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Early Supervised Incremental Resistance Training (ESpIRiT) following cardiac surgery via a median sternotomy: a study protocol of a multicentre randomised controlled trial

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ABSTRACT

Introduction There is no consistency in current practice pertaining to the prescription and progression of upper limb resistance exercise following cardiac surgery via median sternotomy. The aim of this study is to investigate whether less restrictive sternal precautions with the addition of early-supervised resistance training exercise improves upper limb function and facilitates recovery following median sternotomy.

Methods and analysis This is double-blind randomised controlled trial, with parallel group, concealed allocation, blinding of patients and assessors, and intention-to-treat analysis. 240 adult participants who had median sternotomy from eight hospitals in Malaysia will be recruited. Sample size calculations were based on the unsupported upper limb test. All participants will be randomised to receive either standard or early supervised incremental resistance training. The primary outcomes are upper limb function and pain. The secondary outcomes will be functional capacity, multidomain recovery (physical and psychological), length of hospital stay, incidence of respiratory complications and quality of life. Descriptive statistics will be used to summarise data. Data will be analysed using the intention-to-treat principle. The primary hypothesis will be examined by evaluating the change from baseline to the 4-week postoperative time point in the intervention arm compared with the usual care arm. For all tests to be conducted, a p value of <0.05 (two tailed) will be considered statistically significant, and CIs will be reported. The trial is currently recruiting participants.

Ethics and dissemination The study was approved by a central ethical committee as well as the local Research Ethics Boards of the participating sites (UKM:JEP-2019-654; Ministry of Health: NMMR-50763; National Heart Centre: IJNREC/501/2021). Approval to start was given prior to the recruitment of participants commencing at any sites. Process evaluation findings will be published in peer-reviewed journals and presented at relevant academic conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Randomised controlled trial to investigate the prescription and progression of early upper limb exercise following median sternotomy.
⇒ The upper limb exercise protocol has been reported as safe and feasible for phase 1 and early phase 2 cardiac rehabilitation programme.
⇒ Results may inform guidelines for upper limb exercise intervention in cardiac rehabilitation programmes.
⇒ Loss of follow-up and uptake of cardiac rehabilitation, especially for patients with multimorbidity, may prove challenging, as differences between public hospitals and the private centre may reflect different health systems.

Trial registration number International Standard Randomised Controlled Trials Number (ISRCTN17842822).

INTRODUCTION

There is robust evidence to support the implementation of early upper limb activity and resistance exercise following median sternotomy.[1 2] Recent studies have demonstrated that upper limb exercise (active and resistance) has resulted in minimal changes in patient-reported pain and sternal micromotion (>2 mm) of the bone edges with all tasks and exercises affirming the safety and feasibility in patients with or without sternal instability following median sternotomy.[3] A prior randomised controlled trial (RCT) that investigated a programme of modified versus restrictive sternal precautions reported no adverse events and no statistically significant differences in upper limb function or

patient-reported pain.[4] The finding of no adverse events supports progression of upper limb exercise and a less restrictive approach that encourages motion close to the body with short lever arms within the safe limits of comfort.[4]

Approaches, such as 'Keep Your Move in the Tube' (MinT), facilitate early recovery and return to community role, rather than placing restrictions on use of the upper limbs as part of sternal precautions.[1 4–6] The MinT promotes active participation in cardiac rehabilitation by the upper limbs in movements close to the body, guided by the principles of biomechanics and short lever arms.[1 4–6] Limiting the movement of the shoulder girdle and humerus minimises the lateral pull on the sternum and decreases the leverage of the hand and forearm during weighted movements and upper limb weight-bearing activities.[1 4 5 7]

Current evidence suggests that sternal precautions should allow more upper body activity.[1 3 4 7–9] Early exercise targeting upper body inclusive of the upper limbs and trunk should be incorporated into the rehabilitation of patients recovering from median sternotomy.[1 2 4] This is to optimise multidomain recovery including physical, emotional and cognitive function.[1 3 4 7–9] Early rehabilitation and progressive resistance training may help to reduce functional and cognitive decline.[1 4 7–10] Moderate level of activity and non-specific exercise delivery have been reported to improve strength after median sternotomy postoperatively.[2 10] Incremental upper limb resistance training in early postoperative median sternotomy patients can restore strength following bed rest.[11–13] This training can promote exercise capacity, and improve physical function and health-related quality of life (QOL) following median sternotomy.[2 10]

