Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The effect of the transitional care program from hospital to own home using the digital messaging application on self-efficacy, quality of life, cardiac symptoms, and medication adherence among patients undergoing coronary artery bypass graft surgery and caregiving burden in their family caregivers

Protocol summary

Study aim
The effect of hospital-to-home transitional care program based on messaging programs on self-efficacy, quality of life, cardiac symptoms, and medication adherence of patients undergoing coronary artery bypass graft surgery and their family caregiver burden

Design
A randomized, parallel clinical trial with a control group on 70 patients. Random block designs will be used for randomization.

Settings and conduct
The study population in the present study includes all patients undergoing coronary artery bypass graft surgery at Shahid Beheshti Hospital in Shiraz, Iran, and their family caregivers. Participants in the intervention group will receive a transitional care program via WhatsApp within 8 weeks that covers self-care activities, medication use, heart symptom management, diet, sexual and social activity, physical activity, control of risk factors, and time to see a physician. Patients and their family caregivers in the control group will receive routine care during discharge.

Participants/Inclusion and exclusion criteria
Inclusion criteria for patients include undergoing coronary artery bypass graft surgery for the first time and being able to use WhatsApp. Exclusion criteria for patients will include patient dissatisfaction to continue working with the researcher and re-hospitalization during the study. Inclusion criteria for family caregivers of patients include living with the patient and the ability to use WhatsApp. In addition, exclusion criteria include dissatisfaction with continuing to work with the researcher.

Intervention groups
Participants in the intervention group will receive a transitional care program, and participants in the control group will receive routine care.

Main outcome variables
self-efficacy, quality of life, cardiac symptoms, and medication adherence among patients undergoing coronary artery bypass graft surgery and caregiving burden in their family caregivers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180113038347N2**
Registration date: **2022-01-11, 1400/10/21**
Registration timing: **prospective**

Last update: **2022-01-11, 1400/10/21**
Update count: **0**

Registration date
2022-01-11, 1400/10/21

Registrant information

Name
Abbas Mardani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-04, 1400/11/15
Expected recruitment end date
2022-09-22, 1401/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the transitional care program from hospital to own home using the digital messaging application on self-efficacy, quality of life, cardiac symptoms, and medication adherence among patients undergoing coronary artery bypass graft surgery and caregiving burden in their family caregivers

Public title
The effect of the transitional care program from hospital to own home using the digital messaging application on self-efficacy, quality of life, cardiac symptoms, and medication adherence among patients undergoing coronary artery bypass graft surgery and caregiving burden in their family caregivers
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria for patients: Age over 18 years Performing coronary artery bypass graft (CABG) surgery for the first time in patients No concomitant surgery during CABG surgery Absence of respiratory diseases Absence of drug and alcohol addiction No history of seizures or mental health problems No disturbance of consciousness or cognitive problems Living with a family caregiver (spouse or children) Have adequate health literacy Having a smartphone Ability to use WhatsApp Conscious consent to participate in the study Inclusion criteria for family caregivers: Age over 18 years A close family member of the patient Lack of a history of any mental health problems Living with the patient Have adequate health literacy Having a smartphone Ability to use WhatsApp Ability to communicate effectively The first experience of caring for a patient undergoing CABG surgery Conscious consent to participate in the study
Exclusion criteria:
Exclusion criteria for patients: Patient dissatisfaction to continue working with the researcher Re-hospitalization of the patient during the research Patient death during the intervention Exclusion criteria for family caregivers: Dissatisfaction to continue working with the researcher Patient death during the intervention
Age
From **18 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
A quadruple random block design will be used to assign samples to two groups of control and intervention randomly. Code A (for the intervention group) and Code B (for the control group) will be considered. Then the required random blocks and their sequence will be determined using the website: https://www.sealedenvelope.com. Furthermore, sealed envelopes will be used for concealment. Thus, based on the sequence of randomly selected blocks, cards with the letters A (for the intervention group) or B (for the control group) indicating the assignment sequence will be placed inside the envelope. An envelope will then be opened for each participant in the study, respectively, and will be assigned to the control or intervention group based on the card inside the envelope.
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 Iran University of Medical Sciences
Street address
Tehran, Hemmat Highway next to Milad Tower, Iran University of
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2022-01-02, 1400/10/12
Ethics committee reference number
IR.IUMS.REC.1400.903

