Physical Function and Sternal Management

Following Cardiac Surgery via Median Sternotomy

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Dedication

It is the quest for knowledge that opens the doors of progress:

“Whenever I set myself the task to learn, I realize how little I know and the more I learn, the more I realize how ignorant I am”

(Imam Ash-Shafi’i).

This thesis is dedicated to my loving family, especially to my dear parents; Ms Zainab bt Sultan and Mr Md Ali bin Md Ariff. From an early age they instilled in me a strong work ethics and the importance of giving back to society, my profession and my patients. I am also indebted to my siblings, especially Dr Ir Rafee Makbol, Dr Azillah, Dr Nur Ayub, Ms Rafe’aton, Makmur Ali and Siti Asah Md Ali for their love, patience, and unwavering support. They never once doubted or stopped believing in me, and have offered endless reassurances throughout this journey. I could not have accomplished as much as I have without their support and understanding.
Abstract

Median sternotomy is the most common incision used in cardiac surgery worldwide with more than a million procedures operated annually (Epstein et al, 2011; Go et al, 2014), due to its ease of performance and provision of optimal exposure of the heart (El Ansary et al, 2007c; McGregor et al, 1999; Robicsek et al, 2000; Zeitani et al, 2006; Deb et al, 2013) It remains the standard of care for myocardial revascularization in cardiac surgery, in particular for multi-vessel disease (Cheng & Slaughter, 2013; Deb et al, 2013; Rosenfeldt et al, 2012; Taggart, 2013b). Despite the advantages of a median sternotomy, the incidence of sternal complications has remained relatively unchanged for the last two decades and is reported to be between 1 to 8% worldwide (Balachandran et al, 2016; El-Ansary, 2000b; Ho et al, 2002; ASCTS Data 2013) Sternal complications can range from post-sternotomy pain, skin infections, dehiscence, sternal instability/non-union and mediastinitis (Crabtree et al, 2004; El-Ansary et al, 2008; Cahalin et al, 2011; ASCTS Data 2013). These complications are associated with significant morbidity, and prolonged patient hospitalization which is reported to triple the cost of care (Losanoff et al 2002b; Crabtree et al, 2004; Zeitani et al, 2006; El-Ansary et al, 2008; Baskett et al, 1999; Filsoufi et al, 2009; Joseph et al, 2014; Cahalin et al, 2011; Mekontso et al; 2011; Lazar et al, 2016).

In an attempt to facilitate sternal healing and prevent sternal complications, patients who have undergone cardiac surgery via a median sternotomy are routinely asked to follow sternal precautions post-operatively (Balachandran et al, 2014; Tuyl et al, 2012, Cahalin et al, 2011; Overend et al, 2010). These precautions place restrictions on the use of the upper limbs and trunk immediately following surgery (Balachandran et al, 2014; Tuyl et al, 2012, Cahalin et al, 2011; Overend et al, 2010; Brocki et al., 2010). Sternal precautions are applied worldwide for duration of four weeks to three months following surgery despite a paucity of research to support this practice (Balachandran et al, 2014; Tuyl et al, 2012, Cahalin et al, 2011; Overend et al, 2010; Brocki et al, 2010). Recent research has reported that minimal sternal motion takes place between the sternal edges as measured by ultrasound during upper limb and trunk activity (Balachandran, 2015; Balachandran et al, 2017). Furthermore, such sternal micromotion may constitute part of the normative path to bone healing (Balachandran et al, 2014; Balachandran et al, 2017; Cahalin et al, 2011). Sternal precautions in their current
form may be overly restrictive thus delaying recovery and a return to community role healing (Balachandran et al, 2014; Balachandran et al, 2017; Cahalin et al, 2011).

This thesis examined (1) whether change to sternal precautions impact upon function and sternal pain following cardiac surgery via a median sternotomy. A randomized controlled trial (RCT) was conducted to assess how changes to sternal precautions impact upon function, and sternal pain following cardiac surgery via a median sternotomy. Nested within the RCT, a repeated cohort studies were conducted to assess the clinimetric properties of selected physical function tools ie The Short Physical Performance Battery (SPPB) and The Functional Disability Questionnaire (FDQ) used in the cardiac surgery via a median sternotomy. The results provide new clinimetric information on outcome measures targeting the cardiac population and inform the post-operative clinical management and rehabilitation after cardiac surgery.

This thesis is composed of four studies, where each study is focused on specific parameters that are essential in obtaining comprehensive data and results.

In the first study, a protocol for randomised controlled trial was designed to investigate whether changes to sternal precautions impact upon function following cardiac surgery via a median sternotomy. The rationale for developing this study protocol was that the routine implementation of sternal precautions worldwide practice following a median sternotomy may delay recovery and be overly restrictive. This study is the first randomized controlled trial using an intervention group to modify sternal precautions, and study its effectiveness in improving physical function in this population. The intervention was built on foundational evidence that evaluated the effects of upper limb exercise by investigating the effects of modifying sternal precautions to include the safe use of upper limbs and trunk, and assess their impact on patients’ physical following cardiac surgery via median sternotomy in order to optimize functional recovery in this patient population.

The second study nested within the study 1 was conducted to determine the clinical applicability of the Short Physical Performance Battery (SPPB), when used in patients post cardiac surgery. This study evaluated the MCID of the SPPB, an outcome measure that has been validated in older patients who were classified as cardiovascular stable. Importantly, this study is the first to determine the MCID of the SPPB for an adult cardiac surgery population. The results of this study should be considered preliminary.
evidence on the application of the SPPB to evaluate treatment effectiveness by detecting a true improvement. An increase or decrease in performance greater than the MCID indicates a high likelihood of a meaningful change. These measures can be used to document real improvements in physical function through the course of cardiac rehabilitation. Therefore, it is recommended that an MCID reference value above one point of the SPPB scores could serve as an explicit therapeutic goal for rehabilitation intervention and monitoring functional progress following cardiac surgery.

The third study incorporated a novel outcome assessment of upper limb and trunk function specific to cardiac surgery developed by a team of researchers within the Department of Physiotherapy at the Melbourne University. This was a comprehensive clinometric analysis of the FDQ including: the statistical feasibility of a shortened FDQ (FDQ-s), validity, reliability, responsiveness, interpretability, and feasibility. The findings of this study established that the FDQ-s has strong clinimetric properties with moderate to excellent results on all domains. As such, it is recommended that the FDQ-s be adopted as an outcome measure of physical recovery after cardiac surgery within the acute hospital setting, and in the community to plot the trajectory of recovery overtime. Further, the FDQ-s can be utilized in research trials evaluating function and in the clinical setting by health professionals to inform and guide management after cardiac surgery. The FDQ-s may be a useful tool in understanding the benefits of physical limitations after cardiac surgery, and thus lead to more finely tailored and individualized health care interventions.

The final study in this thesis presents the results from a RCT, the Sternal Management Accelerated Recovery Trial (SMART) that investigated a standard restrictive versus a program of modified sternal precautions following cardiac surgery via a median sternotomy. The findings of this study suggest that a program of modified (less-restrictive) sternal precautions for patients following cardiac surgery did not improve physical recovery, pain, or enhance health related quality of life (HRQoL) compared to usual care. With no adverse event, the results of this RCT suggest that a precautionary approach that is less restrictive with a progression of activity will likely facilitate optimal functional recovery after a median sternotomy. Importantly, this result adds further evidence that strict adherence to SP may not be warranted for all patients as it reinforces kinesiophobia which may potentially impact on patient participation exercise.
and in cardiac rehabilitation. It is recommended that a program of sternal precautions based on individual clinical characteristics and risk profile rather than a generic and routine set of SP may result in optimal recovery. Findings in this field of research will be of great importance to enhance, develop and evolve SP to provide patients with the optimal care for post-operative physical and sternal pain management.

The findings of this thesis supported the need in the development, and implementation of clinical and regulatory guidelines to improve patient and community safety; quality of life and standards of care for individuals following cardiac surgery. The thesis addresses the paucity of research and the inconsistent recommendations with respect to sternal precautions and associated restrictions to upper limb and trunk provided to the large number of individuals having open-heart surgery nationwide. In particular, this research will inform guidelines for the commencement of upper limb activities in Cardiac Rehabilitation (CR) and standards for sternal precautions following cardiac surgery.

This thesis further addressed the gaps in the literature pertaining to the outcome measures used following cardiac surgery performed via sternotomy. The results of the two outcome measure studies recommended that the SPPB and FDQ be used as measure tools for outcome assessment in research studies, to assess the impact of post-operative rehabilitation management, and better elucidate the process of recovery after cardiac surgery in the acute clinical setting.

Please note that this thesis will utilise English spelling in compliance with the University of Melbourne Guidelines.
Declaration

This is to certify that:

1. the thesis comprises only my original work towards the PhD except for chapter five. The data was derived of others people works combined with my work to ensure robust results for the work to be published.

2. due acknowledgement has been made in the text to all materials used.

3. this thesis is less than 100,000 words in length, excluding tables, references and appendices.
Acknowledgements

The Research involved in this thesis was carried out in the Department of Physiotherapy, University of Melbourne.

The quest for my doctoral education would have not been possible without the support and assistance of many individuals to whom I offer my deepest and sincerest thanks. I graciously acknowledge those, whose wisdom, support and inspiration enriched my work, and made my dissertation writing and graduate school experience an immensely pleasant one.

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Publications


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Published abstract


Publications submitted and under peer review


Planned Submission

Conference Presentations


<table>
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<tr>
<th>Abbreviation</th>
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<tr>
<td>ACRA</td>
<td>Australian Cardiovascular Health and Rehabilitation</td>
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<td>ADL</td>
<td>Activities of Daily Living</td>
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<td>AIHW</td>
<td>Australian Institute of Health and Welfare</td>
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<td>ANOVA</td>
<td>Analysis of Variance</td>
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<td>ARDS</td>
<td>Acute Respiratory Distress Syndrome</td>
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<td>BARI</td>
<td>Bypass Angioplasty Revascularization Investigation</td>
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<td>BMI</td>
<td>Body Mass Index</td>
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<td>BP</td>
<td>Bodily Pain</td>
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<tr>
<td>CABG</td>
<td>Coronary Artery Bypass Grafting</td>
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<tr>
<td>CCC</td>
<td>Canadian Cardiovascular Society grading of angina pectoris</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<tr>
<td>CG</td>
<td>Control group</td>
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<td>CHD</td>
<td>Coronary Heart Disease</td>
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<td>CI</td>
<td>Confidence Interval</td>
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<td>CM</td>
<td>Centimetre</td>
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<td>CONSORT</td>
<td>Consolidated Standards of Reporting Trials</td>
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<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<td>CPB</td>
<td>Cardiopulmonary Bypass</td>
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<td>CR</td>
<td>Cardiac Rehabilitation</td>
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<td>CS</td>
<td>Cardiac Surgery</td>
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<td>CT</td>
<td>Computed Tomography</td>
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<td>CVD</td>
<td>Cardiovascular Disease</td>
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<td>Abbreviation</td>
<td>Definition</td>
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<tr>
<td>DM</td>
<td>Diabetes Mellitus</td>
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<td>DSMC</td>
<td>The Data Safety Monitoring Committee</td>
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<td>DSWIs</td>
<td>Deep Sternal Wound complications</td>
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<td>ES</td>
<td>Effect Size</td>
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<td>FDQ</td>
<td>Functional Difficulties Questionnaire</td>
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<td>FEV₁</td>
<td>Forced Expiratory Volume in one second</td>
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<td>FRC</td>
<td>Functional Residual Capacity</td>
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<td>Force Vital Capacity</td>
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<td>GEA</td>
<td>Gastroepiploic Artery</td>
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<td>GH</td>
<td>General Health</td>
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<td>GRC</td>
<td>Global Rating of Scale</td>
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<td>HGS</td>
<td>Hand Grip Strength</td>
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<td>HRQoL</td>
<td>Health Related Quality of Life</td>
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<td>IASP</td>
<td>International Association on the study of pain</td>
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<td>ICC</td>
<td>Intra-class Correction Coefficient</td>
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<tr>
<td>IG</td>
<td>Intervention group</td>
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<tr>
<td>IMA</td>
<td>Internal Mammary Artery (the term IMA is used instead of internal thoracic artery in this thesis)</td>
</tr>
<tr>
<td>ITT</td>
<td>Intention to treat analysis</td>
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<tr>
<td>IQR</td>
<td>Inter-quartile Range</td>
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<tr>
<td>Kg</td>
<td>Kilogram</td>
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<td>Km</td>
<td>Kilometres</td>
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<td>L</td>
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<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>LAD</td>
<td>Left Anterior Descending</td>
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<tr>
<td>LIMA</td>
<td>Left Internal Mammary Artery</td>
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<td>LV Grade</td>
<td>left ventricular function grade</td>
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<td>m</td>
<td>Metres</td>
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<tr>
<td>MCID</td>
<td>Minimal Clinical Important Difference</td>
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<td>MCS</td>
<td>Mental Component Summary</td>
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<td>MH</td>
<td>Mental Health</td>
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<td>MI</td>
<td>Myocardial Infarct</td>
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<td>MID</td>
<td>Minimal Important Difference</td>
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<td>mm</td>
<td>Millimetre</td>
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<td>MPH</td>
<td>Melbourne Private Hospital</td>
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<td>Newton</td>
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<td>Number of Participants</td>
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<td>NHP</td>
<td>Nottingham Health Profile</td>
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<td>NRS</td>
<td>Numerical Rating Scale of Pain</td>
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<td>NYHA</td>
<td>New York Heart Association Functional Classification</td>
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<td>OLA</td>
<td>Open Lung Approach</td>
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<td>OPCAB</td>
<td>Off Pump Cardiopulmonary Bypass</td>
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<td>OR</td>
<td>Odds Ratio</td>
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<td>PCS</td>
<td>Physical Component Summary,</td>
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<td>PF</td>
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<td>PICP</td>
<td>Patient Identified Cardiac Pain</td>
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<td>PPC</td>
<td>Post-operative Pulmonary Complications</td>
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<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>PS</td>
<td>Propensity Score</td>
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<td>PURE</td>
<td>Prospective Urban-Rural Epidemiology</td>
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<td>R</td>
<td>Right</td>
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<td>RA</td>
<td>Radial Artery</td>
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<td>RCT</td>
<td>Randomized Controlled Trial</td>
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<td>RE</td>
<td>Role Emotion</td>
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<td>RIMA</td>
<td>Right Internal Mammary Artery Right,</td>
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<td>RMH</td>
<td>Royal Melbourne Hospital</td>
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<tr>
<td>ROM</td>
<td>Range of Motion</td>
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<td>ROOBY</td>
<td>Randomized on/off Bypass</td>
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<td>RP</td>
<td>Role Physical</td>
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<td>SC</td>
<td>Standard Care Group</td>
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<td>Sternal Instability</td>
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<td>Sternal Instability Scale</td>
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<td>SIP</td>
<td>Sickness Impact Profile</td>
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<td>S.M.A.R.T</td>
<td>Sternal Management Accelerated Recovery Trial</td>
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<td>SPIRIT</td>
<td>Standard Protocol Items: Recommendations for Interventional Trials</td>
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<td>SPPB</td>
<td>Short Physical Performance Battery</td>
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<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>SPSS</td>
<td>Statistical Package for Social Sciences</td>
</tr>
<tr>
<td>SSV</td>
<td>Small (short) Saphenous Vein</td>
</tr>
<tr>
<td>STEMI</td>
<td>ST-elevation Myocardial Infarction</td>
</tr>
<tr>
<td>STROBE</td>
<td>Strengthening the Reporting of Observational Studies in Epidemiology</td>
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<td>SVG</td>
<td>Saphenous Veins Grafts</td>
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<td>SWC</td>
<td>Sternal Wound Complications</td>
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<td>SWIs</td>
<td>Superficial wound complications</td>
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<td>TEE</td>
<td>Transesophageal echocardiography</td>
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<td>TiDier</td>
<td>Template for Intervention Description and Replication</td>
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<td>TSK-II</td>
<td>Tampa Scale of Kinesiophobia Version 2</td>
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<td>TUG</td>
<td>Time Up and Go Test</td>
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<td>VC</td>
<td>Vital Capacity</td>
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<td>VDS</td>
<td>Verbal Descriptor Scale</td>
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<td>VI</td>
<td>Vitality</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>World Health Organization for a generic health-related QOL</td>
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Chapter 1: Introduction

Chapter Overview

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1.1 Background of the clinical problem

Median sternotomy is the most common incision used in cardiac surgery worldwide with more than a million procedures performed annually (Epstein et al, 2011; Go et al, 2014), due to its ease of performance and provision of optimal exposure of the heart (El Ansary et al, 2007c; McGregor et al, 1999; Robicsek et al, 2000; Zeitani et al, 2006b). It remains the standard of care for myocardial revascularization in cardiac surgery in particular for multi-vessel disease (Cheng & Slaughter, 2013; Deb et al, 2013; Taggart, 2013b; Rosenfeldt et al, 2012). In Australia, 10-13,000 cardiac procedures are performed annually (Australian Institute of Health and Welfare, (2016) website- www.aihw.gov.au). Cardiac surgery via a median sternotomy has been known to provide long-term benefits in terms of survival and it is also cost effective. Despite the advantages of a median sternotomy, the incidence of sternal complications has remained relatively unchanged for the last two decades, and is reported to be between 1 to 10 percent worldwide (Singh et al, 2011; El-Ansary et al, 2000b; Ho et al, 2002; ASCTS Data 2013). Sternal complications can range from post-sternotomy pain, skin infections, dehiscence, sternal instability/non-union and mediastinitis (Crabtree et al, 2004; El-Ansary et al, 2008; Cahalin et al, 2011; ASCTS Data 2013). These complications are associated with significant morbidity, prolonged hospitalisation, and are reported to triple the cost of care (Losanoff et al 2002b; Crabtree et al, 2004; Zeitani et a, 2006b; El-Ansary et al, 2008; Baskett et al, 1999; Filsoufi et al, 2009; Cahalin et al, 2011; Mekontso et al; 2011; Lazar et al, 2016).
It has been established that within the first two weeks following a median sternotomy procedure, there is a significant increase in the difficulties patients experience in the performance of functional tasks that involve mobilisation, and activities of daily living (Min et al, 2015; Sturgess et al, 2014; Lapier et al, 2008; Lapier, 2007). A loss or limited shoulder range of movement (ROM) was reported in several studies (Hoggins, 2009; Lapier et al, 2008; Stiller et al, 1997), while other studies (Hoggins, 2009; Lapier & Schenk, 2002) recognized that a loss of thoracic ROM and posture (Hoggins, 2009) may occur post-operatively, that impacts on the quality of life, and physical function with variations in time taken for these patients to achieve their pre-operative ROM, ranging from four weeks to three months post-operatively (Hoggins, 2009). In addition, patients who suffer post-sternotomy chest pain are more likely to have impairments on functional activity compared to those who have experience less pain (Cahalin et al, 2011). Evidence has shown that mild to moderate pain may interfere with the performance of daily activities, and severe pain may further impair these activities and lead to depression (Eisenberg et al, 2001; Papadopoulos et al, 2013; Watt-Watson et al, 2004). The prevalence of post sternotomy pain has been reported to be between 21–66% worldwide (Choinière et al, 2014; Eisenberg et al, 2001; Hunt et al, 2000; Kalso et al, 2001; MacRae, 2008; Meyerson et al, 2001; Mueller et al, 2000). Of those patients, 33% to 66% experienced chronic pain lasting more than three months, and 25% to 33% experienced more than one year of chronic pain that interferes with everyday tasks and increased cost of care (El Ansary et al, 2000b; Kalso et al, 2001; Lapier, 2003b; Macrae, 2008; Papadopoulos et al, 2013; Sturgess et al, 2014; Ucak et al, 2011; Vymazal et al, 2009).

Activities such as coughing, sneezing, deep breathing, unilateral upper limb tasks, turning in bed, getting up to the chair and ambulation have been reported to result in the greatest levels of pain during the first week after cardiac surgery via a median sternotomy (Balachandran et al, 2017; Brocki et al, 2010; Parker et al, 2008; Milgrom et al, 2004). Even mild pain interfered with rest, coughing and sleeping for up to one year at home following discharge (Lahtinen et al, 2006). As such, pain post-operatively regardless of intensity, has been shown to positively correlated with low physical function scores as well as reduced general health, vitality, social function, and mental health scores in the self-administered SF36 health related quality of life (HRQoL) scales (Bitkover & Gårdlund, 1998; Eisenberg et al, 2001). Additionally, 47% of patients
reported having incision or breast pain for up to 12 months after surgery (King et al, 2009). Women have been known to suffer greater levels of pain (Morone et al, 2010; Sethares et al, 2013), and lower physical function levels than men, this could possibly be due to their major role in home management responsibilities (Zimmerman et al, 2004). Older patients are reported to have less post-sternotomy pain, but have lower physical function and quality of life scores compared to younger patients due to the greater number of surgeries, pre-morbid functional impairment and comorbidities (Gjeilo et al, 2010; Papadopoulos et al, 2013). Hence, early intervention to restore function is essential as impairment of upper limb movements, and sternal pain may interfere with self-care and functional activities that prevent a timely return to normal activities (LaPier, 2007; Lapier & Schenk, 2002; LaPier et al, 2008).

Physiotherapists usually prescribe upper limb and trunk exercises post-operatively, which are built upon in cardiac rehabilitation programs to promote recovery and return to normal daily function (Sturgess et al, 2014; Price et al, 2016). Exercises of the trunk and upper limb have also been shown to significantly reduce sternal pain during the first 6 weeks post-operatively (Sturgess et al, 2014). This is significant, for if patients have pain that persists beyond 6 weeks, it is most likely to continue as chronic sternal pain, thus highlighting the importance of optimal pain management in the initial post-operative period. Additionally, physical activity and exercise appears to be imperative for healing and remodelling of bone which responds to loading (Balachandran et al, 2017; Balachandran et al, 2014; Mekontso et al, 2011; Cahalin et al, 2011; El Ansary et al, 2007c). Current evidence for functional recovery support moderate intensity exercise and upper limbs exercise to facilitate safe and optimal post-operative recovery (Balachandran et al, 2017; Price et al, 2016; Hirschhorn et al, 2008). However, exercise guidelines worldwide are broad and lack detail to guide for optimal exercise prescription (Price et al, 2016).

Following cardiac surgery sternal precautions that place restrictions on the use of the upper lims and trunk, are routinely prescribed to all patients in an attempt to facilitate sternal healing, and prevent sternal complications (Adams et al, 2016; Adams et al, 2014; Brocki et al, 2010; Cahalin et al, 2011). These restrictions are usually applied by health professionals for a time period that can span from four weeks, to three months post-operatively, (Balachandran et al, 2014; Tuyl et al, 2012; Cahalin et al, 2011;
Overend et al, 2010) with 95% placing restrictions on upper limb exercise and in 25% of Cardiac rehabilitation programs omitting them all together, thus posing a clinical dilemma (Balachandran et al, 2014). This restrictive approach limits the ability of the patients to progress their activity to a moderate intensity as recommended whilst in hospital (Balachandran et al, 2014; Tuyl et al, 2012; Cahalin et al, 2011; Overend et al, 2010). Hirschhorn et al, 2012 demonstrated that the majority of physical activity after cardiac surgery is Physiotherapy-supervised mobilisation. The amount of supervised therapy at hospital is limited, and aside from the therapy period, most patients do not undertake any activities following hospital discharge (Santos et al, 2016; Zomorodi et al, 2012). This is further compounded as following hospital discharge, fewer than half of the patients are unable to attend or access cardiac rehabilitation programmes (Menezes et al, 2014; Niebauer, 2016; Sandesara et al, 2015). In particular, women are less likely to be referred or attend rehabilitation programmes (Menezes et al, 2014; Niebauer, 2016; Sandesara et al, 2015).

It has been postulated that sternal precautions may be unnecessarily overly restrictive, and may even compromise the ability of patients to mobilise causing delay in functional recovery (Adams et al, 2016; Balachandran et al, 2014; Brocki et al, 2010; Cahalin et al, 2011; Irion et al, 2013; Adams et al, 2008; Lapier, 2003). There is no definitive evidence drawn from the clinical setting to support the use of sternal precautions following a median sternotomy (Adams et al, 2016; Cahalin et al, 2011; Brocki et al, 2010). A recent survey concluded that sternal precautions are based on expert opinions, historical institutional protocols, and based on cadaver studies (Balachandran et al, 2014; Cahalin et al, 2011). A review of the literature reported that sternal precautions are mostly applied uniformly for all patients without regard to individuals differences (Cahalin et al, 2011). As such, patients are encouraged where possible not to use their arms during everyday tasks, such as bed transfers or lifting objects. However, these restrictions are not consistent or standardised, with significant variation in what constitutes ‘sternal precautions’, as well as the duration for which these are applied patients in Australia (Balachandran et al, 2014; Tuyl et al, 2012), and overseas (Adams et al, 2006; Adams et al, 2008; Cahalin et al, 2011; Irion et al, 2013; Overend et al, 2010). The evidence for these restrictive SP has been derived from studies of cadavers, and from orthopaedic research on healing of the long limb bones (Balachandran et al, 2014; McGregor et al, 1999). More recently, Balachandran et al (2017) investigated the
effects of upper limb and trunk tasks, and reported that minimal pain and sternal motion took place between the sternal edges as measured by real-time ultrasound. However, it remains unknown if a more liberal and individualized approach to sternal precautions that is based on risk assessment of sternal complications would accelerate physical recovery after cardiac surgery.

1.2. Significance of the Thesis

Despite a paucity of evidence, health professionals usually prescribe sternal precautions that restrict the use of upper limbs and trunk in attempt to prevent sternal complications, and at the same time encourage mobilization and active movement of the upper limbs and trunk without regard to individual difference, risks factors for complications and clinical status immediately following surgery (Balachandran et al, 2014; Cahalin et al, 2011; Brocki et al, 2010). This poses a clinical dilemma as sternal precautions may be overly restrictive delaying functional recovery, progression of mobility thus posing a barrier to discharge from hospital (Balachandran et al, 2014; Cahalin et al, 2011; Brocki et al, 2010).

To date, there are no national or international post-operative clinical management guidelines for cardiac surgery via a median sternotomy (Price et al, 2016; Tuyl et al, 2012; Cahalin et al, 2011). Therefore, the aims of this thesis are to examine whether changes to sternal precautions impact function and sternal pain following cardiac surgery via a median sternotomy; and to review pain, function and physical activity tools used in these population. The outcomes of this research will inform the development and implementation of clinical guidelines to improve patient recovery and restoration of function. It is anticipated that the findings will be translated to evidence based guidelines for medical practitioners and health care professionals involved in the overall care of pre- and post-operative cardiac surgery patients via a median sternotomy.
1.3. Concise statement of the research and research aims

This thesis will examine whether changes to sternal precautions impact physical function and sternal pain following cardiac surgery via a median sternotomy by conducting a randomized controlled trial (RCT) comparing restrictive standard and an intervention of modified sternal precautions. Nested within the RCT, a repeated cohort study will be conducted assessing the clinimetric properties of selected physical function tools used in the cardiac surgery. A flowchart summarising the research studies presented in this thesis is illustrated in Figure 1.1. The following questions will be addressed in the thesis:

1. Does a program of modified sternal precautions for patients following cardiac surgery via a median sternotomy result in improved physical function compared with standard care sternal precautions at four weeks post-operatively?

2. Does a program of modified sternal precautions for patients following cardiac surgery via a median sternotomy result in improved upper limb function, sternal pain and discomfort, kinesiophobia and health related quality of life (HRQoL) at four weeks post-operatively?

3. Are comorbidities and/or pre, peri and post-operative risk factors associated with the development of the modified sternal precautions post-sternotomy, for patients following cardiac surgery via a median sternotomy?

4. What is the level of adherence to sternal precautions by patients following cardiac surgery via a median sternotomy?

5. What are the clinimetric properties of the selected physical function assessment tools (the SPPB and the FDQ) used in the cardiac surgery via a median sternotomy?
Thesis Structure

Study 1: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T)- standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial

Study 2: The Short Physical Performance Battery (SPPB) can be utilized to evaluate physical function in patients following cardiac surgery


Study 4: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): Standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy - a randomized controlled trial

Figure 1.1: Flowchart of studies illustrated in this thesis
1.4. Overview of thesis

The following is the structural overview of the thesis focusing on Physical Function, and Sternal Management following Cardiac Surgery.

Chapter 1: Introduction
A summary of the clinical problem and significance of the research is presented in this chapter. It also provides an outline of the structure of this thesis.

Chapter 2: Literature Review
This literature review provides an overview of cardiac surgical procedures performed via a median sternotomy, common post-operative complications associated with the procedures and physiotherapy management for this target population. This chapter concludes with a description of the outcomes measured in the literature review studies.

Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T)-Standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial
This chapter presents an overview of the protocol for the randomised controlled trial, designed to investigate whether changes to sternal precautions impact on physical function following cardiac surgery via a median sternotomy.

Chapter 4: The Short Physical Performance Battery (SPPB) can be utilized to evaluate physical function in patients following cardiac surgery
This chapter presents a prospective cohort study that was nested within the RCT, to determine the clinical applicability of the Short Physical Performance Battery (SPPB), when used in patients post cardiac surgery.

Chapter 5: The Functional Disability Questionnaire (FDQ): Evaluation of Clinimetric Properties of a New Tool for measuring Physical Function Following Cardiac Surgery
This was a prospective cohort study nested within the two RCT study conducted to evaluate clinimetric properties of new developed FDQ, as a measure of functional
recovery in both the short term (four weeks post-operatively), and long term (three months post-operatively) following cardiac surgery.

Chapter 6: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): Standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy - a randomized controlled trial
This was a prospective, double blinded (patients and assessors), randomised controlled trial conducted at two hospitals (one public and one private) in Melbourne, Australia to investigate whether changes to sternal precautions impact physical function following cardiac surgery.

Chapter 7: Conclusion, and future directions
This chapter presents a summary of the main finding(s) on each of the studies conducted, as well as their clinical relevance and impact on current practice, with recommendations for future research.
# Chapter 2: Literature Review

## Chapter Overview

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## 2.1 Introduction

This chapter provides an overview of cardiovascular disease and its cardiac surgical management. The most common post-operative complications after cardiac surgery via sternotomy are described. The chapter summarises the clinical practice and evidence base of physiotherapy post cardiac surgery including cardiac rehabilitation, post-operative respiratory physiotherapy, and upper limb and trunk exercises. In particular, there is focus on sternal precautions as an intervention to prevent sternal complications. The final section of this chapter describes commonly used outcome measures to measure physical function, pain and other patient important outcomes after cardiac surgery. Many of these measures are used within the studies of this thesis.

## 2.2 Cardiovascular Disease

### 2.2.1 Prevalence

Cardiovascular disease (CVD), is the leading cause of morbidity and mortality worldwide (World Health Organisation Cardiovascular disease fact sheet, 2016). CVD encompasses all diseases affecting the heart, and/or blood vessels, including coronary heart disease (CHD), and cerebrovascular accidents (AIHW 2016). It is estimated that approximately 1.5 million cardiac surgical operations are performed annually in all parts of the world for mainly coronary and valve related surgery. Overwhelmingly this
is performed through full sternotomy. It was estimated that 4.2 million Australian adults aged 18 years and over were diagnosed with at least one or more cardiovascular diseases in the years 2014 and 2015, this accounted for 22% of the total population (AIHW, 2016b). In the period of 2014 to 2015, the prevalence of CVD among adults was similar for men and women (22%), with a greater incidence in the older population. It is reported in the same period that half (53%) of 65 to 74 year olds, and two-thirds (66%) of those aged more than 75 years of age, had CVD (AIHW 2016).

Cardiovascular disease (CVD) kills one Australian every 12 minutes, and affects one in six Australians; which equates to over three and a half-million people in Australia. In the years 2012 and 2013, the main cause of hospitalisation in Australia was patients who presented with CVD, with over five hundred thousand cases being recorded. Cardiovascular disease (CVD) is a leading cause of premature death and disability. In 2013 in Australia, there were 43,602 deaths. The disease was responsible for nearly 43,603 deaths in Australia (30% of all deaths) in 2013, including more than 20,000 deaths from ischaemic heart disease, which is largely preventable. Death rates from heart disease are substantially higher for Aboriginal and Torres Strait Islander Australians, ranging from 1.5 to 3 times higher than non-Indigenous Australians (AIHW 2016).

### 2.2.2 Burden of disease in Australia

CVD accounted for 11% of direct healthcare expenditures and more than 2 billion dollars of health-care expenditure in Australia in the years 2008 and 2009; of which 75% was directed towards hospital-admitted patient services. Direct costs of CVD are estimated at almost 6 billion dollars in 2006 to 2007, and CVD accounted for 18% of overall disease burden; four fifths of this burden was due to CHD and stroke (Begg et al, 2007). As such, CVD is a national health priority that should have a nationally funded action plan to drive improvements in prevention, early detection and management (Authors/Task Force et al, 2016; Begg et al, 2007; Sellke et al, 2010).
2.2.3 Surgical intervention for Coronary Heart Disease

Three major treatment strategies are medical therapy, percutaneous revascularization and surgical revascularization to prevent further ischemia once significant coronary artery stenosis is established (Authors/Task Force et al, 2016; ESC/EACTS Guidelines on myocardial revascularization 2014; Sur et al, 2014). Surgical revascularization also known as CABG includes the use of the cardiopulmonary bypass (CPB) machine or off pump cardio pulmonary bypass (OPCAB-without the use of the CPB machine) (Kouchoukos et al, 2013; Sellke et al, 2010). OPCAB surgery may include sternotomy, thoracotomy (Minimally Invasive Direct Coronary Artery Bypass-MIDCAB) or robotically assisted thoracotomy (Kouchoukos et al, 2013; Ling et al, 2016; Sur et al, 2014). The prevalent incision utilised in cardiac surgery is the median sternotomy. The following section will focus specifically on a median sternotomy.

2.3 Cardiac Surgery

Cardiac surgery via a median sternotomy remains one the most frequently performed procedures in the world today, with a total of 1.5 million operations being performed despite the development of interventional cardiology, and minimal invasive surgical techniques (Deb et al, 2013; Epstein et al, 2011). It remains the gold standard procedure for multiple vessels disease due to its ease of performance, and provision of optimal exposure of the heart and surrounding structures (McGregor et al, 1999; Robicsek et al, 2000; McGregor et al, 2003; El-Ansary et al, 2007a; Deb et al, 2013). The past four decades have seen an increase in the frequency of patients undergoing this procedure has accommodated advances in surgery (Diodato & Chedrawy, 2014). These include the use of internal mammary artery, advances in cardiopulmonary bypass, vigilant myocardial protection, and optimal post-operative pharmacology therapy (Kouchoukos et al, 2013; Diodato and Chedrawy 2014). It is cost effective overall compared to interventional procedures that require long term anti-coagulant therapy (ESC/EACTS Guidelines on myocardial revascularization 2014: De Luca et al, 2014; Sipahi et al, 2014). Consistent evidence from randomized controlled trials (Sipahi et al, 2014), meta-analyses (De Luca et al, 2014; Sipahi et al, 2014) and Propensity Matched Registries
(Habib et al, 2015) have demonstrated that CABG, in comparison to percutaneous coronary intervention (PCI) by five years results in better survival (Luscher et al, 2007); reduces the risk of myocardial infarct (MI) and the risks of repeat revascularization by at least 50% (ESC/EACTS Guidelines on myocardial revascularization 2014; Sipahi et al, 2014). Despite the cost involved, it appears cardiac surgery will continue to be a practical option for coronary heart disease treatment, until a viable, non-operative substitute is found (Alexander & Smith, 2016; Deb et al, 2013; Kouchoukos et al, 2013; Sur et al, 2014; Weisse, 2011).

### 2.3.1 Preparation of the surgical field

The procedure requires the patient to be in the supine position in order to expose their anterior chest (Figure 2.1). The arms may be abducted and placed on arm boards, or they may be secured at the patients’ sides at the preference of the surgeon and the anaesthesiologist (Hodge, 2016; Kouchoukos et al, 2013; Punjabi, 2014) Occasionally, a roll or pad is placed in the inter-scapular region to improve access to the sternum, by extending the neck and elevating the sternal notch (Hodge, 2016; Kouchoukos et al, 2013; Punjabi, 2014). Once positioned, the patient is prepared to ensure a sterile surgical filed. The patient is then draped with sterile sheets to prevent contamination from the operation theatre environments (Hodge, 2016; Kouchoukos et al, 2013; Punjabi, 2014). Several antiseptic agents are available for pre-operative preparation of skin at the incision site (Hodge, 2016; Kouchoukos et al, 2013; Punjabi, 2014). Chlorhexidine gluconate, the iodophors and alcohol containing products are the most commonly used agents (Hodge, 2016; Kouchoukos et al, 2013; Punjabi, 2014). Additionally, pre-medication preparations are used to minimize myocardial oxygen demands by; reducing heart rate and systemic arterial pressure, and to improve myocardial blood flow with vasodilators (Kouchoukos et al, 2013; Hodge 2016). Subsequently, standard monitoring equipment is attached, and peripheral venous access is achieved before the arterial line is inserted (Kouchoukos et al, 2013; Hodge 2016). During induction and tracheal intubation, a steady heart rate and blood pressure is maintained (Hodge, 2016; Kouchoukos et al, 2013; Kouchoukos et al, 1990; Punjabi, 2014). In addition to the standard anaesthetic monitoring (electrocardiography, pulse oximetry, nasopharyngeal temperature, urine output, and gas analysis), there are a
number of specific monitoring requirements for cardiac surgery (Hodge, 2016; Kouchoukos et al, 2013; Punjabi, 2014) including the following:

- Invasive blood pressure
- Central venous access
- Transesophageal echocardiography (TEE)
- Neurology monitoring

The median sternotomy then commences with a vertical incision which extends from the supra-sternal notch, to below xiphoid process (Hodge, 2016; Kouchoukos et al, 2013; Punjabi, 2014). During the procedure, the surgeons will use the pneumatic saw to cuts through and divide the sternum (Figure 2.2). The electro cautery is used to control bleeding from both halves of the sternum. Bone wax may be applied to seal the bone marrow, though some surgeons prefer to simply apply towels (Hodge, 2016; Kouchoukos et al, 2013; Punjabi, 2014). Once the sternum is split in half, a progressive opening of the sternum with retractor is placed to aid visualisation of the surgical field (Hodge, 2016; Kouchoukos et al, 2013; Punjabi, 2014) (Figure 2.3).

Next, the remnant of thymus gland is dissected free from the pericardium. The thymic vessels are all electro-coagulated to prevent the formation of a hematoma or bleeding during the operation. Incision of pericardium is started with the use of electrocautery or maybe a pair of scissors or scalpel depend of the surgeon’s preference (Alexander & Smith, 2016). The pericardium can then be opened with the usual T fashion and suspended to skin edges or towels (Alexander & Smith, 2016). For a successful surgery, the heart is arrested (Alexander & Smith, 2016; Kouchoukos et al, 2013). This is a common is step by occluding the ascending aorta and perfusing the heart with cold, high potassium cardioplegia solution with the aid of cardiopulmonary bypass machine (Alexander & Smith, 2016; Hodge, 2016; Kouchoukos et al, 2013; Punjabi, 2014) (Figure 2.4).
Chapter 2: Literature review

**Figure 2.1:** Preparation of patient in supine position (Courtesy of University of Melbourne image library)

**Figure 2.2:** Use of electro cauter to stop the bleeding from the sternum along its midline (Courtesy of University of Melbourne image library)
Upon completion of the bypass graft, a chest tube is placed in the mediastinal and pleural spaces through separate stab incisions below the cutaneous incision to drain any blood and fluid that may accumulate (Alexander & Smith, 2016; Kouchoukos et al, 2013). Epicardial pacing wires are attached to the surface of the heart depending the on patient condition and surgeon preference either atrial or ventricular pacing is carried out (Alexander & Smith, 2016; Kouchoukos et al, 2013). The lung is reinflated, the heart re-started and haemodynamic stability is achieved before the chest can be closed (Alexander & Smith, 2016; Kouchoukos et al, 2013). The retractors are then removed and the sternal edges are re-approximated, usually with stainless steel wires utilizing 5-8 parasternal sutures (Alexander & Smith, 2016; Kouchoukos et al, 2013). The varying methods of sternal closure will be elaborated on later within this chapter. Sterile dressings are placed over the incision and the patient is prepared for transport to the intensive care unit.

![Figure 2.3](image-url): A Superior view of the surgical field depicting the heart and surrounding structure following positioning of the sternal retractors (courtesy of the Hospital Canselor Tunku Muhriz image library)
2.3.2 Considerations for CABG procedures

Coronary artery bypass graft (CABG) procedures often involve the implantation of blood vessels directly from the aorta to a point beyond existing obstructions; bypass the blocked vessels and restoring adequate blood flow to the heart and optimise its function (Alexander et al, 2007; He, 2013; Sur et al, 2014; Taggart, 2013b). A durable conduit is vital for a successful CABG procedure. Venous (saphenous vein), and/or arterial conduits are often used (Alexander et al, 2007; He, 2013; Sur et al, 2014; Taggart, 2013b). There are a number of sites from which the conduits can be harvested, including the following: saphenous vein, radial artery, left internal thoracic (mammary) artery, Right internal thoracic (mammary) artery, right gastroepiploic artery, inferior epigastric artery and splenic artery (Alexander et al, 2007; He, 2013; Sur et al, 2014; Taggart, 2013b). However, since the late 1980’s the preferred conduits for grafting are arteries as they have been shown to achieve long-term patency (Tatoulis et al, 2004; Alexander et al, 2007; He, 2013; Sur et al, 2014; Taggart, 2013b).

Arterial conduits

In the 1980’s Loop and colleagues published their landmark study describing that the routine used of arteries, rather than exclusive use of vein graft during coronary artery bypass grafting (CABG). Studies has demonstrated that the used of these arteries led to improved survival and was accompanied by a reduction in the subsequent incidence of myocardial infarct, recurrent angina and the need for repeat intervention (Tatoulis et al, 2004; Alexander et al, 2007; He, 2013; Sur et al, 2014; Taggart, 2013b). Most studies have outlined some of the differences between the two type of conduits, owing to the variations in the long-term patency rate (He, 2013; Sur et al, 2014; Taggart, 2013b) which include the following:

a. Arteries are less susceptible to vasoactive substances than veins;

b. The arterial wall may be supplied through the lumen in addition to the vasa vasorum whereas the venous wall is supplied by the vasa vasorum;

c. The endothelium of arteries may secrete more endothelium-derived relaxing factor and may release more nitric oxide and endothelium derived hyperpolarizing factor. As
such they prevent vasospasm, and resistance against intravascular thrombus formation and atherogenesis. The structure of the vein is marked by less smooth muscle being is subject to low pressure whereas that of the artery has more smooth muscle and is subject to high pressure. After grafting to the aorta-coronary system, venous grafts have to adapt to the higher pressure.

**Internal mammary artery**

The most common conduit is the internal thoracic artery. The internal thoracic artery is commonly referred to by medical practitioners in the clinical setting and the literature as the internal mammary artery (IMA). The IMA comprises a left (LIMA) and right (RIMA) branches arise from their respective subclavian arteries (Kouchoukos et al, 2013; Punjabi, 2014; Singh et al, 2011; Khuri 2006). These branches can be harvested either as a skeletonized or a pedicled harvest (Sur et al, 2014; Kouchoukos et al, 2013; Taggart, 2013a; Singh et al, 2011; Boodwani et al 2006; Khuri 2006) (Figure 2.4).

The pedicled harvest dissects the IMA artery away from the sternum along with accompanying veins, transversus thoracic muscle fascia, extrapleura tissues, adipose tissue, nerves and lymphatics (Kouchoukos et al, 2013; Punjabi, 2014; Singh et al, 2011; Calafiore et al, 1999; Calafiore et al, 1995). A pedicled graft has been shown to decrease sternal blood flow by up to 90% (Singh et al, 2011; Peterson et al, 2003; Calafiore et al, 1999; Calafiore et al, 1995). The skeletonized technique requires that the internal mammary artery (IMA) are removed alone without surrounding tissue (Kieser et al, 2014; Singh et al, 2011; Boodhwani et al, 2006; Khuri 2006; Peterson et al, 2003; Higami et al, 2001). It has been reported that the skeletonized technique maintains better sternal blood supply as it leaves the chest wall arterial collateral, IMA veins and lymphatic intact, thus reducing chest wall devascularization, denervation and infection (Kieser et al, 2014; Singh et al, 2011; Berdajs et al, 2006; Peterson et al, 2003, Higami et al, 2001; Cohen et al, 1999; Bical et al, 1996). This also adds significant length to the IMA conduit (Lytle 2013; Singh et al, 2011). Commonly, the LIMA is harvested as a pedicle whereas the RIMA is generally skeletonized because a RIMA pedicle may interfere with sternal wound healing (Kieser et al, 2016; Taggart 2013b;
Kouchoukos et al, 2013; Lytle et al, 2004; Berdajs et al, 2006). The LIMA is the graft of choice for the left anterior descending (LAD) artery anastomosis, and has a good patency rate in this setting (98% at 1 year and 90% at 10 years) (Lytle et al, 2004; Dorman et al, 2012; Puskas et al, 2012; Lytle 2013). The RIMA has a good patency rate when anastomosed to the LAD (96% at 1 year and 90% at 5 years), but a reduced rate when grafted to the circumflex or the right coronary artery (75% at 1 year) (Benedetto et al, 2015; Kouchoukos et al, 2013; Hillis et al, 2011).

When anatomically and clinically suitable, use of a second internal mammary artery to graft the left circumflex or right coronary artery is reasonable to improve survival and decrease likelihood of re-sternotomy (Puskas et al, 2012; Dorman et al, 2012; Taggart 2013b; Hillis et al, 2011). The Bypass Angioplasty Revascularization Investigation (BARI) trial demonstrated that there is significantly higher survival in diabetes patient in CABG with IMA grafting in comparison with percutaneous transluminal angioplasty (BARI) Investigators (BARI Investigator, 2000). However, controversial opinion still remains on the bilateral IMA harvest technique as this has been suggested to further increase the risk of sternal complications especially in those patients with comorbidities that compromise bone healing (Kouchoukos et al, 1990; Losanoff et al, 2002b; Savage et al, 2007; Sellke et al, 2010; Kouchoukos et al, 2013). It is reported that patients with less collateral vessels in the sternum are at more risk of sternal complications (Seyfer et al, 1988; Carrier et al, 1992; Cohen et al, 1999; Kouchoukos et al, 1990; Loop et al, 1990; El-Ansary et al, 2000a; Losanoff et al, 2002b). As BIMA harvesting may compromise blood supply to the sternum it is precluded in Diabetes, Chronic obstructive pulmonary disease (COPD) and obesity (Kouchoukos et al, 1990; Losanoff et al, 2002b; Savage et al, 2007; Sellke et al, 2010; Kouchoukos et al, 2013). However, the skeletonization harvest technique has demonstrated to severely reduce the incidence of DSWI - particularly in diabetic and obese patients - because of the better preservation of collateral sternal blood flow and internal thoracic veins (Peterson et al, 2003; Cotogni et al, 2015, Raja 2015). However, many cardiothoracic surgeons are reluctant to application this technique as it can easily lead to graft conduit damage (Saso et al, 2009; Cotogni, et al, 2015).
Studies have also shown a divergence of opinion exist comparing the outcomes of participants undergoing unilateral versus bilateral IMA grafting (Kouchoukos et al., 1990; Carrier et al., 1992; Losanoff et al., 2002b; Savage et al., 2007; Sellke et al., 2010; Dorman et al., 2012; Kouchoukos et al., 2013; Benedetto et al., 2014). Several studies reporting improved long-term survival in patients undergoing bilateral harvesting (Calafiore et al., 2004; Lytle et al., 2004; Di Mauro et al., 2005; Dorman et al., 2012; Mohammadi et al., 2014; Kurlansky et al., 2010; Kurlansky et al., 2011; Kieser et al., 2011; Galbut et al., 2012; Grau et al., 2012; Kinoshita et al., 2012; Locker et al., 2012; Jomjev et al., 2013; Weiss et al., 2013; Smith et al., 2014; Benedetto et al., 2014). In a recent review, Raja (2015) demonstrated that there were no significant differences in the incidence of post-operative sternal wound complications and/or total complications, as well as operative mortality in diabetic participants undergoing unilateral versus bilateral IMA grafting. Excellent outcomes have been reported following bilateral IMA grafting in diabetic patients with significantly greater long-term survival (approximately 13 years versus 10 years) (Dorman et al., 2012). However, most of these studies were observational studies and potentially have several methodologies flaws that limit the usefulness of their finding (Raja, 2015). However, in the absence of RCTs current evidence validates the safety and efficacy of bilateral IMA grafting especially skeletonised conduits in people with diabetes with multi-vessel disease (ESC/EACTS Guidelines on myocardial revascularization 2014; 2011 ACCF/AHA guideline for CABG surgery; Weiss et al., 2013; Hills et al., 2011).
Radial artery

The radial artery (RA) is often selected as the next conduit of choice following the IMA for coronary artery bypass grafting operations (CABG) (Lim et al, 2014; Sur et al, 2014; Taggart, 2013c; Tatoulis et al, 2002). Similarly, with IMA, there are now strong and consistent evidence of the superior patency of radial arteries over the longer term (Lim et al, 2014). Carpentier and colleagues in 1973 pioneered the use of RA graft in CABG however due to a high failure rate this procedure was discontinued (Carpentier et al, 1973). As RA are prone to spasm, the Allen test is performed to ensure the patency of Ulnar nerve before RA is harvested from either from left or right wrist. Structurally, the RA has a thin continuous intima of endothelial cells, a single internal elastic lamina and a relatively thick media of tightly-packed smooth muscle cells, which predisposes to spasm, occlusion and thrombosis (Blitz et al, 2013; Taggart, 2013c). Therefore, the harvested process is commonly via open approach or endoscopically (Figure 2.5); and dipped in special solution to reduce spasm. As such, nitroglycerin and diltiazem are administered intravenously to prevent spasm post-operatively. This is continued until oral anti-spasmostic medication is tolerated by patients. Furthermore, histopathological comparison of proximal and distal RA segments demonstrates significantly reduced

Figure 2.4: Harvesting of the internal mammary artery. Favalaro retractor in situ (courtesy of the University of Melbourne image library)
luminal diameter and increased intimal hyperplasia (intimal thickening of the aorta) distally. The RA still has a relatively low rate of atherosclerosis at around 6% which is still very low and demonstrates overall resistance to atherosclerosis. Although the incidence of atherosclerosis is low but compared to the IMA, incidence of atherosclerosis in RA is higher (0.7% vs 5.3%). In 1992, Acar and colleagues re-popularized the use of the RA when they reported a series of 56 radial artery grafts with 100% patency. Four systematic review (Benedetto et al, 2010; Benedetto et al, 2015) and a meta-analysis addressed the issue of graft patency comparing the RA as a second conduit to SVG or surgical myocardial revascularization with variable results (Benedetto et al, 2010; Benedetto et al, 2015). Current literature suggests that there is no difference in functional patency between RA and saphenous vein grafts (SVG) over the first year. However, there is strong and accumulating evidence for higher mid and long-term patency rates for the RA in comparison to SVG, due to an ongoing attrition of vein grafts over the long-term. There is now also growing evidence that the superior long-term patency of the RA is translating into substantial improvements in clinical outcomes.

**Figure 2.5**: Exposure of radial artery for endoscopic harvest. Dissection is carried down through the fascia to expose the RA pedicle (image adapted from Blitz et al, 2013, page 539)
**Gastroepiploic artery**

The right Gastroepiploic artery GEA is one of four arteries that supply blood to the stomach. It is the largest terminal branch of the gastroduodenal artery, which originates from the common hepatic artery (Kouchoukos et al, 2013; Suma, 2016). (Aldea et al, 2016). The GEA contains many smooth muscle cells in the media and is considered a muscular artery in comparison with the IMA (Suma, 2016). Because of the difference in histology presentation, GEA graft is more prone to spasm during surgical manipulation and arteriosclerosis following CABG (Suma, 2016; Suma et al, 2007). The GEA conduit is a commonly pedicled graft allowing arterial revascularization of the right coronary artery and often used in similar fashion as the RA (Suma, 2016) (Figure 2.6). Long-term follow-up shows a good patency of this graft when used adequately with patency rapidly reducing at least 62%-85 at 5-10 years duration (Aldea et al, 2016; Suma, 2016; Glineur et al, 2012; Suma et al, 2007). However, its long-term patency is inferior to the more commonly utilised IMA conduit described above, with a maximum five-year patency rate of at least 82%, and a study by Suma et al (2007) demonstrating a 10-year patency rate of 87% (Voutilainen et al, 1996; Suma et al, 2007; Sellke et al, 2010; Kouchoukos et al, 2013). Although, the early graft patency is high, a skeletonized GEA graft is recommended for the coronary artery with a severe (>90%) stenosis to improve long-term graft patency to more than 90% (Suma, 2016). Suzuki et al (2013) reported 97.8%, 94.7%, and 90.2% cumulative patency rates immediately, and 5 and 8 years after surgery, respectively using this technique (Suzuki et al, 2013). Several studies have demonstrated the GEA artery to be inferior to IMA grafts in terms of patency, whereas no significant differences are found between the GEA and RA or SVG conduits (Fukui et al, 2010, Takemura et al, 2003, Hirose et al, 2002, Kim et al, 2006). Similarly, no significant difference in terms of clinical outcomes particularly in event-free survival between the right GEA, RA, or SVG was reported (Aldea et al, 2016, Glineur et al, 2008; Di Mauro et al. 2009; Esaki et al, 2007, Pevni et al, 2005, Lev-Ran 2003, Glineur et al, 2012; Jeong et al, 2013). Therefore, based on these findings, the right GEA can be used as an alternative arterial conduit for CABG and may be considered in patients with poor conduits or as an adjunct to more complete arterial revascularization (Glineur et al, 2012; Aldea et al, 2016; ESC/EACTS Guidelines on myocardial revascularization 2014; Suma, 2016).
Venous conduit

Although the IMA have clinical and patency advantage in comparison with the saphenous vein graft (SVG) harvesting, SVG conduits continues to be the most common conduits for CABG (Sabik et al, 2005; Zetani et al, 2011). The great (long) saphenous vein (GSV) is located two cm anterior to the medial malleolus, traverses the tibia, and ascends posteriorly up the tibial border before emptying into the femoral vein. Key associated structures are the saphenous nerve, femoral cutaneous nerve, and saphenous branch of the genicular artery. The small (short) saphenous vein (SSV) is located one cm posterior to the lateral malleolus, runs centrally up the posterior calf, and drains into the popliteal vein. Both the GSV and SSV can be utilized as a single or sequentially conduits (Selke et al, 2010, Kouchoukos et al, 2013). The Y graft technique is employed if the length of conduit is short. (Selke et al, 2010, Kouchoukos et al, 2013; Tatoulis, 2013). As CABG conduits, the saphenous veins have an 80-90% early patency rate, which decreases to 50% at 10 years (Benedetto et al, 2015; Benedetto et al, 2010; Taggart, 2013b). As such, the saphenous vein is generally acceptable as a conduit in the absence of other vascular pathologies in the leg (varicosities in the vein,
venous insufficiency, previous deep vein thrombosis, or small lumen diameter), or overlying infection years (Benedetto et al, 2015; Benedetto et al, 2010; Taggart, 2003).

The GSV can be dissected either via an open harvest technique, starting from either the ankle or groin and using a vein stripper, or via an endoscopic technique (Figure 2.7). Likewise, the SSV vein can be harvested either with an open procedure or endoscopically (Grover and Mack 2016; Zenati et al, 2011). There has been suggestion that endoscopic technique may reduce conduit performance with conflicting results (Grover and Mack 2016; Zenati et al, 2011). In the randomized on/off bypass (ROOBY) Trial, comparing both open harvest technique and endoscopic technique, Zenati et al, 2011 concluded that endoscopic technique was associated with worse outcome; significantly lower 1-year patency and increase re-vascularization rate. The reduced graft patency was related to intra-operative technique during conduits harvesting causing trauma to the endothelial cells, resulting in platelet aggregation and thrombosis (Zenati et al, 2011; Rousou et al, 2009). However, encouraging short term (six-months) clinical and graft patency outcomes for CABG using endoscopic techniques was described. Because of the conflicting evidence, the topic is currently being evaluated in a Randomized Endo-vein Graft Prospective (REGROUP) Trial to assess the endoscopic technique on clinical outcomes (Zenati et al, 2014).

Figure 2.7: Harvesting of saphenous vein (courtesy of the Hospital Canselor Tunku Muhriz image library)
2.3.3 Consideration for cardiac valve procedures

To date cardiac valve procedures are performed to repair and/or replace damaged valves with either biological or mechanical prosthesis to restore blood flow to the heart, thus optimising its functional efficiency (Acker et al, 2014; Dasi et al, 2009; Nishimura et al, 2017; Nishimura et al, 2014; Moorjani et al, 2013). The median sternotomy is the most commonly incision for valve surgery however, minimal invasive procedures are emerging with good clinical outcomes (Acker et al, 2014; Dasi et al, 2009; Nishimura et al, 2017; Nishimura et al, 2014; Moorjani et al, 2013). The decision on which valve replacement to use requires careful consideration of the specific advantages and disadvantages of the valve types and integration of this knowledge into the clinical characteristics and personal preferences of the individual patient (Acker et al, 2014; Dasi et al, 2009; Nishimura et al, 2017; Nishimura et al, 2014) Until recently, heart valve replacement was commonly performed using mechanical heart valves. Mechanical valves offer greater durability at the expense of lifelong anticoagulation, higher bleeding risks, and the attendant lifestyle modifications and considerations to minimize these risks (Acker et al, 2014; Dasi et al, 2009; Moorjani et al, 2013; Nishimura et al, 2017; Tillquist & Maddox, 2011). Despite their widespread use, mechanical heart valves are plagued by the need for life-long anticoagulation therapy and the accompanying bleeding problems associated with haemolysis, platelet activation and thromboembolic events arising from clot formation and their subsequent detachment (Acker et al, 2014; Dasi et al, 2009; Nishimura et al, 2017) Accordingly, mechanical valves are generally recommended for younger patients since a patient with a longer life expectancy is more likely to outlive a bioprosthetic valve and require a re-operation (Acker et al, 2014; Dasi et al, 2009; Nishimura et al, 2017).

