

Effectiveness of acupoint hot compress on early puerperal rehabilitation of parturients after natural childbirth: study protocol for a prospective, multi-center, randomized controlled clinical trial

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DOI: [10.31083/j.ceog4806214](https://doi.org/10.31083/j.ceog4806214)

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Submitted: 26 April 2021 Revised: 24 June 2021 Accepted: 1 July 2021 Published: 15 December 2021

Background: Early puerperal rehabilitation can interfere with a woman's ability to care for herself and her infant. Acupoint hot compress, with a combination of acupoints and natural physical agent heat, has significant potential to alleviate symptoms experienced during early puerperium. Current evidence regarding the effects of acupoint hot compress therapy on early puerperal rehabilitation is insufficient. The aim of this study is to address this with a multi-center design and large sample size. **Methods:** This is a prospective, multi-center, and randomized controlled clinical trial. A total of 1400 nulliparous women with a singleton pregnancy experiencing natural childbirth from 14 hospitals will be enrolled and randomly allocated to either an intervention group or a control group in a 1:1 ratio. Subjects in the control group will only receive routine postpartum care. In addition to routine postpartum care, the subjects in the intervention group will be administered a 4-hour acupoint hot compress with a constant temperature of $45 \pm 2^\circ\text{C}$ respectively within 30 minutes after delivery, 24 hours and 48 hours after delivery. The primary outcome will be the time elapsed from delivery to the first urination. The secondary outcomes will be postpartum uterine contraction pain intensity, the Edinburgh Postnatal Depression Scale for screening postpartum depression and the assessment of lactation including recording the lactation initiation time, postpartum diet, appetite, weight, neonatal weight. **Discussion:** These results will provide evidence for obstetricians and parturients on considering nonpharmacologic and noninvasive intervention in early puerperal rehabilitation.

Keywords

Acupoint hot compress; Early puerperal rehabilitation; Study protocol; Randomized controlled clinical trial

1. Introduction

Early puerperium is the period of adjustment after delivery, which extends until the first week postpartum [1–3]. World Health Organization guideline for postnatal care recommends that mothers and newborns should receive care at least 24 hours after birth including assessment of micturition, urinary incontinence and bowel function, healing of any perineal wound, fatigue, pain, uterine tenderness and lochia, breastfeeding progress and emotional well-being [4]. These issues can interfere with a woman's ability to care for herself and her infant [5, 6].

Traditional Chinese medicine, with its unique theory system and long-term clinical practice, has significant potential for early puerperium rehabilitation. Acupuncture and electroacupuncture have been shown to have positive significant effects in facilitating the first urination following vaginal delivery [7, 8]. Hot compress, as a nonpharmacologic and non-invasive intervention, can effectively avoid the potential side effects of medications [9, 10]. Acupoint hot compress, with a combination of acupoints and natural physical agent heat, is more acceptable, both physically and mentally for puerperal patients and their family due to the non-invasive character [9, 11]. Hot compress has been widely used by midwives to decrease the events of genital trauma and to improve the comfort during delivery [12]. However, little evidence could be found regarding the clinical practice of using an acupoint hot compress for women during early puerperal rehabilita-

Table 1. SPIRIT schedule of enrolment, interventions, and assessments.

Timepoint (After delivery)	Study period									
	Enrolment Allocation		Post-allocation			Follow-up				
	0	0	t ₁	t ₂	t ₃	t ₁	t ₂	t ₃	t ₄	
			<i>Within 30 minutes</i>	<i>24 hours</i>	<i>48 hours</i>	<i>6 ± 0.5 hours</i>	<i>28 ± 0.5 hours</i>	<i>52 ± 0.5 hours</i>	<i>76 ± 0.5 hours</i>	
Enrolment										
Eligibility screen	X									
Informed consent	X									
Randomization	X									
Allocation		X								
Interventions										
Routine postpartum care & Acupoint hot compress			X	X	X					
Routine postpartum care			X	X	X					
Assessments										
Postpartum urinary retention						X				
Postpartum uterine contraction pain (VAS)						X	X	X	X	
Emotion symptoms (EPDS)										X
Lactation							X	X	X	

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

tion. A well-designed prospective, multi-center and randomized controlled clinical trial is needed to provide clinical evidence.