Despite this evidence, guidelines worldwide recommend commencing supervised cardiac rehabilitation exercise training 3–6 weeks after surgery,[14] during which time functional capacity may deteriorate rapidly.[1 14] In a recent survey conducted in 18 hospitals (13 public and 5 private) with outpatient cardiac rehabilitation in Malaysia, 80.5% of health professionals placed restrictions on upper limb activities and resistance training exercises from 6 to 8 weeks after median sternotomy.[15] This is the current standard practice in Malaysia.[15] Resistance training following median sternotomy is not currently the standard practice[1 10 14] despite evidence to support this mode of exercise be included as a safe component of early cardiac rehabilitation (less than 6 weeks) post-surgery.[1 10 14] There is no consistency in current practice pertaining to the prescription and progression of upper limb and trunk exercises for patients following median sternotomy.[1 16 17] There is also insufficient evidence to support current guidelines of a 6-week wait post-surgery; this seems to be based on limited cadaver studies and historical practice.[1 2 9–11]

Safety does not appear to be compromised by earlier postoperative cardiac rehabilitation.[5 6 9 11] A recent RCT comparing standard care with early resistance training in the community setting reported a significant improvement in cognitive recovery and the safe implementation of this mode of exercise.[2] While the growing evidence base for earlier post-sternotomy cardiac rehabilitation exercise training is relatively compelling, good-quality prospective trials have been scarce.[1 9 10] There have been no robust randomised controlled studies that have compared a programme of usual care that encompasses restrictions on the upper limb and trunk with one that encourages incremental resistance exercise in the early postoperative period within the hospital setting following median sternotomy.

OBJECTIVES

Primary objective

To evaluate the effectiveness of a programme of early supervised incremental upper limb resistance exercise in the acute hospital setting in improving upper limb function and pain in patients following median sternotomy.

Secondary objectives

i. To assess the effectiveness of a programme of early supervised incremental upper limb resistance exercise in improving functional capacity, multidomain recovery, hospital length of stay, incidence of respiratory complications, recovery of physical function and heath-related QOL at 4 weeks and 3 months postoperatively following median sternotomy.
ii. To explore whether demographic factors, comorbidities, and/or preoperative, perioperative and postoperative risk factors are associated with the development of postoperative pulmonary and sternotomy complications. This will be an exploratory analysis, which may identify trends of predictors reported in the literature.
iii. To perform cost-effectiveness analysis comparing early supervised incremental upper limb resistance exercise versus standard care at 3 months post-intervention.

Hypothesis

We hypothesise that supervised incremental upper limb resistance exercise that is delivered in the early postoperative period will significantly improve upper limb function, pain, functional capacity, multidomain recovery, psychological recovery, hospital length of stay, incidence of respiratory complications, recovery of physical function and health-related QOL in patients following median sternotomy compared with patients receiving standard care.

METHODS AND ANALYSIS

The method is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials guidelines for clinical trials,[18] and the Template for Intervention Description and Replication reporting of interventions.[19] This is a phase II,

prospective, assessor-blinded RCT that will be carried out at three tertiary care hospitals in Malaysia. This study is being conducted at major metropolitan hospitals (one academic centre, one national heart centre and six public hospitals), and the findings may be generalised to both private and public healthcare settings. Prospective consecutive patients will be invited to participate in the study prior to elective median sternotomy from 11 March

