

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

Country

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's 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

Street address

Chamran East Highway, Baqerkhan St

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Web page address

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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Mansoreh Movahedin

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Tarbiat Modares University, No. 7, Jalal Al Ahmad street, Tehran

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sedigheh Hantoushzadeh

Position

Professor

Latest degree

Specialist

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Gynecology and Obstetrics

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Narges Momenyan

Position

Student

Latest degree

Bachelor

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