

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Investigating the effect of Virtual Reality on perceived hospital anxiety, worry and depression and the rate of pregnancy in women who are candidates for intrauterine sperm insemination

#### Protocol summary

##### Study aim

Determining the effect of virtual reality on the severity of perceived hospital worry, anxiety and depression and the rate of pregnancy in women who are candidates for intrauterine sperm insemination.

##### Design

The clinical trial with intervention and control groups, single blind, randomized, on 114 patients, will be used for randomization by random allocation rule.

##### Settings and conduct

Location: Infertility Clinic, Kausar Hospital, Urmia .  
Methodology: completion of relevant questionnaires before and after the process of sperm transfer by all the people in the intervention and control groups, and the people in the intervention group benefited from virtual reality glasses with soothing content and images for 30 minutes together. Onesided blind study: selection of white envelopes with no name and sign determining the group with the presence of a person other than the researcher and leaving the participant unaware of the content inside the envelope.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: not having children at home, the first experience of treatment with intrauterine sperm insemination, infertility of female origin, not having vision, hearing and movement disorders. Exclusion and nonentry criteria are male infertility, refusal to continue participating in the research.

##### Intervention groups

Completion of hospital anxiety and depression and worry questionnaires by all participants before and after the sperm transfer process, the benefit of the intervention group for 20 minutes before the start of the transfer process and 10 minutes during the transfer from the virtual reality glasses and the benefit of the people The control group only received standard care

##### Main outcome variables

The possibility of reducing the severity of worry and hospital anxiety and depression and the possibility of increasing positive pregnancy test results after using virtual reality glasses.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231013059702N2**

Registration date: **2024-02-11, 1402/11/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-02-11, 1402/11/22**

Update count: **0**

##### Registration date

2024-02-11, 1402/11/22

##### Registrant information

##### Name

Ghazaleh Gholami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 4553 4222

##### Email address

ghazalehgholamii76@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-11, 1402/10/21

##### Expected recruitment end date

2024-04-19, 1403/01/31

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of Virtual Reality on perceived hospital anxiety, worry and depression and the rate of pregnancy in women who are candidates for intrauterine sperm insemination

**Public title**  
Investigating the effect of Virtual Reality in intrauterine sperm insemination

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Consent to participate in the study Not having children at home The first treatment experience with sperm intrauterine insemination Infertility of female origin No physical illness Not having mental disorders and no history of drug use in the mental and psychological field No visual impairments No hearing disorders No movement disorders No addiction to smoking, drugs and alcohol The absence of stressful events in the last 6 months, such as the death of loved ones, accidents, etc  
**Exclusion criteria:**  
Infertility of male origin A candidate for treating infertility with methods other than intrauterine sperm insemination

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **114**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization method will be of a limited type called random allocation law; First, 114 cards (numbered from 1 to 114) will be prepared for the total number of people under study; Group membership will be determined based on the removal of cards; It should be noted that these cards will be placed inside white envelopes without name and mark and the cards will be chosen by the participants in the presence of a person other than the researcher; The participant and the researcher will be unaware of the content inside the envelope ; Even numbers will be assigned in the intervention group and odd numbers in the control group ; Then the removed card will be discarded.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The cards identifying the groups of participants will be

inside anonymous white envelopes and these cards will be chosen by the participants in the presence of a person other than the researcher ; The participant and the . researcher will be unaware of the content inside the envelope

**Placebo**  
Not used

**Assignment**  
Parallel

**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

Midwifery group, School of Nursing and Midwifery, Urmia University of Medical Sciences, Kilometer 11 Sero Road, Urmia

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5714783734

#### Approval date

2024-01-10, 1402/10/20

#### Ethics committee reference number

IR.UMSU.REC.1402.321

## Health conditions studied

### 1

#### Description of health condition studied

Adjustment disorders (occurrence of worry, anxiety and depression following a special and critical situation in life)

#### ICD-10 code

F43.2

#### ICD-10 code description

Adjustment disorders

### 2

#### Description of health condition studied

Reaction to extreme stress, unspecified (commonly seen in infertility)

#### ICD-10 code

F43.9

#### ICD-10 code description

Reaction to severe stress, unspecified

### 3

#### **Description of health condition studied**

Dangerously obsessive thoughts or ruminations (which prevents the infertile person from going to the hospital to receive further treatment and can lead to more dangerous results for the person)