Bioprosthetic heart valves are currently implanted just as frequently as mechanical heart valves owing to their resemblance to the native valve and their freedom from anticoagulant therapy (Acker et al, 2014; Dasi et al, 2009). The main advantage with bioprosthetic valves is that they do not require lifelong warfarin therapy, due to their lower thrombotic risk compared with mechanical valves (0.87% and 1.4%, per year respectively) (Dasi et al, 2009). Accordingly, patients with bioprosthetic valves have a significantly decreased risk of bleeding. However, major disadvantage for bioprosthetic
valves are that they are less durable, plagued with leaflet calcification and leaflet tearing with structural valve deterioration. For most patients with a bioprosthetic valve, structural valve deterioration begins around five years post-implantation and rapidly increases (Rahimtool et al, 2003; Tillquist & Maddox, 2011). Although many caveats exist, the general recommendation is for patients younger than 60 to 65 years to receive mechanical valves due to the valve’s longer durability and for patients older than 60 to 65 years to receive a bioprosthetic valve to avoid complications with anticoagulants (Tillquist & Maddox, 2011). Despite the widespread use of artificial heart valve designs, neither mechanical nor bioprosthetic heart valves are free from complications. The overall complications associated with prosthetic heart valves can be divided into six main categories: structural valvular deterioration, non-structural dysfunction, valve thrombosis, embolism, bleeding and endocarditis (Grunkemeier and Anderson, 1998; Dasi et al, 2009). Given the extensive complication above-mentioned, an alternative approach to valve replacements has been proposed i.e. repair of the native structure. This approach was tested on mitral valve disease but has since become the gold standard approach for all cardiac valve surgical procedures. Several advantages of mitral-valve repair over replacement, include lower operative mortality, preservation of left ventricular function, improved freedom from endocarditis, thromboembolism, and from anticoagulant and higher rates of long-term survival (Thourani et al, 2003; Micovic et al 2008; Milano et al. 2008; Silberman et al 2006; Vassileva et al. 2011(Yanagawa et al, 2016). For these reasons, the use of mitral-valve repair has greatly exceeded the use of replacement in the past few years (Acker et al, 2014; Gammie et al, 2009).

2.3.4 Sternal closure/fixations

At the conclusion of the median sternotomy procedure, to achieve a stable sternal approximation and apposition between the sternal edges, the sternal halves are fused together with wires, and the soft tissue is approximated with sutures and staples (Robicsek et al, 2000; Losanoff et al, 2002a; Fedak et al, 2010; Sellke et al, 2010; Fedak et al, 2011; Kouchoukos et al, 2013) (Figure 2.8). By providing optimal fixation and stability of the sternal closure, it is hypothesised sternal osteosynthesis and healing can be achieved, and in turn minimise the incidence of sternal complications.
Numerous and various techniques for optimizing sternal closure have been used in clinical field and have been described such as stainless steel wires, sternal lock and sternal cable (Figure 2.9) but only few have been rigorously tested in vivo (Alhalawani & Towler, 2013). However, there is no empirical data to suggest one technique has superiority in terms of reducing wound infection over the other (Alhalawani & Towler, 2013; Casha AR, 1999; Casha et al, 1999; Shaikhrezai et al, 2012) Nevertheless stainless steel wiring is currently still the routine method of a median sternotomy closure in cardiothoracic surgery (Alhalawani & Towler, 2013; Casha AR, 1999; Casha et al, 1999; Shaikhrezai et al, 2012).

Attaining a stable sternal closure can be difficult given that the sternum forms a bony platform, which facilitates respiration (including deep breathing, huffing and coughing), as well as movements of the upper limbs and trunk (El-Ansary et al 2000b; Robicsek et al, 2000). In particular, an increase in intra-thoracic pressures and activation of the pectoral muscles has been postulated to challenge the sternal closure in both the lateral (coronal plane) and anterior-posterior (sagittal plane) directions (McGregor et al, 1999; Robicsek et al, 2000; El-Ansary et al, 2009). El-Ansary et al
(2009) investigated sternal micromotion that occurred during unilateral upper limb elevation in a patient who had developed chronic sternal instability, following cardiac surgery with conventional stainless steel wire sternal closure. Using real-time ultrasound, the study confirmed that sternal micromotion is indeed multi-planar, occurring in both the lateral and anterior-posterior directions (El-Ansary et al, 2009). Similarly, in a subsequent study, Balachandran et al (2017) measured sternal micromotion, during dynamic upper limb and functional tasks (unilateral and bilateral arm elevation; pushing up with support through both arms to standing from a seated position, deep inspiration and coughing), following cardiac surgery with conventional stainless steel wire sternal closure using real-time ultrasound. This study confirmed that the motion of the sternal edges (from the rest position) to the end of each task was multi-planar. Given that the stainless-steel wires are aligned in the coronal plane, it has been postulated that conventional sternal closure may be limited in its capacity to limit micromotion in the sagittal plane (El-Ansary et al, 2009; Robicsek et al, 2000). Casha et al (1999) reported that for any closure technique to provide suitable stability, it must be able to resist twice the maximum potential stresses applied on the sternum. As such, several alternatives to this method have been developed and described in the literature. The following section will focus on stainless steel wiring fixation for sternal closure as it is the most commonly used technique worldwide.

Wiring using stainless steel has been the standard technique for sternal closure due to its simplicity, strength, short healing time, and rigidity (Alhalawani & Towler, 2013; Casha et al, 1999; McGregor et al, 1999; Shaikhrezai et al, 2012). The most common way to close the sternum is to use the alternating trans and peristernal closure technique as these techniques offered significantly greater stability (Losanoff et al, 2004; Alhalawani & Towler, 2013) (Figure 2.10). Typically, at least 3 single intra-manubrium have to pass either transversely through the sternal body (trans-sternal closure) and 5-6 single peri sternal pairs of fixation around (peri-sternal closure) the sternal halves (Alhalawani & Towler, 2013; Casha et al, 1999; Losanoff et al, 2004; McGregor et al, 1999; McGregor et al, 2003; Shaikhrezai et al, 2012) from which three pairs are applied on the one-third distal of the sternum (as this are prone to dehiscence) (McGregor et al, 1999; Shaikhrezai et al, 2012). Once positioned, the stainless steel wires are twisted, ensuring optimal alignment and apposition of the sternal edges
Chapter 2: Literature Review

(Losanoff et al, 2002; Robicsek et al, 2000) (Robicsek et al, 2000; Losanoff et al, 2002a, Sellke et al, 2010, Kouchoukos et al, 2013). However, care must be taken not to twist the stainless steel wires under tension, or too tightly, as it may result in the wires cutting through the sternum resulted in sternal separation (Robicsek et al, 2000; Losanoff et al, 2002b; McGregor et al, 2003).

Casha et al (1999) investigated six different sternal wiring/ suturing techniques and found by increasing the number of wires will result in improved sternal closure. This study also recommended the use of at least eight straight wires: four figure-of-eight wires or four multi-twist wires in order to have a safety margin able to withstand double the maximum force applied (Casha et al, 1999). Limitations of this study involved the analysis of wire fracture only and the use of a steel sternal model, which differs from the biological, or cadaver sternum (Casha et al, 1999). Despite these shortcomings, they demonstrated that the multi-twisted technique is useful in bleeding-fractured sternums as it appears to be able to stop the bleed by the lateral part. The advantageous use of interlocking multi-twisted wires over conventional or figure-of-eight sternal closures was also evident from a further study performed by the same group to assess the rates of wire cutting through the bone on various closure techniques (polyester, figure-of-eight, steel wire, sternal bands, and peristernal) (Casha, 1999). These techniques is believed to be more secure and less likely to cut the sternum, because of redistribution of shearing forces (Harjula & Järvinen 1983; Luciani et al, 2006; Shaikhrezai et al, 2012. The study found that sternal band and peristernal techniques are superior to conventional sternal wiring (Casha, 1999). Additionally, the use of the figure-of-eight or polyester technique requires caution since it is associated with faster cut-through in comparison with the control model (Casha, 1999). Studies have indicated the advantages of the wiring techniques over plating systems due to their practicality and cost-effectiveness (Jolly et al, 2002; Gunja et al, 2004). However, other studies contradicted the advantageous use of these conventional wiring techniques (Cohen and Griffin, 2002; Lopez et al, 2008; Ozaki et al, 1998). The disadvantages are that closure techniques with these wires sometimes lead to dehiscence, wound infection and bone healing problems (Cohen and Griffin, 2002; Lopez et al, 2008; Ozaki et al, 1998). This is mostly due to the biomechanical failures such as sternal wires cutting into the bone,
especially for patients with osteoporosis (Shaikhrezai et al, 2012; Alhalawani and Towler, 2013).

Recent developments in sternal closure have resulted in the development of alternative sternal closure techniques in an attempt to optimise apposition and alignment of the sternal edges, and prevent the development of sternal complications post-median sternotomy. In a recent literature review, Alhalawani and Towler (2013) have reported several closure techniques and found many of the technique is tested in vivo including conventional sternal wires. In the past four decades several alternatives to conventional stainless steel wire closure have been developed such as interlocking, plate-screw and adhesive enhanced closure technique e.g Kryptonite, which is a biocompatible adhesive polymer that prevents pathologic sternal displacement (up to 600 N) (Fedak et al, 2010). They found only small proportion of studies analysed the use of sternal interlocking system and only a single study analyzed the effect of using kryptonite cement with wires. Plating and interlocking techniques have been shown to be superior to wiring in terms of stability and reduced rate of post-operative complications; however, further clinical studies and long-term follow-up are required. The ideal sternal closure should ensure stability, reduced rate of post-operative complications, and a short hospitalization period, alongside cost-effectiveness. However, it remains unclear whether such alternative techniques enhance the sternal healing process. Based on this gap in the literature, it may be useful for future research to compare and contrast different sternal closure techniques with respect to sternal healing and the incidence of sternal complications in the target population. Additionally, few studies have followed up patients beyond six weeks to three months and evaluated patient outcomes. Moreover, not all studies are conducted in vivo and most use computed tomography (CT) scan and conventional radiography to screen for and monitor sternal complications (Goodman et al, 1983; Kay et al, 1983; Templeton and Fishman, 1992; Hayward et al, 1994; Bitkover et al, 1999; Losanoff et al, 2002b; Li and Fishman, 2003; You et al, 2010) as and end point (Bitkover et al, 1999; You et al, 2010). These modes of investigation have been shown to have poor sensitivity in the correct diagnosis of sternal instability and/or infection (Bitkover et al, 1999; You et al, 2010) and identifying sternal wound complications (Bitkover et al, 1999; Papadopolus et al, 2013). More recently, alternative assessment using ultrasound stability (El-Ansary et al, 2007a; El-
Ansary et al, 2007b; El-Ansary et al, 2007c; El-Ansary et al, 2008; El-Ansary et al, 2009) demonstrated validity and reliability in the measurement of sternal micromotion (El-Ansary et al, 2007b). The limitation of these studies is that they were conducted in vivo with small sample sizes and focused on patients diagnosed chronic sternal instability. Further research is needed into the clinical utility of this tool in the acute population without complications.

Figure 2.9: Some of the difference type of sternal closure (Image adapted from from Mary Greeley Medical Center, Ames, Iowa; 2004. Downloaded image on the 4th of September 2017 (http://tsteele7.weebly.com/uploads/9/4/3/3/9433273/sternal_precautions_inservice.pptx)
2.4. Post-Operative Complications

Despite the advantages of a median sternotomy a small but significant number of patients have post-operative complications (Balachandran et al, 2016; Braxton et al, 2000; El Oakley & Wright, 1996; Milano et al, 1995). Although the incidence of post-operative complication is relatively low ranging from 1% to 8% of all cardiac surgery procedures, they continue to be associated with increased morbidity and mortality, and decreased long-term life expectancy (Braxton et al, 2000; El Oakley & Wright, 1996; Lazar et al, 2016; Milano et al, 1995; Singh et al, 2011). It is associated with high mortality rate ranging from 14 to 50% (Loop et al, 1990; El Oakley and Wright, 1996; Casha et al, 1999; Robicsek et al, 2000; Losanoff et al, 2002b; El-Ansary et al, 2007a; Voss et al, 2008; Cahalin et al, 2011; Lazar et al, 2016). Studies have shown that there is increase in the four-year survival rate of patients diagnosed with sternal complications is only 65%, compared to 85% in patients who heal without such complications (Braxton et al, 2000; Diez et al, 2007; Cahalin et al, 2011). The most critical stage where a patient is most vulnerable to post-operative complications is during the first two weeks following a median sternotomy (Wilkinson et al, 1988), a
stage before sternal healing is considered to be significant. Impaired sternal healing may lead to an increase in post-operative pain, delay functional recovery and increase patient morbidity; which can treble the cost of care (Robicsek, 2000; Robicsek et al, 2000, El-Ansary et al, 2007a; El-Ansary et al, 2008, Fedak et al, 2010; Cahalin et al, 2011; Fedak et al, 2011). Further, the costs for patients with post-operative complications have been estimated to be 2.8 times that for patients with uncomplicated post-operative courses (Loop et al, 1990; Voss et al, 2008; Cahalin et al, 2011; Lazar et al, 2016). Prevention measures and early detection during pre, intra and post-operative phases is important as to institute timely intervention and prevent the development of further post-operative complications (El Oakley and Wright, 1996; Robicsek, 2000; Robicsek et al, 2000; El-Ansary et al, 2007b; Cahalin et al, 2011; Lazar et al, 2016). As this thesis is concerning physiotherapy management of CHD (i.e CABG/valve or combination) after surgical intervention, the reader is directed to post-op complications that are commonly managed by physiotherapy intervention.

2.4.1 Sternal wound complications

Sternal wound complications (SWC) are still a significant complication after a median sternotomy for cardiac surgery with a reported incidence of 1-8 % (Balachandran et al, 2016; Cahalin et al, 2011; Singh et al, 2011; Lazar et al, 2016). These complications can present in varying forms of severity affecting both the sternal incision as well as the harvested graft (Singh et al, 2011). SWC include prolonged incision pain, osteomyelitis, sternal instability or non-union and mediastinitis (deep infection). SWC are associated with significantly reduced long-term survival (Rines et al, 2010; Braxton et al, 2000, Diez et al, 2007; Cahalin et al, 2011; Loop et al, 1990; El-ansary et al, 2007a). At 10 years follow-up, these patients had a 59% higher mortality risk compared with the patients without SWC (Rines et al, 2010; Braxton et al, 2000, Diez et al, 2007; Cahalin et al, 2011). Furthermore, these complications are associated with impaired sternal healing leading to an increase in post-operative pain, delayed functional recovery, increase in morbidity and an increase in the cost of care. Timely detection and management is paramount for optimal management and prevention of secondary post-operative complications. These complications can be divided in two subgroups:
(1) sternal instability and (2) sternal infections. The complications will be described briefly in the following section.

**Sternal instability**

Sternal instability (SI) has been reported to occur in 2-16% patients following a median sternotomy (Loop et al, 1990; El-Ansary et al, 2000b; Trumble et al, 2002). SI occurs as results of sternum separation at the midline causing abnormal and/or excessive micromotion due to fracture or disruption of sternal wires (Robiscek et al, 2000). Deep wound breakdown (dehiscence) and secondary instability of sternal closure have been reported to facilitate tissue infection and mediastinitis (Robiscek et al, 2000).

Pain and sternal clicking are two of the most common complaints reported by patients who presented with SI (Chepla et al, 2011). A thorough history and physical examination are used to diagnose SI and this is confirmed with subsequent radiographic and ultrasound imaging (Chepla et al, 2011; El-Ansary et al, 2007a). SI is divided into: (1) sternal dehiscence if diagnosed within the 2 weeks post-operatively and (2) sternal non-union, if persisting more than 6 weeks post-operatively. SI can be classified as complete (the separation may be total involving the entire sternum or partial (usually the lower third of the sternum) (Robicscek et al, 2000; El-Ansary et al, 2000b; Chepla et al, 2011). Partial SI usually presents in the lower third of the sternum. This area has less blood supply and is subject to more distractive forces resulted from the “bucket-handle” motion that increases the lateral diameter of the lower ribcage during respiration (El-Ansary et al, 2000b). Complete SI can be further divided into four categories based on the presence of transverse fractures or missing bone segments. See Figure 2.1. Type I describes a midline non-union without any associated transverse fractures (Hendrickson et al, 1996). Type II is non-union with a unilateral transverse fracture, and type III refers to non-union with single or multiple bilateral transverse fractures (Hendrickson et al, 1996). Type IV non-unions involve multiple fractures with a missing bone segment and subsequent free-floating bone fragments (Hendrickson et al, 1996).
Bitkover et al. 1999 examined the reports of the CT scans in 20 patients with a normally healing incision at one week, one month, three months, and six months interval following cardiac surgery via sternotomy and showed that none of patients had radiological signs of healing at three months, and 50% of patients demonstrated consolidation at six months. It was further suggested that sternal gaps seen on a CT scan may not be necessarily indicative of sternal instability and that minor gaps (less or equal to 3.00mm in lateral direction) seen up to six months post-operatively should not be regarded as pathological unless correlated with clinical instability. Similar findings were reported by Vestergaard et al (2014) who found, none of the 68 patients in a study showed complete radiological sternal healing at three months after the operation. Further, Shin et al (2015) enrolled 197 patients who underwent isolated CABG using skeletonized bilateral internal thoracic arteries. The author reported the average total score of sternal healing was 2.07±1.52 with 34.5% (n=68) of participants in their study showing poor healing at three to months (Shin et al, 2015). Poor healing was most frequently found in the manubrium in 72.6% of patients. However, 98% patients demonstrated complete long-term sternal healing at two years despite poor early sternal healing (Shin et al, 2015). These results suggest that the sternum may take more than three months to demonstrate signs of complete radiological union. It remains unclear how much sternal separation and subsequent micromotion of the sternal halves constitutes sternal instability. Studies have reported that clinical union of the sternum may ensue prior to radiological union (Balachandran et al, 2017; Bitkover et al, 1999), which is similar on orthopaedic literature on fracture healing in long bones (Corrales et al, 2008; Axelrad and Einhorn, 2010). Therefore, it may be more relevant to combine clinical signs of sternal complications with radiological findings, to monitor sternal instability.
The treatment for symptomatic sternal instability requires stable fixation of the bony fragments and chest wall following the debridement of all non-viable bony and soft tissue (Robicsek et al, 2000). Multiple fixation techniques have been described and incorporate a wide variety of materials including combinations of wires, cables, pins, bands, staples, and plates (Robicsek et al, 2000). Most recently, several new commercially available plating systems have demonstrated low recurrence and complication rates and resolution of the patient's symptoms on follow-up evaluation (Chepla et al, 2011) While it is no always clear whether instability is the primary cause or has occurred secondary to infection, the two are closely linked (Robicsek et al, 2000).
**Sternal infection**

Infections following a sternotomy are generically termed in the literature as mediastinitis, although infection may be limited to a tissue or anatomical area, not necessarily involving the mediastinum (Anger et al, 2015; Lazar et al, 2016; Ridderstolpe et al, 2001). Other terms that are used to describe infections include: esternites, mediastinitis, dehiscence of sternotomy and post-sternotomy infection (Anger et al, 2015).

Based on the Center for Disease Control and Prevention (CDC), sternal infection can be classified into three types: (A) surface when only the skin and subcutaneous are involved; (B) when the infection reaches the sternum, but not affecting it, and (C) of cavity or organ when there is sternum osteomyelitis and/or when there is involvement of the mediastinum (Anger et al, 2015; Garner et al, 1988; Lazar et al, 2016; Ridderstolpe et al, 2001) (Garner et al, 1988) (Figure 2.12). These definitions are generic term which explain the site of infection, and are not correlate with the existing real anatomical change; and used primarily for the purpose of surveillance and reporting (Anger et al, 2015). Craig et al, 2007 is the first to specify sternal infection based on anatomical site (Greig et al, 2007). However, the concept of emphasizing only the location of the wound was not widely adopted in scientific literature; instead classifications based on infection continued to be the most used (Brito et al, 2009).
**TABLE 1**

**Criteria for Defining a Surgical Site Infection (SSI)***

<table>
<thead>
<tr>
<th><strong>Superficial Incisional SSI</strong></th>
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<tbody>
<tr>
<td>Infection occurs within 30 days after the operation</td>
</tr>
<tr>
<td>and</td>
</tr>
<tr>
<td>Infection involves only skin or subcutaneous tissue of the incision</td>
</tr>
<tr>
<td>and at least one of the following:</td>
</tr>
<tr>
<td>1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.</td>
</tr>
<tr>
<td>2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.</td>
</tr>
<tr>
<td>3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.</td>
</tr>
<tr>
<td>4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.</td>
</tr>
<tr>
<td>Do not report the following conditions as SSI:</td>
</tr>
<tr>
<td>1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).</td>
</tr>
<tr>
<td>2. Infection of an episiotomy or newborn circumcision site.</td>
</tr>
<tr>
<td>3. Infected burn wound.</td>
</tr>
<tr>
<td>4. Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).</td>
</tr>
<tr>
<td>Note: Specific criteria are used for identifying infected episiotomy and circumcision sites and burn wounds.11</td>
</tr>
</tbody>
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<table>
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<tr>
<th><strong>Deep Incisional SSI</strong></th>
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</thead>
<tbody>
<tr>
<td>Infection occurs within 30 days after the operation if no implant2 is left in place or within 1 year if implant is in place and the infection appears to be related to the operation</td>
</tr>
<tr>
<td>and</td>
</tr>
<tr>
<td>Infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision</td>
</tr>
<tr>
<td>and at least one of the following:</td>
</tr>
<tr>
<td>1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.</td>
</tr>
<tr>
<td>2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (&gt;38°C), localized pain, or tenderness, unless site is culture-negative.</td>
</tr>
<tr>
<td>3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.</td>
</tr>
<tr>
<td>4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.</td>
</tr>
<tr>
<td>Note:</td>
</tr>
<tr>
<td>1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.</td>
</tr>
<tr>
<td>2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Organ/Space SSI</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection occurs within 30 days after the operation if no implant2 is left in place or within 1 year if implant is in place and the infection appears to be related to the operation</td>
</tr>
<tr>
<td>and</td>
</tr>
<tr>
<td>Infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation</td>
</tr>
<tr>
<td>and at least one of the following:</td>
</tr>
<tr>
<td>1. Purulent drainage from a drain that is placed through a stab wound3 into the organ/space.</td>
</tr>
<tr>
<td>2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.</td>
</tr>
<tr>
<td>3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.</td>
</tr>
<tr>
<td>4. Diagnosis of an organ/space SSI by a surgeon or attending physician.</td>
</tr>
</tbody>
</table>

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* Jones TC et al9
9 National Nosocomial Infections Surveillance definition: a nonhuman-dwelled implantable foreign body (e.g., prosthetic heart valve, nonhuman vascular graft, mechanical heart, or hip prosthesis) that is permanently placed in a patient during surgery.
10 If the area around a stab wound becomes infected, it is not an SSI. If it is considered a skin or soft tissue infection, depending on its depth.

**Figure 2.12:** Centers for Disease Control and Prevention’s definition for surgical site infection to define sternal infection (adapted from Mangram et al, 1999, page 252)
Therefore, classifications based on infection are used in defining sternal wound infections. It is important to distinguish between superficial sternal wound infections (SWIs) (Figure 2.13) and deep sternal wound infections (DSWIs) (Figure 2.14) (Garner et al, 1988; Lazar et al, 2016; Ridderstolpe et al, 2001). Superficial wound infections (SWIs) are limited to the skin and subcutaneous tissue and involve the sternal bone, substernal space, or deep at the mediastinum (mediastinitis) (Cove et al, 2012; Balachandran et al 2016; Lazar et al, 2016). SWIs infection ranges between 1.6-6.4% with a combined morbidity and mortality of 0.5% to 9%, respectively (Singh et al, 2011; Baskett et al, 1999; Ridderstolpe et, 2001). As defined by the CDC, DSWIs require the presence of one of the following criteria: (1) an organism isolated from culture of mediastinal tissue or fluid; (2) evidence of mediastinitis seen during operation; or (3) presence of either chest pain, sternal instability, or fever (>38C), and purulent drainage from the mediastinum, or isolation of an organism present in a blood culture or a culture of the mediastinal area (Garner et al, 1988). DSWIs are less common than SWIs, with incidence ranging between 0.4 to 2% and carrying a 40-50% mortality rate (Cove et al, 2012). More recently, a new classification based on the primary causal infection, as well as the anatomical description of the wound including the deepness and the vertical extension showed to be more useful has been described (Anger et al, 2015) to standardise sternal infection definition for optimal intervention (Figure 2.15). However, the proposed classification has not been validated in any scientific literature to be utilised in defining sternal infection overtime. For comparisons to be valid over time, the same surveillance methods and classifications of sternal infections must be used (Ridderstolpe et al, 2001) in order to reduce infections and continuously monitoring sternal infection. Because early diagnosis of SI is crucial, it is also importance to identify range of risks factors that are associated with the development of SWC.
Figure 2.13: Superficial wound infections at 6 weeks post-operative after a median sternotomy (courtesy of University of Melbourne image library)

Figure 2.14: Deep sternal wound infections at 6 weeks post-operative after a median sternotomy (courtesy of the Hospital Canselor Tunku Muhriz image library)
There are several well-known risk factors associated with SWC (Balachandran et al, 2016; Cahalin et al, 2011; Baskett et al, 1999). Several studies have identified a range of risks factors that are associated with the development of SWC (Balachandran et al, 2016; Cahalin et al, 2011; Baskett et al, 1999). These complications are commonly divided pre-, peri and post-operative factors (Balachandran et al, 2016; Cahalin et al, 2011; Baskett et al, 1999). Cahalin et al (2011) in a narrative review further classified primary and secondary risk factors. Table 2.1 outlines the primary and secondary risk factors associated with sternal wound complications. Balachandran et al, 2016 conducted a systematic review and meta-analysis to identify risk factors associated with sternal complications. The review included 17 full-text studies, of which 10 were included in the meta-analyses. Female gender, diabetes mellitus, obesity, bilateral internal mammary artery grafts, reoperation for postoperative complications, and blood product requirement were reported as significant predictors of sternal infection (Balachandran et al, 2016). The compilation of these risk factors may potentially assist clinician to screen and stratify patients at risk of impaired sternal healing (Balachandran et al, 2016). If sternal wound complications are identified early, timely medical

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**Risks factors for sternal wound complications**

There are several well-known risk factors associated with SWC (Balachandran et al, 2016; Cahalin et al, 2011; Baskett et al, 1999). Several studies have identified a range of risks factors that are associated with the development of SWC (Balachandran et al, 2016; Cahalin et al, 2011; Baskett et al, 1999). These complications are commonly divided pre-, peri and post-operative factors (Balachandran et al, 2016; Cahalin et al, 2011; Baskett et al, 1999). Cahalin et al (2011) in a narrative review further classified primary and secondary risk factors. Table 2.1 outlines the primary and secondary risk factors associated with sternal wound complications. Balachandran et al, 2016 conducted a systematic review and meta-analysis to identify risk factors associated with sternal complications. The review included 17 full-text studies, of which 10 were included in the meta-analyses. Female gender, diabetes mellitus, obesity, bilateral internal mammary artery grafts, reoperation for postoperative complications, and blood product requirement were reported as significant predictors of sternal infection (Balachandran et al, 2016). The compilation of these risk factors may potentially assist clinician to screen and stratify patients at risk of impaired sternal healing (Balachandran et al, 2016). If sternal wound complications are identified early, timely medical
management can reduce the risk of further progression to mediastinits, which has an associated mortality of up to 50% (Lazar et al, 2016; Main & Denehy, 2016; Robicsek et al, 2000). Early detection of patients at risk of sternal complications is essential to facilitate prevention and optimize timely intervention. Despite the significant clinical and economic consequences of sternal wound infections, there are currently no specific guidelines in cardiac surgery for the prevention and treatment of sternal wound infections (Lazar et al, 2016). Lazar et al, 2016 performs a systemic review and describes guidelines for the prevention and management of sternal wound infections (Figure 2.16) during the preoperative, intraoperative, and postoperative periods, as well as principles for the most effective methods and techniques to treat sternal wound infections as to achieve the lowest morbidity and mortality.
### Chapter 2: Literature Review

#### Primary Risk factors

- Obesity/high body mass index
- Chronic obstructive pulmonary disease
- Internal mammary artery grafting (bilateral)
- Diabetes mellitus
- Re-thoracotomy
- Increased blood loss/number of transfuse units
- Higher disability classification (CCS or NYHA)
- Smoking
- Prolonged cardiopulmonary bypass/surgical/time
- Prolonged mechanical ventilation
- Peripheral vascular disease
- Female gender with large breast size

#### Secondary Risk factors

- Osteoporosis/decreased sternal thickness
- Longer intensive care unit length of stay
- Time of surgery
- Antibiotic administration > 2 hours pre-surgery
- Staple use for skin closure
- Impaired renal function
- Immunocompromised status
- Closure by non-cardiovascular surgeon
- Cardiac re-infarction
- Inadvertent paramedian sternotomy
- Emergency surgery
- ACE inhibitor use
- Use and duration of temporary pacing wires
- Septic shock
- Depressed left ventricular function

| Table 2.1: Risk factors associated with sternal wound complications (adapted from Cahalin et al, 2011, Page 8) |  |
TABLE 2. Summary and recommendations

The prevention and treatment of sternal wound infections is multifactorial: here we summarize our recommendations to eliminate sternal wound infections. Obtain nasal swabs or PCR testing if available on all cardiac surgery patients (Class I recommendation; Level of Evidence = A).

Administer intranasal mupirocin within 24 h of surgery and continue for 5 d in all patients in the absence of negative PCR testing or a negative nasal swab for staphylococcal organisms (Class I recommendation; Level of Evidence = B).

Perform a chlorhexidine bath or shower on the evening before surgery (Class IIb recommendation; Level of Evidence = B).

Administer a cephalosporin antibiotic intravenously within 60 min of surgery, continue for procedures of more than 4 h, and for not more than 48 h. The dosing should be weight-based (Class I recommendation; Level of Evidence = A).

Restrict vancomycin to patients with a history of type I allergic reactions to β-lactam agents or in those patients in whom MRSA is of special concern (Class IIa recommendation; Level of Evidence = B).

Do not use vancomycin as the sole prophylactic antibiotic for cardiac surgical procedures (Class III recommendation; Level of Evidence = B).

Vancomycin should be administered intravenously between 60 and 120 min before the incision and at most for only 1 additional dose when it is used with cephalexin (Class I recommendation; Level of Evidence = A).

An aminoglycoside should be added for 1 preoperative and, at most, 1 additional dose for gram-negative coverage when vancomycin is the primary prophylactic antibiotic (Class IIa recommendation; Level of Evidence = C).

Patients with preoperative hyperalimentation should have their surgery postponed to receive enteral nutrition for 7-10 d if the procedure can be safely delayed (Class I recommendation; Level of Evidence = B).

All distant extrathoracic infections should be treated before cardiac surgical procedures if the procedure can be safely delayed (Class I recommendation; Level of Evidence = C).

Smoking cessation and aggressive pulmonary toilet should be performed in patients who are active smokers and in those with chronic obstructive pulmonary disease and in whom surgery can be safely delayed (Class I recommendation; Level of Evidence = B).

Continuous insulin infusion should be instituted in patients with glucose levels >200 mg/dL preoperatively, and in all patients to keep serum glucose level <180 mg/dL during surgery and for at least 24 h postoperatively (Class I recommendation; Level of Evidence = A).

Topical antibiotics (vancomycin) should be applied to the cut edges of the sternum on opening and before closing in all cardiac surgical procedures involving a median sternotomy (Class I recommendation; Level of Evidence = B).

Bone wax should not be applied to the cut edges of the sternum at any time (Class III recommendation; Level of Evidence = B).

Closing the sternum using a figure-of-eight technique may be preferable to prevent sternal dehiscence and infections (Class IIb recommendation; Level of Evidence = B).

Closing a sternum with multiple fractures using the Robicsek weave technique may prevent sternal dehiscence and wound infection (Class IIa recommendation; Level of Evidence = B).

The following is a summary for recommendations for management of sternal infections:

Use of dilute povidone-iodine irrigation for the treatment of deep sternal wound infections and mediastinitis should be avoided (Class III recommendation; Level of Evidence = B).

Negative pressure wound therapy should be initiated whenever possible in patients when delayed sternal closure is anticipated following deep sternal wound infections (Class IIa recommendation; Level of Evidence = B).

A dressing barrier between the sponge and heart and great vessels is necessary when using negative pressure wound therapy to prevent tissue erosion and subsequent blood loss (Class IIa recommendation; Level of Evidence = B).

Figure 2.16 Guidelines for the prevention and management of sternal wound infections during the preoperative, intraoperative, and postoperative periods; methods and techniques to treat sternal wound infections (adapted from Lazar et al 2016, page 968)
2.4.2 Pulmonary dysfunction and complications

Cardiac surgery is associated with post-operative alterations in respiratory function. The pathophysiology of these alterations is complex and inevitably results from combination of factors related to the procedures causing subsequent development of a systemic inflammatory response with a subsequent pulmonary inflammation (Badenes et al, 2015; Taggart, 2000). Many factors have been described to contribute to this inflammatory response, which are surgery related that predispose cardiac surgery patients to the pathogenesis of post-operative pulmonary complications, such as the effects of general anaesthesia combined with the effects of a median sternotomy incision, cardiopulmonary bypass (CPB), internal mammary artery dissection, and the use of topical cooling for myocardial protection (Westerdahl et al, 2016; Badenes et al, 2015; Taggart, 2000).

As a result of the systemic inflammatory response, patients will present with post-operative pulmonary dysfunction, which is associated with abnormalities in gas exchange, such as an increased pulmonary shunt fraction, increased pulmonary vascular resistance, and intrapulmonary aggregation of leukocytes and platelets. There are also alterations in lung mechanics, resulting in a reduction of pulmonary compliance, functional residual capacity (FRC) and vital capacity (VC) (Main and Denehy, 2016; Westerdahl et al, 2016; Ximenas et al, 2015; Badenes et al, 2015; Taggart 2000). Decrease in lung volumes and lung capacities contribute to alterations in gas exchange, resulting in hypoxemia and decreased diffusion (Main and Denehy, 2016; Westerdahl et al, 2016; Badenes et al, 2015; Taggart 2000). It was suggested that the decrease in forced vital capacity (FVC) and forced expiratory volume in one second (FEV₁) occurs by increased respiratory effort, shallower breathing due to pain and decreased chest expansion secondary to sternotomy and surgery, resulting in restrictive ventilatory dysfunction after surgery (Ximenas et al, 2015; Oliveira et al, 2009). Decreased FVC and FEV₁ after cardiac surgery affects coughing and sputum clearance, which may lead to obstruction of small airways, predispose to the occurrence of micro-atelectasis and reduction of oxygenation, increasing hospital stay (Ximenas et al, 2015; Leguisamo et al, 2005).
Post-operative pulmonary complications (PPC) are the most frequent and significant contributor to morbidity, mortality, and costs associated with hospitalization following cardiac surgery (Weissman 2004; Wynne and Botti, 2004). There is a wide disparity in the reported incidence of PPC following cardiac surgery due to the lack of a standard definition as to what constitutes a PPC (Main and Denehy 2016; Badenes et al, 2015; Brasher et al, 2003; Stiller et al, 1995). However, those most frequently referred to in the literature include pneumonia; radiographic changes such as atelectasis or infiltrates; postoperative fever; respiratory failure and the prolonged mechanical ventilation; or the presence of pleural effusions, pneumothorax and pulmonary oedema (Main and Denehy, 2016; Westerdahl et al, 2016; Ximenas et al, 2015; Badenes et al, 2015; Taggart 2000). The reported prevalence of PPC following cardiac surgery was estimated to be between 2-4% and the most common complications were reported as: atelectasis (27-95%), pleural effusion (16.6-88%) (Badenes et al, 2015; Wynne and Botti, 2004; Brasher et al, 2003; Stiller et al, 1995). For major surgery the presence of a PPC is associated with a 30-day mortality of 18 % compared with 2.5 % for those without a PPC (Khuri et al, 2005). Even after risk adjustment, at 5 years post-surgery, PPC is associated with a 66 % lower survival (Khuri et al, 2005). In those who do survive, the limited available evidence suggests a detrimental effect of PPC on early and late health-related quality of life (Thompson et al, 2006). Other studies have shown further implications for long-term patient morbidity (Westerdahl et al, 2016; Shenkman et al, 1997).

Westerdahl et al (2016) evaluated pulmonary function and HRQoL in a long-term post-operative patient one year after cardiac surgery via a median sternotomtomy. The follow up period was the longest to date described in the literature. The study reported there was a delay in the post-operative recovery with impairment in pulmonary function (measured by FVC and FEV₁) being significantly decreased (by 4–5 %) compared to pre-operative values. Further, pulmonary function was found to be severely reduced in the early period after cardiac surgery, and impairments have been described up to four to six months after surgery. Of note, pronounced decrease in pulmonary function was associated with dyspnoea limitations and impaired subjective breathing and coughing ability. It was postulated that alterations in chest wall mechanics induced by surgery and sternotomy may persist for a long time (Westerdahl et al, 2016). This indicates that
impairment of pulmonary function following cardiac surgery is long lasting, and may even be permanent (Westerdahl et al, 2016). In an earlier study, Shenkman et al (1997), noted there was an even more pronounced decrease in pulmonary function at 3.5 months after cardiac surgery; FVC reduced by an average of 24 % and FEV1 by an average of 23%.

There are several risk factors associated with a PPC such as advanced age, extensive smoking, obesity, and pre-existing COPD, prolonged anaesthesia time (> 3 hours), large intra-operative blood transfusion requirements and duration of CPB which is linked to severity of post-operative atelectasis (Main and Denehy, 2016; Wynne and Botti, 2004; Weissman 2004). Despite the low prevalence of these complications in cardiac surgical patients, recognition, diagnosis, and management of this problem vary widely (Wynne and Botti, 2004; Weissman 2004). In the absence of evidence-based practice guidelines for the care of cardiac surgical patients with post-operative pulmonary dysfunction, an understanding of the pathophysiological basis of the development of post-operative pulmonary complications is fundamental to enable clinicians to assess the value of current management interventions (Main and Denehy, 2016; Westerdahl et al, 2016; Price et al, 2016; Wynne and Botti, 2004). More challenging aspects associated with PPC include the exact diagnosis of its varied presentation and the resultant clinical manifestations (Main and Denehy, 2016; Westerdahl et al, 2016; Price et al, 2016; Badenes et al, 2015). PPC need to be clearly defined in order to determine the necessity for therapeutic intervention (Main and Denehy, 2016; Boden et al, 2015). Several studies investigating the efficacy of peri-operative physiotherapy have investigated the incidence of PPC using an eight-factor diagnostic screening tool to detect PPC called the Melbourne Group Scale (MGS) (Agostini et al, 2013; Reeve et al, 2010a; Boden et al, 2015). This scale was originally designed for use in upper abdominal surgery (Boden et al, 2015; Parry et al 2014; Browning et al, 2007, Denehy et al, 2001) and adapted for use in thoracic surgery (Reeve et al, 2008). It has been validated within the thoracic surgery population (Agostini et al, 2011) and abdominal surgery (Boden et al, 2015). This scale has been shown to have high inter-rater and intra-rater reliability and sensitive to change following thoracic (Reeve et al, 2010) and abdominal surgery (Boden et al 2015). To date, a multi-centre observational study is currently being conducted to measure the prevalence of PPC using the MGS as to validate its use across
the major surgical groups inclusive of cardiac surgery (Boden et al, 2015). Considering the high morbidity, mortality and cost of PPC (Main and Denehy, 2016; Weissman 2004; Wynne and Botti, 2004, the changing demographic of the surgical patients who are presenting with increased prevalence of co-morbidities and advanced age there is an urgent need to review the prevalence of PPC within this population (Boden et al, 2015).

### 2.4.3 Musculoskeletal and neurological complications

Musculoskeletal and neurological complications can develop post operatively primarily affecting the musculoskeletal structures (i.e. specific joint, muscle and nerve) (Stiller et al, 1997). Although pulmonary dysfunction is common in post-operative period, musculoskeletal and neurological complications are underdiagnosed after cardiac surgery, with reported incidence of 30% (El-Ansary et al, 2000b). Such complications have been suggested to result from the mechanical demands of the surgical procedure, which arise from patient positioning, retraction of the sternal halves, harvesting and dissection of the IMA and devascularisation of the sternum (Selvaratnam et al, 1994; El-Ansary et al, 2000b; Sellke et al, 2010, Kouchoukos et al, 2013). Previous studies have reported varying results with respect to the location of these complications. However, all have reported approximately a 30% incidence of musculoskeletal complications in cardiac patients. Stiller et al (1997) demonstrated 30% of post-CABG patients developed shoulder complication that interfered with their level of comfort and function. Furthermore, Roy et al (1988) and El-Ansary et al (2000b) established an association between IMA harvest and musculoskeletal complaints and/or neurological dysfunction. More specifically El-Ansary et al (2000b) reported that 39% of patients with IMA graft had musculoskeletal complaints and/or neurological dysfunction, compared with 17% of patients with SVG. El-Ansary et al (2000b) stated that the predominant areas for musculoskeletal complications are anterior chest wall, cervical spine, thoracic spine, lumbar spine, and the shoulder. In turn, these complications have been suggested to manifest in physical findings of localised regions of pain and tenderness on palpation of structures of the anterior chest wall, as well as instability, stiffness and/or restriction of both the passive and active range of motion of structures of the thoracic cage and upper extremities (including passive accessory range of...
movement) (El-Ansary et al, 2000b). The following sections will outline the common musculoskeletal complications in this patient population.

**Upper limb (UL) and trunk dysfunction**

Upper limb dysfunction after CABG is accepted as being an inevitable consequence of surgery and have been documented with the incidence ranging from 2-37% (El-Ansary et al, 2000a; Roy et al, 1988; Shaw et al, 1985; Stiller et al, 1997). The wide variation of the reported incidence is probably related to several factors, including variability in CABG procedures, different methodologies used to assess UL and trunk dysfunction, variations in the follow-up time interval, and a paucity of studies with control groups. Shaw et al (1989) documented the changes that occur in shoulder range of motion, secondary to CABG procedures performed via a median sternotomy. The authors added twice-weekly shoulder and trunk exercises to a program of standard care (i.e. mobilisation) and reported no difference in shoulder function. It was hypothesised that impairment in shoulder function may be due to the impact of the surgical procedure (Shaw et al, 1989). Stiller et al (1997) reported a similar finding with approximately 30% of participants developing a musculoskeletal complication affecting the shoulder girdle and/or upper back, eight to ten weeks post-operatively. However, one of the limitations of these studies is the lack of consistency in the outcome measures utilised as well as the fact that each only measured impairments in shoulder ROM. El-Ansary et al (2000b) identified that musculoskeletal complications effect not only the anterior chest adjacent to the incision but other body regions such as the cervical spine, thoracic spine, lumbar spine, and the shoulder. This suggests that the study by Stiller et al (1997) may have underestimated the incidence of musculoskeletal complications. Furthermore, there was a higher incidence of anterior chest wall pain, with those undergoing IMA grafting (79%) compared to saphenous vein grafting (45%) (El-Ansary et al, 2000b). It was postulated that this discrepancy was due to the additional mechanical demands of the IMA harvesting procedure, as explained in Section 2.3 (El-Ansary et al, 2000b). As the benefits of IMA have been widely reported with widespread usage worldwide, these complications are likely to become an ongoing concern (El-Ansary et al, 2000b; Taggart, 2013a). Early detection of musculoskeletal problems is important as this may impact on patient comfort and function, which in turn
may influence an individual’s ability to return to work and undertake leisure activities (El-Ansary et al, 2000b). Seyfer et al (1985) studied a similar patient population and found 38-50% of patients exhibited post-operative motor and sensory neuropathies in the upper extremity with approximate. Selvaratnam et al, 1994 reported an incidental finding when investigating brachial plexus problems in sporting people and using cardiac surgery patient as the control group. The cardiac patients in the above study reported an incidence of 50% unilateral shoulder and UL pain and impairment. The average duration of symptoms for these complications was 2.3 months, but several patients have long-term unresolved symptoms (Seyfer et al 1985). It has been hypothesized that previous neuropathies, wide sternum retraction, and longer CPB duration predispose to such injury (Seyfer et al 1985; Ben-David and Stahl, 1997). Other contributing factors to musculoskeletal and/or neurological complications are fractures of the first rib and/or clavicle, which may result secondary to higher placement of the sternal retractors (Vander Salm et al, 1980; Vander Salm et al, 1982; El-Ansary et al, 2000b; Bansal et al, 2012; Aigner et al, 2013).

**Post Sternotomy Chest Pain**

Defalque and colleagues (1989) first described chronic post sternotomy pain as post sternotomy neuralgia unique to CABG. A specific syndrome of chronic pain after internal mammary artery grafting was then described in a case series of eleven Canadian patients in 1989 (Mailis et al, 1989). Since then, abundant literature have been written on this topic with the International Association on the study of pain (IASP) in 1994, which recognized “Internal Mammary Artery Syndrome” as chronic pain.

Post sternotomy chest pain is a common sequel of cardiac surgery, and is associated with serious consequences with regards to patient’s health related quality of life. It is a multidimensional and multifactorial entity that proves challenging for researchers to assess and manage in clinical settings (Bruce et al, 2003; Padapoluous et al, 2013; Sondekoppam et al, 2014). Generally, post-sternotomy pain results in sympathetic stimulation and increase in myocardial oxygen consumption. A mismatch in the myocardial oxygen supply and demand may lead to myocardial ischemia, causing detrimental effects to patient post-operative outcome (Padapoluous et al, 2013; Sondekoppam et al, 2014). Uncontrolled pain appears to be the cause of this mismatch,
thus becoming a risk factor for the development of chronic pain following cardiac surgery. It is a common notion that the etiology of chronic pain after midline sternotomy is multifactorial (Lahtinen et al, 2002; Papadopolous et al, 2013). Hence, post-sternotomy pain is often underrated and undertreated (Sondekoppam et al, 2014), and may persist for a long duration after surgery, extending patients discomfort and slowing down their rehabilitation. It has been noted that chronic pain is more common than other morbidities of cardiac surgery such as mediastinitis, renal dysfunction, and neurologic deficits (Alston and Pechon, 2005, Sondekoppam et al, 2014).

**Prevalence and incidence**

It is difficult to state the true incidence of post sternotomy chest pain as there are varying rates of incidence being reported. It is the inconsistent definition of post-op sternotomy pain in these studies that causes variability in the prevalence and incidence post-op sternotomy pain; hence the varying results in the prevalence and incidence of pain found in the literature (Choineire et al, 2014, Bruce et al, 2003). Most literature reports the incidence of post sternotomy chest pain to be between 21–56% (Meyerson et al, 2001; Mueller et al, 2000a; Hunt et al, 2000; Eisenberg et al, 2001; Kalso et al, 2001, Bruce et al, 2003; Macrae, 2008; Cogan et al, 2010). Of those patients, 33% to 66% experienced chronic pain lasting more than 3 months, and 25% to 33% experienced more than one year of chronic pain (El Ansary et al, 2000b; Kalso et al, 2001; LaPier, 2003; Macrae, 2008; Papadopoulos et al, 2013; Sturgess et al, 2014; Ucak et al, 2011; Vymazal et al, 2009; Cogan et al, 2010). In Papadopoulos et al, (2013) observational study, they found that there is association between sternal healing and late post-operative chest pain after a median sternotomy, has an incidence of 53.5%, which was in line with other findings from almost three decades ago. Papadopoulos et al (2013) further noted that the incidence of persisting severe chest pain accounts for 2 to 4% of patients following one year after midline sternotomy, with 2.8% of patients suffering from severe incapacitating pain after 2.1 years (± 9 months), after cardiac surgery. In another study, pain was reported to be persistent post-operatively for up to 24 months at 3.6% (Choineire et al, 2014). Females have been shown to have worse pain (Yorke et al, 2004) with 47% of patients reported having incision or breast pain for up 12 months after surgery, and soreness in chest and leg incision remained up to 3 months.
post-surgery (King et al, 2009). Chronic post-sternotomy pain has been found to be more common among patients under 70 years of age, than in older patients. Mailis et al (2000) reported that the incidence of chronic post sternotomy pain was only 34% in patients over 70 years compared with 55% in younger patients (Mailis et al, 2000). Similarly, it was reported that there is a reduced chronic post sternotomy pain incidence of 34.2% in patients over 70 years, compared with 43.6% in younger patients with pain intensity at chest and shoulder regions; chronic post sternotomy pain was notably higher in younger patients (Padapoulous et al, 2013). Despite the high incidence rate reported in this surgical population, it still remains a commonly overlooked complication that is under recognized and under treated (Eisenberg et al, 2001; Kalso et al, 1992, Perttunen et al, 1999, Sondekoppan et al, 2014). This is a significant indication that post sternotomy pain remains consistent, and deserves further attention (Kalso et al, 1992, Perttunen et al, 1999).

**Etiology of post sternotomy chest pain**

Studies have identified several factors causing post sternotomy chest pain post-surgery. Possible mechanisms may be due to various factors such as osteomyelitis of the sternum, fracture or incomplete healing of the bone (Perttunen et al, 1999; Papadopoulos et al, 2013), sternocostal chondritis (Weber and Peters, 1986), costal fracture (Woodring et al, 1985), injury of the brachial plexus (Sharma et al, 2000; Vahl et al, 1991), entrapment of nerves due to sternal wire sutures (Delfaque and Bromley, 1989; Eastridge et al, 1991) or a hypersensitivity reaction against the metal wire (Eastridge et al, 1991; Fine et al, 1990). It has been suggested that the use of internal mammary artery would increase the risk of chronic post-sternotomy pain (Cohen et al, 1993; Moore et al, 1994; Vahl et al, 1991). Presence of entrapment neuropathy are associated with sternal or rib retraction, musculoskeletal trauma during surgery, sternal dehiscence or non-union, harvesting the IMA with cautery, fractured ribs, painful sternal wires, and postoperative infection (El- Ansary, 2000b; Bruce et al, 2003); in particular, manipulation of the sternum and IMA harvesting from the chest wall that requires elevation of the ribs using electrocautery may cause an iatrogenic injury to the intercostal nerves and associated neuralgia or neuropathy (Sharma et al, 2000; Mailis et al, 1989; El-Ansary, 2000b).
Predisposing factors post sternotomy chest pain

Empirical evidence has established several predisposing factors that contribute to sternal complications associated with post sternotomy chest pain, which relate to problems of blood flow, osteoporosis, infection, or degenerative conditions (Kouchoukos et al, 1990; Robicsek, 2000; Abid et al, 2001; Bitkover and Gardlund 1998). Thus, post sternotomy pain is more likely to occur in patients with concomitant pathologic conditions affecting wound healing, such as, diabetes, obesity, chronic obstructive pulmonary disease, osteoporosis, peripheral vascular disease, or after extensive sternal devascularisation following bilateral mammary artery grafting (Robicsek, 2000; Peivandi et al, 2003; Loop et al, 1990; Kouchoukos et al, 1990; Bucerus, 2003; Bitkover et al, 1998; Molina, et al, 2004; Gjeilo et al, 2010). Instability of the sternum associated with anterior wall chest pain may also develop secondary to prolonged mechanical ventilation (> 24 hours), large breast size, the use of alpha adrenergic medications, falls on the outstretched arm/s or inappropriate asymmetrical activity with the upper limbs (Loop et al, 1990; Kouchoukos et al, 1990; (King et al, 2009; Robicsek, 2000; El-Ansary, 2000b; Meisler, 2003). Previous surgery (Gjeilo et al, 2010) and occurrence of inadvertent (off centre) sternotomy, have also been identified to be a highly significant factor that jeopardises successful sternal closure (Zeitani et al, 2006). Beside the above factors, chronic pain after midline sternotomy has been reported to be induced by incomplete sternal ossification, sterno-costal chondritis, costal fracture, injury of brachial plexus, entrapment of nerves due to sternal wire sutures, intrathoracic scar formations, or allergic reactions to the metal wires. Harvesting both internal mammary arteries has been reported to increase the incidence of chronic postoperative pain. Incomplete sternal healing increased the incidence rate of post sternotomy pain to 56.5%, with mild to moderate pain intensity than the patient group with complete sternal healing (Papadopoulos et al, 2013). Even after complete sternal healing, 43% of patients still experienced persistent pain intensity (Papadopoulos et al, 2013). In addition, age, gender and negative beliefs of the use of pain relief medications have been reported to contribute to the risk of acquiring persistent pain post CABG (Zimmerman et al, 2004; Lee et al, 2010; Sethares et al, 2013; Choiniere et al, 2014). Although the literature is extensive, conclusive evidence about the etiology and risk factors on patients most likely to develop post sternotomy pain is still lacking. A recent systematic review and meta-analysis was conducted to
identify risk factors associated with sternal complications. Balachandran et al (2016) found that female gender, diabetes mellitus, obesity, bilateral internal mammary artery grafts, reoperation for post-operative complications, and blood product requirement were reported as significant predictors of sternal infection (Balachandran et al, 2016). Early detection of patients at risk of sternal complications is essential to facilitate prevention and optimize timely intervention for the target population.

**Acute Post Sternotomy Chest Pain**

There is a considerable variability in the degree and experiences of pain, distress, and disability reported by individuals who have undergone cardiac surgery (LaPiers et al, 2007; LaPier & Wilson, 2007; Bauer et al, 2010; Cutshall et al, 2010; Guo et al, 2012; Leegaard et al, 2010). Several studies have reported that following cardiac surgery, patients suffer significant amount of pain in the acute post-operative period; in intensive care and after their transfer to the general wards (Meehan et al, 1995, Puntillo et al, 1990, Valdix et al, 1995). In a prospective cohort study of 213 CABG patients, 49% had severe pain at rest, 78% had severe pain during coughing, and 62 % had severe pain during movement at four days after surgery using the visual analog scale (Lahtinen et al. 2006). In another prospective study of 200 post CABG patients, the participants reported significantly less pain in the first five days after surgery at rest, when compared to pain levels during activity (Mueller et al, 2000). In this study, the highest pain scores were recorded on days one and two, with a significant decrease on day three and day seven based on the VAS scale. The authors noted that the location of the most intense pain change over time, was shoulder pain on day seven post operation. Milgrom et al, (2004) found that by using the VAS scale, patients experienced their most severe pain during activities such as coughing, sneezing, deep breathing, turning in bed, getting up to the chair during the first week after surgery. Although the pain scores were highest during the immediate post-operative period, mean pain scores of 4.33 and 3.09 were reported while coughing and deep breathing during day six post-operation.

Intense acute post-operative pain in the first week following cardiac surgery has been reported to be predictive of chronic pain (Choineire et al, 2014; Lee et al, 2010; Mueller et al, 2001; Kalso et al, 2001), which is associated with significant personal and financial costs (Janssen-Sanders et al, 2008; Mazzeffi and Khelemsky, 2011). Lee and
colleagues in 2010 showed that patients who had a pattern of increased pain between days 10 and 30 post-surgery, were more likely to later report chronic pain that impacts upon their function and quality of life. Pain was one reason for emergency department visits and/or readmissions for patients associated with reduced length of stay following discharges after CABG (Weber et al, 1996). This will predispose patient’s utilization of expensive community services such as emergency services, that are costly and may have been prevented and managed during inpatients stay (Watt-Wattson 2004).

**Chronic Chest Pain (Persistent)**

The evidence suggests that pain after CABG surgery may continue well after wound healing has taken place, and in some patients, chronic pain persists for several months (Choineire et al, 2014; Papadopoulos et al, 2013; Mazzeffi & Khelemsky 2011). Post sternotomy pain that progresses over a long period of time from one month to two years is a common musculoskeletal problem, with an estimated prevalence between 38-66% (Choineire et al, 2014; Papadopoulos et al, 2013; Lee et al, 2010; Macrae, 2008; Mueller et al, 2001; Kalso et al, 2001. It is associated with potential morbidity and is frequently disabling (Mazzeffi & Khelemsky 2011; Ho et al, 2002). This persistent pain can be severe enough to interfere with activity of daily living and quality of life, and often has an adverse effect on mood (Sullivan and Spertus, 2001; Nalysnyk et al, 2003; Elliot et al, 2010), as well as causing sleep disturbance for patients (King et al, 2009; LaPier, 2003a; Edell-Gustafsson et 1997).

Most studies focus on chronic pain for the time duration between two months, and three years after surgery (Meyerson et al. 2001, Bruce et al, 2003, carle et al, 2009, van Gulick et al. 2011, Gjeilo et al. 2010; Eisenberg et al, 2001; King et al, 2008; Tailefelar et al, 2006; Ho et al, 2002; Kalso et al, 2001; Setahres et al, 2013, Choineire et al, 2014). In a prospective cohort study of 71 patients who have undergone median-sternotomy, severe persisting chest pain accounted for 2 to 4% of patients one year following midline sternotomy, and 2.8% of patients suffered severe incapacitating pain two years after surgery (± 9 months) (Papadapoulos et al, 2013). The authors found that the location of the most intense and significant increase in pain to be in the chest and
shoulder regions. However, the pain intensity, when it persisted, was mostly mild, with a mean visual analogue scale score of 24.5 ± 17 mm at the chest region, and 36 ± 25 mm at the shoulder region. It is noted even with a stable sternum, a dehiscence measuring more than 3 mm in width extending over more than one rib level, led to significantly higher pain intensity; possibly due to the relative movement of the sternum halves. In another study, pain was reported to be persistent post-operatively for up to 24 months at a rate of 3.6% (Choineire et al, 2014). The author noted that those patients with higher ratings for acute pain and interference with daily functioning in the first week after surgery, were more likely to report persistent post-operative pain irrespective of study sites (sternotomy incision and harvesting limbs).

**Physical Function Impairments**

A significant number of patients report anterior chest pain and discomfort that impacts on their recovery and function (Eng and Wells, 1991; Moore, 1994; Stiller et al, 1997, El-Ansary et al, 2000, Mueller et al, 2000; LaPier and Schenk, 2002; Bruce et al, 2003). In individuals following CABG, it is common that functional status may be impaired due multiple factors including; surgical procedure (infection, wound breakdown), tissues trauma (pain), coronary heart disease on cardiac functionality pre-operatively (angina symptoms) and other related factors. However, the presence of pain, regardless of intensity, can prevent participation in activities necessary for recovery, further impair functional status, negatively affect health-related quality of life (LaPier & Wilson, 2007; LaPier et al, 2008), and contribute to mortality (Bauer et al, 2010). It has been noted that moderate degree of post sternotomy chest pain may interfere with the performance of daily activities at a significant level for some patients whereas, severe pain may impair daily life activities and lead to depression (Eisenberg et al, 2001; Papadopoulos et al, 2013).

