Comparing Effect of Auricular Acupressure and Body Acupressure on Pain and Duration of First Stage of Labor: Study Protocol for a Randomized Controlled Trial

Zainab Alimoradi
Qazvin University of Medical Sciences
Farideh Kazemi (faridehkazemi21@yahoo.com)
Hamadan University of Medical Sciences School of Nursing and Midwifery https://orcid.org/0000-0001-9525-1010
Mahboubeh Valiani
Isfahan University of Medical Sciences
Maryam Gorji
Qazvin University of Medical Sciences

Study protocol

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Abstract

Background

Labor pain is one of the leading causes for fear of childbirth. Acupressure is a non-pharmacological pain relief method which showed promising results. Comparing the effect of body acupressure at multiple points and auricular acupressure on the pain and duration of labor, the present study is designed.

Methods/Design

In a randomized controlled trial, 90 primigravida women who attend for childbirth would be randomly assigned to three groups (interventions: body acupressure and auricular acupressure, control: routine care). In order to determine the allocation sequence with 1:1:1 ratio, the computer-generated 6-block randomization techniques would be used. To hide the allocation, the type of intervention will be written based on the generated sequence and put in opaque enveloped pockets; then, the pockets as well as questionnaires are encoded respectively. The pain score of all the participants would be measured at the peak uterine contraction at the 4cm cervical dilation and at 10 cm dilation based on visual analog scale (VAS). Duration of the active phase of labor in these groups are recorded too. Data are imported into SPSS-16 software. First, normality of the data distribution will be investigated. To compare the labor duration among the research groups, ANOVA would be used, which will be followed, in case of significance, by the Scheffe post-hoc test. Furthermore, Chi-squared test would be used to compare the categorized demographic variables and ANOVA or Kruskal-Wallis tests will be used to compare the quantitative variables in the studied groups. significance level of 0.05 is considered significant.

Discussion

In this study the effect of auricular acupressure and body acupressure on pain and duration of first stage of labor will be compared.

Background

Labor pain is one of the most intense pains experienced by women during their lifetime.(1, 2) Labor pain is caused by the interaction of physiological factors, such as uterine contractions and cervical dilation, and psychological factors, such as fear and anxiety.(3) Labor pain engenders an experience, from which most women tend to avoid and is always a source of anxiety and distress for pregnant women.(4) A considerable portion of C-section (CS) deliveries has been performed merely due to mothers' fear from labor pain.(5)

Labor pain relief methods are divided into two major groups, namely pharmacological and non-pharmacological techniques.(6) The most common technique for relieving pain of labor is the use of medications, known as pharmacological methods. However, the potential side-effects of pharmacological

methods for fetus and mother have resulted in a growing interest in the use of non-pharmacological labor pain relief techniques.(7)

Acupressure is a non-pharmacological pain relief method, which is based on the principles of TCM (*traditional Chinese medicine)*.. There are several acupressure points on the body for the progression of birth and reduction of its pain, the stimulation of which is believed to induce stimulation of uterine contractions and, consequently, progression of birth, on the one hand, and balance of energy as well as reduction of labor pain, on the other hand.(8) Among the numerous points used in acupuncture and acupressure for labor induction and management, the *Sanyinjiao* (SP6), *Taichong* (LV3), *Ciliao* (BL32), *Weishu* (BL21), *Shangliao* (BL31), and *Hogu* (LI4) can be mentioned.(8) Various studies have reported reduced labor pain achieved by single stimulation or a combination of two points.(9–12) Besides, the GB21, BL32, LI4, and SP6 are the major points commonly proposed for enhancing uterine contractions, hard and prolonged labor, and dropping improvement. Results of an observational study of women receiving acupuncture as part of their antenatal care showed 35% reduction in the use of labor induction, 31% reduction in epidural analgesia, 9% increase in the natural birth success rate, as well as shorter duration of labor among the women in the group undergoing acupuncture compared to the local population rates.(13) Moreover, in a systematic review conducted to investigate the effect of acupressure on the onset and duration of labor, *Mollart et al.* (2015) reported acupressure could significantly reduce labor duration in the intervention group compared to the standard care and control groups.(14) Theoretically, when labor has a slow procedure and contractions are not intense enough, the cervical dilation will be slow as well. Stimulating the acupoints (acupuncture and acupressure points) can yield a balanced labor by adjusting the contractions and improved contractions can thereby lead to reduced labor duration.(15)

