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A Randomised Controlled Clinical Trial of a Post-Discharge, Nurse-Led Educational Intervention to Reduce Anxiety and Enhance Self-Efficacy in Percutaneous Coronary Intervention (PCI) Patients Within the First Week Post-Discharge: A Pilot Study

CLINICAL TRIAL ID: ACTRN12612000971831

THE 'REALITY CHEC PROJECT'

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Abstract

Introduction: Cardiovascular disease (CVD) is the world's biggest killer. In 2012, 43,946 people in Australia died from preventable cardiovascular-related diseases. Among cardiovascular diseases, coronary heart disease (CHD) is recognised as the leading cause of death in both men and women in Australia. Percutaneous coronary intervention (PCI) is a treatment option that patients with severe CHD may undergo as an elective or emergency procedure. Over the last 25 years the numbers of PCIs have steadily increased, both nationally and internationally. The literature identifies length of stay for PCI as anywhere between 1.0 and 3.6 days in Australia. This short length of stay has been shown to heighten patient anxiety, prevent the detection of both anxiety and depression, while also limiting nurse teaching time and patient opportunities for learning. Patients who undergo PCI may be discharged home without receiving and understanding education about their chronic disease state and self-management. As a result, patients may develop various health misconceptions that may also contribute to a limited understanding of cardiac rehabilitation (CR) and its benefits. With the aforementioned issues identified, patients' confidence or self-efficacy (SE) to manage post-PCI may be reduced, while anxiety may be enhanced. Thus, a nurse-led clinic was trialled with the primary aim to enhance SE and reduce anxiety. Secondary aims were to reduce symptoms of depression and to encourage effective post-discharge self-management. Areas of self-management targeted included complication identification and management, medication adherence, and CR attendance.

Methods: This study was undertaken as a pilot study in two phases utilising an experimental design and Bandura's self-efficacy (SE) theory as the underpinning theoretical framework. Phase One implemented a nurse-led clinic intervention and was undertaken to determine the feasibility for a Phase Three, multicentre study. In Phase Two, the principal investigator (PI) interviewed a subset of intervention group participants and healthcare professionals about the nurse-led clinic in relation to the educational benefits, content, timing, and its potential effect on primary and secondary aims. Participants were recruited from two hospital sites, one private and one public hospital. After satisfying eligibility criteria, participants gave informed consented and baseline data were collected. A total of 188 participants were screened, with only 33 participants recruited and randomised to the study. Well-validated assessment tools were used to measure primary and secondary outcomes. Salivary cortisol assays were undertaken to measure acute stress in all participants. In Phase One, intervention group participants attended a one-on-one, face-to-face, nurse-led clinic on day 5–7 post-discharge from hospital. Participants received tailored education and support while also undergoing a primary health assessment, physical examination, and psychological assessment for anxiety and depression. The nurse-led clinic assessment took approximately 45 to 60 minutes to complete. Follow-up measures for all participants were assessed at the following time-points: Baseline (Time 1), day 5–7 post-discharge (Time 2: pre-intervention), 1 month post-discharge (Time 3: post-intervention), and 3 months post-discharge (Time 4: post-intervention).

Results: Although it was expected that this intervention would

achieve primary and secondary aims, results did not demonstrate strong support for the study's hypotheses. Cardiac Self-Efficacy (CSE) (d=0.60) and trait anxiety (d=0.50) evidenced a positive moderately reducing effect for intervention group participants, while nil effect was evidenced on CSE (d= -0.19) or trait anxiety (d=0.16) on randomisation to the standard care group. The primary endpoint at Time 3 (1 month) was chosen as this was the best time to gauge an effect of the nurse-led clinic on psychological distress, salivary cortisol levels, and post-discharge complications. Small enhancements were evidenced in mean ratings for some CSE items and included: (a) confidence to lose weight, (b) confidence to change diet, (c) confidence in physical activity, (d) confidence to maintain usual work activities, and (e) confidence to control breathlessness by taking medications. Medication adherence was maintained in both groups while re-attendance to CR was a challenge.

Phase Two analytical findings indicated that intervention group participants felt supported by the nurse-led clinic and, thus experienced a sense of self-awareness and an ability to self-manage (i.e., complications, medications) after attending. Healthcare professionals commented on the potential benefit to participants in terms of the level of interaction and methods of information delivery. Early repetition of PCI education outside a busy hospital setting was highlighted as potentially effective in enhancing SE, reducing anxiety, and facilitating self-management. Furthermore, as the nurse-led clinic was conducted by a registered nurse (RN), the PI considered this to be a substantial benefit as participants could ask questions from an informed healthcare professional and, therefore, reduce post-discharge

anxieties. Suggestions for nurse-led clinic improvements by healthcare professionals included greater influence to encourage CR re-attendance, and encouraging patient discussion with a doctor (i.e., general practitioner [GP] or cardiologist) if contemplating medication cessation. Additionally, healthcare professionals also recommended cautioning participants about the potentially inaccurate health information available on the internet and offer a list of reputable websites.

Conclusion: This intervention, particularly Phase Two descriptive evaluative feedback, has demonstrated preliminary evidence to support a Phase Three, multi-centre study investigating the effects of the nurse-led clinic on SE and psychological distress in cardiovascular patients. Although the Phase One quantitative results did not demonstrate unequivocally the utility of the nurse-led clinic, Phase Two feedback from both healthcare professionals and intervention group participants provided support for the clinic's potential. This nursing intervention is within the scope of practice of an RN and could be carried out by a level 2 clinical nurse (CN) in the cardiac catheterisation theatre (CCT), hospital ward and/or outpatient setting (i.e., cardiology practice). Overall, the present study has provided some initial evidence that nurse-led clinics may be effective in providing post-PCI patients with early post-discharge support and education. This study provides preliminary evidence that nurse-led clinics undertaken within the first week post-PCI may fill a much-needed gap in support and information for patients during a potentially vulnerable post-discharge period and is in line with a focus on person-centred care. Undertaking a Phase Three, multi-centre study is thus an important future consideration to establish whether

behavioural changes following nurse-led clinic attendance can be

maintained in the medium to long term.

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List of Abbreviations

ACRA: Australian Cardiovascular Health & Rehabilitation Association

ACS: Acute coronary syndromes

ACNC: Australasian Cardiovascular Nurses Association Conference

ACTRN: Australian Clinical Trial Registration Number

ADL: Activities of daily living

ADON: Assistant Director of Nursing

AE: Adverse event

AF: Atrial fibrillation

AIHW: Australian Institute of Health and Welfare

AMI: Acute myocardial infarction

ANZCTR: Australian New Zealand Clinical Trials Registry

APN: Advanced practice nurse

AVCC: The Australian Vice-Chancellors' Committee

BGL: Blood glucose level

BHF: British Heart Foundation

BMI: Body mass index

CABG: Coronary artery bypass graft

CAD: Coronary artery disease

CBT: Cognitive–behavioural therapy

CCT: Cardiac catheterisation theatre

CCU: Coronary care unit

CDS: Cardiac Depression Scale

CHD: Coronary heart disease

CHF: Congestive heart failure

CP: Chest pain

CKD: Chronic kidney disease

CN: Clinical nurse

CNM: Clinical nurse manager

CONSORT: Consolidated Standards of Reporting Trials

CR: Cardiac rehabilitation

CSANZ: Cardiac Society of Australia and New Zealand

CSE: Cardiac Self-Efficacy

CVD: Cardiovascular disease

DBP: Diastolic blood pressure

DCF: Data collection form

DHS: Department of Human Services

DON: Director of Nursing

ECG: Electrocardiogram

EU: European Union

GP: General practitioner

HREC: Human research ethics committee

ICD-8: International classification of diseases, eighth revision

ICD: Implantable cardioverter defibrillator

ICU: Intensive care unit

IDACC: Identifying Depression as a Comorbid Condition

IHD: Ischaemic heart disease

IRB: Institutional Review Boards

IVRS: Interactive voice response system

MI: Myocardial infarction

MMAS-8: Morisky Medication Adherence Scale (8-Item)

MMS: Multimedia messaging service

NCD: Non-communicable diseases

NEAF: National ethics application form

NHFA: National Heart Foundation of Australia

NHMRC: National Health & Medical Research Council

NHS: National Institute for Health Research

NP: Nurse practitioners

NSTEACS: non-ST-segment-elevation acute coronary syndrome

NSTEMI: non-ST segment elevation myocardial infarction

OPD: Outpatients Department

PASW Statistics: Predictive Analytics SoftWare

PCC: Person-centred care

PCI: Percutaneous coronary intervention

PPCI: Primary percutaneous coronary intervention

PI: Principal investigator

PICF: Participant information and consent form

QOL: Quality of life

QUT: Queensland University of Technology

RA: Research assistant

RCI: Reliable Change Index

RCT: Randomised controlled clinical trial

RGO: Research governance office

RN: Registered nurse

SAE: Serious adverse event

SBP: Systolic blood pressure

SCT: Social Cognitive Theory

SE: Self-efficacy

SIGN: Scottish Intercollegiate Guidelines Network

SMS: Short message service

SON: School of Nursing

SSA: Site-specific Assessment

STAI: State–Trait Anxiety Inventory

STEMI: ST-segment-elevation myocardial infarction

UK: United Kingdom

USA: United States of America

WHO: World Health Organization

Statement of Original Authorship

The work contained in this thesis has not been previously submitted to meet requirements for an award at this or any other higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

QUT Verified Signature

Signature:

Date: 17/02/2016

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Dedication

To one of the strongest, intelligent and compassionate women I

have ever known

Matron Kathleen Agnes Theresa Bede Daly

I dedicate this thesis to you!

Chapter 1: Introduction

Chapter 1 outlines the research background, context, purpose, and problem. The research aims, questions, and hypotheses for Phase One and Phase Two of the study are also presented. An overview of the theoretical framework that guides this study is discussed and its application and importance specified. The remaining chapters of the thesis are outlined in Section 1.6

1.1   Background and Context

The following section provides background and context to justify undertaking the present study. The subsections explore and highlight the research gap and issues surrounding the post-discharge period after a percutaneous coronary intervention (PCI). Furthermore, the problems identified aim to clarify how they may affect SE from hospitalisation through to the post-discharge period. The concept of a nurse-led clinic will also be introduced in subsection 1.1.6 with the benefits to healthcare and managing patients with chronic illness highlighted. Chapter Two explores the theoretical framework, the research problem and post-discharge gap in greater depth.

1.1.1   Cardiovascular Disease (CVD) Statistics, Coronary Heart Disease (CHD), and Implications

The term cardiovascular disease (CVD) describes a group of disorders of the heart and blood vessels (World Health Organization [WHO], 2015). This group of diseases is responsible for the death of one Australian every 12 minutes and may include: coronary heart disease (CHD), cerebrovascular disease, peripheral arterial disease, rheumatic heart disease, congenital heart disease, deep vein thrombosis, and pulmonary embolism (National Heart Foundation of Australia [NHFA], 2015; WHO, 2015).

Cardiovascular disease is still annually the world's biggest killer (WHO, 2015). Between 2011 and 2012, there were 523,805 people hospitalised in Australia as a result of CVD, while in 2012 some 43,946 Australians died from preventable cardiovascular-related diseases (NHFA, 2015). Of the cardiovascular diseases, CHD is responsible for the death of 55 Australians daily and 20,046 in 2012 (NHFA, 2015). In 2012, approximately 17.5 million deaths occurred worldwide as a result of CVD, with one American dying every 40 seconds (Go et al., 2013; WHO, 2015). While cardiovascular disease is no longer the biggest killer in the United Kingdom (UK), CHD was responsible for 74,000 deaths in 2012 (Townsend, Williams, Bhatnagar, Wickrahmsinghe, & Rayner, 2014). Cardiovascular disease is the cause of most deaths in Europe, with CHD and stroke identified as the highest precursor (Nichols, Townsend, Scarborough, & Rayner, 2013a; Nichols, Townsend, Scarborough, & Rayner, 2013b). Furthermore, CVD is accountable for over 4 million deaths in Europe and the European Union with CHD responsible for approximately 1.8 million deaths annually (Nichols et al., 2012; Nichols et al., 2013a; Nichols, Townsend, Scarborough, & Rayner, 2014). Cardiovascular disease is the leading cause of deaths in males and females both nationally and internationally (Go et al., 2013; NHFA, 2015; Nichols et al., 2012; Nichols et al., 2013a, Nichols et al., 2014; Townsend et al., 2014; WHO, 2015).

It is estimated that, each year, the effects of CVDs are costly to the healthcare system both nationally and internationally, with $7.6 billion dollars spent on the disease in Australia annually (Go et al., 2013; National Vascular Disease Prevention Alliance [NVDPA]/NHFA, 2014; Nichols et al., 2012; Tarride et al., 2009; Townsend et al., 2012). With the burden of CVD (a non-communicable disease [NCD]), the WHO (2014) highlight the importance of implementing a group of NCD

interventions globally. The WHO (2014) aim to achieve nine targets and reduce the burden and cost of NCDs by 2025. Tarride et al. (2009) and the NVDPA/NHFA (2014) also highlight the increasing financial burden (both direct and indirect) on healthcare as a result of growing population obesity rates and increasing life expectancy. The burden of CVDs and, in particular, CHD means that health funders are favouring prevention programs, therapies, and management systems and procedures such as percutaneous coronary interventions (PCIs) that require shorter lengths of stay in hospital or are managed outside of the hospital system entirely (Blair, Corrigall, Angus, Thompson, & Leslie, 2011; Chin et al., 2011; Laarman & Dirksen, 2010; Mavromatis, 2013; Tarride et al., 2009).

Percutaneous coronary intervention aims to restore blood flow to the myocardium in patients with CHD (Australian Institute of Health and Welfare [AIHW], 2014). It is not only cost efficient to discharge patients who have undergone successful PCIs early, but it is vital for individuals to be in the comfort of their own home, and to be mobile (Laarman & Dirksen, 2010). Furthermore, being discharged to home minimises the patients' risk of infection and psychological distress (Laarman & Dirksen, 2010). There have been some consequences of this rationalisation of healthcare that include longer waiting times for follow-up to access GPs, cardiologists, and cardiac rehabilitation (CR) clinics in the outpatient setting (British Heart Foundation [BHF], 2010; 2011; Cupples et al., 2010; Dafoe, Arthur, Stokes, Morrin, & Beaton, 2006; Lacey, Tozer, & Cacavas, 2010). More concerning are the extremely poor and varying compliance and attendance rates to programs like CR worldwide. Referral rates to CR are also a problem, with Australia reporting as low as 11% and course attendance rates ranging from 10 to 30% (Arena et al., 2012;

BHF, 2014; Colbert et al., 2013; Clark, Redfern, & Briffa, 2013; Cupples et al., 2010; Gallagher et al., 2013; Heartwire, 2011; NHFA, 2014; Varnfield et al., 2011).

1.1.2 Percutaneous Coronary Intervention (PCI), Post-Discharge Issues and Gaps

Clearly, there are gaps within current practice that emphasise the importance of understanding CHD. The intention of this research was to study and test the effectiveness of a nurse-led follow-up clinic within 5–7 days post-PCI. The two main types of PCIs are with and without coronary stenting (AIHW, 2014). Percutaneous coronary intervention without stenting, or coronary angioplasty, involves the inflation of a balloon in the affected coronary artery to dilate the artery(ies) and remove the plaque (AIHW, 2014). Coronary artery stenting entails the deployment of stents, which are identified as "expandable mesh tubes", to allow for revascularisation of the diseased coronary artery(ies) (AIHW, 2014, p. 74).

1.1.3 Percutaneous Coronary Intervention: Statistics

Although PCI procedure rates in Australia appear to be stabilising, there has been a steady increase in PCIs in the last 25–30 years both nationally and internationally (AIHW, 2014; Dehmer et al., 2014; Go et al., 2013; Nichols et al., 2012; Townsend, Williams, Bhatnagar, Wickramasinghe, & Rayner, 2014). The age-standardised rates for PCI in Australia between 2000/2001 and 2012/2013 increased by approximately 27%, while it remained stable for men and women in 2007/2008 (AIHW, 2014). The rates for PCI in Australia gradually increase for all groups until the ages of 75–84 and then decline for the 85 years and older age group (AIHW, 2014). Percutaneous coronary intervention rates in European countries and the EU vary with Germany displaying the highest rates for PCI, while PCI rates in the US have increased (Go et al., 2013; Nichols et al., 2012). Interestingly, in Australia,

coronary angiography rates and medical treatment for acute coronary syndrome (ACS) is increasing (i.e., antiplatelet, antihypertensive, and lipid-reducing therapies) (AIHW, 2012; 2014). With the current trends changing, an intervention to improve the post-discharge follow-up care, education, and support of PCI patients was deemed necessary. Additionally, with an increase in medical therapies and an ageing population, the intervention appeared timely as it can be extended to the management of patients with ACS, and diagnostic cardiovascular procedures such as coronary angiography (i.e., with CHD diagnosis) outside the hospital setting (AIHW, 2010; 2012; BHF, 2010; Molina & Heng, 2009; NVDPA/NHFA, 2014; Townsend et al., 2014). Moreover, as hospital length of stay for PCI and cardiac events are declining, the need to investigate the effects of post-discharge follow-up within the first week of discharge in chronic disease patients it appeared that an outpatient, tailored post-PCI nurse-led educational intervention with a person-centred approach was warranted (AIHW, 2012, 2014; Tuso et al., 2013; Yu, 2014). Furthermore, with the cost burden to the healthcare system (for CVDs and in particular, CHD), an outpatient, nurse-led clinic may assist in reducing or keeping costs to a minimum by preventing or minimising post-discharge readmissions (Blair et al., 2011; Go et al., 2013; Nichols et al., 2012; NVDPA/NHFA, 2014; Tarride, 2009; Townsend et al., 2012; WHO, 2014). The following section identifies further issues surrounding hospitalisation and the post-discharge period for cardiac patients.

1.1.4 Psychological Distress, Patient Education, and Timing

Anxiety disorders affect approximately 20% of the population and are the most common psychological disorders in the population (Weiner & Craighead, 2009). Symptoms that can be experienced include fear, muscle tension, sleep disruption, poor concentration, and avoidance (Weiner & Craighead). Diagnosis of anxiety

disorders may include individuals reporting feeling distressed by the symptoms suffered or that their lives may have been considerably affected by symptoms experienced (Weiner & Craighead). Approximately 70–80% of patients who experience an "acute cardiac event" experience anxiety (Moser, 2007, p. 362). An international study of 912 post-acute myocardial infarction (AMI) patients identified anxiety in participants—46% (Australian), 35% (English), 43% (Japanese), 52% (South Korean), and 50% (American) (Moser, 2007, p. 363). While patients identified in the present study underwent PCI, patients in Moser's (2007) study experienced a cardiac event, highlighting anxiety experienced by cardiac patients. Moreover, the findings of anxiety in such large numbers of patients are important and support the need to undertake the present study to provide early post-discharge education and support, routinely screen for anxiety, and refer for management if required (Moser, 2007, p. 363).

The link between anxiety, depression, and cardiovascular events is highlighted in the literature and was investigated in this study, given the nature of the PCI procedure and the declining length of stay for PCI patients (AIHW, 2011; Chin et al., 2011; Colquhoun et al., 2013; Damen et al., 2011; Davidson et al., 2008; Heart Foundation, South Australia Division, 2011; Lane, Carrol, & Lip, 1999; NVDPA, 2012; Parissis et al., 2011; Riccardi et al., 2012). With the current trends based on sound clinical grounds favouring an earlier discharge, some patients may fail to receive any pre-discharge education or advice on the management of their condition (phase one CR) or even referral to a CR program (AIHW, 2011; Briffa et al., 2009; Bunker & Goble, 2003; Clark et al., 2013; Fischer, 2008; Flynn, Cafarelli, Petrakos, & Christopherson, 2007). Additionally, with the period between discharge and CR commencement being reported as a vulnerable time (particularly the first week post-

discharge), the present study was warranted (Günal et al., 2008; Rassaf, Steiner, & Kelm, 2013; Trotter, Gallagher & Donoghue, 2011; Tuso et al., 2013; Yan et al., 2011; Wong, Wu, Chan, & Yu, 2006).

The ongoing debate concerning best timing for patient education and delivery mode (i.e., face-to-face, online, telephone) is well argued and continues within the literature, with recommendations for pre-procedural education, ongoing repetition into the post-discharge period, and self-education (Asilioglu & Celik, 2004; Catherine, 2005; Chair & Thompson, 2005; Davis, Maguire, Haraphongse, & Shaumberger, 1994; Di'Amore, Murray, Powers, & Johnson, 2011; Hobbs; 2002; Johnson, 2000; Lyons, Fanshawe, & Lip, 2002; Trotter, Gallagher, & Donoghue, 2011; Tuso et al., 2013). Based on experiences as an RN and an in-depth review of the literature, the PI selected a time (day 5–7) and delivery mode (face-to-face) best suitable to review (physical and psychological assessment) post-procedural PCI patients, and to repeat basic post-PCI patient education (Tuso et al., 2013; Wong et al., 2006). Furthermore, the intervention was undertaken to allow for questions to be asked as patients would have had time to reflect on their recent hospitalisation and procedure. The first week post-discharge was selected, along with a face-to-face delivery mode, as it was anticipated that more-effective education could take place, and SE may be enhanced. Additionally, with less distraction (unlike during hospitalisation), it was hoped that health behaviour change and maintenance could occur through enhancing SE, reducing anxiety, and effectively communicating the importance of health promotion and prevention (Holloway & Watson, 2002).

As patient education is imperative, the short length of stay, limited staffing, knowledge deficits, limited nurse-teaching time, and patient anxiety during hospitalisation all contribute to poor information retention (Holloway & Watson,

2002). The importance of early follow-up has been widely discussed within the literature, with recommendations for post-discharge telephone follow-up for high-risk patients within 72 hours post-discharge and a post-discharge visit with a "primary care physician" within 1 week post-hospital discharge (Grace et al., 2012; Lane et al., 1999; Lauck et al., 2009; Tuso et al., 2013; Wong et al., 2006). Moreover, recommendations from a heart failure study by Hernandez et al. (2008) revealed that if patients were followed up within 1 week post-discharge the hospital readmission rate for those reviewed was 10% versus 31% for those who were not followed up by a primary care physician at this time (Tuso et al., 2013, p. 61). Tuso et al. (2013) encourage further research investigating the implications of early post-discharge follow-up (the first week post-discharge by a primary care physician) in patients with chronic disease as research in this area is limited, highlighting the importance of the present study. Thus, the timing of the nurse-led intervention at Time 2 (day 5–7 post-discharge) was investigated utilising a face-to-face mode for education based on the aforementioned arguments presented.

1.1.5 Health Misconceptions and Wait Times

It is interesting to note that some patients may have altered perceptions of their disease state and may both believe and accept that they have been cured of CVD (Carroll, 2005; Gaw, 1992; Young & Murray, 2011). The impression that they are cured may be as a result of their healthcare professional advising that "We fixed the artery", or "We fixed the culprit narrowing" (Carroll, 2005; Young & Murray, 2011, p. 29). Moreover, the short length of stay, coupled with anxiety, a decreased capacity to concentrate (in the presence of psychological distress), poor information retention, and inadequate pre-discharge education may result in additional health misconceptions (Carroll, 2005; Gallagher et al., 2013; Heart Foundation, South

Australia Division, 2011; Young & Murray, 2011). The lack of preparedness for discharge home and ongoing health management as a result of patients' misconceptions may result in (a) risk factor and behaviour misconceptions, (b) poor CR attendance (or not at all), (c) poor medication adherence and compliance, and (d) complication identification and management issues (Carroll, 2005; Clark et al., 2013 Gallagher et al., 2013; Heart Foundation, South Australia Division, 2011; Young & Murray, 2011).

The short amount of time for hospitalisation is discussed well in the literature and comes with both positive and negative consequences, which will be presented later in this chapter. The average length of stay in Australia after undergoing PCI ranges from 1.0 to 3.6 days; while internationally, hospitalisation in the USA ranges between 2.7 and 3.6, and between 2.8 and 10.2 days in London, UK (AIHW, 2012; Astin, Closs, McLenachan, Hunter, & Priestly, 2009; Astin, Jones, & Thompson, 2005; Chin et al., 2011; Corones, Coyer, & Theobald, 2009; Cronin, Freeman, Ryan, & Drake, 2000; Davis et al., 1994; Department of Human Services [DHS], 2008; Kattainen, Merilainen, & Jokela, 2004; National Institute For Health Research [NHS], 2008; Thomson Reuters, 2013; Tooth & McKenna, 1995; Wong et al., 2006; Yan et al., 2011). Cosman, Arthur, and Natarajan (2011) highlight the short hospitalisation for coronary artery catheterisation and uncomplicated PCI to be anywhere between 6 to 24 hours, reinforcing the diminishing length of stay. Importantly, coupled with a coronary event, patients who undergo PCI may also experience anxiety and depression (AIHW, 2011; Lane et al., 1999). Anxiety and depression are well-reported in the literature, with the presentation of symptoms often occurring in the post-discharge period due to the short hospitalisation (AIHW, 2011; Astin et al., 2009; Astin et al., 2005; Colquhoun et al., 2013; Corones et al.,

2009; Chin et al., 2011; Cronin et al., 2000; Davis et al., 1994; Kattainen et al., 2004; Lane et al., 1999; Tooth & McKenna, 1995; Wong et al., 2006; Yan et al., 2011).

Currently, a significant gap of between 7 and 64 days exists between the period in which patients are discharged from hospital post-PCI, reviewed by their GP or cardiologist, and attend a CR program (BHF, 2014; Cupples et al., 2010; Dafoe et al., 2006; Grace et al., 2012; Heart Foundation, Western Australia, 2012; Lacey et al., 2010; Pack et al., 2013; Shakib, Philpott, & Clark, 2009). The presence of anxiety and depression during this period is highlighted and may preclude the understanding of information delivered during hospitalisation, thus warranting the trial of the present study in the early post-discharge period (Kattainen et al., 2004; Kristofferzon, Lofmark, & Carlsson, 2007; Lauck, Johnson, & Ratner, 2009). Furthermore, the short hospitalisation for PCI precludes effective nurse–patient teaching, therefore limiting time for effective health education, promotion and prevention (Holloway & Watson, 2002; Young & Murray, 2011).

Effectively delivering tailored health-specific education can increase SE and enable behaviour change; however, given the short length of stay for PCI patients, facilitating enhancements in SE and encouraging behaviour change and correcting health misconceptions may not be possible (Holloway & Watson, 2002). As a result of the short length of stay and consequences, the literature highlights a poorer understanding of patient experience, their underlying CVD, risk factor modification, medication knowledge, and adherence (The Heart Foundation, South Australia Division, 2011; Young & Murray, 2011). Young and Murray (2011) highlight the post-discharge period as a challenge in that, during a short admission, patients are essentially forced to comprehend and absorb the information disclosed to them and are expected to be able to effectively manage themselves post-discharge.

Additionally, the associated health misconceptions post-PCI have been widely reported in the literature, with patients believing they are cured of their CHD and do not need to make lifestyle adjustments (i.e., diet and exercise), or attend a secondary prevention program (Astin et al., 2009; Gaw, 1992; Young & Murray, 2011).

There is a large under-referral and under-attendance rate to secondary prevention programs, along with issues surrounding the post-discharge period and the patient's needs during this time (Bethell, Evans, Turner, & Lewin, 2006; Briffa et al., 2009; Cupples et al., 2010; Corones et al., 2009; Dolansky et al., 2010). Moreover, complication identification and management and medication adherence also present with issues during the post-discharge period (Bethell et al., 2006; Briffa et al., 2009; Cupples et al., 2010; Corones et al., 2009; Dolansky et al., 2010; Yan et al., 2011). The table displayed in Appendix A presents various publications highlighting the presence of anxiety among patients who have experienced a coronary event, along with potential post-discharge complications. Furthermore, this table highlights a post-discharge period gap between the day of discharge from hospital, cardiologist review, and commencement of CR, thus supporting the need for this study. Subsection 1.1.6 introduces the concept of a nurse-led clinic, the benefits to patients with chronic illness and healthcare. Chapter 2 discusses nurse-led clinics in greater depth.

1.1.6 Nurse-led Clinics

Schadewaldt and Schultz (2011) identify a nurse-led clinic as a service for patients that is solely directed by specialist nurses. In addition to managing the clinics, the clinic nurses also engage in patient monitoring and support (Schadewaldt & Schultz). Nurse-led clinics exist for patients with chronic disease in areas such as respiratory, vascular, obesity, diabetes, cancer, palliation, chronic kidney disease

(CKD), hypertension, and CHD identified in the literature. These clinics focus primarily on patient education and health promotion (Chummun, 2011; Hatfield et al., 2008; The Joanna Briggs Institute [JBI], 2010; Schadewaldt & Schultz, 2011). There are various types of nursing care in chronic disease management (CDM), with Forbes and While (2009, p. 122) identifying the following types of nursing involvement:

> Nurse-led care: "the nurse identifies the needs and then organises a care package or refers to others; independent nursing practice".

> Nurse-led and nurse-delivered care: "the nurse identifies the needs and manages the problem herself; independent nursing practice".

> Nurse-delivered care: "the nurse provides care under the direction of others, a more advanced nurse or a doctor; dependent nursing practice".

Nurse-led clinics have been identified as successful in meeting short-, medium- and some long-term goals, with further research suggested to investigate the maintenance of long-term patient outcomes in nurse-led clinics (Hatfield et al., 2008; JBI, 2010; Schadewaldt & Schultz, 2011). Chummun (2011) highlights success in hypertension management with nurse-led clinics receiving recognition for exceptional team support, achieving medication compliance, and diminishing patient complications; while Hatfield et al. (2008) highlight the benefits in risk reduction in nurse-led vascular clinics that use patient care-paths and encourage effective self-management.

While not curative, nurse-led clinics may provide a better quality of life (QOL) for patients with chronic disease as they may be more closely monitored in the community, thus preventing the worsening of their condition (Hatchett, 2005). Furthermore, while nurse-led clinics may encourage effective self-management and

prevent patient deterioration, they may also offer a therapeutic nurse–patient

relationship (Hatchett, 2005; Hatfield et al., 2008). Continuity of care and patient

centeredness may contribute to this relationship in that patients should be treated as

people, as opposed to their illness (Hutchison et al., 2011). Conversely, while

continuity of care presents as beneficial, in order for patients to be satisfied with the

relationship they needed to have trust in the healthcare professional (Mahomed, St.

John, & Patterson, 2012).

Nurse-led clinics for patients with CHD are widely discussed in the literature

with the benefits highlighted (JBI, 2010; Schadewaldt & Schultz, 2011; Thompson,

Quinn, & Stewart, 2002). Thompson et al. (2002) identify that, if undertaken early,

nursing interventions aimed at psychological wellbeing and education may result in a

reduction in psychological distress, enhanced patient knowledge and satisfaction

reported at 6-months post-hospitalisation (Thompson et al., 2002). Furthermore,

nurse-led clinics are reported to reduce cardiac risk factors in both healthy patients,

patients with diagnosed CHD, and those with cardiovascular risk factors (JBI, 2010).

As a result of modern medicine, people are living longer, including those with

chronic illness, with a rise in chronic diseases observed (Barlow, Wright, Sheasby,

Turner, & Hainsworth, 2002; Forbes & While, 2008; Thorne, 2008). While acute

illnesses place a demand on the healthcare system, so too does chronic illness

(Barlow et al., 2002). With this increased demand placed on the healthcare system

and medical staff, there is a need for nurse-led clinics (Hatchett, 2005; Hutchison et

al., 2011; Queensland Health, 2013). Additionally, as the cost to manage chronic

diseases is high, developing and instituting cost-effective and clinically effective

measures to support patients with chronic disease is essential (Forbes & While,

2008). Furthermore, while nurses are currently providing supportive roles (i.e.,

primary and secondary prevention) in supporting patients with chronic illness, it is timely and important to undertake the present study in the form of a nurse-led clinic (i.e., nurse-led care), with a person-centred approach (Forbes & While, 2008; WHO, 2007; Yu et al., 2014).

1.2 Theoretical Framework: The Self-Efficacy Theory

1.2.1 Self-Efficacy Theory (SE), Self-Management, and Cardiovascular Disease

Bandura's (1977) SE theory, which developed from the social cognitive theory (SCT) was used as the theoretical framework to guide this study. Bandura's (1977) SE theory is based on the premise that a person's beliefs about their individual abilities, "mastery and vicarious experiences" can forecast performance outcomes (Bandura, 1995; Callaghan, 2003). Bandura highlights how mastery and vicarious experiences can lead to a strong SE (Bandura, 1995, p. 3). SE influences a person's feelings, thoughts, behaviours, and motivation (Zulkosky, 2009). Zulkosky (2009, p. 94) identifies an association between low perceived SE and "stress, anxiety and helplessness" and highlights how individuals with lower SE experience poor motivation, low self-esteem, and are pessimistic, particularly concerning personal achievements and growth (Zulkosky, 2009). Conversely, those with higher SE perform at a high level, are motivated, and will persist in order to accomplish challenges (Zulkosky, 2009). Bandura (1989, p. 1175) identifies SE beliefs as essential in that they influence "motivation, affect and action". Thus, a person with a higher perceived SE will have greater confidence, ambition, and dedication to achieve their goals (i.e., both short- and long-term) (Zulkosky, 2009).

The concept of SE was important to this study as the primary aim was to enhance patients' SE and reduce anxiety. It was anticipated that, by undertaking the

nurse-led clinic within the first week post-discharge, participants' perceived SE would improve. The PI anticipated that as participants developed the confidence and motivation to manage aspects of their post-discharge health and behaviours that SE would be enhanced and anxiety (i.e., trait anxiety) reduced. As highlighted earlier, a person with high perceived SE is more motivated and has the confidence and persistence to accomplish personal tasks and achieve growth (Zulkosky, 2009).

Anxiety, in relation to SE as identified by Schuster (1990, p. 11), is due to "coping inefficacy". In stressful situations, where inefficacy is experienced, anxiety is heightened (Bandura, 1988). In the present study, it was hoped that by enhancing participants' SE, any anxiety experienced in the post-discharge period could be reduced. The PI also anticipated that in reducing anxiety, and enhancing SE as primary aims, that secondary aims facilitating post-PCI effective self-management would be initiated and/or improved. Butki, Rudolph, and Jacobsen (2001, p. 1129) identify how Bandura's theory proposes a relationship between high perceived SE, reduced anxiety, and "biological response" to stress, which is why anxiety reduction was identified as a primary aim. In the present study, Spielberger's trait anxiety construct was measured.

Dehdari, Heidarnia, Ramezankhani, Sadeghian and Ghofranipour (2008) highlight the impact of anxiety after a coronary event, particularly on health outcomes, symptoms, and QOL. Dehdari et al. (2008) recognise the negative psychological effects of anxiety post-cardiac event and identify SE as essential health determinant in this group of patients (Dehdari et al., 2008). As patients who undergo PCI endure a short hospitalisation, the authors identify limited time available for psychological interventions and to prepare patients for discharge (Dehdari et al., 2008). Dehdari et al. (2008) reinforce the relationship between SE

and anxiety in PCI patients, highlighting that a patient with higher uncertainty has lower "perceived control" (pertaining to SE), high anxiety and depression levels, and poorer coping (Dehdari et al., 2008). It was anticipated that undertaking a nurse-led clinic, providing education and support for PCI patients in the first week post-discharge, could enhance SE, reduce anxiety, while also achieving the secondary aim to reduce symptoms of depression. It was also hoped that by highlighting areas of self-management and behaviour change that short-term goals could be identified, set, further explored and maintained long-term through attendance at a CR program (i.e., medication adherence, CR attendance, complication identification and management).

The SE theory is based on the premise that an individual's beliefs (or efficacy beliefs) and confidence in their abilities to master a task can predict the outcome and enhance SE (Bandura, 1977). The SE theory has been widely used in health educational interventions to encourage or measure behaviour change and to facilitate effective self-management (Bandura 1995; Holloway & Watson, 2002; Sarkar, Ali, & Whooley, 2007). Self-efficacy is often of interest in sufferers of chronic disease, particularly patients with CVD and, more specifically, those with CHD as it illustrates how behaviour, personal factors, and the environment all interact in chronic illness (Frei, Svarin, Steurer-Stey, & Puhan, 2009; Kang, Yang, & Kim, 2010; Rasheed et al., 2012; Sarkar et al., 2007; Sullivan, LaCroix, Russo, & Katon, 1998). Sarkar et al. (2007) highlight the extensiveness of the SE theory and how the construct of SE may be applied in areas other than psychology, with successful application in health behaviour change and chronic disease.

Cardiac rehabilitation (CR) programs often adopt the SE theory to gauge the outcomes of CR on SE in patients with CVD (Sarkar et al., 2007). Frei et al. (2009) highlight how SE assessment in patients suffering chronic diseases is essential as it

aids patient education. Furthermore, Frei et al. (2009) identify that by measuring SE, its levels (i.e., low levels in patients) can be identified and the CR program can then be tailored to the patient with the view to enhance SE. The authors also identify the importance of SE measurement over time so that the effect of the educational intervention can be gauged (Frei et al., 2009, p. 2). Lastly, measuring SE can also allow for comparison and contrast between patients and potentially anticipate various health-related outcomes and events (Frei et al., 2009).

Corbin and Strauss (1988, p. 30) identify that after a person receives a diagnosis of a chronic illness there may be a time of "diagnostic limbo" for patients and they may continue to seek answers. Corbin and Strauss (1988) highlight that during this period of uncertainty patients explore and seek information about their diagnosis. Furthermore, although after receiving a diagnosis, there may still be uncertainty about the physiological implications and treatment options, often leading patients to read about and/or identify with others who have experienced a similar diagnosis and experience (Corbin & Strauss, 1988). This period of post-diagnosis has been identified as traumatic due to its uncertainty; however, it is also a time of learning, questioning, and maintaining control (Corbin & Strauss, 1988). Thus, as highlighted above, it was important to undertake the nurse-led clinic in the early post-discharge period so that support and education offered could help participants with understanding their diagnosis and offer information to enhance their SE and reduce post-discharge anxiety. Moreover, in educating participants, it was hoped that they may be empowered and learn the importance of effective self-management of their chronic disease.

Self-efficacy and its importance in CVD is also highlighted in the literature in terms of its effects on clinical outcomes and on self-management (Katch & Mead,

2010; Sarkar et al., 2007). It has been identified that the better educated a patient is about their disease, the more efficiently and effectively they manage their health and risk factors (Katch & Mead, 2010). The literature identifies the term 'self-management' in terms of a person's "ability to manage symptoms, treatment protocols, physical and psychosocial consequences and lifestyle changes inherent to living with a chronic condition" (Katch & Mead, 2010, p. 34). The literature highlights how people make health-behaviour decisions on a daily basis and label this as "unavoidable" (Katch & Mead, 2010, p. 34). What is most important when making these choices is being able to make quality health behavioural choices, also known as "effective self-management", as this enhances an individual's health (Katch & Mead, 2010, p. 34). Studies have been undertaken in the area of chronic disease that reveal the positive outcomes of effective self-management (Barlow et al., 2002; Bodenheimer, Lorig, Holman, & Grumbach, 2002; Katch & Mead, 2010; Sarkar et al., 2007). Corbin and Strauss (1988) reveal three constituents to effective self-management as: illness management; maintenance, adoption or change behaviours; and emotional management (current or future emotional changes).

Kang et al. (2010) highlight the importance of learning positive health behaviours in those with coronary artery disease (CAD) in that it may preclude future coronary events while also maintaining good health. Importantly, Kang et al. (2010) further identify how CAD sufferers are passive in their learning and often fail to comprehend the significance of effective self-management and how it may prevent symptom and event recurrence. The authors, therefore, recommend nursing interventions that encourage and address positive health maintenance practices in those with CAD (Kang et al., 2010). Moreover, Kang et al. (2010) identify how a positive or high SE predicts health behaviour change and maintenance in CAD

sufferers, therefore reinforcing the importance of undertaking the study. It was, therefore, identified as important that SE in CHD and, more specifically, PCI patients was measured over time. Section 1.3 identifies the purpose of the study and presents the study's aims, research questions and hypotheses.

1.3   Purpose

The study was undertaken in two phases as a pilot study to determine the feasibility for a Phase Three, multicentre study. Phase One was undertaken as a randomised controlled clinical trial (RCT), while in Phase Two the PI undertook interviews with healthcare professionals and intervention group participants to analytically explore their views and attain feedback of the potential effectiveness of the nurse-led clinic.

1.3.1   Phases One and Two

The primary aim of Phase One of the study was to investigate the effectiveness of a nurse-led educational intervention in the early post-discharge period on participant SE and anxiety after undergoing a PCI procedure. As identified, the present study was guided by Bandura's (1977) SE theory, which is based on the premise that a person's beliefs of their individual abilities, mastery, and vicarious experiences can forecast performance outcomes (Bandura, 1995; Callaghan, 2003).

The present study undertook a second phase to analytically evaluate the effectiveness of the nurse-led clinic from the perspectives of participants who were randomised to the intervention, as well as healthcare professionals. Secondary aims were also investigated as a range of issues surrounding the post-discharge period emerged from the literature as highlighted earlier in this chapter. Post-discharge period concerns and issues identified included: post-discharge depression, low cardiac rehabilitation referral and attendance rates, poor medication adherence, and

post-discharge complication identification and management.

After undertaking an extensive literature review, the PI identified secondary aims and key factors that would ultimately affect a patient's SE and post-discharge psychological health and wellbeing. Furthermore, it was essential that secondary aims were explored as PCI patients' ability to effectively self-manage post-discharge and beyond was highlighted as important. Therefore, to gauge the effectiveness of the intervention on primary and secondary aims, and to achieve greater depth and richness in data, the study, the study was undertaken in two phases with the problems, aims, questions, and hypotheses guided by the SE theory (Bandura, 1977).

1.3.2 Phase One: Research Aims, Questions and Hypotheses

Phase One investigated the effect of the nurse-led clinic on primary and secondary aims. Research aims, questions, and hypotheses for Phase One are identified below.

Primary Aim

- Evaluate if a post-discharge, nurse-led clinic providing education and support can increase SE and reduce anxiety in post-PCI patients.

Secondary Aims

- Evaluate if a post-discharge nurse-led clinic, providing education and support can reduce depressive symptoms in intervention group participants.

- Evaluate if a post-discharge, nurse-led clinic, providing education and support can encourage effective patient self-management (i.e., complication identification and management, medication adherence, and CR attendance)?

With the primary and secondary aims identified above, the primary and

secondary research questions are as follows:

Primary Research Question

Can the post-discharge, nurse-led clinic providing education and support increase SE and reduce anxiety in post-PCI patients as measured by the Cardiac Self-Efficacy Scale (CSE) (see Appendix B) and STAI-Y2 Form, respectively (see Appendix C)?

Secondary Research Questions

- Can the post-discharge, nurse-led clinic providing education and support within the first 5–7 days post-discharge reduce depressive symptoms as measured by the Cardiac Depression Scale (CDS) (see Appendix D)?;

- Can the post-discharge, nurse-led clinic, providing education and support within the first 5–7 days post-discharge encourage effective self-management (i.e., complication identification and management, medication adherence, and CR attendance)?

Primary Aim: Null Hypothesis

H°: Attending the post-discharge, nurse-led clinic providing education and support within the first 5–7 days post-PCI will not improve SE and reduce anxiety in intervention group participants.

Secondary Aims: Null Hypotheses

H°: Attending the post-discharge, nurse-led clinic providing education and support within the first 5–7 days post-PCI will not reduce depressive symptoms in intervention group participants.

H°: Attending the post-discharge, nurse-led clinic providing education and support within the first 5–7 days post-PCI will not lead to effective

self-management in intervention group participants (i.e., complication

identification and management, medication adherence, and CR

attendance).

1.3.3   Phase Two: Descriptive–Evaluative

Phase Two aimed to evaluate the effectiveness of the nurse-led, educational

intervention in greater detail. Participant interviews involved reapproaching

intervention group participants, as well as healthcare professionals, seeking detailed

feedback to gauge the effect of the intervention. Greater depth of information was

sought from participants who attended the clinic, as well as healthcare professionals,

regarding their thoughts on the clinic (i.e., education, support), enhancing SE (post-

discharge confidence), anxiety reduction, and overall potential impact of the nurse-

led clinic. Data analysis in Phase Two was descriptive-evaluative and utilised an

abductive approach to ensure greater understanding and breakdown of the data and

personal interpretation (Alvesson & Karreman, 2011; Brinkmann, 2014). Charmaz's

(2006) techniques to code, analytically evaluate data and determine relationships

between Phase One and Two were utilised to analyse data in the present study and

will be explored further in Chapter 3.

1.4   Significance, Scope and Definitions

As highlighted above, the gap in research identified for patients who

experience a cardiac event and/or PCI is multifactorial and surrounds hospitalisation

for PCI and the early post-discharge period. Moreover, without appropriate hospital

and post-discharge support, patients may experience low SE and psychological

distress. With the primary aim to enhance SE and reduce anxiety, it was hoped that

the following self-management problems, issues, and/or concerns could be addressed

as they may affect, or be affected by, a lower SE. The research problems are,

therefore, as follows:

- importance of SE (particularly enhancing SE in cardiac patients);

- cardiovascular events and post-PCI anxiety;

- cardiovascular events and post-PCI depression;

- deficits in nurse health promotion and prevention (during hospitalisation);

- post-PCI self-management;

- poor referral, attendance, and compliance rates to a CR program post-PCI;

- poor medication knowledge, adherence and compliance; and

- risk period post-PCI (i.e., puncture-site management, medications, chest pain).

As identified earlier, low SE can impact on all individuals, particularly during hospitalisation, in the post-discharge period and recovery. Participants who may have low efficacy beliefs and do not feel they have the ability to achieve mastery in tasks such as changing and maintaining health behaviours (i.e., reducing modifiable risk factors), and undertaking post-PCI cares and self-management will not achieve success in these areas. Moreover, patients with low efficacy beliefs will experience low self-confidence or low SE, reduced motivation, negativity and thus, psychological distress. Having a high or low SE may not only influence the post-discharge period, but post-discharge experiences, emotional wellbeing, health behaviours, maintenance, and practices—thus SE theory was chosen as the framework to guide the present study.

This study highlights the importance of enhancing SE in post-PCI patients given the aforementioned problems discussed. Furthermore, the present study

identifies the benefits of enhanced SE in the post-discharge period, the effect of enhanced SE on participants' emotional wellbeing, and how increased SE offers patients the confidence to resume their pre-discharge roles. This study also reinforces the benefits of high SE and its impact on patients' health behaviour choices and change, maintenance practices, and overall self-management. Aiming to enhance SE for all patients admitted and hospitalised for elective coronary angiography, elective PCI or primary PCI (PPCI) can and should begin on admission and continue into the post-discharge period. Furthermore, earlier post-discharge follow-up, as highlighted in the present study, is essential. Section 1.5 identifies a list of the study's terms with definitions provided.

1.5 Definition of Key Terms

The following definitions are used to describe the meanings of keywords used in the present study. Definitions are as follows:

- **Acute coronary syndromes (ACS):** "An umbrella term for heart attacks and unstable angina". (National Heart Foundation of Australia, 2010, p. 1)
- **Acute myocardial infarction (AMI):** "the early critical state of myocardial necrosis caused by blockage of a coronary artery". (Anderson, Anderson, & Glanze, 1998, p. 31)
- **Anxiety: "**anticipation of impending danger and dread accompanied by restlessness, tension, tachycardia, and breathing difficulty not associated with an apparent stimulus". (Anderson et al., 1998, p. 110)
- **Anxiety state**: "a mental or emotional; reaction characterised by apprehension, uncertainty, and irrational fear. Anxiety states may be accompanied by physiologic changes such as sweating, tremors, rapid heartbeat, dilated pupils, and dry mouth". (Anderson et al., 1998, p. 110)

- **Atherosclerosis**: "a common arterial disorder characterised by yellowish plaques of cholesterol, lipids, and cellular debris in the inner layers of the walls of large and medium-sized arteries". (Anderson et al., 1998, p. 142)

- **Chronic diseases:** "conditions that last one year or more and require ongoing medical attention or limit activities of daily living or both" (Centers for Disease Control and Prevention, 2015).

- **Coronary artery disease (CAD):** See coronary heart disease (CHD) as term is used interchangeably.

- **Coronary heart disease (CHD)**: "the collective term for diseases that occur when the walls of the coronary arteries become narrowed by a gradual build-up of fatty material called atheroma. The two main forms of CHD are heart attack (also known as myocardial infarction) and angina". (Townsend et al., 2012, p. 11)

- **Coronary revascularisation:** "The group name for the set of surgical procedures to improve blood flow to the heart muscle. These include coronary artery bypass graft surgery ('CABG', 'bypass surgery' or 'open heart surgery') and percutaneous transluminal coronary intervention (coronary angioplasty)". (NHFA, 2010, p. 1)

- **Depression:** "Major depression is sometimes called major depressive disorder, clinical depression, unipolar depression or simply depression. It involves low mood and/or loss of interest and pleasure in usual activities, as well as other symptoms. The symptoms are experienced most days and last for at least two weeks. Symptoms of depression interfere with all areas of a person's life, including work and social relationships. Depression can be described as mild, moderate or severe; melancholic or psychotic". ("Types of depression", Beyondblue, 2015)

- **Nurse-led clinic:** "A clinic where the nurse has his or her own patient caseload. This involves an increase in the autonomy of the nursing role, with the ability to admit and discharge patients from the clinic, or to refer on to other more appropriate healthcare colleagues. This power to refer to others is often highly variable between clinics, but can include referrals to professionals allied to medicine, such as dieticians, physiotherapists, chiropodists and social work teams, through to medical teams or consultants. An educative role – explaining the illness to the patient and carers. This includes the significance of symptoms, differentiating between those of concern that require further treatment or adjustment of medication and those that may be from alternative causes. The issues of health education and promotion fall into this category. Psychological support – this does not appear in all of the literature focussing on nurse-led clinics, but listening to the patient's concerns, fears and perceived improvements in health is clearly an important role. Monitoring the patient's condition – this is an area which has developed rapidly in recent years. This involves the skills of history taking and physical assessment, considering the significance of assessment and ordering further investigations. This will also involve referring on to more appropriate colleagues or initiating treatments. The emergence of Patient Group Directions (PGDs) and nurse prescribing has meant that manipulating medications is an increasing role of the nurse-led clinic". (Hatchett, 2003, p. 2)

- **Patient education:** "Patient education is a process of assisting people to learn health-related behaviours so that they can incorporate those behaviours into everyday life. As stated previously, the purpose of patient education is to help clients to achieve the goal of optimal health and independence in self-care. It involves establishing a relationship between the teacher and learner so that the information needs (cognitive, affective, and psychomotor) of a client can be met through the process of education". (Bastable, 2005, p. 11)

- **Patient-centred communication**: "invites and encourages the patient to participate and negotiate in decision-making regarding their own care". (Langewitz, Eich, Kiss, & Wössmer, 1998, p. 269)

- **Primary prevention:** "Primary prevention describes reducing the risk of a heart event or heart disease among people who do not have heart disease" (National Heart Foundation of Australia [NHFA], 2013, p. 1).

- **Psychological traits**: "trait anxiety, life change events, and emotion suppression". (Nakatani et al., 2013, p. 50)

- **Self-efficacy theory:** see Section 1.2.

- **Self-management**: "The individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition. Efficacious self-management encompasses the ability to monitor one's condition and to effect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life". (Barlow, 2001, p. 545)

- **Trait anxiety**: "Individual differences in the likelihood that a person would experience state anxiety in a stressful situation". (Caci, Baylé, Dossios, Robert, & Boyer, 2003, p. 394)

- **Unstable angina**: "is due to the detachment of a stable clot or plaque from the wall of the coronary artery. This may cause spasm of the coronary artery, which results in myocardial ischaemia, at least temporarily". (Mittal, 2006, p. 169)

1.6   Thesis Outline

This chapter has provided an overview of the thesis and presented the background, research problems, followed by the research aims and hypotheses. The chapter presented the underpinning theoretical framework, while detailing the two phases in which the study was undertaken. Chapter 2 will discuss and justify the reasons for undertaking this study, as supported by the literature. Furthermore, Chapter 2 will present various arguments from major cardiovascular nursing and medical research areas supporting the study while also identifying the importance of

nurse-led clinics and presenting the differences between the present study and other nurse-led clinics trialled for cardiovascular patients. Chapter 3 will discuss the methodology and research design addressing participants, instruments utilised, procedure, analysis, ethics, and ethical limitations. Chapter 4 will present the study's results, while Chapter 5 will present a Phase 3, multi-centre study based on Phase One and Two findings for future consideration. Chapter 6 will discuss the results in greater depth and detail. Lastly, Chapter 7 will discuss the study's key findings, while reporting on its various strengths, limitations, difficulties; it also offers recommendations for future research, nursing practice and policy. The final chapter will discuss the literature with respect to the theoretical framework and the area of investigation. The following chapter will highlight the problems and research gap, justify the importance of nurse-led clinics with a person-centred approach for cardiac patients and chronic disease.

Chapter 2: Literature Review

This chapter begins with a background on coronary heart disease (CHD) and reviews the literature with respect to the theoretical framework and both primary and secondary aims. This literature review is divided into seven sections and critically reviews the background surrounding CHD and its management, trends, and treatment, and highlights the importance of the first week post-discharge. Furthermore, this chapter discusses nurse-led clinics and how this pilot study differs from other post-operative, nurse-led cardiovascular interventions for patients with CHD or who have undergone a percutaneous coronary intervention (PCI) procedure. Lastly, Chapter 2 provides evidence to validate completing the present study.

2.1 Coronary Heart Disease (CHD), Acute Coronary Syndromes (ACS) and Treatment

Coronary heart disease, also referred to as ischaemic heart disease (IHD) or used interchangeably with coronary artery disease (CAD), is a disease that is characterised by a decreased supply of blood to the heart due to blockages within the artery wall (American Heart Association [AHA], 2015; Stanner, 2005) (see Appendix E). These blockages are often referred to as lesions or plaques and can either rupture, causing a clot within the artery and therefore inhibiting blood flow to the heart, or solely decrease blood flow to the heart leading to the patient experiencing chest pain and/or exertional breathlessness (Stanner, 2005). The result of a complete arterial occlusion is a heart attack or myocardial infarction (MI) (Stanner, 2005).

Acute coronary syndrome is the term used to describe the signs and symptoms of myocardial ischaemia and may include any of the following: "unstable angina; non-ST-segment elevation myocardial infarction; and ST-segment elevation

myocardial infarction" (Overbaugh, 2009, p. 42). These diagnoses can determine the gravity of the patient's condition and determine the direction of care required (Overbaugh, 2009).

2.1.1 Guidelines for the Management of Coronary Heart Disease (CHD) and Acute Coronary Syndromes (ACS)

In Europe, the United States of America (USA), United Kingdom (UK), Australia, and New Zealand, evidence-based guidelines direct the management of patients who present with ACS (Achar, Kundu, & Norcross, 2005; Amsterdam et al., 2014; Aroney, Aylward, Kelly, Chew, & Clune, 2006; Aroney et al., 2008; Chew et al., 2011; Dracup et al., 2009; O'Gara et al., 2013; Scottish Intercollegiate Guidelines Network [SIGN], 2013; Steg et al., 2012). For example, the management guidelines for acute chest pain in Australia and New Zealand identify the phases from the initial identification of chest pain to the type of intervention patients may undergo based on diagnosis (Aroney et al., 2006). Furthermore, these guidelines are in place to provide optimal patient care to establish and manage the diagnosis and prognosis of ACS (Aroney et al., 2006).

In Australia and New Zealand the definition and management of ACS has changed over the years. The terminology to describe ACS was based on a presentation diagnosis; however, terminology has shifted towards a "working diagnosis", with the introduction of "NSTEACS" or "non-ST-segment-elevation acute coronary syndrome" (Aroney et al., 2006, p. S10). Aroney et al. (2006, p. S10) advise how this working diagnosis provides practitioners with an appropriate management pathway as they reach a final diagnosis.

An ST-segment elevation myocardial infarction is defined as:

Presentation with clinical symptoms consistent with an acute coronary

syndrome with ECG features including any of: Persistent ST-segment elevation $\geq$ 1mm in two contiguous limb leads; ST-segment elevation of $\geq$ 2mm in two contiguous chest leads; or new left bundle branch block (LBBB) pattern. (Aroney et al., 2006, p. S13)

Patients with a ST-segment-elevation myocardial infarction (STEMI) may be managed as per the ACS guidelines (Aroney et al., 2006; Aroney et al., 2008; Chew et al., 2011). Grades of recommendation should be followed when managing an ACS patient (Chew et al., 2011). These grades reflect evidence supporting the practice and are rated from "grade A" through to "grade D" (see Appendix F, Table F1) (Chew et al.). Grades of recommendation are based on data from high-quality randomised controlled clinical trial data (i.e., grade A), through to panel judged, non-evidence-based recommendations (i.e., grade D). Management of patients with NSTEACS is determined by a patient's level of risk. The levels consist of low, intermediate, and high-risk NSTEACS. The pathway guiding clinician treatment is dependent on the patients risk level with management recommendations, as evidenced in Appendix G, Table G1.

Further to the aforementioned recommendations, the CSANZ and NHFA also provide management pathways consisting of long-term recommendations for medications, lifestyle modifications, CR, and chest pain management (Aroney et al., 2006). Therefore, as these recommendations for management are in place, the need for the present study was warranted as it aimed to: (a) enhance participant SE and reduce anxiety as its primary aim, (b) reduce symptoms of depression, (c) encourage post-discharge effective self-management by reiterating post-PCI education, and (d) provide nurse-led support as secondary aims.

Coronary artery revascularisation (i.e., PCI) and current trends towards its use as a treatment option for CHD internationally has become an increasingly popular

and more prevalent procedure due to its lower risk and quicker recovery (AIHW, 2010; British Heart Foundation [BHF], 2011; Lloyd-Jones et al., 2010; Mavromatis, 2013; Scarborough, Wickramasinghe, Bhatnagar, & Rayner, 2011; Townsend et al., 2012; Townsend et al., 2014; Wijns et al., 2010). For patients who are suitable candidates, PCI as opposed to coronary artery bypass surgery (CABG) offers less risk, immediate symptom relief, and a faster return to activities of daily living (ADLs) and work (Leeper, 2004; Lyons et al., 2002; White & Frasure-Smith, 1995).

Prior to PCI, a diagnostic coronary angiogram is performed to determine the degree of coronary artery stenosis (Mathur, 2002). This procedure involves the insertion of a coronary artery catheter through into the leg (femoral artery) or arm (radial or brachial artery) (Bates, 2008) (see Appendix H). Under X-ray guidance, together with the use of a contrast medium, the degree of coronary artery stenosis can be gauged (AIHW, 2010; Bates, 2008; Mathur, 2002; Wijns et al., 2010). If there is an appropriate candidate and revascularisation via PCI is to proceed (as opposed to CABG surgery), a balloon catheter is placed into the coronary artery or arteries where the blockage or blockages are present and is inflated, thereby compressing the plaque (Mathur, 2002; O'Grady, 2007). Additional measures such as stenting, artherectomy, and ablation can be incorporated to allow for better patient outcomes (Mathur; O'Grady). Percutaneous coronary intervention can be performed either electively or as a primary procedure, with the average time spent hospitalised post-PCI having decreased over time (AIHW, 2012; Higgins, Theobald, & Peters, 2009; Lauck et al., 2009; Leeper, 2004; Radcliffe et al., 2009; Rolley, Salamonson, Dennison, & Davidson, 2010; Wong et al., 2006; Yan et al., 2011).

In 2011, the AIHW (2014) reported that, of the group of cardiovascular diseases, CHD was the leading cause of death in both men (11,733 deaths) and

women (9780 deaths) in Australia. The AIHW highlight that between 2000 and 2001 and 2007 and 2008 there was a 57% increase in the number of PCIs with an increase of 57% and 52% for both males and females, respectively (AIHW, 2015). Coronary artery bypass graft surgeries between 2000 and 2001 and 2007 and 2008 have reduced by 19%—from 16,696 to 13,612—suggesting PCI as the preferred treatment option for CHD during this time (AIHW, 2015). Notably, the reduction in CABG surgery has reduced more significantly for women (25% reduction) than men (16% reduction) (AIHW, 2015). The USA reports approximately 1 million PCIs per year, with approximately 1,313,000 PCI procedures performed as compared to 448,000 CABG surgeries in 2006 (Khouzam, Soufi, Nakhla, & Naidu, 2014; Lloyd-Jones et al., 2010, pp. 202-203; Mavromatis, 2013). While a positive upward trend in PCI volume was evidenced, stabilisation in procedure volume is highlighted in the literature (AIHW, 2014; 2015; Dehmer et al., 2014; Molina & Heng, 2009; Riley, Don, Maynard, Powell, & Dean, 2011)

In Europe, a widespread variation in statistics concerning the areas of CVD, PCI, and CABG surgery exists (Nichols et al., 2012). Rates for PCIs were low in Portugal and Romania, while the most PCIs were performed in Germany, followed by Austria and the Czech Republic, respectively (Nichols et al., 2012). The highest rates for CABG surgery were in Switzerland, Germany, and Estonia, while Finland, Slovakia, and Romania reported the lowest procedure rates (Nichols et al., 2012).

In the United Kingdom (UK) the rate of PCI procedures has increased twofold over the last 10 years with 92,445 interventions undertaken annually versus 16,791 CABG surgeries (Townsend et al., 2014). These figures represent a slight reduction in CABG surgeries and a doubling of PCI procedures (Townsend et al., 2014). Trends show the number of PCIs are increasing annually, with CABG surgeries

remaining either stable or declining (Lauck et al., 2009; Molina & Heng, 2009; Townsend et al. 2014). The data have been presented not to suggest superiority of PCI over CABG, but rather propose that the combination of factors such as improvements in technology and informed decision-making by the patient has led to this upward trend (Lauck et al., 2009; Mathur, 2002; Rolley et al., 2010; Wijns et al., 2010). Furthermore, the attractiveness of lower risk (as opposed to CABG) surgery, instant symptom relief, faster recovery, and return to ADLs and work appear to be a more attractive alternative to consumers if they have the treatment choice (Lauck et al., 2009; Leeper, 2004; Mathur, 2002; Mavromatis, 2013; Widimsky, Fajadet, Danchin, & Wijns, 2009; Wijns et al., 2010).

2.2   Hospitalisation for the PCI Procedure

Reducing patients' length of stay is a prevalent topic within the literature, with researchers looking to further reduce the hospitalisation time for patients with a femoral artery access approach, while investigating and encouraging the use of a radial approach if the patient is an appropriate candidate (AIHW, 2011; Blicq et al., 2010; Dalby et al., 2003; Kaluski et al., 2008; Lauck et al., 2009; Ludman, 2013). It is interesting that in the UK, use of the radial approach has increased from 10% in 2004 to 58% in 2011 (Ludman, 2013, p.5). The AIHW (2014) identify the decreasing length of stay in CVD patients, identifying discharge for some on the same day. In the years 2007–2008 approximately 46% of patients were discharged on the same day of hospital admission (AIHW, 2011, p. 31). The AIHW (2011) attribute a variety of factors, such as treatment changes and diagnostics and transfers to other facilities, for the larger number of same-day discharges.

In 2009, Lauck et al. followed 98 PCI patients who underwent their revascularisation procedure and were discharged on the same day they were

admitted. The authors identified same-day discharge post-PCI as a feasible option; however, several issues surfaced as a result of the shortened length of stay. These issues included poor post-PCI health-related behaviours, vascular complications, and misguided beliefs about their disease management, with half of participants unsure of the cause and management of their disease process. Furthermore, approximately 77% of these patients had no plans on attending a CR program, with 37.8% believing they had been cured of CAD (p. 194). This study also highlighted the stress and anxiety surrounding PCI, while identifying the shortened length of stay as problematic. Given the aforementioned concerns, and as identified by these authors, recommendations for additional methods of follow-up for short-stay patients, including telephone and internet are suggested so that this groups' learning and educational requirements are met. Mavromatis (2013) highlights the shift towards same-day discharge in the US and identifies how hospitals may, at some point in the near future, be required to undertake PCI as a day procedure because the number of hospital beds may not meet the demands of a growing population. While the shortened length of stay and movement towards same-day discharge for PCI patients is imminent, the first week post-PCI appears to be problematic and the post-discharge issues are highlighted in the next section.

2.2.1 The First Week Post-PCI

The first week post-PCI is important for both psychological and physical reasons. Among cardiac patients, psychological distress may either present, continue, or subside after approximately one week (Lane et al., 1999). Psychological distress in the post-discharge period highlights a concern and the importance of the present study is supported by the aim to reduce psychological symptoms that cardiac patients may experience. Additionally, the first week following PCI is important for the

patient as this is the time that they are at risk of post-PCI-related complications (Rassaf et al., 2013; Trotter et al., 2011; Wong et al., 2006).

As identified in Chapter 1, Tuso et al. (2013) reviewed hospital initiatives with the aim to reduce readmissions in PCI patients. The authors reported one-third of readmissions occurring within the first week, highlighting the first 7 days to be a particularly vulnerable period for patients with psychosocial issues and low treatment success highlighted (2013). In Tuso et al.'s study, initiatives to prevent readmission of high-risk patients were established and included educative measures (2013). Furthermore, to reduce 30-day readmission it was noted that primary physician follow-up within the first week post-discharge needed to be initiated that was tailored, patient-centred, had a strong focus on disease prevention, and addressed social issues (2013). Timeliness was also highlighted as important, with recommendations to trial with chronic disease patients (Tuso et al., 2013).

