Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of the transitional nursing care on functional independence, quality of life, and cardiac self-efficacy of the elderly undergoing coronary artery bypass graft surgery

Protocol summary

Study aim
To determine the effect of transitional nursing care on functional independence, quality of life, and cardiac self efficacy in elderly patients undergoing coronary artery bypass graft surgery.

Design
A block-randomized clinical trial with a control group and no blinding, conducted on 70 patients

Settings and conduct
This randomized controlled trial is conducted in collaboration with Shahid Sadoughi School of Nursing and Midwifery and Afshar Cardiac Rehabilitation Center. The study population includes adults aged ≥60 years undergoing CABG and receiving cardiac rehabilitation services at Afshar Hospital. The intervention lasts 8 weeks with a 16-week follow-up. Due to the nature of the intervention, blinding of researchers and participants is not feasible.

Participants/Inclusion and exclusion criteria
Inclusion criteria: -Willingness to participate. -Age 60–75 years. -Intact consciousness and cognitive competence. -First-time, non-emergency CABG surgery. -No history of psychiatric disorders. -Literacy of the patient or an active caregiver. -Access to a smartphone and the internet by the patient or caregiver. Exclusion criteria: -Inability to attend required in-person visits, especially during the first two weeks (if stated at enrollment).

Intervention groups
-The intervention group includes older patients (≥60 years) undergoing CABG who receive a four-phase program consisting of preoperative education, in-person counseling in the first postoperative week, telephone follow-ups in weeks 2, 4, 6, and 8, and final follow-ups in weeks 12–16. -The comparison group includes older patients (≥60 years) undergoing CABG who receive routine cardiac rehabilitation care, including preoperative psychological counseling, standard postoperative education, and usual post-discharge follow-ups.

Main outcome variables
Quality of life, functional independence; cardiac self efficacy; hospital readmission

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251119068047N1**
Registration date: **2025-12-08, 1404/09/17**
Registration timing: **prospective**

Last update: **2025-12-08, 1404/09/17**
Update count: **0**

Registration date
2025-12-08, 1404/09/17

Registrant information

Name
Moein Mollamohammadi Ardakani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-01-21, 1404/11/01

Expected recruitment end date
2027-01-21, 1405/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of the transitional nursing care on functional independence, quality of life, and cardiac self-efficacy of the elderly undergoing coronary artery bypass graft surgery

Public title

The effect of implementing transitional nursing care in the elderly undergoing coronary artery bypass graft surgery.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Young elders (age group 60 to 75 years) Being alert and mentally healthy Performing coronary artery bypass grafting for the first time The patient's coronary artery bypass grafting procedure is not an emergency. No history of mental disorder The patient or their active companion must be literate. The patient or their active companion must have a smartphone and the patient or their companion must be able to use the internet.

Exclusion criteria:

The patient's condition should be such that he/she is unable to visit in person, especially in the first two weeks, and this should be mentioned from the beginning.

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to the intervention or control group using block randomization. The random allocation sequence will be generated by the third researcher using the online tool available at www.random.org/sequences/ . This sequence will then be placed as coded assignment labels inside 70 opaque, sealed envelopes. The allocation order will only be revealed upon opening each envelope at the time of a participant’s entry into the study. In this way, allocation concealment is ensured, minimizing the risk of selection bias. To prevent contamination between the two study groups, patients in the control and intervention groups will be accommodated in separate rooms from admission until discharge. Additionally, participants in the intervention group will be instructed not to share any educational materials with other patients during the study period. Patients and their companions will be reminded not to disclose the educational content or study procedures to other patients, especially to those who are candidates for CABG surgery.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Deputy of Research and Technology, Imam Reza Complex, Imam Hossein Square, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8916877443

Approval date

2025-09-17, 1404/06/26

Ethics committee reference number

IR.SSU.REC.1404.085

Health conditions studied

1

Description of health condition studied

Chronic ischemic coronary artery disease

ICD-10 code

I25

ICD-10 code description

Chronic ischaemic heart disease

2

Description of health condition studied

Patients undergoing coronary artery bypass surgery

ICD-10 code

T82.9

ICD-10 code description

Unspecified complication of cardiac and vascular prosthetic device, implant and graft

3

Description of health condition studied
Transitional nursing care of patients undergoing coronary artery bypass surgery
ICD-10 code
Z74.3
ICD-10 code description
Need for continuous supervision

4

Description of health condition studied
Nursing-led multidisciplinary care for patients undergoing coronary artery bypass graft surgery
ICD-10 code
Z51.8
ICD-10 code description
Encounter for other specified aftercare