Auriculotherapy (AT) (also known as auricular therapy) is a branch of acupressure spreading throughout the world. Auricular therapy is based on long-standing tradition and was modified and updated by Dr. Paul Nogier. Also, World Health Organization considers auricular therapy a form of microacupuncture that can affect the whole body.(16) AT subsumes several types including auricular acupuncture, electro stimulation, and acupressure. Various studies have reported promising results in terms of the effects of using AT on the control of pain caused by backache,(17) pelvic fractures,(18) dysmenorrhea,(19–21) and polycystic ovarian syndrome.(22) However, there are only a limited number of studies on the effect of auriculotherapy on labor pain, which have yielded inconsistent results. Accordingly, in *Rastegarzadeh*'s work, auriculotherapy led to a significant reduction in the labor pain among nulliparous women, whereas *Maftoni*'s study indicated that use of auriculotherapy caused no significant reduction in the studied women's labor pain.(23, 24)

As can be inferred from investigations, most of the studies on body acupressure have more frequently applied pressure on one or two points; only a few studies have been focused on a combination of the points affecting the pain and progress of labor. Furthermore, some studies have been conducted on the effect of auricular acupressure on the reduction of different pain throughout the body, the results of which have confirmed the effectiveness of this technique. However, only a few studies have addressed

the effect of auricular acupressure on labor pain, which have yielded inconsistent results.(3, 4) As few number of studies on the effect of body acupressure at multiple points and auricular acupressure on the pain and duration of labor, the present study were designed. In the present clinical trial, the primary objective is to compare the effects of auricular acupressure, body acupressure, and routine treatment on the pain score in the 4cm and 10cm cervical dilations. Besides, the secondary objective is to investigate the effects of the described interventions on the duration of the first stage of labor, which is defined as the time interval between the 4cm and 10cm cervical dilations. This is a single-center, parallel, double blinded randomized controlled trial to investigate the superiority of *auricular acupressure, body acupressure* compared with *routine care* during first stage of labor. Allocation ratio of each group is 1:1:1.

Methods/design

Research setting and design

The present randomized controlled trial with parallel control group will be conducted on all the pregnant women referring to Kowsar Hospital in Qazvin for labor that tended to participate in the study and met the inclusion criteria. Qazvin is the largest city and capital of the province of Qazvin in Iran and located in 150 km (93 mi) northwest of Tehran, in the Qazvin Province, it is at an altitude of about 1,800 m (5,900 ft) above sea level.

Intervention and comparator

The participants are divided into three groups, namely *body acupressure* (*Intervention−1),, auricular acupressure* (*Intervention−2),,* and *routine care* (*Comparison)* groups (Fig.1).

Inclusion and exclusion criteria

Inclusion criteria

The inclusion criteria in the present study included primigravida women, aging 19–35 years old, gestational age of 37–42 weeks, singleton pregnancy, cephalic presentation, no history of chronic diseases such as diabetes, cardiovascular diseases, hypertension, hepatic and renal disorders, etc., lack of pregnancy complications such as preeclampsia, gestational diabetes, bleeding, etc., height of above 150 cm, and admission at the beginning of the active phase (3–4cm dilation).

Exclusion criteria

Refusal to continue participation in the study, receiving pain relief drugs 3 h before or during the study, labor induction or enhancement by medications, and emergency CS birth constituted the exclusion

criteria of this study.

Informed consent process

First author will explain the research objectives and method for those pregnant women having the inclusion criteria at the time of their admission to the labor and birth ward then, first author will obtain written consent from patients willing to participate in the trial.

