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How effective is an early supervised incremental resistance exercise program for the arm following heart surgery

Submission date 06/03/2020	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 11/03/2020	**Overall study status** Ongoing	
Last Edited 05/12/2024	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Delayed participation in cardiac rehabilitation exercise training promotes muscle atrophy, reduces cardiovascular fitness and prolongs recovery. While the growing evidence base for early cardiac rehabilitation exercise training is relatively compelling, good quality evidence is limited. To date, there have not been studies designed to provide solid evidence through comparing a program of usual standard care with precautions to a program that encourages incremental resistance exercise of the arms in the early period following heart surgery.

Current guidelines recommend restriction from supervised cardiac rehabilitation exercise training for 6 weeks in the management of patients following heart surgery. This is not based on evidence, so potentially unnecessary activity restrictions could be being imposed. There is evidence that supports the safety and feasibility of arm movements and activity following cardiac surgery. There is also no consistency in current practice regarding the clinical recommendations given in terms of arm exercises following cardiac surgery.

Research is needed to establish clinical guidelines for early supervised arms resistance training of patients following heart surgery. The aims of this project are to examine whether early supervised incremental resistance training exercises will improve upper limb function and facilitate recovery following heart surgery.

Who can participate?
Patients over 18 who have planned cardiac surgical procedure, involving a median sternotomy at Hospital Canselor Tuanku Muhriz.

What does the study involve?
If the participants agree to participate in the study, they will undergo initial assessments so that the researcher can determine if they are eligible to participate. If they are eligible, they will be randomly assigned to either receive standard care after their operation or to receive an early supervised incremental resistance training exercise program. Participants will have an equal chance of being assigned to each of the two groups.

If the participant is allocated to receive the early supervised incremental resistance training exercise program, they will be given advice and, arm exercises and breathing exercise to complete. This program will continue for the next four to six weeks with sessions two to three times per week supervised by a physiotherapist at the outpatient Physiotherapy Department. The exercises will increase in intensity weekly based on the health and progress of each participant.

A follow-up assessment will be done in the first week after the operation/before discharge from the hospital, at 4 weeks postoperatively, and then at 3 months postoperatively. Your doctor who will complete these assessments will not know which group you have assigned to but in the case of emergencies, this information will be made available to your doctor.

What are the possible benefits and risks of participating?
The risk of issues arising as a result of participating in this research is very minimal because this research is supported by good evidence and will be supervised by an experienced physiotherapist and the support of the medical team in the participating hospital. In the event of a bodily injury or illness directly resulting from the study, all necessary treatment will be provided.

The study will benefit the participant as it will potentially enhance the recovery process and improve quality of life after the surgery. For participants who are in the group receiving exercise training there will be no significant difference in performing activities of daily living because there are no limits on movement.

Where is the study run from?
1. Hospital Canselor Tuanku Muhriz, UKM (Malaysia)
2. Institul Jantung Negara (Malaysia)
3. Hospital Serdang (Malaysia)

When is the study starting and how long is it expected to run for?
June 2019 to December 2027

Who is funding the study?
University Kebangsaan Malaysia (Malaysia)

Who is the main contact?
Dr Katijjahbe Mohd Ali
katijjahbe@yahoo.com

Contact information

Type(s)
Public

Contact name
Dr Katijjahbe Mohd Ali

ORCID ID
http://orcid.org/0000-0002-1348-3617

Contact details

No 6 Jalan Suadamai
Cheras
Kuala Lumpur
Malaysia
43200
+60 0390766454
katijjahbe@yahoo.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NMRR ID 50763

Study information

Scientific Title
Efficacy of Early Supervised Incremental Resistance Training (ESPRiT) following Cardiac Surgery via Median Sternotomy – A Multi- Centre RCT

Acronym
ESPRiT

Study objectives
We hypothesize that a program of early supervised incremental upper limb resistance exercise will significantly improve upper limb function, pain, functional capacity, multi-domain recovery, psychological recovery, hospital length of stay, incidence of respiratory complications, recovery of physical function, and health-related quality of life in patients following cardiac surgery via median sternotomy compared with patients receiving standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/02/2020, Research Ethics Committee, The National University of Malaysia (Tingkat 1, Blok Klinikal, Hospital Canselor Tuanku Muhriz, Pusat Perubatan UKM, Jalan Yaacob Latif, Bandar Tun Razak, Cheras, 56000 Kuala Lumpur, Malaysia; +603 9145 5046 / 5048; secukm@ukm.edu.my), ref: JEP-2019-654

