Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of peer-based blended education on health-promoting lifestyle and family caregiving burden in patients undergoing angioplasty 2026 : A Randomized Control Trial Study

Protocol summary

Study aim

Estimate the effect of peer-based education on health-promoting lifestyle and family caregiving burden in patients undergoing angioplasty

Design

The samples will be selected from among patients referred to the Payambar Center, after their clinical condition has stabilized, and eligible individuals will be assigned to two groups, "intervention" and "control," using block randomization (blocks of four). Each group will consist of 40 patients, totaling 80 patients.

Settings and conduct

The intervention group will receive training over eight sessions, including two in-person sessions at the hospital or clinic and six virtual sessions via messaging apps (Eitaa and WhatsApp).

Participants/Inclusion and exclusion criteria

Inclusion criteria Patients undergoing angioplasty for the first time Age between 30 -75 Ability to communicate verbally Access to a phone and the internet Having a consistent caregiver Exclusion criteria Unwillingness to cooperate Absence from raining session Recurrence of a cardiac event during the study Transfer to other hospitals

Intervention groups

Intervention: Participants will receive the routine care, plus eight sessions of peer-based education. Control : Participants will receive the routine care of the medical center.

Main outcome variables

Health-promoting lifestyle: An individual engages in behaviors that are essential for maintaining and promoting health, preventing diseases, and improving quality of life, and it includes all behaviors that affect an individual's health and hygiene. Family Caregiving Burden: This term refers to the psychological, social, and financial burden associated with a family member’s medical condition. Many physical and mental illnesses place considerable strain on caregivers’ resources and may lead to depression, social isolation, and physical health problems among caregivers.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261010071364N1**
Registration date: **2026-10-22, 1405/07/30**
Registration timing: **prospective**

Last update: **2026-10-22, 1405/07/30**
Update count: **0**

Registration date

2026-10-22, 1405/07/30

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2026-11-22, 1405/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of peer-based blended education on health-promoting lifestyle and family caregiving burden in patients undergoing angioplasty 2026 : A Randomized Control Trial Study

Public title

The effect of peer-based blended education on health-promoting lifestyle and family caregiving burden in patients undergoing angioplasty 2026 : A Randomized Control Trial Study

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing angioplasty for the first time Age between 30 - 75 years Ability to communicate verbally Access to a smartphone and the internet Having a fixed caregiver who cares for only one patient and spends at least four hours per day with the patient

Exclusion criteria:

Unwillingness to cooperate at any stage of the study Absence from 2 or more in training session Recurrence of a cardiac event during the study Transfer to a hospital outside the research setting

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be divided to two groups, intervention and control using block randomization (blocks of four).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IR.GOUMS

Street address

60KOLA

City

GORGAN

Province

Golestan

Postal code

4934174515

Approval date

2026-10-05, 1405/07/13

Ethics committee reference number

IR.GOUMS.REC.1405.292

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

Y84.8 Othe

ICD-10 code description

Y84.0

Primary outcomes

1

Description

Health-promoting lifestyle

Timepoint

before - end of session - 1 month later

Method of measurement

HPLP-II

2

Description

family care giver burden

Timepoint

before - end of session - 1 month later

Method of measurement

Zarit

Secondary outcomes

empty

Intervention groups

1

Description

This experimental study is a randomized controlled clinical trial without blinding, designed to investigate the effect of peer-led blended (in-person/virtual) education on two variables: "health-promoting lifestyle" and "family

