Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of using virtual reality on the fear and pain of labor in primiparous women referred to Alavi educational and therapeutic hospital in Ardabil city

Protocol summary

Study aim
The effect of using virtual reality on the fear and pain of labor in primiparous women referred to Alavi Medical Teaching Hospital in Ardabil.

Design
A clinical trial with 42 primiparous women were randomly assigned to intervention and control groups.

Settings and conduct
A trial on 42 primiparous women referred to Alavi hospital in Ardabil city, they are randomly assigned to two intervention and control groups. First, both groups answer Harman's fear of childbirth questionnaire. Then, VR glasses in the intervention group dilate 4-5 cm and load. He watches his favorite virtual reality movie for 20 minutes in 7-8 cm dilation

Participants/Inclusion and exclusion criteria
Conditions for inclusion in the study: primiparous women with gestational age of 38-41 weeks without chronic diseases Conditions of non-entry into the study, gestational age less than 37 weeks, blind

Intervention groups
Using virtual reality glasses on primiparous women in the intervention group for 20 minutes once in 4-5 cm dilation and once in 7-8 cm dilation. In the control group without virtual reality glasses, they will receive normal care

Main outcome variables
Fear of childbirth; pain of childbirth; virtual reality

General information

Reason for update
Write the actual sampling start and end dates.

Acronym

IRCT registration information
IRCT registration number: **IRCT20240917063073N1**
Registration date: **2025-02-05, 1403/11/17**
Registration timing: **prospective**
Last update: **2025-05-29, 1404/03/08**
Update count: **2**

Registration date
2025-02-05, 1403/11/17

Registrant information

Name
Mansoureh Delfekar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3337 1529

Email address
delfekarm@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-11, 1403/07/20

Expected recruitment end date
2024-12-10, 1403/09/20

Actual recruitment start date
2025-02-07, 1403/11/19

Actual recruitment end date
2025-04-09, 1404/01/20

Trial completion date
2025-04-09, 1404/01/20

Scientific title
The effect of using virtual reality on the fear and pain of labor in primiparous women referred to Alavi educational and therapeutic hospital in Ardabil city

Public title
The use of virtual reality on the fear and pain of labor

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparous women Gestation age 38 to 41 weeks No underlying disease singleton pregnancy

Exclusion criteria:

Chronic diseases Gestational age less than 37 weeks Mental illnesses blind people

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: **42**

Actual sample size reached: **42**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Ardabil University of Medical Sciences

Street address

At the end of University Street, the administrative complex of the University of Medical Sciences

City

Ardabil

Province

Ardabil

Postal code

8599156189

Approval date

2023-07-15, 1402/04/24

Ethics committee reference number

IR.ARUMS.REC.1402.099

Health conditions studied

1

Description of health condition studied

Fear of child birth

ICD-10 code

F40.232

ICD-10 code description

Fear of other medical care

2

Description of health condition studied

Labor pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

The variable of fear of childbirth is the fear score in the pre-test and post-test in the Harman questionnaire

Timepoint

The fear of childbirth questionnaire will be evaluated first at 4.5 cm dilation and then at 7.8 cm dilation.

Method of measurement

Harman fear of childbirth questionnaire

2

Description

Labor pain

Timepoint

At 4.5 cm dilation and then at 7.8 cm dilation

Method of measurement

visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

The fear questionnaire and pain intensity measurement scale (research tool) will be completed at the beginning of the active phase of labor (4-5 cm dilatation) for both groups, then the virtual reality headset will be provided to the participants after entering the active phase of labor (headset Virtual reality is a 3D glasses that the mother is asked to wear. The glasses contain relaxing images, including new immersive virtual environments such as orange sunsets, green meadows, blue oceans, red savannas. The mother chooses one of the images and watches for 20 minutes. The minimum time to use the headset will be 20 minutes until the end of the first stage of labor. The pain and fear of childbirth in the second stage will be evaluated at 4-5 cm dilatation and 7-8 cm dilatation.

Category

Prevention

2

Description
Control group: Routine delivery care for mothers and babies in the control group will be performed according to the hospital routine
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Alavi Hospital
Full name of responsible person
Mansoure Delfekar
Street address
Ayatollah Moghaddis Ardabili St. - Shahid Maadi St. - Alavi Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Fahad Pourfarzi
Street address
Jhanbazan Square, the end of University Street, above University Square - Ardabil Medical Sciences
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کدپستی: 5618953141
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Email
F.pourfarzi@arums.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Leila Reisy
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Shahada Highway, between Hafez and Saadi Bridge, Ardabil Nursing and Midwifery College
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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
Not applicable
Informed Consent Form
No - There is not 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
Not applicable
Data Dictionary
Not applicable