Wong et al. (2006, p. 582) identify that patients' "immediate post-discharge care" should surround the identification of complications, which may be due to any of the following: access site, contrast dye, medications, and/or stent(s) (i.e., thrombosis formation). Curtis et al. (2009) also reinforce post-discharge complications and subsequent readmission to hospital post-PCI to include the vascular access site, bleeding, contrast-induced nephropathy, patient co-morbidities and cardiovascular disease-related complications. Grace et al. (2012) highlight the importance of the post-discharge period after an acute cardiac event and reinforce how patients and their families can suffer emotionally as a result. The authors stress the importance of "timely access" to a CR program to enhance patients' health and wellbeing post-discharge, with recommendations for a reduction in wait times post-PCI (Grace et al., 2012, p. 1). Thus, as patients may suffer emotional distress as a

result of the procedure and post-discharge isolation, the psychological distress experienced by cardiac patients is reviewed in Section 2.3.

2.3 Psychological Distress, Cardiac Events and Coronary Heart Disease (CHD)

Lane et al. (1999) highlight how anxiety and depression symptoms present instantaneously after an MI. The AIHW (2011) and Colquhoun et al. (2013) recognise the strong link between depression and cardiovascular events and highlight the importance of post-discharge patient follow-up and screening. As anxiety and depression may co-morbidly exist, the present study measured the effect of the nurse-led clinic on both anxiety and depression (NHFA, 2007; Tully, Baker & Knight, 2008). Janszky, Ahnve, Lundberg, and Hemmingsson (2010) undertook a longitudinal study involving 49,321 male participants between the ages of 18 and 20 years formally diagnosed with anxiety disorder (ICD-8 Classification). The authors found a stronger prognostic relationship between coronary heart events and early-onset anxiety over depression, with a doubling of coronary events noted in participants with diagnosed anxiety (Janszky et al., 2010).

A study of the effects of anxiety versus depression on vascular function was undertaken with 89 patients with CVD and 54 healthy participants (Stillman, Moser, Fiedorowicz, Robinson, & Haynes, 2013). The study identified significant effects of anxiety on vascular dysfunction (depression was controlled for). Although Stillman et al. (2013) highlighted a strong correlation between anxiety and depression ($r = .682$, $p = <.001$) with respect to vascular function, overall, anxiety was reported to worsen atherosclerosis and vascular functioning independently of medications, depression, and CVD risk factors. Of note, body mass index (BMI) did not appear to affect atherosclerosis or vascular function (Stillman et al., 2013). The authors

concluded that anxiety should be studied further, and noted that anxiety is often not factored in when identifying cardiovascular risk, thus, highlighting the importance of undertaking the present study (Stillman et al., 2013). Moreover, the authors highlight the degree to which anxiety contributes to CVD, identifying strong associations with sudden cardiac death and atherosclerotic events (Stillman et al., 2013). Further research investigating the exact processes concerning the relationship between anxiety and CVD are warranted and discussed in the literature. Stillman et al. (2013, p. 1) recommend behavioural interventions and pharmacotherapy aimed at: "1. anxiety; 2. lifestyle; 3. risk-factors; and/or 4. sympathetic nervous system".

Narita et al. (2007) highlight an increased risk (2–5 times greater) of developing CVD in those with anxiety and depression. Narita et al. (2007) investigated the effects of anxiety and depression on CVD highlighting a greater risk for CVD in patients with higher trait anxiety. The authors reported more significance in endothelial dysfunction and abnormalities in sympathetic activity and recommend further research into the pathophysiology of anxiety and its contribution to atherosclerosis and CVD (Narita et al.). Thus, given the aforementioned recommendations and, as depression is already well-investigated within the literature, the PI chose to explore anxiety and the potential effects of nurse-led support and education on SE, psychological distress, and self-management in the present study.

Roest, Martens, de Jonge, and Denollet (2010) recognise how anxiety may predict future cardiac events, reporting an average of 11 years into the future and internationally, with predictions for America, Norway, Russia, Sweden, Japan, and the UK highlighted. Janszky et al. (2010) undertook a study of 49,321 Swedish men (18–20 years of age) to investigate the long-term effects of anxiety and depression

over time. Janszky et al. (2010, p. 35) reported early-onset anxiety to be a predictor

of CHD and cardiac events in male participants, suggesting "sympathetic

overactivity and autonomic dysfunction" increases the chance of a coronary event.

Nabi et al. (2010) reinforce the association between anxiety and CHD,

identifying that somatic and psychological effects of anxiety contribute greatly to

CHD development, particularly in women. This highlights the importance of the

present study as the PI aimed to not only screen participant for anxiety (and refer for

psychological intervention if required) in the post-discharge period, but to also

provide an early post-discharge, supportive, and educational intervention to reduce

post-discharge issues and concerns by enhancing SE and reducing anxiety.

The AIHW (2011) identify how depression may occur simultaneously with a

coronary event, while conversely increasing the likelihood of CVD. They advise that

patients presenting with CVD be assessed for depression; while patients presenting

with psychological signs of depression be assessed for CVD. There has been a shift

in focus towards psychological distress (i.e., anxiety and depression) and coronary

events and post-event mortality within the literature (Davidson et al., 2008; Lane et

al., 1999; Turner et al., 2010). Lane et al. (1999) identify that the severity of

psychological disturbances are dependent on the following: (a) the physical event,

(b) personal characteristics, and (c) psychological adjustment ability. Psychological

distress may subside after approximately 1 week in some cardiac patients, while

others endure their symptoms for much longer (Lane et al.). Importantly,

psychological symptoms may not be detected during hospitalisation due to the focus

on treating the physical effects of the cardiac event (Lane et al.). Given the

prevalence of depression in AMI patients is approximately 40–65 %, and there is

strong evidence of high post-event mortality, the assessment of anxiety and

depression in the present study was warranted (Davidson et al., 2008; Sardinha, Araujo, Soares-Fiho, & Nardi, 2011). Furthermore, as patients with anxiety and depression have poorer adherence to post-discharge rehabilitative programs, screening participants in the present study was important given that low or non-adherers could be identified and referred to their general practitioner (GP) if required (Davidson et al., 2008; Sardinha et al., 2011).

The urgency to undergo coronary artery catheterisation and PCI, along with the short length of stay often, precludes effective patient education and can cause the patient anxiety (Astin et al., 2005; Astin et al., 2009; Cronin et al., 2000; Davis et al., 1994; Kattainen et al., 2004; Tooth & McKenna, 1995). The literature identifies patient anxieties surrounding PCI as being awake intra-operatively and potential post-operative complications (Chair & Thompson, 2005; Corones et al., 2009; Harkness, Morrow, Smith, Kiczula, & Arthur, 2003; Kern, 1999; Koo & Brouwer, 2001). Astin et al. (2009) and Carroll (2005) identify how the speed of treatment required for primary PCI is often overwhelming and indicate that patients endure diverse emotional reactions as a result of this experience. Carroll (2005, p. 15) further highlights that hospital education for patients is "less than optimal" in that patients are suffering various levels of psychological distress and their capacity for learning and information retention is often diminished. Carroll (2005) also identifies how the complexity of information type also contributes to patient and family confusion during this time. Furthermore, Jaarsma, Kastermans, Dassen, and Philipsen (1995), Kristofferzon et al. (2007), and Roebuck, Furze, and Thompson (2001) reinforce the emotionality surrounding patients who undergo cardiac events and identify how patients in this group assign high importance to their emotional state—this is highlighted in the following literature presented.

In 2001, Denollet and Brustaert undertook a non-RCT in 150 CR male participants with diagnosed CHD in Belguim. The authors investigated the effects of CR on emotional distress and mortality over time, as the literature suggested psychological improvements in CR patients may predict patient outcomes. The authors reported enhanced emotional states, while also suggesting that the improvement in short-term emotional wellbeing as a way to enhance long-term prognosis. Denollet and Brustaert recommended further interventions for CHD sufferers to reduce emotional distress, therefore highlighting the importance of the present study.

West, Rose, and Brewis (1995) reinforce the presence of emotionality after a coronary event and identify how CHD sufferers experience clinical levels of distress for up to 12 months while undertaking CR. The authors highlight how emotional distress may lead to poor adherence (particularly to the advice of medical practitioners), decreased return to work, greater use of the medical system, and increased risk of mortality (West et al., 1995, p. 168). There are many contributing factors attributed to a poorer recovery and may include personality type and lifestyle (West et al. 1995). Good social support, modification of personality-type behaviours, and making lifestyle changes greatly influence post-coronary event outcomes such as associated mortality and esteem support (West et al., 1995).

Dehdari et al. (2008) reinforce the effects of anxiety post cardiac event and, in particular, highlight the effects on quality of life (QOL), morbidity, mortality, and potential rehospitalisation. The authors report a sixfold increase in MI and death in patients who are clinically anxious. Importantly, an individual's social support network and SE have been identified as pertinent factors in post-event survival. The authors advise that education and emotional support post-PCI are not as widely

recognised as with CABG patients. Dehdari et al. (2008) highlight that, as the length of stay post-PCI is considerably shorter (as compared to CABG surgery), there is limited time for education and psychological intervention. Moreover, with the aforementioned issues surrounding the post-PCI period the authors undertook a study measuring anxiety, SE and perceived social support in this group of patients. The results displayed higher anxiety in PCI participants (as compared to CABG participants) and lower perceived social support. They found that SE in PCI participants was high (Dehdari et al., 2008). Again, this study reinforces the need for an early post-discharge, nurse-led educational intervention for post-PCI patients to try to enhance SE and reduce anxiety suffered during this time.

Holt et al. (2013) investigated the association between anxiety, depression, and CVD in 1,578 men and 1,417 women using the Hospital Anxiety and Depression Scale (HADS). The results revealed a greater association between CAD and those who had anxiety and depression. Furthermore, depression and the risk of CVD was found to be twofold higher in those likely to have depression. Anxiety in study participants was consistent with findings in other studies, presenting in approximately 30% of participants. There is evidence to suggest a synergistic effect of anxiety and depression and the risk of increased cardiac mortality, especially in those with generalised anxiety disorder and major depression (Phillips et al., 2009). Furthermore, depression itself has a "bidirectional" effect with CVD, meaning that depression is both the cause and consequence of CVD (Holt et al., 2013).

Lichtman et al. (2008) highlight how depression is threefold higher in those who experience an AMI compared to the general population without CHD. Furthermore, of those diagnosed with an MI, approximately 15–20% of these patients meet depression criteria, while a larger number of patients present with

significant depressive symptoms (Lichtman et al., 2008). Lichtman et al. also highlight how the prevalence of depression in PCI, CABG, valve replacement, and unstable angina is similar to that found in AMI. Colquhoun et al. (2013, p. 1) reinforce this prevalence rate reporting major depression in approximately 15% of patients post-AMI or CABG, while those with mild depressive symptoms post cardiac event occur in approximately 40%. Colquhoun et al. recommend screening patients for depression; however, do caution the diagnosis of depression in this group due to the similar symptoms experienced such as tiredness and limited energy. Furthermore, diagnoses may also be masked by patients' response to their illness and report denial, avoidance, withdrawal, and anxiety as barriers to depression diagnosis (Colquhoun et al., 2013).

A meta-analysis investigating the relationship between anxiety and CHD was undertaken between 1980 and 2009 (Roest, Martens, de Jonge, & Denollet, 2010). A strong relationship between anxiety and CHD was found, with patients suffering anxiety being 26% more at risk for CHD (Roest et al., 2010). Roest et al., (2010) highlight how having anxiety may predict future cardiac events, identifying that symptoms of anxiety can predict the onset of CHD approximately 11.2 years later. Furthermore, there was a strong association between anxiety and cardiac death, with anxiety sufferers 48% more at risk of death as a result of a cardiac event. Also, being depressed placed participants at greater risk of CVD by 46% and at 55% increased risk of cardiac mortality (Roest et al., 2010). While depression is clearly highlighted as a strong risk factor for CVD, as identified, considerable research has been undertaken investigating and supporting this relationship. As reported, attention has become increasingly focused on anxiety and its effects on the coronary vasculature and cardiac events, demonstrating significant effects on vascular dysfunction and

cardiac events equal to that of depression (Stillman et al., 2013). While the mechanisms of anxiety are not yet identified, a strong relationship exists (Stillman et al., 2013). Thus, while anxiety and depression often coexist, in the present study the effects of the nurse-led clinic and SE effects on both anxiety and depression were investigated.

The AIHW (2011) also identify the influential nature of depression on other CVD risk factors. For example, inactivity in a person with depression can lead to a more sedentary lifestyle and the uptake of smoking than among a non-depressed person. Poor social support networks and social isolation were recognised as causes of CVD in those with depression (AIHW, 2011). Thus, with a greater risk for post-event mortality and a short hospitalisation, it is essential that the early detection and management of psychological distress occurs (Davidson et al., 2008). Moreover, as the primary focus on the treatment of cardiovascular events is a high priority, psychological distress may not be recognised (AIHW, 2011; Davidson et al., 2008; Lane et al., 1999; Turner et al., 2010). It was therefore the intention of this study to detect psychological distress early, and refer participants for appropriate and timely management. With the link between psychological distress and cardiac events, the PI sought to measure stress experienced by participants via salivary cortisol levels. The following subsection discusses the measurement of salivary cortisol as a biological marker of stress.

2.3.1 Stress and Salivary Cortisol Measurement

Cortisol is "a glucocorticoid and is synthesised from cholesterol, secreted by the adrenal cortex and released into the blood" (Bozovic, Racic, & Ivkovic, 2013, p. 375) and is released during the body's response to stress (Smyth, Hucklebridge, Thorn, Evans, & Clow, 2013). Smyth et al. (2013) identify that the release of cortisol

is often understood to demonstrate a stress–health relationship. Given that 25% of serum cortisol is metabolised by the liver and 75% by the kidneys, salivary cortisol measurement has become increasingly popular as opposed to blood or serum cortisol (Bozovic et al., 2013). Bozovic et al. (2013) highlight how taking blood or serum cortisol may cause the patient further stress resulting in a false-positive result, that the test does not measure biologically active cortisol and may be affected by illness and medications (Bozovic et al., 2013). In the last decade saliva collection has become a significant diagnostic method undertaken in areas of psychology to investigate social factors and cortisol release (Smyth et al., 2013; Streckfus & Bigler, 2002).

The technique for measuring salivary cortisol is uncomplicated, while cortisol has been identified as highly stable (Bozovic et al., 2013). Salivary cortisol samples may be left at room temperature for up to 4 weeks unaffected, after which it must be stored at -20 degrees Celsius (Bozovic et al., 2013). It is best measured in the morning due to the highest readings attained within 30 to 50 minutes of awakening (Bozovic et al., 2013).

Bozovic et al. (2013) also highlight how episodes of acute stress (i.e., physical, biological, psychological) have been shown to considerably increase the secretion of cortisol with blood levels at their peak within 10 to 30 minutes of exposure to the stressor. As highlighted by Bozovic et al. the benefits of using salivary cortisol is in its ease of measurement in both the natural or laboratory setting, the fact that it is non-invasive and does not stimulate further stress in the participant. Moreover, Smyth et al. (2013) highlight the importance of measuring cortisol in that it may validate or contribute to patient self-report data attained. Thus, as participants in the present study may have encountered acute episodes of stress (i.e., both biological

and psychological) during their hospitalisation, after reviewing the literature the PI decided to measure salivary cortisol.

In addition to emotional distress, participants who experience a cardiac event or PCI procedure have other needs to be met during hospitalisation including education. Section 2.4 will discuss patient education, issues surrounding in-patient delivery of information, and timing for best impact.

2.4   Education, Timing, Repetition and Modes

2.4.1   Timing of Patient Education for Highest Impact

Previous research in this area has explored participant information needs and best timing for delivery of education (Brezynski et al., 1998; Corones et al., 2009; Gaw, 1992; Gulanick et al., 1998; Murphy et al., 1989; Tooth & McKenna, 1995; White & Frasure-Smith, 1995). A number of studies recommend that, although timing is important, the most effective method of patient education is to individually tailor the information to suit each patient's needs (Corones et al., 2009; Page, Jackman, & Snowden, 2008). A large group of studies have also trialled nurse-led initiatives that involve pre and/or post-procedural and post-discharge education (Brezynski et al., 1998; Catherine, 2005; D'Amore, Murray, Powers, & Johnson, 2011; Gaw, 1992; Gould, 2009; Gulanick et al., 1998; Johnson, Inder, Nagle, & Wiggers, 2001; Murphy et al., 1989; Scherrer-Bannerman et al., 2000; Tooth & McKenna, 1995; White & Frasure-Smith, 1995). These studies have assessed the use of a variety of information delivery methods, including telephone and internet communication, take-home lists of informative websites, and pocket-sized information cards (Brezynski et al., 1998; Catherine, 2005; D'Amore et al., 2011; Gaw, 1992; Gould, 2009; Gulanick et al., 1998; Murphy et al., 1989; Scherrer-Bannerman et al., 2000; Tooth & McKenna, 1995; White & Frasure-Smith, 1995).

While timing for education and specific interventions have been trialled in other studies, the present study aimed to meet post-discharge period needs at a more comprehensive level through tailored face-to-face education, physical examination, and the measurement of anxiety, depression and management (if required), along with referral to CR.

Recommendations for teaching include the procedure and comprise the following content areas: intravenous therapy, bed-rest post-procedurally, nutrition, medications, post-discharge complications management, and activity levels (Corones et al., 2009; Kern, 1999). The requirement for immediate and ongoing education is essential among this group of patients as they perceive themselves to be cured of CAD post-PCI, although this is clearly not the case (Astin et al., 2009; Gaw, 1992; Sampson, O'Cathain, & Goodacre, 2009).

In addition to the benefit of education in general to gain greater knowledge and skills, is it essential to educate patients as this may also result in the reduction of anxiety (Palmer, 2007). As identified, a number of studies argue the preferred timing for patient education; however, what is of most importance is the focus of an individualised education program to enhance SE and reduce patient anxiety (Palmer, 2007). Palmer (2007) undertook a preoperative nurse-led educational intervention for plastic surgery patients to evaluate if they experienced less anxiety, greater post-operative confidence and knowledge. After undertaking the intervention, participants in this group reported less anxiety, as measured pre and post-intervention using the State-Trait Anxiety Inventory (STAI) when compared to standard-care group participants. As the study by Palmer (2007) was a preoperative intervention and the patients were different to the present study (i.e., plastic surgery patients as opposed to PCI patients), the question of timing of patient education, as identified above,

should be continuous throughout hospitalisation and information individualised (Corones et al., 2009; Kern, 1999; Koo & Brouwer, 2001; Page et al., 2008).

Dracup et al. (2009) held education groups for patients with CAD with the aim to reduce hospital admission time. The authors highlighted to patients the management of their ACS symptoms should they reoccur. Although results did not demonstrate a reduction in time-delay as hypothesised, patients involved in the experimental group were shown to be more conscious of their actions in the event of chest pain symptoms. These included the self-administration of aspirin and the reporting of symptoms to emergency services within the first 6 months of attending the ACS clinic as opposed to the responses of those in the control group (Dracup et al., 2009). Thus, as patients in Dracup et al.'s study benefited from the education providedit was hoped that patients in the present study may benefit in knowledge as education is reiterated early in the post-discharge period.

It is, therefore, for the following reasons that the present study was undertaken:

- Patients who experience a cardiovascular event may experience psychological distress (i.e., anxiety and depression).
- The presence of anxiety prevents the absorption and retention of vital information, and thus, inhibits patient learning.
- This group of patients may not display symptoms of anxiety and depression until days to weeks post-event.
- Cardiovascular patients are discharged after a short hospitalisation.
- The short hospitalisation precludes effective nurse-teaching.

After experiencing a cardiac event and PCI, patients often await CR, cardiologist, and/or GP follow-up at approximately 7 to 64 days. (AIHW, 2011; BHF, 2009, 2010; Carroll, 2005; Cupples et al., 2010; Dafoe et al., 2006; Goble &

Worchester, 1999; Kattainen et al., 2004; Kristofferzon et al., 2007; Lacey et al., 2010; Lane et al., 1999; Lauck et al., 2009; NHFA, 2010; Wenger, 2008; Young & Murray, 2011).

Thus, it was because of the aforementioned reasons that this nurse-led intervention was undertaken within the first 5 to 7 days post-PCI. While the timing of patient education is highlighted, issues surrounding referral to and attendance at secondary prevention or CR programs will be considered. Section 2.5 discusses barriers and initiatives concerning CR programs.

2.5   Post-Discharge Problems

2.5.1   Cardiac Rehabilitation: Timing, Barriers, and Initiatives

Participation in a secondary prevention or CR program is strongly advised in the post-discharge period. Cardiac rehabilitation is a secondary preventative service available to patients who have experienced a cardiovascular event (Australian Cardiovascular Health & Rehabilitation Association [ACRA], 2008). Cardiac rehabilitation encourages positive behavioural changes, promotes self-management of the disease process with an aim to return the individual to normal ADLs and, thus, prevent future cardiac events (ACRA, 2008). In Australia, the commencement of a CR program is recommended to begin on admission to hospital and continue with an outpatient phase, followed by a maintenance phase (ACRA, 2008; Goble & Worchester, 1999). Canyon and Meshgin (2008) highlight the reduction in hospital readmissions in patients who attend CR as opposed to those who do not. In their study of 308 patients, 110 attended CR and 198 did not (Canyon & Meshgin, 2008, p. 576). Of the 198 non-attending, 56 were readmitted to hospital, with only nine patients readmitted in the CR intervention group, demonstrating the importance and effectiveness of attending CR (Canyon & Meshgin, 2008, p. 576).

Outpatient CR programs are ideally recommended to commence within several days post-discharge. Courses vary in length from 4 to 12 weeks in Australia, 6 to 12 weeks in the UK, 2 to 24 weeks in Europe, and 35 days to 6 months in the US (BHF, 2009, p. 19; Bjarnason-Wehrens et al., 2010, p. 413; Briffa et al., 2009, p. 683; Dafoe et al., 2006; NHFA/ACRA, 2004, p. 6; Pack et al., 2013; Thomas et al., 2007, p. 1617). The European Society of Cardiology (ESC) advise the commencement of the outpatient phase within 7 to 14 days after a primary PCI for STEMI patients and after 24 hours for elective PCI patients (Wijns et al., 2010). For patients who have extensive damage to the myocardium, it is recommended that they are clinically stable prior to commencing CR (Wijns et al., 2010).

Although recommendations suggest early CR commencement, the literature has identified waiting times to commence up to 1 month or more post-PCI (BHF, 2009; Goble & Worchester, 1999; NHFA, 2010; Wenger, 2008). Goble and Worchester (1999) and Worcester, Murphy, Mee, Roberts, and Goble (2004) highlight the many barriers to the commencement of a CR program and identify the short hospitalisation period, as well as patient anxieties during this time, are obstacles to effective in-patient education and referral. Furthermore, the patient's perception that CR is unwarranted may also contribute to their decision not to partake in the program (Worcester et al., 2004). Bethell et al. (2006), Briffa et al. (2009), Bunker and Goble (2003), and Dolansky et al. (2010) further identify patient and CR commencement delays that may include poor funding, the patient's health status, demographic and societal issues, and poor practitioner referral. These issues are not only on a national scale but internationally, with reports of worldwide under-referral and attendance rates to CR programs post-discharge (BHF, 2009; Dafoe et al., 2006; Fernandez, Salamonson, Juergens, Griffiths, & Davidson, 2008; NHF,

2010; Wenger, 2008).

Grace et al. (2012) undertook a study of patients, CR programs, and specialists regarding CR wait times, while comparing current wait times and perceived reasons behind this delay. Participants reported a mean of 65.6 $\pm$ 88.4 days after hospital discharge and commencing a CR course. Approximately 91.5% of patients reported this wait time as satisfactory; however, noted that their preferred wait time was between 33.1$\pm$22.3 days. It was interesting that PCI patients reported a preference for a shorter wait time than patients who had been admitted for a CABG, pacemaker, or arrhythmia. As identified earlier, hospitalisation for PCI is an anxious time coupled with the short time for hospitalisation and limited nurse–patient teaching opportunities (Grace et al., 2012). In Grace et al.'s study, specialist and CR teams were of the opinion that patients were commencing at favoured wait times, while CR teams also believed benchmarked times were being met. The aforementioned issues surrounding CR wait times not only reinforce the need for a post-PCI, nurse-led clinic—as it aims to enhance SE and reduce anxiety—but its secondary aims to reduce symptoms of depression and encourage effective self-management are relevant. Thus, as patients await CR program commencement, the nurse-led clinic may offer early post-discharge support, reiteration of education, with the aim of increasing patients' confidence or SE by enhancing knowledge and understanding the benefits of attending CR.

Briffa et al. (2009) performed a systematic review of secondary prevention programs in the literature with the aim to promote change and allow for the enhancement of CR and secondary prevention within Australia. The authors identified a set of strategies that may assist in overcoming barriers to commencing a CR program. Strategies included communication between the healthcare practitioner

and the CR team, an automatic referral system, flexibility in the program, and a personalised, culturally sensitive approach (Briffa et al., 2009). Additionally, Bunker and Goble (2003) identified the poor suitability of CR to certain societal groups, including elderly women, non-English-speaking persons, Indigenous Australians, patients of low socioeconomic status and from rural areas. Bunker and Goble (2003) recommended similar strategies as highlighted by Briffa et al. (2009) including the further investigation and rectification of referral issues, the individualisation of the program, and content at an organisational level (Bunker & Goble, 2003).

As a result of the under-referral and non-attendance of patients at CR, the BHF (2009), Bjarnason-Werens et al. (2010), Lloyd-Jones et al. (2010), the NHFA (2010), and Wijns et al. (2010) highlighted the importance of, and sought to rectify, this problem over time through the composition of new CR guidelines and initiatives. In particular, the NHFA (2010, p. 3) in Australia developed a set of nine actions aimed at "governments, health system planners, policy makers, health professionals and consumers" in a plan to improve the health of all Australians with new and previously diagnosed CVD. These actions aim to promote secondary prevention programs, enhance program accessibility, and patients' health (NHFA, 2010). Lastly, it is through the implementation of the nine actions that may allow for a decrease in the morbidity and mortality rates associated with CVD (NHFA, 2010). Additional initiatives to improve CR attendance have also included early post-discharge orientation (within 10 days post-discharge). Pack et al. (2013) undertook an RCT of 150 patients and assessed whether early enrolment appointment would encourage attendance to the first CR orientation session. This intervention proved to be effective with recommendations to apply this intervention on a national level (Pack et al., 2013).

This critical review of the literature undertaken for this study has highlighted that a gap between the day of discharge, review by a cardiologist, and the commencement of a CR program exists. Furthermore, as a large number of under-referrals and poor attendance to CR has been identified, this study aimed for a 100% referral and attendance rate. Further to the issues surrounding the post-discharge period are matters concerning medication adherence and compliance. Subsection 2.5.2 identifies the types and reasons for medication non-compliance.

2.5.2 Medication Adherence, Compliance, Barriers, and Management in PCI and Chronic Disease

Based on current evidence-based practice, a patient experiencing a cardiac event and PCI for the first time will be discharged on an average of six new medications (based on A and B grade recommendations and in addition to medications prescribed for other co-morbidities) (Aroney et al., 2006). This may create various problems surrounding medication adherence and compliance. Brown and Bussell (2011) identify the difference between adherence and compliance in that adherence refers to the patient being in full understanding and agreement with the medications and regime, while compliance suggests a submissiveness and obedience.

Brown and Bussell (2011) identify 50% of patients with chronic illness are non-compliant with their medications and highlight how non-adherence contributes significantly to mortality and is costly to the healthcare system. Brown and Bussell undertook a literature review of articles relating to CVD, health literacy, medication adherence and pharmacotherapy between 1990 and 2010. Brown and Bussell highlight long-term medication adherence issues in patients with CVD, especially in adherence to hypoglycaemics (lowers blood glucose), anticholesterolaemics (reducing cholesterol), and antihypertensives (lowering blood pressure). In the group

of CVDs, the authors draw attention to non-adherence in patients who have experienced a cardiac event and highlight non-adherence in approximately 50–80% of patients prescribed antihypertensive medications. Their literature search uncovered several issues surrounding medication adherence and involve the patient, the physician, and the healthcare system. Table 2.1 identifies the factors presenting as barriers to medication adherence as highlighted by Brown and Bussell (2011).

Table 2.1.   Medication adherence barriers for patients in CVD

Factors affecting medication adherence and barriers in CVD		
Patient factors	**Physician factors**	**Healthcare system factors**
limited understanding of their illness	failure to identify non-adherence	system barriers
limited participation in their treatment	prescription of a complicated medication regime	poor access to care
poor health literacy	poor communication	medication cost
health misconceptions	not identifying of medication side effects and benefits	co-payments
medication misconceptions	financial burden to patients not reflected on	limited health information technology access (for treating doctors)
prior medication utilisation	not attaining appropriate medication history	
poor motivation	(i.e., use of alternative medicines)	
cost		limited consultation time
socioeconomic status		
transportation issues		
poor social support networks		
pharmacy wait times		
poor information recall		

Source: Brown & Bussell (2011)

Patient-related factors: Solutions to medication adherence issues

While medication adherence is complex, there are approaches to achieving enhanced adherence and thus, better patient health and wellbeing (Brown & Bussell, 2011). The strategies involve consideration of the aforementioned problems and providing alternate solutions to encourage patient empowerment and medication adherence (Brown & Bussell, 2011). The authors highlight that for patient-related factors, education programs engaging in formal patient education may encourage medication adherence. For patients who may not have access to a formal educational program, offering a variety of information (i.e., books, internet) and community

resources (i.e., libraries, pharmacists, courses) may encourage medication adherence. Further interventions, such as improving patient health literacy is discussed with alternative information sources to be offered (i.e., visual and/or audio) to meet the needs of the. Moreover, acknowledging the financial burden on patients and referring them to programs that offer financial support may also facilitate medication adherence. As the issues surrounding medication adherence are complicated, the authors highlight a multifaceted approach to management and given its complexity (Brown & Bussell, 2011).

Physician-related factors: Solutions to medication adherence issues

Brown and Bussell (2011) also highlight the importance of effective communication and patient-centredness in enhancing the physician–patient relationship and encouraging medication adherence. Involving the patient in their care and decision-making may empower the patient and thus, encourage adherence. It is also encouraged that physicians be more culturally aware and acknowledge cultural beliefs to create a trusting relationship. Furthermore, offering praise (as opposed to blaming) is also encouraged in achieving goals and will also lead to better medication adherence. By asking the correct questions, physicians may gain further insight to patients' medication regimes and adherence status. Questions recommended example include: "Of the medications you listed, which ones are you taking" and/or "Have you had to stop any of your medications for any reason?" (Brown & Bussell, 2011, p. 310). Lastly, establishing an easier medication regime (i.e., once per day frequency) may encourage or improve adherence as the effects of daily dosing has been proven to encourage medication adherence (Brown & Bussell, 2011).

Healthcare system related factors: Solutions to medication adherence issues

As identified above in Table 2.1, Brown and Bussell (2011) highlighted the time constraints for physician consultation as barriers to medication adherence. Solutions offered to increase consultation time include the training of staff and encouraging a "team-based approach" (p. 311) to undertake responsibilities of the physician, so that the physician may have more time to discuss issues such as medication adherence. Alternatively, other suggestions to assess and address medication adherence include consultations with pharmacists, office personnel, medication reminder services (i.e., telephone), highlighting available internet resources, or case manager referral (Brown & Bussell, 2011).

The use of electronic systems for prescribing and medical records are also offered so that at-risk patients may be identified and flagged for intervention. Interventions may include automatic medication reminders to patients to have medications dispensed, while physicians may also be reminded if their patient has not had their prescriptions filled. Furthermore, the commencement of all long-term medications during hospitalisation and the creation of medication lists may also prove to be effective in encouraging medication adherence. As these issues of medication adherence and solutions are multifaceted, patient medication administration and handling issues will be discussed further.

Rudd, Ramesh, Bryant-Kosling, and Guerrero (1993) investigated the medication administration behaviours in cardiology clinic and primary care patients. An important finding reinforced by additional research highlights what is described as 'outpatient subgroups' (Rudd et al., 1993). These groups consist of the following:

- "near-optimal compliers": included 50 to 60% of participants; are aware of the benefits of medication administration; and believe they

are effective in self-administration and adherence and compliance.

- "partial compliers": are accepting of treatment concept; have poor adherence; and most commonly omit medications.

- "noncompliers": have good intentions; and have very poor adherence (i.e., medication administration just prior to doctor review). (Rudd et al., 1993, p. 665)

Fernandez, Davidson, Griffiths, Juergens, and Salamonson (2007) identify high medication adherence in post-PCI patients; however, they also highlight poor medication storage and individual cessation of medications undertaken unnecessarily by the patient. Two percent of patients ceased their medications after believing they felt better and they were no longer necessary, while 4.5% ceased medications as they believed they were feeling worse (Fernandez et al., 2007, p. 57). An additional 5% did not take medications as they were going on an outing (Fernandez et al., 2007, p. 57). Approximately 7.5% of patients were reported to have missed 1 to 3 tablets within a period or 1 week, while 2% missed 4 and more medications within 1 week (Fernandez et al., 2007, p. 57). Furthermore, 4% were unable to recall if they consumed their medications (Fernandez et al., 2007, p.57).

It is, therefore, imperative that patients are well educated on their medications and the importance of adherence and compliance. Post-procedural complications also present as a problem in the post-discharge period. Subsection 2.5.3 will discuss post-procedural complications and hospital readmissions in post-PCI patients.

2.5.3 Post-procedural Complications and Readmission

Post-procedural complications and self-management were investigated throughout the course of the present study as part of its secondary aims. It was hoped that the one-on-one nurse-led support and reinforcement of patient education may

facilitate effective self-management by increasing SE. Early post-PCI complications may include chest discomfort, bleeding (both puncture site and other), pseudoaneurysm, pulmonary emboli, deep vein thrombosis, contrast-induced allergies, and renal failure (Bates, 2008; Laarman & Dirksen, 2010; Perret et al., 2009). Gallagher et al. (2008, pp. 73-74) assessed chest pain in 129 post-PCI patients at both 4 and 10 weeks post-PCI. The authors reported 68% of patients experienced chest pain up until 10 weeks post-PCI, with CR identified as an important service in educating patients on the identification and management of these symptoms during this time (Gallagher et al., 2008, p. 76). Patients in a study by Burney, Purden, and McVey (2002) identified the need for more information on the post-discharge period, recommending information on chest pain and management, return to physical activities, management of stress, complication identification, and family education. The authors recommend an educational intervention for discharge that not only meets patients' needs but is also conducive to the working environment in a hospital setting (Burney et al.). Thus, as post-discharge capabilities and psychological distress have been highlighted as an important aspect of patient education, the present study measured participant anxiety and depression.

In a retrospective observational analysis, Gupta et al. (2010, p. E1049) highlight the number of readmissions to four hospitals in the USA over a 1-year period, 2095 of whom underwent PCI. The authors identify that, of the 2095 patients, 1070 patients were readmitted. Of the 1070 readmissions, 254 patients underwent revascularisation. Importantly, 148 patients returned with angina, 32 experienced an MI, 61 experienced heart failure, 20 were diagnosed with cardiac arrhythmias and 51 with IHD. These results reinforce the importance of the present study and the reiteration of symptom identification and management education as a

way to reduce hospital readmissions.

Curtis et al. (2009, p. 904) performed a retrospective analysis of 315,241 patients who had undergone PCI in the USA. Curtis et al. (2009, p. 906) identified that, within 30 days post-PCI, 1 in 7 patients are readmitted to hospital, with approximately one-quarter of participants requiring repeat PCI. Other causes for readmission within 30 days post-discharge included vascular complications, bleeding, and contrast-induced nephropathy, while other patients were required to return as their revascularisation procedure was to be undertaken in stages. Lastly, other causes for readmission were of cardiovascular origin and co-morbidity related (Curtis et al., 2009).

In the UK and Belgium, Fox et al. (2010, p. 2756) studied a total of 3,721 ACS patients over approximately 5 years. In the UK group of patients ($n = 2065$) 320 patients experienced an MI within 24 hours and up to 5 years after their first event (2010, p. 2759). Furthermore, in the UK, 292 of these patients underwent PCI and 393 underwent revascularisation procedures taking place within 6 days after the index procedure. These results identified the need for early post-discharge period follow-up, support, and education, with a focus on short- and long-term post-PCI cares and self-management. Referral and attendance to a CR program to reinforce post-discharge education and long-term health management was deemed paramount.

McCaul, Hobbs, Knuiman, Rankin, and Gilfillan (2004, p. 1036) studied 423,922 Western Australian patients over a 20-year period to determine whether there was a decline in repeat revascularisation procedures and/or mortality in patients who had previously undergone PCI or CABG. The authors highlight a significantly higher risk of repeat revascularisation procedures after undergoing the first PCI procedure (as opposed to CABG) (McCaul et al., 2004). Furthermore, from the

period 1980–2001, McCaul et al. (2004, p. 1043) identified a change in the characteristics of these patient groups, but in particular noting from 1989 to 1990 the risk of repeat PCI within one year being greater than 30%, with CABG less than 2%; whereas from 2000 to 2001, the risk of repeat revascularisation after 2 years had decreased to 12.4% with repeat CABG risk after 2 years declining further.

The data evidenced above reinforced the importance of the present study. Not only did they highlight the groups in the population at risk for repeat revascularisation (be it PCI or CABG surgery), but they established the need for an early post-PCI intervention providing post-discharge support, while reiterating post-procedural education and encouraging post-discharge self-management. Furthermore, with the repetition of education—and in a one-on-one, face-to-face environment—it was hoped that participants could identify and appropriately manage any complications, symptoms (i.e., angina) and, thus, effectively self-manage. With early review of access sites, a 100% referral and initial attendance to CR was to be achieved, it was therefore anticipated that, with the early repetition of education, participants' SE would be enhanced, they would experience less anxiety, reduced depressive symptoms, and may effectively manage post-discharge and beyond with reiteration, support, and long-term follow-up in CR. Another issue occurring post-procedurally is that of haematomas and this will be discussed in the following subsection.

2.5.4 Haematoma: Signs, Symptoms, and Assessment

Haematomas are a common complication after undergoing PCI (Higgins, Theobald, & Peters, 2008; O'Grady, 2007; Sherev, Shaw, & Brent, 2005). Banfić et al. (2008, p. 386) observed the access sites of 319 patients who underwent coronary artery catheterisation by using ultrasound at 24 to 48 hours after the artery was

successfully manually sealed. In this group, 232 patients underwent coronary angiography and 87 underwent PCI (p. 385). The authors highlighted the most common complications being haematoma, pseudoaneurysm, arteriovenous fistula, and femoral artery dissection (pp. 386–388). Approximately 5.3% of patients experienced a pseudoaneurysm, while 15.1% developed haematomas (p. 386). These results, therefore, highlight the need for the present study to identify potential post-discharge complications early.

Sherev et al. (2005) in their study of 868 diagnostic cardiac catheterisations and 702 PCI cases noted specific vascular-related complications post-procedurally (p. 198). From the 1,570 femorally catheterised patients, the authors reported 20 haematomas, six retroperitoneal haemorrhages, two pseudoaneurysms, and five femoral artery dissections (p. 198). Complications were reportedly due to the arteriotomy location; however, the authors highlight how additional factors may predispose a patient to access site complications (Sherev et al., 2005). They include the following:

- female gender;

- weight (over and underweight);

- older age;

- uncontrolled hypertension;

- previous catheterisation at the same site;

- high level of anticoagulation;

- larger arterial sheaths;

- renal failure;

- concomitant venous sheath;

- prolonged sheath duration. (Sherev et al., 2005, p. 200)

The discussion of radial versus femoral approaches, as identified earlier, is present in the literature. Patients who are appropriate candidates for a transradial approach usually suffer less haemorrhagic complications when undergoing PCI (Koutouzis, Matejka, Olivecrona, Grip, & Albertsson, 2010). While haemorrhagic complications are reportedly low, post-PCI haemmorhage can still occur; however, there is lower risk associated with this procedure (Koutouzis et al., 2010; Rao et al., 2008; Ziakas et al., 2010). Thus, as access site complications can occur within hours post-procedurally and up to 1 year post-discharge, participants were followed up in this study as soon as 5–7 days post-discharge (Higgins, Theobald, & Peters, 2008; Sherev et al., 2005).

With vascular complications identified above, Ndrepepa et al. (2010, p. 297) highlight how PCI-related haemorrhage most commonly occurs in patients who present with a higher "cardiovascular risk profile" or those who have additional co-morbidities pre-PCI. The authors advise that patients who have an increased risk of bleeding at the time of PCI are most likely to die in the first 3 months post-PCI (Ndrepepa et al., 2010, p. 297).

Signs of a haematoma are assessed by observing any swelling to the inguinal area, if access was via the femoral artery (O'Grady, 2007). Assessment of the arm or wrist are required for brachial or radial approaches (O'Grady, 2007). Tingling and numbness to both lower limbs and digits should be assessed as recommended by O'Grady (2007). Bruising is common and may also accompany the haematoma and spread down the leg or arm. Bruising may begin as a "dark blue to greenish yellow" colour (O'Grady, 2007, p. 27). In addition to the complication of bruising, a pseudoaneurysm may also be experienced. Subsection 2.5.5 discusses this complication and methods to confirm the diagnosis.

2.5.5 Pseudoaneurysm

A pseudoaneurysm is another commonly identified complication associated with coronary artery catheterisation and PCI and is often referred to as a "false aneurysm" (Banfić et al., 2008; O'Grady, 2007, p. 27). A pseudoaneurysm forms when the artery accessed for PCI is not adequately sealed due to an insufficient application of pressure (O'Grady, 2007). A haematoma with a surrounding casing then forms with a connection maintained to the artery accessed, forming a hardened, lumpy, bounding mass that can be heard with a stethoscope placed over the access site (O'Grady, 2007). An ultrasound can verify this finding. A pseudoaneurysm may resolve naturally; however, should the mass enlarge, the patient may need to undergo a non-surgical, ultrasound-guided procedure to repair the aneurysm (O'Grady, 2007). As identified earlier, the study by Banfić et al. (2008) highlighted pseudoaneurysm as a common complication in PCI patients. Furthermore, the authors reported 5.3% of their patients having experienced a pseudoaneurysm between 24 to 48 hours after haemostasis had been achieved (Banfić et al., 2008, p. 386). These results, therefore, highlighted the importance of undertaking the post-PCI, nurse-led clinic, so that possible complications could be detected early. Stethoscope auscultation just above the incision site to assess for a bruit should be undertaken and is characterised by "an extra whooshing sound" heard over the vessel (O'Grady, 2007, p. 241). Access site infections may also occur post-PCI and these post-discharge complications will be identified next.

2.5.6 Post-PCI Access Site Infection: Signs and Symptoms

Wong et al. (2006) identify how access site wound infections may occur; however, they are rare and mostly identified in patients who have a closure device present to seal the artery (i.e., Angioseal, Femoseal, Perclose). Wong et al. highlight

how wound site infections post-PCI may lead to femoral arterial rupture if not treated and highlight the importance of antibiotic treatment for this if an infection occurs. Similarly, Merriweather, and Sulzbach-Hoke (2012) reinforce the low rate of access site infections in post-PCI patients, highlighting that <0.1% of patients may be affected. The authors identify that access site infection causes may include extended arterial sheath presence, insertion technique, personal hygiene issues, and closure device used (Merriweather & Sulzbach-Hoke, 2012). Prada-Delgado et al. (2011) undertook a study of 558 patients and compared the safety and efficacy of vascular closure devices ($n = 464$) versus manual compression ($n = 94$) in patients who experienced a primary PCI (PPCI). While closure devices proved to be safe and have a lower risk of a major vascular complication, the authors also identified the presence of access site infection in this group. While only a lower risk of infection in the closure device group (0.2%), no participants in the manual compression group experienced an infection, therefore, demonstrating the increased risk (although low) of access site infections (Prada-Delgado et al., 2011).

Signs of infection in PCI patients should be assessed by taking the patient's body temperature and observing the access site for any redness, palpating the area, and feeling for any heat, swelling or site pain (Gould, 2001). Furthermore, accompanying an access site infection may be a pus-like and odorous ooze (Gould, 2001). O'Grady (2007) recommends that patients who are, and continue to be, febrile should have pathology tests taken, along with a urine specimen. Importantly, contrast dye used in the procedure may also result in an increase in body temperature; however, this usually resolves within 24 hours (O'Grady, 2007). Other post-discharge concerns include angina (i.e., chest pain) and patient self-management, these will be reviewed next.

2.5.7 Chest Pain: Angina Identification and Management

Chest pain in the post-discharge period could potentially indicate "stent thrombosis or re-stenosis" (Levine et al., 2003, p. 130). Levine et al. (2003, p.130) highlight re-stenosis in <10% of patients with bare metal stents and 10–20% of patients with drug eluting stents. Furthermore, the authors identify in-stent re-stenosis occurring within 1 to 8 months post-PCI, with most patients (i.e., 25–85%) presenting with exertional angina symptoms (Levine et al., 2003, p. 129). The occurrence of stent re-stenosis thus reinforces the study's primary endpoint of 1 month (Time 3) post-discharge from hospital (Levine et al., 2003). Additionally, with stent thrombosis occurring in approximately 1% of PCI patients, those presenting with chest pain within days to weeks post-PCI require hospital readmission to undergo investigations (Levine et al., 2003, p. 130). Wong et al. (2006, p. 584) identify chest pain in approximately 50% of patients post-PCI. The origin of the chest pain can range from the sensation experienced after stent implantation to ischaemic chest pain. The authors highlight that re-stenosis usually occurs within 3 months post-PCI and stabilises at approximately 12 months (Wong et al., 2006).

Chest pain identification and management reiteration is essential as delay in symptom recognition and management is highlighted as a worldwide concern (Gallagher et al., 2012). Gallagher et al. undertook a nurse-led, chest pain educational intervention of CR patients ($n = 137$) to test if participants could be better educated on symptom recognition and action using the NHFA's "Chest Pain Action Plan" to avoid delay to hospitalisation. The study reported statistically significant results in participant reporting heart attack warning signs but no changes were observed in the time participants tolerated these symptoms. The study by

Gallagher et al. (2012) is important and supports the need for the completion of the present study for the following reasons from the literature presented thus far. As CR does not commence until approximately 4–8 weeks post-discharge, it is essential that patients are educated, are able to recognise their chest pain symptoms, and take appropriate recommended actions early. The issues surrounding the post-discharge period after undergoing PCI, as identified above, reinforce the need for a post-discharge, nurse-led clinic. In the following section Bandura's Self-Efficacy (SE) theory is discussed as the chosen theoretical framework and its application to the present study, nursing and chronic illness. Section 2.7 later discusses the importance and benefits of nurse-led clinics, and person-centred care for cardiac patients and chronic disease, while presenting a detailed review of literature to demonstrate the present study has not been previously undertaken or replicated.

2.6 Bandura's Self-Efficacy (SE) Theory

2.6.1 Expectancies

As identified in Chapter 1, Bandura's (1977, 1995) SE theory was chosen as the theoretical framework to guide the study over other psychological constructs as it is based on the foundation that an individual's inherent beliefs and confidence in their abilities to master a task can predict the outcome and enhance their SE. In developing the nurse-led clinic utilising the SE theory, it was anticipated that by offering participants early, face-to-face, nurse-led post-discharge support—coupled with the reiteration of post-PCI education—SE may be enhanced and anxiety may be reduced. Furthermore, it was hoped that participants could engage in the management of their post-discharge health and wellbeing by both believing and engaging in potential behaviours that may then lead to positive outcomes or mastery, as highlighted by the SE theory.

The aim for healthcare professionals is to facilitate independence in the health-management of their patients (Lenz & Shortridge-Baggett, 2002), and this was one overarching aspect of the present study. Therefore, as the study aimed to enhance SE and reduce psychological distress, while also encouraging effective self-management, the present study also aimed to provide participants with the knowledge and skills, emotional and clinical support, reassurance and feedback. Moreover, ongoing telephone follow-up and assessment throughout the course of the study was also provided, given that the aforementioned influences are required to achieve behaviour change (Shortridge-Baggett, 2002). Additionally, so that health independence and management could be achieved through behaviour change, a strong support network in the healthcare team and family was ensured (Shortridge-Baggett, 2002). Self-efficacy and the SE theory are important considerations and widely used in the healthcare arena (i.e., chronic illness and health promotion). In achieving behaviour change, the SE theory postulates that individuals can perform behaviours by (a) believing in their abilities or confidence to do so, and (b) allowing others to comprehend and impact on behaviours, thus leading to change (Shortridge-Baggett, 2002).

The SE theory posits two main expectancies that influence behaviour modification (a) "efficacy expectations or perceived SE", and (b) "outcome expectations" (see Appendix I) (Bandura, 2004, p. 144; Bandura, 1977, p.193; Callaghan, 2003, p. 248). Efficacy expectations refer to an individual's beliefs in their ability to carry out a certain behaviour, while outcome expectations propose that participation in certain behaviours will lead to particular outcomes (Callaghan, 2003). Bandura (1995) highlights how efficacy expectations play a part in stress and anxiety control and arousal, respectively, and how people with poor efficacy beliefs

suffer more distress and poorer functioning as compared to those who have strong efficacy beliefs.

An individual's efficacy beliefs in combination with two additional expectancies—"perceived coping SE" and "thought control efficacy"—may also have a positive impact on coping behaviour as they act to decrease stress and anxiety by altering environmental perceptions and threats within (Bandura, 1995, pp. 9–10). Therefore, when SE beliefs are high, challenges are undertaken with greater confidence and control; whereas lower SE beliefs may lead to episodes of anxiety and depression (Bandura, 1995). Thus, the nurse-led clinic aimed to provide post-PCI patients with early post-discharge education and support with the anticipation of impacting on each participant's efficacy expectancies so that their SE could be enhanced and anxiety reduced. Furthermore, by educating participants and enhancing SE, it was hoped that participants' ability to effectively manage their health would be achieved (or self-management). It was hoped that the intervention would encourage participants to either adopt and/or continue with positive health behaviours and be able to overcome challenges when faced by them with the additional skills offered in the repeated, uninterrupted, face-to-face, nurse-led clinic (i.e., post-discharge chest pain management).

Schwarzer and Fuchs (1995) recognise the impact of poor health behaviours on disease and identify stress and poor coping as the cause of this unhealthy behaviour adoption. The authors highlight three expectancies that can facilitate health change through positive self-belief, namely:

- Expectancy 1: "Situation-outcome expectancies": Outcomes are the result of the environmental occurrences as opposed to individual acts.

- Expectancy 2: "Action-outcome expectancies": Resultant outcomes

caused by the individual.

- Expectancy 3: "Perceived SE": The individual's personal conviction in their own potential to act accordingly and that it will result in the outcome they are aspiring to achieve. (Schwarzer & Fuchs, 1995, p. 261)

While the aforementioned efficacies are responsible for facilitating behaviour change, the actual adoption of healthy behaviours or discontinuation of harmful behaviours is subject to three "cognitions" (Schwarzer & Fuchs, 1995, p. 261). The three cognitions are identified below and include examples for the present study:

- Cognition 1: "The expectancy that one is at risk" (Schwarzer & Fuchs, p. 261). For example, some participants in the intervention group may have believed that there is a high probability that they may have another heart attack being smokers.

- Cognition 2: "The expectancy that behavioural change will reduce the threat" (Schwarzer & Fuchs, 1995, p. 261). Participants in this study may have considered that attending a CR program may support them in smoking cessation, and the risk of a future heart attack would therefore be reduced.

- Cognition 3: "The expectancy that one is sufficiently capable of exercising control over a risky habit" (Schwarzer & Fuchs, 1995, p. 261). Participants may have then believed that they do have the ability to attend CR and engage in smoking cessation and, thus, attend a secondary prevention program.

This process is identified as "functional optimism" (previously defensive optimism) and is dependent on both personal coping and positive outcome

expectancies (Schwarzer & Fuchs, 1995, p. 262). To both adopt and maintain positive health behaviours Schwarzer and Fuchs (1995) highlight that an individual must believe that they can carry out the behaviour. Therefore, both efficacy beliefs and outcome expectancies are essential when assuming healthy behaviours, eliminating poor practices, and maintaining change (Schwarzer & Fuchs, 1995). Moreover, and as identified by these authors, individuals firstly have intent (to change behaviour), followed by an attempt (to change behaviour). Most importantly, however, it is noted that both SE beliefs and outcome expectancies work together to achieve behavioural change. Outcome expectancies act to establish intention (to change) while SE plays a large role in intent, actioning behaviour change, maintenance and overcoming challenges (Schwarzer & Fuchs, 1995). Thus, it is a combination of inherent beliefs that patients may be able to cope in the face of risk and have the vital skills necessary to overcome stressful circumstances such as those faced by post-PCI patients.

2.6.2 Self-Efficacy (SE) Theory: Achieving Beliefs

Holloway and Watson (2002) identify how the SE theory has served as a framework for many educational interventions, including those promoting and facilitating health behaviour change. Holloway and Watson (2002) highlight the four main information sources to which SE beliefs may be achieved (see also Appendix J), these include:

- performance attainment/accomplishments or mastery;

- vicarious experience;

- verbal persuasion; and

  physiological feedback/emotional arousal. (Bandura, 1995; 2004, p. 195; Holloway & Watson, 2002, pp. 109–111)

Performance attainment is highlighted to be the most "influential source of efficacy information" and encompasses performance accomplishment (Holloway & Watson, 2002, p. 109). Performance attainment involves participants achieving mastery through learning, and it is through achieving mastery that SE is enhanced and task competence is achieved. (Holloway & Watson, 2002).

Holloway and Watson (2002) describe how vicarious experience encompasses observational learning and includes learning from events or from others. This expectancy can influence SE and mastery if a person observes successful modelling of a similar task undertaken. Conversely, if a task observed is failed, the observer's SE may be reduced (Holloway & Watson, 2002). The authors highlight that healthcare professionals may and do act to model behaviour change. They advise, however, exercising caution and accounting for environmental changes experienced by participants attempting behaviour change through observational learning (Holloway & Watson, 2002).

As an efficacy expectancy, verbal persuasion encourages an individual to adopt particular behaviours in certain health practices (Holloway & Watson, 2002). It is highlighted by these authors that verbal persuasion increases a person's inherent ability and skill to perform a task as it enhances SE. The persuader can have a great effect on a person's SE if they demonstrate proficiency and can convey a sense of trust to the patient. However, if the patient does not comprehend the task to be undertaken, the outcome of persuasion may not result in increased perceived SE (Holloway & Watson, 2002).

Physiological feedback is the last of the efficacy expectancies and identifies how achieving enhanced SE can be affected by a person's physiological state (Holloway & Watson, 2002). The authors highlight that increased physiological

states can impair performance in that patients may perceive themselves to be less competent. Emotions such as anxiety can also impact on a person's physiological state and may be eliminated by undertaking interventions to eliminate negative emotions (Holloway & Watson, 2002).

The adopted framework (see Appendix K) presents how nurse-led clinic participants may make positive health-related changes or engage in effective self-management after attending the early intervention post-procedurally. It suggests that, by participating in the intervention, participants will be able to set goals that will lead to behaviour adoption and, lastly, positive health-related outcomes. Importantly, and as displayed in Appendix K, some standard-care group participants may also follow this path. For example, if standard-care group participants possess high SE or efficacy expectations, the routine care received during hospitalisation will naturally lead to goal setting, behaviour adoption, and positive health outcomes. Conversely, if standard-care group participants do not have high SE due to influencing factors, no health behaviour changes will be achieved and, consequently, lead to poor post-PCI health outcomes. Adoption of Bandura's SE theory as the theoretical framework was therefore essential for this study as it was anticipated that attending a nurse-led clinic may increase participants' SE, enhance their motivation, and provide them with the confidence to effectively manage their post-discharge health, behaviours, and emotions. Moreover, in enhancing SE it was hoped that problems, issues, and concerns such as accompanying anxiety may be reduced. Lastly, it was hoped that risky post-discharge behaviours could be avoided through the adoption of positive self-beliefs and, thus, healthy practices and more effective post-discharge self-management.

Lau-Walker (2007) highlights the importance of early pre-cardiac

rehabilitation intervention in that it may address control, illness beliefs, and management of symptoms. Furthermore, Lau-Walker (2007) identifies that an early intervention may also enhance the effectiveness of CR in terms of making and maintaining lifestyle changes. The author reports how identifying and addressing psychological needs is essential in those who experience a cardiac event and how it is often is not self-resolving. Lau-Walker (2007, p. 188) does reinforce though, in order to address psychological needs, patients "beliefs and expectations" must be managed. She also argues how addressing psychological needs may lead to positive attitudes (towards health and recuperation) and can be best achieved applying the SE theory as it can be individualised. Thus, as a pre-rehabilitation intervention, it was essential that the present study be trialled so that SE could be enhanced, psychological needs could be met, positive attitudes could be achieved, and participants could engage in self-management.

2.6.3 Self-Efficacy (SE) in the Healthcare Setting

Holloway and Watson (2002, p. 106) reinforce the strong link between SE and "health-related behaviours" in the healthcare setting. They emphasise how the SE theory and its constructs combined with health education in the hands of nurses (as they are in frequent contact with patients) presents as an "ideal" situation to encourage health behaviour change (Holloway & Watson, 2002, p. 106). Furthermore, in order for nurses to facilitate behaviour change through health prevention, promotion, and to enhance SE, any health intervention must be patient-specific, the RN should be knowledgeable in the area (Holloway & Watson, 2002). The authors highlight how health education in the hospital setting can be ineffective in encouraging health behaviour change due to patient allocation workloads, limited teaching time, poor staffing, and limited understanding of the concept of health

promotion and education. Thus, the aforementioned reasons provided grounds for undertaking the present study in the early post-discharge period. Moreover, as healthcare organisations are under pressure to "reduce, ration, and delay health services to contain health costs", application of the SE theory in encouraging individual long-term health management as the theoretical framework to guide this study was appropriate (Bandura, 2004, p. 144). The SE theory and its constructs were used to guide this study in order to identify poor health behaviours, educate patients, and facilitate health behaviour change over time by enhancing SE and reducing anxiety. As recommended by Holloway and Watson (2002), the present study was patient-specific as it pertained to PCI patients only, and at the time of undertaking the nurse-led clinic the PI had approximately 7 years' experience as an RN in the cardiology field, including secondary prevention and CCT training.

2.6.4 Effective Self-Management, Self-Efficacy (SE) and Chronic Illness

With advances in modern medicine, patients with chronic illnesses are surviving longer (Thorne, 2008). As the healthcare system struggles to cope with the rise in the number of chronically ill patients and costs, a shift in the delivery of care for this group of patients has occurred (Thorne, 2008). Thorne (2008) highlights how nurse-researchers over many decades have successfully and qualitatively captured the experiences and journeys of chronically ill patients, identifying a gap between what the healthcare system feels patients need versus what patients believe they actually need. Thorne (2008, p. 8) recognises the disparity between the healthcare system and the "social reality of illness" and highlights how the mismatch has led to a change in the management of chronic illness from an acute-care approach to addressing the context of chronic illness.

While chronic illness has been identified as a burden on society, if optimally

treated a patient's life expectancy and QOL may be enhanced (Farrell, Wicks, & Martin, 2004). Furthermore, while many patients are provided with education and are aware of the need to engage in modification of lifestyle behaviours to enhance overall wellbeing, a majority fail to maintain behavioural changes (Farrell et al., 2004). Farrell et al. highlight how aiming to enhance a patient's perceived SE, in combination with medical treatment and health education, can enhance a patient's self-confidence or SE to self-manage, particularly in chronic disease (Farrell et al., 2004). The authors undertook a 6-week quasi-experimental pretest–posttest pilot study on a group of 48 rural, low socioeconomic participants to determine if participation in a chronic disease self-management intervention enhanced SE, SE health, and encouraged self-management. The study demonstrated significant enhancements SE to perform self-management of symptoms ($p = .1$) and SE health ($p = .001$), demonstrating the effectiveness of self-management programs on SE. Enhancements were also evidenced in communication with healthcare professionals and walking. These findings are important to the present study in that it aimed to enhance SE to encourage effective self-management as a secondary aim. Both primary and secondary aims will be discussed in greater detail in Chapter 3.

Bodenheimer et al. (2002, p. 2469) identify how chronic disease sufferers are more involved in their health management and engaging in self-management. Bodenheimer et al. (2002) discuss how traditional health education complements "disease-specific" education coupled with management skills. Self-management is described as differing from traditional approaches as it offers problem-solving approaches to disease management. Importantly, self-management is not a replacement for conventional health education but rather an adjunct that combines traditional patient education while teaching and encouraging problem identification,

decision-making, management and action where health and illness states may alter (Bodenheimer et al., 2002).

Bodenheimer et al. (2002) highlight the difficulty in generalising findings concerning self-management education; however, they do conclude that self-management education programs are superior in achieving self-management compared to conventional education styles directly delivering information to patients. Furthermore, the authors identify that some chronic disease outcomes may be enhanced and cost may be reduced as a result of such enhanced outcomes. It was therefore important that the present study and nurse-led, educational intervention be trialled, as it offered patients both education (verbal and written) and was complemented by offering skills and techniques for health decision-making, management, action.

Barlow et al. (2002) reviewed the literature surrounding the effectiveness of self-management methods for chronic disease sufferers. Barlow et al. (2002) bring to light the ageing population and increased life expectancy in those suffering with chronic illness, and highlight the demands placed on the healthcare system for acute illness management alone. Methods of self-management delivery may include a clinical setting or home and be undertaken by various health professionals, with various modes of delivery, including group, one-on-one, and telephone to name a few (Barlow et al., 2002). The format of self-management can also vary, with booklets and role-play being offered.

The authors highlight the effectiveness of self-management interventions, versus that of standard care for patients, reporting that knowledge, undertaking self-management tasks, SE, and health status can be enhanced (Barlow et al., 2002). Furthermore, the authors recognise potentially equal benefits in attending either a

group or an individual education session, with the only issues in one-on-one sessions for patients being cost. Finally, it is argued that the self-management approach may also be equally as advantageous as "cognitive–behavioural interventions", which is of interest given the present study was undertaken as a nurse-led clinic and utilised techniques to encourage effective self-management. The potential effectiveness of self-management interventions is important for the present study in that it aimed to not only enhance SE and reduce anxiety as a primary aim, but to reduce symptoms of depression and encourage effective self-management as secondary aims.

Thorne (2008) recognises the importance of nurses and how they are in the position to better understand patients with chronic illness and how their lives and social contexts may affect how they respond and learn about their disease. The author highlights how nursing research has and will assist in the alignment of chronic illness management with the patient's experience to enhance patients' lives and wellbeing. With nurses highlighted as essential components of patients' interaction and empowerment (particularly in chronic disease), Section 2.7 will discuss the importance of nurse-led clinics and person-centred care in educating and empowering patients in the post-discharge period.

2.7   Nurse-Led Clinics and Community Follow-Up Initiatives for Acute Coronary Syndromes (ACS)

Both in the field and captured in the literature, patients have commented on their lack of post-discharge knowledge, capabilities and feelings of isolation, with a large prevalence of emotional distress evident (Brezynski et al., 1998; Chair & Thompson, 2005; Corones et al., 2009; Davidson et al., 2008; Gulanick et al., 1998; Higgins, Dunn, & Theobald, 2000, 2001; Higgins et al., 2005; Kimble & King, 1998; Murphy, Fishman, & Shaw, 1989; Sardinha et al., 2011; Tooth & McKenna,

1995; White & Frasure-Smith, 1995). Although CR is available, there appears to be a gap between discharge, cardiologist review, and the commencement of a CR program where participants appear concerned about their post-discharge capabilities (Bronskill, Normand, & McNeil, 2002; Burney et al., 2002; Corones et al., 2009; Shoulders-Odom, 2008).

Nurse-led clinics are widely discussed within the literature, particularly in relation to chronic disease management (i.e., CHD, chronic heart failure, hypertension, diabetes mellitus, peripheral vascular disease) (Chummum, 2011; Clark, Smith, Taylor, & Campbell, 2011; Mason, Freemantle, Gibson, & New, 2005; Murray, 1997; Page, Lockwood, & Conroy, 2005; JBI, 2010). While nurse-led clinics have, and continue to be, trialled, the concept of a nurse-led, post-discharge clinic for patients within or up to 1 week post-PCI does not appear to be present in the literature reviewed. The PI undertook a broad search of the literature to ensure the present study had not been previously undertaken. A table of cardiology nurse-led clinics for PCI and CHD patients was prepared to demonstrate the uniqueness of the present study (see Appendix L).

In a randomised clinical trial, Carroll, Rankin, and Cooper (2007, p. 315) assessed the effectiveness of a community follow-up of 247 older MI and CABG patients by an Advanced Practice Nurse (APN) and peer advisor. Participants in the treatment group received a home visit by an APN at 72-hours post-discharge, followed by a telephone call at 2, 6, and 10 weeks and a telephone call by an advisor every 12 weeks post-discharge (Carroll et al., 2007, pp. 313–-319). Cardiac rehabilitation attendance and rehospitalisation was tracked over 12 months. Carroll et al. (2007) achieved their aim of increased participation in CR and lower hospital readmission rates. The authors attribute the role of the APN and peer advisor in

attaining such results.

Alfakih et al. (2009) set up a follow-up clinic for patients diagnosed with ACS. Their main aim was to reduce 6-monthly readmissions to hospital through early detection of chest pain and appropriate management. The authors reported effectiveness of the intervention with a decrease in readmissions by approximately 14.3%. The difference between the clinic trialled by Alfakih et al. (2009) and the present study are clearly identified in their aims. Alfakih et al.'s (2009) study aimed to detect chest pain in the early discharge period and to reduce the number of hospital readmissions, while the present study aimed to enhance SE and reduce patient anxiety as its primary aim. As secondary aims, the present study aimed to reduce depressive symptoms and enhance participant confidence or SE to effectively self-manage in the early post-discharge period after undergoing PCI. A consequence of achieving primary and secondary aims is reduced hospital readmissions; however, while these were not identified as aims in the present study they could be trialled in a larger scale project.