Sample size estimation

To calculate the Minimal Clinically Important Difference (MCID) for the duration of the first stage of labor and the pain score, we used previous study data which examined the effect of auricular (24) and body (25) acupressure on labor pain intensity and labor duration. Using the method of Wyrwich et al, (26) MCID obtained 1 score for the score of pain. Using the G*Power software 3.1.9.2, α = 0.05 and power = 0.80, considering SD = 1.4 and M0 = 7.2 for the labor pain score and 10% drop in subjects, the sample size was calculated 30 patients for each group

Randomization and blinding

In order to determine the allocation sequence with 1:1:1 ratio, the person who isn't involved in the study will use the computer-generated 6-block randomization techniques. In order to allocation concealment, this person will write the type of intervention based on the predetermined sequence and put in opaque enveloped pockets; then, the pockets will be encoded. The questionnaires are encoded respectively as well. Accordingly, for a participant receiving the intervention in the pocket encoded with "1", a questionnaire with the same code will be completed. To observe blinding during data collection, one of the coworkers perform the intervention plan and another coworker who know nothing about the intervention, would collect the data. Finally, once the questionnaires are gathered and their data are imported into SPSS–16 software, it will be determined which codes should be assigned to *Group-A* and which codes to *Group-B* or *C.* Afterwards, analysis of the data will be performed. The person performing the data analysis would be also blind to the type of intervention of each group (Fig.1).

[Insert Fig. 1 here] Trial flow overview.

Follow-up

Assessments

Duration of the first stage of labor is determined in minutes and written in the questionnaire. To assess the pain score, a visual pain measurement VAS (*visual analogue scale)* ruler will be used at 4 and 10cm

dilations. Furthermore, the midwifery and demographic characteristics questionnaires are completed after finishing the birth.

Administration of intervention

Selection of Acupoints is based on ear and body microsystems and meridians. There are some treatment plans that include a combination of some acupoints for every problem. These selections of points are originally derived from treatment plans developed in China, but modified by auriculotherapy discoveries in Europe and the United States. Theoretically every acupoints can exert some identified effect for the selected condition. (27–30). For the present research, a set of primary and master acupoints was selected. Using combination sets of points is proposed to be more effective than single points. As there was scant evidence on efficacy of applying multiple acupoints, researchers aimed to investigate efficacy of multiple acupoints on labor pain and duration.

In the *body acupressure* group, the pressure is applied to the GB30, GB21, BL32, LI4, and SP6 points (13, 29) (fig 3) by a researcher who had been well trained for this purpose. GB 21 point has an action of release and descent, which is purported to facilitate fetal descent in active phase and second stage of labor.(31) Stimulating LI 4 point is effective for reduction of labor pain and promoting stronger and/or more coordinated contractions.(9, 32–34) Stimulating BL 32 is effective for reduction of labor pain40 and induction of labor.(35, 36) One of the most important and frequently used points for obstetric and gynecologic concerns is SP 6. Indications of this point include labor augmentation, for irregular contractions to encourage efficient labor and reducing a persistent cervical lip (37–39) reduction of labor pain (34, 38–41) and reduction of the length of labor (34, 38). To perform the acupressure on the specified points on the body, each point would be pressed by the thumb for 2 min, so that one-third of the nail bed became white. Pressure to these points would be applied at 4, 6, and 8cm dilations.

[Insert Fig 2. here] Body acupoints

In the *auricular acupressure* group, the pressure would be applied to the Master auricular Points on the external ear (point Zero, Shen Men point, and thalamic point) and Primary auricular points (Uterus points 1 and 2, external genitalia point, oxytocin and/or prostaglandin points) (27) by a well-trained researcher. Ear acupoints are shown in figure 3. The master points are so identified because they are typically active in most patients and they are useful for the treatment of a variety of health disorders. Point Zero brings the whole body toward homeostasis, producing a balance of energy, a balance of hormones, and a balance of brain activity and is frequently combined with the Shen Men point for treatment of most health disorders. The purpose of Shen Men is to tranquilize the mind and to facilitate a state of harmony, serenity, and a deeper connection to one's essential spirit. This master point alleviates stress, pain, tension, anxiety, depression, insomnia, restlessness, and excessive sensitivity. Thalamic point affects the relay of sensory information to the cerebral cortex and modulates hypothalamic regulation of autonomic nerves and endocrine glands. It is also used for alleviating most pain disorders, both acute and chronic. Primary auricular points are the most effective set of auricular points for the treatment of a health

disorder in a particular body organ or for a physiological dysfunction.(27) The given pressure would be applied using an adhesive containing auriculotherapy-specific Vakharia seeds. Furthermore, auricular stimulation at the specified points would be performed every 30 min. It should be noted that the comparator group received the routine care (fig. 4).

