Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effectiveness and non-effectiveness of peer-led education with family-based education on sleep quality in patients undergoing hemodialysis

Protocol summary

Study aim
comparative investigation of effectiveness of peer-led education with family-based education on sleep quality in patients undergoing hemodialysis

Design
In this study, 90 patients undergoing hemodialysis treatment, Who are eligible to enter the study, will be selected randomly and divided into three groups (two intervention and one control group).To hide the intervention group, each participant will be assigned a code.

Settings and conduct
This study will be conducted at Imam Reza hospital in Kermanshah. First, the conditions for entering the study will be explained for the patient clearly and, if desired, the informed consent form will be completed.This study will be done as not blinded study.

Participants/Inclusion and exclusion criteria
Inclusion criteria:No history of participating in training programs related to lifestyle and adaptation methods during the last 6 months.No speaking or hearing impairment Exclusion criteria: No participation in training courses for more than one session

Intervention groups
In the family-based intervention group, patient accompanied will receive 60 minutes training each session, three days a week (sunday - tuesday - thursday). Then, in collaboration with the patient accompanied , training sessions will be held for intervention groups in 5 sessions of 60 minutes. In the peer-led group, 4 patients will be selected as the peer group leader.The peer group is divided into four groups, and each of these four individuals is randomly assigned to a group of eight people.Then, with the collaboration of the peer group, the training sessions will be held for intervention groups in 5 sessions of 60 minutes. The control group will not receive any interventions

Main outcome variables
Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N85**
Registration date: **2018-02-11, 1396/11/22**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-11, 1396/11/22**
Update count: **0**

Registration date
2018-02-11, 1396/11/22

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 83 1821 4653

Email address
fforoughi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-04, 1396/11/15

Expected recruitment end date
2018-04-04, 1397/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of effectiveness and non-effectiveness of peer-led education with family-based education on sleep quality in patients undergoing hemodialysis

Public title
Investigation the effectiveness of peer-led education with family-based education on sleep quality
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
No history of participating in training programs related to lifestyle and adaptation methods during the last 6 months No speech impairment or hearing impairment Catching other acute or chronic physical or mental disorders (such as cardiovascular, respiratory, musculoskeletal, liver or psychiatric disorders)
Exclusion criteria:
Non-participation in training courses for more than one session Use of sleep medications during the study
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization method will be used to implement random assignment.In this way, 90 consecutive (from 1 to 90) will written individually on a paper and will be placed in a container.Then, each of the participants in the trial is asked to randomly select one of these 90 numbers in the container containing the numbers.Individuals who have selected numbers from 1 to 30 will be assigned to group A ("control group") and those who have chosen numbers 31 to 60 to group B ("peer-led education group ") and those who have selected numbers 61 to 90 to group C ("family-based education Group")
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
Ethics committee of Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2017-10-24, 1396/08/02
Ethics committee reference number
ir.kums.rec.1396.392

Health conditions studied

1

Description of health condition studied
Hemodialysis - Chronic kidney disease
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Sleep quality
Timepoint
The beginning and end of the study
Method of measurement
Based on the Pittsburgh Sleep Quality Questionnaire (PSOI)

Secondary outcomes

empty

Intervention groups

1

Description
In the family-based intervention group, patient accompanied will receive 60 minutes training each session, three days a week (sunday - tuesday -

thursday). Then, in collaboration with the patient accompanied , training sessions will be held for intervention groups in 5 sessions of 60 minutes.

Category

Treatment - Other

2

Description

In the peer-led group, 4 patients will be selected as the peer group leader.The peer group is divided into four groups, and each of these four individuals is randomly assigned to a group of eight people.Then, with the collaboration of the peer group, the training sessions will be held for intervention groups in 5 sessions of 60 minutes.

Category

Treatment - Other

3

Description

The control group will not receive any interventions

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Maryam Mardanpour

Street address

Imam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

mardanpour.m@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

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Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Kermanshah University of Medical Sciences

Full name of responsible person

Maryam Mardanpour

Position

Maryam Mardanpour

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Yesarat Square, Dolatabad Blvd, Faculty of Nursing and Midwifery

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Postal code

6715847141

Phone

+98 83 3826 6429

Email

mardanpour.m@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Aliakbar Veisiraygan

Position

Faculty Member of Kermanshah University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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City

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Maryam Mardanpour

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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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

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

Comments