caregiver burden" in patients undergoing angioplasty. The study population will include patients referred to the educational-therapeutic center affiliated with Payambar Azam (PBUH) Hospital and the regular caregivers of these patients. In the study by Khodabandehloo et al. (33), the mean lifestyle scores in the intervention and control groups were reported as 71.3 and 41.3, respectively, with a standard deviation of 0.46. Using the above information, at a statistical significance level of 0.05 and a power of 80%, the sample size was calculated using GPower software, the output of which is presented below. With a predicted 5% sample attrition probability, the sample size in each group will be 40 patients, and a total of 80 eligible patients will be selected based on inclusion and exclusion criteria to conduct the study.Analysis: A priori: Compute required sample size Input: Tail(s) = Two Effect size d = 0.6521739 α err prob = 0.05 Power (1-β err prob) = 0.8 Allocation ratio N2/N1 = 1Output: Noncentrality parameter δ = 2.8427601 Critical t = 1.9925435 Df = 74 Sample size group 1 = 38 Sample size group 2 = 38 Total sample size = 76 Actual power = 0.8011473In the study by Abbasi et al. (34), the mean (standard deviation) caregiver burden scores at the end of the study in the intervention and control groups were reported as 56.97 (11.35) and 78.23 (15.54), respectively. Using the above information, at a statistical significance level of 0.05 and a power of 80%, the sample size was calculated using GPower software, the output of which is presented below. With a predicted 5% sample attrition probability, the sample size in each group was estimated at 9 patients, and a total of 18 patients.t tests - Means: Difference between two independent means (two groups)Analysis: A priori: Compute required sample size Input: Tail(s) = Two Effect size d = 1.5624033 α err prob = 0.05 Power (1-β err prob) = 0.8 Allocation ratio N2/N1 = 1Output: Noncentrality parameter δ = 3.1248066 Critical t = 2.1447867 Df = 14 Sample size group 1 = 8 Sample size group 2 = 8 Total sample size = 16 Actual power = 0.8276221The maximum of the above sample sizes, i.e., 40 patients in each group and a total of 80 patients, was considered as the required sample size in this study.Inclusion criteria• Patients undergoing angioplasty for the first time• Age between 30 and 75 years• Ability to communicate verbally• Access to a smartphone and the Internet• Having a regular caregiver who cares for only one patient and spends at least four hours a day with the patient.Exclusion criteria• Unwillingness to cooperate at any stage of the study• Absence from more than one in-person education session• Recurrence of a cardiac event during the study• Transfer to a hospital outside the research settingSample selection will be carried out among those referred to the Payambar Azam (PBUH) Educational-Therapeutic Center in the CCU department and after their clinical condition has stabilized. Eligible individuals will be selected by convenience sampling, and written informed consent will be obtained from them. Samples will be allocated to two groups, "intervention" and "control," by block randomization (blocks of four). Then, for the patients and caregivers in the intervention group, the time, place, and manner of starting the intervention (in-person sessions), as well as the necessity of the regular caregiver's presence, will be explained. Patients in the control group will be informed of the times of visits and the need to complete the questionnaires at specific intervals, as well as the necessity of their regular caregiver's presence at the time of the first visit. During hospitalization, no education beyond the routine ward education will be provided to patients in either group.Caregiver selection criteria in the 2 intervention and control groups: age 18 to 75 years, ability to read and write, ability to work with a smartphone, spending at least 4 hours a day with the patient under study.Peer selection criteria: Peer selection criteria include at least six months having passed since a successful angioplasty without major complications, stable clinical condition (confirmed by a cardiologist), willingness to help others, having communication skills, obtaining a score of 75% or higher on the health-promoting lifestyle instrument, ability to express themselves properly, and the possibility of using a mobile phone. Also, the peer's capability and competence in the dimensions of ability to interact and communicate with clients, motivation and willingness to learn and teach, responsibility and observance of ethical standards, and awareness of the cultural differences of different ethnic groups will be assessed by the researcher. The content prepared by the principal investigator will be recorded as educational videos in which the peer is the instructor, and the peer will also be present in the in-person sessions to introduce themselves, establish initial communication with the clients, and provide education.A maximum of two peers will be selected, and the peers will be trained by the researcher before the start of the intervention, during multiple sessions and based on need. To maintain uniformity and standardize the educational content across all groups, a standardized Scripted Educational Package including a comprehensive guide to the educational content, slides, spoken text, and standard videos will be used. This package will be provided to the peer, and the content presented to all patients will be based on it.These trainings include familiarization with the educational content, the manner of interacting with patients, how to answer questions, and the method of conveying personal experiences.Intervention: The intervention will be implemented by the principal investigator, a second-year Master of Science in Nursing student (thesis project). The student plays an active role in all stages of developing and collecting data and preparing the final report of the project, and is supervised by the research team (supervisor and advisors) throughout the implementation process. The intervention consists of eight educational sessions for patients undergoing angioplasty:• Two in-person sessions (at least 30 minutes each) with patients present in groups of 8 to 10, taught by the peer under the supervision of the principal investigator.• Six virtual sessions as offline educational videos, accompanied by text and images, which will be filmed by the peer according to the existing economic conditions and in order to reduce the costs of conducting the study, filming and renting cameras and lighting equipment in the acoustic rooms of the Philosophy Medical Complex (Vice-