As identified in Chapter 1, the present study aimed to provide support for patients between the day of discharge from hospital until specialist follow-up and the commencement of CR. It aimed to provide early support and to reiterate patient education delivered during hospitalisation and to reinforce the benefits of CR. From the literature reviewed, nurse-led clinics include both primary and secondary preventative initiatives for patients who have experienced a cardiovascular event, surgical or interventional procedure (i.e., PCI), or who have diagnosed CHD as opposed to early, first-week interim support for patients who have undergone PCI as per the present study. While psychological distress and cardiovascular risk factors (i.e., cholesterol, physical activity, smoking, diabetes, hypertension) and

management interventions (i.e., medication adherence, self-care, angina management) have been investigated by other researchers (as identified in Appendix L), no similar study appears to have been undertaken.

The Queensland Government and Department of Health acknowledge the benefits of nurse-led outpatient clinics to both patients and the healthcare system and aim to introduce more clinics to the communities so that healthcare may be more accessible to all Queenslanders(QLD Health, 2013), this reinforced the undertaking of the present study. The JBI (2010) and Hatchett (2005) highlight how nurse-led clinics have become much more widely recognised and utilised in the healthcare community and benefit patients in many ways, including managing chronic illnesses in the community, preventing health deterioration, and reducing specialist follow-up, while also providing a therapeutic relationship. The JBI (2010) also highlight the health-promotive component of nurse-led clinics and how they benefit both the patient and nurse. Hatchett (2005) identifies that, in order to fulfil the role of a nurse-led cardiology clinic, it must comprise some of the following characteristics: offer education, provide psychological support and clarification, monitor the participant, undertake physical assessment, undertake investigations and clarification, engage with a multidisciplinary team in individualising care-paths, offer medication management, and encourage the participant or guardian to engage in self-care. Thus, the aforementioned roles were acknowledged in designing the present study and adapting the underlying theoretical framework.

Schadewaldt and Schultz (2011), in a systematic review, sought to determine the effectiveness of nurse-led clinics on participants' short- and long-term health outcomes. The authors identified a greater effect on short-term health outcomes with regard to nurse-led clinics. Furthermore, they identified more success of the

programs with greater nurse–patient support and a better quality of life. The authors recommend longer patient support to achieve long-term health goals and earlier access as being essential to patient survival. Additionally, Schadewaldt and Schultz (2011) advise that nurses should have appropriate clinical qualifications prior to the initiation of a nurse-led clinic, while advising the consideration of funding and the healthcare system. These recommendations were taken into account in the set-up of the present nurse-led clinic.

2.7.1 Nurse-Led Clinics and Person-Centred Care (PCC)

In addition to encouraging effective self-management and providing nurse-led education and care, healthcare professionals engage more in a person-centred approach to healthcare delivery, particularly in respect of patients with specific chronic illnesses (Yu, 2014). Yu (2014) suggests that a person-centred approach to patient care is pertinent to effectively managing chronic illness and patients with multiple co-morbidities. Dudas et al. (2013) highlight the importance of PCC in that it identifies patients as people, as opposed to their illness. Patient-centred care recognises the illness experience and how patients' symptoms affect their daily lives. Dudas et al. (2013) highlight how PCC may improve hospital length of stay and activities of daily living in patients with CHF through the collaboration between the healthcare provider and patient throughout their hospital admission. Further to this, a care path, based on a patient's account of their illness, can more effectively manage the individual's specific needs as a result of the illness encountered. Dudas et al. (2013) argue that the structure provided by PCCs may facilitate greater patient assurance in their illness and management.

Dudas et al. (2013) undertook a controlled, before-and-after design study of 248 patients with worsening heart failure to determine if a patient who received a

PCC approach in their health and illness management reported lower illness uncertainty. Patients in the intervention group reported less uncertainty in their illness as opposed to standard-care group participants. Participants in the intervention group were reportedly more symptomatic of their heart failure versus standard-care group participants. The authors propose the potential effectiveness of PCC in empowering and preparing patients in their illness management. Additionally, Dudas and colleagues suggest that PCC transpires into everyday practice for patients receiving hospital treatment for deterioration with heart failure (2013).

The WHO released a policy framework on PCC and identifies how healthcare organisations are engaging in a more holistic approach to patient care and interest in understanding the patient to address their needs (WHO, 2007). The WHO highlight the importance of a people-centred approach in that people, prior to assuming the role of a patient, should be both "informed and empowered" in their health protection and promotion (WHO, 2007, p. 5). People-centred healthcare is highlighted to uphold values of international law to improve outcomes for both individuals, families, the community, healthcare professionals, healthcare organisations and systems. The WHO (2007) identify the following measures to improve outcomes for all:

- informing and involving consumers of healthcare of their options and decisions;

- holistic approach by healthcare providers towards consumers; and

- support within the healthcare environment.

Further to the aforementioned measures, the WHO (2007) identify strategies to achieve holism and compassion in healthcare and thus, person-centred healthcare.

The strategies identified are targeted at individuals, families, communities, healthcare professionals, organisations and systems to meet the needs of healthcare consumers and providers in a positive, compassionate and humanitarian manner (WHO, 2007).

This critical review has identified clear gaps within the literature for patients who have experienced a cardiac event and/or undergone PCI. Section 2.8 now summarises the findings and implications as a result of this critical review.

2.8   Summary and Implications

As identified, a post-discharge gap is apparent from the day of discharge to the recommencement of a CR program, and cardiologist follow-up. The literature review critically highlighted that the present study is not a secondary prevention program but rather aims to provide early post-discharge education, follow-up and support to patients awaiting cardiology review and CR program attendance. This chapter discussed the literature with respect to theoretical framework and the primary and secondary aims. It reviewed, examined, and highlighted the importance of SE to patients, particularly those diagnosed with a chronic disease and highlighted how education, support, and a high SE can positively impact on post-discharge anxiety. As psychological distress, particularly anxiety and depression, are identified in the literature and strongly linked to CHD, coronary events, and cardiovascular procedures, the post-discharge, nurse-led clinic was warranted. Moreover, with heightened anxiety, limited time for nurse-teaching (during hospitalisation), and poor information absorption, support of the primary aim to enhance SE and reduce anxiety through early reiteration of post-PCI discharge education and nurse-led support may be maintained. Furthermore, this chapter reviewed the literature in relation to nurse-led clinics in CDM and in particular CHD. Moreover, a summary of

CHD literature was presented to demonstrate that the present study has not been previously undertaken. This chapter also discussed how high SE may positively impact on the post-discharge period and, in particular, patient self-management.

Thus, with a short hospitalisation, the effect of a high SE on CHD patients, the presence of psychological distress (from admission to the post-discharge period), the importance of effective self-management, and under-referral and attendance to CR, the present study was deemed as necessary. Moreover, not only are ACS patients commenced on a mean of six new medications (in addition to possible other medications consumed), adherence and compliance appears to be problematic. Although there has been a large reduction in post-discharge complications, they may still be experienced, thus highlighting the importance of early detection and management. Lastly, the importance of nurse-led clinics with a person-centred approach for the management of chronic disease was highlighted in the literature and supported. With the aforementioned issues surrounding PCI patients and their recovery, the study aimed to test the timeliness and effectiveness of a nurse-led clinic within 5–7 days post-discharge, post-PCI versus standard care and follow-up using Bandura's SE theory to guide the research. The next chapter discusses the methods utilised to undertake the study's two phases.

Chapter 3: Research Design

This chapter details the development of Phases One and Two, while also discussing the methodology and design, to achieve the study aims and objectives. Study participants, the procedure, instruments, and associated validity and reliability are also presented. Timelines for the procedure and data collection in Phases One and Two are also described and ethical considerations and limitations are examined. Lastly, this chapter presents the data analysis techniques for both study phases.

3.1 Methodology and Research Design: Phases One and Two

3.1.1 Study Development: Phase One

The PI considered it paramount, given the healthcare agenda and demands currently placed on the healthcare system, that a nurse-led clinic be undertaken in outpatient setting by a cardiology trained RN or Clinical Nurse (CN) (Queensland [QLD] Health, 2013). The decision to undertake a face-to-face, nurse-led clinic was also determined by the potential to reduce the workload on GPs, cardiologists, and emergency departments, while optimising patient outcomes (Queensland Health, 2013). Furthermore, given the geographical isolation of many patients, the PI deemed it important that the study be undertaken as a face-to-face nurse-led clinic with a telephone treatment arm that might benefit remote and rural patients and those unable to attend a face-to-face clinic. Lastly, with a short hospitalisation, follow-up within 4–6 weeks post-discharge, and given the relationship between a cardiac event and psychological distress coupled with health-related misconceptions, the PI aimed for early post-discharge follow-up and support. Thus, the study's early design took the form of a three-arm, randomised controlled clinical trial with participant follow-up within the first 72 hours over a 12-month period (see Appendix M).

Recommendations from the university panel, however, suggested that given (a) the timeline for a PhD, (b) the number of participants required to achieve a well-powered study, (c) the PI's intention to undertake such a sizeable study using multiple modes of communication without the assistance of a research assistant (RA), the telephone intervention arm was removed and study arms reduced to two (i.e., face-to-face intervention versus standard care). Additionally, the research team and literature recommended the first week for post-discharge follow-up was an ideal time to review this group of patients (Günal et al., 2010; Rassaf et al., 2013; Trotter et al., 2011; Tuso et al., 2013; Yan et al., 2011; Wong et al., 2006). Thus, the nurse-led clinic emerged as a clinic to be held within the first 5 to 7 days post-PCI.

The PI and supervisory team began approaching three hospital sites for feedback regarding the potential study, research protocol and real-world application. The research team met with various hospital executives and teams on numerous occasions and included the following:

- two Directors of Nursing (DON);
- one nursing Director of Research;
- three Cardiology Directors;
- one Director of Medical Services;
- one Director of Emergency Medicine;
- one Nurse Practitioner (NP);
- three senior CR Clinical Nurses (CNs)
- a group of senior CNs (provided a detailed study presentation);
- one research institute;
- one site contact;
- two Clinical Nurse Managers (CNMs); and

- two outpatient departments (OPD).

The study protocol and risk management protocols were drafted and multiple versions created to ensure the safety of all potential participants and the suitability for each study site. Once all executives agreed on the potential study, the PI submitted an application for ethical approval at two potential sites and to one research institute. The main area of concern raised by the committees were: risk management of acute psychological distress, medical emergencies, a request for a detailed sample size calculation, and desired effect or units of change of the nurse-led clinic on the study's main outcomes. The research institute requested that as their patient review system coincided with the present study's follow-up the PI should undertake telephone review at their site and collect data utilising both the research institute assessment tool in conjunction with The 'REALITY CHEC' Project data collection form.

Prior to the commencement of the nurse-led clinic, the PI conducted hospital in-service sessions to brief both nursing and medical staff regarding the study and management of potential adverse events on-site. Staff members provided the PI with input on management and their potential concerns regarding risk management at the sites. After such consultation, the PI negotiated the use of rooms and materials at the sites, which also presented as a delay to the commencement of participant recruitment. Overall, the total time from the commencement of initial meetings at each site, receipt of ethical and research governance approval, gaining clinic access, to participant recruitment was approximately 16 months. A contract with the university legal team was also drawn up and agreed upon with each site regarding study related data and access. One site requested a detailed protocol and assistance with a post-discharge, outpatient clinic set-up. In addition to legal team discussion,

QUT's Bluebox (i.e., innovation and knowledge transfer company) was updated about the study regularly throughout the course of the study and offered assistance with the packaging of the intervention.

Prior to the commencement of the study, the PI prepared participant packages, which consisted of the following (see Appendix N):

- one salivette and prepaid envelope;

- saliva sample instruction sheet (with images and documentation);

- educational booklet, 'My Heart, My life';

- three access site diagrams and three prepaid, addressed envelopes (to document wound healing and observations); and

- tape measure (for waist measurements).

In addition to the preparation of participant packages, the PI created the following templates on QUT letterhead:

- potential risk reporting to the Human Research Ethics Committees (HRECs);

- participation letters to cardiology groups and GPs for their patients' participation (also emailed if this was provided by participant);

- missed nurse-led clinic follow-up call and rescheduling;

- lost to follow-up and giving thanks for participation; and

- thank-you letters for participation.

In addition, if the PI had concerns regarding a participant, telephone communication was followed up with a formal letter. The PI also prearranged car-parking tickets and vouchers at each site for participants.

Following Phase One, it was anticipated that a second phase would provide detailed feedback on the nurse-led clinic if the PI reapproached intervention group

participants and healthcare professionals (i.e., cardiologists and cardiology nurses). The PI applied for ethics variation approval for Phase Two, with all committees in agreement.

3.1.2 Research Design

Research methodology and design: The pilot study

This study employed an experimental design and was undertaken in two phases as a pilot study, which is "a small scale version of the study that goes in advance, incorporating all aspects of the procedures of the main study and providing guidance for the larger study" (Roberts & Taylor, 2002, p. 259). Phase One, as identified above, investigated the effect of a nurse-led, educational intervention at 5–7 days on anxiety and SE after participants were discharged from hospital and focused on the collection of data via quantitative means. Phase One was undertaken to determine the safety and efficacy of the nurse-led intervention (see Appendix O). Baseline data collection occurred at day of discharge (Time 1) and follow-up occurred at day 5–7 (Time 2), 1 month (Time 3), and 3 months (Time 4) post-hospital discharge.

Phase Two explored intervention group participants' and healthcare professionals' opinions of the effectiveness of the nurse-led educational intervention, as well as its efficacy and safety. Participants undertook an interview at a date and time convenient for them at approximately 6-months post-discharge from hospital with analytical findings explored through participants' narratives. The study's third phase is presented in Chapter 5 and was undertaken to determine the efficacy of the intervention on a significantly larger group of participants utilising an electronic visual mode of communication to reach a broader population. A pilot study was chosen to determine the feasibility for a Phase 3 study and to determine the adequacy

of the study design and methodology.

As identified, the present study was undertaken as a pilot to determine the feasibility for a Phase Three, multi-centre study. The purpose of the present study was to evaluate the effectiveness of the nurse-led clinic from the perspective of participants and healthcare professionals through more formative evaluative means (Clarke & Dawson, 1999). Clarke and Dawson (1999, p. 11) highlight that, in undertaking formative evaluation, "the aim is to ascertain if any changes are needed in order to improve the programme". Information concerning the process of the intervention implementation and operation, strengths and weaknesses, difficulties encountered and the opinions and feedback of participants and healthcare professionals was thus attained to determine the effectiveness of the study and feasibility for a Phase Three, multi-centre study (Polit & Beck, 2010).

As highlighted by Connelly (2008), the conduct of pilot studies within the clinical setting is essential in that they may facilitate the management of any unforeseen events and gauge participant recruitment. The PI, in undertaking the pilot study, was able to determine the strengths and limitations in the research protocol, methods, and tools utilised, while also measuring effect size and therapeutic outcomes. Although pilot studies are of smaller sample size, conducting the present study has assisted greatly in the planning of a Phase Three, multi-centre study. Furthermore, after engaging in post-study critical reflection, areas noted for improvement were identified and may offer ideas for planning a nurse-led clinic of this nature. Issues encountered in the present study are identified with suggestions for enhancements offered.

Phase One used a randomised controlled clinical trial design to test the effectiveness of the nurse-led clinic, while Phase Two utilised a descriptive-

evaluative technique to analytically explore participants' and healthcare professionals' feedback related to the nurse-led clinic to inform a Phase Three, multi-centre study. The study's first phase is discussed below in detail. Figure 3.1 below diagrammatically presents the research plan for Phase One:
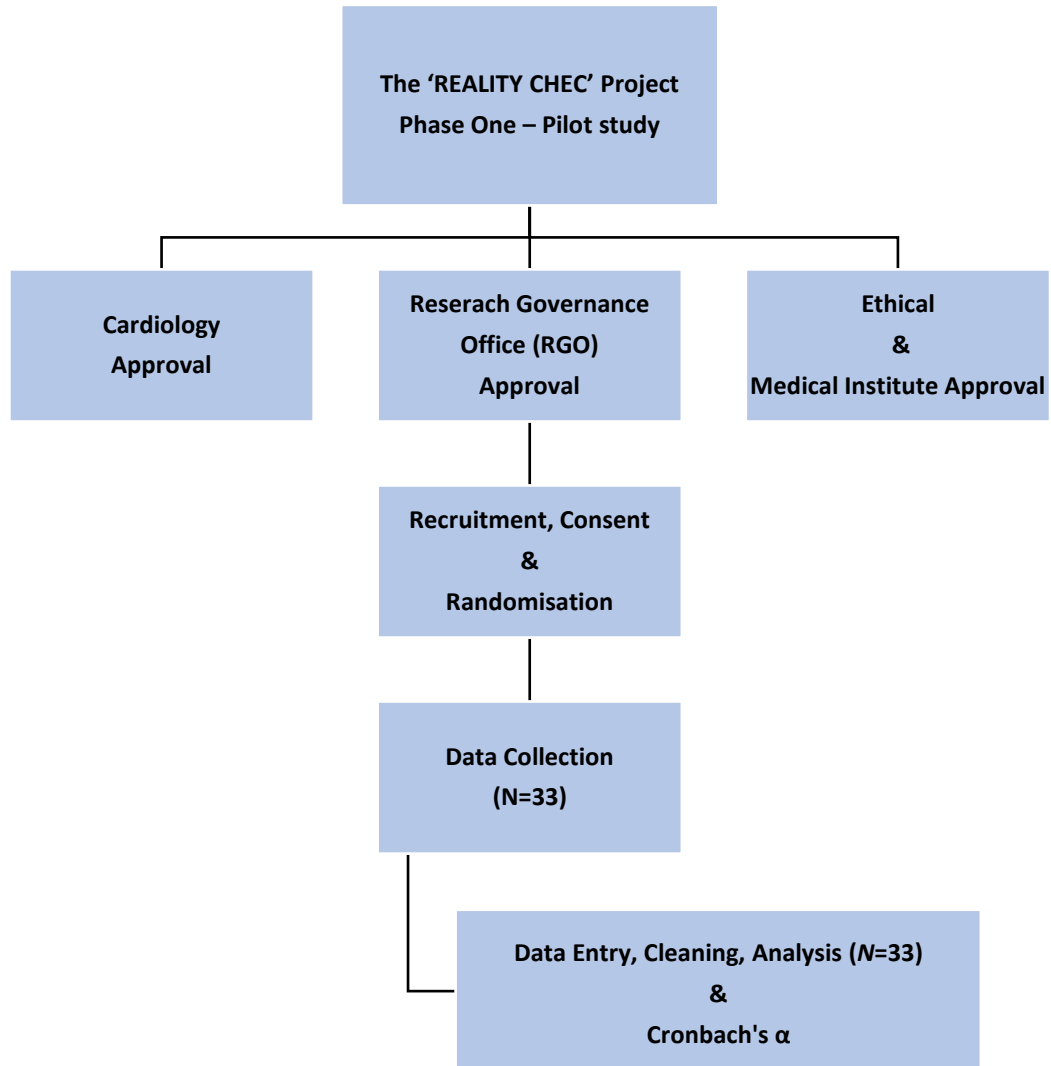
Figure 3.1. **Research plan – Phase One of the 'REALITY CHEC' Project**[©]

3.1.4 Study Phases

Phase One: Randomised controlled clinical trial (RCT): A pilot study

Phase One involved the delivery of the nurse-led educational intervention in an outpatient clinic setting and was strongly guided by Bandura's Self-Efficacy (SE) theory (1977, 2004). The SE theory, as discussed in chapters 1 and 2, identifies how

mastery and vicarious experience positively influence beliefs in one's self and abilities and lead to positive behavioural changes, thoughts, and feelings (Bandura, 1977, 2004). Consequently, motivation and an individual's SE are strengthened and enhanced (Bandura, 1977, 2004). Furthermore, in enhancing one's SE, it was hoped that anxiety would be reduced and participants would be able to effectively engage in their health and wellbeing management in the post-discharge period and beyond.

The key constructs of Bandura's (1977, 2004) SE theory have been adapted for this study and are represented in the theoretical framework (see Appendix K). The theoretical framework diagrammatically represents how external influences, the individual, socio-structural factors, and outcome expectations can affect goal setting and lead to long-term behaviour change or, conversely, no change at all. The main aim in Phase One was the delivery of the nurse-led clinic to intervention group participants and collection of quantitative data. Furthermore, Phase One aimed to determine the overall effect of the intervention on participants' SE and anxiety levels in the post-discharge period versus post-PCI standard care. Some qualitative data were collected throughout Phase One of the study. Quantitative data were also collected around the secondary aims and included post-discharge depression, CR attendance, medication adherence, and post-discharge complications.

The Phase One pilot study involved the collection of quantitative data and comprised a prospective, randomised controlled clinical trial (see Appendix O). Houser (2008) and Parahoo (2006, p. 247) highlight how randomised controlled designs are the "gold standard" in testing the efficiency of both new and existing interventions. Randomisation of participants assumes equality, thus allowing the effect of the intervention to be measured (Houser, 2008). Furthermore, by randomising participants, the effects of confounding variables may be diminished or

removed (Ryan, 2007). Therefore, to achieve accuracy and reliability and controlling for bias and variability, participants in this study were randomised (Chow & Liu, 2004). Chow and Liu also encourage blinding to control for bias and to ensure accuracy and reliability of the study. Participants in this study were not blinded as it would be easily discernible (by participants) which group was receiving the intervention. Chow and Liu also identify how both the investigator and research team can introduce bias into the study. It was suggested that a research assistant could be employed to undertake blinded follow-up to control for researcher bias and to ensure accuracy and reliability of the study's data and results. Queensland University of Technology (QUT) staff members serving on a student review panel recommended and encouraged the candidate to undertake this position as part of the PhD learning process. Furthermore, as the PhD student allocation did not allow for the employment of an RA, the candidate undertook participant recruitment, randomisation, data collection, data entry and analysis.

Although "gold standard", there are limitations associated with experimental designs, particularly within the healthcare setting (Houser, 2008; Parahoo, 2006, p. 247). These limitations were taken into account in the design of this study and included the (a) difficulty and complexity in design; (b) requirement of time, skill, and participant accessibility; (c) inability to control health and disease progression; and (d) greater control of the study may produce an unnatural, less generalisable study and results (Houser, 2008).

Parahoo (2006) and Roberts and Taylor (2002) identify both external and internal validity and the subsequent threats they may pose. Internal validity can include factors that may affect the study on an internal level (Parahoo, 2006). Moreover, they may both mutually and independently affect the outcome of the

study (Parahoo, 2006). Therefore, the authors advise that a researcher consider possible design flaws and measure the internal validity of a study to remove or limit undesirable outcomes (Brennan & Croft, 1994; Parahoo, 2006). Internal threats include both subject and measurement changes and can involve procedures and instruments and changes to observation (Roberts & Taylor, 2000). Observational changes may comprise experimenter effects on participants and the study (Roberts & Taylor, 2000). The researcher acknowledges the possibility of experimenter effects as the PI undertook all stages of the study, thus, there is the possibility that validity of the study may have been threatened. Additionally, extraneous variables, those variables that may influence study outcomes, were also considered in the design of this project (Roberts & Taylor, 2002). Roberts and Taylor (2002) recommend control of these variables by selecting participants who have similarities in variables or by including the subgroup within the study to assess for dependent variable differences. An important consideration made in this study included the selection of participants who underwent PCI only. Additional internal threats in this study identified by the PI may have also resulted from participant withdrawal, randomisation and the unequal participant numbers in study groups, and type-two error potential due to a small participant sample size.

For a study to have external validity, findings need to be generalisable to the population or reflect population validity (Roberts & Taylor, 2002). Parahoo (2006) and Roberts and Taylor (2002) highlight that, to ensure external validity is achieved, participant selection should take place in the general population. The authors identify the difficulty in selecting participants in the healthcare setting and recommend that, as the findings may not be applicable to the entire population, they may be generalisable to the population and particular area of healthcare studied (Parahoo,

2006; Roberts & Taylor, 2002). To ensure greater external validity in the present study, randomisation took place in the hospital setting where patients underwent primary or elective PCI. By recruitment of participants in the hospital setting this aimed to ensure that findings would be applicable to the group of patients who underwent PCI. Additionally, a reactive effect as a result of the study may have also occurred and will be addressed in Chapter 6 (Houser, 2012, p. 264). The PI has considered the reactive effect and that enrolment in this study may have facilitated positive changes in study participants (irrespective of the intervention), particularly in standard-care group participants (Houser, 2012). Lastly, to ensure greater external validity or ecological validity, the study was undertaken in the hospital setting, which was identified as important so that findings could be generalised to participants in this setting (Houser, 2012).

3.2   Participants, Procedure, and Timeline

3.2.1 Sample and Power

The sample size for Phase One comprised 33 participants who underwent PCI from the two hospital sites. A sample size calculation was undertaken based on a study by Yohannes, Doherty, Bundy, and Yalfani (2010) who investigated the benefits of CR on anxiety, depression, and physical and psychosocial wellbeing. As the present study's primary outcome was to enhance SE and reduce participant anxiety, the calculation of the sample size using standard deviations for anxiety as displayed by Yohannes et al. (2010) was warranted. The first part of the calculation revealed that 58 participants per study group were required to ensure a statistical power of 90%, to detect an effect, and to decrease the chance of error. Then, accounting for a design effect of 1.7 units of variance, 10% attrition, and 90% power, 109 participants were required per study arm. The PI rounded this up to 110

participants per study group or 220 participants in total. To maximise and ensure

steady participant recruitment, the PI prepared a recruitment plan (see Table 3.1). On

days where the PI was recruiting at hospital site two, telephone contact was made

with the CNM at site one to verify if there were any potential study participants.

Table 3.1.   Recruitment Plan: Hospital Sites

Day	Site(s)
Monday	Site one: 07:00 am–10:30 am
	Site two: 11:00 am onwards if nil or if few participants reviewed at site one
Tuesday	Site one: 07:00 am–10:30 am
	Site two: 11:00 am–13:00 am
Wednesday	Site one: 07:00 am–10:00 am
	Site two: 10:30 am–13:00 am
Thursday	Site one: 07:00 am onwards
	Site two: visit site if nil or if few participants reviewed at site one
Friday	Site one: 11:30 am onwards
	Site two: 07:00 am–11:00 am

Note: If no participants meet inclusion criteria or participants already reviewed at one site, PI to visit other site.

In order to join in the study, potential participants were required to satisfy the

inclusion criteria. Inclusion criteria are defined as "Guidelines for choosing subjects

with a predetermined set of characteristics that include major factors important to the

research question" (Houser, 2008, p. 217). Conversely, exclusion criteria remove

potential candidates from participation in a study (Houser, 2008). Houser (2008)

highlights how the development of inclusion criteria helps to reduce study biases but

advises not to be too extensive nor too specific as this may lead to the introduction of

extraneous variables or significantly reduce accessibility to potential participants.

The study's criteria for inclusion or exclusion were as follows:

Inclusion Criteria

- aged 18 years and above;

- informed consent for primary or elective PCI signed by patient and

cardiologist;

- have undergone a primary or elective PCI;

- understand or speak the English language; and

- have post-discharge telephone access (mobile phone and/or landline).

Exclusion Criteria

- children and/or young people (i.e., < 18 years of age);

- inability to understand or speak the English language;

- overseas resident:

- unable to be followed up due to return to home country;

- on vacation in Australia for less than 12 months;

- patients suffering from a mental illness/cognitive impairment and unable to legally consent;

- pregnancy;

- people in existing dependent or unequal relationships;

- people highly dependent on medical care; and

- have no telephone communication access.

Importantly, a cognitive impairment/mental illness in this study was not grounds for exclusion. If any participant had been unable to satisfy the following criteria, they would have been excluded: "unable to weigh the risks and benefits of participation; unable to make informed decisions; and be unable to fulfil the requirements of obtaining informed legal consent" (Polit & Beck, 2010, p. 131).

3.2.2 Study Setting

Participants were recruited from one large metropolitan private and one public hospital to determine the effect of the intervention at two different sites. Cardiologist consent was granted from directors at both sites, with written approval given to

approach patients. A National Ethics Application Form (NEAF) was completed and submitted to all Human Research Ethics Committees (HRECs) involved. A Site-Specific Agreement (SSA) was submitted to the Research Governance Office (RGO) at one of the sites, while research agreements were established and agreed on for each site and one hospital research institute.

The private hospital site where the study was undertaken was a 250-bed acute care facility specialising in advanced surgical procedures and general medicine. The hospital had a technologically advanced intensive care unit (ICU), Coronary Care Unit (CCU), Cardiac Catheterisation Theatre (CCT), Day Surgery Unit, and Endoscopy unit. The hospital annually performed approximately 403 PCI procedures (Foster, K [Research manager], personal communication, July 26, 2013).

The public hospital site was a tertiary-level, public hospital facility, with a 953-bed capacity (Queensland Government, 2011, p. 71). This facility offers all adult care specialties, excluding obstetrics (Queensland Government, 2013, p. 4). This site is a leader in medical research and teaching and admits approximately 82,000 patients per annum (Queensland Government, 2013, p. 4). The hospital has a strong cardiology division that performed approximately 875 PCI procedures between 2011 and 2012 (Queensland Government, 2013, p. 38).

Meetings with hospital medical, nursing, research executive and CR teams took place on several occasions prior to and post ethical approval to ensure support for the PI and that sites and staff were adequately prepared and informed of the study and its requirements. Strong support from executive-level directors, unit managers, and CR facilities at both hospital sites was given to undertake this study.

3.2.3 Recruitment and Consent

Potential participants were identified on admission to hospital through

collaboration with ward staff at the sites. The recruitment process was as follows:

- consultation with the CNM;

- consultation with the CN in charge of the shift; and

- consultation with the nurse caring for the patient.

On the day of discharge from hospital—following the process of participant identification as presented above and on patient instruction by the CNM, CN, or RN—potential participants were approached and offered a participant information and consent form (PICF) in the presence of their nurse. Only one consent form was signed by participants and this included consent to participate and the following:

- the release of medical information (i.e., medical and bedside progress chart);

- access site digital image collection and use (i.e., health education and conference presentation); and

- saliva sample collection.

Patients were given time to review the documents. After reading the documents, if the patient agreed to speak with the PI to clarify or to sign the consent form they did so through their nurse or instructed the PI to return within a certain time frame (i.e., 30 minutes) had their nurse been unavailable. Participants, if agreeable, were consented to the study.

Consent forms were photocopied for all participants and returned to them after signing. Study withdrawal without comment or penalty was emphasised during the consent process and highlighted in the PICF in full. Participation in Phase One of the study was voluntary. No incentives were offered to participate in Phase One; however, the potential benefits of participation (i.e., tailored post-discharge education and follow-up, and benefits for future PCI patients) were identified to

maximise participation. Additionally, the contribution to nursing and medical knowledge was also highlighted to participants. Car-parking vouchers were provided for on-site car parking to ease the burden of searching for a car-park space and to assist in overcoming any potential logistical barriers on return to the hospital site. The same sites (i.e., hospitals) were chosen for nurse-led clinic follow-up so that participants would be familiar with the surrounds. For ethics, privacy, and confidentiality reasons, all health facilities, participants, and personal details were de-identified and coded. On completion of the study, participants were given a certificate of thanks and mailed a summary of key results.

3.2.4 Instruments, Validity and Reliability

The instruments used in this study included the following: Individual data collection form (DCF) (see Appendix P); CSE Scale (see Appendix B); STAI (see Appendix C); Cardiac depression scale (CDS) (see Appendix D); Morisky Medication Adherence Scale (MMAS-8) (see Appendix P1); wound assessment tool (see Appendix Q); and a neurovascular assessment tool (see Appendix R). The PI obtained written permission from all authors to use these instruments (see Appendix S).

Data were collected in paper format and managed electronically using IBM's Statistical Package for the Social Sciences (SPSS) predictive analytic software (PASW) version 19 and Microsoft Excel. All data collected using the assessment tools were kept in each participant's file, both in hard copy and saved electronically. Since completion of the study, hard copy and electronic data continue to be stored in a secure location at QUT in the School of Nursing (SON) for at least 12 months as per section 2 of the *Revision of the Joint NHMRC/AVCC Statement and Guidelines on Research Practice Australian Code for the Responsible Conduct of Research*

(NHMRC/AVCC, 2007) addressing data collected for the purpose of assessment. Data and ownership were discussed with hospital sites and agreed on in contracts.

3.2.5 Cardiac Self-Efficacy Scale (CSE)

The CSE Scale was used to assess how SE affects CHD patients' physical function and role while controlling for anxiety and depression (Sullivan et al., 1998). The CSE has excellent internal consistency and good convergent and discriminant validity for the following two factors: control symptoms (CS); and maintain function (MF) (Sullivan et al., 1998). Alpha reliability for both factors were $\alpha = .90$ for CS and $\alpha = .87$ for MF (Sullivan et al., 1998). A moderate correlation was identified between the scales $r(33) = .38$, $p < .05$. The CSE was used in all participants at baseline and post-discharge, particularly after undertaking the nurse-led educational intervention. The CSE was used to measure whether or not perceived SE was enhanced by participating in the intervention in which participants are encouraged to make appropriate lifestyle adjustments and maintain positive health behaviours and activities post-intervention and post-PCI. The PI reviewed each CSE item to observe trends and obtain more detailed data on individual CSE items after attending the nurse-led intervention over time. Alpha reliability for individual scale items was high at $\alpha = 0.9$.

3.2.6 Anxiety and Depression Measurement: STAI, CDS, and Saliva Specimen

Participant anxiety levels were measured along with an assessment of depression pre and post-discharge. The STAI for adults was used to collect data about patients' anxiety, while the CDS assessed participants for depression. The STAI is a psychological tool measuring both state and trait anxiety (Kendall, Finch, Auerbach, Hooke, & Mikulka, 1976). The STAI was chosen as it was proven to be

uncomplicated and had a broad application in both clinical and non-clinical settings over time (Lam, Michalak, & Swinson, 2004). Furthermore, as it takes five to ten minutes to complete, it was identified as cost-effective and could be distributed to a large number of groups (as compared with other measurement tools). It was, therefore, selected to attain baseline, post-intervention, and post-discharge trait anxiety scores (Tilton, 2008). The STAI assesses both state and trait anxiety using two scales (Lane, Carroll, Ring, Beevers, & Lip, 2000). Both scales have good internal consistency, with an alpha value of $\alpha = 0.92$ for the state anxiety and $\alpha = 0.90$ for trait anxiety scales. The trait anxiety assessment tool was used in the present study to measure pre- and post-test trait anxiety levels (Lane et al., 2000). Trait anxiety represents consistent and stable individual tendencies in response to threatening situations, it was, therefore, chosen as the main outcome measure for anxiety in the present study (Tovilović, Novović, Mihić, & Jovanović, 2009).

The CDS is specific to the measurement of depression in cardiac patients and was created to distinguish between actual cardiovascular symptoms and depression (Davidson et al., 2008; Di Benedetto, Lindner, Hare, & Kent, 2007). Davidson et al. (2008) identify how patients who experience a cardiovascular event may experience feelings (which are very normal) such as "sadness and grief"; however, it is essential that these feelings be identified and differentiated so that depression is not overlooked (Davidson et al., 2008, p. 313). Davidson et al. (2008) and Di Benedetto et al. (2007) highlight the reliability and validity of the instrument and advise how significant depression is reflected by a higher score. Psychosocial data for depression using the CDS underwent initial validation and reported an alpha value of 0.90 (Hare, 1996). Subsequent studies have reported high internal reliability in this instrument with a Cronbach's alpha of 0.93 (Birks, Roebuck, & Thompson, 2004).

Thus, the CDS was used to measure depression in all participants. The PI undertook a reliability test, with the resultant alpha value of $\alpha = 0.83$.

The collection of saliva to measure serum cortisol levels, in addition to the use of the STAI and CDS tools on discharge from hospital and at 1 month post-discharge, was taken to measure stress levels in all participants. The literature highlights how saliva collection in the last decade has become a significant "diagnostic medium" (Streckfus & Bigler, 2002, p. 69). Serum cortisol is recommended to be measured in the morning (O'Donovan et al., 2010). O'Donovan et al. (2010, p. 1076) highlight how patients who are "clinically anxious" have higher levels of morning cortisol and higher levels of IL-6. Dahlgren, Kecklund, Theorell, and Akerstedt (2009, p. 1076) reinforce the early morning collection of cortisol particularly because it is a good indicator of stress and a person's "psychological health and psychological well-being".

Participants were given strict instructions on the collection of saliva on the day of discharge from hospital. Although mornings are the recommended time to take serum cortisol, participants were advised to provide specimen number two at the same time of day that the baseline sample was taken (O'Donovan et al., 2010). This approach was recommended by the study's clinical biochemist, who performed the salivary cortisol assays. The PI gave verbal and written instructions to each participant when obtaining the first saliva specimen as this was on the day of discharge from hospital. Participants were also provided with a specimen collection kit and written information with images detailing the procedures required to attain the second sample at 1-month post-discharge (see Appendix T). The kits in this study contained the following:

- 1 x salivette collection tube;

- 1 x biological hazard bag; and

- 1 x prepaid, pre-addressed envelope.

A clinical biochemist at QUT undertook the salivary cortisol assays for the purpose of the project. These samples were de-identified, coded (i.e., sample number, study ID, and date) and stored for the required period of time per the NHMRC/AVCC National Health and Medical Research Council (NHMRC)/Australian Vice-Chancellors' Committee (AVCC) guidelines section 2.0, point 2.1.1 on data storage for a clinical trial (NHMRC/AVCC, 2007). All samples were disposed of according to QUT's policy on the disposal of pathological waste (QUT, 2011).

3.2.7 Cardiac Rehabilitation (CR) Program: Referral and Attendance

Cardiac rehabilitation teams were contacted via telephone and/or e-mail on the day of the nurse-led clinic (i.e., face-to-face) if participants were not identified during hospitalisation. Contact was made with CR teams to ensure participants were referred to a CR program. An appointment was made for a first visit if the participant had not already been enrolled. The benefits of attending a CR program were highlighted to all intervention group participants who returned to the nurse-led clinic. Cardiac rehabilitation program attendance was tracked throughout the course of participant follow-up by means of self-report. Hospital readmission(s) and procedural-related complications were also tracked up until 3-months post-discharge by means of self-report.

3.2.8 Medication Adherence and Compliance: Tracking and Validity

To track medication-taking behaviours, adherence, and compliance, and as recommended by Morisky, Ang, Krousel-Wood, and Ward (2008, p. 348), "the first step to understanding adherence, or lack thereof, is assessing or measuring

adherence". Thus, medication adherence was assessed using the MMAS-8 (see Appendix P1). The scale asks eight questions and requires only a 'yes' or 'no' response, scoring either one point for a yes response, and zero for no (Rigby, 2007). Items 5 and 8 were reverse-scored and with adherence identified as *low* (<6), *medium* (6-8), and *high* (8) (Morisky et al., 2008, p. 351).

Medication-taking behaviours were assessed at various intervals for all participants using the MMAS-8. Assessment time frames were as follows:

- time 1: day of hospital discharge;

- time 2: day 5-7 post-discharge;

- time 3: at 1 month post-discharge; and

- time 4: at 3 months post-discharge.

Participants were asked additional questions about the medications they were consuming, their medication knowledge, and regime. Although participants were followed up within 5–7 days post-discharge, a review of current medication knowledge and use of the MMAS-8 at each follow-up appointment assisted in identifying adherence issues. Furthermore, in recognising poor adherence, it was hoped that participating in the nurse-led clinic would reinforce the importance of taking medications and promote adherence. The MMAS-8 has good internal reliability and predictive validity demonstrated from previous studies undertaken (Krousel-Wood et al., 2009). Alpha reliability for the tool was $\alpha = .83$, as compared with the previous 4-item scale at $\alpha = .61$ (Krousel-Wood et al., 2009, p. 59). This tool was used to measure medication adherence pre and post-intervention.

3.3   Phase One: Timeline, Procedure, and Data Collection

3.3.1 Timeline

Participant recruitment, data collection, and analysis were undertaken by the PI

after ethical approval was granted. Participant recruitment at site one commenced in August 2012, while recruitment at site two commenced in October 2012. Participant recruitment ceased in April 2013, while follow-up continued until August 2013. Data cleaning and analysis were completed between April and September, 2013 (see Table 3.1). The breakdown of these periods is as follows:

Table 3.2.   Timeline for Participant Recruitment, Data Cleaning, and Analysis.

Site	Recruitment	Data cleaning	Data analysis
Site 1.	August, 2012 to April, 2013 *On hold December 21, 2012 until January 2, 2013.	April 2013– June 2013	July 2013– August 2013
Site 2.	October, 2012 to April, 2013 *On hold December 17, 2012 to January 14, 2013 due to area closures.		

3.3.2   Procedure and Data Collection

Baseline data collection: Day of hospital discharge–all participants

Following consent, baseline data were collected from all participants on the day of discharge from hospital. Data collection took approximately 30 to 45 minutes to undertake and occurred either at the patient's bedside or in an allocated consultation room. Baseline data collected included the following: general patient demographics, medical history, primary survey, physical examination and medical record details (pertaining to their admission), and psychosocial assessment (questionnaires and saliva sample). An electrocardiogram (ECG) taken within 24 hours of reviewing the patient was photocopied from the participant's medical records at both sites.

On baseline measurement, some salivettes were sent to the laboratory via postal mail while others were delivered via internal mail in a cool transport container to prevent bacterial contamination. Samples taken later on a Friday were either kept refrigerated until Monday and then posted immediately via internal mail, or hand-

delivered to the site. All salivettes were packaged appropriately for transport. Prior to the purchase of salivettes, the PI, clinical biochemist, and colleagues trialled their use so they could identify with participants' experiences and be able to answer any questions with regard to providing a salivary sample for cortisol analysis.

The procedure for attaining salivary cortisol samples was as follows. Participants were required to:

- not have eaten or food or consumed fluids within one hour prior to taking the sample;

- rinse mouth with water (10 minutes prior to taking the sample);

- chew the salivette for 60 seconds;

- ensure the sample was placed in a biohazard bag after taking; and

- ensure the sample was refrigerated (in the coldest part of the fridge immediately if participants did not have the time to post the salivette at the time it was taken).

3.3.3 Nurse-Led Clinic: Physical Examination, Medical Records, and Instruments

Education on wound care and neurovascular assessment was discussed with participants prior to discharge as they were required to undertake assessment at home and provide feedback face-to-face or via telephone. All participants were actively involved and took note of what was required for post-discharge period assessment. Validated tools were used to undertake wound site and neurovascular assessments with prior permission granted for use.

Permission to access, photocopy, and de-identify medical records was agreed upon in both site contracts; however, site one withdrew permission shortly after commencement of participant recruitment. The PI was permitted to transcribe data

required from medical records into the data collection form (DCF) instead. Only, electrocardiograms were permitted to be photocopied. Access site assessment involved taking a digital image, site palpation, and performing a visual inspection. The access site image was taken and filed together with each participant's DCF. Baseline assessment for psychological distress using the STAI and CDS were measured along with participant SE using the CSE. All questionnaires and their relevance were discussed with participants prior to their completion. Medication adherence was also assessed using the MMAS-8. Participants completed all questionnaires individually at baseline. The PI clearly discussed each questionnaire, its relevance to the study prior to completion, and the importance of taking time and answering honestly. The PI highlighted that if participants had any questions regarding completion of the questionnaires they should seek further clarification from the PI. After baseline data collection, participants underwent randomisation.

Randomisation

After consent and baseline data collection, participants were randomised to either the standard-care or intervention group. The randomisation procedure employed the method of blocking in, by which participant allocation occurred in blocks (Korosteleva, 2009). This method was chosen to ensure that both study groups were equal in size. Each number was individually placed in an opaque, lined envelope so that the number would not be permeable to light. The PI generated the random allocation sequence and placed the envelopes containing each number into one of two boxes for selection. For both sites, the numbers present in each envelope originally ranged from 1 to 110. As recruitment was slow and difficulties were encountered (i.e., slow recruitment and greater randomisation to the standard-care group with the larger blocks), the PI regrouped with the study team and it was

decided to block numbers into smaller groups of 10 to ensure equal randomisation. Recruitment slowed as a result of closure to clinical areas and outpatient departments.

As part of the randomisation process, the RN caring for the participant selected an envelope in the presence of the PI and the patient. On occasions where an RN was unavailable, the participant selected the envelope in the presence of another staff member or witness. Selection of an even number placed participants in the intervention group while selection of an odd number placed participants in the standard-care group. The allocation sequence was withheld from all participants and hospital staff. The PI had originally planned on utilising a telephone randomisation service; however, purchasing the service would have exceeded the study's budget.

The date and time for follow-up was arranged with each participant on the day of discharge from hospital. A business card detailed the essential information regarding the first follow-up, including the location of the face-to-face post-discharge clinic, date, and time. A courtesy phone call, e-mail, or short message service (SMS) was made by the PI from up to 2 days prior to all follow-ups to confirm appointments on request of the participant. All follow-up appointments were made at the end of each session.

3.3.4 Standard-Care Group ($n = 20$)

Follow-up: Current practice

Current practice for participant standard-care involves the delivery of general education about the procedure, post-procedural cares, complication identification and management and activity throughout the patient's hospital admission. Information given may include verbal and written education. Follow-up post-discharge usually includes CR team follow-up to arrange for course admission. Some facilities contact

their patients at 1-month post-discharge to collect information on the post-discharge period. Importantly, follow-up may differ for each site. Current research is now recommending telephone follow-up at 72-hours post-discharge and primary care physician review within the first week post-discharge (Rassaf et al., 2013; Tuso et al., 2013). Tuso et al. (2013) suggest that future studies track the effect of primary care physician follow-up in chronic disease patients. In the present study, participants (chronic disease sufferers) in the standard-care group were followed up post-discharge via telephone. Follow-up occurred at Time 2 (5–7 days), Time 3 (1 month), and Time 4 (3 months).

Standard-care group: Follow-up, study procedure, and requirements

Telephone follow-up for Time 2 (day 5–7), Time 3 (1 month), and Time 4 (3 months) took approximately 45 to 60 minutes. On commencement of all follow-up calls, participants were asked if there were any concerns or discomfort. Participants were also advised at this time to report any medical emergencies if they experienced any symptoms during the conversation. Examples of symptoms, such as chest pain and light-headedness, were explained. Participants were asked questions concerning their psychosocial status and physical health post-discharge using both open-ended questions and validated research questionnaires. The PI reconfirmed how the participant was feeling and if there were any initial concerns (i.e., chest pain at time of interview). Participants appeared, and were encouraged to be, open and honest in responding to open-ended questions regarding their psychological and physical health status. Most participants had recalled physical examination undertaken on baseline measurement and reported on their physical wellbeing with great attention to detail. Participants reported positively concerning the wound site (bruising, bleeding, lumps, or bumps), chest symptoms (if experienced), neurovascular

observations, activity, and diet (although diet was not a large focus) at telephone follow-up.

At each follow-up, a digital photograph and completion of a diagram documenting the appearance of the procedural access site was requested, with only a small number of participants complying. Participants were given the option of returning diagrams and/or photographs via e-mail or postal mail and were supplied with prepaid, addressed envelopes so that they would not have to bear the cost. All participants were reminded at each telephone follow-up appointment to complete the diagram and take a photograph (if able to).

Standard-care group participants were also required to provide a baseline salivary cortisol sample that would be measured for signs of stress. The saliva sample was usually collected by the PI on the day of discharge from hospital (had participants not eaten within the hour, which was a requirement for salivary cortisol collection). A second saliva sample was taken by participants at Time 3 (1-month post-discharge). Verbal and written instructions (with visuals) were supplied to all participants (see Appendix T). Participants were all reminded about the saliva sample on the day they were followed up and they also had been provided with details on the day of discharge and Time 2 (day 5–7) follow-up with the date and time for the second sample. Two standard-care group participants accidently took the second saliva sample at Time 2 (day 5–7) and were subsequently posted an additional salivette so that the measurement could be taken at Time 3 (1 month).

Medication knowledge and adherence were also assessed using the MMAS-8 assessment tool and CR attendance was assessed at each follow-up via self-report. Any concerns raised by the participant or identified by the PI (i.e., post-discharge complication) throughout the course of the study was actioned immediately (i.e.,

contacted cardiologist or GP) as per the study's risk protocols. Risk protocols were (a) site-specific; and (b) telephone follow-up for all participants (see Appendix U).

3.3.5 Nurse-Led Educational Intervention: Study Intervention ($n = 13$)

Intervention group participants underwent primary survey, psychosocial, and physical examination as identified earlier. Data were collected using validated questionnaires and self-report data to determine post-discharge health outcomes that included: physical outcomes, coping, emotional distress, and psychosocial support. Questionnaires included the following tools: CSE, STAI, and CDS, with the scales measuring SE and psychological distress. At 5–7 days post-discharge, intervention group participants were required to participate in a face-to-face nurse-led, educational clinic at the hospital site where they underwent their procedure. Clinic assessment and education took approximately 45 to 60 minutes. Participants received tailored education and support concerning the post-discharge period, recovery, cares and appropriate activities at the face-to-face clinic. Sessions incorporated both physical and psychosocial assessments and patient education provision.

Overview of nurse-led clinic activities

The following procedures were followed and undertaken on arrival at the clinic for all participants:

- participant greeted and directed to an examination table for a physical examination;
- physical examination: primary survey, vital signs (i.e., blood pressure, heart rate, temperature), an ECG, wound site assessment, and neurovascular observations;
- comparison of vital signs and ECGs to participants' baseline measurements;

- wound site inspection: palpation of the area for haematoma, visual inspection (skin colour to the area and surrounds, bruising, and bleeding) and auscultation (for bruit);

- neurovascular assessment of lower limbs: sensory, motor function, and circulation assessment;

- questionnaire completion;

- nurse-led education delivered; and

- opportunity for participants to ask questions.

Initially on consultation, the PI undertook a primary survey to determine the urgency for priority review with their cardiologist or hospital emergency centre by observing the following: airway (A), breathing (B), circulation (C), disability/distress (D); exposure/environmental (E) (Estes, Cajella, Theobald, & Harvey, 2013). The primary survey was followed by a focused physical examination as detailed above. The PI encouraged participants to discuss how they felt physically during the first week recovering from their procedure. Participants were encouraged to voice concerns about their wound, vital signs, chest symptoms, and neurovascular status during this time. Most participants were happy to discuss their progress during the first week, their physical symptoms, and observations. A majority of participants were proactive and had automatic sphygmomanometers at home and were monitoring their own blood pressure and provided details on recent readings.

Questions asked during this time included how they were feeling physically, if there were any concerns with respect to their access site (i.e., new or changes in lumps, bumps, stinging/pain, signs of infection or bruising), and new or continuing tingling or numbness to their lower limbs since the procedure (particularly access site limb). Participants appeared happy and were open in contributing physical

examination information, with most reporting they paid significantly more attention to their wound site and the healing process due to involvement in the study. The PI also listened to each wound site to assess for signs of a pseudoaneurysm as discussed in Chapter 2. No bruits were heard.

Lastly, neurovascular observations were undertaken and recorded in a validated assessment tool (see Appendix R). Lower limbs were visually inspected for colour and pulses were palpated (dorsalis pedis and popliteal pulses and posterior tibial pulses). Capilliary refill was also assessed whereby the PI squeezed the nail-beds of toes on both feet to check for a fast return to normal colour. Motor function was assessed by asking patients to plantar and dorsiflex feet and wiggle toes. Sensation was assessed whereby the PI ran a gloved index finger up the sole of each participant's foot and gently squeezed each toe and in between toes. The PI, while undertaking all assessments, encouraged participants to observe and gave direction as they would be required to undertake individual physical examination at home.

Nurse-led clinic: Questionnaire completion

Following a physical examination and primary survey, participants completed questionnaires, except the MMAS-8 which the PI integrated completing through general conversation. The MMAS-8 was intentionally not handed to participants so that only three questionnaires were required to be completed, as opposed to four to reduce the amount of time required by patients to complete all assessment tools. Prior to each questionnaire, participants were again (as per baseline) given instructions and advised to ask questions at any time if there were any queries (the PI was present in the room during this time). Most participants discussed the similarities in questions of the STAI and CDS questionnaires or questioned how they were relevant to them, while others voiced that they could identify with the

questions.

After completion of assessment tools, participants received the educational intervention—an informal interactive session between the PI and the participant (see Appendix V). Education was delivered verbally and displayed visually using Microsoft PowerPoint as an adjunct. Additionally, as identified earlier, the SE theory was used as the theoretical framework to guide this study, the CSE was used to assess SE for all study participants. Psychological assessments involved the measurement of anxiety and depression using two highly validated instruments, as identified. After questionnaire completion, the PI spoke with each participant and discussed general post-discharge period education, care, and management, with a focus on post-discharge emotions (i.e., what might be experienced), and psychological distress. As each participant's experience of their procedure, hospitalisation, and early post-discharge period was different, the PI kept the educational session interactive. Participants were reminded throughout the session if they had any questions to feel at ease to ask at any time.

As identified earlier, the STAI and CDS measured anxiety and depression. During the education session, participants were advised of the link between CHD, anxiety, and depression and why the questionnaires were undertaken. Furthermore, emotions surrounding participants' experiences and those who have had a cardiac event were discussed (with their experiences highlighted as individual). Participants were educated regarding the emotional impact of PCI and cardiac events and what emotions were normal after the procedure and event; however, the main message delivered was that if participants experienced ongoing emotional distress, to seek help. The PI offered support services to all participants, had they been required for emotional distress. Support services included referral to: 'BeyondBlue', The

University's Psychology Clinic and 'Lifeline'. Finally, the PI discussed support networks and clarified each participant's support person and encouraged speaking with these if participants were concerned or if they found it helpful to discuss their emotions and/or experiences. Two participants commented on the benefits of this discussion as the first time they had a PCI they had not been made aware of this and subsequently were anxious and later clinically diagnosed with anxiety.

Education delivered was a combination of verbal and visual information, supported by written material. Written material included hospital-specific post-discharge instructions. Essential written documentation supplied to all participants included a National Heart Foundation of Australia (NHFA) book to assist participants in their self-education and making positive lifestyle and health behavioural changes. The NHFA document contained information and education about CHD, diet, risk factor modification, exercise, and a chest pain action plan and magnet. As post-discharge angina and management was discussed during the intervention, the PI went through the steps of the action plan and provided a hypothetical scenario to each participant. Participants were then asked to guide the PI through the action plan, and the actions they would follow if angina were experienced at home. Participants were engaged during this scenario and most commented on the fact that they were not aware of dialling '112' (the number displayed on the magnet) if calling for an ambulance from their mobile phones. Additionally, the PI recommended participants place the magnet on the fridge or somewhere nearby to the home telephone and/or charging facility for the mobile phone for quick and easy reference should it be required.

Complication identification and management was also discussed and included: bruising, haematoma, bleeding, infection, and neurovascular complications. Closure

devices were also briefly mentioned for patients. Again, to encourage interaction, scenarios were worked through highlighting complication management, in particular, haematoma and bleeding. Participants were able to recall how much digital pressure, length of time required, and where to apply pressure (just above the incision) for bleeding and haematoma management. Recall for how to apply access site digital pressure was clear for participants as they had been awake during femoral arterial sheath removal. Importantly, throughout the course of the educational intervention, it was highlighted to participants that the ambulance service be notified for acute situations (i.e., unrelieved CP per NHFA action plan, active bleeding, or haematoma). Prior to study commencement, potential ambulance overuse was highlighted (i.e., calling for bruise discomfort or cold toes on neurovascular self-assessment). For each complication identified, an example was given, with a pathway of who to contact. Finally, neurovascular complications were discussed at the clinic, with pre-documented complications present in several participants. Participants reported the following pre-existing injuries/complications, highlighting that they were not as a result of the procedure or hospitalisation and included: a previous ankle fracture, toe numbness, and gout. Any changes in neurovascular observations such as, tingling, pain, or numbness in the procedure site limb warranted investigation and was emphasised to all participants.

Medication knowledge, education, and adherence were assessed and discussed. The three main messages were: (a) take all medications as prescribed, (b) never to cease administration abruptly, and (c) always maintain supply of medication at home. Participants' medication knowledge about the major medication groups (that PCI and ACS patients are usually discharged on) was also identified and this knowledge was briefly discussed. Participants were advised to bring along their

medications and/or lists; however, only some participants did so.

The importance of CR attendance and course compliance was also discussed. The PI identified why participants should attend—who can attend (patient and family), who would be present (i.e., patient groups and speakers), and what the program would entail—with the aim of enrolling those who had not been approached at the end of the clinic. Most participants had attended previously and declined re-enrolment. First-time participants were enrolled either prior to discharge or at the clinic. A saliva sample was taken at 1-month post-discharge to perform a salivary cortisol assay for physiological signs of emotional distress and was posted to the QUT laboratory for testing. The PI contacted intervention group participants again at Time 3 (1 month), and Time 4 (3 months) via telephone for further collection of data concerning their psychosocial wellbeing and physical health post-PCI, although the Time 3 (1 month) follow-up point was the study's key endpoint. Intervention group participants were given the opportunity to ask questions during the clinic session and follow-up. The PI contacted each participant's cardiologist and/or GP via e-mail and/or postal mail on study enrolment. No adverse events (AEs) or serious adverse events (SAEs) were experienced.

Follow-up periods and justification

As identified above, the follow-up periods after randomisation and consent on the day of discharge were Time 2 (day 5–7), Time 3 (1 month), and Time 4 (3 months). Follow-up at Time 2 (5–7 days) and Time 3 (1 month) was selected due to the short length for hospitalisation and, thus, the need to repeat education, knowing the strong link between psychological distress (i.e., anxiety and depression) and a cardiovascular event at this time (AIHW, 2011; Davidson et al., 2008; Holt et al., 2013; Lane et al., 1999; Lauck et al., 2009; Turner et al., 2010; NVDPA, 2012).

Furthermore, as the PI sought preliminary data to determine the anxiety-reducing effect of the intervention on participants, early follow-up for signs of psychological distress, as recommended by the AIHW (2011) and Das and O'Keefe (2006), was undertaken. Time 3 (1 month) was chosen as the primary endpoint and a satisfactory follow-up time as most participants had not seen their cardiologist or commenced a CR program (BHF, 2009; Cupples et al., 2010; Goble & Worchester, 1999; NHF, 2010; Trotter et al., 2011; Wenger, 2008). First, this approach allowed for more accuracy in the assessment of the effects of the intervention on participant anxiety. Second, as referral and attendance to CR is often low, one of the secondary aims of this project was to ensure 100% attendance (Cupples et al., 2010; Heartwire, 2011). Third, as new ACS patients are commenced on an average of six new medications and with compliance issues highlighted in the literature, early medication education and the encouragement of compliance through education was warranted (Aroney et al., 2006; Morisky et al., 2008; Rudd et al., 1993).

Final participant follow-up at Time 4 (3 months) was also important to this study as it is identified in the literature to be a high-risk period (Curtis et al., 2009, pp. 303–307; Sherev et al., 2005). Many studies follow participants suffering psychological distress long-term (Birket-Smith, Hansen, Hanash, Hansen, & Rasmussen, 2009). Studies' follow-up have ranged from 6 months to 6 years (Birket-Smith, Hansen, Hanash, Hansen, & Rasmussen, 2009). Studies of cardiovascular interventional origin and clinic provision include a 12-month follow-up marker to assess for patient readmissions to hospital post-PCI (i.e., CP), and health status (Grumann, Diehl, Bode, & Moser, 2007; Schadewaldt & Schultz, 2011). First-generation drug eluting stents became a topic of discussion within the literature with late stent thrombosis/restenosis occurring up to 12 months post-PCI (Palmerini et al.,

2013; Grumann et al., 2007). Second-generation drug eluting stents are continuing to be investigated in larger trials and appear to have a lower risk of the aforementioned complications; however, it is acknowledged that larger, more well-powered studies are required to comment on this effect (Palmerini et al., 2013). As identified earlier, because this study was to fulfil the requirements of a PhD, with limited funding and time, the PI was required to perform the last follow-up on post-PCI patients at Time 4 (3 months) rather than any time frame beyond this point.

3.3.6 The Nurse-Led Clinic Intervention Details: Intervention Group – Face-to-Face, Nurse-led Clinic (Time 2)

Measures

At Time 2 (day 5–7), intervention group participants were followed up as prearranged. As identified earlier, content in the intervention group visit included a comprehensive physical examination, primary survey, and specific neurovascular and wound assessments. Physical examination ensured that patients were monitored for any post-procedural complications. Complications that may occur post-PCI as discussed in Chapter 2 may include any of the following: haematoma, pseudoaneurysm, access site infection and contrast-induced pyrexia, and chest pain (CP) (Levine et al., 2003, p. 130; O'Grady, 2007, pp. 25–30). Participants' self-efficacy (SE) was measured using the CSE (Appendix B) while anxiety was measured using the STAI (see Appendix C). Depression was measured using the CDS (see Appendix D). Participants' medication-taking behaviours using the MMAS-8 were also assessed (see Appendix P1). Additionally, new medications, management, and adherence, along with the promotion and referral of participants to CR, were discussed. Appointments to attend CR were made on the day of the nurse-led clinic if an appointment had not yet been arranged by the CR team during

hospitalisation. Course attendance and compliance was tracked via participant self-report.

Throughout the course of the study, the PI assessed participants in both groups using quantitative and qualitative self-report techniques. Questions asked of participants were open-ended questions and assessed for psychological distress and post-PCI health and wellbeing as recommended by Das and O'Keefe (2006). Das and O'Keefe (2006) highlight the importance of screening patients with CVD for psychosocial distress due to the strong association between psychosocial health and CVD; therefore, participants in the present study were asked questions concerning psychological distress. Furthermore, to assess for risk of psychological distress, the Das and O'Keefe (2006) recommended screening and asking simple open-ended questions, this was therefore applied to participants throughout the present study (Das & O'Keefe, 2006). As similar questions were asked in the STAI and CDS, only some of these suggested questions as recommended by Das and O'Keefe (2006) were adopted for assessment of psychological distress and risk in the present study. Other questions evaluated participants' health knowledge.

The face-to-face visit took place at clinical consultation rooms at the hospital in which the PCI procedure was undertaken, at Time 2 (day 5–7). Approval to undertake the clinic in consultation rooms was granted by both sites. These rooms were all in close proximity to emergency centres and participants' cardiologists in the event that an urgent review was required. One site provided nurse practitioner support, should any participant require urgent review. As identified earlier, site-specific and telephone follow-up risk protocols were created so that the appropriate procedures (both actions and reporting) could be followed should an AE or SAE occur (see Appendix U). Participants attending the clinic were offered car-parking

vouchers if they had driven to the facility. Some participants elected to park in surrounding streets and declined a car park voucher, although supply of vouchers was highlighted prior to clinic attendance.

Nurse-led clinic and achieving efficacy beliefs

It was hoped that by participating in the nurse-led clinic post-PCI participants' efficacy beliefs, or beliefs relating to successfully carrying out a certain behaviour or control concerning aspects of their lives and functioning, would be enhanced and/or achieved (Bandura, 1993). Positive efficacy beliefs may in turn affect an individual's thought processes, feelings, and thus, their motivation and behaviour (Bandura, 1993). In the present study, it was hoped that participation in the nurse-led clinic may enhance SE by encouraging positive efficacy beliefs. Efficacy beliefs may be met through the four following information sources: mastery, vicarious experience, verbal persuasion, and physiological feedback (Bandura 1995, 2004, p. 195; Holloway & Watson, 2002, pp. 109–111). Through the repetition of education and provision of early post-discharge support, it was hoped that post-PCI anxiety and depression symptoms could be reduced and effective self-management achieved by enhancing SE by meeting efficacy beliefs.

The nurse-led clinic was, therefore, modelled around the aforementioned information sources so that both primary and secondary aims could be achieved. As identified, the nurse-led clinic provided the participants with the skill to achieve efficacy beliefs as it used both verbal and visual means of education. The nurse-led clinic provided verbal, written, and electronic means of education, with a practical component. Scenarios were provided for participants to work through with the PI (i.e., talking through CP action plan), while practical skill demonstrations (i.e., access site complication management) were offered with encouragement to

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participate in undertaking of the skill. Thus, with the nurse-led clinic modelled around the four information sources, it was hoped that efficacy beliefs may be achieved through both performance accomplishment, observational learning (i.e., the PI demonstration and CP action plan scenarios), verbal persuasion (i.e., trust and confidence in the PI as educator), and physiological feedback (i.e., reduction in anxiety or control of negative emotions).

3.3.7 Standard-Care Group

Measures

Although randomised to the standard-care group for this study, participants received usual education and follow-up given to patients by the hospital sites and secondary prevention services as highlighted above. As identified earlier, this group were followed up and required to undertake various assessments, including the CSE, STAI, CDS, and MMAS-8, and provide a saliva sample on the day of consenting and at 1 month post-discharge. The CSE was used to assess SE in the standard-care group pre and post-discharge from hospital. The STAI and CDS allowed for the measurement of trait anxiety or signs of depression pre and post-discharge versus intervention and standard-care groups. Saliva was measured to assess participant stress levels pre and post-discharge as compared to intervention group participants. Additionally, the MMAS-8 was undertaken to determine individual and group medication adherence as well as behaviours between groups. Tracking of CR attendance occurred while post-discharge complications (i.e., procedure access site, chest pain) were assessed over the course of the study at each follow-up point. A risk protocol was in place for standard-care group participants so that immediate action could be taken if an AE or SAE occurred.

