women's Hospital, School of Medicine, Zhejiang University (No. IRB-20230379-R). The results of the main trial will be submitted for publication in a peer-reviewed journal.

Trial registration: This trial is registered at Chinese Clinical Trial Registry, ChiCTR2300079244.

Strengths and limitations of this study:

- The study will employ a multi-center, prospective, randomized controlled design across 18 institutions.
- Central stratified block randomization with stratification by clinical center will be implemented to minimize selection bias.

- No blinding method will be used due to the lack of a feasible placebo for the hot compress intervention.
- A standardized, non-individualized treatment protocol will be applied, potentially limiting personalization of acupoint therapy.
- Fixed-size hot compress devices may unintentionally stimulate adjacent acupoints, confounding intervention specificity.

1. Introduction

Pain is described as an unpleasant subjective sensation and represents one of the five vital signs [1]. Labor pain is an unavoidable feature of childbirth and is characterized by extreme intensity [2]. Adequate pain management is thus essential, not only for addressing physiological pain but also for mitigating the negative effects of pain on the psychological well-being of parturients [3]. The presence of fear and anxiety may adversely affect the parturients' health, and may also influence the decision to request an elective caesarean section [4-6]. Hence, the discovery of an effective method for the alleviation of labor pain is needed.

The treatments for relieving labor pain are classified primarily into pharmacological and non-pharmacological approaches [7]. Medication is the most frequent form of pain relief used in mainstream medical practice [8,9]. However, the possible negative consequences of the drugs on both the mother and fetus have led to interest in non-pharmacological treatments to reduce labor pain during childbirth [10,11].

As noted in ACOG Committee Opinion No. 766, non-pharmacologic pain management techniques may be beneficial for women experiencing pain during the latent phase of labor [12]. Several studies have indicated that non-pharmacological interventions have shown promising results in alleviating labor pain during the latent phase of labor. A systematic review of relaxation techniques for labor pain management has suggested that methods such as relaxation and music therapy could reduce pain and improve satisfaction with pain relief during the latent phase [13]. Another research has revealed that massage therapy can effectively alleviate labor pain during the latent phase [14].

Acupoint hot compress, as a non-pharmacological intervention, is a non-invasive treatment based on the principles of Traditional Chinese Medicine (TCM). Many studies have shown the benefits of acupoint hot compress; notably, it is inexpensive, simple to use, safe, and effective, and can assist in reducing pain as well as preventing emotional disturbances and disorders [15-17]. However, to date, little is known of its use for alleviating labor pain, particularly during the latent phase of the first stage of labor. We thus plan to conduct a randomized controlled clinical trial to investigate the efficacy of acupoint hot compress in the reduction of labor pain in primiparous women during the latent phase.

In Chinese clinical practice, pregnant women are typically hospitalized during the early stages of labor, often before the onset of regular uterine contractions, driven by cultural preferences and the healthcare system's emphasis on close monitoring during childbirth [18]. This ensures that participants in our trial will already be under medical supervision when interventions are initiated. The acupoint hot compress will be administered in hospital settings by trained obstetric professionals (obstetricians, midwives, and nurses) who have completed standardized training in this technique. These

professionals will closely monitor the participants to ensure that the intervention is administered safely and effectively.

2. Methods and analysis

2.1 Objective

This study aims to evaluate the effect of acupoint hot compress on pain relief in primiparous women during the latent phase of labor, as well as its impact on key maternal and neonatal outcomes, including labor duration, intrapartum and postpartum bleeding, maternal depression symptoms, and neonatal Apgar scores.

2.2 Hypothesis

We hypothesise that using acupoint hot compress during the latent phase of labor will effectively alleviate labor pain, reduce labor duration, lower intrapartum and postpartum blood loss, ease the maternal depression symptoms and improved neonatal Apgar scores.

2.3 Design of the trial

This study is a prospective, multi-center, open-label, randomized controlled trial. It will enroll 1100 primiparous women across 18 clinical centers in China. Participants will be allocated 1:1 to either the control (standard obstetric care) or intervention group (standard care plus acupoint hot compress). Participants may withdraw voluntarily at any time, with the reasons documented to assess potential bias. The trial may be terminated early if significant safety concerns (e.g., severe intervention-related adverse events) arise. The protocol follows the the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [19] (**Supplementary material 1**)

and will be undertaken in accordance with the Consolidated Standards of Reporting Trials (CONSORT) [20] guidelines (**Figure 1**).