Several studies have reported activities such as coughing, sneezing, deep breathing, turning in bed, getting up to the chair and ambulation to bring about the greatest levels of pain during the first week after surgery (Gallagher et al, 2004; Milgrom et al, 2004; LaPier & Wilson, 2007). Even mild pain interfered with rest, coughing and sleeping for
up to one-year post surgery (Lahtinen et al, 2006). Denton et al (2001) reported that some patients described a reduction in hand function following radial artery harvesting with cold exposure and/muscular fatigue, causing a decline in motor task related to fine movement. A significant number of patients showed moderate (71%) to severe (65%) pain related interference at from day two, to day five post operation; 25% patients experienced extremely unpleasant pain before discharge related to deep breathing, coughing, general activity, walking, mood and sleep; they further continued to have these problems at home following discharge (Watt-Wattson et al, 2004; LaPier et al, 2008). Women have been reported to have lower physical activity levels than men, and less relief of pain related symptoms, including mediasitinal discomfort (Watt-Wattson et al, 2004, King et al, 2009). Moreover, the presence of cognitive and memory deficits are also high and reported to be 90% impacting on the patient’s ability to complete gross and fine motor related tasks (Diegeler et al, 2000). Deficits in the above tasks, and a reduced capacity to focus when experiencing pain can interfere with learning, self-care, and functional activities that promote wellness (LaPier et al, 2002, 2008, LaPier & Wilson, 2007). Sethares et al (2013) found that post CABG patients limit their activities to a greater level than recommended by physicians following surgery, in order to manage the continued post-operative pain experienced between two to twelve weeks. The authors found that if an activity caused pain at the wound site, either at the sternum or legs, then that activity was discontinued or avoided, rather than the taking of a non-opioid medication. Conversely, if patients learn that limiting activity is a successful strategy to combat pain during hospitalization, it is natural that this behaviour would continue at home following discharge. Limiting activities beyond what is recommended for this cohort of patients not only puts patients at risk of developing complications, but can also prevent a timely return to normal activities and successful rehabilitation.

**Post Sternotomy Chest Pain (Characteristics)**

Post-operative pain after cardiac surgery is different from cardiac angina symptoms experienced before CABG surgery, and is typically considered as nociceptive pain related to stimulation of peripheral mechanoreceptors during surgery (Ucak et al, 2011). The International Association on the study of pain (IASP) in 1994, recognized “Internal Mammary Artery Syndrome” as chronic pain and its association with numbness, with
or without sensation of allodynia at the anterior intercostal nerves T1-T2 and T5-T6. Eisenberg et al (2001) defined Post-CABG pain (PCP) as chest wall pain of at least three months’ duration, which first appeared after the CABG surgery, or which was different from the pre-operative pain (angina pectoris), in case it was present prior to the operation. Presence of signs and symptoms include constant pain, shooting intra muscular pain on the side of the harvest with tenderness on palpation of manubrium, sterno clavicular joints and anterior rib cage (Mailis et al, 2000, El-Ansary et al, 2000a; Macrae et al, 2001; Cogan et al, 2010). Post sternotomy chest pain can be somatic type of pain, a symptom that stems from musculoskeletal structures (e.g. ligaments, facet, muscle, joints, intervertebral disks, muscles, bursa tissue Injury) and aggravated by movement (Wallace et al, 1997; Cogan et al, 2010). Post sternotomy chest pain via a median sternotomy incision may causes nerve and joint injuries due to sternal retraction (Meyerson et al, 2001). Conacher et al (1993) noted that dissection of the internal mammary artery (IMA) from the chest wall could damage the intercostal nerves. The study showed that sternal wires and chest tubes placed through intercostal spaces can lead to surgical damage to the anterior ramie of the intercostal nerves, and stimulation of the peripheral nerve endings. The finding is supported by Mailis et al (2000) who studied a relatively homogenous patient population with ischemic heart disease. Most of the patients had CABG surgery through a median sternotomy with left IMA harvesting performed using cautery. The authors reported that anterior intercostal nerve damage occurred in 73% of patients undergoing CABG surgery with IMA harvesting. Of those patients, 15% suffered from chronic chest wall pain from five to twenty-eight months after surgery. The authors believed that this type of procedure could be associated with post-operative neuropathic pain. Despite the high prevalence, pain levels after cardiac surgery are often severe and undertreated (Cogan et al, 2010; Sondekoppam et al, 2014). Pain management is achieved with regular and systematic evaluation and the use of multimodal regimens. Treatment strategies that are commonly used include opioids, paracetamol, NSAIDS, and more recently anticonvulsants (Cogan et al, 2010; Sondekoppam et al, 2014) in addition to thoracic exercise (Sturgess et al, 2014)
2.5 Post-operative Physiotherapy Management

2.5.1. Cardiac Rehabilitation (CR)

The efficacy of physiotherapy techniques used for patients following uncomplicated coronary artery bypass surgery (CABG) is well documented with the aim to promote post-operative recovery (Price et al., 2016; Lawler et al., 2011; Heran et al., 2011; Oldrige 2012). Historically, this consists of the delivery of prophylactic respiratory physiotherapy such as breathing namely deep breathing, coughing and exercises, as a component of Phase 1 cardiac rehabilitation (Jenkins et al., 1989; Stiller et al., 1994; Tucker et al., 1996; Patman et al., 2001; Brasher et al., 2003; Pryor and Prasad, 2004). Cardiac rehabilitation (CR) incorporates exercise training and education (Price et al., 2016; Lawler et al., 2011; Heran et al., 2011; Oldrige 2012). It was initially developed in 1950s for patients recovering from myocardial infarction (MI) (Levine and Lown, 1951). It has come a long way from the initial ‘bed-rest’ approach used to treat ST-elevation myocardial infarction (STEMI) and has evolved to encompass patients with heart failure, stable angina, and those following PCI, CABG, and other cardiac surgery procedures (Price et al., 2016; Goel et al., 2015; Oldrige 2012; Mampunya 2012; Lawler et al., 2011; Heran et al., 2011;). Meta-analyses have shown significant reductions in both all-cause and cardiac mortality from exercise based rehabilitation compared to standard medical care without structured exercise training or advice, with the reduction associated with long-term rather than short-term follow-up for patients with CHD including cardiac surgery via sternotomy (Heran et al., 2011). Exercise-based cardiac rehabilitation results in a significantly lower risk of fatal and non-fatal re-infarction through improved cardiac and coronary vascular function, as well as improved CVD risk factor profiles when compared to cardiac rehabilitation without an exercise component (Price et al., 2016; Lawler et al., 2011; Heran et al., 2011; Oldrige 2012).

Attendance at a CR program following an acute cardiac event has been advocated by published guidelines worldwide (Price et al., 2016). There is level 1 evidence for the effectiveness of exercise-based CR programs (www.heart.au) (WHO, 1993; Goble and Worcester, 1999; Ades, 2001; Hedback et al, 2001; National Heart Foundation of Australia, 2004; Pryor and Prasad, 2004; Heran et al., 2011). Exercise is a major component of all phases of cardiac rehabilitation. Cardiac Rehabilitation has been
conventionally divided into four phases. Phase-1 involves the hospitalized period of the patient, phase-2 is the immediate post discharge period, phase-3 is the stage of a structured exercise program, and phase-4 is the maintenance phase (Price et al, 2016; De Macedo et, 2011; Leon et al, 2005; Ades 2001). However, a more contemporary approach is emerging with cardiac rehabilitation being defined as a continuum of care that targets primary and secondary intervention. Generally, CR has a set of core components that should be included in every program. These components include baseline patient assessment, nutritional counselling, risk factor modification, psychosocial interventions, physical activity counselling, and exercise training (Mampuya, 2012). The traditional CR programs focused on supervised exercise to counter deconditioning with the aim of improving exercise capacity (Balady et al, 2000). It has been reported that around 70% of secondary prevention programs offered in Australia continue to follow the traditional cardiac rehabilitation six- to eight-week group-based model (Redfern et al, 2014; Briffa et al, 2009; Wenger, 2008). However, utilisation of facility-based preventive interventions remains unacceptably low with suboptimal participation at 15 to 50% for those who are eligible (Niebauer, 2016; Redfern et al, 2014; Scott et al, 2003; Suaya et al, 2007). Further, the effects of modifiable risk factor interventions on the progression of cardiac pathology remain low with non-participants believing that rehabilitation is not necessary (Redfern et al, 2014). This is despite non-participants having higher baseline risk than those who participate in the program (Redfern et al, 2014; Steg et al, 2007; Kotseva et al, 2009; Cooper et al, 2007). A strong body of evidence has shown that patients who participate in secondary prevention and CR have significantly better outcomes than those who do not (Niebauer 2016; Goel et al, 2015; Clark et al, 2001).

More recently, Redfern et al, 2011 developed a new model for utilisation of facility-based preventive intervention including cardiac rehabilitation to increase access to and uptake of effective secondary prevention. Redfern et al, 2011 recommend that CR in any format within varied settings should consistent of four core essential components including assessment, education, individual risk factor modification and ongoing support, and re-assessment (Figure 2.17). Despite strong and consistent evidence for exercise-based cardiac rehabilitation, attendance after hospital discharge in CR programs is suboptimal. CR programs remain considerably underutilized mainly because of referral problems, waiting time and poor access (Mampuya et al, 2012). As
such, alternate approaches and the use of trans telephonic and other means of monitoring and surveillance may expand the utilization of cardiac rehabilitation (Mampuya et al, 2012).

![Table showing diagnostic and assessment, risk reduction, and ongoing prevention strategies.]

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>INFORMATION SESSION</th>
<th>INDIVIDUAL PROGRAM</th>
<th>REASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical, physical, and psychological factors</td>
<td>Heart disease</td>
<td>Based on preferences, mood and goals</td>
<td>Repeat baseline measures</td>
</tr>
<tr>
<td>Medications</td>
<td>Symptom management plan</td>
<td>Target relevant risk factors and psychosocial issues</td>
<td>Assess adherence</td>
</tr>
<tr>
<td>Resilience to change and beliefs</td>
<td>Medication adherence</td>
<td>Ongoing care and support to encourage, reinforce, and achieve behavioral change</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Being active</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Healthy eating</td>
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<tr>
<td></td>
<td>Role/work resumption</td>
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</table>

Redfern (2016) recommended health management and support of CR programs delivered by via electronic devices known as eHealth or mHealth (Chow et al, 2016). They have the potential to create new opportunities to communicate with, and support, patients with CHD and post myocardial revascularization (Chow et al, 2016; Redfern, 2016). Both authors proposed several strategies that include 1. the use of telephone coaching and text messaging, 2. interactive online programs that can be delivered remotely or via smartphone applications; and 3. the use of sensors and trackers that monitor daily activity levels via devices worn by patients. The two earlier methods have been shown to improve CHD risk management (Chow et al, 2015; Redfern, 2016; Vale et al, 2003). The later method is in a form of devices which are typically worn on the hip or wrist and provide the user with information about physical activity measures such as steps taken, energy expenditure, and time spent in moderate to vigorous physical activity (Hickey & Freedson, 2016). The user may also use the computer interface (e.g. [Figure 2.17: Secondary prevention for all in need (SPAN) organisation of care (adapted from Redfern et al, 2011, page 2)](image-url))
device websites, smartphone applications) to monitor and track achievement of physical activity goals and compete with other users (Hickey & Freedson, 2016; Redfern, 2016). Exploring these new methods of cardiac rehabilitation delivery is crucial to improve uptake and participation (Mampuya, 2012; Niebauer, 2016; Redfern et al, 2011). The potential for this mode of delivery lies in its potential to reach rural and remote regions to impact on life-long behaviour change that targets secondary prevention (Chow et al, 2016; Redfern et al, 2011). Despite promising developments, one of the greatest disadvantages of the current eHealth/mHealth strategies is the lack of scientific evidence for their effectiveness (Chow et al, 2016; Redfern et al, 2011). Future research is warranted to deliver new models of exercise and rehabilitation training, which are more effective, versatile and incorporate new technologies in CR (Chow et al, 2016; Mampuya, 2012).

2.5.2 Respiratory Physiotherapy

Respiratory Physiotherapy has been routinely used to prevent or reduce PPC (Westerdahl et al, 2016; Patman et al, 2001; Brasher et al, 2003; Pryor and Prasad, 2004). Although, the incidence of clinically significant post-operative pulmonary complications is relatively low there is limited evidence in the literature supporting the efficacy of prophylactic chest physiotherapy in this patient population (Jenkins et al, 1989; Stiller et al, 1994; Tucker et al, 1996; Weissman, 1999; Patman et al, 2001; Brasher et al, 2003; Weissman, 2004; Wynne and Botti, 2004; Ji et al, 2013; Westerdahl et al, 2016; Westerdahl et al, 2014; Westerdahl and Olsen, 2011; Pasquina et al, 2006; O'Donohue 1985; Herdy et al, 2008; Pasquina et al, 2003; Brasher et al, 2003). Pasquena et al (2003) in a rigorous a systematic review inclusive of 18 studies (n=1457 patients) concluded that evidence is lacking on the benefits of any type of prophylactic respiratory physical therapy following cardiac surgery. In addition, this study reported that they were no consensus regarding the most suitable and effective therapy in preventing pulmonary complications following cardiac surgery (Pasquina et al, 2003). Further, there is also no optimal therapy considered as superior in preventing or treating long-term changes in pulmonary function following cardiac surgery (Westerdahl & Olsen, 2011; Westerdahl et al, 2014; Westerdahl et al, 2016).
2.5.3 Early mobilisation

Early Mobilisation has been advocated to prevent complications related to immobility and accelerate functional recovery (Santos et al, 2016; Westerdahl & Moller, 2010). Santos et al, 2016 conducted a systematic review on randomised controlled trials (RCTs) to define element of early mobilisation in patients after cardiac surgery, and their effects specifically on post-operative complications, functional return and length of hospital stay. Nine studies were included with The PEDro scale showed that the studies had a low risk of bias (range 5 to 9 points). The trials revealed diversity in definition, techniques used for mobilisation, as well as periods considered early for the start of the intervention. Only two studies from this review provided a clear definition of early mobilisation, i.e. ‘the gradual increase of activity starting on the first postoperative day until independent ambulation on the fifth post-operative day. The remaining seven studies cited in the study did not provide a specific definition for early mobilisation. Further, among the studies that compared active treatment protocols, the interventions differed in terms of exercise technique and therapy intensity. Despite the lack of definition on the control group, this study demonstrated early mobilisation groups had improved outcomes compared with control groups (without treatment/bed rest). When different techniques and periods of mobilisation were compared, there is no evidence for an optimal prescription. Further, in the short term, it was found that early mobilisation does not promote significant changes in functional capacity. Therefore, the author recommended alternative outcomes, such as muscle strength and level of assistance, are more relevant in assessments in acute care setting considering the many variables such as patient status (which changes rapidly), different professionals involved in treatment, other interventions needed, and resources available which may affect interventions involving exercises. The limitation of this review is that meta-analysis was not possible due to the variability of the interventions proposed as early mobilization and hinders an effective conclusion regarding the evidence of this therapy in patients after cardiac surgery. Despite the high scores on the PEDro scale, the lack of sample size calculation, with poor blinding criteria as well as a no clear definition of the control group result in a low quality of evidence.

Brasher et al (2003) investigated the impact of removing prophylactic deep breathing and coughing exercises from a routine post-operative physiotherapy program, which
included pre-operative education and early mobilisation after cardiac surgery. All patients received physiotherapy treatment pre-operatively and post-operatively for three days. Patients were mobilised as soon as possible after surgery. The patient in the breathing group (control) performed a set routine of deep breathing exercises at each physiotherapy visit whilst those in the intervention group did not perform. Breathing group participants were asked to perform (four sets of five deep breaths from functional residual capacity (FRC) to total lung capacity (TLC) and interspersed by supported coughs (Brasher et al, 2003). These exercises were supervised/assisted by the treating physiotherapist twice daily on the first two post-operative days, then once of the third post-operative day and encouraged to be completed independently hourly whilst the participant was awake (Brasher et al, 2003). Additionally, early mobilisation included sitting out of bed on the first post-operative day and ambulation (minimum 10 m increasing to minimum of 30 m) on the second and third post-operative days (Brasher et al, 2003) for both group. All participants perform supported coughs for airway clearance (Brasher et al, 2003). The results confirmed that the incidence of post-operative pulmonary complications was relatively low in both groups (less than 5%) with no significant differences in the incidence of post-operative pulmonary dysfunction or complications between groups (Brasher et al, 2003). In a later study Herdy et al (2008) conducted RCT comparing two group of intervention following CABG. The intervention group (exercise) received cardiopulmonary rehabilitation which lasted at least 5 days pre-operatively and consisted of phase I cardiac rehabilitation associated with respiratory physiotherapy, while the other group (usual care) received the standard care usually available to these patients. The exercise protocol consisted of exercises that were progressed from passive movements on the first day after surgery to walking and finally to climbing two flights of stairs on the fifth day. Additional respiratory exercises included spirometer training and intermittent positive pressure breathing. Participants in the control group received no physical therapy, unless formally prescribed by the medical staff. The intervention presented a shorter time to endotracheal extubation, a reduction in the incidence of pleural effusion, atelectasis, pneumonia and atrial fibrillation or flutter. Length of in-hospital stay after surgery was also significantly reduced in the in the early mobilisation group. In addition, the incidence of all types of complications was lower in the intervention group compare to control group. These results support the conclusions of previous researchers who suggested: 1) the importance of early mobilisation. Although early mobilisation is
prescribed for patients after cardiac surgery, no consensus exists regarding the best
types of mobilisation and their optimal intensities and durations (Santos et al, 2016).
The absence of a definition, the variety of physiotherapeutic techniques, and the
different starting points for the intervention described in the studies show that ‘early
mobilisation’ is a complex intervention and prophylactic chest physiotherapy may not
be warranted in all patients following cardiac surgery (Brasher et al, 2003; Santos et al,
2016).

2.5.4 Prescription of upper limb and trunk

Upper limb and trunk exercises are routinely prescribed as part of post-operative
management in patients following cardiac surgery via a median sternotomy. These
exercises are prescribed with the rationale to prevent post-operative complications,
improving pulmonary function, preserving thoracic mobility and controlling pain
(Westerdahl and Moller, 2010; Lomi and Westerdahl 2010). Despite the routine use of
these exercises in the post-operative period, there is limited evidence to support their
efficacy (Stiller et al, 1997). Stiller et al (1997) reported that routine range of motion
exercise compared to no exercise did not lead to a change in the incidence of post-
operative musculoskeletal complications at 8-10 weeks post-operatively. However, a
limitation of this study was that other health professionals may have encouraged upper
limb exercises in all and that less than 21% of the participants in the intervention group
reported to adhering to their trunk exercise program (Stiller et al, 1997). Similarly,
Shaw et al (1989) reported no differences in the reduction of range of motion between
participants who completed a thoracic mobilisation program compared to a control
group (Shaw et al, 1989; Stiller et al, 1997). However, the exercises were prescribed by
non-physiotherapist staff (nursing), which may have influenced the method of
prescription and progression of exercises (Shaw et al, 1989). Further, the lack of follow
up beyond hospital discharge also limits the ability to extrapolate the true impact of
these exercise programs. Additionally, the study recruited only male participants
limiting the generalisability of the results, and the impact of post-operative pain was
not investigated (Shaw et al, 1989).

In a later pilot RCT which investigated the impact of an individually progressed
thoracic mobilisation exercise program a significant improvement in sternal pain four
weeks post-operatively was demonstrated (Sturgess et al, 2014). Furthermore, the exercise program, which included the use of the upper limbs and trunk, was well tolerated, with participants perceiving that such exercises contributed to their functional recovery (Sturgess et al, 2014). It was proposed that thoracic exercises, which recruited muscles of the anterior chest wall and abdomen, optimised the neuromuscular control of muscles inhibited following a median sternotomy secondary to post-operative pain (Sturgess et al, 2014).

In another study of patients with chronic sternal instability, El-Ansary et al (2007c) reported a decrease in sternal separation and post-operative pain in patients who participated in a six-week individualised, trunk stabilisation exercise program (El-Ansary et al, 2007c). Participating in the targeted exercise program may potentially optimise muscle function and recovery, in contrast to the avoidance of movement to minimise pain, which may lead to muscle deconditioning (El-Ansary et al, 2007c; Balanchandran, 2015). Upper limb and trunk movements may facilitate functional recovery by optimising muscle activation and circulation to the region (Wallace and Wallace, 1997; El-Ansary et al, 2007c; Sturgess et al, 2014; Balanchandran, 2015). Furthermore, upper limb, trunk and/or thoracic exercises have been postulated to increase demand ventilation, which may play a role in minimizing post-operative pulmonary dysfunction and the development of complications discussed in Section 2.4 (Zadai, 1992; Pryor and Prasad, 2004; Balanchandran, 2015). Despite the suggested benefits of upper limb and trunk exercises, there are currently no guidelines supporting their wider clinical application in the target population.

Consistent with this observation, Balachandran et al, 2014 conducted a web survey to investigate physiotherapy practice regarding upper limb exercise guidelines for this population, within outpatient cardiac rehabilitation in Australia. The study concluded that there is significant variation in practice with respect to the prescription and progression of upper limb exercises, within outpatient cardiac rehabilitation in Australia. Further, there was a lack of consensus on the type and timing upper limbs and trunk movement, with patient-reported pain being the main parameter used to guide upper limb exercise prescription and progression. This study found that bilateral upper extremity exercises were commonly prescribed, rather than unilateral range of motion exercises as it reduces sternal pain. This is not surprising as studies has shown that
Chapter 2: Literature Review

elevating both arms simultaneously overhead produced the least amount of sternal separation and reduced stress on the healing sternum (Adam et al, 2006; Adam et al, 2008; 2014; El-Ansary 2007c; Balanchandran et al, 2014; Balanchandran et al, 2016). Additionally, all outpatient cardiac rehabilitation programs in Australia do not routinely screen for sternal complications (Balanchandran et al, 2014). In the event that a sternal complication is diagnosed, there is little agreement on the modification of upper limb and trunk use (Balanchandran et al, 2014). Research is warranted in order to establish evidence-based guidelines for the upper limb and trunk rehabilitation of this patient population (Balanchandran et al, 2014). A key step in this process is to specifically determine the effects of such movements on sternal healing in patients following cardiac surgery via a median sternotomy (Balanchandran et al, 2014).

In a foundational study that built on the research by El-Ansary et al (2007a) in patients with SI, Balanchandran et al (2016) investigated the reliability of ultrasound measures of sternal micromotion in acute patients undergoing conventional wiring for a median sternotomy following cardiac surgery. Sternal micromotion was assessed during upper limb elevation (unilateral and bilateral; deep inspiration, coughing and standing up with support through both arms from a seated position). This longitudinal, prospective observational study (n=64) found that sternal micromotion was multi-planar and of a small magnitude in both the sagittal plane (lateral displacement) and coronal plane (anterior-posterior direction) during all upper limb and trunk movements assessed (the micromotion of the sternal edges as quantified by real-time ultrasound in Table 2.2. and 2.3 with results). The magnitude of sternal micromotion motion (from the rest position) varied from 0.00cm to 2.03cm in the lateral direction and 0.00cm to 0.47cm in the anterior-posterior direction. Of note, coughing produced a significant increase in sternal separation in the lateral direction (0.14-0.16cm) and pain, compared to the other dynamic tasks assessed in the periods (Table 2.2). Given that only one participant was diagnosed with a sternal complication, and compliance with prescribed sternal precautions was inconsistent, the results of this study suggested that a small magnitude of multi-planar sternal micromotion may constitute the usual sternal healing process in the target population. It can be concluded that that based on the above study that the impact of movement and loading on the healing sternum is still unknown (Tuyl et al, 2012; Balanchandran, 2015; Balanchandran et al, 2017). This finding is significant sternal micromotion less than two mm is reported to be within the acceptable range at fracture
A greater amount of sternal micromotion is thought to contribute to bone necrosis and delayed healing (McGregor et al., 1999; Fedak et al., 2011). It was postulated that a small amount of multi-planar motion at the sternal edges during upper limb and trunk tasks may constitute usual sternal recovery in the acute period (Balachandran et al., 2017; El Ansary et al., 2007c; Mekontso et al., 2011). This study established that bilateral upper limb elevation tasks were not only better tolerated than unilateral upper limb elevation, but also resulted in less sternal micromotion, at each of the time points (pre-hospital discharge, six weeks and three months post-operatively).
### Table 2.2: Ultrasound results on mean lateral micro-motion in centimetres (cm), table adapted from Balachandran, 2015, page 216

<table>
<thead>
<tr>
<th></th>
<th>Mean lateral sternal micromotion (cm)</th>
<th>Standard error (cm)</th>
<th>95% confidence interval (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-7 days post-operatively</td>
<td>0.85</td>
<td>0.07</td>
<td>0.71-0.99</td>
</tr>
<tr>
<td>6 weeks post-operatively</td>
<td>0.78</td>
<td>0.07</td>
<td>0.64-0.93</td>
</tr>
<tr>
<td>Three months post-operatively</td>
<td>0.77</td>
<td>0.07</td>
<td>0.63-0.91</td>
</tr>
<tr>
<td>Rest</td>
<td>0.82</td>
<td>0.07</td>
<td>0.67-0.96</td>
</tr>
<tr>
<td>Deep inspiration</td>
<td>0.81</td>
<td>0.07</td>
<td>0.67-0.96</td>
</tr>
<tr>
<td>Cough</td>
<td>0.68</td>
<td>0.07</td>
<td>0.53-0.82</td>
</tr>
<tr>
<td>Unilateral upper limb forward flexion</td>
<td>0.83</td>
<td>0.07</td>
<td>0.69-0.98</td>
</tr>
<tr>
<td>Bilateral upper limb forward flexion</td>
<td>0.83</td>
<td>0.07</td>
<td>0.68-0.97</td>
</tr>
<tr>
<td>Sit to stand</td>
<td>0.84</td>
<td>0.07</td>
<td>0.69-0.98</td>
</tr>
</tbody>
</table>

### Table 2.3: Ultrasound results on mean anterior-posterior sternal micromotion in centimetres (cm), table adapted from Balachandran, 2015, page 216

<table>
<thead>
<tr>
<th></th>
<th>Mean anterior-posterior sternal micromotion (cm)</th>
<th>Standard error (cm)</th>
<th>95% confidence interval (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-7 days post-operatively</td>
<td>1.25</td>
<td>0.08</td>
<td>1.08-1.41</td>
</tr>
<tr>
<td>6 weeks post-operatively</td>
<td>1.18</td>
<td>0.08</td>
<td>1.01-1.35</td>
</tr>
<tr>
<td>Three month post-operatively</td>
<td>1.13</td>
<td>0.08</td>
<td>0.96-1.30</td>
</tr>
</tbody>
</table>
2.5.5 Sternal precautions

Individuals are required to practice activity restrictions known as sternal precautions prescribed by the cardiac surgeon and other health practitioners that limit the use of the upper limbs and trunk movement, from four weeks up to three months post-operatively (Balachandran et al, 2014; Cahalin et al, 2011; Adam et al, 2016). These restrictions are usually taught as a component of cardiac rehabilitation during the hospital stay and continue through to the community setting (Pryor and Prasad, 2004; Overend et al, 2010; Westerdahl and Moller, 2010; Cahalin et al, 2011; Tuyl et al, 2012; Balachandran et al, 2014). Common activity restrictions include limiting the shoulder range of motion, lifting, reaching, dressing, exercise, driving, and a variety of other daily tasks (Adams et al, 2006; Adams et al, 2016; Adams et al, 2014; Balachandran et al, 2014; Cahalin et al, 2011). The rationale of these activities restriction is to reduce risk and prevent SWC.

However, Physiotherapists routinely prescribe upper limb and trunk exercises as a part of standard post-operative care (Stiller et al, 1997; Pryor and Prasad, 2004; El-Ansary et al, 2007a; Sturgess et al, 2014). The prescription of such exercises alongside sternal precautions poses a clinical dilemma as they contradict each other (Balachandran et al, 2014; Cahalin et al, 2011) (Referred Figure 2.18 and 2.19). Given that the majority of patients following cardiac surgery performed via a median sternotomy heal without any sternal complications sternal precautions maybe overly restrictive or perhaps not warranted in all patients (Balachandran et al, 2017; Adams et al, 2016; Adams et al, 2008; Cahalin et al, 2011; Brocki et al, 2010; Parker et al, 2008; Parker and Adams, 2008). A recent survey that investigated Physiotherapy current practice with respect to exercise prescription after cardiac surgery found that sternal precautions were applied based on prior expert opinion and historical institutional protocols and may not be necessary for all patients (Balachandran et al, 2014). In the study, the majority of respondent (96%) prescribed upper limb exercises to patients following median sternotomy, with 95% placing restrictions on these exercises. At six weeks post-operatively, 58% and 73% of respondents still placed restrictions on unloaded and loaded unilateral upper limb elevation exercises respectively; similarly, 55% and 74% placed restrictions on unloaded and loaded bilateral upper limb elevation exercises, respectively. Only 43% reported screening for sternal instability, and if detected, the majority based their management on clinical experience. There was a lack of consensus on the type and timing of these restrictions, with patient-reported pain being the main
parameter used to guide upper limb exercise prescription and progression (Balachandran et al, 2014). Further, these restrictions are not consistent or standardised, with significant variation in what constitutes “sternal precautions” as well as for what duration they should be applied (Balachandran et al, 2014; Tuyl et al, 2012) and overseas (Adams et al, 2006; Adams et al, 2008; Cahalin et al, 2011; Irion et al, 2013; Overend et al, 2010).

In a recent narrative review Cahalin et al (2011), outline key limitations of the current sternal precautions which include; not having a universal sternal precautions guideline; current SP’s are mainly based on unscientific methods such as anecdotes or expert opinions; no differentiated application of sternal precautions to address the physiological diversity of patients thus impeding patient recovery by prescribing unnecessary physical activity restrictions (Cahalin et al, 2011). A review of the literature that examines current practice of sternal precautions is presented in Table 2.4.

The evidence for sternal precautions remains inconsistent, with no clear support of its routine application as highlighted in Table 2.4; Figure 2.18 and 2.19). While some institutions limit against upper limb movements above shoulder level, as well as scapular adduction, others advised patients not to lift more than five to ten pounds, avoid weight bearing through the upper limbs and/or limit reaching backwards with one upper limb (Figure: 2.18).

Restrictions such as those described above-mentioned are difficult to establish in the scientific literature with no evidence drawn from the clinical setting to support the use of sternal precautions following median sternotomy (Brocki et al, 2010; Cahalin et al, 2011). It seems that the evidence for these restrictions has been derived from studies of cadavers and from orthopaedic research on healing of the long limb bones (Balachandran et al, 2014; McGregor et al, 1999). Previous research that focused on sternal closure methods showed that excessive physiological force can disrupt traditional sternal closure (Cohen & Griffin, 2002; McGregor et al, 1999). McGregor et al, 1999 analysed the application of four types of distracting forces, (lateral, anterior-posterior, cephalocaudal, and a simulated Valsalva force), in multiple directions and found that a force of 220 ± 40 N (Newton) was required to attain 2.0 mm distraction between sternal edges in the lateral direction, 263 ± 74 N in the anterior-posterior direction and 325 ± 30 N in the cephalocaudal direction (McGregor et al, 1999). In a
later study, Cohen and Griffin (2002) analysed the biomechanical characteristics of the three main sternotomy closure techniques, and reported that surgical wires cutting through the sternum resulted in sternal separation. Both these studies, did not inform practice regarding sternal precautions to promote optimal sternal healing. Having no universal guidelines for sternal precautions practice, leaves the arena open to arbitrary sternal precautions practices for physicians and therapists to prescribe their patients, which may hinder optimal physical recovery (Cahalin et al, 2011). McGregor et al (1999) suggested that bilateral upper limb movements may potentially cause activation of the pectoral muscles, counter the sternal closure force by pulling the sternal edges apart and result in separation in the lateral direction. This in addition to the cadaver studies presented above prompted a recommendation to discourage the bilateral use of the upper limbs as this was thought to increase the distractive forces at the sternum. Consequently, health care professionals including surgeons, nurses and physiotherapists routinely reinforce these sternal precautions to patients immediately following surgery in their clinical practice (Cahalin et al, 2011, Brocki et al, 2010; Parker and Adams, 2008; Parker et al, 2008). However, these studies were not conducted in vivo and focused on the efficacy of sternal closure techniques, or sternal complications caused by sternal closure techniques, rather than on the effects of upper limb and trunk motion on sternal healing (Balachandran et al, 2014). As detailed previously measures of motion at the sternal edges obtained in vivo during upper limb and trunk tasks have demonstrated that bilateral upper limb movements are better tolerated than unilateral movements in patients with chronic sternal instability; and resulted in minimal increases in sternal micromotion in patients with SI and those who have had an uncomplicated recovery following conventional sternal close with stainless steel wires respectively (El-Ansary et al, 2007a; Balachandran et al, 2014). Upper limb movements have also been shown to increase circulation to muscles of the anterior chest wall, which may facilitate sternal healing in patients following a median sternotomy, particularly in those who have undergone grafting of the IMA (Celli, 1994; Wallace and Wallace, 1997; Harms, 2000; El-Ansary et al, 2007c). As such, post-operative sternal precautions may not be warranted in all patients following cardiac surgery performed via a median sternotomy (Balachandran, 2015; Balachandran et al, 2017; Adams et al, 2016; Tuyl et al, 2012; Cahalin et al, 2011).

Other factors, such as a stable and enduring approximation, may be more important in promoting sternal union (Balachandran et al, 2017). Parker et al (2008) suggested
coughing, which is considered to be a safe and routine activity immediately post-operatively, creates a larger force (27.5kg-mass) on the sternal incision than lifting 25-lbs. In a related study by Adams et al (2014), the force produced on the sternum during sneeze was reported to be equal to people performing a bench press at 70% of the 1RM with controlled breathing. Therefore, if a sneeze can be tolerated post-operatively, this meant the patients could safely lift 25 lbs of weight (Adams et al, 2014). In a narrative review, Brocki et al (2010) advocated that unsupported, frequent coughing is the single main cause of mechanical stress through the sternum. Indeed, coughing may be a far more significant factor in the development of sternal complications as opposed to restricting activity in people who have undergone a median sternotomy (Tuyl et al, 2012; Balachandran, 2015; Balachandran et al, 2017). Therefore, coughing should not be a routine intervention as it produced the greatest magnitude of sternal micromotion in the lateral direction, as well as sternal pain (Parker et al, 2008, Adams et al, 2014; Balachandran et al, 2017; Brocki et al, 2010). This is consistent with previous biomechanical studies, which reported that coughing increases intra-thoracic pressures to 300mmHg and imposes greater strain to the sternal wires than other upper limb and trunk tasks (Casha et al, 1999; Parker et al, 2008; Brocki et al, 2010; Balachandran et al, 2017). Cahalin et al (2011) recommend that it may be appropriate to tailor sternal precautions based on individual clinical characteristics and risk profile rather than restricting specific functional tasks and physical activity in all patients as presented in the Figure 2.20. It is currently unknown how the effects of clinicians modifying sternal precautions to include the safe use of the upper limbs and trunk impact on sternal recovery and pain following a median sternotomy. The RCT study in Chapter 4 will address this gap in the literature.
**Figure 2.18:** Example of sternal precautions guidelines after cardiac surgery (image adapted from Cahalin et al, 2011, page 7)
Figure 2.19: Example of sternal precautions practiced with less restriction for Inpatient CABG exercise regimen Redrawn from handout obtained from Mary Greeley Medical Center, Ames, Iowa; 2004 (Image adapted from Cahalin et al, 2011, page 7)
Figure 2.20: Proposed algorithm for the stratification of sternal precautions on patient risk factors (image adapted from Cahalin et al, 2011, page 12)
Table 2.4: Literature review on sternal precautions

<table>
<thead>
<tr>
<th>Primary Author (year)</th>
<th>Population</th>
<th>Methods</th>
<th>Findings</th>
</tr>
</thead>
</table>
| Balachandran et al (2014) | Physiotherapists working in outpatient cardiac rehabilitation in Australia | web survey | • No consistency in sternal precautions  
• No consistency in duration of SP  
• Greater restrictions placed on unilateral exercise of the upper limb versus bilateral exercise of the upper limb  
• Greater restriction on loaded exercise versus unloaded exercise |
<p>| Swanson and LaPier (2014) | Cardiac surgery via a median sternotomy | Convenience sample of 15 participants | • SP should be individualised and functionally based. |
| Tuyl et al (2012) | A cross-sectional, observational design: Web based survey | | • Significant variation exists in the sternal precautions and protocols used |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Type of Study</th>
<th>Methodology</th>
<th>Findings</th>
</tr>
</thead>
</table>
| Overend et al (2010)  | Cardiorthoracic physical therapists in hospital setting | A telephone survey (n = 18) of Canadian hospitals                           | - Discrepancies in sternal precautions guidelines  
- Lifting limit was reported as ranging between 5 lb. and 10 lb.  
- Bilateral upper-limb exercises were restricted more commonly than unilateral exercises. |
| Cahalin et al (2011) | Not appropriate                 | Narrative review                                                            | - Inconsistent definition of SP, duration and type.                                                                                   |
| Irion et al (2013)    | Cardiac surgery via a median sternotomy | Observational study                                                         | - Avoiding lifting more than 10 pounds, bilateral shoulder flexion and abduction greater than 8 degrees, reaching behind, pushing up from a bed or chair with extended arms. |
| Brocki et al (2010)   | Not appropriate                 | Literature review on mechanical factors causing sternal instability and infection. | - No evidence was found to support weight limitation regarding activity.  
- Loaded upper limbs movement within pain free and with elbows kept close to body  
- When coughing cross the arms in a “self-hugging” |
<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Description</th>
<th>Study Type</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Westerdahl and Moller 2010</td>
<td>Physiotherapists in cardiac rehabilitation program</td>
<td>National survey of Sweden</td>
<td>• No need for overly restrictive precautions regarding activity</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Sternal precautions were commonly enforced, they also were variable.</td>
</tr>
<tr>
<td>LaPier et al, 2008</td>
<td>Cardiac surgery via a median sternotomy</td>
<td></td>
<td>• Depressed physical function immediately following surgery may be related to surgeon-determined activity restrictions, fear of activity, and/or exacerbation of symptoms from sternal precautions</td>
</tr>
<tr>
<td>Adams et al, 2008</td>
<td>Cardiac surgery via a median sternotomy</td>
<td>Observational study using a simulated lawn mowing protocol matches the pull and push forces in outdoor activities on 13 male post median sternotomy</td>
<td>• Bilateral upper limbs activity using simulated lawn mowing activity did not cause adverse effects on the sternal incision</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• SP should be individualized and functionally based.</td>
</tr>
<tr>
<td>Adams et al, 2006</td>
<td>Cardiac surgery via median sternotomy</td>
<td>Observational study</td>
<td>• Strict post-operative lifting and movement restrictions may be unnecessary</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Methodology</td>
<td>Findings</td>
<td></td>
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</tbody>
</table>
| Adams et al., 2014| Cardiac surgery via a median sternotomy, Observational study.             | • Lifting load more in the range of 90 lbs is safe  
• No need for overly restrictive precautions regarding activity                      |
| Adams et al., 2016| Cardiac surgery via a median sternotomy, Clinical audit                  | • Lifting load and time restriction studies have led to insignificant results.  
• Develop alternative to SP using “Keep your Move in the Tube”. Using standard kinesiological principles based on the ergonomics principles by keeping upper arms close to the body enables the patients to perform movement without discomfort. |
| Ge et al, 2017    | Convenience sample, Cross sectional non-experimental descriptive study  | • Upper limbs activities does not cause mechanical loading to the sternum  
• No need for overly restrictive precautions for shoulder movement and upper limbs activities |
2.6. Outcome Measures

Patients following cardiac surgery, frequently experience impairments in physical function (Cahalin et al, 2011, LaPier et al, 2006; 2008; Min et al, 2014) and HRQoL (LaPier & Wilson, 2007; LaPier, 2007; Jokinen et al, 2010, Kurfirst et al, 2014, Nicolini et al, 2014). This is a growing concern due to the rising prevalence of adults presenting after cardiac surgery at an older age and with greater morbidities (Tran et al, 2013; Kurfirst et al, 2014; Myles, 2014). They are at increased risk of numerous surgical and medical complications in the weeks and months after surgery (Myles, 2014). There is insufficient information about what happens to patients in the months after surgery (Myles, 2014). Therefore, the choice of outcome measures in clinical studies enrolling patients undergoing cardiac surgery is crucial as to provide indication of the patient’s recovery profile and exposure to complications after surgery (Tully, 2013; Myles, 2014). The following section discusses the outcome measures applied in this thesis to address the gaps identified in the literature review as well as the primary and secondary research questions presented in chapter. This chapter will discuss briefly the SPPB and FDQ as functional measures. The detailed of these outcome measures will be discussed in depth on its clinimetric properties in chapter 4 and chapter 5.

**Functional measures**

Functional status in cardiac surgery is measured in two manners: self-report and performance-based measures (Tully 2013; LaPier, 2007). Self-reported measures include basic and instrumental activities of daily living, overall level of physical activity, and self-assessment of physical health. Assessments of basic and instrumental activities of daily living, such as with the use of Functional Status Index, Duke Activity Status Index, Heart Surgery Symptom Inventory, Medical Outcomes Study are self-report instrument and the Katz Index of Activities of Daily Living (ADL) (Tully, 2013; LaPier, 2007). This measures are questionnaires that can easily be administered in the clinical setting to determine level of dependency) (Tully, 2013; LaPier, 2007). Performance-based measures include evaluation of mobility, gait, walking capacity, and grip strength (Tully, 2013; LaPier, 2007). Examples of performance-based measures include the Time and Go test (TUG) (mobility and gait), 6-minute walk test
(gait and walking capacity), the SPPB (overall function) and the use of a handheld dynamometer (grip strength) (Gary, 2012). Objective performance-based measures provide a more valid assessment than self-report measures following cardiac surgery especially for older adults who either do not walk long distances in their daily lives or have an inaccurate perception of how much they walk (LaPier, 2007; Vasunilashorn et al, 2009, Tully, 2013). Identifying valid and reliable measures of mobility disability is particularly important to improve randomized clinical trials (Vasunilashorn et al, 2009).

2.6.1 Primary Outcome Measure

**Short Physical Performance Battery**

The SPPB was selected as it assesses overall function performance that reflects physical function required of everyday tasks following surgery until the months follow as it encompasses several of the items necessary for daily function. It is hypothesized that the intervention designed in Chapter 3 will impact on overall functional performance as this is the primary concern of most patients at medium to long term follow up (6 weeks to 12 months) (Min et al, 2015; Molino-Lova et al, 2013). The SPPB holds considerable promise as an outcome measure as it is a practical, feasible and brief test to conduct in the clinical setting. Besides, the SPPB instrument being one of the most widely used outcome measures (Freiberger et al, 2012; Pavasini et al, 2016), this outcome measure was also selected due to its high validity and reliability. The test has established validity and reliability in measuring physical performance in the elderly (Guralnik et al, 2000; Pahor et al, 2006; Studenski et al, 2003) with intra-class correlation coefficient (ICC) equal to 0.82m (Studenski et al, 2003) and is a strong predictor of disability in non-disabled older persons (Guralnik et al, 1995). Furthermore, several studies used the SPPB instrument or component of SPPB as an outcome measure reporting on patient undergoing cardiac rehabilitation (LaPier, 2012; Molino-Lova et al, 2013) or general rehabilitation (Perera et al, 2006). The minimal detectable change values range from 0.54 (Perera et al, 2006) to two points (Volpato et al, 2008), which suggests that, a change in physical performance of one to two points is a clinically meaningful change in an older (Perera et al, 2006) and in-patient stable cardiovascular population (Volpato et al, 2008). The SPPB has been shown to be
reliable, valid, and sensitive to change (Ostir et al, 1998). ICC ranged from 0.88 to 0.92 for measures made one week apart, with a six months average correlation coefficient of 0.78 (Ostir et al, 1998).

The SPPB test includes gait speed (8-foot walk), standing balance, and lower extremity strength and endurance (chair rise task). These areas represent essential tasks important for independent living and are thus an important outcome measure for patients with cardiovascular disease and following surgery. It is comprised of the following:

i. **Gait speed (Figure 2.21):** participants will be instructed to walk a distance of 8 feet as determined by traffic cones on a flat surface at their normal comfortable pace. The average of two trials will be used. For safety reasons, participants are encouraged to walk with their gait aids if these are usual or part of their post-operative care at the time of testing.

*Figure 2.21: Gait speed on 8 feet walking course (courtesy of University of Melbourne image library 2016)*
ii. **Standing balance (Figure 2.22):** participants were assessed in three different static positions (side by side stand, semi-tandem stand and tandem stand). Participants will be instructed to try to hold each of these positions for 10 seconds.

![Standing balance](image)

**Figure 2.22:** Standing balance with side-by-side stand (courtesy of University of Melbourne image library 2016)

iii. **Chair rise task (Figure 2.23):** participants were instructed to stand up and sit down 5 times in a row as quickly as possible.
Figure 2.23: Chair rise 5 times in a row (courtesy of University of Melbourne image library 2016)

The Short Physical Performance Battery score is based on timed measures of standing balance, walking speed, and ability to rise from a chair. Each test is scored on a scale of zero to four points, with a summary performance score range of zero to 12 points using cut point criteria established by Guralnik et al (2000). A zero score indicates poor function whilst 12 indicates excellent function. If the participant is unable to perform a specific test, a score of zero (0) will be assigned. A score of 10 or lower is considered the cut point for mobility impairment (Guralnik et al, 2000). Detailed instructions for the SPPB are listed in Appendix 7 and a sample score sheet is given in Appendix 7. The SPPB has sufficient clinical clinimetric properties making it a useful tool for measuring outcomes, however, the amount of improvement that reflects a clinically meaningful change needs to be established to enhance clinical utility following cardiac surgery via a median sternotomy. However, the MCID of the SPPB for assessing physical function for patients specifically following cardiac surgery is unknown. Establishing this value is important to allow clinicians to accurately interpret changes in patient outcomes using the SPPB across time following cardiac surgery. Understanding improvements in the SPPB can be used to facilitate evaluation of rehabilitation interventions and patient recovery, evaluate treatment effectiveness and guide individual care plans including phase I/II cardiac rehabilitation programs.
2.6.2 Secondary Outcome Measures

*Functional Difficulties Questionnaire*

The Functional Difficulties Questionnaire (FDQ) is a new developed questionnaire designed by Melbourne team of researcher to assess functional outcomes post cardiac surgery. The FDQ focus on thoracic and shoulder movement assessment as the thoracic region is directly affected by the surgical process in the acute and subacute stages of recovery. It comprises 13 separate functional tasks, likely to cause difficulty following CS based on previous literature reviewed (Hoggins, 2009; Levangie and Norkin 2005; El Ansary 2000b; Neumann 2002) and are listed below.

Upright sitting (Question 1)

Walking with arms swinging freely

Coughing/sneezing

Rolling over in bed

Getting out of bed

Washing hair

Scratching back

Sitting and picking an object off the ground by leaning sideways

Sitting and turning to reach behind oneself

Doing up a bra or tucking in shirt at the back of pants

Putting on a dressing gown/cardigan/jacket which highlighted previous reports of difficulties with functional tasks following CS.

Drying the back with a towel

Pushing shut drawers

It is an inexpensive tool, which can be easily administered in the clinical settings and suitable for use pre-operatively and post operatively. It takes less than 15 minutes to
administers and easy to use on average. The cost of administration of the tool is negligible as the items on the FDQ are often completed by a physiotherapist as part of an initial examination before or after cardiac rehabilitation classes.

The questionnaire asks patients to rate the difficulty they experience when completing a series of thirteen upper limb and trunk functional tasks. Participants were required to mark on an unmarked 10cm VAS the level of difficulty they experienced when completing each of the tasks, based on the last time they completed each activity, or to complete the activity whilst undertaking the survey, where appropriate. If the participant could not complete tasks, it was score as a 10, to indicate maximal difficulty. Individual VAS scores, measures to nearest centimetre, were aggregate to form a total out of a possible 130, with the higher scores representing greater difficulty experienced during functional activities (Appendix 7)

Previous research has demonstrated that the FDQ is a valid and responsive measure in this patient population and has been used to measure the functional status of patients following cardiac surgery, in both the short term (four weeks post-operatively) and long term (three months post-operatively) (Hoggins, 2009). The questionnaire has good internal consistency with Cronbach’s alpha coefficient of 0.971. Hoggins (2009) has established the questionnaire’s criterion related validity by testing its concurrent validity with measures of HRQOL, pain, functional mobility and thoracic and shoulder range of movement. There was moderate to good correlations between FDQ scores and: 1) the Short Form 36 Vitality and Mental Health domains; 2) shoulder pain; 3) sternal pain and 4) total pain. The FDQ score was found to have the strongest correlations with sternal pain (r=0.60) and total pain (r=0.69) scores (Hoggins, 2009). With respect to reliability, the FDQ has demonstrated good internal consistency, with a Cronbach alpha coefficient of 0.97 (Hoggins, 2009). The FDQ is also responsive to change, demonstrating a significant decrease in total scores from pre-operative to post-operative measures, and a significant decrease in total scores as time after surgery increased from: 1. immediately post-operatively to four weeks post-operatively and 2. four weeks post-operatively to three months post-operatively (Hoggins, 2009). The tool is easily administered in the clinical setting and suitable to track patient progress. It takes less than 10 minutes to administer and requires little training for the patient to complete. In
addition, the FDQ-s is within the International Classification of Functioning, Disability and Health framework as it captures impairment, activity limitation and participation restrictions across the continuum of recovery (WHO, 2001) in the target population. It is a potential tool to be used in clinical practice and to evaluate interventions.

**Hand Grip Strength**

Hand grip strength (HGS) has now been widely reported or used as an outcome measure in older patients with CVD. HGS is a proper predictor of immune system, nutrition, aging process, bone density, overall body strength, especially in old age group (Smith et al, 1989). Several epidemiological studies have shown that muscular weakness in middle-aged and older individuals is strongly related to functional limitations and physical disability (Hairi et al, 2010; Hirsch et al, 2012; Rantanen et al, 1999). HGS assessment is gaining as important measures in cardiac rehabilitation protocols since it is a predictor of multimorbidity than chronological age (Cheung et al, 2013). Studies have shown age, gender, and body mass index influence handgrip strength (Mangione et al, 2010; Steinwachs et al, 2000; Gary, 2012). In a large cohort study of one million Swedish men, muscle strength in young adulthood was an important predictor of coronary heart disease and stroke risk in later life, and this association persisted for both normal weight and obese individuals (Silventoinen et al, 2009). Men have been reported to have higher handgrip strength than women (Cheung et al, 2013), and a decline in strength occurs around 40 years old in both genders (Sayer et al, 2006; Gale et al, 2007; Gary, 2012). Handgrip strength is also highly correlated with peak VO2, adverse clinical events, and outcomes such as falls, disability, prolonged hospital stays, and reduced HRQOL in older adults (Sayer et al, 2006; Gale et al, 2007; Gary, 2012). In addition, studies among older people have further suggested that there is a strong association between low muscle strength and both cognitive impairments and the risk of neurodegenerative diseases (Shin et al, 2012; Gustafsson et al 2015; Buchman et al, 2007; Alfaro-Acha et al, 2006). Leong et al (2015) has reported that HGS is generally lower for patients following cardiac surgery and this is reported to be an indicator of general health, cardiovascular risk and disease (Leong et al, 2015) The assessment is simple, is easily measured, and provides an approximation of overall muscle strength (Gary, 2012). Two previous studies demonstrated that HGS are reliable and responsive
physical performance measures for patients in cardiac rehabilitation with findings support their use in clinical practice and cardiac rehabilitation after cardiac surgery via sternotomy (Puttoff et al, 2013; Mroszczyk-McDonald et al, 2007). The later study reported hand grip strength for 1960 patients enrolled in cardiac rehabilitation and found strong correlation to age, gender, and self-reported function (Mroszczyk-McDonald et al, 2007).

There is wide variability in the choice of equipment and protocol for measuring grip strength. The Jamar hand dynamometer is the most widely used instrument with established test–retest, inter-rater and intra-rater reliability (Robert et al, 2011). In this study, the HGS was measured in kilograms with a hand-held JAMAR dynamometer (Sammons Preston Rolyan, Brooklyn, USA) (Figure 2.24). There is evidence that variation in approach can affect the values recorded hence the need for a standard protocol to improve the validity of assessment. HGS was measured in kilograms with a hand-held JAMAR dynamometer (Sammons Preston Rolyan, Brooklyn, USA). The participant was tested in the position recommended (Fess, 1992). The peak value of the maximal squeeze over five seconds will be recorded (Peolsson et al, 2001). The time interval were allowed between tests were short and were approximately 2 minutes to allow for recovery. Previous study has found similar test–retest reliability with one trial alone, the mean of two or three trials and the maximum of three trials (Hamilton et al, 1994). In addition, due to influences of pain after surgery, the average may not reflect of true performance. Therefore, in this study three serial tests of maximum grip strength with the dominant hand will be performed, and best of the three values will be recorded. Hand-held dynamometry is a reliable, objective tool for muscle strength measurement (Roberts et al, 2011), and a predictor of postoperative complications, mortality, and functional decline (Bohannon, 2001). The test is a reliable and responsive measure for patients in cardiac rehabilitation (intra-class correlation coefficient right and left hand grip strength = 0.97) (Puthoff & Saskowski, 2013). A recent population based study in the Prospective Urban-Rural Epidemiology study of 140,000 adults from 17 countries reported a decreased in grip strength showed highly significant inverse associations between grip strength and all-cause, CV, and non-CV mortality, as well as MI and stroke (Leong et al, 2015). In addition, grip strength was a significantly stronger predictor of all-cause mortality than systolic blood pressure (Cheung et al, 2013).
Kinesiophobia

Kinesiophobia, refers to the anxiety that many individuals with persistent pain experience regarding engaging in activities or physical movements (Kori et al, 1990). The onset and development of kinesiophobia is typically in response to previous movement that produced significant pain during recovery or periods of disability (Pells et al, 2007, Vlaeyen et al, 1995; Kori et al, 1990). This fear possible is based in an irrational perception that movement will produce excessive pain or further (re)-injury in the absence of experiential evidence in a small number of patients (Vlaeyen and Linton, 2012). Pain-related fear is a particular characteristic of patients in subjects hospitalized for acute CV disease when compared with stable CAD and healthy controls (Back et al, 2013; Brunetti et al, 2017). A high level of kinesiophobia can be found in 20% of patients with CAD attending cardiac rehabilitation (Back et al, 2013). These patients often presented with low level of physical activity, general health, and physical functioning (Back et al, 2013). In a related study on 62 patients with a first episode of
acute coronary syndrome compared with controls, patients attending exercise-based cardiac rehabilitation led by a registered physiotherapist demonstrated higher levels of fear-avoidance beliefs at baseline (48%), which decreased over time (21%) at follow-up (Ahlund et al, 2013). Furthermore, attendees increased their level of physical activity and exercise over time. The authors advocate the important of exercise-based cardiac rehabilitation with myocardial infarction, especially for those with increased fear of movement (Ahlund et al, 2013).

Kinesiophobia can lead to the stopping/reduction of various activities though to generate pain with progressive limitation of mobility in some individuals (Brunetti et al, 2017; Herbert et al, 2015; Pells et al, 2007, Vlaeyen et al, 1995; Kori et al, 1990). The consequent disuse and deconditioning generate further loss of muscle tone, flexibility, and aerobic capacity (Back et al., 2013, Hartigan et al, 2013). Clinicians who treat patients with CVD (Ahlund et al, 2013; Back et al, 2013) especially following with cardiac surgery via sternotomy have often observed that they reduce physical activities as a way of limiting their experience to pain (Back et al, 2016). It is unknown whether fear of experiencing pain, fear of activities that may elicit pain (e.g. work and physical activity), fear of movement/(re)injury, and pain-related anxiety will cause the patients to restrict their activity level below than recommended by health practioners following cardiac surgery. Whether this cycle of pain and decreased physical activity is associated with fear of movement, or kinesiophobia has yet to be explored with individuals following cardiac surgery via sternotomy. Vlaeyan and Linton (2012) postulated that fear of pain leads to activity avoidance and therefore functional limitations.

Studies has reported that patients often reduce their activity levels in response to painful episodes (Roelofs et al, 2007; Vlaeyan and Linton, 2013; Crombez et al, 2005; Ahlund et al, 2013; Back et al, 2013) but little is known about physical inactivity and anticipatory behaviours associated with prior onset of anterior chest, sternal or leg pain in these populations (Back et al, 2016). Pain related fear has been reported to influence attendance at exercise based cardiac rehabilitation (Back et al, 2016). Since physical activity/exercise is a crucial part of rehabilitation programs after cardiac surgery, it was hypothesized that kinesiophobia may have been a contributing factor that influenced
physical recovery (Back et al, 2013; Hartigan et al, 2013). Kinesophobia should therefore be acknowledged in patients following cardiac surgery in the immediate post-operative period (Back et al, 2013). Research is needed to assess the interrelationship between kinesiophobia and functional recovery in the target population.

Kinesiophobia was measured by an 11-item version of the Tampa Scale of Kinesiophobia (TSK-II). The Tampa Scale of Kinesiophobia (TSK-II) is a widely used tool to measure pain related fear beliefs about movement and re-injury (Kori et al, 1990). This tool is an adaptation of the original 17-item instrument (Kori et al, 1990), designed to assess fear of movement or re-injury that excludes the four original reverse-scored items that were found to have small item-to-total score correlations. The 11 items of the scale each have four response options; all anchored with the answers “strongly disagree”, which scores one point, and “strongly agree”, which scores four points. The total sum score is calculated and can range between 11 and 44 points. Considering the whole range of the scale (11–44 points), a change of more than 10% should reasonably be corresponding to a clinically relevant change and equivalent to a change of more than three points on TSK-11 (Woby et al, 2005; Larsson et al, 2014). Therefore, a reduction of at least four points on the measure maximises the likelihood of correctly identifying an important reduction in fear of movement (Woby et al, 2005). TSK-II is a reliable and valid measure of fear of movement or re-injury in patients with chronic pain (Larsson et al, 2014; Tkachuk & Harris, 2012; Woby et al, 2005). TSK-II has been clinimetrically evaluated and has shown good construct validity and reliability among older people (i.e. internal consistency (Cronbach alpha, 0.74–0.87) and test-retest reliability (ICC r = 0.747) (Larsson et al, 2014). It has internal consistency, reliability, and convergent validity with Cronbach’s α was 0.80 for the total score (Tkachuk & Harris, 2012).

