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Research

Standard restrictive sternal precautions and modified sternal precautions had similar effects in people after cardiac surgery via median sternotomy ('SMART' Trial): a randomised trial

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KEY WORDS

Randomized controlled trial
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ABSTRACT

Question: In people who have undergone cardiac surgery via median sternotomy, does modifying usual sternal precautions to make them less restrictive improve physical function, pain, kinesiophobia and health-related quality of life? **Design**: Two-centre, randomised, controlled trial with concealed allocation, blinded assessors and intention-to-treat analysis. **Participants**: Seventy-two adults who had undergone cardiac surgery via a median sternotomy were included. **Intervention**: Participants were randomly allocated to one of two groups at 4 (SD 1) days after surgery. The control group received the usual advice to restrict their upper limb use for 4 to 6 weeks (ie, restrictive sternal precautions). The experimental group received advice to use pain and discomfort as the safe limits for their upper limb use during daily activities (ie, less restrictive precautions) for the same period. Both groups received postoperative individualised education in hospital and via weekly telephone calls for 6 weeks. **Outcome measures**: The primary outcome was physical function assessed by the Short Physical Performance Battery. Secondary outcomes included upper limb function, pain, kinesophobia, and health-related quality of life. Outcomes were measured before hospital discharge and at 4 and 12 weeks postoperatively. Adherence to sternal precautions was recorded. **Results**: There were no statistically significant differences in physical function between the groups at 4 weeks (MD 1.0, 95% CI –0.2 to 2.3) and 12 weeks (MD 0.4, 95% CI –0.9 to 1.6) postoperatively. There were no statistically significant between-group differences in secondary outcomes. **Conclusion**: Modified (ie, less restrictive) sternal precautions for people following cardiac surgery had similar effects on physical recovery, pain and health-related quality of life as usual restrictive sternal precautions. Similar outcomes can be anticipated regardless of whether people following cardiac surgery are managed with traditional or modified sternal precautions. **Trial registration**: Australian and New Zealand Clinical Trials Registry ANZCTRN12615000968572. **[Katijjahbe MA, Granger CL, Denehy L, Royse A, Royse C, Bates R, Logie S, Nur Ayub MA, Clarke S, El-Ansary D (2018) Standard restrictive sternal precautions and modified sternal precautions had similar effects in people after cardiac surgery via median sternotomy ('SMART' Trial): a randomised trial. *Journal of Physiotherapy* 64: 97–106]**

Introduction

Cardiac surgery via median sternotomy is performed in over a million cases per year worldwide.[1] It is the procedure of choice for patients with multiple vessel disease and comorbidities because it provides the best clinical outcomes.[2] Sternal complications following median sternotomy may include infection, non-union and instability. The incidence of sternal complications has remained relatively unchanged for the last two decades and is reported to be between 1 and 8% worldwide.[3–5] These complications are associated with significant patient morbidity, prolonged hospital stay and contribute to increasing healthcare costs.[5,6]

In an attempt to reduce or prevent sternal complications, current practice involves the routine prescription of sternal precautions immediately after surgery. These precautions place restrictions on the use of the upper limbs immediately following surgery for 6 to 12 weeks, depending on the institution.[4,7] Patients are encouraged to not use their upper limbs during everyday tasks such as bed transfers or lifting objects.[4,8,9] The rationale for these

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restrictions is to promote solid osteosynthesis and bone healing by minimising the forces and the amount of micromotion between the sternal edges, which can promote progression to non-union and/or infection.[4,7]

Few studies have investigated the rationale for clinical implementation of sternal precautions. A comprehensive search in Medline, PubMed and CINAHL revealed no systematic reviews on the topic; instead, the evidence for these restrictions was scarce and based on limited cadaver studies.[4,7] Those studies reported that this rationale is based on historical practice, expert opinion, and extrapolation from bone fracture healing research (eg, radius).[4,7]

Healthcare professionals, including surgeons, nurses and physiotherapists, routinely advise patients to follow sternal precautions following median sternotomy. However, a recent study demonstrated minimal micromotion of the sternal edges (< 2 mm as measured by real-time ultrasound) during tasks such as cough, sit to stand, and bilateral and unilateral upper limb elevation.[10] These findings challenge the rationale for the restrictions.[10] The rationale for the restrictions is further undermined by the fact that health professionals also actively encourage patients to perform upper limb and trunk exercises following cardiac surgery as part of their postoperative care to promote recovery and return of function.[4,7,11] The prescription of such exercises alongside sternal precautions poses a clinical dilemma, as they contradict each other.[4,7] Furthermore, physical activity and upper limb exercises reduce sternal pain[12] and may be imperative for healing and remodelling of bone, which responds to loading.[4,13] It has been postulated that sternal precautions may be unnecessarily restrictive, thereby compromising the ability of patients to mobilise and delaying functional recovery.[4,13]

To date, no robust randomised controlled studies have compared a program of usual standard precautions to one that encourages less-restrictive use of the upper limbs and trunk in the cardiac surgery population.

Therefore, the research question for this randomised controlled trial was:

> In people who have undergone cardiac surgery via median sternotomy, does modifying usual sternal precautions to make them less restrictive improve physical function, pain, kinesiophobia and health-related quality of life?