2.4 Recruitment of participants

Recruitment will take place from January 2024 to August 2025. Eligible primiparous women will be identified upon hospital admission for labor, with obstetricians, midwives and nurses screening participants based on inclusion and exclusion criteria. After receiving a comprehensive explanation of the purpose, procedures, risks, and benefits regarding the study, eligible women will provide written informed consent (**Supplementary material 2**). Consented participants will be enrolled and randomized into the control or intervention group using a central stratified block randomization method. To ensure adequate enrollment, regular training sessions will be conducted for obstetricians, midwives, and nurses at each center to familiarize them with the study protocol and recruitment process. The study will be undertaken at 18 clinical centers in China: Women's Hospital, School of Medicine, Zhejiang University; Gansu Provincial Maternal and Child Health Care Hospital; Hangzhou First People's Hospital; Hangzhou Women's Hospital; Yiwu Maternity and Children Hospital; Jiaxing Maternity and Child Health Care Hospital; The Second Affiliated Hospital of Wenzhou Medical University; Lishui Central Hospital; Wenzhou Central Hospital; Hangzhou Fuyang Women and Children Hospital; Hangzhou Linping District Maternity and Child Health Care Hospital; The Fourth Affiliated Hospital, Zhejiang University School of Medicine; Tonglu Maternal and Child Health Hospital; The First People's Hospital of Jiashan; The First Affiliated Hospital of Ningbo University; The First People's Hospital of Xiaoshan District; Tongxiang Maternal and Child Health Hospital;

Huzhou Maternity and Child Health Care Hospital. Recruitment will not discriminate against any particular cultural, racial, or socio-economic group.

2.5 Inclusion criteria

The inclusion criteria are: Age ranging from 20 to 34 years; gestational age ranging from 37 to 41 weeks; primiparous parturient women with planned vaginal delivery; singleton pregnancy; meet the diagnostic criteria of the latent phase of the first stage of labor [21]; ability to communicate well with the researcher and comply with the test requirements; and provided written informed consent.

2.6 Exclusion criteria

(1) Prior uterine surgery or uterine abnormalities;

(2) Fetal anomalies, chromosomal abnormalities, or stillbirth;

(3) Prenatal diseases, including infectious, central nervous system, urogenital diseases, and internal and surgery-related diseases, as well as the use of long-term medication;

(4) A history of psychiatric or neuropsychological disorders, as well as impaired verbal communication;

(5) The presence of severe diabetes, skin diseases, sensory disorders, acute inflammation, high fever, and allergies to the material used in the study product;

(6) Patients with incomplete information.

2.7 Withdrawal criteria

(1) Adverse events (AEs) related to the intervention (e.g., skin burns, severe allergic reactions) occur;

(2) Participants fail to comply with the study protocol;

(3) Participants will have the option to voluntarily withdrawal at any time and for any reason.

2.8 Drop-out criteria

(1) Change from vaginal delivery to cesarean section;

(2) Non-completion of the intervention;

(3) The principal researcher will have the authority to conclude the study at any time when the benefits are considered to outweigh the risks;

(4) Poor treatment compliance by the subject.

2.9 Calculation of sample size

The sample size calculation will be based on the primary outcome of pain intensity during the latent phase of labor, rated on a VAS. The pilot study was conducted with 50 participants (25 in the control group and 25 in the intervention group). The difference between the means of the two groups was found to be 0.61 with a standard deviation of 1.08. With 90% power, a two-sided threshold of 0.05, and a 20% dropout rate, the size of the sample was found to be 1100, with 550 participants in each group. The pilot study sample was representative of the main study population in terms of demographic characteristics and clinical setting, ensuring the generalizability of the findings.

2.10 Randomization and blinding

The eligible subjects will be randomly allocated to the control and intervention groups in a 1:1 ratio using central stratified block randomization method, which will be generated by an independent statistician using conventional statistical computer software (SPSS version 25.0; IBM Corp., USA).

No blinding method will be used due to the lack of a feasible placebo for the hot compress intervention.

2.11 Interventions

2.11.1 Control group

The participants will receive only obstetrical care, including monitoring of maternal vital signs, fetal position and heart rate, uterine contractions, vaginal bleeding, and labor progress, as well as conventional pain management (breathing techniques and massage), and psychological and social support [22].

2.11.2 Intervention group

Participants in the intervention group will receive the same obstetrical care as the control group (detailed in Section 2.11.1), including the conventional pain management. Additionally, they will receive acupoint hot compress therapy at 42 ± 2 °C for four hours, starting one hour after the onset of regular uterine contractions during the latent phase of labor. Specifically, regular contractions refer to uterine contractions that occur at a consistent frequency (every 5-6 minutes) and duration (lasting at least 30 seconds) [22]. To ensure accuracy, we adopt a combination of clinical assessments to measure and confirm the presence of regular contractions. These assessments primarily include: periodic palpation by midwives or obstetricians to evaluate the regularity, intensity, and pattern of the contractions. Furthermore, cervical examinations are conducted to further validate the contractions by evaluating cervical dilation and effacement.