2.6.3 Pain Measurements

Most measures of pain are based upon self-report but can provide sensitive and consistent results if performed properly (Main and Denehy 2016). Several different
instruments may be used to measure pain, including: numerical rating scales (NRSs), verbal descriptor scales (VDSs), pain questionnaires (e.g. The McGill Pain Questionnaire – Short Form version 2 (SF-MPQ-2), visual analogue scales (VASs). There is an extensive literature regarding the use of these measures to assess the results of an intervention or to measure intensity of pain, such as post-operative pain. The Joint Commission on Accreditation of Healthcare Organization in the United States has set standards for the assessment of pain in hospitalized patients. It is recommended that pain assessment should integrate pain intensity (NRS, VDS), pain affect (MPQ-2) and pain drawing that visually represents a description of the pain to allow for more comprehensive assessment (Haefeli and Elfering 2006). Pain assessment should be ongoing, individualized, and documented. Patients should be asked to describe their pain in terms of the following characteristics: location, radiation, mode of onset, character temporal pattern, exacerbating and relieving factors, and intensity (Haefeli and Elfering 2006). Measure such as Patient Identified Cardiac Pain (PICP) using Numeric and Visual Prompts and MPQ2 fit the criteria above mentioned. However, the PICP measure was commonly used in acute coronary syndrome patients and it was never tested on cardiac surgery via sternotomy. For the purpose of this thesis, the focus was on the assessment of pain following cardiac surgery performed via a median sternotomy, in an English speaking population. Based on the above recommendation The PICP and MQ-2 was selected as pain outcome measure in the study.

The Patient Identified Cardiac Pain using Numeric and Visual Prompts (PICP)

This was a pain outcome measurement tool that was developed by Teoh et al (2007). Participants were required to complete a brief three questions survey. To identify the locations of their pain or discomfort symptoms, participants were asked to draw on a schematic diagram of the front and back views of the upper body regions. They were also required to identify their ‘chief’ or ‘main’ symptom, describe its nature by pointing to pictorial identifiers that visually represents a description of the pain (i.e., stabbing, heavy, shooting, burning, squeezing) (Teoh et al, 2007). The intensity of the pain forms the last domain and utilises a Likert-type scale (Numerical Rating Scale (NRS) of pain), as seen in Appendix 7. This was performed by the researcher through an interview with the patient, who was asked about the presence of pain at the moment of this assessment.
The NRS, ranging from 0 to 10 and where 0 means absence of pain and 10, the worst pain ever felt, was used to quantify this symptom. The PICV was selected as it evaluates multiple dimensions of pain and discomfort, is easy to administer and accounts for cultural diversity (Teoh et al, 2007). Participants were also instructed to shade areas on a body chart for pain presentation and location.

The McGill Pain Questionnaire – Short Form version 2 (SF-MPQ-2).

The McGill pain Questionnaire (MPQ) was developed in 1975 (Melzack 1975). However, the large number of items it contains makes it too time intensive for routine clinical practice (Melzack 1987). Dworkin et al (2009) expanded the SF-MPQ-2 (Short-form McGill Pain Questionnaire-2), which in addition to a more accurate 10-point pain rating scale, also includes 7 questions assessing pain caused by neurological disorders. This version was tested on patients with chronic pain syndromes and painful diabetic neuropathy. Excellent validity and reliability was found for this new version (Dworkin et al, 2009; Lovejoy et al, 2012; Gauthier et al, 2014; Dworkin et al, 2015) and has been translated into multiple languages (Maruo et al, 2015; Kachoovei et al, 2015; Adelmanesh et al, 2012). In this updated version, the SF-MPQ-2 is more versatile (Lovejoy et al, 2012; Gauthier et al, 2014; Dworkin et al, 2015) as it can evaluate nociceptive pain (Maruo et al, 2015; Dworkin et al, 2009; Lovejoy et al, 2012), which is a common symptom following cardiac surgery via sternotomy (Muller et al, 2000; Macrae et al; 2001; Alston & Pechon, 2005). The McGill Pain Questionnaire (MPQ) has become one of the most widely used tests for the measurement of pain (Melzack 1987, Dworkin et al, 2009) and following cardiac surgery via sternotomy (Watt-Wattson 2004, Yorke et al, 2004). It provides valuable information on the sensory, affective and evaluative dimensions of pain experience and is capable of discriminating among different pain problems (Dworkin et al, 2009; Lovejoy et al, 2012).

The Short Form McGill Pain Questionnaire version two consists of 22 items investigating four dimensions of pain quality (Continuous, Intermittent, Neuropathic and Affective) on an 11-point numerical rating scale (Dworkin et al, 2009; Lovejoy et al, 2012; Gauthier et al, 2014). The total score is calculated from the mean of 22 items,
and scores for the 4 dimension subscales is calculated from the mean of the items included in each subscale. Scores on each subscale can range from zero (0) to 10. A higher score indicates a more severe pain (Lovejoy et al, 2012). Participants was instructed to choose the number that best describes their intensity of pain and related symptoms experienced during the past week. Zero was assigned if the word did not describe their pain or related symptoms. The tool is reliable and comprehensive tool for pain quality assessment following cardiac surgery via a median sternotomy. The original version of scale, The Short Form McGill Pain Questionnaire (SF-MPQ-2) has well-established reliability in cardiac populations with alpha coefficients ranging from 0.75 to 0.83 across various post-operative days (Puntillo et al, 1994; Yorke et al, 2004). The SF-MPQ-2 is sensitive to change in chronic pain, and total and subscale scores are responsive to change, and the changes are associated with patient ratings of global improvement in clinical trials (Lovejoy et al, 2012).

The Medical Outcome Study 36-Item Short Form Health Survey version 2 (SF36-V2)

An overall measure of quality of recovery after surgery is useful in that it can provide a global measure of outcome from the patient’s perspective (Mailard et al, 2015; Myles et al, 2014; Tully, 2013; Jokinen et al, 2010). This is significant as most patients scheduled for cardiac surgery have a significant previous history of physical and psychological suffering that impairs their HRQoL (Afilao et al, 2010; Min et al., 2015; Tully, 2013; LaPier, 2003a). It is acknowledged that HRQoL are important patient-centered outcomes, which may reflect how well patients can function in the months and years after cardiac (Mailard et al, 2015; Myles et al. 2014; Tully, 2013; Jokinen et al, 2010). Therefore, this measure should be part of outcome measure after surgery in order to identify the interventions that offer the patients more benefits in terms of their well-being and functioning (Mailard et al, 2015; Myles et al, 2014; Jokinen et al, 2010). A poor HRQoL score have been shown to reflect poor patients satisfaction with surgery, poor perioperative management and may incur increase in health care utilisation (Mailard et al, 2015; Myles et al. 2014; Jokinen et al, 2010).
Two most commonly used to measure HRQoL are (1) Generic quality of life measures which are applicable to a range of health conditions other than heart disease (e.g., cancer, Parkinson’s disease, arthritis, etc.) (2) Disease-specific measures designed to measure particular aspects of QOL affected by a specific condition (e.g., MI) Tully et al., 2013. Three most commonly used are the Nottingham Health Profile (NHP), the Sickness Impact Profile (SIP) and the Medical Outcome Study 36-Item Short Form Health Survey (SF36-V2) (LaPier, 2003; Tully, 2013). All three of the mentioned generic instruments cover the key areas of physical, social, and emotional functioning. However, the later measure will be discussed as it is the most widely used tools for the evaluation of HRQoL following cardiac surgery (Tully, 2013). The SF-36-V2 and the NHP have been reported to have better content validity in the field of cardiac surgery because each covers energy/vitality and bodily pain (Tully, 2013). This subscale is important aspect following cardiac surgery recovering for ischemic heart diseases and procedures involving sternotomy (Tully, 2013). Falcoz et al. (2002) compared the SF-36 and NHP on 299 patients undergoing cardiac surgery at baseline and 5 weeks post-operatively. The study suggested the SF-36 is more favourable in comparison to the NHP with acceptable clinimetric properties and sensitivity to change in angina and dyspnoea following cardiac surgery via sternotomy (Falcoz et al, 2002). This study also established the SF-36 as a useful generic quality of life measure for the target population (Jokinen et al, 2103; LaPier, 2007; Falcoz et al, 2002). While generic measures such as the SF-36 (Ware & Sherbourne, 1992) are valid and reliable, some of the subscale are likely to be less sensitive in detecting treatment effects (Hirschhorn et al, 2008; Guyatt et al, 2007; Takousi et al, 2016; Wiebe et al, 2003) especially following cardiac surgery via a median sternotomy (Hirschhorn et al, 2008; Jokinen et al, 2010; Schroter & Lamping, 2004). For example, in a rehabilitation program, the results of a generic measure led to the conclusion that the program did not improve quality of life despite improving in walking capacity from hospital (Hirschhorn et al, 2008). There is no accurate quality of life measure to administer as to better inform treatment efficacy studies and clinical decision-making (Tully, 2013). However, this measure is needed to look into the broader impact of health (or surgery) for patients’ recovery particularly in the mid and longer term period following cardiac surgery (Min et al, 2015; Tully, 2013; Jokinen et al, 2010).
Therefore, the Medical Outcome Study 36-Item Short Form Health Survey (SF36-V2) is used to measure HRQoL following cardiac surgery (Jokinen et al, 2010; Tully, 2013). This tool assesses eight domains including: physical functioning, role physical functioning, role emotional functioning, mental health, vitality, social functioning, bodily pain and general health. The broad dimensions of subscale are consistent with the recommendations of the World Health Organization for a generic health-related QOL instrument (WHOQOL Group, 1993). It provides multidimensional clinimetrically sound to measure overall health status. The scores are presented as norm-based T-scores (mean 50, SD=10), relative to Australian population norms (Ware et al, 2000). Responses are recorded on a five-point Likert scale and then transformed onto a 100-point scale on which a higher score (>50) represents a better health state and less pain. Norm-based physical and mental component summary (PCS, MCS) scores were also calculated from raw sub-scale scores with higher scores indicating better quality of life; while a high score on the bodily pain score indicates freedom from pain (Ware et al, 2000). The scale has good reliability with Cronbach’s α ranging from 0.65 to 0.96 for all subscales (Falcroz et al, 2002). The instrument can differentiate between levels of health among post CABG individuals at a single time point, and over time. Furthermore, the SF36-V2 is valid in written format, as well as verbal administration over the telephone in cardiac patients. Additionally, it required short time to answer the questions (approx. 15 min) surgery (Tully, 2013).

**The Sternal Instability Scale (SIS):** The SIS is a manual test based on a 5-point scale. The scale was established to assess and monitor the stability of sternum in patients following cardiac surgery via a sternotomy (El-Ansary 2000b). The test involves manual palpation of the sternum along the median sternal ridge, and the allocation of a single grade that reflects the instability (El-Ansary 2000b) (Figure 2.25 a-d). This test assesses the motion and the degree of separation between the sternum edges during dynamic movement of upper limbs and trunk including shoulder flexion and abduction, trunk rotation and lateral flexion, deep inspiration and coughing (El-Ansary 2000b). In line with the clinical presentation of sternal instability, the test should be conducted for the upper half of the sternum and the lower half of the sternum to account for regional variation. To ensure that the testing procedure is standardised a checklist was developed to facilitate consistency of testing (Table 2.5) (El-Ansary 2000b).
Table 2.5: Standardisation when testing for sternal instability

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Record the position of testing: standing/sitting.</td>
<td>Place the palpating fingers of one hand along the median sternal</td>
</tr>
<tr>
<td></td>
<td>ridge and the other hand on the posterior aspect of the thoracic</td>
</tr>
<tr>
<td></td>
<td>cage for support.</td>
</tr>
<tr>
<td>Note the degree of separation.</td>
<td>Note the extent of excessive motion.</td>
</tr>
<tr>
<td>Eliminate other sources of “clicking” (e.g. crepitus at other</td>
<td>Co-relate subjective with objective findings.</td>
</tr>
<tr>
<td>joints in the region such as the costochondral joints).</td>
<td>Assign the grade that best matches the findings.</td>
</tr>
</tbody>
</table>

Originally, the SIS was based on five-point scale anchored by a score of zero which corresponded to a clinically stable sternum (with no detectable motion or separation of the sternal edges) and grade four, which corresponded to completely separated sternum (with marked increased motion or separation of the sternal edges) (Table 2.6).
Figure 2.25: a to d:

Manual palpation of the sternum along the median sternal ridge (using three fingers) to assess sternal stability a) palpation of the upper half of the median sternum model and b) palpation of the upper half of the median sternum using a sternal model c) palpation of the upper sternum and d) lower half of the sternum in vivo.

Table 2.6: The original five-point sternal instability scale (SIS)

<table>
<thead>
<tr>
<th>Grades of Motion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No detectable motion (normal).</td>
</tr>
<tr>
<td>1</td>
<td>Slight increase in motion upon special testing(^a) with no significant bony separation</td>
</tr>
<tr>
<td>2</td>
<td>Moderate increase in movement upon special testing(^a) and with activities of daily living (i.e. walking) Minimal bony separation &lt; finger space. Audible/palpable clicking/crepitus may be present.</td>
</tr>
<tr>
<td>3</td>
<td>Marked instability with marked sternal separation &gt; 1 finger space</td>
</tr>
<tr>
<td></td>
<td>Complete instability &gt; 1.5 finger spaces(^b)</td>
</tr>
</tbody>
</table>
special testing included: bilateral upper limb forward flexion, abduction; trunk rotation, lateral flexion. The sternum can be further challenged with coughing, and opposing movements of the upper limb (e.g. flexion, abduction, and external rotation of the upper limb accompanied by extension, adduction, and internal rotation of the other upper limb.\textsuperscript{b} 1 finger space=1.0-1.25cm (wide).

In prior research the validity and reliability of the SIS was demonstrated in patients following a median sternotomy (El-Ansary et al. 2000b). It was reported to have excellent inter and intra-rater reliability, with intra-class correlation coefficients of 0.97 and 0.98 respectively (El-Ansary et al, 2000b). Recently it was modified to a 4-point scale (El-Ansary et al, 2011) (Table 2.7). A score of 0 corresponds to a clinically stable sternum with no detectable motion or separation of the sternal edges, whilst a score of three corresponds to a completely separated sternum with marked increased motion or separation of the sternal edges (El-Ansary et al, 2011).

Table 2.7: Modified four-point sternal instability scale (SIS)

<table>
<thead>
<tr>
<th>Grades of Motion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Clinically stable sternum (no detectable motion) – normal.</td>
</tr>
<tr>
<td>1</td>
<td>Minimally separated sternum (slight increase in motion upon special testing\textsuperscript{a} - upper limb, trunk).</td>
</tr>
<tr>
<td>2</td>
<td>Partially separated sternum - regional (moderate increase in movement upon special testing\textsuperscript{a}).</td>
</tr>
<tr>
<td>3</td>
<td>Completely separated sternum - entire length (marked increase in motion upon special testing\textsuperscript{a}).</td>
</tr>
</tbody>
</table>

\textsuperscript{a}special testing included: bilateral upper limb forward flexion, abduction; trunk rotation, lateral flexion. The sternum can be further challenged with coughing.
2.7 Conclusions

This chapter provided a critical appraisal of the current literature pertaining to CVD, with a focus on CHD and the surgical management of this condition. It also provided a literature review on common post-operative complications and the physiotherapy management of the patient following cardiac surgery via a median sternotomy. The foundational studies that have examined the effects of upper limb movements and tasks in vivo conducted by El-Ansary et al, 2007a and Balachandran et al, 2014 have informed an enquiry about the warranty of the widespread and routine prescription of sternal precautions and subsequent upper limb restrictions. This has prompted the development of a study protocol for a randomised controlled trial to examine standard restrictive sternal precautions versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy. This is presented within the next chapter.
Chapter 3:
The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

Chapter Overview

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This study was published in 2017

Author contributions for this chapter are the following:
KMA, DE, LD, and CG conceived the idea for the paper. KMA, DE, LD, AR, CR, and CG contributed to research design. KMA, DE, LD, and CG contributed to data
3.1 Background

Cardiac surgery via a median sternotomy is performed in over a million cases worldwide (Epstein et al, 2011; Go et al 2014) as it provides the best clinical outcome for patients with multiple vessel disease and comorbidities (Authors/Task Force et al, 2014; Cheng & Slaughter, 2013; Deb et al, 2013; Rosenfeldt et al, 2012; Taggart, 2013b). Despite these advantages, the incidence of sternal complications has remained relatively unchanged for the last two decades, and is reported to be between 0.4 to 8% worldwide (Balachandran et al, 2016; Cahalin, et al 2011; Mazzeffi & Khelemsky, 2011; Tran et al, 2013). Sternal complications include dehiscence, wound infection, sternal instability/non-union and mediastinitis (Balachandran et al, 2016). These complications are associated with significant morbidity, prolonged hospital length of stay and contribute to increasing health care costs (Balachandran et al, 2016; Cahalin, et al, 2011; Mekontso, et al 2011).

To prevent sternal complications, the routine implementation of sternal precautions that place restrictions on the use of the upper limbs and trunk, commences immediately post-operatively. These precautions are used worldwide although they are applied for variable periods of time (four weeks to three months) post-operatively (Balachandran et al, 2014; Cahalin et al, 2011; Tuyl et al, 2012). The evidence to support sternal precautions is limited to cadaver and replica bone model studies (Fedak et al, 2010; McGregor et al, 1999). In a foundational study, McGregor found that a force of $220 \pm 40$ N (Newton) was required to attain $2.0$ mm distraction between sternal edges in the lateral direction; $263 \pm 74$ N in the anterior-posterior direction and $325 \pm 30$ N in the rostral-caudal direction (McGregor et al, 1999). This prompted a recommendation to discourage the bilateral use of the upper limbs as this was thought to increase the distractive forces at the sternal edges (McGregor et al, 1999). From the outset, health care professionals including surgeons, nurses and physiotherapists routinely reinforced sternal precautions in their clinical practice. However, a recent study demonstrated that
upper limb and trunk tasks cause only minimal micromotion of the sternal edges (< two mm) as measured by real-time ultrasound, and this was the case for all tasks including bilateral and unilateral arm elevation (Balachandran, 2015). Based upon these data, restricting the use of upper limbs and trunk in an attempt to prevent excessive sternal motion may not be required. Sternal precautions in the form of physical restrictions may delay recovery, prolong return to function and delay hospital discharge, and as such may be overly restrictive (Adams et al, 2008; Brocki et al, 2010; Cahalin et al, 2011). Upper limb and trunk exercises are encouraged as part of post-operative care to promote recovery and return of function (Adams et al, 2008; Balachandran et al, 2014; Cahalin et al, 2011; Tuyl et al, 2012). Sturgess et al (2014) found that exercises of the trunk and upper limb significantly reduced sternal pain during the first six weeks post–operatively (Sturgess et al, 2014). The prescription of such exercises alongside sternal precautions poses a clinical dilemma as they contradict each other (Balachandran, et al 2014; Cahalin, et al 2011; Tuyl et al, 2012). Further, physical activity and upper limb exercises may be imperative for healing and remodelling of bone, which responds to loading (Harm, 2000; Cahalin et al, 2011).

3.1.1 Trial Objective and hypothesis

The primary aim of this study is to evaluate the effectiveness of a program of modified sternal precautions on physical function compared with standard care sternal precautions following cardiac surgery via a median sternotomy at four weeks post-operatively. We hypothesize that those receiving the modified sternal precautions will have improved physical function at four weeks post-operatively compared to participants receiving standard care precautions. The secondary aims are 1) to evaluate the effectiveness of modified sternal precautions compared with standard care on sternal pain and discomfort, kinesiophobia, and HRQoL at four weeks and three months post-operatively; and on physical function at three months post-operatively.; 2) to measure the participant’s adherence to sternal precautions and 3) to explore whether demographic, comorbidities and/or pre, peri and post-operative risk factors are associated with the development of post-sternotomy complications. This will be an
3.2 Method

The methods are reported in accordance with the Standard Protocol Items: Table 3.1: World Health Organization (WHO) Trial Registration Data Set for SMART. Recommendations for Interventional Trials (SPIRIT) guidelines for clinical trials (Chan et al, 2013) (see Additional file 1, Table 3.2) and the Template for Intervention Description and Replication (TIDieR) (Yamato et al, 2016) reporting of interventions (see Additional file 2, Table 3.3).

Table 3.1: World Health Organization (WHO) Trial Registration Data Set for SMART.

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<th>DATA CATEGORY</th>
<th>INFORMATION</th>
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<td>Secondary identifying numbers</td>
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<td>Trial protocol version</td>
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<td>Primary sponsor</td>
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<td>Secondary sponsor</td>
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</tr>
<tr>
<td>Contact for public queries</td>
<td>Professor Alistair Royse</td>
</tr>
</tbody>
</table>
### Contact for scientific queries
Dr Catherine Granger

### Public title
Sternal Management Accelerated Recovery Trial (S.M.A.R.T.):
The efficacy of modified sternal precautions on improving physical function in patients following cardiac surgery via a midline sternal incision.

### Scientific title
A randomized controlled trial of the efficacy of modified sternal precautions versus standard care on improving physical function following cardiac surgery via a median sternotomy.

### Countries of recruitment
Australia

### Health condition(s) or problem(s) studied
Cardiac surgery via a median sternotomy

### Intervention(s)
Active comparator:
Placebo comparator:

### Key inclusion and exclusion criteria
Ages eligible for study: ≥ 18yrs
Sexes eligible for study: both
Accepts health volunteers: No
Inclusion criteria: All adults underwent elective cardiac surgery involving a median sternotomy
Exclusion criteria: 1. Unable to understand verbal instructions in English. 2. Residing outside Melbourne metropolitan area (i.e. 52 km radius).

### Study type
Type: Investigator initiated, interventional, non-pharmacological, pragmatic, study
Allocation: Concealed randomization
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

<table>
<thead>
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<table>
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<table>
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<table>
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<tr>
<th>Recruitment status</th>
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<tr>
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<table>
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<tr>
<th>Primary outcome(s)</th>
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<td>Short Physical Performance Battery (SPPB)</td>
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<th>Key secondary outcomes</th>
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<td>2. Patient Identified Cardiac Pain Using Numeric And Visual Prompts, McGill Pain Questionnaire-Short Form (SF-MPQ-2), Functional Difficulty Questionnaire (FDQ), Grip Strength, Tampa Scale of Kinesiophobia (TSK-11), The Medical Outcome Study 36-item Short Form (SF-36V2), Global Rating of Change Scale</td>
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</table>
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

**Table 3.2:** Additional File 1: SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
<th>Addressed on page number</th>
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<td>2a</td>
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<td>2b</td>
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<tr>
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<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
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<td>5b</td>
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<td>5c</td>
<td>Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities</td>
<td>n/a</td>
</tr>
</tbody>
</table>
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

5d Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) 21

Introduction

Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention 4-6

6b Explanation for choice of comparators 9-11, 23-25

Objectives 7 Specific objectives or hypotheses 5-6

Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) 6

Methods: Participants, interventions, and outcomes

Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained 6-7

Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) 7-8

Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered 9-11
### Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)

**11b**

<table>
<thead>
<tr>
<th>Criteria for discontinuing or modifying allocated interventions for a given trial participant</th>
<th>12-13</th>
</tr>
</thead>
<tbody>
<tr>
<td>(eg, drug dose change in response to harms, participant request, or improving/worsening disease)</td>
<td>12-13</td>
</tr>
</tbody>
</table>

### Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)

**11c**

<table>
<thead>
<tr>
<th>Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>(eg, drug tablet return, laboratory tests)</td>
<td>12</td>
</tr>
</tbody>
</table>

### Relevant concomitant care and interventions that are permitted or prohibited during the trial

**11d**

<table>
<thead>
<tr>
<th>Relevant concomitant care and interventions that are permitted or prohibited during the trial</th>
<th>11-12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11-12</td>
</tr>
</tbody>
</table>

### Outcomes

**12**

<table>
<thead>
<tr>
<th>Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended</th>
<th>13-20</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13-20</td>
</tr>
</tbody>
</table>

### Participant timeline

**13**

<table>
<thead>
<tr>
<th>Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)</th>
<th>Figure 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Figure 2</td>
</tr>
</tbody>
</table>

### Sample size

**14**

<table>
<thead>
<tr>
<th>Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations</th>
<th>21</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>21</td>
</tr>
</tbody>
</table>

### Recruitment

**15**

<table>
<thead>
<tr>
<th>Strategies for achieving adequate participant enrolment to reach target sample size</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12</td>
</tr>
</tbody>
</table>

### Methods: Assignment of interventions (for controlled trials)

**Allocation:**

**Sequence generation**

**16a**

<table>
<thead>
<tr>
<th>Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions</td>
<td>8</td>
</tr>
</tbody>
</table>
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

<table>
<thead>
<tr>
<th>Allocation concealment mechanism</th>
<th>16b</th>
<th>Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation</td>
<td>16c</td>
<td>Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions</td>
<td>8</td>
</tr>
<tr>
<td>Blinding (masking)</td>
<td>17a</td>
<td>Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>17b</td>
<td>If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial</td>
<td>n/a</td>
</tr>
</tbody>
</table>

**Methods: Data collection, management, and analysis**

| Data collection methods          | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 13-20 |
|                                  | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 12-13 |

| Data management                  | 19  | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 21  |

| Statistical methods              | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 21-23 |
Methods for any additional analyses (eg, subgroup and adjusted analyses) 21-23

Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) 21-23

Methods: Monitoring

Data monitoring 21a Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed 21

21b Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial 21-23

Harms 22 Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct 21

Auditing 23 Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor 21

Ethics and dissemination

Research ethics 24 Plans for seeking research ethics committee/institutional review board (REC/IRB) approval n/a

Protocol amendments 25 Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) n/a
<table>
<thead>
<tr>
<th>Consent or assent</th>
<th>26a</th>
<th>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
<td>n/a</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>27</td>
<td>How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial</td>
<td>21</td>
</tr>
<tr>
<td>Declaration of interests</td>
<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
<td>27</td>
</tr>
<tr>
<td>Access to data</td>
<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
<td>21, 26-27</td>
</tr>
<tr>
<td>Ancillary and post-trial care</td>
<td>30</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
<td>n/a</td>
</tr>
<tr>
<td>Dissemination policy</td>
<td>31a</td>
<td>Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions</td>
<td>21, 26-27</td>
</tr>
<tr>
<td></td>
<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
<td>21, 26-27</td>
</tr>
</tbody>
</table>

**Appendices**
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

<table>
<thead>
<tr>
<th>Informed consent 32</th>
<th>Model consent form and other related documentation given to participants and authorised surrogates</th>
<th>Provided on request</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological specimens 33</td>
<td>Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable</td>
<td>n/a</td>
</tr>
</tbody>
</table>

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.*
Table 3.3: Additional file 2: The TIDieR (Template for Intervention Description and Replication) Checklist*:
Information to include when describing an intervention and the location of the information

<table>
<thead>
<tr>
<th>Item number</th>
<th>Item</th>
<th>Where located **</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Primary paper (page or appendix number)</td>
</tr>
<tr>
<td>BRIEF NAME</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>1.</td>
<td>1.</td>
<td>4-5, 9-11, 23-25</td>
</tr>
<tr>
<td>WHY</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>2.</td>
<td>2.</td>
<td>9-11, Figure 1a and 1b</td>
</tr>
<tr>
<td>WHAT</td>
<td></td>
<td>9-11</td>
</tr>
<tr>
<td>3.</td>
<td>3.</td>
<td>-</td>
</tr>
<tr>
<td>4.</td>
<td>4.</td>
<td>-</td>
</tr>
</tbody>
</table>

WHO PROVIDED
### Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

5. For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.  

**HOW**  
6. Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.  

**WHERE**  
7. Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features. 

<table>
<thead>
<tr>
<th>WHEN and HOW MUCH</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.</td>
<td>9-11</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TAILORING</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>9. If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.</td>
<td>9-11</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MODIFICATIONS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10. If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**HOW WELL**
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

<table>
<thead>
<tr>
<th></th>
<th>Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td></td>
<td>11-12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>12†</td>
<td></td>
<td>11-12</td>
</tr>
</tbody>
</table>

**Authors - use N/A if an item is not applicable for the intervention being described. Reviewers – use ‘?’ if information about the element is not reported/not sufficiently reported.**

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

† If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see BMJ 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a randomised trial is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement**. When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

3.2.1 Trial design

The Sternal Management Accelerated Recovery Trial (S.M.A.R.T) is a phase II, prospective, parallel group, concealed allocation, randomized (1:1) controlled, patient and assessor blinded clinical trial, at two tertiary hospitals powered for superiority. Participants will be randomized to the trial if they meet the eligibility criteria, gives informed consent, and have completed baseline measurement testing by a blinded assessor located in an outpatient setting. Participants will be informed that they will be randomised to receive either standard or modified sternal precautions pre-hospital discharge and be allocated to one of two groups: 1. control group (standard care) and 2. intervention group (modified sternal precautions). In addition, participants are also asked to provide a global rating of change on physical function using a numeric scale.

3.2.2 Trial setting

The trial will be carried out at two tertiary hospitals: The Royal Melbourne Hospital (RMH), and the Melbourne Private Hospital (MPH), both in Victoria, Australia. The RMH is a government funded, university affiliated, teaching hospital, and MPH is a private hospital adjacent to RMH. This study is being conducted at two major metropolitan hospitals (one private and one public) and the findings can be generalized to both private and public health care settings. Most participants recruited will be geographically located in the same precinct with the same surgical staff seeing the same population catchment area with the only difference being the source of funding and reimbursement for surgery. Ethics approval for the study was obtained from Melbourne Health Human Research Ethics Committee in May 2015 (protocol reference: 2015.035) The trial is conducted in accordance with the Declaration of Helsinki (2000) and was registered on 16/9/2015 with the Australian and New Zealand clinical trials registry (http://www.anzctr.org.au): ANZCTR1261500096857(Refer Appendix 1 to 7 for relevant ethic approvals documents).
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

3.2.3 Eligibility and exclusion criteria

Eligible participants following cardiac surgery via a median sternotomy at the participating centres will be invited to participate in the study. They will be identified through their admission to the cardiothoracic ward of both the public and private hospitals.

3.2.4 Inclusion/exclusion criteria

Participants are eligible for the trial if they meet the following criteria:

- Adults undergoing isolated valve, Coronary Artery Bypass Graft surgery (CABG) or a combination of both.
- Able to provide informed consent.
- Aged 18 years and older

Participants are ineligible if they have any of the following criteria:

- insufficient English comprehension
- reside outside the Melbourne metropolitan area (i.e. 52 km radius),

3.2.5 Recruitment Feasibility:

We aimed to recruit 72 participants from a pool of those admitted to surgery at each centre. There are approximately 650 sternotomy procedures performed at the Royal Melbourne (RMH) and 450 sternotomy procedures performed at Melbourne Private (MP) Hospital per annum. Therefore, recruitment of 72 participants is estimated to take 12 months with an average of 6 participants per week.
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

3.2.6 Randomization and allocation

Randomization will be conducted by an independent person offsite using a computer generated random 72 sequence numbering system one (1) to (72) and a 1:1 allocation ratio. Concealment is via sealed, numbered, double layered opaque envelopes. Allocation occurs after baseline testing, by opening of the next study envelope by one of the staff of the University department of physiotherapy not involved in the study. They then inform the treating physiotherapist of group allocation. The envelopes will be stored, locked in cabinet and security measures in place to prevent unblinding. Steps will be taken to limit authorized personnel (n=2) with access/permission to open the study envelopes, to avoid allocation bias.

3.2.7 Trial Intervention

The implementation of the sternal precautions is performed by the same ward physiotherapist according to allocation for both groups. There will be a different physiotherapist for each participating hospital providing the intervention for both groups. Both physiotherapists are senior clinicians with over five (5) years of clinical experience in cardiac surgery. Training will be provided by one independent physiotherapist to ensure consistency in each institution. Standard care is consistent across centres.

3.2.8 Control group (Standard care)

Whilst “standard care” was not consistent in the literature cited previously (Balachandran et al, 2014; Cahalin, et al 2011; Overend et al, 2010; Price et al, 2016; Tuyl et al, 2012). Centres worldwide limit the use of the upper limbs for a minimum of six weeks (Balachandran et al, 2014; Cahalin et al, 2011; Overend et al, 2010; Price et al, 2016; Tuyl et al, 2012). The protocol we will apply is across both institutions in this study. Therefore, consenting participants in the Standard Care group (SC) will receive the education and restrictive sternal precautions for duration of 6 weeks. The sternal precautions will be delivered in both verbal and written formats by the treating physiotherapists as single individualized session for 15 minutes on the ward prior to
discharge from the hospital. Patients will be instructed to adhere to the sternal precautions for the first four to six weeks post-operatively (Figure 3.1).

The participants will be specifically instructed to:

1) avoid pushing or pulling through the arms

2) avoid one arm (unilateral) activity

3) limit the elevation of the arms to 90°

4) avoid lifting objects greater than two kg

5) use a cushion or perform sternal preservation technique (crossing the arms in a “self hugging” posture) when coughing

6) Limit the use of the arms when moving from sitting to standing and getting out of bed

7) Avoid placing arms behind back.

Participants will be advised not to continue tasks and/or exercises that are painful, to rest as required and focus on a gradual return to their pre-surgery level of function.

3.2.9 Intervention group

The modified sternal precautions will be delivered in both verbal and written formats by the treating physiotherapists as single individualized session for 15 minutes on the ward prior to discharge from the hospital. Patients will be instructed to adhere to the sternal precautions for the first four to six weeks post-operatively (Figure 3.2). Participants in the intervention group will be specifically encouraged to:

1) use pain and discomfort to guide the safe use of their arms.

2) avoid pushing or pulling with one arm.

3) use both arms close to the body during lifting.

4) use of arms is possible but to keep them close to the body.
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

5) avoid stretching one or both arms backwards at the same time.

6) use a cushion or perform sternal preservation technique (crossing the arms in a “self hugging” posture) when coughing (same as above).

7) roll onto their side, ease their legs over the edge of the bed and carefully use their arms to sit up from a lying position.

Pain and discomfort should be used to guide the safe limits of movement.

The intervention pertaining to sternal management including the type of sternal precautions will be delivered in both verbal and written formats to each participant separately with a flyer developed specifically for the study to ensure standardization.

In both groups, all other aspects of patient care including pre-operative 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.

### 3.2.10 Intervention Fidelity

Training will be provided for the two unblinded, dedicated staff to conduct the follow-up phone calls to ensure consistency in evaluating adherence to sternal precautions guidelines for the first 6 weeks after cardiac surgery. One staff member will evaluate the intervention group and another will follow-up the standard care group for both institutions. The staff are required to encourage patients to continue with their allocated sternal management strategy using the standardized written instructions in addition to participants’ flyers as to minimize bias. Participants will be informed that they will be contacted verbally via telephone, weekly to help reinforce their exercise and precaution guidelines for the first 6 weeks after cardiac surgery. Specifically, the Standard Care participants will be asked to follow the restriction on the use of upper limbs and limit the activities of upper limbs and trunk during activities of daily living, bed transfers, and sit to stand. The Intervention group will be encouraged to use their upper limbs bilaterally to perform activities of daily living, bed transfers and sit to stand. They will
also be encouraged to perform upper limbs exercise three times daily within the limits of pain and discomfort.

**Figure 3.1:** Control group (standard care) participant information flyer
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

**Figure 3.2**: Intervention group (modified sternal precautions) participant information flyer. S.M.A.R.T. Sternal Management Accelerated Recovery Trial

<table>
<thead>
<tr>
<th>Cardiac Surgery Sternal Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please follow these guidelines for 4-6 weeks from the time of your operation</td>
</tr>
<tr>
<td>If you experience any pain, STOP and inform your health professional</td>
</tr>
</tbody>
</table>

| Use **BOTH ARMS** for exercises and activities |
| You may lift light objects with **BOTH ARMS**. Keep the load close to your body. |
| To get in and out of bed: |
| a. Move feet to edge. Roll onto your side |
| b. Ease your legs over the edge of the bed |
| c. Carefully use your arms by placing close to your body to sit up |

---

**S.M.A.R.T. TIPS**

- **Use both arms and keep close to body when**
  - Lifting light objects
  - Sitting out of bed
  - Standing up from a chair

- **Avoid pushing or pulling with one arm.**

- **Use pain and discomfort as a guide for safety for all activities**

- **Always** support your chest with both arms when coughing
3.2.11 Blinding

Patients, outcome assessors and data management are blinded to treatment allocation. Participants will be advised that they will be randomized to 1 of 2 groups of sternal precautions guidelines. The treating physiotherapist and nursing staff cannot be blinded to group allocation. The details of sternal management are not documented in the medical record. A blinded assessor located off-site of the hospital will assess all outcomes. Trial staff will conduct education at set times on the ward that are on separate days to days scheduled for outcome assessment. If a treatment group participant informs the assessor of their post-operative education session, this will be noted and reported and the reason entered when the randomization was unblinded and analysed as intention to treat.

3.3 Withdrawal from Trial

All participants will be followed-up after their surgery and measured. Every attempt will be made to accommodate individual requirements to facilitate attendance at follow-up time points beyond discharged from hospital (i.e. taxi vouchers, flexible dates and time for appointment). Participants will be withdrawn if they withdraw their consent and this will be reported. Data collected until this time will be included.

3.4 Data Collection

Demographic data as well as pre-, intra- and postoperative variables will be collected as listed in Table 3.4. Data will be collected from the participants and their medical records (Refer Appendix 7 for all the data collection forms). All baseline assessments will be performed at the same time of day (08:00–17.00) for each participant in the post-operative period at day 4 (±1 day) in the in-patient setting across centres to minimise potential bias in recruiting participants. The follow-up, outpatient testing at four weeks (±14 days) and three months (±14 days) will take place in the research room.
at RMH (Fig. 3.3). An independent and trained assessor (located off-site) who is blinded to allocation will conduct all measurement sessions. All tests and questionnaires will be administered face-to-face by the outcome assessors and carried out at four weeks and three months postoperatively to ensure consistency across participants. Post-hospital discharge follow-up will be conducted 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 purposes of post-discharge outcome measurement.
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

**Figure 3.3:** Additional file include recommendation for interventional trials (SPIRIT) checklist for the schedule of enrolment, interventions, and assessments. Arrow indicate outcome measure performed. * primary outcome

<table>
<thead>
<tr>
<th>TIMEPOINT</th>
<th>STUDY PERIOD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Eligibility</td>
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<tr>
<td>ENROLMENT:</td>
<td>Enrolment</td>
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<tr>
<td></td>
<td>Eligibility screen</td>
</tr>
<tr>
<td></td>
<td>Informed consent</td>
</tr>
<tr>
<td></td>
<td>Random allocation</td>
</tr>
<tr>
<td>INTERVENTIONS:</td>
<td>CONTROL: Standard care + flyers</td>
</tr>
<tr>
<td></td>
<td>INTERVENTION: Modified sternal precautions+ flyers</td>
</tr>
</tbody>
</table>
Chapter 3: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T): standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial.

<table>
<thead>
<tr>
<th>VARIABLES:</th>
<th>Demographics, medical history, Charlson Comorbidity Index, return to work, functional history</th>
<th>X</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Pre-operative variables</td>
<td>X</td>
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<td></td>
<td>Intra-operative variables</td>
<td>X</td>
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<tr>
<td></td>
<td>Post-operative variables</td>
<td>X</td>
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<tr>
<td>OUTCOMES:</td>
<td>*Short Physical Performance Battery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Functional Difficulties Questionnaire</td>
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<td></td>
<td>Grip Strength</td>
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<td>The McGill Pain Questionnaire-Short Form</td>
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<td>Patient Identified Cardiac Pain Using Numeric And Visual Prompts</td>
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<td></td>
<td>Postoperative Quality Recovery Scale</td>
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<td>The Tampa Scale of Kinesiophobia</td>
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<td></td>
<td>The Medical Outcome Study 36-Item Short Form Health Survey</td>
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<td>Sternal Instability Scale</td>
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<td></td>
<td>Global rating of change scale</td>
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</table>
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### Table 3.4: Data collection details

<table>
<thead>
<tr>
<th>Demographic data</th>
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<tbody>
<tr>
<td>• Name and contact details</td>
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<tr>
<td>• Date of birth</td>
</tr>
<tr>
<td>• Gender</td>
</tr>
<tr>
<td>• Marital status</td>
</tr>
<tr>
<td>• Height and weight</td>
</tr>
<tr>
<td>• Occupation status</td>
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<tr>
<td>• Education status</td>
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<tr>
<td>• Smoking history</td>
</tr>
<tr>
<td>• Past medical history and comorbidity index (Charlson Comorbidity Index)</td>
</tr>
<tr>
<td>• Functional history (including pre-morbid functional level, use of gait aids, dominant upper limb)</td>
</tr>
<tr>
<td>• Date of admission to, discharge from acute setting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pre-operative, Intra-operative and Post-operative Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Date of cardiac surgery</td>
</tr>
<tr>
<td>• Clinical information (left ventricular function, Canadian cardiovascular society functional classification, comorbidities, graft type)</td>
</tr>
<tr>
<td>• Type of cardiac surgery (including whether it was an emergency or elective procedure)</td>
</tr>
<tr>
<td>• Other intra-operative details (including method of sternal closure, cardiopulmonary bypass time, operation time, adverse events)</td>
</tr>
<tr>
<td>• Date of admission to and discharge from intensive care unit post-operatively</td>
</tr>
<tr>
<td>• Risk factors for pre-operatively, intra-operative and post-operative (i.e. duration of mechanical ventilation)</td>
</tr>
<tr>
<td>• Type and use of pain medication (pre-operatively and post-operatively)</td>
</tr>
<tr>
<td>• Type and use of other medications (pre-operatively and post-operatively)</td>
</tr>
<tr>
<td>• Date of admission to and discharge from acute physiotherapy services</td>
</tr>
</tbody>
</table>
• Details of physiotherapy treatment (including exercises and education provided)
• Other adverse events during hospital admission (pre-operatively and post-operatively leading to increase in length of stay). This includes superficial sternal infection, deep sternal infection, re-wiring, re-operation, pneumonia as defined in An Initiative of The Australian Society of Cardiac and Thoracic Surgeons (ASCTS) Data.
• Date of readmission.

3.5 Outcomes Assessment:

3.5.1 Primary outcome - Short Physical Performance Battery

The Short Physical Performance Battery is a functional test that measures daily functional activities in the acute care in-patient older population, including cardiac surgery (Molino-Lova et al, 2013). The test is a well-established and validated measure of lower extremity performance, designed to simulate routine physical activities in older adults (Guralnik et al, 2000). The test includes gait speed (8-foot walk), standing balance, and lower extremity strength and endurance (chair rise task). It is comprised of the following:

i. Gait speed: participants will be instructed to walk a distance of eight feet as determined by traffic cones on a flat surface at their normal comfortable pace. The average of two trials will be used. For safety reasons, participants are encouraged to walk with their gait aids if these are usual or part of their post-operative care at the time of testing. An 8 feet course was used and scoring will utilize the faster of the 2 walk times to calculate speed in meters/second (m/s). A reduction of the distance to measure gait speed has been shown to provide valid data in measuring of functional limitation (Freiberger et al, 2012; Ostchega et al, 2000).
ii. **Standing balance**: participants will be assessed in three different static positions (side by side stand, semi-tandem stand and tandem stand). Participants will be instructed to try to hold each of these positions for 10 seconds.

iii. **Chair rise task**: participants will be instructed to stand up and sit down five times in a row as quickly as possible.

The Short Physical Performance Battery score is based on timed measures of standing balance, walking speed, and ability to rise from a chair. Each test is scored on a scale of zero to four points, with a summary performance score range of zero to 12 points using cut point criteria established by Guralnik (Guralnik et al, 2000). A zero score indicates poor function whilst 12 indicates excellent function. If the participant is unable to perform a specific test, a score of zero (0) will be assigned. A score of 10 or lower is considered the cut point for mobility impairment (Guralnik et al, 2000). The Short Physical Performance SPPB was selected as it assesses overall functional performance that reflects physical function required of everyday tasks. It is hypothesized that the intervention will impact on overall functional performance and as this is the primary concern of most patients at medium to long term follow up (six weeks to 12 months) (Min et al, 2015; Molino-Lova et al, 2013). The test has established validity and reliability in measuring physical performance in the elderly (Guralnik et al, 2000; Pahor et al, 2006; Studenski et al, 2003) with intraclass correlation coefficient (ICC) equal to 0.82 (Studenski et al, 2003) and is a strong predictor of disability in non-disabled older persons (Guralnik et al, 1995). The minimal detectable change values range from 0.54 (Perera et al, 2006) to 2.0 points (Volpato et al, 2008), which suggests that, a change in physical performance of one to two points is a clinically meaningful change in an older (Perera et al, 2006) and in-patient stable cardiovascular population (Volpato et al, 2008). Therefore, in the absence of data for cardiac surgery populations the MID for this study was derived from prior research on a cohort of patients with stable cardiovascular conditions of 2.0 points which is representative of our participants population. The SPPB has been shown to be reliable, valid, and sensitive to change (Ostir et al, 1998). Intraclass correlation coefficients (ICC) ranged from 0.88 to 0.92 for measures made 1-week apart, with a 6-month average correlation coefficient of 0.78 (Ostir et al, 1998).
3.5.2 Secondary Outcomes:

Functional difficulties questionnaire (FDQ): aims to measure the functional status of patients following cardiac surgery, with a particular focus on upper limb and trunk function in patients following a median sternotomy (Hoggins, 2009). The questionnaire requires patients to rate the difficulty they would experience when completing a series of 13 upper limb and trunk functional tasks. Specifically, patients are asked to place a mark along a 10 cm line, with anchors indicating “no difficulty” and “maximum difficulty” on the left and right side of the line respectively. For those activities that participants cannot complete while filling out the questionnaire, they will be asked to recall the last time they performed the tasks. The 13 functional tasks included in the questionnaire are everyday tasks that were nominated as difficult to perform in a pilot study of patients following cardiac surgery (Hoggins, 2009). Previous research has demonstrated that the FDQ is a valid, reliable and responsive measure in this patient population with minimal recall bias, and has been used to measure the functional status of patients following cardiac surgery, in both the short term (four weeks post-operatively), and long term (three months post-operatively) (Hoggins, 2009). The follow-up time points are a minimum of four weeks to two months apart, thus, further reducing recall bias.

Patient Identified Cardiac Pain Using Numeric And Visual Prompts – This is a pain outcome measurement tool that was developed by Teoh (Teoh et al., 2007). To obtain data regarding symptom presentation, participants are required to identify, on a gender-neutral silhouette torso of all locations of their pain or discomfort. The participants are also required to identify their ‘chief’ or ‘main’ symptom, describe its nature by pointing to pictorial identifiers that visually represents a description of the pain (i.e., stabbing, heavy, shooting, burning, squeezing) (Milner et al., 2004). The intensity of the pain forms the last domain and utilises a Likert-type scale. This tool was selected as it evaluates multiple dimensions of pain and discomfort, is easy to administer and accounts for cultural diversity (King-Shier et al., 2015).

The McGill Pain Questionnaire – Short Form version 2 (SF-MPQ-2). Pain quality will be measured using The Short Form McGill Pain Questionnaire version two, which consists of 22 items investigating four dimensions of pain quality (Continuous,
Intermittent, Neuropathic and Affective) on an 11-point numerical rating scale (Lovejoy et al, 2012). The total score is calculated from the mean of 22 items, and scores for the 4 dimension subscales is calculated from the mean of the items included in each subscale. Scores on each subscale can range from zero (0) to 10. A higher score indicates a more severe pain (Lovejoy et al, 2012).

Participants will be instructed to choose the number that best describes their intensity of pain and related symptoms experienced during the past week. Zero will be assigned if the word did not describe their pain or related symptoms. The original version of scale, The Short Form McGill Pain Questionnaire (SF-MPQ-2) has well-established reliability in cardiac populations with alpha coefficients ranging from 0.75 to 0.83 across various post-operative days (Puntillo et al, 1994; Yorke et al, 2004). The SF-MPQ-2 is sensitive to change in chronic pain, and total and subscale scores are responsive to change, and the changes are associated with patient ratings of global improvement in clinical trials (Lovejoy et al, 2012).

**The Tampa Scale of Kinesiophobia (TSK-II):** is a widely used tool to measure pain related fear beliefs about movement and re-injury (Kori et al 1990). It is an adaptation of the original 17-item instrument (Kori et al 1990), designed to assess fear of movement or re-injury that excludes the 4 original reverse-scored items that were found to have small item-to-total score correlations. The adapted score has 11-item instrument, where respondents will be asked to rate each item on a 4-point Likert scale, ranging from 1 (strongly disagree) to 4 (strongly agree). The Tampa Scale of Kinesiophobia is a reliable and valid measure of fear of movement or re-injury in patients with chronic pain (Tkachuk & Harris, 2012; Woby et al, 2005). It has, internal consistency, reliability, and convergent validity with Cronbach’s $\alpha$ was 0.80 for the total score (Tkachuk & Harris, 2012). A reduction of at least four points on the measure maximises the likelihood of correctly identifying an important reduction in fear of movement (Woby et al, 2005).

**Grip strength.** Hand-grip strength will be measured in kilograms with a hand-held JAMAR dynamometer (Sammons Preston Rolyan, Brooklyn, USA). The participant will be tested in the position recommended (Fess, 1992). The peak value of the maximal squeeze over 5 seconds will be recorded (Peolsson et al, 2001). The time interval were allowed between tests were short and were approximately 2 minutes to allow for
recovery. A previous study has found similar test-retest reliability with one trial alone, the mean of two or three trials and the maximum of three trials (Hamilton et al, 1994). In addition, due to influences of pain after surgery, the average may not reflect of true performance. Therefore, in this study three serial tests of maximum grip strength with the dominant hand will be performed, and best of the three values will be recorded. Hand-held dynamometry is a reliable, objective tool for muscle strength measurement (Roberts et al, 2011), and a predictor of postoperative complications, mortality, and functional decline (Bohannon, 2001). The test is a reliable and responsive measure for patients in cardiac rehabilitation (intraclass correlation coefficient right and left hand grip strength = 0.97) (Puthoff & Saskowski, 2013).

**The Medical Outcome Study 36-Item Short Form Health Survey (SF36-V2).** Health related quality of life will be evaluated by SF36-V2, which is a generic measure to assess eight domains including: physical functioning, role physical functioning, role emotional functioning, mental health, vitality, social functioning, bodily pain and general health. All scale or single item measurements range in score from 0-100 and will be administered by interview. The raw sub-scale scores were transformed to ‘norm-based’ scores using published algorithms (Ware et al, 2000). Norm-based physical and mental component summary (PCS, MCS) scores were also calculated from raw sub-scale scores with higher scores indicating better quality of life. A higher score on the SF 36V-2 sub-domains represents a high level of functioning, and higher quality of life (Ware et al, 2000). The scale has good reliability with Cronbach’s α ranging from 0.65 to 0.96 for all subscales (Falcoz et al, 2003). The instrument can differentiate between levels of health among post CABG individuals at a single time point, and over time (Morone et al, 2010). Furthermore, the SF36-V2 is valid in written format, as well as verbal administration over the telephone in cardiac patients (Wattson et al, 1996).

**Modified Sternal Instability Scale (SIS):** This study will used the modified SIS to assess for sternal instability. The modified SIS is a manual test that measures the stability of the sternum based on a 4-point scale (0-3). A score of 0 corresponds to a clinically stable sternum with no detectable motion or separation of the sternal edges, whilst a score of three corresponds to a completely separated sternum with marked increased motion or separation of the sternal edges. The original 5-point (0-4) SIS is a valid and reliable clinical tool for measuring the stability of the sternum in patients
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following a median sternotomy (El Ansary et al, 2007c). It has excellent inter and intra-rater reliability, with intra-class correlation coefficients of 0.97 and 0.98 respectively (El Ansary et al, 2000b). The Blinded Assessor received education and training in the SIS and had over 4 years of the utilisation of this tool clinically. The blinded assessor was instructed by A/P Doa El-Ansary (who developed the SIS scale). The blinded assessor underwent a fidelity check with respect to the competency of performing this task (n=15 patients).

Adherence monitoring

A questionnaire was developed by the researchers to monitor the level of adherence of all patients following cardiac surgery via a median sternotomy (Refer Appendix 10). The questions follow a closed, multiple-choice format where respondents are required to recall a list of activities, duration of their adherence and the rate of their adherence on a numeric scale. Participants are prompted to complete the questionnaire by telephone on a weekly basis. They are additionally encouraged to follow the guidelines on sternal management as per their specific flyers. An adherence threshold for the experimental group was set at a participant self-perceived reported rating of ≥70%.

Global rating of change scale (GRC).

The global rating of change scale (7 point scale) will be administered to participants prior to performance based assessment at four weeks and repeated at three months. Participants will be asked to answer the following statement: “How does your overall physical function now, compare to your physical function just before you went home from the hospital?” and respond according to a 7 point scale ranging from ‘1 – very much improved’ to ‘7 – very much worse’ (Table 3.5 and Table 3.6). It has been previously reported in the literature that in the case whereby patients rate their change as “minimally improved”, “no change” or “minimally worse” it is unlikely that a clinically important difference has occurred (Davidson et al, 2002). In this case these responses will be re-defined as “unchanged” (Davidson et al, 2002; de Morton et al, 2010). A clinical important difference will be considered to have occurred if patients rate their change as “much worse”, “very much worse”, “much improved” or “very much improved” and these will be re-defined as “changed” (de Morton et al, 2010).
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Table 3.5: Global rating of change scale for overall physical function

How does your overall physical function now, compare to your physical function just before you went home from the hospital?

<table>
<thead>
<tr>
<th>Global Rating of Change Scale</th>
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<tbody>
<tr>
<td>1. Very much improved</td>
</tr>
<tr>
<td>2. Much improved</td>
</tr>
<tr>
<td>3. Minimally improved</td>
</tr>
<tr>
<td>4. No change</td>
</tr>
<tr>
<td>5. Minimally worse</td>
</tr>
<tr>
<td>6. Much worse</td>
</tr>
<tr>
<td>7. Very much worse</td>
</tr>
</tbody>
</table>

Table 3.6: Global rating of change scale for upper arm and body function

How does your arm and upper body function now, compare to your arm and upper body function just before you went home from the hospital?

<table>
<thead>
<tr>
<th>Global Rating of Change Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Very much improved</td>
</tr>
<tr>
<td>2. Much improved</td>
</tr>
<tr>
<td>3. Minimally improved</td>
</tr>
<tr>
<td>4. No change</td>
</tr>
<tr>
<td>5. Minimally worse</td>
</tr>
<tr>
<td>6. Much worse</td>
</tr>
<tr>
<td>7. Very much worse</td>
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</tbody>
</table>
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3.6 Sample Size

Sample size calculations were performed for the primary outcome: Short Physical Performance Battery. Based upon acute care in-patients populations and using the MID between treated group of two points out of total score of 12 points, with a standard deviation (SD) of 2.7 points (Volpato et al, 2008), it is anticipated that 29 participants are required per group (58 in total) based on a two-sample t-test. This was based on a Type 1 error rate of 0.05, which was consistent with recommendations and a power of 0.80 (Portney & Watkins, 2009). This sample was increased to 72 participants, based upon a predicted 20% drop out rate based on our previous study in the same population conducted at both participating centres (Balachandran 2015).

3.7 Data Management and Quality

We will use the online REDCap database (http://redcape.healthinformatics.unimelb.edu.au/) supported by The University of Melbourne. High data quality will be aimed for through training of those who collect, check and enter study data; regular data checks for inconsistency between and within measurements and missing data. A check will be performed to evaluate the correctness of the randomisation before start of the statistical analysis. The Data Safety Monitoring Committee (DSMC), with two independent clinical members and one independent statistician, will act in an advisory capacity to the clinical investigators to monitor withdrawals, review ethical conduct and serious adverse events. Further details will be provided in the DMSC charter once developed.

3.8 Statistical Methods

Statistical analyses will be performed by the biostatistician. Data analyses will be performed using the SPSS Windows Version 23.0 (SPSS, Chicago, IL, USA). All data will be analyzed using the intention to treat principle. Descriptive statistics including mean and SD; median and interquartile range; number and percentage; and frequency will be used to summarize data (depending on distribution and type of data). This also
includes participant demographics and adherence to sternal precautions. A comparison between the two hospitals will be conducted on the demographic profile of the participants to establish and differences in each presenting population.

The primary outcome, the change from baseline to four weeks in the SPPB, will be analysed using a mixed between-within subjects ANOVA with repeated measures across participants. The primary hypothesis will be examined by a contrast evaluating change from baseline to the four week time point in the modified sternal precautions group compared to the standard care group. The analysis will be under the intention-to-treat principle based on the groups to which participants were randomized. The interactions between group and time will be first examined to assess the effect of intervention, and, if no interaction was present, group and time main effects will be examined. If there are issues with non-normality or ceiling/floor effects of the SPPB, transformation or dichotomization will be considered. If there are participants who are not following the assigned group protocol, we will consider a supplementary per protocol analysis.

Key secondary outcome data (including, upper limb function, pain, kinesiophobia and HRQoL) will be summarized and analysed similarly to the primary outcome.

Logistic regression will be used to determine pre, peri, and post-operative risk factors associated with the development of post-sternotomy complications. This will be an exploratory analysis, which may identify trends of predictors reported in the literature having an individual effect on post-operative sternal complications (i.e. female gender, diabetes mellitus, obesity, bilateral internal mammary artery grafts, re-operation for post-operative complications, and blood product requirement were reported as significant predictors of sternal infection).

For all tests conducted, a p value of <0.05 (two-tailed), will be considered statistically significant, and mean differences (95% confidence interval) will be reported.
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3.9 Duration and Timeline

All 72 participants completed recruitment in November 2016. Data collection will be completed, analysed, and the manuscript prepared for submission by May 2017. The final manuscript will be written in accordance with the proposed CONSORT extensions for a pragmatic trial using a non-pharmacological intervention as illustrated in Figure 3.4

![Figure 3.4: Proposed S.M.A.R.T CONSORT Flowchart](image-url)
3.10 Discussion

The S.M.A.R.T. study will examine whether modified sternal precautions will facilitate recovery and function following cardiac surgery via a median sternotomy. The benefits of modifying sternal precautions have not been established, despite emerging evidence indicating that a precautionary approach rather than a restrictive approach may be preferable in this patient population (Adams et al, 2016; Balachandran, 2015; Brocki et al, 2010; Cahalin et al, 2011). This will be the first randomized controlled trial using an intervention group to modify sternal precautions, and study its effectiveness in improving physical function in this population.

Patients worldwide are currently being prescribed sternal precautions that restrict the use of their upper limbs and trunks to prevent sternal complications for four to six weeks (Cahalin et al, 2011; Overend et al, 2010; Tuyl et al, 2012). The aims of this restriction are to promote sternal osteosynthesis and bone healing by minimizing micromotion between the sternal edges (Cahalin et al, 2011; Fedak et al, 2011; Fedak et al, 2010). However, the effect of sternal precautions on patient’s outcomes is unknown with significant variation among institution worldwide (Balachandran et al 2014; Cahalin et al, 2011; Overend et al 2010; Tuyl et al 2012). In addition, there is limited evidence to support its widespread application in clinical practice (Adams et al 2006; Adams et al, 2016; Adams et al, 2008; Balachandran et al, 2014; Cahalin et al, 2011; Fedak et al, 2011; Fedak et al, 2010).