All groups: Time 3 (1 month) and Time 4 (3 months)

At Time 3 (1 month) and Time 4 (3 months), participants in both groups were required to complete all assessment tools—CSE, STAI, and CDS. In addition, participants in all groups were also required to undertake a MMAS-8, as identified earlier. Cardiac rehabilitation attendance and compliance were also assessed with reasons for attendance/non-attendance requested, along with complication identification and management. Participants had the opportunity to ask questions concerning their post-procedural health, wellbeing, and concerns. The PI also asked questions of participants throughout the course of the study. Assessment at Time 3 (1 month) and Time 4 (3 months) occurred via telephone and took approximately 45 to 60 minutes in total. Participants were made aware of follow-up times and duration on the day of consenting. All follow-up telephone visits were arranged at the end of each follow-up session. At Time 4 (3 months), participants in the intervention group were asked questions about the educational intervention and its effectiveness in their recovery. These questions were present in the DCF and consisted of a mix of structured open and closed-ended questions (see Appendix P).

3.3.8 Phase One – Both Study Groups: Early withdrawal, participant withdrawal and lost to follow-up

As identified, in the consent process, participants were advised of their freedom to withdraw at any time from the study without comment or penalty. Participants were provided with contact details (i.e., telephone and email) so that they were able to communicate with the PI throughout the course of the study (questions, concerns or withdrawal).

Early withdrawal

No participants in the present study were withdrawn by the PI; however, the

following conditions were in place if early withdrawal was required:

- unexpected illness (i.e., suffering acute psychological/psychiatric distress, diagnosis of fatal illness, poor progression of current illness, requiring major surgery)
- as a result of participation or possibly as a result of participation in the study (i.e., acute psychological/psychiatric distress).

Early participant withdrawal would have been formally and immediately reported to the study monitor, HREC, university had it been required. The following processes were in place for participants lost to follow-up.

Lost to follow-up

Participants lost to follow-up were contacted in accordance with the following protocol:

- Maximum of:
  - two telephone calls to landline or mobile phone
  - two emails
  - two certified letters.
- Telephone message — to be clear and detailed:
  - **state:** name, position, date, and organisation and study
  - **request**: participant to return the call between business hours, Monday to Friday
  - **advise**: PI will follow up with certified letter via postal mail.

As identified, consent to retain and use all participant study data for analysis was attained given the application of the intention-to-treat principle. The principle of intention-to-treat is discussed in section 3.4.

3.4   Phase One: Data Analysis

As highlighted above, the intention-to-treat principle was used in analysing study data. This principle has been identified as a "strategy for the analysis of randomised controlled trials that compares patients in the groups to which they were originally randomly assigned" (Hollis & Campbell, 1999, p. 670). The intention-to-treat principle was applied to participant withdrawals, participants lost to follow-up, protocol deviations, and treatment received (Hollis & Campbell, 1999). Hollis and Campbell (1999) highlight two important objectives of the intention-to-treat principle which include: (a) similarity in treatment groups, with exception of randomisation; and (b) allowance for clinician non-compliance and deviations (Hollis & Campbell, 1999). Although the randomisation process assists decreasing study bias, the intention-to-treat principle ensures all participants are included in the analysis, therefore offering greater validity to the study and results while reducing the risk of study error (Montori & Guyatt, 2001).

The PI undertook initial exploration of the data and this included descriptive statistics. First, data cleaning was used to identify any abnormal and repeated values and outliers. Descriptive tests and visual inspections were undertaken using SPSS in the cleaning process. Descriptive statistics were used to summarise study participants' characteristics while frequencies were used to establish the distribution of data. Effect-size calculations were completed to determine the effect of the nurse-led clinic on intervention group participants versus standard care and are displayed in Chapter 4. Additionally, reliable change index (RCI) calculations were also completed to determine the therapeutic outcomes of the nurse-led clinic versus standard care. Reliable change index calculations provided further detail regarding the percentage of participants who experienced improvements or 'recovered' (i.e.,

returning to normal functioning) after attending the nurse-led clinic. Statistical analysis of participants' demographics and clinical characteristics were employed by means of descriptive statistics and are presented as frequencies, percentages, means, and standard deviations and are presented in the results chapter. Descriptive statistics were used to describe the groups (i.e., standard care and intervention) and individual participants recruited to the study. Characteristics such as gender, age and/or differences, risk factors, medical history, education, and marital status are presented as descriptive statistics.

SPSS version 19 and Microsoft Excel were used to undertake data entry and analysis, as identified earlier. Effect-size (ES) calculations and RCI calculations were used to determine the effectiveness of the nurse-led clinic and feasibility for a Phase Three study. See Table 3.3 for further detail:

Table 3.3.   **Research Questions Tested**

Research Question/Outcome(s)	Test
Changes in participant SE over time	
Changes in anxiety scores over time	
Changes in salivary cortisol levels over time	Effect size (ES) or Cohen's d
	Reliable Change Index (RCI)
Changes in depression scores over time	Frequencies
Changes in medication adherence scores over time	
CR attendance	
Complications (i.e., wound site bruising, haematomas, CP)	Descriptive statistics: Frequencies

3.4.1 Interim Analysis, Auditing, and Reporting

With a statistics background, the team's associate supervisor reviewed and monitored data independently at multiple occasions. An interim analysis was performed around the midpoint of the study and at the end of data collection.

Additionally, the study was audited by the Research Governance Office (RGO) from one of the study sites. Participant files were randomly selected for review and viewed in the presence of the Principal Supervisor, the PI, and the Postgraduate Research Coordinator. Auditors also ensured the security of electronic files (i.e., password protection). No actions were required post review.

3.4.2 Ethical Approval, Risk, and Strategies

Ethical approval was sought from the following four committees according to Section 1.8 of the Revision of the Joint NHMRC/AVCC Statement and Guidelines on Research Practice Australian Code for the Responsible Conduct of Research (NHMRC/AVCC, 2007, p. 11): (a) Hospital HRECs, (b) Medical Institute HREC, and (c) QUT. Section 1.8 states that "as a responsible researcher, appropriate and prior written authorisation concerning ethical approval, participant safety and additional organisations will be sought" (NHMRC/AVCC, 2007, p.11). The ethical principles of integrity, respect for persons, justice, and beneficence were adhered to at all times (NHMRC/AVCC, 2007). QUT's 'Code of Conduct for Research D/2.6' was also regularly reviewed to ensure appropriate conduct for the duration of the study. Section D/2.6 covers ethical considerations, policies, and procedures for research and were strictly followed (QUT Code of Conduct for Research, D/2.6, Manual of Policies and Procedures [MOPP], 2009).

As identified in the NEAF, the PI works as a RN at one of the hospital sites. The PI coordinated with the CNM that, when working as a RN on the ward, she would be allocated non-PCI patients where possible. This strategy was to eliminate the possibility of potential study discussion; to avoid placing any pressure on the patient to participate, if approached on the day of discharge (day participants were recruited); or undue inducement. As identified earlier, participants were approached

to participate in the study by the ward CNM or RN taking care of them so they would not be placed under any pressure to participate. When indicating interest in study participation, the CNM or RN would inform the PI who then approached the participant. Participants were fully informed and given a written PICF, which was signed and witnessed during the consent process. All participants were given a photocopy of their signed PICF. Participants were informed of anonymity procedures and their ability to withdraw at any time without comment or penalty. Please see Appendix W for the Phase One consent form and HREC approval.

3.4.3   Limitations

There were several limitations to the study identified by the PI and research team. They are as follows:

- **Study wait times:** Wait times for ethical approval to the commencement of the study were prolonged. Following NEAF approval, it took 12 months for the approval of the SSA, site risk management strategies, and to secure clinic office space to undertake the study. Additional delays to recruitment were experienced for one month from December 2012 to January 2013 as both sites experienced planned area and ward closures.

- **Self-report**: The PI identified the possibility of measurement error with the collection of self-report data. To reduce the potential for measurement error, the PI was careful to give clear instruction to all participants regarding the completion of each questionnaire. Care was also taken to explain the questionnaires, answer any questions, and advise of the respective responses during telephone follow-up to reduce the risk of measurement error. Additionally, participants were

encouraged to respond honestly and take their time to complete questionnaires. Finally, with pre and multiple post-test self-reporting using the same tools, questions and responses may have been recalled by participants and answers modified, therefore changing the study's outcome. This effect is known as the "Testing effect" (Grove, Burns, & Gray, 2013, p. 199).

- **Measurement effect**: Is also likely that this effect could have occurred in this study whereby participants (i.e., standard-care group) changed certain behaviours, felt better, or had overall improvements as a result of participating in the study (LoBiondo-Wood & Haber, 2010). LoBiondo-Wood and Haber (2010, p. 172) highlight how administering pre-intervention tests can "prime" participants and encourage them to think about what is being measured and facilitate change.

- **Low statistical power**: There is great potential for a type II error in this study as the PI was unable to recruit participant numbers for several reasons, as identified earlier. In the early stages of the study, as stated previously, a sample size calculation was undertaken to potentially avert type II error occurring; however, the sample size could not be achieved. Given that the present study was undertaken as a pilot, results should be considered cautiously, pending replication in a future study, as described in Phase Three. Recommendations to enhance participant recruitment in future research will be addressed in Chapter 6.

A Consort Flow chart was created to track participant flow throughout the

course of the study alongside a detailed Excel spreadsheet documenting participant recruitment, reasons for declining enrolment, loss to follow-up, and why exclusion criteria were met (see Figure 3.2 and Table 3.4). The trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) and assigned a clinical trial registration identification number, 12612000971831.
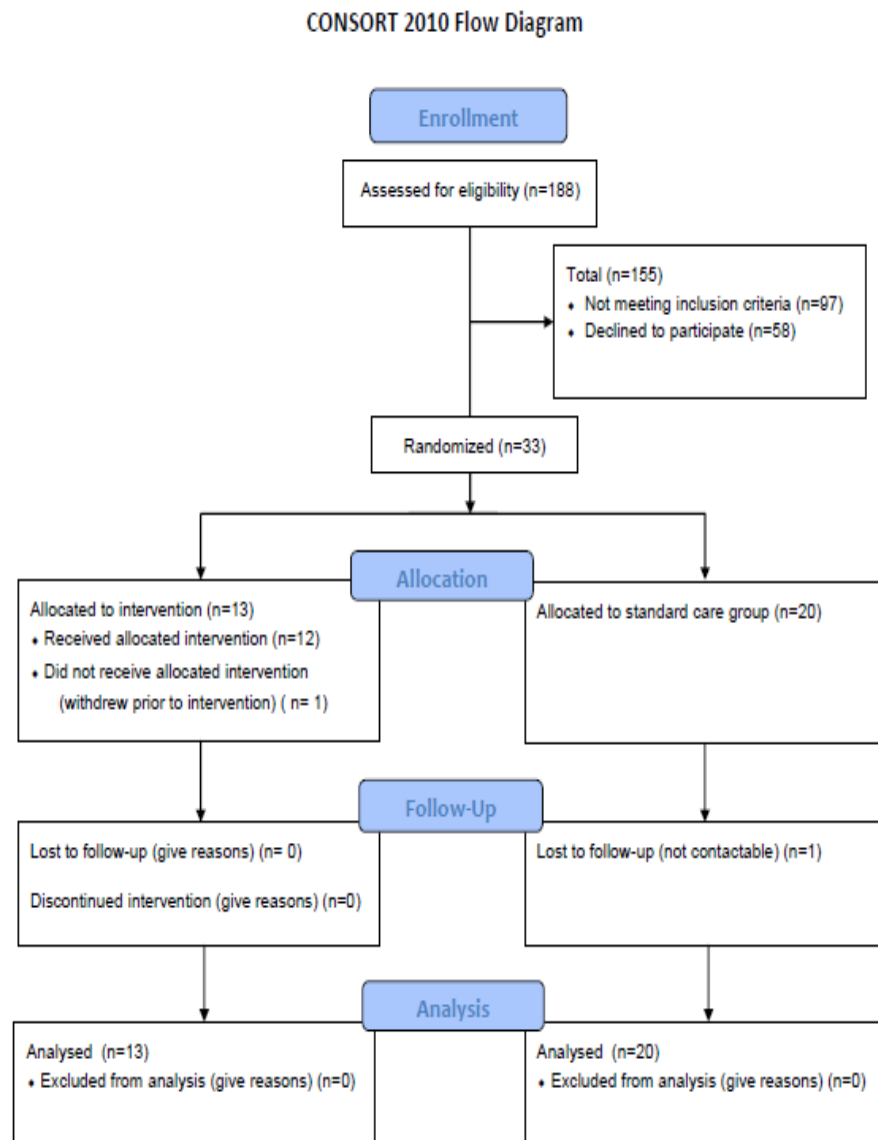
Figure 3.2.   CONSORT Flow Diagram: The 'REALITY CHEC' Project©.

As presented in the CONSORT Flow chart above, the PI screened 188 potential participants during the recruitment phase, with 97 not meeting the inclusion criteria and 58 declining to participate due to the reasons outlined in Table 3.4.

Table 3.4.   **Reasons for Declining and Excluding Participation**

Declining Participants ($n = 58$)	Excluded Participants ($n = 97$): Justification
face-to-face nature of the study (preference for telephone follow-up)	medical treatment of CAD only
general inconvenience of returning for follow-up	no appreciable disease
geographical location/isolation	multiple co-morbidities: Full medical cares
transportation issues	staff advice not to approach
going on leave	for CABG surgery
too busy	staging of PCI
inability to drive for 2-4 weeks as advised by specialist	registered in another site clinical trial
limited support networks	confusion
illness	failed PCI
too much required of them to participate	further ongoing hospitalisation and investigations for recurrent seizures
participated in research in the past and not eager to participate again	
for additional surgery	
not of interest	
nil reason offered	

Participants who met inclusion criteria and consented to participate, justified their participation as follows: participation in previous clinical trial(s), participant(s) or a family member had undertaken a Master's or PhD, participants felt if it would benefit others and themselves, and participants generally enthusiastic to participate. As highlighted earlier, the PI solely undertook extensive screening at both hospital sites over several months and, as a result, was not able to meet the sample size calculated. The pilot study undertaken, however, greatly informed the PI for a proposed Phase Three, multi-centre study that will be discussed in greater detail in Chapter 5.

3.5   Phase Two: Descriptive Evaluation of the Nurse-Led Clinic

In Phase Two of the present study the PI undertook semistructured interviews to analytically explore study participants' and healthcare professionals' feedback of the nurse-led, educational intervention. After obtaining ethical approval to undertake Phase Two, intervention group participants and healthcare professionals were approached to provide detailed feedback regarding the nurse-led clinic so that the "acceptability, feasibility and preliminary effectiveness" of the pilot, as highlighted by Sidani and Braden (2011, p. 155), could be appraised. The program evaluation discussed the overall educative effectiveness of the nurse-led clinic (i.e., educational content and method of delivery), repetition, and timing of education delivered. All participants were asked to critique the nurse-led clinic and report on positive and negative aspects, while also offering suggestions for improvement. The PI discussed the potential of the clinic to achieve primary aims to increase SE, while reducing participant anxiety. The PI also discussed the potential for the nurse-led clinic to reduce depressive symptoms, encourage CR attendance, and its potential effectiveness in increasing medication knowledge and adherence, while encouraging effective self-management. Moreover, the PI sought feedback regarding its overall application in a real-world setting (i.e., Phase Three study).

The PI undertook an analytic evaluation of participants' interview transcripts adopting aspects of Charmaz's (2006, p. 28) analytic techniques and Brinkmann's (2014) abductive approach to facilitate the PI's interpretation and understanding of participants and healthcare professionals' view of the nurse-led clinic, cardiovascular and psychological health, wellbeing and self-management, CR attendance, medication adherence and knowledge. Furthermore, using aspects of this technique allowed the PI to link analytical findings from Phase Two to Phase One preliminary

findings. Figure 3.3 presents the flow of Phase Two.
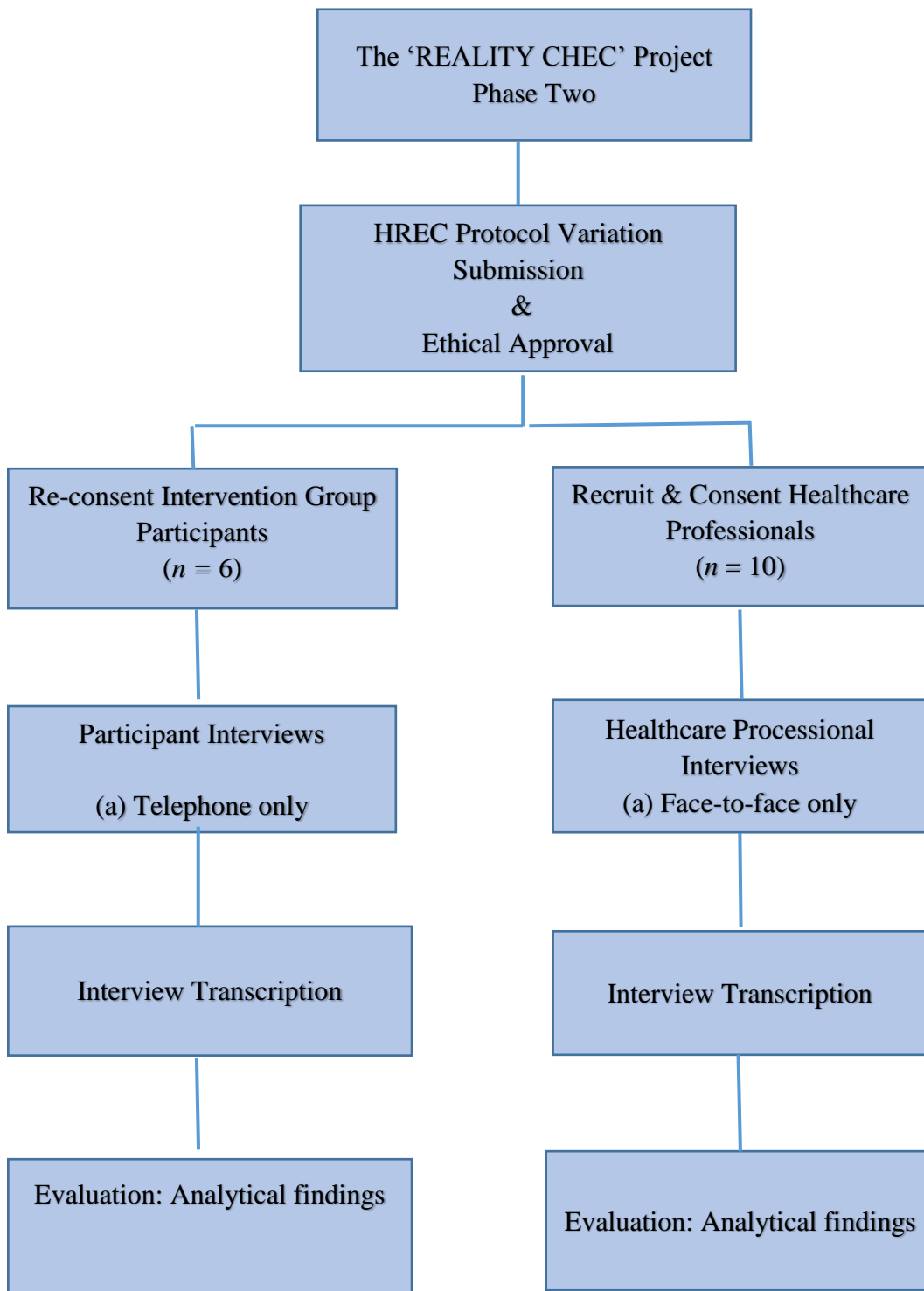
Figure 3.3.   **Phase Two Flow of The 'REALITY CHEC' Project©.**

3.5.1 Phase Two: Research Aim and Questions

As identified, the main aim of Phase Two was to analytically explore both healthcare professionals' and intervention group participants' feedback of the nurse-led clinic.

Together, the Phase Two aim and research questions presented below guided the semistructured interviews constructed for participant and healthcare professionals (see Appendix X).

Participant interviews: Research questions

- Did attending the intervention meet the participant's needs?

- How did the intervention meet the participant's needs?

- Were there additional participant needs to be met?

Health care professional interviews: Research questions

- What was the overall impression of the educational value and timing (i.e., day 5–7 post-discharge) in terms of clinic effectiveness?

- Were the methods of delivery effective (i.e., PowerPoint, written material, verbal)?

- What were healthcare professionals views concerning the practical component (i.e., beneficial to participants?)?

- Could the intervention assist in increasing SE and reducing anxiety, and in what way?

- Were the messages of CR attendance importance made clear?

- Were the messages of CR encouragement (to attend) made clear?

- How could CR be packaged to encourage attendance for both first-time patients and those who have had repeat procedures?

- Were the messages of medication attendance made clear?

- Were the basic cardiac medication groups discussed in the clinic clear and not overwhelming?

- How do healthcare professionals feel with regards to online medication access and the caution placed on it?

- Were the messages of complication identification and management made clear?

- What were the highlights of the information presented?

- In what way could the nurse-led clinic be enhanced?

3.5.2 Phase Two: Randomised Controlled Clinical Trial (RCT) Pilot Evaluation

As identified, Phase One modelled an RCT to determine the efficacy in undertaking a Phase Three multi-centre study. In Phase One, the PI undertook experiential and theoretical work to gain an understanding of the research problem, and how to effectively create an intervention to suit the needs of the study population (i.e., PCI patients). Phase Two of the study drew on the interpretive paradigm and adopted a descriptive-evaluative method adapting analysis techniques used by Charmaz (2006) to analyse data obtained through participant and healthcare professional interviews. The purpose of using this approach was to determine the effectiveness of the nurse-led clinic and to inform the research and, therefore, facilitate enhancements that could be applied to the Phase Three study protocol. Clarke and Dawson (1999) advise how evaluation research informs and facilitates improvements; thus, it was chosen to guide the study's second phase and particularly in the data analysis process.

Sidani and Braden (2011) highlight the importance of a Phase Two to the development of a study. The authors encourage the evaluation of a Phase One pilot

study so that potential problems may be managed and enhanced for all future participants. Sidanin and Braden (2011) highlight how evaluation of an intervention should place importance on gaining participants' and investigators' feedback on the pilot in order to (a) evaluate the ease and operation of undertaking the intervention, (b) determine the reliability or fidelity of the intervention to achieve a successful study and outcomes, (c) determine the participants' experiences and contentment with the intervention, and (d) develop means to the achievement of study outcomes. Drawing on the interpretive paradigm to evaluate Phase Two data facilitated a greater depth of understanding of interview material, as a richness is placed on participants' words and experiences (Guba & Lincoln, 1981).

In addition to the adoption of the work of Charmaz (2006) to organise data coding and evaluation, an abductive approach as identified by Brinkmann (2014) was assumed to further evaluate and gain an understanding of Phase Two interview data. Brinkman (2014, p. 722) highlights how abductive reasoning is an ongoing process with no "hard and fast line between life, research, theory and methods". Brinkmann (2014) further highlights how abduction is not data or theory motivated and is essentially a breakdown in personal understanding or reasoning with respect to a situation, inquiry, and the relationship.

3.5.3 Phase Two: Sample and Procedure

Sample one: Intervention group participants

All intervention group participants ($n = 6$) at the private hospital site were approached initially via postal mail and then contacted via telephone during the recruitment stage of Phase Two. Six intervention group participants consented to participate, while two declined due to illness or unavailability due to work commitments. A purposive sampling technique was used in selecting all study

participants. Patton (1990, 1999) explains how this method of sampling gathers rich data in its process and participants. The PI was unsure how many participants would be required to achieve information-rich data as well as facilitating a full analysis of the study phenomena. Becker (2012) identifies that there are no set rules in qualitative research for sample size requirements. Charmaz (2012) recommends that researchers consider both the research purpose, depth of investigation, and the epistemology when considering interview sample size, while Back (2012) asserts that the number of interviews undertaken should represent the truth. Adler and Adler (2012, p. 8) also advise that the collection of data can occur until the point of "empirical saturation"; however, they do caution that reaching the point of saturation is often not feasible. Therefore, with the aforementioned recommendations taken into account, healthcare professional interviews were ceased at number 10, while participant number 6 was the final interview for intervention group participants.

Sample two: Healthcare professionals (n = 10)

A total of 10 healthcare professionals working in the cardiology field were recruited for interviews in Phase Two of the study. Participants consisted of staff members from the ward, cardiac catheterisation theatre (CCT), hospital executive nursing team and a cardiology group. The staff skill mix comprised of RNs, CNs, one DON, one CNM, and two leading cardiologists. Participants were all recruited from the private hospital site after the study variation and ethical approval was granted at this hospital, a medical institute, and QUT HREC.

Setting

All healthcare professionals' interviews in Sample Two were undertaken at the hospital site at a time convenient for each participant. Intervention group participants in Sample One undertook interviews via telephone only. The PI was allocated a

private office at QUT to undertake telephone follow-up. No other person was present in the office at the time of follow-up.

3.6   Instruments, Validity and Reliability

3.6.1 MP3 Recorder and Participant Interviews

An MP3 recorder was used to audio record all interviews. Recording allowed for the transcription of participant interviews and for the descriptive evaluation analysis to be undertaken. The PI was the only person in possession of the MP3 recorder at all times. When not in use, the recorder was locked in a filing cabinet on campus at the university. Recordings were only heard by the PI and the transcriber. All recordings were kept anonymous during recording and were coded to ensure participant confidentiality (i.e., 001).

3.6.2 Validity and Reliability

Qualitative research views validity and reliability in terms of "truth value" (Guba & Lincoln, 1981, p.105; 1985, p. 294). Guba and Lincoln (1981, 1985) also highlight that the internal validity in qualitative research is measured and termed 'credibility' as opposed to the quantitative term, 'internal validity'. Moreover, in qualitative research, when a phenomenon or phenomena are acknowledged as one's own, internal validity has been said to have been achieved (Guba & Lincoln, 1981, 1985).

Further to achieving validity, it is essential that the interviewer have the skill to elicit rich data (Appleton, 1995). Appleton (1995) encourages pre-pilot interviews be undertaken to enhance interviewer technique, and importantly, increase the validity and reliability of the data. The PI had undertaken several patient interviews in previous studies; however, to ensure data validity and reliability, the PI conducted

pre-interview role plays with the Principal Supervisor so that interview technique could be critiqued and feedback provided. Lastly, Appleton (1995) adds how study tools used can also enhance reliability and validity. Consequently, the PI utilised an MP3 player to record participant interviews to achieve this goal (Appleton, 1995).

Further to achieving qualitative research validity, there are four criteria established by Guba and Lincoln (1981) that are used to determine qualitative research validity. All criteria are used interchangeably and are as follows: "Trustworthiness; credibility; reliability; and rigour" (Morrow, 2005, p. 250; Pitney, 2004, pp. 26–28). Guba and Lincoln's (1981) criteria for ensuring a study's trustworthiness were adopted by the PI to achieve greater reliability and validity in the research and findings.

Credibility is used to assess if a researcher has accurately interpreted study participants and their voiced experiences (Guba & Lincoln, 1981; Morrow, 2005; Theobald, 2001; Tobin & Begley, 2004). In ensuring credibility of study findings, it is recommended that "member checks" or review of transcripts be undertaken by participants (Guba & Lincoln, 1981, p. 314). In this study, all participants reviewed their interview transcripts for accuracy. No changes were requested by participants. The second term, transferability, refers to the generalisation of findings to one's own situation, in particular, the reader (Morrow, 2005). Morrow (2005, p. 252) argues that the results of a study should be presented so that the readers may partially or completely identify with some aspects of the study. Furthermore, Morrow (2005) highlights that if readers are able to relate to findings then transferability is considered achieved. It is hoped that participants and future PCI patients reading a publication or summary of the study's results may be able to identify with findings (or aspects of), thus achieving transferability. The term dependability refers to the

identification of the research process, steps and documentation and validation in an audit trail and confirms the trustworthiness of a study (Morrow, 2005; Twycross & Sheilds, 2005). The PI kept detailed documentation regarding the study and processes with audits being performed internally and externally. Participant confidentiality was maintained at all times.

Confirmability refers to the authenticity of the study's results and whether interpretation actually reflects the true findings (Guba & Lincoln, 1981; Morrow, 2005). It is highlighted that when interpreting findings the researcher should assume neutrality and view the data objectively (Guba & Lincoln, 1982). Maintenance of confirmability can be ensured when evidence of bias elimination is seen (Theobald, 2001). A confirmability audit was undertaken to ensure maintenance of confirmability. The confirmability audit was carried out by the Principal Supervisor who reviewed Phase Two data and compared it against the researcher's interpreted findings.

3.7   Timeline, Procedure and Data Collection

3.7.1 Timeline

The timeline for all participant interviews and data analysis is presented in Table 3.5. It took approximately 2.5 months to undertake all interviews, transcription, and analytical evaluation of transcripts. Organising a convenient date and time for each interview to be undertaken was challenging with parties on annual leave, at work, or unavailable due to other commitments. The PI expressed flexibility in arrangements with all participants so that they did not feel under pressure to make an appointment at an inconvenient time.

Table 3.5.   **Phase Two Timeline**

Interviews: Commenced	Interviews: Completed	Data Analysis
Thursday 13 June 2013	Friday 9 August 2013	Monday August 12–Friday August 30 2013

3.7.2 Participant Recruitment

Phase one participants: Intervention group participants approached

After ethical approval, participants were approached via mail and subsequently telephoned to assess interest in participating in the study (see Appendix Y). If in agreement, a time and date was arranged with participants to undertake one telephone interview regarding the nurse-led clinic they attended at Time 2 (day 5–7), its educational benefits, and assistance in the post-discharge period and beyond. All participants were thanked and mailed a $25.00 store voucher for their participation after each interview was undertaken.

Healthcare professionals

Healthcare professionals who were interviewed were approached by the PI to participate and were offered an information and consent form and a detailed explanation about the requirements after reviewing the PICF. Fourteen healthcare professionals were approached during the recruitment phase, with 10 participants consenting. Work and/or family commitments were identified as reasons for not being able to participate. As identified earlier, a purposive sampling technique was used in selecting participants for Phase Two of the study.

Once participants consented to the study, a time and date suitable for both parties was arranged for interviews. At the time of interviews, the PI revealed the nurse-led intervention, methods of delivery (i.e., visual, verbal and written), timing and length of intervention (i.e., day 5–7 post-discharge), and assessment tools used. The main aims of the study were identified, in addition to the rationale for

undertaking the intervention within 5 to 7 days (Time 2) post-PCI. Grounds for the study identified included: potentially low SE to manage in the post-discharge period, anxiety and psychological distress surrounding procedure and post-discharge period, recommendations for repetition of education (and early post-PCI), and poor information retention and absorption (during hospitalisation). Furthermore, with limited nurse-teaching time and cardiology and CR follow-up between 4 and 8 weeks post-discharge, it was vital that PCI patients had post-discharge nurse-led support, especially for those with limited or no social support networks. At the end of each interview, participants were thanked and presented with a $25.00 store voucher for their participation.

Data collection: Intervention group participants

All participants who were previously involved in the intervention were reapproached to partake in the study after ethical approval of the study variation was granted. Potential participants were initially notified via mail of Phase Two and then subsequently via telephone. As identified earlier, six participants agreed to re-consent while two declined participation. A date and time convenient for participants was chosen for the telephone interview. The interview was also recorded on an MP3 player. Telephone follow-up was chosen so that participants would not be inconvenienced as they were required to attend a face-to-face clinic in Phase One of the study (Polit & Beck, 2010). Moreover, as scripted consistent telephone follow-up is reportedly a good predictor of hospital readmission, it was chosen as the communication method (D'Amore et al., 2011). Lastly, as participants had already met and communicated with the PI on previous occasions, the time to undertake interviews was short (i.e., maximum of 45 minutes to 1 hour required); therefore, the method deemed most suitable by both parties was a telephone follow-up (Polit &

Beck, 2010).

Data collection: Healthcare professionals

A semistructured interview method was chosen to explore healthcare professionals' thoughts about the intervention and to allow for flexibility in the interview and thus greater depth and clarity in the data (Britten, 1995; Dearnley, 2005). Interview questions were open-ended, semistructured, and pre-written to guide the interviewer, but also to allow for interviewer divergence (Britten, 1995; DiCicco-Bloom & Crabtree, 2006). The PI chose to undertake semistructured interviews as they facilitate greater understanding of the participant and words (Theobald, Worral-Carter, & McMurray, 2005). Moreover, as new themes may arise throughout the course of an interview, the open and "loose structure" may allow for further exploration of these while ensuring data consistency and reliability (Britten, 1995, p. 251; Roberts & Taylor, 2002).

As identified earlier, data were recorded on an MP3 player and forwarded to a professional transcribing service. All healthcare professionals' interviews took approximately 30 to 45 minutes to both reveal and explain the nurse-led intervention and undertake interviews in a face-to-face format. Face-to-face interviews were chosen as the study materials were highly confidential and could not be forwarded electronically. As document protection and copyright measures were in place, no material could be forwarded electronically to the interviewee for alternate interview methods (i.e., Skype or telephone). Additionally, as a face-to-face interview format allows for questions to be clarified and richer data attained, personal interviews were undertaken with healthcare professionals (Polit & Beck, 2010). Confidentiality was maintained and reinforced at all times with coding used to identify and protect participants. Interviews were recorded to ensure greater interviewer–interviewee

interaction and richer data while ensuring research validity. Furthermore, recording interviews was chosen solely to avoid the distraction of documenting field notes, thus enhancing interviewer—interviewee communication and eliciting richer data (Goffman, 1989; Liamputtong & Ezzy, 2005).

Evaluation of transcripts for analytical findings

Phase Two, as identified in the present study, was more descriptive-evaluative in nature and approached analysis from a higher analytical standpoint to interpret findings from the data. To ensure a greater depth to analysis and interpretation of raw data, an abductive approach was chosen in that it facilitates further breakdown and understanding of data (Brinkmann, 2014). Greater understanding is achieved as it draws connections and facilitates understanding of events or circumstances through the further breakdown of an individual's interpretation (Alvesson & Karreman, 2011; Brinkmann, 2014). Lipscombe (2012, p. 249) identifies the positives and negatives of abductive reasoning and highlights that, in order to achieve abduction while requiring a degree of subjectivity, an individual requires great "reflective abilities". Haig (2005) also identifies additional requirements in undertaking abductive reasoning to include both logic and psychological processes. Interpretation and analysis of participants' voiced experiences and feedback was ongoing and developed throughout the course of the analysis process through abduction to better understand the data and the relationship between the "situation and inquiry" in that it involves a breakdown in understanding (Brinkmann, 2014). Brinkman (2014, p. 722) advises how the goal of abduction is to understand through "sense-making" with the use of theories and methods. In addition to the use of Brinkmann's (2014) abductive reasoning to facilitate understanding of data and, as identified earlier, Charmaz's (2006) analytic steps and techniques were adopted and

used to review the data and better interpret, understand, and link findings between categories in Phases One and Two and between healthcare professionals and participants as detailed in Chapter 4. Although a grounded theory standpoint, the steps facilitated the understanding of participants' experiences through their narratives (Charmaz, 2006).

As identified, participants and healthcare professionals undertook semistructured interviews that sought detailed information regarding the nurse-led clinic for purposes of improvement. Over half of the raw data files recorded were transcribed by a transcription service to ensure a quick turnaround while the PI continued to undertake interviews. The PI undertook the other half of interview transcription to maintain research rigour and ensure participant confidentiality (Dearnley, 2005). As recommended by Dearnley (2005), recordings were carefully coded to ensure participant confidentiality. Copies were printed for all participants to review while electronic copies were saved by the PI. All raw transcribed data were examined closely by the PI with the adoption of Charmaz's analytical steps to code, evaluate and relate data.

Charmaz's (2006) steps included:

- coding interviews and personal accounts;

- development of categories;

- writing notes/memos categories;

- linking of categories and connecting results between study phases;

- abductive reasoning/evaluation of findings (i.e., researcher's interpretation of findings);

- findings interpreted through the key constructs of the SE Theory (i.e., does a relationship exist/not exist?).

By following this process, the PI was able to attain a greater depth of understanding of analytical data while also using Brinkmann's (2014) abductive approach to further interpret analytical findings. Furthermore, analytical findings generated from participants' narratives were identified and associations were made between Phase One and Two data and the theoretical framework highlighted.

Ethical considerations

Written informed consent was obtained from all participants. To enhance interviewer skill and technique and to calm pre-interview nerves, role plays were undertaken by the PI prior to commencement of interviews (Morse & Field, 1996). The only potential risks identified by the PI for Phase Two included psychological distress as a result of discussing emotions surrounding the procedure and the post-discharge period recovery. The following strategies were employed to ensure the aforementioned risks were minimised: (a) full written and informed consent prior to interviews, (b) coding of interview recordings and transcripts, (c) withdrawal without comment or penalty highlighted, and (d) support offered should participants become distressed. Lastly, as the PI had connections to all participants (previous contact with intervention group and employment at the site), confidentiality and privacy were reinforced both verbally and highlighted in the PICF. Furthermore, withdrawal without comment or penalty was reinforced to all intervention group participants.

Limitations and strategies

Potential limitations in Phase Two may have included interviewer bias in the interpretation of findings, as discussed earlier in Phase One (Creswell & Plano Clark, 2010). Furthermore, interviewer effects may have contributed study biases (Lavrakas, 2013). The PI acknowledges that having a presence during follow-up (i.e., both telephone and face-to-face) may have potentially affected participants'

responses. Prior to undertaking the interviews, the PI considered seeking assistance from the research team to undertake all interviews; however, as this strategy can introduce other biases into the study, the PI undertook the role (Lavrakas, 2013). Potential ethical conflict was identified pre-interview as work colleagues were interviewed in Phase Two. Strategies in place to reduce this potential ethical limitation included: (a) advising participants to answer the questions honestly, irrespective of the relationship; (b) advising potential participants not to feel pressure to agree to participate; (c) advising participants that declining participation would not incur any comment or penalty; and (d) a clear explanation of study requirements during recruitment was given. Lastly, the fact that Phase Two interviews were only undertaken at the private hospital site may have also presented as a limitation to the study, with findings therefore only generalisable to patients at the private site. Future studies will ensure that all participants be reapproached to ensure greater applicability of findings.

3.8 Summary

This chapter discussed the methods, study development, research design, and aims for Phase One, while the methods used to explore and understand Phase Two analytical findings were presented. Justification for undertaking the study in two phases was also identified along with the instruments used, study participants, settings, and methods. Ethical concerns and potential limitations were raised while strategies were identified to minimise risk. Chapter 4 presents the study's preliminary results while identifying relationships between the findings in both study phases.

Chapter 4: Results

This chapter details the results of the study from Phases One and Two. Results are presented in line with the research questions identified in Chapter 1. Sample demographics are provided, followed by results addressing the primary and secondary aims and research questions.

4.1   Phase One: Nurse-Led Clinic

4.1.1   Randomised Controlled Clinical Trial

Sample demographics

A total of 33 participants were recruited to Phase One of the Pilot Study. The mean age of all participants was 65.03 years ($SD = 9.76$, 45–81). There were more male participants (81.8%, $n = 27$) than females (18.2%, $n = 6$) involved in this study. Of the 33 participants, 78.8% were married ($n = 26$) and 21.2% ($n = 7$) were not married. Most participants (84.8%, $n = 28$) were born in Australia, with 93.9% ($n = 31$) of participants speaking English as a first language at home. Most participants attained a secondary school education or less (54.5%, $n = 18$) with 45.5% ($n = 15$) of participants indicating they had attained a post-secondary school education. Overall, demographic and risk factor data evidenced appeared to be similar between intervention and standard-care group participants (see Appendix A1, A2).

Sample: Risk factors, procedure and health behaviours

Of the 33 participants involved in this study, 69.7% ($n = 23$) reported a family history of coronary heart disease (CHD), while the remainder reported no family history (30.3%, $n = 10$). Three percent of participants ($n = 1$) reported they had been diagnosed in the past with anxiety while 9.1% ($n = 3$) had been diagnosed and had been or were receiving treatment for clinical depression. Familial

hypercholesterolaemia (in first-degree relatives) was reported by 60.6% (n = 20) of participants, with 78.8% (n = 26) reporting being treated for high cholesterol (i.e., on oral hypocholesterolaemics). Gender (i.e., being male) presented as a risk for most participants with 81.8% (n = 27) of participants being male, while all participants 100% (n = 3) were at risk due to their age alone. Of the other risk factors for CHD, no-one reported or recalled being diagnosed with CKD (100%, $n = 33$). A history of hypertension was reported by 57.6% ($n = 19$) of participants while 21.2% ($n = 7$) of participants identified a history of atrial fibrillation. All participants (100.0%, $n = 33$) underwent PCI either as a primary case (i.e., emergency) or electively. Access to the coronary arteries for all participants occurred via the right and/or left femoral artery (100.0%, $n = 33$). Approximately 12.1% ($n = 4$) of participants were clinically diagnosed with type 1 or type 2 diabetes mellitus. Blood glucose readings on baseline data collection ranged from 4.5 to 13.1 mmol/L.

Participants' weight recorded on baseline ranged from 50.0 kg to 137.0 kg. Of interest was that 66.7% (22) of participants' baseline body mass index (BMI) readings were >25 kg/m². Waist measurements taken on baseline ranged between 80 cm to 135 cm and were taken according to the World Health Organization (WHO) recommendations (WHO, 2008). Approximately 97% ($n = 32$) of participants reported being active to some degree on a daily basis. Approximately 81.8% ($n = 27$) of study participants reported consuming alcohol while 18.2% ($n = 6$) reported consuming alcohol socially and 18.2% ($n = 6$) reported no alcohol consumed.

Overall, baseline data collected displayed significant modifiable and non-modifiable risk factors for CHD. Areas of concern, as identified above, included family history, waist measurements, BMI, weight, gender, age, diabetes, alcohol

consumption, and a history of smoking. Participant risk factor and demographic data compared similarly between both groups.

Access site, baseline complications and vital signs

Prior to research investigations, haematomas were identified and managed in 15.2% ($n = 5$) of participants by clinical staff. Haematomas occurred either immediately after the PCI procedure or post-femoral arterial sheath removal. No bruits were diagnosed on or prior to baseline data collection. Nursing staff had recorded post-procedural access-site bleeds in 9.1% ($n = 3$) of patients. All patients achieved successful haemostasis after application of either digital pressure or a device. Access-site pain was reported by 12.1% ($n = 4$) participants post-procedure. Femoral arterial sheath removal post-PCI occurred in 90.9% ($n = 30$) of participants. The remaining 9.1% ($n = 3$) of participants had closure devices in situ (i.e., angioseal or femoseal). There were no signs of infection in participants on baseline visit and no new neurovascular complications recorded. Pre-existing neurovascular complications in the lower limbs as a result of prior trauma (pre-hospitalisation) were identified in 24.2% ($n = 8$) of participants. No participants experienced chest pain or discomfort at baseline visit. Baseline systolic blood pressure readings recorded were less than 140mmHg in 78.8% ($n = 27$) of participants, while the remaining 21.2% ($n = 6$) had a systolic blood pressure equal to or greater than 140mmHg. All participants' diastolic blood pressure readings were less than 90mmHg on baseline measurement.

On baseline data collection, 93.9% ($n = 31$) participants reported they were able to recall all prescribed medications. When asked to recall and describe medications, only 27.3% ($n = 9$) participants were able to do so accurately (i.e., without prompting or viewing a list). On the day of discharge from hospital, cardiac

rehabilitation (CR) teams had visited 30.3% ($n = 10$) of participants. Approximately 6.1% ($n = 2$) of participants reported they had been informed about CR from a source other than the CR team. After baseline data collection, two key areas of concern emerged and included: (a) medication knowledge, and (b) CR perceptions. The following subsections present descriptive data concerning complication identification and management and risk factor modification, physical activity and vital signs (i.e., blood pressure, pulse rate, blood oxygenation) throughout the course of the study and participant follow-up.

Complication identification

There were no reported post-discharge access site bleeds, bruits, or infections in either group. Neurovascular observations remained intact for all participants with the exception of those reporting pre-existing neurovascular impairments. No medication complications were experienced and reported by participants; however, some medication doses were reportedly adjusted by cardiologists or GPs as required over time as advised by participants.

Angina: All participants

All participants (i.e., intervention and standard-care groups) were asked about episodes of angina and actions taken as part of a duty of care at the commencement of each follow-up communication. Participants did not experience any angina at the time of any follow-up throughout the course of the study; however, episodes were recalled being experienced in between follow-up times and reported to the principal ivestigator (PI). From baseline assessment on the day of discharge from hospital to Time 2 (day 5–7), 36.4% ($n = 12$) of participants reported experiencing angina (see Table 4.1).

Participants who reported their responses to angina management within the

first week post-discharge were to rest and/or self-administer glyceryl trinitrate sublingual spray (also known as anginine). Two participants reported they did not have anginine with them at the time they experienced their chest pain symptoms. One intervention group participant was referred to their cardiologist on the day of follow-up as they had experienced an episode of severe angina on the way to the nurse-led clinic. The participant did not require hospital admission. Chest pain action and management will be discussed in Chapter 5. Between Time 2 (day 5–7) and Time 3 (1 month), 39.4% ($n = 13$) of participants reported angina while 30.3% ($n = 10$) of participants experienced angina between Time 3 (1 month) and Time 4 (3 months). No angina was experienced at Time 4 (3 months) (see Appendix Z). Overall, angina reduced over time in all study participants.

Table 4.1. **Summary of Post-Discharge Angina as a Percentage of the Sample**

	Study Participants
Time	% (n)
Time 1–2	36.4% (12)
Time 2	–
Time 2–3	39.4% (13)
Time 3	–
Time 3–4	30.3% (10)

Note. Time 1–2 = Between day of discharge and day 5–7 follow-up; Time 2 = Day 5–7 follow-up;

Time 2–3= Between day 5–7 and 1 month follow-up; Time 3 = 1 month.

4.1.2 Femoral Arterial Access Site(s): Images, Diagrams, Bruising, and Haematoma — All Participants

Femoral arterial sheath removal and complications

Approximately 93.9% ($n = 31$) participants underwent digital femoral arterial sheath removal post-PCI. The remaining 6.1% ($n = 2$) participants had collagen closure devices (i.e., Femoseal or Angioseal) implanted to achieve haemostasis. The length of time to achieve haemostasis for participants who had digital pressure applied ranged from 6 to 33 minutes. One participant experienced a vasovagal

episode during arterial sheath removal, while another required further pressure to the femoral access site using an adjunct in addition to digital pressure (i.e., Femstop) to achieve haemostasis.

Femoral arterial access sites: Descriptions and images

At Time 1 (day of discharge), 100% ($n = 33$) of access sites were photographed by the PI. At Time 2 (day 5–7), 16 wound sites were photographed. This consisted of 100% ($n = 13$) intervention group participants and 15% ($n = 3$) of standard-care group participants. Images and/or descriptions were requested of all participants (i.e., intervention and standard-care group) as a duty of care (i.e., in the event of a major complication) and to review post-PCI access site wound healing. One standard-care participant provided an image at Time 3 (1 month), while no intervention group participants provided images at this time. There were no images provided at Time 4 (3 months) as participants voiced their access sites had completely healed.

Femoral arterial access sites: Haematoma

On baseline measurement, 3.0% ($n = 1$) of participants experienced a haematoma, while 27.3% ($n = 9$) participants experienced and reported a haematoma at Time 2 (day 5–7). Times 3 (1 month) and 4 (3 months) saw a reduction in the size and number of haematomas developing, indicating recovery. Table 4.1 displays a summary of haematoma complications over the course of the study.

Table 4.2. **Summary of Haematoma Complications as a Percentage of the Sample**

Time	Study Participants ($N = 33$)
	% (n)
Time 1	3.0% (1)
Time 2	27.3% (9)
Time 3	12.1% (4)

Note. Time 1 = Baseline; Time 2 = Pre-intervention (day 5–7); Time 3 = 1 month.

Bruising: All participants

Access-site bruising was recorded in 48.5% (*n* = 16) participants on day of discharge, with mean measurements recorded between 4.88cm wide and 6.84 cm in length (see Table 4.3 and 4.4). Time 2 (5–7 days) identified 39.4% of participants with bruising, while the area of bruising increased in size with a mean size of 7.78 cm width, and 9.57 cm in length (see Table 4.1). Bruises began to fade between Time 2 (5–7 days) and 3 (1 month), and Time 3 (1 month) and 4 (3 months), respectively, with participants reporting bruises unmeasurable as they were fading and very faint in colour.

Table 4.3. **Summary of Bruising Complications as a Percentage of the Sample**

	Study Participants (*N* = 33)
Time	**% (*n*)**
Time 1	48.5% (16)
Time 2	39.4% (13)
Time 3	6.1% (3)

Note. Time 1 = Baseline; Time 2 = Pre-intervention (day 5–7); Time 3 = 1 month.

Table 4.4. **Summary of Mean Bruising Measurements in Centimetres**

Time	**Bruise Dimensions (cm)**
Time 1	4.88: 6.84
Time 2	7.78: 9.57
Time 3	–

Note. Time 1 = Baseline; Time 2 = Pre-intervention (day 5–7); Time 3 = 1 month. Time 3 bruises reported as faded and unmeasurable by participants.

4.1.3. Modifiable Risk Factors

Weight, BMI, and waist measurements

Mean weight in intervention group participants increased by 0.6 g between Time 1 (day of discharge) to Time 3 (1 month), while a mean reduction of 0.013 g was demonstrated in standard-care group participants. Between Time 3 (1 month) to Time 4 (3 months) a mean weight reduction of 0.128 g and 1.009 g was

demonstrated in intervention group and standard-care group participants, respectively. It was noted that mean BMI slightly increased in intervention group participants between Time 1 (day of discharge) to Time 3 (1 month), while standard-care group participants saw a small reduction in BMI of 0.0864 kgm² between Time 1 (day of discharge) to Time 3 (1 month). Time 3 (1 month) to Time 4 (3 months) demonstrated slight reductions in BMI of 0.1 kgm² and 0.19 kgm² for intervention group and standard-care group participants, respectively.

Corresponding with mean increases and reductions in weight and BMI, mean waist measurements in intervention group participants increased by 2.0 cm between Time 1 (day of discharge) and Time 3 (1 month), while standard-care group participants' mean waist measurement increased by 2.1 cm. Between Time 3 (1 month) to Time 4 (3 months) intervention group participants demonstrated a mean reduction of 1.92 cm, while standard-care group participants' mean waist measurement were reduced by 2.8 cm.

Physical activity

Physical activity was measured via self-report only as the PI sought data concerning pre-procedural physical activity engagement; how soon post-PCI participants resumed or newly commenced physical activity; and what activity (if any) they were engaging in. Additionally, the PI was interested in whether participants' physical activity aligned with post-procedural education and if participants were motivated to change their behaviour (i.e., resume or commence physical activity).

Prior to hospital admission 100% ($n = 33$) of participants reported undertaking some degree of physical activity. Levels of intensity ranged from light to high, with the frequency of exercise engagement ranging from 1 to 7 days per week. Most

participants reported undertaking aerobic activity, while others undertook a combination of aerobic and resistance training. At Time 2 (day 5–7) 24.2% ($n = 8$) of participants reported being inactive, while 63.60% ($n = 21$) were engaged in light activity, 6.10% ($n = 2$) undertaking physical activity at a moderate intensity, and one participant (3.03%) reported recommencing high intensity physical activity and attending a group mountain hike. At Time 3 (1 month) 27.27% ($n = 9$) of participants were undertaking light activity and identified undertaking walking or attending a CR program, while 57.57% ($n = 19$) reported an increase their intensity from light to a moderate level.

Participants reported attending the gym, cycling, hiking, swimming, or walking three to five times per week for at least 30 minutes to 1 hour. One (3.03%) standard-care group participant had not recommenced any activity as they were finding it difficult to initiate. Two (6.06%) intervention group participants reported not commencing physical activity as one had been experiencing frequent episodes of angina and the other participant reported runs of rapid atrial fibrillation (AF). Both aforementioned participants were receiving medical treatment for their angina and AF. At Time 4 (1 month), 57.57% ($n = 19$) of participants were still actively participating in moderate intensity physical activity, while 21.21% ($n = 7$) were undertaking light intensity, and 6.06% ($n = 2$) undertaking high intensity physical activity. Two (6.06%) intervention group participants reported being inactive at Time 4 (3 month) follow-up due to illness and recent hospitalisation.

Smoking status

Participants' smoking history, recency and behaviours were measured via self-report. A history of smoking was reported by 51.5% ($n = 17$) of participants at Time 1 (day of discharge). All past smokers had ceased this behaviour prior to

baseline data collection as a result of either a prior or recent diagnosis of CHD. At Time 2 (day 5-7), Time 3 (1 month) and Time 4 (3 months) all past smokers 51.5% (n = 17) reported maintaining abstinent.

Vital signs: Systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate, respirations, and oxygen saturation

Mean systolic blood pressure (SBP) at Time 2 (day 5–7) for all participants remained stable at 128.27 mmHg, while mean diastolic blood pressure (DBP) at Time 2 (day 5–7) was 68.20 mmHg (see Tables 4.5 and 4.6).

Table 4.5. **Summary of Mean Scores: Systolic Blood Pressure Readings (mmHg)**

		All participants		
Time	**N**	**Minimum**	**Maximum**	**M(SD)**
Time 1	33	100	158	125.58(14.923)
Time 2	15	106	155	128.27(17.388)

Note. Time 1 = Day of hospital discharge; Time 2 = Pre-intervention (day 5–7); Systolic blood pressure expressed as millimetres of mercury (mmHg).

Table 4.6. **Summary of Mean Scores: Diastolic Blood Pressure Readings (mmHg)**

		All participants		
Time	**N**	**Minimum**	**Maximum**	**M(SD)**
Time 1	33	50	88	69.88(9.443)
Time 2	15	55	90	68.20(10.605)

Note. Time 1 = Day of hospital discharge; Time 2 = Pre-intervention (day 5–7); Diastolic blood pressure expressed as millimetres of mercury (mmHg).

Mean heart rate at Time 2 (day 5–7) was 62.85 beats per minute (bpm) (see Table 4.7), while mean respirations were 17.1667 respirations per minute (see Table 4.8). Mean oxygen saturation level at Time 2 (day 5–7) was 97.25% on room air, while mean temperature was recorded at 36.05 Degrees Celsius (see Tables 4.9 & 4.10).

Table 4.7.   **Summary of Mean Scores: Heart Rate (bpm)**

		All participants		
Time	**N**	**Minimum**	**Maximum**	***M(SD)***
Time 1	33	49	81	65.97(9.071)
Time 2	13	49	91	128.27(14.387)

Note. Time 1 = Day of hospital discharge; Time 2 = Pre-intervention (day 5–7); Heart rate expressed

as beats per minute (bpm).

Table 4.8.   **Summary of Mean Scores: Respiration Rate (breaths per minute)**

		All participants		
Time	**N**	**Minimum**	**Maximum**	***M(SD)***
Time 1	33	14	19	16.97(1.045)
Time 2	12	16	18	17.1667(0.71774)

Note. Time 1 = Day of hospital discharge; Time 2 = Pre-intervention (day 5–7); Respiration rate

expressed per minute.

Table 4.9.   **Summary of Mean Scores: Oxygen Saturations (%) on Room Air**

		All participants		
Time	**N**	**Minimum**	**Maximum**	***M(SD)***
Time 1	33	95	99	96.82(1.261)
Time 2	4	96	98	97.25(0.957)

Note. Time 1 = Day of hospital discharge; Time 2 = Pre-intervention (day 5–7); Oxygen saturations

expressed as a percentage (%) on room air.

Table 4.10.   **Summary of Mean Scores: Temperature (°C)**

		All participants		
Time	**N**	**Minimum**	**Maximum**	***M(SD)***
Time 1	32	35.8	37.0	36.21(0.2770)
Time 2	4	36.0	36.1	36.05(0.0577)

Note. Time 1 = Day of hospital discharge; Time 2 = Pre-intervention (day 5–7); Temperature

expressed as degrees Celsius (°C).

Electrocardiogram (ECG)

There were no significant ECG changes in participants on follow-up at the

post-discharge nurse-led clinic. At Time 1 (day of discharge), 66.70% ($n = 22$) of

participants presented in a normal sinus rhythm, while 3.03% ($n = 1$) presented with

AF, 24.24% ($n = 8$) were recorded in sinus bradycardia, one participant (3.03%) in a

sinus tachycardia and one participant 3.03% with sinus arrhythmia. Of those recorded in a normal sinus rhythm, 9.09% ($n = 3$) were captured in a first-degree heart block. At Time 2 (day 5–7), a 12-lead ECG was taken by the PI, with no remarkable ECG changes recorded in intervention group participants. One participant (3.03%) who at baseline presented in a normal sinus rhythm, was captured in a sinus bradycardia at 50 bpm. The ventricular rate captured on baseline ECG was recorded at 59 bpm. At Time 2 (day 5–7), 18.18% ($n = 6$) participants were captured in a normal sinus rhythm, while 18.18% were recorded in a sinus bradycardia. One participant (3.03%) remained in AF from baseline measurement.

Cholesterol and blood glucose level readings

Inspection of mean scores for cholesterol and blood glucose levels evidenced the following for times 1 (Baseline) to Time 4 (3 months). Mean total cholesterol for all participants at Time 1 (day of discharge) was 4.191 mmol/L and ranged between 2.5 mmol/L to 6.5 mmol/L. Post-PCI total cholesterol was only available for one participant and measured 5.9 mmol/L. Mean blood glucose levels at Time 2 (day 5–7) 8.267 mmol/L and ranged between 6.0 mmol/L and 10.8 mmol/L. Time 3 (1 month) mean BGLs ranged from 4.0 mmol/L to 13.4 mmol/L, with a mean of 7.75 mmol/L. The mean BGL at Time 4 (3 months) was 7.567 mmol/L. Levels ranged between 6.4 mmol/L to 9.0 mmol/L. Overall, a broad range of results were observed after closer inspection of mean ratings for cholesterol and blood glucose levels. Results for the study's primary aims are presented below.

4.1.4 Primary Aims: Results

A multivariate analysis of the data could not be conducted as the sample size recruited was less than originally anticipated; however, the PI, as identified in Chapter 3, undertook two analyses: (1) Effect Size (ES), and (2) Reliable Change

Index (RCI) calculations. Effect size (ES) and RCI calculations were undertaken to demonstrate the potential effect and importance of the intervention on primary and secondary research aims and to identify the potential for a Phase Three study. Furthermore, RCI calculations were undertaken to determine if a reliable change occurred while the therapeutic outcomes of randomisation to the intervention group were also reviewed to determine if participants were better or worse after attending the nurse-led clinic.

Descriptive statistics are also presented for primary and secondary aims. Although participants were followed up over a period of 3 months in the present study, a primary endpoint of 1 month (Time 3) was chosen to gauge the effect of the intervention versus standard care. The primary endpoint of 1 month (Time 3), as identified in Chapter 2, was selected as the literature also identified 1 month to be the best time to determine effects of interventions on psychological distress while also limiting the impact of non-relevant stressors and events. Furthermore, the clinical biochemist who undertook salivary cortisol assays recommended that 1 month (Time 3) after attending the nurse-led clinic would be the best time to determine if the intervention was effective in reducing stress in participants as demonstrated by a reduction in salivary cortisol levels. Results for follow-up to the primary endpoint (Time 3) are presented below.

4.1.5 Results: Cardiac Self-Efficacy Scale (CSE)

Cohen's d – Population effect size

Overall, results did not demonstrate strong support for study hypotheses with a reduction in overall CSE evidenced in intervention group participants. Cohen (1992, p. 157) identifies the indexes and values for ES as small (0.20), medium (0.50), and large (0.80). Attending the nurse-led clinic had a moderately reducing effect on CSE

in intervention group participants, $d = 0.60$. Randomisation to the standard-care group alone did not demonstrate any effect on CSE, $d = -0.19$. Full calculations of Cohen's d for both groups of participants are detailed in Appendix B1. Overall, ES calculations suggest a moderately reducing effect of the intervention on overall CSE in intervention group participants as compared with standard-care group participants where no effect on CSE is evidenced.

Reliable change index (RCI)

Calculations to determine a reliable change in participants over time were undertaken for both groups according to the Jacobsen criterion. In order to report a reliable change, the following criteria must be satisfied: $RCI > + 1.96$, $p < .05$. Reliable Change Index (RCI) calculations were undertaken to determine if there was any change and the degree of change, in study participants over time after receiving the intervention (i.e., Time 2 [day 5–7] to Time 3 [1 month]). Please see Appendix C1 for full calculations and RCI values for study participants demonstrating a reliable change (Fisher & Durham, 1999, p. 1429).

A positive reliable change was evidenced in one participant in the intervention group and one in the standard-care group, with an RCI of 2.84 and 2.14, respectively. For the CSE questionnaire, a positive $RCI > +1.96$ indicates that a reliable change has occurred. Full calculations for participants 082 and 005 are presented in Appendix C1. The RCI for intervention group participant 082 is significant at 2.84 ($>+1.96$) after attending the nurse-led clinic. Of interest is a positive reliable change in CSE that occurred in participant 005 after randomisation to the standard-care group. The RCI for participant 005 is significant at 2.14 ($>+1.96$) and will be discussed in Chapter 6.

Cut-off point 'c'

Treatment outcomes determine the effect of an intervention on participants' recovery. Full 'recovery' or return to normal functioning is established when an RCI of > +1.96 is achieved and participants' questionnaire scores move from above to below the calculated cut-off value. As a cut-off point (i.e., *'c'*) for clinically significant change for CSE was not available, the PI calculated this to be 2.68 as per Fisher and Durham (1999) (see Appendix B1 for full calculations). This cut-off point suggests that CSE scores of >2.68 will fall within the normal distribution, thus indicating clinically significant change.

Treatment outcomes

Of the intervention group participants, 7.7% ($n = 1$) recovered, 23.1% ($n = 3$) improved, and 61.5% ($n = 8$) had poorer CSE post-intervention. One participant withdrew prior to attending the intervention and data for Time 2 (day 5–7) and Time 3 (1 month) were, therefore, unavailable. Standard-care participants saw 5.0% ($n = 1$) participant recover, while 45% ($n = 9$) improved and 45% ($n = 9$) worsened (see Table 4.11).

Table 4.11.   Pre- to Post- Intervention CSE Standardised Recovery Rates

Group	Frequency (Percentage)			
	Worse	**No Change**	**Improved**	**Recovered**
Intervention ($n = 13$)	8 (61.53%)	0 (0%)	3 (23.10%)	1 (7.70%)
Missing ($n =1$)				
Standard Care ($n = 20$)	9 (45%)	1 (5.0%)	9 (45%)	1 (5.0%)
Total ($N = 33$)	17 (51.52%)	1 (3.03%)	14 (36.40%)	2 (6.10%)

Overall, ES calculations demonstrated a moderately reducing effect of the intervention on participants attending the nurse-led clinic. Reliable change index (RCI) calculations undertaken demonstrated a reliable change in only one intervention group participant. Tabulation of treatment outcomes revealed

improvements and recovery in approximately one-third of participants over time, while over half of intervention group participants' CSE worsened.

Overall mean cardiac self-efficacy (CSE) scores

Mean CSE scores for intervention group participants at Time 2 (day 5–7) were 2.48 units and 2.35 units for standard-care group participants (i.e., each scale item scored 0 to 4). Time 3 (1 month) scores for overall CSE were 2.11 units and 2.45 units for intervention and standard-care group participants, respectively. See Appendix D1 for further detail regarding overall mean CSE scores.

Cardiac self-efficacy (CSE): Time 4 (3 months)

An inspection of the means shows that an increase in overall CSE scores was demonstrated in intervention group participants at Time 4 (3 months), while reductions were evidenced between Time 2 [day 5–7] and Time 3 (1 month). Standard-care group participants' overall CSE scores demonstrated reductions at Time 4 (3 months), while enhancements were evidenced between Time 2 (day 5–7) and Time 3 (1 month).

Cardiac self-efficacy (CSE): Items

As overall mean scores did not demonstrate increases in total CSE, each CSE item was explored to examine if effects occurred for specific areas of confidence as a result of attending the nurse-led clinic. (Please see Appendix C1 for a full list of mean scores for each of the 16 CSE items from baseline measurement until Time 4 for both groups of study participants.) Selected items below show increases in CSE items at the primary endpoint (Time 3). In general, an inspection of the means shows that increases in mean CSE item scores were evidenced in intervention group participants at Time 3 (1 month) in the following areas:

- confidence to lose weight

- confidence to change diet

- confidence in knowing how much physical activity is good (for them)

- confidence to maintain usual work activities

- confidence to control breathlessness by taking medications.

4.1.6 Results: State–Trait Anxiety Inventory (STAI) Y-2 Form, Trait Anxiety

Cohen's d population effect size (ES)

Effect size (ES) for the STAI Y-2 Form demonstrated a moderately reducing effect of the nurse-led clinic on intervention group participants' trait anxiety, $d = 0.50$. Randomisation to the standard-care group did not see an effect on trait anxiety, $d = 0.16$. Effect size (ES) calculations for study participants are presented in Appendix E1. Overall, participation in the nurse-led intervention demonstrated a moderate reduction in trait anxiety while randomisation to the standard-care group did not have an effect on trait anxiety.

Reliable change index (RCI)

Five participants in the intervention group and two participants in the standard-care group demonstrated a reliable change. Full calculations for participants demonstrating reliable change are detailed below. Appendix F1 contains full RCI values for study participants. For the STAI-Y2 questionnaire, a negative RCI > -1.96 indicates that a reliable change (P < 0.05) has occurred. Furthermore, to ensure a reliable change, as per Fisher and Durham (1999), an 8-point difference on the STAI-Y2 was necessary. Lastly, in the calculation of the RCI, values detailed for the STAI-Y2 form were utilised as calculated by Fisher and Durham (1999, p. 1429) (see Appendix E1).