Primary outcomes

1

Description
Health-Related Quality of Life
Timepoint
The time points for measuring quality of life in this study include: at the beginning of the study (before surgery), the end of the eighth week after the start of the study (end of intervention phase), and the end of the sixteenth week after the start of the study (end of follow-up phase).
Method of measurement
SF-36 questionnaire

Secondary outcomes

1

Description
Hospital Readmission
Timepoint
The time points for measuring hospital readmissions in this study include: at the beginning of the study (before surgery), the end of the eighth week after the start of the study (end of intervention phase), and the end of the sixteenth week after the start of the study (end of follow-up phase).
Method of measurement
Follow up form

2

Description
Cardiac Self-Efficacy
Timepoint
The time points for measuring Cardiac Self-Efficacy in this study include: at the beginning of the study (before surgery), the end of the eighth week after the start of the study (end of intervention phase), and the end of the sixteenth week after the start of the study (end of follow-up phase).
Method of measurement
Cardiac self-efficacy scale

3

Description
Functional Independence
Timepoint
The time points for measuring functional independence in this study include: at the beginning of the study (before surgery), the end of the eighth week after the start of the study (end of intervention phase), and the end of the sixteenth week after the start of the study (end of follow-up phase).
Method of measurement
Barthel scale

Intervention groups

1

Description
Intervention group: The structured transitional nursing care intervention for the intervention group is delivered over four phases during 16 weeks. Before surgery, patients and one family member receive a validated multimedia CABG educational package consisting of seven short (5–10 minute) videos delivered via smartphone messenger or in-person, covering surgical preparation, procedure stages, hospital care, symptom monitoring, self-assessment, and post-discharge self-care. In the first week post-surgery (in-hospital and immediate post-discharge phase), the lead nurse conducts face-to-face consultation, assesses living conditions, support systems and medication adherence, reviews the educational package and answers questions while the surgeon performs clinical follow-up, the dietitian provides nutritional counseling, and the physiotherapist teaches rehabilitation exercises. From weeks 2 to 8 post-surgery, the lead nurse performs scheduled telephone follow-ups at weeks 2, 4, 6, and 8, reinforces self-care education, completes specific home-care follow-up forms, and refers patients to the multidisciplinary team as needed. From weeks 12 to 16, telephone follow-ups continue at weeks 12, 14, and 16 to monitor rehospitalization, complications, medication continuity, and medical visits, with completion of general follow-up forms and referral when necessary. All activities are coordinated by the coordinating nurse under the supervision of the principal investigator (lead nurse), and research instruments are completed at baseline, week 8, and week 16.
Category
Behavior

2

Description
Control group: The control group receives routine hospital and cardiac rehabilitation center care, including pre-operative psychological counseling, general post-operative education in the ward, and telephone follow-up

at one month and one year by the rehabilitation center. No additional research intervention is provided; participation in routine programs is only recommended.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Mohammad Sadegh Afshar Hospital

Full name of responsible person
Hassan Haghani Nejad

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Mohammad Sadegh Afshar Hospital, Jomhouri Eslami Boulevard, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Amir Houshang Mehrparvar

Street address
Imam Hossein (AS) Square, Beginning of Daneshjoo Boulevard, Imam Reza (AS) Educational and Research Complex, Vice President for Research and Technology, Shahid Sadoughi University of Medical Sciences

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Email
dvc.research@ssu.ac.ir

Web page address
http://www.research.ssu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Fatemeh Bakhshi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Nursing and Midwifery School, Bu Ali Street, Opposite the Infertility Center

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Person responsible for scientific inquiries

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Full name of responsible person
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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)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is 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 participant personal data in the study can be shared after anonymization. Data sharing can be done by uploading to official data repositories or upon request by the applicant via email to the corresponding author.

When the data will become available and for how long
6 months after publication of the article

To whom data/document is available
The data will be available to researchers working in universities and scientific institutions.

Under which criteria data/document could be used
For scientific application and use for systematic review studies

From where data/document is obtainable
Fatemeh Bakhshi, Yazd, Bouali St., Safaieh, Shahid Sadoughi Nursing and Midwifery School, Yazd, Nursing and Midwifery Care Research Center, Postal Code: 8916877443, Contact Phone: 00989139684626, Email Addresses: fateme.bakhshii@gmail.com - f.bakhshi@ssu.ac.ir

What processes are involved for a request to access data/document
One week after the applicant's email

Comments