Method

Design

This was a prospective, randomised, controlled trial with concealed allocation, blinded assessors and intention-to-treat analysis. It was conducted at two hospitals in Melbourne, Australia. The trial compared usual advice to restrict upper limb use (ie, restrictive sternal precautions) with advice to use pain and discomfort as the safe limits for upper limb use during daily activities (ie, less restrictive precautions) in people who had undergone median sternotomy. Participants were randomised to the trial after surgery, once they had met the eligibility criteria, given informed consent, and completed baseline measurement testing. Randomisation was conducted by an independent person offsite using a computer-generated, randomly ordered list of 72 allocations with a 1:1 allocation ratio. The allocations were concealed in sealed, numbered, double-layered, opaque envelopes. In order to minimise placebo and Hawthorne effects, participants enrolling in the study were only advised that they would be randomised to one of two sets of sternal precautions, without being given detail of the two sets.

Later, when the randomly allocated precautions were being explained to the participants, the alternative precautions were not discussed. The treating physiotherapists and nursing staff were not blinded to group allocation. The outcome assessor was located offsite, and only attended to assess all outcomes while remaining blinded to each participant's allocated intervention. To preserve blinding of the assessor, details of sternal management were not documented in the medical records and the treating physiotherapist avoided delivering the intervention to participants on the ward during a set daily time period when the blinded outcome assessor was present. If a participant's allocation became unblinded to the outcome assessor, this was recorded. Members of the research team involved in data management were blinded to treatment allocation. Outcomes were measured immediately before randomisation and at 4 and 12 weeks after surgery.

The trial was reported in accordance with the CONSORT guidelines for clinical trials of non-pharmacologic treatment[14] and the intervention was reported in accordance with the TIDieR checklist for reporting of interventions.[15] The full protocol for this trial has been published.[16]

Participants, therapists and centres

Patients at the two sites were eligible to participate if they were: aged ≥ 18 years, able to provide informed consent, and undergoing cardiac valve surgery, coronary artery bypass graft surgery, or a combination of both via median sternotomy. Usual care at the recruitment sites is that patients underoing cardiac surgery via a median sternotomy have sternal closure achieved using a series of single stainless steel wires placed through the manubrium and around the lateral edge of the body of the sternum. Patients were excluded if they had insufficient English comprehension to complete the questionnaires or lived outside of the Melbourne metropolitan area (ie, 52 km radius) precluding their ability to return to the hospital for follow-up testing.

One physiotherapist at each participating hospital was responsible for providing the intervention for both groups. Both physiotherapists were senior clinicians with > 5 years of clinical experience in cardiac surgery. Each site was a metropolitan hospital that performs ≥ 500 cardiac surgeries via median sternotomy annually.

Interventions

Each participant was randomly allocated their sternal precautions on Day 4 ($\pm$ 1 day) after surgery. Each participant received standardised verbal and printed sternal precautions by the treating physiotherapist. These precautions were delivered during a single 15-minute session in an enclosed room on the ward prior to discharge from the hospital. Telephone follow-up was conducted weekly for 6 weeks, to encourage patients to continue with their allocated precautions.

The experimental group was provided with instructions to encourage the use of upper limbs within the limits of pain or discomfort. This included being permitted to use the arms during transfers and other tasks within the limits of pain and discomfort, as well as encouragement to perform upper limb exercise three times daily within the limits of pain and discomfort. The verbal instructions explained to participants in the experimental group are listed in Box 1. The printed instructions given to participants in the experimental group are presented in Figure 1.

Box 1. Precautions explained to participants in the experimental group.

- Use pain and discomfort to guide use of the arms
- Avoid pushing or pulling with one arm
- Keep both arms close to the body during lifting
- Use of the arms for other tasks is permitted but keep them close to the body
- Avoid stretching both arms backwards at the same time
- When coughing, support sternum with a cushion or the arms in a self-hugging position
- When getting out of bed, roll onto side, ease legs over the edge of the bed, and carefully use the arms to help you sit up from lying position