2. Materials and methods

2.1 Objectives

The trial is designed to evaluate the effects of an acupoint hot compress in reducing the incidence of postpartum urinary retention, relieving postpartum uterine contraction pain, preventing emotional disorders, and promoting lactation.

2.2 Trial registration

The final protocol version is 2.1, dated 25 August 2020. The protocol was approved by the Ethics Committee of Women's Hospital, School of Medicine, Zhejiang University with the Approval No. IRB-20200223-R on 7 September 2020. The trial was registered at World Health Organization International Clinical Trial Registration Platform, Chinese Clinical Trial Registry (Chictr) with the registration number ChiCTR2000038417. Registered 22 September 2020, <http://www.chictr.org.cn/showproj.aspx?proj=57108>.

2.3 Study design

The study is a prospective, multi-center, and randomized controlled clinical trial, which will be conducted in China. All enrolled subjects will be comprehensively briefed on the study, including the purpose, procedure, and possible risks of the study. Informed consent will be obtained from all participants before the start of this study. The demographic data, information about pregnancy, delivery, and newborns will be recorded as baseline data. When the protocol need to be modified, the implementation will be started only after the corresponding revised parts approved by the ethics com-

mittee, and all research centers, investigators and the funder are notified at the same time. The study will follow the Code of Ethics of the World Medical Association (Declaration of Helsinki). This protocol is compliant with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [13] statement (Table 1) and the Consolidated Standards of Reporting Trials (CONSORT) [14] guidelines (Fig. 1).

2.4 Recruitment

The study will be conducted in 14 hospitals in China: Women's Hospital, School of Medicine, Zhejiang University; Tongde Hospital of Zhejiang Province; Hangzhou First People's Hospital; The First Affiliated Hospital of Wenzhou Medical University; Yiwu Maternity and Child Health Care Hospital; Jiaying Maternity and Child Health Care Hospital; Zhejiang Xiaoshan Hospital; Zhoushan Women and Children Hospital; Shaoxing Maternity and Child Health Care Hospital; The Women & Children Hospital of Dongyang; Ruian People's Hospital; Cixi Maternity and Child Health Care Hospital; Wenling Maternity and Child Health Care Hospital and Xianju People's Hospital. Posters will be placed in each institution's bulletin board to recruit subjects. No specific culture, race, or socio-economic group will be targeted or restricted from the recruitment. On submission, the study is now in the process of patient recruitment and the first patient was recruited on 17 January 2021.

2.5 Participants

2.5.1 Inclusion criteria

- (1) Age is more than 18 years old;
- (2) Nulliparous women with a singleton pregnancy;
- (3) Gestational age of delivery is 37–42 weeks;
- (4) Parturient undergoing vaginal delivery;