Previous studies have shown that unsupported, frequent coughing is the single main cause of mechanical stress through the sternum and may be a far more significant factor in the development of sternal complications (Balachandran, 2015; Brocki et al 2010). Further, recent evidence demonstrated that upper limbs and trunk movement cause minimal micromotion of the sternal edges (< two mm) as measured by real-time ultrasound (Balachandran, 2015; Balanchandran et al, 2017). Therefore, it was proposed that strict post-operative lifting and movement restrictions may be unnecessary (Balanchandran et al, 2014; Cahalin et al, 2011). However, upper limbs movements are part of post-operative standard physiotherapy treatment. In some institutions, this represents instructions on “no use of the arms”, or limiting the use of the arms to 90 degrees elevation for varying period of time (Balanchandran et al, 2014;
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Cahalin et al, 2011; Overend et al, 2010; Tuyl et al, 2012). Concurrently patients are encouraged to perform active movements of the upper limbs as part of their postoperative care following cardiac surgery with the aim of restoring physical function (Cahalin et al, 2011). This creates a clinical dilemma collectively for both health professional and patients (Balachandran et al, 2014; Cahalin et al, 2011). Based on the findings of a recent survey conducted in Australia (Balachandran et al, 2014), we have chosen to modify sternal precautions guidelines encouraging the use of bilateral upper limbs and trunk activities with pain and discomfort as a safety guide in the intervention group, in order to optimize sternal healing and functional recovery in this patient population. Specifically, participants will be allowed to resume their normal load-bearing activities at their own pace within pain-free limits, by keeping their upper arms close to their body for common activities (e.g. getting out of bed, lifting and transferring). We hypothesize that this intervention will be safe and cause no harm to the participants. In addition, 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 (Adams et al, 2016; Brocki et al, 2010; Cahalin et al, 2011; El-Ansary et al, 2007b).

Encouraging movement of upper limbs and trunk activities early after cardiac surgery in the post-operative period is recommended in clinical practice worldwide (Cahalin et al, 2011; Overend et al, 2010; Tuyl et al, 2012) to improve functional outcome. Clinical recommendations will be informed by future analysis on the efficacy of the trial in improving physical function and other associated outcomes. This study will address the paucity of research, and the inconsistent recommendations worldwide with respect to sternal precautions, and associated restrictions to upper limb and trunk provided to the large number of individuals having cardiac surgery via median sternotomy worldwide. In particular, this research will inform guidelines for the commencement of upper limb exercises in cardiac rehabilitation, and standards for sternal precautions and management following cardiac surgery.
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3.11 Conclusion and Clinical Relevance

The routine implementation of sternal precautions to prevent complications are currently worldwide practice following a median sternotomy. However, evidence is limited and drawn primarily from cadaver studies and orthopaedic research. Sternal precautions may delay recovery, prolong hospital discharge, and may be overly restrictive. Recent research has shown that upper limb exercise reduces post-operative sternal pain and results in minimal micromotion between the sternal edges as measured by real time Ultrasound (Sturgess et al, 2014; Balachandran et al, 2014). However, it remains unknown if a more liberal and individualized approach to sternal precautions that is based on risk assessment of sternal complications would accelerate physical recovery after cardiac surgery. The Short Physical Performance Battery (SPPB) has been validated and the MCID of the SPPB has been estimated for various populations (Perera et al, 2006) including heart failure with variable result (Gary, 2012; Volpato et al, 2008). However, the clinical utility of the SPPB has not been established in a cohort of acute patients following cardiac surgery. This prompted the study presented in Chapter 4.
Chapter 4:
The Short Physical Performance Battery (SPPB) can be utilized to evaluate physical function in patients following cardiac surgery

Chapter Overview

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This study will be published in the April 2018 issue of the journal

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Author contributions for this chapter are the following:

KMA, DE, LD, and CG conceived the idea for the paper. KMA, DE, LD, AR, CR and CG contributed to research design. KMA DE LD and CG contributed to data acquisition. KMA, DE, LD, and CG contributed to research design. KMA, CG, CR and SC contributed to data analysis. KMA completed all statistical analysis. KMA wrote the first draft of the manuscript and managed manuscript submission. All authors revised and provide scientific input. All Authors approved the final version of the manuscript.
4.1 Introduction

Patients following cardiac surgery frequently experience impairments in physical function and HRQoL (Cahalin et al, 2011; Jokinen et al, 2010). This is a growing concern due to the rising prevalence of adults presenting for cardiac surgery at an older age and with greater co-morbidities (Kurfirst et al, 2014; Tran et al, 2013). A growing body of literature supports the pre-operative evaluation of physical function and performance of activities of daily living to enhance surgical risk assessment and inform interventions for patients undergoing scheduled surgery (Afilalo et al, 2010; Bagnall et al, 2013; Min et al, 2015; Wilson et al, 2013). Post-operative evaluation of physical function and HRQoL is also recommended as an important part of the recovery process particularly for older surgical patients to guide their rehabilitation needs (Jokinen et al, 2010; Maillard et al, 2015; Makary et al, 2010; Min et al, 2015). Given this finding, functional impairments should be routinely assessed for patients recovering from cardiac surgery both at the time of hospital discharge and as they commence phase II outpatient cardiac rehabilitation.

Despite the various functional outcome measures available with acceptable clinimetric properties, there are no clear recommendations regarding the best outcome measure to use to measure physical function in the cardiac surgery population (Lapier et al, 2003; LaPier et al, 2006; LaPier et al, 2008). We suggest that the Short Physical Performance Battery (SPPB) holds considerable promise as an outcome measure as it is a practical, feasible and brief test to conduct in the clinical setting (Freiberger et al, 2012). The SPPB measures functional performance across multiple domains and has been widely used in healthy elderly populations, predicts hospital admissions and the onset of disability (Guralnik et al, 1994; Pahor et al, 2006; Pavasini et al, 2016). The SPPB has sufficient clinical clinimetric properties making it a useful tool for measuring outcomes, however, the amount of improvement that reflects a clinically meaningful change needs to be established to enhance clinical utility (Freiberger et al, 2012; Puthoff, 2008). The minimal clinically important difference (MCID) is the smallest level of change in a given outcome measure that clinicians’ consider to be clinically meaningful (de Morton et al, 2010; Perera et al, 2006). The MCID of the SPPB has been estimated for various populations (Perera et al, 2006) including heart failure with variable result (Gary, 2012; Volpato et al, 2008). In general, a one to two point increase in the SPPB overall score
Chapter 4: The Short Physical Performance Battery (SPPB) can be utilized to evaluate physical function in patients following cardiac surgery

reflects a clinical meaningful change (improvement) in physical function (Perera et al, 2006; Volpato et al, 2008). However, the MCID of the SPPB for assessing physical function for patients specifically following cardiac surgery is unknown. Establishing this value is important to allow clinicians to accurately interpret changes in patient outcomes (Volpato et al, 2008).

There are at least nine methodological approaches for calculating the MCID (Wells et al, 2001; Wright et al, 2012). Two general approaches commonly used in the scientific literature to determine the MCID are the anchor-based and the distribution-based methods, both of which have varying merits and weaknesses (Copay et al, 2007; Wells et al, 2001; Wright et al, 2012). A single standardized methodology for calculating MCID has yet to be determined and therefore the current recommendation is to use a combination of different approaches (Wright et al, 2012). Anchor-based methods compare the changes in patient-rated outcomes using an anchor which is usually a patient-rated outcome such as a global assessment scale or a questionnaire. This approach includes: within-patients score change, between-patients score change, social comparison approach and the receiver-operating curve approach to calculate the MDIC (Wells et al, 2001). In contrast, distribution-based methods are based on the statistical characteristics of the sample, where results rely on statistically significant changes in relation to the probability that the change has occurred by chance (Copay et al, 2007; Wright et al, 2012). The distribution-based approaches include: the standard error of measurement, reliable change index, minimal detectable change, standard deviation (SD), and effect sizes to calculate the MCID (Copay et al, 2007; Wells et al, 2001; Wright et al, 2012.).

The aims of this study were to determine (1) the MCID of the SPPB and (2) the floor and ceiling effects of the SPPB when used in patients post cardiac surgery. Based on the controversy within the literature, in this study we used a combination of distribution-based and anchor-based methods to calculate the MCID. The hypothesis was: there will be a meaningful change of SPPB score between testing periods for patients following cardiac surgery using both distribution-based and anchor-based methods.
4.2 Method

The study was conducted and reported in accordance with the strengthening the reporting of observational studies in epidemiology STROBE guidelines for observational study (von Elm et al, 2008).

This was a nested study within a randomized controlled trial (Chapter 3). Consecutive participants were recruited prospectively from two tertiary hospitals (one public and one private) in Melbourne, Australia, from September 2015 to November 2016. Patients were eligible to participate if they were English-speaking adults, aged 18 years or over, who underwent cardiac surgery via a median sternotomy, including isolated valve and/or coronary artery bypass graft or a combination of both. Patients were excluded if they had insufficient English comprehension, resided outside the Melbourne metropolitan area (i.e. 52 km radius), had chronic alcoholism, drug abuse or no fixed address. Ethical approval and written consent was obtained at both sites.

The randomized controlled trial aimed to investigate if modified sternal precautions following cardiac surgery were associated with greater improvements in physical function. The control group received standard physiotherapy care which included advice for the patients to restrict their use of their upper limbs for four to six weeks after surgery (Balachandran et al, 2014). The intervention group were provided with instructions to use pain and discomfort as a guide for the use of their upper limbs after surgery and were not given the same restrictions. Both groups received usual medical care. As part of the randomized controlled trial, participants completed the SPPB, the Medical Outcome Study 36 item version 2 (SF36-V2) and Global Rating of Change scale (GRC) at four weeks and three months post-operatively.

4.2.1 Outcome Measures

Short Physical Performance Battery (SPPB). The SPPB compromises of three tests: 1) Gait speed: participants are instructed to walk a distance of eight feet (2.4 meters) and the average of two trials is used (Figure 4.1) Standing balance: participants are assessed in three different static positions (side-by-side stand, semi-tandem stand and tandem stand) for 10 seconds each Figure 4.2. Chair rise task: participants are instructed to
The Short Physical Performance Battery (SPPB) can be utilized to evaluate physical function in patients following cardiac surgery. Stand up and sit down five times in a row as quickly as possible (Figure 4.3). Each individual test is scored on a scale of zero to four points (higher scores are better performance) (Guralnik et al, 1995). The three test scores are summated to give an overall SPPB performance score ranging from zero to 12 points (Guralnik et al, 1995). A zero score indicates poor function whilst 12 indicates excellent function. If the participant is unable to physically perform a specific test, a score of zero is assigned. It has been previously reported in the literature that for older adults a score of less than 10 is considered the cut-off for mobility impairment (Guralnik et al, 1995). The SPPB scale has established validity and reliability in measuring physical function in the elderly (Guralnik et al, 1995; Pahor et al, 2006; Studenski et al, 2003) with intra-class coefficient of 0.88-0.92 (Ostir et al, 1998) and is strong predictor of disability in non-disabled older persons (Guralnik et al, 1995; Pavadini et al, 2016).

Figure 4.1: Gait speed on 8 feet walking course (courtesy of University of Melbourne image library 2016)
Chapter 4: The Short Physical Performance Battery (SPPB) can be utilized to evaluate physical function in patients following cardiac surgery.

Figure 4.2: Three different static positions a. side by side stand; b. semi-tandem stand and; tandem stand)

Figure 4.3: a to c: Chair rise 5 times in a row (courtesy of University of Melbourne image library 2016)
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4.2.2 Anchor Measure

The SF36-V2 and the GRC scale were used as anchor measures for this study.

4.2.3 Medical Outcome Study 36 item version 2 (SF36-V2)

The SF36-V2 is a self-reported questionnaire that assesses eight health domains: physical functioning, role physical functioning, role emotional functioning, mental health, vitality, social functioning, bodily pain and general health (Ware et al, 2000). The scores are presented as norm-based T-scores (mean 50, SD=10), relative to Australian population norms (Ware et al, 2000). Higher scores (>50) represent better health. Change specifically in the physical function domain of the SF36 was used as an anchor to determine improvement, deterioration or no-change in participants’ physical function between the testing time points. The MCID for change in the physical function domain of the SF36 is two points (Ware et al, 2000). The SF36 questionnaire has been shown to correlate well with symptoms of coronary artery disease, and is sensitive to change over time in patients undergoing cardiac surgery (Falcoz et al, 2002).

4.2.4 Global Rating of Change (GRC)

The GRC scale is a self-reported measure of patients’ perceived change (de Morton et al, 2010; Garrison & Cook, 2012). This was administered prior to the performance-based assessments at four weeks and three months post-operatively. Participants were asked: “How does your overall physical function now, compare to your physical function just before you went home from the hospital?” and responded 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 (de Morton et al, 2010), therefore these patients are grouped into a “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 groups into a “changed” category (de Morton et al, 2010).
4.3 Sample Size

A sample size of at least 43 participants was required to allow detection of a minimal difference between measurements of 0.5 (SD 1.0) in the SPPB scale, assuming a two tailed distribution, and using a matched pairs t-test with alpha 0.05 and power of 90%. In addition, sample sizes of ≥50 participants are recommended for studies assessing clinimetric properties of questionnaires (Terwee et al, 2010).

4.4 Analysis

Data were analysed through SPSS Version 23. Data were assessed for normality using the Kolmogorov-Smirnov test. Descriptive statistics were used to summarize the participant demographics. Paired t-tests were used to determine any significant changes in the SPPB and the SF36V2 domains between measurement time points. Alpha was set at 0.05 for analyses.

4.4.1 Anchor based calculation of the MCID:-

All participants were categorized into two groups based on their change in SF36-V2 physical function scores between four weeks and three months post-operatively. Participants were classified as ‘changed’ if they had an increase or decrease in the SF36-V2 physical function domain of ≥2 points or ‘not-changed’ if they had an increase or decrease in the SF36-V2 physical function domain of <2 points as per the published MCID for this domain (Ware et al, 2000). Pearson’s correlations were used to assess the bivariate relationship between change in SPPB and change in SF36-V2 physical function domain. Puhan et al (2011) recommend that anchor based estimations for the MCID can only be performed if correlations between change in outcome measure of interest (SPPB) and change in anchor is >0.30, however, correlations of >0.50 are required for more robust estimates of the MCID. In our study, the correlation between change in the SPPB and change in the SF36-V2 physical function domain was r=0.16 yielding the anchor based approach to calculate the MCID inappropriate to conduct and these analyses were ceased.
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4.4.2 Distribution based calculation of the MCID:-

Given the variety of tests available to calculate the MCID using distribution based methods, we adopted a variety of formulae commonly used (Wyrwich et al, 2004; Wyrwich et al, 1999; Wyrwich et al, 2002): First, the effect size of the SPPB was calculated using the following formula: effect size (ES) = (μ1–μ2)/σ1, where μ1 and μ2 are the means at baseline and follow-up respectively, and σ1 is the SD at baseline. The 95% confidence intervals (CI) for this value were calculated using bootstrapping. ES indices of 0.2, 0.5, and 0.8 have been interpreted to represent small, moderate and large responsiveness to change, respectively (Husted et al, 2000). A positive ES denotes improvement in health status. Second, the small effect sizes were calculated as 0.2 x σ1 and substantial change was computed as 0.5 x σ1. Third, the standard error of measurement of the SPPB was calculated using the following formula: standard error of measurement = σ1 √ (1 - r), where σ1 is baseline SD and r is the test-retest reliability coefficient. Reliability (ICC = 0.88-0.92) estimates for SPPB measures were obtained from a published study of 1002 women with stable cardiovascular conditions (Ostir et al, 1998) as there is no relevant literature in cardiac surgery to draw reliability information from.

4.4.3 Floor and ceiling effects of the SPPB

Floor effects for the SPPB were determined using the percentage of participants scoring 0 out of 12 at each time point and ceiling effects were determined using the percentage of participants scoring 12 out of 12 at each time point.

4.5 Results

Demographic characteristics of the 72 participants recruited for the study are shown in Table 4.1. Fifty-nine percent (n=43) of participants underwent coronary artery bypass graft surgery, 29% (n=21) underwent valve surgery, 10% (n=7) underwent combined coronary artery bypass graft and valve surgery, and 1% (n=1) underwent type A aortic dissection repair (Table 4.1). Four patients were missing repeat data and were therefore
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excluded from analyses. Over the period of four weeks to three months after surgery the mean change (95%CI) in SPPB was 1.04 (0.67 to 1.42) points (Figure 4.4) and for the SF36 physical function domain was 9.96 (7.69 to 12.2) points.
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Table 4.1: Baseline demographic and clinical characteristics of sample following cardiac surgery

<table>
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<tr>
<th></th>
<th>Total Cohort (n=72)</th>
<th>Changed group* (n=64)</th>
<th>Unchanged group* (n=4)</th>
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<td></td>
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<td>n (%)</td>
<td>n (%)</td>
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<td>360 (144 to 360)</td>
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<th>Type A Aortic dissent</th>
<th>Operation duration, minutes, M (SD)</th>
<th>Mechanical Ventilation duration, hours, M (SD)</th>
<th>Cardiopulmonary bypass duration, minutes, M (SD)</th>
<th>Used of gait aid post-operatively</th>
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* grouped according to their change in SF36-V2 physical function scores by greater than the published MCID (Ware et al, 2000b). Abbreviations: SD, standard deviation; M, Mean; Med, Median; IQR, interquartile range; SF36 PF, The Medical Outcome Study 36-item Short Form Version 2 Physical Function domain; CABG, coronary artery bypass graft.
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**Figure 4.4:** Box plot demonstrating the mean (SD) of the Short Physical Performance Battery scores at each testing time point, the distribution of change values and the ceiling effect.

### 4.5.1 Meaningful change in the SPPB estimated using anchor-based measures:

Based on change in the SF36 physical function domain, 94% (n=64) of participants were classified as ‘changed’ and 6% (n=4) were classified as ‘not changed. The mean difference (95% CI) in the SPPB change scores between these groups was 0.88 (-0.69 to 2.44). The correlation between the change in SPPB and change in the SF36 physical function domain was $r = 0.16$. Therefore, estimation of the MCID using anchor-based approach (including Receiver Operator Curves) was not possible.

In the GRC scale 71% (n=48) of participants reported their physical function between testing time points to be “very much improved”, 26% (n=18) reported “much improved”, 1.5% (n=1) reported “minimal improved” and 1.5% (n=1) reported “no change”. Based on the GRC, 98% (n=67) were classified as ‘changed’ and 1.5% (n=1) was classified as “not changed”. Further analyses grouped according to these categories were unable to be conducted due to lack of separation of groups.
The Short Physical Performance Battery (SPPB) can be utilized to evaluate physical function in patients following cardiac surgery.

### Table 4.2: Effect size, SD and SEM-based Minimal Clinical Important Difference for the Short Physical Performance Battery overall score and tests

<table>
<thead>
<tr>
<th></th>
<th>SPPB</th>
<th>Gait Speed (m/sec)</th>
<th>RCS (sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effect Size-based Estimate*</td>
<td>0.44</td>
<td>0.41</td>
<td>0.43</td>
</tr>
<tr>
<td>SD-based Estimate#</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.2 (small) small meaningful change</td>
<td>0.54</td>
<td>0.34</td>
<td>0.84</td>
</tr>
<tr>
<td>0.5 (moderate) substantial meaningful change</td>
<td>1.35</td>
<td>0.85</td>
<td>2.11</td>
</tr>
<tr>
<td>SEM-based Estimate</td>
<td>0.77-0.99</td>
<td>0.78</td>
<td>1.89</td>
</tr>
</tbody>
</table>

* effect size = (μ1−μ2)/σ₁, # = 0.2 x σ₁ and 0.5 x σ₁

Abbreviations: Standard deviation (SD); Standard error of measurement (SEM); repeated chair stand (RCS)

#### 4.5.2. Meaningful change in the SPPB estimated using “distribution-based” methods:

Table 4.2 shows the estimates of effect size-based MCID, standard deviation-based MCID and SEM-based MCID for the SPPB. The effect size-based MCID of the SPPB calculated using the formula (μ1−μ2)/σ₁ was 0.44 (95%CI 0.191 to 0.613) points which represents a small responsiveness to change (Husted et al, 2000). Changes in SPPB scores corresponding to small and moderate effect sizes were 0.54 and 1.35 points, respectively. Therefore, based upon our results calculating the MCID of the SPPB with a variety of different approaches, we determined that the MCID for SPPB is between 0.44 to 1.35 points.

#### 4.5.3. Floor and ceiling effects of the SPPB.

There were no floor effects in the SPPB at four weeks or three months post-operatively (no participants scored 0 for the SPPB at any time point). There was a 45% and 69% ceiling effect at four weeks and three months post-operatively respectively where participants scored 12 out of 12.

#### 4.6 Discussion

The SPPB has been used widely in older adult populations (Pavasini et al, 2016) and in individuals with stable cardiovascular disease (Puthoff, 2008; Volpato et al, 2008). The
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results of the present study are the first to determine the MCID of SPPB for an adult cardiac surgery population and indicate that the MCID is between 0.44 to 1.34 points out of a total 12 points. Our results may assist clinicians to interpret changes in their patient’s functional performance using the SPPB across time following cardiac surgery. Understanding improvements in the SPPB can be used to facilitate evaluation of rehabilitation interventions and patients recovery, evaluate treatment effectiveness and guide individual care plans (King et al, 2011) including phase I/II cardiac rehabilitation programs (Puthoff, 2008). We suggest that the MCID score in the current study should be considered preliminary evidence on the application of the SPPB to evaluate treatment effectiveness by detecting a true improvement. An increase or decrease in performance greater than MCID indicates a high likelihood of a meaningful change. Thus, these measures can be used to document real improvements in physical function through the course of cardiac rehabilitation. Therefore, an MCID reference value above one point of SPPB scores could serve as an explicit therapeutic goal for rehabilitation intervention and monitor functional progress for individuals following cardiac surgery.

Our findings are consistent with previous reports of the MCID established for other patient populations including older adults and those with chronic disease. The results of the present study are comparable with (Perera et al, 2006)(Kwon et al, 2009) who investigated older adults and reported the MCID (0.27 to 0.55 points) and the substantial change estimates (0.99 to 1.34); MCID (0.30 to 0.80 points) and substantial change estimates (0.40 to 1.50) respectively for the SPPB. Contrary to our findings, in a cohort of elderly people (mean age 78 years), Volpato et al (2008) reported an MCID of 2.7 points and in a sample of frail individuals, Mangione et al (2010) reported the MCID to be 3.0 points. The variances in the finding of the MCID may be due to the significant ceiling effect observed in our study. It is possible that our MCID estimates might be biased by the absence of data pre-operatively and the focus of a delayed post-operative assessment at 4 weeks and 3 months which may have contributed a greater ceiling effect. These results may lead to a shortcoming in the discriminative ability of the SPPB to detect clinically relevant changes particularly for both the four week and three month post-operative periods. As such, this would lead to an underestimate of the threshold of the effect size-based MCID, the standard deviation and SEM-based MCID. Further research is required to confirm if the MCID range calculated in our study is the
same for patients in the immediate post-operative period (such as days to weeks pre to post-operatively). Beyond the three months time point we recommend alternative measures of physical function such as the Late Life Function and Disability Instrument (LLFDI) which is likely to have a lower ceiling effect due to the higher difficulty of the assessment (Lapier, 2012).

The SPPB and SF36 scores were high in the current cohort with the majority of patients rating their function as ‘changed’ on the GRC scale between the testing time periods. This improvement was expected as the testing time points occurred during a critical period of recovery early in the post-operative period. Elective cardiac surgery is aimed at increasing life expectancy, and importantly for patients, the procedure assists them in improving their HRQoL and independence by alleviating symptoms such as chest pain, shortness of breath and (or) dysrhythmia (Nicolini et al, 2014) Therefore, early improvements at baseline or better than pre-operative function often occur (Jokinen et al, 2010; LaPier et al, 2008). In addition, patients received physiotherapy in hospital and the majority also attended outpatient cardiac rehabilitation as per standard care. We would expect most patients to attain functional benefits from cardiac rehabilitation. We were unable to use the GRC as a discriminative tool for change as a high percentage of patients rated that they had improved in their physical function. This result is consistent with the finding by Kamper et al (2009), who reported that those with less severe dysfunction at baseline have smaller change scores over time, and this contributed to a reduction in the strength of association between the change score and the GRC. In addition, patients may have been unable to remember accurately their previous condition, especially since the recall period was two months compared to other studies with a shorter recall period of 2 to 6 weeks (Fischer et al, 1999; Guyatt et al, 2002; Jaeschke et al, 1989; Kamper et al, 2009). The GRC is a retrospective judgment tool and has been criticized for recall bias, biases in administration, and poor reliability over time (Fischer et al, 1999; Kamper et al, 2009). Our findings, captured from a sample of patients following cardiac surgery, suggest that all these concerns are of merit. Although the anchor-based estimate is the ideal approach to determine the MCID, the shortcoming of this method is that there are currently no accepted standards for appraising the credibility of MCID estimates associated with patient reported outcomes (Johnston et al, 2015; Walters & Brazier, 2003).
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Our results suggest the SPPB does not have a floor effect but does have high ceiling effects meaning that the test may be too easy as time from surgery increases and participants recover. Yet in comparison a recent systemic review reported (Freiberger et al, 2012) that the SPPB has a low floor effect (with 0-7% patients achieving the lowest score) and low ceiling effect (2-16% scoring the highest score of 12 points) in general population community dwelling adult patients with 60 years of age and older who are at risk for functional decline (Guralnik et al, 1995; Vasunilashorn et al, 2009). A possible explanation to the different results we found might be the younger age of our sample cohort (mean age 63) who improve overtime consistent with improvement as a result of cardiac surgery or it might be that the three subtests composing the SPPB may present different age-related declines (Cesari et al, 2008). Similar to our findings, in one of the cited studies from the systemic review, 77% achieved the highest SPPB score in non-disabled older persons consistent with our study (Vasunilashorn et al, 2009). A concern of the high ceiling effect is that it may impair the responsiveness of the SPPB for high-functioning patients following cardiac surgery between the two time points, posing a serious concern for type II errors in clinical trials (Pardasaney et al, 2012). Despite the high ceiling effect in our study, we still detected a statistically significant change over time with the SPPB to three months post-operatively but suspect further improvement beyond this time may not be captured with the SPPB. Further research is warranted to explore the predictors of patients who do not reach the maximum score (ceiling effect) in the short period post-operatively.

Clinical trials measuring physical function in patients following cardiac surgery with longer follow-up period (such as 6 and 12 months post-operatively) may benefit from using alternative measures with higher difficulty (and hence less chance of patients scoring 100%). A related study compared the SPPB and the 400-metre walk test of 101 older adults to discriminate physical performance and similarly found a high ceiling effect in the SPPB and better results for the 400-metre walk (Sayers et al, 2006). More specifically, certain items were “too easy” (side by side balance test) or “too difficult” (tandem balance and five times repeated chair stand) and most of the domains has been reported to be valid (Motl et al, 2015) and good discriminator in 20-80% of the participants for lower body functioning assessment (Giuliani et al, 2008; Guralnik et al, 1995; Seeman et al, 1994) but not upper limb functioning (Motl et al, 2015). However,
there were no floor effects observed in the study suggesting, that the scale is more appropriate as a measure in the post-acute hospital wards or immediately post-hospital discharge. It is important to note that the SPPB is biased towards assessment of lower limbs and therefore does not capture upper limb and thorax function which is paramount following cardiac surgery by sternotomy which impacts on these regions (Motl et al, 2015). An additional domain that aims to target upper limb and thorax function that is representative of activities of daily livings may be a warranted addition to the SPPB. This is of particular relevance in the cardiac surgical population given the impact of surgery on the chest wall; subsequent upper limb function and sternal pain. One such validated test in the chronic lung disease population that may act as a reference point that aims to assess upper limb is the “Unsupported Upper Limb Test” (Takahashi et al, 2003).

A strength of this study is that it is the first study to be conducted in the acute cardiac surgery population over a 3-months period to calculate the MCID. In addition, it applied established methods of calculating the MCID to ensure robust results. The most notable limitation of this study is its small sample size, as this result in reduced chance of detecting a true effect. In future, bootstrapping techniques could be used to address sample size limitations. Furthermore, reliability data for the calculation of the minimal important different using distribution based methods were extrapolated from cardiovascular conditions rather than specifically from patients post cardiac surgery. There is a possibility of external validity errors due to the use of a reliability estimate from a study composed solely of females. Future research is required to confirm whether the reliability coefficient used is the same following cardiac surgery cohort. The outcome measures used in this study were obtained at four weeks and three months post-operatively. At this time point, it is possible the SPPB was not challenging enough or may have limited number of difficult items as time after surgery increases and the majority of patients have recovered further. This may have caused a lower threshold of the MCID estimates due to significant ceiling effects observed. It is possible that the results would alter across differing time points and this is worthy of further investigation at different intervals across time relative to surgery including in the pre-operative periods.
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4.7 Conclusion

The minimal clinically important difference (MCID) of the SPPB to assess physical function of patients following cardiac surgery is between 0.44 and 1.35 points out of a maximum of 12 points. We did not find any floor effects in the SPPB, meaning that no patients scored 0 out of 12 on the test; however nearly half of the participants scored the maximum score at four weeks, increasing to two thirds at three months meaning that the SPPB may be too easy as time from surgery increases and patients recover. Further research is required to confirm this MCID range due to the high ceiling effects observed in our study.

The FDQ was developed to assess physical function of the upper limbs and trunk in the cardiac population. This tool was developed to address the paucity of tools that assess functional recovery in the surgical population. Sturgess et al (2017) have established the test-retest reliability of this tool in a cohort of acute cardiac surgery patients however a comprehensive clinometric analysis of this outcome measure has to date not been conducted. This prompted the next study presented in Chapter 5.
Chapter 5:
The Functional Disability Questionnaire: Evaluation of the Clinimetric Properties of a New Tool for Measuring Physical Function Following Cardiac Surgery

Chapter Overview

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This study submitted for peer review in Archives of Physical Medicine and Rehabilitation Journal


Author contributions for this chapter are the following:
KMA, DE, LD, and CG conceived the idea for the paper. KMA, DE, LD, AR, CR and CG contributed to research design. KMA DE LD and CG contributed to data acquisition. KMA, DE, LD, and CG contributed to research design. KMA, CG, CR and SC contributed to data analysis. KMA completed all statistical analysis. KMA wrote the
5.1 Background

Median sternotomy remains the gold standard incision for cardiac surgical procedures worldwide (Authors/Task Force et al, 2014; Deb et al, 2013. However, a significant proportion of patients experience impairments, which can impact upon return to functional independence and health related quality of life (Adams et al, 2006; LaPier & Wilson, 2007; LaPier et al, 2008; Zimmerman et al, 2011). In particular, the number of elderly people presenting for cardiac surgery with functional impairment is increasing with a reported mean age of 70 years old worldwide (Bargehr et al, 2017; Nicolini et al, 2014; Tran et al, 2013). These patients often present with concurrent co-morbidities and clinical conditions, including severe dependence, cognitive impairment, and depression (Montilla Padilla et al, 2017; Nicolini et al, 2014; Tran et al, 2013). Specific clinical measures to evaluate physical function are paramount in this population with priority on frail and vulnerable patients (LaPier, 2003; LaPier & Wilson, 2007) Such assessment can guide individual care plans, discharge planning and wellness beyond discharge. Studies have shown that 4 to 6 weeks after surgery is a critical time frame to assess physical recovery post-operatively and after hospitalization (Cahalin et al, 2011; LaPier, 2003; Min et al, 2015) Previous reports have highlighted the difficulties with functional tasks that challenge the thoracic cage and upper limbs following cardiac surgery (LaPier & Wilson, 2007; Min et al, 2015). These activities were representative of everyday tasks that challenged the thoracic cage such as changes in position when supine, lying on the side, getting in and out of bed /chair, coughing, sneezing, bending and reaching (Adams et al, 2006; Adams et al, 2008; El-Ansary et al, 2007b; Hoggins, 2009). The inability to incorporate these movements into daily activities may limit a patient’s independence in the community (LaPier, 2007; LaPier & Schenk, 2002; LaPier & Wilson, 2007). However, there are currently no other disease-specific measures assessing physical recovery that focus on upper limb and trunk function thereby informing evaluation of activity limitation in this population (Hoggins, 2009; LaPier & Schenk, 2002; LaPier & Wilson, 2007; LaPier et al, 2008). HRQoL measures of physical function domain are most commonly used as opposed to global function or specific functional mobility assessments (Maillard et al, 2015; Myles et al, 2014; Tully et al, 2013). As such, there
is a need for a tool that specifically evaluated upper limb and trunk function as a clinical measure (LaPier, 2003; LaPier et al, 2006; LaPier, 2007; Hoggins, 2009). Hoggins (2009) developed the FDQ to specifically evaluate physical function of the UL and trunk following cardiac surgery via sternotomy. This is self–reported instrument that can be administered by any health professional. The tool comprised of 13 separate functional task necessary in everyday life that challenge the body in the sagittal and frontal planes as well as multiplanar motion across the body (Hoggins, 2009). Each component task was selected following consultation with a team of seniors clinician and a pilot with 10 cardiac surgery patients (Hoggins, 2009).

These tasks included: upright sitting, walking with arms swinging freely, coughing/sneezing, rolling over in bed, getting out of bed, washing hair, scratching the back, picking up an object off the ground, turning to reach backwards, doing the clasp of a brassiere or tucking in a shirt at the back of pants, putting on a dressing gown/cardigan/jacket, drying the back with a towel, and pushing a set of drawers shut based (Hoggins, 2009). In a pilot study(n=38) it was shown to be valid, reliable and responsive measure following acute cardiac surgery (Hoggins, 2009) However, rigorous testing of its clinimetric properties, in a much larger sample, was required before it could be recommended for use in clinical practice. The original FDQ potentially was overlapping and duplication of some items and therefore it is proposed that a shorter version may be feasible to reduce the time burden for patients and clinicians. This study aimed to (1) investigate the statistical feasibility of a shortened version of the tool (FDQ-s) by examining the item-scale structures of the original FDQ and (2) determine the construct validity, predictive utility, reliability, and clinical applicability (floor and ceiling effects, responsiveness and minimal clinical important difference (MCID) of the newly developed FDQ-s in patients following cardiac surgery. The study was conducted and reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (von Elm et al, 2008).
5.2 Methods

5.2.1 Procedures

225 consecutive participants who underwent cardiac surgery via a median sternotomy were included from FOUR different hospitals. The FDQ was administered by physiotherapists and nurses (with seven to 20 years of clinical experience). Patients were eligible for inclusion if they were adults undergoing isolated valve, CABG surgery or a combination of both procedures; able to read and write English; and able to provide consent. Patients were excluded if they lived 50km or more from the hospital.

5.2.2 Part 1:

Data were collected from nested studies within 2 randomized controlled trials Study 1 was an assessor blinded, parallel group pilot randomized controlled trial at Monash hospital investigating the effect of thoracic mobilisation exercises (n=38). (Sturgess et al, 2014) Study 2 was a double blinded (patients and assessor) randomized controlled trial at Royal Melbourne Hospital and Melbourne Private Hospital investigating the effect of modified sternal precautions post-operatively on physical function (n=72) (Katijjahbe et al, 2017). As part of these trials, participants completed outcome measures (physical function, pain and health-related quality of life) at hospital discharge, four weeks and three months post-operatively. For this investigation, data from all participants and both trial arms were pooled and included.

5.2.3 Part 2:

Data were collected for reliability analyses from four different sub-groups of participants within a multi-site observational study. Intra-rater reliability was measured in 55 participants in Victoria and inter-rater reliability was measured in 60 participants in Canberra (n=30) and Victoria (n=30). The FDQ was measured twice (four hours apart) and the order of the testing for inter-rater reliability was random.
5.2.4 Ethical approval for the study

Studies were approved by the Human Research Ethics Committees: Melbourne Health (project number: 2015.035), Monash Health (project number 06071B) and Canberra Hospital project number (ETHLR.14.068) in Australia.

5.3 Data collection

The clinical characteristics and post-operative variables for participants following cardiac surgery were collected (Table 5.1).

5.4 Measures

5.4.1 The Functional Difficulty Questionnaire (FDQ).

The clinical characteristics and post-operative variables for participants following cardiac surgery were collected. Participants from Part 1 of this investigation completed the original FDQ at each time point. The FDQ is a 13 item questionnaire which asks the participant to rate the difficulty they experience when completing a series of 13 upper limb and trunk activities by placing a mark along a 10cm line, with anchors indicating “no difficulty” and “maximum difficulty”. (Hoggins, 2009) For those activities that participants could not attempt whilst completing the questionnaire due to the institution sternal precautions, they were asked to think back to the last time they performed the task (Hoggins, 2009). Individual scores, measured to the nearest centimetre (cm), were aggregated to form a total out of 130 with higher scores representing greater difficulty experienced during functional activities (Hoggins, 2009).
Table 5.1: Clinical Characteristics of study sample adult following cardiac surgery

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Part 1 (n=110)</th>
<th>Part 2 (n=55)</th>
<th>Part 2 (n=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (year), mean (SD)</td>
<td>62.7 ±11.17</td>
<td>64.8 ±9.53</td>
<td>63.7 ±10.61</td>
</tr>
<tr>
<td>Gender, n male; n female (%)</td>
<td>92 (83.6); 18</td>
<td>36 (65.5); 19</td>
<td>41 (68.3); 19</td>
</tr>
<tr>
<td></td>
<td>(16.4)</td>
<td>(34.5)</td>
<td>(31.7)</td>
</tr>
<tr>
<td>Type of cardiac surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CABG, n (%)</td>
<td>75 (63.6)</td>
<td>35 (63.6)</td>
<td>34 (56.7)</td>
</tr>
<tr>
<td>Off pump, n (%)</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Valve, n (%)</td>
<td>27 (22.9)</td>
<td>13 (23.6)</td>
<td>20 (33.3)</td>
</tr>
<tr>
<td>Combination of CABG and valve, n (%)</td>
<td>7 (5.9)</td>
<td>6 (10.9)</td>
<td>5 (8.3)</td>
</tr>
<tr>
<td>Type 1 Aortic dissent, n (%)</td>
<td>1 (0.8)</td>
<td>1 (1.8)</td>
<td>1 (1.7)</td>
</tr>
<tr>
<td>Type of graft</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saphenous vein, n</td>
<td>24</td>
<td>16</td>
<td>13</td>
</tr>
<tr>
<td>Bilateral internal mammary artery, n</td>
<td>11</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Unilateral internal mammary artery, n</td>
<td>66</td>
<td>33</td>
<td>33</td>
</tr>
<tr>
<td>Radial artery, n</td>
<td>57</td>
<td>35</td>
<td>26</td>
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<tr>
<td>Co-morbidities</td>
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<tr>
<td>Chronic obstructive airways disease, n</td>
<td>12</td>
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</tr>
<tr>
<td>Diabetic mellitus, n</td>
<td>31</td>
<td>17</td>
<td>12</td>
</tr>
<tr>
<td>Osteoarthritis /Rheumatoid arthritis, n</td>
<td>13</td>
<td>12</td>
<td>14</td>
</tr>
<tr>
<td>Hypertension, n</td>
<td>50</td>
<td>55</td>
<td>49</td>
</tr>
<tr>
<td>Peripheral vascular disease, n</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

Abbreviation: CABG=Coronary artery bypass graft; n=number of participants; SD = Standard deviation
Chapter 5 The Functional Disability Questionnaire: Evaluation of the Clinimetric Properties of a New Tool for Measuring Physical Function Following Cardiac Surgery

5.5 Additional Measures

5.5.1 Short Physical performance Battery (SPPB)

The Short Physical Performance Battery (SPPB). Participants completed a range of other measures depending on the original study that they were involved in. These included the SPPB (Part 1, study 2) which is a test of functional mobility for older adults. The SPPB includes assessment of gait speed (8-foot walk), standing balance, and lower extremity strength and endurance (chair rise task) (Guralnik et al., 2000; Guralnik et al., 1995; Guralnik et al., 1994).

5.5.2 Time up and Go Test

The TUG (Part 1, study 1) which is a test of functional mobility for older adults (Beauchet et al., 2011). The TUG test measures the time (seconds) taken to stand from a chair, walk three meters and return to the sitting position (Beauchet et al., 2011).

5.5.3 Numerical rating scale for pain (NRS).

The NRS (Part 1 study 2) which, requires participants to rate their pain from 0 to 10 (11 points scale) from 0/no pain to 10/worst possible pain (Hawker et al., 2011).

5.5.4 The Medical Outcome Study 36 item version 2 (SF36-V2)

The SF36-V2 (Part 1, study 1 and 2) which is a self-reported questionnaire that assesses eight health domains: physical functioning, role physical functioning, role emotional functioning, mental health, vitality, social functioning, bodily pain and general health. The scores are presented as norm-based T-scores (mean 50, SD=10), relative to Australian population norms (Ware et al., 2000) Higher scores (> 50) represent better health. The eight scores are aggregated into two summary measures: physical component summary and mental component summary. The MCID for change in the physical function domain of the SF36 is 2 points (Ware et al., 2000). The SF36-V2 questionnaire has been shown to correlate well with symptoms of coronary artery disease, and is sensitive to change over time in patients undergoing cardiac surgery (Falcoz et al., 2002).
5.5.5 The Global Rating Change Scale (GRC)

The GRC (Part 1, study 2) which is a self-reported measure of patients’ perceived change. (de Morton et al, 2010; Garrison & Cook, 2012) This was administered prior to the performance-based assessments at four weeks and three months post-operatively. Participants were asked: “How does your overall arms function now, compare to your arms function just before you went home from the hospital?” and responded 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 (de Morton et al, 2010), therefore these patients are grouped into a “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 groups into a “changed” category (de Morton et al, 2010).

5.6 Sample Size

Sample size of 225 is in accordance with recommendations for studies assessing clinimetric properties of questionnaires (≥ 50) (Terwee et al, 2010).

5.7 Statistical analysis

Data analyses were performed using the SPSS Windows Version 23.0 (SPSS, Chicago, IL, USA). Data were assessed for normality using the Kolmogorov-Smirnov. Descriptive statistics including mean and SD; median and interquartile range; number and percentage; and frequency were used to summarize data. Pearson or Spearman’s correlation coefficient to assess the bivariate relationships between test scores. Coefficients were interpreted as: little (0.00–0.25), fair (0.25–0.50), moderate (0.50–0.75) and excellent association (0.75–1.0) (Portney & Watkins, 2009). Alpha was set at 0.05 for all analyses.
5.7.1 Exploratory Factor Analysis: Item reduction

The item reduction and clinimetric validation analyses were performed on data from 110 subjects. The 13 items were reduced to 10 items, based on the following assessments. Firstly, correlations between the 13 items were assessed to determine which items would serve as suitable proxies for others. Secondly, an exploratory Principal Component Analysis using a varimax rotation on the correlation matrix was performed to assess which items loaded on to the same factors. And, lastly, the corrected item-total correlation was determined. Items were excluded if they were highly correlated with other existing items; a high item corrected scale, and loaded on to the same components as other existing items, consistently across the three time points. A scale based on these 10 items was then assessed in terms of; (1) items-to-domain correlation (item discrimination), defined a priori as the corrected item–total score correlation for each domain must be between 0.30 to 0.90 and a positive value. (Field, 2013) If < 0.30 means, the items it’s not measuring what it supposed to measure and, if > 0.9 means the items testing the same meaning (redundancy); and (2) reliability (internal consistency reliability), in which a Cronbach’s coefficient of >0.7 is considered desirable for each domain and the removal of an item should not increase the internal consistency.

5.7.2 Internal consistency and test-retest reliability

Both internal consistency (Cronbach’s α) and test–retest (intra-class correlation) reliability were assessed. Intra-class correlation model (2,1) for single raters and similar raters were used. The strength of the correlations was assessed with a value above 0.70 considered acceptable (Portney & Watkins, 2009) Absolute reliability was calculated using the standard error of measurement formula: standard deviation of the mean overall of FDQ-s measures multiplied by the square root of one minus the reliability coefficient for the FDQ-s measure which quantifies the precision of an individual result and gives result in the same unit as the measurement (Portney & Watkins, 2009) Bland-Altman plots were also developed to investigate the limits of agreement and identify any systemic errors in the mean of overall FDQ-s between two raters (Giavana, 2015).
5.7.3 Predictive Utility

Multivariate logistic regression was used to investigate the predictive utility (the ability of an instrument to predict future health states of the baseline FDQ-s and selected clinical variables. The outcomes of interest are the baseline FDQ-s (dependant variables) and the Short Physical Performance Battery, Numerical Rating Scale of pain score, SF36-V2 physical function domain, physical component summary and patients used of gait aids or without gait aids after surgery (as independent variables) as this variable had a priori significant bivariate correlation with the dependent variable. Other potential baseline covariates were patient age (in years), gender (male and female), Charlson Comorbidity Index, cardiopulmonary bypass duration (in minutes), operation duration (in hours), and body mass index (kg/m2). Potential covariates with a significant univariate correlation with outcome and an absence of collinearity were initially included in the regression model and retained if identified as a significant factor in the model. Goodness of fit was examined using the Hosmer-Lemeshow Goodness of Fit Test and poor fit was defined as alpha < 0.05 (Portney & Watkins, 2009).

5.8 Clinical applicability

5.8.1 Floor and ceiling effects

Floor effects for the FDQ-s were determined by the percentage of participants scoring minimally (i.e. 0/100) at each time point, and ceiling effects were determined by the percentage of participants scoring maximally (i.e. 100/100) at each time point. The threshold in defining these effects was 15% or more of participants achieving the best or the worst level of the score (Terwee et al, 2007).

5.8.2 Responsiveness

Change over time of FDQ-s scores was assessed using paired t-tests. Responsiveness of each test was determined with the calculation of the effect size. this was defined as Cohen’s d and calculated as the mean difference divided by pooled standard deviation. The effect size-based MCID of the FDQ was calculated using the following formulae:
effect size (ES) = \((\mu_1 - \mu_2)/\sigma_1\), where \(\mu_1\) and \(\mu_2\) are the means at baseline and follow-up respectively, and \(\sigma_1\) is the standard deviation at baseline. Es of 0.2, 0.5, and 0.8 have been interpreted to represent small, moderate and large responsiveness to change, respectively (Husted et al, 2000). A positive ESI denotes improvement in health status.

5.8.3 The minimal clinical important difference (MCID)

The MCID is defined as the minimum change that needs to occur to reflect a clinically meaningful change in patient function (Wyrwich et al, 2004; Wyrwich et al, 2002; Wyrwich & Wolinsky, 2000). Two general approaches commonly used in the scientific literature to determine the MCID are the anchor-based and the distribution-based method (HaleY, 2006; Wyrwich et al, 2004; Wyrwich et al, 1999), therefore these methods were used to approximate the MCID for the FDQs.

**Distribution based calculation of the MCID.** The standard error of measurement-based MCID of the FDQ-s was calculated using the following formula: standard error of measurement = \(\sigma_1 \sqrt{(1 - r)}\), where \(\sigma_1\) is baseline standard deviation and \(r\) is the test-retest reliability coefficient obtained from the current study (\(r = 0.899\) to \(0.922\)). The standard deviation-based MCID, where small effect sizes were calculated as \(0.2 \times \sigma_1\), and substantial change was computed as \(0.5 \times \sigma_1\) (Husted et al, 2000). The 95% confidence intervals for this value were calculated using bootstrapping.

**Anchor based calculation of the MCID:** All participants were categorized into two groups based on their change in SF36-v2 physical function scores between 4 weeks and 3 months post-operatively. Participants were classified as ‘changed’ if they had an increase or decrease in the SF36 physical function domain of \(\geq 2\) points or ‘not-changed’ if they had an increase or decrease in the SF36 physical function domain of \(< 2\) points as per the published MCID for this domain (Ware et al, 2000) Pearson’s correlations were used to assess the bivariate relationship between change in FDQ-s and change in SF36-V2 physical function domain. Puhan et al (2011) recommend that anchor-based estimations for the MCID can only be performed if correlations between change in outcome measure of interest (FDQ-s) and change in anchor is \(> 0.30\), however, correlations of \(> 0.50\) are required for more robust estimates of the MCID. Data were available from Part 1(Study 2) with exclusion of missing data (n = 68).
Chapter 5  The Functional Disability Questionnaire: Evaluation of the Clinimetric Properties of a New Tool for Measuring Physical Function Following Cardiac Surgery

5.9 Results

A summary of the demographic and clinical characteristics of this sample is presented in Table 5.1. There were a total of 225 participants in the study. Four patients were missing repeat data and were therefore excluded from analyses for part 1 study 2.

5.9.1 Item Reduction

An initial exploratory factor analysis was undertaken, along with assessment of correlations between items and corrected item-total correlation. On this basis, items 6, 9 and 13 were excluded. Item 6 was highly correlated with item 11, item 9 was highly correlated with items 7 and 8 and item 12 was highly correlated with item 13. The exploratory two factor principle-components analysis of the remaining 10 items, using varimax rotations was conducted across the 3 time points, with 1 factor explaining 58%; at post-operative before discharge; 61% at four weeks for first factor; 64% at three months, respectively. The factors loading matrix for this final solution is presented in Table 5.2. A validation of the 10 items further showed all items had high internal consistencies reliability analysis. The Cronbach’s α = 0.914 to 0.926 (Table 5.3) and the mean inter item correlations (from item statistics) is more > 0.3 across three time points, by the rule of:

i. The highest value for each item looking at Inter-item correlation matrix is between 0.3-0.9 at four weeks and three months

ii. The lowest value of corrected item total correlation (from item total statistics) is not lower than 0.3 (0.512) before discharge after surgery, 0.602 at four weeks and 0.652 at three months respectively.

iii. The Cronbach’s α is rated as good, >0.90
Table 5.2: The PCA was performed for each of three time points

<table>
<thead>
<tr>
<th>Percentage (%) of explained variance</th>
<th>Prior to discharge post-operatively</th>
<th>four weeks</th>
<th>three months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component</td>
<td>58.2</td>
<td>13.1</td>
<td>60.5</td>
</tr>
<tr>
<td>Item</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>1 Upright sitting</td>
<td>.70</td>
<td>.30</td>
<td>.81</td>
</tr>
<tr>
<td>2 Walking with arms swinging freely</td>
<td>.84</td>
<td>.24</td>
<td>.85</td>
</tr>
<tr>
<td>3 Coughing/sneezing</td>
<td>.20</td>
<td>.82</td>
<td>.11</td>
</tr>
<tr>
<td>4 Rolling over in bed</td>
<td>.15</td>
<td>.90</td>
<td>.39</td>
</tr>
<tr>
<td>5 Getting out of bed</td>
<td>.50</td>
<td>.68</td>
<td>.56</td>
</tr>
<tr>
<td>7 Scratching back</td>
<td>.65</td>
<td>.36</td>
<td>.68</td>
</tr>
<tr>
<td>8 Sitting and picking an object off the ground by leaning sideways</td>
<td>.80</td>
<td>.26</td>
<td>.47</td>
</tr>
<tr>
<td>10 Doing up a bra or tucking in shirt at the back of pants</td>
<td>.90</td>
<td>.06</td>
<td>.750</td>
</tr>
<tr>
<td>11 Putting on a dressing gown/cardigan/jacket</td>
<td>.87</td>
<td>.21</td>
<td>.65</td>
</tr>
<tr>
<td>12 Drying the back with a towel</td>
<td>.80</td>
<td>.30</td>
<td>.64</td>
</tr>
</tbody>
</table>
Table 5.3: Results of the FDQ-s internal consistency, test-retest reliability, ceiling and floor effects and mean (SD) across three time points

<table>
<thead>
<tr>
<th>Assessment time points</th>
<th>N</th>
<th>Internal consistency</th>
<th>Mean (SD)</th>
<th>ICC</th>
<th>Floor effects (%)</th>
<th>Ceiling effects (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>After surgery before discharge</td>
<td>110</td>
<td>0.914</td>
<td>38.71 (19.61)</td>
<td>0.515</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>At four weeks</td>
<td>107</td>
<td>0.914</td>
<td>15.46 (14.01)</td>
<td>0.516</td>
<td>0</td>
<td>3.7</td>
</tr>
<tr>
<td>At three months</td>
<td>109</td>
<td>0.926</td>
<td>7.97 (12.01)</td>
<td>0.555</td>
<td>0</td>
<td>24.5</td>
</tr>
</tbody>
</table>

5.9.2 Reliability analysis

The reproducibility coefficients intra-class correlation exceeded the acceptable criteria with a value above 0.90 for all FDQ-s scales. The intra-rater reliability of the mean of overall new FDQ-s score was shown by intra-class correlation (2,1) 0.922 and standard error of measurement 2.30. The inter-rater reliability of the mean of overall new FDQ-s score was intra-class correlation (2,1) 0.899 and standard error of measurement 2.30 for different raters.

The Bland-Altman analysis demonstrated smaller mean difference with wide limits of agreement indicative of a random variability and revealed the present of small systemic error which is 2.93 (in cm) which represent 27.6% error of the overall mean between 2 raters (Figure 5.1). The data points all fall near but not on the line of equality, suggesting there is some degree of disagreement between different rater (Figure 5.2). The correlation coefficient is r=0.89 (p < 0.0001; 95% CI = -4.74, -1.10). There is a negative bias with most data falling below 0. Although the differences are skewed, the sample distribution is approximately normal as indicated by the Kolmogorov-Smirnov test for normal distribution (p = 0.198).
Figure 5.1: The Bland-Altman plots for inter-rater data the representation of the limits of agreement (dotted line), from -1.96 to +1.96 (in cm).

Figure 5.2: correlation coefficient (r), and 95 % confidence interval (CI) of FDQ-s (in cm)
5.9.3 Validity

**Convergent validity**

Convergent validity was present with moderate to good correlation found for the discharge FDQ-s with NRS (r = 0.54), physical domain of the SF36-V2 (r = -0.45), PCS (r = 0.42) and SPPB (r = 0.56). High correlation was found between FDQ-s and NRS at four weeks (r = 0.74) but fair correlation at three months (r = 0.44) postoperatively. The FDQ-s score had moderate to strong relationships with physical domain of SF36-V2 (r = -0.59; 0.56), PCS (r = 0.54; 0.63) and identical results for SPPB (r = 0.50) at four weeks and three months. No significant correlation was found with TUG test (rho = 0.28) at discharge but there was a weak correlation with TUG test at four weeks and three months (rho = 0.39 and rho = 0.34), respectively (Table 5.4).

**Knowns-groups validity**

There was a significant difference on the level of functional difficulty of FDQ-s score at baseline between participants who used gait aids (52.88 ±16.12) and those without gait aids after surgery (36.63 ±16.82). The mean difference was 16.25 95% CI (7.78 to 24.72, p < 0.0005) demonstrating known-groups validity.

**Discriminant validity**

Low correlation was found between age; body mass index (kg/m2) and the pre-discharge FDQ-s (r=0.114; r=0.136 respectively) demonstrating discriminant validity.

**Predictive Utility.**

The FDQ-s demonstrated predictive utility with the pain at baseline is associated with risk of getting higher FDQ-s scores at baseline (OR 0.412, 95% CI 1.54 to 6.00, p = 0.01). Higher FDQ-s (maximal difficulty in function) scores were positively associated with obtaining a higher pain scores on NRS.
Table 5.4: Pearson’s correlations between the FDQ-s, SF36 physical function (n=110), PCS, (n=110), SPPB (n=72), TUG (n=38), and NRS (n=72)

<table>
<thead>
<tr>
<th>Measures</th>
<th>Prior to discharge post-operatively</th>
<th>Four weeks</th>
<th>Three months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FDQ</td>
<td>FDQ</td>
<td>FDQ</td>
</tr>
<tr>
<td><strong>NRS of pain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior to discharge post-operatively</td>
<td>$r^{**} = 0.54$</td>
<td>$p = 0.000$</td>
<td></td>
</tr>
<tr>
<td>4 weeks</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Three months</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>SF36 Physical functioning</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior to discharge post-operatively</td>
<td>$r^{**} = 0.45$</td>
<td>$p = 0.000$</td>
<td></td>
</tr>
<tr>
<td>4 weeks</td>
<td>-</td>
<td>-</td>
<td>$r^{**} = 0.586$</td>
</tr>
<tr>
<td>Three months</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>SF36 PCS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior to discharge post-operatively</td>
<td>$r^{**} = 0.42$</td>
<td>$p = 0.000$</td>
<td></td>
</tr>
<tr>
<td>4 weeks</td>
<td>-</td>
<td>-</td>
<td>$r^{**} = 0.54$</td>
</tr>
<tr>
<td>Three months</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>SPPB</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior to discharge post-operatively</td>
<td>$r^{**} = 0.56$</td>
<td>$p = 0.000$</td>
<td></td>
</tr>
<tr>
<td>4 weeks</td>
<td>-</td>
<td>-</td>
<td>$r^{**} = 0.50$</td>
</tr>
<tr>
<td>Three months</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>TUG</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior to discharge post-operatively</td>
<td>$rho = 0.28$</td>
<td>$p = 0.087$</td>
<td></td>
</tr>
<tr>
<td>4 weeks</td>
<td>-</td>
<td>-</td>
<td>$ rho = 0.39$</td>
</tr>
<tr>
<td>Three months</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*p < 0.05 level (2-tailed).

**p <0.01 level (2 tailed).
5.9.4 Responsiveness

The effect size index for the FDQ-s was 1.22 at four weeks to 1.60 at three months which represents a large responsiveness to change. (Husted et al, 2000) There was a significant difference on the level of functional difficulty of FDQ-s score post-operatively (p < 0.001) prior to hospital discharge to four weeks and three months following surgery. The mean change from baseline was 23.25 cm (95% CI 20.10 to 26.39) to four weeks and 30.78 cm (95% CI 27.24 to 34.32) to three months (Figure 5.3).

![Box plot demonstrating the mean (SD) of the FDQ score (in cm) at each testing time point](image)

**Figure 5.3:** Box plot demonstrating the mean (SD) of the FDQ score (in cm) at each testing time point
5.9.5 Meaningful change estimated using anchor-based measures

Based on change in the SF36-V2 physical function domain, 96% (n = 65) of participants were classified as ‘changed’ and 4% (n = 3) were classified as ‘not changed’. The mean difference (95% CI) in the FDQ-s scores between these groups was 7.06 (4.64 to 9.48). The correlation between the change in FDQ-s and change in SF36-V2 Physical function was r = 0.291. Therefore, the estimation of the MCID using anchor-based approach (including Receiver Operating Curves) was inappropriate to conduct and these analyses were ceased.

