Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

The effect of the designed transitional care plan from the Open Heart Intensive Care Unit to the general ward in patients undergoing coronary artery bypass graft surgery

Protocol summary

Study aim

Determine the effect of designed transitional care plan from OH-ICU to general ward in patients under Coronary artery BYPASS graft surgery

Design

The non-randomized clinical trial, with the control group, on 62 patients

Settings and conduct

The research environment is OH-ICU and cardiac surgery wards of Imam Khomeini hospitals in Tehran. First, the patients in the control group are sampled by the convenience sampling method and then the participants of the intervention group are selected and receive the transfer care program. Questionnaires related to expected outcomes are completed before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients undergoing CABG surgery who are candidates for transfer from the OH-ICU to the general ward at least two days after surgery; level of consciousness 15; no chronic progressive disease or acute unpredicted complications of the surgery; no history of diagnosed psychological disorders. Exclusion criteria: reluctance to continue participating in the study during the intervention; death of the patient; the occurrence of an unpredictable accident that interferes with the implementation of the program.

Intervention groups

The intervention group receives a transitional care plan that includes designed measures to transfer the patient from the physician's decision to transfer the patient from the OH-ICU until discharge from the general ward (5-7 days). This program is implemented with the cooperation of the patient, trained nurses, the treating physician, and the patient's companion (friend, spouse, or relatives). The researcher monitors the patient and the implementation of the program during the intervention and records how the program is implemented in the registration forms.

Main outcome variables

Anxiety; relocation stress syndrome; patient satisfaction; family satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100531004062N2**
Registration date: **2021-08-02, 1400/05/11**
Registration timing: **prospective**

Last update: **2021-08-02, 1400/05/11**
Update count: **0**

Registration date

2021-08-02, 1400/05/11

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

-

Email address

khoshkesht@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the designed transitional care plan from the Open Heart Intensive Care Unit to the general ward in patients undergoing coronary artery bypass graft surgery

Public title

The effect of the designed transitional care plan from the Open Heart Intensive Care Unit to the general ward in patients undergoing coronary artery bypass graft surgery

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

All patients undergoing Coronary artery bypass graft(CABG) surgery who are candidates for transfer from the Open Heart Intensive Care Unit (OH-ICU) to the general ward at least two days after surgery as directed by the physician Level of consciousness 15 according to Glasgow Coma Scale (GCS) No chronic progressive disease or acute unpredicted complications of surgery No history of diagnosed psychological disorders

Exclusion criteria:

Reluctance to continue participating in the study during the intervention Death of the patient The occurrence of an unpredictable accident that interferes with the implementation of the program

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study is part of a mixed-method study that aims to design, implement and evaluation of the transitional care plan from OH-ICU to general ward; The result of the doctoral dissertation of Nursing, Tehran University of Medical Sciences, School of Nursing and Midwifery, Number: 961199997. In order to design a transitional care program, while examining the concept of transitional care from the perspective of stakeholders (patients, patient companions, physician, and nurse responsible for patient transfer), the needs of patients undergoing CABG surgery eligible for transfer to the general ward have been identified (qualitative study). The program takes into account the preferences and needs of patients and stakeholders, using the best available evidence (systematic review of literature, guidelines, protocols, programs, and models of transitional care over the past 10 years), and the opinions of the Experts panel (Focus group) to be designed. Finally, the transitional care program was designed and developed in four dimensions: 1- Transfer expectation 2- Support, gradual reduction of dependence and increase of independence 3- Communication and strengthening of Care triangle 4- continuity of Integrated and need-based care.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Joint institutional research ethics Committee of School of Nursing and Midwifery & Rehabilitat

Street address

Nosrat St., Tohid Sq., School of Nursing & Midwifery, Tehran University of Medical Sciences, Tehra, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2019-05-19, 1398/02/29

Ethics committee reference number

IR.TUMS.FNM.REC.1398.020

Health conditions studied

1

Description of health condition studied

Transitional care program for patients undergoing coronary artery bypass graft surgery from the open heart intensive care unit to the general ward

ICD-10 code

I25.7

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris

Primary outcomes

1

Description

Patients Satisfaction

Timepoint

After the intervention

Method of measurement

Patients Satisfaction Instrument

2

Description

Family Satisfaction

Timepoint

After the intervention

Method of measurement

Family Satisfaction Questionnaire

3

Description

Anxiety

Timepoint

Before and after the intervention

Method of measurement

Speilberger State – Trait Anxiety Inventory (STAI-Y)

4

Description

Relocation Stress Syndrome

Timepoint

After the intervention

Method of measurement

Relocation Stress Syndrome Scale

5

Description

Total Comfort Score

Timepoint

Before and after the intervention

Method of measurement

Visual Analog Scale to Total Comfort

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: after the necessary explanations to the research samples and obtaining informed consent, before transferring the patient from the open heart surgery-intensive care unit, questionnaires related to the expected outcomes (anxiety and perceived social support) are completed. Patients then have a transitional care program that includes measures designed to transfer the patient from the physician's decision to transfer the patient from the open heart surgery-intensive care unit to discharge from the general ward, which is designed to maintain the continuity of the integrated care while transferring the patient. It is performed in a multidisciplinary manner and with the cooperation of the patient, the patient care nurses from the open heart intensive care unit and general care, and the physician with the participation of the patient companions (friend, spouse, or relatives). Interventions are performed by trained nurses to implement this program in the intensive care unit and the general ward. The researcher monitors and tracks the patient and the implementation of the program during the course and records how the program is implemented in the registration forms of the transitional care program. On the day of the patient's discharge, questionnaires related to the expected outcomes (perceived anxiety and social support, patient satisfaction, and family satisfaction) are completed.

Category

N/A

2

Description

Control group: after the necessary explanations to the research samples and obtaining informed consent, before transferring the patient from the open heart surgery-intensive care unit of , questionnaires related to the expected outcomes (anxiety and perceived social support) are completed. Patients then receive routine care during the transfer to the general ward until the day of discharge. The researcher follows the patient throughout the course to be excluded from the study if they meet the exclusion criteria.On the day of the patient's discharge, questionnaires related to the expected outcomes (perceived anxiety and social support, patient satisfaction and family satisfaction) arecompleted.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Sahar Khoshkesht

Street address

Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran

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Web page address

Sponsors / Funding sources

1

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Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
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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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The data file, participants' details, information about the outcomes, and the study protocol with the designed program will be published as an articles
When the data will become available and for how long
6 months after publishing the results
To whom data/document is available
For researchers working in academic institutions with the approval of supervisors and advisors
Under which criteria data/document could be used
Only for use of the designed program with cited to the source
From where data/document is obtainable
The main researcher, Ms. Sahar Khoshkasht
What processes are involved for a request to access data/document
Send email to supervisors Dr. Masoumeh ZakeriMoghadam and Dr. Shahrzad Ghiyasvandian
Comments