Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the Effects of Micro-learning and Teach-back Educational Methods in Discharge Planning on Self-efficacy and Quality of Life among Patients Admitted to the Cardiac Care Unit

Protocol summary

Study aim

Comparison of the Effects of Microlearning and Teach-back Methods in Discharge Education on Self-efficacy and Quality of Life among Patients Hospitalized in the Cardiac Care Unit

Design

A three-arm parallel randomized controlled trial with a 1:1:1 allocation ratio will be conducted. Variable block randomization will be used. Participants and the intervention provider cannot be blinded; however, data analysis will be performed by a person unaware of group allocation. Clinical trial phase: Not applicable.

Settings and conduct

The study will be conducted in cardiac care units of teaching hospitals affiliated with Shahid Beheshti University of Medical Sciences in Tehran. Outcomes will be assessed at baseline, one month, and two months after discharge.

Participants/Inclusion and exclusion criteria

Participants will include patients aged 18 years and older with a confirmed diagnosis of acute coronary syndrome, hospitalized in the coronary care unit for at least 24 hours, who are fully conscious, able to communicate verbally, and have access to a smartphone. Patients with cognitive impairment or severe psychiatric illness, hemodynamic instability, transfer to another healthcare facility, failure to complete the study, or death during the study will be excluded.

Intervention groups

The microlearning group will receive 14 short educational units over 14 consecutive days after discharge. The teach back group will receive the same educational content during three inpatient sessions and one discharge session using the teach back method. The usual care group will receive routine discharge education.

Main outcome variables

Cardiac self-efficacy; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260811070623N1**
Registration date: **2026-08-29, 1405/06/07**
Registration timing: **prospective**

Last update: **2026-08-29, 1405/06/07**
Update count: **0**

Registration date

2026-08-29, 1405/06/07

Registrant information

Name

Reza Heydari Chegeni

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-10, 1405/07/18

Expected recruitment end date

2027-04-10, 1406/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the Effects of Micro-learning and Teach-back Educational Methods in Discharge Planning on Self-efficacy and Quality of Life among Patients Admitted to the Cardiac Care Unit

Public title
The Effect of Microlearning and Teach-Back Education in Cardiac Patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of acute coronary syndrome (ACS) confirmed by a cardiologist Age 18 years or older Hospitalization in the cardiac care unit (CCU) for at least 24 hours Full consciousness and the ability to communicate verbally Access to a smartphone and the ability to use it No cognitive impairment, severe psychiatric disorders, or physical disabilities that may interfere with participation in the educational intervention

Exclusion criteria:
Withdrawal of the participant from the study at any stage Development of hemodynamic instability or a critical condition that makes continued participation impossible Receipt of less than 80% of the educational content Failure to complete the research instruments Death of the patient during the study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be individually randomized to one of three study groups using variable block randomization with an equal allocation ratio of 1:1:1. Given the three-arm design, variable block sizes that are multiples of three (e.g., 3, 6, and 9) will be used to maintain balance among the three groups while minimizing the predictability of the allocation sequence. The random allocation sequence will be generated before the start of participant recruitment by a statistician using the R statistical software. Individual randomization will be used, and neither stratified nor cluster randomization will be performed. The generated allocation sequence will be kept by an individual who is independent of the research implementation team. To ensure allocation concealment, the allocation sequence will be placed in sequentially numbered, opaque, sealed envelopes (SNOSE). Each envelope will contain the allocation code for one participant. After eligibility has been confirmed, written informed consent has been obtained, and the baseline assessment and pre-intervention measurements have been completed, the envelope corresponding to the participant's enrollment order will be opened by the designated independent person to reveal the assigned study group. The researcher and other members of the study team responsible for participant recruitment and baseline assessment will have no access to the allocation sequence before assignment. Therefore, the assigned group cannot be predicted or altered before the participant is randomized.

