Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of virtual reality glasses on the intensity of pain and anxiety caused by hysterosalpingography of infertile women

Protocol summary

Study aim
Determining the effect of virtual reality glasses on the severity of pain and anxiety caused by hysterosalpingography in infertile women

Design
A randomized, controlled clinical trial with parallel groups on 100 infertile women, using a simple randomization method for randomization. The study is not blinded.

Settings and conduct
The samples will be selected conveniently at the clinic of the Kausar Educational and Therapeutic Center in Urmia and will be randomly assigned to two intervention and control groups using a block-based randomization method. Then, the virtual reality headset will be provided to the intervention group for 20 minutes during the sampling of infertile women, and the control group will receive routine care. The study is not blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Definite diagnosis of (primary) infertility by a gynecologist, 2- First experience with hysterosalpingography, 3- Age 18-49 years, 4- Candidate for hysterosalpingography with infertility indication, 5- Willingness to participate in the study. Exclusion criteria: 1- History of seizures and epilepsy, 2- Impaired vision and hearing.

Intervention groups
Group 1 (control) also underwent hysterosalpingography without any intervention. Group 2 (intervention) was given virtual reality glasses at the same time as hysterosalpingography. The game was called Smiling Snowmen, which was designed in 20 minutes and 5 stages. This game can be played using virtual reality glasses.

Main outcome variables
Severity of pain and anxiety caused by hysterosalpingography

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241001063221N2**
Registration date: **2025-02-07, 1403/11/19**
Registration timing: **prospective**

Last update: **2025-02-07, 1403/11/19**
Update count: **0**

Registration date
2025-02-07, 1403/11/19

Registrant information
Name
Leila Aghdami
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 3484 5433
Email address
sry.aliaghdami@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-02-20, 1403/12/02
Expected recruitment end date
2025-05-20, 1404/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigating the effect of virtual reality glasses on the intensity of pain and anxiety caused by hysterosalpingography of infertile women

Public title
Investigating the effect of virtual reality glasses on the intensity of pain and anxiety caused by hysterosalpingography of infertile women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Definite diagnosis of infertility (primary) by a gynecologist, First experience of hysterosalpingography, Age 18-49 years, Candidate for hysterosalpingography with infertility indication.
Exclusion criteria:
History of seizures and epilepsy Impaired vision and hearing
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: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are randomly assigned to the intervention and control groups by a non-researcher who is unaware of the allocation. In order to minimize contact between groups, the first person to volunteer each day to participate in the study determines the type of group for that day. The first participant selects one of the balls from a bag containing balls A-B-C-D. If the first participant selects ball A or C that day, they enter the intervention group and all participants are placed in the intervention group that day. If the first participant selects ball B or D that day, all participants are placed in 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
Urmia University of Medical Sciences Ethics Committee
Street address
Nazlu, Urmia University of Medical Sciences, Faculty of Nursing and Midwifery
City
Urmia
Province
West Azarbaijan
Postal code
6257757168
Approval date
2024-12-11, 1403/09/21
Ethics committee reference number
IR.UMSU.REC.1403.300

Health conditions studied

1

Description of health condition studied
Women undergoing hysterosalpingography
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Severity of pain caused by hysterosalpingography
Timepoint
The pain intensity scale will be used immediately after the completion of hysterosalpingography in the two control and intervention groups.
Method of measurement
Visual Pain Scale

Secondary outcomes

1

Description
Severity of anxiety caused by hysterosalpingography
Timepoint
The anxiety scale will be used before and immediately after the completion of hysterosalpingography in both the control and intervention groups.
Method of measurement
Spielberger Overt Anxiety Scale

Intervention groups

1

Description
Intervention group: Virtual reality glasses will be provided to the intervention group at the beginning of

the hysterosalpingography for 20 minutes. The virtual reality game, which is designed and developed by experienced experts in the field of virtual reality, is a game in which the most important point in its construction is the implementation of a snowy and white space that conveys a sense of peace. This game is played using virtual reality glasses. Therefore, its tools are a three-dimensional display similar to a combination of large glasses with a helmet. It has two very small monitors that cover a wide field of view and provide adequate visual input in such a way that the individual does not see anything other than the space of his eyes and can easily view the images in it. On the display, in the area of each ear, there are two speakers with sound reproduction and also enter the individual into the virtual environment through sound. On the glasses, there is a head-tracking sensor that signals the user's head movements from the top of the helmet to the computer, and the user can change their viewing angle by shaking their head. At first, the game guide explains to the women that to start the game and aim, they must move their head to place the red dot in front of their eyes on the word start. The main character moves forward in this space. This character can move in any direction in space. After a while, some smiling snowmen would arrive and the person would aim and throw snowballs at the snowmen approaching from the surrounding area. With each correct shot, a point would be added to the user's score, and if a ball was not thrown at the snowman and the player passed by it, he would lose the chance to gain points from it and the snowman would melt. Then this game does not have a loser and therefore does not bring negative emotions with it. Finally, the player's record, which is his evaluation criterion and motivating factor, is recorded.

Category
Treatment - Other

2

Description
Control group: Infertile women undergo hysterosalpingography only without receiving any intervention.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Kausar Educational and Medical Center

Full name of responsible person
Sarah Kazemzadeh

Street address
Diyant Street

City
Urmia

Province
West Azarbaijan

Postal code
6257757168

Phone
+98 914 447 0621

Email
samira_barjaste_70@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Assistant Researcher (Research and Technology) Urmia University of Medical Sciences

Full name of responsible person
Dr. Saber Gholizadeh

Street address
Resalat Boulevard

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Phone
+98 44 3223 4897

Email
saber@umsu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Assistant Researcher (Research and Technology) Urmia 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
Sarah Kazemzadeh

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Diyanet Street
City
Urmia
Province
West Azarbaijan
Postal code
6257757168
Phone
+98 44 3348 4543
Email
Samira_barjaste_70@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Samira Barjaste
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Azadegan Street
City
Urmia
Province
West Azarbaijan
Postal code
6257757168
Phone
+98 44 3344 6085
Email
Samira_barjaste_70@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Sarah Kazemzadeh
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Dianat Street
City
Urmia
Province
West Azarbaijan
Postal code
6257757168
Phone
+98 44 3348 4543
Email
Samira_barjaste_70@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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available