Chancellor for Education or the International Faculty), and only editing and compilation services will be outsourced. Then the content will be provided to patients on virtual platforms (Eitaa and WhatsApp).The first in-person session will be held at the participants' first visit to the clinic after discharge in the hospital amphitheater or at a location agreed upon by the members of the group's in-person session, and before the start of the session, patients and their caregivers will complete the questionnaires. In the in-person sessions, patients will become familiar with the study objectives, the research team, the peer instructor, the virtual groups created, and how to interact with the peer and the research team. Part of the educational content will also be presented orally and in writing (guide notes and educational booklets). Also, the phone number and address of the patient and regular caregiver will be obtained.In the virtual sessions, educational materials including videos and images prepared (by the research team) by the peer will be uploaded twice a week over three weeks in the virtual groups. If patients have questions, they can raise them in the group; the answers will be prepared in coordination with the principal investigator and the research team and provided by the peer. The members of the virtual groups will include patients, one regular companion for each patient, the principal investigator, the physician, and the project collaborators.Educational content: The educational content designed in this study will include the following main axes:• Understanding angioplasty and its possible complications• The importance of treatment adherence and familiarity with medications• Control of daily activities and appropriate exercise• Healthy diet and management of risk factors• Responsibility for health and prevention of disease recurrence• Effective interpersonal communication and stress managementValidation of educational content: In order to ensure the validity and appropriateness of the educational content developed for patients undergoing angioplasty, the Expert Panel Validation method will be used. Thus, the standardized educational package (including slides, spoken text, educational videos, and guide booklets), which is developed based on credible scientific sources (Brunner & Suddarth textbook, Braunwald's textbook, AHA and ACC clinical guidelines, and systematic review articles), will be provided to the expert panel before the implementation of the intervention.Composition of the expert panel: The expert panel will include 7 specialists selected by purposive sampling: 1 cardiologist (faculty member), 2 nurses from the cardiac intensive care unit (who have at least 5 years of experience in direct care of cardiac patients), 1 clinical psychology or social work specialist (to evaluate psychological dimensions and stress management), 1 health education or educational technology specialist (to evaluate the principles of educational design and the appropriateness of the content to patients' health literacy level), 1 nutrition specialist (to evaluate the scientific accuracy of the dietary content), 1 physiotherapy or physical activity specialist (to evaluate the physical activity content and control of daily activities).For validation, an educational content validation checklist including 10 criteria will be used: 1) appropriateness to educational objectives, 2) scientific accuracy, 3) logical coherence, 4) appropriateness to patients' health literacy level, 5) visual and cognitive appeal, 6) appropriate cognitive load, 7) feasibility in both in-person and virtual settings, 8) cultural and social appropriateness, 9) adequacy of content coverage, 10) clarity and fluency of language. Responses will be recorded on a 4-point Likert scale (inappropriate = 1 to completely appropriate = 4). Experts' opinions will be assessed using the Content Validity Ratio (CVR); given the 7 experts, the minimum acceptable CVR value according to the Lawshe table will be considered 0.99. Also, the final educational content will be reviewed and finally approved before implementation by the supervisor, advisors, and the patients' attending physician (who are present as consultants in the present project).This content is prepared by the principal investigator and will be presented to patients only by the peer. The peer will not convey any information to patients without the approval and supervision of the research team and the principal investigator. In the in-person sessions, part of the material will be presented orally and in writing (educational booklets and guide notes). In the virtual sessions, the educational content, including text, images, and videos recorded by the peer, will be uploaded on virtual platforms (Eitaa and WhatsApp) over a period of 3 weeks.To ensure that the educational videos are viewed, patients will be asked to send important topics that they find prominent in the clips as a private message to the researcher. Also, a checklist will be provided to patients so that they can mark it after watching each video and send it to the researcher at the end of the session.Clients can raise their questions after each session, and the peer, after coordinating with the research team, will provide the correct answer to them in text or audio form.The data required for this research will be collected through standard international instruments. Initial demographic and clinical information will be recorded using a researcher-made checklist through interviews and review of medical records. To measure the health-promoting lifestyle variable, the HPLPII (Health-Promoting Lifestyle Profile II) questionnaire (35) will be used, and to measure the family caregiver burden variable, the Zarit questionnaire will be used, both of which have proven their reliability and validity in the Iranian population (36).Assessment schedule: The questionnaires will be completed on three occasions by the patients and the regular caregiver:• Health-Promoting Lifestyle Profile (HPLP II) questionnaire- First occasion: at the first visit after discharge at the clinic and before the intervention- Second occasion: immediately after the end of the educational sessions- Third occasion: one month after the last educational session (37)Zarit Caregiver Burden questionnaire• Completed by the patient's regular companion (family member or closest caregiver).• First occasion: at the patient's first visit after discharge at the clinic and before the intervention• Second occasion: immediately after the end of the intervention• Third occasion: one month after the last educational session- Braunwald's Heart Disease textbook - section on coronary artery disease and angioplasty- American Heart