For the intervention, this will be applied using a Hu-Chao-Nuan-Gong-Bao, a licensed Class II item of medical equipment (license No. 20192090292) manufactured by Jiangxi Shenghe Industrial Development Co., Ltd. (Nanchang, China). Acupoint hot compress includes two sizes (**Figure 2**), model A (measuring 16x9 cm) and model B (measuring 13x10 cm). These comprises four hot cores, each measuring 8x7 cm (Model A), as well as one hot core measuring 11.5x8 cm (Model B). Agents such as inorganic salts and activated carbon can be placed within the hot cores in specific proportions in a sealed inner bag. The temperature can be maintained at a constant level due to the specific rates of oxygen and water vapor transmission within the breathable layer (**Figure 3**).

The selection of acupoints will be determined according to our hospital's clinical experience and in consultation with 10 experts. The Nomenclature and Location of Acupuncture Points (National Standard of the People's Republic of China, 2006 [GB/T 12346-2006]) describes the acupoint locations [23]. As shown in **Figure 4**, two of the hot cores shown in Model A will be applied separately on Bilateral Yongquan (KI1) 1 h after the onset of regular uterine contractions, while two of the other hot cores in Model A will be applied separately on Bilateral Sanyinjiao (SP6) and one hot core from Model B will be applied on Baliao (BL31-34).

2.12 Primary outcome

2.12.1 Labor pain

Pain during the latent phase of labor will be assessed using a VAS in which, on a scale of 0 to 10, "0" represents "no discomfort" and "10" indicates "terrible pain". Pain intensity will be assessed using the VAS at 1, 3, and 5 h following the onset of regular uterine contractions. The VAS is a widely

validated and reliable tool for pain assessment, demonstrating high sensitivity in detecting pain intensity variations[24]. To reduce potential confounding effects, participants will be allocated using a central stratified block randomization method to ensure balanced group allocation. Moreover, all clinical centers will follow the same standardized protocols for labor monitoring and pain assessment to minimize variability.

2.13 Secondary outcomes

2.13.1 Labor duration

The labor duration will be measured from the start of labor until birth. The durations of all labor stages (first, second, third), as well as the overall duration, will be recorded.

2.13.2 Blood loss

Blood loss estimation after the delivery and at 2 h postpartum will be recorded. The method of measuring blood loss is the quantitative measurements of the blood volume and weight [25]. The quantification of the blood loss is as follows: A calibrated under-buttocks drape will collect all fluids immediately after delivery. The total volume of collected fluid will be recorded, and pre-placental fluids (e.g., amniotic fluid, urine) will be subtracted to isolate blood loss. Blood-soaked materials (e.g., gauze, pads) will be weighed, and blood volume calculated as: Blood Volume (mL)=Wet Weight (g)-Dry Weight (g). Cumulative blood loss will be determined by combining the volumes from the drapes, and weighed materials.

2.13.3 Symptoms of depression

The symptoms of depression may cover physical, emotional, and cognitive abnormalities. Depressed mood and a loss of interest or pleasure are the primary symptoms of depression. The Edinburgh Postnatal Depression Scale (EPDS) will be administered within 48 hours postpartum to identify depression symptoms. The EPDS is a well-validated instrument widely used to assess depression and anxiety symptoms in perinatal populations [26,27]. Participants will complete the EPDS questionnaire independently, as it is a self-reported tool. The completed questionnaires will be collected and recorded by trained researchers.

2.13.4 Apgar scores

The Apgar score is utilized to access the five physical signs of the newborn, including pulse, respiration, appearance, muscle tone and reflex irritability. The Apgar scores will be documented at 1 and 5 min after delivery. The Apgar score serves as a predictive indicator for neonatal mortality, morbidity, and long-term neurodevelopmental outcomes [28,29].

2.14 Safety

The medical device to be used is a hot compress, which has been authorized by the Medical Products Administration under license number 20192090292.

The pilot study did not find any AEs. The potential AEs will be described to the participants in this study, and people with sensory abnormalities will be excluded.

2.15 Data collection and management

Standardized training for conducting the study and the involved procedures will be provided to all researchers. All data will be collected using standardized case report forms (CRFs) and entered into a secure electronic database with a double data-entry system to minimize errors. Regular audits conducted by the research team will ensure data accuracy and completeness. Access to the database will be restricted to authorized personnel only, and all data will be anonymized to protect participant confidentiality. Incomplete or missing data will be documented and addressed through follow-up with the participating clinical centers.

2.16 Statistical methods

Independent analysts will conduct the statistical analysis using SPSS 25.0. All analyses will be undertaken using the intention-to-treat approach. No interim analyses will be conducted. For continuous data, t-tests, covariance analysis, or Wilcoxon-Mann-Whitney tests will be used for analysis, while for categorical data, chi square tests or Fisher's exact tests will be utilized. In addition, a logistic regression analysis will be undertaken to determine associations between the independent variables.