[Insert Fig 3. here] Ear acupoints

[Insert Fig. 4 here] SPIRIT Schedule of enrolment, interventions, and assessments

Intervention fidelity

One of the researchers (MG) who is responsible for intervention is trained to perform auriculotherapy. Training and monitoring of her performance on implementing the intervention will be carried out by MV, who is expert in this field.

Primary outcome measurements

Pain score in first stage of labor: In the present study, the pain score (pain intensity) at 4 and 10 cm dilations is measured in all three groups using VAS scale and, then, compared.

Additional outcomes

Duration of first stage of labor: The present study is aimed to determine whether the auricular acupressure and body acupressure would reduce the duration of the first stage of labor in nulliparous women compared to the routine care.

Data collection and storage

Based on the predetermined allocation sequence, the studied women are divided into three groups, including *auricular acupressure, body acupressure,* and *routine care* groups. The pain score of all the participants would be measured at the peak uterine contraction at the 4cm cervical dilation and, then, recorded in the questionnaire. Subsequently, at 10 cm dilation, the pain score of all the participants in the three groups would be re-measured and recorded. Furthermore, in order to investigate the duration of the active phase of labor in these groups, the onset and termination times of the active phase of the first stage of labor are recorded in the questionnaire. The difference of these two recorded times indicated the duration of this stage. The remaining parts of the questionnaire are completed after the birth. Because it is not applicable Follow-up to this study we will not form the Data Monitoring Committee.

Data analysis

Once being collected, the data are imported into SPSS–16 software. Firstly, normality of the data distribution will be investigated (via three methods, including Kolmogorov-Smirnov, Histogram, and dispersion and central indices) and if the distribution of variables is not normal, then it will be used appropriate transformation. To compare the labor duration and pain score among the research groups, one way ANOVA test would be used, which will be followed, in case of significance, by Scheffe post-hoc test. If there is a potential confounding variables, the multiple linear regression test will be used. We will check for the assumptions and concerns of the regression model. Furthermore, Chi-squared test would be used to compare the categorized demographic variables in the studied groups. On the other hand, in order to compare the quantitative variables, in case of normal and abnormal distribution of the variables, ANOVA and Kruskal-Wallis tests are used, respectively. The post-hoc of these tests will be reported if needed. The study will be analyzed using an intention-to-treat (ITT) approach and using multiple imputation strategy to account for missing outcomes in ITT. Also, apropos of the significance level, 0.05 is considered significant.

Reporting of adverse events

Any kind of unwanted outcome in the participants will be reported.

Patient and public involvement

Patients and public were not directly involved in the development of this study protocol. However, the development of the research question and outcome measures is according the previous published studies on patients' priorities, experience, and preferences. We will disseminate results to the study participants through the journal publication, as well as from research conferences.

Discussion

Improving the health of mothers and babies is one of the international obligations of the country in line with the Millennium Developing Goals. Achieving these goals involves reducing the maternal and neonatal mortality rate due to complications of pregnancy and delivery, reducing the cesarean section without indication and promoting normal delivery (42). One way to promote natural childbirth is a painless labor. The American College of Obstetricians and Gynecologists has confirmed that the request for pain relief from the patient is indicative of the need for pain relief (43). Labor pain relief methods are divided into non-pharmacological methods and pharmaceutical methods. Hypnosis, Acupuncture, Therapeutic Touch, Relaxation, Massage Therapy, Music Therapy are non-pain relief methods (6). Systemic medications, inhalation anesthesia, local anesthesia and general anesthesia are drug methods of pain relief (43).

Based on available scientific resources, massage can reduce labor pain by the gate control mechanism of pain. In this way, massage activates large neural fibers and closes the gates of pain transfer. Another

theory in this area is that massage may release endorphins and thereby reduce the pain (44). In this study we will compare the effect of auricular acupressure and body acupressure on labor pain. In addition, we will study the effect of the two noted methods on duration of first stage labor.

Declarations

Trial status

Recruitment has begun since August 2018 and is still ongoing. Data collection will probably complete in December 2018.

