Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Effect of Self-Care Education on Self-Efficacy of Cardiac Surgery Patients and the Caregiver Burden of Their Caregivers

Protocol summary

Study aim

Determining the effect of self-care program training on self-efficacy of patients undergoing cardiac surgery and the caregiving burden of their caregivers. Determining the level of self-efficacy of patients undergoing open heart surgery before and after intervention in the control and experimental groups Determining the level of caregiving burden of caregivers of open heart surgery patients before and after intervention in the control and experimental groups

Design

The clinical trial has a control group and an intervention group and is being conducted on 66 patients.

Settings and conduct

The questionnaires are completed by the control group before and after the operation in the hospital, and also by the caregivers before the operation and one month after the operation in the clinic. The intervention group also completes the questionnaire before training and before the operation, and the questionnaires are completed again after training and after the operation. The questionnaires are completed for the caregivers of the intervention group before the operation, and after training and after the operation, one month after the operation in the clinic.

Participants/Inclusion and exclusion criteria

No history of previous open heart surgery Age 18 to 75 years Willingness to participate in the educational session No history of psychological illness based on the physician's history Ability to communicate verbally and understand educational materials

Intervention groups

Patients undergoing heart surgery and their caregivers

Main outcome variables

Patient age Patient gender Patient education level Patient marital status Patient underlying disease Patient smoking history Self-care education Self-efficacy of cardiac surgery patients Caregiver care burden Caregiver age Caregiver gender Caregiver education level Caregiver marital status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251215068340N1**
Registration date: **2026-05-04, 1405/02/14**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-04, 1405/02/14**
Update count: **0**

Registration date

2026-05-04, 1405/02/14

Registrant information

Name

Arsalan asoudeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 954 2310

Email address

arsalanasoudeh13701375@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-04, 1405/02/14

Expected recruitment end date

2026-08-05, 1405/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the Effect of Self-Care Education on Self-Efficacy of Cardiac Surgery Patients and the Caregiver Burden of Their Caregivers

Public title
Investigating the Effect of Self-Care Education on Self-Efficacy of Cardiac Surgery Patients and the Caregiver Burden of Their Caregivers

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
No history of previous open heart surgery Age 18 to 75 years Willingness to participate in the training session No history of psychological illness according to the doctor's history Ability to communicate verbally and understand educational materials

Exclusion criteria:
Patient's unwillingness to cooperate Simultaneous participation of the patient in another study with similar educational content

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
shakh bhayi

City
tehran

Province
Tehran

Postal code
1676745516

Approval date
2026-03-16, 1404/12/25

Ethics committee reference number
IR.BMSU.REC.1405.007

Health conditions studied

1

Description of health condition studied
Workload of cardiac surgery patients and the caregiving burden of their caregivers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Score obtained from the Patient Self-Efficacy Questionnaire and Caregiver Burden

Timepoint
From May 15, 1405 to August 15, 1405

Method of measurement
Sullivan Self-Efficacy Questionnaire and Novak and Gast Caregiver Burden Questionnaire

Secondary outcomes

1

Description
Self-efficacy scores of patients undergoing open heart surgery and caregiver burden scores of their caregivers

Timepoint
One day before training and one month after training

Method of measurement
Sullivan's 16-item self-efficacy questionnaire and Novak and Gast's 24-item caregiving burden questionnaire

Intervention groups

1

Description
Intervention group: Group one: patients undergoing open heart surgery Group two: caregivers of patients undergoing open heart surgery

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
بیمارستان قلب جماران تهران
Full name of responsible person
ارسلان اسوده
Street address
SHAKH BAHAYI
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
DR .SAEED HASHMI
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Arsalan asoudeh
Position
student
Latest degree
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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 do not want to explain
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