

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of blended learning in cardiac rehabilitation based on the model of knowledge, attitude, and performance on medication adherence and self-efficacy of patients undergoing coronary artery bypass graft surgery

Protocol summary

Study aim

Determining the effectiveness of the model of knowledge, attitude, and performance on medication adherence, and self-efficacy of patients after coronary artery bypass surgery

Design

A parallel-group, single-blind, randomized controlled clinical trial on 70 patients

Settings and conduct

This study will be conducted at Farshchian Cardiovascular Hospital affiliated with Hamadan University of Medical Sciences in Hamadan City. The study is one-way blind, the health care provider (nurse of the rehabilitation department), the data analyst, and the outcome assessment will not know about the division of patients into test and control groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria include patients who have undergone coronary artery bypass surgery, are literate, willing to participate in the study, have an ejection fraction above 35%, have the physical ability to do an exercise test, and have access to a smartphone and the Internet; and the criteria for not admission include class III and IV insufficiency and occurrence of severe musculoskeletal problems.

Intervention groups

Intervention group: despite receiving routine cardiac rehabilitation in the hospital, patients in this group will receive 4 sessions of in-person treatment and care training based on the model of knowledge, attitude, and performance; after completing cardiac rehabilitation, they were monitored and trained through the designed application for 3 months. Control group: Patients will receive routine cardiac rehabilitation according to the current program of the rehabilitation center and will not receive any additional training.

Main outcome variables

Medication adherence; self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230902059333N1**

Registration date: **2024-01-02, 1402/10/12**

Registration timing: **prospective**

Last update: **2024-01-02, 1402/10/12**

Update count: **0**

Registration date

2024-01-02, 1402/10/12

Registrant information

Name

Ghazal Veisi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3329 1708

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-20, 1402/10/30

Expected recruitment end date

2024-08-20, 1403/05/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of blended learning in cardiac rehabilitation based on the model of knowledge, attitude, and performance on medication adherence and self-efficacy of patients undergoing coronary artery bypass graft surgery

Public title
The effect of blended learning in cardiac rehabilitation

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Reading and writing literacy Patients after coronary artery bypass graft Desire to participate in the study Performing coronary artery bypass graft surgery for the first time Ejection fraction above 35% Physical ability to perform exercise test Access to a smartphone Internet access
Exclusion criteria:
Heart Failure class III and IV Presence of severe musculoskeletal problems

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
First, among the patients who have undergone coronary artery bypass surgery and meet the inclusion criteria, they were selected by the available sampling method and based on the random block method in the cardiac rehabilitation group based on the knowledge, attitude, and performance model (intervention) and the routine cardiac rehabilitation group (control). For this purpose, the researcher will prepare 4 sheets, the number "1" will be written on two sheets for the first group, and the number "2" will be written on the two sheets for the second group. The cards are mixed in a container and randomly drawn one at a time for each patient without replacement until all four cards are drawn. Then four sheets are returned to the container, which is repeated until the sample volume is reached.

Blinding (investigator's opinion)
Single blinded

Blinding description

A cardiac rehabilitation nurse will perform assessments at each stage, blinded to random allocation. Also, the statistical analysis and outcome assessment will not know about the assignment of patients to two intervention and control groups during the analysis.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hamadan University of Medical Sciences
Street address
Shahid Fahmideh Blvd., Pajouhesh Sq.
City
Hamadan
Province
Hamadan
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6517838698

Approval date
2023-12-11, 1402/09/20
Ethics committee reference number
IR.UMSHA.REC.1402.551

Health conditions studied

1

Description of health condition studied
Patients undergoing coronary artery bypass surgery
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Self-efficacy
Timepoint
Before, immediately after, and 3 months after the end of the intervention
Method of measurement
Using the cardiovascular disease management self-efficacy questionnaire of Steca et alii: The cardiovascular disease management self-efficacy questionnaire was designed and compiled by Steca et alii in 2015 to measure the self-efficacy of cardiovascular disease management. This questionnaire has 9 questions and 3

components of heart risk self-efficacy, treatment adherence self-efficacy, and symptom recognition self-efficacy. It is based on the Likert spectrum with questions such as (you can avoid life problems and difficult situations and daily stress well) Minimize stress well.). It measures the self-efficacy of cardiovascular disease management. The distribution of questionnaire questions is such that questions 1 to 4 examine the self-efficacy of heart risk, questions 5 and 6 examine the self-efficacy of following the treatment, and questions 7, 8, and 9 examine the self-efficacy of detecting symptoms.

Secondary outcomes

1

Description

Medication adherence

Timepoint

Before, immediately after, and 3 months after the end of the intervention

Method of measurement

Using the medication adherence reporting scale by Yan Chen et alii: The medication adherence reporting scale was compiled by Yan Chen et alii in 2019. This questionnaire contains 5 questions, and the frequency rating of each behavior in this questionnaire is based on a 5-point scale that is graded from never to always. The total score of the scale ranges from 5, which indicates the lowest level of adherence, to 25, which indicates the highest level of adherence.

Intervention groups

1

Description

Intervention group: After introducing the study and stating its objectives, if desired, the patients will complete the informed consent form, the demographic information form, the drug treatment adherence, and cardiac self-efficacy questionnaires. In addition to receiving routine cardiac rehabilitation provided at the hospital's cardiac rehabilitation center, this group of patients will receive the necessary training and care in the form of combined learning in both face-to-face and virtual departments. In the face-to-face department, patients will receive face-to-face training in various fields such as heart disease, diet, physical activity, and the benefits of cardiac rehabilitation for 1 month. In the virtual department, after completing the routine rehabilitation in the hospital, the patients will receive training and support for 3 months based on an application developed by the research team which will be installed on the phones of the patients or a family member who lives with them. This application will be designed based on the model of knowledge, attitude, and performance so that for each part of the model, a part will be seen in this application. Besides improving patients' knowledge in this way, they can communicate with the researcher and send their questions through it. At the same time as improves the knowledge of patients

in the field of heart disease and cardiac rehabilitation and trying to change their attitude. The researcher changes their performance through this software by providing action plans, including sports activities, tailored to each person. The study's results will be examined through a questionnaire before the study, immediately after the completion of cardiac rehabilitation in the hospital, and 3 months later.

Category

Rehabilitation

2

Description

Control group: In this group, patients will enter the study after receiving informed consent and will complete the questionnaires. These people will only undergo routine cardiac rehabilitation in the hospital for one month (12 sessions, 3 times a week) and will not receive face-to-face and virtual training and care. At the end of the study, the training booklet will be given to this group. The study's results will be examined through a questionnaire before the study, immediately after the completion of cardiac rehabilitation in the hospital, and 3 months later.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Cardiovascular Hospital

Full name of responsible person

Ghazal Veisi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Gazal Veisi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Assistant Professor

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

I must provide all information for the sponsoring institution.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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