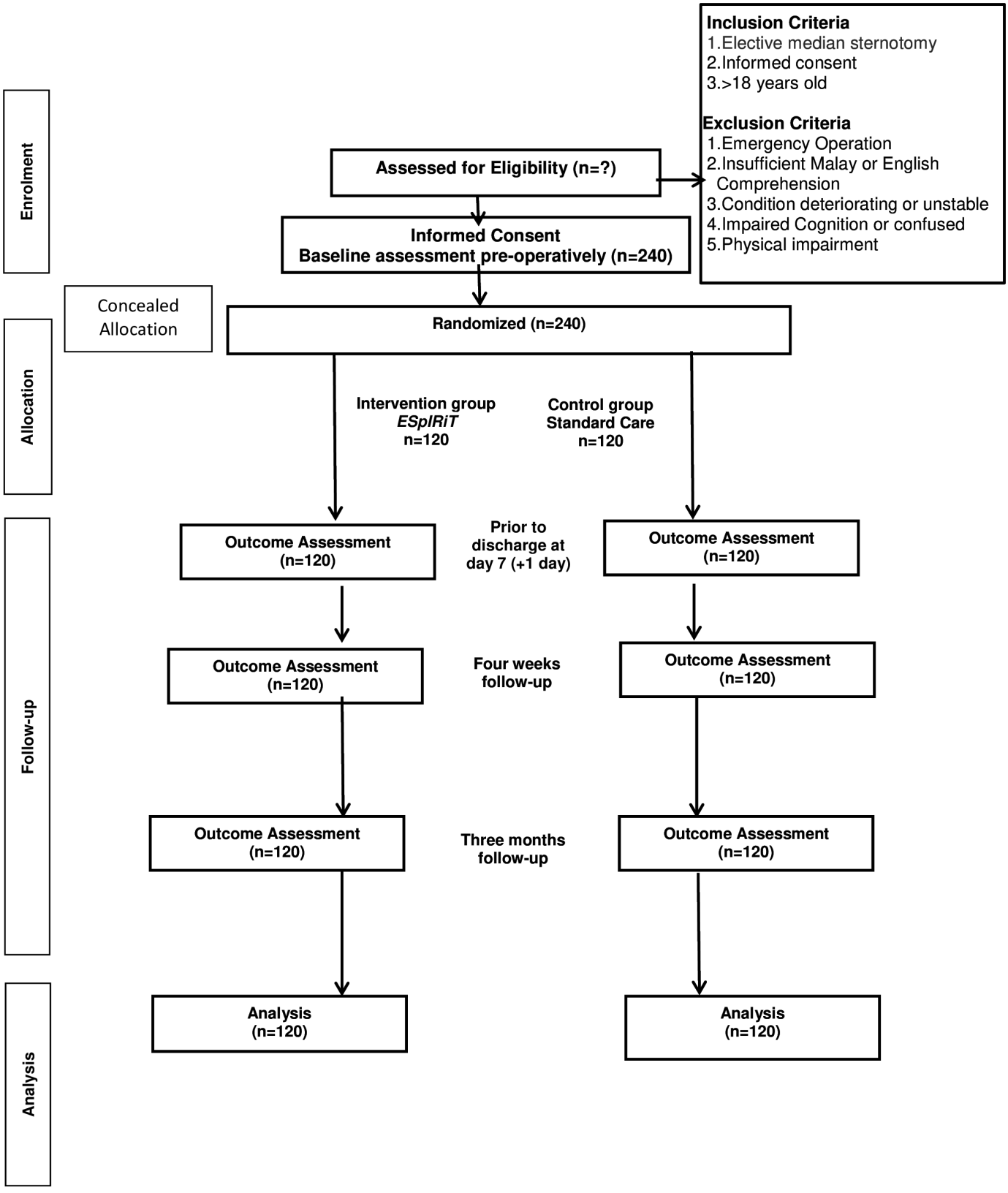

Figure 1 Proposed Consolidated Standards of Reporting Trials flow chart.

2020 to 29 January 2024. Figure 1 summarises the design of the trial, and each of the trial's aspect is described in detail below.

Eligibility criteria

Participants will be randomised to participate in the trial if they meet the eligibility criteria, give informed consent and have completed baseline measurement testing performed by a blinded assessor in an inpatient setting. Participants will be informed that they will be randomised to receive either standard or supervised incremental upper limb resistance exercise preoperatively and will be allocated to one of two groups: (1) the control group (standard care) or (2) the intervention group (supervised incremental upper limb resistance exercise).

Inclusion criteria

- Prior to elective cardiac surgical procedure, involving a median sternotomy.
- Able to provide informed consent.
- Adults over the age of 18 years.

Exclusion criteria

- Emergency operation.
- Unstable or deteriorating clinical condition.
- Impaired vision, cognition or physical impairment.

Informed consent

If a patient meets the above inclusion criteria, he/she will be invited to participate in the study by the research team who will provide the informed consent form detailing the study aims and time commitment. Once a potential participant provides informed consent, they will be enrolled to participate in the study. Participants can choose to withdraw at any time. If an investigator deems that it is detrimental or risky for the participant to continue, the participant will be withdrawn from the study.

Sample size estimation and justification

We calculated that for a change in the unsupported upper limb exercise test (UULEX) between the two groups, a change of 44 s using an SD of 106 s (established in acute care inpatients and outpatient population),[20] 92 participants will be required for each group. This was based on a type I error rate for 80% power with an α of 0.05, which is consistent with widely accepted recommendations.[21] The total sample size was increased to 120 each group to allow for 20% possible loss to follow-up. For safety and feasibility, a pilot study (20% of participants with 24 participants from each group) will be conducted in Universiti Kebangsaan Malaysia Medical Centre.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting or dissemination plans of our research. However, one of the patients with lived experience of cardiac surgery is part of our main research committee. They gave us feedback to enable us to select appropriate outcome measures relevant to patients' physical functioning and reduce burden of assessment during follow-up.