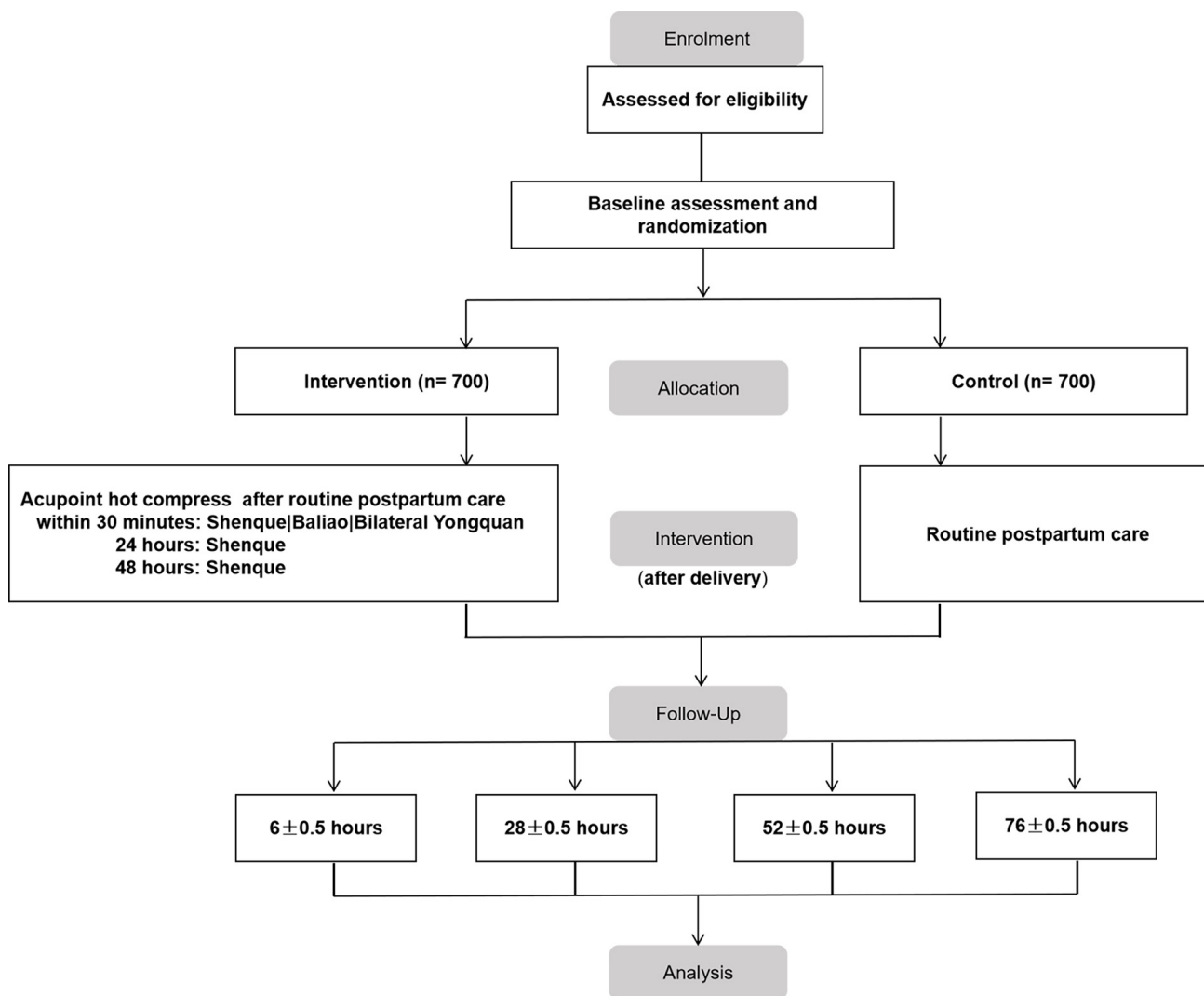


Fig. 1. Consort Flow Diagram: Flow of the participants throughout the study.

- (5) Breastfeeding;
- (6) Provision of the signed informed consent.

2.5.2 Exclusion criteria

- (1) Termination of pregnancy due to fetal malformation or stillbirth;
- (2) Family history of mental illness or tumor;
- (3) Mental and psychological diseases, traumatic events, or communication barriers;
- (4) Pre-pregnancy central nervous system diseases, internal and surgical diseases, breast dysplasia, urogenital related diseases, infectious diseases, and long-term drug treatment;
- (5) Skin damage, ulceration, sensory disorders, acute closed injury, suppurative infection, acute inflammation and other infectious diseases, skin diseases, severe diabetes, high fever and allergy to product materials;
- (6) Incomplete provision of information.

2.5.3 Subject withdrawal

On request, the enrolled subjects can withdraw from the clinical trial at any stage of the study.