Reliable Change Index (RCI): Intervention and standard-care group participants

Five intervention group participants demonstrated a negative reliable change in trait anxiety scores over time. Full calculations are displayed in Appendix F1. A significant reliable change of - 3.99 was evidenced in participant 010 over time after attending the nurse-led intervention, while a reliable change of -2.74 and -4.24 were demonstrated in participants 006, and 066 respectively. Participant 020 demonstrated a reliable change of -1.99, while a significant reliable change of -6.48 was evidenced in participant 106 over time.

A negative reliable change was also evidenced in two participants randomised to the standard-care group over time. Participants 039 and 023 demonstrated a reliable change of -2.50, and -2.99 in trait anxiety, respectively (see Appendix G1 for full calculations). Reliable change in both groups of participants will be discussed in greater detail in Chapter 6.

Cut-off point 'c'

As identified earlier in this chapter, treatment outcomes and full recovery are determined when the RCI are $> +1.96$ coupled with the movement of questionnaire scores from above to below the calculated cut-off value. The cut-off point for the STAI-Y2 form was identified by Fisher and Durham (1999, p. 1429) as being < 46 (see Appendix G1). Thus, post-intervention scores falling within this cut-off point are identified as the normal distribution and indicate clinically significant change.

Treatment outcomes

Of the intervention group participants, 15.4% ($n = 2$) achieved recovery, 53.8% ($n = 7$) improved, 15.4% ($n = 2$) experienced no change, and 7.7% ($n = 1$) demonstrated worse trait anxiety post-intervention (see Table 4.12). Standard-care

participants saw no participants recover and 30% (*n* = 6) participants worsen; however, 55% (*n* = 11) demonstrated improvements in trait anxiety over time (see Table 4.12). Three (11%) participants in the standard-care group experienced no change in trait anxiety.

Table 4.12.   **Pre- to Post- Intervention STAI Y-2 Form Standardised Recovery Rates**

Group	Frequency (Percentage)			
	Worse	**No Change**	**Improved**	**Recovered**
Intervention (*n* = 13) Missing (*n* =1)	1 (7.70%)	2 (15.40%)	7 (53.85%)	2 (15.40%)
Standard Care (*n* = 20)	6 (30%)	3 (15%)	11 (55%)	0 (0%)
Total (*N* = 33)	7 (21.20%)	5 (15.15%)	18 (54.54%)	2(6.10%)

Overall, randomisation to the nurse-led clinic demonstrated a moderate effect (*d* = 0.50) in participants over time while randomisation to the standard-care group had no effect (*d* = 0.16). A reliable change was evidenced in 5 (RCI = > +1.96, *P* = 0.05) intervention group participants compared with two standard-care group participants. Preliminary evidence demonstrates reliable change and positive therapeutic outcomes in intervention group participants compared with standard care group participants over time.

Mean trait anxiety scores

Mean baseline scores for the STAI-Y2 form or trait anxiety questionnaire for intervention group participants was 38.33 while the mean baseline score for the standard-care group was 34.37 (i.e., scale range 20 to 80). Mean scores for intervention group participants at Time 2 (day 5–7) was 36.75 (pre-intervention) while standard-care group participants demonstrated a mean anxiety score of 30.95 at Time 2 (day 5–7). Between Time 2 (day 5–7) and Time 3 (1 month), a mean reduction of 6.83 units in trait anxiety was identified in intervention group

participants versus 1.48 units in standard-care group participants. A total mean reduction of 8.41 units was seen in intervention group from baseline measurement until Time 3 (1 month), and 4.9 units in standard-care group participants. Thus, inspection of those means show that, overall, a larger reduction in mean trait anxiety scores (i.e., based on decreases in mean trait anxiety scores) was seen in intervention group participants from baseline and Time 2 until Time 3 (1 month), after attending the nurse-led clinic. Table 4.13 presents a summary of mean trait anxiety scores.

Table 4.13.   Summary of Means for Scores on the STAI Questionnaire: Trait Anxiety (Y2 Form)

	Intervention Group	Standard-Care Group
Time	*M(SD)*	*M(SD)*
Time 1	38.33 (13.28)	34.37 (8.84)
Time 2	36.75 (14.10)	30.95 (9.43)
Time 3	29.92 (12.66)	29.47 (8.13)

Note. CSE = Cardiac Self-Efficacy Scale. Time 1 = Baseline; Time 2 = Pre-intervention (day 5–7); Time 3 = 1 month.

Trait Anxiety: Time 4 (3 Months)

Mean trait anxiety scores for both groups of participants increased at Time 4 (3 months) with intervention group participants scoring 37.75 units and standard-care group participants scoring 37.72 units, respectively. It was interesting to note that a reduction in mean trait anxiety was evidenced in both groups between Time 1 (Baseline), Time 2 (day 5–7) and Time 3 (1 month) while an increase was demonstrated at Time 4 (3 months). These results will be discussed in greater detail in Chapter 6. Please see Appendix H1 to view Time 4 (3 months) results.

4.1.7   Secondary Research Questions: Results

Stress and salivary cortisol assays

Of the sample, participants' mean baseline salivary cortisol levels were 0.10 ug/dl for intervention group participants and 0.16ug/dl for standard-care group

participants, respectively. At measurement two (Time 3, 1 month), mean cortisol

levels were 0.092ug/dl for intervention group participants and 0.134 ug/dl for

standard-care group participants. Mean salivary cortisol levels for intervention group

participants decreased by 0.008 units and 0.026 units for standard-care group

participants. Overall, inspection of these means demonstrate a greater mean

reduction in cortisol assay levels in standard-care group participants over time. See

Table 4.14 for a summary of mean salivary cortisol assay measurements. Reference

ranges for salivary cortisol were adopted from Salimetrics® (Salimetrics®, 2010).

Overall, assay results for both groups of participants fell within reference ranges;

however, standard-care group participants presented with slightly higher cortisol

levels. Furthermore, inspection of the means show that salivary cortisol levels fell at

a greater rate over time in standard-care group participants as opposed to

intervention group participants. Findings will be discussed in greater detail in

Chapter 6.

Table 4.14.   Summary of Mean measurements for Salivary Cortisol Assays (ug/dl)

Time/Group	Intervention group (ug/dl)	Standard-care group(ug/dl)
Time 1	0.10	0.16
Time 2	0.092	0.134

Note: Expected morning reference ranges for adults mornings for adults 0.094–1.551 ug/dl; and

afternoon 0.359 ug/dl.

Personal referral

A number of interactions with participants required action by the PI to initiate

referral to a general practitioner (GP) as participants either reported emotional

distress and/or their assessment tool scores indicated they may be at risk. Some

participants were also referred to their cardiologists by the PI as they were unable to

distinguish between anxiety symptoms and angina.

Time Two follow-up: Day 5–7 post-discharge

Referral of 12.1% (*n* = 4) of participants to their GPs and/or cardiologists at Time 2 (day 5–7) for follow-up was actioned based on their post-discharge feelings reported, coupled with assessment tool scores (i.e., feeling emotional and/or teary). At Time 2 (day 5–7) follow-up, one participant voiced they had felt angry the first 2–3 days post-discharge after which the negative feelings subsided. One of the aforementioned participants was referred to both a cardiologist and GP as they were unable to distinguish whether the symptoms experienced were anxiety or chest pain-related symptoms; thus, communication with both the specialist and GP was initiated by the PI.

Time Three follow-up: 1-month post-discharge

Referral at Time 3 (1 month) occurred as a result of patient symptoms reported to the PI. One participant (3.0%) was referred to their GP as they were feeling emotional while 9.1% (*n* = 3) participants reported experiencing angina between Time 2 (day 5–7) and Time 3 (1 month). Of the three participants experiencing angina referred to their cardiologist, one participant underwent immediate cardiology review after reporting to the PI that they were experiencing intermittent light-headedness and chest heaviness while exercising; a new coronary artery lesion was discovered and stented as a result. One participant had access-site discomfort and was referred to their GP. Lastly, one participant was referred for lower limb swelling, mottling and calf redness, and had an audible wheeze (that could be heard during telephone conversation). As the participant had a history of deep vein thrombosis, the PI recommended urgent GP or emergency centre examination. The participant took the PI's advice and had a family member drive them to a local emergency centre for review. They did not require hospitalisation and were

discharged home with medications. One standard-care group participant's antiplatelet medication was depleted (Clopidogrel) at Time 3 ("for a couple of days") and then had the stock replenished. Although not an intervention group participant, as the PI is ethically responsible for all participants, the importance of this medication was highlighted.

Time Four follow-up: 3 months post-discharge

Only 3.0% ($n = 1$) participant was referred to their GP at Time 4 (3 months) and the cardiology rooms at one hospital site at Time 4 (3 months) as they reported increased frequency of their chest pain and shortness of breath. Furthermore, this one participant also reported consuming an entire bottle of glyceryl trinitrate tablets for angina over a period of 1 week while they had been heavily involved moving house. On contact with the hospital site, it was recommended that the PI notify the GP for immediate consult; however, the PI had already actioned this. Again, the standard-care group participant who did not replenish their script for their antiplatelet medication (clopidogrel) at Time 3 (1 month) reported they, again, had not had their script dispensed and as a result had missed one dose of the medication. This participant also reported missing other medications at times. Medication adherence and compliance will be discussed in Chapter 6.

4.1.7   Cardiac Depression Scale (CDS): Cohen's d - Population Effect Size (ES)

Effect size (ES) calculations undertaken demonstrate a small reducing effect on depressive symptoms in both intervention ($d = 0.26$) and standard-care group ($d = 0.37$) participants (see Appendix I1 for full ES calculations).

4.1.8   Cardiac Depression Scale (CDS): Reliable Change Index (RCI)

One participant in the intervention group and one participant in the standard-

care group demonstrated a negative reliable change in depression scores over time.

Full calculations for participants demonstrating a reliable change are detailed in

Appendix K1. For the CDS questionnaire, a negative RCI > -1.96 indicates that a

reliable change ($p < .05$) has occurred.

A reliable change of -1.97 was evidenced in intervention group participant 010

after participation in the nurse-led clinic while standard-care group participant 013

demonstrated a significant reliable change of -5.4. Results will be discussed in

further detail in Chapter 6.

Cut-off point 'c'

Redfern, Ellis, Briffa, and Freedman (2007) identified the cut-off point '*c*' for

depression as $\geq$ 90. Thus, the cut-off point for clinically significant change and

treatment recovery in the present study was identified as <90.

Treatment outcomes

Table 4.15 displays the standardised recovery rates for participants involved in

this study. It was noteworthy that the breakdown of treatment outcomes

demonstrates 7.7% ($n = 1$) of participants experiencing recovery, 61.5% ($n = 8$)

improving, and 23.10% ($n = 3$) with worsening CDS scores after participating in the

intervention. Similarly, standard-care group participants demonstrate 5.0% ($n = 1$)

recovery, 70% ($n = 14$) improved, and 25% ($n = 5$) worse over time.

Table 4.15.   **Pre- to Post- Intervention CDS Standardised Recovery Rates**

	Frequency (Percentage)			
Group	**Worse**	**No Change**	**Improved**	**Recovered**
Intervention ($n = 13$)				
Missing ($n = 1$)	3 (23.10%)	0 (0.0%)	8 (61.54%)	1 (7.69%)
Standard Care ($n = 20$)	5 (25%)	0 (0%)	14 (70%)	1 (5.0%)
Total ($N = 33$)	8 (24.24%)	0 (0%)	22 (66.66%)	2 (6.06%)

Overall, only a small ES was demonstrated in both intervention and standard-care group participants. Reliable change was evidenced in one participant in each group. Similarly, over half of the participants in both groups demonstrated improvements and one in each group achieved recovery.

Aim 2(a): Mean Cardiac Depression Scale (CDS) Scores

Reductions in mean CDS scores were evidenced at each time point for both study groups (i.e., scale range 26 to 182). Intervention group participants' mean CDS scores reduced from 73.83 (Time 2, day 5–7) to 65.83 (Time 3, 1 month), while standard-care group participants' mean CDS scores for Time 2 (day 5–7) and Time 3 (1 month) were 68.58 and 58.26 units, respectively. A summary of mean CDS scores are presented in Appendix K1.

4.1.9 Cardiac Depression Scale (CDS): Time 4 (3 Months) — Descriptives

Inspection of the group means show that the intervention group participants displayed higher mean baseline CDS scores than did the standard-care group participants. Slight increases in CDS scores were identified at Time 4 (3 months) in intervention group participants. Overall, based on inspection of the means, a greater reduction in mean CDS scores were identified in standard-care group participants from baseline measurement and Time 2 (day 5–7) until Time 4. Please see Appendix J1 to review Time 4 (3 months) CDS results.

Overall, changes in depressive symptoms were only small and occurred in both groups. Effect size (ES) calculations, coupled with RCI, treatment recovery assessment, and review of mean CDS scores demonstrate similarities in intervention and standard-care group participants' treatment outcomes over time.

Aim 2(b): Cardiac Rehabilitation (CR) Attendance

Overall, 15.4% ($n = 2$) intervention group participants (who were referred to CR by the PI) attended a CR program while 30% ($n = 6$) participants in the standard-care group attended CR. One (5.0%) standard-care group participant withdrew from the program prior to commencement due to work commitments, while one (7.70%) intervention group participant withdrew and committed to a telephone rehabilitation program run by their private healthcare provider. Reasons for non-attendance and compliance will be discussed in Chapter 5.

4.1.10 Results: Aim 2(b) – Morisky Medication Adherence Scale – 8 Item (MMAS-8) and Medication Recall

Cohen's d: Population Effect Size (ES)

Overall, it can be concluded that the nurse-led clinic had no effect on intervention group participants' medication adherence. No effect was demonstrated on medication adherence in intervention group participants $d = 0$, while randomisation to the standard-care group evidenced a small effect on medication adherence, $d = -0.22$ (see Appendix L1). The following section presents results for reliable change and treatment outcomes in study participants in relation to medication adherence.

Reliable Change Index (RCI)

No participants in the intervention or standard-care group demonstrated reliable change in medication adherence over time. For the MMAS-8, a positive RCI > 1.96 would have indicated a reliable change ($P < 0.05$) in study participants. The SE and S*diff* were calculated for all participants. Following this, RCI were calculated for each individual participant.

Cut-off point 'c'

The cut-off point for the MMAS-8 was identified by Lee et al. (2013) as ≥ 6. Thus, post-intervention scores falling within this cut-off point are identified as the normal distribution and indicate clinically significant change.

Treatment outcomes

Of the intervention group participants, none achieved recovery, 15.4% ($n = 2$) improved, 61.5% ($n = 8$) experienced no change, and 15.4% ($n = 2$) demonstrated poorer medication adherence over time (see Table 4.16). Similarly, among standard-care participants none recovered, 15% ($n = 3$) improved, 75% ($n = 15$) participants remained stable (i.e., no change), and 10% ($n = 2$) participants worsen (see Table 4.16).

Table 4.16.   Pre- to Post- Intervention MMAS-8 Standardised Recovery Rates

	Frequency (Percentage)			
Group	**Worse**	**No Change**	**Improved**	**Recovered**
Intervention ($n = 13$)	2 (15.38%)	8 (61.53%)	2 (15.38%)	0 (0.0%)
Missing ($n = 1$)				
Standard Care ($n = 20$)	2 (10%)	15 (75.0%)	3 (15.0%)	0 (0.0%)
Total ($N = 33$)	4 (12.12%)	23 (69.70%)	5 (15.15%)	0 (0.0%)

Overall, preliminary evidence demonstrates no effect of the intervention on medication adherence, with a non-significant ES, no reliable change in any intervention group participants, and only minor improvements. Effect size calculations in standard-care group participants demonstrated a small effect on medication adherence. Recovery over time was not evidenced in either groups. Data for medication adherence in intervention group participants were similar for those in the standard-care group.

MMAS-8: Time 2 (Day 5–7) to Time 3 (1 Month) — Mean Medication Adherence Scores

Based on inspection of means for both groups the intervention group participants' mean medication adherence scores were maintained at 7.71 from Time 2 (day 5–7) to Time 3 (1 month); whereas standard-care group participants' mean scores increased from 7.76 units to 7.89 units (see Appendix M1) (i.e., scale range 0–8). Overall, a larger mean increase in medication adherence was demonstrated in standard-care group participants over time.

At Time 1 (day of discharge), when intervention group participants were asked to recall current medications, 92.3% reported they were able to do so. However, when asked by the PI to recall their medication details (name, dose, and action, without prompting), only 23.1% of participants could do so. At Time 3 follow-up, 92.3% agreed they knew what medications they were taking. An improvement was seen where 38.5% of participants recalled current medications, actions, and doses.

Approximately 95% of standard-care group participants reported being able to recall their medications on baseline assessment; however, when asked to verbalise specific details (i.e., frequency, dose, action) about their medications, only 30% were able to recall this information. It was interesting to note that, at Time 3 (1 month), 100% of standard-care group participants reported knowing about their medications; however, only 25% could recall and verbalise their medication details. Medication recall was not assessed at Time 2 as this time point was only 5–7 days post-discharge and, given the event of hospitalisation itself and coupled with discharge home, the PI deemed that it would be best to review recall post-intervention at Time 3 (1 month) and Time 4 (3 months). Overall, in response to the PI's questions about medication details, intervention group participants demonstrated greater knowledge and recall of medications after attending the nurse-led clinic.

Medication adherence and knowledge: Time 4 (3 months)

Based on inspection of mean scores, increases in mean medication adherence scores were identified at Time 4 (3 months) in both groups. Medication adherence scores for Time 4 (3 months) are listed in Appendix L1. At Time 4 (3 months), 92.3% of intervention group participants reported knowing the medications they were consuming while 80% of standard-care group participants reported they had adequate knowledge about their medications. There were 53.8% of intervention group participants who were able to recall specific details regarding their medication as opposed to 35% of standard-care group participants.

The following section reports on the results of semistructured interviews undertaken with 16 participants. Participants included intervention group participants and experienced healthcare professionals working with PCI patients. All participants were interviewed to evaluate the effectiveness of the nurse-led clinic and with particular focus on the study's primary and secondary aims. Furthermore, participant and healthcare professional feedback was sought in a Phase Two study and used in conjunction with aspects of Phase One outcomes to enhance the nurse-led clinic and inform a Phase 3 multi-centre study.

4.2 Phase Two: Nurse-Led Clinic Program Evaluation and Analytical Findings

Phase Two explored the experiences of six intervention group participants and 10 healthcare professionals. Intervention group participants were invited to undertake a semistructured interview and to offer feedback regarding their experiences of attending the nurse-led clinic, while also providing constructive feedback to enhance the intervention for the benefit of future participants. Healthcare professionals were shown the clinic intervention with the aim of seeking constructive

criticism and recommendations to gauge the effect of the nurse-led clinic on participants' SE, psychosocial wellbeing, and ability to facilitate effective self-management. It was hoped that feedback provided by healthcare professionals could assist in enhancing and further developing the nurse-led clinic for implementation as a Phase Three, multi-centre study for future application in the healthcare setting.

As further analytical data regarding the process of the nurse-led clinic implementation and function were required, an implementation or process analysis was undertaken. Questions asked about the intervention concerned the operation of the nurse-led clinic. The implementation analysis facilitated further identification of the study's strengths and weaknesses, explicit identification of the intervention, and its comparison to current standard care. Furthermore, potential barriers to implementation and, importantly, healthcare professional and participant feedback regarding the intervention and its effects on primary and secondary aims were sought. Importantly, as identified earlier, analytical evaluation, interpretation and understanding of participants' data (i.e., from interview transcripts) were undertaken using aspects of the work of Charmaz (2006) and Brikmann (2014).

4.2.1 Phase Two: Participant Background and Demographics

All participants involved in Phase Two were born in Australia and spoke English as their first language. Six participants who undertook the nurse-led clinic went on to participate in Phase Two. One participant had experienced previous PCI procedures, while it was the first PCI procedure for one other participant. Of the six nurse-led clinic participants who consented to Phase Two interviews, five had previously attended a CR program. One participant had undergone their first PCI and had never attended a CR program prior to this procedure. Of the healthcare professionals participating in Phase Two face-to-face interviews, two were highly

experienced cardiologists, five cardiology ward nurses, one cardiac catheterisation

laboratory nurse, and two managerial-level nursing staff. Healthcare professional

interviews highlighted impressions of the nurse-led clinic, cardiac rehabilitation,

medication adherence, delivery mode, timing, and repetition of education after being

taken through the nurse-led clinic component. Analytical findings for participant and

healthcare professional interviews are presented below.

4.2.2 Analytical Findings

Support enhances recovery

A sense of strong clinical support was identified by participants. Supportive

concepts centred around post-discharge clinic information and confidence in the

clinician and follow-up. Most participants reported confidence in the nursing health

professional after attending the nurse-led clinic. Participants also highlighted the

benefits of attending follow-up with a health professional in the post-discharge

period and the reassurance they felt it provided, particularly concerning post-

discharge physical recovery and symptom management (i.e., chest symptoms and

access site bruising). Thus, with the literature highlighting an increase in the

prevalence of anxiety and depression in patients with CAD, post-PCI, and those who

experience a coronary event, early post-procedural follow-up (i.e., within the first

week post-PCI) was warranted and noted by both participants and healthcare

professionals (Colquhoun et al., 2013; Rassaf et al., 2013; Trotter et al., 2010; Wade,

Cheok, Shrader, Hordacre, & Marker 2005; Zuidersma, Conradi, van Melle, Ormel,

and de Jonge, 2012).

While the intervention had a moderately reducing effect on participant anxiety,

as evidenced in Phase One, only a small reducing effect on depression was

demonstrated. Furthermore, reductions in psychological symptoms were not

accompanied by an expected increase in SE, as highlighted in the literature (Bandura, 1977, 2004; O'Neil, Berk, Davis, & Stafford, 2013). O'Neil et al. (2013) suggest that increased baseline depressive symptoms may influence SE enhancement and, thus, health outcomes, suggesting a possible explanation as to the results achieved in the present study (O'Neil et al., 2013). It was noteworthy, however, that participants verbalised personal enhancements in self-confidence or SE to manage post-discharge as opposed to CSE tool results. Further exploration of the present study's results will be undertaken in Chapter 6, with a greater depth of explanation offered to better understand the study's results and to enhance future research.

Intervention group participants reported that speaking with an experienced cardiac nurse was both reassuring and beneficial. Moreover, while feeling supported, participants also reported being well treated in the post-discharge period. Participants who had previously undergone a PCI procedure commented on the potential benefits of early post-discharge follow-up in terms of reassurance and repetition of education. Although participants who had a repeat PCI procedure reported they had the knowledge to self-manage, repeating and reinforcing education early post-PCI was highlighted as positive.

Participants reported feeling relaxed knowing they were going to attend a clinic and be followed up multiple times (via telephone) by a health professional. One participant commented on not being concerned about complications as they had full confidence in the healthcare professional (and their knowledge) and felt that they could contact the health professional for further advice. Perhaps the repetition of education and subconscious awareness of follow-up with the healthcare professional provided participants with feelings of confidence or enhanced SE (as identified above) to engage in post-discharge cares and management, although not evidenced in

self-report tools in Phase One.

> Knowing you were there, I felt like I could pick up the phone and call you at
> any time.... Very reassuring. (Particiapant020)

Participants appeared to view the relationship as nurse–patient, as opposed to investigator–patient or researcher–patient, with reference to the PI as a nurse. Trust is and was an important factor held by the PI in undertaking the intervention and following up with participants. Participants appeared relaxed in their body language, and voice, seeming to trust in the professional relationship during the course of the study. It was essential in both roles assumed (i.e., as a RN and PI) that participants felt a sense of trust, both in the education provided and nursing assessment (i.e., physical and psychological), while maintaining patient confidentiality and having faith in the PI to protect them (i.e., physically, ethically). Trusting relationships are important in nurse–patient interaction (Dinc & Gastmans, 2013). Patients are highly vulnerable and most often have to trust the nurse as they spend a large proportion of the time interacting with the patient (Dinc & Gastmans, 2013). It was, therefore, important in the present study to establish a rapport and, thus, a trusting relationship with participants to ensure their needs (i.e., post-PCI) could be met and so they felt comfortable and confident in themselves and the PI (i.e., enhanced SE) (Falvo, 2004). Moreover, it was hoped that the PI was able to demonstrate confidence in knowledge and skill so that participants would gain confidence and trust in the PI, which would then lead to enhanced SE in undertaking tasks such as post-PCI cares and self-management (Holloway & Watson, 2002).

Knowing that there were further follow-up telephone calls also presented as a positive to participants where they could ask questions of the healthcare professional and thus be less bothersome to their specialists. Participants sounded at ease during

telephone interviews and reported feeling relaxed and confident in themselves regarding the management of their health (i.e., CAD) and spoke positively about the future. Overall, participants reported great confidence or SE to self-manage in interviews.

> It's good to talk to someone like that with a bit more knowledge and give some different ideas of how to improve your life if you're not really comfortable about what's going to happen when you leave hospital. (Participant 054)
>
> Well, you explained a lot to me and you told me I suppose you know you made me aware that I was going to do the rehab course, which I think has been fantastic. I think well you looked at my wound, you explained what had happened to me in the operation as everyone has an individual experience I suppose. And you made me feel as though you were there for me. (Participant 020)

Positive feedback was also provided on the timing of the nurse-led clinic implementation in relation to hospital discharge and the benefits of such timely intervention for future post-PCI patients. While timeliness was discussed, some participants and healthcare professionals offered suggestions for earlier post-discharge follow-up, coupled with a shorter length of time (e.g., 30 to 45 minutes maximum). Given the short length of stay and potentially emotionally overwhelming post-discharge period, both participants and healthcare professionals proposed earlier follow-up and a shorter duration for clinic follow-up (BHF, 2011; Cupples et al., 2010; Dafoe et al., 2006; Grace et al., 2012; Heart Foundation, Western Australia, 2012; Lacey et al., 2010; Pack et al., 2013). The literature identified in Chapter 2 suggests follow-up from 72 hours up to 1 week post-procedurally (Chow et al., 2010; Rassaf et al., 2013; Wong et al., 2006). This suggestion was based on potential first-time PCIs, the emotionality surrounding the procedure (i.e., realisation of the gravity

of the situation), and for those who may experience complications early in the first week post-discharge. Healthcare professionals reinforced early follow-up in the first week post-discharge to reassess for post-discharge complications and to reiterate education undertaken in the hospital setting. Furthermore, and as highlighted by healthcare professionals anecdotally, as some remote and rural participants often stay at accommodation close to the hospital site for anywhere up to 3 days post-discharge, earlier face-to-face follow-up may be undertaken so that education can be revisited and reinforced. Furthermore, earlier post-discharge follow-up with remote and rural patients was recommended by healthcare professionals so that patients could ask any questions that may have arisen since discharge and so that they may also have a peace of mind and further understand the physical and emotional recovery post-PCI. Moreover, as remote and rural PCI patients are faced with geographical isolation (to CR programs), even in their own communities they face access issues (i.e., to closest CR facility) (Demiris, Shigaki, & Schopp, 2005; Harrison & Wardle, 2005).

Other issues such as ailing health and poverty also pose as a problem in the underutilisation of CR services in the community (Demiris et al., 2005; Harrison & Wardle, 2005). It is, therefore, essential that this group be captured and undertake early post-discharge, nurse-led follow-up. Furthermore, the reiteration of post-PCI education, health assessment (i.e., physical and psychological), and reassurance provided by attending a nurse-led clinic prior to returning home to enhance SE, reduce anxieties and improve self-management skills may be of great benefit with the aforementioned issues identified.

Coming to understand the situation

Participants developed a sense of self- and physical awareness after attending

the nurse-led clinic. Participants reported feeling calm about their procedure; however, it was not until the post-discharge period that the gravity of their cardiac event and procedure became clear. Given the short duration of hospitalisation, it is comprehensible that some PCI patients come to realise the significance of their procedure in the post-discharge period and may become distressed (BHF, 2011; Cupples et al., 2010; Dafoe et al., 2006; Grace et al., 2012; Heart Foundation, Western Australia, 2012; Lacey et al., 2010; Pack et al., 2013). Self-management for PCI patients, as identified, includes complication identification and management (i.e., chest pain, access site, medication allergies), medication adherence and compliance, activity recommencement, and making lifestyle and behavioural changes.

Participants reported that this awareness and realisation led to a sense of determination to initiate post-discharge lifestyle changes. Changes were made in the areas of diet and exercise, resulting in subsequent weight loss post-clinic attendance. Participants retrospectively reported being too busy prior to their procedure and, since undergoing their PCI and attending the post-discharge clinic, had learned to relax and enjoy their families and lives.

Although not a large area of focus of the nurse-led clinic, participants in the present study were regularly questioned regarding their daily diet and exercise intensity and frequency at each follow-up appointment. Participants were referred to the healthy food pyramid in the National Heart Foundation of Australia's (NHFA) book provided to them, *My Heart, My Life,* for dietary recommendations. Activity and exercise recommencement education was also offered at the nurse-led clinic with detail regarding exercise recommencement up until CR program recommencement. Participants reported enhancements in activity and intensity over

time post-discharge. Weight was also discussed at each follow-up appointment, with participants asked to offer their current weight, hip, and waist measurements to track weight gain and loss over time. Success was reported by some participants, while others maintained their weight. Currently, after attending a CR program, 60% of patients fail to maintain healthy and new lifestyle and behavioural after approximately 6 months and reportedly revert to old behaviours (Janssen, De Gucht, van Exel, & Maes, 2013). Participants in the present study were interviewed at approximately 6-months post-discharge, with a majority reporting (anecdotally) that they were still committed to new changes or maintaining healthy behaviours previously made. This may have been due to the fact that some were still undertaking CR programs.

> I am probably not eating any butter at all, apart from what is in cooking, what is already in the meal. I wouldn't add butter to any toast or scones or whatever I make. I have probably cut down dramatically on the salt. (Participant 020)
>
> I've made an enormous change in my lifestyle. I've slowed down from 100 miles an hour to 50 miles an hour. I decided to do a lot of travelling which I'm doing at the moment and I have done. (Participant 106)
>
> Just occasionally I thought, I must hurry up and do more and more things because I don't know how much longer my life is. But of course at my age it is good to have a reality check to make sure you just don't sit down and waste a single moment. (Participant 020)

Prior to attending the nurse-led clinic, some participants reported feeling shocked in the early post-discharge period, while others were not concerned at all due to their confidence in the procedure, modern medicine, and/or their specialist. Initial euphoria was reported by some participants post-PCI, while others commented on their calmness and feeling in control throughout the procedure and

post-discharge period. Overall, a majority of participants in the present study experienced shock and the realisation that changes were to be made became evident in the early post-discharge period and were reinforced at the clinic.

> I felt fairly anxious about it all initially but after talking and also having a few doctor friends come in and talk about what was going on, I don't know whether that helped or hindered me but I still had a few days of anxiousness but it calmed down pretty quickly. (Participant 054)
>
> About 2–3 days after discharge almost euphoric and over the weekend it hit like a brick wall. I felt a bit despondent knowing this was around and like I missed a bullet. I am very lucky. I had been feeling a little teary and emotional. (Participant 031)

As identified in Chapter 2, the short length of stay and experience of PCI and/or cardiac event in its entirety is emotionally overwhelming and can precipitate an anxious post-discharge period (Astin et al., 2005; Carroll, 2005; Jaarsma et al., 1995; Kriztofferzon et al., 2007; Lane, 1999; Roebuck et al., 2001). Reasons for initiating lifestyle changes surrounded a yearning to "be around longer" for their family. It was interesting that, among the minority reporting no concerns, some commonly identified health misconceptions were noted, particularly as participants reported that they had been "fixed" (Carroll, 2005; Young & Murray, 2011). Other participants identified feeling happy that blockages had been found and managed and reported confidence to make positive lifestyle adjustments and maintain good health post-PCI (i.e., self-manage). Participants' emotions and realisation of the gravity surrounding their procedure and diagnosis as well as post-procedural misconceptions were evident.

> Bit of a shock that I've got this thing inside my veins forever. I don't want to take tablets forever, but I will. I'm a bit lucky though that I'm still alive

(Participant 001)

Couldn't ask for a better present. Very happy. Fixed (Participant 067)

Hoping stents haven't moved, but very happy and we found very early as opposed to the latter. (Participant 083)

Self-awareness enhances self-management

General awareness and reiteration of education at the nurse-led clinic resulted in greater focus on symptom recognition and management, particularly angina symptom recognition and management. With patients often delaying taking action in their chest pain management, post-PCI nurse-led education was warranted (Gallagher et al., 2012). Participants were confident in their ability to manage their post-discharge cares, particularly concerning their access site and complications after attending the clinic (see Table 4.17). The amount of pressure and time required to manage a post-discharge bleed or haematoma was linked to in-patient femoral arterial sheath removal, while positioning during a complication was reinforced at the nurse-led clinic. With this association made, and as participants were awake during sheath removal and interacting with the nurses, they easily recalled the amount of pressure and time required to manage a bleed or haematoma, feeling confident to self-manage a post-discharge bleed if required. Furthermore, the importance of revisiting basic education to enhance awareness of their procedure, heart disease and post-PCI care was acknowledged. Although most participants had undergone this procedure in the past and attended a CR program, participants highlighted the importance of revisiting education. As identified in Chapter 2, the literature reinforces the importance of patient follow-up and education, with emphasis placed on timeliness, particularly for patients with chronic disease such as those with CAD who have undergone PCI or experienced a coronary event (i.e., being the within the first week) (Rassaf et al., 2013; Tuso et al., 2013).

Participants reported a greater awareness of and attention to medication adherence and administration after attending the nurse-led clinic. Medication adherence was high on baseline measurement in Phase One; however, participants reported being more conscious of taking their medications, especially anticoagulants that worked to prevent in-stent thrombosis and stenosis. As identified earlier in this chapter, small quantitative improvements in medication adherence were also recorded as measured by the MMAS-8. With medication adherence notably problematic in patients with chronic disease, it was essential to identify the general groups of medications participants were most commonly prescribed post-PCI, while highlighting why adherence is critical (Fernandez et al., 2007; Haynes, Ackloo, Sahota, McDonald, & Yao, 2008). Participants' perceptions concerning their self-awareness after attending the clinic were highlighted in Phase Two interviews.

> I think when it's a matter of personal health I don't think you could be reminded too often at all as to what you should do and what I find is with the number of people that I talk to that are going through similar things quite frankly how little some people even know or understand about what's causing it and what steps they have to take to try and prevent it. (Participant 014)
>
> I did take up more walking than I had been doing and found that beneficial. That was one of the main things that I did and lifestyle for good. (Participant 082)
>
> I am very careful to take medications at the same time every morning and I haven't missed any. (Participant 020)

Healthcare professionals commented on the simplicity, yet succinctness of the medication education component offered at the nurse-led clinic, the detail offered to patients, and the effectiveness and simplicity of grouping and discussing cardiac medications participants may be discharged with post-PCI. Furthermore, with the

three main messages of adherence reinforced visually and verbally by the PI,

healthcare professionals reported clarity in the messages of medication adherence

(i.e., maintaining adequate supply; not discontinuing medications abruptly; continue

taking medications as advised by cardiologist). The education delivered was reported

as clear and concise, with interviewees highlighting how it may lead to patients'

greater confidence in managing at home. Additional suggestions offered by

healthcare professionals for future clinics included warning about internet content

and speaking to a doctor if contemplating medication cessation.

> Yes, I thought that was well done and I've already mentioned that I think
> medications is one of the really critical factors that they need to understand
> the value and the risks around it and what they should and shouldn't do and I
> thought you looked like you had a good cover of that. (Healthcare
> professional, 002)
> Yes, I think breaking it down into the groups of medications because
> generally patients are confused about what their medication is called and
> what it's for. So breaking it down into the different groups of medications of
> what they are meant to do for them is really helpful for them and just
> reiterating to them what they are because I think they're thrown so much
> information or thrown so many medications that sometimes I knew that
> they're all over confused about why they're taking them. (Healthcare
> professional, 004)

Healthcare professionals commented on their overall impressions after the

nurse-led intervention was shown and explained to them, reporting their likes, and

offering recommendations to enhance the clinic. The overall visual appeal, stages,

and order in which the clinic and education was undertaken were positively

commented on, as well as how the clinic was undertaken in a face-to-face setting and

as an outpatient nurse-led clinic. Nurse-led clinics and outpatient support (i.e., home

visits, telephone follow-up, outpatient clinics) for patients who have experienced a

cardiovascular event have been trialled and are highlighted in literature (Alfakih et al. 2009; Carroll et al., 2007; Schadewaldt & Schultz, 2011; JBI, 2010). As identified in Chapter 2, cardiovascular nurse-led clinics appear to be successful in achieving short-term goals; however, in order to achieve long-term goals and outcomes, further follow-up with patients is recommended (Schadewaldt & Schultz, 2011; JBI, 2010). As the present study aimed to act as a bridge between hospital discharge, specialist follow-up, and CR commencement, it aimed to achieve short-term aims, while preparing patients for their long-term goals (i.e., health behaviour changes, risk reduction, lifestyle, exercise prescription) which are major CR goals.

As identified earlier in this chapter, considerations for future studies included telehealth options for patients in remote and rural locations. Healthcare professionals also commented on the appeal of the visual presentation and interactivity (i.e., slide presentation and ability to ask questions throughout the session), highlighting to the PI how it could appeal to and cater for different learners and learning styles. Blevins (2014, p. 59) recognises the different learning styles and requirements of adults in the healthcare setting for nurse educators (i.e., visual, auditory, kinaesthetic) and highlights how approximately 80% of the adult population are visual learners.

Furthermore, Blevins (2014) highlights the generational distinctions to consider in adult learning and teaching, which was a consideration in undertaking the nurse-led clinic. Blevins (2014) highlights how adult patient education should focus largely on teaching style as opposed to course content and in accordance with the following six principles which adult learning is based: (a) need to know, (b) self-concept, (c) experiences, (d) readiness (i.e., to learn), (e) learning orientation, and (f) motivation (Blevins, 2014).

Recommendations to shorten the timing of the clinic was also identified to

limit patient distraction and loss of concentration. Important areas of discussion identified by healthcare professionals included the NHFA *Chest Pain Action Plan*, wound site visuals, and the education offered in the form of scenarios and role play. Lastly, healthcare professionals identified its adaptability to ACS patients and those who have undergone other cardiovascular procedures such as permanent pacemaker and implantable cardioverter defibrillator implantation, electrophysiological studies, and ablation procedures.

> A lot of patients will think "I've got a stent, I'm fixed, I'm not going to get chest pain again, I don't need these medications" etc. and you actually are going through the plan with them and then doing a scenario and getting them to talk through the plan, that really stood out. I think that's great because we don't do that when the patient's in hospital. (Healthcare professional, 001)
> It looks clear and it goes through step by step. I see that it allows for the people to ask questions and that's good. They might think of a question later on and I can see that it offers a number of different steps for them to think about and probably highlights to them something that they might not have already thought about while they were having their procedures because it would be mind boggling. (Healthcare professional, 004)
> I think it's quite comprehensive and a lot of it's about a lot of very commonsense stuff that often doesn't occur to the patient, so I think the program that you've designed does cover a lot of ground. (Healthcare professional, 009)

Repetition of education for PCI patients was highlighted by all interviewees as essential and described as being effectively undertaken in this study. Patients and healthcare professionals identified timing and setting as important, given the distraction of a hospital ward, psychological distress, coupled with a short hospitalisation and limited time for nurse–patient teaching. The timing of this nurse-led intervention at day 5–7 post-discharge was also commented on as effective in

that the distraction of a hospital ward was removed and would possibly enhance

nurse–patient teaching and patient learning. With recommendations for PCI patients

to be reviewed within the first week post-procedurally and then 3 to 6 monthly for

the first 12 months, the time chosen for follow-up in the present study, and as

identified by both healthcare professionals and patients, was highlighted as effective

(Rassaf et al., 2013). Furthermore, it was hoped that early follow-up and repetition of

education would enhance SE, symptoms of anxiety, and depression and, thus,

enhance post-discharge self-management and maintenance of positive health

behaviours. Not only was repetition of education highlighted as important, but the

fact that it was and can be led by a knowledgeable healthcare professional was also

identified as essential as it may enhance patient learning and allay any possible

anxieties held by participants during this time.

> My impression was it was good standard cardiac rehabilitation information. I
> would have thought all that had been very clearly given to them by cardiac
> rehabilitation staff while they were in-patients but then we also all know that
> sometimes that information doesn't get absorbed at that time so it would be
> very sound reiteration of whatever they should have had. If they didn't have
> it then it's vitally important that they receive that information. (Healthcare
> professional, 002)
> I think it's a great idea, especially the five to seven days follow-up. I think
> our patients do need that emotional support when they go home. Obviously
> any sort of big procedure that they have, it does hit home and any education
> that they can get outside after being discharged is a great idea because it's
> just going to reduce their anxieties; and it should be led by the nurses who do
> work in cardiology all the time I think because that's what we're doing
> constantly. (Healthcare professional, 005)

In addition to, or as opposed to, taking access site photographs, participants

were offered picture diagrams of a wound site and area to colour and describe their

perceptions of the site, wound healing and recovery. A majority of bruising appeared within the first week post-discharge, and began to subside by Time 3 (1 month) follow-up. At Time 4 (3 months), participants voiced full recovery of access sites. Participants who had previously undergone a PCI procedure reported on this occasion having a greater awareness of their access site(s) (as opposed to previous PCIs) as they were required to report on wound site recovery. As identified in Chapter 3, participants were required to take photographic images and/or describe in their own words and colour on a wound site diagram how their wound was recovering post-procedurally. Most reported undertaking regular observations of their wound site(s), keeping note of swelling, bruising, discharge and odour, which was evident in their documentation on their wound site diagrams. Participants' observations and documentation of their wounds were clear and detailed. Effective self-management appeared evident with patients engaging in their post-discharge care. Bodenheimer et al. (2002) highlight the importance of encouraging self-management through patient empowerment. The authors reinforce how effective self-management is essential, particularly in chronic disease, as patients are assuming both carer and healthcare professional roles (Bodenheimer et al., 2002). Patient empowerment and, thus, effective self-management can be achieved through the offering of information (as opposed to ordering) and allowing patients to accept their role in their personal health management and actively participate in problem-solving (Bodenheimer et al., 2002).

The nurse-led clinic aimed to encourage effective self-management through patient education (i.e., information giving) so that participants had the knowledge to both care for themselves and problem solve (i.e., in the event of a complication). As a nurse and PI, it was of great interest and importance to receive the verbal feedback

accompanied by an image and/or diagram of the wound sites in the post-discharge period. With a short length of stay (i.e., an uncomplicated PCI), unless a patient is readmitted with a post-discharge wound site complication, healthcare professionals are unable to fully ascertain post-procedural wound site recovery and the anxieties that may present during this time of observation and management. Thus, at such an anxious time, it was essential to discuss post-PCI physical and emotional recovery to both gain an understanding of patients' experiences and to offer information so that they may manage and work through post-discharge health matters. Again, and as per Barlow et al. (2002) discuss, enhancements in self-management see increases in SE. Although, SE was not enhanced in intervention group participants in the present study, it appears as though self-management was. These results will be discussed further in Chapter 6. The following access-site descriptions were offered by participants of their recovery between Times 1 to 4 with or without the support of a diagram or photograph.

Table 4.17.   **Access-Site Descriptions: Time 2 (day 5–7) to 4 (3 months)**

Participant ID	Time 2	Time 3	Time 4

Participant ID	Time 2	Time 3	Time 4
PT019	"The wound bruising was the size of a 50 cent piece and fading. Colours: Outer blue, green and inner yellow discolouration". (see Appendix N1).	"The wound site is clear except for a small red spot".	"Not a mark on me".
PT105	"No lumps, bumps or bruises."	"Slight bruising of skin; pale blue colour; No bleeding or swelling; Tender under left arm pit". (see Appendix N1)	"All healed. No problems".
PT054	Nil site concerns per participant.	"Both left and right wounds appear totally healed, but for very, very slight shading on the left side associated with healing bruise. No lumps or residual haematoma evident" (see Appendix N1).	"Took a long time to heal. Nothing visible any more".
PT010	"No site concerns".	"At this time, there is no evidence of having had the procedure at all. There is no bruising, no marks at the wound site and no lumps or bumps. All is as normal" (see Appendix N1).	"All clear. No scarring or lumps. No bruising".
PT082	Nil participant comments.	"The cut in my groin has completely healed and bruises are gone and I have no after effects at all".	"Healed up perfectly".

Pressure on the patient - Attending cardiac rehabilitation (CR)

Throughout the course of the study, the PI asked all participants to comment about CR and offered referral for intervention group participants at day 5–7 post-discharge. While some participants were unsure of the nature of CR, a majority had attended a course in the past and/or had accurate perceptions of the program and its benefits. While all participants highlighted the importance of CR and the information provided during the course, there was a reluctance to accept referral for some first-time attendees, and more so to re-attend. Declining attendance at CR is common with approximately 30 to 60% of first-time attendees declining referral after an AMI (Cooper, Jackson, Weinman, & Horne, 2005). At baseline data collection, participants appeared eager to attend CR; however, within the first week post-discharge, participants' views on attendance changed. It was concerning to hear that

a large proportion of patients placed CR attendance second to work and other

commitments. Reasons for declining CR attendance included:

- busy life

- adequately enough informed from past attendance (i.e., up to 10 years
  since attendance)

- family commitments

- group activities not of interest

- co-morbidities affecting attendance

- belief CR possibly ineffective

- not contacted by CR team

- distance (i.e., geographical isolation)

- surgical procedure preventing early attendance.

As identified in the literature, some of the major barriers to CR attendance

include referral, geographical isolation, health, and affordability. The literature has

highlighted the barriers to CR referral and attendance, with researchers trialling

alternate methods to the delivery of CR (i.e., home-based, telehealth, online, early

enrolment) (Maclure, 2011; Neubeck et al., 2009; Niebauer, Mayr, Tschentscher,

Pokan, & Benzer, 2012; Pack et al., 2013; Wenger, 2008). It was, therefore, an

important component of the present study to enrol participants in CR. Although

attendance could not be controlled, enrolling all participants (i.e. both first-time and

repeat PCIs), as the first step was vital in overcoming the aforementioned barriers.

First-time potential attendees' comments regarding CR attendance are depicted

below:

Depends on when it is. I have to babysit. (Participant 019)
I lead a busy life, so no, don't think I will go. (Participant 105)

Think with my background of fitness instruction, I could do this myself. (Participant 083)

Not into group things, so may not go. (Participant 031)

Not sure what it is about. Probably not effective anyway. (Participant 018)

Have changed my diet and am aware of need to make changes. GP will check cholesterol. I am quietly confident the problem is fixed. Won't attend CR at this stage. (Participant 067)

While participants (i.e., both first-timers and repeat PCIs) offered reasons for attendance and non-attendance, most participants held firm beliefs that all PCIs should attend CR, irrespective of the number of revascularisation attempts. Emphasis was placed on re-attendance, particularly if the program had not been revisited for several years. Areas of CR highlighted to be of benefit post-PCI, as perceived by participants, comprised of the following:

- exercise (i.e., how to commence/recommence)

- diet (i.e., required changes)

- general wellbeing

- self-management

- physical health benefits

- how to make and maintain lifestyle adjustments.

Perceptions of CR appeared accurate for those who had never attended CR, while some reported they were unsure. It was interesting that the perceptions highlighted by participants did in fact reflect the benefits of CR as reported in the literature and included risk factor and lifestyle modification and maintenance, education, structured physical activity (Blair et al., 2011; Grace et al., 2012; NHFA, 2004). Participants who had previously attended a CR program reported that they could no longer recall specific course content and structure; however, diet and

exercise were identified as a main constituent of the course and was highlighted by participants. Excerpts from all first-time participants concerning CR information recall, perceptions and some misconceptions were discussed with participants. An important finding regarding CR perceptions included the thought that CR predominantly involved exercise and dietary changes, and thus, may therefore be undertaken at home without the need to attend a program. Other first-time participants were highly motivated to attend in light of their recent coronary event and procedure.

> I assume how to look after yourself so you don't overwork and put your heart under stress. (Participant 105)
> I presume, better eating and exercise. Would like to attend with my wife. (Participant 059)
> What you should and shouldn't do. What to look out for, symptoms, what to eat and lifestyle. (Participant 067)
> Just how to look after yourself in terms of exercise and diet post operation. I have a good routine. See how I go. I may attend (a program). (Participant 017)

As highlighted earlier, those who had undergone previous revascularisation procedures and attended a CR program in the past felt confident to manage or alter their lifestyle and risk factors without the support of a CR team. Magalhães et al. (2013) highlight how adherence to lifestyle and behavioural changes may reduce after Phase II CR and identify that this may be due to patient's initial motivation to make changes following their procedure and/or cardiovascular event. As identified earlier, after attending a CR program, most patients revert to their old behaviours by approximately 6 months (Janssen et al., 2013). Koelewijn-van Loon et al. (2009, p. E267) identify that approximately 20 to 90% of patients with CVD actually adhere to lifestyle advice. Furthermore, Koelewijn-van Loon et al. (2009) recommend

appropriate intervention focusing on cognitive–behavioural and affective elements, while also appropriately informing and sharing risk-reduction options and decision-making. It is interesting that participants in the present study aim to undertake their own rehabilitation and make positive lifestyle modifications learnt on previous occasions at CR given that there is a poor maintenance of new behaviours.

Given poor participant re-attendance to CR in the present study, it might be useful to consider secondary prevention as a non-negotiable for all post-PCI patients (i.e., not just first-time PCIs). Furthermore, strengthening the message of CR attendance during hospitalisation by medical and nursing staff may encourage secondary prevention attendance and re-attendance. Additionally, it may be beneficial to consider the utilisation of cognitive–behavioural therapy in conjunction with post-discharge CR to achieve cardiovascular risk reduction, behaviour change, and maintenance. To ensure that new behaviours and lifestyle changes are being adhered to, Magalhães et al. (2013) recommend 3-monthly face-to-face exercise and education coupled with monthly telephone communication and online patient activities post-Phase II CR.

Various studies as identified in Chapter 2 have trialled alternate modes of CR attendance for patients who have experienced a cardiac event and/or PCI (i.e., Skype, telephone, mobile phone; home-based) due to the problematic nature of CR and, furthermore, in anticipation that program attendance and adherence could be increased and sustained (Blair et al., 2011; Cupples et al., 2010; Gallagher et al., 2013; Heartwire, 2011; Karmali et al., 2014; Varnfield et al., 2014). As identified earlier, some participants believe that they can self-rehabilitate and are of the opinion that CR is similar to attending a gym and, thus, decline enrolment (Cooper et al., 2005). Some patients may miss or forget (i.e., if previously attended) the purpose of

CR in that CR assists in both physical and psychological recovery from a cardiac event and/or procedure. Reinforcement of these messages should be undertaken by ward nursing staff and cardiologists during hospitalisation and will be offered as recommendations to all hospital sites with cardiology units. The belief that CR is identical to attending the gym is noted in the literature and should be corrected in patients who believe they can self-rehabilitate solely through exercise (Cooper et al., 2005).

As highlighted previously, it is interesting to observe and hear the initial enthusiasm participants expressed to attend or re-attend CR early on during hospitalisation (i.e., on baseline data collection). While participants initially appeared eager to partake in CR, as early as the first week post-discharge, reasons for their inability to attend were identified. One standard-care group participant with an exercise prescription background who declined CR enrolment when contacted by a CR team member felt they could undertake their own cardiac rehabilitation. Within weeks after being discharged, the participant was referred by the PI to their cardiologist after reporting what appeared to be exertional angina while undertaking exercise at the gym. On follow-up, the participant reported having been admitted for a further PCI for a different coronary artery. A change was observed in this participant from baseline data collection. The participant was eager to enrol in a CR program and undertake the full course as opposed to self-rehabilitating as originally intended. Although not verbalised, perhaps experiencing PCI in such close proximity to their index procedure shocked the patient into attending CR. As highlighted earlier in this chapter, healthcare professionals reinforced the need to exert greater pressure to refer to people CR, with the use of shock tactics suggested to encourage some participants.

Did it in 1998. Have very bad arthritis and painful to exercise which is why I haven't gone back. Took through how to exercise, diet, guest speakers, trying to get mobile again. Think I will. (Participant 067)

It's just an extra thing I will have to do on my list and I don't see why I should attend as no big problems. I don't have any cardiac issues. (Participant 077).

I had been 3 years ago and have the knowledge to rehabilitate myself again. (Participant 089)

I don't think it did much for me. I wouldn't go again. (Participant 066)

Messages of CR encouragement in the nurse-led clinic were highlighted by healthcare professionals as positive; however, given most patients had repeat revascularisation procedures, greater emphasis was requested to ensure those who believed they did not require to re-attend and even undertake CR for the first time were enrolled. Analytical findings from interviewees included that, although the onus to commence CR and make changes was on PCI patients (be they first-time PCI patients or having previously undergone the procedure), they still needed to attend due to the significant physical and psychological benefits of attending. Furthermore, it was noted that, if participants are returning for further treatment for their CHD (i.e., another PCI), then clearly they need to revisit a CR program. Most healthcare professionals commented on the use of greater force or emphasis to encourage attendance, while some suggested scare tactics as an option. Suggestions for short refresher courses were offered as a recommendation for those candidates who had undergone multiple PCIs and did not feel they needed to revisit the full-length course again. The message of CR attendance at the nurse-led clinic was reported to be clear by healthcare professionals; however, greater emphasis to convince patients to attend was reported as necessary.

I think the onus should be put on them to ensure that they go because it's for

their health benefits. It's a long-term health benefit. We can encourage people to go but you can't make them go. But I think it needs to be encouraged as much as possible. But at the end of the day the patient has a choice but all we can do is present it in the most positive light that we can do and the benefits that they're going to get for it. (Healthcare professional, 006) I think as far as my practice goes emphasising cardiac rehab is a critical thing for these patients, particularly the ones who say they don't need it, who need it, who need the support, they're in denial, they don't change their lifestyle so getting some encouragement to go there and a little bit of pressure is actually a good idea. Then they are always grateful. (Healthcare professional, 008)

The aforementioned findings in relation to secondary prevention perceptions, misconceptions, and, thus, non-re-attendance are important and warrant further investigation. It was particularly intriguing that participants could highlight the importance of attendance and re-attendance and then decline enrolment and this may influence healthcare professionals (i.e., cardiologists and nurses) to rethink their approach to in-patient CR encouragement. Furthermore, the misconceptions of what CR involves should be highlighted (i.e., similar to attending the gym) with the differences identified so that participants may understand that CR is more than just exercising. Furthermore, while PCI is minimally invasive, it is still a significant procedure and is often underestimated. Moreover, if repeat revascularisation is warranted, so too is CR, particularly if CR was declined after the index procedure or if a significant amount of time has lapsed since the participant's first CR program attendance. These results will be discussed in greater detail in Chapter 6.

Overall, the semistructured interviews reinforced the value of offering a nurse-led clinic. Furthermore, Phase Two interviews highlighted the importance of undertaking early post-discharge follow-up the first week after undergoing PCI. Moreover, based on Phase One and Two findings, a Phase Three multi-centre study

is recommended. Changes to the current study protocol arising from the findings of Phases One and Two may include:

- Earlier follow-up within 3 to 5 days post-discharge
- shorter duration for nurse-led clinic: 30 to 45 minutes
- it would be preferable if all research assistants (RAs) undertook accredited training in CBT
- use of telemedicine (i.e., telephone and/or Skype/FaceTime follow-up)
- nil contact with standard-care group participants
- automatic CR referral (i.e., without option)
- assistance of community GPs, nurses, or nurse practitioners to undertake post-discharge physical and psychological assessment (i.e., ECGs, access-site images, STAI, CDS).

The aforementioned changes to the study will be presented in greater detail in Chapter 5 in the form of a study protocol with justification for changes provided. The protocol will detail the new approach to the nurse-led clinic (i.e., follow-up times, clinic duration, assessment tools) that have been informed by Phases One and Two.

4.3   Summary

This chapter presented details regarding participant background and demographics for Phases One and Two. Results for questionnaires and salivary cortisol assays were presented as raw data for Phase One, while analytical findings from both participant and healthcare professional interviews were presented for Phase Two. Overall, the result of the Phase One pilot did not demonstrate significant effects of the nurse-led intervention on the study hypotheses. The results of Phase Two, however, did identify support and positive benefits of the potential

effectiveness of the nurse-led clinic on some of the primary and secondary aims.

Grounds for a Phase Three, multi-centre study have been highlighted in this chapter.

A detailed Phase Three study protocol illustrating the development of the

intervention with justification will be presented in Chapter 5.

Chapter 5: Phase Three Development & Clinical Research Protocol

5.1   Introduction

This chapter presents Phase Three of the study in the form a clinical trial protocol. The chapter commences with the identification of study changes between Phases One and Three. The study aims, objectives, hypotheses, risk assessment, and management strategies are also described. Phase Three has reconceptualised the Phase One pilot study to a randomised controlled clinical trial (RCT) and has been modified to be delivered via electronic visual medium by a cardiology nurse trained in cognitive–behavioural therapy (CBT). The study protocol details the Phase Three intervention, design and conduct of a multi-centre study based on the findings arising from Phases One and Two, critical reflection and observations made by the PI and in the current literature. Standard care versus the nurse-led, educational intervention for Phase Three is also presented in significant detail throughout the chapter.

5.1.1   Phase Three Changes: The Nurse-Led Clinic

Changes to the nurse-led clinic between Phases One and Three include earlier follow-up as highlighted by study findings, critical reflection by the PI, and as reinforced by current literature (Trotter et al., 2011; Tuso et al., 2013; Yan et al., 2011; Wong et al., 2006). Participant follow-up in Phase Three will occur between day 3 to 5 post-discharge. These changes were influenced by Phase One and Two findings and the current literature that highlighted this time as vital for post-discharge follow-up (Günal et al., 2008; Rassaf et al., 2013; Trotter et al., 2011; Tuso et al., 2013; Yan et al., 2011; Wong et al., 2006). Importantly, the follow-up method was adapted from face-to-face and on-site, to using an electronic visual medium as

the mode of communication. The mode of follow-up was changed as a result of the PI's recruitment experiences and Phase Two recommendations. Aspects of health assessment will be undertaken during follow-up; however, participants will be verbally and visually guided by the RA using Skype or FaceTime (i.e., finding a pulse, access-site assessment). Unlike Phase One, an electrocardiogram (ECG) will not be undertaken on review due to the mode of follow-up and the expense of providing each individual participant with a portable ECG monitor. Additional improvements to the nurse-led clinic include the provision of a list of reputable medication websites.

Where participants originally (i.e., in Phase One) undertook all assessment tools at the commencement of follow-up, in Phase Three, all questionnaires will be undertaken at the end of follow-up by each participant. The RA will remain online to explain and clarify questionnaire items; however, the participant will have a print version of the questionnaire available and undertake them individually, as opposed to Phase One where the PI read all questionnaire items to each participant during the follow-up visit and documented their responses. Cardiac rehabilitation (CR) referral will be automatic in Phase Three study as a result of Phase One and Two findings, coupled with the PI's observations after undertaking the nurse-led clinic and participant follow-up. If participants have not attended CR in > 2 years, they will be referred to undergo the course again to refresh and confirm current, evidence-based cardiac rehabilitation course content. Recommendations for short courses are highlighted in Chapter 7. Justification for Phase Three changes are presented in Chapter 6.

Differences in Phase Three baseline assessment, as compared with Phase One, include that patients will no longer need to provide a salivary cortisol specimen due

to the costly undertaking in equipment and analysis. Baseline data collection will still occur face-to-face. Patients who undergo coronary angiography with diagnosed coronary artery disease (CAD) will be approached for Phase Three; whereas in Phase One, only percutaneous coronary intervention (PCI) patients were approached. It is anticipated that participants who are diagnosed with CAD will also benefit from the nurse-led clinic in that they will be provided with nurse-led support in the early post-discharge period. Given that it is a recommendation to screen those with CAD for psychological distress (i.e., anxiety and depression), all participants with CAD will be screened over time (Colquhoun et al., 2013).

Phase Three Protocol

The Phase Three protocol was carefully considered and developed in response to critical reflection, after undertaking each study phase (i.e., participant follow-up), and further reflection on the study plan, procedure, and Phase One and Two findings (see Appendix O1). As highlighted briefly in Chapter 4, to maximise the opportunity for participation in the study and to be available for potential participants in remote and rural communities who may forgo post-procedural education due to geographical isolation, the inclusion criteria will extend to those who undergo coronary angiography, who are diagnosed with CAD, as well as individuals undergoing PCI. Phase Three will be undertaken over the course of 12 months, using an electronic visual medium to follow participants' progress. In Phase One, the limitations of a PhD timeline did not permit medium- to long-term measurements of psychological distress and self-efficacy (SE). Furthermore, Phase Three will engage in minimal contact with standard-care group participants to gauge an effect of the nurse-led clinic on psychological distress and SE in intervention group participants versus standard care alone. Cardiac rehabilitation and attendance appeared to be

problematic, with changes to the referral approach made for Phase Three. Additionally, given the primary aims are to reduce psychological distress and enhance SE and self-management, all RAs involved will undergo training in cognitive–behavioural therapy (CBT). Cognitive–behavioural therapy is "an evidence-based psychological approach, practiced by a range of professionals for the treatment of mental health and other personal and family problems" (Sheldon, 2010, p. 3). Sheldon (2010) highlights how CBT facilitates self-analysis of thought processes, emotional responses and behaviour by encouraging change through ongoing monitoring and evaluation. Training in CBT may assist participants in the Phase Three study to achieve their post-procedural goals, overcome obstacles, and to facilitate behaviour change by challenging negative thoughts and/or beliefs regarding their post-procedural health and wellbeing. It is hoped that participation in the nurse-led clinic facilitated by a nurse with CBT training may lead to patients' enhanced SE and an outcome whereby effective self-management can be achieved and maintained.

5.2   Study Summary

Title	A randomised controlled clinical trial of a nurse-led educational intervention held within 3 to 5 days post-discharge to reduce psychological distress and enhance self-efficacy (SE) in patients who have undergone percutaneous coronary intervention (PCI) or coronary angiography. THE 'REALITY CHEC PROJECT' II
Short Title	The 'REALITY CHEC' Project_II
Protocol Number	NLED_INT_2015
Phase	Phase III
Methodology	Randomised Controlled Clinical Trial
Study Duration	Dates TBA
Study Centre(s)	Four hospital sites
Objectives	The primary objectives of this study are to reduce psychological distress (anxiety and depression), while enhancing SE in patients who have undergone coronary angiography or PCI
Number of Participants	$N = 220$ ($n = 55$ per hospital site)

Diagnosis and Main Inclusion Criteria	Main disease state: Coronary artery disease (CAD)
	Procedures:
	   • Diagnostic: Coronary angiography (with diagnosed CAD)
	   • Interventional: Percutaneous coronary intervention (PCI)
	Inclusion criteria:
	   • aged 18 years and over
	   • informed consent for primary or elective PCI signed by patient and cardiologist
	   • diagnostic procedure: Coronary angiography with diagnosed CAD
	   • Interventional procedure: Primary or elective PCI
	   • understand or speak English language
	   • post-discharge telephone access, mobile and internet access

Study Product, Dose, Route, Regimen	Nurse-led clinic education and clinical follow-up within 3 to 5 days post-discharge from hospital
Duration of administration	Visit 1: Baseline (Randomisation) — Day of hospital discharge Visit 2:Within 3–5 days post-discharge from hospital (Electronic visual medium [i.e., FaceTime/Skype]) (45–60 minutes) Visit 3: At 1 month post-discharge (30–40 minutes; electronic visual medium) Visit 4: At 3 months post-discharge (Electronic visual medium) Visit 5: At 6 months post-discharge (Electronic visual medium) Visit 6: At 12 months post-discharge (Electronic visual medium)

Reference therapy	• Intervention versus Standard care alone • Intervention group: Electronic visual medium, FaceTime or Skype (Using iPad; iPad Mini; Home Personal Computer [PC]; or Laptop) Note: RA to undergo training in Cognitive–Behavioural Therapy (CBT); RA employed will have a minimum of 5 years cardiology experience or be a Clinical Nurse (CN). Standard-care group: • Usual hospital care post-PCI/Coronary angiography • Nil contact with research assistant (RA) or principal investigator (PI)
Statistical methodology	Multivariate linear regression

5.2.1 Study Aims

The aim of this project is to evaluate the effectiveness of a nurse-led clinic offered to patients within 3 to 5 days post-coronary angiography (i.e., diagnosed CAD and PCI) or PCI (Appendix O1).

The study's primary and secondary aims are as follows and will be explained in greater detail throughout the chapter:

Primary Aim:

1 Evaluate if a post-discharge, nurse-led clinic providing education and support can reduce symptoms of psychological distress, while increasing self-efficacy (SE) and encouraging effective self-management.

Secondary Aims:

2 Evaluate if the nurse-led clinic can achieve 100% referral to a CR program post-education, through the use of an automatic referral system on study enrolment.

3 Evaluate if individualised medication education can enhance participants' SE, and improve post-discharge medication adherence.

4 Evaluate if a post-discharge, nurse-led clinic can enhance patients' SE and encourage effective self-management in patients.

Study objectives

The objective of this study is to evaluate if a post-discharge, nurse-led clinic providing education and support can reduce symptoms of psychological distress while increasing SE. It is also anticipated that training RAs in CBT may assist in altering participants' health misconceptions and encouraging positive thoughts and behaviours concerning their diagnoses (i.e., CAD) and post-PCI health. In doing so, it is hoped that by attending the nurse-led clinic participants' SE will be enhanced and they may engage in in effective self-management.

Primary Hypothesis

H°: Attending a post-discharge, nurse-led clinic providing education and support within 3–5 days post-coronary angiography or PCI will not reduce symptoms of psychological distress or improve SE, nor facilitate effective self-management in intervention group participants.

