Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Impact of Virtual Reality on Happiness and Quality of Life Among Elderly Hemodialysis Patients : A Randomized Controlled Trial

Protocol summary

Study aim
Determining the effect of using virtual reality on happiness and quality of life of elderly people undergoing hemodialysis

Design
This study is implemented in a crossover manner. The first group is exposed to watching 3D 360-degree virtual reality movies on the theme of entertainment and recreation (travel, tourism and pilgrimage) using a virtual reality headset. This intervention is performed for 10-15 minutes and 3 times a week. The second group will also watch VR films in the same way, with a relaxing and exciting axis. After a 2-week washout period to clear the intervention effect, the content of the VR films will be switched between the two intervention groups over the next 4 weeks.

Settings and conduct
Hemodialysis Department of Razi Educational and Medical Center, Rasht

Participants/Inclusion and exclusion criteria
The inclusion criteria for this study included: age 65 years and older, diagnosis of ESRD, having a minimum duration of hemodialysis of 3 months, having at least 3 hemodialysis sessions per week, willingness and informed consent to participate in the research project, having the ability to speak and communicate Non-entry criteria included: Severe cognitive impairment, visual or hearing impairments, previous experience with VR technology, severe visual and hearing problems, musculoskeletal problems in the head and neck area, a history of severe and frequent headaches and migraines, having malignant diseases such as cancer and neurological and psychiatric diseases and epilepsy such that the patient is under treatment, a history of taking antidepressants and having other physical diseases except diabetes and hypertension.

Intervention groups
In this study, there are two intervention groups (1 and 2) that are implemented using a simple random allocation method, a crossover design.

Main outcome variables
Happiness and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190315043062N4**
Registration date: **2025-07-04, 1404/04/13**
Registration timing: **prospective**

Last update: **2025-07-04, 1404/04/13**
Update count: **0**

Registration date
2025-07-04, 1404/04/13

Registrant information

Name
Azar Darvishpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 4256 5060

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darvishpour@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-01, 1404/06/10

Expected recruitment end date
2025-12-01, 1404/09/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Impact of Virtual Reality on Happiness and Quality of Life Among Elderly Hemodialysis Patients : A Randomized Controlled Trial

Public title

Impact of Virtual Reality on Happiness and Quality of Life Among Elderly Hemodialysis Patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 65 years and older diagnosis of end-stage renal disease (ESRD) having a minimum duration of hemodialysis of 3 months having at least 3 hemodialysis sessions per week, willingness and informed consent to participate in the research project having the ability to speak and communicate obtaining a score of 7 or higher on the AMT tool to assess normal cognitive status

Exclusion criteria:

Severe cognitive impairment Visual or hearing impairments that prevent the use of VR Previous experience with VR technology Severe vision and hearing problems Musculoskeletal problems in the head and neck area, a history of severe and frequent headaches and migraines Malignant diseases such as cancer and neurological and psychiatric diseases and epilepsy such that the patient is under treatment History of taking antidepressants Physical diseases other than diabetes and hypertension

Age

From **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, In this study, participants will be randomly assigned to one of the following two intervention sequences: Group A: Intervention 1 → Washout Period → Intervention 2 Group B: Intervention 2 → Washout Period → Intervention 1 To ensure equal allocation of participants to each sequence, a block randomization method with a fixed block size of 6 will be used. In total, 9 blocks of 6 will be considered to allocate 54 participants (27 per sequence) equally. The allocation sequence will be generated via the following website: https://www.sealedenvelope.com/simple-randomiser/v1/lists Participants will be allocated to one of the two sequences based on the order of entry into the study, according to the generated randomization list. To reduce bias, the randomization sequence will be generated and implemented by an individual independent of the research team who has no role in the data collection, assessment, or analysis process.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

Street address

Vice Chancellor for Research and Technology., in front of the 17 Shahrivar Hospital., Shahid Siadati Street., Namjo Street

City

Rasht

Province

Guilan

Postal code

66949- 41466

Approval date

2025-06-25, 1404/04/04

Ethics committee reference number

IR.GUMS.REC.1404.139

Health conditions studied

1

Description of health condition studied

End stage renal disease

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description

Happiness

Timepoint

Data will be collected in three stages: pre-test, post-test, and follow-up.

Method of measurement

Oxford Happiness Questionnaire

2

Description
Quality of Life
Timepoint
Data will be collected in three stages: pre-test, post-test, and follow-up.
Method of measurement
Kidney Patients Quality of Life Questionnaire (KDQOL-SF)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group will be exposed to watching 360-degree virtual reality 3D movies in the entertainment and entertainment axis (travel, tourism and pilgrimage) using a virtual reality headset. This intervention will be done for 10-15 minutes and 3 times a week. After observing a 2-week time interval to clear the effect of the intervention, during the next 4-week period, the content of the virtual reality movies will be switched between the two intervention groups. After the end of the intervention, the follow-up period will be conducted within 2 weeks.
Category
Other

2

Description
Intervention group: The second group will be exposed to watching 360-degree virtual reality 3D movies in the relaxing and exciting axis using a virtual reality headset. This intervention will be done for 10-15 minutes and 3 times a week.After observing a 2-week time interval to clear the effect of the intervention, during the next 4-week period, the content of the virtual reality movies will be switched between the two intervention groups. After the end of the intervention, the follow-up period will be conducted within 2 weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hemodialysis Department, Razi Educational and Medical Center, Rasht
Full name of responsible person
Azar Darvishpour
Street address
School of Nursing and Midwifery., Shahid Yaghoub Sheikhi Street., Leylakooh road., Langeroud
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Ramyar Farzan
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Vice Chancellor for Research and Technology., in front of the 17 Shahrivar Hospital., Shahid Siadati Street., Namjo Street
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Email
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Web page address
http://www.gums.ac.ir/research
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Azar Darvishpour
Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Azar Darvishpour

Position

Associate professor

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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

No - There is not 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

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable