Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of nurse-led medication care program on medication adherence and symptom burden in patients undergoing hemodialysis.

Protocol summary

Study aim
Determining the effect of nurse-led medication care program on medication adherence and symptom burden in patients undergoing hemodialysis.

Design
A randomized controlled trial with a control group on 62 patients, non-blind with parallel-group

Settings and conduct
The study will involve 62 hemodialysis patients at Shayan Hemodialysis Center and Shahid Rahimi Hospital in Khorramabad who will be randomly assigned to intervention and control groups. The intervention group will be received training in pharmacologic care in patients with chronic renal failure.

Participants/Inclusion and exclusion criteria
Inclusion 1.Having chronic renal failure 2.Having at least two comorbid disease including hypertension, diabetes 3. Hemodialysis three times a week for at least three months 4. Orientation to time, location and person and having stable hemodynamic status. 5. Absence of any disabling hearing, vision, or speech impairment 6. Having stable physical and mental conditions 7. Being literate Exclusion criteria 1. Participation in other similar training and empowerment programs in the field of medication care 2. Hemodialysis patients younger than 18 years and older than 60 years .

Intervention groups
After visit by nephrologist and clinical pharmacist, the participants in the intervention group will receives by researcher nurse, 30 minute training each week for eight sessions, in accordance with the educational booklet titled “Medication care in patients with chronic Kidney disease. The control group will receives routine training.

Main outcome variables
Medication adherence and symptom burden in patients undergoing hemodialysis.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250514065726N2**
Registration date: **2026-05-02, 1405/02/12**
Registration timing: **prospective**

Last update: **2026-05-02, 1405/02/12**
Update count: **0**

Registration date
2026-05-02, 1405/02/12

Registrant information

Name
Shourangiz Beiranvand

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 66 3312 0140

Email address
shourangiz.beiranvand@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-22, 1405/03/01

Expected recruitment end date
2026-12-22, 1405/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of nurse-led medication care program on medication adherence and symptom burden in patients undergoing hemodialysis.

Public title
The effect of medication care program on medication adherence and symptom burden in dialysis patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having chronic renal failure Having at least two comorbid disease including hypertension, diabetes Hemodialysis three times a week for at least three months Orientation to time, location and person and having stable hemodynamic status. Absence of any disabling hearing, vision, or speech impairment Having stable physical and mental conditions Being literate
Exclusion criteria:
Participation in other similar training and empowerment programs in the field of medication care Hemodialysis patients younger than 18 years and older than 60 years .
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
62 eligible dialysis patients will be conveniently recruited into the study. It using a four-block randomization method to assign patients to two group. After obtaining written informed consent from the participants, 6 different combinations of four-block (AABB- ABAB- ABBA- BBAA- BABA- BAAB) were created. It randomly selected using the Blockrand package of R software, and the random sequence will be formed as a sequence of letters A and B.
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 Lorestan University of Medical Sciences
Street address
Shahid Anoushirvan Rezaei Square, Moalem St., Khorramabad, Lorestan, Iran University of Medical Sciences
City
Khorramabad
Province
Lorestan
Postal code
6813833946
Approval date
2025-11-11, 1404/08/20
Ethics committee reference number
IR.LUMS.REC.1404.327

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Medication adherence
Timepoint
The questionnaire will be completed before, one and two months after the educational intervention
Method of measurement
Morisky Medication Adherence Questionnaire (MMAS)

2

Description
Symptom burden in patients undergoing hemodialysis
Timepoint
The questionnaire will be completed before, one and two months after the educational intervention
Method of measurement
Edmonton Symptom Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Medication care program was focused on the interdisciplinary care (nurse, nephrologist, and pharmacist). Patients in the intervention group receive a monthly visit from a

nephrologist who prescribes routine medications and laboratory tests. A clinical pharmacist also visits patients monthly to monitor adherence, identify any errors in dosage, timing, or route of administration, detect adverse drug reactions, and drug interactions. The nurse conducted individualized 30 minute training each week for eight sessions, in accordance with the educational booklet titled “Medication care in Patients with Chronic Kidney Disease. The total intervention time was two months.

Category

Lifestyle

2

Description

Control group: The control group received routine training

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shayan Hemodialysis Center, Khorramabad and Shahid Seyyed Fakhroddin Rahimi Hospital , Khorramabad

Full name of responsible person

Shourangiz Beiranvand

Street address

Shahid Seyyed Fakhroddin Rahimi Hospital, Mojahedin Street, Before Safavi Bridge, Azadi Square, Khorramabad, Lorestan province.Shayan Hemodialysis Centre, No.72, Ghods Alley, Enghelab Street, Khorramabad, Lorestan Province.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Shorangiz Beiranvand

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad University of Medical Sciences

Proportion provided by this source

50

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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Shourangiz beiranvand

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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inquiries

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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