#### **ICD-10 code**

F42.0

#### **ICD-10 code description**

Predominantly obsessional thoughts or ruminations

### **Primary outcomes**

#### 1

##### **Description**

Worry score in the Pennsylvania Worry Questionnaire

##### **Timepoint**

Measuring people's level of concern using a questionnaire one hour before the start of the sperm transfer process into the uterus and half an hour after the sperm transfer process into the uterus

##### **Method of measurement**

Pennsylvania Anxiety Inventory

#### 2

##### **Description**

Hospital anxiety and depression score in Zigmond and Snaith hospital anxiety and depression questionnaire

##### **Timepoint**

Measuring the level of anxiety and depression of people using a questionnaire one hour before the start of the sperm transfer process into the uterus and half an hour after the sperm transfer process into the uterus

##### **Method of measurement**

Zigmond and Snaith Hospital Anxiety and Depression Questionnaire

### **Secondary outcomes**

#### 1

##### **Description**

The percentage of people who have a positive or negative pregnancy test result

##### **Timepoint**

14 days after the sperm transfer process into the uterus

##### **Method of measurement**

Beta pregnancy blood test

### **Intervention groups**

#### 1

##### **Description**

Intervention group: People in the intervention group will complete the Pennsylvania anxiety and hospital anxiety and depression questionnaires by Sigmund and Snaith one hour before the sperm transfer process into the uterus and half an hour after the sperm transfer process.

It should also be noted that these people will use virtual reality glasses that contain sounds and images of nature with soothing content for twenty minutes before the start of the sperm transfer process and for ten minutes during the sperm transfer process.

##### **Category**

Treatment - Devices

#### 2

##### **Description**

Control group: People in the control group will complete the Pennsylvania anxiety and hospital anxiety and depression questionnaires by Sigmund and Snaith one hour before the start of the sperm transfer process into the uterus and half an hour after the sperm transfer process. It should be noted that the people of the control group will only benefit from the conditions, training and standard care of the respective center.

##### **Category**

Treatment - Devices

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Kausar Medical Training Center (the infertility clinic) in Urmia

###### **Full name of responsible person**

Ghazaleh Gholami

###### **Street address**

Kausar Women's Comprehensive Hospital., Ayatollah Hasani St

###### **City**

Urmia

###### **Province**

West Azarbaijan

###### **Postal code**

5715859497

###### **Phone**

+98 44 3346 1466

###### **Email**

research@umsu.ac.ir

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Oroumia University of Medical Sciences

###### **Full name of responsible person**

Dr. Saber Gholizadeh

###### **Street address**

Midwifery group, School of Nursing and Midwifery, Urmia University of Medical Sciences, Kilometer 11 Sero Road, Urmia

###### **City**

Urmia

###### **Province**

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research@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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Ghazaleh Gholami

**Position**

Senior professional student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

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Urmia University of Medical Sciences, Kilometer 11  
Sero Road, Urmia

**City**

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ghazalehgholamii76@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

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**Position**

Senior professional student

**Latest degree**

Bachelor

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## Person responsible for updating data

**Contact**

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Oroumia University of Medical Sciences

**Full name of responsible person**

Ghazaleh Gholami

**Position**

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**Latest degree**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data from hospital worry, anxiety and depression questionnaires and demographic questionnaire will be shared.

**When the data will become available and for how long**

Access to documents and data files starts six months after the publication of the article and results.

**To whom data/document is available**

The obtained data will be accessible to researchers working in academic and scientific institutions, as well as people working in the relevant industry, from the time of access to them.

**Under which criteria data/document could be used**

The data will be provided to the mentioned people for further guidance in conducting similar studies (for example, the use of an intervention similar to virtual reality in the field of infertility or the use of virtual reality glasses in other fields other than infertility).

**From where data/document is obtainable**

Dear applicants, they can send more information to the email address: ghazalehgholamii76@gmail.com or postal address: Bostan Girls Student Dormitory, Zakir Street ,Apadana Crossroads, Shahid Bahonar Highway, Urmia by zip code:6257757168 or contact number : 0098 09909358804 (respondent: Ghazaleh Gholami) refer.

**What processes are involved for a request to access data/document**

Applicants for documents can contact the respondent through one of the mentioned communication channels, And after stating their reasons for requesting documents, The necessary information will be provided to them within a maximum period of one week.

**Comments**