In the global rating of change scale 69.1% (n = 47) reported “very much improved”, 26.5% (n = 18) reported “much improved”, and 4.4% (n = 3) reported “no change”. Based on the global rating of change scale, 96% (n=65) were classified as ‘changed’ and 4.0% (n=3) was classified as ‘not changed’. Further analyses grouped according to these categories were unable to be conducted due to lack of separation of groups.

5.9.6 Meaningful change estimated using distribution-based method approaches

Distribution based methods indicated the MCID \((\mu_1-\mu_2)/\sigma_1\) of the FDQ-s was 20.04 (bootstrap 95%CI 0.972 to 1.500) at four weeks and 20.04 (bootstrap 95% CI 1.309 to 1.853) at three months for the Part 1 sample population. For the subset of 68 participants, using bootstrapping the MCID \((\mu_1-\mu_2)/\sigma_1\) of the FDQ-s was 12.96 (bootstrap 95%CI 0.4399 to 0.8623) between testing time points (4 weeks and 3 months). Table 5.5 shows the effect size, standard deviation and SEM-based MCIDs of the FDQ-s score. Changes in FDQ-s scores corresponding to small and moderate effect sizes were 4.01 and 10.02, respectively. The smallest meaningful change in the FDQ-s score was 4.01 and a change of 10.02 was related to a substantial change. Overall the MCID for FDQ-s is range was 4.01 to 10.02 out of 100 (in cm).
Chapter 5 The Functional Disability Questionnaire: Evaluation of the Clinimetric Properties of a New Tool for Measuring Physical Function Following Cardiac Surgery

**Table 5.5:** The effect size, standard deviation and Standard error of measurement based MCIDs of the FDQ-s scores between testing period

<table>
<thead>
<tr>
<th></th>
<th>four weeks</th>
<th>three months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effect size*</td>
<td>1.22</td>
<td>1.60</td>
</tr>
<tr>
<td>0.2 (small) small meaningful change#</td>
<td>4.01 cm</td>
<td></td>
</tr>
<tr>
<td>0.5 (moderate) substantial meaningful change#</td>
<td>10.02 cm</td>
<td></td>
</tr>
<tr>
<td>SEM small meaningful change# (r= 0.899 to 0.92)</td>
<td>5.596 to 6.37 cm</td>
<td></td>
</tr>
</tbody>
</table>

*effect size = (\(\mu_1 - \mu_2\)/\(\sigma_1\)), #standard deviation=0.2 x \(\sigma_1\) and 0.5 x \(\sigma_1\)

5.9.7 **Floor and ceiling effects**

There were no floor effects (no participants scored minimal difficulty 0/100 (in cm)) on the FDQ-s at any time point) and no ceiling effect (no participants scored maximal difficulty 100/100 in (cm)) during hospitalisation after surgery. However, complete recovery was demonstrated in 3.7% (n=4) of the participants at four weeks and in 24.5% (n=26) of participants at three months post-operatively.

5.10 **Discussion**

This study was carried out on large sample of patients thus facilitating a thorough analysis of the clinimetric properties of the FDQ following cardiac surgery via sternotomy. Our findings demonstrated that the proposed shortened version of the FDQ, the FDQ-s, has strong clinimetric properties measuring aspects of physical function impairment and recovery that are specific to the needs of patients following cardiac surgery via sternotomy.

The FDQ-s revealed robust clinimetric properties after item reduction. The 10 items have strong loading on the factors identified by the PCA using FDQ-s scores across three time points indicative of strong internal consistency (Refer appendix 9 for the 10 items FDQ-s form). The 10 remaining items of the FDQ-s represent different aspects of physical recovery deemed important and specific to upper limb and trunk movement and activity after cardiac surgery (e.g. item 13 ‘pushing a set of drawers shut’ was
removed as hand function was less affected and the majority of patients were able to perform this task with minimal limitation after surgery). The Cronbach’s alpha values of the FDQ-s components that were deleted from the questionnaire were assessed. No single item yielded a value greater than 0.98, thus indicating that each item of the questionnaire related to every other item and to the questionnaire as a whole (de Vet et al, 2006) The construct validity (convergent and discriminant) was moderate against measures of physical performance, HRQOL and pain. These results indicate the holistic approach of the FDQ-s for reflecting improvement in physical capacity and the association with HRQOL. Further, we found a significant difference in the FDQ-s scores at baseline between people using a gait aid compared to those without a gait aid indicating that the FDQ-s may be able to discriminate mobility impairments early in the post-operative. However, these finding should be interpreted with caution as analysis using regression did not demonstrate the predictive utility of FDQ-s on the need for gait aids in the target population.

As suspected the physical function of participants improved over time and sternal pain decreased over time. The positive correlation between physical function, and sternal pain as well as reduced physical function scores on self-administered SF3-V2 HRQOL scales (Bitkover & Gårdlund, 1998; Eisenberg et al, 2001) is consistent with previous studies (DiMattio & Tulman, 2003; LaPier & Wilson, 2007; LaPier et al, 2008; Sturgess et al, 2014). There was a significant decrease of physical function post-operatively before discharge followed by a significant improvement at four weeks and three months. Importantly, higher pain scores were shown to be predictive of higher FDQ-s (maximal difficulty in function). This result is not surprising as pain has been reported to be closely related with activity restriction after cardiac surgery (Balachandran, 2015; LaPier & Wilson, 2007; Sturgess et al, 2014; Tully, 2013). Moreover, in the short term, perception of HRQOL is influenced more by physical functioning than emotional functioning with physical HRQOL typically improving steadily in a linear fashion over time. (Hofer et al, 2005; Tully, 2013). Based on these results we can conclude that patients with distinctly high FDQ-s have increased pain, poor SPPB scores and poor HRQOL related physical function status and are also at risk of poor clinical conditions post-operatively (Cahalin et al, 2011). This finding is important and contributes towards the understanding of the association between pain, activity limitations and HRQOL in this population.
The FDQ-s displayed responsiveness to change, which showed physical recovery following cardiac surgery. The FDQ-s was able to discriminate difficulty level in physical function post-operatively as time from surgery increases and participants recover. The intra-rater and test-retest reliability was also extremely high. This means the FDQ-s is a potential option as primary outcome measure for clinical trials interested in post-operative physical function. We were also able to calculate the MCID which is useful to interpret clinically meaningful change for patients. We found no floor effect and less than 15% ceiling effect at the four-week assessment time point in the study, suggesting that the FDQ-s is best used in the post-acute hospital wards or early in post-hospital discharge setting. This is because further improvement beyond three months may not be captured with the FDQ-s (Barnason et al, 2003; LaPier & Wilson, 2007; Zimmerman et al, 2011). Patients in this study received physiotherapy in hospital and in the form of outpatient cardiac rehabilitation. We expect most patients to respond to cardiac rehabilitation and experience improvements in their physical function. Despite this, a small number of patients still demonstrated ongoing impaired function, which is consistent with others studies at four-week follow-up (Cahalin et al, 2011; LaPier & Wilson, 2007; Min et al, 2015).

The FDQ-s will allow the clinician to quantify important activity limitations of the upper limb function and trunk. The tool is easily administered in the clinical setting and suitable to track patient progress. It takes less than 10 minutes to administer and requires little training for the patient to complete. In addition, the FDQ-s is within the International Classification of Functioning, Disability and Health framework as it captures impairment, activity limitation and participation restrictions across the continuum of recovery in the target population. (Hopfe, 2017; World Health Organization. The international Classification of Functioning) Based on the findings of our study, we recommend it as a potential tool to be used in clinical practice and to evaluate interventions.

This study is strengthened by the fact that the sample is large, data is from a number of different hospitals and is representative of the general cardiac surgery population. We had low risk of attrition bias with on 4% of participants lost to follow-up. A limitation to the study is that in establishing validity of the FDQ-s there was no true gold standard to act as a comparison to provide evidence for construct validity. However, we
employed robust methodology by performing triangulation of validation (Portney & Watkins, 2009) conducted over three time points to strengthen the quality and credibility of results. Additionally, as this tool is a patient reported outcome which focuses on upper limb and trunk function, there is a possibility that it may fail to capture the full physical burden of disease experienced by the individual patient following a sternotomy (e.g. lower limb function). However, there is a potential for the tool to be used alongside other assessments in determining optimal recovery after cardiac surgery.

The limitation is that, the original FDQ did not clearly distinguish between the number of tasks listed in the FDQ that were not achieved by the patient at various time points after the cardiac surgery, and, the number of tasks that were not performed as a consequence of the sternal precaution instructions. If such data were available, this would provide more useful information on how the sternal precaution instructions may limit physical function after cardiac surgery.

5.11 Conclusion

The proposed FDQ-s demonstrated strong clinimetric properties with moderate to excellent validity, reliability, responsiveness, interpretability, and feasibility respectively, in the evaluation of physical function in patients following cardiac surgery via sternotomy (Portney & Watkins, 2009). There was no floor effect and negligible ceiling effects as items reflect a wide range of activity limitations specifically for upper limb and trunk function after cardiac surgery. We recommend that the FDQ-s be adopted as an outcome measure of physical recovery after cardiac surgery within the acute hospital setting, and in the community to plot the trajectory of recovery overtime. The FDQ-s can be utilized in research trials evaluating function and in the clinical setting by health professionals to inform and guide management after cardiac surgery.

Within Chapters 3 and 4 the clinical utility of the SPPB and a clinometric analysis of the FDQ were presented, respectively. Both these studies have informed the rationale for using these outcome tools within the RCT that examines restrictive versus modified sternal precautions following cardiac surgery via a median sternotomy presented within Chapter 6.
Chapter 6:
The Sternal Management Accelerated Recovery Trial (S.M.A.R.T) - Standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: a randomized controlled trial

Chapter Overview

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This study has been accepted for publication in the Journal of Physiotherapy

Author contributions for this chapter are the following:

KMA, DE, LD, and CG conceived the idea for the paper. KMA, DE, LD, AR, CR, and CG contributed to research design. KMA, DE, LD, and CG contributed to data acquisition. KMA, DE, LD, CG, CR, and SC contributed to statistical analysis. KMA wrote the first draft of the manuscript and managed manuscript submission. All authors
revised and provide scientific input. All Authors approved the final version of the manuscript.

6.1 Introduction

Cardiac surgery via a median sternotomy is performed in over a million cases worldwide annually (Epstein et al, 2011; Go et al, 2014). It is the procedure of choice for patients with multiple vessel disease and comorbidities (Authors/Task Force et al, 2014; Cheng & Slaughter, 2013; Deb et al, 2013; Rosenfeldt et al, 2012; Taggart, 2013b) as it provides the best clinical outcome. The incidence of sternal complications following a median sternotomy has remained relatively unchanged for the last two decades and is reported to be between 1 to 8% worldwide (Australian Institute of Health and Welfare, 2013; Cahalin et al, 2011; Mazzeffi & Khelemsky, 2011). However, these complications are associated with significant patient morbidity, prolonged hospital length of stay and contribute to increasing health care costs (Cahalin et al, 2011; Filsoufi et al, 2009; Mazzeffi & Khelemsky, 2011; Mekontso et al, 2011). Post-operative sternal pain is more prevalent and reported to occur in 21–66% of patients worldwide (Choiniere et al, 2014; Eisenberg et al, 2001; Hunt et al, 2000; Kalso et al, 2001; King et al, 2008; Macrae, 2008; Meyerson et al, 2001; Mueller et al, 2000). Of these patients, 33% to 66% experience chronic pain lasting more than three months after their surgery, and 25% to 33% experience chronic pain for more than a year (Choiniere et al, 2014; King et al, 2008).

Chronic pain following sternotomy is associated with prolonged hospital stay, increased cost of care and interference in the patients activities of daily living (El Ansary et al, 2000b; Kalso et al, 2001; Lapier, 2003; Macrae, 2008; Papadopoulos et al, 2013; Sturgess et al, 2014; Ucak et al, 2011; Vymazal et al, 2009). Current practice worldwide involves the routine prescription of sternal precautions immediately after surgery in attempt to prevent sternal complications and chronic pain. These precautions recommend restricted use of both upper limbs immediately following surgery for 6 to 12 weeks (variable depending on local hospital practices) (Balachandran et al, 2014; Cahalin et al, 2011; Overend et al, 2010; Tuyl et al, 2012). Patients are encouraged to not use their upper limbs during everyday tasks such as bed transfers or lifting objects.
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(Adams et al, 2016; Brocki et al, 2010; Cahalin et al, 2011; Price et al, 2016). The rationale for these restrictions is to promote solid osteosynthesis and bone healing by minimizing the amount of forces and micromotion between the sternal edges that can progress to non-union and/or infection (Balachandran et al, 2014; Brocki et al, 2010; Cahalin et al, 2011). However, evidence for these restrictions appears to have been drawn from cadaver studies, historical practice, expert opinion (Balachandran et al, 2014; Cahalin et al, 2011; Tuyl et al, 2012) and generalised from the pathology of long limb bone healing (e.g. radius).

Previous research that focused on sternal closure methods showed physiologic amounts of force can disrupt traditional sternal closure (Cohen & Griffin, 2002; McGregor et al, 1999). In a foundational study, McGregor (1999) found that a force of 220 ± 40 N (Newton) was required to attain 2.0 mm distraction between sternal edges in the lateral direction, 263 ± 74 N in the anterior-posterior direction and 325 ± 30 N in the rostral-caudal direction (McGregor et al, 1999). This prompted a recommendation to discourage the bilateral use of the upper limbs as this was thought to increase the distractive forces at the sternum. Consequently health care professionals including surgeons, nurses and physiotherapists routinely reinforce these sternal precautions to patients immediately following surgery in their clinical practice. However, a recent study demonstrated that upper limb and trunk tasks cause only minimal micromotion of the sternal edges (< 2mm) as measured by real-time ultrasound, inclusive of bilateral and unilateral upper limbs elevation, cough and sit to stand which challenges the rationale for the restrictions (Balachandran, 2015).

In contrast, health professionals also actively encourage patients to perform upper limb and trunk exercises following cardiac surgery as part of their post-operative care to promote recovery and return of function (Balachandran et al, 2014; Cahalin et al, 2011; El-Ansary et al, 2007b; Sturgess et al, 2014). Sturgess et al (2014) found that exercises of the trunk and upper limb significantly reduced sternal pain during the first 6 weeks post-operatively (Sturgess et al, 2014). However, the prescription of such exercises alongside sternal precautions poses a clinical dilemma as they contradict each other (Balachandran et al, 2014; Cahalin et al, 2011). Further, physical activity and upper limb exercises may be imperative for healing and remodelling of bone, which responds
to loading (Adams et al, 2014; Harm, 2000; Cahalin et al, 2011). It has been postulated that sternal precautions may be unnecessarily over restrictive compromising the ability of patients to mobilise, contribute to a delay in discharge from hospital and impact on functional recovery (Adams et al, 2014; Cahalin et al, 2011).

The research questions for this randomised trial were:

1. Does a program of modified sternal precautions for patients following cardiac surgery via a median sternotomy result in improvement in physical function compared with standard care sternal precautions at four weeks post-operatively?
   It was hypothesized that those receiving the modified sternal precautions will have improved physical function at 4 weeks post-operatively compared to participants receiving standard care precautions.

2. Does a program of modified sternal precautions for patients following cardiac surgery via a median sternotomy result in improvement in upper limb function, sternal pain and discomfort, kinesiophobia and health related quality of life (HRQOL) at four weeks post-operatively and three months post-operatively; and on physical function at 3 months post-operatively?

3. Are comorbidities and/or pre, peri and post-operative risk factors associated with the development of post-sternotomy complications for patients following cardiac surgery via a median sternotomy? This was an exploratory analysis, which may identify trends of predictors reported in the literature (Balachandran et al, 2016).

6.2 Method

6.2.1 Design

The following method is reported in accordance with the CONSORT guidelines for clinical trials of non-pharmacologic treatment (Chan et al, 2013) and Tidier reporting of interventions (Yamato et al, 2016). The full protocol for this trial has been published (Katijjahbe et al, 2017). This was a prospective e, double blinded (patients and
6.2.2 Ethical approval for the study

The trial was conducted in accordance with the Declaration of Helsinki (2000) and approved by the Melbourne Health Human Research Ethics Committee (Project number: 2015.035) and registered with the Australian and New Zealand clinical trials registry (http://www.anzctr.org.au): ANZCTR12615000968572 (Refer appendix 1-7 for relevant ethic approval documents)

6.2.3 Randomization and allocation

Participants were randomized to the trial after surgery, once they met the eligibility criteria, had given informed consent, and completed baseline measurement testing. Randomization was conducted by an independent person offsite using a computer generated random 72 sequence numbering system (1 to 72) and a 1:1 allocation ratio. Concealment was via sealed, numbered, double layered opaque envelopes. Allocation occurred after baseline testing, by opening of the next study envelope. This was done by one of the staff of the University department of physiotherapy not involved in the study. They then informed the treating physiotherapist of group allocation. Steps were taken to limit authorized personnel (n=2) with access/permission to open the study enveloped, to avoid allocation bias. 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 patient, the alternative precautions were not discussed. Patients were instructed in a face-to-face session on their specific allocated sternal precautions. They had an opportunity to ask questions to clarify any concerns regarding their program.

6.2.4 Blinding

Participants, the outcome assessor and data management were blinded to treatment...
allocation. The blinded outcome assessor was located off-site from the hospital and assessed all patient outcomes. If a participant became unblinded or unblinded the outcome assessor this was recorded. The treating physiotherapists and nursing staff were not blinded to group allocation. The treating physiotherapist avoiding delivering the intervention to participants on the ward during a set daily time when the blinded outcome assessor was present.

6.2.5 Participants, therapist and centres

Adult patients who had undergone cardiac surgery via a median sternotomy at the two sites were invited to participate in the study. This included cases of isolated valve and / or CABG (Coronary Artery Bypass Graft) surgery or a combination of both. As per usual care, participants underwent cardiac surgery via a median sternotomy with stainless steel wire sternal closure using a figure of “8” technique. Specifically, the wires were placed through the manubrium and around the lateral edge of the body of the sternotomy. Patients were excluded if they had insufficient English comprehension to complete the questionnaires or lived outside of the Melbourne metropolitan area (i.e. 52 km radius) precluding their ability to return to the hospital for follow-up testing.

6.2.6 Intervention

Both groups received standardised verbal and written guidelines after surgery by the treating physiotherapist on the ward as a single individualised session for 15 minutes in the ward prior to discharge from the hospital. This was delivered by way of face-face education with flyers to support. A telephone follow-up was conducted weekly for six weeks to encourage patients to continue with their allocated sternal management intervention using standardised written instructions and to determine their adherence to their sternal precautions. The education and advice delivered to the two groups during the individual session and telephone sessions was different between the two groups:

Participants in the control group received usual post-operative care. Participants were specifically instructed to avoid: pushing or pulling through their arms, unilateral arm activity, lifting heavy objects greater than 2kg and placing the arms behind the back.
They were required to limit the use of the arms when transferring from sitting to standing and when getting out of bed. When coughing, they were encouraged to support the sternum with cushion or the arms in a self-hugging position. Participants in the intervention group were encouraged to use pain and discomfort to guide the safe use of their arms. They were instructed to keep both arms close to their body when mobilising, and to avoid lifting and pushing/pulling with only one arm. They were asked to use a cushion to support over their sternum when coughing.

A questionnaire, developed by the researchers, was used to measure patient adherence to the intervention (stenral precautions) (Refer Appendix 10). This was administered at each follow-up phone call. An adherence threshold for the experimental group was set at participant self-perceived reported rating of ≥ 70% or more of the instructions, and was classed as ‘adherent’.

6.3 Outcome Assessment:

Full details of the outcome assessment are available in the protocol (Katijjahbe et al, 2017) and are briefly described below. Outcome measures were performed prior to discharge following cardiac surgery (pre-randomisation), and at four weeks and three months post-operatively. All baseline assessments were performed at the same time of day (08.00-17.00) for each participant in post-operative period at day 4 (± 1 day) in the in-patient setting across centres. The follow-up testing at 4 weeks (±14 days) and 3 months (±14 days) was conducted in the research room at the RMH.

6.3.1 Primary outcome

The primary outcome was physical function measured by the Short Physical Performance Battery (SPPB) (Guralnik et al, 1994). The SPPB consists of three tests:
1) Gait speed: participants were instructed to walk a distance of eight feet (2.4 meters) and the average of two trials is used; 2) Standing balance: participants were assessed in three different static positions (side-by-side stand, semi-tandem stand and tandem stand) for 10 seconds each; and 3) Chair rise task: participants were instructed to stand
up and sit down five times in a row as quickly as possible (Guralnik et al, 1994). Each individual test was scored on a scale of zero to four points (higher scores are better performance). The three test scores were summated to give an overall SPPB performance score ranging from zero to 12 points (Guralnik et al, 1995). A zero score indicates poor function whilst 12 indicates excellent function. If the participant was unable to physically perform a specific test, a score of zero was assigned. It has been previously reported in the literature that for older adults a score of 10 is considered the cut-off for mobility impairment (i.e. scores <10 = poor mobility) (Guralnik et al, 1995).

In general, a 1 to 2 point increase in the SPPB overall score reflects a clinical meaningful change (improvement) in physical function (Perera et al, 2006; Volpato et al, 2008). The SPPB data were then classified ≤ 6 as ‘moderate’ to ‘severe’ impairment, 7-9 as ‘mild’ impairment and >10 ‘no’ impairment in physical function as recommended (Guralnik et al, 1995) at baseline and at follow-up the SPPB score were according to improvement, worsened and unchanged according to clinical meaningful change of 1 and 2 points.

### 6.3.2 Secondary outcomes

The secondary outcomes were upper limb function, grip strength, sternal pain and discomfort, kinesiophobia, HRQoL and sternal instability. Upper limb function was measured using the Functional Difficulties Questionnaire (FDQ) (Balanchandran, 2015; Sturgess et al, 2014). This questionnaire requires participants to rate the difficulty they experience when completing a series of 13 upper limb and trunk functional tasks. 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 sides of the line respectively (Balanchandran, 2015; Hoggins, 2009). Lower scores indicate less difficulty in performing functional tasks. Hand-grip strength was measured in kilograms using a JAMAR dynamometer (Sammons Preston Rolyan, Brooklyn, USA) (Bohannon, 2001).

Pain intensity was measured with the numeric rating scale for pains (NRS). The tool is a 11-point visual analogue numeric scale used to measure any kind of pain with a score ranging from 0 (no pain) to 10 (the most severe pain) (Teoh et al, 2007). Participants use the schematic picture to localize their pain. Pain quality was
measured using The Short Form McGill Pain Questionnaire version 2 (MPQ-2) (Dworkin et al, 2009). Higher scores indicate more severe pain. The Tampa Scale of Kinesiophobia (TSK-II) measured pain related fear beliefs about movement and re-injury (Kori et al, 1990). This is an 11-item instrument, whereby participants were asked to rate each item on a four-point likert scale. A reduction of at least four points on the measure maximises the likelihood of correctly identifying an important reduction in fear of movement (Woby et al, 2005).

Health-related quality of life was measured with the Medical Outcome Study 36-item Short Form version 2 (SF36) (Ware et al, 2000). This questionnaire measures 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 (Ware et al, 2000). Norm-based physical and mental component summary (PCS, MCS) scores were also calculated from raw sub-scale scores with higher scores indicating better quality of life.

Sternal stability was measured with the Modified Sternal Instability Scale (SIS); a 4-point scale (El-Ansary et al, 2000a). A score of zero corresponds to a clinically stable sternum with no detectable motion or separation of the sternal edges, whilst a score of three corresponds to a completely separated sternum with marked increased motion or separation of the sternal edges. The Blinded Assessor received education and training in the SIS and had over 4 years of the utilisation of this tool clinically. The blinded assessor was instructed by A/P Doa El-Ansary (who developed the SIS scale). The blinded assessor underwent a fidelity check with respect to the competency of performing this task (n=15 patients).

6.4 Sample Size Calculations

The sample size calculation was performed for the primary outcome of physical function measured with the SPPB. A sample of 29 patients in each group was calculated apriori to be acceptable to identify a statistically significant difference between the two groups using the minimal important difference (MID) of 2 points out of total score of
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12 points, with a standard deviation (SD) of 2.7 points (Volpato et al, 2008). The total sample was increased to 72 to allow for an estimated 20% possible loss to follow-up. This was based on a Type 1 error rate of 0.05, which was consistent with recommendations and a power of 0.80 (Portney & Watkins, 2009).

6.5 Statistical Methods:

Data analyses were performed using the SPSS Windows Version 23.0 (SPSS, Chicago, IL, USA). Data were assessed for normality using the Kolmogorov-Smirnov test. Descriptive statistics including mean and SD; median and inter-quartile range (IQR); and number and percentage 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-within subjects ANOVA with repeated measures across participants. The primary hypothesis was examined by a contrast evaluating change from baseline to the 4 week time point in the modified sternal precautions group compared to the standard care group. The analysis followed the intention-to-treat principle based on the groups to which participants were randomized. The interactions between group and time was first examined to assess the effect of intervention, and, if no interaction was present, group and time main effects were examined. Key secondary outcome data (including upper limb function, pain, kinesiophobia and HRQoL) were summarized and analysed similarly to the primary outcome. Because non-significant differences were observed between the two groups 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. As there were minimal sternal complications (see results), no further analysis was able to be performed for the third aim. Supplementary per protocol analysis was not necessary as no participants deviated from the protocol.
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6.6 Results

6.6.1 Flow of participants, therapist and centres through the study

There were 274 adults who had cardiac surgery via a median sternotomy and were screened during the time period of the trial (September 2015 to November 2016) and 72 were recruited (Figure 6.1). They were randomised to the intervention (n = 36) or control (n = 36) group (Figure 6.1). The final follow-up measures for the trial were completed in April 2017. Four participants were lost to follow-up and the outcome measure data were not available (Figure 6.1). We performed the “complete case” intention to treat analysis (ITT), using the number of participants as denominator the number of participants who attended follow-up (34 in each group, n=68). With no participants deviated from the protocol, per protocol analysis was not necessary. The baseline demographic and clinical characteristics of the groups are presented in Table 6.1 and 6.2. The two groups were comparable in terms of all medical and social demographics. The baseline characteristics were mostly well matched between patients from private and public hospitals as well.

6.6.2 Compliance to the trial

All participants received the intervention according to group allocated regardless of compliance. With respect to compliance to 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). In particular, participants demonstrated an overall better understanding of the restrictions regarding lifting and driving compared to those of the upper limb. Specifically, participants used pain (27%) and discomfort (29%) as a guide to upper limb movements. They also reported that they followed advice regarding sternal precautions given by health professionals (29%) and medical staff (15%).
6.6.3 Adverse events

There were no serious adverse events resulting from the study. Two (2.7%) participants (one in each group) developed deep sternal wounds complications which required return to theatre and re-wiring before three months post-operatively. Seven (9.7%) participants (n=3 control, n=4 intervention) required hospital re-admission within 6 weeks of surgery due to post-operative complications: superficial wound infection (n=3), pleural effusion (n=2), pneumonia (n=1), and phrenic nerve palsy (n=1).
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Figure 6.1: Design and flow of participants through the trial
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Table 6.1: Clinical Characteristic of Study Sample

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Randomised (n=72)</th>
<th>Lost to follow up (n=4)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td></td>
<td>(n=54)</td>
<td>(n=34)</td>
</tr>
<tr>
<td>Participants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>63.1±11.5</td>
<td>63.9±11.5</td>
</tr>
<tr>
<td>Gender (male), n (%)</td>
<td>29 (80.6)</td>
<td>32 (88.9)</td>
</tr>
<tr>
<td>BMI (kg/m²), mean (SD)</td>
<td>30.44±4.7</td>
<td>29.44±5.7</td>
</tr>
<tr>
<td>Length of stay, median [IQR], days</td>
<td>8 (3.2)</td>
<td>8 (3.0)</td>
</tr>
<tr>
<td>Hand dominance, R, n (%)</td>
<td>33 (97)</td>
<td>32 (94)</td>
</tr>
<tr>
<td>Smoking History, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never smoker</td>
<td>13 (36.1)</td>
<td>18 (50)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>5 (13.9)</td>
<td>3 (8.8)</td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>15 (45.1)</td>
<td>15 (44.1)</td>
</tr>
<tr>
<td>Co-morbidities, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic obstrucitive airways disease</td>
<td>9 (26.5)</td>
<td>2 (5.9)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>12 (35.3)</td>
<td>9 (26.5)</td>
</tr>
<tr>
<td>Osteoarthritis or rheumatoid arthritis</td>
<td>5 (14.7)</td>
<td>3 (8.5)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>26 (76.5)</td>
<td>23 (67.6)</td>
</tr>
<tr>
<td>Peripheral nerve disease</td>
<td>1 (2.9)</td>
<td>1 (2.9)</td>
</tr>
<tr>
<td>Previous sternotomy</td>
<td>3 (8.8)</td>
<td>3 (8.3)</td>
</tr>
<tr>
<td>Use of gas post-operative, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No gas aid</td>
<td>23 (63.9)</td>
<td>26 (72.2)</td>
</tr>
<tr>
<td>4WF</td>
<td>13 (36.1)</td>
<td>10 (29.4)</td>
</tr>
<tr>
<td>Baseline SPPB, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤6 (severe impairment)</td>
<td>22 (65)</td>
<td>16 (47)</td>
</tr>
<tr>
<td>&gt;6 (moderate impairment)</td>
<td>9 (26)</td>
<td>12 (35.3)</td>
</tr>
<tr>
<td>&gt;10 (severe)</td>
<td>5 (14.7)</td>
<td>6 (17.6)</td>
</tr>
<tr>
<td>Type of Cardiac Surgery, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CABG</td>
<td>19 (54.8)</td>
<td>24 (66.7)</td>
</tr>
<tr>
<td>On pump, n</td>
<td>16</td>
<td>24</td>
</tr>
<tr>
<td>Off pump, n</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Valve surgery</td>
<td>12 (33.3)</td>
<td>9 (25)</td>
</tr>
<tr>
<td>Combination of CABG and valve surgery</td>
<td>5 (13.9)</td>
<td>2 (5.6)</td>
</tr>
<tr>
<td>Type 1 Aortic dissection</td>
<td>0</td>
<td>1 (2.8)</td>
</tr>
<tr>
<td>Type of CABG graft, n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saphenous vein, n</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Radial artery, n</td>
<td>15</td>
<td>17</td>
</tr>
<tr>
<td>Unilateral internal mammary artery, n</td>
<td>19</td>
<td>22</td>
</tr>
<tr>
<td>Bilateral internal mammary artery, n</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Operation duration (min), mean (SD)</td>
<td>291.9±79.1</td>
<td>280.7±91.3</td>
</tr>
<tr>
<td>Cardiopulmonary bypass, duration (min), mean (SD)</td>
<td>101.47±44.2</td>
<td>110.33±248.1</td>
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<tr>
<td>Mechanical ventilation duration (hrs), mean (SD)</td>
<td>16.36±14</td>
<td>12.64±6.3</td>
</tr>
<tr>
<td>Attended cardiac rehabilitation programme within four - six weeks, n (%)</td>
<td>10 (29.4%)</td>
<td>13 (38.2%)</td>
</tr>
<tr>
<td>Attended cardiac rehabilitation programme at three months, n (%)</td>
<td>25 (69%)</td>
<td>24 (71)</td>
</tr>
<tr>
<td>Centres</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public, n (%)</td>
<td>23 (63.9)</td>
<td>21 (59.4)</td>
</tr>
<tr>
<td>Private, n (%)</td>
<td>13 (36.1)</td>
<td>15 (41.7)</td>
</tr>
</tbody>
</table>

Abbreviation: R=right hand dominance; n=Numbers of participants; SD=Standard deviation; IQR=interquartile; min=minutes; Body mass index (BMI); hrs=hours; CABG=Coronary artery bypass graft; SPPB=Short Physical Performance Battery; kg=kilogramme; m=metre
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Table 6.2: Clinical Characteristics of Study Sample on New York Heart Association Functional classification; Canadian Cardiovascular Society grading of angina pectoris, left ventricular function grade.

<table>
<thead>
<tr>
<th>Clinical Characteristics pre-operatively</th>
<th>Randomized (n=72)</th>
<th>Lost to follow-up (n=4)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IG (n=34)</td>
<td>CG (n=34)</td>
</tr>
<tr>
<td>NYHA classification, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>11 (30.6)</td>
<td>11 (30.6)</td>
</tr>
<tr>
<td>II</td>
<td>16 (44.4)</td>
<td>17 (47.2)</td>
</tr>
<tr>
<td>III</td>
<td>8 (22.2)</td>
<td>7 (19.40)</td>
</tr>
<tr>
<td>IV</td>
<td>1 (2.8)</td>
<td>0</td>
</tr>
<tr>
<td>Missing</td>
<td>0</td>
<td>1 (2.8)</td>
</tr>
<tr>
<td>Angina (CCC), n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>23 (63.9)</td>
<td>16 (44.4)</td>
</tr>
<tr>
<td>I</td>
<td>9 (25)</td>
<td>15 (41.7)</td>
</tr>
<tr>
<td>II</td>
<td>4 (11.1)</td>
<td>4 (11.1)</td>
</tr>
<tr>
<td>III</td>
<td>0</td>
<td>1 (2.8)</td>
</tr>
<tr>
<td>V</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>LV grade, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>4 (11.1)</td>
<td>1 (2.8)</td>
</tr>
<tr>
<td>I</td>
<td>21 (58.3)</td>
<td>27 (75)</td>
</tr>
<tr>
<td>II</td>
<td>6 (16.7)</td>
<td>6 (16.7)</td>
</tr>
<tr>
<td>III</td>
<td>5 (13.9)</td>
<td>2 (5.6)</td>
</tr>
<tr>
<td>IV</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Abbreviations: Program: IG=Intervention group; CG= Control group G; NYHA =New York Heart Association Functional classification; CCC=Canadian Cardiovascular Society grading of angina pectoris; LV Grade = left ventricular function grade.
6.6.4 Primary outcome

There was no significant difference between groups in physical function as measured by the SPPB at four weeks (mean difference 1 points, 95% CI -0.2 to 2.3) or three months post-operatively (mean difference 0.4 points, 95% CI -0.9 to 1.6) (Table 6.3). During hospitalisation, 92% of participants overall had moderate to severe impairment as measured by the SPPB. The intervention group had a higher proportion of participants (64%, n=23) with severe impairment compared to control group (47%, n=17) (Table 6.4). Between the first two testing time points, 94% (n=32) of participants in the intervention group improved by the minimal clinically important difference of 2 points in the SPPB and 74% (n=25) in control group (Table 6.4). Nearly half of the participants scored the maximum score (12/12) at four weeks, increasing to two thirds at three months for both groups meaning the SPPB may be too easy as time from surgery increases and patients recover.

6.6.5 Secondary outcomes

There were no significant differences between groups for any of the secondary outcomes, as shown in Tables 6.3, 6.5 and 6.6. 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 6.6). 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 difficulty on the Functional Difficulties Questionnaire initially but tended to have less difficulty over time (Table 6.2). 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 6.4). Overall, persistent post-operative 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 in participants 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 at Week 12 (MD 2, 95% CI –1 to 4).
There were no significant differences between groups in quality of life on any of the sub-scales or component summary scores of the SF36 (Table 6.6). The physical component summary scores improved over time, but there was no significant change in the mental component summary scores. At week 4, one participant (2.7%) in each group was diagnosed with sternal instability, which persisted until week 12. Therefore, there was no significant difference between the groups in the risk of developing sternal instability (RR 1.0, 95% CI 0.07 to 15.36).
### Table 6.3: Results of the primary and secondary outcomes of physical function and hand grip strength as per intention to treat analysis ± (SD); mean difference 95%CI

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Groups (mean SD)</th>
<th>Difference within groups (mean SD)</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Week 0</td>
<td>Week 4</td>
<td>Week 12</td>
</tr>
<tr>
<td></td>
<td>IG n=34</td>
<td>CG n=34</td>
<td>IG n=34</td>
</tr>
<tr>
<td>SPPB</td>
<td>5.8 ±2.9</td>
<td>6.3 ±3.3</td>
<td>10.4 ±2.4</td>
</tr>
<tr>
<td>FDQ</td>
<td>54.6±25.7</td>
<td>51.5±22.7</td>
<td>15.9±16.1</td>
</tr>
<tr>
<td>HGS</td>
<td>2.5 ±1.3</td>
<td>2.5 ±0.9</td>
<td>3.3 ±1.6</td>
</tr>
</tbody>
</table>

Abbreviations: Program: IG= Intervention group; CG =Control, SPPB=Short Physical Performance Battery, FDQ=The Functional Difficulties Questionnaire (in cm), HGS=Hand grip strength (in kg).
Chapter 6: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T)- Standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: a randomized controlled trial

**Table 6.4:** Change in SPPB from baseline measurement (week 0) categorized relative to the minimal clinically important difference of 1 and 2 points

<table>
<thead>
<tr>
<th>Post-operative time</th>
<th>IG, n (%)</th>
<th>CG, n (%)</th>
<th>Post-operative time</th>
<th>IG, n (%)</th>
<th>CG, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>4 weeks follow-up</strong></td>
<td></td>
<td></td>
<td>4 weeks follow-up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improved ≥ 2 points</td>
<td>32 (94)</td>
<td>25 (74)</td>
<td>Improved ≥ 1 points</td>
<td>33 (97)</td>
<td>31 (91)</td>
</tr>
<tr>
<td>Unchanged</td>
<td>1 (3)</td>
<td>0 (0)</td>
<td>Unchanged</td>
<td>1 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Worsened &lt; 2 points</td>
<td>1 (3)</td>
<td>9 (26)</td>
<td>Worsened ≥ 1 points</td>
<td>0 (0)</td>
<td>3 (9)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>34 (100)</strong></td>
<td><strong>34 (100)</strong></td>
<td><strong>Total</strong></td>
<td><strong>34 (100)</strong></td>
<td><strong>34 (100)</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3 months follow-up</strong></td>
<td></td>
<td></td>
<td>3 months follow-up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improved ≥ 2 points</td>
<td>33 (97)</td>
<td>31 (91)</td>
<td>Improved ≥ 1 points</td>
<td>33 (97)</td>
<td>33 (97)</td>
</tr>
<tr>
<td>Unchanged</td>
<td>1 (3)</td>
<td>3 (9)</td>
<td>Unchanged</td>
<td>1 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Worsened &lt; 2 points</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>Worsened ≥ 1 points</td>
<td>0 (0)</td>
<td>1 (3)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>34 (100)</strong></td>
<td><strong>34 (100)</strong></td>
<td><strong>Total</strong></td>
<td><strong>34 (100)</strong></td>
<td><strong>34 (100)</strong></td>
</tr>
</tbody>
</table>

Abbreviations: SPPB=Short Performance Physical Battery, Program: IG=Intervention group; CG=Control group
Table 6.5: Results of the secondary outcomes of pain and kinesiophobia as per intention to treat analysis in ± (SD); mean difference 95%CI

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Groups (mean SD)</th>
<th>Difference within groups (mean SD)</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Week 0</td>
<td>Week 4 minus week 0</td>
<td>Week 12 minus week 0</td>
</tr>
<tr>
<td></td>
<td>IG n=34</td>
<td>CG n=34</td>
<td>IG n=34</td>
</tr>
<tr>
<td>NRS</td>
<td>3.5 ±1.6</td>
<td>3.7 ±2.3</td>
<td>1.6 ±1.8</td>
</tr>
<tr>
<td>TSK-II</td>
<td>25.5 ±4.3</td>
<td>23.8 ±4.9</td>
<td>23.5 ±5.0</td>
</tr>
<tr>
<td>MPQ-2</td>
<td>1.0 ±0.5</td>
<td>1.0 ±0.6</td>
<td>0.5 ±0.4</td>
</tr>
</tbody>
</table>

Abbreviations Program: Intervention group=IG; Control group =CG; SD:=Standard Deviation, NRS= Numerical Rating Scale of pain, SF-MPQ-2=The McGill Pain Questionnaire, TSK-II =The Tampa scale of Kinesiophobia version II,
Table 6.6: Results of the secondary outcome of health-related quality of life measured by the SF36- Australian Normed T-score as per intention to treat analysis± (SD); mean difference 95%CI

<table>
<thead>
<tr>
<th>Domains</th>
<th>Groups (mean SD)</th>
<th>Difference within groups</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Week 0</td>
<td>Week 4</td>
<td>Week 12</td>
</tr>
<tr>
<td>IG (n=34)</td>
<td>CG (n=34)</td>
<td>IG (n=34)</td>
<td>CG (n=34)</td>
</tr>
<tr>
<td>PF</td>
<td>19.1±6.8</td>
<td>21.7±7.5</td>
<td>39.2±11.6</td>
</tr>
<tr>
<td>RP</td>
<td>37.3±11.7</td>
<td>39.2±11.3</td>
<td>33.3±9.1</td>
</tr>
<tr>
<td>BP</td>
<td>43.7±14.2</td>
<td>42.6±12.3</td>
<td>42.0±11.3</td>
</tr>
<tr>
<td>GH</td>
<td>46.2±7.8</td>
<td>48.7±6.3</td>
<td>51.0±6.9</td>
</tr>
<tr>
<td>VI</td>
<td>46.9±9.7</td>
<td>48.5±9.3</td>
<td>47.9±7.8</td>
</tr>
<tr>
<td>SF</td>
<td>38.9±13.2</td>
<td>42.5±11.8</td>
<td>39.2±10.6</td>
</tr>
<tr>
<td>RE</td>
<td>42.3±13.7</td>
<td>42.2±16.2</td>
<td>40.0±15.8</td>
</tr>
<tr>
<td>MH</td>
<td>44.2±10.7</td>
<td>45.9±10.3</td>
<td>46.6±10</td>
</tr>
<tr>
<td>PCS</td>
<td>32.6±8.4</td>
<td>34.5±7.2</td>
<td>40.3±8.6</td>
</tr>
<tr>
<td>MCS</td>
<td>49.3±12.9</td>
<td>50.6±11.1</td>
<td>45.7±11.4</td>
</tr>
</tbody>
</table>

Abbreviations: Program: Intervention group=IG; Control group =CG; SD=Standard Deviation, SF36-V2=The Medical Outcome Study 36-item Short Form Health Survey; PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VI=Vitality, SF=Social Function, RE=Role Emotion, MH=Mental Health, PCS=Physical Component Summary, MCS=Mental Component Summary
6.7 Discussion

This trial found no significant between-group differences in patients receiving modified sternal precautions compared to usual care following cardiac surgery via a sternotomy in physical function, upper limb function, pain, kinesiophobia or HRQoL at four weeks or three months post-operatively. Patients in both groups improved in these measures over time after surgery. However, 2 participants developed deep sternal wound complications also have sternal instability at 4 weeks persistent to three months post-operatively consistent with previous study (Cahalin et al, 2011; El Ansary et al, 2000b; El Ansary et al, 2008). Our results suggest a program of modified sternal precautions delivered by a health professional in a single face-to-face individualized session prior to hospital discharge and weekly telephone consultations over the following six weeks did not significantly improve physical recovery, pain or enhance HRQOL compared to usual care. However, there is a demonstrable trend of improvement in physical function within the intervention group. There was also a trends towards no association on the secondary measures as this study was not powered for the secondary outcomes.

The SPPB is a measure that can provide information on the potential impact of cardiac surgery via a median sternotomy on the patients functional impairment early after surgery (Zimmerman et al, 2011). A recent study by Molino and colleagues similarly found moderate to severe mobility impairments in patients following cardiac surgery, with more than 95% scoring ≤ 9 on the SPPB prior to hospital discharge (Molino-Lova et al, 2013). In addition, 18% of their cohort had an SPPB score ≥6 indicating 'severe' impairment (Molino-Lova et al, 2013) which is consistent with our study. Our results demonstrated that one third of participants immediately after surgery were so functionally impaired (SPPB score ≤6 points) that they would have benefited from any form of intervention, irrespective of their treatment group (Molino-Lova et al, 2013). Whilst not statistically significant, there may be a slight trend towards the intervention group recovering better at 4 weeks post-operatively. Not surprisingly, most of participants in our study recovered over time with SPPB scores (≥ 10) at four weeks to three months for both groups as time from surgery increased. This improvement was expected as the testing time points occurred during a critical period of recovery that was early and most patients would have attained functional benefits from cardiac
Chapter 6: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T)- Standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: a randomized controlled trial

rehabilitation (Min et al, 2015; Molino-Lova et al, 2013). Despite this, a small but significant number of patients still demonstrated ongoing impaired function consistent with others studies at 4 weeks follow up (Barnason et al, 2000; Lapier & Wilson, 2007; Min et al, 2015; Zimmerman et al, 2011). Limitations in physical function in the current study may be explained by the imposed medical and health professional sternal precautions, fear of activity, and/or pain exacerbated by movement (Adams et al, 2006; Cahalin et al, 2011; LaPier et al, 2008).

One potential reason for our negative trial findings is that we may have been underpowered based on the SPPB. The sample size calculation was performed using the estimate of MID (2 points) extrapolated from a slightly different population (on a cohort of patients with stable cardiovascular conditions (Volpato et al, 2008) due to the lack of data specifically in cardiac surgery. This hypothesis is further supported by a recent study determining the MID of the SPPB to be 1 point in the acute cardiac surgery population (Katijjahbe et al, 2017). Perhaps utilization of the MID of one point, with a larger sample size, may have resulted in significant between group differences (Kwon et al, 2009; Perera et al, 2006; Volpato et al, 2008). A subsequent larger trial is required to confirm this hypothesis. In addition, the SPPB may also lack responsiveness (in terms of effect size) due to the high ceiling effect of SPPB at follow-up time points (49% of participants at 4 weeks scored 10/10 and 69% at three months) which is consistent with another study (Guralnik et al, 1995). This means the SPPB may have been unable to detect change between testing periods due to a lack of discriminatory power of the scores as opposed to a lack of change as time after surgery increases and patients recover. A concern of the high ceiling effect is that it may impair the responsiveness of the SPPB for high-functioning patients following cardiac surgery between the time points, posing a serious concern for type II errors in clinical trials (Portney & Watkins, 2009). Careful consideration should be used by researchers for the use of the SPPB as a primary outcome measure over the first three months post cardiac-surgery. Alternative tests such as the Late Life Function and Disability Instrument (LLFDI) may be more appropriate (Lapier, 2012).

There was wide variability in the FDQ results. The literature is in agreement with our results, indicating that four to six weeks post-discharge is the critical time period for
recovery (Balanchandran, 2015; Min et al, 2015; Sturgess et al, 2014). The FDQ may not be suitable beyond three months post-operatively, as it is specifically designed for evaluation of short term post-operative functional difficulty following cardiac surgery (Hoggins, 2009). Consistent with the results, hand grip strength measures were generally lower for all participants (compared to population norms based on age and gender) and this is reported to be an indicator of general health, cardiovascular risk and disease (Leong et al, 2015).

We suggest that the lack of significant difference between the groups may be due to the fact that the intervention program was not 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 to 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 (Adams et al, 2016). Several studies strongly suggest that a progressive type of rehabilitation is needed for normal bone healing and improved functional status after a median sternotomy (Adams et al, 2014; Cahalin et al, 2011; El Ansary et al, 2007c; LaPier et al, 2008; Price et al, 2016; Sturgess et al, 2014). Two studies report significant improvement in pain following a program of incremental trunk stabilization exercises (El Ansary et al, 2007c; Sturgess et al, 2014). It is suggested that an incremental program that challenges the upper limb and trunk can facilitate improvement in circulation to the chest wall to achieve optimal bone healing; potentially reduce pain and enhance physical recovery (Adams et al, 2014; Cahalin et al, 2011; Sturgess et al, 2014). However, the optimal intensity, mode and frequency for exercise training remains unknown especially during the medium to long term periods of recovery (Price et al, 2016; Santos et al, 2016). Another potentially significant confounder may have been the education component of the intervention. This was delivered by way of face-to-face education with flyers to support it and weekly telephone follow-up. However, the flyers developed for this research project were given to patients separately and were not included as part of the written information issued to participants whilst in hospital. Even though we attempted to standardize the intervention according to the protocol, this may have been confounded by further advice
given regarding sternal precautions by carers and other health professionals within hospital and Cardiac Rehabilitation programs in the community setting (Adams et al, 2016; Swanson & LaPier, 2014).

With respect to pain, the results of this study showed that pain intensity reduced from the first post-operative week to three months consistent with other studies (Bauer et al, 2010; Leegaard et al, 2010; Sethares et al, 2013). Although patients in this study appeared to have appropriate pain control, and the presence of persistent pain post-operatively was found to be comparable with those previously reported (Choiniere et al, 2014; El-Ansary et al, 2000a; Lapier & Wilson, 2007; Yorke et al, 2004; Zimmerman et al, 2011). This highlights the prevalence of musculoskeletal pain that is secondary to the mechanical demands of surgery (El-Ansary et al, 2000a). Importantly, we found the magnitude of TSK-II scores in both groups was high immediately following surgery and similar to the TSK-II scores reported in patients with chronic musculoskeletal disorders (Roelofs et al, 2007). Perhaps, education on a restrictive program that is marked by avoidance of upper limbs movements further contributed to the increase onset of kinesiophobia post-operatively and beyond 4 weeks. This mechanism may be explained by 1. pain related fear associated with avoidance of movement and physical activity (Brunetti et al, 2017; Crombez et al, 2005; Herbert et al, 2015) and; 2. Increased bodily awareness and pain hypervigilance which may in turn exacerbate pain experience (Brunetti et al, 2017; Crombez et al, 2005; Herbert et al, 2015) after discharge. Valeeyan and Linton (2012) postulated that fear of pain leads to activity avoidance and therefore functional limitations (Vlaeyen, 2012). Pain related fear has been reported to influence attendance at exercise based cardiac rehabilitation (Back et al, 2016). Since physical activity/exercise is a crucial part of rehabilitation programs after cardiac surgery, it was hypothesized that kinesiophobia may have been a contributing factor that influenced physical recovery in our study (Hartigan et al, 2013; Roelofs et al, 2007). Kinesophobia should therefore be acknowledged in patients following cardiac surgery in the immediate post-operative period (Bäck et al, 2013). Future research is needed to assess the interrelationship between kinesiophobia and functional recovery.
Chapter 6: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T)- Standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: a randomized controlled trial

We also found improvement in HRQoL consistent with a previous study along with improvement in sternal pain and functional recovery following cardiac surgery (DiMattio & Tulman, 2003; Hirschhorn et al, 2008; Sturgess et al, 2014). The improvements in quality of life beyond one month may be related to an ongoing healing process sequential to post-operative acute systemic inflammatory response syndrome after major surgery (Maillard et al, 2015). These findings suggest that educating patients to monitor and manage sternal pain may assist them to set safe limits for activity participation. However, SF-36 sub-scale and component summary scores in the present study are similar to those reported previously for patients undergoing CABG (Hirschhorn et al, 2012) hence reflecting the general nature of the scale. A review of studies using generic HR-QoL measures in patients undergoing CABG concluded that these measures lacked sensitivity to detect differences between intervention groups (Hirschhorn et al, 2012; Jokinen et al, 2010).

The incidence of post-operative sternal complications in the current study was 2.7% consistent with previous studies reporting an incidence of 1% to 8% (Balachandran et al, 2016; Cahalin et al, 2011; Casha et al, 1999; Losanoff et al, 2002b; Robicsek et al, 2000). In addition, there were no adverse events reported indicating that this intervention was safe. Unloaded movements within a pain-free range and loaded activity with the upper arms close to the body have been not reported to cause excessive stress on the sternal surgical site or bone (Balanchandran, 2015; Balanchandran et al, 2014; Cahalin et al, 2011; El-Ansary et al, 2007a). Using these biomechanical principles, with the intervention strategy, the movements encouraged placed symmetrical loads on the two sides of the sternum and minimized the stresses applied to the healing sternum, thus ensuring safety (Adams et al, 2016; Brocki et al, 2010). However, in the absence of any adverse events this study does provide medical and health professionals with further evidence to evaluate moderate intensity upper limb exercise to inform optimal management and the development of clinical guidelines (Santos et al, 2016). Consistent with our finding, Cahalin et al (2011) reported that surgeon dictated sternal precautions, fear of activity, and/or pain exacerbated by movement may be related to reduce physical function immediately following cardiac surgery and contribute to functional limitations and hindering optimal recovery (Cahalin et al, 2011). The authors recommend that it may be appropriate to tailor the
sternal precautions based on individual clinical characteristics and rather risk profile rather than restricting specific functional tasks and physical activity. In view of this, it is imperative to review the current sternal precautions guidelines within institutions (Cahalin et al, 2011) as recommending strict adherence to sternal precautions for all patients may not be warranted. Our study is the first randomised controlled trial to report data on a program of modified sternal precautions using pain and discomfort as a guide for upper limbs and trunk movements associated with activities of daily livings. 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 (Adam et al, 2016). This may better facilitate functional recovery after a median sternotomy rather than placing restrictions on use of the upper limbs as part of sternal precautions (Cahakin et al, 2011; Adams et al, 2016).

6.8 Strength and Limitations

This study included a heterogeneous group of patients who underwent a cardiac surgical procedure via sternotomy. Although this could increase risk inclusion bias, it improves external validity of the study. Attrition bias is a low risk as only 6% of participants were lost to follow-up. Performance bias was reduced by the intervention and outcome measurement performed by single individuals. Our negative results may also be explained by the difficulty in conducting a RCT with participant blinding to allocation and a pragmatic study of the effects of an implementation program may be more feasible yielding significant findings (Patsopoulos, 2011).

6.9 Conclusion

Our results suggest a program of modified sternal precautions provided in a single individualized education session and a support program, delivered by telephone is efficacious resulted in no adverse events and did not significantly improve physical recovery, pain or enhance HRQoL for individuals in the early weeks following cardiac surgery compared to usual care. We hypothesised that strict adherence to sternal
precautions for all patients may not be warranted as it reinforces kinesiophobia, potentially impacts on patient participation in cardiac rehabilitation and delays overall recovery. A larger trial is needed powered for non-inferiority to support this hypothesis. In addition, in the absence of any adverse events, future research should evaluate the effects of an implementation program of modified sternal precautions and the role of moderate intensity upper limb exercise performed with patient-specific precautions based on risk factors to promote recovery following cardiac surgery.
Chapter 7: Conclusion and Future Directions

Chapter Overview

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7.3 Future Directions .............................................................................. 212
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7.1 Overview of main findings

The main objective of this thesis was to build on foundational evidence that established the efficacy and safety of the effects of upper limb movements in vivo by real-time Ultrasound in patients following cardiac surgery by a median sternotomy. As such, the focus of this thesis was to investigate the effects of modifying sternal precautions to include the safe use of the upper limbs and trunk, and evaluate their impact on patient physical function and recovery following cardiac surgery. This thesis implemented an RCT that evaluated a novel program of modified sternal precautions based on evidence that supports the use of the upper limbs and trunk within safety limits following cardiac surgery. In addition, the studies presented in this thesis define clinimetric properties including the MCID associated with specific measures of functional recovery including the SPPB and the FDQ. Collectively the studies presented in this thesis will inform the translation of modified sternal precautions and the development of postoperative clinical guidelines for patients following cardiac surgery.

7.1.1 Study 1: The Sternal Management Accelerated Recovery Trial (S.M.A.R.T)-Standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: a randomized controlled trial: study protocol for a randomized controlled trial.

In chapter 3, study 1 (The Sternal Management Accelerated Recovery Trial (S.M.A.R.T)-Restrictive versus modified sternal precautions following cardiac surgery via a median sternotomy: study protocol for a randomized controlled trial), the protocol
for the RCT was described. The rationale for developing this study was that the routine implementation of sternal precautions worldwide practice following a median sternotomy may delay recovery and be overly restrictive. According to best RCT practice, we published the protocol for this RCT. This study was the first randomized controlled trial using an intervention group to modify sternal precautions in order to optimize functional recovery in this patient population.

### 7.1.2 Study 2: The SPPB can be utilized to evaluate physical function in patients following cardiac surgery

In chapter 4, study 2 (The SPPB can be utilized to evaluate physical function in patients following cardiac surgery) the MCID of the SPPB was investigated. The SPPB is an outcome measure that has been validated in older patients who did not have cardiovascular disease. Importantly this study is the first to determine the MCID of the SPPB for an adult cardiac surgery population. The MCID was between 0.44 to 1.34 points out of a total 12 points. The MCID score in this study should be considered preliminary evidence on the application of the SPPB to evaluate treatment effectiveness by detecting a true improvement. An increase or decrease in performance greater than the MCID indicates a high likelihood of a meaningful change. These measures can be used to document real improvements in physical function through the course of cardiac rehabilitation. Therefore, it is recommended that an MCID reference value above one (1) point of the SPPB scores could serve as an explicit therapeutic goal for rehabilitation intervention and monitoring functional progress following cardiac surgery.

### 7.1.3 Study 3: The FDQ: Evaluation of the Clinimetric Properties of a New Tool for Measuring Physical Function Following Cardiac Surgery

In chapter 5, study three (The FDQ: Evaluation of the Clinimetric Properties of a New Tool for Measuring Physical Function Following Cardiac Surgery) the FDQ was investigated. This study incorporated a novel outcome assessment of upper limb and trunk function specific to cardiac surgery developed by a team of researchers within the Department of Physiotherapy at the Melbourne University. This was a comprehensive
clinimetric analysis of the FDQ including: the statistical feasibility of a shortened FDQ (FDQ-s), validity, reliability, responsiveness, interpretability, and feasibility. The findings of this study established that the FDQ-s has strong clinimetric properties with moderate to excellent results on all domains. As such it is recommended that the FDQ-s can be adopted as an outcome measure of physical recovery after cardiac surgery within the acute hospital setting, and in the community to plot the trajectory of recovery overtime. Further, the FDQ-s can be utilized in research trials evaluating function and in the clinical setting by health professionals to inform and guide management after cardiac surgery.

7.1.4. The Sternal Management Accelerated Recovery Trial (S.M.A.R.T)-Standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via a median sternotomy: a randomized controlled trial

In chapter 6, study four (The S.M.A.R.T)-Restrictive versus modified sternal precautions following cardiac surgery via a median sternotomy: a randomized controlled trial) the results from the RCT are described. The findings of this study suggest that a program of modified (less-restrictive) sternal precautions for patients following cardiac surgery did not improve physical recovery, pain or enhance HRQoL compared to usual care. With no adverse events, the results of this RCT suggest that a precautionary approach that is less restrictive with a progression of activity will likely facilitate optimal functional recovery after a median sternotomy. Importantly, this result adds further evidence that strict adherence to sternal precautions may not be warranted for all patients as it reinforces kinesiophobia which may potentially impact on patient participation exercise and in cardiac rehabilitation. It is recommended that a program of sternal precautions based on individual clinical characteristics and risk profile rather than a generic and routine set of sternal precautions may result in optimal recovery.

