Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Peer-Support–Based Education on Self-Management and eHealth Literacy of Hemodialysis Patients: A Randomized Clinical Trial

Protocol summary

Study aim
To determine the effect of peer-support–based education on self-management and eHealth literacy among patients undergoing hemodialysis.

Design
Clinical Trial with Control Group, with Parallel Groups, Randomized

Settings and conduct
Eligible hemodialysis patients at Imam Hossein hospital will be enrolled after consent and randomly allocated to intervention and control groups. The intervention group will receive peer-support–based education, and the control group will receive usual care. The data analyst will be blinded to group allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Have been receiving maintenance hemodialysis for more than 6 months, be 18 years of age or older, undergo hemodialysis at least three times per week, with each session lasting a minimum of 3 hours, be residents of Tehran, have no known diagnosed psychiatric disorders, have no speech or hearing impairments that could interfere with participation in the study, have access to a smartphone, have not received any hemodialysis-related educational intervention other than the routine education provided by the dialysis center.

Intervention groups
Intervention group: Participants in this group will receive a peer-support–based educational program in addition to routine care. The intervention includes peer supporter training through four 90-minute sessions, followed by peer-led education and support for participants over 4 weeks through face-to-face sessions, group discussions, and multimedia materials. The content includes hemodialysis management, dietary and fluid restrictions, vascular access care, medication adherence, and self-management strategies. Control group: Participants in this group will receive routine hemodialysis care and standard education, including usual instructions regarding diet, fluid restriction, medications, and vascular access care.

Main outcome variables
Self-management, E-health Literacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260721070283N1**
Registration date: **2026-08-20, 1405/05/29**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-20, 1405/05/29**
Update count: **0**

Registration date
2026-08-20, 1405/05/29

Registrant information

Name
Fatemeh Estebsari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-01, 1405/05/10

Expected recruitment end date
2027-01-30, 1405/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Peer-Support–Based Education on Self-Management and eHealth Literacy of Hemodialysis Patients: A Randomized Clinical Trial

Public title
Peer-Support–Based Education in Hemodialysis Patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Have been receiving maintenance hemodialysis for more than 6 months. Be 18 years of age or older. Undergo hemodialysis at least three times per week, with each session lasting a minimum of 3 hours. Be residents of Tehran. Have no known diagnosed psychiatric disorders. Have no speech or hearing impairments that could interfere with participation in the study. Have access to a smartphone. Have not received any hemodialysis-related educational intervention other than the routine education provided by the dialysis center.
Exclusion criteria:
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
After confirming eligibility criteria, obtaining written informed consent, and completing the baseline assessment, participants will be randomly assigned to the intervention or control group with a 1:1 allocation ratio. Randomization will be performed using permuted blocks with variable block sizes of 4 and 6. The random allocation sequence will be generated by an independent statistician who is not involved in participant recruitment or study implementation, using the R statistical software. The unit of randomization is the individual participant. To ensure allocation concealment, the randomization sequence will be placed in sequentially numbered, opaque, sealed envelopes. Following enrollment and completion of the baseline assessment, the corresponding envelope will be opened sequentially by the researcher, and participants will be assigned to either the intervention or control group according to the predetermined randomization sequence.
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
Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University
Street address
School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Vali-e Asr St., Intersection of Ayatollah Hashemi Rafsanjani Expressway, Opposite Shahid Rajaei Heart Center, Tehran, Iran.
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Postal code
1996835119
Approval date
2026-02-16, 1404/11/27
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1404.258

Health conditions studied

1

Description of health condition studied
Self-Management and Health Literacy in Hemodialysis Patients
ICD-10 code
N18.6
ICD-10 code description
End stage renal disease

Primary outcomes

1

Description
Self-Management
Timepoint
Before the intervention, immediately after the intervention, and 3 months after the intervention.
Method of measurement
Hemodialysis Self-Management Instrument (HDSMI-18)

2

Description
eHealth Literacy

Timepoint

Before the intervention, immediately after the intervention, and 3 months after the intervention.