Randomisation and allocation

After recruitment and baseline testing, participants will be randomised postoperatively by an independent person using a computer-generated random number sequence, which will allocate each participant to one of two groups that include standard care or intervention group via block randomisation table (12 blocks of 20). An administration assistant independent to the trial will prepare 240 sequential numbers (1–240) in an opaque envelope each containing an allocation paper. A physiotherapist who has been trained with the protocol will deliver the intervention. The standard care group will be given a standard postoperative management programme and the intervention group will be given a programme of early supervised incremental resistance training as allocated. Both group sessions will begin and terminate with a warm-up and cooldown to avoid any adverse events.

Blinding

Patients, outcome assessors and data management are blinded to treatment allocation. The treating physiotherapists cannot be blinded to group allocation. The details of intervention will not be documented in the medical record. A blinded assessor located off-site from the outpatient department will assess all outcomes in the inpatient and outpatient setting. The intervention sessions will be conducted on days separate from days scheduled for outcome assessment. If a treatment group participant informs the assessor of their intervention session, this will be noted and reported, and the reason will be entered when the randomisation is unblinded and analysed on an intention-to-treat basis.

Trial intervention

The intervention will be performed by the same physiotherapists in the inpatient and outpatient setting, according to allocation for both groups. There will be a different physiotherapist for each participating hospital providing the intervention for both groups. All physiotherapists are senior clinicians with over 5–7 years of clinical experience in cardiac surgery. Training will be provided by one to two independent physiotherapists to ensure consistency in each institution.

Standard care

Participants in the standard care group will receive postoperative care, including education on standard sternal precautions based on the MinT principles in the acute setting.[1 5 8] The MinT conceptual framework uses simple graphics depicting movements 'in a green tube' and 'out of a red tube' as illustrated in figure 2.[1 5 8] By moving within the tube, no particular precautions or restrictions need to be imposed on patients as long as the patient is pain free.[2 3 22] This strategy promotes the use of short lever arm during load-bearing upper limb movements to facilitate safe bed mobility, transfers and functional activities.[1 4 5 8]

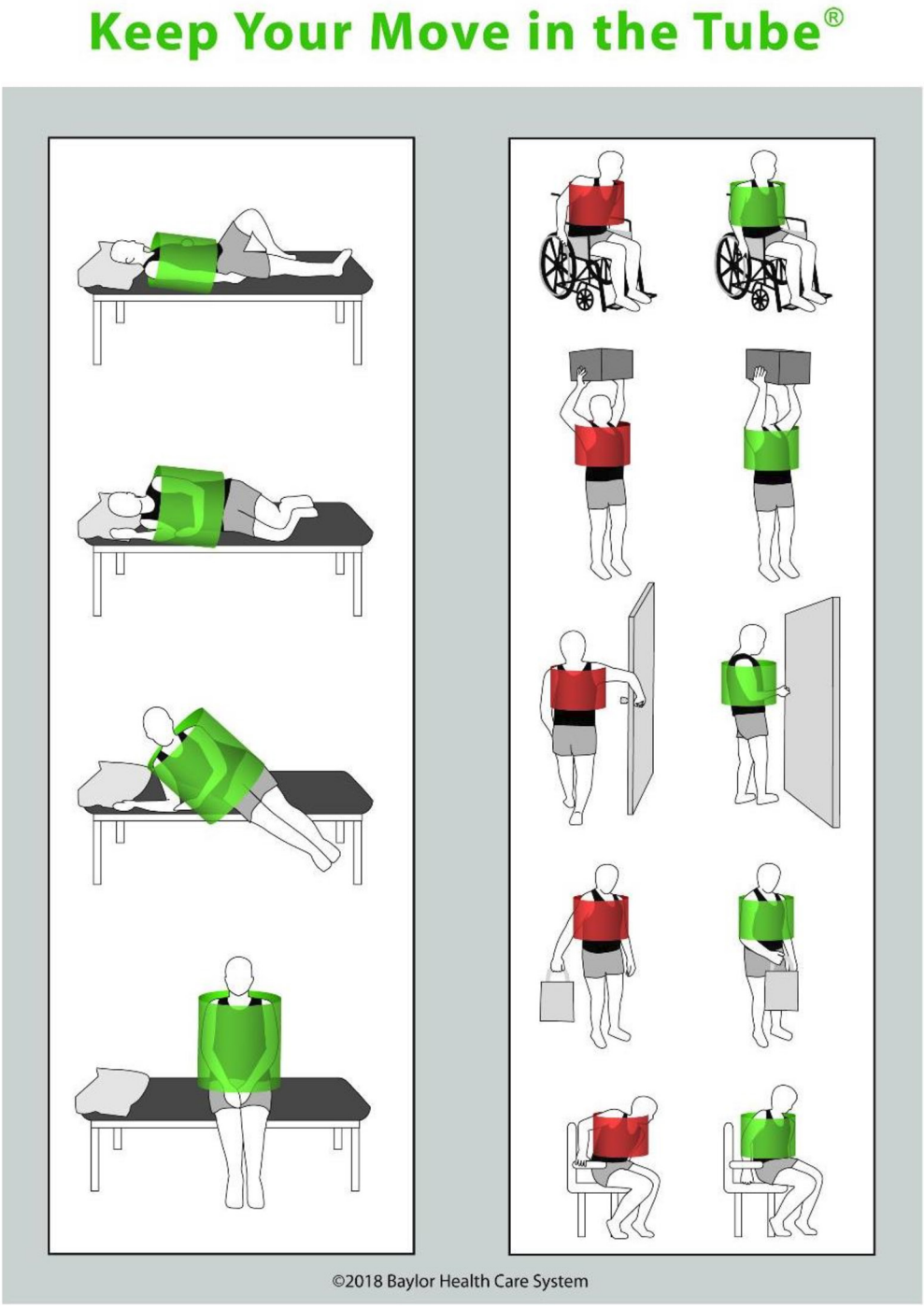

Figure 2 Keep Your Move in the Tube.[8]

Furthermore, patients are allowed unlimited movement of their arms when unloaded.[1] The standard treatment will be delivered in both verbal and written formats by the treating physiotherapists and recommended for the first 6 weeks postoperatively. Physiotherapy care will commence preoperatively in the form of education. Patients will be routinely assessed and screened for risk of postoperative pulmonary complications. Following extubation, progressive mobilisation (ie, walking), and active upper limb, foot and ankle exercise will commence. Prior to discharge, the physiotherapist will educate the patient in continuing MinT and a progressive programme of mobilisation. Patients will be routinely referred to a cardiac rehabilitation programme in the outpatient hospital setting and will be able to commence this programme 4–8 weeks following surgery pending availability. Cardiac rehabilitation (phase 2) will predominantly consist of low to moderate intensity (on 6-20 of Rating Perceived Exertion Scale (RPE) of 10-13) cardiovascular aerobic exercise training and education for secondary prevention 1-3 times per week (60 minutes) for a typical duration 6-12 weeks.

Table 1 Sample of incremental supervised weight resistance exercise

Week 1	Sit over edge of bed/sit in chair minimum of 2 min with (0.5 kg) PVC exercise bar. 10–12× repetitions, 2–4 sets, rest 2 min in between on 70%–80% of the estimated 10–12× repetitions maximum.
Week 2	Sit in chair minimum of 2 min with 0.5–1 kg PVC exercise bar. 10–12× repetitions, 2–4 sets, rest 2 min in between on 70%–80% of the estimated 10–12× repetitions maximum.
Week 3	Sit/stand 1.5–2 kg PVC exercise bar. 10–12× repetitions, 2–4 sets, rest 2 min in between on 70%–80% of the estimated 10–12× repetitions maximum.
Week 4	Sit/stand 2.5–3 kg PVC exercise bar. 10–12× repetitions, 2–4 sets, rest 2 min in between on 70%–80% of the estimated 10–12× repetitions maximum.
Week 5	Sit/stand 3.5–4 kg PVC exercise bar. 10–12× repetitions, 3–4 sets, rest 2 min in between on 70%–80% of the estimated 10–12× repetitions maximum.
Week 6	Sit/stand 4.5–5 kg PVC exercise bar. 10–12× repetitions, 3–4 sets, rest 2 min in between on 70%–80% of the estimated 10–12× repetitions maximum.

PVC, polyvinyl chloride.

Intervention group

Participants in the intervention group will receive the same care as the control group including MinT as standard sternal precautions with the addition of the early supervised incremental upper limb resistance exercise with moderate to high intensity exercise of upper limb from the first week postoperatively. For the progressive resistance exercise, the following muscle groups will be targeted: biceps brachii, triceps brachii, pectoralis major and minor, latissimus dorsi, deltoid and rhomboids using free weights. Specifically, participants will be educated to start resistance training by keeping their upper arms close to their body. Pre-exercise: heart rate, blood pressure and oxygen saturation will be measured. The first 5 min will be for warm-up, with stretching exercise and running on the spot at an RPE 6–8 (very lightly). The resistance exercise will be face to face (1:1) postoperatively from cardiac rehabilitation phase 1 and in a small group (1:4) and continue to phase 2 for 6–8 weeks and beyond in the outpatient setting (table 1). This will be incremental and progressive at moderate intensity with duration of 15 min for upper limb resistance training (total exercise duration 60–90 min) for typical duration of 8 weeks postoperatively.