3. Ethics and dissemination

The study has been approved by the Ethics Committee of Women's Hospital, School of Medicine, Zhejiang University (No. IRB-20230379-R). This report is based on protocol version 2.1, date 16 May 2024. Any modifications to the protocol will be submitted for ethics approval, and updated in the ChiCTR. All participants will receive a comprehensive explanation of the purpose, procedures, and potential risks associated with the trial and will be required to provide informed

consent before taking part. The data obtained in the study will be made available by the corresponding author on reasonable request. The results will be published in international scientific journals.

4. Discussion

In our study, we aim to address labor pain relief, a critical aspect of maternity care that aligns with the WHO Sustainable Development Goals prioritizing maternal and newborn healthcare [30]. These goals emphasize reducing pregnancy-related complications, a leading cause of global maternal mortality [31]. Effective interventions across all stages of maternity care are essential to achieve these objectives. Our focus on labor pain management during the latent phase reflects a key priority in maternal health, given its significant impact on childbirth outcomes [32,33].

Currently used methods for labor pain relief include pharmacological approaches, such as epidural analgesia, narcotics, and intravenous opioid administration [34,35], as well as non-pharmacological interventions, including acupuncture, hot compress, massage, and music therapy [36-38]. Most pharmacological methods are expensive and can have negative effects on both the mother and newborn [39]. This has led to increased exploration of non-pharmacological techniques, which may enhance the delivery experience.

The hot compress is an economical, safe, and non-invasive non-pharmacological method for pain management [40]. According to the gate control theory, the hot compress can stimulate endorphin release, thereby reducing pain perception by inhibiting the transmission of pain signals to the brain [41]. Additionally, the hot compress dilates blood vessels, enhancing local blood circulation and further contributing to pain relief [42].

Building on these physiological mechanisms, acupoint hot compress integrates the benefits of heat therapy with TCM by targeting specific acupoints. Compared to other therapies, acupoint hot compress is particularly well-received by patients and their families due to its non-invasive nature, low cost, and psychological comfort [16]. The combination of physiological and psychological benefits makes acupoint hot compress a promising intervention for labor pain management.

It should be noted that pain intensity and tolerance during the latent phase demonstrate significant inter-individual variability. While some women may experience mild discomfort requiring no intervention, others may perceive the pain as intolerable and actively seek relief [43]. Given this heterogeneity in pain perception, we emphasize that decisions regarding pain relief administration should be made on a case-by-case basis, considering each woman's preferences, pain tolerance, and the potential risks and benefits of available interventions. To ensure both methodological rigor and participant safety, our study will exclude individuals with psychiatric disorders or sensory abnormalities. This exclusion criterion is based on two considerations: First, psychiatric conditions may confound self-reported pain assessments [44,45] and affect the validity of EPDS scores for depression evaluation. Second, sensory abnormalities increase the potential risk of thermal injury from the hot compress intervention.

There remain some limitations in this protocol. First, since there is no suitable placebo for the hot compress intervention, the group randomization is not concealed from the subjects. This lack of blinding may introduce performance bias, since subjects' awareness of group allocation may bias pain perception and reporting, potentially overestimating the efficacy of the intervention. Second, while it is widely recognized that TCM should be tailored based on syndrome differentiation, our study adopts

a uniform treatment protocol for all participants. This approach may limit the generalizability of the findings, as the lack of individualized treatment could reduce the effectiveness of intervention for certain participants, leading to variability in outcomes. Third, the fixed sizes of the hot compress devices may not fit all participants' body shapes and acupoint locations. This could cause either inadequate stimulation of the target acupoints or unwanted stimulation of nearby ones, possibly introducing bias in measurements.

In summary, the findings of our study will have important practical implications for the management of labor pain. Firstly, acupoint hot compress represents a cost-effective alternative to pharmacological methods for pain management during labor, which can be particularly beneficial in resource-limited settings. Secondly, the technique is safe and does not require specialized training, making it feasible for widespread use among healthcare providers. Thirdly, the use of acupoint hot compress may improve the experience of the latent phase for primiparous women, leading to psychological benefits and better perinatal outcomes. Furthermore, this study only includes short-term observation indicators, but lacks long-term outcomes, such as postpartum recovery and infant development, which may limit the evaluation of the effects. Future studies should incorporate long-term follow-up to assess the sustained benefits and potential risks of acupoint hot compress for labor pain management.

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Contributors

FQ conceived and formulated the trial, reviewed and revised the manuscript. XYL and YQP wrote the manuscript. NL, TYZ, YJL, YHZ, FFW, DX contributed to revision of the manuscript. All authors read and approved the final manuscript. FQ is the guarantor.

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Competing interests statement

The author(s) report no conflicts of interest in this work.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication

Not applicable.