Study design
Prospective phase II multi-centre concealed allocation double-blind parallel-group randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please contact katijjahbe @yahoo.com to request participation information sheet

Health condition(s) or problem(s) studied
Cardiac Surgery via Median Sternotomy

Interventions
Current interventions as of 05/12/2024:
Participants will be recruited from patients who are anticipated to undergo cardiac surgery via median sternotomy at Hospital Canselor Tuanku Muhriz, Institut Jantung Negara, and Hospital Serdang. After recruitment and baseline testing, participants will be randomized 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. Participants will be randomly allocated to either the intervention or the control group at a ratio of 1:1. An administration assistant independent of the trial will prepare the allocation papers and put one in each of 240 sequentially numbered (1 to 240) opaque envelopes.

Participants in the standard care (SC) group will receive postoperative care, including education on standard sternal precautions in the acute setting. For the sternal precautions, the patients will be instructed to use "Keep Your Move in the Tube" (MinT).

Participants in the intervention group will receive the same care as the control group with the addition of the supervised incremental progressive moderate-intensity exercise of the upper limb.

The total duration of each treatment session will be 60- 90 min. All baseline assessments will be performed for each participant in the pre-operative period on the inpatient ward. For follow-up, assessment will be done in the post-operative period 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 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.

Participants will be assessed using clinical tests and questionnaires for functional capacity, pain, and other measures of recovery following completion of care using the protocol.

Previous interventions as of 21/07/2020 to 05/12/2024:
Participants will be recruited from patients who are anticipated to undergo cardiac surgery via median sternotomy at Hospital Canselor Tuanku Muhriz, Institut Jantung Negara, and Hospital Serdang. After recruitment and baseline testing, participants will be randomized 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. Participants will be randomly allocated to either the intervention or the control group at a ratio of 1:1. An administration assistant independent of the trial will prepare the allocation papers and put one in each of 240 sequentially numbered (1 to 240) opaque envelopes.

Participants in the standard care (SC) group will receive postoperative care, including education on standard sternal precautions in the acute setting. For the sternal precautions, the patients will be instructed to use "Keep Your Move in the Tube" (MinT).

Participants in the intervention group will receive the same care as the control group with the addition of the supervised incremental progressive moderate-intensity exercise of the upper limb.

The total duration of each treatment session will be 60- 90 min. All baseline assessments will be performed at the same time of day for each participant in the pre-operative period. The postoperative follow-up assessments will take place after 7 days (± 1 day) in the in-patient setting, at 4 weeks (+ 14 days) in the outpatient setting, and at 3 months (± 14 days) which 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 post-operatively to ensure consistency across participants.

Post-hospital discharge follow-up will be contacted 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.

Participants will be assessed using clinical tests and questionnaires for functional capacity, pain, and other measures of recovery following completion of care using the protocol.

Previous interventions as of 16/03/2020:
Participants will be recruited from patients who are anticipated to undergo cardiac surgery via median sternotomy at Hospital Canselor Tuanku Muhriz. After recruitment and baseline testing, participants will be randomized 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. Participants will be randomly allocated to either the intervention or the control group at a ratio of 1:1. An administration assistant independent of the trial will prepare the allocation papers and put one in each of 240 sequentially numbered (1 to 240) opaque envelopes.

The standard care group will be given standard post-operative management and the intervention group will be given early progressive incremental resistance training as allocated. Both group sessions will begin and terminate with a warm-up and cool down to avoid any adverse events.

Participants in the intervention group will follow the same care as the control group with the addition of the supervised incremental progressive moderate-intensity exercise of the upper limb. With respect to the sternal precautions, they will be provided with instructions to encourage the use of the upper limb within the safe limit of pain and discomfort as per the protocol previously published by Katijjahbe et al, 2018.

The total duration of each treatment session will be 1 h. All baseline assessments will be performed at the same time of day for each participant in the pre-operative period. The postoperative follow-up assessments will take place after 7 days (+/- 1 day) in the in-patient setting, at 4 weeks (+14 days) in the outpatient setting, and at 3 months (±14 days) which 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 post-operatively to ensure consistency across participants.

Post-hospital discharge follow-up will be contacted 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.

Participants will be assessed using clinical tests and questionnaires for functional capacity, pain and other measures of recovery following completion of care using the protocol.

