Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the impact of an education based on Leventhal's self-regulation model on resilience and treatment adherence among patients with kidney failure undergoing hemodialysis

Protocol summary

Study aim

Determining the Effect of Education Based on Leventhal's Self-Regulation Model on Resilience and Treatment Adherence in Patients Undergoing Hemodialysis

Design

A single-blind, parallel-group, randomized controlled clinical trial was conducted. A total of 102 patients were enrolled in the study. Participants were randomly allocated to the intervention and control groups using Random Allocation Software (RAS) through permuted block randomization, consisting of 26 blocks of four participants each.

Settings and conduct

This quasi-experimental study will include patients undergoing hemodialysis at the Payambar Azam Educational, Research, and Therapeutic Center in Bandar Abbas, Iran (2026–2027). Eligible participants will be recruited through consecutive convenience sampling and randomly assigned to the intervention or control group. Following ethics approval, written informed consent will be obtained. Participation will be voluntary, confidentiality will be maintained, and participants may withdraw at any time. At baseline, all participants will complete a demographic form and the study questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Age 18–65 years. Literate and questionnaire completion ability. No cognitive or psychiatric disorders. Effective communication ability. Social media application proficiency. Written informed consent provided. Exclusion Criteria Withdrawal from the study. Hospitalization during the study. Previous educational intervention participation. Death during the study.

Intervention groups

intervention group: Patients undergoing hemodialysis who receive an educational intervention based on Leventhal's Self-Regulation Model. Control group: These patients will receive the routine care provided by the hemodialysis unit.

Main outcome variables

Resilience; adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260705070075N1**
Registration date: **2026-07-25, 1405/05/03**
Registration timing: **prospective**

Last update: **2026-07-25, 1405/05/03**
Update count: **0**

Registration date

2026-07-25, 1405/05/03

Registrant information

Name

Hamidreza Mohebi

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

2026-08-23, 1405/06/01

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the impact of an education based on Leventhal's self-regulation model on resilience and treatment adherence among patients with kidney failure undergoing hemodialysis

Public title
Investigating the impact of an education based on Leventhal's self-regulation model on resilience and treatment adherence among patients with kidney failure undergoing hemodialysis
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The patient is between 18 and 65 years of age.The patient is literate and able to read and complete the questionnaire.The patient has no diagnosed cognitive or psychiatric disorders.The patient is able to communicate effectively.The patient is able to use social media applications.The patient is willing to participate in the study and provides written informed consent.
Exclusion criteria:
The patient withdraws from the study at any time. The patient is hospitalized during the study period. The patient has previously participated in another educational intervention. The patient dies during the study period.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **102**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, random permuted block randomization will be used for ensure a balanced allocation of participants between the intervention and control groups throughout the study period. The randomization procedure was conducted as follows: Block Size A block size of four is selected. A total of 26 blocks, each containing four allocations, are generated. Generation of All Possible Block Combinations All possible allocation sequences for blocks of four participants, with two assignments to each group (A = intervention and B = control), are generated (e.g., AABB, ABAB, ABBA, BAAB, BABA, BBAA). Random Generation of the Allocation Sequence The random allocation sequence is generated using Random Allocation Software (RAS). The software randomly arranges the blocks to minimize selection bias and ensure an unpredictable allocation sequence. Allocation of Participants After confirming eligibility and obtaining written informed consent, each participant is assigned to either the intervention or control group according to the predetermined randomization sequence. Following the enrollment of eligible patients and the completion of informed consent forms, participants will be allocated to either the intervention or control group according to a randomized list. Allocation Concealment Allocation sequences will be placed in sequentially numbered, opaque, sealed envelopes (SNOSE), which will only be opened at the time of patient enrollment. This procedure aims to prevent selection bias during the allocation process. This procedure prevents foreknowledge of treatment assignments and reduces allocation bias. Randomization Management and Documentation The entire randomization process is managed by an independent researcher who is not involved in participant recruitment, intervention delivery, or outcome assessment. The randomization list and related documentation are securely maintained and archived throughout the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding of Outcome Assessors Outcome assessors are responsible for collecting study outcome data (e.g., treatment adherence and resilience). To ensure assessor blinding, the following procedures will be implemented: Participant Coding: Following random allocation to the intervention or control group, each participant will be assigned a unique identification code. These codes will be used in place of any information indicating group allocation. For example, a participant assigned to the intervention group may be identified as P001, while a participant in the control group may be be identified as P002. The identification codes will not reveal participants' group assignments. Separation of Assessors from the Randomization Process: Outcome assessors will not be involved in the randomization or allocation of participants to the study groups. Randomization will be performed by an independent research team. Assessors will work exclusively with anonymized participant codes and outcome data. Restricted Access to Participant Information: Outcome assessors will have access only to the information necessary for data collection (e.g., treatment adherence scores and resilience scores). They will not have access to any information regarding participants' group allocation. Training of Outcome Assessors: Before the commencement of the study, all outcome assessors will receive standardized training emphasizing the importance of maintaining blinding and avoiding any attempts to identify participants' treatment assignments throughout the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Bandar Abbas University of Medical Sciences

Street address
Chamran Clinic, Chamran Town, opposite the IRIB Broadcasting Center

City
Bandar Abbas

Province
Hormozgan

Postal code
7915844153

Approval date
2026-02-15, 1404/11/26

Ethics committee reference number
IR.HUMS.REC.1404.395

Health conditions studied

1

Description of health condition studied
patients undergoing hemodialysis

ICD-10 code
N18.6

ICD-10 code description
End stage renal disease

Primary outcomes

1

Description
resilience

Timepoint
Before the intervention, immediately after the intervention, and one month after the intervention

Method of measurement
Connor–Davidson Resilience Scale (CD-RISC)

2

Description
treatment adherence

Timepoint
Before the intervention, immediately after the intervention, and one month after the intervention

Method of measurement
Modanloo Treatment Adherence Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
At baseline, participants will complete the Connor–Davidson Resilience Scale (CD-RISC) and the Modanloo Treatment Adherence Questionnaire. The intervention will consist of six educational sessions lasting 60–75 minutes each, based on Leventhal's Self-Regulation Model. The sessions will address end-stage kidney disease, causes and management of the disease, illness perceptions, treatment adherence, resilience, personal and treatment control, emotional regulation, self-care planning, and available support resources. Immediately after completing the six-session program and again one month later, participants will complete the CD-RISC and the Modanloo Treatment Adherence Questionnaire. The educational content will be reviewed and approved for content validity by a nephrologist, a psychologist, and five nursing faculty members.

Category
Other

2

Description
Before the educational intervention (baseline), participants will complete the Connor–Davidson Resilience Scale (CD-RISC) and the Modanloo Treatment Adherence Questionnaire. Immediately after completion of the 6 session educational intervention, participants will again complete the Connor–Davidson Resilience Scale and the Modanloo Treatment Adherence Questionnaire. Finally, one month after completion of the educational intervention, participants will complete the Connor–Davidson Resilience Scale and the

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Payambar azam center

Full name of responsible person
Sayed Hamidreza Mohebi

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Sponsors / Funding sources

1

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Grant name
NONE
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bandare-abbas 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
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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

No - There is not 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