

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effect of virtual reality on pain caused by needle insertion into venous arterial fistula in hemodialysis patients

#### Protocol summary

##### Study aim

The effect of virtual reality on pain caused by needle insertion into venous arterial fistula in hemodialysis patients

##### Design

Clinical trial with control group, with parallel groups, Two blind, randomized, with a sample size of 30

##### Settings and conduct

In the intervention group, after selecting the desired video, the smartphone is placed inside the headset and the selected video is played through the virtual reality application.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: with chronic renal failure. Conditions of non-entry: do not want to continue participating in the research.

##### Intervention groups

In the intervention group, the patient is first explained how to perform the intervention. After selecting the desired video, the smartphone is placed inside the headset and the selected video is played through the virtual reality application. In the control group, without the patient realizing that routine care was performed and no other intervention was performed, the pain intensity and quality of pain will be measured at the same time intervals as the intervention group using the mentioned scales.

##### Main outcome variables

pain

#### General information

##### Reason for update

Termination of trial

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180429039463N3**

Registration date: **2022-03-28, 1401/01/08**

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

Last update: **2023-01-03, 1401/10/13**

Update count: **1**

##### Registration date

2022-03-28, 1401/01/08

##### Registrant information

###### Name

mohammad namazinia

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 5222 5280

###### Email address

namazinm951@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-06, 1400/12/15

##### Expected recruitment end date

2022-06-20, 1401/03/30

##### Actual recruitment start date

2022-03-01, 1400/12/10

##### Actual recruitment end date

2022-08-10, 1401/05/19

##### Trial completion date

2022-08-12, 1401/05/21

##### Scientific title

The effect of virtual reality on pain caused by needle insertion into venous arterial fistula in hemodialysis patients

##### Public title

The effect of virtual reality on pain

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Have informed consent to participate in all study sessions. Hemodialysis sessions should be three times a week. Have vascular access to venous arterial fistulas. The minimum time for hemodialysis through a fistula is 6 months. Be 18-70 years old. Be aware of time, place and person. Fluency in verbal communication in Persian. Absence of underlying disease (neuropathy, Guillain-Barre, MS, etc.) that affects pain and pain perception. No fever more than 37.5 degrees oral Do not take oral or topical analgesics or sedatives less than 6 hours before hemodialysis Do not take psychotropic drugs in the 24 hours before hemodialysis Absence of skin disorders at the injection site Absence of vision problems and impaired myopia (30 cm or less)

**Exclusion criteria:**

Reluctance to continue cooperation Take painkillers or sedatives in more than two consecutive sessions Taking psychotropic drugs in the previous 24 hours Try to get a vein or needle more than twice in each vascular pathway Fistula failure Absence of the patient in two or more consecutive sessions Existence of hearing problems

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **30**

Actual sample size reached: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Dividing people into two groups randomly will be used by the random permutation block method. In this way, using blocks with two treatments and a table of random numbers, individuals were assigned to two groups of control and intervention. Then, the personal information questionnaire in both intervention and control groups is completed through interviews. This questionnaire includes information about personal characteristics and medical records (age, sex, type of disease, etc.).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, participants and outcome assessors did not know whether participants were in the control or intervention group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Research Ethics Committee of Torbat Heydariyeh University of Medical Sciences

**Street address**

Torbat Heydariyeh University of Medical Sciences, Razi St., Torbat Heydariyeh, Iran

**City**

Torbat Heydariyeh

**Province**

Razavi Khorasan

**Postal code**

9519633787

**Approval date**

2021-12-27, 1400/10/06

**Ethics committee reference number**

IR.THUMS.REC.1400.041

**Health conditions studied**

1

**Description of health condition studied**

Chronic renal failure

**ICD-10 code**

N18

**ICD-10 code description**

chronic renal failure

**Primary outcomes**

1

**Description**

pain

**Timepoint**

Pain intensity is measured and recorded immediately, 15 minutes after the needle is inserted into the fistula, and pain quality is recorded and recorded 15 minutes after the needle is inserted into the fistula.

**Method of measurement**

Pain intensity scale (VAS) and pain quality will be measured and recorded with a short, modified form of the McGill Questionnaire.

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: In the intervention group, the pain measurement will be measured with virtual reality in such a way that the pain measurement questionnaire is filled by the patient and then the distraction technique

will be used once by the Shineken 4 virtual reality headset. First, the patient will be explained about the intervention method, then a list of 5 360-degree videos with nature content and at least 5 minutes will be provided to the patient to be selected to play a video. After selecting the desired video, the smartphone is placed inside the headset and the selected video is played through the virtual reality application. Prior to headset placement, VAS pain intensity and pain quality will be measured and recorded in a short, modified form of the McGill Questionnaire. From 5 minutes before the needle enters the venous arterial fistula, the headset is placed for the patient and the video will be played. At the end of the fifth minute, the nurse inserted the needle into the venous arterial fistula according to the standard method, and after the needle was fixed to the fistula, the video player stopped and the glasses were removed from the patient's eye. The severity of pain is measured and recorded immediately and 15 minutes after insertion of the needle into the fistula and the quality of pain 15 minutes after insertion of the needle into the fistula.

**Category**

N/A

**2****Description**

Control group: In the control group, without the patient realizing that routine care was performed and no other intervention was performed, the pain intensity and quality of pain will be measured at the same time intervals as the intervention group using the mentioned scales.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Nohome day Hospital, Torbat Heydariyeh University of Medical Sciences

**Full name of responsible person**

Mohammad Namazinia

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Torbat Heydariyeh University of Medical Sciences Building., Razi St., Ferdawsi St.

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Torbate-Heidaria University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Rezaei Manesh

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Torbate-Heidaria 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**

Torbate-Heidaria University of Medical Sciences

**Full name of responsible person**

Mohammad Namazinia

**Position**

Member of the faculty of Torbat Heydariyeh University of Medical Sciences

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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

Information about the main consequence after being unidentified will be shared

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

Start the access period 6 months after Publish results

### To whom data/document is available

Everyone

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

The results obtained in this study can be used without restriction by researchers.

### From where data/document is obtainable

Referring to Torbat Heidarieh Nursing and Midwifery Faculty

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

After sending the email to the person responsible for the response process begins.

### Comments