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

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
Severity of pain and anxiety caused by amniocentesis

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
Street address
Zakir St
City
Urmia
Province
West Azarbaijan
Postal code
6257757168
Phone
+98 939 800 7443
Email
zeinab.maloom75@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Zeinab Maloum
Street address
Zaker St
City
Urmia
Province
West Azarbaijan
Postal code
6257757168
Phone
+98 939 800 7443
Email
zeinab.maloom75@yahoo.com
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
Midwifery
Street address
Zaker
City
Urmia
Province
West Azarbaijan
Postal code
6257757168
Phone
+98 61 3552 1720
Fax
Email
zeinab.maloom75@yahoo.com

Person responsible for scientific 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
Midwifery
Street address
Zaker
City
Urmia
Province
West Azarbaijan
Postal code
6257757168
Phone
+98 61 3552 1720
Fax
Email
zeinab.maloom75@yahoo.com

Person responsible for updating data

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
Midwifery

Street address
Zaker

City
Urmia

Province
West Azarbaijan

Postal code
6257757168

Phone
+98 61 3552 1720

Fax

Email
zeinab.maloom75@yahoo.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
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