Study design

The study design is a randomised controlled clinical trial.

Standard-care group (n = 110)

Current practice for participant standard care involves the delivery of general education about the PCI procedure, post-procedural cares, activity and complication identification and management throughout the patient's hospital admission. Current standard education may include both verbal and written education. Follow-up post-discharge usually includes the cardiac rehabilitation team (CR) who arrange for course admission. Some facilities contact their patients at 1-month post-discharge to collect information about the post-discharge period. In the 'REALITY CHEC' Project, participants in the standard-care group will only be contacted via email or short message service (SMS) to remind them to complete their questionnaires at the

appropriate time frame. Follow-up for standard-care group participants will be at 3–5 days, 1 month, 3 months, 6 months and 12 months and will take approximately 15 to 30 minutes for them to complete all questionnaires at each time point. Participants will be asked questions concerning their psychosocial status and physical health post-discharge by use of both open-ended questions and validated assessment tools. Assessment tools will be posted to each participant the week prior to questionnaire completion. Participants will also be sent a reminder text message or email to complete the questionnaires. Questionnaires include the following: State Trait Anxiety Inventory (STAI), Cardiac Self-Efficacy Questionnaire (CSE), Cardiac Depression Scale (CDS), Morisky Medication Adherence Scale (MMAS-8 Item). A reply-paid, pre-addressed envelope will be enclosed for the return of all questionnaires. At each follow-up until 3 months, a digital photograph of the participant's access site(s) will be required of the participant. Digital photographs may be returned via email or post. Medication knowledge and adherence will also be discussed along with CR attendance.

Nurse-led clinic: Study intervention (n = 110)

Intervention group participants will be required to undertake a component that involves the use of an online, electronic visual medium (i.e., Skype or FaceTime). The nurse-led clinic will take approximately 45 to 60 minutes. Participants will receive tailored education and support concerning the post-discharge period, recovery, cares, and physical activity. Both verbal and written education and questionnaires will be supplied on discharge from hospital (i.e., randomisation), with participants instructed to open only on the day of the nurse-led clinic. Participants will undergo psychosocial and physical assessment. Data will be collected using validated questionnaires and self-report data to determine post-discharge health

outcomes including: physical outcomes, coping, emotional distress, and psychosocial support. Questionnaires include the following: STAI, Cardiac Self-Efficacy Questionnaire (CSE), CDS, and Morisky Medication Adherence Scale (MMAS-8 Item). Questionnaires may be returned to the RA via postal mail in the enclosed reply-paid envelope. Medication knowledge, education and adherence will also be assessed and discussed, along with CR attendance, and adherence. Participants will be educated on the importance of attending CR and will be enrolled in a program on the day of the clinic if they have not already been registered.

Research assistants will contact intervention group participants using an online, electronic visual medium (i.e., FaceTime or Skype) at 1 month, 3 months, 6 months, and 12 months post-discharge for further collection of data concerning their physical health and psychosocial wellbeing. Participants will have the opportunity to ask questions regarding their recovery, health and wellbeing. Participants will be mailed questionnaires one week prior to each follow-up visit and be instructed not to open the envelope until the date highlighted. Each envelope will be labelled as 1 month, 3 months, 6 months, and 12 months. Participants will be sent a reminder text message or email two days prior to their follow-up and reminded to complete their questionnaires after each online visit.

Study setting

This study is a Phase Three, multi-centre study and will be undertaken at approximately four hospital sites—two private and two public hospitals. Approximately 55 participants will be recruited from each hospital site.

Study population

Approximately $N = 220$ participants will be recruited from two private and public hospitals. Participants will be randomised to either the intervention group

(nurse-led, educational intervention) or standard-care group (control group) using an interactive voice response system (IVRS). Randomisation will occur after baseline data collection on the day of discharge from hospital for both coronary angiography and PCI patients.

Eligibility criteria

Inclusion criteria: aged 18 years and above, informed consent for coronary angiography and primary or elective PCI signed by patient and cardiologist, having undergone coronary angiography and a subsequent diagnosis of CAD, having a primary or elective PCI, understands or speaks English, has post-discharge telephone access (i.e., mobile phone or landline), has internet access (i.e., for use of online, interactive medium).

Exclusion criteria: children and/or young people (i.e. < 18 years), inability to understand or speak English, an overseas resident and unable to be followed up due to return to home country, on vacation in Australia for < 12 months, suffering from a mental illness/cognitive impairment and unable to legally consent, pregnant, in existing dependent or unequal relationship(s), highly dependent on medical care, has no telephone communication or internet access.

5.2.2 Study Outcomes

Primary outcome

With anxiety and depression highlighted as a national and global health priority, the primary outcome for this nurse-led educational intervention is to and reduce symptoms of anxiety and depression (Department of Health & Ageing, 2010; WHO, 2000, 2014). It is hoped that, if identified early, participants may be referred for further ongoing assessment and management of anxiety and depression.

Secondary outcome(s)

The following secondary outcomes will evaluate:

1   if using an automatic referral system can achieve 100% referral to a CR program

2   if the nurse-led clinic can encourage medication adherence through individualised patient education, encouraging effective self-management, and enhancing SE

3   if, by improving patients' SE, the nurse-led clinic can assist in the early detection, prevention and effective self-management of post-discharge complications.

5.2.3 Study Procedures

Recruitment of participants

Once ethical approval has been granted, potential participants will be identified on admission to hospital through collaboration with ward staff at the sites identified. The recruitment process will be as follows:

- consultation with the nurse unit manager (NUM)

- consultation with the nurse in charge of the shift

- consultation with the nurse caring for the patient.

On the day of admission to hospital, and following the process of participant identification as presented above and provided the patient expresses to their nurse that they agree to speak with the RA, potential participants will be approached and offered a participant information and consent form (PICF) in the presence of their nurse. The consent process will cover release of medical information (i.e., medical and bedside progress chart), and image release (i.e., wound site) to the immediate research team for educative purposes only (i.e., teaching, conference education,

publication, specialist viewing). Patients will be given time to review the documents. If the patient wishes to speak with the RA after reading the documents to clarify or to sign the consent forms, they may advise their nurse who will contact the RA. Participants, if agreeable, will be consented to The 'REALITY CHEC' Project. Baseline data will be collected and participants will be randomly assigned to a study group (i.e., online medium or standard-care group). The following conditions will apply to a participant who has undergone coronary angiography (i.e., diagnosed CAD) or PCI procedure and the RA may only approach the patient if:

- the patient is in agreement

- the cardiologist is in agreement

- the patient is pain free

- the patient is not under the influence of any sedation (i.e., morphine, fentanyl, midazolam, diazepam, oxazepam, temazepam).

If potential participants meet both inclusion criteria and the aforementioned conditions, the RA may inform and consent the potential participant.

Participant recruitment, screening and consent

Participants will be recruited from referring physicians, and via advertisement within the hospital (i.e., flyers, brochures). Study brochures will be disseminated to potential study participants on admission, prior to their procedure. Approval for brochures will be sought from the hospital and university Human Research Ethics Committee (HREC) and Institutional Review Boards (IRBs).

Participant identification and consent process

- After following the formal process of participant identification and if the patient wishes to consent to participation, a witness (i.e., nurse or relative), together with the RA or PI, will undertake formal written

consent. The nurse caring for the patient or a relative may be present at the time of consenting.

- The RA or PI will highlight the voluntary nature of participation and that withdrawal of participation may occur at any time throughout the course of the study without penalty.

- The RA or PI will highlight that there will be no penalties for declining participation in the study.

- All data collected about participants will be used for the purpose of the study. Participant's personal information will be de-identified and be stored in accordance with National Health and Medical Research Council (NHMRC) guidelines.

- The RA or PI must advise the participant that, on withdrawal, any data collected up until that time will be used for analysis.

5.2.4 Participant Withdrawal/Early Withdrawal of Participants

Participant withdrawal

Participants may withdraw at any time from the study prior to the completion date without comment or penalty. Participants will be given contact details of the RA who will be contactable via telephone or email and individuals may withdraw at any time throughout the course of the study without comment or penalty. Participant withdrawal will be reported immediately to the PI, study monitor and HREC.

Early withdrawal

Participants will be withdrawn from the research project by the RA for any of the following reasons. These conditions will apply for both the participant and their families:

- unexpected illness (i.e., suffering acute psychological/psychiatric

distress, diagnosis of fatal illness, poor progression of current illness, requiring major surgery)

- as a result of participation or possibly as a result of participation in the study (i.e., acute psychological/psychiatric distress).

The RA will report formally and immediately to the study monitor, HREC, university and PI.

Lost to follow-up

Participants lost to follow-up will be contacted via the following methods:

- Maximum of:
  - two telephone calls to landline or mobile phone
  - two emails
  - two certified letters.
- Telephone message — to be clear and detailed:
  - **state:** name, position, date, and organisation and study
  - **request**: participant to return the call between business hours, Monday to Friday
  - **advise**: RA will follow up with certified letter via postal mail.

Data collection and follow-up for withdrawn participants

The research team will obtain participants' permission to attain their survival data until the final follow-up visit. During the consent process, participants will be advised of their data retention for analysis. Survival data on all participants withdrawn and lost to follow-up will be sought via the hospital sites and/or cardiology groups/clinics. Participants will not be directly contacted.

Consent forms will be photocopied and returned to participants immediately after signing. Participants reserve the right to withdraw their involvement in the

study at any time and without penalty. Withdrawal of participation will be emphasised during the consent process and highlighted in the PICF in full. Participants will be offered a $25.00 store gift voucher to participate in the study. Vouchers will be posted to each participant after final follow-up and will be documented in the PICF (i.e., 12 months). Participants will not incur any out-of-pocket expenses. All health facilities, participants and personal details will be de-identified and coded on randomisation. On completion of the study, participants will be mailed a letter of thanks for their participation in the study, a summary of key findings and their gift voucher.

Randomisation

After consent and the collection of baseline data, participants will be randomised to either the standard-care or intervention group. As identified earlier, randomisation will be undertaken using IVRS to ensure equal and ethical randomisation to all groups. All sites will be blinded to the randomisation of participants.

5.2.5 Study Procedure

Day of hospital discharge: Baseline data collection

Following consent, baseline data will be collected from all participants on the day of discharge from hospital. Data collection will take approximately 30 minutes to collect and will occur in a private consultation room or at the patient's bedside. Data to be collected will include the following: general patient demographics, medical history, physical assessment (i.e., waist measurement, vital signs) and medical record details pertaining to their current hospital admission. A recent and de-identified electrocardiogram (ECG) taken on admission will be photocopied from participants' medical records. Access-site assessment will involve capturing a digital

image, site palpation and performing a visual inspection. Table 5.1 details specific

information concerning the study and procedure for both standard-care and

intervention group participants from admission through to the final follow-up at 12

months post-discharge from hospital.

Table 5.1.   Baseline Data Collection

On admission: Baseline Data Collection — All participants	
Assessment	*Tool/Instrument/Method*
General Information/ Health history (Medical records)	1. General information, demographics and medical history. 2. Research assistant (RA) to make copies of procedure related medical records for the purpose of the study only (To be de-identified). Items will include: - consent for coronary angiography - consent for PCI (PCI) procedure (inclusion criteria) - observation chart - ECG - medical history form or verbal medical history - procedure report only - medication chart or verbal list of medications from patient - progress notes relevant to admission (i.e., procedure report, notes concerning any post-procedural complications)
Psychosocial	**Anxiety:** State Trait Anxiety Inventory (STAI) Questionnaire **Depression**: Cardiac Depression Scale (CDS) Questionnaire **Self-Efficacy**: Cardiac Self-Efficacy Questionnaire (CSE) **Medication Adherence**: Morisky Medication Adherence Scale — 8 Item (MMAS-8) Questionnaire
Physical	**Physical assessment:** Primary and secondary survey **Primary survey:** Airway, Breathing, Circulation, Disability, Exposure (environment) (A, B, C, D, E) **Secondary survey**: Head-to-toe and physical assessment **Neurovascular assessment**, waist measurement **Access site:** Wound assessment — Visual inspection and palpation and access site photograph **Chest pain** (CP) assessment: National Heart Foundation of Australia (NHFA), Chest Pain Action Plan

After baseline data collection, participants will undergo telephone

randomisation and be assigned to either the standard care or the study intervention

group.

5.3   Study Intervention (*n* = 110)

The nurse-led educational intervention will be delivered by an RA within 3–5 days post-discharge from hospital. The RA will be a qualified cardiology RN, with a minimum of 5 years' experience, or a CN with a cardiology background. It would be preferable if study RAs were accredited in CBT to assist the participant in identifying and reducing psychological distress, enhancing SE, challenging negative thoughts, achieving individual health-related goals, and facilitating effective self-management. Training will be provided if RAs do not have accreditation in CBT to ensure that accreditation conditions and criteria are met. As identified, the intervention group will undertake the nurse-led clinic online using either Apple's FaceTime application or Skype. Undertaking the intervention using this application will enable the RA and participant to visually and verbally interact to view access sites and wound healing and facilitate instructed physical self-assessment. For this study, participants will undergo psychosocial and physical assessment. Psychosocial data will be collected using questionnaires and self-report tools regarding post-discharge health, coping, psychological distress (i.e., anxiety and depression), and psychosocial support. Each participant will be provided with assessment tools one week prior to each study follow-up time in a labelled A4 envelope. The assessment tools will be labelled to remind participants when they are to complete the questionnaires. Participants will also be sent a text message or email reminder two days prior to the specified date of questionnaire completion.

As identified, intervention group participants will attend a nurse-led educational clinic using an online visual medium to communicate (i.e., FaceTime or Skype). All participants will receive an instruction manual regarding the use of FaceTime and Skype for their specific electronic device. The nurse-led clinic will

take approximately 45 to 60 minutes to undertake. Intervention group participants who do not have an Apple iPhone (containing FaceTime application), iPad, iPad mini, laptop or home personal computer will be lent an iPad mini for the duration of the study. Participants will receive tailored education (i.e., verbal and written documentation) and support concerning the post-discharge period, recovery, cares and appropriate activities post-PCI. Medication knowledge, education and adherence will also be discussed, along with CR attendance and activity recommencement. Post-discharge physical activity education delivered will include exercise and activities permitted post-procedurally until the commencement of a CR program. Physical assessment (i.e., primary and secondary survey) will be undertaken via an online visual medium (i.e., FaceTime, Skype). If the RA suspects any post-discharge complications (i.e., psychological distress, bleed, wound site infection), by following the study's risk protocol they will ensure that they are referred to the appropriate person for clinical assessment and management.

Research assistants will contact all intervention group participants again at 1 month, 3 months, 6 months, and 12 months post-discharge using the aforementioned online medium for further collection of data concerning participants' psychosocial wellbeing and physical health post-PCI. Participants will also be given the opportunity to ask questions they may have concerning their health and wellbeing post-PCI. All questionnaires will be completed at the end of each follow-up.

The RA will make contact with each participant's cardiologist and GP via email for all private patients. Research assistants will only contact GPs for participants recruited from public hospitals. Cardiologists and/or GPs will be contacted on participant enrolment, on the occurrence of any adverse events (AEs) or serious adverse event (SAEs), and on completion of the study. Data collection for

participants in the nurse-led clinic will occur between 3 to 5 days post-discharge

from hospital and at 1, 3, 6, and 12 months. A greater depth of explanation for

changes is discussed in Chapter 6.

Table 5.2.   Study Intervention Group Summary

Study intervention group summary: Intervention at Day 3 to 5 days post-discharge, plus Follow-up:1, 3, 6 and 12 months post-discharge	
Assessment	**Tool/Instrument/Method**
Note: Primary survey: A, B, C, D, E. Ask participant if any immediate concerns (i.e., chest pain).	
Tools/Assessment Note: Participant to complete at end of each follow-up	**Anxiety**: State Trait Anxiety Inventory (STAI) Questionnaire (Trait Anxiety Inventory) **Depression**: Cardiac Depression Scale (CDS) Questionnaire **Self-Efficacy**: Cardiac Self-Efficacy Scale (CSE) Questionnaire
	Chest Pain (CP) assessment: Chest pain assessment and CP action plan **Medication adherence**: Morisky Medication Adherence Scale — 8 Item (MMAS-8) **Access-site assessment**: Wound care pathway/assessment tool **Neurovascular assessment:** Neurovascular assessment tool
Educational intervention (3–5 days post-PCI)	**Note**: Refer patients to hospital-specific information where appropriate
	Secondary Survey: Head-to-toe and physical assessment
Physical and Psychosocial assessment integrated throughout intervention	Access site, neurovascular assessment/Wound care: Digital photograph of site to be taken by patient (multimedia messaging service [MMS], digital photograph. Patient to email or post to RA) Visual observation and palpation of site by participant with verbal instruction and guidance by RA (i.e., what to look and feel for) **Tool**: Wound care pathway — Applied Wound Management (Wounds UK, 2010)
	Neurovascular assessment: To follow access site assessment **Tool:** Neurovascular assessment tool
	Education: • discuss post-discharge wound care/access site management • encourage reference to hospital-specific brochure on post-discharge cares
	Chest pain (CP)/Discomfort: • introduce CP assessment, education and management: • assess for CP within 3 to 5 days and current CP at time of follow-up

Study intervention group summary: Intervention at Day 3 to 5 days post-discharge, plus Follow-up:1, 3, 6 and 12 months post-discharge	
Assessment	**Tool/Instrument/Method**
	Chest Pain (CP) education: • Follow Chest Pain Action Plan. Guide participant through signs and symptoms; action / management (i.e., if experiencing CP or complication at home); and offer scenarios for patient to work through
	Medication adherence and compliance: • Assess patient's understanding of own medications, medication taking behaviours, compliance and education
	Medication knowledge and awareness: • assess: Medication knowledge (i.e., current medications) • medication name, indication (i.e., ask participant what the medication is for if they do not know the name), dose, frequency
	Medication education: • discuss main groups of medications generally prescribed post-PCI or on diagnosis of CAD • discuss medication adherence (highlight the importance of), compliance, and management • RA to educate participants on the importance of all medications currently being taken • highlight the importance of anticoagulants/platelet aggregation inhibitors (i.e., aspirin, clopidogrel) and continuation until cardiologist advises otherwise
	Caution: The use of some internet material • **Note**: Offer participants a list of reputable medication websites to view
	Secondary prevention: Cardiac rehabilitation (CR) and activities • assess participant's perceptions regarding CR (pre-attendance) • clarification regarding their procedure (i.e., coronary angiogram or PCI) • discuss their procedure, the outcome (i.e., PCI or medical management) and what it means for them now
	Secondary prevention: CR re-attendance (> 2 years) • automatic referral for all participants who have not attended CR in 5 years or greater • **Note**: Reinforce that CAD is a chronic disease

Study intervention group summary: Intervention at Day 3 to 5 days post-discharge, plus Follow-up:1, 3, 6 and 12 months post-discharge	
Assessment	**Tool/Instrument/Method**
	Education: • reinforce and promote the importance of CR attendance: • make appointment and track attendance (i.e., CR units will be telephoned to ask of participant attendance) • discuss post-discharge physical activity recommencement with participant (i.e., what activities/exercise permitted until commencement of CR program) • provide participant with a hospital-specific CR brochure and activity recommencement guide • for reference: Use hospital-specific brochure/booklet on discussion of activity recommencement or *My Heart, My Life*
	Research assistant (RA) questions: • Mixture of structured, open and closed-ended questions concerning: Quality of life, support networks, stress and coping post-PCI or coronary angiography (i.e., after diagnosis of CAD)
	Participant knowledge: • Post-procedural cares, activity, CR (expectations), medications, complications and management. Effectiveness of follow-up post-PCI
	Participant questions/issues/concerns: • Participants may have concerns/questions to ask the RA

5.3.1 Standard-Care Group (*n* = 110)

Hospital standard care

Standard care at all hospital sites involves the hospital staff providing education to patients concerning the procedure and general post-procedural cares. Standard care delivered involves management of the access site, and identification and management of complications such as access-site bleed, haematoma (i.e., size/appearance), chest pain and medication complications. Closer to discharge, a CR nurse reviews each in-patient to ensure they are educated about their procedure, diagnosis, medications and the need to make lifestyle changes, while offering enrolment in a CR program. Post-discharge follow-up usually includes CR contact to arrange for course enrolment. Importantly, standard care and follow-up for patients may vary for each hospital site.

The 'REALITY CHEC' project changes: Standard-care group

As compared with Phase One follow-up, there will be no formal communication with the PI. Participants in this group will be followed up by the RA post-hospital discharge via telephone, email or short message service (SMS) as a reminder to complete all documentation provided and return to the PI. Follow-up will be between 3 to 5 days, 1 month, 3 months, 6 months, and 12 months. Completion of documentation will take approximately 30 minutes. Participants will be asked questions concerning their psychosocial health status and physical health post-discharge, using both open and closed-ended questions and questionnaires. Additionally, at each follow-up until 3 months post-discharge from hospital only, a digital photograph of participant's access sites will be requested. Phase One access-site follow-up displayed full recovery in all images requested of participants at this time point, hence no further images will be sought throughout the course of the Phase Three study. Participants may return access site images via email or post to the RA. Medication knowledge and adherence will also be discussed along with attendance to CR, activity recommencement and CP experienced post-discharge from hospital and on follow-up.

Table 5.3.   **Standard-Care Group Follow-Up**

Standard-Care Group At 3–5 days post-discharge, 1 month, 3 months, 6 months, and 12 months post-discharge	
Assessment	**Tool/Instrument/Method**
	• Nil formal communication with participants. RAs only to communicate with participants to remind on the completion of assessment tools
Psychosocial	**Anxiety**: State Trait Anxiety Inventory (STAI) Questionnaire (Trait Anxiety only) **Depression**: Cardiac Depression Scale (CDS) Questionnaire **Self-Efficacy**: Cardiac Self-Efficacy Scale (CSE) Questionnaire **Medication adherence**: Morisky Medication Adherence Scale — 8 Item (MMAS-8) Questionnaire
Physical assessment	**Note:** All physical assessment will be documented by standard-care group Participants to complete data collection form (DCF) provided **Chest pain assessment** (CP) assessment and action taken (i.e., if any experienced) **Complication identification:** • Participant to document in DCF provided and actions taken (i.e., self-management, GP, emergency services required) **Access site: Wound & Neurovascular assessment** • Access site photograph (camera, mobile phone or device camera). To email, send via MMS, or post in the mail.

Any concerns raised by the participant or identified by the RA (i.e., post-discharge complications, psychological distress) throughout the course of the study will be actioned immediately (i.e., contact cardiologist and/or GP) and reported in accordance with the study's risk protocol.

Safety considerations: Risk management and clinical governance

The research team will adhere to the study protocol throughout the course of the project. The study protocol includes a risk protocol that will be reviewed and approved by cardiology directors and the Nursing Executive at each of the sites where the clinics will be undertaken. The protocols will be available to all research team members taking part in the clinical trial and have been adapted from Phase One risk protocols (see Appendix W).

A risk management plan is in place to protect both study participants and

research team members from any AEs or SAEs that may be experienced both at study sites (i.e., on recruitment) and at the participant's home.

- Hospital orientation and competency-based assessments will be undertaken to ensure the safety of participants and research team members.

- AEs and SAEs will be reported to the appropriate site Human Research Ethics Committees (HRECs).

- An interim audit may be conducted by site Research Governance Offices at any time on request.

- Regular debriefing with site contacts and research team members will occur to ensure patient safety is being maintained.

Ethical considerations

The study will be conducted according to the 'Declaration of Helsinki', Good Clinical Practice, per the Revision of the *Joint NHMRC/AVCC Statement And Guidelines On Research Practice Australian Code For The Responsible Conduct Of Research*, and the *QUT Code of Conduct for Research D/2.6* and per the laws of the country in which the study will be undertaken (NHMRC, 2007; QUT Code of Conduct for Research, D/2.6, MOPP, 2009). The ethical principles that include integrity, respect for persons, justice and beneficence will be strictly adhered to at all times (NHMRC/AVCC, 2007).

Significance

This intervention is a new approach to the continuum of care for all patients post-coronary angiography (i.e., with diagnosed CAD) and post-PCI, providing vital support in the early post-discharge period. Implementation of the nurse-led clinic will aim to reduce anxiety and depressive symptoms early in the post-discharge

period. Furthermore, this study aims to improve SE through the reduction in anxiety and encouragement of effective self-management through the use of a person-centred approach. Additionally, by training RAs in CBT, it is hoped that healthier thoughts and participant outcomes may be encouraged (i.e., health and behavioural goals) and that any negative beliefs may be challenged. It is also hoped that depression may be detected early and participants may be referred (i.e., to GP for referral to psychologist or psychiatrist) for early intervention.

Clinical trial registration

The study will be registered with the Australian New Zealand Clinical Trials Registry (ANZCTR).

Collaborative arrangement evidence

A collaborative agreement between the research team and all hospital sites has been made through the Office of Commercial Services at the university.

Insurance

The university has adequate insurance to cover the research team over the course of the study.

Investigational agent

This will be a nurse-led clinic, providing education, support and screening for psychological distress within 3 to 5 days post-discharge from hospital utilising an online, visual medium (i.e., FaceTime and Skype).

Primary study endpoints

The primary endpoint for this study is reduced post-discharge anxiety levels, enhanced SE, and the reduction of depressive symptoms.

5.3.2 Statistical Plan

Sample size determination

A sample size calculation was undertaken to determine the sample for the proposed study. The number of participants required to determine an effect of the intervention is $N = 220$ (n = 110 per group). Thus, as a multi-centre study (four sites) will be undertaken, $n = 55$ participants per site will be recruited.

Stopping rules

The study will be stopped if participants, primarily as a result of participation in the study, experience acute psychological/psychiatric distress requiring immediate treatment (i.e., hospitalisation). The study's risk protocol will be adhered to should any participant experience an acute psychological /psychiatric event requiring hospitalisation. Such an event will be reported to the study monitor, all HRECs, specialists, and GPs.

Safety monitoring

The PI will oversee the safety of the project at all sites and report on all AEs and SAEs. A risk protocol, as identified, is in place to ensure appropriate reporting. An independent data and safety monitoring board may audit the sites and data storage practices at any time on request. Interim analyses will be undertaken throughout the course of the study by an independent data monitoring committee.

5.3.3 Data Handling and Record Keeping

Confidentiality

Personal information and all data will be kept confidential and stored at the university site in a locked filing cabinet. All personal information collected will be de-identified RAs. Electronic data stored will be password protected.

Research team members authorised to access data will include:

- Principal investigator

- Research manager

- Research assistants (entering data).

Should any participant withdraw from the study, all data up until the time of withdrawal will be held by the research team for data analysis. The retention of data collected for participants withdrawing from the study will be highlighted during the consent process.

5.3.4 Study Monitoring, Auditing, and Inspecting

Auditing and monitoring

Study auditing and monitoring will be permitted by site research governance office (RGO) officials and QUT monitors. Items to be audited and monitored will include:

- source documents and case report forms: random files may be selected

- instruments (i.e., assessment tools, salivary cortisol specimen collection containers)

- data storage (i.e., where and level of security)

- electronic data (i.e., ensure password protected).

Funding source

The PI will apply for a National Heart Foundation of Australia (NHFA) research grant to fund the study.

Conflict of interest

There are no conflicts of interest to declare in this study.

Participant stipends or payments

Participants will all be given a $25.00 store voucher on completion of the study.

Publication plan and commercialisation

Results from this study will only be published by the PI and Queensland University of Technology (QUT). Results may not be published by any third party without written consent from both the PI and the university. One hospital site where Phase One was undertaken has requested a detailed plan to regarding the detailed structure of the nurse-led clinic so that they may implement such a clinic at their site. As a result, the PI has met with QUT's Bluebox™ to discuss Phase Three and potential research commercialisation. Agreements will be made with any organisations prior to the provision of information concerning the nurse-led clinic structure and implementation.

5.4 Summary

This chapter presented the development of Phase Three of the 'REALITY CHEC' Project that arose from Phase One and Two findings and as a result of the depth of time engaged in the study by the PI, coupled with observations made and critical reflection undertaken. The Phase Three nurse-led clinic, as identified, will therefore be undertaken by using electronic visual modes of communication and be available to both coronary angiography (i.e., with diagnosed CAD) and PCI participants, so that a greater number of patients may benefit from the support provided by the nurse-led clinic. As highlighted, follow-up will continue over a 12-month period and be undertaken by a nurse trained in cognitive–behavioural therapy so that participants may be more formally supported in achieving their goals and changes in behaviour over time. Moreover, study follow-up over 12 months will

enable screening and referral of participants with psychological distress over time and may facilitate reductions in anxiety, enhancements in SE, and encourage effective self-management. Due to the problematic nature of CR program referral acceptance, those who have previously attended (> 2 years) will be automatically referred. Chapter 6 will discuss the findings of the study in relation to the theoretical framework and current literature. Phase Three study changes will also be discussed in greater detail in the following chapter, with explanation provided for modifications which were informed by the research process and current literature.

Chapter 6: Discussion

This chapter discusses in detail the study's results for Phases One and Two with respect to the theoretical framework, current literature, primary, and secondary research aims. Findings will be compared and contrasted against the literature with similarities and differences identified. Furthermore, the development of Phase Three will be highlighted.

6.1 Phase One Discussion

This section discusses participant demographics together with the study's primary and secondary aims for Phase One. Anxiety and CSE questionnaire results will be examined with the literature, while explanations for the results will be offered. Overall, although it was expected that this intervention would achieve primary and secondary aims, results have not demonstrated strong support for the study's hypotheses. For the primary aim of increasing SE and reducing trait anxiety, CSE and trait anxiety were both moderately reduced in intervention group participants, while standard-care group participants demonstrated small enhancements in CSE and no effect on trait anxiety. For secondary aims, depression scores demonstrated reductions in both groups, while re-attendance to cardiac rehabilitation (CR) was minimal, and medication adherence remained stable over time. Post-operative complications experienced by participants were minimal, expected, and successfully self-managed by all participants over the course of the study. Overall, the results for these particular constructs did not meet expectations after undertaking the intervention and will be discussed throughout this chapter.

6.1.1 Demographics

Participants recruited to the study were predominantly male. The prevalence of

CHD in males is well-recognised in the literature with current data revealing CHD to be twice as high for males than females (AIHW, 2012). The AIHW identifies a greater hospitalisation of males as opposed to females, thus accounting for the greater ratio of males to females treated for CHD (2012). Furthermore, approximately 61% of patients hospitalised with CHD were 65 years of age and over (AIHW, 2012, p. 268), with the mean age of participants in the present study being 65.03 years of age. Both medical and behavioural risk factors for CHD reported by participants were consistent with those identified in the literature (NHFA, 2014). Risk factors included (see Table 6.1):

Table 6.1. **Risk Factors for CHD as Reported by Participants in the Present Study**

Risk factors	Medical	Behavioural
	Hypertension	Smoking (Recent and history)
	Hypercholesterolaemia	Alcohol consumption
	Type 1 and Type 2 Diabetes	Inactivity
	Obesity	Dietary inadequacies
	Mental health status	

Source. Adapted from Nichols, Petersen, Alston, & Allender (2014) *Australian Heart Disease Statistics*, NHFA, 2014.

6.1.2 Primary Aim

Self-efficacy (SE) and anxiety

Although it was expected that participants in the intervention group would show increased SE and reduced anxiety as related to the primary aims, this was not demonstrated in the present study. Results of the study, as evidenced by effect size calculations, showed little improvement in CSE over time in intervention group participants, with a moderately reducing effect on CSE, $d =0.60$. No effect was demonstrated in standard-care group participants, $d = $ -0.19. On closer inspection of CSE items, mean ratings, not based on formal testing demonstrated improvements in some aspects of CSE. Mean CSE ratings will be discussed in greater detail later in

the chapter. These results may be reflective of many issues surrounding the intervention, delivery, interpretation, and completion of the questionnaire. Issues that may have impacted on the results may have included: failure of the intervention, general misunderstanding, recall bias, interviewer error, and questionnaire timing.

As noted above, there are various explanations that elucidate the results of the study; however, it is possible that the intervention alone failed to produce the expected results. A longer study of 6 to 12 months with frequent clinic sessions may benefit participants more in terms of enhancing SE. The suggested Phase Three study, as discussed in Chapter 5, following participants until 12-months post-discharge may determine and facilitate the medium- to long-term effects of the nurse-led intervention on SE. With nurse-led clinics offering small short-term benefits (between 6 and 12 months) in risk factor modification, patient outcomes, quality of life and patient targets, the benefits were apparent (JBI, 2010; Schadewaldt & Schultz, 2011). While endeavouring to offer early nurse support, nurse-led clinics offer "sustained encouragement" and "early assessment" to reduce patient risk factors (Schadewaldt & Schultz, 2011, p. 211). Although the pilot study did not demonstrate effectiveness in achieving all study objectives, preliminary evidence, particularly from Phase Two, supports a Phase Three, multi-centre study being undertaken to determine the medium- and long-term (i.e., over 12 months or more) effects of the nurse-led clinic on SE, psychological distress, and self-management in both PCI patients and patients diagnosed with diagnosed CAD. The JBI (2010) highlight how nurse-led interventions have demonstrated effectiveness in achieving short- and medium- term patient objectives and while some long-term outcomes may be achieved (i.e., modifiable risk factors) further investigations and approaches to achieve long-term patient outcomes are highlighted. The recommendations as

highlighted by Schadewaldt and Schultz (2011) and JBI (2010) reinforce the importance of undertaking long-term follow-up investigating the effectiveness of a Phase Three, nurse-led clinic on the aforementioned outcomes (i.e., >12 months).

Carroll (2005) highlights how nurses are paramount in assisting patients with their personal health goals and in encouraging lifestyle changes, particularly post-PCI. Perhaps, and as identified earlier, longer follow-up and a more intense intervention (i.e., RN trained in cognitive–behavioural therapy [CBT] to undertake the nurse-led clinic) would be of benefit to participants, with a greater focus and time to set and achieve goals (although discussed with participants). The combination of CBT coupled with health professional post-discharge support and education may assist patients in dealing with problematic beliefs (i.e., health misconceptions, not wanting to quit smoking) that may impact on positive behaviour change, maintenance, and effective self-management. Various methodological explanations for the present study's outcomes were considered and are provided later.

The CSE tool was originally designed to assess CSE in heart failure patients and has since been adapted by the original authors to suit the broader cardiovascular patient population; however, questions more specific to heart failure present in the questionnaire appeared to be misinterpreted by some participants (Sullivan et al., 1998; Sarkar et al., 2007). For example, some participants had reported breathlessness on baseline measurement, but at Time 2 (day 5–7) reported they had never experienced breathlessness and responded as 'not applicable'. Misinterpretation of questionnaires is common for individuals as identified by Roberts and Taylor (2002). Subsequently, limited clarification of misinterpretation often leads to invalid or incomplete data, as noted in the present study, potentially affecting the results (Roberts & Taylor, 2002). On baseline assessment all

participants undertook questionnaires individually after pre-completion instructions were given. Intervention group participants completed questionnaires individually again at day 5–7 post-discharge (Time 2), while standard-care group participants completed the questionnaire via telephone from day 5–7 post-hospital discharge onwards.

Questionnaire delivery (i.e., timing) after the nurse-led clinic attendance may also have been problematic. Questionnaires were completed at the commencement of follow-up at day 5–7 (Time 2) post-discharge to measure SE and any changes from the baseline visit for both groups of participants. Subsequent questionnaires undertaken at 1 month (Time 3) and 3 months (Time 4) were measured at the end of each follow-up session. In retrospect, it may have been more appropriate to measure CSE immediately post-intervention at day 5–7 post-discharge (Time 2) to gauge the effect of the nurse-led clinic on SE.

An explanation to account for effect size (ES) and reliable change on CSE may be attributed to the high level of anxiety measured by the STAI in intervention group participants. Carroll (2005, p. 12) highlights how "negative psychological states" may affect learning and lifestyle changes and, in particular, how anxiety is heightened on discharge from hospital in patients with CHD. Thus, higher levels of anxiety may have contributed to the reduction in learning in the nurse-led clinic, therefore attributing to only a small percentage of participants' CSE recovering and improving, as evidenced in CSE and RCI calculations. Dehdari et al. (2008) identify how both SE and anxiety affect the adoption and maintenance of good health behaviours in cardiac patients, which may explain the results.

The theoretical framework and literature highlights that an increase in SE should see a reduction in anxiety (Bandura, 1977, 1995; Dehdari et al., 2008). The

present study had a moderate reduction in trait anxiety in the intervention group over time, while no effect was demonstrated on anxiety in standard-care group participants, as measured by the STAI Y2 Form. Only a small percentage of intervention group participants saw improvements and recovery in CSE as evidenced by RCI calculations. It was interesting that intervention group participants appeared more anxious on baseline measurement compared with standard-care group participants. This was reflected in mean trait anxiety scores, which were higher in intervention group participants than standard-care group participants. Furthermore, trait anxiety as evidenced in ES and RCI calculations had a moderately reducing effect on trait anxiety in intervention group participants and recovery in a small percentage post-intervention; no effect on trait anxiety was evidenced in standard-care group participants and no participants achieved recovery. Improvements in anxiety were evidenced, however, in a similar percentage of both groups of study participants. As noted in the literature, it is difficult to reduce anxiety in patients who have high baseline trait anxiety—this finding was important (Muris, Mayer, & Merkelbach, 1998). Notably, trends observed in mean ratings for CSE and anxiety at Time 3 (1 month) demonstrated enhancements in CSE, and reductions in anxiety. Possible conclusions, which will require testing in the form of a Phase Three study drawn from these findings, may indicate that:

- given the seriousness of the circumstances, the procedure itself (i.e., PCI) may have been life-changing for participants; and

- the intervention may potentially be effective in reducing trait anxiety post-procedurally.

Updegraff and Taylor (2000, p. 3) highlight how stressful life events may have a positive or negative effect on an individual. The authors identify three specific

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areas from their review of literature on individuals' perceived benefits from life events. Positive changes were reported in the areas of: (a) "self-concept", where individuals believe they are stronger from their experience; (b) "relationships with social networks", where relationships are enhanced as individuals request the support of their family and friends; and (c) personal growth and life priorities", where personal changes and change in priorities in life occur (Updegraff & Taylor, 2000, p. 5).

The positive effects of stressful life events may be sustained long term, and may benefit the individual as they may have a better understanding of themselves, their social support system, personal priorities, and their life (Updegraff & Taylor, 2000). Conversely, negative effects can be experienced as a result of stressful life events and may include "depression, anxiety and cognitive disruptions" (Updegraff & Taylor, 2000, p. 11). Authors identify how negative effects may include: "psychological arousal, distractibility, and other negative effects" that may persist for days to years post-event (Updegraff & Taylor, 2000).

While expert opinion and the literature suggest positive effects on anxiety and depression, when stressful or life change events are perceived negatively they may impact on psychological distress (Smith, Johnson, & Sarason, 1978). Furthermore, Sarason et al. (1978) suggest that those with a negative perspective on life events tend to suffer anxiety and depression. Nakatani et al. (2013) undertook a study of 33 participants, post-breast cancer surgery to investigate the association between psychological distress and psychological traits. Results revealed a propensity for patients who negatively viewed life events to both view and react negatively to certain circumstances on diagnosis, and treatment of breast cancer (Nakatani et al., 2013). Although a different context to the focus of the present study's intervention, it

is demonstrated how life events and trait anxiety can negatively impact on psychological distress, causing a "psychological distress-enhancing effect" (Nakatani et al., 2013).

Muris et al. (1998) undertook a 2.5 hour behavioural intervention on 36 women with spider phobias to determine if trait anxiety could predict outcomes in phobic disorder therapy. The authors highlight how patients with high trait anxiety levels in medical settings are often slower in their recovery, experience greater discomfort, and are more likely to be distressed than those with lower trait anxiety. Although a psychological intervention, results showed a significant correlation between high trait anxiety and limited effect of the intervention. In the present study, intervention group participants, although presenting with high trait anxiety may have benefited from attending the nurse-led clinic. Although the intervention was not a cognitive–behavioural intervention, a moderate effect was noted in the reduction of trait anxiety, while full recovery was evidenced in two intervention group participants. Reductions in mean ratings for trait anxiety from Time 2 (day 5–7) to Time 3 (1 month) was larger than that of standard-care group participants at this time. Lastly, although the overall reductions in mean ratings for trait anxiety from baseline measurement was greater in standard-care group participants, intervention group participants presented with higher trait anxiety. The smaller overall reductions in mean ratings for trait anxiety in intervention group participants may have been due to slower recovery and potentially as a result of greater distress suffered in this group of patients. These findings will need to be tested in a Phase Three study to confirm the accuracy of these preliminary results.

While PCI is less invasive, Dehdari et al. (2008) undertook a study comparing anxiety and SE and social support in 150 CABG versus PCI patients and CR referral.

Dehdari et al. (2008) highlight how patients in their study were more anxious (as opposed to CABG patients), with greater state and trait anxiety scores identified, as did participants in the present study (compared to standard-care group participants). The authors also identified how the outcome of PCI is anxiety provoking and uncertainty surrounding this procedure and the future may lead to less control and poor coping (Dehdari et al., 2008). Furthermore, some participants in the study with high levels of anxiety also had poorer social support networks (Dehdari et al., 2008). It may be possible that intervention group participants in the present study had poorer social support networks and, therefore, greater trait anxiety than standard-care group participants. Thus, with greater trait anxiety, overall SE enhancements were not evidenced. Mean ratings for some CSE items demonstrated enhancements only at a single-item level when reviewed.

Sipötz et al. (2013) assessed emotional distress in 163 PCI patients over 24 months using the MacNew Health-Related Quality of Life Questionnaire and the Hospital Anxiety and Depression Scale. Corresponding with the present study, the researchers found improvements in MacNew "intra-individual change" up to 1-month post-PCI, physical and social improvements at 6 months, and maintenance from 6 months until 24 months (Sipötz et al., 2013, p. 5). This study identified similar conclusions to the present study regarding participants' experiences of PCI and identified the life-changing effect in participants after undergoing PCI. The authors recommended a time frame between 1 month to 6 months maximum in reviewing PCI patients and to measure the effects of the procedure on their HRQOL. Although the present study did not review the HRQOL, it did investigate psychological distress and the effects of the nurse-led clinic on CSE and trait anxiety as the primary aim. Furthermore, as participant follow-up over 12 months in the

present study was not feasible due to the time constraints of a PhD, patients were therefore reviewed over 3 months, with the primary endpoint at 1 month post-discharge from hospital.

In the present study, as identified earlier, reductions in trait anxiety were moderate in intervention group participants as evidenced in effect size calculations. Preliminary evidence demonstrates reliable change, and positive therapeutic outcomes in intervention group participants compared with standard-care group participants over time for trait anxiety. Effect size calculations for CSE saw moderate reductions in intervention group participants, while standard-care group participants did not demonstrate any increases in CSE. Recovery and improvement in CSE in a small percentage of participants was also evidenced in RCI calculations, while a larger percentage worsened. When reviewed at an item level, some CSE items showed improvements in mean ratings in intervention group participants' SE, while overall CSE mean ratings saw improvements between Time 2 (day 5–7) and Time 3 (1 month) in standard-care group participants.

Mean CSE ratings were also reviewed, with overall reduction in CSE of 5.84 units from Time 2 (day 5–7) (pre-intervention) to Time 3 (1 month) (post-intervention) evidenced. Overall mean CSE ratings in standard-care group participants reduced by 1.89 units over time from their baseline measurements. Cardiac Self-Efficacy (CSE) questionnaire items, as identified, were reviewed to observe if there were any increases over time for SE in more specific areas rather than a global assessment across multiple behaviours/areas. Small enhancements were demonstrated in mean ratings concerning participants' confidence in their ability to change their diet, and lose weight. Furthermore, participants' confidence in knowing how much physical activity to undertake improved, while participants' confidence to

maintain usual activities at work and to control their breathlessness by taking their medications was enhanced. These results are interesting and are reflected in participants' qualitative feedback as detailed in the Phase Two interviews, whereby study participants reported making changes concerning diet, weight loss, physical activity, and their medication regime and adherence. While ES calculations demonstrated an overall reducing effect in intervention group participants, small increases in mean ratings for some CSE items were evidenced.

Katch and Mead (2010) reviewed strategies to encourage self-management in those with CVD. Katch and Mead (2010) identified that programs aiming to enhance SE to be most effective in encouraging disease and self-management. As per the present study, intervention group participants' CSE as evidenced in ES calculations was not affected after attending the nurse-led clinic; however, when reviewed at an item level, five main CSE areas demonstrated small increases in mean ratings. Weight loss was a topic frequently discussed by intervention group participants throughout follow-up and most reported how this was progressing well for them, with overall body weight being gradually reduced over time due to changes in dietary intake and physical activity. Thus, as increases in mean ratings in some areas of CSE were evidenced, intervention group participants reported greater confidence to continue and maintain these changes over time, as reinforced by participant interviews as part of Phase Two. In light of these preliminary findings, and after undertaking critical reflection and Phase Two evaluation, the PI recommends that a well-powered, Phase Three, multi-centre study be undertaken to determine actual effect of the nurse-led clinic on SE and psychological distress.

Small trends in mean ratings were also observed in CSE item confidence to control breathlessness by taking medications post-intervention (Time 3, 1 month)

whereas standard-care group participants saw a decline in CSE to control their breathlessness at Time 3 (1 month). Intervention group participants saw enhancements in mean ratings for medication adherence from Time 1 (baseline), while they were maintained at Time 3 (1 month). Medication adherence is reinforced in Phase Two of the study whereby intervention group participants reported greater adherence and care in taking and learning about their medications as a result of attending the nurse-led clinic. As identified earlier, CSE to change diet, knowing how much physical activity was appropriate, and confidence to maintain usual activities at work all increased after attending the nurse-led clinic as evidenced by mean ratings (Time 3, 1 month). Phase Two interviews demonstrated small enhancements in these areas with participants reporting greater focus on dietary intake and enhancing physical activity so that they could return to their work and activities.

As patients are discharged from hospital and given that there is generally a short length of stay following PCI, it is a highly anxious time; information absorption may be obstructed and, as there may be limited time for nurse teaching, patients often seek information and self-educate post-discharge (Francombe & Knott, 2013; Neubeck et al., 2011). Although in seeking education patients are being proactive, internet self-education may also present as a negative and cause the patient additional distress, create health misconceptions concerning the post-discharge period, their cardiovascular health, and return to activities (Francombe & Knott, 2013). Thus, undertaking the present pilot study was essential so that participants could receive correct post-discharge information (verbal, visual, and written), be able to ask questions, and raise post-discharge concerns regarding their recovery.

While trends evidenced were maintained over a short period, due to PhD time constraints, this nurse-led clinic concept for PCI and CAD patients may act as a potentially effective support between hospital discharge, CR and cardiology follow-up and warrants further investigation. Furthermore, it may assist in the adherence and compliance to a CR program if CBT is offered in a Phase Three study. Moreover, given that patients with high trait anxiety may be less susceptible to interventions further demonstrates the importance and necessity to trial a larger scale study over a longer period of time (Muris et al., 1998).

6.1.3 Depression

Although the study did not demonstrate effectiveness in achieving the secondary hypotheses, a small reducing effect was demonstrated on depression in both intervention and standard-care group participants. Additionally, a reliable change was evidenced in a small percentage of participants in both groups, along with improvement, recovery, and worsening of depression as highlighted in standardised recovery rates. Mean depression ratings for the Cardiac Depression Scale (CDS), as identified in the results chapter, were higher in intervention group participants at baseline and reduced at each follow-up. The strong association between depression and CHD is reinforced by Colquhoun et al. (2013) as well as by Bhattacharyya, Molloy, and Steptoe (2008), with diagnoses often missed during hospitalisation in patients due to a strong focus on the coronary event (AIHW, 2011; Davidson et al., 2008; Lane et al., 1999; Parissis et al., 2006; Turner et al., 2010). Routine screening for depression is recommended on hospital presentation, at follow-up and again 2–3 months post-coronary event, and routinely annually (Colquhoun et al., 2013). The present study screened participants at each follow-up visit and, as recommended by Colquhoun et al. (2013), any signs of depression were

to be referred for treatment if required. As mild depressive symptoms may resolve, depression in CHD patients is usually longstanding, and, therefore, warrants further investigation into the effectiveness of long-term nurse-led support and follow-up on long-term physical health and psychological distress (Colquhoun et al., 2013). As identified in Chapter 4, 9.1% ($n = 3$) of participants in the present study had been diagnosed in the past with clinical depression and were being treated (two intervention group and one standard-care group participant). As identified earlier, the PI highlighted longer participant follow-up to determine the effect of the nurse-led clinic on psychological distress.

Zuidersma et al. (2013) reviewed the effectiveness of self-report on depressive symptoms, and clinical depression in 2,704 patients post-MI. Patients were screened over 3 months post-MI, recommending longer follow-up post-discharge (as opposed to screening during hospitalisation). The study by Zuidersma et al. (2013) highlights the present study's follow-up and screening time up until 3 months post-discharge to detect actual clinical depression. Zuidersma et al. (2013) recommend screening to distinguish between life-changing depressive symptoms to the actual recognition of clinical depression post-coronary event (requiring five symptoms to be present for a minimum of 2 weeks, and affecting a patient's daily living). As various patient factors (i.e., physiological and psychosocial), outcome expectations and socio-structural factors and SE may affect an individual's ability to set goals and achieve behaviour change it was important to screen for depression at Time 4 (3 months). While the study's primary endpoint was at Time 3 (1 month), it was deemed essential to continue follow-up in light of the potential to detect psychological distress and ensure physical health maintenance (i.e., complications, medications, and lifestyle factors).

Rymaszewska, Kiejna, and Hadrys (2003) undertook a study measuring pre-surgical depression and state and trait anxiety in 53 CABG candidates over 3 months. Rymaszewska et al. (2003) identify how high levels of depression and state and trait anxiety measured pre-CABG surgery may predict post-procedural psychological outcomes and recommend pre-procedural screening to identify those at risk and arrange referral for appropriate treatment. The CABG surgery candidates had findings similar to the present study and demonstrate a reduction in depressive symptoms over time. Mean CDS scores for patients in the present study were <84 at all times post-discharge and were <66 at Time 3 (1 month). Hare et al. (2011) identify a score of >84 as with depression, and a CDS score >95 indicating major depression. It was interesting that on baseline measurement, 38.5% of intervention group participants in the present study had scored ≥84, while 61.5% of participants scored <84. Furthermore, on baseline measurement, 25.0% of participants scored >84, while 75.0% scored <84 on the CDS. Rymaszewska et al. (2003) demonstrated how 67.9% of patients did not have any depressive symptoms pre-operatively, while 28.4% presented with mild depressive symptoms, and 3.80% presented with moderate depression. At Time 2 (day 5–7) in the present study, there were no changes in the percentages of all participants with and without depressive symptoms. Similarly, at Time 3 (1 month), the percentage of standard-care group participants with depressive symptoms reduced to 10%, while intervention group participants with depressive symptoms reduced to 15.4% ($n = 2$). Post-operatively, Rymaszewska et al. (2003) reported 71.7% of patients were symptom free, while 18.9% had mild depression and 9.4% had moderate depressive symptoms. At 3-month follow-up, Rymaszewska et al. (2003) identified how 73.6% of patients presented without depressive symptoms, while 17% presented with mild symptoms, and 9.4% with

moderate depressive symptoms. Depression, as identified in the study's theoretical framework, coupled with socio-structural factors (i.e., anxiety, depression, poor social support), outcome expectations (i.e., weighing up the positives and negatives of performing a behaviour), and low SE or efficacy beliefs may be an impediment to achieving post-operative goals and behaviours (Bandura, 1977, 2004). Therefore, the reduction in depressive symptoms identified in participants in the present study is important in that it may have contributed to participants feeling confident to effectively manage their post-discharge health, as highlighted in Phase Two interviews. Although SE reductions as evidenced in CSE effect size and reliable change calculations in the present study do not reinforce the SE theory, the PI encourages the undertaking of a well-powered Phase Three study to determine the effectiveness of the nurse-led clinic on SE and depression.

The 'Identifying Depression as a Comorbid Condition (IDACC)' study recruited 669 cardiac patients between 2000 and 2002 (Wade et al., 2005). Participants had experienced either an MI, unstable angina, cardiac arrhythmias, heart failure, PCI or CABG surgery, and were followed over a 12-month period. Individuals were either screened and treated for depression, or randomised to a standard-care group without any treatment. This study saw large reductions in depressive symptoms in all treatment arms (GP, case conference, and telephone), with the psychiatrist telephone follow-up arm achieving significant reductions in depressive symptoms in those with moderate to severe depression over a 12-month period post-hospitalisation. The IDACC trial not only reinforces the importance of screening all cardiac patients for psychological distress; however, it also highlights the need for post-discharge follow-up, screening, and referral for treatment (if required). As the prevalence of depression in this group of patients is high, the need

for the present pilot and future Phase Three is warranted, with preliminary findings demonstrating small reductions in depressive symptoms over time and reliable change. It was notable that standard-care group participant 013 experienced a significant reliable change; however, the significance may have been attributed to a changed dose of anti-depressive medication. The participant reported medication levels had been sub-therapeutic, and after adjustment of the dose, the participant reported they had begun to feel the therapeutic effects. Participant 013 was elated, in that they had not felt this good in a long time. Lastly, as interdisciplinary team communication can be problematic (as encountered in the IDACC trial), nurse focus and referral of this group of patients for psychological treatment until the time of CR commencement or over 12-months post-discharge is warranted (Wade et al., 2005). Overall, although the study did not achieve primary and secondary objectives, the present study's findings demonstrated a small reduction in mean ratings for depression in intervention group participants over time. Standard-care group participants also experienced a small effect and reliable change.

As identified, mean ratings for depression also reduced over time for both groups of participants in the present study, with intervention group participants displaying higher baseline mean scores after closer inspection. It is important that a Phase Three study be undertaken to further explore the potential and effect of the nurse-led, educational intervention on the reduction of psychological distress, enhancement of SE, and encouragement of effective self-management, behaviour change and maintenance. As SE, psychological state, social support, and other factors influencing SE may affect patient goal-setting and achieving outcomes, although only held once the nurse-led clinic and its preliminary findings demonstrate efficacy to undertake a future Phase Three study. As detailed in Chapter 5, the Phase

Three study aims to examine the effect of a nurse-led clinic on psychological

distress, efficacy beliefs, and self-management. Furthermore, it was proposed in

Chapter 5 that all RAs involved in undertaking the nurse-led clinic be trained in CBT

so that study participants' negative thoughts and behaviours may be challenged. The

beliefs surrounding CBT include how cognition affects a person's emotions and

behaviours and, conversely, how emotions and behaviours both affect cognition

(Lewin, Furze, & Donnison, 2008). As the Phase Three study aims to enhance SE,

reduce psychological distress, and encourage effective self-management and

behaviour change, it is essential that CBT techniques be used to assist in the change

of behaviour through change in thought process (Lewin et al., 2008).

Lewin et al. (2008) explain the effectiveness of CBT in chronic disease

management and how it focuses on three levels of cognition to achieve change.

These levels of cognition include:

- "core beliefs": unconditional beliefs held that may be positive or
  negative

- "assumptions or rules" conditional, more accessible cognition that
  guides a person's behaviour

- "automatic thoughts and images": most accessible and highly
  influential on a person's mood; they occur very often throughout the
  day.

In addition, a trusting relationship is also essential in achieving effective

therapy with the authors highlighting the counsellor needs to show authenticity and

be non-judgemental while communicating and feeling empathy (Lewin, 2008).

6.1.4 Self-Management

Research suggests that self-management programs may be equally as

beneficial as cognitive–behavioural interventions (Barlow et al., 2002). Barlow et al. (2002) highlight that patients with chronic illness who do not volunteer to participate should be flagged and further support offered as they may find the notion of self-management and transition somewhat difficult. It is recommended that self-management interventions follow participants over a longer period to measure psychosocial, disease, and cost-related outcomes (Barlow et al., 2002). Barlow et al. (2002) identify how self-management programs may be undertaken by various health professionals (including nurses) and "lay tutors". Self-management programs aim to enhance knowledge, encourage symptom management, engage in self-management behaviours learnt (in the program), enhance SE, and address health-related issues, such as psychological distress as did the present study (Barlow et al., 2002). Although secondary aims sought to encourage effective self-management in intervention group participants, it is important to address how effective self-management is not only affected by psychological factors, but also SE. Thus, as primary aims focused on enhancing SE and reducing anxiety, engaging in the nurse-led clinic, receiving education concerning post-discharge cares, health maintenance and goal-setting, may have led to small increases in CSE item mean ratings. Additionally, participating in the nurse-led clinic also acted to reduce depressive symptoms and, thus, encouraging effective self-management behaviours as evidenced in preliminary trends and in Phase Two self-report. However, as the study was undertaken as a pilot, with study objectives not achieved as expected, and as full formal analyses were not able to be undertaken, these results must be confirmed in a Phase Three study.

Barlow et al. (2002) highlight that although effective (as compared to receiving standard care), not all outcomes are achieved in self-management programs. Overall,

the present study demonstrated a moderately reducing effect on CSE and trait

anxiety in intervention group participants, while CSE in standard-care group

participants evidenced a small increasing effect and minor reductions in trait anxiety.

A small reducing effect was demonstrated on depressive symptoms in both groups.

Participants spoke frequently regarding their personal self-management, with

reference given often to chest pain and management, access sites, lifestyle and

dietary changes made (and subsequent weight loss), exercise, and medication

adherence.

6.1.5 Secondary Aims: Salivary Cortisol

Salivary cortisol assays

Overall, there were no significant expected reductions in salivary cortisol assay

results in the present study for intervention and standard-care groups. Standard-care

group participants' salivary cortisol assay results demonstrated a larger reduction in

mean cortisol level ratings than the intervention group over time. Hellhammer, Wūst,

and Kudielka (2009), and Hjortskov, Garde, Ørbæk, and Hansen (2004) identify how

salivary cortisol is widely used as a biomarker of psychological distress. As

identified in the Chapter 4, a reduction in mean cortisol and psychological distress

ratings was evidenced from baseline assessment and at Time 3 (1 month), although

all mean cortisol levels measured (including baseline measurements) fell within the

reference ranges for cortisol levels (Salimetrics®, 2010). It was interesting that while

mean anxiety and depression ratings observed were higher in intervention group

participants at baseline, mean salivary cortisol assay results presented highlighted

standard-care group participants as experiencing greater stress than intervention

group participants. Although results differed, as mean anxiety and depression ratings

reduced, so did salivary cortisol at Time 3 (1 month). Hellhammer et al. (2009)

identify a variety of factors affecting salivary cortisol that may include: gender, medications, environment, the presence of medical personnel; and the medical diagnosis. Moreover, Hellhammer et al. (2009, p. 164) highlight a poor association between salivary cortisol and stress measured in self-report "stress questionnaires". The authors identify how self-reported stress differs as it measures "theoretical stress concepts and foci" and may be affected by gender and personality. The differences between self-report tools and salivary cortisol assay readings as identified by Hellhammer et al. (2009) may account for the differences seen in anxiety and depression tools used in the present study.

Hjortskov et al. (2004) undertook a systematic review of the literature to investigate the association between self-reported stress and self-report measures in workplace stress. Results of the review revealed no association between salivary cortisol measured versus self-reported stress in study participants. The authors offer several explanations for this finding, suggesting inconsistencies in: (a) cortisol sampling techniques and times, (b) effects of chronic stress, (c) difference in cortisol during work versus off days, (d) stressors (i.e., type), (e) self-report tools, and (f) study designs (Hjortskov et al., 2004). Although Hjortskov et al. (2004) reported no association between salivary cortisol and self-reported stress, the authors do identify the possibility of a correlation between cortisol and more specific stress measurement tools, with anxiety highlighted. The present study used a more specific measurement tool for anxiety as recommended by Hjortskov et al. (2004). As mean ratings for trait anxiety reduced, so did salivary cortisol levels. Thus, while overall reductions in mean ratings for salivary cortisol levels were identified and are comparable with mean reductions in trait anxiety ratings, mean cortisol level ratings appeared to be slightly higher in standard-care group participants. As per Hjortskov

et al. (2004), reductions in mean ratings in both cortisol and anxiety demonstrate preliminary evidence that differences between objective and self-report measures may exist. A larger, well-powered study must be undertaken with formal testing to comment on study effect and significance.

6.1.6 Medication Adherence

Overall, medication adherence in the present study was not consistent with the study's hypothesis and did therefore not increase in intervention group participants after attending the nurse-led clinic. In standard-care group participants, however, small enhancements in medication adherence were noted. Medication adherence is a significant issue in patients with CVD, with approximately 50% of patients following with their prescribed medication regime (Coleman, 2012; Haynes et al., 2008). Admission for PCI (i.e., both primary and elective) can be overwhelming, with a short length of stay, and a multitude of new medications prescribed, patients may feel overcome with emotions, which may affect medication adherence (Young & Murray, 2011). Young and Murray (2011) highlight the importance of measuring medication adherence while also continuing in-patient education (for post-discharge management) given the short length of stay (Young & Murray, 2011). Jackevicius, Li, and Tu (2008) identify how medication non-adherence can occur at a primary and secondary level, with most patients secondary non-adherers. Primary non-adherence has been reported in approximately 1–21% of patients and requires further investigation on outcomes, while secondary non-adherence is widely reported on, particularly in the management of dyslipidaemia and hypertension (Jackevicius et al., 2008).

Effect size calculations demonstrated nil effect on medication adherence in intervention group participants, while in standard-care group participants, a small

increasing effect was evidenced. Standardised recovery rates displayed in Chapter 4 clearly illustrated a large percentage of intervention group participants maintaining medication adherence behaviours, with small percentages of participants worsening and improving. Reliable change calculations demonstrated maintenance of adherence to their current medication regime, while a small percentage of participants in both groups of participants improved. Increases in mean medication adherence ratings were seen in intervention group participants from baseline to Time 1 (baseline), and were maintained from Time 2 (5–7 days) to Time 3 (1 month), then enhanced from Time 3 to 4, although mean ratings for both groups were at a medium adherence level from baseline to time 4 (upper end of high medium adherence). The greater increase in medication adherence in standard-care group participants over time may have been attributed to CR attendance (6 attended, while 1 discontinued), and/or cardiology review. It is noted, however, that 23 participants in total declined CR attendance as they had either attended in the past and reported that they could recall information received, had exercise knowledge, and/or a medical background. Of note, the longest time that a participant had not attended a CR program was 10 years. Cardiac rehabilitation attendance will be discussed later in this chapter. Standard-care group participants may have actively sought post-discharge education or alternately, the education that they were provided with may have assisted in their recovery and thus, had an effect on medication adherence. Participation in a study alone can lead to changes in behaviour and is known as the Hawthorne effect, which may have also contributed to the improvements in measured variables over time (Polit & Beck, 2010).

When asking participants if they knew what medications they were consuming, as identified in Chapter 4, most reported they could do so; however, when

medication knowledge and recall was assessed (i.e., medication name, action, dose, and frequency), most participants could not recall all details, and required prompting, and/or requested to view a list. Importantly, intervention group participants' ability to recall the aforementioned medication details was enhanced over time with 23.1% recalling information at baseline measurement, to 38.5% recalling post-intervention, and 53.8% recalling their medication details at final follow-up post-discharge compared with 30%, 25%, and 35% in standard-care group participants recalling medication details throughout the course of follow-up. Although standard-care group participants reported greater adherence in taking their medications throughout the course of follow-up (as measured by the MMAS-8), intervention group participants, while also slightly improving in adherence as evidenced on inspection of mean ratings, after attending the nurse-led clinic, had better medication knowledge and recall.

As identified in the literature, medication adherence, particularly in chronic disease is poor (Fernandez et al., 2007; Haynes et al., 2008). Medication adherence in all participants in the present study remained stable in a majority of participants over time and enhanced in a small percentage in both groups of participants; medication recall and knowledge was only enhanced in the intervention group participants. Similar results are reinforced in a study of 270 PCI patients by Fernandez and colleagues (2007). High medication adherence was reported by participants; however, medication knowledge gaps were identified (i.e., poor storage knowledge) and medications were reported as discontinued, skipped, or missed. Medication knowledge has been identified as a reason behind poorer adherence with several factors affecting medication adherence and compliance such as: (a) poor knowledge, (b) medication and medicine beliefs, (c) personal experience and beliefs,

and (d) family and friends' experiences (Vermeire, Hearnshaw, Van Royen, & Denekens, 2001). The authors also highlight that a major determinant of compliance is knowledge and patient attitude (Vermeire et al., 2001). These findings are reflected in the present study where intervention group participants' medication knowledge and adherence at baseline measurement was at the lower end of medium for adherence. As time passed, medication knowledge enhanced, while adherence to their medication regime was maintained for a large percentage of participants.

Vermeire et al. (2001, p. 337) advise that "adherence-aiding" approaches to medication compliance and adherence are more effective when merged and recommend strategies to include knowledge enhancement, information recall, and enhancing motivation. Vermeire et al. (2001) also highlight the benefits of one-on-one education and counselling, and highlight how written material combined with verbal education encourages medication compliance as opposed to literature only. They also recommend interventions that combine education and behavioural strategies to enhance compliance, and adherence issues. The present study delivered verbal education to complement written pharmacological information delivered in hospital, while presenting visual information via a PowerPoint presentation. As reinforced above, poor medication adherence is common and determined by a range of factors. As medication knowledge appeared to be enhanced in the present study, it may have been attributed to the delivery mode, and methods used in the nurse-led clinic. Although standard-care group enhancements were also seen, this group were less anxious, and may have simultaneously sought education post-PCI outside of the hospital setting (i.e., internet or the literature). Importantly, as identified earlier, although most participants had previously participated in CR, medication adherence scores remained at the upper end of medium for the MMAS-8 after attending the

nurse-led clinic. Additional factors affecting medication adherence may include depression, socioeconomics, and lifestyle (Colquhoun et al., 2013; Katch & Mead, 2010; Zuidersma et al., 2013).

