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The effectiveness of individualized self-care program based on Orem's theory among post-coronary artery bypass surgery patients

Submission date
26/02/2023

Recruitment status
No longer recruiting

Registration date
01/04/2023

Overall study status
Completed

Last Edited
30/06/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Shorter post-coronary artery bypass graft (CABG) surgery hospital stays emphasize the need for timely patient education. An individualized self-care program post-discharge can effectively replace in-hospital education. This study aims to examine whether the individualized self-care program is effective in improving patients' knowledge of self-care behaviors and performance of self-care behaviors, as well as reducing symptoms severity, at both 1 and 3 weeks after hospital discharge following CABG surgery.

Who can participate?
Adult post-CABG surgery patients who can read, write, and communicate verbally in Arabic and have access to a telephone

What does the study involve?
The study is designed to evaluate the effectiveness of an individualized self-care program in improving patients' knowledge of self-care behaviors and performance of self-care behaviors, as well as reducing symptom severity in these patients. Participants in this study will be randomly assigned to one of two groups: the intervention group or the control group. Participants in the intervention group will receive an individualized self-care program tailored to their specific needs and preferences. This program includes education and training on self-care behaviors such as physical activity, medication adherence, and diet. Participants in the intervention group will also receive regular follow-ups and support from the research team to ensure that patients possess adequate knowledge of self-care behaviors, which can help them maintain such behaviors and ultimately alleviate symptom severity. Participants in the control group will receive standard postoperative care, which may include education from healthcare providers in a hospital setting about post-operative care.

What are the possible benefits and risks of participating?
The possible benefits of participating include receiving closer monitoring and attention from healthcare providers, which can lead to improved health outcomes and participants may contribute to scientific research that can help improve understanding and treatment of the

disease or condition being studied. Possible risks associated with participating in this study are considered minimal. Inconvenience to study participants included the time and energy spent during telephone sessions to provide education or collect data.

Where is the study run from?
The study is run from two hospitals in the Kingdom of Saudi Arabia

When is the study starting and how long is it expected to run for?
April 2021 to December 2023

Who is funding the study?
The University of Ha'il (Saudi Arabia)

Who is the main contact?
Dr Mohannad Jamil Alkuwaisi, mohannad20083040020@live.com (Saudi Arabia)

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IFP-22145

Study information

Scientific Title
Is an individualized self-care program more effective than usual care or standard post-operative care in improving knowledge of self-care behaviors, the performance of self-care behaviors and reducing symptom severity among patients after coronary artery bypass surgery?

Acronym
ISCP-ACS

Study objectives
Current hypothesis as of 03/10/2023:

1. Patients who receive an ISCP after CABG surgery will show a significant decrease in learning needs at week 3 (day 15) compared to week 1 (day 2) post-discharge.
2. Patients who receive an ISCP at 1 and 3 weeks after CABG surgery have a significant improvement in the knowledge of self-care behaviour compared to patients in the control group.
3. Patients who receive an ISCP at 1 and 3 weeks after CABG surgery significantly improve self-care behaviour compared to patients in the control group.
4. Patients who receive an ISCP at 1 and 3 weeks after CABG surgery have a significant decrease in the severity of symptoms compared to patients in the control group.

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Previous hypothesis:

1. Patients who receive an individualized self-care program at 1 and 3 weeks after coronary artery bypass graft (CABG) surgery significantly improve self-care behavior compared to patients in the control group
2. Age, gender, educational level, and comorbidities are associated with post-test self-care behaviors
3. Patients who receive an individualized self-care program at 1 and 3 weeks after CABG surgery have a significant improvement in the knowledge of self-care behavior compared to patients in the control group
4. Patients who receive an individualized self-care program at 1 and 3 weeks after CABG surgery have a significant decrease in the severity of symptoms compared to patients in the control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/06/2021, Institutional Review Board of King Abdullah University Hospital (P.O.Box: (630001) Irbid (22110), Jordan; +962-2 7200600; kauh@just.edu.jo), ref: 13/2/1022

Study design
Randomized double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Telephone

Study type(s)
Quality of life

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Post-coronary artery bypass surgery

Interventions
This study is a randomized, double-blind, controlled trial comparing an individualized self-care program (ISCP) versus usual care in improving self-care behaviors in a multicenter setting. The ISCP was designed to address the self-care learning needs of CABG postoperative patients in weeks 1 (day 2) and 3 (day 15). Eligible patients who consent to participate in the study will be randomly assigned by researchers using a simple random assignment (flipping coin method) to experimental or control groups. Patients in the experimental group will receive the ISCP via two telephone calls over two weeks (weeks 1 and 3). Patients in the control group receive usual care, which may include education from healthcare providers in a hospital setting about post-operative care. Data concerning self-care behaviours performance is collected by blinded research assistants from both the experimental and control groups prior to discharge at the baseline point (time 1) and then again at two subsequent time intervals (times 2 and 3), which were 1 and 3 weeks after the delivery of the ISCP.

Intervention Type
Behavioural

Primary outcome measure
1. Self-care Behaviors measured using a self-administered instrument at baseline, week 1 and week 3 post-discharge
2. Learning Needs measured using a survey at week 1 and week 3 post-discharge
3. Knowledge of self-care behavior measured using the self-care behavior knowledge inventory (KI) at baseline, week 1, and week 3
4. Severity of symptoms measured using the symptoms inventory (SI) at baseline, week 1, and week 3

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
02/04/2021

Completion date
02/12/2023

Eligibility

Key inclusion criteria
1. Patients aged ≥18 years old
2. Patients who have had their first CABG surgery
3. Patients could read, write, and communicate verbally in Arabic
4. Patients who have access to a telephone

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
164

Total final enrolment
128

Key exclusion criteria
1. Surgery for cardiac valve repair
2. Patients with major postoperative complications such as stroke, serious wounds, infections, pulmonary emboli, and renal illnesses

Date of first enrolment
01/04/2022

Date of final enrolment
03/06/2022

Locations

Countries of recruitment
Jordan

Saudi Arabia

Study participating centre
King Abdullah University Hospital
Jordan
Irbid

Jordan
11731

Study participating centre
Abdali Hospital
Amman
Amman
Jordan
11731

Study participating centre
King Salman Specialist Hospital-Hail
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Sponsor information

Organisation
University of Hail

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Sponsor type
University/education

Website
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ROR
https://ror.org/013w98a82

Funder(s)

Funder type

University/education

Funder Name
University of Hail

Alternative Name(s)
UOH

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Saudi Arabia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/11/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the corresponding author upon request, Dr Mohannad Jamil Alkuwaisi, mohannad20083040020@live.com.

• The type of data that will be shared: Participant data, such as demographic information, medical history, and outcomes
• Timing for availability: Upon request
• Whether consent from participants was required and obtained: Yes
• Comments on data anonymization: removing names, addresses, and other identifying information from study documents, assigning unique study IDs to participants, and de-identifying or encrypting data sets.
• Any ethical or legal restrictions: Nil
• Any additional comments: Nil

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			28/02/2023	No	Yes
Results article		02/11/2024	30/06/2025	Yes	No