

## RESEARCH INFORMATION SHEET

**Research Title:** Effectiveness of The Individualized Self-Care Program Following Coronary Artery Bypass Surgery among Patients

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**Name of co-Researcher(s)/ (MMC No.):**

2. Mohammed K. Aldalaykeh

*\*To be included if applicable*

## INTRODUCTION

You [or the person under your care / guardian] are invited to take part voluntarily in a research project. This research is about **the effectiveness of individualized self-care program (ISCP) in patients who have Undergone Coronary Artery Bypass Graft**. It is important that you read and understand this research information before agreeing to participate in this study. If you agree to participate, you will receive a copy of this form to keep for your records.

Data will be collected from both groups at three points in time. Pre-test data will be conducted by the researcher through a face-to-face interview for both groups (Time1). The participants will receive the teaching by two telephone sessions after discharge (Time 2&3). The length of time for the interview and each telephone teaching is **15-20 minutes**. So the total expected time for each patient is **45-60 minutes**. This study is estimated to include up to **142** participants.

## PURPOSE OF THE STUDY

The purpose of this study is to **examine the effectiveness of the individualized self-care program (ISCP) in patients following CABG surgery at 1 and 3 weeks of hospital discharge**.

## TYPE OF RESEARCH

This research will be placed the patients in one of two groups, based on chance, just like a flip of a coin. Patients in experimental group will receive patient education at 1 and 3 weeks after discharge from hospital by telephone at home. The length of time for the teaching is 1 hour. So the total expected time for each patient is 2 hours. The participation in the study involve answering questions, right now, after signed the consent form; and again at 1 and 3 weeks after discharge about: a.) What self-care behaviours patient would like to learn about in order to be able to care at home. b.) knowledge of how to perform self-care behaviours while at home. c.) performance of self-care behaviours while at home d.) The symptoms that patient experiencing.

## PARTICIPANTS CRITERIA

You are eligible to take part in this study, if this is your first CABG surgery and you can read, write, and communicate verbally in Arabic, have access to a telephone, and your age  $\geq 18$  years.

This study will not include individual who have **surgery for cardiac valve repair**. **Patients with major postoperative complications such as stroke, serious wound infections, pulmonary emboli and renal illnesses will be excluded from the study**. [If the participant is selected as a "control" then it should be stated clearly on the inclusion and exclusion criteria using the similar template as above]

## **VOLUNTARY PARTICIPATION**

Your participation in this study is entirely voluntary.

You may refuse to participate in the study or you may stop your participation in the study at anytime, without any penalty or loss of benefits to which you are otherwise entitled **[your care will not be affected in any way, now or in the future as a result of being involved in this study]**

Your participation may also be stopped by the research team at any time without your consent if it is found that you have violated the study eligibility criteria. The research team member will discuss with you if this matter arises.

## **STUDY PROCEDURE**

If you agree to participate in this study, you will be assigned by chance to one of two groups. Participants in one group will be telephoned at their homes by the researcher and receive the intervention, which entails being asked questions about post-operative symptoms that are bothering them that day and will be offered strategies to manage those symptoms. This will occur during the first two days after discharge (week 1) and then during the third weeks after discharge (week 3). You may choose not to answer any of the questions asked. Patients in the second group will not receive the intervention but will be called at home by the research assistant during the first two days after discharge and then during the third weeks after discharge and asked questions about their post-operative symptoms.

If you are assigned to the group that receives the educational intervention, you will be called by the researcher assistant six days after you received the intervention from the researcher. At that time the research assistant will read you a list of questions about symptoms experience.

If you are assigned to the group that does not receive the educational intervention, you will be called by the research assistant during week one, and three after discharge who will read you a list of questions about symptoms experience. You may choose not to answer any of the questions asked.

Each telephone call from both the researcher and the research assistant will take about 1 hour of your time. So the total expected time for you is 2 hours.

## **RISKS**

It is anticipated that there will be no risks to you if you participate in the study. However, if you feel tired during the telephone sessions, the session will be terminated and the researcher will call you later that day or the next day

Please contact, at any time, the following researcher if you experience any health problem either directly or indirectly related to this study.

**Mohannad Al Kuwaisi [MMC Registration No. \_\_\_\_\_\*] at +966531345674 or <H/P No.>.**

[\* if applicable]

## **POSSIBLE BENEFITS [Benefit to Individual, Community, University]**

While you may not benefit directly from this study, the results may improve educational programs for future patients who have heart bypass surgery. During the study, if you have symptoms that require medical attention, you will be referred to your family doctor or cardiologist. The decision to contact your doctor will be left entirely up to you.

Your participation is also likely to help us find the answer to the research questions.

## **REIMBURSEMENTS**

You will not receive any financial reimbursement during the duration of this study.

## **CONFIDENTIALITY**

Your information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Your information may

be held and processed on a computer. Only research team members are authorized to access your information.

### **ENQUIRES**

If you have any question about this study or your rights, please contact;

Mohannad Al Kuwaisi  
School of Nursing Sciences  
Faculty of Medicine  
Universiti Sultan Zainal Abidin  
Contact No. 00966531345674

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Secretariat,  
UniSZA Human Research Ethics Committee (UHREC)  
Faculty of Medicine  
Medical Campus  
Universiti Sultan Zainal Abidin  
Tel. No. : 09-6687981 / 09-6688763  
Email : uhrec@unisza.edu.my

### **DECLARATION**

To be entered into the study, you or a legal representative must sign the Informed Consent Form (UniSZA-PTPIP-42-GP 001-BR 008(01))

By signing the informed consent form, you authorize the record review, information storage and data process as described above.