Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of virtual reality and acupressure on pain intensity and duration of the first stage of labor on primiparous

Protocol summary

Study aim

- Determine the effect of virtual reality and acupressure on pain level of first stage of labor in primiparous women
2- Determine the impact of virtual reality and acupressure on the length of the first stage of labor in the first stage of labor in primiparous women

Design

Clinical trial with control group, parallel intervention groups including acupressure and virtual and hybrid reality, without blinding and randomization by permutation block method

Settings and conduct

The sampling location of Imam Khomeini Hospital in Esfarayen is that the primiparous mothers who have inclusion criteria are randomly assigned to the intervention groups and the intervention is performed for them in the control group only routine care is performed. The essence of the study is that it is not blinded.

Participants/Inclusion and exclusion criteria

Pregnant women, first childbirth, gestational age 37 weeks to 41 weeks (based on first trimester abdominal or vaginal sono or first last menstrual day), having a healthy, single fetus, vertex fetus presentation, not having a high-risk pregnancy, no history or current mental illness under medication, no Chronic diseases (diabetes, hypertension, heart, pulmonary disease), lack of specific skin diseases, eye diseases and Initialize active phase of labor

Intervention groups

In acupressure group, pressure on sp6 and L14 points Virtual Reality Group Virtual reality headset with tranquil three-dimensional landscapes such as beach, river and waterfall The combination group will use acupuncture and virtual reality headsets at the same time. The control group will receive routine childbirth care. These interventions are performed and labor duration and pain rate recorded in 4 cm dilatation 5-7 cm and 8-10 cm in 4 groups.

Main outcome variables

Pain score Visual analog scale of pain and duration of active phase of labor per hour

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191221045832N1**
Registration date: **2020-01-09, 1398/10/19**
Registration timing: **prospective**

Last update: **2020-01-09, 1398/10/19**
Update count: **0**

Registration date

2020-01-09, 1398/10/19

Registrant information

Name

ali asghar firouzian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3155 0623

Email address

a.firouzian@esfrums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-04-22, 1400/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of virtual reality and acupressure on pain intensity and duration of the first stage of labor on primiparous

Public title
The effect of virtual reality on labor pain

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
To have informed consent. Iranian citizenship. Be married. At least a diploma degree. First childbirth. The gestational age is 37 weeks to 41 weeks. (Based on Sono first trimester abdominal or vaginal or first day of last menstruation). Pregnancy asked. Have a live, healthy and singleton fetus. Show the vertex embryo. Do not have a high-risk pregnancy. Do not use opiates, alcohol or psychotropic drugs No primary indication for cesarean section. Not suffering from chronic diseases (diabetes, hypertension, heart, lung). Do not suffer from specific skin diseases and eye diseases. She plans to give birth at Imam Khomeini Hospital in Esfarayen. There have been no accidents for the mother in the past six months. The active phase of labor has begun. The age of the mother is between 18 and 35 years.

Exclusion criteria:
Have a history of hypertension or gestational diabetes. Have a family history of difficult childbirth The fetus weighs more than 4 kg. Amniotic fluid index greater than 24 cm.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **33**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling is done by random permutation blocks. So that 6 blocks of 20 and one of 12 blocks are specified. Within 5 blocks, 5 replicates and 3 replicates in each block were randomly assigned using unbiased coin method. After specifying the samples in each block, the blocks are also randomly selected.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of Esfarayen Faculty Of Medical Sciences

Street address
Imam Reza Street, Shahid Rajaei, EsfarayenEaculty Of Medical Sciences

City
Esfarayen

Province
North Khorasan

Postal code
96618-76981

Approval date
2019-12-09, 1398/09/18

Ethics committee reference number
IR.ESFARAYENUMS.REC.1398.011

Health conditions studied

1

Description of health condition studied
labor pain

ICD-10 code
O80.0

ICD-10 code description
Pregnancy, childbirth and the puerperium, Delivery, spontaneous vertex delivery

Primary outcomes

1

Description
Visual Analogue Scale of Pain.

Timepoint
Pain score before intervention, 5 to 7 cm cervical dilatation, 8 to 10 cm cervical dilatation.

Method of measurement
Visual Analogue Scale for pain

2

Description
Duration of active phase of labor per hour.

Timepoint
duration of labor from 5 cm to 10 cm

Method of measurement
stopwatch for active phase duration

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Virtual Reality Group: 33 people with inclusion criteria turn their eyes on the active phase of the virtual reality headset that will use distracting three-dimensional landscapes such as beach, river and waterfall.
Category
Rehabilitation

2

Description
Intervention group: Acupuncture group: With the onset of the first contraction, points L14 and SP6 are gently pressed for 30 seconds and gradually added to the pressure level to become completely intense. The thumb is then held in place for 1 minute and then the pressure is gradually lowered, releasing the point within 30 seconds. This intervention is performed for 20 minutes only during contractions.
Category
Rehabilitation

3

Description
Intervention group: Combining Acupuncture and Virtual Reality Interventions
Category
Rehabilitation

4

Description
Control group: Routine childbirth care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Esfarayen's Imam Khomeini hospital
Full name of responsible person
Ameneh Safari
Street address
Imam Reza Street, Shahid Rajaei, Esfarayen Faculty Of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfarayen University of Medical Sciences
Full name of responsible person
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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
Esfarayen University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfarayen University of Medical Sciences
Full name of responsible person
Ameneh Safari
Position
Educator, Faculty Member
Latest degree
Master
Other areas of specialty/work
Health Information Technology
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Person responsible for updating data

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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