

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Investigating effect of virtual reality Game Therapy on fear of child birth in primiparous women referring to perinatal clinic of Emam Khomeini hospital in Mahabad in 2021

Protocol summary

Study aim

Determining the effect of virtual reality-based play therapy on the severity of fear of childbirth in nulliparous women referred to the prenatal clinic of Emam Khomeini hospital in Mahabad in 2021

Design

A clinical trial with a control group, with parallel groups of 130 participants and allocating 65 people in the intervention group and 65 people in the control group randomly using block randomization method.

Settings and conduct

Research environment: Imam Khomeini Hospital, Mahabad Research population: All nulliparous women referred to the prenatal clinic of Imam Khomeini Hospital in Mahabad Research examples: Primiparous women with inclusion criteria Samples with inclusion criteria are selected by random sampling method.

Participants/Inclusion and exclusion criteria

Major Inclusion criteria: Willingness to participate in the study, Nulliparous women; Gestational age 37 full weeks of pregnancy and above, age 18 to 45 years of mother, single pregnancy Etc. Major non-entry criteria :Women with previous pregnancy experience, Primiparous women under 37 weeks of gestation, Twin pregnancies and more, Women under 18 and over 45 years.

Intervention groups

Intervention group: The virtual reality headset will be provided to the members of the intervention group after entering the active phase of labor and regular uterine contractions as many times as the participant wants. It depends, but the minimum time to use the headset will be 20 minutes until the end of the first stage of labor (10 cm dilation) . Control group: do not receive any intervention and receive routine care according to the hospital routine.

Main outcome variables

The main variable in the present study is the fear of

childbirth. In this study, the degree of fear of childbirth means the score that pregnant women gain before and after the intervention based on the Harman fear of childbirth questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200808048334N1**

Registration date: **2021-03-01, 1399/12/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-01, 1399/12/11**

Update count: **0**

Registration date

2021-03-01, 1399/12/11

Registrant information

Name

halime Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 4222 1227

Email address

mid.asrin.m@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2641-12-22, 2020/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating effect of virtual reality Game Therapy on fear of child birth in primiparous women referring to perinatal clinic of Emam Khomeini hospital in Mahabad in 2021

Public title
Investigating effect of virtual reality Game Therapy on fear of child birth

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous women Gestational age 37 weeks and older single pregnancy Women 18 to 45 years old
Exclusion criteria:
Primiparous women with twin pregnancies and more Illiterate women Women with vision or hearing problems Women with chronic diseases History of mental illness

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: **130**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be divided into two groups of intervention and comparison by Blocked Randomization method. In this study, the allocation of two groups of intervention and comparison will be such that all possible modes for placing the letters A and B in the four blocks will be considered, which includes a total of 6 modes. These 6 modes are numbered from 1 to 6 and the required number of 4 blocks will be determined based on the number of samples studied. Then we will line up the required number, a random number based on a table of random numbers in a row: Of course, numbers above 6 will not be considered. Finally, based on the order of the numbers extracted from the table, the blocks related to each number will be listed in order, and when the samples are entered into the study, each person will take a specific letter in the order obtained. For example, according to the order (AABB / ABAB), the 5th person will be in group A.

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
Ethic committee of Tehran University of Medical Sciences
Street address
University of Nursing and Midwifery and Faculty of Rehabilitation - Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1417613151

Approval date
2020-12-22, 1399/10/02

Ethics committee reference number
IR.TUMS.FNM.REC.1399.156

Health conditions studied

1

Description of health condition studied
Fear of childbirth

ICD-10 code
F40.232

ICD-10 code description
Fear of other medical care

2

Description of health condition studied
Childbirth pain

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
fear of childbirth

Timepoint
The fear of childbirth questionnaire will be evaluated at the beginning of the active phase of labor (dilation of 4 cm) and by entering the active phase in several stages, during the first phase of labor in dilatations of 4-6-8-10 cm.

Method of measurement

Secondary outcomes

1

Description

Childbirth pain

Timepoint

Childbirth pain questionnaire at the beginning of the active phase of labor (dilatation 4 cm) and entering the active phase in several stages, during the first phase of labor in dilatations of 4-6-8-10 cm will be evaluated.

Method of measurement

The visual scale for measuring pain intensity is a 10 cm ruler with the word painless written on the left end and the most severe pain on the right end.

2

Description

Childbirth Self-Efficacy

Timepoint

Childbirth Self-Efficacy Inventory at the beginning of the active phase of labor (dilatation 4 cm) and entering the active phase in several stages, during the first phase of labor in dilatations of 4-6-8-10 cm will be evaluated.

Method of measurement

Childbirth Self-Efficacy Inventory

Intervention groups

1

Description

Intervention group: Fear questionnaire and pain intensity measurement scale (research tools) will be completed at the beginning of the active phase of labor (4 cm dilatation) for both groups, then the virtual reality headset will be available to the intervention group after entering the active phase of labor and regular uterine contractions will be inserted (The virtual reality headset is a 3D glasses that the mother is asked to wear, while wearing glasses, a game begins in three-dimensional space. The game called "Snow World" is designed in such a way that there is a black dot on the scene that we ask the mother to mark that point on the snowmen and earn points with each correct marking. It's just a fun game and can be stopped whenever the mother feels tired.) depending on the participant's wishes, but the minimum time to use the headset will be 20 minutes until the end of the first stage of labor (10 cm dilation) By entering the active phase of labor, pain and fear of childbirth in several stages, during the first stage, labor will be evaluated in dilatations of 4-6-8-10 cm.

Category

Prevention

2

Description

Control group: Routine delivery care for mothers and

infants in the control group will be performed in accordance with the hospital routine

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Halime Mohammadi

Street address

Mahabad - Sarbaz St. - Shahid Abdollahpour Blvd. - Imam Khomeini Hospital Mahabad

City

Mahabad

Province

West Azarbaijan

Postal code

7311113399

Phone

+98 44 4222 6166

Fax

Email

ravabetomumi_mahabad@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Urmia, Resalat Boulevard, end of the emergency dormitory, University Headquarters, Vice Chancellor for Research and Technology

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3193 7224

Fax

Email

mohebbi_iraj@yahoo.co.uk

Web page address

<http://faculty.umsu.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia 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

Tehran

Province

Tehran

Postal code

141973317

Phone

+98 21 6691 4368

Email

Ebrahimi_308@yahoo.com

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Halime Mohammadi

Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No. 6, West imam khomeini hospital., Mahabad town

City

Mahabad

Province

West Azarbaijan

Postal code

5913754841

Phone

+98 44 4222 6155

Email

mid.asrin.m@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Elham Ebrahimi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Nosrat st. Tohid sq. Tehran I.IRAN

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

Tehran University of Medical Sciences

Full name of responsible person

Halime Mohammadi

Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No. 6, West imam khomeini hospital., mahabad town

City

Tehran

Province

Tehran

Postal code

5714783734

Phone

+98 44 4222 1227

Email

mid.asrin.m@gmail.com

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

No - There is not a plan to make this available