Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of visual relaxation techniques during hemodialysis on the quality of life and happiness of patients referred to the hemodialysis centers of Kerman University of Medical Sciences in Kerman city

Protocol summary

Study aim

Investigating the effect of visual relaxation exercises during hemodialysis on the quality of life and happiness of patients referred to hemodialysis centers affiliated to the University of Medical Sciences in Kerman.

Design

This research is a clinical trial with two intervention and control groups with random assignment, and block random assignment is used to assign the study subjects to the intervention and control groups. In this method, blocks of 4 are used, in each block two people are in the intervention group and two people are in the control group. R software is used for random block allocation. The research population is 70 patients.

Settings and conduct

A total of 12 sessions of visual relaxation exercises are performed twice a week during hemodialysis under the supervision of a researcher.

Participants/Inclusion and exclusion criteria

Criteria for samples to be included in the study: 1. Having an average age of 18-75 years 2. Having a schedule of hemodialysis at least twice a week 3. The patient's ability to communicate with others in order to complete the questionnaire Criteria for not entering the study: 1. Presence of functional disability (skeletal-muscular) 2. Suffering from extensive physical and mental diseases affecting the variables of the study, including Alzheimer's, delirium

Intervention groups

The intervention group will be asked to do 12 sessions twice a week during dialysis under the supervision of the researcher. Each stage of relaxation lasts about 20 minutes. The control group receives only the usual care in the hemodialysis department.

Main outcome variables

The quality of life score of hemodialysis patients was obtained from the quality of life questionnaire of kidney patients; the happiness score of hemodialysis patients was obtained from the Oxford Happiness Questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241029063544N1**
Registration date: **2025-02-11, 1403/11/23**
Registration timing: **prospective**

Last update: **2025-02-11, 1403/11/23**
Update count: **0**

Registration date

2025-02-11, 1403/11/23

Registrant information

Name

Rahele Moghbeli bahraseman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4245 0017

Email address

rahelemoghbeli.70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-21, 1404/02/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of visual relaxation techniques during hemodialysis on the quality of life and happiness of patients referred to the hemodialysis centers of Kerman University of Medical Sciences in Kerman city

Public title
Investigating the effect of visual relaxation techniques during hemodialysis on the quality of life and happiness of patients referred to the hemodialysis centers of Kerman University of Medical Sciences in Kerman city
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
1-Having an average age of 18-75 years2-Having a schedule of hemodialysis at least twice a week 3- The patient's ability to communicate with others in order to complete the questionnaire
Exclusion criteria:
1- Presence of functional disability (skeletal-muscular)2- Suffering from extensive physical and mental diseases affecting the variables of the study, including Alzheimer's, delirium
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Random block allocation is used to allocate the studied subjects to intervention and control groups. In this method, blocks of 4 are used, in each block two people are in the intervention group and two people are in the control group. R software is used for block random assignment.
Blinding (investigator's opinion)
Single blinded
Blinding description
After collecting the data of both intervention and control groups, without informing the data analyst which data is related to the control group and which data is related to the intervention group, it is given to them to analyze and extract statistics. In fact, the data analyst is blind to which data is related to which group.
Placebo
Not used
Assignment
Other
Other design features
The characteristics of the participants are completed using a demographic and clinical questionnaire, and then people are randomly assigned to one of the intervention and control groups by a person who is blind to the study.Patients in the control group will receive only the usual care of the dialysis unit.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Imam Khomeini Hospital, Rabor City, Kerman Province
City
Rabor
Province
Kerman
Postal code
7856136737
Approval date
2025-02-05, 1403/11/17
Ethics committee reference number
IR.KMU.REC.1403.484

Health conditions studied

1

Description of health condition studied
The effect of visual relaxation on the quality of life and happiness of hemodialysis patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of life score in the quality of life questionnaire of kidney patients
Timepoint
before the start of the intervention and immediately after the end of the intervention and 1 month after the end of the intervention
Method of measurement
Standard Questionnaire of Quality of Life of Kidney Patients (KDQOL-SF)

2

Description
Happiness score in Oxford Happiness Questionnaire
Timepoint
Before the start of the intervention and immediately after the end of the intervention
Method of measurement
Oxford Happiness Questionnaire

Secondary outcomes

1

Description
In this study, the secondary outcome variable is not measured
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Intervention group: First, calming images, including images of the sky, forest, and sea, are shown to the patients of the intervention group using LCD or laptop, then the relaxation technique is performed. He shuts up and, concentrating on breathing, takes three deep breaths, filling the lungs with air and emptying it out.After this stage, the patients respectively contract and expand muscles for 14 groups of facial muscles (forehead, eyelids, jaw and lips), neck muscles, fingers and palms, forearms, arms and shoulders, back, back, chest, Abdomen done. , hips, thighs, legs and feet. The contraction of each muscle takes 7-10 seconds and its expansion takes 15-20 seconds. Also, patients should not tighten their muscles during muscle contraction. But the contraction is enough.Finally, ask the patient to imagine a wave of relaxation slowly spreading throughout your body, starting at your feet and continuing slowly through each muscle group to your head and then slowly to your eyes. opens and returns to normal.
Category
Rehabilitation

2

Description
Control group: Patients in the control group will receive only the usual care of the dialysis unit
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Javadalaime Kerman Specialized Clinic
Full name of responsible person
Siddiqa Nili
Street address
North Abuzar St., 29th Abuzar St., Delshad St
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2

Recruitment center
Name of recruitment center
Hemodialysis Department of Shafa Hospital
Full name of responsible person
Siddiqa Soltani Nejad
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3

Recruitment center
Name of recruitment center
Saman al-Hajj charity institution
Full name of responsible person
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At the end of Shahid Rajaei Street, Saman Al-Hajj Charity Institution
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Hamid Sharifi
Street address
Imam Khomeini Hospital, Rabor Road
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Rahele Moghbeli Bahr Asman
Position
nurse
Latest degree
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Person responsible for updating data

Contact
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Full name of responsible person
Rahele Moghbeli Bahr Asman
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Latest degree
Bachelor
Other areas of specialty/work
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Kerman
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Rahelemoghbeli.70@gmail.com

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

The scores related to the quality of life and happiness of the patients will be published in the form of theses and possible articles in the form of a comparison of the scores before and after the intervention after de-identification.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in scientific and academic institutions and hospital staff

Under which criteria data/document could be used

In order to use the non-identifiable data of the study subjects, the requesting individual or group must use the data to conduct research or activities in the field of improving the living conditions of patients and their families and provide documentation related to the mentioned items.

From where data/document is obtainable

09136215820 Rahelemoghbeli.70@gmail.com Smnouhi@yahoo.com 09133407727

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

You must submit a letter containing confirmation and the reason for your request to use the study data from your respective institution.

Comments