2.5.4 Subject drop-out and discontinuation

- (1) Implementation of rescue due to postpartum hemorrhage, eclampsia, or other obstetric conditions;
- (2) Change of vaginal delivery to cesarean section;
- (3) Infection during delivery;
- (4) Indwelling catheter and the need to use diuretics due to disease within 6 hours after delivery;
- (5) Degree III laceration above the perineal fissure;
- (6) Neonatal transfer after birth;
- (7) The investigator can terminate the subject from continuing the clinical trial at any stage, if the investigator deems that the risks of continuing the clinical trial outweigh the benefits;
- (8) Subject's poor compliance to this trial.

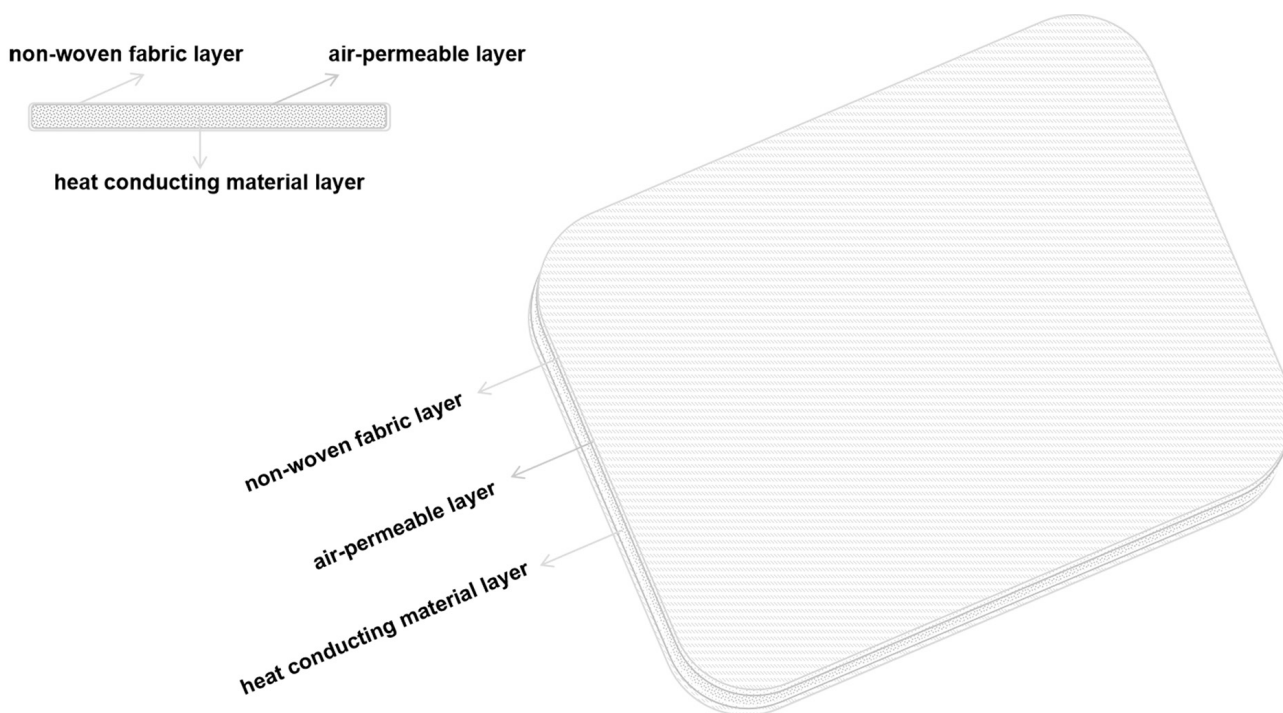


Fig. 2. Structure diagram of hot core: From the outside to the inside are the non-woven fabric layer, air-permeable layer and heat conducting material layer.

2.6 Sample size calculation

This study will use a superiority design. According to the pilot study, the incidence rate of urinary retention was 7.7% in the intervention group and 25.7% in the control group. Assuming a 1:1 ratio of intervention to control group and using a one-sided test, a significance level (α) of 0.025 and a power ($1-\beta$) of 80% and a possible drop-out rate of 20%, the estimated sample size is 700 cases in each group with 50 cases at each center in each group. Intervention and control groups would require a total sample size of 1400 cases.

2.7 Randomization and blinding

Eligible subjects will be randomly assigned to the intervention group or control group in a ratio of 1:1. The randomization number sequence will be generated with the software SAS 9.4 (SAS Institute, Cary, NC, USA) by an independent statistician. Randomization number sequence will be stored by a non-involved investigator. The design is open label, but the outcome assessors and statisticians who are blinded to group allocation will be responsible for collecting and analyzing the data, respectively.

2.8 Interventions

2.8.1 Control group

The subjects in the control group will only receive routine postpartum care, including observing vital signs (blood pressure, heart rate, pulse, temperature and oxygen saturation of blood), monitoring amount of vaginal bleeding and discharge of lochia, palpating fundus and cleansing vulva [15].

2.8.2 Intervention group

In addition to routine postpartum care, the subjects in the intervention group will be administered a 4-hour acupoint hot compress with a constant temperature of 45 ± 2 °C respectively within 30 minutes after delivery (Intervention I), 24 hours (Intervention II), and 48 hours (Intervention III) after delivery. Hot compress will be performed using a licensed Class II medical device, Hu-Chao-Nuan-Gong-Bao (produced by Jiangxi Shenghe Industrial Development Co., Ltd., Nanchang, China with a license No. 20192090292). Four hot cores of Model A (13×10 cm) and another two hot cores of Model B (16×9 cm) are included in the licensed device. The material layer of a hot core consists of iron powder, water, activated carbon and inorganic salts, which are put into a sealed inner bag with a specific proportion. A specific water vapor transmission rate and a specific oxygen transmission rate of the air-permeable layer can keep a constant temperature (Fig. 2).

The selection of acupoints is based on the clinical experiences of our hospital and the consultation with 10 experts in Chinese medicine. The location of acupoints is described as per the Nomenclature and Location of Acupuncture Points (National Standard of People's Republic of China, 2006 [GB/T 12346-2006]) [16]. As seen in Fig. 3, during Intervention I (within 30 minutes after delivery), two hot cores (Model A) will be respectively administered on Shenque (RN8, in the center of the umbilicus) and Baliao (BL31-34, in the region of the sacrum, between the posterior superior iliac spine and the posterior midline, in the 1st,

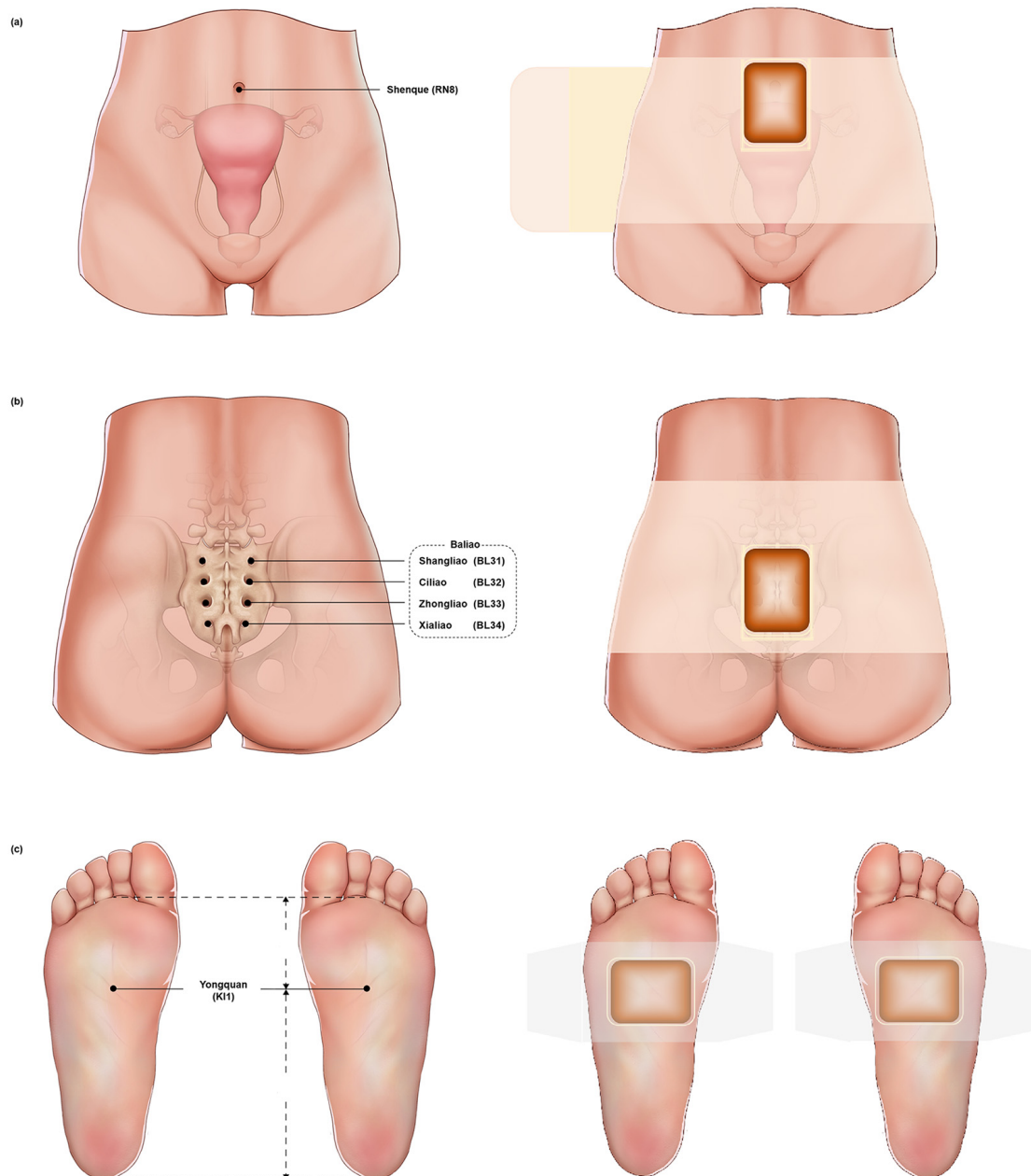


Fig. 3. Acupoints. (a) Shenque (RN8), in the center of the umbilicus. (b) Baliao (BL31-34), in the region of the sacrum, between the postero-superior iliac spine and the posterior midline, in the 1st, 2nd, 3rd and 4th posterior sacral foramen, from top to bottom are Shangliao, Ciliao, Zhongliao, and Xialiao. (c) Yongquan (KI1), on the sole, in the depression when the foot is in plantar flexion, and in the anterior depression when the foot is flexed, approximately at the junction of the anterior 1/3 and posterior 2/3 of the sole.

2nd, 3rd and 4th posterior sacral foramen, from top to bottom are Shangliao, Ciliao, Zhongliao, and Xialiao). Two hot cores (Model B) will be respectively administered on Bilateral Yongquan (KI1, on the sole, in the depression when the foot is in plantar flexion, and in the anterior depression when the foot is flexed, approximately at the junction of the anterior 1/3 and posterior 2/3 of the sole). During Intervention II and III (24 hours and 48 hours after delivery), only one hot core (Model A) will be administered on Shenque (RN8).

2.9 Outcomes measures

2.9.1 Primary outcome

Assessment of postpartum urinary retention will be conducted at 6 ± 0.5 hours after delivery, and the time of the first urination after delivery will be recorded [4, 17–19].