Previous interventions:
Participants will be recruited from patients who are anticipated to undergo cardiac surgery via median sternotomy at Hospital Canselor Tuanku Muhriz. After recruitment and baseline testing, participants will be randomized 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. Participants will be randomly allocated to either the intervention or the control group at a ratio of 1:1. An administration assistant independent of the trial will prepare the allocation papers and put one in each of 240 sequentially numbered (1 to 240) opaque envelopes.

The standard care group will be given standard post-operative management and the intervention group will be given early progressive incremental resistance training as allocated. Both group sessions will begin and terminate with a warm-up and cool down to avoid any adverse events.

Participants in the intervention group will follow a supervised incremental progressive moderate-intensity exercise and early mobilization protocol developed by Boden et al, 2018. With respect to the sternal precautions, they will be provided with instructions to encourage the use of the upper limb within the safe limit of pain and discomfort as per the protocol previously published by Katijjahbe et al, 2018.

The total duration of each treatment session will be 1 h. All baseline assessments will be performed at the same time of day for each participant in the pre-operative period. The postoperative follow-up assessments will take place after 7 days (+/- 1 day) in the in-patient setting, at 4 weeks (+14 days) in the outpatient setting, and at 3 months (±14 days) which 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 post-operatively to ensure consistency across participants.

Post-hospital discharge follow-up will be contacted 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.

Participants will be assessed using clinical tests and questionnaires for functional capacity, pain and other measures of recovery following completion of care using the protocol.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 21/07/2020:
Upper limb exercise capacity measured using the unsupported limb exercise test prior to discharge, at 4 weeks, and 3 months

Previous primary outcome measure:
Upper limb exercise capacity measured using the unsupported limb exercise test at discharge (or 7 days), 4 weeks, and 3 months

Secondary outcome measures
Current secondary outcome measures as of 21/07/2020:
1. Pain measured by the Numerical Rating Scale For Pain (NPRS) and the Visual Analog Scale (VAS) for pain prior to discharge prior (or 7 days), at 4 weeks, and 3 months
2. Thoracic physical function measured by the Functional Difficulty Questionnaire (FDQ) shortened version prior to discharge (or 7 days), at 4 weeks, and 3 months
3. Multi-domain recovery measured by the Postoperative Quality Recovery Scale (PostopQRS) prior to discharge (or 7 days), at 4 weeks, and 3 months
4. Functional exercise capacity measured by the 6-Min Walk Test (6MWT) prior to discharge (or 7 days), at 4 weeks, and 3 months
5. Levels of anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS prior to discharge (or 7 days), at 4 weeks, and 3 months
6. Sternal stability measured using the Sternal Instability Scale (SIS) prior to discharge (or 7 days), at 4 weeks, and 3 months
7. Handgrip strength (kg) measured using a handheld dynamometer prior to discharge (or 7 days), at 4 weeks, and 3 months
8. Self-perceived recovery of physical function and quality of life measured using the modified Iowa Level of Assistance Scale (mILOA), the World Health Organisation Disability Assessment Schedule V2 (WHODAS), the Self-Assessment of Physical Activity Questionnaire (SAQ), and the Global Rating of Change (GRC) scales at discharge (or 7 days), 4 weeks, and 3 months
9. Respiratory Complications/Sternal Complications assessed through hospital notes at discharge (or 7 days), or via phone at 4 weeks, and 3 months
10. Hospital Length of Stay (LOS) assessed through hospital notes at discharge
11. Discharge Destination assessed through hospital notes prior to discharge (or 7 days), at 4 weeks, and 3 months
12. Major adverse and cerebral events (MACCE) assessed through hospital notes at discharge (or 7 days), or via phone at 4 weeks, and 3 months