Haynes et al. (2008) undertook a comprehensive review of 93 RCTs in the literature to determine the effects of long and short interventions on medication adherence and the effects of treatment. The authors identify the effectiveness of some short interventions on medication adherence; however, highlight that complex long-term intervention studies may be more effective in achieving outcomes (Haynes et al., 2008). Haynes et al. (2008) report that while significance in some outcomes and adherence were achieved, they were not large effects. Overall, intervention group participants did not demonstrate increased medication adherence after participation in the intervention. What was demonstrated was maintenance in adherence to medication regimes, and enhancements in medication knowledge. Notably, mean ratings for medication adherence were increased in standard-care group participants only, while overall medication knowledge reduced. Potentially, effective medication self-management in intervention group participants may have encouraged sustained adherence, which may explain maintenance of regimes. Further investigation of the effects the nurse-led clinic on medication knowledge is recommended. Furthermore, a Phase Three study may assist in determining if increases in mean ratings in CSE items contribute to effective medication adherence, knowledge and effective self-management.

6.1.7 Cardiac Rehabilitation (CR): Referral, Attendance, and Adherence

As identified, 74% (23) of participants in the study declined CR as they had either attended a CR program in the past or believed they had the knowledge to commence their own rehabilitation at home. The reasons that participants declined

CR enrolment were due to exercise instruction qualifications, or medical knowledge (i.e., bachelor's degree level health knowledge). Among the intervention group participants, two accepted referral (onw had attended CR in the past), while six standard-care group participants agreed to referral to a CR program. Reasons for non-attendance were that participants were either too busy, had been in the past and could self-rehabilitate, had adequate knowledge (i.e., qualified exercise instructor, health degree) or due to illness or surgery (i.e., severe rheumatoid arthritis or underwent a total knee replacement). Convincing participants to re-attend proved to be problematic in this study. Notably, one intervention group participant who had attended CR in the past and had accepted CR enrolment cancelled from the course and undertook and adhered to a private health-fund driven, telephone follow-up CR program. Reasons given were that it was convenient as they could rehabilitate from home and would not have to travel to attend the program. Thus, a more flexible approach to CR course mode attendance for future programs is recommended in view of the results of the present study.

The demand for home-based and/or alternate delivery mode for CR is a trend noted and evident in the literature, with current research suggesting similar health outcomes to that of a clinic-based CR program (Clark et al., 2013; Cupples et al., 2010; Hall & Lorenc, 2010; Varnfield et al., 2011). Although participants had attended a CR program in the past, most believed they had the knowledge to continue rehabilitation from home (it had been 10 years since attending CR for one participant). These results are reinforced by the literature where referral, attendance, and adherence to a CR program is identified as poor (Dafoe et al., 2006; Pack et al., 2013; Varnfield et al., 2011; Zuidersma et al., 2013). As identified in Chapter 2, the issues affecting the uptake of CR and self-management may include geography,

psychological distress, social support, community issues, funding, and organisational issues (Cupples et al., 2010; Dafoe et al., 2006; Katch & Mead, 2010; Lichtman et al., 2008; Varnfield et al., 2011; Zuidersma et al., 2013). Geography, time constraints, and reliance on family for transportation were identified as deterrents among patients attending a program in the present study.

Effective self-management and, thus, attending or re-attending CR, may have been affected not only by patient factors such as physiological and psychological states, but also by their beliefs and SE level at the time (Bandura, 1977, 2004). Although most first-time PCI patients attended CR, there is the issue of repeat PCIs' non-attendance (especially those who have not been in several years). Further studies may be required to investigate CR needs and delivery mode for repeat PCIs; in particular, the effectiveness of a CR short course, timing, and frequency. Research questions could be posed about course length, content, flexibility, and frequency of repeat attendance (e.g., bi-annually after first course attendance), as well as the efficacy of repeating CR clinics on SE, psychological distress, and effective self-management. Yu et al. (2004) highlight the effectiveness of CR in enhancing a patient's quality of life (QOL) post-AMI and elective PCI. The authors identify the lasting effects of CR on QOL at 2 years post-CR (Yu et al., 2004). Given the benefits of CR on QOL and maintenance, it would be advantageous to trial a biannual CR short course and measuring the effects on QOL, SE, psychological distress, self-management, behaviour change.

Potential participants gave similar reasons for declining participation in the present study on recruitment and concerning CR attendance as is highlighted in the literature. The PI, as identified, approached 91 participants, with 64 declining due to geographical limitations, time constraints, or reliance on others for transportation to

the nurse-led clinic. As CR and post-discharge nurse-led follow-up and support are important to recovery and the adoption of positive health behaviours, alternate options for attendance (i.e., electronic delivery and nurse-led clinics) are warranted. Recruitment issues, predominantly geographical isolation in the present study, assisted in informing the Phase Three study. As identified in Chapter 5, rather than a face-to-face intervention, the Phase Three study will be undertaken using an electronic visual medium so that a broad range of patients may partake in the nurse-led clinic. In the literature, an intervention study on diabetes and lifestyle management (i.e., diet, weight, exercise) had to abandon recruitment after five months (Jelinek et al., 2012). The authors highlight various reasons for poor recruitment that include complacency, distress, study design, and lack of clinician support (Jelinek et al., 2012). After reflecting on the study by Jelinek et al. (2012) coupled with Phase Two interviews, the PI was able to redesign the study. In doing so, future participation in the Phase Three study will be less time-consuming, require no travel arrangements, and facilitate ease of recruitment in that participants may undertake the intervention from home.

6.1.8 Complication Identification and Management

Described below are the complications experienced by participants throughout the course of the study. Complications experienced were minimal; however, they included small haematomas, bruising, and angina.

Haematoma and bruising

Participants reported confidence in self-management of post-discharge haematomas at each follow-up. Participants remained aware of their access- site wound and felt especially confident in effectively managing any potential complication. At the nurse-led clinic, and on discharge from hospital, participants

were educated on normal, expected post-discharge haematoma size, while also being informed on when and how to take action. Notably, participants recalled the amount of digital pressure required should their haematoma increase beyond the sizes that were normal, and all recalled to lie flat and call for an ambulance if required. Recall of actions (i.e., pressure required) for haematoma management may be attributed to both the hospital experience and the nurse-led clinic. Patients recalled the removal of femoral arterial sheaths by nursing staff, in particular, the pressure and length of time required at the site to achieve haemostasis. Thus, femoral arterial sheath removal coupled with the repetition offered at the nurse-led clinic may have assisted in encouraging confidence to effectively self-manage access sites and potential complications. The nurse-led clinic reinforced access site education and specific information concerning site pressure, position, length of time for pressure, and calling for an ambulance. No actions were required from a nursing perspective as small haematomas post-PCI are common (Wong et al., 2006).

Mild and major bruising was identified in the present study, and is a common post-PCI complication (Cosman et al., 2011; Wong et al., 2006). Cosman et al. (2011) highlight how early post-discharge bruising after cardiac catheterisation and/or PCI is not well documented and undertook a study investigating access site complications via telephone at 5–7 days post-discharge. As identified, participants were observant and noted any access-site changes (i.e., bruising, haematoma). Cosman et al. (2011) identified that a majority of patients experience significant bruising post-discharge and the importance of nurse education and preparation for discharge. The authors identified (via self-report data) reports bruising in approximately 68.6% of access sites after undergoing cardiac catheterisation and/or PCI in their study, with major bruising identified in 47% of participants (i.e., > 7.5

cm) (Cosman et al., 2011, p. 1349). In the present study half of the participants developed bruising at Time 1 (baseline), with the mean bruising size 7.78–9.57 cm. The extent of bruising increased from normal bruising to major bruising between Time 1 (baseline) and Time 2 (day 5–7) in the present study. By Times 3 (1 month) and 4 (3 months), bruising was minimal and disappearing.

Overall, no haematomas were experienced by participants. Currently, access site education appears to be well attended to in hospital, with participants recalling wound site complication management and, in particular, the pressure required to effectively manage a haematoma. While position and length of time were reinforced at the nurse-led clinic, participants reported confidence to effectively self-manage a post-discharge haematoma. Almost half of participants experienced major bruising that became evident at Time 2 (day 5–7). Participants were not concerned but expressed astonishment at the extent of their bruising and were offered education and reassurance from the PI at the nurse-led clinic. Bruising began to disappear between Time 2 (day 5–7) and Time 3 (1 month). Participants reported feeling confident that they could effectively self-manage and action any access site complication.

Angina

Post-PCI angina experienced by participants in the present study is supported by the literature, with approximately 20–30% of patients in The 'REALITY CHEC' Project reporting post-discharge angina at their first clinical review, and up to 40% at 3 months post-procedurally (Marzilli, Huqi, & Morrone, 2010). The literature highlights that up to 50% of patients in the post-PCI population will experience angina post-procedurally with symptoms ultimately increasing (Marzilli et al., 2010, p. 27; Wong et al., 2006, p. 583). Actions taken by participants varied from rest and anginine administration, to rest without anginine. Some participants reported they

did not have anginine with them at the time they experienced their chest discomfort, while others carried it on them at all times. One participant presented at a hospital emergency department and was released later that afternoon, while others contacted their GP or cardiologist to arrange for follow-up.

Management of angina varies among patients, with the literature highlighting delayed action and management as found in some participants in the present study (Farooq, Quereshi, & Squire, 2007; Gallagher et al., 2012). Gallagher et al. (2012) also highlight that, although patients can be educated regarding angina self-management, the knowledge gap needs to be investigated and the potential to correct the knowledge misconceptions must be gauged. Furthermore, even with CR programs in place, correcting misconceptions may still not be possible and requires further investigation (Gallagher et al., 2012). Thus, intervention group participants in this study may have delayed actions and angina self-management even though management strategies were provided using the NHFA's "Chest Pain Action Plan" and hypothetical scenarios. At Time 3 (1 month), six of the participants experiencing angina were intervention group participants. All reported resting, while three reported taking anginine in addition to resting, while two participants made immediate contact with their GP and cardiologist. Symptoms disappeared within a few seconds to 10 minutes and included twinges, niggles, heaviness, and shortness of breath. One participant reported tolerating symptoms for up to 3 hours while pain was experienced at a level of 2–3 out of 10. Another participant self-administered a bottle of anginine over a period of 1 week and still did not access medical treatment. Delays in calling an ambulance or accessing medical assistance are very common with patients tolerating CP for up to 3 hours in developed countries (Gallagher et al., 2012).

Farooq et al. (2007) highlight how most participants tolerate angina and withstand their symptoms, often delaying hospital admission, or GP consultation. Rasmussen, Munck, Kragstrup, and Haghfelt (2003) undertook a study investigating the time it took from the onset of angina until participants accessed medical treatment, with the aim to determine reasons for delayed access (Rasmussen et al., 2003). Of the 377 participants, the mean time to access medical treatment was 2.85 hours (Rasmussen et al., 2003). Patients self-medicated and waited for symptoms to abate, while also identifying that they did not want to be a burden on the healthcare system as reasons for delaying access to medical assistance (Rasmussen et al., 2003). Delaying time to hospitalisation is reinforced in the present study where some participants attempted to tolerate their symptoms. Self-management of angina and symptoms in most patients was reported effective as identified by a majority of participants in both groups. Most intervention group participants commented on further clarity offered in reviewing the "Chest Pain Action Plan" followed by a clinical scenario. Participants voiced that the education received, coupled with the "Chest Pain Action Plan", was clear, concise, and could be followed in the event of angina. Particular attention was directed at the phone number ("112") to dial if calling from a mobile phone. Most intervention group participants reported they were not aware that a different telephone number was to be dialled if "000" was not effective from their mobile phone. Participants' confidence to effectively self-manage angina post-intervention may have been enhanced as a result of chest pain education as reported by participants. As most patients had PCIs in the past, most were able to identify their CP symptoms immediately, and were effective in their self-management. Those who significantly delayed treatment or who consumed anginine in excess were referred to their cardiologist or GP for follow-up.

Potentially, participants who were not successful in their self-management may have been suffering greater psychological distress and/or a lower SE at the time of their angina, therefore feeling less confident to self-manage their discomfort and delaying access to medical treatment. While most participants had good social support networks, poor social support may also reduce SE and lead to poorer confidence to set and achieve goals and, thus, make positive health behavioural changes.

The following discussion of Phase Two results identifies the analytical findings from the nurse-led clinic program evaluation. Analytical findings include (a) support enhances recovery, (b) coming to understand the situation, (c) self-awareness enhances self-management, and (d) pressure on the patient—attending cardiac rehabilitation (CR). Analytical findings offer rich data from participants' own experiences of undertaking the nurse-led clinic. Findings are presented with respect to the literature and Phase One findings.

6.2 Phase Two: Discussion

6.2.1 Analytical Findings: Support Enhances Recovery

This finding, as identified in Chapter 4, emerged in response to the support offered by the PI who undertook all nurse-led consultations. The importance of follow-up with a healthcare professional was highlighted by participants as beneficial to recovery, and during the post-discharge period. The degree of reassurance felt was reflected in participants' comments. Participants' voiced that the sense of reassurance surrounded knowing that any post-discharge questions could be asked, and that they would not have to inconvenience their specialist or GP for advice. Schadwaldt and Schultz (2011) and The JBI (2010) identify the effectiveness of cardiology nurse-led clinics. Schadewaldt and Schultz (2011) highlight that the level of support provided by the nurse determines success in achieving patient goals

and behaviour change. The authors highlight the significance of nurse-led clinics (as opposed to clinics run by non-nurses) on behaviour, risk factor modification, and treatment for CHD (JBI, 2010; Schadewaldt & Schultz, 2011).

Nurse–patient relationships and communication plays an important part in-patient support, motivation to change behaviours, and recovery, particularly in vulnerable situations such as being hospitalised (Liljeroos, Snellman, & Ekstedt, 2011). Liljeroos et al. (2011) explored the nurse–patient relationship and communication in 10 MI patients with a trusting and positive relationship reported, as well as a sense of feeling valued. The study by Liljeroos et al. (2011) reinforces Phase Two findings where participants felt comfort in the presence of their nurse to share their views on making lifestyle adjustments, which may have enhanced participants' motivation to make modifications. This finding is important as participants reported nurse support as strengthening their motivation to change and adopt healthy behaviours. The discussion and responses of the nurses in identifying the benefits of adopting healthy behaviours may have also acted to enhance motivation to change (Liljeroos et al., 2011). Participants in the present study identified the PI's support as essential in that it was reassuring during the early post-discharge period, where they felt it was a period of unknown. Offering patient support as the healthcare professional may have benefited the patients in many ways, including allaying any anxieties. While a small reducing effect was evidenced on CSE, anxiety was moderately reduced along with a small effect on depression scores. Although, overall CSE was not enhanced, small reductions in some mean CSE items were identified. Potentially, the reduction on anxiety and depression may have offered participants the clarity to set and reach health goals, and more effectively manage their post-discharge health.

Moore et al. (2002) report the success of nurse-led care in a RCT of 203 lung cancer patients and demonstrated very high satisfaction with nurse-led follow-up (as measured by a satisfaction scale). Participants were so satisfied that they declined post-study GP follow-up, wanting to continue with the nurse-led clinic (Moore et al., 2002). Success was achieved in the areas of physical symptom management and emotional status, with the participants reporting no reduction in quality of life (Moore et al., 2002). Furthermore, this proved to be safe and cost-effective, while reducing the burden on outpatient departments, GPs, and specialists (Moore et al., 2002). It is interesting that the Queensland (QLD) Government together with the Department of Health have developed a 'Strategic Plan' that aims to both enhance the health of all Queenslanders, while reducing the burden on the current healthcare system (QLD Government, 2013). As part of the plan it is anticipated that more nurse-led clinics will be initiated to facilitate access to specialists and diagnostic areas, reduce hospital admission, provide access to rural, remote and indigenous communities, and to set in place a new model of care and delivery for nursing (QLD Government, 2013). As reinforced by Moore et al. (2002) nurse-led clinics are effective in achieving various goals, including patient health and wellbeing (QLD Government, 2013). The study by Moore et al. (2002) coupled with the evidence reported by the QLD Government (2013) reinforces the importance of the present study, where nurse-led clinics and follow-up may achieve positive outcomes and patient satisfaction. Furthermore, in achieving patient satisfaction, symptom and emotional relief, a more trustful relationship may develop. Patient satisfaction and a trustful relationship may have been demonstrated in the present study. The evidence of a trustful relationship may be reflected in Phase One and Two findings, where effect size, RCI calculations and anxiety and depression mean ratings reduced over

time. Moreover, participants also reported satisfaction, support, and confidence in the PI while simultaneously reporting greater confidence to undertake post-discharge cares and to self-manage. While overall CSE was not enhanced, small enhancements in trends of some CSE items were observed. Furthermore, a moderate reduction in trait anxiety and small reduction in depression as evidenced in ES calculations may have been attributed to the support offered by the PI as verbalised in Phase Two interviews. A well-powered Phase Three study, however, may offer far more conclusive evidence to support the link between supportive relationships in enhancing SE, reductions in psychological distress and effective self-management.

Importantly, in situations of vulnerability, establishing a trustful relationship can be difficult (Liljeroos et al., 2011). Negative relationships are common in nurse–patient relationships where power imbalances may develop, and the need to encourage patient-centred communication is paramount. Patient-centred communication was used in the present study to enhance and develop a positive nurse–patient relationship (McCabe, 2004). The PI used effective communication techniques in the delivery of education, not only to facilitate the comprehension and application of information delivered but to also develop client rapport and, thus, a positive nurse–patient relationship (Falvo, 2004). Falvo (2004) argues that achieving a good rapport with patients is an essential part of the healthcare professional–patient relationship, highlighting that it creates respect, shows care, and creates trust. Effective participant education and a good nurse–patient relationship in the present study could not have been achieved if the PI did not use the following patient education components: (a) recognition of verbal and non-verbal cues, (b) accuracy and appropriateness in response to participant signs, and (c) offering feedback and support (Falvo, 2004). The successful use of the aforementioned skills is essential in

attaining correct information, encourages patient expression, and assists in the recognition of patients' misperceptions (Falvo, 2004). Thus, overall, in applying effective communication strategies to the present study, a good rapport and trust was developed with the PI, therefore achieving a positive nurse–patient relationship and patient satisfaction.

The finding that support enhances recovery in the present study after attending the nurse-led clinic, was an important finding. Through the analysis of trends in Phase One and analytical findings from Phase Two data, it was noted that when patients reported support and satisfaction with the nurse-led clinic, it appeared to coincide with an increase in knowledge, greater compliance, and adherence with self-care. Hill (1997) identifies the importance of patient satisfaction, particularly in chronic disease. Hill (1997, p. 347) highlights how patient satisfaction is measurable and determines successful healthcare professional–patient relationships, compliance, and whether or not medical opinion is sought. It has been argued that the level of satisfaction in care received is similar to QOL in those suffering chronic disease and, if satisfaction is felt in the healthcare professional–patient relationship, it is almost equal to reporting good QOL (Hill, 1997). Overall, the support provided by the PI at the nurse-led clinic was reported as effective by participants, offering reassurance in education and physical assessment and, thus, the confidence to manage in the early post-discharge period.

With a short hospitalisation following PCI and limited nurse teaching time, participants raised the issue of an emotionally filled post-discharge period. The importance of repetition and timing for delivery of the educational intervention at day 5–7 post-discharge was advocated by both participants and healthcare professionals. Furthermore, healthcare professional education and follow-up was

commented on, suggesting that patients should find this reassuring, thus facilitating learning, and allaying potential post-discharge anxieties. As highlighted in Chapter 4, both participants and healthcare professionals identified the potential to offer education earlier given the short length of stay, emotionality surrounding the post-discharge period, potential for post-discharge complications and to provide early post-discharge education and support to those geographically isolated and due to return home (BHF, 2011; Chow et al., 2010; Cupples et al., 2010; Dafoe et al., 2006; Demiris et al., 2005; Harrison & Wardle, 2005; Grace et al., 2012; Heart Foundation, Western Australia, 2012; Lacey et al., 2010; Pack et al., 2013; Rassaf et al., 2013, Wong et al., 2006). Thus, as recommended by both intervention group participants, healthcare professionals, and as reinforced by the literature, follow-up for a Phase Three study, will occur at 3 to 5 days post-discharge.

Coming to understand the situation

Participants reported becoming more aware of their health and self after attending the nurse-led clinic, while also identifying and communicating the gravity of their procedure and the need to make lifestyle adjustments, such as making dietary changes, engaging in exercise, and losing weight. Dullaghan et al. (2013) undertook semistructured interviews with 15 participants who were treated for an AMI and explored whether treatment urgency influenced behaviour change and illness perceptions. They found that participants who experienced a primary PCI (PPCI) and STEMI (with thrombolysis) viewed the procedure as "life-threatening", knew they faced a serious situation and treatment was rapidly required (Dullaghan et al., 2013, p. 4). Conversely, participants who experienced a NSTEMI (not as fast as PPCI and STEMI treatment) did not report their experience as traumatic and, therefore, believed their diagnosis and medical condition was insignificant (Dullaghan et al.,

2013). Most participants in Dullaghan et al.'s study reported the significance of the event, while also reporting the speed of the procedure and recovery time. Participants in the present study underwent elective and primary PCIs, but they still viewed and reported their diagnosis as serious. Dullaghan et al. (2013) highlight that their group of PPCIs and STEMIs were more motivated to modify current lifestyle choices for positive behaviours with the view of long-term maintenance. It was interesting that all of these patients had full intentions of attending a CR program, as opposed to participants in the present study (although it is not known whether these patients were first-time PCIs as compared to participants in The 'REALITY CHEC' Project). The NSTEMI group identified that changes needed to be made post-event but did not report confidence in achieving them. Although participants in the present study realised the significance of their procedure and seriousness of their diagnosis, this was not the case for all PCI patients. It must, therefore, be highlighted that timing (for treatment), type of treatment, and diagnosis may greatly affect patients' perceptions post-cardiac event (Dullaghan et al., 2013).

As participants in the present study reported making lifestyle changes, the importance of lifestyle modification and effects on CVD is strongly supported in the literature (AIHW, 2012; BHF, 2012; Katch & Mead, 2010; NVDPA, 2012). Specialists often recommend modification of risk factors and lifestyle change post-PCI—such as weight loss, exercise and dietary changes, along with smoking cessation. Katch and Mead (2010) identify how making these changes, coupled with symptom management (i.e., physical, psychological) can be difficult for patients and recommend enhancing SE in order to encourage these changes. Although SE, as evidenced in ES calculations reduced, trends identified in some CSE items, and in self-report appeared to be enhanced in the present pilot study. Undertaking a Phase

Three study may assist in the measurement of the relationship between SE and self-management. As inspection of mean ratings demonstrated enhancements in some CSE items in Phase One and, coupled with the Phase Two findings, may suggest that the realisation of their procedure and cardiac event, combined with attending the clinic may have enhanced participants' motivation to modify their lifestyle behaviours post-discharge. Overall, after undergoing the procedure, receiving both verbal and written education (i.e., during hospitalisation and post), as well as the support and education provided at the nurse-led clinic, CSE trends concerning weight reduction, dietary intake, exercise, stress management evidenced in preliminary findings in Phase One and in self-report data attained in Phase Two appeared to be enhanced in some participants. Again, a Phase Three study will provide a more rigorous test of the relationship.

Self-awareness enhances self-management

Participants in the present study identified that after attending the nurse-led clinic, greater awareness surrounding symptoms, potential complications and management was realised. Angina and haematoma identification and management was raised frequently by participants. Furthermore, greater adherence and compliance with medications was also reported by intervention group participants during participant interviews. Barlow et al. (2002) highlight the effectiveness of self-management interventions with short follow-up; however, the authors suggest follow-up should occur over a longer period of time (i.e., years specified). Barlow et al. (2002) highlight how most self-management programs, such as the present study, are aimed at chronic disease management, enhancing SE, and patient knowledge, while encouraging positive behaviours. Katch and Mead (2010, p. 34) identify that self-management in the area of medication adherence needs to be of a "high level" to

abide by strict regimes. Factors affecting medication self-management include socioeconomics, cognition, lifestyle factors, and personal choice that is based on previous experience and individual beliefs (Katch & Mead, 2010). Katch and Mead highlight that, in order to achieve overall effective self-management and medication self-management, SE needs to be enhanced. Although not consistent with Phase One findings, participants did verbalise in Phase Two feeling more confident to self-manage with respect to their post-procedural health and wellbeing. Some CSE items, as identified earlier, showed promising trends in certain areas of SE. Additionally, participants reported an increase in self-management capabilities, predominantly medication adherence, knowledge, symptom, and complication management.

Importantly, there are barriers to achieving effective self-management, particularly in patients with CVD (Katch & Mead, 2010). Katch and Mead (2010) highlight expense, time (for treatment and recovery), rehabilitation, and medication management as significant patient barriers, particularly in those with multiple co-morbidities. The authors identify how physical restrictions, coupled with poor coping and psychological distress act as barriers to effective self-management, while the absence or limitations of health insurance may also affect patient healthcare in lower socioeconomic groups. Thus, the authors recommend overcoming self-management barriers and identify enhancing SE as the tool to assist this process, while encouraging patients' engagement in their own care (Katch & Mead, 2010). The authors, as per the present study, identify the effects of psychological distress of CVD and highlight how this can not only affect morbidity and mortality, but health and illness beliefs, treatments, and behaviours (Katch & Mead, 2010). Katch and Mead (2010) recommend interventions to increase SE; these are essential in patients with CVD as they not only enhance patient outcomes, but also their QOL. The

present study aimed to enhance patients' SE so that psychological distress could be reduced, and secondly to encourage effective self-management. Although ES did not demonstrate enhancements in CSE, participants verbalised greater confidence to manage in Phase Two interviews, while some CSE items showed promise in mean ratings, as identified earlier.

As previously outlined, medication adherence and compliance among patients is an issue, with approximately 50% of patients not adhering or complying with their medication regime (Brown & Bussell, 2011). With a variety of factors influencing medication adherence—such as poor health literacy, limited involvement in health decision-making, polypharmacy, poor communication and information, being cared for by a group of doctors, healthcare access issues—it is certainly understandable, why medication non-adherence and compliance occurs (Brown & Bussell, 2011). Chapter 4 presented study results, with great value placed on the medication education component identified by healthcare professionals. Participants identified that the intervention was easily understandable, succinct, while three important messages regarding medications were delivered. Messages included: to maintain supply, not discontinuing medications in an abrupt manner, and continuing medications as prescribed. Additional suggestions were included to warn post-PCI patients regarding internet content and speaking with a doctor if considering medication cessation.

Chronic disease sufferers are more at risk of ignoring steps to change in that their motivation and intentions may be affected by their disease state and may often lead to healthcare professionals assuming an authoritative role, or conversely, assuming defeat (Patterson, 2001). Healthcare professionals have greater knowledge of health and patient behaviour, and may have greater effect on involving patients in

their health care, thus leading to greater adherence, and compliance (Patterson, 2001). Low adherence is most often due to a variety of factors, predominantly due to the lack of "behavioural skills", limited understanding, or possibly as they may be experiencing psychological distress (Patterson, 2001). Falvo (2004) advises how important it is for the patient to remain adherent and thus compliant with their health and how it not only benefits the patient, but healthcare as an organisation, and society. By modifying health behaviours and becoming adherent, patients may effectively prevent the onset of illness, associated complications, resultant disability, and mortality (Falvo, 2004). As identified in the literature, medication adherence and compliance is a significant problem, particularly in the cardiac population where statin and antihypertensive therapies are the most non-adhered to in this group of patients (Brown & Bussell, 2011; Falvo, 2004). Thus, it was important to encourage the message of adherence and compliance to participants in the present study, while offering a basic overview of medications. Nunes et al. (2009) highlight the importance of patient decision-making in their medication taking regimes, and while this may be the case, the onus is on the healthcare professional to ensure that patients' decisions are informed. The present study provided medication education information while encouraging questions and allaying medication misconceptions to facilitate current and future medication choices (Nunes et al., 2009).

The internet now plays a major role in health and medication education (Coleman, 2003). While this is a positive step toward health education, the varying quality of information provided is reportedly of great concern (Coleman, 2003). Healthcare professionals in the present study, as identified earlier, highlighted warning about internet medication education and recommended reinforcing the message to consult with a GP prior to making any decisions regarding cessation.

With no control of what information is posted, coupled with poor evidence base and sometimes erroneous information presented, misinterpretation is likely (Coleman, 2003). There is potential in using the internet to educate and accurately inform patients on their medication and encourage compliance; however, patients must be educated on where to find quality information (Coleman, 2003).

Thus, as messages of medication adherence and education were highlighted by healthcare professionals, intervention group participants' medication knowledge in Phase One increased, while adherence was maintained between Time 2 (Day 5–7) and Time 3 (1 month). Intervention group participants reported they were more adherent and compliant in their medication taking, while their knowledge and mean ratings for CSE reflected enhancements in taking medications to control breathlessness. Thus, as mean ratings for medication adherence measured by the MMAS-8 at Time 3 (1 month) remained stable, further studies are required to investigate long-term medication adherence and CSE to take medications in PCI patients after attending a nurse-led clinic.

Participants and healthcare professionals reported full confidence in the education provided and in the PI as nurse-educator, while healthcare professionals also reinforced the benefits of repetition and variation of information to support different learning styles. The principles of learning are relevant to the area of health education and patient teaching and were used in the development of the nurse-led clinic (Miller & Stoeckel, 2011). First, as identified by healthcare interviewees in the present study, clinic education accommodated different types of learners. Miller and Stoeckel (2011) highlight how each individual learns differently, identifying verbal and visual learners, while others may need to apply what is learnt in a practical setting. Thus, it was important to take learning into consideration and incorporate

this into the present study, offering visuals, verbal education, while complementing the session with interactive scenarios to encourage deeper, more lifelong learning. Miller and Stoeckel (2011) recommend tailoring education so that the teaching style and delivery method best suits the learning style of the individual. Importantly, with Bandura's SE theory as the underpinning theoretical framework guiding the study and given the social cognitive theory of learning was applied with the aim to enhance SE, it was important to consider that participants may not instinctively change behaviours by either internal or external influences. Wiles (1997) highlights the importance of instilling confidence in the patient, as this is interpreted in terms of competence in the management of follow-up care. Moreover, it was conceded that participants may learn and change behaviour by being proactive, observing, and imitating (Miller & Stoeckel, 2011).

Recency in information delivery is highlighted by Miller and Stoeckel (2011), and also identified by healthcare professionals and participants in the present study. Miller and Stoeckel (2011) highlight that when information is repeated, and the more clients are exposed to it (or undertake a competency), this will enhance recall. Thus, it was important to undertake the nurse-led clinic within the first week post-discharge as participants are educated in the hospital setting, and are discharged home with written material. The PI, to enhance information understanding and retention, presented a small amount of information for each topic area (as opposed to large quantities) as it was identified that individuals primarily recall earlier items presented, and up to "five to seven" pieces of information (Miller & Stoeckel, 2011, p. 82). While presenting smaller quantities of information, spacing the delivery of information, and encouraging revision of written material, it was hoped that participants' understanding could be enhanced, and information thus retained.

Repetition of education is reiterated in the literature with recommendation for PCI education to continue into the post-discharge period (Tuso et al., 2013).

Association and application of skill was practised in complication identification and management scenarios provided at the nurse-led clinic, where for example, haematoma or bleeding would require firm pressure over the access site (Miller & Stoeckel, 2011). Participants were encouraged to recall (and were successful in recalling) the amount of pressure required to achieve access site haemostasis as an association with their procedural arterial sheath removal. Participants were both shown and advised of the site of pressure and length of time required; however, in offering association, participants were able to retain, recall, and apply the information as it was significant to them (Miller & Stoeckel).

Lastly, to ensure that participants knew how their learning was progressing, questions were permitted throughout the course of the clinic, while discussion was also encouraged to determine the success of information delivered. Questions and discussions were supported to ensure that feedback was provided to participants, and it was immediate, and corrections were offered (Falvo, 2003). Feedback of information allows for positive reinforcement of desired behaviours, while correction (where necessary) is essential, as it identifies areas requiring further effort. Thus, as patient misconceptions can occur, correction was offered (Falvo, 2003).

Pressure on the patient attending cardiac rehabilitation (CR)

As identified in Chapters 2 and 4, CR referral, attendance, and course compliance is an issue both nationally and internationally (Balady et al., 2011; Meillier, Nielsen, Larsen, & Larsen, 2012). In the present study, difficulty was encountered in referring patients who had already attended CR in the past (one participant had not attended CR since first attending 10 years prior). Some first-time

participants also withdrew from the program as they reported being too busy;

however, the main difficulty was encouraging program re-attendance. Healthcare

professionals recommended various tactics to encourage re-attendance, which

included "pressure" on the participant, and providing shorter courses. Various

initiatives have addressed the referral, uptake, adherence, and compliance regarding

CR; however, program re-attendance after multiple revascularisation attempts is not

widely documented. Phase 3 of CR, also known as the maintenance phase, is offered

after the initial post-discharge program (Phase 2) is accomplished and may vary

accordingly in length and content (Goble & Worcester, 1999). Participants may

receive doctor or nurse follow-up calls, exercise programs, education, and

psychosocial support (Goble & Worcester, 1999). Bock, Carmona-Barros, Esler, and

Tilkemeier (2004) highlight the benefits of Phase 3 CR on ongoing physical activity,

and exercise behaviours. The authors suggest that both engagement in a Phase 2 CR

program (and the longer duration), will lead to exercise maintenance practices

beyond the program (Bock et al., 2004). Thus, it is important that participants

originally attend and adhere to CR to ensure that they are motivated to continue

maintenance and positive self-management practices. Hospital readmissions and

repeat revascularisation may be reduced if patients with CHD continue to attend CR

maintenance programs after completing a Phase 2 program (Bock et al., 2004).

To ensure the uptake of CR (with barriers identified), and ongoing

maintenance, the NHFA developed a set of nine key action areas to ensure that CR

barriers are overcome (NHFA, 2010). The action areas involve collaboration at all

levels and include governmental organisations, individuals, healthcare professionals,

and healthcare consumers while endeavouring to improve the health of those with

CVD (both new and previously diagnosed) (NHFA, 2010). The actions aim to

promote CR programs while improving accessibility, enhancing patients' overall health and wellbeing, and reducing morbidity and mortality rates. The key action areas are important in terms of encouraging re-attendance to CR of patients with CHD (NHFA, 2010). The first of these two action areas aims to encourage CR attendance as ongoing care for all patients with CVD and CHD, promoting flexible delivery, and availability for all levels of healthcare (NHFA, 2010). Action area three is important as it ensures that CR is "integrated into the patient journey", and rather than undertaken as an option is integrated into primary care services, the community and acute care services (NHFA, 2010, p. 10). In doing so, action area three identifies the need to encourage physical activity in the prevention and maintenance of chronic disease to encourage effective self-management (NHFA, 2010). Thus, with CR re-attendance presenting as an issue, recommendations for maintenance program encouragement, or short, biannual refresher courses for CHD patients who have had multiple PCIs may also assist in achieving all key action areas (Bock et al., 2003; NHFA, 2010). In encouraging and attending and adhering to CR and Phase 3 courses, it is hoped that patients' self-management skills will be enhanced, hospital readmissions and potentially future revascularisation procedures reduced (Bock et al., 2003; NHFA, 2010).

Low SE or efficacy beliefs, coupled with psychosocial (i.e., poor support network) and physiological state (i.e., patient factors), outcome expectations and socio-structural factors may have also contributed to participants declining CR referral, attendance, or adhering to a program. Intervention group participants in the present study demonstrated lower mean ratings for CSE (i.e., overall scores and items) at Time 2 (day 5–7) (where CR referral was encouraged). Although some participants reported recalling education, low SE coupled with their psychological

state at Time 2 (day 5–7) may have potentially led to their decision to decline participation (although it was highly encouraged). Participants' poor outcome expectations may also have contributed to the decision to decline CR participation as they weighed up the positives and negatives of attending CR, linked with their individual beliefs that they may or may not achieve their desired outcome (i.e., CR attendance will not assist in recovery) (Prodaniuk, Plotnikoff, Spence, & Wilson, 2004). Although most participants voiced they had the knowledge, this is an important finding and warrants further investigation in future studies. As highlighted earlier, potential for a study investigating the benefits of repeating short biannual refresher courses in CR on SE, psychological distress, effective self-management, behaviour change and maintenance is warranted.

6.3   Phase One and Phase Three Study: Critical Reflection for Improvement

The Phase One pilot study, as identified, was undertaken to determine the efficacy for a Phase Three, multi-centre study. On critical reflection after undertaking Phase One, and after receiving detailed feedback in Phase Two from healthcare professionals and intervention group participants, the following changes were made to facilitate a more effective Phase Three study as highlighted in Chapter 5 (see Table 6.2). Changes include:

- extending the nurse-led clinic to patients who have undergone diagnostic coronary artery angiography and have received a diagnosis of CAD;
- longer participant follow-up to determine the medium- and long-term effectiveness of the nurse-led clinic on SE, psychological distress, health behaviour and self-management;

- online, electronic visual mode of delivery;

- no further salivary cortisol samples;

- no PI or RA contact; and

- use of telephone randomisation service.

Table 6.2.   Phase Three Study Changes

Phase One	Phase Three	Differences and why?
PCI patients only	Coronary angiography patients with diagnosed CAD and PCI patients	• To benefit all groups of patients with coronary artery disease (i.e., with and without coronary intervention).
Follow-up: 5–7 days, 1 month, 3 months *Note*: Limited by PhD study timeline.	3–5 days, 1 month, 3 months, 6 months, 12 months	Earlier post-discharge follow-up. • Longer follow-up to measure enhancements in SE, reductions in psychological distress, effective self-management, behaviour change and maintenance.
Face-to-face	Online, electronic visual medium	Electronic follow-up • To offer services to a broader population.
Saliva sample	No saliva sample for future studies	Use of self-report assessment tools only to measure anxiety and depression. • Why no salivary cortisol sample? Due to expense of laboratory equipment and to process.
Principal Investigator (PI) contact	No PI or research assistant (RA) contact	• To determine the effectiveness of the intervention versus standard care alone. Phase One all groups had contact with the PI.
Blocked randomisation	Interactive Voice Response Systems (IVRS): Telephone randomisation	• To ensure equal randomisation • To ensure hospital site staff are blinded to randomisation • So that RAs do not have to search for staff to witness randomisation.

On critical reflection, it was identified that the nurse-led clinic should be offered to patients who undergo coronary angiography. Furthermore, the PI decided that coronary angiography patients who are diagnosed with CAD may benefit, particularly if there are current unhealthy behaviours (i.e., diet, lifestyle) requiring change, new medications commenced, health misconceptions, and potential disbelief in their diagnosis. The overall effectiveness of the Phase One nurse-led clinic cannot be commented on at this stage; however, preliminary evidence as demonstrated in ES, RCI calculations, and frequencies suggest the efficacy in undertaking a future

Phase Three, multi-centre study. It has been highlighted that basic education alone may be ineffective in facilitating behaviour change and effective self-management, with more intensive methods of education and follow-up required to achieve such goals (Jovicic, Holroyd-Leduc, & Straus, 2006; Mejia, Richardson, Pattenden, Cockayne, & Lewin, 2014). Therefore, in addition to education and nurse support with a person- centred approach, all RAs will be professionally trained in CBT. Using CBT techniques will encourage participant goal-setting towards overall individual goals in small steps that may facilitate enhancements in SE (Jovicic et al., 2006; Mejia et al., 2014). Cognitive–behavioural therapy, as identified, may assist participants in overcoming negative thoughts and facilitate goal-setting and therefore enhance SE, reduce symptoms of anxiety and depression and assist participants in achieving effective self-management, behaviour change, and maintenance.

The limitation of time in the present study did not enable long-term goal achievement. The present study engaged participants in goal-setting and covered a variety of material concerning the procedure, post-discharge period, medications, CR and lifestyle and change; however, study time restrictions, sample size, and contact with both groups of participants may have presented as limitations to this study. As identified throughout this chapter, additional limitations consisted of participant recruitment and randomisation methods, sample size, various obstacles to the study implementation, the study protocol. Similarly, ambiguity in questionnaire clarity (i.e., for participants) and timing of administration may have resulted in the weakness evident in the present study in the relationship between the SE theory and psychological distress (which typically is evidenced as a strong relationship) (Bandura, 1977, 1995; Dehdari et al., 2008). Furthermore, as education alone may not facilitate behaviour change, recommendations to use more intense methods are

highlighted. Shortridge-Baggett (2002) identifies that the influences required to achieve behaviour change may include: knowledge, skill, beliefs, attitude and support networks. Thus, the Phase Three study will engage participants in CBT over a 12-month period (Meija, et al., 2014).

While the present study may not have been effective in enhancing overall SE, after critical reflecting on Phase One, the feedback received in Phase Two, and as reinforced by the current literature, a nurse-led clinic for both PCI and coronary angiography patients with diagnosed CAD delivered via an online mode of education is necessary. Nurse-led education and support (i.e., CBT training) is vital given the psychological distress experienced post-discharge from hospital (Colquhoun et al., 2013; Dehdari et al., 2008; Sipötz et al., 2013). Furthermore, as highlighted in Chapter 2, this nurse-led clinic (i.e., Phase One) and Phase Three study is unique and vital given the current healthcare climate and demands placed on it (QLD Government, 2013).

6.4   Summary

This chapter has discussed the results of the research phases in detail, while comparing and contrasting with current literature. Chapter 6 also highlighted how the underpinning theoretical framework guided the research. The importance of undertaking a Phase Three, multi-centre study was highlighted, while Phase One and Phase Three studies were compared and contrasted and the changes described in detail. Chapter 7 summarises and concludes the study, while presenting strengths, limitations, and recommendations for future research.

Chapter 7: Conclusions

This chapter summarises Phases One and Two findings in relation to the theoretical framework, identifies the generalisability of study results, and addresses the theoretical and practical implications of the study. Chapter 7 also discusses the potential benefits and implications of undertaking a Phase Three, multi-centre study as noted in Chapter 6 and how this may contribute to future research. Lastly, this chapter addresses the study's strengths and limitations and proposes recommendations for future research and clinical practice.

7.1   Integration of Findings: Phases One and Two

Overall, the Phase One pilot study was not supportive of the study hypothesis that the nurse-led clinic intervention would enhance self-efficacy (SE) and reduce anxiety. Preliminary findings as evident in ES calculations and mean ratings, combined with Phase Two interview outcomes, produced encouraging findings and highlighted the importance of early post-discharge education, support, and screening for psychological distress in patients who undergo PCI or who have experienced a coronary event. These findings highlight the benefits of early education and support and the importance of offering different educational delivery modes, including telehealth.

Overall, initial evidence from both study phases suggest that a post-discharge, nurse-led clinic offering education and support within the first week post-PCI may be effective. Recommendations also highlight the importance of undertaking a well-powered, Phase Three, multi-centre study to test the efficacy of a nurse-led clinic. Although the present study demonstrated some preliminary evidence only of a short-term effect on some preliminary findings, the Phase Two analytical findings point to

the potential benefits of nurse-led clinics. Further studies, however, are needed to investigate the effects of an earlier commencing nurse-led clinic (i.e., 3–5 days) for all patients with CHD, with a longer patient follow-up (i.e., >12 months). Moreover, to ensure health behaviour change and maintenance in patients who have experienced a coronary event and for those with diagnosed CHD, it may be of benefit to utilise cognitive–behavioural therapy (CBT) techniques to assist participants in the initial management of psychological distress (i.e., anxiety, depression), risk reduction, health behaviour change, maintenance, and achieving effective self-management.

7.1. Primary Aim

As identified earlier, findings with respect to the primary aim do not demonstrate evidence to support the effectiveness of a nurse-led clinic on reducing post-discharge SE. Notably, however, anxiety was moderately reduced in intervention group participants. Overall, CSE evidenced a moderately reducing effect in intervention group participants, while nil effect was demonstrated on CSE in standard-care group participants. Only one participant in each group achieved a reliable change. Inspection of the mean ratings showed that some areas of CSE for the intervention group participants were enhanced between Time 2 (day 5–7) and Time 3 (1 month). Areas of mean CSE increases included: confidence to lose weight, make dietary changes, knowing how much physical activity was appropriate, confidence in maintaining usual activities at work, and controlling breathlessness by taking medications. These are important findings because goal-setting, changing health behaviours, and making lifestyle modifications can be effective in patients with chronic disease (Bodenheimer et al., 2002). Although patients with chronic disease tend to be more engaged in their care, all identified outcomes may not be

achieved (Bodenheimer et al., 2002).

After undergoing PCI and/or a coronary event, patients may suffer psychological distress, and as a consequence may also experience reduced SE or confidence to self-manage (Bandura, 1995; Sipötz et al., 2013; West et al., 1995). Furthermore, patients' motivation and ability to make positive health behavioural changes may be obstructed by patient factors such as psychosocial support, physiological health state, and low SE beliefs (Bandura, 1977, 2004). Phase Two qualitative interviews reinforce the Phase One study findings on CSE items identified above. After a coronary event and/or PCI, emphasis is placed on the modification and maintenance of lifestyle and behavioural risk factors (Chow et al., 2010). Findings in the present study demonstrate areas of post-PCI focus in goal-setting and confidence, while reinforcing the educational content received at the nurse-led clinic. Thus, it is important that these areas of patient focus, combined with areas of low SE, are concentrated on in future nurse-led clinics where education is limited to five to seven key areas (Falvo, 2004).

Standard care alone did not have any effect on CSE in participants; however, visual inspection of the means showed that, over time, enhancements in mean ratings for some CSE items were evident at Time 3 (1 month). There are several reasons that may explain enhancement in mean ratings at this time for standard-care group participants including post-discharge self-education, cardiac rehabilitation (CR) attendance, cardiologist and/or GP follow-up, the Hawthorne effect, or possible interviewer effects. A recommendation for future studies is limiting PI contact with standard-care group participants during follow-up. Furthermore, longer follow-up on a larger group is also suggested to determine the effects of the nurse-led clinic, as highlighted in Chapters 5 and 6.

An important finding identified in the present study was the moderately reducing effect on trait anxiety in intervention group participants compared to standard-care group participants, who did not experience an effect on trait anxiety. A reliable change for trait anxiety was evident in five intervention group participants and two standard-care group participants, respectively. While reductions in mean ratings for trait anxiety were evident in both groups over time, a greater reduction was observed in intervention group participants at Time 3 (1 month). This finding is interesting and, as identified in Chapter 6, individuals with high trait anxiety are less susceptible to the effects of interventions and slower to achieve recovery (Muris et al., 1998). Although Muris et al. (1998) highlight the effect of cognitive–behavioural interventions on high trait-anxiety individuals, the present study did not utilise CBT. The fact that a moderately reducing effect occurred in relation to trait anxiety was an important preliminary finding in the present study.

As noted above, the reduction in trait anxiety may have occurred as a result of various factors as identified in Chapter 6 and include: potential life-changing effect of the PCI procedure, nurse-led clinic, change in self-concept, and strong support networks. These findings reinforce the need to undertake a Phase Three, multi-centre study to determine the significance and relationship between CSE and anxiety in the present study, as identified in Chapter 5.

The literature identifies a relationship between psychological distress and SE (Bandura, 1995). Although overall CSE was not reduced in intervention group participants, preliminary evidence of a potential relationship between CSE items and anxiety were identified in participants after involvement in the nurse-led clinic (Bandura, 1995). While ES calculations for anxiety demonstrated no overall effect on anxiety or CSE on receiving standard care alone, reductions in mean ratings for

trait anxiety and some CSE items were observed over time at Time 3 (1 month).

Reasons for these trends may be the aforementioned explanations (i.e., self-education, sample size, interviewer effect, positive support networks). The potential for a greater effect of the nurse-led clinic on CSE and anxiety may have been limited by participants' higher baseline trait anxiety levels (Muris et al., 1998). Overall, the preliminary and short-term findings in the present study are not supported by the SE theory literature where SE beliefs lessen or remove anxiety (Bandura, 1995).

While study follow-up was limited to 3 months post-discharge (Time 4), preliminary findings from Phase Two indicated the potential short-term effectiveness of nurse-led clinics on patient targets or goals. The potential for behavioural change, maintenance of patient goals, and QOL may be limited in the setting of a nurse-led clinic; however, the literature does recommend long-term follow-up (i.e., > 12 months) to determine the effects of a clinic on achieving health goals and reduction on cardiovascular risk (JBI, 2010; Schadewaldt & Schultz, 2011). Thus, given the achievement of some participant goals, and change in some CSE beliefs, the present study is important as it makes an important contribution around targeted modifications in the context of ongoing cardiovascular health maintenance (Chow et al., 2010).

Thus, as the present pilot study aimed to act as a support between hospital discharge, CR commencement, and cardiologist follow-up, preliminary findings encourage a Phase Three study. As argued, investigation of the long-term effectiveness of nurse-led interventions on behaviour change, health management, and outcomes in patients with chronic disease is warranted (JBI, 2010; Schadewaldt & Schultz, 2011). The first week post-discharge is both a physically and emotionally vulnerable time for post-PCI patients; therefore, where patients are discharged home

with or without social support, the nurse-led clinic may potentially act as a source of support for these patients.

Healthcare professionals interviewed in Phase Two identified the potential for the nurse-led clinic to enhance SE and reduce psychological distress as a result of early post-discharge follow-up (i.e., day 5–7 post-discharge), nurse-led education, support, and repetition of vital post-discharge education. These participants also emphasised the importance of a cardiology nurse-led clinic to provide information that may not have been fully understood during hospitalisation due to distractions, anxiety, and limited nurse-teaching time. The nurse-led clinic was able to provide a service to participants that was face-to-face, one-on-one (with family or a support person in attendance on occasion) and without the distraction of the hospital setting to facilitate learning. It was considered essential that any nurse selected to undertake a future post-PCI nurse-led clinic has experience in the cardiology field to ensure the application of person-centred care. Furthermore, being person-centred, patients may have full trust and confidence in the nurse so that SE may be enhanced and psychological distress may be reduced.

Intervention group participants, after undertaking Phase Two interviews, reinforced their confidence and trust in the PI. Participants reported trust in the nurse-led clinic and feeling supported, less anxious and more confident. Thus, as trust is important, it may have facilitated an effective nurse–patient relationship and enhanced nurse–patient communication (Liljeroos et al., 2011). Moreover, a trusting relationship with participants may have encouraged goal-setting, lifestyle change, and maintenance of healthy behaviours, the enhancement of some SE beliefs, and led to participants reporting less anxiety.

Healthcare professionals highlighted the importance of a one-on-one,

interactive, face-to-face, nurse nurse-led clinic that could deliver and reiterate general health-specific information. These participants also recommended a telehealth nurse-led clinic that could be part of a Phase Three study. This group identified how the nurse-led clinic may potentially act to increase PCI patients' confidence to undertake post-discharge care and identify and manage complications. Furthermore, the health professional participants suggested that a nurse-led clinic may also assist in addressing and establishing the importance of health behaviour change and maintenance. These are all important Phase Two findings and demonstrate the potential benefits of attending a post-PCI, nurse-led clinic. Although Schadewaldt and Schultz (2011) identify nurse-led clinics to be limited in achieving behavioural change, analytical findings as highlighted by interviewees in the present study indicate the potential for health behaviour change.

The patient participants reported that, as they were involved in the study and were required to report on their wound and post-discharge cares (to the PI), they took greater care and were more aware of their access sites. Engaging participants in their wound care may have created a greater overall sense of awareness, enhanced some SE beliefs, and facilitated a moderate reduction on anxiety. Intervention group participants in Phase Two reported altering dietary intake, increasing physical activity, and reducing their body mass. This was supported in CSE items reviewed in Phase One, which demonstrated improvements in these areas after attending the nurse-led clinic. Thus, a long-term, well-powered, Phase Three study could investigate the potential relationship between these aspects in patients who have experienced PCI and who have been diagnosed with CHD

Another important preliminary finding was the potentially life-changing or positive effects patients experienced as a result of their cardiac event and after

undergoing PCI. This finding is supported by the literature where positive effects are brought about by stressful life events and may be sustained over time (Updegraff & Taylor, 2000). Where negative effects such as psychological distress are also emphasised, participants in the present study appeared to respond positively to their life-changing experience (i.e., PCI). Thus, a combination of the nurse-led clinic and the positive effects of their PCI may have enabled participants to recognise the importance of modifying risk factors (i.e., dietary intake modification, increase in exercise) engaging in positive health behaviours and participating in post-discharge cares and management. Previous CR program attendance and strength in support networks, as identified in Chapter 6, may have also contributed to the aforementioned changes in health behaviours. An increase in some item SE beliefs and reduction in psychological distress may have also encouraged this change. However, given that the pilot study findings are only preliminary findings and overall CSE evidenced a moderately reducing effect, a Phase Three study is indicated. Undertaking a Phase Three study will allow further investigation to determine if the nurse-led clinic is effective in encouraging positive health behavioural changes by utilising CBT and offering the skills for effective self-management through the reinforcement of health education, providing early post-discharge support, and enhancing SE beliefs.

7.1.2 Secondary Aims

Secondary aims investigated the effect of the nurse-led clinic on depression due to the strong relationship between coronary events, post-discharge symptom emergence, and on post-discharge self-management (Colquhoun et al., 2013). As identified, only a small effect was evident on depression scores in both groups, as one participant in each group achieved 'recovery' or a return to normal functioning.

Reduction in mean ratings for depression scores were demonstrated in both groups of participants; however, where intervention group participants scored higher on mean trait anxiety (and depression scores), reduction of depressive scores over time may have been affected by high trait anxiety levels as measured by the STAI-Y2 form (Muris et al., 1998). Low SE may lead to an individual experiencing stress, anxiety, or depression; thus, small reductions in mean ratings for anxiety and depression may have been affected by low SE given that SE beliefs regulate emotions and affect coping (Bandura, 1995).

Salivary cortisol as an indicator of stress evidenced higher mean ratings in cortisol levels in standard-care group participants as demonstrated in salivary cortisol assays; however, levels were maintained within normal reference ranges at all times. Conversely, where salivary cortisol levels were higher in standard-care group participants, self-report data reflected greater psychological distress on baseline measurement in intervention group participants where STAI-Y2 and CDS measurement tools demonstrated higher mean ratings for anxiety and depression. As discussed in Chapter 5, disparities between salivary cortisol assay levels and self-report data are frequently reported in the literature, with multiple reasons given for the poor association (Hellhammer et al., 2009; Hjortskov et al., 2004; Vedhara et al., 2003). It was interesting that while evidence appeared conflicting, as salivary cortisol levels reduced at Time 3 (1 month) in both groups, so too did mean ratings for STAI and CDS scores.

It was notable that CR re-attendance was poor in patients who had attended CR in the past, which is an important finding in this study with an abundance of literature identifying how referral, attendance, and adherence continue to be problematic both nationally and internationally (BHF, 2011; Cupples et al., 2010;

Gallagher et al., 2013; Heartwire, 2011; Varnfield et al., 2011, p. S15). While there is a strong focus on achieving greater referral and attendance rates for first-time CR participants, patients who have undergone repeat revascularisation procedures and who believe that they have the knowledge would also benefit from re-attending. In the present study, where repeat PCI patients were offered attendance at CR, most participants declined as they believe they have the knowledge after having attended a course in the past. While those who had only recently completed a course (within the previous 1 to 2 years) may have had the knowledge, those who decline, and who have experienced multiple revascularisation attempts and are not involved in a maintenance program should be flagged. Furthermore, as re-attending a short course is not an option, the present study, the healthcare professional feedback in Phase Two, strongly suggests trialling short refresher courses for repeat PCI patients or biannual CR course re-attendance. If participants require repeat procedures, there may be a need to reassess and reinforce education on medication adherence, lifestyle, and health behaviours by means of CR in this group, as highlighted in the present study.

Not only did the Phase One pilot study and Phase Two interviews highlight the potential and importance of trialling a CR short course for those with repeat PCIs, the need to more overtly encourage referral was identified. Participants and healthcare professionals all acknowledged the importance of attending CR; however, when a referral was offered, most participants declined as they believed they had the knowledge, limited time, or reported geographical constraints. Thus, as patients are aware of the importance of CR attendance, referral for re-attendance appears to be problematic for repeat revascularisation candidates, with the present study identifying the need to provide greater strength in referral.

Participant confidence in the ability to effectively self-manage post-discharge was identified in the study's two phases. Phase Two analytical findings reflected a strong focus on access site management, CP identification and management, dietary intake, physical activity, and weight management. Similar CSE items (i.e., confidence to change diet) demonstrated small enhancements in mean ratings in intervention group participants in these areas. While overall CSE was not enhanced, the ability of the nurse-led clinic to potentially facilitate effective self-management was identified by healthcare professionals. These findings are important and reinforce the effectiveness of self-management programs as opposed to standard care alone, where participants may benefit through enhanced SE, knowledge, greater involvement in self-management, and personal health (Barlow et al., 2002). The present study undertook an interactive educational component offering verbal, visual, and written information while engaging patients in their learning, health management, and action planning (if complications were to arise). Importantly, confidence in self-management may also reflect the tendency for some chronic disease sufferers to be more motivated and engaged in their health and management, thus further encouraging participants to self-manage (Bodenheimer et al., 2002).

There was no effect on medication adherence in intervention group participants in the present study, with maintenance evidenced in mean ratings. Medication knowledge appeared to be enhanced in intervention group participants at Time 3 (1 month), while standard-care group participants' knowledge decreased at this time. Whether or not the nurse-led clinic solely contributed to medication knowledge enhancements requires further investigation. To avoid overwhelming participants and as highlighted by Falvo (2004), medication education consisted of general information on the standard groups of medications PCI patients may be prescribed

and dispensed on discharge home. Although intervention group participants, as measured by the MMAS-8, maintained adherence at the upper end of moderate, knowledge also appeared to increase. These findings are important and reinforce current medication adherence literature. Nonetheless, it has been argued elsewhere that while medication adherence is identified as high in some chronic disease suffers, knowledge may be poor (Fernandez et al., 2007; Haynes et al., 2008). Thus, the fact that medication knowledge appeared to be enhanced in intervention group participants was an important preliminary finding. A Phase Three study may demonstrate the effectiveness of nurse-led clinics where the focus is on effective self-management in the enhancement of medication knowledge in post-PCI and CHD patients.

In this study, Phase Two healthcare professional interviews also pointed to the importance and potential effectiveness of the medication education component of the nurse-led clinic. Issues concerning abrupt medication cessation and replenishment of supply were perceived as important by healthcare professionals as was the need for referral to a doctor on considering cessation. These participants also reinforced the nurse-led clinic's message of taking medications as prescribed and that patients be warned about the poor quality of some internet education (if accessing online information).

As 50% of patients are medication non-adherers, because of factors such as health literacy, polypharmacy, and poor communication affecting medication adherence, to avert secondary non-adherence, it was essential to discuss the aforementioned potential issues with participants in clinic attendance (Brown & Bussell, 2011; Jackevicius et al., 2008). Furthermore, as medication adherence and compliance may be affected by personal beliefs or experience, consultation with

friends, or by accessing supplementary information, it was essential that the nurse-led clinic approach such issues. Phase Two findings identified the need to caution patients on internet health and medication information, while offering patients details on sourcing reputable health material so that they may engage in safe self-education (Coleman, 2003; Vermeire et al., 2001). Thus, as medication knowledge appeared to be enhanced and adherence maintained, the nurse-led clinic may have been effective in conveying these messages, as reflected in the findings from Phases One and Two.

7.2   Theoretical Implications

With factors such as anxiety, short hospitalisation coupled with poor information absorption and retention; and limited nurse teaching time identified in this study as affecting post-PCI patients, an intervention examining their self-confidence beliefs or SE to successfully accomplish post-discharge period management and cares was warranted. Furthermore, with limited post-discharge support and medical contact, it has been estimated that patients wait between 7 and 64 days to see their GP and/or cardiologist and to commence their CR course (BHF, 2011; Cupples et al., 2010; Dafoe et al., 2006, p. 909; Grace et al., 2012; Heart Foundation of Western Australia, 2012; Lacey et al., 2010; Pack et al., 2013; Shakib et al., 2009).

Bandura's SE theory posits that efficacy beliefs or SE may enhanced by mastery, vicarious experience, and social persuasion, and an individual's physiology and emotions (Bandura, 1995). While overall CSE evidenced a reducing effect, reductions in mean ratings in some areas of CSE were reduced. The nurse-led clinic, as identified, demonstrated a moderately reducing effect on anxiety. Reductions in psychological distress (i.e., anxiety and depression) appeared to be demonstrated in both study phases, while confidence to self-manage (i.e., medications) was

marginally evidenced in Phase One, but reinforced in Phase Two. While efficacy influences were applied in the present study, a Phase Three study is needed to determine if the application in the present nurse-led clinic may enhance overall SE by targeting efficacy beliefs.

SE theory has been widely used to inform interventions in patients with chronic disease, and, thus was chosen as the theoretical framework to guide the present study (Barlow et al., 2002; Corbin & Strauss, 1988; Schadewaldt & Schultz, 2011). While cardiology nurse-led clinics have been recognised and recommended in the literature, as highlighted in Chapter 2, there are no identical studies to The 'REALITY CHEC' Project investigating the effects of early post-discharge support while awaiting CR and cardiology review on SE, psychological distress and self-management (Campbell et al., 1998; Cossette, Frasure-Smith, & Lespérance, 2002; Jolly et al., 1999; Jones & West, 1996; Lapointe et al., 2006; Mainie, Moore, Riddell, & Adgey, 2005; Moher et al., 2001). The pilot study's preliminary findings gave support for the potential of a nurse-led clinic to enhance some areas of CSE and to reduce anxiety. The findings of Phase Two also pointed to the potential effectiveness of a nurse-led clinic to enhance self-management (i.e., diet, weight, exercise). The literature emphasises the impact of SE on effective self-management and hence, small increases in CSE items, reflected in Phase Two findings were important (Bandura, 1995; Barlow et al., 2002). Participants in Phase Two expressed confidence to self-manage aspects of post-discharge care and make positive lifestyle changes (i.e., weight management, diet, physical activity, access site management, complication identification, and management). The SE theory adapted to the PCI population also allowed for the review of external influences such as patient factors on participants' SE, goal-setting, and health management throughout the course of

the study, while also permitting the PI to assess what factors may have affected participants' SE.

An assumption of SE theory, where SE is that where SE is low, anxiety is enhanced (Bandura, 1986). While overall CSE was not enhanced, as identified earlier, when viewed at an item level there were small increases in mean ratings of some CSE areas and a moderately reducing effect on anxiety. Given these are preliminary results and that the study was significantly underpowered, a larger Phase Three study could examine the effectiveness and significance of the intervention on both primary and secondary aims. A future study could investigate the long-term effects of the nurse-led clinic on SE, and as highlighted by the JBI (2010) and Schadewaldt and Schultz (2011), nurse-led clinics have demonstrated short- to medium- term and some long-term success on patient outcomes. These authors argue that nurse-led clinics can assist patients in reaching goals and enhance their QOL and recommend long-term studies to determine the maintenance of long-term health behaviour changes and management (JBI, 2010; Schadewaldt & Schultz, 2011). In relation to secondary aims, a small effect on depression was evidenced in both groups on closer inspection of mean ratings, while greater medication knowledge was demonstrated in intervention group participants only. While the significance of these results cannot be commented on, given the nature of the study and sample size, results are promising and will be investigated further in the study's third phase.

7.3.   Strengths and Limitations

7.3.1 Study Strengths
This study is innovative in that it was undertaken as a pilot, in two phases and modelled an RCT. The PI was able to collect data on multiple measures for both psychological and physiological outcomes from both study participants and

healthcare professionals. Psychological distress, as identified, is a common post-cardiac event and may often be missed during hospitalisation (AIHW, 2011; Bhattacharyya, Molloy, & Steptoe, 2008; Colquhoun et al., 2013; Davidson et al., 2008; Lane et al., 1999; Parissis et al., 2006; Turner et al., 2010). Four participants were flagged for medical referral in the present study, reinforcing the benefits of holding an early post-discharge nurse-led clinic. Trends, as evidenced on inspection of mean ratings and analytical findings (Phases One and Two combined), demonstrated participant confidence to accomplish tasks and positive health behaviours post-PCI while also reducing anxiety. Preliminary findings also suggest the nurse-led clinic may be effective in enhancing medication knowledge; however, other variables such as, self-education may have affected medication knowledge and must be investigated in a Phase Three study. The maintenance of medication adherence in intervention group participants and increase in knowledge after attending the nurse-led clinic were important preliminary findings, as 50% of patients are reportedly non-compliant and secondary non-adherers to antihypertensive and lipid-lowering therapies (Brown & Bussell, 2011; Jackevicius et al., 2008).

Early post-discharge intervention and follow-up may be beneficial as patients are usually discharged within 6 to 24 hours post-PCI and wait from 7 to 64 days until they are reviewed (BHF, 2011; Cosman et al., 2011; Cupples et al., 2010; Dafoe et al., 2006, p. 909; Grace et al., 2012; Heart Foundation of Western Australia, 2012; Lacey et al., 2010; Pack et al., 2013). Providing early post-discharge nurse-led support and follow-up may assist patients in answering any post-discharge concerns regarding cares and self-management that they may have forgotten to ask during their hospitalisation, on discharge, or had given thought to during day 1–4 post-

discharge. Benefits to the healthcare community and system include less demand.

Post-PCI patients may ask vital questions of the RN at the clinic, as opposed to the

patient arranging a GP or cardiologist appointment for this purpose. Furthermore,

continuity of care will be maintained with appropriate actions (i.e., referral) should a

patient raise concerns or the RN assess and deem referral an appropriate action.

