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
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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
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Hamedan - the beginning of Eram Boulevard - Shahid Beheshti Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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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
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Assistant Professor
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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