Training will start using a load equivalent to 70%–80% at 10–12 repetitions maximum. In this study, we developed a new weighted polyvinyl chloride (PVC) exercise bar based on biomechanical principles to prevent distraction forces on the sternum while keeping both arms by the side during exercise training. The weighted bar consists of two parts with one off PVC tube and two off caps at both ends with the same material. The internal bar is filled with steel bar and plaster of Paris to achieve the designed weight from 100 g to 3 kg. The bars are 20 mm and 25 mm in diameter with length of 711 mm. The new weighted bar encourages bilateral use of the arms, providing symmetrical loads on both sides of the sternum. Prior research suggests that unloaded movements within a pain-free range and loaded activity with the upper arms close to the body will not cause excessive stress on the sternal surgical site or bone.[1 5] The PVC weighted bar of 0.5 kg will be used as baseline and progressively increased until 8 weeks postoperatively, at an intensity of 70%–80% of estimated 10 repetitions maximum to accelerate recovery. The loads will be increased when the patients can manage 12 repetitions for both sets on two consecutive training sessions, provided no sternal or joint pain, or severe muscle fatigue and/or arm fatigue on RPE score of 10–13 on 6–20 of RPE. In addition, we will use different types of resistance training such as therabands, dumbbells and kettlebells. Five-minute cooldown: walking at RPE 6–8 (very light) will end the whole session. Oxygen saturation, blood pressure and heart rate will be monitored for return to baseline levels. Before and after each exercise, patients will be asked to rate their arm fatigue using RPE score. All upper limb exercises will be conducted bilaterally. Frequency will be one to three times weekly (table 1). In addition, participants will be given an illustrated handout to assist further training support by the carer (see online supplemental appendix 1 for exercise flyer).

In both groups, all other aspects of patient care including preoperative management, general anaesthesia, intraoperative ventilation parameters, fluid delivery, prophylactic antibiotic prescription, pain management, use of lines and drains, general nursing care and discharge planning will be provided at the discretion of nurses and physicians according to routine clinical practice at both hospitals.

Primary outcome

The UULEX is a symptom-limited, incremental test first described by Takahashi *et al* to assess upper limb peak exercise capacity in patients with chronic obstructive pulmonary disease (COPD).[23] UULEX test–retest reliability has shown excellent intraclass correlation coefficient (ICC) for UULEX total exercise time (ICC=0.98).[23] The participants will be asked to hold a plastic bar (0.2 kg) at shoulder width.[24] The UULEX consists of eight levels; participants perform each level for 1 min with two hands at a rate of 30 beats/min set by a metronome, from the hip to the UULEX eight-level chart of 15 m in height. The

test is continued until the participant can go no further (symptom limitation).[23] The test starts with a 2-minute warm-up at the lowest level; the warm-up is included in the final time. The first level is adjusted to be at the level of the patient's knees by altering the position of the UULEX chart on the wall.[23] Once they have reached their maximum height, the bar will be replaced with a heavier one (0.5<1<1.5<2 kg). The UULEX has previously been used on patients with COPD (acute care inpatient and outpatient population).[20 23] Total time to exhaustion will be recorded in seconds. For this study, one single test will be used to assess arm exercise capacity.[22]

Secondary outcome measures

The Numerical Rating Scale for Pain

The Numerical Rating Scale for Pain (NPRS) requires participants to rate their pain from 0 to 10 (11-point scale), with 0=no pain and 10=worst possible pain.[24 25] The NPRS 1–3 was related to mild, 4–6 to moderate and 7–10 to severe pain.[26 27] The minimal clinical important difference for the average NPRS for all patients was 2.17, for both the surgical and non-surgical subgroups.[28] The NPRS is an established tool for measuring pain, and is known for its validity, reliability and sensitivity to change, and is easy to administer for measurement of severity of pain.[24 25 28]

The Functional Difficulty Questionnaire Shortened Version

The Functional Difficulty Questionnaire Shortened Version (FDQ-s) comprised of 13 separate functional tasks necessary in everyday life that challenge the body in the sagittal and frontal planes as well as result in multi-planar motion across the body.[29 30]The FDQ-s has robust psychometric properties as a measurement tool assessing upper limb function and thoracic region following median sternotomy.[30]

Multidomain recovery: Postoperative Quality Recovery Scale

The Postoperative Quality Recovery Scale is a quality of recovery scale that was developed by an international group of anaesthesiologists and neuropsychologists.[31] It aims to detect change in multiple domains of recovery over time (physiological, nociceptive emotive, functional recovery, self-assessed recovery and cognitive recovery). The scale is completed prior to surgery to provide baseline values, and then repeated postoperatively.[31] Recovery is broadly defined as return to baseline or better. This tool has been validated in over 700 patients including patients following median sternotomy.[31]