Health conditions studied

1

Description of health condition studied

Coronary artery bypass graft surgery

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

Self- efficacy

Timepoint

Before the intervention, at the end of the intervention and two months after the intervention

Method of measurement

Cardiac Self-Efficacy Scale

2

Description

Quality of life

Timepoint

Before the intervention, at the end of the intervention and two months after the intervention

Method of measurement

MacNew Heart Disease HRQL questionnaire

3

Description

cardiac symptoms

Timepoint

Before the intervention, at the end of the intervention and two months after the intervention

Method of measurement

Cardiac Symptom Scale

4

Description

medication adherance

Timepoint

Before the intervention, at the end of the intervention and two months after the intervention

Method of measurement

Morisky Medication Adherence Scale

5

Description

caregiving burden

Timepoint

Before the intervention, at the end of the intervention and two months after the intervention

Method of measurement

Caregiver Burden Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group will receive an intervention designed according to a person-centered care approach based on evidence-based practice and clinical knowledge. This program will include the following: (1) The researcher (nurse) will interview the patient and his / her family caregiver after the patient's hospitalization and will receive information about the patient's daily life before surgery, symptoms, impact of symptoms on daily life, assessment of social status, need for post-discharge support, daily life activities, and motivation/goals. Then, a post-discharge care plan for the patient based on the needs extracted in the previous stage will be developed with the cooperation of the patient himself, his / her family caregiver, and the researcher based on the literature. The designed program will also be approved by the patient's physician in the hospital. This program, by default, covers self-care activities, how to take medication, management of cardiac symptoms, diet, sexual and social activity, physical activity, control of risk factors, and time to see a doctor. It should be noted that this program is person-centered and will be based on the needs of patients and their family caregivers. In addition, before discharge, if needed, patients and their family caregivers are taught how to use WhatsApp and the functions associated with this application. General educational content will be created by the research team based on a review of the literature and includes additional training on heart disease, regular monitoring of blood pressure and heart rate, nutrition (general recommendations), and wound care; (2) Then, in the intervention group, the educational content related to the designed care program will be sent by the researcher in the form of text messages, video messages, and video and voice calls using the WhatsApp program to the patients and their family caregivers twice a week in the first 4 weeks of the intervention and then once a week in the second 4 weeks of the intervention (based on agreement with them). In addition, additional training on heart disease, regular control of blood pressure and heart rate, nutrition (general recommendations), wound care (number of participants in each WhatsApp group for effective management by the researcher 5-8 people Will be) will be provided in a WhatsApp group. Moreover, twice a week patients will be asked about the presence of cardiac symptoms (angina, shortness of breath, fatigue, depression, sleep problems and pain at surgery, swelling of the legs, increased heart rate, anxiety, and anorexia) and If there are any symptoms, the necessary training will be provided in the form of a message according to the needs of patients and their family caregivers and the researcher will adjust the care program according to the needs of the patient at this stage. Furthermore, patients and their family caregivers will be free to share their concerns and questions with the researcher 24 hours a day, 7 days a week. At this stage, patients will be regularly encouraged to follow the

care plan.

Category

Rehabilitation

2

Description

Control group: Patients and their family caregivers in the control group will receive routine care during discharge, including advice on cardiac symptom management, physical activity, medication, diet, and time to see a doctor based on face-to-face instruction and pamphlets by the ward nurse.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital

Full name of responsible person
Raziyeh Iloonkashkooli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

Iran 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
Iran University of Medical Sciences

Full name of responsible person
Abbas Mardani

Position
PhD candidate

Latest degree
Master

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
-

When the data will become available and for how long
Unlimited

To whom data/document is available
Unlimited

Under which criteria data/document could be used
For use for scientific purposes

From where data/document is obtainable
Corresponding author

What processes are involved for a request to access data/document
The application must be submitted to the corresponding author.

Comments