Author Contributions

FK, ZA, and MV designed the study and prepared the protocol. MG performed the interventions and ZA carried out the data collection and completion of the questionnaires. All the authors scrutinized and confirmed the final protocol.

Funding

This work is supported by Vice Chancellor for Research and Technology, Qazvin University of Medical Sciences, Qazvin, Iran. But no financial support would be received to disseminating and publishing protocol and results of the study.

Ethical Approval and Consent to participate

After explaining the aim and procedure of study and their autonomy to involve or leave study, written informed consent will be acquired. Participation in the study would be voluntary and the participants would be reassured that their refusal to participate in the project would have no impact on their required care services. Personal contact information would be accessible only to the research team members. The questionnaires will be completed using codes assigned to patients (and without mentioning patients' names). The results of this study will be disseminated at several research conferences and as published articles in peer-reviewed journals. The present study protocol was prepared in accordance to the Standardized Protocol Items: Recommendations for Intervention Trials (SPIRIT) statement (45). The present study is established in Committee of Ethics, Qazvin University of Medical Sciences and coded IR-QUMS.REC.1396.416. In addition, it has been registered in *Iranian Registry of Clinical Trials* with the code of IRCT20180218038789N1 in 2018–03–04. If important modifications are made, the Ethics Committee of the Qazvin University of Medical Sciences would be informed, and new protocols would be uploaded to IRCT.

Consent for publication

Not applicable.

Availability of supporting data

Original research data could be requested from the corresponding author.

Competing interests

The authors declare that they have no competing interests.

Authors' information

[1] Ph.D. Assistant Professor of Midwifery, Social Determinants of Health Research Center, Research Institute for prevention of Non-Communicable Diseases, Qazvin University of Medical Sciences, Qazvin, Iran. [2] Ph.D. Department of midwifery, school of nursing and midwifery, Hamadan University of Medical Sciences, Hamadan, Iran. [3] PhD. Nursing and Midwifery Care Research Center, Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran. [4] MSc. Kowsar clinical & educational center, Qazvin University of Medical Science, Qazvin, Iran.

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Table

Table 1. Recommendations for Intervention Trials (SPIRIT) statement

Section/item	ItemNo	Description	Page No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1, 2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	10
	2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	3	Date and version identifier	n/a
Funding	4	Sources and types of financial, material, and other support	11
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	11
	5b	Name and contact information for the trial sponsor	11
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4, 5
	6b	Explanation for choice of comparators	n/a
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants,			

interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	n/a
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence	16a	Method of generating the allocation sequence (eg,	7

generation		computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	This part will be explained when publishing results
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9, 10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	9, 10
	20c	Definition of analysis population relating to protocol	9, 10

		non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	9
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	10
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	10
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	10
Access to data	29	Statement of who will have access to the final trial	10

		dataset, and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	10
	31b	Authorship eligibility guidelines and any intended use of professional writers	Author Contributions is written in page 10
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	10
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	They are all acquired/ if necessary will be downloaded
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