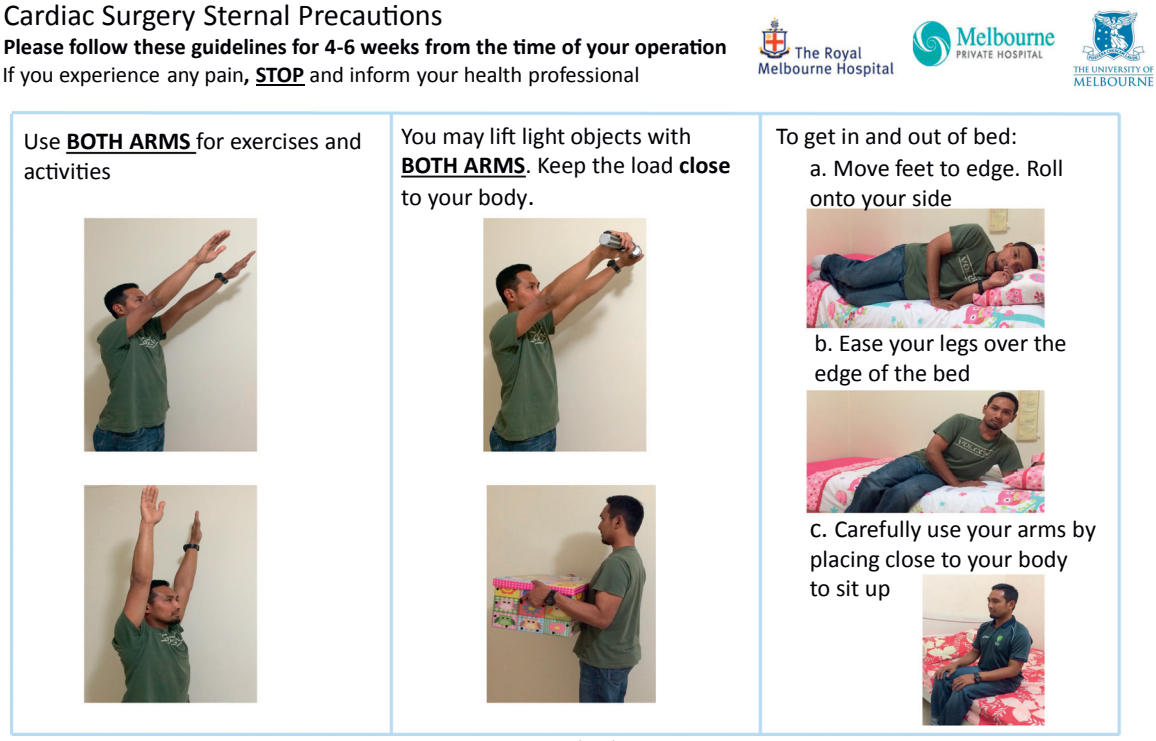

Figure 1. Printed summary of sternal precautions given to participants in the experimental group.

The control group received standard physiotherapy care, which included advice to restrict use of the upper limbs for 4 to 6 weeks after surgery. The verbal instructions given to participants in the control group are listed in Box 2. The printed instructions given to participants in the control group are presented in Figure 2.

In both groups, all other aspects of patient care (including pain management, use of lines and drains, general nursing care, and discharge planning) were provided at the discretion of the treating clinicians and according to routine clinical practice at both hospitals, which was consistent between the sites.

Outcome measures

The outcomes measures used in the trial are described below, with further detail available in the published protocol.[16] Out-

Box 2. Precautions explained to participants in the control group.

- Avoid pushing or pulling through the arms
- Avoid unilateral arm activity
- Limit elevation of the arms to 90 degrees
- Avoid lifting objects heavier than 2 kg
- When coughing, support sternum with a cushion or the arms in a self-hugging position
- Limit use of the arms when transferring from sitting to standing and when getting out of bed
- Avoid placing the arms behind the back

Figure 2. Printed summary of sternal precautions given to participants in the control group.

comes were measured after cardiac surgery but before randomisation and before discharge from hospital (baseline, Week 0) and at 4 and 12 weeks postoperatively. All baseline assessments were performed at the same time of day for each participant across centres. The follow-up testing at Week 4 (± 14 days) and Week 12 (± 14 days) was conducted at the Royal Melbourne Hospital.

Primary outcome

The primary outcome was physical function measured by the Short Physical Performance Battery (SPPB).[17] The SPPB consists of three tests: gait speed, standing balance and a chair rise task. Gait speed was measured as participants walked 2.4 m, and the average of two trials was used. Standing balance was measured in three different static positions (side-by-side stand, semi-tandem stand and tandem stand) for 10 seconds each. In the chair rise task, participants were instructed to stand up and sit down five times in a row as quickly as possible.[17] Each individual test was scored on a scale of 0 to 4 points, with higher scores indicating better performance. The three test scores were summed to give an overall SPPB performance score ranging from 0 (poor function) to 12 points (excellent function).[18] If the participant was unable to physically perform a specific test, a score of 0 points was assigned. A 1-to-2 point increase in the SPPB overall score is often considered to represent a clinical meaningful change (improvement) in physical function.[19,20] The SPPB was selected as the primary outcome because it assesses overall functional performance

of everyday physical tasks. It was hypothesised that the intervention would impact on overall functional performance. Functional performance is also the primary concern of most participants in the medium to long term (6 weeks to 12 months).[16]

Secondary outcomes

Upper limb function was measured using the Functional Difficulties Questionnaire.[21] This questionnaire required participants to rate the difficulty they experienced when completing a series of 13 functional tasks involving the upper limb and trunk. Participants were asked to place a mark along a 10-cm line, with anchors indicating 'no difficulty' and 'maximum difficulty' on the left and right ends of the line, respectively. The total score therefore ranged from 0 to 130, with lower scores indicating less difficulty in performing functional tasks.[21]

Hand grip strength was measured in kg using a hand-held dynamometer[a], with three attempts. The peak pressure of each 5-second attempt was recorded and the highest value was used in the analysis.[22]

Pain intensity was measured with the numerical rating scale for pain. The tool is an 11-point visual analogue numerical scale used to measure any kind of pain with a score ranging from 0 (no pain) to 10 (the most severe pain).[23] Participants used a schematic picture to localise their pain. Pain quality was measured using the Short Form McGill Pain Questionnaire version 2.[24] Higher scores indicated more severe pain.

