

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Investigating the effect of women's game therapy on virtual reality on the severity of pain and illness caused by pregnant amniocentesis

Protocol summary

Severity of pain and anxiety caused by amniocentesis

Study aim

Determining the effect of game therapy based on virtual reality on the intensity of pain and anxiety from amniocentesis of pregnant women

Design

A clinical trial with a randomized control group will be assigned to two intervention and control groups using a random block method on 56 patients.

Settings and conduct

The samples will be selected as available in the clinic of Kausar Urmia Oozashi Therapy Center and will be allocated to two intervention and control groups by random block method. Then, the virtual reality headset will be provided to the people of the intervention group for 20 minutes while taking samples from pregnant women, and the control group will receive the usual care.

Participants/Inclusion and exclusion criteria

1- singleton pregnancy 2- Gestation age 15-18 weeks 3- Mother's age is 18 to 45 years 4- Have minimum literacy 5- No vision and hearing impairment 6- Not having chronic diseases before or during pregnancy

Intervention groups

The game titled Sesame Collection is designed in 20 minutes and 5 stages. This game can be played with virtual reality glasses. Therefore, its tools will be a 3D display similar to a combination of large glasses with a helmet. There are two very small monitors in it, which cover a wide field of vision and provide proper vision so that a person does not see anywhere else except his eye space and can easily see images in it. There are two speakers on the display in both ears, and it brings the person into the virtual environment. On the glasses, there is a head motion detector sensor that signals the user's head movements from the top of the helmet to the computer, and the user can change the angle of vision by shaking his head. In the control group, mothers only undergo amniocentesis without receiving any intervention.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230507058109N2**

Registration date: **2023-08-14, 1402/05/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-14, 1402/05/23**

Update count: **0**

Registration date

2023-08-14, 1402/05/23

Registrant information

Name

Zeinab Maloum

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3552 1720

Email address

zeinab.maloom75@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-14, 1402/05/23

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Investigating the effect of women's game therapy on virtual reality on the severity of pain and illness caused by pregnant amniocentesis
Public title	Investigating the effect of virtual reality-based game therapy on the intensity of pain and anxiety caused by amniocentesis
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Willingness to participate in the study singleton pregnancy Gestation age 15-18 weeks Mother's age is 18 to 45 years Have minimum literacy No vision and hearing impairment Not having chronic diseases before or during pregnancy Exclusion criteria: Participant's unwillingness to continue cooperation during each stage of the study History of seizures and epilepsy Dizziness and active vomiting
Age	From 18 years old to 49 years old
Gender	Female
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 56
Randomization (investigator's opinion)	Randomized
Randomization description	. People are placed in two intervention and control groups by a simple random allocation method by a non-researcher who is unaware of the divisions. Thus, to minimize contact between groups, each day the first person who volunteers to participate in the study determines the type of group for that day. In this way, the first participant chooses one of the balls from the bag that contained balls A-B-C-D, that day if the first participant chooses ball A or C, he enters the intervention group and that day all the participants in They are placed in the intervention group, and if the first participant chooses ball B or D, then all the participants will enter the control group.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Other
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics Committee of Urmia University of Medical Sciences
Street address	Nazlu, Urmia University of Medical Sciences, Faculty of Nursing and Midwifery
City	Urmia
Province	West Azarbaijan
Postal code	6257757168
Approval date	2023-08-13, 1402/05/22
Ethics committee reference number	IR.UMSU.REC.1402.135
Health conditions studied	
1	
Description of health condition studied	Women undergoing amniocentesis
ICD-10 code	
ICD-10 code description	
Primary outcomes	
1	
Description	Severity of pain and anxiety caused by amniocentesis
Timepoint	Measuring anxiety caused by amniocentesis before amniocentesis and measuring anxiety caused by amniocentesis and pain intensity after amniocentesis.
Method of measurement	Visual pain measurement scale and anxiety questionnaire for prenatal diagnostic procedures (perinatal)
Secondary outcomes	empty
Intervention groups	
1	
Description	Intervention group: Pregnant women undergoing amniocentesis
Category	Lifestyle

2

Description

Control group: Pregnant women undergoing amniocentesis

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kausar educational and therapeutic center

Full name of responsible person

Zeinab Maloum

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

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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

Oroumia University of Medical Sciences

Proportion provided by this source

50

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

Oroumia University of Medical Sciences

Full name of responsible person

Zeinab Maloum

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available