

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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)

##### Phone

+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 be 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 (PSQI)

**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**

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**Postal code**

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**Phone**

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**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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+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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**Province**

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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

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Maryam Mardanpour

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Province**

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**Postal code**

6715847141

**Phone**

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**Email**

mardanpour.m@yahoo.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**

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**