The 11-item Tampa Scale of Kinesiophobia measured pain-related fear beliefs about movement and re-injury.[24] Participants were asked to rate each of the 11 items on a 4-point, Likert-type scale. A reduction of at least 4 points on the measure maximises the likelihood of correctly identifying an important reduction in fear of movement.[24]

Health-related quality of life was measured with the Medical Outcome Study 36-item Short Form version 2 (SF36).[25] This questionnaire measured eight conceptual domains of: physical functioning, physical limitation, bodily pain, general health, vitality, social functioning, emotional limitation, and mental health. The raw sub-scale scores were transformed to 'norm-based' scores using published algorithms.[25] Norm-based physical and mental component summary scores were also calculated from raw sub-scale scores. Higher scores indicated better quality of life.

Sternal stability was measured with the Modified Sternal Instability Scale, which is a 4-point scale.[5] A score of 0 corresponded to a clinically stable sternum with no detectable motion or separation of the sternal edges, whilst a score of 3 corresponded to a completely separated sternum with marked increased motion or separation of the sternal edges.

Adherence

The weekly follow-up telephone contacts from the trial investigators were used to administer a questionnaire to determine adherence to ten instructions from the allocated program of sternal precautions. Standardised written instructions were used to ensure consistent verbal administration of the questionnaire. The estimate of adherence derived from this questionnaire was dichotomised; participants who reported adherence to at least seven of the ten instructions were classified as 'adherent'.

Data analysis

A sample of 29 patients in each group was calculated a priori to be sufficient to identify a statistically significant between-group difference using the minimum important difference of 2 points out of total score of 12 points, and anticipating a SD of 2.7 points.[20] This was based on a Type-I error rate of 0.05 and a power of 0.80, which are consistent with widely accepted recommendations.[26] The total sample was increased to 72 to allow for possible loss to follow-up.

Data analyses were performed using the SPSS software[b]. Data were assessed for normality using the Kolmogorov-Smirnov test. Descriptive statistics were used to report participant demographics and adherence to sternal precautions. A comparison between the two hospitals was conducted on the demographic profile of the participants to establish differences in each presenting population. The primary outcome, SPPB, was analysed using a mixed between-subject ANOVA with repeated measures across participants. The primary hypothesis was examined by comparing change from baseline to Week 4 between the randomised groups. The analysis followed the 'complete case' intention-to-treat principle. The secondary outcome data (including upper limb function, pain, kinesiophobia and HRQoL) were summarised and analysed similarly to the primary outcome. Because non-significant between-group differences were observed for all variables, further analyses were not carried out. For all tests conducted, a p-value of < 0.05 (two-tailed) was considered statistically significant, and mean differences (95% confidence interval) were reported. A supplementary 'per protocol' analysis was not necessary, as no participants deviated from the protocol.

Results

Flow of participants through the study

Recruitment occurred from September 2015 to November 2016. Across the two sites, 274 adults had cardiac surgery via a median sternotomy and were screened. Of these, 72 were recruited and 36 were randomised to each group. The final follow-up measures for the trial were completed in April 2017. Two participants were lost to follow-up from each group, making their outcome data unavailable. The flow of participants through the trial is presented in Figure 3. Therefore, the 'complete case' intention-to-treat analysis included data from 34 participants in each group.

Compliance with the trial protocol

One originally registered outcome (the Postoperative Quality Recovery Scale) was abandoned because it required comparison to preoperative values, which were too burdensome to collect given postoperative randomisation. The removal of this outcome was indicated in the published protocol[16] and the trial registry entry was also updated.

With respect to compliance with the allocated sternal precautions, 81% of participants in the experimental group and 70% of the participants in the control group were classified as adherent. This difference was not statistically significant (RR 1.10, 95% CI 0.94 to 1.30).

Participant characteristics

The baseline demographic and clinical characteristics of the groups are presented in Table 1. The two groups were comparable in terms of all medical and social demographics. There were no important differences between those who remained in the trial and the few who were lost to follow-up (data not shown). The baseline characteristics were mostly well matched between patients from private and public hospitals (data not shown).

Primary outcome

At baseline (ie, 4 days after surgery), 88% of participants overall had moderate to severe impairment ($\leq 9/12$) as measured by the SPPB (Table 1). Both groups showed substantial improvement thereafter. Nearly half of the participants scored the maximum score (12/12) at Week 4, increasing to two-thirds at Week 12 for both groups. However, there was no significant between-group difference in the amount of improvement in physical function as measured by the SPPB at Week 4 (MD 1.0 point, 95% CI –0.2 to 2.3) and Week 12 (MD 0.4 points, 95% CI –0.9 to 1.6). Group data are presented in Table 2. Individual participant data are presented in Table 3 on the eAddenda.

