Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Educational Intervention Based on Transition Theory on the Readiness for Hospital Discharge in Patients Undergoing Open Heart Surgery

Protocol summary

Study aim

Determining the effectiveness of transition theory-based training on the discharge readiness of patients undergoing open heart surgery

Design

The clinical trial will be conducted as a quasi-experimental study using a convenience sampling method, with a control group, on 60 patients in two phases.

Settings and conduct

This quasi-experimental study will be conducted in the open heart ICU ward of Baqiyatallah Hospital in two phases using convenience sampling. In the first phase, the development and validation of educational content for open heart surgery patients from 2020 to 2024 will be carried out by reviewing the literature and examining it in a group of experts. In the second phase, patients will be randomly assigned to two control and experimental groups based on the sample size and inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No history of previous open heart surgery - Age 30 to 75 years - Willingness to participate in the educational session - Literacy - No history of psychological disorders

Intervention groups

Control group: Patients who are candidates for cardiac surgery who are randomly assigned to the control group and receive routine hospital care. Intervention group: First, written consent to participate in the study will be obtained. Then, one day before surgery (the day of patient preparation for surgery), discharge readiness, anxiety, and treatment compliance questionnaires will be completed. The experimental group will receive discharge readiness training based on Mellis' transition theory in addition to usual care.

Main outcome variables

Increasing readiness for discharge in open heart surgery patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241208063990N1**
Registration date: **2025-02-14, 1403/11/26**
Registration timing: **prospective**

Last update: **2025-02-14, 1403/11/26**
Update count: **0**

Registration date

2025-02-14, 1403/11/26

Registrant information

Name

Ali Bayanati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8755 9886

Email address

reza.asgar57@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-19, 1403/12/01

Expected recruitment end date

2025-03-18, 1403/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Educational Intervention Based on Transition Theory on the Readiness for Hospital Discharge in Patients Undergoing Open Heart Surgery

Public title

A study of a new training for preparing cardiac patients before discharge after open heart surgery.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

No history of previous open heart surgery Age 30 to 75 years Willingness to participate in an educational session Literacy No history of psychological disorders

Exclusion criteria:

History of open heart surgery Simultaneous participation in another study with similar educational content Deterioration of the patient's condition and return to the intensive care unit

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a block randomization method will be used to allocate patients to intervention and control groups. Initially, using random number generator software, blocks of size 4 will be created, consisting of combinations of intervention (I) and control (C) groups (such as IICC, ICIC, CCII). These blocks will be randomly arranged to create the final group allocation list. Each eligible patient entering the study will be assigned to either the intervention or control group in order from this randomized list. To maintain allocation concealment, sealed and numbered envelopes will be used. The person responsible for group allocation will not be involved in outcome assessment to ensure blinding. This method ensures that the number of participants in each group is balanced and minimizes the possibility of predicting group allocations, thereby increasing the internal validity of the study.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Baqiyatallah Al-Azam Educational and Therapeutic Center

Street address

No. 150, West Brazil Street, Tehran

City

Tehran

Province

Tehran

Postal code

1435814817

Approval date

2024-12-03, 1403/09/13

Ethics committee reference number

IR.BMSU.BAQ.REC.1403.190

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Score obtained using the Readiness for Discharge Scale

Timepoint

Before the intervention and two months after surgery

Method of measurement

Score obtained from the Morisky questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Patients who are candidates for heart surgery at Baqiyatallah Hospital will be randomly selected to participate in the study. They will receive education over five days through in-person sessions, structured step-by-step based on the Transition Theory as follows: Session One (Day before surgery): To assess patient awareness,

patients will complete an anxiety questionnaire and a readiness for discharge survey. Session Two (60-minute group session on the second day after surgery): Face-to-face education based on identified educational needs from reviewing literature on patient awareness, engagement, and participation. Education continues until patients demonstrate independence. Session Three (60-minute group session on the third day after surgery): Focuses on patient engagement and participation during the transition period to another ward. Feedback is provided on previously taught lessons, with additional instruction if needed. Patients are encouraged mentally to continue learning as they move wards. Session Four (15-20 minute individual or family interview): Considering critical aspects when preparing patients for home transfer, encouraging adherence to care plans taught earlier, motivating families to create a stress-controlled environment, monitoring medication intake. Session Five (Phone follow-up): Focusing on event aspects by contacting patients and their families two weeks post-discharge to review dietary and medication adherence; completing a medication regimen compliance questionnaire. This structured approach aims to enhance patient recovery through comprehensive support throughout their transition from hospital care back home.

Category
Lifestyle

2

Description
In the control group, patients who are candidates for heart surgery are randomly assigned to the control group and receive routine hospital care.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiyatallah Al-Azam Hospital, Tehran

Full name of responsible person
Saeed Hashemi

Street address
Vanak Square, Mulla Sadra Street, Sheikh Bahai Street

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Tehran

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1435916471

Phone
+98 912 464 3976

Email
hashemisaeed65@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Saeed Hashemi

Street address
Vanak Square, Mulla Sadra Street, Sheikh Bahai Street

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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
Saeed Hashemi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
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Person responsible for updating data

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All questionnaire questions, including researcher-made variables and scores of the questionnaires used, are available.

When the data will become available and for how long
Immediately after the article was published

To whom data/document is available
Researchers, professors and students of medical universities and healthcare workers

Under which criteria data/document could be used
The results of this study can be used in medical centers to improve the health of patients and to benefit the educational system.

From where data/document is obtainable
University Library, Published Article

What processes are involved for a request to access data/document
The request is sent via email or other means of communication to the responsible author or colleagues, and then the required information is made available to the applicants.

Comments