Previous secondary outcome measures:
1. Pain measured by the Numerical Rating Scale For Pain (NPRS) and the Visual Analog Scale (VAS) for pain (FDQ) at discharge (or 7 days), 4 weeks, and 3 months
2. Thoracic physical function measured by the Functional Difficulty Questionnaire (FDQ) shortened version at discharge (or 7 days), 4 weeks, and 3 months
3. Multi-domain recovery measured by the Postoperative Quality Recovery Scale (PostopQRS) at discharge (or 7 days), 4 weeks, and 3 months
4. Functional exercise capacity measured by the 6-Min Walk Test (6MWT) at discharge (or 7 days), 4 weeks, and 3 months
5. Levels of anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS) at discharge (or 7 days), 4 weeks, and 3 months
6. Sternal stability measured using the Sternal Instability Scale (SIS) at discharge (or 7 days), 4 weeks, and 3 months
7. Handgrip strength (kg) measured using a handheld dynamometer at discharge (or 7 days), 4 weeks, and 3 months
8. Self-perceived recovery of physical function and quality of life measured using the modified Iowa Level of Assistance Scale (mILOA), the World Health Organisation Disability Assessment Schedule V2 (WHODAS), the Self-Assessment of Physical Activity Questionnaire (SAQ), and the Global Rating of Change (GRC) scales at discharge (or 7 days), 4 weeks, and 3 months
9. Respiratory Complications/Sternal Complications assessed through hospital notes at discharge (or 7 days), or via phone at 4 weeks, and 3 months
10. Hospital Length of Stay (LOS) assessed through hospital notes at discharge
11. Discharge Destination assessed through hospital notes at discharge (or 7 days), 4 weeks, and 3 months
12. Major adverse and cerebral events (MACCE) assessed through hospital notes at discharge (or 7 days), or via phone at 4 weeks, and 3 months

Overall study start date
04/06/2019

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Anticipated elective cardiac surgical procedure, involving a median sternotomy at Hospital Canselor Tuanku Muhriz
2. Able to provide informed consent
3. Aged ≥18 years.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Key exclusion criteria
Current participant exclusion criteria as of 21/07/2020:
1. Insufficient Malay/English comprehension to provide informed consent, complete simple, written questionnaires and/or understand simple, verbal instructions.
2. High risk patients with admission in ICU with Intra-aortic balloon pump (IABP) or without IABP (as determined by their respective cardiothoracic surgeons/team pre-operatively)
3. Physical impairment that prevents participation in the upper/lower limb and trunk tasks tested in the functional task components. This includes patients who have been diagnosed with severe osteoarthritis, significant rotator cuff injury or who are bed/wheelchair-bound

Previous participant exclusion criteria:
1. Insufficient Malay/English comprehension to provide informed consent, complete simple, written questionnaires and/or understand simple, verbal instructions.
2. Deterioration in patient's condition as determined by their respective cardiothoracic surgeons /teams pre-operatively
3. Unstable coronary or other medical condition
4. Physical impairment that prevents participation in the upper/lower limb and trunk tasks tested in the functional task components. This includes patients who have been diagnosed with severe osteoarthritis, significant rotator cuff injury or who are bed/wheelchair-bound

Date of first enrolment
11/03/2020

Date of final enrolment
29/01/2026

Locations

Countries of recruitment
Malaysia

Study participating centre
Hospital Canselor Tuanku Muhriz, UKMMC
Universiti Kebangsaan Malaysia Medical Centre
Jalan Yaccob Latiff
Kuala Lumpur
Malaysia
56000

Study participating centre

Institul Jantung Negara
145, Jalan Tun Razak
Kuala Lumpur
Malaysia
50400

Study participating centre
Hospital Serdang
Jalan Puchong
Kajang
Malaysia
43000

Sponsor information

Organisation
University Kebangsaan Malaysia Medical Centre

Sponsor details
43600 UKM
Bangi
Selangor
Selangor
Malaysia
43600
+60 111025381
katijjahbe@yahoo.com

Sponsor type
Hospital/treatment centre

Website
http://www.ppukm.ukm.my

ROR
https://ror.org/01590nj79

Funder(s)

Funder type
University/education

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

Publication and dissemination plan
The findings will be used to provide evidence-based guidelines for medical practitioners and health care professionals involved in pre and post-operative cardiac surgery care.

Planned publication in a peer-reviewed journal of:
1. Study protocol titled "Efficacy of Early Supervised Incremental Resistance Training (ESPRiT) following Cardiac Surgery via Median Sternotomy – A Multi-Centre RCT Protocol"
2. The results of a pilot study to assess safety and feasibility titled "Efficacy of Early Supervised Incremental Resistance Training (ESPRiT) following Cardiac Surgery via Median Sternotomy – A Pilot RCT"
3. The results of the main trial titled "Efficacy of Early Supervised Incremental Resistance Training (ESPRiT) following Cardiac Surgery via Median Sternotomy – A Multi-Centre RCT"

Intention to publish date
30/06/2028

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

We will use the excel database for through training of those who collect, check and enter study data; regular data checks for inconsistency between and within measurements and missing data. The data will be available with publications of the final manuscript as a supplemental document. All data will be obtained following the participants' consent.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	14/07/2023	17/07/2023	Yes	No