The 6-Minute Walk Test

The 6-Minute Walk Test is a standard measure of functional walking capacity.[32] This test consists of walking up and down a 30 m indoor track as many times as possible within a 6-minute period.[33 34] In accordance with the American Thoracic Society guidelines, this test will be conducted prior to commencing cardiac rehabilitation, with the better of the two tests recorded as baseline.[35] Participants will be notified of elapsed time at each minute of the assessment. No other encouragement will be given.[35]

The Hospital Anxiety and Depression Scale

Anxiety and depression will be assessed with the 14-item Hospital Anxiety and Depression Scale (HADS). It has seven subscales for anxiety (HADS-A) and seven for depression (HADS-D).[36] Each item is rated on a 4-point Likert scale from 0 (not present) to 3 (maximum), with a total score of 12 for each subscale.[37] A cut-off score of ≥8 points will used in the study to define cases of anxiety or depression. This cut-off has been shown to balance sensitivity and specificity for both subscales.[37] The HADS has demonstrated to be a valid and reliable instrument with Cronbach's α of 0.81 for HADS-A and 0.88 for HADS-D.[37 38] The HADS has been translated into many languages and is well documented in international research,[37 39] with high internal consistency for inpatient populations including median sternotomy patients.[38]

Sternal Instability Scale

The Sternal Instability Scale (SIS) is a manual test that measures the stability of the sternum based on a 4-point scale.[40]A score of 0 corresponds to a clinically stable sternum with no detectable motion or separation of the sternal edges, while a score of 3 corresponds to a completely separated sternum with marked increased motion or separation of the sternal edges.[40] The SIS is both a valid and reliable clinical tool for measuring the stability of the sternum in patients following median sternotomy with excellent inter-rater and intrarater reliability, with ICCs of 0.97 and 0.98, respectively.[40]

Recovery of physical function, QOL and cost-effectiveness

- Rate of change of the Modified Iowa Level of Assistance (mILOA). The mILOA consists of four mobility tasks (supine to sitting on the edge of the bed, sit to stand, walking and negotiation of one step), which are graded according to the level of assistance required, use of gait aid and the distance that can be walked[41] for the first 5 days postoperatively.
- Hand grip strength will be measured in kilogram using a hand-held dynamometer with three attempts. The peak pressure of each 5-second attempt was recorded and the highest value is recorded.[42 43]
- Health-related QOL will be measured using the EuroQol (EQ-5D-5L) score[44] and the WHO Disability Assessment Schedule V.2 change from self-rated status.[45 46]
- Self-Assessment of Physical Activity Questionnaire (SAQ) will be used for physical capacity. The SAQ is a 13-item, self-administered activity questionnaire assessing common physical activities associated with personal care, ambulation, household tasks and recreation.[46] All these activities have a known metabolic equivalent (MET) obtained from the Compendium of Physical Activities. Each question required a 'yes' or 'no' response. A SAQ score will be obtained by

recording the corresponding MET value of the most demanding activity that the participant perceived they could complete without symptoms. All scores will be correlated against measured of peak oxygen consumption.[46 47]

- The costs of both interventions will be calculated based on societal viewpoints, which include healthcare provider/hospital and patient. Direct and indirect costs of the interventions will be included such as human resources, equipment, consumables, medications, investigations, utilities, loss of productivity and others. Meanwhile, the effectiveness will be assessed based on the difference of the outcome measures between pre-intervention and post-intervention. Some of the outcome measures that will be used in this cost-effectiveness analysis are functional difficulty and QOL.[48]

The Global Rating of Change Scale

This is a self-reported measure of patients' perceived change. It will be administered prior to the performance-based assessments preoperatively, prior to discharge, 4 weeks and 3 months postoperatively. Participants will be asked: 'Overall, how do your arms function now, compared with how your arms functioned at the initial assessment before surgery?' Responses will be recorded according to a 7-point scale from 'very much improved' to 'very much worse'. It has been previously reported that when participants rate their change as 'minimally improved', 'no change' or 'minimally worse', it is unlikely that a clinically important difference has occurred[49]; therefore, these patients are grouped into an 'unchanged' category. Responses of 'much worse', 'very much worse', 'much improved' and 'very much improved' indicate a clinically important difference has occurred and therefore these patients are grouped into a 'changed' category.[49]