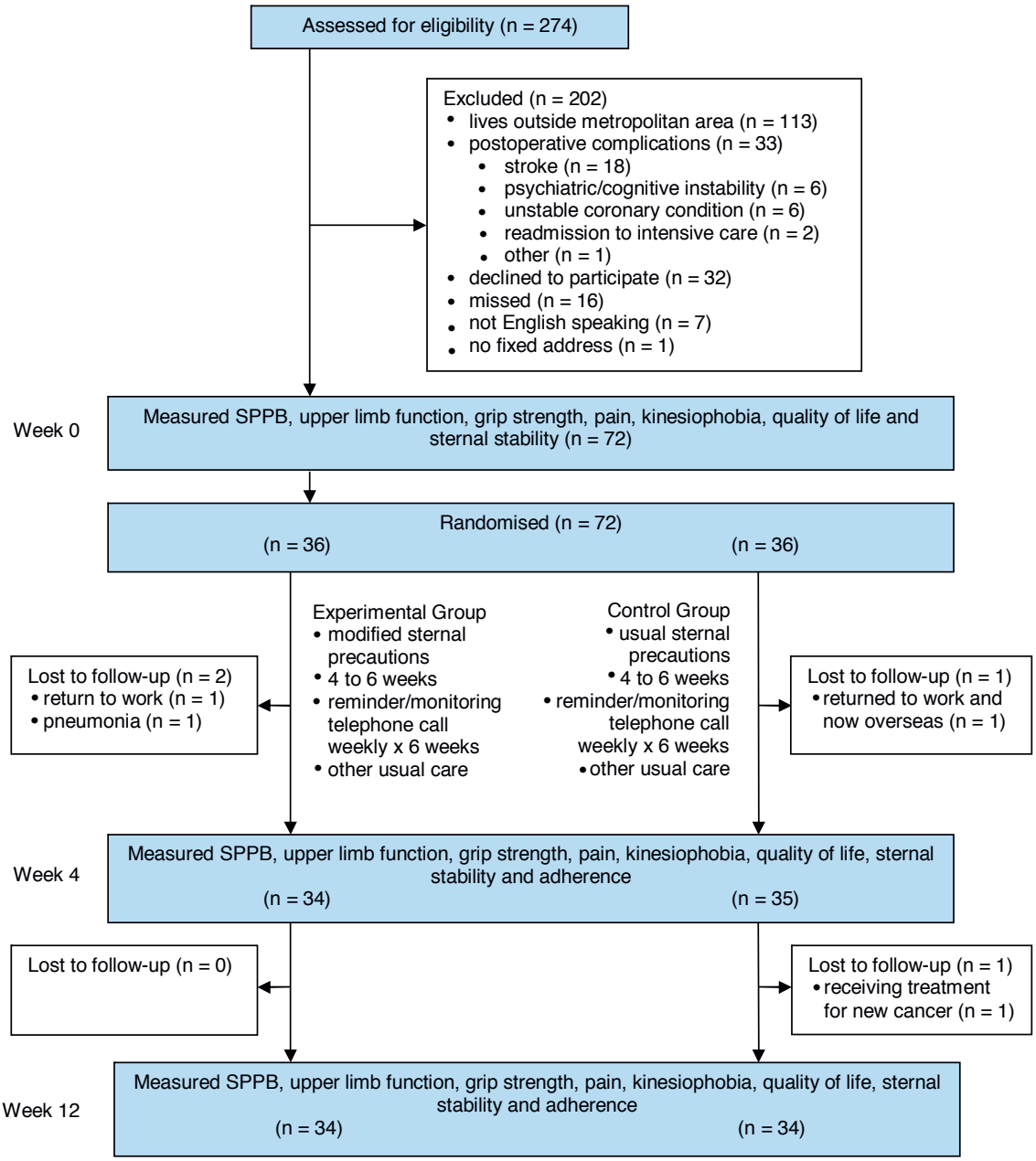

Figure 3. Design and flow of participants through the trial.
SPPB = Short Physical Performance Battery.

Secondary outcomes

There were no significant between-group differences for any of the secondary outcomes, as shown in Tables 2, 4 and 5. Individual participant data are presented in Table 3 on the eAddenda. All secondary outcomes had a time-effect interaction, with patients in both groups improving in all measures significantly over time ($p < 0.05$) except the mental component summary of the SF36 ($p = 1.21$, Table 5).

There were no differences in physical function as measured by the Functional Difficulties Questionnaire or hand grip strength. The majority of participants subjectively reported great initial difficulty on the Functional Difficulties Questionnaire but tended to have less difficulty over time (Table 2).

A significant reduction in pain scores was noted over time, as indicated by a decrease in pain intensity reflected in the numerical rating scale and McGill Pain Questionnaire data (Table 4). Overall, persistent postoperative pain was reported in 16% of participants at Week 4 and 5% at Week 12, based on the numerical rating scale data. Both groups had Tampa Scale for Kinesiophobia scores consistent with having high fear of movement and a mean of 26 (SD 4) points and 24 (SD 5) points in the intervention group and control group, respectively, at baseline. The scores overall demonstrated a decreasing trend over time, with very similar results in the two groups seen at Week 4 (MD 1, 95% CI −2 to 3) and Week 12 (MD 2, 95% CI −1 to 4).

There were no significant between-group differences in quality of life on any of the subscales or component summary scores of the SF36 (Table 5). The physical component summary scores decreased significantly over time, but there was no significant change in the mental component summary scores. At Week 4, one participant (3%) in each group was diagnosed with sternal instability, which persisted until Week 12. Therefore, there was no significant between-group difference in the risk of developing sternal instability (RR 1.0, 95% CI 0.07 to 15.36).

One participant (3%) in each group developed deep sternal wound complications, which required return to theatre and re-wiring before Week 12. Seven (10%) participants (n = 4 experimental, n = 3 control) required hospital re-admission within 6 weeks of surgery due to postoperative complications: superficial wound infection (n = 3), pleural effusion (n = 2), pneumonia (n = 1), and phrenic nerve palsy (n = 1). Therefore, there was no significant between-group difference in the risk of adverse events.

Table 1
Baseline characteristics of all participants.

