Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of Virtual Reality and Acupressure at the SP6 Point on Labor Pain Intensity and Anxiety in Primiparous Women: A Randomized Clinical Trial

Protocol summary

Study aim
Comparing the effects of virtual reality and SP6 acupressure on labor pain and anxiety in nulliparous women during the active phase of labor.

Design
Randomized controlled clinical trial with three parallel groups and pretest-posttest design.

Settings and conduct
Study setting: Labor wards of Hazrat Abolfazl and Motazedi hospitals, Kermanshah. Eligible primiparous women (37–42 weeks, active labor, dilatation >6 cm) will be randomized into three groups: 1) VR group: 20-minute VR headset use with nature scenes and relaxing audio; 2) Acupressure group: SP6 point pressure applied by a researcher for 15 minutes (3–5 min intervals) until 8 cm dilatation; 3) Control: Routine care

Participants/Inclusion and exclusion criteria
Inclusion criteria: Nulliparous women, 37–42 weeks singleton pregnancy, cephalic presentation, intended vaginal delivery, active labor (cervical dilatation >6 cm), and providing informed consent. Exclusion criteria: Indicated cesarean section or acute maternal/fetal complications during labor.

Intervention groups
Participants will be randomly allocated into three parallel groups: 1) Virtual reality group (VR intervention); 2) SP6 acupressure group (acupressure at SP6 point); 3) Control group (routine intrapartum care).

Main outcome variables
Outcomes: Labor pain intensity (Visual Analog Scale - VAS); labor anxiety (State-Trait Anxiety Inventory - STAI).

General information

Reason for update

Acronym
VR vs SP6 Acupressure in Labor

IRCT registration information
IRCT registration number: **IRCT20260720070269N1**
Registration date: **2026-09-10, 1405/06/19**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-10, 1405/06/19**
Update count: **0**

Registration date
2026-09-10, 1405/06/19

Registrant information

Name
Kimia Karimi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date
2027-02-26, 1405/12/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Virtual Reality and Acupressure at the SP6 Point on Labor Pain Intensity and

Anxiety in Primiparous Women: A Randomized Clinical Trial

Public title
Comparison of the Effectiveness of Virtual Reality and Acupressure on Labor Pain Intensity and Anxiety in Women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Nulliparous pregnant women with a singleton, cephalic, term pregnancy (37–42 weeks of gestation).Singleton pregnancy.Intention to undergo vaginal delivery.Ability to understand the study procedures, pain assessment scale, and questionnaire content, and to complete the questionnaires.Voluntary participation in the study and provision of written informed consent.Enrollment during the active phase of the first stage of labor (cervical dilatation >6 cm).Moderate or greater labor pain according to the pain intensity assessment tool.No chronic medical conditions or obstetric complications that could affect labor (e.g., hypertension, gestational diabetes, etc.).No history of psychiatric disorders.Pregnancy not achieved through assisted reproductive technologies (ART).No previous experience with virtual reality technology.No history of receiving systemic analgesics or sedatives before labor that could influence pain intensity or response to non-pharmacological interventions.Absence of fetal abnormalities, including major chromosomal or structural anomalies, fetal growth restriction, amniotic fluid disorders, and significant placental abnormalities.

Exclusion criteria:
Conversion of vaginal delivery to cesarean section at any stage of labor due to obstetric or emergency indications.Occurrence of any acute and unforeseen maternal or fetal complication (e.g., fetal distress, severe hemorrhage, or sudden fetal heart rate abnormalities) that makes continuation of the intervention or data collection impossible, even if cesarean section is not performed.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly allocated to the study groups using block randomization with a 1:1:1 allocation ratio. The random allocation sequence will be generated by a computer using randomly permuted blocks, and participants will be assigned according to the predetermined randomization list.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will be conducted as a single-blind trial. The statistician responsible for data analysis will be blinded to group allocation. The data will be coded before analysis, and the intervention groups will not be identifiable to the data analyst.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ilam University of Medical Sciences

Street address
Shahrak Shahrdari, Block 51, Row 3

City
Kermanshah

Province
Kermanshah

Postal code
6717768634

Approval date
2026-07-07, 1405/04/16

Ethics committee reference number
IR.MEDILAM.REC.1405.087

Health conditions studied

1

Description of health condition studied
Nulliparous women with singleton cephalic term pregnancy (37–42 weeks of gestation) in the active phase of labor.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Labor pain intensity and maternal anxiety during the active phase of labor.

Timepoint
Measurements will be taken at baseline, during the active phase of labor, and immediately post-delivery.

Method of measurement
Labor pain intensity will be measured using the Visual

Analog Scale (VAS), and labor anxiety will be assessed using the State-Trait Anxiety Inventory (STAI).

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Participants receive routine prenatal care according to the health center protocol and do not receive the BASNEF model-based educational intervention.
Category
Lifestyle

2

Description
Intervention group: Participants receive a BASNEF model-based educational program in addition to routine prenatal care.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Moatazedi Hospital
Full name of responsible person
Kimia Karimi
Street address
Ferdowsi Square, Moatazedi Hospital, Kermanshah, Iran
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motazedihospital.kermanshah@gmail.com
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Sponsors / Funding sources

1

Sponsor
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Ilam University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Kimia Karimi
Position
Midwife
Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available