Provenance and peer review

Not commissioned; externally peer reviewed.

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Figure Legend

Figure 1 Flow chart of study procedures;

Figure 2 Two style of acupoint hot compress;

Figure 3 Structure diagram of hot core;

Figure 4 Locations of acupoint hot compress

Supplementary material

Supplementary material 1 Schedule of Enrollment, Intervention and Assessments

Supplementary material 2 Informed Consent

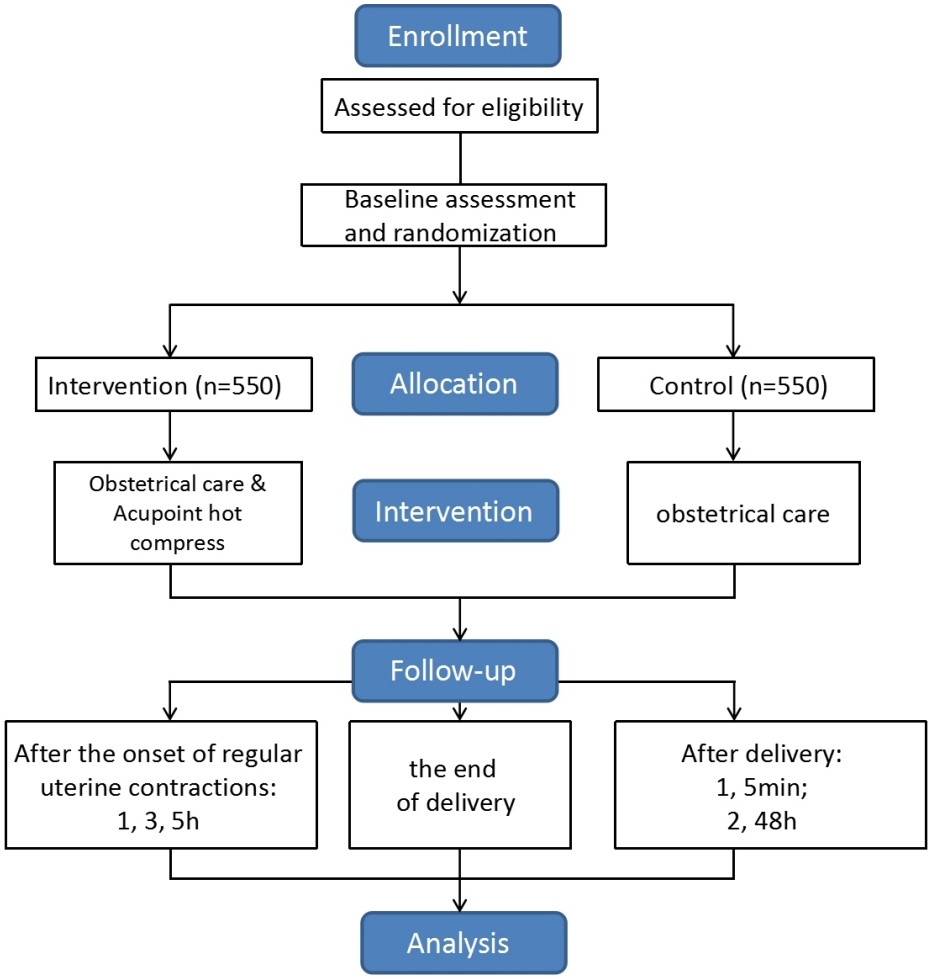

Figure 1 Flow chart of study procedures

314x305mm (96 x 96 DPI)