Characteristic	Randomised (n = 72)	
	Exp (n = 36)	Con (n = 36)
Age *(yr)*, mean (SD)	63 (12)	64 (12)
Gender, n males (%)	31 (86)	34 (94)
Body mass index *(kg/m²)*, mean (SD)	31 (10)	30 (6)
Length of stay *(d)*, median (IQR)	8 (3 to 15)	8 (3 to 15)
Right hand dominant, n (%)	35 (97)	34 (94)
Smoking history, n (%)		
nil	13 (36)	18 (50)
ex	18 (50)	15 (42)
current	5 (14)	3 (8)
Comorbidities, n (%)		
chronic obstructive pulmonary disease	9 (25)	2 (6)
diabetes mellitus	13 (36)	9 (25)
arthritis	5 (14)	3 (8)
hypertension	27 (75)	25 (69)
peripheral nerve disease	1 (3)	1 (3)
Previous sternotomy	3 (8)	3 (8)
Use of gait aid postoperatively, n (%)	14 (39)	11 (31)
Baseline SPPB, n (%)		
≤ 6 (severe impairment)	23 (64)	17 (47)
7 to 9 (moderate impairment)	10 (28)	13 (36)
≥ 10 (no impairment)	3 (8)	6 (17)
Type of surgery, n (%)		
CABG	21 (58)	26 (72)
valve surgery	12 (33)	9 (25)
CABG and valve surgery	5 (14)	2 (6)
type 1 aortic dissection	0 (0)	1 (3)
Type of CABG graft, n (%)[a]		
saphenous vein	7 (19)	4 (11)
radial artery	17 (47)	19 (53)
unilateral internal mammary artery	21 (58)	24 (67)
bilateral internal mammary artery	1 (3)	2 (6)
Surgical duration *(minutes)*, mean (SD)		
operation	292 (79)	281 (91)
cardiopulmonary bypass	102 (44)	110 (48)
Mechanical ventilation *(hr)*, mean (SD)	16 (14)	13 (6)

CABG = coronary artery bypass graft, Con = control group, Exp = experimental group, SPPB = Short Physical Performance Battery.
[a] Data are the number (%) of participants who received the stated vessel. Participants may have received more than one vessel. Therefore, data do not sum to 36 and percentages do not sum to 100.

Discussion

Between participants receiving modified sternal precautions and those receiving usual restrictive sternal precautions, this study found no significant differences in physical function, upper limb function, pain, kinesiophobia or quality of life at 4 and 12 weeks after cardiac surgery via a sternotomy. Participants in both groups improved in these measures over time after surgery. Sternal instability was infrequent and sternal complications were consistent with previous studies.[4,27–29] More importantly, these sternal complications did not differ significantly between the groups. Therefore, this trial highlighted that the implementation of modified sternal precautions did not cause any harm or adverse events, which is something that is often a concern for practitioners managing people after cardiac surgery.

The use of modified sternal precautions using unloaded movements within a pain-free range and loaded activity with the upper arms close to the body is more feasible and practical for everyday tasks. This was reflected in the trend towards better uptake of the encouragement to use the upper limbs in the experimental group. Based on biomechanical principles, these movements were encouraged in the experimental group because they placed symmetrical loads on the two sides of the sternum and minimised the stresses applied to the healing sternum, to promote safety.[11,30] Studies have reported that this strategy results in no significant changes in pain, minimal sternal micromotion and are safe, which is consistent with the current finding.[4,31]

Interestingly, at the postoperative baseline, both groups had moderate to severe impairment in the SPPB scores. It is not possible to discern from the collected data how much of this impairment was pre-existing impairment secondary to the cardiac disease and how much was peri-operative change. Participants in both groups improved in this measure over time after surgery, which was consistent with improvement as a result of cardiac surgery. Despite this, a small but significant number of participants still demonstrated ongoing impaired function, which is consistent with other studies reporting data at 4 weeks' follow-up.[32,33]

One potential reason for the non-significant trial findings could be lack of statistical power to analyse the between-group difference in the SPPB. The sample size calculation was performed using an estimate of minimum important difference of 2 points, extrapolated from a slightly different population with stable cardiovascular conditions,[20] due to the lack of data specifically in cardiac surgery. This is further supported by a recent study determining the minimum important difference of the SPPB to be 1 point in the acute cardiac surgery population.[34] Utilisation of a minimum important difference of 1 point would have necessitated a larger sample size, which may have resulted in a significant between-group difference, given the variability that was documented. A subsequent larger trial is required to test this hypothesis. However, the relatively narrow 95% CIs that were generated by the current study indicate that if a significant between-group difference in SPPB were identified in a future study comparing the two sternal precaution programs that our study compared, it would likely be a fairly small difference.

Another potential reason for the non-significant trial findings could be that the primary outcome (SPPB) did not specifically assess upper limb and trunk function, as impacted by surgery. However, this was assessed in the Functional Difficulties Questionnaire.

Two more plausible reasons for the non-significant result on the primary outcome are suggested. First, the SPPB data showed a substantial ceiling effect. Four days after surgery, almost all

Table 2
Mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups for the outcomes related to physical function and strength.