2.9.2 Secondary outcomes

Postpartum uterine contraction pain: The visual analogue scale (VAS) will be used to evaluate the postpartum uterine contraction pain intensity: Using a horizontal ruler of 100

mm, “0” representing no pain and “100” representing unbearable pain. The pain VAS intensity will be respectively measured at 6 ± 0.5 hours, 28 ± 0.5 hours, 52 ± 0.5 hours, and 76 ± 0.5 hours after delivery [20].

Emotion symptoms: The Edinburgh Postnatal Depression Scale (EPDS) will be used for screening the depressive symptoms at 76 ± 0.5 hours after delivery. It contains 10-item: pessimism, lack of interest, self-blame, worry, fear, impaired ability, sleep disorder, sadness, tearfulness, self-injury/suicidal ideation, each of which is scored from 0 to 3 [6].

Lactation: Assessment of lactation will be conducted at 28 ± 0.5 hours, 52 ± 0.5 hours, and 76 ± 0.5 hours after delivery, including recording the lactation initiation time, postpartum diet, appetite, weight, neonatal weight [21, 22].

2.10 Safety

The medical device for hot compress used in the present study is licensed by Medical Products Administration (Jiangxi Province, China) with a Licensed Number 20192090292. No adverse events (AEs) has occurred. In the pilot study, the safety evaluation was also comprehensively followed, and no AEs occurred. In the study, the participants with sensory disorders have been excluded. Prior to obtaining consent from the participants, the potential AEs have been explained to the participants. AEs will be monitored and recorded in detail throughout the whole study period.

2.11 Data collection, management and monitoring

All the investigators will receive standard training and will operate strictly according to the standard operating procedure. Double data entry will be applied to ensure the data entry accuracy. A data monitoring committee will be set up before the first enrolment of participants. The original data will be collected and recorded in the form of case report forms (CRFs). Each participant and the investigator will sign and record the date on CRFs, which will be maintained in a secure location. All the data and the CRFs during the current study are available from the corresponding author on reasonable requests. After publication of the study, all the relevant data will be stored for 3 years in Women’s Hospital, School of Medicine, Zhejiang University.

2.12 Statistical methods

Statistical analysis will be performed by independent analysts by using SAS 9.4 statistical analysis software. All the analyses will be based on an intention-to-treat principle. Continuous data will be represented by the average, standard deviation, median, minimum and maximum value; categorical data will be represented by the number and percentages. Continuous data will be analyzed using the *t* test or one-way ANOVA; Wilcoxon-Mann-Whitney test will be used when necessary. Categorical data will be analyzed using the chi-square test or Fisher’s exact test. The logistic regression analyses will also be used to find the relationship between independent variables. $p < 0.05$ will be considered statistically significant.

3. Discussion

Postpartum urinary retention (PUR) is the inability to void spontaneously within 6 hours of vaginal delivery [17], and its prevalence varies from 1.5% to 45% [23]. Episiotomy is a key factor, instead of an independent one, for increasing the incidence rates of PUR after vaginal delivery [24, 25]. PUR increases the risk of permanent voiding difficulties, recurrent urinary tract infections, and urinary incontinence [26, 27], which, in turn, increases the risk of postpartum depression [28]. Pregnancy and early puerperium represent a sensitive period for the human maternal brain [29]. The prevalence of postpartum depression varies from 1.9% to 82.1% in developing countries and from 5.2% to 74.0% in developed countries [30]. Nearly 60.5% of women who experience postpartum depressive symptoms do not seek help [31]. It was reported the prevalence of having a clinical diagnosis of any anxiety disorder was 9.6% at 5–12 weeks postpartum, 9.9% at 1–24 weeks postpartum and 9.3% at >24 weeks postpartum [32]. The prevalence of a generalized anxiety disorder was 6.7% at 5–12 weeks postpartum, 5.7% at 1–24 weeks postpartum, and 4.2% at >24 weeks postpartum [32]. Postpartum depression is a frequent comorbidity associated with anxiety in 4.3% of women [6]. Mood disturbances at 3 days postpartum are the best predictor of postpartum depression at 6 weeks postpartum [33]. Moreover, the intense uterine contractions induced by the newborn’s suckling cause intense maternal abdominal pain, which decreases the amount of breast stimulation and eventually decreases the milk supply [21, 34, 35]. In a survey, nearly 90% of new mothers reported that uterine contraction pain possess negative effects on the newborn care and disturb daily living [36]. However, to maintain a strong uterine myometrium tonicity in the first few days of postpartum period may help decrease postpartum hemorrhage and promote uterine involution [37].

