Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of a Digital Health Education Intervention Based on the Health Belief Model on Promoting Self-Care in Patients After Open-Heart Surgery: A Randomized Controlled Trial

Protocol summary

Study aim
Evaluation of the Effectiveness of a Digital Health Education Intervention Based on the Health Belief Model on Improving Self-Care in Patients After Open-Heart Surgery

Design
A clinical trial with a control group, a randomized blind strain, will be conducted on 90 samples

Settings and conduct
Study participants will be selected from individuals visiting Tehran Heart Center Hospital and will be assigned to the intervention and control groups before the study.

Participants/Inclusion and exclusion criteria
Inclusion and Exclusion Criteria (Concise): Participants must be post-heart surgery patients in stable condition at least five days after surgery, able to provide written consent, literate, and have access to and ability to use internet-connected devices (with family support if needed). Internet costs will be covered if necessary. Patients with language barriers, unstable conditions, severe cognitive or psychiatric disorders, major sensory impairments, or medical conditions interfering with training will be excluded.

Intervention groups
The present quasi-experimental study includes 45 participants in each of the control and experimental groups. The experimental group will receive an educational pamphlet before discharge and participate in an 8-session, two-month web-based program alongside standard post-discharge treatment. Pre- and post-tests will be conducted for both groups.

Main outcome variables
Awareness, Attitude, and Self-Care Behavior in Patients Candidates for Heart Surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251110067943N1**
Registration date: **2025-12-27, 1404/10/06**
Registration timing: **prospective**

Last update: **2025-12-27, 1404/10/06**
Update count: **0**

Registration date
2025-12-27, 1404/10/06

Registrant information

Name
Hadi Darvishigilan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 4322 4127

Email address
hadidarvishi2000@yahoo.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-04-20, 1405/01/31

Expected recruitment end date
2026-11-21, 1405/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effectiveness of a Digital Health Education Intervention Based on the Health Belief Model on Promoting Self-Care in Patients After Open-Heart Surgery: A Randomized Controlled Trial

Public title
Effectiveness of a Digital Health Education Intervention Based on the Health Belief Model on Improving Self-Care in Patients After Open-Heart Surgery: A Randomized Controlled Trial

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients must have successfully undergone open-heart surgery and be in a stable clinical condition for at least five days after surgery (or based on the opinion of the relevant specialist). Be able to provide written informed consent to participate in the study (i.e., be literate in reading and writing). Have access to a smartphone or computer with an internet connection. Have the ability to use an online system.If the patient does not have internet literacy, one of the family members should agree to support the patient during the training sessions. Be willing to cover the cost of internet access; if they have financial difficulties, this cost will be provided through the project's budget and the hospital's research unit

Exclusion criteria:
Have language impairments that prevent the patient from completing the questionnaire. Have an unstable clinical condition (for example, in the early postoperative period or in case of acute complications). Have serious cognitive problems such as Alzheimer's disease or delirium. Have psychiatric disorders that impair judgment and cognition, such as schizophrenia. Have severe visual or hearing impairments that prevent participation in the educational sessions. Have specific medical conditions requiring special treatment that interfere with participation in the educational program, such as patients undergoing chemotherapy for cancer.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling method is sequential and available based on entry and exit criteria and until the sample volume is completed. Allocation of people in intervention and control group is done by simple random allocation method and using Blockrand package of R software. After the random sequence is specified by the study epidemiologist, the researcher will put the people into 2 control and intervention groups based on the specified random sequence.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is designed as a single-blind trial, meaning that participants will not be aware of the type of intervention they receive (intervention or control group). Due to the nature of the intervention, namely digital health education, blinding the researcher or educator is not feasible since they are directly delivering the training. However, participants' lack of awareness regarding their group assignment helps reduce performance bias, and data analysis will be conducted by a blinded statistician to minimize assessment bias. This level of blinding is sufficient to ensure the validity of the results and to reduce bias in educational and behavioral intervention studies.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences

Street address
Shahid Beheshti Boulevard – Central Building, Kermanshah University of Medical Sciences

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2025-10-19, 1404/07/27

Ethics committee reference number
IR.KUMS.REC.1404.432

Health conditions studied

1

Description of health condition studied
The patients, having undergone complex cardiac surgery

ICD-10 code
I25.10

ICD-10 code description
Atherosclerotic heart disease of native coronary artery without angina pectoris

Primary outcomes

1

Description

Improvement in self-care behaviors Measured using a validated self-care questionnaire specific to cardiac surgery patients, assessed at baseline and at the end of the intervention period.2. **Clinical indicators related to post-surgical recovery** Such as incidence of complications (e.g., infections, hospital readmissions) monitored during the follow-up period.3. **Quality of life** Assessed by a standardized tool (e.g., SF-36 or a cardiac-specific quality of life questionnaire) before and after the intervention.

Timepoint

Immediately after the intervention and one month after the intervention and three months after the intervention

Method of measurement

Several questionnaires, particularly the **Self-Care of Coronary Heart Disease Inventory (SC-CHDI)**, and a **researcher-made self-care questionnaire for patients after open-heart surgery based on the Health Belief Model**.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in the intervention group, in addition to receiving standard post-discharge pharmacological treatment, will receive a web-based educational package and participate in 8 online and offline discussion sessions over a period of two months. The intervention in this group will be conducted according to a pre-designed checklist by two facilitators. It should be noted that these facilitators do not play any role in assessing the study outcomes and have full supervision to ensure the correct and complete implementation of the intervention process.

Category

Prevention

2

Description

Control group: All patients in the control group will receive the standard discharge education provided by the hospital at the time of discharge. However, unlike the intervention group, which receives both the standard education and the study-designed intervention, the control group will only receive the standard hospital discharge education. Participants who receive any education related to the intervention group will be excluded from the study.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center Hospital

Full name of responsible person

Hadi Darvishigilan

Street address

Tehran, above Enghelab Square, North Kargar Street, Tehran Heart Center Hospital

City

Tehran

Province

Tehran

Postal code

1411713138

Phone

+98 21 8802 9600

Fax

+98 21 8802 9731

Email

hadidarvishi2000@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Zohreh Rahimi

Street address

Vice President of Research and Technology of Kermanshah University of Medical Sciences,Shahid Beheshti Boulevard – Central Building, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 918 334 6889

Email

zrahimi@kums.ac.ir

Grant name

Vice President of Research and Technology of Kermanshah University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Hadi Darvishigilan
Position
Ph.D. in Health Education and Health Promotion, Non-Faculty Member
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Kermanshah – Shahid Beheshti Boulevard – Central Building, Kermanshah University of Medical Sciences
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
38358943-083
Email
hadidarvishi2000@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Hadi Darvishigilan
Position
Health Education Specialist
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Kermanshah – Shahid Beheshti Boulevard – Central Building, Kermanshah University of Medical Sciences
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
38358943-083
Email
hadidarvishi2000@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Hadi Darvishigilan
Position
Ph.D. in Health Education and Health Promotion, Non-Faculty Member
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Kermanshah – Shahid Beheshti Boulevard – Central Building, Kermanshah University of Medical Sciences
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Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
38358943-083
Email
hadidarvishi2000@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Awareness, Attitude, and Self-Care Behavior in Patients Candidates for Heart Surgery
When the data will become available and for how long
six month after publishing the result
To whom data/document is available
other researchers
Under which criteria data/document could be used
for re- analyses the data
From where data/document is obtainable
to researchers by email
What processes are involved for a request to access data/document

maximum six month

Comments