Outcome	Groups						Within-group difference				Between-group difference	
	Week 0		Week 4		Week 12		Week 4 minus Week 0		Week 12 minus Week 0		Week 4 minus Week 0	Week 12 minus Week 0
	Exp (n = 34)	Con (n = 34)	Exp (n = 34)	Con (n = 34)	Exp (n = 34)	Con (n = 34)	Exp	Con	Exp	Con	Exp minus Con	Exp minus Con
Short Physical Performance Battery *(0 to 12)*	5.8 (2.9)	6.3 (3.3)	10.4 (2.4)	10.2 (2.5)	11.2 (1.6)	11.5 (1.2)	4.6 (2.1)	3.9 (2.7)	5.4 (2.4)	5.1 (3.0)	1.0 (−0.2 to 2.3)	0.4 (−0.9 to 1.60)
Functional Difficulties Questionnaire *(0 to 130)*	55 (26)	52 (23)	16 (16)	14 (14)	6 (10)	4 (7)	−39 (22)	−37 (20)	−48 (23)	−47 (23)	−3 (−13 to 7)	−2 (−12 to 9)
Hand grip strength *(kg)*	2.5 (1.3)	2.5 (0.9)	3.3 (1.6)	3.3 (1.2)	3.7 (1.6)	3.6 (1.3)	0.7 (0.9)	0.8 (1.0)	1.1 (0.9)	1.1 (1.0)	−0.1 (−0.5 to 0.4)	0.0 (−0.4 to 0.5)

Shaded row indicates the primary outcome.
Con = control group, Exp = experimental group.

Table 4
Mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups for the outcomes related to pain and kinesiophobia.

Outcome	Groups						Within-group difference				Between-group difference	
	Week 0		Week 4		Week 12		Week 4 minus Week 0		Week 12 minus Week 0		Week 4 minus Week 0	Week 12 minus Week 0
	Exp (n = 34)	Con (n = 34)	Exp (n = 34)	Con (n = 34)	Exp (n = 34)	Con (n = 34)	Exp	Con	Exp	Con	Exp minus Con	Exp minus Con
Pain numerical rating scale *(0 to 10)*	3.5 (1.6)	3.7 (2.3)	1.6 (1.8)	1.1 (1.5)	0.6 (1.4)	0.4 (0.8)	−1.9 (2.0)	−2.6 (2.6)	−2.9 (2.0)	−3.3 (2.4)	0.7 (−0.4 to 1.8)	0.4 (−0.7 to 1.4)
McGill Pain Questionnaire version 2 *(0 to 10)*	1.0 (0.5)	1.0 (0.6)	0.5 (0.4)	0.5 (0.4)	0.5 (0.4)	0.3 (0.3)	−0.4 (0.6)	−0.6 (0.6)	−0.5 (0.7)	−0.7 (0.7)	−1.0 (−0.2 to 0.4)	0.1 (−0.3 to 0.4)
Tampa Scale for Kinesiophobia-11 *(11 to 44)*	26 (4)	24 (5)	24 (5)	21 (6)	20 (6)	17 (5)	−2 (6)	−3 (4)	−5 (6)	−7 (5)	1 (−2 to 3)	2 (−1 to 4)

Con = control group, Exp = experimental group.

participants had moderate to severe impairment on the SPPB, but by Week 4 nearly half had the best possible score and by Week 12 two-thirds had the best possible score. This ceiling effect may have reduced the ability of the SPPB to detect true differences between the groups. Second, the experimental sternal precauations may not have been targeted enough to accelerate physical recovery. While participants in the study were encouraged to use their upper limbs early with an increased frequency in comparison with the control group, the participants in the study were not prescribed a targeted and progressive program of upper limb exercise during their hospitalisation. Additionally, carers and family members may have played a role in further reinforcing activity restrictions, causing the participants to be fearful, inactive and overly cautious.[8] Other health professionals and carers reinforced strict sternal precautions verbally and by way of written information at the outpatient cardiac rehabilitation programs in the community setting,[8] which may have confounded the results, particularly at Week 12.

Interestingly, it was found that the magnitude of kinesiophobia scores in both groups was high immediately after surgery and similar to that reported by patients with chronic musculoskeletal disorders.[35] Perhaps education on a restrictive program that is marked by avoidance of certain upper limb movements further contributed to the kinesiophobia postoperatively and beyond 4 weeks. Pain-related fear has been reported to influence attendance at exercise-based cardiac rehabilitation.[36] It was hypothesised that kinesiophobia may have been a contributing factor that influenced physical recovery in the current study. Future research is needed to assess the relationship between kinesiophobia and physical recovery.

Consistent with our findings, Cahalin et al[4] proposed that surgeon-dictated sternal precautions, fear of activity, and/or pain exacerbated by movement may be related to reduced physical function and optimal recovery immediately following cardiac surgery.[4] It may be appropriate to tailor the sternal precautions based on individual clinical characteristics and risk profile rather than restricting specific functional tasks and physical activity.[4] In view of this, it is imperative to review the current sternal precaution guidelines within institutions[4] because recommending strict adherence to sternal precautions may not be warranted for all patients.

Table 5
Mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups for domains and component summaries of the Medical Outcomes Study Short Form 36 (SF36) quality of life questionnaire (Australian normed T scores, *0 to 100*).