7.2 Strengths and limitations

The strengths and limitations of the individual studies comprising this thesis have been previously discussed in their respective chapters. In summary, the key strength of this
thesis was that it presents the first randomized controlled trial using an intervention group to modify sternal precautions, and evaluate its effectiveness in improving physical function in the cardiac surgery population. Although the results suggest a program of modified sternal precautions provided in a single individualized education session and a follow-up support program, delivered by telephone did not improve physical recovery, pain or enhance HRQoL in the early weeks following cardiac surgery, our study reported no adverse events. In addition, this RCT is the first to report data on a program of modified sternal precautions using pain and discomfort as a guide for upper limbs and trunk movements associated with activities of daily livings. Importantly the RCT had low attrition bias with the majority of patients having data at all-time points and none were drop-outs. The results of this RCT suggest that a precautionary approach that is less restrictive with a progression of activity will likely facilitate optimal functional recovery after a median sternotomy. Perhaps a more sound approach would be to evaluate individual risk profiles for sternal wound complications and prescribe sternal precautions in those individual at greater risk. As such the current widely used sternal precautions may not be warranted in all cardiac surgery patients. In addition, the clinical utility of two physical functional measures were explored and established in the acute patient population. This may have broader clinical application for the assessment and monitoring of physical recovery as a routine component of post-operative physiotherapy management following cardiac surgery via median sternotomy.

The sample size in this study was powered on function and in the absence of data for cardiac surgery populations a MID of two point for this study was derived from prior research on a cohort of patients with stable cardiovascular conditions. Perhaps utilization MID of one point with a larger sample size, the results would have shown a significant difference and facilitated an evaluation of changes in physical function in this population. Moreover, we found lack of responsiveness (in terms of effect size) of the SPPB was due to the vast ceiling effect. This means the SPPB was unable to capture change between testing periods due to a lack of discriminatory power of the scores as opposed to a lack of change as time after surgery increases and patients recover. An additional domain that aims to target upper limb and thorax function that is representative of activities of daily livings may be a warranted addition to the SPPB. This is of particular relevance in the cardiac surgical population given the impact of
surgery on the chest wall; subsequent upper limb function and sternal pain. Adding to this, two major cofounders has been identified (causing insignificant results) were due to the fact that the intervention program was not progressive enough to accelerate physical recovery and the education component regarding sternal precautions by carers and other health professionals within hospital and CR programs in the community setting.

However, the results add valuable information to the current literature with respect to sternal precautions education and upper limbs movement following cardiac surgery. The result of this study may also be explained by the difficulty in conducting a RCT with participant blinding to allocation and a pragmatic study of the effects of an implementation program may be more feasible and yield significant findings.

### 7.3 Future directions

The results of the three studies presented in this thesis may be used to inform future research and the development of clinical guidelines to optimise the post-operative care and recovery of patients following cardiac surgery (via a median sternotomy).

#### 7.3.1 Restrictive sternal precautions versus less restrictive sternal precautions

The main finding of the RCT reported that a program of modified sternal precautions provided in a single individualized education session and a support program, delivered by telephone did not significantly improve physical recovery, pain or enhance HRQoL for individuals in the early weeks following cardiac surgery. In the absence of any adverse events, future research should evaluate the effects of an implementation/translation program of modified sternal precautions, progressive type of rehabilitation and the role of moderate intensity upper limb exercise performed with patient-specific precautions based on risk factors to promote recovery following cardiac surgery. An alternative approach/program to sternal precautions such as “Keep Your Move in The Tube” which aims to educate patients in the safe use of their upper limbs for transfers and everyday tasks and is based on the ergonomics principles that keeping the arms close to the body will reduce the load of the sternum may be warranted (Adams
et al, 2016). “Keep Your Move in The Tube” is a graphic contains visual tips for staying “within the tube” while performing commonly ADL tasks that patients do when they get home as to promote active living following cardiac surgery via median sternotomy. This approach allows the patients to resume normal load-bearing activities by modifying movements within pain free limits and to stay “within the tube” for all daily tasks. To date the preliminary implementation of this approach to sternal precautions has promoted active participation, progression to moderate intensity exercise, positive wellness behaviour, independence in line with secondary prevention and return to an active life. However, large robust studies are warranted to further investigate the impact of such a program on discharge disposition, patient reported outcomes and health economics.

7.3.2 The application of the SPPB to assess physical function after cardiac surgery

The measurements used in the study were obtained at four weeks and three months post-operatively to determine the MCID of SPPB for an adult cardiac surgery population. At this time point, it is possible the SPPB was not challenging enough or may have a limited number of difficult items as time after surgery increases and the majority of patients have recovered further. This may have caused a lower threshold of MCID estimates due to the significant ceiling effects observed. It is possible that the results would alter across differing time points and this is worthy of further investigation at different intervals across time relative to surgery including in the pre-operative period. Further research is required to further inform the MCID range due to the high ceiling effects observed. Despite the high ceiling effect in study, we still detected a statistically significant change over time with in the SPPB to three months post-operatively but suspect further improvement beyond this time may not be captured with the SPPB. Further research is warranted to explore the predictors of patients who do not reach the maximum score (ceiling effect) in the short period post-operatively. The addition of an upper limb domain within the SPPB or the use of the SPPB combined with the FDQ-s is recommended to capture more targeted functional assessment following cardiac surgery.
7.3.3 The FDQ-s as tool for Measuring Physical Function in other surgical population

As the FDQ-s has been rigorously investigated with respect to its clinimetric properties it is recommended that this tool be adopted as an outcome measure of physical function after cardiac surgery within the acute hospital setting, and in the community to plot the trajectory of recovery over time. Further research may be warranted to explore the use of FDQ-s in the acute and community settings. Further, it may be evaluated in other surgical populations that target the thorax such as thoracic and abdominal surgery. The validity of the FDQ-s in different languages needs to also be explored so that it may be utilized in a clinically meaningful way to cater for diverse communities.

7.4 Conclusions and clinical relevance

Cardiac surgery via sternotomy is the most common procedure for myocardial revascularization worldwide with more than a million procedures annually. Although a small but significant number of patients develop sternal complications the routine prescription of restrictive sternal precautions may not be warranted for all patients especially if they at low risk for developing sternal complications. It can be hypothesised that patient-specific sternal care that focuses on movement within comfort, and function that is informed by the assessment of risk for sternal complications may be more appropriate to facilitate recovery in the target population. The results of this thesis also provide new clinimetric information on outcome measures targeting the cardiac population and inform post-operative clinical management and rehabilitation. Additionally, these outcome measures will facilitate a more robust evaluation of exercise and physiotherapy interventions and their impact on physical function. Perhaps if these outcomes are utilised to screen risk pre-operatively patients may be identified early for more targeted intervention that optimizes post-operative care and recover.
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Appendices

Appendix 1: Ethics approval: the Royal Melbourne Hospital (Melbourne Health- ID: HREC 2015.0.35)

MELBOURNE HEALTH HUMAN RESEARCH ETHICS COMMITTEE
ETHICAL APPROVAL OF A RESEARCH PROJECT

Dr Doa El-Ansary
Department of Physiotherapy
Level 7 Alan Gilbert Building
The University of Melbourne
CARLTON VIC 3010

29th May 2015

Dear Dr El-Ansary,

MH Project Number: 2015.035

Project Title: Sternal Management Accelerated Recovery Trial (S.M.A.R.T) Following Cardiac Surgery via a Median Sternotomy

HREC Approval Date: 27th May 2015

I am pleased to advise that the above project has received ethical approval.

Participating Sites:
- Royal Melbourne Hospital
- Melbourne Private Hospital

Approved Documents:
- Protocol Version 2.0 dated 20th March 2015
- Participant Information and Consent Form Version 2.0 dated 20th March 2015
- Flyer Version 2.0 dated 20th March 2015
- Short Physical Performance Battery (SPPB) Questionnaire Version 2.0 dated 20th March 2015
- Testing Battery Data Collection Forms Version 2.0 dated 20th March 2015
- Cardiac Surgery Sternal Precautions Guidelines Group A Version 1 dated 28th January 2015
- Cardiac Surgery Sternal Precautions Guidelines Group B Version 1 dated 28th January 2015

Site Specific Assessment:

Please note: You cannot commence this study until you have completed all the requirements of the Site Specific Assessment and have received the "Approval to Conduct a Research Project at Melbourne Health" certificate.

Conditions of Ethics Approval:

The Melbourne Health HREC operates and is constituted in accordance with the National Statement on Ethical Conduct in Human Research 2007.

HREC Approval Of New Project (non SERP)
In order to comply with the National Statement on Ethical Conduct in Human Research 2007, Guidelines for Good Clinical Research Practice and Melbourne Health Research Policies and Guidelines you are required to:

- Submit a copy of this letter to the Radiation Safety Officer (RSO) at Melbourne Health, for addition of the project to the Licence for Research Involving Human Volunteers held by the Department of Human Services Radiation Safety Section Radiation Safety Licence (if your project involves exposure to ionising radiation). Note: You cannot commence the project until you have received notification from the RSO that the project has been added to the Licence;
- Notify the HREC of the actual start date of the project;
- Submit to the HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure;
- Notify the HREC of any adverse events in accordance with the Melbourne Health Guidelines for Monitoring and Reporting of Safety in Clinical Trials Involving Therapeutic Products and Other Clinical Research, July 2009;
- Notify the HREC of any unforeseen events;
- Notify the HREC of your inability to continue as Principal Investigator or any other change in research personnel involved in the project;
- Notify the HREC if a decision is taken to end the study prior to the expected date of completion or failure to commence the study within 12 months of the HREC approval date;
- Notify the HREC of any other matters which may impact the conduct of the project.
- If the study is a clinical trial, Melbourne Health requires registration of clinical trials in a public trials registry at or before the time of first patient enrolment as a condition of consideration for publication, in accordance with ICMJE http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

Reporting

You are required to submit to the HREC:

- An Annual Progress Report every 12 months (or more frequently as requested by the reviewing HREC) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report in a timely manner; and
- A comprehensive Final Report upon completion of the project.

The HREC may conduct an audit of the project at any time.

Please refer to the Office for Research website to access forms such as the Amendment Form, Annual Report/Final Report Form, Guidelines for Monitoring and Reporting of Safety in Clinical Trials Guidelines and Adverse Event Report Forms, and other information and news concerning research at Melbourne Health: http://www.mh.org.au/www/342/1001127/displayarticle/1001352.html

A list of those HREC members present at the review of this project can be obtained from the above website.

Yours sincerely

Ms. Jessica Turner
Manager - Human Research Ethics Committee

The Melbourne Health HREC operates and is constituted in accordance with the National Statement on Ethical Conduct in Human Research 2007.
Appendix 2 Ethics Approval: Amendment (Melbourne Health- ID: HREC 2015.0.35)

Dear Dr Doa El-Ansary,

HREC Reference Number: SSA/15/MH/104
SSA Reference Number: SSA/15/MH/104
Local Project Number: 2015.035
Research Title: Sternal Management Accelerated Recovery Trial (S.M.A.R.T) Following Cardiac Surgery via a Median Sternotomy
Type of review: HREC and Governance Review

I am pleased to advise that the amendment to the above project has been reviewed and approved by the Melbourne Health HREC (ethical approval). This approval applies to all sites for which the Melbourne Health HREC has issued ethical approval. The amendment has also been approved to be conducted at Melbourne Health (governance approval).

Amendment Approval Date: 9th December 2015

Approved Documents:
- PICF, Version 3.0, dated 11th November 2015
- Questionnaire, Version 3, dated 11th November 2015
- Phone Script for Control Group, Version 1.0 Dated 11th November 2015
- Phone Script for Invention Group, Version 1.0, dated 11th November 2015

Please refer to the Melbourne Health Office for Research website to access guidelines and other information and news concerning research at: http://www.mh.org.au/www/342/1001127/displayarticle/1001352.html

Please Note: Template forms for reporting Amendments, Adverse Events, Annual Report/Final Reports, etc. can be accessed from: www.health.vic.gov.au/ccire.

For any queries about this matter, please contact Ms Jessica Turner on 9342 8530 or via email on: Jessica.Turner@mh.org.au

Yours sincerely,

Ms Jessica Turner
Manager - Human Research Ethics Committee
Ph: 9342 8530
Appendix 3 Ethics approval: the Royal Melbourne Hospital (Site-specific- ID: HREC 2015.035)

SITE SPECIFIC ASSESSMENT (SSA) AUTHORISATION

APPROVAL TO CONDUCT A RESEARCH PROJECT AT MELBOURNE HEALTH

Dr Doa El-Ansary
Department of Physiotherapy
Level 7 - Alan Gilbert Building
The University of Melbourne
CARLTON
VIC 3010

15 July 2015

Dear Dr Doa El-Ansary

Local Project Number: 2015.035

Study Title: Sternal Management Accelerated Recovery Trial (S.M.A.R.T) Following Cardiac Surgery via a Median Sternotomy

HREC Reference Number: HREC/15/MH/65

SSA Reference No: SSA/15/MH/104

SSA Authorisation Date: 13 July 2015

HREC Approval Date: 27 May 2015

I am pleased to advise that the above project is approved to be conducted at Melbourne Health. This approval is subject to compliance with any conditions imposed by the reviewing HREC.

SSA Approved Documents:

- Participant Information and Consent Form – RMH / Melbourne Private / UoMelb Site Specific, Version 2.0, dated 20 Mar 2015
- University of Melbourne - Schedule C – Undertaking (Katiijahbe Binti MD Ali)

Research governance

You are required to notify the Office for Research of:

1. The actual start date of the project at Melbourne Health.
2. Any amendments to the project after these have been approved by the reviewing HREC.
3. Any adverse events involving patients of Melbourne Health, in accordance with the Melbourne Health Guidelines for Monitoring and Reporting of Safety in Clinical Trials Involving Therapeutic Products and Other Clinical Research, July 2009.
4. Any unforeseen events.
5. Any changes to the indemnity, insurance arrangements or Clinical Trial Research Agreement for this project. This includes changes to the project budget or other changes which may have financial or other resource implications for Melbourne Health.

6. Your inability to continue as Principal Investigator or any other change in research personnel involved in the project.

7. Any other matters which may impact the conduct of the project at Melbourne Health.

You are also required to submit to the Office for Research:

8. A copy of the TGA acknowledgement letter in respect of the CTN notification (if applicable).

9. An Annual Progress Report every 12 months (or more frequently as requested by the reviewing HREC) for the duration of the project. This report is due on the anniversary of HREC approval. Continued SSA and HREC approval are contingent on receipt of an annual report by the reviewing HREC and the Research Governance Office.

10. A comprehensive Final Report upon completion of the project.

**Melbourne Health requires that every participant enrolled in a research project be registered on the IPM patient database as a research participant at the time they are first enrolled or consented. This must be done in real time in order to ensure patients safety. For further information please refer to the Office for Research website IPM page at [http://www.mh.org.au/research-participation-ipm/w1/i1018219/](http://www.mh.org.au/research-participation-ipm/w1/i1018219/).**

The Office for Research may conduct an audit of the project at any time.

Please refer to the Office for Research website to access forms such as the Amendment Form, Annual Report/Final Report Form, Guidelines for Monitoring and Reporting of Safety in Clinical Trials Guidelines and Adverse Event Report Forms, and other information and news concerning research at Melbourne Health: [http://www.mh.org.au/ww/342/1001127/displayarticle/1001352.html](http://www.mh.org.au/ww/342/1001127/displayarticle/1001352.html)


Yours sincerely,

[Signature]

Dr Angela Watt
Director Research Governance and Ethics
Appendix 4 Ethics approval: Melbourne Private Hospital (ID: HREC 2015.035)

9 December 2015

Dear Dr Doha El-Ansary

HREC Reference Number: HREC 2015.035

Study Title: Sternal Management Accelerated Recovery Trial (S.M.A.R.T.) Following Cardiac Surgery via a Median Sternotomy

Research Governance Approval: Yes

Reviewing HREC: Melbourne Health

HREC Approval Date: 27th May 2015

I am pleased to advise that the above project is approved to be conducted at Melbourne Private Hospital. This approval is subject to compliance with any conditions imposed by the reviewing HREC.

Research Governance

You are required to notify the MPH Research Governance Officer (HIM Manager):

1. The actual start date of the project at Melbourne Private Hospital.
2. Any amendments to the project after these have been approved by the reviewing HREC.
3. Any adverse events involving patients of Melbourne Private Hospital.
4. Any unforeseen events.
5. Any changes to the indemnity, insurance arrangements of Clinical Trial Research Agreement for this project. This includes changes to the project budget or other changes which may have financial or other resource implications for [Melbourne Private Hospital].
6. Your inability to continue as Principal Investigator or any other change in research personnel involved in the project.
7. Any other matters which may impact the conduct of the project at Melbourne Private.

You are also required to submit to the MPH Research Governance Officer:

1. A copy of the TGA acknowledgement letter in respect of the CTN notification (if applicable).
2. An Annual Progress Report every 12 months (or more frequently as requested by the reviewing HREC) for the duration of the project. This report is due on the anniversary of HREC approval. Continued site specific approval is contingent on receipt of an annual report by the MPH Research Governance Officer.
3. A comprehensive final report upon completion of the project.

Melbourne Private Hospital Research Governance Officer may conduct an audit of the project at any time.
Appendix 5 Patient information and consent form for Studies 1 and 4

Participant Information and Consent Form
The Royal Melbourne Hospital, Melbourne Private Hospital and the University of Melbourne

Version 3.0 Dated 11 November 2015
HREC Project No: 2015.035

Full Project Title:
“Sternal Management Accelerated Recovery Trial (S.M.A.R.T) Following Cardiac Surgery via a Median Sternotomy”

Principal Researcher:
Dr Doa El-Ansary, Physiotherapy Department, Faculty of Medicine, Dentistry and health Sciences, The University of Melbourne
Professor Alistair Royse- Cardiothoracic Surgery Department, The Royal Melbourne Hospital; Cardiothoracic Surgery Department, Melbourne Private Hospital; Melbourne School of Medicine, The University of Melbourne

Associate Researchers:
Dr Catherine Granger, Department of Physiotherapy, The University of Melbourne
Katijahbe bt Md Ali, Department of Physiotherapy, The University of Melbourne
Professor Linda Denehy, Department of Physiotherapy, The University of Melbourne
Professor Colin Royse, Department of Anaesthesia and Pain Management, The Royal Melbourne Hospital
Rebecca Bates, Physiotherapy Department, The Royal Melbourne Hospital

1. Introduction
You have been invited to take part in this research project as you have undergone a cardiac surgery procedure. This research project aims to identify how a change in arm and body movement restrictions may affect your speed of recovery following cardiac surgery.

This participant information and consent form tells you about this research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in this research project.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this research project is voluntary. If you don’t want to take part, you don’t have to. You will receive the best possible care whether you take part or not.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
- understand what you have read;
- consent to take part in this research project;
- consent to take part in the research processes that are described;
- consent to the use of your personal and health information as described.
You will be given a copy of this participant information and consent form to keep.

Version 3.0 Dated 11 Nov 2015
Page 1 of 5
Appendices

2. **What is the purpose of this research project?**

After cardiac surgery, patients are routinely asked to follow precautions that restrict arm and trunk movements. These restrictions may limit performance of everyday tasks and may not be necessary for all patients. The primary aim of this research project is to identify how a change in this practice affects your physical function after surgery. To achieve this, the research team will measure aspects of how well you are able to move and any symptoms of pain and discomfort that you may experience. We will observe you performing selected physical tasks to see how much you are able to move early after your surgery using pain as a guide.

Participants will be randomised to receive either standard hospital sternal precautions or a modified sternal precautions protocol. The outcomes for each group in terms of upper limbs and lower limbs function, pain and discomfort, recovery, fear of movement, hand strength, adherence and quality of life will be compared. This research project is a collaborative project between The Royal Melbourne Hospital, Melbourne Private Hospital and The University of Melbourne.

This research is part of a PhD student project for Ms Katijahe Md Ali. The results of this research project will be published as part of her thesis.

3. **What does participation in this research project involve?**

If you choose to take part you will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

Participants in the trial will receive standard care on the first 3 days following surgery and will be randomized either to receive a standard hospital sternal precautions protocol or a modified sternal precautions protocol on the fourth day following surgery. In both groups you will be receiving guidelines in arm and body movement restrictions. If you choose not to participate in the study, you will be treated in the usual care group (standard hospital sternal precautions).

We will collect and record baseline information from your health records and you will be asked to answer questions relating to your general health following your cardiac surgery and undertake testing sessions. These will occur prior to your hospital discharge. The assessment will form a part of your standard post-operative care whilst in hospital. The session will take no longer than 45 minutes and will seek to obtain measures of physical performance, pain and discomfort, recovery, fear of movement, hand strength, and quality of life.

Following your cardiac surgery, you will be required to undertake 3 testing sessions. These will occur prior to your hospital discharge, 4 weeks after your operation and again at 3 months after your operation. The assessment will form a part of your standard post-operative care whilst in hospital. You will be asked a series of questions that will help us to assess how well you have recovered from your surgery. The assessment prior to your discharge will be conducted on the ward. The follow up sessions at 4 weeks and 3 months will occur in the research area in the department of cardiac surgery located at The Royal Melbourne Hospital, after you have been discharged from hospital. It is anticipated that each testing session will take no longer than 45 minutes.

At the testing sessions, you will be required to complete 10 quick tests (3 physical tests and 7 questionnaires) that assess aspects of physical function, pain and discomfort, recovery, fear of movement, hand strength, and quality of life. During the sessions a member of the research team will also complete a physical examination to assess the stability of your sternum (breastbone) and ask you to answer questions relating to your pain and discomfort symptoms following cardiac surgery. After discharge, a follow-up telephone call will be conducted weekly for the first 6 weeks post-operatively to measure adherence to the sternal precautions guidelines.
4. What are the possible benefits?
   Your participation in this research project will help to provide information that may assist with providing better care for patients after cardiac surgery.

5. What are the possible risks?
   The research team will monitor you carefully during all assessment sessions and ask you to notify them of any discomfort or pain. The research team also advise you to perform the physical tasks within your level of comfort to minimise any such occurrence.

6. Do I have to take part in this research project?
   Participation in any research project is voluntary. If you do not wish to take part you don’t have to. If you decide to take part and later change your mind, you are free to withdraw from the research project at any stage.
   Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your treatment or relationship with The Royal Melbourne Hospital/Melbourne Private Hospital and/or The University of Melbourne.

7. What if I withdraw from this research project?
   If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisors to discuss any health risks or special requirements linked to withdrawing. Your decision whether not to take part, or withdraw, will not affect your treatment or relationship with The Royal Melbourne Hospital/Melbourne Private Hospital and/or The University of Melbourne staff.
   If you decide to withdraw from the research project, the researchers would like to keep the personal and health information collected about you. If you do not want this to occur, you must inform the research team.

8. How will I be informed of the results of this research project?
   Participants will be provided with a written summary of their results at the completion of the research project. This will be mailed to all participants.

9. What else do I need to know?
   **What will happen to information about me?**
   Information about you will be obtained from your health records held at this health service for the purposes of this research project. Upon enrolment in the study, each participant will be assigned a code number under which all personal information, health information and data collected will be recorded. All information related to the study will be stored in a locked cabinet at Royal Melbourne Hospital and University of Melbourne and will only be accessible to the following listed principal and associate researchers in this study - Prof Alistair Roysie, Prof Collin Royse, Dr Doa El-Ansary, Dr Catherine Granger, Ms Rebecca Bates and Ms Katiyaha Md Ali. The encoded hard copy data will be stored in a separate locked cabinet at The University of Melbourne and will be accessible to the principal and associate researchers.

   Any information obtained for the purposes of this research project that can identify you will be treated as confidential and stored securely. This information will only be accessible to the research team and will be disclosed only with your permission, or as permitted by law.

   In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Data we collect from you will be collated with the data from other participants and presented as a group.

   In accordance with the Australian Code for the Responsible Conduct of Research (2007), the research team intends to keep information collected about you for a minimum of 5 years from the time of publication of results. After this time, the information will be disposed of in such a way that maintains your confidentiality.
It is desirable that your local doctor be advised of your decision to participate in this research project. By signing the consent section, you agree to your local doctor being notified of your decision to participate in this research project.
Information about your participation in this research project will be recorded in your health records.

How can I access my information?
In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

What happens if I am injured as a result of participating in this research project?
If you suffer an injury as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you if you elect to be treated as a public patient.

Is this research project approved?
The ethical aspects of this research project have been approved by the Human Research Ethics Committee of Melbourne Health.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

10. Consent
I have read or have had read to me, in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.
I give permission for my doctors and other health professionals to release information to The Royal Melbourne Hospital/Melbourne Private Hospital and/or The University of Melbourne concerning my treatment that is needed for this research project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.
I freely agree to participate in this research project as described.
I understand that I will be given a signed copy of this document to keep.

Participant’s name (printed): ________________________________

Signature: ________________________________ Date: ____________

Name of witness (printed): ________________________________

Signature: ________________________________ Date: ____________

Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood this explanation.

Researcher’s name (printed): ________________________________

Signature: ________________________________ Date: ____________
11. **Who can I contact?**

Who you may need to contact will depend on the nature of your query, therefore, please note the following:

**For further information:**

If you want any further information concerning this project, you can contact:

<table>
<thead>
<tr>
<th>Name</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Doa El-Ansary</td>
<td>Katijahibe Md All</td>
</tr>
<tr>
<td>Role: Chief Researcher</td>
<td>Role: Researcher</td>
</tr>
<tr>
<td>Telephone: 0422 036 899</td>
<td>Telephone: 0456 007 056</td>
</tr>
<tr>
<td>Email address: <a href="mailto:d.el-ansary@unimelb.edu.au">d.el-ansary@unimelb.edu.au</a></td>
<td>Email address: <a href="mailto:kmd@student.unimelb.edu.au">kmd@student.unimelb.edu.au</a></td>
</tr>
</tbody>
</table>

**For complaints:**

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

<table>
<thead>
<tr>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jessica Turner</td>
</tr>
<tr>
<td>Role: Manager</td>
</tr>
<tr>
<td>Melbourne Health</td>
</tr>
<tr>
<td>Human Research Ethics Committee</td>
</tr>
<tr>
<td>Telephone: 03 9342 8530</td>
</tr>
</tbody>
</table>
Appendices

Appendix 6 Participant Information Flyers studies 1 and 4

S.M.A.R.T.

This ward is participating in the S.M.A.R.T. study.

This study aims to evaluate care of the sternum (breast bone) after surgery.

If you are interested in participating and want any further information concerning this project, you can contact:

Role: Chief Researcher, Dr Doa El-Ansary,
Telephone: 0422036899

Katijahbe Md Ali
Role: Co-Researcher, Telephone: 0456007056

Research Team Members
Professor Alistair Royse, Professor Colin Royse, Professor Linda Denehy, Dr Catherine Granger, Ms Rebecca Bates, Ms Sarah Logie.

Version 2.0 Dated 30 March 2013
Appendix 7 Testing Battery Data Collection Forms

T1: Post Operative Period

RN

Patients Initial

Study ID

Admission Date

Date of Surgery

Discharge Date

SITE

Royal Melbourne Hospital

Private Melbourne

Date of Birth

Sex

Male

Female

Height (cm)

Weight (kg)

BMI Score

Past Medical History (Pre-morbid)

Previous Median Sternotomy

Hypertension

COPD / COAD

Chronic / Persistent Cough

Diabetes Mellitus

Peripheral vascular disease

Vascular disease

Osteoporosis

Dexa score (if available):

Others:

DEXA score

Others:

Smoking Status

Yes

No

Ex smoker

a. On average how long you smoke?

b. On average how many packets per day do you smoke?

Current Smoker

a. On average how long you smoke?
b. On average how many packets per day do you smoke?

i. Employment status
   - Working full time
   - Working part time
   - Sick leave/leave of absence - temporary
   - Sick leave/leave of absence - permanent
   - Not employed/taking time off work
   - Retired
   - Home duties
   - Studying
   - Other: __________
   (Please circle the nearest answer describe you current employment status)

   Other: __________

ii. Occupational class
   - Managers and administrators
   - Professionals
   - Para-professional
   - Tradies
   - Clerks
   - Sales and personal service workers
   - Drivers and machinery operators
   - Labourers and related workers
   - Others

iii. Average hours worked per week

Education level
   - No formal schooling
   - Some primary schooling
   - Finished primary schooling
   - Some secondary or high school
   - Completed secondary or high school
   - Some trade community or TAFE college
   - Completed trade, community, TAFE college
   - Some university
   - Completed Bachelor's degree
   - Completed Masters or PhD degree
   - Other: __________
   (Please circle the nearest answer describe you current employment status)

Pre-morbid Mobility
   - Independent
   - Supervision
   - Assisted
## Appendix

### Angina (Canadian Cardiovascular Class)

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No angina</td>
</tr>
<tr>
<td>1</td>
<td>Ordinary physical activity such as walking or climbing stairs does not cause angina. Angina may occur with strenuous, rapid, or prolonged exertion at work or recreation.</td>
</tr>
<tr>
<td>2</td>
<td>Slight limitation of ordinary physical activity. Angina may occur with moderate activity such as walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals or in the cold, in the wind, or under emotional stress, or walking more than two blocks on the level, and climbing more than one flight of stairs at normal pace under normal conditions.</td>
</tr>
<tr>
<td>3</td>
<td>There is marked limitation of ordinary physical activity. Angina may occur after walking one or two blocks on the level or climbing one flight of stairs under normal pace.</td>
</tr>
<tr>
<td>4</td>
<td>There is inability to carry on any physical activity without discomfort; angina may be present at rest.</td>
</tr>
</tbody>
</table>

### Dyspnea (NYHA Class)

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or dyspnea.</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation or dyspnea.</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity results in fatigue, palpitation or dyspnea.</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency may be present even at rest. If any physical activity is undertaken, discomfort is increased.</td>
<td></td>
</tr>
</tbody>
</table>

### Primary Gait Aid Used (Pre-Morbid)

- [ ] No gait aid
- [ ] SPS
- [ ] 4PS
- [ ] AFO
- [ ] C Walk
- [ ] PIIF
- [ ] ZWF
- [ ] WVF
- [ ] GF
- [ ] Other

### Comments:
### Appendices

#### LV Function Grade
- 1. Grade 1
- 2. Grade 2
- 3. Grade 3
- 4. Grade 4

#### EF (%):

*In percentage*

#### Estimate:
- Normal (>60%)
- Mild Impairment (40-60%)
- Mod (30-45%)
- MIN (Severe < 30%)

#### Type of Cardiac Surgery
- CABG
- Valve Replacement
- Combination of Valve and CABG
- Other

#### Comments

#### Type of Graft
- Saphenous Vein
- Unilateral IMA, Left or Right
- Bilateral
- Radial Artery
- Thoracic Artery
- Others

#### Comments

#### Unilateral IMA Option
- Left
- Right

#### Method of Sternal Closure

#### Anaesthetic

#### Off-centre median sternotomy

#### Operation Duration (In minutes)

#### Cardiopulmonary Bypass Time (In minutes)

#### Duration of Post-op ICU Admission (Hours)

#### Duration of Post-op Mechanical Ventilation (Hours)

#### Intra-aortic Balloon Pump
- Yes
- No
Confidential

Complications Post Operative
- Bleeding
- Deep sternal wound infection
- Superficial sternal wound infection
- Forearm infection
- CVA
- Increased blood loss/number of post op blood transfusion
- Pneumonia
- Return to Theatre
- Others

Comments

Discharge/Readmission
- Home
- Hospital in the home
- Rehabilitation until Hospital
- Local or referring hospital
- Hospital mortality

Does the patient still require analgesia for this problem?
- Yes
- No

Please list all medications the patient is currently taking:

Has the patient felt any abnormal movement or sensation at their breastbone?
- Yes
- No

If YES, how do they describe it and when it occurs?
# Charlson Comorbidity Index

**RN**

Comorbidity (Choose all that are present):

- Myocardial infarct (+1)
- Congestive heart failure (+1)
- Peripheral vascular disease (+1)
- Chronic pulmonary disease (+1)
- Connective tissue disease (+1)
- Ulcer disease (+1)
- Mild liver disease (+1)
- Diabetes (without complications) (+1)
- Diabetes with end organ damage (+2)
- Hemiplegia (+2)
- Moderate or severe renal disease (+2)
- Solid tumor (non metastatic) (+2)
- Leukemia (+2)
- Lymphoma, Multiple myeloma (+2)
- Metastatic solid tumor (+6)
- AIDS (+6)

Assigned weights for each condition the patient has:

- 50 - 59 (+1)
- 60 - 69 (+2)
- 70 - 79 (+3)
- 80 - 89 (+4)
- 90 - 99 (+5)

**Comments:**

Total points:

---


Additional information:

SCORING - [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC545968/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC545968/)
T2 : 4 Weeks Post-Operatively

PIN

Date:

Employment status

1. Employment status
   - Working full time
   - Working part time
   - Sick leave/leave of absence - temporary
   - Sick leave/leave of absence - permanent
   - Not employed/taking time off work
   - Retired
   - Home duties
   - Studying
   - Other
   (Please circle the nearest answer describe you current employment status)

Average hours per week:

Others:

ii. Occupational class
   - Managers and administrators
   - Professionals
   - Para-professional
   - Tradesperson
   - Clerks
   - Sales and personal service workers
   - Drivers and machinery operators
   - Labourers and related workers

Does the patient still requiring analgesia FOR THIS PROBLEM?
   - Yes
   - No

Please list ALL medications the patient is currently taking:

Has the participant felt any abnormal movement or sensation at their breastbone?
   - Yes
   - No

If yes, how do they describe it and when it occurs:

Sternal Instability Scale (0-3):

How does your function now, compare to your function at the initial assessment after surgery
   - 1. Very much improved
   - 2. Much improved
   - 3. Minimally improved
   - 4. No change
   - 5. Minimally worse
   - 6. Much worse
   - 7. Very much worse

Instruction: Please circle Only One number best describe your function post-week

Cardiac rehab program attendance
   - Yes
   - No

05/02/2017 9:57am

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REDCap
Global Rating of Change

H. How does your overall physical function now, compare to your physical function just before you went home from hospital?

e.g. standing up from sitting:

○ 1. Very much improved
○ 2. Much improved
○ 3. Minimally improved
○ 4. No change
○ 5. Minimally worse
○ 6. Much worse
○ 7. Very much worse

How does your arm and upper body function, compared to your arm and upper body function just before you went home from hospital?

e.g. brushing hair, doing up skirts, turning to pick up things from the back:

○ 1. Very much improved
○ 2. Much improved
○ 3. Minimally improved
○ 4. No change
○ 5. Minimally worse
○ 6. Much worse
○ 7. Very much worse
Modified Sternal Instability Score

RN

Standardisation When Testing for Sternal Instability

Instruction:
Record the position of testing: standing/sitting.
Place the palpatory fingers of one hand along the median sternal ridge and the other hand on the posterior aspect of the thoracic cage for support.
Note the degree of separation.
Note the extent of excessive motion.
Eliminate other sources of "clicking" (e.g., crepitation at other joints in the region such as the costo-chondral joints).
Correlate subjective with objective findings.
Assign the grade that best matches the findings.

- 0: Clinically stable sternum (no detectable motion) - normal
- 1: Minimally separated sternum (slight increase in motion upon special testing - upper limb, trunk)
- 2: Partially separated sternum - regional (moderate increase in motion upon special testing)
- 3: Completely separated sternum - entire length (marked increase in motion upon special testing)
Appendices

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T3 : 3 Months Post-Operatively

RN

Date:

Employment Status

i. Employment Status

- Working full time
- Working part time
- Sick leave/leave of absence - temporary
- Sick leave/leave of absence - permanent
- Not employed/taking time off work
- Retired
- Home duties
- Studying
- Other

Others:

ii. Employment Class

- Managers and administrators
- Professionals
- Para-professional
- Tradepersons
- Clerks
- Sales and personal service workers
- Drivers and machine operators
- Labourers and related workers

iii. Average hours worked per week:

Discharge/Readmission

- Home
- Hospital in the Home
- Rehabilitation Unit/Hospital
- Local or Referring Hospital
- Hospital Mortality

Readmission:

- Readmitted < 3 months from procedure:
  - Yes
  - No

Readmitted reason:

(choose one of the following)

- Anticoagulant/Complication
- Arrhythmia
- Congestive heart failure (CHF)
- Deceased
- Infection
- Other Incisional Complication
- Sternal instability
- Pneumonia or other Respiratory Complication
- Myocardial infarction (MI)
- Recurrent Angina
- Others

Others:

Comment:

Does the patient still requiring analgesia FOR THIS PROBLEM?

- Yes
- No

03/03/2017 9:37 AM

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REDCap
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<table>
<thead>
<tr>
<th>Please list ALL medications the patient is currently taking:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the participant felt any abnormal movement or sensation at their breasts?</td>
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<tr>
<td>If yes, how do they describe it and when it occurs?</td>
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<tr>
<td>Sternal Instability Scale (0-3):</td>
</tr>
<tr>
<td>How does your function now, compare to your function at the initial assessment after surgery</td>
</tr>
<tr>
<td>1. Very much improved</td>
</tr>
<tr>
<td>2. Much improved</td>
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<td>3. Minimally improved</td>
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<tr>
<td>4. No change</td>
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<tr>
<td>5. Minimally worse</td>
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<tr>
<td>6. Much worse</td>
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<tr>
<td>7. Very much worse</td>
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<tr>
<td>Cardiac rehab program attendance</td>
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<tr>
<td>Yes</td>
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<tr>
<td>No</td>
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</tbody>
</table>
Appendices

Confidential

SPPB

RN

1. Repeated Chair Stands
Instructions: Do you think it is safe for you to try and stand up from a chair five times without using your arms? Please stand up straight as quickly as you can five times, without stopping in between. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. Please watch while I demonstrate. I’ll be timing you with a stopwatch. Are you ready? Begin

Grading: Begin stop watch when subject begins to stand up. Count aloud each time subject arises. Stop the stopwatch when subject has straightened up completely for the fifth time. Also stop if the subject uses arms, or after 1 minute if subject has not completed rises, and if concerned about the subject’s safety. Record the number of seconds and the presence of imbalance. Then complete ordinal scoring.

Time: ______ sec (if five stands are completed)

Number of Stands Completed:

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<th>1</th>
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</table>

Chair Stand Ordinal Score: ______

- 0 = unable
- 1 = > 16.7 sec
- 2 = 16.6 to 11.7 sec
- 3 = 12.6 to 11.2 sec
- 4 = < 11.1 sec

2. Balance Testing

Begin with a semitandem stand (heel of one foot placed by the big toe of the other foot). Individuals unable to hold this position should try the side-by-side position. Those able to stand in the semitandem position should be tested in the full tandem position. Once you have completed time measures, complete ordinal scoring.

a. Semitandem Stand
Instructions: Now I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you. Please watch while I demonstrate.

Grading: Stand next to the participant to help him or her into semitandem position. Allow participant to hold onto your arms to get balance. Begin timing when participant has the feet in position and lets go. Circle one number.

Number of seconds held ______

- 0. Not attempted
- 1. Held for less than 10 sec
- 2. Held for 10 sec

b. Side-by-Side Stand
Instructions: I want you to try to stand with your feet together, side by side, for about 10 sec. Please watch while I demonstrate. You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.
Appendices

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Grading: Stand next to the participant to help him or
her into the side-by-side position. Allow
participant to hold onto your arms to get balance.
Begin timing when participant has feet together and
lets go.

number of seconds held ______

2. Tandem Stand
Instructions: Now I want you to try to stand with the heel of one foot in front of and touching the toes of the other
foot for 10 sec. You may put either foot in front, whichever is more comfortable for you. Please watch while I
demonstrate.

Grading: Stand next to the participant to help him or
her into the side-by-side position. Allow
participant to hold onto your arms to get balance.
Begin timing when participant has feet together and
lets go.

number of seconds held ______

Balance Ordinal Score: ______

3. 8' Walk (2.44 meters)
Instructions: This is our walking course. If you use a cane or other walking aid when walking
outside your home, please use it for this test. I want you to walk at your usual pace to the
other end of this course (a distance of 8'). Walk all the way past the other end of the tape
before you stop. I will walk with you. Are you ready?

Grading: Press the start button to start the
stopwatch as the participant begins walking. Measure
the time it takes to walk 8'. Then complete ordinal
scoring.

Time: ______ sec

Gait Ordinal Score: ______

Summary Ordinal Score (0-12): ______

(Add up 1, 2, 3 above)
Functional Difficulties Questionnaire

Please mark on each of the lines below the level of difficulty that you experience when completing each of the following tasks. Make sure that you read each question fully, as it will explain to you the exact way in which the task has to be completed.

Feel free to try any of the activities (where appropriate) while you are completing the questionnaire. For those activities that you cannot trial whilst filling out the questionnaire, think back to the last time that you did them.

Date:

Code Number:

1. Sitting fully upright in a chair, aiming to sit as tall as possible (in mm)
   Difficulty
   
2. Walking with arms swinging freely (in mm)
   Difficulty
   
3. Coughing or sneezing (in mm)
   Difficulty
   
4. Rolling over in bed (in mm)
   Difficulty
   
5. Getting out of bed (in mm)
   Difficulty
   
6. Washing your hair in the shower. You must be standing upright, with both arms lifted to your hands and touching your head, Your elbows need to be held out to the sides (in mm)
   Difficulty
   
7. Scratching your back by taking your arm up and over the top of your shoulder on the same side. You should reach as far down your back as possible (in mm)
   Difficulty
8. Sitting in a chair and bending down sideways to pick up an object from the ground (in mm)

9. Turning to reach behind you as far as possible when sitting in a chair. Feet must be firmly planted on the ground and your bottom must remain fixed in the same position (in mm)

10. Doing up your bra behind your back OR Tucking in your shirt to the back of your pants (in mm)

11. Putting on a dressing down, cardigan or jacket (which involves you putting it on behind your back, one sleeve at a time) (in mm)

12. Drying your back with a towel, using the towel in both hands behind your back. Your back should be dried with the towel moving back and forth repeatedly (in mm)

13. Pushing shut drawers (e.g. clothing drawers) (in mm)
# hand grip strength

**RN**

- Please circle prior to test
  - [ ] RIGHT (1)
  - [ ] LEFT (0)

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<tr>
<td>1st attempt (in Kg)</td>
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<td>2nd attempt (in Kg)</td>
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<td>3rd attempt (in Kg)</td>
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<td>Best of three (in Kg)</td>
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</table>
This questionnaire provides you with a list of words that describe some of the different qualities of pain and related symptoms. Please put an X through the numbers that best describe the intensity of each of the pain and related symptoms you felt during the past week. Use 0 if the word does not describe your pain or related symptoms.

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<th>Term</th>
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<td>Sharp pain</td>
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<td>Clamping pain</td>
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<td>Hot-burning pain</td>
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<td>Aching pain</td>
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<td>Tingling-exhausting</td>
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<td>Fearful</td>
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<td>Punishing cruel</td>
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<td>Electric-shock pain</td>
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<td>Cold-freezing pain</td>
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<td>Piercing</td>
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<td>Pain caused by light touch</td>
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<td>Tingling or ‘pins and needles’</td>
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<td>Numbness</td>
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## TSK-11

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<tbody>
<tr>
<td>I'm afraid that I might injure myself if I exercise</td>
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<tr>
<td>If I were to try to overcome it, my pain would increase</td>
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<tr>
<td>My body is telling me I have something dangerously wrong</td>
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<tr>
<td>People aren't taking my medical condition seriously enough</td>
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<td>My accident has put my body at risk for the rest of my life</td>
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<tr>
<td>Pain always means I have injured my body</td>
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<tr>
<td>Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening</td>
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<tr>
<td>I wouldn't have this much pain if there wasn't something potentially dangerous going on in my body</td>
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<tr>
<td>Pain lets me know when to stop exercising so that I don't injure myself</td>
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<tr>
<td>I can't do all the things normal people do because it's too easy for me to get injured</td>
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<tr>
<td>No one should have to exercise when they're in pain</td>
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</table>
Appendices

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Cardiac Pain and Patients Reporting Using Visual Prompts

Appendix A
Location of Pain/Discomfort
Instructions: Please mark where you currently feel pain or discomfort.

R. face/head
L. face/head
back
front
R. hand
L. hand
None
Appendices

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Appendix B
Nature of Chief Pain/Discomfort
Circle the picture that best describes your pain/discomfort
Circle ONLY One Picture

1. Shooting/Moving
2. Burning
3. Stabbing
4. Pressure
5. Squeezing English/South Asian
6. Squeezing Chinese
7. Loose
8. Loose (shoes)
9. Loose (ropes)
10. None

Appendix C
Intensity of Chief Pain/Discomfort
How ‘bad/dreadful’ is your pain/discomfort?
Circle ONLY One number

0 1 2 3 4 5 6 7 8 9 10

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ACS Study

Pain Discomfort/Location Grid

The number will be recorded for each grid space occupied by any element of the shading or coloring. The ‘classic’ symptom profile has been defined as [(mid-ternal pain and/or mid-ternal pressure) +/- throat/neck pain +/- shoulder pain +/- arm pain]. Thus on the grid this would represent locations [1 +/- (6, 7, 21 or 22) +/- (4, 5, 25 or 26) +/- (10, 11, 12, 13, 27, 28, 29 or 30)]

This form is for use ONLY at Calgary Project Office

Front

☐ none  ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5  ☐ 6  ☐ 7  ☐ 8  ☐ 9  ☐ 10  ☐ 11  ☐ 12
☐ 13  ☐ 14  ☐ 15  ☐ 16  ☐ 17
Nociceptive Factors

N1. I am going to show you a series of faces and I would like you to indicate which face, number or description most accurately describes your level of pain at the moment?
   Please show appropriate face chart to the patient and record the number corresponding to the actual respond
   - 1 = No Pain
   - 2 = Mild Pain
   - 3 = Moderate Pain
   - 4 = Severe Pain
   - 5 = Worst Possible Pain

N2. I am going to show you a series of faces and I would like you to indicate which face, number or description most accurately describes your level of feeling nauseous or vomiting at the moment?
   Please show appropriate face chart to the patient and record the number corresponding to the actual respond
   - 1 = No nausea, dry retching or vomiting
   - 2 = Mild nausea and no dry retching / vomiting
   - 3 = Moderate nausea and or dry retching / vomiting
   - 4 = Severe nausea and or dry retching / vomiting
   - 5 = Continuous dry retching / vomiting

Emotional Factors

E1. I am going to show you a series of faces and I would like you to indicate which face, number or description most accurately describes to what extent you feel sad, low or depressed at the moment?
   Please show appropriate face chart to the patient and record the number corresponding to the actual respond
   - 1 = Not at all depressed / sad
   - 2 = A little depressed / sad
   - 3 = Somewhat depressed / sad
   - 4 = Quite depressed / sad
   - 5 = Extremely depressed / sad

E2. I am going to show you a series of faces and I would like you to indicate which face, number or description most accurately describes to what extent you feel anxious or nervous at the moment?
   Please show appropriate face chart to the patient and record the number corresponding to the actual respond
   - 1 = Not at all anxious / nervous
   - 2 = A little anxious / nervous
   - 3 = Somewhat anxious / nervous
   - 4 = Quite anxious / nervous
   - 5 = Extremely anxious / nervous

ADL Factors

A1. Are you able to stand without assistance?
   Please record the number corresponding to the actual assessment
   - 1 = Not at all
   - 2 = With difficulty
   - 3 = Easily

A2. Are you able to walk without assistance?
   Please record the number corresponding to the actual assessment
   - 1 = Not at all
   - 2 = With difficulty
   - 3 = Easily

A3. Are you able to eat or drink without assistance?
   Please record the number corresponding to the actual assessment
   - 1 = Not at all
   - 2 = With difficulty
   - 3 = Easily
Appendices

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Are you able to dress without assistance?  
Please record the number corresponding to the actual assessment:  
○ 1 = Not at all  
○ 2 = With difficulty  
○ 3 = Easily

Cognitive Factors

C1. Please tell me your name, the city you are in and your date of birth.  
Please record the number of correct responses:  

C2. I am going to read you a list of numbers. Listen carefully, I would like you to repeat back to me in the same order that I read them. So, if I said 1,2,3, you would say 1,2,3. Read out the digits given at the rate of one per second. Stop after failure at any point. Please record the item number of the last line correctly recalled:  

C3. I am going to read you some more numbers. But this time when I stop I would like you to say them in reverse order. So, if I said 1,2,3, you would say 3,2,1. Read out the digits given at the rate of one per second. Stop after failure at any point. Please record the item number of the last line correctly recalled:  

C4. I am going to read out a list of words. Please listen carefully as when I finished I would like you to repeat back to me as many of the words you can remember. You can say them in any order and if you are not sure if you have said a word, say it just in case. Read the words to the patient at a bout 1 per second. Please record the number of correct responses.  
DOLL, MIRROR, BIRD, NAIL, SAILOR, HEART, DESERT, BED, MACHINE, MILK, HELMET, MUSIC, PENCIL, HORSE, ROAD

C5. I am going to name a letter and I would like you to state as many as you can in 30 secs that begins with this letter. Try to avoid proper nouns, such as peoples names, names of countries, etc. Numbers of the same word with a different ending such as long, longer, longest. The letter is "F".  

Time for 30 seconds using a stopwatch and stop patient at this time point. Please record the number of words correctly given in the 30 second time period:
Overall Patient Perspective

Q1. I am going to show you a series of faces and I would like you to indicate which face, number or description you believe most accurately describes to what extent your surgical procedure has negatively affected your ability to work compared to before your surgery? Please show appropriate face chart to the patient and record the number corresponding to the actual response.

- 1 = Not At All Impacted
- 2 = Minimal Impacted
- 3 = Moderately Impacted
- 4 = Severely Impacted
- 5 = Completely Impacted

Q2. I am going to show you a series of faces and I would like you to indicate which face, number or description you believe most accurately describes to what extent your surgical procedure has negatively affected your ability to undertake daily living activities compared to before your surgery? Please show appropriate face chart to the patient and record the number corresponding to the actual response.

- 1 = Not At All Impacted
- 2 = Minimal Impacted
- 3 = Moderately Impacted
- 4 = Severely Impacted
- 5 = Completely Impacted

Q3. I am going to show you a series of faces and I would like you to indicate which face, number or description you believe most accurately describes to what extent your surgical procedure has negatively affected your clarity of thought now compared to before your surgery? Please show appropriate face chart to the patient and record the number corresponding to the actual response.

- 1 = Not At All Impacted
- 2 = Minimal Impacted
- 3 = Moderately Impacted
- 4 = Severely Impacted
- 5 = Completely Impacted

Q4. I am going to show you a series of faces and I would like you to indicate which face, number or description you believe most accurately describes to what extent you were satisfied with the anesthetic care you received? Please show appropriate face chart to the patient and record the number corresponding to the actual response.

- 1 = Total Satisfied
- 2 = Satisfied
- 3 = Moderately Satisfied
- 4 = Somewhat Impacted
- 5 = Not At All Impacted
**SF-36V2**

**Instructions:**

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

**Example:**

This is for your review. Do **not** answer this question. The questionnaire begins with question 1 below.

For each question you will be asked to fill in a bubble in each line, like this:

**How strongly do you agree or disagree with each of the following statements?**

1. In general, would you say your health is:
   - [ ] Excellent
   - [ ] Very Good
   - [ ] Good
   - [ ] Fair
   - [ ] Poor

2. Compared to one year ago, how would you rate your health in general now?
   - [ ] Much better now than one year ago
   - [ ] Somewhat better now than one year ago
   - [ ] About the same as one year ago
   - [ ] Somewhat worse now than one year ago
   - [ ] Much worse now than one year ago

---

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes, limited a lot (1)</th>
<th>Yes, limited a little (2)</th>
<th>No, not limited at all (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Vigorous activities, such as running, lifting heavy objects,</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>participating in strenuous sports</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Moderate activities, such as moving a table, pushing a vacuum</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>cleaner, bowling, or playing golf</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Lifting or carrying groceries</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>d) Climbing several flights of stairs</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>e) Climbing one flight of stairs</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>f) Bending, kneeling, or stooping</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>g) Walking more than a few hundred metres</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>h) Walking several hundred metres</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>i) Walking one hundred metres</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>j) Bathing or dressing yourself</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
4. [During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?]

<table>
<thead>
<tr>
<th></th>
<th>All of the time (1)</th>
<th>Most of the time (2)</th>
<th>Some of the time (3)</th>
<th>A little of the time (4)</th>
<th>None of the time (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Cut down on the amount of time you spent on work or other activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Accomplished less than you would like</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Were limited in the kind of work or other activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Had difficulty performing the work or other activities (for example, it took extra effort)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. [During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?]

<table>
<thead>
<tr>
<th></th>
<th>All of the time (1)</th>
<th>Most of the time (2)</th>
<th>Some of the time (3)</th>
<th>A little of the time (4)</th>
<th>None of the time (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Cut down on the amount of time you spent on work or other activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Accomplished less than you would like</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Did work or other activities less carefully than usual</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. During the past 4 weeks, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- Not At All (1)
- Slightly (2)
- Moderately (3)
- Quite a Bit (4)
- Extremely (5)

7. How much bodily pain have you had during the past 4 weeks?

- None (1)
- Very Mild (2)
- Mild (3)
- Moderate (4)
- Severe (5)
- Very Severe (6)

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- Not At All (1)
- Slightly (2)
- Moderately (3)
- Quite a Bit (4)
- Extremely (5)
These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

<table>
<thead>
<tr>
<th>Question</th>
<th>All of the time (1)</th>
<th>Most of the time (2)</th>
<th>Some of the time (3)</th>
<th>A little of the time (4)</th>
<th>None of the time (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Did you feel full of life?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Have you been very nervous?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Have you felt so down in the dumps that nothing could cheer you up?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Have you felt calm and peaceful?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Did you have a lot of energy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f. Have you felt downhearted and depressed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g. Did you feel worn out?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h. Have you been happy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. Did you feel tired?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- All of the time (1)
- Most of the time (2)
- Some of the time (3)
- A little of the time (4)
- None of the time (5)

11. How TRUE or FALSE is each of the following statements for you?

<table>
<thead>
<tr>
<th>Question</th>
<th>Definitely true (5)</th>
<th>Mostly true (2)</th>
<th>Don't know (3)</th>
<th>Mostly false (4)</th>
<th>Definitely false (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. I seem to get sick a little easier than other people</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. I am as healthy as anybody I know</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. I expect my health to get</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. My health is excellent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 8 Chapter 3, Study 1 publication

The Sternal Management Accelerated Recovery Trial (S.M.A.R.T) – standard restrictive versus an intervention of modified sternal precautions following cardiac surgery via median sternotomy: study protocol for a randomised controlled trial

Md Ali Katijahb1,2,3, Linda Denneny1, Catherine L. Gango1,3, Alistair Royse4,5, Colin Royse1,3, Rebecca Bates3, Sarah Logie5, Sandy Clarke5 and Doa El-Ansary1

Abstract

Background: The routine implementation of sternal precautions to prevent sternal complications that restrict the use of the upper limbs is currently worldwide practice following a median sternotomy. However, evidence is limited and drawn primarily from cadaver studies and orthopaedic research. Sternal precautions may delay recovery, prolong hospital discharge and be overly restrictive. Recent research has shown that upper limb exercise reduces post-operative sternal pain and results in minimal microconcentration between the sternal edges as measured by ultrasound. The aims of this study are to evaluate the effects of modified sternal precautions on physical function, pain, recovery and health-related quality of life after cardiac surgery.

Methods/design: This is a phase II, double-blind, randomised controlled trial with concealed allocation, blinded of patients and assessors, and intention-to-treat analysis. Patients (n = 72) will be recruited following cardiac surgery via a median sternotomy. Sample size calculations were based on the minimal important difference (two points) for the primary outcome: Short Physical Performance Battery. Thirty-six participants are required per group to counter dropout (20%). All participants will be randomised to receive either standard or modified sternal precautions. The intervention group will receive guidelines encouraging the safe use of the upper limbs. Secondary outcomes are upper limb function, pain, kinesiophobia and health-related quality of life. Descriptive statistics will be used to summarise data. The primary hypothesis will be examined by repeated-measures analysis of variance to evaluate the changes from baseline to 4 weeks post-operatively in the intervention arm compared with the usual-care arm. In all tests to be conducted, a p value <0.05 (two-tailed) will be considered statistically significant, and confidence intervals will be reported.

(Continued on next page)

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5 Department of Physiotherapy, Hospital Karo, Palembang, Indonesia

Full list of author information is available at the end of the article.
**Background**

Cardiac surgery via a median sternotomy has been performed in over 1 million cases worldwide [1, 2] because it provides the best clinical outcome for patients with multiple-vessel disease and co-morbidities [3–7]. Despite these advantages, the incidence of sternal complications has remained relatively unchanged for the last 2 decades and is reported to be between 0.6% and 8% worldwide [8–11]. Sternal complications include dehiscence, wound infection, sternal instability/non-union and mediastinitis [11]. These complications are associated with significant morbidity and prolonged hospital length of stay, and they contribute to increased health care costs [8, 11, 12].

To prevent sternal complications, the routine implementation of sternal precautions that place restrictions on the use of the upper limbs and trunk commences immediately post-operatively. These precautions are used worldwide, although they are applied for variable periods of time (4 weeks to 3 months) post-operatively [8, 13, 14]. The evidence to support sternal precautions is limited to cadaver and replica bone model studies [15, 16]. In a foundational study, McGregor et al. found that a force of 220 ± 40 N was required to attain 2-mm distraction between sternal edges in the lateral direction, 263 ± 74 N in the anteroposterior direction and 325 ± 30 N in the costocaudal direction [16]. This prompted a recommendation to discourage the bilateral use of the upper limbs because this was thought to increase the distractive forces at the sternal edges [16]. From the outset, health care professionals, including surgeons and physiotherapists, routinely reinforce sternal precautions in their clinical practice. However, a recent study demonstrated that upper limb and trunk tasks cause only minimal micro-motion of the sternal edges (<2 mm) as measured by real-time ultrasound, and this was the case for all tasks, including bilateral and unilateral arm elevation [17]. On the basis of these findings, restricting the use of the upper limbs and trunk in an attempt to prevent excessive sternal motion may be overly cautious. Sternal precautions in the form of physical restrictions may delay recovery, prolong return to function and delay hospital discharge, and as such may be overly restrictive [8, 18, 19].

Upper limb and trunk exercises are encouraged as part of post-operative care to promote recovery and return of function [8, 13, 14, 18]. Sturgess et al. found that exercises of the trunk and upper limbs significantly reduced sternal pain during the first 6 weeks post-operatively [20]. The prescription of such exercises alongside sternal precautions poses a clinical dilemma because they contradict each other [8, 13, 44]. Further, physical activity and upper limb exercises may be imperative for healing and remodelling of bone, which responds to loading [8, 21].