Parasympathetic nerve can innervate bladder, internal sphincter and myometrial activity [38, 39]. Breastfeeding is associated with the increased parasympathetic nervous system modulation, decreased neuroendocrine response to stressors and fewer depressive symptoms [40]. Thermotherapy to the lumbar or abdominal region have been found to improve the peripheral hemodynamics and inhibit sympathetic nerve activity, resulting in parasympathetic nerve activity dominance [41]. Heat conduction or hot compress in some specific parts of human body surface can promote local blood circulation, improve tissue metabolism, alleviate pain and relieve anxiety [42, 43]. Anatomically, Baliao face four pairs of posterior sacral foramen, and there are sacral nerves in the deep part. Stimulation of sacral nerve root by hot compress may affect the area dominated by sacral nerve, including urinary system, reproductive system and anal intestine in pelvic cavity. Acupoint hot compress may also affect the functions of bladder and urethra through the urination center. The regulatory effects of acupoint hot compress at lumbosacral points on bladder is related to pudendal nerve, pelvic nerve and other peripheral nerves. However, the pathway

and mechanism of its action are still unclear. Acupuncture appears to be effective for postpartum depression with respect to certain outcomes [44]. However, the evidence thus far is inconclusive and the mechanism is still to be clarified. Moreover, few study has been conducted on the effects and mechanism of hot compress on the postpartum uterine contraction pain and lactation. The mechanism is supposed to be associated with increasing the peripheral blood circulation, regulating the autonomic nerve activity and improving neuroendocrine regulation.

Based on clinical practice, the present study is designed to explore whether acupoint hot compress could be beneficial in decreasing the incidence of PUR, relieving the postpartum uterine contraction pain, preventing emotional disorders and promoting lactation in early puerperium.

The findings of the prospective, multi-center and randomized controlled clinical trial will provide evidences for the obstetricians and parturients on considering the non-pharmacologic and noninvasive interventions of early puerperal rehabilitation.

Abbreviations

CONSORT, the Consolidated Standards of Reporting Trials; SPIRIT, Standard Protocol Items Recommendations for Intervention Trials; VAS, Visual analogue scale; EPDS, Edinburgh Postnatal Depression Scale; AEs, adverse events; CRFs, case report forms; PUR, Postpartum urinary retention.

Author contributions

FQ conceived the study, designed the study protocol, and revised the manuscript. YHZ drafted the manuscript. AHZ and CL contributed to collect and analyze the data of the pilot study. NR, MSL, XMH, HWL and RZ edited and improved the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The protocol was approved by the Ethics Committee of Women's Hospital, School of Medicine, Zhejiang University (No. IRB-20200223-R). Written informed consent will be obtained from all participants at the beginning of the study.

Acknowledgment

The authors would like to thank Yi Zhao (Clinical Trial Center of Women's Hospital, School of Medicine, Zhejiang University, Hangzhou, China), Jing Zhao (Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences, Beijing, China), and Xiaqiu Wu (School of Public Health, Zhejiang Chinese Medical University, Hangzhou, China) for their valuable comments.

Funding

This study was supported by Association for Maternal and Child Health, Zhejiang Province, China (ZY2020-01).

The funder is responsible for the administrative and financial management of the study, and not involved in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Conflict of interest

The authors declare no conflict of interest. MSL, FQ and HWL are the Guest Editors of this journal, given their roles as Guest Editors, MSL, FQ and HWL had no involvement in the peer-review of this article and have no access to information regarding its peer-review.

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