Outcome	Groups						Within-group difference				Between-group difference	
	Week 0		Week 4		Week 12		Week 4 minus Week 0		Week 12 minus Week 0		Week 4 minus Week 0	Week 12 minus Week 0
	Exp (n = 34)	Con (n = 34)	Exp (n = 34)	Con (n = 34)	Exp (n = 34)	Con (n = 34)	Exp	Con	Exp	Con	Exp minus Con	Exp minus Con
Physical function	19 (7)	22 (7)	39 (12)	41 (11)	51 (7)	50 (8)	20 (12)	19 (11)	31 (10)	28 (9)	1 (−4 to 7)	3 (−1 to 8)
Role physical	37 (12)	39 (11)	33 (9)	34 (10)	47 (9)	47 (10)	−4 (14)	−5 (15)	10 (14)	8 (10)	1 (−6 to 8)	1 (−5 to 7)
Bodily pain	44 (14)	43 (12)	42 (11)	42 (11)	51 (11)	54 (9)	−2 (16)	−1 (14)	8 (14)	12 (13)	0 (−7 to 7)	−4 (−10 to 3)
General health	46 (8)	49 (6)	51 (7)	51 (6)	55 (5)	56 (7)	5 (9)	3 (7)	9 (7)	7 (7)	3 (−1 to 6)	2 (−1 to 6)
Vitality	47 (10)	49 (9)	48 (8)	49 (8)	55 (9)	54 (11)	1 (11)	1 (11)	8 (11)	6 (9)	1 (−5 to 6)	3 (−2 to 7)
Social function	39 (13)	43 (12)	39 (11)	42 (10)	49 (9)	51 (8)	0 (13)	−1 (12)	11 (15)	9 (11)	1 (−5 to 7)	2 (−4 to 8)
Role emotion	42 (14)	42 (16)	40 (16)	42 (16)	47 (12)	49 (12)	−2 (18)	0 (19)	5 (18)	7 (5)	−2 (−11 to 7)	−1 (−9 to 7)
Mental health	44 (11)	46 (10)	47 (10)	48 (10)	48 (13)	52 (10)	2 (11)	2 (10)	4 (15)	6 (10)	0 (−5 to 5)	−2 (−8 to 4)
Physical component summary	33 (8)	35 (7)	40 (9)	41 (8)	52 (7)	52 (8)	8 (10)	6 (9)	20 (11)	17 (8)	2 (−3 to 6)	2 (−2 to 7)
Mental component summary	49 (13)	51 (11)	46 (11)	48 (11)	48 (12)	52 (11)	−4 (14)	−3 (12)	−1 (17)	1 (10)	−1 (−7 to 5)	−1 (−7 to 6)

Con = control group, Exp = experimental group.

Our study is the first randomised trial to report data on a program of modified sternal precautions using pain and discomfort as a guide for upper limb and trunk movements associated with activities of daily living. Although significant benefits were not identified, the lack of harmful or adverse events supports progression of upper limb exercise within the safe limits of comfort and approaches such as ``Keep Your Move in the Tube'', which promotes motion close to the body with short lever arms.[8] This may better facilitate functional recovery after median sternotomy than placing restrictions on use of the upper limbs as part of sternal precautions.[4,8]

This study was robust to most potential sources of bias and included a heterogeneous group of patients who underwent a cardiac surgical procedure via sternotomy. Although this could have increased the risk of inclusion bias, it improved the external validity of the study. Attrition bias was a low risk, as only 6% of participants were lost to follow-up. This study may have been underpowered, as the power was based on prior research available in the cardiovascular population in the absence of data in cardiac surgery. Although participants could not be completely blinded to their allocated precautions, we attempted to minimise any placebo or Hawthorne effects by not notifying participants of the details of the other program of sternal precautions.

It is recommended that future research could involve a non-inferiority trial that: is larger, adopts the recently established minimum important difference of 1 point for the SPPB, and incorporates greater assessment of upper limb functional exercise. Specific evaluation of upper limb functional exercise could be expanded to include the unsupported upper limb exercise test (UULEX)[37] to more robustly investigate the effects of a program of modified sternal precautions. In addition, the development of a risk stratification tool to stratify patients for sternal precautions based on their individual risk for the development of sternal complications is warranted.

In conclusion, modified (ie, less restrictive) sternal precautions for people following cardiac surgery had similar effects on physical recovery, pain and health-related quality of life as usual care. Based on reasonably robust evidence from this study, similar outcomes can be anticipated regardless of whether patients are managed with traditional or modified sternal precautions. Until further research is performed, centres that strictly enforce restrictive sternal precautions might consider modified sternal precautions as an equally appropriate option.

What was already known on this topic: After cardiac surgery via median sternotomy, sternal complications may include infection, non-union or instability. Restrictive precautions (such as limiting use of the arms in certain daily tasks) are often prescribed postoperatively in an attempt to minimise motion at the sternal edges during healing; however, there is a lack of robust evidence of the need for such restrictive precautions.

What this study adds: Similar outcomes can be anticipated regardless of whether patients are managed with traditional restrictive sternal precautions or sternal precautions that have been modified to be less restrictive. No increase in sternal complications were noted with the use of the less-restrictive sternal precautions.

Footnotes: [a] JAMAR dynamometer, Performance Health, Warrenville, USA. [b] SPSS Windows Version 23.0, SPSS, Chicago, USA.

eAddenda: Table 3 can be found online at: https://doi.org/10.1016/j.jphys.2018.02.013

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