Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Virtual Reality Glasses on Childbirth Experience and Childbearing Desire

Protocol summary

Study aim

If the use of virtual reality (VR) headsets proves effective in enhancing the vaginal birth experience and increasing the willingness to have future children, this method could be implemented in maternity wards as a safe, low-cost, non-pharmacological intervention. Furthermore, the findings of this research can inform planning aimed at improving the quality of midwifery care, enhancing the childbirth experience, and supporting the country’s population policies.

Design

This is a randomized, single-blind, non-pharmacological clinical trial with parallel control groups and no separate phases. The "CREATE A RANDOMISATION LIST" computer program (available at https://www.sealedenvelope.com/simple-randomiser/v1/lists) was used for randomization.

Settings and conduct

Midwifery and childbirth care; Niknafs Maternity Hospital, Rafsanjan; parallel-group randomized clinical trial; block randomization; intervention consisting of virtual reality (VR) headsets and relaxing music versus routine care; data collection using a demographic and obstetric checklist, the CEQ 2.0 questionnaire, and a researcher-developed questionnaire on the desire to have children; blinding of the statistical analyst.

Participants/Inclusion and exclusion criteria

pregnant women visiting the Nik-Nafs Maternity Hospital in Rafsanjan who meet the inclusion criteria for the study.

Intervention groups

participants will be randomly assigned to either the intervention group (n=42) or the control group (n=42). In the intervention group, women in the active phase of labor will use virtual reality (VR) headsets—featuring 360-degree videos of natural landscapes accompanied by relaxing music—for a duration of up to 60 minutes, in addition to receiving routine care. The control group will receive standard midwifery care.

Main outcome variables

The childbirth experience is based on the CEQ 2.0 questionnaire score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261102071649N1**
Registration date: **2026-11-06, 1405/08/15**
Registration timing: **prospective**

Last update: **2026-11-06, 1405/08/15**
Update count: **0**

Registration date

2026-11-06, 1405/08/15

Registrant information

Name

fatemeh eskandarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3376 2446

Email address

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-11, 1405/08/20

Expected recruitment end date

2027-07-11, 1406/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Virtual Reality Glasses on Childbirth Experience and Childbearing Desire

Public title

The Effect of Virtual Reality Glasses on Childbirth Experience and Childbearing Desire

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study and sign an informed consent form Iranian nationality Singleton pregnancy Gestational age of 37 to 42 weeks Absence of uncontrolled conditions such as hypertension, diabetes, or thyroid disorders Being in the active phase of labor (6 cm cervical dilation) Absence of known visual or hearing impairments that would preclude the use of virtual reality (VR) headsets No history of diagnosed severe psychiatric disorders Absence of active neurological conditions associated with seizures

Exclusion criteria:

Unwillingness to continue participation at any stage of the research Intolerance to the use of virtual reality (VR) headsets (e.g., dizziness, nausea, headache, or severe discomfort) Failure to fully adhere to the intervention as per the research protocol Incomplete questionnaires Occurrence of any obstetric complication, including: labor dystocia, instrumental delivery, severe postpartum hemorrhage, umbilical cord prolapse, placental abruption, uterine rupture, seizures, or eclampsia Performance of an emergency Cesarean section Fetal distress or the need for emergency obstetric interventions

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Mothers were selected using a convenience sampling method. A total of 84 pregnant women were randomly assigned to either an intervention group or a control group using a block randomization technique with a block size of 6 (generated via the computer program "CREATE A RANDOMISATION LIST" at https://www.sealedenvelope.com/simple-randomiser/v1/lists). In each randomization step, one permutation—selected at random from all possible permutations (e.g., AAABBB, ABAABB, ABBAAB, ABBBAA, BBBAAA, etc.) determined the allocation of participants into the intervention group (n=42) and the control group (n=42). The randomization sequence and group assignments were placed inside sequentially numbered, opaque, sealed envelopes. Upon the enrollment of each participant, the researcher opened the corresponding envelope to determine the participant's group allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, blinding of participants and the researcher is not possible; however, statistical analysis will be performed by an individual who is unaware of the group assignments.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Central Headquarters, Rafsanjan University of Medical Sciences, Imam Ali Boulevard, Rafsanjan, Kerman, Iran.

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2026-10-28, 1405/08/06

Ethics committee reference number

IR.RUMS.REC.1405.133

Health conditions studied

1

Description of health condition studied

Childbirth Experience

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Childbearing Desire

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Childbirth Experience
Timepoint
On the first day postpartum, and after the mother's general condition has stabilized
Method of measurement
Childbirth Experience Questionnaire 2.0

Secondary outcomes

1

Description
Childbearing Desire
Timepoint
6 weeks postpartum
Method of measurement
Researcher-developed questionnaire on the childbearing desire

Intervention groups

1

Description
Intervention group: Participants in the intervention group (n=42) will use an immersive virtual reality (VR) headset specifically the SHINECON G04BS model in addition to receiving routine obstetric care in accordance with hospital protocols. The content will consist of high-quality 360-degree videos featuring tranquil natural settings such as lakes, underwater scenes, the aurora borealis, and mountain landscapes accompanied by relaxing music. Before the intervention begins, the mothers will be shown samples of the available videos and may select the environments they prefer. The intervention will be administered in person by a researcher or a midwife within the labor ward. The first session will commence at the onset of the active phase of labor (cervical dilation of 6 cm) and will last for approximately 20 minutes.Provided the mother consents, experiences no discomfort from using the headset (such as dizziness, nausea, or general unease), and remains in the active phase of labor, the use of the headset may be repeated for another 20 minutes following a 10- to 15-minute rest period. As labor progresses and cervical dilation reaches approximately 8 to 9 centimeters, the headset may be used again for approximately 20 minutes, subject to the mother's preference. Should the mother wish to continue using the device and provided her clinical condition remains appropriate further sessions are permitted, up to a total cumulative duration of 60 minutes during the active phase of labor; the minimum duration for any single intervention session is 20 minutes.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Nik-Nafs Maternity Hospital, Rafsanjan
Full name of responsible person
Maryam Mirmotallebi
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Nik Nafs Educational and Medical Center, Shohada Street, Rafsanjan, Kerman Province, Iran.
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Deputy for Research and Technology, Rafsanjan University of Medical Sciences
Street address
Research and Technology Deputy Office, Building No. 3, Central Administration, Imam Ali Boulevard, Rafsanjan, Iran.
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Fax
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Web page address
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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
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Fatemeh Eskandarzadeh
Position
Student
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Midwifery
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Details will be provided upon request.
When the data will become available and for how long
Access begins after the publication of results.
To whom data/document is available
Applications are open to academic, scientific, and industrial researchers.
Under which criteria data/document could be used
Scientific and Research
From where data/document is obtainable

Email of the person in charge
f.t.eskandarzade@gmail.com

What processes are involved for a request to access data/document

After authentication

Comments