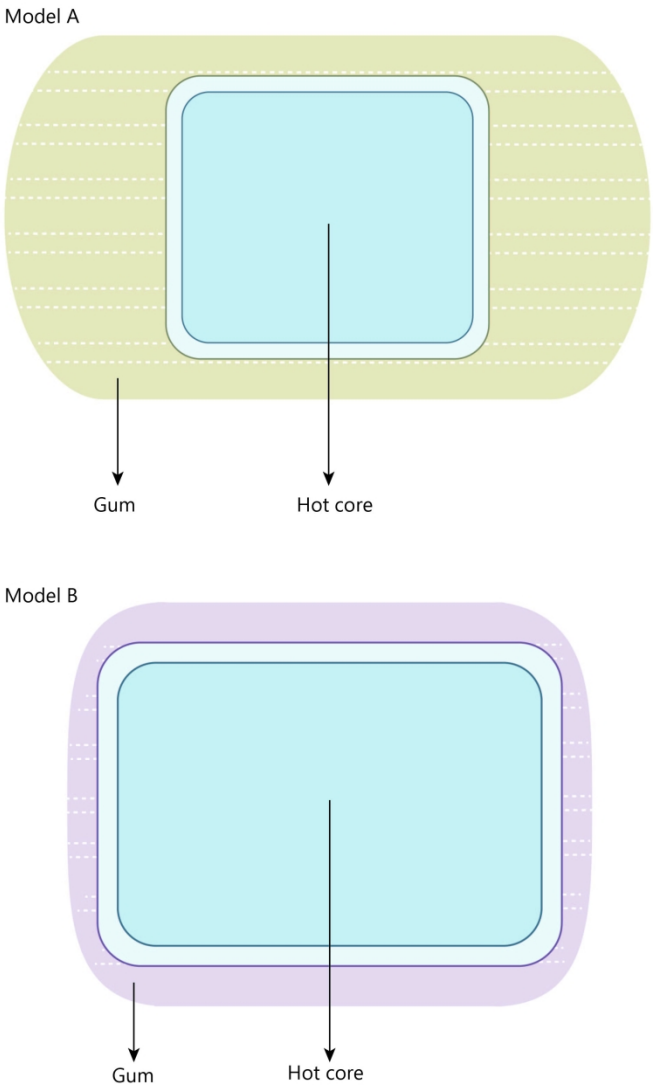

Figure 2 Two style of acupoint hot compress

210x297mm (300 x 300 DPI)

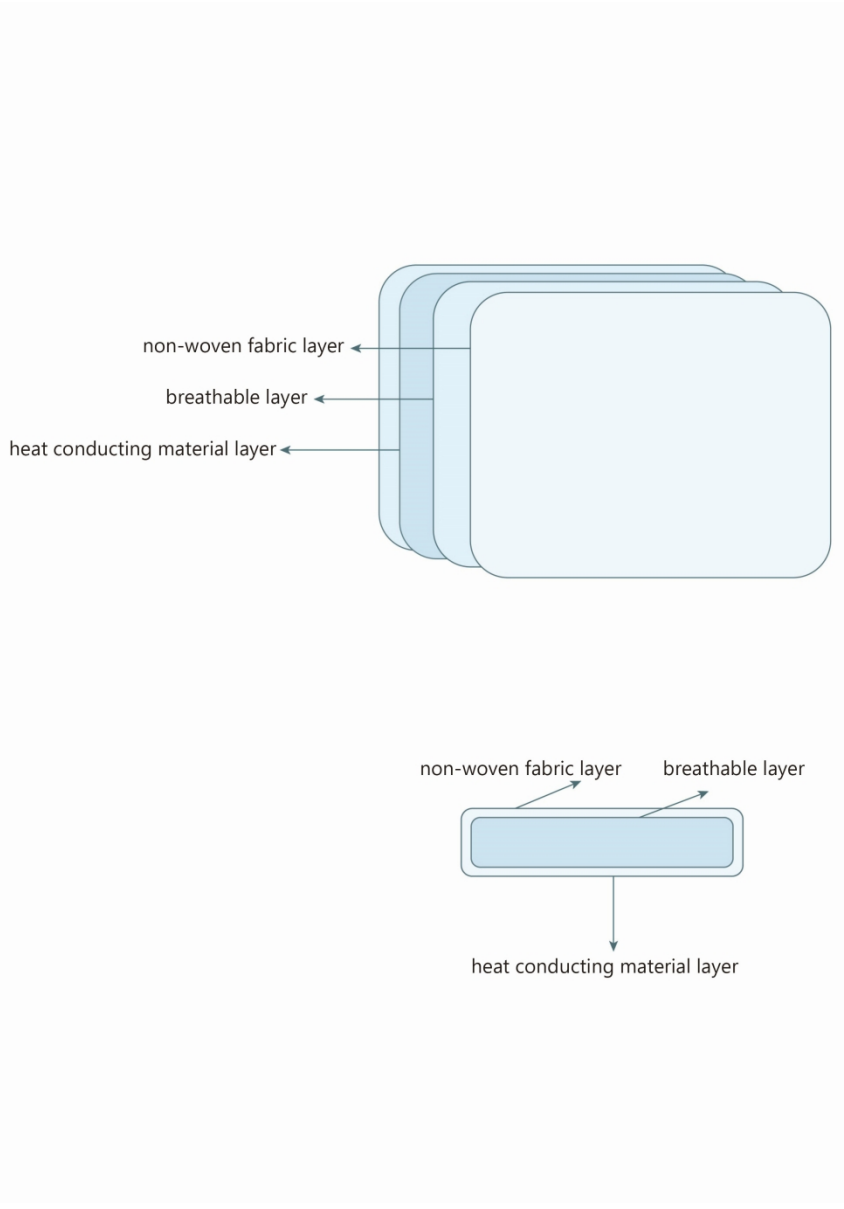

Figure 3 Structure diagram of hot core

656x928mm (96 x 96 DPI)

