Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 commitee 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

Childbirth Attitude Questionnaire

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

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Position
Midwife
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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
No - There is not a plan to make this available