

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

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<b>Registration date</b> 01/04/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/12/2025	<b>Condition category</b> Other	<input type="checkbox"/> 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

### Contact name

Dr Mohannad Alkuwaisi

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## Study type(s)

Quality of life

## **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(s)**

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

## **Key secondary outcome(s)**

There are no secondary outcome measures

## **Completion date**

02/01/2025

## **Eligibility**

### **Key inclusion criteria**

1. Patients aged  $\geq 18$  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

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

70 years

**Sex**

All

**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**

Saudi Arabia

**Study participating centre**

**King Salman specialist hospital**

Jordan

Irbid

Saudi Arabia

11731

**Study participating centre**

**Cardiac Center**

Amman

Amman

Jordan

11731

**Study participating centre**

**King Salman Specialist Hospital-Hail**  
Hail  
Saudi Arabia  
55211

## Sponsor information

### Organisation

University of Hail

### 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

### 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?
<a href="#">Results article</a>		02/11/2024	30/06/2025	Yes	No
<a href="#">Participant information sheet</a>			28/02/2023	No	Yes