Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparative effect of online and nurse led support self-care modules on clinical outcomes among patients undergoing open heart surgery

Protocol summary

Study aim

To determine the comparative effect of online and nurse-led self-care support modules on clinical outcomes in patients undergoing open-heart surgery.

Design

In the first phase of the study, the content of the self-care modules for cardiac surgery will be developed. In the second phase, participants will be selected by convenience sampling. In the nurse-led education group, all educational content will be provided through face-to-face individual and group oral instruction with accompanying written materials, delivered in person by the researcher during hospitalization and after ICU discharge. After discharge, follow-up will be conducted by telephone. Eight weeks after the completion of the intervention, the questionnaires will be re-administered and the data will be analyzed.

Settings and conduct

In the online education group, the self-care modules will be delivered through a platform agreed upon by the participants, starting from the day before surgery and continuing until eight weeks after discharge. In the nurse-led education group, training will be provided verbally, face-to-face, and in written form during hospitalization, and will continue by telephone for up to eight weeks after discharge. .

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 18 and 65 years Patients undergoing coronary artery bypass graft surgery for the first time Not an emergency surgery

Intervention groups

In this study, we aim to investigate the effect of implementing interventions based on self-care modules delivered online and nurse-led on post-operative clinical outcomes in cardiac surgery patients, including quality of life, self-efficacy, and treatment adherence.

Main outcome variables

Quality of life scores of patients undergoing open-heart surgery Treatment adherence scores of patients undergoing open-heart surgery Self-efficacy scores of patients undergoing open-heart surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260217068900N1**
Registration date: **2026-07-20, 1405/04/29**
Registration timing: **prospective**

Last update: **2026-07-20, 1405/04/29**
Update count: **0**

Registration date

2026-07-20, 1405/04/29

Registrant information

Name
Amirhosein Madadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 3615 2401
Email address
amirmadadi1396@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-21, 1405/05/30

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative effect of online and nurse led support self-care modules on clinical outcomes among patients undergoing open heart surgery

Public title

The comparative effect of online and nurse led support self-care modules on clinical outcomes among patients undergoing open heart surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 65 years Patients undergoing coronary artery bypass graft surgery for the first time Not an emergency surgery Not being in a critical or emergency condition At least 24 hours have passed since the patient's admission Not having a debilitating disease No impairment in speech, hearing, or vision and able to communicate and cooperate Not suffering from any known physical or mental illnesses that significantly affect quality of life, such as being on dialysis or other recognized psychological conditions (e.g., depression or schizophrenia) that require specific medications or regimens (based on patient self-report) Access to a smartphone capable of installing a messaging app

Exclusion criteria:

Individuals who have participated in another training program during the study period Individuals who require readmission due to entering the acute phase of the illness Withdrawal from participation in the study Failure to respond to all questionnaire items (incomplete questionnaires) Individuals who are absent from two or more of the total follow-up sessions Transfer from the research unit to another unit

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will first be selected through convenience sampling and then randomly block-allocated into two groups: distance (online) education and face-to-face education. Using randomized blocks of four and prepared envelopes, each patient will be assigned a random code according to the order in which they enter the study, and patients will be placed into the two groups based on these random codes. Considering that sampling will take place in two hospitals and to prevent contamination of the samples, one hospital will be randomly assigned to the online education group and the other to the nurse-led (face-to-face) education group. Then, according to the four-person blocks, each patient will be randomly assigned to group A (online intervention) or group B (in-person intervention). For example, after randomly selecting a block such as BABA, patients will be assigned in the following order: online, in-person, online, in-person; and for the next block, such as AABB, patients will be assigned online, online, in-person, in-person. The number of individuals allocated to each group will be approximately equal. In this study, in addition to random allocation, allocation concealment was also performed. For this purpose, first, the random sequence was generated. Then, based on the study sample size, a number of envelopes were prepared, and each random sequence was recorded on a card, which was then placed inside an envelope in order. To preserve the random sequence, the envelopes were numbered externally in the same order. Finally, the envelopes were sealed and placed inside a box in sequence. At the time of participant registration, and according to the order in which eligible participants entered the study, one envelope was opened each time, revealing the group assigned to that participant. Individuals were assigned to the intended group based on their order of entry into the study and the randomized block sequences.

Blinding (investigator's opinion)

Single blinded

Blinding description

Given that sampling will be conducted in two hospitals, in order to prevent contamination between samples, one hospital will be randomly assigned to the online education group and the other hospital to the nurse-led education group.