Method of measurement

eHealth Literacy Scale (eHEALS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Participants in the intervention group will receive a four-week peer-based education and support program in addition to the usual care provided at the hemodialysis center. The intervention is designed to enhance self-management, increase patients' knowledge about kidney disease and hemodialysis, strengthen self-care skills, and support patients in managing their disease in daily life.Selection and Training of Peer Supporters: Initially, five peer supporters will be selected from among patients with kidney disease who are undergoing hemodialysis. The selection criteria will include a successful history of disease management, adequate self-management skills, appropriate communication skills, at least a high school diploma, and approval by the research team. In addition, the final selection of peer supporters will be made after obtaining the opinions and approval of the nephrologist, the head nurse, and the nurses working in the hemodialysis unit. Based on their professional knowledge and direct experience with the patients, these healthcare professionals will assess the candidates' suitability in terms of communication skills, responsibility, cooperation with the healthcare team, and ability to fulfill the peer-support role.Before the intervention begins, the selected peer supporters will receive four face-to-face training sessions, each lasting 90 minutes, delivered once weekly, for a total of six hours. The training program will be developed based on the latest relevant Ministry of Health guidelines, established nephrology guidelines, and relevant scientific sources. The content will be reviewed and approved by a nephrologist before implementation.The peer-supporter training program will consist of two main components:A) Disease-specific and self-care educationThis component will cover an introduction to chronic kidney disease and the hemodialysis process; principles of dietary management and fluid restriction; correct and regular medication use; vascular access care; physical activity appropriate to the patient's condition; prevention and management of common hemodialysis-related complications; principles of self-management; treatment adherence; and the importance of regular follow-up care.B) Training in peer-support skillsThis component will cover the principles of peer support; the roles and responsibilities of peer supporters; effective communication skills; active listening; empathy; patient education; facilitation of group discussions; responding to patients' questions within the peer supporter's scope of competence; motivation for self-care; problem-solving; maintaining patient confidentiality; appropriate referral of questions and problems beyond the peer supporter's scope of competence to the healthcare team; and introduction to reliable health information resources and principles of appropriate use of electronic health resources to promote patients' eHealth literacy.Peer supporters will be trained using a variety of educational methods, including brief lectures, group discussions, question-and-answer sessions, role-playing, video presentations, podcasts, and other multimedia educational materials. Role-playing and group discussions will be used to practice communication skills, active listening, empathy, patient education, and management of potential situations that may arise during interactions with patients.To reinforce learning and facilitate continuous review of the training materials, the educational content presented during the face-to-face sessions, including educational files, summaries, and multimedia materials, will also be made available to the peer supporters through a dedicated channel on the Bale messaging platform. This channel will be used for reviewing educational materials, providing information about the intervention schedule, sending reminders, and providing supplementary educational content.Delivery of the Intervention by Peer SupportersFollowing completion of the peer-supporter training program, each peer supporter will be responsible for providing education and support to seven patients, and this support will continue for four weeks. The intervention will be delivered sequentially according to the predetermined educational content, with the materials provided progressively throughout the four-week period in accordance with the planned sequence of the educational program. The educational content will be delivered in four consecutive stages, with one major component of the program presented and reviewed each week according to the sequence specified in the study protocol. At the end of each stage, sufficient opportunity will be provided for questions and answers, clarification of uncertainties, and review of previously presented materials.Peer support will be initiated face-to-face during the patients' hemodialysis sessions and will continue between hemodialysis sessions through a dedicated channel on the Bale messaging platform. Face-to-face education and support sessions will be conducted during the patients' scheduled hemodialysis sessions and according to their individual dialysis schedules. During each session, a designated period will be allocated for delivery of the relevant educational content and responding to patients' questions. During the face-to-face interactions, peer supporters will deliver the content corresponding to each stage and support patients in identifying and addressing problems related to self-care and disease self-management. These interactions will involve individual conversations, question-and-answer sessions, and group discussions, according to patients' needs.The educational content provided to patients will include chronic kidney disease and hemodialysis, self-care, dietary management and fluid restriction, appropriate medication use, vascular access care, physical activity,

prevention and management of common complications, treatment adherence, and other topics related to disease self-management. The content of each stage, including educational materials, multimedia files, summaries, and relevant reminders, will also be made available to patients through the Bale channel. This channel will be used to maintain continuity of education and support, review educational materials, and respond to questions related to the educational content.Using active listening, empathy, motivational support, and problem-solving skills, peer supporters will encourage patients to actively participate in their self-care and adhere to recommendations related to disease management. Emotional and informational support will also be provided within the framework of the training received and within the defined scope of the peer-supporter role. If a patient raises a question or encounters a problem that falls outside the peer supporter's knowledge or scope of competence, the peer supporter will refrain from providing an independent response or recommendation and will refer the issue to the research/clinical care team. Peer supporters will not be permitted to diagnose medical conditions, provide independent medical advice, modify the type or dosage of medications, or perform any therapeutic intervention. The intervention will not involve the prescription of any new medication or therapeutic substance or any modification of patients' medication regimens; patients' pharmacological treatment will continue according to usual care and the instructions of the healthcare team. To ensure that the intervention is delivered in accordance with the study protocol, the researcher will monitor the delivery of the educational program, the sequence of educational content, the quality of interactions between peer supporters and patients, and adherence to the defined scope of the peer-supporter role throughout the four-week intervention period. In addition, peer supporters' adherence to the educational content and the predefined framework for intervention delivery will be regularly assessed, and guidance will be provided by the researcher if any deviation from the protocol is identified.

Category

Behavior

2

Description

Control group: Control GroupParticipants in the control group will receive usual care and routine education provided at the hemodialysis center throughout the study period, according to the center's standard practice, and will not receive any peer-based education or support from the research team. After completion of the study period and the final assessments, the educational content and materials used in the peer-based education and support program will also be made available to participants in the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Fatemeh Estebsari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Fatemeh Estebsari

Position
Associate 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

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
De-identified individual participant data (IPD), the final study protocol, the statistical analysis plan (SAP), and the informed consent form. All participant identifiers will be removed before data sharing. The shared dataset will include demographic variables, primary and secondary outcome data, the final study protocol, the statistical analysis plan, and the final informed consent form.

When the data will become available and for how long
The data and study documents will be available 6 months after publication of the primary study results and will remain available for at least 5 years.

To whom data/document is available
Researchers, faculty members, graduate students, and other investigators affiliated with academic or research

institutions who submit a scientifically justified request.

Under which criteria data/document could be used

The data and study documents may be used solely for scientific research purposes, including secondary analyses, systematic reviews, meta-analyses, or validation of the study findings. Applicants must submit a written request, agree to maintain data confidentiality, and use the data only for the approved research purposes. Any attempt to identify participants or use the data for commercial purposes will not be permitted.

From where data/document is obtainable

Requests should be submitted to the Principal Investigator. Contact information will be available through the corresponding author of the published article and the institutional affiliation at Shahid Beheshti University of Medical Sciences.

What processes are involved for a request to access data/document

Applicants must submit a written request describing the research objectives and the proposed use of the data. The request will be reviewed by the research team. Upon approval and compliance with ethical and confidentiality requirements, the requested data and study documents will be provided within 30 days.

Comments