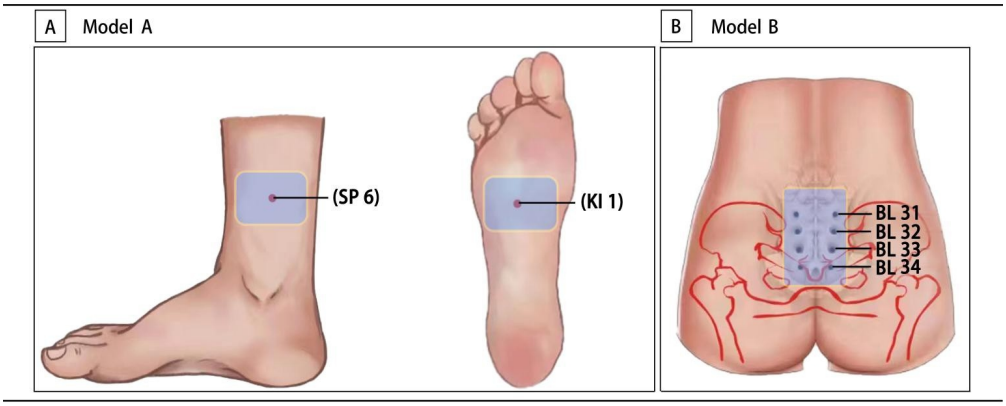

Figure 4 Locations of acupoint hot compress

406x177mm (96 x 96 DPI)

Supplementary material 1 Schedule of Enrollment, Intervention and Assessments

		Enrollment	Allocation	Post-allocation	Follow-up							
Time point		$-t_1$	0	t_1	t_1 1h	t_2 3h	t_3	t_4	t_5 1min	t_6 5min	t_7 2h	t_8 48h
					After the onset of regular uterine contractions			the end of delivery	After delivery			
Enrollment	Eligibility screen	X										
	Informed consent	X										
	Randomization	X										
	Allocation		X									
Interventions	Obstetrical care & Acupoint hot compress			X								
	Obstetrical care			X								
Assessments	pain (VAS)				X	X	X					
	The duration of labor							X				
	Bleeding loss							X			X	
	Emotion symptoms (EPDS)											X
	Apgar scores								X	X		

Abbreviations: VAS, visual analogue scale; EPDS, edinburgh postnatal depression scale.

Version：2.1
Version Date：2024.05.16

Informed Consent-Notification Page

Dear Participant:

We would like to invite you to participate in a clinical study entitled "Effect of acupoint hot compress on relieving pain in primiparous women during the latent phase of the first stage of labor: A study protocol for a prospective, multi-center, randomized controlled clinical trial". Before deciding whether to participate in this study, please read the following information carefully. It will help you understand the purpose, procedures, potential benefits, risks, and discomforts of the study. You may ask your doctor to explain any part of the content to help you make an informed decision.

1. Background

Pain is described as an unpleasant subjective sensation and represents one of the five vital signs. Labor pain is an unavoidable feature of childbirth and is characterized by extreme intensity. Adequate pain management is thus essential, not only for addressing physiological pain but also for mitigating the negative effects of pain on the psychological well-being of parturients.

The treatments for relieving labor pain are classified primarily into pharmacological and non-pharmacological approaches. Medication is the most frequent form of pain relief used in mainstream medical practice. However, the possible negative consequences of the drugs on both the mother and fetus have led to interest in non-pharmacological treatments to reduce labor pain during childbirth.

Acupoint hot compress, as a non-pharmacological intervention, is a non-invasive treatment based on the principles of Traditional Chinese Medicine (TCM). Many studies have shown the benefits of acupoint hot compress; notably, it is inexpensive, simple to use, safe, and effective, and can assist in reducing pain as well as preventing emotional disturbances and disorders. We thus plan to conduct a randomized controlled clinical trial to investigate the efficacy of acupoint hot compress in the reduction of labor pain in primiparous women during the latent phase.

2. Objective

This study aims to evaluate the effect of acupoint hot compress on pain relief in primiparous women during the latent phase of labor, as well as its impact on key maternal and neonatal outcomes, including labor duration, intrapartum and postpartum bleeding, maternal depression symptoms, and neonatal Apgar scores.

3. Interventions

Each participant will be assigned a random number. Based on the random number, you will be assigned to either the intervention group or the control group.The controls will be treated only with obstetrical care, while those in the intervention group will receive the same obstetrical care as the control group, with the addition of acupoint hot compress therapy at 42 ± 2 °C for four hours, starting one hour after the onset of regular uterine contractions during the latent phase of labor. For the intervention, this will be applied using a Hu-Chao-Nuan-Gong-Bao, a licensed Class II item of medical equipment (license No. 20192090292) manufactured by Jiangxi Shenghe Industrial Development Co., Ltd. (Nanchang, China).