Placebo

Not used

Assignment

Parallel

Other design features

Patients undergoing open-heart surgery often experience a wide range of physical and psychological symptoms, which may potentially be associated with a reduced quality of life. By improving self-care ability, the quality of life of cardiac patients can be enhanced. Nurse-led interventions, through active nurse involvement and disease management, lead to reduced hospital readmission rates among cardiac patients, decreased mortality, reduced burden on healthcare systems, improved integrated management of chronic diseases, and enhanced self-care skills. Educational interventions can increase patients' knowledge about self-care and influence their capacity to perform self-care behaviors. The use of self-care modules is a novel educational approach that has been introduced into clinical education within the past decade. In this study, we aim to investigate the effects of implementing self-care module-based interventions delivered through online and nurse-led methods on post–cardiac surgery clinical outcomes, including quality of life, self-efficacy, and treatment adherence in patients after cardiac surgery.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of the Schools of Pharmacy, Nursing, and Midwifery – Shahid Beheshti University

Street address
School of Nursing and Midwifery, across from Shahid Rajaei Heart Hospital, intersection of Vali-Asr Street and Ayatollah Hashemi Rafsanjani Highway, Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1996835119

Approval date
2026-02-15, 1404/11/26

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1404.257

Health conditions studied

1

Description of health condition studied
nurse led support- self-care- modules - open heart surgery- online education

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Treatment adherence

Timepoint
At entry into the study and eight weeks after completion of the intervention

Method of measurement
Medanlou Treatment Adherence Questionnaire

2

Description
Self-efficacy

Timepoint
At entry into the study and eight weeks after completion of the intervention

Method of measurement
Cardiac Self-Efficacy Scale (STECA)

3

Description
Health-related quality of life

Timepoint
At entry into the study and eight weeks after completion of the intervention

Method of measurement
World Health Organization Quality of Life – Brief Questionnaire(WHOQOL-BREF)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Online self-care modules (text, audio, and video) delivered via a messaging platform from one day before surgery until 4 weeks after discharge.Intervention group 2: Nurse-led self-care modules with identical educational content delivered in four 45-minute face-to-face sessions during hospitalization, followed by telephone follow-up for 4 weeks after discharge.

Category
Rehabilitation

2

Description
Evaluating the effect of nurse-led self-care modules on the clinical outcomes of patients undergoing open-heart surgery.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Hosein Hospital

Full name of responsible person
Amirhosein Madadi

Street address
Emam Hosein Hospital - Shahid Madani St - Tehran - Iran

City
Tehran

Province
Tehran

Postal code
02173431000-1

Phone
+98 21 7343 1000

Fax
+98 21 7343 1000

Email

info@sbmu.ac.ir

Web page address

https://ehmc.sbmu.ac.ir/

2

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Amirhosein Madadi

Street address

Iran - Tehran - Yadegar emam highway – saadat abad intersection - shahid modarres hospital

City

Tehran

Province

Tehran

Postal code

021-23515

Phone

+98 21 23515

Fax

+98 21 23515

Email

IPD.modares@sbmu.ac.ir

Web page address

https://modarres.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Neda sanaie

Street address

Tehran, Velenjak, Daneshjou Boulevard, Arabi Street, Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1996835119

Phone

+98 21 23871

Fax

+98 21 23871

Email

info@sbmu.ac.ir

Web page address

https://sbmu.ac.ir/

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

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Neda Sanaie

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Tehran, Valiasr Street, intersection with Ayatollah Hashemi Rafsanjani Highway, opposite Shahid Rajaei Heart Hospital, School of Nursing and Midwifery.

City

Tehran

Province

Tehran

Postal code

1996835119

Phone

02188655366-70

Fax

+98 21 8865 5363

Email

nedasanaie@ymail.com

Web page address

https://nm.sbmu.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Neda Sanaie

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Tehran, Valiasr Street, intersection with Ayatollah Hashemi Rafsanjani Highway, opposite Shahid Rajaei Heart Hospital, School of Nursing and Midwifery.

City
Tehran
Province
Tehran
Postal code
1996835119
Phone
88655366-337
Fax
+98 21 8865 5363
Email
nedasanaie@ymail.com
Web page address
https://nm.sbmu.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.Neda Sanaie
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Tehran, Valiasr Street, intersection with Ayatollah Hashemi Rafsanjani Highway, opposite Shahid Rajaei Heart Hospital, School of Nursing and Midwifery.
City
Tehran
Province
Tehran
Postal code
1996835119
Phone
88655366-337
Fax
+98 21 8865 5363
Email
nedasanaie@ymail.com
Web page address
https://nm.sbmu.ac.ir/

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
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
Title and more details about the data/document
all datails
When the data will become available and for how long
2027
To whom data/document is available
everyone
Under which criteria data/document could be used
any condition
From where data/document is obtainable
author
What processes are involved for a request to access data/document
nothing
Comments