Figures

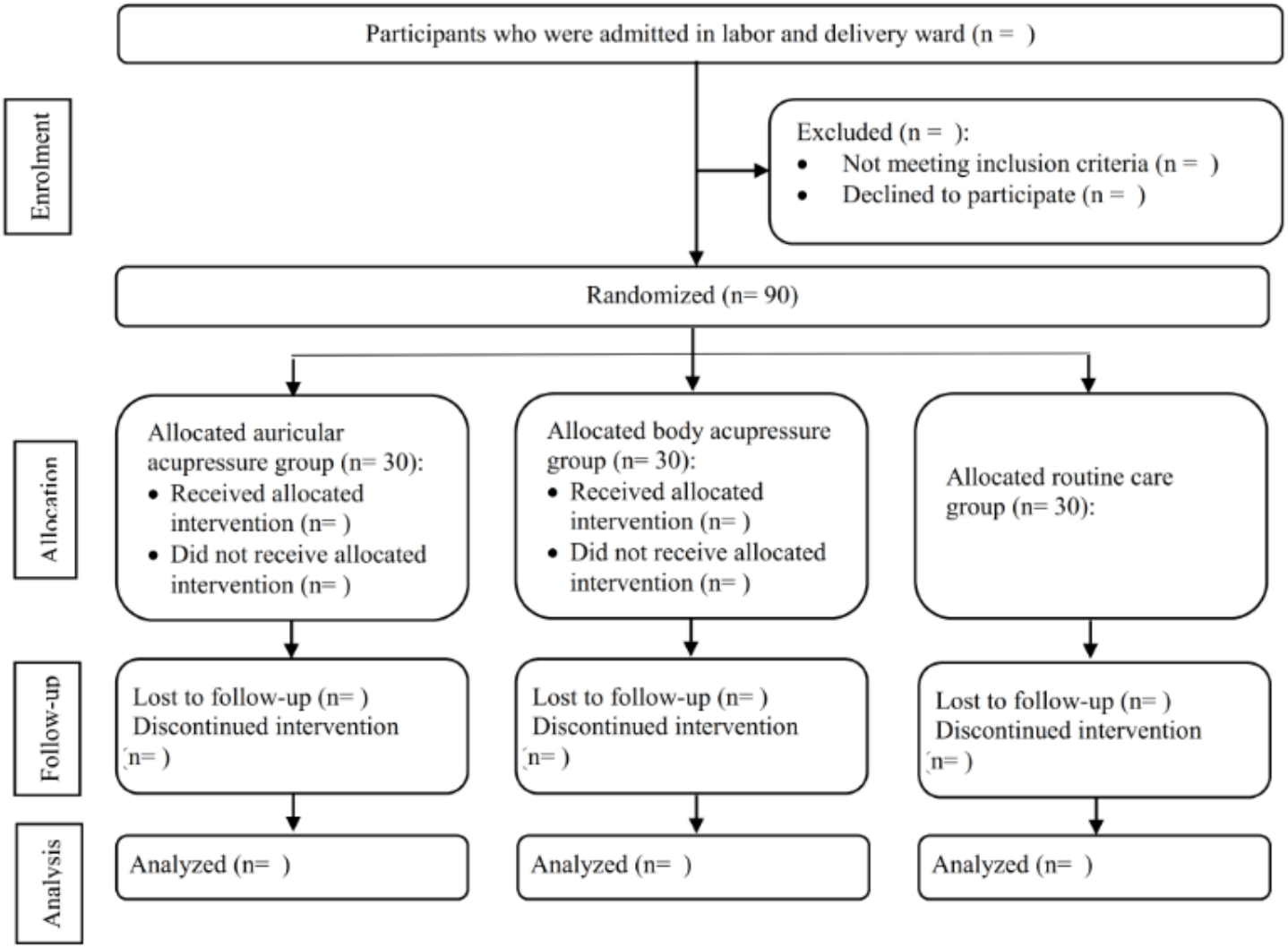

Figure 1

Trial flow overview.