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 and Midwifery; Shahid Beheshti Universi

Street address
Valiasr Street, at the intersection with Ayatollah Hashemi Rafsanjani Expressway, opposite Shahid Rajaei Heart Hospital, School of Nursing and Midwifery

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Approval date
2026-07-20, 1405/04/29

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1405.126

Health conditions studied

1

Description of health condition studied
Acute Coronary Syndrome

ICD-10 code
I24.9

ICD-10 code description
Acute ischemic heart disease, unspecified

Primary outcomes

1

Description
Cardiac self-efficacy score measured using the Cardiac Self-efficacy Scale
Timepoint
At baseline, one month, and two months after hospital discharge.
Method of measurement
Cardiac Self-Efficacy Scale; CSES

2

Description
Quality of life score among cardiac patients based on the MacNew Heart Disease Health-related Quality of Life Questionnaire
Timepoint
At baseline, one month, and two months after hospital discharge.
Method of measurement
MacNew Heart Disease Health-related Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 (Microlearning): Participants will receive a discharge education package for patients with acute coronary syndrome based on the principles of microlearning and spaced learning. The educational package will consist of 14 short and independent units, with one unit delivered daily through an approved electronic platform for 14 consecutive days, starting on the first day after hospital discharge. Each unit will require approximately 3 to 10 minutes and will be presented as short text, images, infographics, audio files, or educational videos, according to the content. The educational content will cover disease awareness, medication use and adherence, healthy nutrition, physical activity and cardiac rehabilitation, risk factor management, warning signs, home care, treatment follow-up, lifestyle modification, and self-care. Before discharge, a 10 to 15 minute face-to-face session will be provided to explain how to use the electronic platform and receive the educational content. After receiving each unit, participants will be asked to confirm that they have viewed the content and answer brief review questions or educational scenarios to monitor content receipt and reinforce learning. Receipt of at least 80% of the educational units will be considered adequate adherence to the intervention.
Category
Behavior

2

Description
Intervention group 2 (Teach-back): Participants will receive the same standardized discharge education package for patients with acute coronary syndrome using the Teach-back method. Education will be provided in three sessions during hospitalization in the coronary care unit and one additional session at discharge, with a total duration of approximately 75 to 110 minutes, delivered by the researcher. The educational content will cover disease awareness, medication use and adherence, healthy nutrition, physical activity and cardiac rehabilitation, risk factor management, warning signs, home care, treatment follow-up, lifestyle modification, and self-care. After each educational section, participants will be asked to explain the information and recommended self-care actions in their own words. If the response is incomplete or incorrect, the content will be re-explained using simpler language, followed by repeated Teach-back until the predefined learning criterion is achieved. Receipt of at least 80% of the educational content will be considered adequate adherence to the intervention.
Category
Behavior

3

Description
Control group: Participants will receive usual discharge education according to the routine practice of the hospital and provided by healthcare staff. No study-specific education based on the research educational package will be provided to this group. The type and amount of usual education received during the study will be documented. After completion of follow-up, the educational content used in the study will be provided to participants in this group, if feasible and in accordance with ethical considerations.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Medical, Educational and Treatment Center
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2

Recruitment center
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4

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5

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Sponsors / Funding sources

1

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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
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Position
Master's Student in Critical Care Nursing
Latest degree
Bachelor
Other areas of specialty/work
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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
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

De-identified Individual Participant Data, Data Dictionary, Study Protocol, and Clinical Study Report. De-identified individual participant data may include baseline characteristics, group allocation, intervention adherence, and outcome data on cardiac self-efficacy and quality of life measured at baseline, one month, and two months after hospital discharge. Direct identifiers will be removed before data sharing.

When the data will become available and for how long

Access will be available beginning 6 months after publication of the primary study results and will remain available for 3 years.

To whom data/document is available

Qualified researchers affiliated with academic, research, healthcare, or scientific institutions may request access to the shared data and study documents, regardless of country or institution, provided that the request meets the requirements of the study data-sharing policy.

Under which criteria data/document could be used

The data and documents may be used for scientifically and ethically justified secondary research, including replication, validation, methodological research, and additional analyses related to the study objectives. Requests must specify the research question, proposed analyses, and intended use of the data. Data may not be used to attempt re-identification of participants or for purposes that conflict with the informed consent provided by participants or applicable ethical and legal requirements.

From where data/document is obtainable

Requests for access should be submitted to the principal investigator or the designated corresponding researcher using the official contact information provided in the trial registration record. The request should include the applicant's name and affiliation, contact information, research question, study objectives, proposed analyses, and intended use of the requested data or documents.

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

Requests will be reviewed by the principal investigator and, when necessary, the relevant institutional ethics authority. The request will be assessed for scientific merit, ethical acceptability, consistency with participant consent, data privacy, and feasibility. Approved applicants will be required to agree to the terms of data use and confidentiality before receiving access. Data will be provided in a de-identified format through a secure method. The review process is expected to take up to 30 days after receipt of a complete request.

Comments