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

Submission date 07/04/2026	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/04/2026	**Overall study status** Ongoing	
Last Edited 15/04/2026	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

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Study information

Scientific Title
Structured interval training for early mobilization versus standard care after cardiac surgery: effects on mobility and physical function—a randomized controlled trial

Study objectives
1. The goal is to assess how a structured interval training for early mobilization protocol affects physical function and mobility in patients who underwent cardiac surgery via median sternotomy.
2. The objective is to evaluate the effect of a structured interval training for early mobilization protocol on health-related quality of life, unplanned length of stay in the ICU, pain and postoperative pulmonary complications (PPC) in patients who underwent cardiac surgery via median sternotomy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/05/2025, Universiti Kebangsaan Malaysia (UKM) Research Ethics Secretariate (Level 1, Clinical Block, Hospital Canselor Tuanku Muhriz, Jalan Yaacob Latif Kuala Lumpur Bandar Tun Razak, Cheras, 56000, Malaysia; +60 0391455046; sepukm@ukm.edu.my), ref: JEP-2025-193

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose

Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Rehabilitation for patient following cardiac surgery.

Interventions
Standard Care (Control Group): Preoperative physiotherapy care will be initiated through education, similar to standard care with an added interval structured for early ambulation protocol based on Boden et al. (2018). This includes instructions on safe movement using the Move in the Tube (MinT) method and the importance of early movement after surgery.

After surgery, once the patient is medically stable, the physiotherapist will repeat this education. Patients will also be assessed to identify their risk of developing lung complications after surgery. It will be provided as soon as practical after surgery by a physiotherapist. Patients will receive one supervised ambulation session per day until a threshold score is met or discharge from hospital, whichever occurs first.

After the breathing tube is removed, patients will start simple exercises. These include arm, foot, and ankle movements, as well as gradual walking. The physiotherapist will guide patients to continue using the MinT method and to increase their activity step by step until discharge.

The key difference from the intervention group is that there is no fixed or structured plan for how long the exercises or walking sessions should be.

Intervention Group: Before surgery, patients will receive the same physiotherapy education as the standard care group. In addition, they will follow a structured walking (ambulation) program. After surgery, this program will begin as soon as it is safe. A physiotherapist will supervise one walking session per day until the patient reaches the target level or is discharged.

At every session, the participant will be progressed sequentially through the protocol stages. The daily aim for the participant is to achieve stage 6 or greater, aiming to achieve a walking time of at least 10 min, but no more than 15 min, at an intensity of at least three on the Borg 10-point visual analogue scale (VAS) of perceived exertion and where breathing is deeper than at rest. The treating physiotherapist will use a stopwatch to ensure the treatment session does not exceed 15 minutes and can provide a walking aid if clinically indicated. If necessary, ambulation sessions can comprise of equal work/rest intervals. Shorter but not longer rest times are allowable. The final achieved ambulation stage corresponds to total time walked, including the marching on the spot time and not including rest periods.

Successful ambulation is defined as continuously marching on the spot beside the bed or walking away from the bedside for more than 1 minute. Time from surgery to time of first successful ambulation will be recorded. If participants are unavailable or unable to achieve ambulation for more than 1 minute, the assisted ambulation session will be attempted once again on the same day. The reasons for participants being unable to ambulate or not achieving a minimum of 10 minutes will be recorded. If a participant is unable to participate in upright ambulation, then no other non-ambulatory exercises will be provided that day.

All treating therapists will be provided with protocol badge cards and trained by the site investigator. An allied health assistant can deliver the ambulation protocol once this is deemed safe to do so by the treating physiotherapist. The professional qualification of the person assisting each ambulation session will be documented.

Intervention Type
Other

Primary outcome(s)
1. Physical Function measured using The 6-Min Walk Test (6MWT) at baseline (pre-op), before discharge, and 1 month post-operatively

2. Hand Grip Strength measured using Jamar Hand Grip at baseline (pre-op), before discharge, and 1 month post-operatively

3. Mobility measured using the Modified Iowa Level of Assistance (mILOA) at daily from the first postoperative day until day seven

Key secondary outcome(s))
1. Pain measured using Numerical Rating Scale (NRS) for Pain at daily postoperatively until discharge and at 1 month post operatively

2. Quality of life measured using the EQ-5D-5L at pre-operatively, before discharge and 1 month postoperatively.

3. Intensive Care Unit (ICU) length of stay measured using data collected on the number of days spent in the intensive care unit from the day of admission for an acute condition to the day of discharge to the general ward at study end

4. Post Operative Pulmonary Complication (PPC) measured using the Melbourne Group Score at daily until post-op day 7. From post-op days 8 to 14, additional PPC assessments are only performed when clinically suspected based on signs or symptoms of respiratory system deterioration reported within the medical record.

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Elective cardiac surgical procedure, involving a median sternotomy
2. Able to provide informed consent
3. Adults over the age of 18 years

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Insufficient Malay/English comprehension to provide informed consent
2. Unable to complete simple, written questionnaires, and/or understand simple, verbal instructions
3. Unable to perform physical assessment/6 min walk test
4. Unwilling to participate in the study

Date of first enrolment
01/05/2026

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
Malaysia

Sponsor information

Organisation
National University of Malaysia

ROR
https://ror.org/00bw8d226

Funder(s)

Funder type

Funder Name
Universiti Kebangsaan Malaysia

Alternative Name(s)
Universiti Kebangsaan Malaysia (UKM), Universiti Kebangsaan Malaysia (UKM), Malaysia, ukminsta, Universiti Kebangsaan Malaysia - UKM, Universiti Kebangsaan Malaysia (Malaysia), University Kebangsaan (Malaysia), UKM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			15/04/2026	No	No
Participant information sheet			15/04/2026	No	Yes
Protocol file			07/04/2026	No	No