Association (AHA) and American College of Cardiology (ACC) clinical guidelines- Systematic review articles on peer education and lifestyle in cardiac patients (such as Cochrane and PubMed).Instruments and data collection method (according to the variables):To measure health-promoting lifestyle, the HPLP II (Health-Promoting Lifestyle Profile II) questionnaire will be used. This instrument is a 52-item questionnaire developed based on Pender's health promotion model by Walker et al. in 1987 (25). The questionnaire measures the frequency of health-promoting behaviors in six subscales, including nutrition (9 items), physical activity (8 items), health responsibility (9 items), stress management (8 items), interpersonal relationships (9 items), and spiritual growth (9 items). Responses are presented at four levels: "never," "sometimes," "usually," and "always," which are scored 1, 2, 3, and 4, respectively. The total score range of the questionnaire is between 52 and 208, and a separate score will be calculated for each subscale. In the study by Mohammadi Zeidi et al. (2011), the validity of the questionnaire was confirmed. Also, the reliability of the questionnaire using Cronbach's alpha coefficient was 0.82 for the whole questionnaire and between 0.64 and 0.91 for the subscales, indicating good internal consistency of the instrument. Also, the test-retest reliability coefficient with a two-week interval was calculated as 0.91 for the whole questionnaire and between 0.71 and 0.89 for the subscales (35).To measure family caregiver burden, the Zarit Burden Interview (1980) will be used. This instrument consists of 22 items that assess the degree of caregiver burden resulting from caring for the patient on the caregiver. Responses are scored at five levels: "never" (0), "rarely" (1), "sometimes" (2), "often" (3), and "always" (4). The total score ranges from zero to 88; a higher score indicates greater caregiver burden and a lower score indicates less caregiver burden. According to the classification of this instrument, a score of 0 to 20 indicates little or no caregiver burden, a score of 21 to 40 indicates moderate caregiver burden, and a score of 41 to 88 indicates severe caregiver burden.The validity and reliability of this questionnaire have been confirmed in domestic studies, including the study by Shafizadeh et al. (36). To examine validity, the content validity method was used using scientific sources and the opinions of university experts (psychiatrists, clinical and educational psychologists), and the reliability of the instrument was calculated by the test-retest method, with a correlation coefficient reported as 0.94.

Category

Other

2

Description

The control group will receive the usual and routine care of the treatment center, which includes receiving the center's standard educational booklets and periodic visits by the attending physician. All assessments (completion of the questionnaire) will be carried out at the scheduled times for both the intervention and control groups.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Payambar Azam Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

gholamreza roshandel

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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

Gorgan 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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Full name of responsible person
akram sadat montazari
Position
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Person responsible for updating data

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
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
Not applicable
Data Dictionary
Not applicable