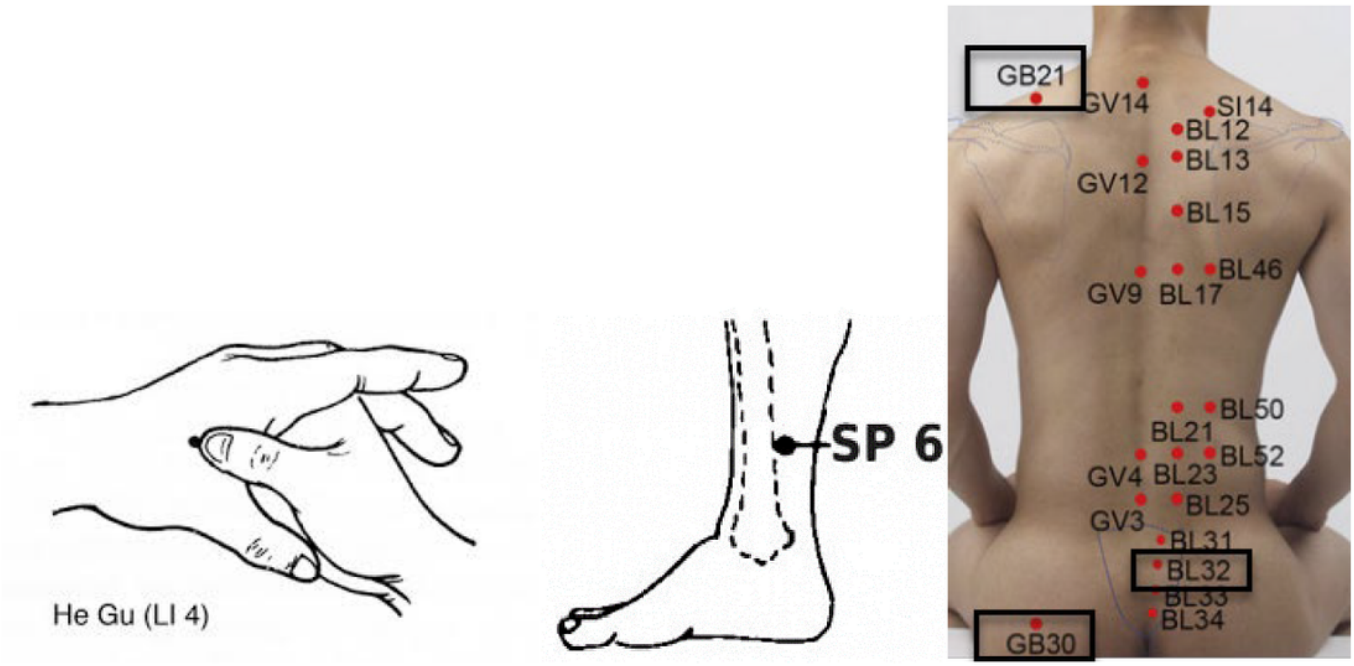

Figure 2

Body acupoints.

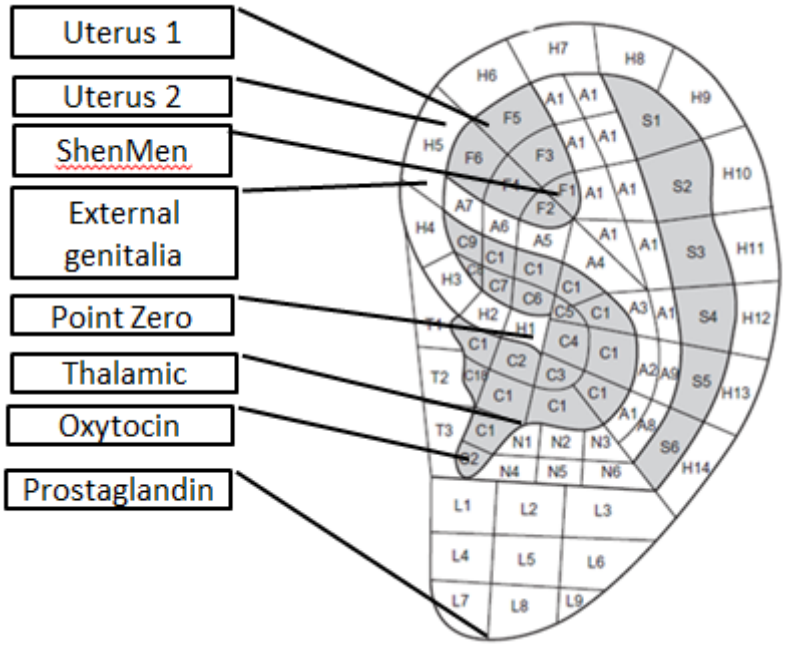

Figure 3

Ear acupoints.

	STUDY PERIOD			
	Enrolment	Allocation	Post-allocation	
TIMEPOINT**	$-T_1$	T_0	T_1	T_2
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
Randomization by independent researcher	X			
Allocation (after baseline assessments)		X		
INTERVENTIONS:				
Intervention group 1: body acupressure		—	—	
Intervention group 2: auricular acupressure		—	—	
Control group: routine care		—	—	
ASSESSMENTS:				
[Demographic and background variables]	X	X		
[Primary outcome variables: Pain score in first stage of labor]		X	X	
[Secondary outcomes Duration of first stage of labor]		X	X	

Figure 4

SPIRIT Schedule of enrolment, interventions, and assessments.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SPIRITChecklistdownload8Jan13.pdf