Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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

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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 Heydarieh 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

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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 Heydarieh University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

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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