4. Expected Number of Participants

1100

5. Inclusion criteria

The inclusion criteria are: Age ranging from 20 to 34 years; gestational age ranging from 37 to 41 weeks; primiparous parturient women with planned vaginal delivery; singleton pregnancy; meet the diagnostic criteria of the latent phase of the first stage of labor; ability to communicate well with the researcher and comply with the test requirements; and provided written informed consent.

6. Exclusion criteria

(1) Prior uterine surgery or uterine abnormalities;

(2) Fetal anomalies, chromosomal abnormalities, or stillbirth;

(3) Prenatal diseases, including infectious, central nervous system, urogenital diseases, and internal and surgery-related diseases, as well as the use of long-term medication;

(4) A history of psychiatric or neuropsychological disorders, as well as impaired verbal communication;

(5) The presence of severe diabetes, skin diseases, sensory disorders, acute inflammation, high fever, and allergies to the material used in the study product;

(6) Patients with incomplete information.

7. Withdrawal criteria

(1) Adverse events (AEs) related to the intervention (e.g., skin burns, severe allergic reactions) occur;

(2) Participants fail to comply with the study protocol;

(3) Participants will have the option to voluntarily withdrawal at any time and for any reason.

8. Drop-out criteria

(1) Change from vaginal delivery to cesarean section;

(2) Non-completion of the intervention;

(3) The principal researcher will have the authority to conclude the study at any time when the benefits are considered to outweigh the risks;

(4) Poor treatment compliance by the subject.

9. Risks and Benefits

Risks: In previous studies, the acupoint hot compress has not shown significant adverse effects. However, there is a possibility that the intervention may not achieve the desired effect, and rare cases of allergies or burns may occur.

Prevention Measures: If you are assigned to the intervention group and experience any adverse reactions during the use of the device, you may contact the researcher at any time for guidance. The study will strictly adhere to inclusion and exclusion criteria and monitor the quality of the medical device.

Benefits: Participants will receive free acupoint hot compress devices and expert consultations, gain knowledge about labor pain relief methods, and may experience reduced pain during the latent phase. The study aims to contribute to the understanding of TCM methods for labor pain relief and improve natural delivery rates. However, individual benefits may vary.

10. Alternatives available

Although the study intervention shows promise, it is not the sole available method

for labor pain relief. If you are unable to continue the study, you may inquire about alternative methods such as free position, music therapy, etc.

11. Costs and Compensation

Costs: The acupoint hot compress device will be covered by the study, with no additional costs to participants.

Compensation: None.

Compensation for Harm: Researchers will make every effort to prevent and treat adverse events that may result from this study. If any harm related to the study occurs and is confirmed, the researcher will provide diagnostic and treatment costs as well as financial compensation in accordance with relevant laws and guidelines.

12. Confidentiality Measures

Your identity will remain confidential. Your name will not appear in any study reports or publications. Medical data will be used solely for research purposes and not for commercial activities. Researchers may access your medical records, and every effort will be made to protect your privacy within legal limits. You have the right to access your information at any time during the study.

13. Voluntary participation

Your participation is completely voluntary. You may not participate or you may withdraw from the study at any time during the course of the study. This will not affect your relationship with the medical staff and your routine medical care will not be affected in any way.

14. Participant Responsibilities

(1) If you meet the inclusion criteria, you may voluntarily participate by signing the informed consent. If you choose not to participate, you will receive appropriate care based on your condition and preferences.

(2) If you participate, you will be assigned to a group and expected to cooperate with the researchers for examinations and follow-ups.

15. Contact information

If you experience any discomfort, or if you have any questions about the study, you may contact the researcher: Name:*** Phone:**********

If you have any questions about your rights as a participants, you can contact the Ethics Committee: Phone:**********

16. Other Matters

It is up to you and/or your family to decide whether to participate in this study. Before making your decision, please ask your doctor any questions until you fully understand the study. Thank you for reviewing this information.

Informed Consent-Signature page

Declaration of Consent

I have carefully read the above information about this study. The researcher has explained the study's characteristics and potential issues in detail and answered my questions.

I fully understand the content, risks, and benefits of participation. After sufficient time to consider, I voluntarily agree to participate and will cooperate with the researchers, providing accurate and objective information about my health and related conditions.

I understand that I may consult the doctor for further information at any time and may withdraw from the study without discrimination or retaliation, with no impact on my medical care or rights. If I fail to comply with the study plan or if study-related injuries or other issues arise, the researcher may terminate my participation.

I acknowledge that I will receive a copy of this informed consent.

Finally, I agree to participate in this study and will follow the instructions to the best of my ability.

Participant Signature:_____ Researcher Signature:_____

Legal Guardian Signature (if applicable):_____ Phone：_____

(Relationship to Participant:_____) Date of signature:_____

Witness (if applicable)：_____

Phone：_____

Date of signature:_____