

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Investigating the effect of spiritual care program on sleep quality and treatment compliance of patients undergoing hemodialysis

Protocol summary

Study aim

Determining the effect of spiritual care program on sleep quality and treatment adherence of hemodialysis patients referred to Urmia hemodialysis centers in 2024

Design

A clinical trial with a parallel, randomized, and control group will be performed on 80 hemodialysis patients. The sample size will be 40 patients for each group in this study. Participants will be randomly divided into intervention and control groups, and a random number generator software will be used for randomization.

Settings and conduct

The study setting will be the Dialysis department of Imam Khomeini and Taleghani hospitals in Urmia. The study population will be all patients undergoing dialysis, and there will be no blindness in our study.

Participants/Inclusion and exclusion criteria

Diagnosis of chronic kidney failure by a nephrologist; having hemodialysis three times a week for 3 to 4 hours; Age between 32 and 68 years; Willingness to participate in the study; having the ability to listen and speak; having literacy to read and write; being a muslim.

Intervention groups

The control group will receive routine hospital care. The intervention group will receive four one-hour sessions twice a week in addition to routine hospital care.

Main outcome variables

Sleep quality, treatment adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131112015390N9**

Registration date: **2024-03-01, 1402/12/11**

Registration timing: **prospective**

Last update: **2024-03-01, 1402/12/11**

Update count: **0**

Registration date

2024-03-01, 1402/12/11

Registrant information

Name

Naser Parizad

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of spiritual care program on sleep quality and treatment compliance of patients undergoing hemodialysis

Public title

Investigating the effect of spiritual care program on dialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The patient's chronic kidney failure has been confirmed by the nephrologist. The patient should be dialyzed three times a week for 3-4 hours. The patient is aged between 32 and 68 years. Patients who are willing to participate in the study. Patients who have no hearing and speech problems. Patients who can read and write. Patients who are Muslim

Exclusion criteria:

Patients with heart failure. Patients who belong to other religions.

Age

From **32 years** old to **68 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization was done in two stages. First, Imam Khomeini Hospital (RH) and Shahid Taleghani Hospital were divided into intervention and control groups by throwing a coin. Then, the patients of the hemodialysis department of Imam Hospital (RH) and Taleghani Hospital entered the study using a simple random sampling. Random numbers were created by the random number generator software.

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 Urmia University of Medical Sciences

Street address

Emergency alley, Resalat Boulevard, Urmia University of Medical Sciences, Urmia.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2023-08-30, 1402/06/08

Ethics committee reference number

IR.UMSU.REC.1402.175

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18.9

ICD-10 code description

Chronic kidney disease, unspecified

Primary outcomes

1

Description

The mean sleep quality score using the Pittsburgh Sleep Quality Questionnaire

Timepoint

Measuring sleep quality at the beginning of the study (before the study started) and after the study was completed

Method of measurement

The Pittsburgh Sleep Quality Questionnaire

2

Description

The mean adherence to treatment score using questionnaire of adherence to treatment in patients with chronic kidney failure

Timepoint

Measuring adherence to treatment at the beginning of the study (before the study started) and after the study was completed

Method of measurement

questionnaire of adherence to treatment in patients with chronic kidney failure

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to receiving ward routine care, patients in the intervention group will receive spiritual care individually for four one-hour sessions twice weekly.

Category

Rehabilitation

2

Description

Control group: The control group will only receive routine ward care. This care includes taking care of the dialysis catheter insertion site and educating the patient about proper nutrition, adequate rest, adherence to the medication regimen, and limiting fluid intake.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Teaching Hospital

Full name of responsible person

Maryam Rahimpour

Street address

Ayat Allah Madras Blvd., Ershad Blvd., Imam Khomeini Teaching Hospital, Urmia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Saber Gholizadeh

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Headquarters of Urmia University of Medical Sciences, Resalat Blvd., Jihad Ave.

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Web page address

Grant name

Urmia University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Naser Parizad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Province

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable