Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of virtual reality (VR) on pain management during labor

Protocol summary

Study aim
Pain management during labor through a non-pharmacological and low-cost method called virtual reality in order to encourage women to natural child birth

Design
A clinical trial with a control and an intervention groups, randomized by permutation block method

Settings and conduct
This clinical trial investigates the effect of virtual reality on labor pain management in the first and second stages of childbirth; it will be accomplished in Imam Khomeini Hospital, Tehran, Iran on 24 women in the control group and 24 women in the intervention group.

Participants/Inclusion and exclusion criteria
Eligible patients are any woman giving birth for the first time at after 38 weeks, who does not have a desire to a non-pharmacologic alternative for pain control, who has a low risk pregnancy without obstetric complications. Exclusion criteria include the need to use other methods of analgesia (epidural analgesia or other opioids) and age<18 and age>45.

Intervention groups
For mothers presenting in labor with standard care, the patient will experience their contractions while using Virtual Reality. Control group: For mothers presenting in labor with standard care the patient will experience their contractions. Then, both groups will be asked to answer pain and satisfaction questionnaires.

Main outcome variables
Pain and Anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181224042099N1**
Registration date: **2019-06-25, 1398/04/04**
Registration timing: **prospective**
Last update: **2019-06-25, 1398/04/04**
Update count: **0**

Registration date
2019-06-25, 1398/04/04

Registrant information

Name
Narges Momenyan

Name of organization / entity
Tarbiat Modares University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2019-08-11, 1398/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of virtual reality (VR) on pain management during labor

Public title
Investigating the effect of virtual reality (VR) on pain management during labor

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
The moder's nationality should be Iran and must be able to read and write. The delivery type should be vaginal delivery. Any woman giving birth for the first time at after 38 weeks The mother does not have drug addiction. The mother does not suffer from a known chronic disease such as diabetes, hypertension, heart disease and infectious diseases. The mother does not have a bad memory of the simulated environment The mother does not have a desire to a non-pharmacologic alternative for pain control Low risk pregnancy without obstetric complications
Exclusion criteria:
Need to use other methods of analgesia (epidural analgesia or other opioids) Younger than 18 or older than 45 years of age Presence of fetal or placental anomaly Any face/head/neck injuries that interfere with the use of Virtual Reality headset Seizure history

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by permutation block method with the size of block 2, so that the number of samples in the two groups would be equal. For this purpose, dual blocks will first be created from codes A and B. Then, according to the random number table, a sequence of these dual blocks will be formed. According to the patient's number, the code A or B would be assigned to the patient according to the sequence, so that patients with code A will be in the intervention group and the patients with code B will be in the control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tarbiat Modares University

Street address
No. 7, Al Ahmad Street

City
Tehran

Province
Tehran

Postal code
1411713116

Approval date
2019-01-01, 1397/10/11

Ethics committee reference number
IR.MODARES.REC.1397.170

Health conditions studied

1

Description of health condition studied
Pain management during labor

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain

Timepoint
One time in the active phase of first stage of labor for the duration of one minute after 10 minutes of contractions, One time in the second stage of labor for the duration of one minute after 10 minutes of contractions

Method of measurement
Visual Analogue Scale questionnaire

2

Description
Anxiety

Timepoint
One time in the active phase of first stage of labor for the duration of one minute after 10 minutes of contractions, One time in the second stage of labor for the duration of one minute after 10 minutes of contractions

Method of measurement
questionnaire

Secondary outcomes

1

Description
Nausea

Timepoint
One time in the active phase of first stage of labor for the duration of one minute after 10 minutes of contractions, One time in the second stage of labor for the duration of one minute after 10 minutes of contractions

Method of measurement
questionnaire

Intervention groups

1

Description
The interventions will be done in the active phase of first stage of labor for 3 contractions almost 10 minutes and in the second stage of labor for 2 contractions almost 10 minutes. The virtual reality headset will be fitted on the mother' head which through it, the mother sees the natural environment and hears the nature's sounds.

Category
Prevention

2

Description
Control group: mothers in in the active phase of first stage of labor for 3 contractions almost 10 minutes and in the second stage of labor for 2 contractions almost 10 minutes will be observed.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Khomeini Hospital

Full name of responsible person
Sedigheh Hantoushzadeh

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Chamran East Highway, Baqerkhan St

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http://ikhc2.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tarbiat Modares University

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
Tarbiat Modares University

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
Tarbiat Modares University

Full name of responsible person
Ali Asghar Safaei

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Informatics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
A paper entitled "Investigating the effect of Virtual Reality on pain management during labor"
When the data will become available and for how long
Start the access period 3 months after printing the results
To whom data/document is available
Researchers
Under which criteria data/document could be used
Research and continue it
From where data/document is obtainable
Narges Momenyan n.momenyan@modares.ac.ir; momenyan@gmail.com
What processes are involved for a request to access data/document
Send the email and make the necessary correspondence
Comments