

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of spiritual intervention program on hemodialysis patients' sleep quality

Protocol summary

Study aim

Determining the effectiveness of spiritual intervention program on hemodialysis patients' sleep quality

Design

The current study is a two-group randomized clinical trial that will be conducted with the participation of 100 patients. The research units will be selected by convenience sampling method and will be allocated into control and intervention groups by using randomization of the permutation block method.

Settings and conduct

The present study is a two-group randomized clinical trial that will be conducted with 100 hemodialysis patients in Hamadan. In the intervention group, spiritual intervention sessions will be held during six sessions, two sessions each week for 45 to 60 minutes by the researcher. The topics of the sessions will include the assessment of spiritual hemodialysis patients' needs, religious care, spiritual-supportive care, spiritual care, psychological care, and spiritual care evaluation. After the spiritual intervention, the patients' sleep quality will be evaluated one month and two months after the last care session. The control group will receive only usual medical care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of chronic kidney failure by a doctor, not having mental disorders, and not having vision and hearing diseases. Exclusion criteria: Patient death during the study, absence more than once in meetings, and Unwillingness to continue participating in the study.

Intervention groups

The sessions of spiritual intervention program will be held in six sessions, two sessions per week for 45 to 60 minutes by the researcher for the intervention group. After the spiritual intervention, the patients' sleep quality will be evaluated one month and two months after the last care session. Control group: Patients in the control group will receive only routine care.

Main outcome variables

Patients' sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N41**

Registration date: **2022-11-11, 1401/08/20**

Registration timing: **prospective**

Last update: **2022-11-11, 1401/08/20**

Update count: **0**

Registration date

2022-11-11, 1401/08/20

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of spiritual intervention program on hemodialysis patients' sleep quality

Public title

Effectiveness of spiritual intervention program on sleep quality

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of chronic kidney failure by a doctor Not having mental disorders Not having vision and hearing diseases

Exclusion criteria:

Patient death during the study Absence more than once in meetings Unwillingness to continue participating in the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method will be done using the permutation block method. In such a way that first, four blocks of ABBA, AABB, and ABAB, BBAA, BAAB, BABA will be produced in a number that covers the study sample and will be placed in envelopes. Then, when the patients enter the study, one of the envelopes will be randomly selected and the first four patients will be assigned to two groups according to the desired block. This process will continue until the total number of samples is completed.

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 Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2022-10-22, 1401/07/30

Ethics committee reference number

IR.UMSHA.REC.1401.626

Health conditions studied

1

Description of health condition studied

Hemodialysis patients

ICD-10 code

Z99.2

ICD-10 code description

Dependence on renal dialysis

Primary outcomes

1

Description

patients' sleep quality

Timepoint

One month and two months after the intervention

Method of measurement

Petersburg sleep quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, the spiritual intervention program's sessions will be held in six sessions, two weekly sessions for 45 to 60 minutes. The content of these sessions is based on identifying the spiritual needs of Iranian patients and matching them with international clinical guidelines and related texts. The Spiritual intervention program has been localized by a group of experts in Iran's health system. The sleep quality questionnaire will be completed one month and two months after the last session of spiritual intervention.

Category

N/A

2

Description

Control group: Control group: The control group will receive only routine medical care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mohammad Torabi

Street address

Hamedan - the beginning of Eram Boulevard - Shahid Beheshti Hospital

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mtorabi316@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokouhi

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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

Deputy of research and technology

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

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Torabi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**Undecided - It is not yet known if there will be a plan to
make this available**Study Protocol**Undecided - It is not yet known if there will be 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**Undecided - It is not yet known if there will be a plan to
make this available**Clinical Study Report**Undecided - It is not yet known if there will be a plan to
make this available**Analytic Code**Undecided - It is not yet known if there will be a plan to
make this available**Data Dictionary**Undecided - It is not yet known if there will be a plan to
make this available