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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Saber Gholizadeh

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

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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
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

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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Latest degree
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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)
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