Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of family-centered distance Nurse-led health literacy training on symptom burden and readmission of patients with ischemic heart disease after discharge

Protocol summary

Study aim
Determining the effect of nurse-led remote family-centered health literacy training on symptom burden and readmission of ischemic heart patients after discharge

Design
A controlled clinical trial, using the alternating block randomization technique on 112 ischemic heart patients

Settings and conduct
At Amir-almomenin Teaching Hospital, caregivers of both groups will receive routine care education provided in the intensive care unit. The intervention group will also receive health literacy education in the field of ischemic heart disease in the form of a written program led remotely by a nurse. A 45-60 minute session will be held each week, including topics related to improving health literacy in the field of the disease and how to manage treatment and care. During the 6 weeks of the intervention, a phone text message will be sent once a week to ensure that the desired intervention is received. On a virtual platform, educational messages on the topics presented will be sent at a specific time three times a week. Data will be collected before and 3 months after the start of the intervention.

Participants/Inclusion and exclusion criteria
Ischemic heart patients who are literate, have a mobile phone and the ability to use social networks and smart phones, and have been diagnosed with the disease by a specialist physician and registered in the patient's file. The caregiver has not participated in other educational programs and similar self-care methods in the past 6 months, and the caregiver participating in the study is the patient's primary caregiver. The caregiver has not had cognitive and psychological problems, and at least 6 months have passed since the diagnosis of the disease.

Intervention groups
Educational sessions on improving health literacy about ischemic heart disease and standard care

Main outcome variables
Reduction in Edmonton symptom score and number of readmissions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240711062391N2**
Registration date: **2026-02-16, 1404/11/27**
Registration timing: **prospective**

Last update: **2026-02-16, 1404/11/27**
Update count: **0**

Registration date
2026-02-16, 1404/11/27

Registrant information

Name
Erfan Mohammadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01

Expected recruitment end date
2026-07-23, 1405/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of family-centered distance Nurse-led health literacy training on symptom burden and readmission of patients with ischemic heart disease after discharge

Public title
Effect of family-centered distance Nurse-led health literacy training on symptom burden and readmission of patients with ischemic heart disease after discharge
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Being literate Having a mobile phone and the ability to use social networks and smartphones Diagnosis of ischemic heart disease by a specialist physician and recording in the patient's file The caregiver of the research participant should be the patient's primary caregiver At least 6 months have passed since the diagnosis of the disease
Exclusion criteria:
Absence of cognitive and psychological problems in the patient's caregiver with questioning Caregiver's lack of participation in other similar educational programs and self-care methods in the past 6 months
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **112**
Randomization (investigator's opinion)
Randomized
Randomization description
The present study will be a two-group before-and-after clinical trial study. The research units will be selected conveniently and randomly assigned to the intervention and control groups using the alternating block randomization technique. Blocks of 4 with 6 conditions will be used. The letter A will indicate the participant in the intervention group and the letter B will indicate the participant in the control group. The samples in the two intervention and control groups will be assigned to the intervention and control groups based on the sequence of entry and according to the block pattern that is randomly selected from the blocks.
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 Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Basij St, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3818887174
Approval date
2025-02-23, 1403/12/05
Ethics committee reference number
IR.ARAKMU.REC.1403.363

Health conditions studied

1

Description of health condition studied
Health Literacy, Symptom Burden, Readmission
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Reduction in Edmonton symptom score
Timepoint
Before and 3 months after the start of the intervention
Method of measurement
Edmonton Symptom Assessment Scale

2

Description
Reduction in the number of readmissions
Timepoint
Before and 3 months after the start of the intervention
Method of measurement
Readmission of patients after discharge within 1 month of follow-up

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: During the study, caregivers in the intervention group will receive routine caregiving training provided in the intensive care unit. In addition, caregivers in the intervention group will receive health literacy training in the field of ischemic heart disease in the form of a written program led remotely by a nurse. This program will include educational sessions on improving health literacy in the field of ischemic heart disease, which will be presented via the sky room platform in the form of lectures and questions and answers during 6 sessions. One session will be held each week for 45-60 minutes, which will include discussions and strategies related to improving health literacy in the field of previous ischemic disease and how to manage treatment and care. During the 6 weeks of the intervention, telephone text messages will be sent once a week to the research units to ensure that the desired intervention is received.In an educational channel, an educational message on the topics presented will be sent three times a week at a specific time on an internal platform that includes members of the research team and research units. Data collection will be carried out before and 3 months after the start of the intervention using a demographic data checklist, an adult health literacy questionnaire, the Edmonton symptom scale, and a patient readmission survey through contact with the caregiver. In order to facilitate data collection in the post-intervention phase through the press line, questionnaires will be designed and provided to participants for completion.

Category

Prevention

2

Description

Control group: During the study, caregivers in the control group will receive routine caregiving training provided in the intensive care unit. Data collection will be conducted before and 3 months after the intervention using a demographic data checklist, the Adult Health Literacy Assessment Questionnaire, the Edmonton Symptom Scale, and a patient readmission survey by contacting the caregiver. In order to facilitate data collection in the post-intervention phase through the Pressline, questionnaires will be designed and provided to participants for completion

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Mo'menin Hospital

Full name of responsible person

Ali Mohtarami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Behzad Khansari Nejad

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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

Arak 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
Arak University of Medical Sciences
Full name of responsible person
Erfan Mohammadi
Position
Bachelor of Science in Nursing
Latest degree
Bachelor
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