Adherence monitoring

Data pertaining to exercise prescription, progression, complaints and injuries as well as symptoms during the training session for intervention group will be recorded. Participants are encouraged to follow the guidelines on sternal management and exercise prescriptions as per their specific flyers weekly. The number of sessions attended will be documented, as will the number of sessions successfully completed.[11] Detailed reasons for incomplete sessions and dropouts will be recorded to assess the non-compliance.[16] Attendance at cardiac rehabilitation exercise sessions will be closely monitored along with compliance with the prescribed exercise regimen. Additional participants will be asked about the duration of their adherence and the rate of their adherence on a numerical scale for those activities at home.[43]

Data collection

Demographic data, and preoperative, intraoperative and postoperative variables will be collected from participants and medical records. All baseline assessments will be performed for each participant in the preoperative period on the inpatient ward. For follow-up, assessment will be done in the operative period at day 7 (+1 day) in the inpatient setting across centres, and at the outpatient setting at 4 weeks (+14 days) and 3 months (±14 days). These assessments will take place in the research room at the physiotherapy unit. An independent and trained assessor (located off-site) blinded to allocation will conduct all measurement sessions. All follow-up tests and questionnaires will be administered face to face by the outcome assessors and carried out prior to discharge, 4 weeks and 3 months postoperatively to ensure consistency across participants. Post-hospital discharge follow-up will be done via phone. If participants are unable to be contacted by phone for a period of 14 consecutive days from the assessment due date, they will be considered lost to follow-up for the post-discharge outcomes measurement.

Statistical methods

- The primary outcomes and the change from baseline to 4 weeks will be analysed using a mixed between/within-participants analysis of variance with repeated measures across participants. The primary hypothesis will be examined by evaluating change from baseline to the 4-week time point in the intervention group compared with the standard care group. The analysis will be under the intention-to-treat principle based on the groups to which participants were randomised. The interactions between group and time will be later examined to assess the effect of intervention. Next, the group and time main effects will be examined. If there are participants who are not following the assigned group protocol, we will consider a supplementary per-protocol analysis. Key secondary outcome data will be summarised and analysed similarly to the primary outcomes. Logistic regression will be used to determine preoperative, perioperative and postoperative risk factors associated with the development of respiratory and sternal complications. This will be an exploratory analysis, which may identify trends of predictors reported in the literature having an individual effect on postoperative respiratory and sternal complications. For all tests conducted, a p value of <0.05 (two tailed) will be considered statistically significant, and mean differences (95% CI) will be reported.
- The cost-effectiveness ratio (CER) will be calculated based on the formula below:
  - CER intervention=total cost of intervention/effectiveness of intervention.
  - The lowest cost per effectiveness of the two interventions will be considered the most cost-effective intervention in improving the upper limb function and QOL in patients following median sternotomy.

Data management and quality

We will use the Excel database via Dropbox for thorough training of those who collect, check, enter and regularly check data for inconsistency between and within measurements

and missing data. Two independent clinical members will act in an advisory capacity to the clinical investigators to monitor withdrawals, and review ethical conduct and serious adverse events.

Duration and timeline

Recruitment of all 240 participants will be completed by January 2024. Data collection will be completed and analysed, and the manuscript will be prepared for submission by December 2024. The final manuscript will be written in accordance with the proposed Consolidated Standards of Reporting Trials extensions for a pragmatic trial using a non-pharmacological intervention as illustrated in figure 1.

DISCUSSION

The trial will examine the effectiveness of a supervised incremental early upper limb resistance exercise in improving upper limb function and pain in patients following median sternotomy. While a number of international guidelines recommend the inclusion of resistance training, worldwide cardiac rehabilitation focuses primarily on aerobic training, with resistance exercise guidelines varying significantly.[1 10 14 16] This will be the first RCT using an intervention group to prescribe progressive resistance exercise training commencing in hospital (phase 1) and continuing post-discharge (phase 2) to facilitate early recovery following median sternotomy. In our study, in addition to the standard use of bands and hand weights, we implemented a new weighted PVC exercise bar. This will complement the use of the MinT that facilitates upper body activity. This approach appears to offer a viable alternative to current sternal precautions. The outcome of the study will address the paucity of research and inconsistent recommendations with respect to the prescription and progression of upper limb exercise during phase 1 cardiac rehabilitation.

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Correction for 'early supervised incremental Resistance Training (ESpIRiT) following cardiac surgery via a median sternotomy: a study protocol of a multicentre randomised controlled trial'

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This article has been corrected since it was published online. Figure 1 Flow chart indicated we added two time points to before discharge destination as our original protocol specifies one time point. The correct supplementary Figure 1 is shown below. Additionally, we have left out the word 'post' which should have been written as post-operative period text prior to discharge at day 7 (+1 day) in the inpatient setting across centres, and at the outpatient setting at 4 weeks (+14 days) and 3 months (±14 days). These changes to the protocol manuscript do not impact on the methodology of the manuscript.

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