Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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
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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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1416614741
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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
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Person responsible for updating data

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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