

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the effect of training using virtual reality on reducing anxiety before performing invasive surgical procedures in patients with maintenance hemodialysis

Protocol summary

Study aim

- Determining the level of anxiety in patients undergoing maintenance hemodialysis before surgical procedures in the control and intervention groups before and after the intervention
- Comparison of anxiety of patients treated with maintenance hemodialysis before surgical procedures in each of the control and intervention groups before and after the intervention

Design

Clinical trial with control group, parallel groups, non-random allocation, phase 2 on 20 patients.

Settings and conduct

The sampling place is Imam Khomeini Hospital. The selection of samples is one of the departments in which patients related to renal failure are admitted and then admitted to prepare for surgery. After receiving the consent of the patients and controlling the inclusion criteria of the patients in the study, they are divided into two groups of intervention and control. Before intervention, Anxiety questionnaire will be given to both groups. The intervention group receives the produced content using virtual glasses. The intervention group will be intervened for one month and two sessions per week. The control group will not receive any intervention. After the intervention for one month, the anxiety questionnaire will be given to both groups again.

Participants/Inclusion and exclusion criteria

informed consent to participate in the study
Fixed final diagnosis Hemodialysis treatment on a weekly basis
No underlying diseases
Have minimum level of literacy

Intervention groups

In this study, the intervention group receives training using virtual reality. This training includes all the events and issues that the patient is going to face in the operating room, will be displayed step by step from the moment of entering the operating room, during the operation and then after that.

Main outcome variables

anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220416054545N1**

Registration date: **2022-04-26, 1401/02/06**

Registration timing: **prospective**

Last update: **2022-04-26, 1401/02/06**

Update count: **0**

Registration date

2022-04-26, 1401/02/06

Registrant information

Name

manijeh hooshmandja

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8850 4058

Email address

hoshmand.66@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-04, 1401/02/14

Expected recruitment end date

2022-06-04, 1401/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of training using virtual reality on reducing anxiety before performing invasive surgical procedures in patients with maintenance hemodialysis

Public title
Investigating the effect of virtual reality in reducing patients' anxiety

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent to participate in the study
Fixed final diagnosis
Hemodialysis treatment on a weekly basis
No underlying diseases
Have a minimum level of literacy
Exclusion criteria:
Dissatisfaction for participating in the study
Once
Absence
Incomplete answer to the questionnaire

Age
From **22 years** old to **68 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Medicine - Tehran University of Medical Sciences (Research Ethics Committee)
Street address
Building no.1, Northern gate of the university, Poursina St. Qods St. Enqelab St
City
Tehran
Province

Tehran
Postal code
1417634981
Approval date
2021-12-12, 1400/09/21
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.1035

Health conditions studied

1

Description of health condition studied
reducing anxiety
Patients with maintenance hemodialysis
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
score
Anxiety in BAI - Beck Anxiety Inventory
Timepoint
One month and two sessions per week
Method of measurement
BAI - Beck Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group is trained in virtual reality about surgical procedures for two months each week for two sessions and on average 10 to 15 minutes after connecting the dialysis system. In this method, virtual reality glasses are used that are placed on the eyes of patients in the intervention group. At this time, images and videos about the surgical procedures are played and in terms of audio, headphones are used that are placed on both ears in a way that by playing the sound of that environment, the person enters the virtual space.
Category
Behavior

2

Description
Control group: The control group did not receive any intervention
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Morteza Noaparast

Street address

No. 19, Shahid Ahmadzadeh Alley, Shahid Arjmandi
Rad St., Mahallati Highway

City

Tehran

Province

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Postal code

1774645513

Phone

+98 912 411 1485

Email

Tho14141414@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Gods St, Keshavarz Blvd, Tehran, Tehran, Iran

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Province

Tehran

Postal code

1416614741

Phone

+98 21 8163 3685

Email

hoshmand.66@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Manijeh Hooshmandja

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

Street address

No 3, 1st Alley, Sarafraz St., Shaheed Beheshti St.,
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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

Contact

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Fax**Email**

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

A piece of data such as information about the main
outcome

When the data will become available and for how long

I have not decided yet

To whom data/document is available

I have not decided yet

Under which criteria data/document could be used

I have not decided yet

From where data/document is obtainable

I have not decided yet

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

I have not decided yet

Comments