Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Impact of augmented reality glasses on labor pain And Anxiety during the first stage of Labor in primiparous women

Protocol summary

Study aim
Determining the effect of using augmented reality glasses on the intensity of pain and anxiety during the first stage of labor in primiparas pregnant women

Design
A randomized, controlled clinical trial with parallel groups on 62 patients. Permutation blocks were used for randomization.

Settings and conduct
This study will be conducted Sina Hospital in Ahvaz. People who have the inclusion criteria will be identified at 37 weeks in the Sina Clinic and will participate if they wish. When they are admitted to the delivery room, they will be randomly divided into two intervention and control groups, For the intervention group, augmented reality glasses will be used at 4 to 5 and 7 to 8 cm cervical dilation. Routine labor care will be provided for both groups

Participants/Inclusion and exclusion criteria
Iranian primiparas women, 18 to 40 years, single pregnancy, gestational age 37 to 41 weeks, cephalic presentation, estimated fetal weight 2500 and 4000 grams, amniotic sac intact , presence of three spontaneous contractions in ten minutes, entry into active phase of childbirth, Absence of any medical and obstetric diseases, absence of depression according to Beck questionnaire, vision and hearing problems, history of severe headache and dizziness, history of migraine

Intervention groups
Augmented reality glasses will be used for the intervention group. This device is a smart glasses that connects to a mobile phone or laptop and can create a 360-degree and multi-dimensional video. The intervention content is two videos of children playing, the first at 4 to 5 cm dilation and the second at 7 to 8 cm dilation for 15 minutes. Routine labor care, including assessment of vital signs, fetal heart rate, fetal health assessment, and vaginal examinations, will be performed equally in the control and intervention groups.

Main outcome variables
labor pain, labor anxiety

General information

Reason for update
Acronym
AR: Augmented reality
IRCT registration information
IRCT registration number: **IRCT20241106063622N1**
Registration date: **2024-11-30, 1403/09/10**
Registration timing: **prospective**

Last update: **2024-11-30, 1403/09/10**
Update count: **0**
Registration date
2024-11-30, 1403/09/10

Registrant information
Name
Mona Sharifi
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-12-21, 1403/10/01
Expected recruitment end date
2025-04-21, 1404/02/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Impact of augmented reality glasses on labor pain And Anxiety during the first stage of Labor in primiparous women

Public title

Investigating the Impact of augmented reality glasses on labor pain And Anxiety during the first stage of Labor in primiparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian primiparous women maternal age between18 to 40 years gestational age 37 to 41 weeks cephalic presentation estimated fetal weight between 2500 and 4000 grams based on sonography presence of three spontaneous contractions in ten minutes three to four centimeters of cervical dilatation normal pelvic examination amniotic sac intact single pregnancy acceptance of augmented reality glasses consent to participate in the study

Exclusion criteria:

Presence of any medical and obstetrical diseases and problems Presence of depression according to the Beck questionnaire Vision and hearing problems History of severe headaches and dizziness History of migraines Mother's request for epidural anesthesia

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be selected based on the inclusion and exclusion criteria and then randomly assigned to intervention and control groups, using a permutation block design. Numbered sealed envelopes will be used for secret allocation.

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 Ahvaz University of Medical Sciences

Street address

Ahvaz Jundishapur University.,Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2024-11-02, 1403/08/12

Ethics committee reference number

IR.AJUMS.REC.1403.429

Health conditions studied

1

Description of health condition studied

Labor pain and anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Labor pain score on the Visual analogue Scale pain tool

Timepoint

At the beginning of the study and in cervical dilation of 4 to 5 and 7 to 8 centimeters, immediately before and after the intervention, and at the end of the study in the two intervention and control groups.

Method of measurement

To measure pain, a visual analogue scale is used, which is a 100 mm long line with 90 degree angles at each end. Bipolar markers are placed at each end of the line. These end markers cover the full range of possible sensations in the phenomenon being measured. In the present study, the no pain marker will be used at the left end and the worst possible pain marker will be used at the right end.

2

Description

Childbirth anxiety score on the Spielberg questionnaire

Timepoint

At the beginning of the study and in cervical dilation of 4 to 5 and 7 to 8 centimeters, immediately before and after the intervention, and at the end of the study in the two intervention and control groups.

Method of measurement

The Spielberg Anxiety Questionnaire will be used to

measure the level of anxiety. This test consists of two separate sections, overt and covert anxiety, and in this study, its situational section (overt anxiety), which consists of 20 questions related to fleeting emotional feelings of the subject dependent on specific and fleeting circumstances, will be used. The items of the Spielberg test are assigned a weight between 1 and 4 based on the answers provided. A score of 4 indicates a high level of anxiety, which is how the ten items of the overt anxiety scale are scored. Other items that indicate a lack of anxiety and are given reverse weight when scoring include items: 1-2-5-8-10-11-15-16-19-20. In this test, the anxiety score that can be obtained is between 20 and 80 (39). Scores of 20-30 indicate very mild anxiety, scores of 31-42 indicate mild anxiety, scores of 43-53 indicate moderate anxiety, and scores of 54 and above indicate severe anxiety.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Augmented reality glasses will be used for the intervention group. This device is a smart glasses that connects to a mobile phone or laptop and can create 360-degree and multi-dimensional video. These glasses include sensors such as cameras and lidar that are used to collect environmental information and images. The glasses track the user's location, by placing a digital object on a virtual map, the glasses analyze that object as if it were a real object. And it allows viewing 3D images in the real world. Before starting the study, how to put the glasses on the eyes and how to do the work will be explained to the intervention group. Two different 15-minute videos whose content will include children playing and the mother can interact with them are the content of the sermon. To produce these films, two children playing and performing tricks will be used with the consent of their mothers or through copyright-free films. The first film will be used at 4 to 5 cm dilation and the second film in 7 to 8 cm dilation with augmented reality glasses in a semi-sitting position for 15 minutes. Routine labor care, which includes assessment of vital signs, fetal heart rate, and fetal health assessment, will also be performed in the intervention group. According to the protocol, vaginal examinations will be performed every two hours in the active phase and fetal heart sounds will be measured every half hour. In the second stage of labor, vaginal examinations will be performed every half hour and fetal heart sounds will be measured every 15 minutes. The labor progress of all mothers will be plotted on a partograph form. It should be noted that whenever the mother experiences danger signs that require medical intervention, she will be removed from the program and therefore from the intervention or control group.

Category

Treatment - Devices

2

Description

Control group: Mothers in the control group will receive routine labor care, including assessment of vital signs, fetal heart rate, and fetal health assessment, similar to mothers in the intervention group. The only difference between the two groups will be that they will not use augmented reality glasses. Vaginal examinations will be performed every two hours during the active phase, and the fetal heart rate will be measured every half hour, according to the protocol.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital, Ahvaz

Full name of responsible person
Somayeh Makvandi

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Ahvaz., Jundishapur University,. Golestan Highway,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Vice President of Research and Technology, Jundishapur University of Ahvaz

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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
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Somayeh Makvandi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive health

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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