**Trial objective and hypothesis**

The primary aim of this study is to evaluate the effectiveness of a program of modified sternal precautions on physical function compared with standard care sternal precautions following cardiac surgery via a median sternotomy at 4 weeks post-operatively. We hypothesise that those receiving the modified sternal precautions will have improved physical function at 4 weeks post-operatively compared with participants receiving standard care precautions. The secondary aims are (1) to evaluate the effectiveness of modified sternal precautions compared with standard care on sternal pain and discomfort, kinesiophobia and health-related quality of life (HRQoL) at 4 weeks and 3 months post-operatively, as well as on physical function at 3 months post-operatively; (2) to measure participants’ adherence to sternal precautions; and (3) to explore whether demographic factors and/ or pre, peri- and post-operative risk factors are associated with the development of post-sternotomy complications. This will be an exploratory analysis which may identify trends of predictors reported in the literature [11].

**Methods/design**

The methods are reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines for clinical trials [22] (see Additional file 1, Table 1) and the Template for Intervention Description and Replication (TIDieR) reporting of interventions [23] (see Additional file 2).
Table 1 Additional file World Health Organisation trial registration data set for S.M.A.R.T.

<table>
<thead>
<tr>
<th>Data category</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary registry and trial identifying number</td>
<td>Ansell's New Zealand Clinical Trial Registry Number: ACTRN12615001982772</td>
</tr>
<tr>
<td>Date of registration in primary registry</td>
<td>16 September 2015</td>
</tr>
<tr>
<td>Secondary identifying numbers</td>
<td>N/A</td>
</tr>
<tr>
<td>Trial protocol version</td>
<td>This is the version 3 of the protocol and was enacted November 2015</td>
</tr>
<tr>
<td>Source(s) of monetary or material support</td>
<td>N/A</td>
</tr>
<tr>
<td>Primary sponsor</td>
<td>N/A</td>
</tr>
<tr>
<td>Secondary sponsor</td>
<td>N/A</td>
</tr>
<tr>
<td>Contact for public queries</td>
<td>Professor Alokiah Royse</td>
</tr>
<tr>
<td>Contact for scientific queries</td>
<td>Dr Catherine Goggin</td>
</tr>
<tr>
<td>Public title</td>
<td>Sternal Management Accelerated Recovery Trial (S.M.A.R.T.)</td>
</tr>
<tr>
<td>Scientific title</td>
<td>A randomised controlled trial of the efficacy of modified sternal procedures versus standard care on improving physical function following cardiac surgery via a median sternotomy.</td>
</tr>
<tr>
<td>Countries of recruitment</td>
<td>Australia</td>
</tr>
<tr>
<td>Health condition(s) or problem(s) studied</td>
<td>Cardiac surgery via a median sternotomy</td>
</tr>
<tr>
<td>Intervention(s)</td>
<td>Active comparator: Placeto comparator:</td>
</tr>
<tr>
<td>Key inclusion and exclusion criteria</td>
<td>Ages eligible for study: &gt;18 years&lt;br&gt;Sexes eligible for study: both&lt;br&gt;Consents health volunteers: Yes&lt;br&gt;Inclusion criteria: all adults undergoing elective cardiac surgery involving a median sternotomy&lt;br&gt;Exclusion criteria: 1. Unable to understand verbal instructions in English&lt;br&gt;2. Residing outside Melbourne metropolitan area (ie, 52-km radius).</td>
</tr>
<tr>
<td>Study type</td>
<td>Type: Investigator initiated, Interventional, non-pharmacological, pragmatic study&lt;br&gt;Allocation: concealed randomisation&lt;br&gt;Intervention model: parallel assignment&lt;br&gt;Masking: patient and assessor blinded&lt;br&gt;Primary outcome: prevention</td>
</tr>
<tr>
<td>Date of first enrolment</td>
<td>16 September 2015</td>
</tr>
<tr>
<td>Target sample size</td>
<td>72</td>
</tr>
<tr>
<td>Recruitment status</td>
<td>Completed recruitment on 16 November 2016</td>
</tr>
<tr>
<td>Primary outcome(s)</td>
<td>Short Physical Performance Battery (SPPB)</td>
</tr>
<tr>
<td>Key secondary outcomes</td>
<td>2. Patient-identified cardiac pain using numeric and visual prompts, Short Form McGill Pain Questionnaire 2 (SF-MPQ-2), Functional Difficulties Questionnaire (FDQ), grip strength, Tampa Scale of Kinesthesia (TSK-15), Medical Outcomes Study 36-item Short Form Health Survey (SF-36v2), Global Rating of Change Scales</td>
</tr>
</tbody>
</table>

S.M.A.R.T. Sternal Management Accelerated Recovery Trial

**Trial design**

The Sternal Management Accelerated Recovery Trial (S.M.A.R.T.) is a phase II, prospective, parallel-group, concealed-allocation, randomised (1:1), controlled, patient- and assessor-blinded clinical trial powered for superiority and being conducted at two tertiary hospitals. 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 outpatient setting. Participants will be informed that they will be randomised to receive either standard or modified sternal precautions before hospital discharge and will be allocated to one of two groups: (1) the control group (standard care) or (2) the intervention group (modified sternal precautions). In addition, participants are asked to provide a global rating of change in physical function using a numeric scale (Global Rating of Change Scales [GRCS]).
Appendices

Trial setting
The trial will be conducted at two tertiary hospitals: Royal Melbourne Hospital (RMH), and Melbourne Private Hospital (MPH), both located in the state of Victoria, Australia. RMH is a government-funded, university-affiliated teaching hospital, and MPH is a private hospital located adjacent to RMH. This study is being conducted at two major metropolitan hospitals (one private and one public), and the findings can be generalised to both private and public health care settings. Most participants recruited will be geographically located in the same precinct, with the same surgical staff seeing the same population catchment area and the only difference being the source of funding and reimbursement for surgery.

Ethics approval for the study was obtained from the Melbourne Health Human Research Ethics Committee in May 2015 (protocol reference 2015/085). The trial is being conducted in accordance with the Declaration of Helsinki and was registered on 16 September 2015 with the Australian and New Zealand Clinical Trials Registry (ACTRN12615000905872).

Eligibility criteria
Eligible participants following cardiac surgery via median sternotomy at the participating centres will be invited to participate in the study. They will be identified through their admission to the cardiothoracic ward of both the public and private hospitals.

Inclusion/exclusion criteria
Participants are eligible for the trial if they meet the following criteria:

- Adults undergoing isolated valve, coronary artery bypass graft (CABG) surgery or a combination of both
- Able to provide informed consent
- Aged 18 years and older

Participants are ineligible for the trial if they meet any of the following criteria:

- Insufficient English-language comprehension
- Resident outside the Melbourne metropolitan area (i.e., 52-km radius)

Recruitment feasibility
We aimed to recruit 72 participants from among a pool of those admitted for surgery at each centre. Annually, approximately 450 sternotomy procedures are performed at RMH and 350 sternotomy procedures are performed at MPH. Therefore, recruitment of 72 participants is estimated to take 12 months with an average recruitment of 6 participants per week.

Randomisation and allocation
Randomisation will be conducted by an independent person off-site using a computer-generated random 72 sequence numbering system (from 1 to 72) and a 1:1 allocation ratio. Concealment is via sealed, numbered, double-layered, opaque envelopes. Allocation occurs after baseline testing by opening of the next study envelope by a member of the staff of the university department of physiotherapy who is not involved in the study. The staff member then informs the treating physiotherapist of group allocation. The envelopes will be stored locked in a cabinet, and security measures are in place to prevent unblinding. To avoid allocation bias, steps will be taken to limit authorised personnel (n=2) with access permission to open the study envelopes.

Trial intervention
The implementation of the sternal precautions is performed by the same ward physiotherapist according to allocation for both groups. There will be a different physiotherapist for each participating hospital providing the intervention for both groups. Both physiotherapists are senior clinicians with over 5 years of clinical experience in cardiac surgery. Training will be provided by one independent physiotherapist to ensure consistency in each institution. Standard care is consistent across centres.

Control group (standard care)
Whilst 'standard care' is not consistent in the literature cited previously [8, 13, 14, 24, 25], centres worldwide limit the use of the upper limits for a minimum of 6 weeks [8, 13, 14, 24, 25]. The protocol we will apply is consistent across both institutions in this study. Therefore, consenting participants in the standard care group will receive the education and restrictive sternal precautions for the duration of 6 weeks. The sternal precautions will be delivered in both verbal and written formats by the treating physiotherapists as single individualised sessions for 15 minutes on the ward prior to discharge from the hospital. Patients will be instructed to adhere to the sternal precautions for the first 4–6 weeks post-operatively (Fig. 1a). The participants will be specifically instructed to do the following:

1. Avoid pushing or pulling through the arms
2. Avoid one-arm (unilateral) activity
3. Limit the elevation of the arms to 90 degrees
4. Avoid lifting objects heavier than 3 kg
5. Use a cushion or perform sternal preservation technique (crossing the arms in a ‘self-hugging’ posture) when coughing
6. Limit the use of the arms when transferring from sitting to standing and getting out of bed
7. Avoid placing the arms behind the back

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Participants will be advised not to continue tasks and/or exercises that are painful, to rest as required and to focus on a gradual return to their pre-surgery level of function.

**Intervention group**

The modified sternal precautions will be delivered in both verbal and written formats by the treating physiotherapists as single individualised sessions for 15 minutes on the ward prior to discharge from the hospital. Patients will be instructed to adhere to the sternal precautions for the first 4–6 weeks post-operatively (Fig. 1b). Participants in the intervention group will be specifically encouraged to do the following:

1. Use pain and discomfort to guide the safe use of the arms
2. Avoid pushing or pulling with one arm
3. Use both arms close to the body during lifting
4. Use of arms is possible, but keep them close to the body
5. Avoid stretching one or both arms backwards at the same time
6. Use a cushion or perform sternal preservation technique (crossing the arms in a ‘self-hugging’ posture) when coughing (same as above)
7. When transferring, roll onto the side, ease the legs over the edge of the bed and carefully use the arms to sit up from a lying position

Pain and discomfort should be used to guide the safe limits of movement. The intervention pertaining to sternal management, including the type of sternal precautions, will be delivered in both verbal and written formats to each participant separately with a flyer developed specifically for the study to ensure standardisation. In both groups, all other aspects of patient care, including pre-operative management, general anaesthesia, intra-operative 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.
Intervention fidelity
Training will be provided for the two unblinded, dedicated staff to conduct the follow-up phone calls to ensure consistency in evaluating adherence to sternum precaution guidelines for the first 6 weeks after cardiac surgery. One staff member will evaluate the intervention group and another will follow the standard care group for both institutions. To minimise bias, the staff are required to encourage patients to continue with their allocated sternum management strategy using the standardised written instructions in addition to participants’ flyers. Participants will be informed that they will be contacted via telephone weekly to help reinforce their exercise and precaution guidelines for the first 6 weeks after cardiac surgery. Specifically, the standard care participants will be asked to follow the restrictions on the use of their upper limbs and to limit the activities of their upper limbs and trunk during activities of daily living, bed transfers, and sit-to-stand maneuvers. The intervention group will be encouraged to use their upper limbs bilaterally to perform activities of daily living, bed transfers and sit-to-stand maneuvers. They will also be encouraged to perform upper limb exercises three times daily within the limits of pain and discomfort.

Blinding
Patients, outcome assessors and data management are blinded to treatment allocation. Participants will be advised that they will be randomised to one of two groups of sternum precautions guidelines. The treating physiotherapist and nursing staff cannot be blinded to group allocation. The details of sternum management for each participant are recorded in the medical record. A blinded assessor located off-site from the hospital will assess all outcomes. Trial staff will conduct education sessions at set times on the ward that are on days separate from days scheduled for outcome assessment. If a treatment group participant informs the assessor of their post-operative education 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.

Withdrawal from trial
All participants will be followed after their surgery and measured. Every attempt will be made to accommodate individual requirements to facilitate attendance at follow-up time points beyond discharge from hospital (i.e., taxi vouchers, flexible dates, appointment times). Participants will be withdrawn if they withdraw their consent, and this will be reported. Data collected until this time will be included.

Data collection
Demographic data as well as pre-, intra- and post-operative variables will be collected as listed in Table 2. Data will be collected from the participants and their medical records. All baseline assessments will be performed at the same time of day (08:00–17:00) for each participant in the post-operative period at day 4 (±1 day) in the in-patient setting across centres to minimise potential bias in recruiting participants. The follow-up, outpatient testing at 4 weeks (±14 days) and 3 months (±14 days) will take place in the on-site ward room at RMH (Fig. 2). An independent and trained assessor (located off-site) who is blinded to allocation will conduct all measurement sessions. All tests and questionnaires will be administered face-to-face by the outcome assessors and carried out at 4 weeks and 3 months post-operatively to ensure consistency across participants. Post-hospital discharge follow-up will be conducted 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 purposes of post-discharge outcome measurement.

<table>
<thead>
<tr>
<th>Table 2 Data collection details</th>
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</thead>
<tbody>
<tr>
<td>Demographic data</td>
</tr>
<tr>
<td>• Name and contact details</td>
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<tr>
<td>• Date of birth</td>
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<tr>
<td>• Sex</td>
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<tr>
<td>• Marital status</td>
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<td>• Weight and height</td>
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<td>• Occupation status</td>
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<tr>
<td>• Education status</td>
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<tr>
<td>• Smoking history</td>
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<tr>
<td>• Past medical history and comorbidity index (↓onset comorbidity index)</td>
</tr>
<tr>
<td>• Functional history (including pre-morbidity functional level, use of &amp; effects, dementia, upper limb)</td>
</tr>
<tr>
<td>• Date of admission and discharge from acute setting</td>
</tr>
<tr>
<td>Pre-, intra- and post-operative variables</td>
</tr>
<tr>
<td>• Date of cardiac surgery</td>
</tr>
<tr>
<td>• Clinical information (left ventricular function, Canadian Cardiovascular Society function and comorbidities, golf type)</td>
</tr>
<tr>
<td>• Type of cardiac surgery (including whether it was an emergency or elective procedure)</td>
</tr>
<tr>
<td>• Other intra-operative details (including method of sternotomy, cardiovascular bypass time, operation time, adverse events)</td>
</tr>
<tr>
<td>• Date of admission to and discharge from intensive care unit post-operatively</td>
</tr>
<tr>
<td>• Risk factors for pre-, intra- and post-operative (i.e., duration of mechanical ventilation)</td>
</tr>
<tr>
<td>• Type and use of pain medication (pre- and post-operatively)</td>
</tr>
<tr>
<td>• Type and use of other medications (pre- and post-operatively)</td>
</tr>
<tr>
<td>• Date of admission to and discharge from acute physiotherapy services</td>
</tr>
<tr>
<td>• Details of physiotherapy treatment (including exercises and education provided)</td>
</tr>
<tr>
<td>• Other adverse events during hospital admission (pre- and post-operatively leading to increase in length of stay) (This includes superficial sternal infection, deep sternal infection, rewarming, reoperation, pneumonia as defined in the Australian Society of Cardiothoracic Surgeons MICTR data)</td>
</tr>
<tr>
<td>• Date of withdrawal</td>
</tr>
</tbody>
</table>
Outcomes assessment
Primary outcome: Short Physical Performance Battery
The Short Physical Performance Battery (SPPB) is a functional test that measures daily functional activities in the acute care in-patient older population, including cardiac surgery [26]. The test is a well-established and validated measure of lower extremity performance and is designed to simulate routine physical activities in older adults [27]. The test includes gait speed (8-foot walk), standing balance, and lower extremity strength and endurance (chair rise task). It is comprised of the following:

1. Gait speed: Participants will be instructed to walk a distance of 8 feet as determined by traffic cones on a flat surface at their normal, comfortable pace. The average of two trials will be used. For safety reasons, participants are encouraged to walk with their gait aids if these are usually used or are part of their post-operative care at the time of testing.

   An 8-foot course was used, and scoring will use the faster of the two walk times to calculate speed in metres/second. A reduction of the distance to measure gait speed has been shown to provide valid data in measuring of functional limitations [28, 29].

2. Standing balance: Participants will be assessed in three different static positions (side-by-side stand, semi-tandem stand and tandem stand). Participants will be instructed to try to hold each of these positions for 10 seconds.

3. Chair rise task: Participants will be instructed to stand up and sit down five times in a row as quickly as possible.

The SPPB score is based on timed measures of standing balance, walking speed and ability to rise from a chair. Each test is scored on a scale of 0 to 4 points, with a summary performance score range of 0–12 points using cut-point criteria established by Guralnik et al. [27]. A 0 score indicates poor function, whilst 12 indicates excellent function. If the participant is unable to perform a specific test, a score of 0 will be assigned. A score of 10 or lower is considered the cut-point for mobility impairment [27]. The SPPB was selected because it assesses overall functional performance that reflects physical function required to perform everyday tasks. It is hypothesised that the intervention will impact overall functional performance because this is the primary concern of most patients at medium- to long-term follow-up (6 weeks to 12 months) [26, 30]. The test has established validity and reliability in measuring physical
Appendices


performance in the elderly [27, 31, 32] with an intra-class correlation coefficient (ICC) equal to 0.82 [32], and it is a strong predictor of disability in non-disabled older persons [33]. The minimal detectable change values range from 0.54 [34] to 2 points [35], which suggests that a change in physical performance of 1 or 2 points is a clinically meaningful change in an older [34] and inpatient stable cardiovascular population [35]. Therefore, in the absence of data for cardiac surgery populations, the minimal important difference (MID) for this study was derived from prior research with a cohort of patients with stable cardiovascular conditions of 2 points, which is representative of our participant population. The SPPB has been shown to be reliable, valid and sensitive to change [36]. ICCs ranged from 0.88 to 0.92 for measures done 1 week apart, with a 6-month average ICC of 0.78 [36].

Secondary outcomes

1. Functional Difficulties Questionnaire (FDQ): The FDQ measures the functional status of patients following cardiac surgery, with a particular focus on upper limb and trunk function in patients following a median sternotomy [37]. The questionnaire requires patients to rate the difficulty they would experience when completing a series of 13 upper limb and trunk functional tasks. Specifically, patients are asked to place a mark along a 10-cm line, with anchors indicating ‘no difficulty’ and ‘maximum difficulty’ at the left and right ends of the line, respectively. For those activities that participants cannot complete while filling out the questionnaire, they will be asked to estimate the last time they performed the task. The 13 functional tasks included in the questionnaires are everyday tasks that were nominated as difficult to perform in a pilot study of patients following cardiac surgery [37]. Previous research has demonstrated that the FDQ is a valid, reliable and responsive measure in this patient population with minimal recall bias, and it has been used to measure the functional status of patients following cardiac surgery in both the short term (4 weeks post-operatively) and long term (3 months post-operatively) [37]. The follow-up time points are a minimum of 4 weeks to 2 months apart, thus further reducing recall bias.

2. Patient identified cardiac pain using numeric and visual prompt: This is a pain outcome measurement tool that was developed by Young et al. [38]. To obtain data regarding symptom presentation, participants are required to identify on a gender-neutral silhouette torso all locations of their pain or discomfort. The participants are also required to identify their ‘chief’ or ‘main’ symptom, describe its nature by pointing to pictorial identifiers that visually represent a description of the pain (i.e., stabbing, heavy, shooting, burning, squeezing) [39]. The intensity of the pain forms the last domain and uses a Likert-type scale. This tool was selected because it evaluates multiple dimensions of pain and discomfort, is easy to administer and accounts for cultural diversity [40].

3. Short Form McGill Pain Questionnaire 2 (SF-MPQ-2): Pain quality will be measured using the SF-MPQ-2, which consists of 22 items investigating 4 dimensions of pain quality (continuous, intermittent, neuropathic and affective) on an 11-point numerical rating scale [41]. The total score is calculated from the mean of 22 items, and scores for the four dimension subscales are calculated from the mean of the items included in each subscale. Scores on each subscale can range from 0 to 10. A higher score indicates more severe pain [41]. Participants will be instructed to choose the number that best describes their intensity of pain and related symptoms experienced during the past week. A 0 score will be assigned if the word does not describe the participant’s pain or related symptoms. The original version of the scale (SF-MPQ) has well-established reliability in cardiac populations with a coefficients ranging from 0.75 to 0.83 across various post-operative days [42, 43]. The SF-MPQ-2 is sensitive to change in chronic pain, and total and subscale scores are responsive to change. The changes are associated with changes in patients’ global ratings of global improvement in clinical trials [41].

4. Tampa Scale of Kinesiophobia shorted version (TSK-11): The TSK-11 is a validated tool to measure pain-related fear beliefs about movement and re-injury [44]. It is an adaptation of the original 17-item instrument [44] designed to assess fear of movement or re-injury that has 4 original reverse-scored items that were found to have small item-to-total score correlations. The adapted score is an 11-item instrument where respondents will be asked to rate each item on a 4-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree). The TSK-11 is a reliable and valid measure of fear of movement or re-injury in patients with chronic pain [45, 46]. It has internal consistency, reliability and convergent validity with a Cronbach’s α of 0.80 for the total score [46]. A reduction of at least 4 points on the measure maximizes the likelihood of correctly identifying an important reduction in fear of movement [46].

5. Grip strength: Hand-grip strength will be measured in kilograms with a hand-held Harpenden dynamometer (Performance Health, Warrenville, IL, USA).
The participant will be tested in the position recommended [47]. The peak value of the maximal squeeze over 5 seconds will be recorded [48]. Time intervals were allowed between tests. A previous study showed similar test-retest reliability with one trial alone, a mean of two or three trials and a maximum of three trials [49]. In addition, because of influences of pain after surgery, the average may not reflect true performance. Therefore, in this study, three serial tests of maximum grip strength with the dominant hand will be performed, and best of the three values will be recorded. Hand-held dynamometry is a reliable, objective tool for muscle strength measurement [50] and a predictor of post-operative complications, mortality and functional decline [51]. The test is a reliable and reproducible measure for patients in cardiac rehabilitation (ICC 0.87 for right and left hand grip strength) [52].

6. Medical Outcomes Study 36-item Short Form Health Survey (SF-36v2): HRQoL will be evaluated by SF-36v2, which is a generic metric to assess eight domains, including physical functioning, role physical functioning, role emotional functioning, mental health, vitality, social functioning, bodily pain and general health. All scale or single-item measurements range in score from 0 to 100 and will be administered by interview. The raw sub-scale scores will be transformed to ‘norm-based’ scores using published algorithms [53]. Norm-based physical and mental component summary scores will be calculated from raw sub-scale scores, with higher scores indicating better quality of life. A higher score on the SF-36v2 sub-domains represents a high level of functioning and higher quality of life [54]. The scale has good reliability, with Cronbach’s a values ranging from 0.65 to 0.96 for all subscales [54]. The instrument can differentiate between levels of health status of patients at a single time point and over time [55]. Furthermore, the SF-36v2 is valid in written format as well as verbal administration over the telephone in cardiac patients [56].

7. Modified Sternum Instability Scale (SIS). The modified SIS will be used to assess sternum instability. It is a manual test that measures the stability of the sternum on a 4-point scale (0–3). A score of 0 corresponds to a clinically stable sternum with no detectable motion or separation of the sternal edges, whilst a score of 3 corresponds to a completely separated sternum with marked increased motion or separation of the sternal edges. The original 5-point (0–4) SIS is a valid and reliable clinical tool for measuring the stability of the sternum in patients following a median sternotomy [6, 57]. It has excellent inter- and intra-rater reliability, with ICCs of 0.97 and 0.98, respectively [58].

Global Rating of Change Scales

The GRC (7-point scale) will be administered to participants prior to performance-based assessment at 4 weeks and repeated at 3 months. Participants will be asked to answer the following question: ‘How does your overall physical function now compare with your physical function just before you went home from the hospital?’ and respond according to a 7-point scale ranging from 1 = very much improved to 7 = very much worse (Tables 3 and 4). It has previously been reported in the literature that in the case where patients rate their change as ‘minimally improved,’ ‘no change’ or ‘minimally worse,’ it is unlikely that a clinically important difference has occurred [60]. In this case, these responses will be re-defined as ‘unchanged’ [59, 60]. A clinically important change is defined as a change of 2 or more on a 7-point scale.

### Table 3: Global Rating of Change Scales for overall physical function

<table>
<thead>
<tr>
<th>How does your overall physical function now compare with your physical function just before you went home from the hospital?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Very much improved</td>
</tr>
<tr>
<td>2. Much improved</td>
</tr>
<tr>
<td>3. Minimal improved</td>
</tr>
<tr>
<td>4. No change</td>
</tr>
<tr>
<td>5. Minimaly worse</td>
</tr>
<tr>
<td>6. Much worse</td>
</tr>
<tr>
<td>7. Very much worse</td>
</tr>
</tbody>
</table>

Excellent inter- and intra-rater reliability, with ICCs of 0.97 and 0.98, respectively [58].

### Table 4: Global Rating of Change Scales for upper arm and body function

<table>
<thead>
<tr>
<th>How does your arm and upper body function now compare with your arm and upper body function just before you went home from the hospital?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Very much improved</td>
</tr>
<tr>
<td>2. Much improved</td>
</tr>
<tr>
<td>3. Minimal improved</td>
</tr>
<tr>
<td>4. No change</td>
</tr>
<tr>
<td>5. Minimaly worse</td>
</tr>
<tr>
<td>6. Much worse</td>
</tr>
<tr>
<td>7. Very much worse</td>
</tr>
</tbody>
</table>
difference will be considered to have occurred if patients rate their change as ‘much worse’, ‘very much worse’, ‘much improved’ or ‘very much improved’, and these will be re-defined as ‘changed’ [60].

Sample size
Sample size calculations were performed for the primary outcome: SPPB. On the basis of acute care in-patient populations and using the MID between the treated group of 2 points of a total possible score of 12 points, with an SD of 2.7 points [36], it is anticipated that 29 participants are required per group (58 in total), based on a two-sample t-test. This was based on a type 1 error rate of 0.05, which is consistent with recommendations and a power of 0.80 [64]. This sample was increased to 72 participants on the basis of a predicted 20% dropout rate, based on our previous study in the same population conducted at both participating hospitals [17].

Data management and quality
We will use the online REDCap database (https://redcap.healthinformatics.anitme.edu.au/) supported by the University of Melbourne. High data quality will be aimed for through training of those who collect, check and enter study data as well as by regular data checks for inconsistency between and within measurements and missing data. A check will be performed to evaluate the correctness of the randomisation before the start of the statistical analysis. The data and safety monitoring committee (DSMC), with two independent clinical members and one independent statistician, will act in an advisory capacity for the clinical investigators to monitor withdrawals and review ethical conduct and serious adverse events. Further details will be provided in the DSMC charter, once it is developed.

Statistical methods
Statistical analyses will be performed by the biostatistician. All data will be analysed using the intention-to-treat principle. Descriptive statistics, including mean and SD, median and interquartile range, number and percent, and frequency will be used to summarise data (depending on distribution and type of data). This also includes participant demographics and adherence to sternal precautions. A comparison between the two hospitals will be conducted on the demographic profile of the participants to establish differences in each presenting population.

The primary outcome—the change from baseline to 4 weeks in the SPPB—will be analysed using a mixed between-and-within subjects analysis of variance with repeated measures across participants. The primary hypothesis will be examined by a contrast evaluating change from baseline to the 4-week time point in the modified sternal precaution group compared with the standard care group. The analysis will be carried out according to the intention-to-treat principle, based on the groups to which participants were randomised. The interactions between group and time will be examined first to assess the effect of intervention, and, if no interaction is present, then group and time main effects will be examined. If there are issues with non-normality or ceiling/floor effects of the SPPB, transformation or dichotomisation will be considered. If there are participants who are not following the assigned group protocol, we will consider a supplementary per-protocol analysis. Key secondary outcome data (including upper limb function, pain, kinesiophobia and HRQoL) will be summarised and analysed similarly to the primary outcome.

Logistic regression will be used to determine pre-, peri- and post-operative risk factors associated with the development of post-sternotomy complications. This will be an exploratory analysis which may identify trends of predictors reported in the literature having an individual effect on post-operative sternal complications (i.e., female sex, diabetes mellitus, obesity, bilateral internal mammary artery grafts, re-operation for post-operative complications, and blood product requirement were reported as significant predictors of sternal infection). For all tests conducted, a p-value <0.05 (two-tailed) will be considered statistically significant, and mean differences (95% confidence intervals) will be reported.

Duration and timeline
The manuscript will be prepared for submission, by July 2017. The final manuscript will be written in accordance with the proposed Consolidated Standards of Reporting Trials (CONSORT) extensions for a pragmatic trial using a non-pharmacological intervention (Fig. 3).

Discussion
The S.M.A.R.T. study will examine whether modified sternal precautions will facilitate recovery and function following cardiac surgery via a median sternotomy. The benefits of modifying sternal precautions have not been established, despite emerging evidence indicating that a precautionary approach rather than a restrictive approach may be preferable in this patient population [8, 17, 19, 62]. This will be the first randomised controlled trial using an intervention group to modify sternal precautions and to study its effectiveness in improving physical function in this population.

Patients worldwide are currently being prescribed sternal precautions that restrict the use of their upper limbs and trunks to prevent sternal complications for 4–6 weeks [8, 14, 25]. The aims of this restriction are to
promote sternal ostiosisynthesis and bone healing by minimizing motion between the sternal edges [8, 15, 63]. However, the effect of sternum precautions on patient outcomes is unknown, with significant variation among institutions worldwide [8, 13, 14, 20]. In addition, there is limited evidence to support their widespread application in clinical practice [8, 13, 15, 18, 62, 64, 65].

Previous studies have shown that unsupported, frequent coughing is the single main cause of mechanical stress through the sternum and may be a far more significant factor in the development of sternal complications [17, 19]. Further, recent evidence demonstrated that upper limbs and trunk movement cause minimal micromotion of the sternal edges (<2 mm) as measured by real-time ultrasound [17]. Therefore, it was proposed that strict post-operative movement restrictions may not be necessary for all patients [8, 13]. However, upper limb movements are part of post-operative standard physiotherapy treatment. In some institutions, this represents instructions on 'no use of the arms', or limiting the use of the arms for 90-degree elevation for varying periods of time [8, 13, 18, 23]. Consequently, patients are encouraged to perform active movements of the upper limbs as part of their post-operative care following cardiac surgery with the aim of restoring physical function [8]. This creates a clinical dilemma collectively for both health professionals and patients [8, 13]. On the basis of findings of a recent survey conducted in Australia [13], we have chosen to modify sternal precaution guidelines encouraging the use of bilateral upper limbs and trunk activities with pain and discomfort as a safety guide in the intervention group to optimise sternal healing and functional recovery in this patient population. Specifically, participants will be allowed to resume their normal load-bearing activities at their own pace within pain-free limits by keeping their upper arms close to their body for common activities (e.g., getting out of bed, lifting and transferring). We hypothesise that this intervention will be
safe and cause no harm to the participants. In addition, 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 stresses on the sternal surgical site or bone [8, 16, 62, 65].

Encouraging movement of upper limbs and trunk activities, especially after cardiac surgery in the post-operative period is recommended in clinical practice worldwide [8, 14, 25] to improve functional outcome [22]. Clinical recommendations will be informed by future analysis of the efficacy of the trial in improving physical function and other associated outcomes. This study will address the paucity of research and the inconsistent recommendations worldwide with respect to physical precautions and associated restrictions to upper limbs and trunk provided to the large number of individuals undergoing cardiac surgery via median sternotomy worldwide. In particular, this research will inform guidelines for the commencement of upper limb exercises in cardiac rehabilitation and standards for physical precautions and management following cardiac surgery.

Trial status
All follow-up was completed in April 2017.

Additional files

Additional file 1: SPIRT 2013 checklist: recommended items to address in a clinical trial protocol and related documents (DOCX 123 KB).

Additional file 2: The TIDIE checklist: information to include when disclosing an intervention and the location of the information (DOCX 33 KB).

Abbreviations

Aknowledgements
The authors acknowledge Adam Byng, Linda Tiede, June Romans and Rosy Share for their support of the contributors to this trial. The authors also thank the physical therapy department managers and physiotherapists at the participating centres.

Funding
No funding bodies or sponsors have contributed to the trial design, data collection or management, and publications relating to the trial can be submitted without permission or requiring approval.

Availability of data and materials
The data sets supporting the conclusions of this article are available in the online REDCap database (https://research.theuniversityofmelbourne.edu.au/), supported by The University of Melbourne. No less than 3 years after the collection of the 1-year post-intervention interviews, we will delete the completely de-identified data set to an appropriate data archive for sharing purposes.

Authors’ contributions
MK designed the trial protocol, obtained the funding and revised the manuscript. DR designed the trial protocol and revised the manuscript. LL designed the trial protocol, provided statistical analysis and drafted and revised the manuscript. KG designed the trial protocol and drafted and revised the manuscript. AR designed the trial protocol and revised the manuscript. BP designed the trial protocol and revised the manuscript. PN performed the physiotherapy intervention at RPMH, and follow-up calls. JC designed the statistical analysis and revised the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate
Ethics approval was obtained from Melbourne Health Human Research Ethics Committee in May 2015 (protocol reference 2015/0012). Written informed consent was obtained from the participants for publication of their individual demographics and accompanying images in this study protocol. The consent form is held by the authors and is available for review by the Editor-in-Chief of this journal.

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References
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Appendix 9

The Functional Difficulties Questionnaire-shortened version (FDQ-s)

**Background:** The Functional Difficulties Questionnaire shortened version (FDQs) is a self-reported questionnaire that aims to assess functional performance of the upper limbs and trunk following Cardiothoracic Surgery (Katijjahbe, 2018). The questionnaire requires subjects to rate the difficulty they experience when completing a series of 10 upper limb and trunk functional tasks. Specifically, subjects are asked to place a mark along a 10-cm line, with anchors indicating ‘no difficulty’ and ‘maximum difficulty’ on the left and right sides of the line, respectively. For those activities that subjects cannot complete while filling out the questionnaire, they are asked to recall the last time they performed the tasks. The 10 functional tasks included in the questionnaire are everyday tasks that were nominated as difficult to perform in a pilot study of patients following cardiac surgery (Katijjahbe et al, 2017; Sturgess et al, 2017).

Previous research has demonstrated that the FDQ is a valid, reliable and responsive measure in the cardiothoracic surgery population this patient population with minimal recall bias, and it has been used to measure the functional status of patients following cardiac surgery in both the short term (4 weeks post-operatively) and long term (3 months post-operatively) (Sturgess et al, 2017).

**Equipment:**

- Desk / Table
- Pen
- Chair

**Set up:**

- Subject sits at a desk / table to complete the survey

**Procedure:**

- Questionnaire is given to subject
- Subject reads questionnaire
- Verbal instructions given by clinician/researcher on how to complete the questionnaire
- Subjects can ask any questions
- Subject completes questionnaire
Instructions to the Clinician /Researcher:

- Subjects should rate 10 activities:
  1. By placing a mark on the line that corresponds to how much difficulty they experience when completing the task

For example

- If the patient experiences **no difficulty** at all, they will place a mark at the far left hand side of the line

- Sitting fully upright in a chair, aiming to sit as tall as possible

- If the patient experiences **maximal difficulty**, they will place a mark at the far right hand side of the line

- Sitting fully upright in a chair, aiming to sit as tall as possible

Other guidelines for completion:

- The clinician /researcher will redirect the subject if they do not place a single, vertical mark on the line. The following redirection will be provided:

- In the event a mark is not placed on the line, the clinician/researcher will direct as follows, “You need to place your mark somewhere along this line. At this end (demonstrating) it means you experience no difficulty at all, and it gradually increases as you move along the line, so that at this end (demonstrating) it means you experience maximal difficulty.”

- In the event the mark is not vertical, the clinician/researcher will direct as follows, “You need to place your mark as a line running top to bottom, like this (drawn demonstration)”

- In the event several marks are placed on the line for a single task, the clinician/researcher will direct as follows, “You can only place a single mark somewhere along this line. Choose how much discomfort you experience when you complete the task now / when you last completed the task (dependent on the task).”

- If the subject reports they cannot complete the task the clinician /researcher will score the task as a 10, to indicate maximal difficulty.
Scoring the FDQ:
- Each question is individually scored by measuring the point marked along the 10cm with a ruler. Each question is of equal value. The scores are then totalled to obtain an aggregated score out of 100.
- A total score of 0/100 equates to the least difficulty completing the task and 100/100 represents the most difficulty.

The Functional Difficulties Questionnaire-shortened version (FDQ-s)

Instructions to the subject:
“Please mark on each of the lines below the level of difficulty that you experience when completing each of the following 10 tasks one at a time. Make sure that you read each question fully, as it will explain to you the exact way in which the task has to be completed.

For example

- If you experience no difficulty at all, then place a mark at the far left hand side of the line

• Sitting fully upright in a chair, aiming to sit as tall as possible

X

No difficulty Maximal difficulty

- If you experience maximal difficulty, then place a mark at the far right hand side of the line

• Sitting fully upright in a chair, aiming to sit as tall as possible

X

No difficulty Maximal difficulty

Feel free to try any of the activities (where appropriate) while you are completing the questionnaire. For those activities that you cannot trial whilst filling out the questionnaire, think back to the last time that you did them”
The Functional Difficulties Questionnaire-shortened version (FDQ-s)

1. Sitting fully upright in a chair, aiming to sit as tall as possible

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>Maximal difficulty</th>
</tr>
</thead>
</table>

2. Walking with arms swinging freely

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>Maximal difficulty</th>
</tr>
</thead>
</table>

3. Coughing or sneezing

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>Maximal difficulty</th>
</tr>
</thead>
</table>

4. Rolling over in bed

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>Maximal difficulty</th>
</tr>
</thead>
</table>

5. Getting out of bed

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>Maximal difficulty</th>
</tr>
</thead>
</table>

6. Scratching your back, by taking your arm up and over the top of your shoulder on the same side. You should reach as far down your back as possible

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>Maximal difficulty</th>
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</table>

7. Sitting in a chair and bending down sideways to pick up an object from the ground

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>Maximal difficulty</th>
</tr>
</thead>
</table>

8. Doing up your bra behind your back OR Tucking in your shirt to the back of your pants

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>Maximal difficulty</th>
</tr>
</thead>
</table>

9. Putting on a dressing down, cardigan or jacket (which involves you putting it on behind your back, one sleeve at a time)

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>Maximal difficulty</th>
</tr>
</thead>
</table>

10. Drying your back with a towel, using the towel in both hands behind your back. Your back should be dried with the towel moving back and forth repeatedly

<table>
<thead>
<tr>
<th>No difficulty</th>
<th>Maximal difficulty</th>
</tr>
</thead>
</table>

Thank you

References:


Appendix 10

S.M.A.R.T. TRIAL TELEPHONE FOLLOW UP

Patient Study Number: 0  
Name of Patient:  
Phone Number:  
Date:  

Week 1  
Week 2  
Week 3  
Week 4  
Week 5  
Week 6

Talking Points

Hello, My Name Is …………….. I Am From the Research Team You Are Participating

As part of the study you were instructed by your physiotherapist to adhere to sternal precautions guidelines. Please answer the following to the best of your ability and note that your response will only be seen by the research staff.

A. “At the time of this survey”. Do you currently follow any restrictions on the use of arms?
   □ Yes  
   □ No

B. “At the time of this survey”. Do you currently follow any restrictions on the use of your trunk?
   □ Yes  
   □ No

C. If yes, what are they? Please circle your answer.
   1. Minimal use of:
      □ one arm above head
      □ both arms above head
      □ when getting out of bed
      □ when sitting from a seated position
   2. Lifting restriction:
      □ < 2kgs
      □ < 5kgs
   3. Supported coughing
   4. Driving

D. During your daily activities, what percentage do you use your arms?
   1. 25%
   2. 50%
   3. 75%
   4. 100%
5. None of the above.

E. Please state which of the following sternal precautions you have followed in the past week

1. Minimal use of:
   - one arm above head
   - both arms above head
   - when getting out of bed
   - when sitting from a seated position

2. Lifting restriction
   - < 2kgs
   - < 5kgs
   - None of the above

3. Supported coughing

4. Driving

F. What guides your activity?

- Pain
- Discomfort
- Written guidelines
- Health professional advice
- Medical practitioner advice

G. How would you rate your level of adherence to the sternal precautions since your operation? (please circle one number)

0 1 2 3 4 5 6 7 8 9 10

Not at all Completely as instructed
Appendix 11

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

Md Ali Kattijahbe,†, Catherine L Granger,§, Linda Denhe,*, Alistair Roys,‡, Colin Roys,‡, Rebecca Bates,‡, Sarah Boigie,§, Md Ali Nur Ayub,§, Sandy Halley,‡, Dede El-Anzor‡

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KEY WORDS

Randomised controlled trial
Cardiac surgery
Median sternotomy
Sternal precautions
Physical therapy

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: A two-centre, randomised, controlled trial with concealed allocation, blinded assessors and intention-to-treat analysis. Participants: Seventy-two patients who had undergone cardiac surgery via a median sternotomy were included. Interventions: Participants were randomly allocated to one of two groups at 1 (SD 1.2) 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 weight at the safe limit for their upper limb during daily activities (ie, less restrictive precautions) for the same period. Both groups received postoperative individualised education in hospital and via phone at 4 to 8 weeks. Outcomes measures: The primary outcome was physical function assessed by the Short Physical Performance Battery. Secondary outcomes included upper limb function, pain, kinesiophobia, and health-related quality of life. Outcomes were measured before hospital discharge and at 4 and 12 weeks post-operatively. Adherence to sternal precautions was recorded. Results: There were no statistically significant differences in physical function between the groups at 4 weeks (MD 10.95, 95% CI -0.2 to 23.3) and 12 weeks (MD 6.93, 95% CI -19.9 to 33.7) postoperatively. There were no statistically significant between-group differences in secondary outcomes. Conclusion: Modified, 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 ANZCTR12615000685772 (Kattijahbe MA, Granger CL, Denhe L, Roys A, Roys C, Bates R, Boigie S, Ayub MA, El-Anzor D, 2015) Standard randomised trial of sternal precautions in patients undergoing cardiac surgery via median sternotomy (SMART Trial): a randomised trial. Journal of Physiotherapy XX: XX-XX

Introduction

Cardiac surgery via median sternotomy is performed in over a million cases per year worldwide. It is the procedure of choice for patients with multiple vessel disease and comorbidities because it provides the best clinical outcomes. 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. These complications are associated with significant patient morbidity, prolonged hospital stay and contribute to increasing healthcare costs. 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. Patients are encouraged to use their upper limbs during everyday tasks such as bending or lifting objects. The rationale for these...
restrictions is to promote solid osteosynthesis and bone healing by minimizing the forces and the amount of micro-motion between the sternal edges, which can promote progression to non-union and/or infection.18

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.16 Those studies reported that this rationale is based on historical practice, expert opinion, and extrapolation from bone fracture healing research (e.g., radius).27

Healthcare professionals, including surgeons, nurses and physiotherapists, routinely advise patients to follow sternal precautions following median sternotomy. However, a recent study demonstrated minimal surgeon success 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.38 These findings challenge the rationale for the restrictions.39 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.40,41 The prescription of such exercises alongside sternal precautions poses a clinical dilemma, as they contradict each other.42 Furthermore, physical activity and upper limb exercises reduce sternal pain43 and may be imperative for healing and remodelling of bone, which responds to loading.44,45 It has been postulated that sternal precautions may be unnecessarily restrictive, thereby compromising the ability of patients to randomise and delay functional recovery.46

To date, no robust randomised controlled trials have compared a program of usual standard precautions to one that adopts a less restrictive use of the upper limits 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, kinesthesia and health-related quality of life?

Method

Design

This was a prospective, randomised, controlled trial with concealed allocation, blinded assessors and intention-to-treat analyses. 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 offline 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 off-site, 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 physiotherapists 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 treatment48 and the intervention was reported in accordance with the TIDieR checklist for reporting of interventions.49 The full protocol for this trial has been published.50

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 undergoing 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. The 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 (± 1 day) after surgery. Each participant received standardised verbal and printed sternal precautions by the treating physiotherapists. 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 limits 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 exercises three times daily within the limits of pain and discomfort. The verbal instructions explained to participants in the experimental group are listed in Box 4. The printed instructions given to participants in the experimental group are presented in Figure 1.

Box 4. 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 closer to the body during lifting
- Use of the arm 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 arm in a softening 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 set up from lying position

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Cardiac Surgery Sternal Precautions

Please follow these guidelines for 4-6 weeks from the time of your operation.

If you experience any pain, STOP and inform your health professional.

Use **BOTH ARMS** for exercises and activities.

You may lift light objects with **BOTH ARMS**. Keep the load close to your body.

To get in and out of bed:
- a. Move feet to edge, roll onto your side
- b. Ease your legs over the edge of the bed
- c. Carefully use your arms by placing close to your body to sit up

**S.M.A.R.T. TIPS**

- **Use both arms and keep close to body when**
  - Lifting light objects
  - Setting out of bed
  - Standing up from a chair
- **Avoid** pushing or pulling with one arm.
- **Use pain and discomfort as a guide for safety for all activities**
- **Always** support your chest with both arms when coughing

Figure 3. 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 TENS 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.65

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

Appendices

ARTICLE IN PRESS

Cardiac Surgery Sternal Precautions

Please follow these guidelines for 4-6 weeks from the time of your operation:

- **DO NOT** lift your arms above 90° (i.e. above your head).
- **DO NOT** lift objects more than 2kg.
- **DO NOT** reach backwards or place your arms behind your back (i.e. tuck your shirt).
- **DO NOT** push through, or pull with your arms.

To get in and out of bed:
- a. Move feet to the edge, roll onto your side.
- b. Ease your legs over the edge of the bed.
- c. Avoid putting weight through your arms.
- d. Use your legs to stand up.

**S.M.A.R.T. TIPS**

**DO NOT**
- Pushing or pulling through your arms during:
  - Lifting objects
  - Sitting out of bed
  - Standing up from a chair
- Lift your arms above 90°

**AVOID**
- Lifting objects more than 2kg
- Placing arms behind your back

**ALWAYS**
- Support your chest with both arms when coughing.

![Image](image_url)

Figure 3: Printed summary of sternal precautions given to participants in the control group.

Coughing:

Coughing was 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). 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 postures (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. 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). 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 clinically meaningful change in physical function. The SPPB was selected as the primary outcome because it assesses overall functional performance.


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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).20 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.22 Hand grip strength was measured in kg using a hand-held dynamometer, with three attempts. The peak pressure of each 5-second attempt was recorded and the highest value was used in the analysis.23 Pain intensity was measured using the numerical rating scale for pain. The tool is an 11-point visual analogue scale used to measure any kind of pain, on a score ranging from 0 (no pain) to 10 (the most severe pain).12 Participants used a schematic picture to localise their pain. Pain quality was measured using the Short Form McGill Pain Questionnaire version 2.23 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 maintains the likelihood of correctly identifying an important reduction in fear of movement.25 Health-related quality of life was measured with the Medical Outcome Study 36-item Short Form version 2 (SF-36).26 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.22 Norm-based physical and mental component summary scores were also calculated from raw sub-scale scores. Higher scores indicated better quality of life. Sterner stability was measured with the Modified Sternal Instability Scale, which is a 4-point scale. A score of 0 corresponded to a clinically stable sternum with no detectable motion or separation of the sternal edges, while 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 26 patients in each group was calculated to be sufficient to identify a statistically significant difference between groups using the minimum important difference of 2 points out of total score of 12 points, and anticipating a SD of 3.7 points.27 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.22 The total sample was increased to 72 to allow for possible loss to follow-up. Data analyses were performed using the SPSS software. 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, SPPR, 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 median sternotomy and were screened. Of these, 72 were recruited and 202 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 1. 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 hazardous to collect given postoperative randomisation. The removal of this outcome was indicated in the published protocol19 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 78% of the participants in the control group were classified as adherent. This difference was not statistically significant (RR 1.08, 95% CI 0.94 to 1.30). Participant characteristics The baseline demographic and clinical characteristics of the groups are presented in Table 2. 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 (i.e., 4 days after surgery), 88% of participants overall had moderate to severe impairment (≥91.2) as measured by the SPPR (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 SPPR at Week 4 (MD 0.9 point, 95% CI −0.2 to 2.3) and Week 12 (MD 0.4 point, 95% CI −0.9 to 1.6). Group data are presented in Table 2. Individual participant data are presented in Table 3 on the eTable.
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 eshiolhini. 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 SF-36 (p = 0.11, Table 3).

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 NRS Pain Questionnaire data (Table 4). Overall, persistent postoperative pain was reported in 16% of participants at Week 4 and 28% 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 28 (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 both groups seen at Week 4 (MD 1.9, 95% CI -2.1 to 4.0) and Week 12 (MD 2.0, 95% CI -1.1 to 5.0).

There were no significant between-group differences in quality of life on any of the subscales or component summary scores of the SF-36 (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 (1%) in each group was diagnosed with a new need for pain, which persisted until Week 12. Therefore, there was no significant between-group difference in the risk of developing a new need for pain (OR 1.0, 95% CI 0.67 to 1.50).

One participant dropped out of the study, which developed deep sternal wound complications, which required return to theatre and re-wiring before Week 12. Seven (34%) 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 a significant between-group difference in the risk of adverse events.

Table 1
Baseline characteristics of all participants.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Randomized</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exp (n = 36)</td>
</tr>
<tr>
<td>Age (years, mean (SD))</td>
<td>43 (12)</td>
</tr>
<tr>
<td>Gender, n male (%)</td>
<td>30 (85)</td>
</tr>
<tr>
<td>Body mass index (kg/m²), mean (SD)</td>
<td>31 (10)</td>
</tr>
<tr>
<td>Length of stay (days, median (IQR))</td>
<td>8 (7 to 15)</td>
</tr>
<tr>
<td>Right hand dominance, n (%))</td>
<td>35 (97)</td>
</tr>
<tr>
<td>Smoking history, n (%)</td>
<td>13 (36)</td>
</tr>
<tr>
<td>nil</td>
<td>18 (50)</td>
</tr>
<tr>
<td>current</td>
<td>5 (14)</td>
</tr>
</tbody>
</table>

Comorbidities, n (%)  
- chronic obstructive pulmonary disease | 9 (25) | 2 (6) |
- diabetes mellitus | 13 (36) | 9 (25) |
- arthritis | 5 (14) | 3 (8) |
- hypertension | 25 (69) | 23 (63) |
- peripheral nerve disease | 1 (3) | 1 (3) |
- previous stroke | 3 (8) | 3 (8) |
- USE of preop anticoagulants, n (%) | 14 (39) | 11 (31) |

Baseline SPPB, n (%)  
- ≥ 3 (severe impairment) | 23 (64) | 12 (40) |
- ≥ 1 (moderate impairment) | 10 (28) | 13 (36) |
- ≥ 0 (no impairment) | 3 (8) | 9 (25) |

Type of surgery, n (%)  
- CABG | 21 (58) | 26 (72) |
- valve surgery | 12 (33) | 9 (25) |
- CABG and valve surgery | 5 (14) | 7 (20) |
- type 1 cardiac arrest | 0 (0) | 1 (3) |

Type of CABG graft, n (%)  
- saphenous vein | 7 (19) | 6 (17) |
- radial artery | 17 (47) | 19 (53) |
- internal mammary artery | 73 (28) | 24 (67) |
- bilateral internal mammary artery | 1 (3) | 2 (6) |

Surgical duration (minutes, mean (SD))  
- median (IQR) | 207 (79) | 281 (92) |
- cardiopulmonary bypass | 107 (44) | 116 (48) |

Mechanical ventilation (h), mean (SD)  
- median (IQR) | 20 (14) | 13 (7) |

CABG = coronary artery bypass graft, Con = control group, Exp = experimental group.
SPPB = Short Physical Performance Battery.

Discussion

Between participants receiving modified sternal precautions and those receiving usual restrictive sternal precautions, this study found no statistical difference 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.12-27 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 patients 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 was 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.12,28 Studies have reported that this strategy results in no significant changes in pain, minimal sternal mechanical strain and is safe, which is consistent with the current findings.24-26

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.27,28

One potential reason for the non-significant trial findings could be lack of statistical power to analyse the between-group differences in the SPPB. The sample size calculation was performed using an estimate of minimum important difference of 2 points, calculated from a slightly different population with stable cardiovascular conditions,28 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.28,29 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. A second 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 Disabilities 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 patients were able to lift a 5-kg weight, which is the highest level of the SPPB. Second, the decrease in the primary outcome was smaller than anticipated, as the sample size calculation was based on a smaller sample size than needed to detect differences of 2 points. However, these two factors are not likely to influence the results.

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.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Gain</th>
<th>Week 0 vs Week 4</th>
<th>Week 12 vs Week 4</th>
<th>Within-group difference</th>
<th>Between-group Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exp</td>
<td>Csm</td>
<td>Exp</td>
<td>Csm</td>
<td>Exp</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short Physical Performance Battery (9 to 12)</td>
<td>5.0</td>
<td>6.3</td>
<td>10.4</td>
<td>10.9</td>
<td>15.5</td>
</tr>
<tr>
<td>Functional Difficulties Questionnaire (0 to 130)</td>
<td>55</td>
<td>57</td>
<td>56</td>
<td>54</td>
<td>4</td>
</tr>
<tr>
<td>Hand grip strength (kg)</td>
<td>2.5</td>
<td>2.5</td>
<td>3.3</td>
<td>3.3</td>
<td>3.3</td>
</tr>
</tbody>
</table>

participants had moderate to severe impairment on the SPNI, but by Week 4 nearly half had the best possible score and by Week 12 two-thirds had the best possible score. This score effect may have reduced the ability of the SPNI to detect true differences between the groups. Second, the experimental mental precautions 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 provided a targeted and progressive program of upper limit exercise during their hospitalization. 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.10 Other health professionals and care-reinforced strict mental precautions verbally and by way of written information at the outpatient cardiac rehabilitation program’s community setting, which may have confounded the results, particularly at Week 12. Interestingly, it was found that the magnitude of kinesiophobia scores in both groups was higher immediately after surgery and similar to that reported by patients with chronic musculoskeletal disorders.33 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.29 It was hypothesized 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.34 proposed that surgeons dictate mental precautions, fear of activity, and/or pain exacerbated by movement may be reduced to related physical function and optimal recovery immediately following cardiac surgery.32 It may be appropriate to tailor the mental precaution based on individual clinical characteristics and risk profile rather than restricting specific functional tasks and physical activity.32 In view of this, it is imperative to improve the current mental precaution guidelines within institutions because recommending strict adherence to mental precautions may not be warranted for all patients.

Table 3
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Groups</th>
<th>Within-group difference</th>
<th>Between-group difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Week 0</td>
<td>Week 4</td>
<td>Week 12</td>
</tr>
<tr>
<td></td>
<td>Exp (n = 34)</td>
<td>Con (n = 34)</td>
<td>Exp (n = 34)</td>
</tr>
<tr>
<td>Physical function</td>
<td>19 (12)</td>
<td>22 (18)</td>
<td>19 (11)</td>
</tr>
<tr>
<td></td>
<td>19 (11)</td>
<td>21 (10)</td>
<td>19 (11)</td>
</tr>
<tr>
<td>Role physical</td>
<td>37 (12)</td>
<td>39 (19)</td>
<td>35 (15)</td>
</tr>
<tr>
<td></td>
<td>37 (12)</td>
<td>39 (19)</td>
<td>35 (15)</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>44 (12)</td>
<td>42 (15)</td>
<td>43 (11)</td>
</tr>
<tr>
<td></td>
<td>44 (12)</td>
<td>42 (15)</td>
<td>43 (11)</td>
</tr>
<tr>
<td>General health</td>
<td>46 (15)</td>
<td>49 (16)</td>
<td>51 (15)</td>
</tr>
<tr>
<td></td>
<td>46 (15)</td>
<td>49 (16)</td>
<td>51 (15)</td>
</tr>
<tr>
<td>Viscosity</td>
<td>47 (10)</td>
<td>49 (10)</td>
<td>49 (10)</td>
</tr>
<tr>
<td></td>
<td>47 (10)</td>
<td>49 (10)</td>
<td>49 (10)</td>
</tr>
<tr>
<td>Social function</td>
<td>29 (12)</td>
<td>43 (15)</td>
<td>42 (11)</td>
</tr>
<tr>
<td></td>
<td>29 (12)</td>
<td>43 (15)</td>
<td>42 (11)</td>
</tr>
<tr>
<td>Role emotion</td>
<td>42 (11)</td>
<td>42 (12)</td>
<td>42 (11)</td>
</tr>
<tr>
<td></td>
<td>42 (11)</td>
<td>42 (12)</td>
<td>42 (11)</td>
</tr>
<tr>
<td>Mental health</td>
<td>44 (10)</td>
<td>44 (10)</td>
<td>48 (10)</td>
</tr>
<tr>
<td></td>
<td>44 (10)</td>
<td>44 (10)</td>
<td>48 (10)</td>
</tr>
<tr>
<td>Physical component summary</td>
<td>33 (8)</td>
<td>40 (8)</td>
<td>41 (8)</td>
</tr>
<tr>
<td></td>
<td>33 (8)</td>
<td>40 (8)</td>
<td>41 (8)</td>
</tr>
</tbody>
</table>

Con-control group, Exp-experimental group.

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Appendices

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Our study is the first randomised trial to report data on a progranমed modification in sternal precautions using pain and discomfort as a guide for upper and lower truncus movements associated with activities of daily living. Although significant benefits were not identified, at least the lack of significant harm supports Cahalan et al’s suggestion that cautious progression of activity may better facilitate functional recovery after a median sternotomy rather than an arbitrarily restrictive protocol.

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 cardovascular 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 phantoms 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, a study to further establish the role of unique sternal precautions using pain and discomfort as a guide for upper and lower truncus movements associated with activities of daily living. Although significant benefits were not identified, at least the lack of significant harm supports Cahalan et al’s suggestion that cautious progression of activity may better facilitate functional recovery after a median sternotomy rather than an arbitrarily restrictive protocol.

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 of 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 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.

Footnotes:

JAMAR dynamometer, Performance Health, Warrendale, USA. 
SPSS Windows Version 23.0, SPSS, Chicago, USA. 
evidence: Table 3 can be found online at: https://doi.org/10.1093/mjdr/ajy023

Ethics approval: The Melbourne Health Human Research Ethics Committee approved this study. All participants gave written informed consent before data collection began.

Competing interest: There were no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Source of support: Nil.

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Provenance: Not invited. Peer reviewed.

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Md Ali, Katijjahbe

Title:
Physical function and sternal management following cardiac surgery via median sternotomy

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2017

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