

PARTICIPANT INFORMATION SHEET

Study Title:

Does early exercise help recovery after heart surgery? comparing structured interval training with standard care in a randomized study

Introduction:

You are invited to participate in a research study conducted by the Faculty of Medicine, Universiti Kebangsaan Malaysia (UKM). Before making a decision to participate, it is important for you to understand the purpose of this study, what will be required of you, and any potential benefits or risks involved.

Purpose of the Study:

This study aims to evaluate the effects of a structured early mobilization protocol on physical function and mobility among patients who have undergone cardiac surgery by **cutting open the middle of the chest**. Additionally, the study will assess its impact on pain levels, **postoperative lung complications, health-related quality of life, and unplanned length of stay in the Cardiac Care Unit (CCU)**.

How is the Study Conducted?

You will be required to sign a consent form indicating your willingness to participate in this study. Information such as your medical history and demographic data will be recorded.

If you agree to participate, you will be randomly assigned to one of the following two groups:

1. **Control Group (Standard Care):** You will receive routine post-operative physiotherapy, including monitored walking exercises and breathing exercises.
2. **Intervention Group (Structured Early Mobilization Protocol - ICEAGE):** You will undergo a structured mobilization program involving progressive walking sessions starting from the first day after surgery.

Study Duration:

- **Before Surgery:** You will receive information and education about movement and breathing exercises.
- **After Surgery (During Hospitalization):** You will undergo a mobility program under the supervision of a physiotherapist.
- **Follow-up Assessments:** Evaluations will be conducted before discharge, at the 4th week, and at the 3rd month after surgery.

Potential Benefits of the Study:

By participating in this study, you may experience the following benefits:

- Faster recovery after surgery.
- Improved mobility and reduced pain.
- Lower risk of post-operative complications and a shorter hospital stay.

There is no cost associated with participating in this study.

Potential Risks of the Study:

- Risks are minimal and may include temporary fatigue or mild discomfort during mobilization exercises.
- Your participation will be closely monitored by trained physiotherapists and doctors.
- If you experience severe discomfort or complications, you may withdraw from the study at any time.
- All information provided will remain strictly confidential.

Is Participation in This Study Necessary?

Participation in this study is entirely voluntary. If you agree to participate, you will be required to sign a **Consent Form**. You will receive a copy of this consent form along with this Participant Information Sheet.

Your medical treatment will not be affected if you choose not to participate in the study. If you have already joined the study but decide to withdraw, you may do so at any time without any penalties. Your data will not be used and will be deleted.

Confidentiality of Information:

The information collected in this study will be compiled into a report for publication. Access to this information will be limited to the researchers and the Research Ethics Committee of Universiti Kebangsaan Malaysia. Data will be presented collectively and will not identify individual participants. Therefore, your information will remain confidential and protected.

Payments and Compensation:

You will not be required to pay or receive any payment for participating in this study. However, you will still be responsible for your usual hospital treatment costs.

Who Can I Contact for More Information About the Study?

If you have any questions, you may contact the Research Team. You may also reach out to the UKM Research Ethics Committee for verification.

Research Team:

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