In addition to providing early nurse-led care, the application of a person-

centred approach to the delivery of patient care presents as another strength,

particularly in chronic disease and patient management (Yu, 2014). The benefits in

using this approach in the present study and in chronic illness include that it

individualises the patient, encourages multidisciplinary team collaboration and

allows the patient to more effectively manage in their daily lives (Dudas et al.,

2013).

Further potential benefits of the nurse-led clinic include early post-discharge

reiteration of education, clarification of misconceptions, and primary and physical

examination to ensure no significant changes in health status (i.e., blood pressure,

temperature, electrocardiogram [ECG]). Additionally, complication identification

and management and screening for post-discharge psychological distress may be

undertaken by a qualified cardiac RN. Thus, as a first contact in the early post-

discharge period (unless a GP appointment attended within the first week), the post-

PCI nurse-led clinic is, arguably, a beneficial post-discharge concept with

preliminary evidence favouring a Phase Three study.

7.3.2 Study Limitations

The study has a strong theory base; however, while it is underpinned by

Bandura's SE theory (1977, 1995), the latter does not reflect the theory or support

the primary hypothesis that an increase in SE and SE beliefs may lead to a reduction

in psychological distress. While overall CSE reflected a moderate reduction, only some CSE items were enhanced. While redesigned as a pilot study, the sample size for Phase One intervention presented as a limitation to this research. It was acknowledged that the time of year when recruitment commenced was a notably quiet period where wards and outpatient departments were closing thus limiting recruitment and sample size. Second, with a smaller sample size, the results of this pilot study may not be generalisable to the PCI patient population. As a consequence, data analysis did not permit the full range of tests and the PI was, therefore, unable to comment on significance levels, but rather ES, reliable change, and mean ratings for trends. A future powered study will allow for the control of potential confounders and generalisability to the study population. Randomisation at the commencement of the study was undertaken in large blocks and was later reduced to smaller groups to ensure equal randomisation.

Blocking was identified as a study limitation and in future studies should be undertaken in smaller blocks or use telephone randomisation to ensure equal randomisation to all study arms. Participants reported that returning to the hospital (i.e., geography) should they be randomised to the intervention group was inconvenient and declined participation on these grounds. Potential participants reported they may have joined the study had they been able to select the option for telephone follow-up. Improvements observed in standard-care group participants may have occurred as a result of self-education, CR attendance, the Hawthorne and/or interviewer effects (i.e., supported RN telephone contact). Thus, as standard-care group participants received post-discharge telephone follow-up, enhancements in CSE, reductions in psychological distress, and confidence in self-management may have also occurred as a result of telephone contact with the PI.

A Phase Two limitation was that interviews were only undertaken at one of the two hospital sites. The results of the interviews may, therefore, be relevant to the participants in this setting. As Phase Two post-PCI interviews were undertaken up to 6 months post-discharge, the ability and depth of information participants were required to recall about the nurse-led clinic may have been vague for some. Additionally, as two participants declined participation in Phase Two, intervention group interviews may have limited the research in terms of depth of qualitative findings reported. Lastly, as Phase One assessment tools (i.e., STAI, CDS) were collected post-intervention at Time 3 (1 month), this may have presented as a limitation. Future studies should aim to collect data immediately post-intervention (i.e., Time 2, day 5–7) to gauge an immediate effect and then again at times reinforced by the literature to determine further change and maintenance of measures post-intervention.

7.4   Recommendations

The PI identifies and recommends that a larger scale study be undertaken and patients followed up for at least 12 months or more post-PCI to gauge the full effect of the intervention on SE, psychological distress, behaviour change, and self-management. Furthermore, in post-PCI goal-setting, to achieve post-discharge self-management, the PI aims to place a greater focus on patients' goals while using CBT techniques to achieve goals and maintain positive health behaviours. Second, it would be beneficial to offer the option of different methods of communication with the nurse-led clinic such as Skype, FaceTime, or telephone intervention. Offering alternate modes of communication may also accommodate for participants who are unable to travel post-procedurally, who do not hold a driver's licence, and for those who live in remote and rural settings. Offering online or telephone follow-up options

would be of benefit to patients in relation to convenience, and may facilitate study recruitment. Future nurse-led clinics should also be offered to patients who have been diagnosed with CHD, experienced a coronary event, and/or PCI as opposed to PCI alone.

The present study demonstrates flexibility to be adapted and may benefit future participants, their SE, and emotional wellbeing, while encouraging positive lifestyle choices, health behaviours, and effective self-management. Furthermore, to gauge the full effect of the intervention and to minimise the potential for the Hawthorne and interviewer effects, follow-up with standard-care group participants should only occur via email, postal mail (i.e., to fill out questionnaires), or short message service (SMS) as opposed to full PI contact, as used in the present study. This clinic can be held within or outside the hospital setting (i.e., cardiology rooms or GP clinic), and be undertaken by a qualified RN.

Cognitive–behavioural therapy accreditation is recommended; however, it should not be a prerequsite. Some CBT training should serve as a minimum requirement for the role of a facilitator. Family and support networks will be strongly encouraged from recruitment and significant others will be encouraged to attend the nurse-led clinic to receive education, provide support, and thereby better understand and support the patient in their recovery. Patients with limited or no support networks will be identified and flagged for increased risk of psychological distress and hospital readmission. Importantly, patients should be offered trustworthy internet material or relevant website addresses so that they may to engage in post-clinic self-education. As a result of undertaking this study, further research investigating the life-changing effects (positive or negative) following PCI would be beneficial to both current and future PCI patients and healthcare professionals and

should be investigated.

An important finding uncovered in the present pilot study concerning CR highlights the requirement for a further emphasis on the benefits of re-attending if PCI patients have participated in the past. Furthermore, with some patients requiring repeat revascularisation procedures, the importance of maintenance programs will be emphasised to both first-time and repeat PCIs. As CR attendance is vital to patients' post-PCI health and wellbeing, a shorter refresher course should be trialled with different modes of attendance also offered (i.e., Skype, DVDs, FaceTime) or, alternatively, biannual attendance to CR programs.

7.4.1 Implications for Research

This study provides preliminary evidence that psychological distress may occur after a coronary event or procedure, as identified in the present study and the relevant literature (AIHW, 2011; Bhattacharyya et al., 2008; Colquhoun et al., 2013). Furthermore, it may demonstrate that high trait anxiety could be affected by educational and behavioural interventions (Muris et al., 1998). The present study provides some initial evidence to support the short-term benefits of nurse-led clinics, with long-term follow-up recommended (Schadewaldt & Schultz, 2011). Patients, healthcare organisations and professionals may benefit from further research investigating the long-term effects of nurse-led clinics on SE, psychological distress, and self-management given that nurse-led clinics may have some effects on long-term health outcomes (JBI, 2010; Schadewaldt & Schultz, 2011).

This pilot study is promising and provides evidence to support a Phase Three multi-centre trial to investigate the effects of the nurse-led clinic as it may be effective in enhancing areas of patients' CSE and psychological distress, while also encouraging behaviour change and effective self-management. Significance of the

present study cannot be commented on given the study is a pilot only and underpowered. The present nurse-led clinic undertaken as a Phase Three study may assist patients by providing early post-discharge support, encouraging CR attendance, and enhancing knowledge by identifying personal goals in the early post-discharge period. Lastly, this study may not only benefit post-PCI patients but all patients who have experienced a coronary event or who are diagnosed with CHD and should, therefore, be investigated in this group of patients for an effect.

7.4.2   Implications for Clinical Practice

A larger study of this nature may benefit the healthcare system in a number of ways. First, by reinforcing education, patients may be more informed about their healthcare requirements and management, which may subsequently reduce the strain on the healthcare system. Second, providing early post-discharge education and support may encourage patients to identify and manage post-discharge complications while highlighting the importance of seeking medical assistance. Achieving the aforementioned outcomes may be possible by enhancing SE, reducing psychological distress as a result of enhancing patients' knowledge, encouraging goal-setting, and encouraging the adoption of positive health behaviours. The nurse-led clinic may be undertaken by a qualified cardiology RN in an outpatient department, through cardiology clinic rooms, or at a general medical practice room. Importantly, as participant recruitment may be difficult due to geographical issues, offering earlier (i.e., 3–5 days) face-to-face follow-up or telehealth options is recommended. The importance and benefits of the nurse-led clinic should be highlighted to cardiologists so that support may be gathered to establish a post-discharge follow-up clinic within the first week post-discharge in cardiology rooms or using an electronic visual medium (i.e., Skype or FaceTime). Moreover, 91 potential participants were unable

to partake in the study as they lived too far away but offered their availability via means of telephone follow-up. Thus, future patients should be provided with options for study involvement and follow-up as identified above.

7.5   Summary

While the pilot study did not demonstrate overall effectiveness of the nurse-led clinic, it did provide some initial evidence to suggest potential for a Phase Three, multi-centre study held within the first week post-PCI (i.e., 3–5 days). Although overall enhancements in CSE were not demonstrated in intervention group participants, selected CSE items demonstrated small increases in mean ratings over time. The intervention demonstrated a moderate effect on trait anxiety on study participants and was viewed as important to this study given that individuals with higher trait anxiety are less susceptible to intervention and treatment (Muris et al., 1998, Tovilović et al., 2009). Reductions in mean ratings for anxiety and depression were identified in both groups of study participants. The following explanations were offered for enhancements in standard-care group, (a) post-discharge self-education, (b) effective support networks, (c) CR attendance, (d) the Hawthorne effect, and (e) interviewer effects (i.e., supported RN telephone contact). It was interesting that salivary cortisol levels demonstrated slightly higher levels in standard-care group participants, as opposed to self-report instruments, which demonstrated higher anxiety and depression scores in intervention group participants. Notably, however, mean ratings were identified at Time 3 (1 month) with reductions in mean trait anxiety (and depression) scores identified alongside reductions in salivary cortisol levels.

Cardiac rehabilitation referral, attendance, and adherence still require effort from both healthcare professionals and patients, while continuation of the

maintenance stage requires further investigation. Whether it be 1 month or 10 years since CR attendance, the importance of education and maintenance of positive lifestyle changes and behaviours is essential. Phase Two interviews suggest greater persuasion and non-negotiable attendance or re-attendance to CR. An important finding arising from this study is the need for CR short courses for repeat revascularisation patients or biannual CR course attendance. This finding was also reinforced in Phase Two analytical findings and should be undertaken to support repeat PCI patients. Enhancements in medication knowledge were identified in intervention group participants while medication adherence remained stable based on inspection of mean ratings. Phase Two analytical findings highlighted the importance of medication education, detailing its potential effectiveness. Recommendations to caution participants on potentially incorrect internet education material and suggesting patients seek medical advice prior to self-cessation of medications also emerged from Phase Two analytical findings.

The pilot nurse-led clinic was viewed positively by both participants and healthcare professionals in that it was person-centred and offered a tailored approach, while also providing options to suit learning styles to maximise support in the early post-discharge period. Participants voiced full confidence in the PI, and felt reassured with the nurse-led clinic and follow-up. The gravity of their procedure and surrounding events were brought to light in the early post-discharge period and after attending the nurse-led clinic. Participants reported greater self-confidence to effectively manage their health and make positive lifestyle choices as they gained an awareness after attending the clinic and undergoing their procedure. Phase One and especially Phase Two findings are promising and highlight the potential for a Phase Three, multi-centre study. While only some areas of SE were enhanced, the present

study shows promise in reducing psychological distress and encouraging effective self-management after experiencing a life-changing event.

The results of the present pilot study may be used to develop a model of care that can be applied to the areas of cardiovascular nursing, CR nursing, CCT teams, and cardiology in both private and public organisations engaged in primary and secondary prevention. The present study's results may also assist in refining and extending existing knowledge in the area of PCI, coronary angiography and CHD patient management—in particular, the early post-discharge period where there is often an increased risk of post-discharge psychological distress. Moreover, it is hoped that the present study can offer additional information regarding post-discharge experiences, behaviours, and health management practices post-PCI.

Appendices

Problem	Authors	Aims/Discussion/Results	Conclusions/Recommendations
Hospitalisation time	Laarman & Dirksen (2010, pp. 584–587)	Discussion on the topical question of early discharge post primary PCI.	• Early discharge may be beneficial to both patient and hospital; however, it should only be available to those identified as low-risk.

	Kaluski et al. (2008, pp. 345–348)	**Aim**: To assess the feasibility of a decreased length of stay post-PCI in a quality improvement program in the US.
		
		Results: A decrease in length of stay from 48 hours to 30 hours between the years 2000–2006.
			• The authors highlight the success of the decrease in hospitalisation time to 30 hours.
			• The authors highlight that although this a shorter length of stay proved successful, this will require close and effective management practices, in particular in patients with the following characteristics as safety can be severely compromised. Characteristics are as follows:
			  • Poverty stricken;
			  • Addictive disabilities;
			  • Socially isolated;
			  • Non-compliance; and
			  • Several co-morbidities.

	Kotowycz et al. (2009, pp. 585–588)	**Aim:** To assess the viability and safety of early discharge of 54 low-risk STEMI patients at 72 hours post-PCI.	• It is concluded that early discharge of lower-risk STEMI patients can occur, however, it is recommended that this group of patients are followed up closely by an acute practice nurse.

Problem	Authors	Aims/Discussion/Results	Conclusions/Recommendations
		Results: • 74% discharged within 72 hours; and • Median length of stay 55 hours. • **Acute practice nurse follow-up** 100% of patients Within 3 days post-discharge 74 % face-to-face follow-up; 26% telephone communication; All patients had $\geq$ follow-up sessions with the nurse. **At 6 weeks post-discharge** **Medication compliance** • Most patients were compliant in self-administering their medications • Only 15 of 27 patients in the intervention group attended CR once; • Only 14 of 27 control group patients attended CR; and • Approximately 63% of patients in the intervention group continued smoking versus 58% in the control group.	

Problem	Authors	Aims/Discussion/Results	Conclusions/Recommendations
	Chin et al. (2011, pp. 1052–1061)	**Aim:** To examine the CathPCI Registry and length of stay for Primary PCIs in 115,113 patients and 958 hospitals from the years 2005–2009. **Results:** The mean length of stay between 2005–2009 decreased from 4 ± 3.0 to 3.6 ± 2.7 days. There were no changes in in-hospital mortality. Patient stays longer than two days were high-risk and suffered either of the following: cardiogenic shock, required blood transfusion or balloon pump insertion, post- PPCI complications or were of an older age group. Low-risk patients were discharged within 2 days from 45.6 % of hospitals reviewed.	**Conclusions/Recommendations:** • Length of stay is decreasing for both patient types (i.e., PPCI and Elective patients). • Discharge is based on the following and differs between hospitals. • Discharge is dependent on: • a. The hospital; b. the patient (i.e., complications and risk); and c. the procedure. • Additional research on safety of early PPCI discharge recommended.

	Authors	**Aim/Discussion/Results**	**Conclusion/Recommendations**
Post-discharge period	Yan et al. (2011, pp. 122–127)	**Aim:** To review DES trends and 12 month outcomes in Australia in 9204 PCI patients between 2004 and 2008. **Results:** a. A decline in DES use (53.9% to 32%) over this time due to long term safety concerns (i.e., in-stent thrombosis, MI or death at >30 days and >12months). b. Increase in clopidogrel use (54.7% to 98%).	**Recommendations/Conclusions:** a. Increase in long-term dual antiplatelet treatment. a. AE's: Low during this time. b. High procedural success rates
	Tuso et al. (2013)	**Aim:** Review of initiatives to reduce hospital readmission rates. **Findings**: • 1/3 of 30 day readmissions within 7 days after hospital discharge. • • The first 7 days post-discharge a vulnerable period with reasons as follows: • Social issues – non-compliance; medication expenses and adverse reactions; low success rate of hospital treatment.	**Recommendations/Conclusions:** 1. Tailored, patient-centred approach, with focus on social setting will reduce hospital readmissions and assist in reducing healthcare costs. 2. Focus should be on the patient and their social issues. 3. Focus on disease prevention and timely treatment.

	Authors	Aim/Discussion/Results	Conclusion/Recommendations
		To reduce readmission rates: • Telephone follow-up within 72 hours in high-risk patients to reduce readmission within one week post-discharge with focus on education and recent hospital admission. • Primary care physician review within the first week post-discharge to reduce 30 day readmission.	
	Lane et al. (2000)	**Aim**: To examine CHD and the relationship with anxiety and depression up to 12 months post-MI. **Findings:** • Grounds for concern post-MI • Mild to severe depressive symptoms suffered; • High levels of anxiety; • Intervention required for post-MI patients.	
	Lane et al. (1999)	**Aim:** To identify the psychological needs of patients with CHD and MI.	

	Authors	Aim/Discussion/Results	Conclusion/Recommendations
		Findings: • Psychological symptoms may be subside at 5–6 days post event in some patients; • Psychological distress may present in weeks post event. **Why**? Realisation of event recognised. **Conclusions**: • Routine screening for psychological distress; • Offer psychological referral; • Offer stress management; and • CR to be individually tailored.	
	Das & O'Keefe (2006)	**Aim**: To investigate the effects of psychological distress on cardiovascular health. **Findings and conclusion:** • Associated with non-compliant behaviours • Stress is modifiable • Protective factors: Support, exercise, stress reduction education, humour, optimism, altruism, faith, pet ownership. • Screening for emotional distress should be undertaken.	

	Authors	Aim/Discussion/Results	Conclusion/Recommendations
	Turner et al. (2010)	**Aim:** To investigate the relationship between anxiety, depression, social support and clinical outcomes in CR participants. **Conclusion:** • Patients requiring screening for emotional distress and intervention.	
	Barnason, Zimmerman, Brey, Catlin, & Nieven (2006, pp. 31–37)	**Aim**: To study PCI patient recovery post-discharge from hospital. **Findings**: **First 2 weeks after discharge** • Depression and Anxiety; • Tiredness; • Chest pain; • Short of breath; **At 6 weeks post-discharge** • Tiredness; • Short of breath; • Lower limb oedema and discomfort; • Coronary artery re-stenosis.	An understating of the differences in patients' recovery is warranted as it may allow for improved patient outcomes through enhancements in the field. This study highlights that patients post cardiac events do suffer from psychosocial difficulties. Secondly it presents the significance of incorporating such content within secondary prevention programs. Lastly, the results highlight the need to employ a broad group of clinicians to assist patients in their recovery and beyond.

	Authors	Aim/Discussion/Results	Conclusion/Recommendations
	Arndt, Murchie, Schembri, & Davidson (2009, pp. 328–335)	**Aim:** To explore the post-discharge psychosocial needs of patients who have experienced a cardiac event. **Methods**: • Survey • Journal • Focus Group **Results**: Four themes • **Theme 1:** "The need for provision of Hope"; • **Theme 2:** A Desire for Structure and Support"; • **Theme 3:** "An Appreciation of Support of Fellow Group Participants"; and • **Theme 4:** "The Need to Review, Process, Interpret Their Illness Trajectory" (Arndt et al., 2009, p. 332).	

	Authors	Aim/Discussion/Results	Conclusion/Recommendations
	Lauck et al. (2009, pp. 190–199)	**Aim**: To assess patients self-caring abilities and behaviour 2–5 days post-discharge. **Results:** - A large number of patients followed discharge instructions; - Antiplatelet medication compliance: 97 % - Patient understanding of reason for antiplatelet medication: 77.5% - Exercise: Under-exercising: 52% Over-exercising: 20.4%	Discharge on the same day feasible, however, those patients "socially isolated" require identification and support during their recovery (Lauck et al., 2009, p.198).
	Rudd et al. (1993, pp. 659–666)	**Aim:** To assess medication administration gaps in cardiovascular patients. **Methods**: Self-report; Electronic monitoring; Doctor monitoring; & Counting medications. **Results:** - Most participants compliant - Found subgroups of patients - **Group 1**: Near-optimal compliers 50–60% compliant	

	Authors	Aim/Discussion/Results	Conclusion/Recommendations
		• **Group 2:** Partial compliers 30–40% compliant • **Group 3:** Non-compliers 10 % compliant (p. 665).	
	Fernandez et al. (2007, pp. 53–61)	**Aim:** The evaluation of long-term PCI patient medication adherence. **Methods:** • Self-report Questionnaire; and • MMAS-8. **Results:** • 90.6% never missed medications per week; • 7.5 % miss 1–3 tablets per week; • 2% miss ≥4 tablets per week; • 4% could not remember if they missed any; • 2% cease medications if feeling well; • 4.5% cease medications if feeling ill; • 5 % cease medications if they are going on an outing; and • 31.9% stored medications incorrectly.	
	Radcliffe, Harding, Rothman, & Feder	**Aim**: To explore participants' experiences of PCI in the UK.	• The authors highlight participants' disappointment with poor primary care

	Authors	Aim/Discussion/Results	Conclusion/Recommendations
	(2009, pp. 216–222)	**Methods**: Interview at home or hospital 13–90 days post-PCI. **Results**: • Patients were extremely satisfied with treatment they received by the interventionalist and carers. • Patients had expected they would have CABG surgery as opposed to PCI. • Post-discharge needs not met.	post-discharge follow-up. • A large number of participants had questions of their condition and post-discharge management/care.
	Secondary prevention Foster, K, personal communication, November 15, 2010.	**Data**: Complications post-PCI in the year 2008. **Results:** **At 1 month post-PCI (n = 424)** • Repeat coronary angiogram: 2.8% • Repeat PCI: 2.4% • Mortality: 1.2% • Stroke: 0.2% • Puncture site complication: 2.4% **At 12 months post-PCI (n = 392)** • Repeat coronary angiogram: 7.1%	

	Authors	Aim/Discussion/Results	Conclusion/Recommendations
		• Repeat PCI: 5.9% • Mortality: 2.8% • Stroke: 0.5% • Puncture site complication:3.3%	
	Gallagher et al. (2013)	**Aim:** To trial and examine the effect of an educational intervention on chest pain, knowledge and management in PCI and AMI patients attending CR between 2010 and 2011. Intervention: At baseline CR assessment and review of knowledge at 6–8 weeks on CR course completion. **Results:** Improvements in patients' symptom knowledge and actions at 6–8 weeks post-intervention. **Actions for CP management reported by patients included**: • 4% driving to hospital • 14% having someone drive them to hospital • 11% calling GP **Post-intervention**: Improvements in knowledge, actions at 8 weeks post-intervention.	**Recommendations / Conclusions:** • Tailored patient education on CP and management required. • Allows for misconceptions in CP knowledge and actions to be clarified. • Requirement for this education to be repeated due to low CR attendance rates with recommendations as follows: a. Post-discharge; b. medical rooms; and c. outside of CR.

	Authors	Aim/Discussion/Results	Conclusion/Recommendations
	Bethell et al. (2006, pp. 57–61)	**Aim**: CR programmes followed for a period of 7 years (1998–2004) in the UK. **Patients**: Post- AMI, CABG, and PCI **Results**: Increase in patients treated over the course of the study.	**Rates of patients enrolled in CR 1998 – 1999**: 25% to 31.5%; **Rates from 2002–2004:** Decline 31.3% to 28.5%. **National Service Framework aim for these patients:** • 85% enrolment rate to CR • **Actual enrolment**: 1/3 of patients and declining.
	Dafoe, Arthur, Stokes, Morrin, & Beaton (2006, pp. 905–911)	**Problem**: The absence of national benchmarks for patients requiring cardiovascular care and follow-up in Canada. **Methodology**: • Literature review • Value of CR; • Accessibility barriers and referral issues. • Review • Current guidelines of CR	• Attendance leads to a reduction in morbidity and mortality; • Referral irregularities; • Poor utilisation of CR; • CR course issues (i.e., not patient specific enough and geographical location). • All patients with cardiovascular disease would benefit from CR. • Further guidelines need to be established as to what type of patient is classed as appropriate.

	Authors	Aim/Discussion/Results	Conclusion/Recommendations

		accessibility.
		• National survey
		    • 14 programs; and
		    • information: referral and delay.
		
		Review of Pilot Study:
		• 'The Ontario Cardiac Rehabilitation Pilot Project'.	

	Rolley, Salamonson, Dennison, & Davidson (2010, pp. 75–84)	**Aim:** To review the literature and update nurses on current PCI patient management and practices from admission to post-discharge. **Results:** • PCI journey highlighted as important; • Limited information and policy and procedure available on PCI patient nursing management; and • Shorter length of stay acts as a barrier to the provision of discharge education and secondary prevention information.	The authors encourage further nursing research so as to establish strong foundations and substantiate protocol development.

Appendix B: Cardiac Self-Efficacy (CSE) Questionnaire Sample Questions

How confident are you that you **<u>know</u>**:

1. When you should call or visit your Doctor about your heart disease?

    Responses: Not at all (0), Somewhat confident (1), Moderately confident (2),

    Very confident (3), Completely confident (4), N/A (9).

2. How to make your doctor understand your concerns about your heart?

    Responses: Not at all (0), Somewhat confident (1), Moderately confident (2),

    Very confident (3), Completely confident (4), N/A (9).

How confident are you that you **<u>can:</u>**

1. Control your breathlessness by taking your medications?

    Responses: Not at all (0), Somewhat confident (1), Moderately confident (2),

    Very confident (3), Completely confident (4), N/A (9).

2. Control your chest pain by taking your medications?

    Responses: Not at all (0), Somewhat confident (1), Moderately confident (2),

    Very confident (3), Completely confident (4), N/A (9).

Source: Sullivan, M. D., Lacroix, A. Z., Russo, J., & Katon W. J. (1988). Self-efficacy and self-reported functional status in coronary heart disease: A six-month prospective study. *Psychosomatic Medicine*. Copyright [1998] by the American Psychosomatic Society. Reprinted with permission.

Appendix C: State-Trait Anxiety Inventory For Adults Form Y2 Sample Questions

Question	**Responses**
d. I lack self-confidence (Y2)	Almost never (1)
	Sometimes (2)
	Often (3)
	Almost always (4)

Source: Spielberger, C. D. in collaboration with Gorsuch, R. L. Jacobs, G. A. Lushene, R., & Vagg, P.

R. (1983). The *State-Trait Anxiety Inventory for adults*. Menlo Park, CA: Mindgarden. Copyright

[1968, 1977] by Charles D. Spielberger. Reprinted with permission.

Appendix D: Cardiac Depression Scale Sample Sheet (CDS)

CDS

CHECK TO MAKE SURE YOU HAVE ANSWERED ALL QUESTIONS	Strongly Disagree — Strongly Agree	
1. I have dropped many of my interests and activities...	1 2 3 4 5 6 7 None dropped All dropped	
2. My concentration is as good as it ever was...	1 2 3 4 5 6 7 Very poor Concentration Excellent Concentration	
3. I can't be bothered doing anything much...	1 2 3 4 5 6 7 Keen to do things Can't be bothered	
4. I get pleasure from life at present...	1 2 3 4 5 6 7 No pleasure Great pleasure	
5. I am concerned about the uncertainty of my health...	1 2 3 4 5 6 7 Not concerned Very concerned	
6. I may not recover completely...	1 2 3 4 5 6 7 Will recover completely Will not recover	
7. My sleep is restless and disturbed...	1 2 3 4 5 6 7 Not restless Very restless	
8. I am not the person I used to be...	1 2 3 4 5 6 7 Just the same Completely different	

Appendix E: Coronary Artery Plaque

Source: The National Heart Foundation of Australia (2008). *Coronary angiography.*

Author. Copyright 2008, Reprinted with permission.

Appendix F: STEMI Management – 'A' Grade Recommendations

Table F1. **STEMI management**

	Management: 'A' Grade Recommendations

STEMI	Electrocardiogram:
	
	Reperfusion therapy for STEMI:
	
	    Consider early routine coronary angiography and revascularisation amongst patients receiving finbrinolysis, regardless of the success of pharmacologic reperfusion.
	
	    Antiplatelet therapies should be continued for 12 months after the insertion of drug-eluting stents.
	
	    The use of mechanical thrombectomy techniques to reduce thrombus burden during primary PCI should be considered. (Chew et al., 2011, p. 488).

Note. Adapted from Chew et al. (2011). 2011 "Addendum to the National Heart Foundation of Australia/Cardiac Society of Australia and New Zealand Guidelines for the Management of Acute Coronary Syndromes (ACS) 2006." by, *Heart, Lung, and Circulation, 20,* 487–502.

Appendix G: NSTEACS Management – Recommendations

Table G1.   **NSTEACS Management**

	Management: 'A' Grade Recommendations

NSTEACS	Antithrombotic therapy for NSTEACS:
	
	a. For all patients with high-risk NSTEACS, consider methods to reduce bleeding risk:
	   • Titrate antithrombotic agents to optimal dose for weight and renal function.
	b. For all patients with high-risk NSTEACS, assess bleeding risk individually according to the number and severity of bleeding risk factors.
	c. Use a standard management strategy for patients at low risk of bleeding:
	   • Choose the most effective antithrombotic regimen (e.g. prasugrel or ticagrelor). (Chew et al., 2011, p. 488).

Note. Adapted from Chew, D. et al. (2011). 2011 Addendum to the National Heart Foundation of Australia/Cardiac Society of Australia and New Zealand Guidelines for the Management of Acute Coronary Syndromes (ACS) 2006." by, *Heart, Lung, and Circulation, 20,* 487–502.

Appendix H: Access sites: Coronary artery catheterisation
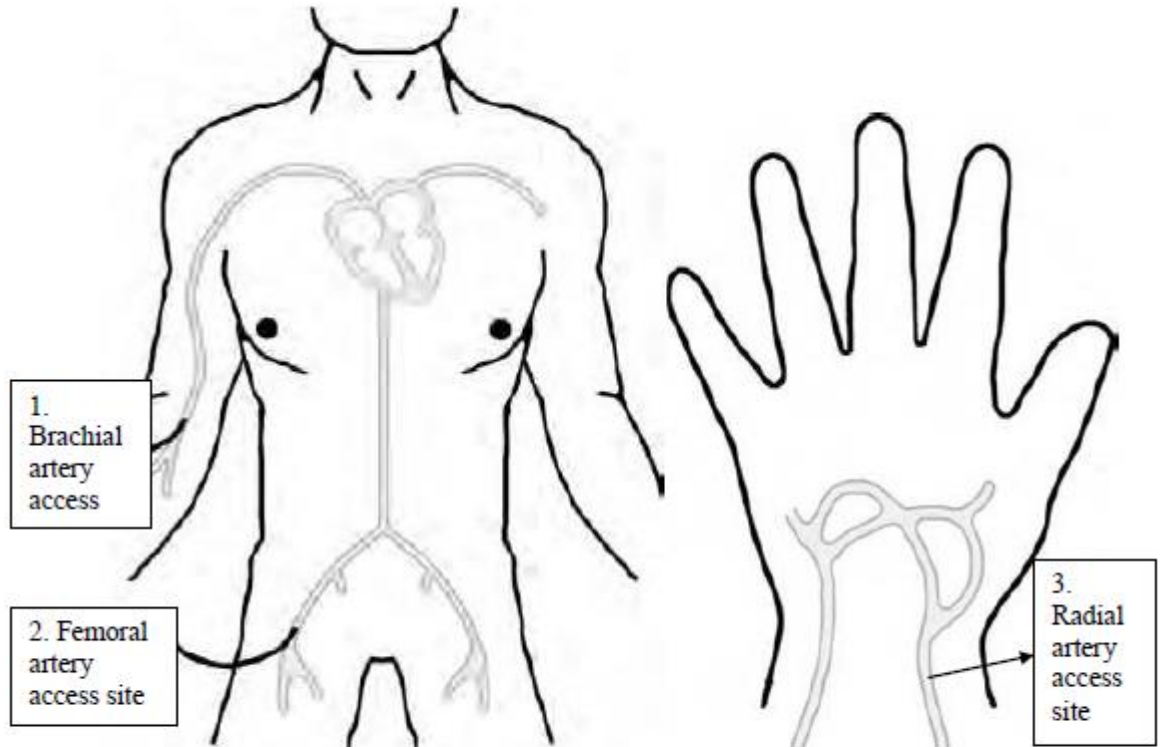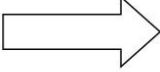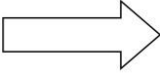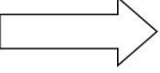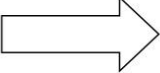
Adapted from O'Grady E. (2007). *A nurse's guide to caring for cardiac intervention patients* (p. 2). Chichester: John Wiley & Sons.

Appendix I: Efficacy and Outcome Expectations
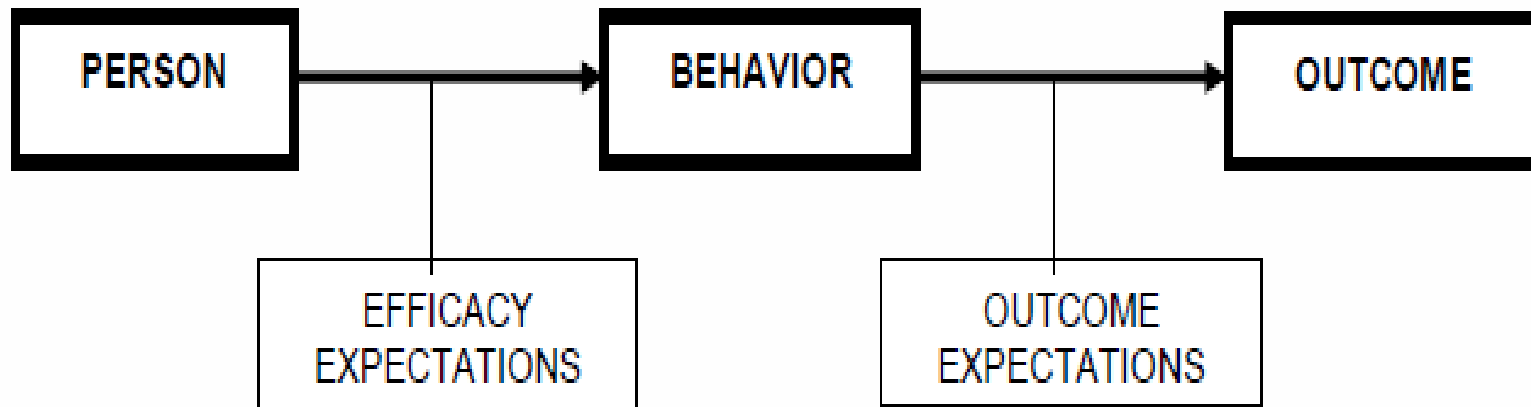
Source: Bandura, A. (1977). Self-efficacy: Toward a unifying theory of behavioral change. *Psychological Review*, *84*(2), 191–215.

Appendix J: Information Sources

SOURCE		MODE OF INDUCTION

PERFORMANCE APPCOMPLISHMENTS
1. Participant modelling
2. Performance desensitization
3. Performance exposure
4. Self-Instructed Performance

VICARIOUS EXPERIENCE
1. Live modelling
2. Symbolic modelling

VERBAL PURSUASION
1. Suggestion
2. Exhortation
3. Self-instruction
4. Interpretive treatments

EMOTIONAL AROUSAL
1. Attribution
2. Relaxation, biofeedback
3. Symbolic desensitization
4. Symbolic exposure

Source: Bandura, A. (1977). Self-efficacy: Toward a unifying theory of behavioral change. *Psychological Review*, *84*(2), 191–215.

Appendix K: Theoretical Framework – The 'REALITY CHEC' Project©

PATIENT FACTORS INFLUENCING SE
- **PHYSIOLOGICAL STATE OF HEALTH**
  - CHD
  - ANXIETY
- **PSYCHOSOCIAL SUPPORT**
  - WARD
  - CARDIOLOGIST
  - FAMILY/FRIENDS
  - OTHER (i.e. GP)
- **EDUCATION**
- **AGE**

SELF-EFFICACY (SE) or **EFFICACY EXPECTATIONS**

All participants (Different levels of SE)

*The patient's own beliefs of their ability to carry out a certain behaviour

INFORMATION SOURCE
- Performance attainment/ accomplishments
- Vicarious experience
- Verbal persuasion
- Physiological feedback / Emotional arousal

INTERVENTION GROUP

INTERVENTION: Education to increase SE and decrease anxiety.

Effect of intervention on OE an SSF

OUTCOME EXEPECTATIONS (OE):
Post-operative behaviours will lead to certain outcomes (i.e., attendance to CR will assist in post-PCI recovery)

SOCIO-STRUCTURAL FACTORS (SSF):
Facilitators & Impediments

Facilitators: Intervention; Good psychosocial support; High SE/EE; Physiological state of health

Impediments: Stress/Anxiety/Depression; Poor psychosocial support networks; Low SE/EE; Physiological state of health

GOAL SETTING

Some SCG participants with high SE

STANDARD CARE GROUP (SCG)

ROUTINE CARE & FOLLOW-UP
- OUTCOME EXPECTATIONS
- SOCIO-STRUCTURAL FACTORS

BEHAVIOUR/CHANGE(S) & OUTCOME(S)
- NO BEHAVIOUR CHANGE
- **OUTCOME:** Nil changes to health practices post-PCI; Nil improvements in health post-PCI; Nil improvements in SE and emotional state

BEHAVIOUR / CHANGE(S)
- Greater post-PCI knowledge
- Effective self-management
- Attendance and completion of CR
- Medication adherence
- Complication identification and management

OUTCOME(S) (Long term)
1. Increased SE
2. Reduced anxiety (about their CHD)
3. Effective self-management
4. Positive health behaviours
5. Health improvements

Adapted from: Bandura, A. (2004). Health promotion by social cognitive means. *Health Education & Behaviour*, *31*(2), 143–164, and

Corbin, J. & Strauss, A. (1988). *Unending work and care: Managing chronic illness at home*. San Francisco: Jossey-Bass.

Appendix L: Cardiac Nurse-led Clinics versus present Pilot Study

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
Authors: Cosette, Frasure-Smith, & Lesperance (2002) **Title:** Nursing approaches to reducing psychological distress in men and women recovering from myocardial infarction (MI) **Aim:** Investigation of nursing methods to reduce psychological distress in patients who have experienced an MI patients in the Montreal Heart Attack Readjustment Trial (M-HEART). **Participants**: $N = 1376$ • Intervention group: 692 • Standard care group: 684 **Design:** A secondary analysis of data set. **Methods**: **Monthly telephone calls** • Patients suffering	• Post-MI: Home-based psychosocial nurse-led intervention • Tailored to individual • Total of 6–7 hours nursing contact (i.e., home visitation and telephone follow-up) • Identification of causative variables of distress • Approaches: cognitive • Educational • Listening/Reassurance/Encouragement • Advice • Other: left contact telephone number if concerns <u>**Standard care group**</u> • Doctor follow-up **Results:** $n = 692$ • Nil effect on distress overall • Little effect on anxiety and depression in men ($p = 0.13$ and 0.061) • Nil effect on anxiety and depression in women ($p = 0.56$ and 0.66) • Nil effect on cardiac mortality in men ($p = 0.94$) • Cardiac mortality in women in intervention group ($p = 0.064$) (p.480)	<u>**Phase One:**</u> **Theoretical Framework:** • Bandura's Self-Efficacy (SE) Theory • **Intervention:** Face-to-Face visit • **Delivery:** Post-PCI At 5–7 days post-discharge from hospital • **Primary aim:** To determine if a nurse-led, Post-PCI clinic can enhance Self-efficacy (SE) and reduce anxiety • **Secondary aims:** Attending the nurse-led clinic may: • Reduce symptoms of depression • Facilitate effective self-management (i.e., medication adherence, wound-site care management, angina management) • Education provision (i.e., visual and verbal, and scenario provision); clinician physical assessment; primary assessment (i.e., Electrocardiogram, blood pressure, waist measurement,

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
psychological distress identified utilising 20-item General Health Questionnaire (GHQ) measured monthly. • GHQ scores ≥5 each month received at least two home visits	**Secondary analysis**: *n* = **431** • Evidenced an effect on half of participants in intervention group after the first two home visits. • Participants demonstrating short-term improvements evidenced enhancements in 1 year health outcomes and prognoses.	weight, temperature). • **Utilisation of:** active listening; providing feedback, health misconception clarification, participant questions. • **Multi-disciplinary team communication:** General practitioner or cardiology referral if required • **Telephone follow-up**: 1 month, 3 months post-discharge **Assessment and tools**: • State-Trait Anxiety Inventory (STAI) • Cardiac Self-efficacy Questionnaire (CSE) • Cardiac Depression Scale (CDS) • Morisky Medication Adherence Scale – 8 Item • (MMAS-8) • Self-report: diet, activity, weight, CR attendance **Phase Two: Evaluation of Phase One** • Semi-structured interviews • Recorded and transcribed interviews

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
		Participants: • Healthcare professionals and • Patients who undertook Phase One intervention
Authors: Lapointe, Lapage, Larrivée, & Maheux (2006) **Title:** Surveillance and treatment of dyslipidaemia in the post-infarct patient: Can a nurse-led management approach make a difference? *N* = 127 study participants **Aim:** To investigate the effects of nurse-led monitoring and treatment in lipid management to achieve national recommended reference ranges. **Design:** Randomised, open-label clinical trial.	**Method:** **Intervention group:** • Follow-up over 18 months • Telephone follow-up post-MI and some face-to-face contact with nurse-manager; • Quality of life (QOL) measurement (SF-36) • Nurse-led (communication with physician, dietician, pharmacist); • Measurement of lipid levels *First lipid measurement at 3 months post-discharge (*Regular measurement of lipids with close contact and monitoring by physician to ensure reference ranges were met). • When lipid reference ranges were met participants discharged from the intensive intervention and then reassessed at 12 and 18 months by a pharmacist to ensure medication compliance. • Total average time spent with nurse-manager for each intervention group participant ($\pm$ SD) 52.2$\pm$ 29.8 minutes.	

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
	Standard care group: • Follow-up over 18 months by a primary physician only • Total average time in contact with nurse-manager for each standard care group participant 19.3±15.5 minutes. **Results:** Nil effect demonstrated on lipids, QOL and long-term medication adherence in intervention group participants.	
Authors: Jones, & West (1996) **Title:** Psychological rehabilitation after myocardial infarction. N=2328 study participants **Aim:** Evaluation of the effect of rehabilitation post-MI **Design:** Randomised controlled clinical trial *Physicians, clinical psychologists, nurses, managers assisted in the study's design.	**Psychological interventions**: counselling, relaxation, stress management **Duration:** Seven 2 hour clinic sessions for both patients and partner's. Commenced 2–6 weeks post-hospital discharge over 12 months. **Methods**: Cardiovascular education to reduce anxiety and fears; generate awareness about stress and stressful circumstances; teach skill of relaxation; improve reactions and coping with stress; teaching optimism in response to illness; confidence building for both patient and partner. Sessions were undertaken directed by clinical psychologists and healthcare professionals. Patients encouraged to diarise and rehearse techniques in-between sessions. **Results**: Suggest little effect on anxiety, depression, morbidity, mortality, medication and disability. Clinical anxiety and depression remained unchanged at 6 months. Nil major differences between intervention and standard care groups as reported by the authors.	

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
Author: Mainie, Moore, Riddell, Adgey (2005) **Title:** To examine the effectiveness of a hospital-based nurse-led secondary prevention clinic (N=563) **Aims:** To assess and monitor cardiac patients with CHD/post-PCI /Post-MI/ post- CABG risk factors To determine the overall effectiveness of the hospital-based, nurse-led secondary prevention service on to risk factor modification and to enhance medial therapy. **Design:** Pilot study	**Method:** Hospital-based, nurse-led secondary prevention clinic visits to reduce risk factors for CHD **Baseline visit**: Full patient medical and family history Exercise status **Physical assessment**: blood pressure, height, weight, BMI, pathology **Health behaviours**: smoking status, alcohol consumption **Medications**: Prescription of new medications (if required) ***Referral to GP throughout the course of follow-up if required. **Results:** The clinic saw positive trends in reaching targets for the following areas: - Exercise - Blood pressure management - Smoking cessation - Alcohol consumption - Weight reduction - Cholesterol reduction (i.e., total and low density lipoprotein [LDL]) - Nurse-led clinics of benefit in secondary prevention	

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
	Recommendations: • Application in primary care setting • Utilisation in GP practice setting • 6 monthly or annual visits recommended for low risk patients • Referral for high-risk patients to clinic whenever required	
Authors: Campbell, Thain, Deams, Ritchie, Rawles, & Squair (1998) **Title:** Secondary prevention for coronary heart disease: randomised trial of effect on health (N=1173) Intervention group: *n* = 593 Standard care group: *n* =580 **Aim:** To determine the effect of the nurse-led secondary prevention clinic in patients with CHD versus GP management and standard care on: • General health and well-being (SF-36) • Anxiety and depression (HADS)	**Methods:** • Patients randomised from 19 general practice clinics and then separated into two groups • Participants randomised to standard care group or intervention group **Intervention and intervention group:** • Nurse and healthcare professional run secondary prevention clinic • Duration of 12 months • Data entry blinded **Standard care group**: • GP follow up only	

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
• Clinic attendance • Hospital readmission **Design:** RCT	**Results:** • Statistically significant health improvements evidenced in physical function and physical role SF-35scores (*P*=0.001) in intervention group participants • Improvements in angina in intervention group participants • Angina in standard care group worsened • Nil statistically significant changes in HADS scores • Statistically significance in hospital readmissions between groups at 12 month follow-up. Improvements evidenced in intervention group	

Authors: Moher, Yudkin, Wright, Turner, Fuller, & Schofield (2001)
 	
Title: Cluster randomised controlled trial to compare three methods of promoting secondary prevention of coronary heart disease in primary care
 	
Aim: To investigate three methods of secondary prevention to prevent CHD in primary healthcare in the community.
	Method: Randomised to attend nurse-led secondary prevention clinic, GP and audit group. Measurement of 3 risk factors: 1. blood pressure; 2. cholesterol; and 3. smoking status. Medication prescription and pathology were undertaken. Follow-up over 2 years.
	
	Intervention and groups:
	1. Nurse-led recall group –
	  • advised of the patients to approach
	  • establishment of disease register
	  • methodical recall of patients to nurse-led clinic
	2. GP recall group – advised of the patients to approach
	  • establishment of disease register	

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
Design: Pragmatic, unblinded cluster RCT	• methodological recall of patients to GP clinic **Standard care group:** Audit group –received audit data Received standard care with no additional support **Results:** Statistically significant assessment of all groups (*P*= <0.001) • effectiveness in nurse-led recall assessment of participants (*P*=<0.004) • Statistically significant improvements in blood pressure in both intervention groups (*P*=<0.001) • Statistical significance in all groups for cholesterol level assessment (*P*=<0.001) • Independent analysis between GP recall and nurse-led recall group demonstrated greater • Statistical significance in cholesterol levels between nurse-led recall group and audit group • Statistical significance in cholesterol levels between GP recall group and audit group (*P*=<0.001) • For cholesterol level management, both nurse-recall and GP recall groups equally as effective • Statistical significance evidenced in reduction in smoking in participants in both intervention groups (*P*=<0.001) • Nurse-led recall group demonstrated statistical significance in the increase in the prescription of cholesterol lowering medication treatment.	

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
Authors: Jolly et al. (1999) **Title:** Randomised controlled trial of follow up care in general practice of patients with myocardial infarction and angina: final results of the Southampton heart integrated care project (SHIP) **Aim:** To investigate the effectiveness of a nurse-led follow-up and liaison with general practice nurses post-MI ($n = 422$) or angina diagnosis ($n = 175$) **Design:** RCT, stratified randomisation to groups	<u>**Methods**</u> **Intervention:** Liaison nurses to enhance communication between general practice nurses to enhance hospital-general practice communication and coordinated patient follow-up • Liaison nurse contact with GP clinic or clinic nurse (if available) on patient's discharge from hospital to arrange first follow-up appointment and patient care • GP clinic nurses encouraged to call liaison nurse to discuss issues (i.e., clinical, organisational) • Participants or family members given a clinical pathway for post-discharge care for GP • Liaison nurse support to GP practice at 3–6 months post-discharge (i.e., visits and telephone calls) • Clinic nurses attendance of courses for behaviour change, and support for educative needs • Patients given records to direct follow-up **Outcome measures:** • total cholesterol • blood pressure • six minute walk test distance • smoking and cessation • BMI **Follow-up:**	

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
	- Independently undertook questionnaire - Questionnaire tools: HADS, EuroQol visual analog scale 1 month, 4 months, and 12 months 12 months – assessment of lifestyle factors, cardiac rehabilitation, utilisation of additional resources, chest pain, psychological distress and independent liaison nurse follow-up and assessment (different to intervention liaison nurse). A parallel qualitative study undertaken to explore participants' experiences of MI and their care **Results:** - Nil significant effects were evidenced on outcome measures - Demonstrated effectiveness in encouraging follow-up in general practice post-discharge	
Authors: Lewin et al. (2002) **Title:** A randomised controlled trial of a self-management plan for patients with newly diagnosed angina. **Aim:** To investigate the	**Methods:** - Follow-up of 142 participants over 6 months - Patients randomised to study groups and given a self-help manual or education group, plus additional information books **Self-management group:** Self-help manual plus; 20 minute audio relaxation program for patient and partner; 30–40 minute nurse-interview;	

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
effectiveness of angina management plan by practice nurse versus educational program **Primary outcome:** Anxiety and depression **Secondary outcomes: Diarised angina –** severity, duration, episodes, number of GTN tablets or sprays consumed. Quality of life (QOL) – Seattle Angina Questionnaire (SAQ) **Design:** Blinded RCT	identification of angina misconceptions and nurse correction **Education group:** Coronary heart disease risk factor identification; and education regarding the reduction, and participant education package. **Results:** • Participation in the self-management group demonstrated greater effects on anxiety and depression; less episodes of angina; used less GTN spray; and saw significant enhancements in physical limitation as measured by the SAQ (P=<0.001)	
Authors: Koelewijn-van Loon et al. (2009) **Aim:** To investigate participant involvement in nurse-led risk-management programs on adherence to lifestyle changes and cardiovascular risk. **Title:** Involving patients in cardiovascular risk management with nurse-led clinics: a cluster randomized controlled trial	**Methods:** Nurse-led risk assessment, management and risk communication; decision support and motivational interviewing in risk reduction. **Assessment and follow-up:** At baseline and 12 months **Intervention group:** **Practice nurses:** • Received 2 days of intense training concerning a. risk assessment; b. risk communication; c. decision support; d. motivational interviewing **Intervention group participants:** • Two 15–20 minute, face-to-face sessions at GP clinic with practice nurse	

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
(*N* = 615) **Design:** Cluster RCT, block randomisation.	**Standard care group:** **Nurses:** Received 2 hours of risk assessment training **Standard care group participants**: risk assessment (10 year) and usual care **Results:** • Nil significant effects of attending the nurse-led clinic and techniques utilised • Nil effects of nurse-led clinic on cardiovascular risk at 10 years	
Authors: Lisspers et al. (1999) **Title:** Multifactorial Evaluation of a Program for Lifestyle Behavior Change in Rehabilitation and Secondary Prevention of Coronary Artery Disease **Aim:** To investigate the effects of a secondary prevention and rehabilitation intervention on lifestyle behavioural change in patients with coronary heart disease over 12 months **Participants:** *N* = 292 • Recent CABG, PCI and acute myocardial	**Methods:** • 12 month rehabilitation and secondary prevention program **Phase One:** • 4 weeks as inpatient stay in a unit to undertake intervention • In-depth education concerning: health education, behaviour change, lecture attendance, discussion, practical component on exercise, stress management, smoking • Group (5–8 participants) and individual education • Each participant assigned an RN to act as a personal coach (i.e., structured interviews) and to motivate and facilitate behaviour change • Stress and lifestyle profile assessment tools utilised • Goal setting undertaken	

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
infarction (AMI) **Design:** Evaluation study	**Phase Two:** • Maintenance phase – 11 months • Regular follow-up with RN coach to reflect on Phase One goal setting and behaviour change • Participant recoded and discussed all aspects of their lifestyle and behaviour change (i.e., self-reporting, self-observation) with their coach • Assessment of health related quality of life (HRQOL) utilising AP-QLQ questionnaire • Type A behaviour assessment – Bortner Type A index; HALTAM questionnaire • Cynical distrust, anger (Anger Expression Scale; State-Trait Anger Scale [STAS]), anxiety (STAI), and depression assessment (Beck Depression Inventory [BDI]) • Assessment for angina and physical exertion: electronic braked bicycle ergometer (angina, shortness of breath and leg discomfort) **Results** (*p =<0.05*) Statistically significant results achieved in following areas: • Quality of life • Symptoms • Exercise capacity • Triglycerides • Cholesterol • BMI • Items of anger, hostility • Depression	
Authors: Vale, Jelinek, & Best	**Methods:**	

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
(2005) **Title:** Impact on coaching patients on coronary risk factors: Lessons from The COACH Program **Total participants** $N = 792$ **Intervention group:** $n = 398$ **Standard care group:** $n = 394$ **Aims:** To investigate if a coaching program may have an effect on total cholesterol and cardiac risk factors in patients with coronary heart disease **Primary outcome:** To achieve a reduction in total cholesterol from baseline visit to 6 month follow-up **Secondary outcomes:** • Fasting triglycerides • Blood pressure • Fasting glucose readings • Weight (self-report) • Smoking status (self-report) • Dietary consumption (self- report of fats,	• **Visit 1:** Telephone follow-up at two weeks post-randomisation to group (30 minutes) • **Visit 2–4:** A further 3 telephone follow-up coached calls every 6 weeks (20 minutes) • **Visit 5:** At 24 weeks to organise 6 month appointment **Standard care group**: • Usual care with medical practitioner • Medical practitioner and patients given hospital discharge summary and details on risk factor targets as COACH patients given • Contacted at 24 weeks only for follow-up appointment **Results:** The COACH program had a statistically significant effect on: • Mood, health and increased uptake of walking ($p = <0.0001$) • Total cholesterol ($p = <0.0001$) • Fasting lipids: LDL-cholesterol ($p = <0.0001$) • Cholesterol: LDL-C ($p = <0.0001$)	\

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
cholesterol and fibre consumption) • Activity status (i.e., walking self-report) • Anxiety and depression: • measured by the STAI and CDS **Design:** Multicentre, RCT		
Authors: Jiang, Sit, & Wong (2007) **Title:** The Effect of a Nurse-led Cardiac Rehabilitation Programme on Coronary Heart Disease in Chengdu, China **Aim:** To investigate the effectiveness of a 12-week hospital-initiated home-based cardiac rehabilitation program for patients with coronary heart disease in China **Participants:** $N = 167$ **Design:** RCT	**Methods: 12 Week CR program** **Data collection:** • Baseline, 12 Week follow-up, and programme conclusion **Intervention:** • Supported cardiac rehabilitation at home • Medication management • Angina management • Physical activity • Nutrition • Support systems (i.e., families) **Standard care:** Usual follow-up and care **Outcomes:** • Cardiovascular risk • Angina	

Study/Authors/Aim/Design	Intervention versus Standard Care Group	Comparison: Present Pilot Study
	• GTN use • Health behaviour • QOL • Unexpected utilisation of healthcare system (i.e., cardiovascular consultations) **<u>Results</u>** Statistical significance achieved in following areas: • Medication adherence • Physical activity • Diet • Cholesterol levels • Lipid levels • Blood pressure control • Reduced angina episodes • Reduced consumption of GTN • Enhanced QOL: Six SF-36 items (i.e., general health, mental health, physical functioning, role physical, vitality) • Reduction in medical reviews related to cardiovascular health	

Appendix M: The 'REALITY CHEC' Project© – Three Arm RCT_OCTOBER_12_2011

Satisfy Inclusion Criteria:

Day of discharge; Post PCI; Primary and elective patients; 18 years of age and over

Consent & Randomisation (n=300)

Baseline measurements:

Vital signs; ECG; Chest pain assessment (CP); Access site;

Saliva Specimen (Cortisol); STAI; CDS; & MMAS-8.

Day 5-7: Post-discharge

Day 5-7 post-discharge

Face-to-face group (n=100)

a. STAI; & CDS

b. Access site and neurovascular assessment (digital photograph);

c. ECG

d. CP assessment and management;

e. Complications;

f. Medication discussion;

g. Morisky Medication Adherence Scale (MMAS-8 Item)

h. Medication compliance and management;

i. Cardiac rehabilitation (CR) appointment and tracking;

j. Researcher questions; &

k. Participant questions.

Day 5-7 post-discharge

Telephone follow-up (n=100)

a. STAI; CDS

b. Photograph of access site to be forwarded via mobile phone or picture diagram;

c. CP assessment and management;

d. Complications;

e. Medication discussion;

f. MMAS-8;

g. Medication compliance and management;

h. Cardiac rehabilitation (CR) appointment and tracking;

i. Researcher questions; &

j. Participant questions.

At 5-7 days post-discharge (n=100)

Control/Standard care group

a. Standard education and follow-up;

b. STAI; CDS; CP; Access site assessment; Complications;

c. MMAS-8 (via telephone);

d. Cardiac rehabilitation (CR);

e. Researcher questions; &

f. Participant questions.

At 3 months post-PCI:

Track: Stress / Anxiety / Depression

CR commencement; Cardiology review; Complications; CP.

At 3 months post-discharge:

Telephone Follow-up:

Saliva specimen; STAI; CDS; CP; Complications; MMAS-8; CR; Researcher questions; & Participant questions.

At 3 months post-discharge

Telephone Follow-up:

Saliva specimen; STAI; CDS; CP; Complications; MMAS-8; CR; Researcher questions; & Participant questions.

At 3 months post-discharge

Telephone Follow-up: Saliva specimen; STAI; CDS; CP; Complications; MMAS-8; CR; Researcher questions; & Participant questions

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At 12 months post-PCI

Tracking: CR attendance;

Complications; Readmissions;

Stress/Anxiety/Depression

At 12 months post-discharge:

Telephone follow-up:

STAI; CDS; CP; Complications; MMAS-8; CR; Researcher questions; & Participant questions.

At 12 months post-discharge

Telephone follow-up:

STAI; CDS; CP; Complications; MMAS-8; CR; Researcher questions; & Participant questions.

At 12 months post-discharge

Telephone follow-up: STAI; CDS; CP; Complications; MMAS-8; CR; Researcher questions; & Participant questions

Appendix N: Participant Packs for The 'REALITY CHEC' Project©

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OIC 5-7 1 min 3 mths

Appendix O: Study Protocol

The 'REALITY CHEC' Project© – Study Protocol _2012_V2_ ACTRN: 12612000971831

Satisfy Inclusion Criteria:
Day of discharge; Post-PCI; Primary and elective patients; 18 years of age and over

Consent
Baseline measurements:
Vital signs; ECG; Chest pain assessment (CP); Access site; Saliva Specimen (Cortisol); STAI; CDS; CSE Scale; & MMAS-8.
Randomisation

Day 5-7: Post-discharge

Day 5-7 post-discharge
Face-to-face group
a. STAI; CDS ; CSE Scale;
b. Access site and neurovascular assessment (digital photograph);
c. ECG
d. CP assessment and management;
e. Complications;
f. Medication discussion:
g. Morisky Medication Adherence Scale (MMAS-8 Item)
h. Medication compliance and management;
i. Cardiac rehabilitation (CR) appointment and tracking;
j. Researcher questions; &
k. Participant questions.

At 5-7 days post-discharge
Standard care group
a. Standard education and follow-up;
b. STAI; CDS; CP; CSE Scale; Access site assessment; Complications;
c. MMAS-8 (via telephone);
d. Cardiac rehabilitation (CR);
e. Researcher questions; &
f. Participant questions.

At 1 month post-PCI:
Stress / Anxiety / Depression; CR commencement; Cardiology review; Complication(s); Readmission(s)

At 1 month post-discharge:
Telephone Follow-up:
Saliva specimen; STAI; CDS; CSE Scale; CP; Complications; MMAS-8; CR; Researcher questions; & Participant questions.

At 1 month post-discharge
Telephone Follow-up: Saliva specimen; CSE Scale; STAI; CDS; CP; Complications; MMAS-8; CR; Researcher questions; & Participant questions.

At 3 months post-PCI
Stress / Anxiety / Depression CR attendance; Complication(s); Readmission(s).

At 3 months post-discharge:
Telephone follow-up:
STAI; CDS; CSE Scale; CP; Complications; MMAS-8; CR; Researcher questions; & Participant questions.

At 3 months post-discharge
Telephone follow-up:
STAI; CDS; CSE Scale; CP; Complications; MMAS-8; CR; Researcher questions; & Participant questions .

Phase Two
1. Evaluation of Phase One;
2. Semi-structured interviews;
3. Healthcare professionals; &
4. Intervention group participants.

ECG: Electrocardiogram
STAI: State-Trait Anxiety Inventory

CSE: Cardiac Self-Efficacy
CP: Chest Pain
CDS: Cardiac Depression Scale

CR: Cardiac rehabilitation
MMAS-8: Morisky Medication Adherence Scale – 8 Item

Randomisation no:
ACTRN:12612000971831

The REALITY CHEC Project©
DATA COLLECTION FORM VERSION no. 9.1, 2012

Appendix P: Data Collection Form (DCF) The 'REALITY CHEC' Project©

PCI Clinic – Data Collection Form (DCF) ©　　　　**Date__/__/2012/2013**

Section 1:

Criteria	Tick Yes or No	
Inclusion Criteria		
Age of 18 years and over	Yes □	No □
Informed consent for primary or elective PCI signed by patient and cardiologist	Yes □	No □
Undergone primary or elective PCI	Yes □	No □
Understand or speak English language	Yes □	No □
Post-discharge telephone access (mobile phone and / or landline)	Yes □	No □
Exclusion Criteria		
Child or young person (i.e., <18 years of age)	Yes □	No □
Unable to understand or speak the English language	Yes □	No □
Overseas resident returning to home country	Yes □	No □
Overseas resident on holiday in Australia for less than 12 months	Yes □	No □
Suffering a mental illness and: 1. Unable to legally consent 2. Unable to weigh the risks and benefits of participation 3. Unable to make informed decisions	Yes □ Yes □ Yes □	No □ No □ No □
Pregnant	Yes □	No □
In existing dependent or unequal relationship	Yes □	No □
Highly dependent on medical care	Yes □	No □
No telephone communication access	Yes □	No □
Consent signed for participation in: The 'REALITY CHEC' Project	Yes □	No □

	Randomisation no:
	ACTRN:12612000971831

The REALITY CHEC Project©
DATA COLLECTION FORM VERSION no. 9.1, 2012

Section 2: Demographics / Patient History

	Details
Name	
Date of birth	
Sex	Male / Female
Address	
SEIFA: Socio-Economic Indexes for Areas (Post code)	
Mobile phone	
Home phone	
e-mail address	
Country of birth (COB)	
Primary language spoken	
Highest level of education	Primary/Secondary/Tertiary/Certificate/Diploma/Other Document other: _____ _____ _____ _____
Marital Status	Single/Married/De Facto/ Separated/Divorced/Widowed
Local Hospital Name	

Distance to local hospital from home (km) (approximate)	_____km	
Study Enrolment Notification	Please tick Yes or No	Communication source
Cardiologist	Yes ☐ No ☐	Writing ☐ e-mail ☐
GP	Yes ☐ No ☐	Writing ☐ e-mail ☐

Emergency Contact	Name:_____ H:_____ M:_____
Cardiologist (s)	Name:_____ Address:_____ Phone: _____ Mobile phone:_____ e-mail:_____
General Practitioner	Name:_____ Address:_____ Phone:_____ Mobile phone:_____ e-mail:_____

	Randomisation no: ACTRN:12612000971831

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Cardiac Rehabilitation Unit NOTE: If after 3 month follow-up standard care group are not referred to CR, follow-up with hospital site.	Name:_____ Address:_____ Phone:_____ Mobile phone:_____ e-mail:_____

Procedure	Percutaneous transluminal coronary angioplasty / Coronary artery stents / Directional coronary atherectomy/ Rotational atherectomy Emergency / Elective (***Researcher to please circle***) Combination:_____ Notes:_____ _____

Medical History:

Medical History	Details	Additional Information
_____ _____ _____ _____	_____ _____ _____ _____	_____ _____ _____ _____

Risk factors:

Risk Factors	Details	Additional Information
Non-modifiable, modifiable and cardiac risk factors		
Age	Yes / No (DOB documented above)	
Sex	Male / Female (As above)	
Family History	Yes /No	
Hypertension	Yes / No	See: Australian Institute of Health and Welfare (2010). Chapter 3 *Australia's Health.*

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Conditions		
Chronic kidney disease: Yes / No (Please circle)		
Atrial Fibrillation: Yes / No (Please circle) (New or previous history of)		
Family history: Hypercholesterolaemia Yes / No (Please circle)		
Cholesterol	a. Yes / No b. mmol/L	See: Australian Institute of Health and Welfare (2010). Chapter 3 *Australia's Health*.
Smoking	History of smoking? How many cigarettes/cigars/ pipes ***did you*** smoke per day/wk (approximate)? Do you currently smoke? Number of cigarettes currently smoked:	Yes/No (please circle) _____ per day/wk (please document) N/A (For non-smoker) Yes/No/N/A (please circle) _____ per day/wk (please document) (n/a for non-smoker)
Alcohol consumption	History of alcohol consumption (have you ever consumed alcohol)?	Yes/No (please circle)
	How many standard drinks of alcoholic beverages would you consume per day (approx)?	_____ per day/wk/N/A (please document)
	Do you currently consume alcohol?	
	Number of standard alcoholic beverages:	Yes/No/N/A (please circle) _____ per day/wk /N/A(please document)

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Stress	Yes/No	
Diabetes	a. Yes/No b. Type 1 c. Type 2	Control of blood glucose levels (i.e., what are current readings like and description): **mmol/L**:_____ **Description**:_____
Weight	kg	
Height	cm	
BMI	Yes/No kg/m2	
Hip to Waist ratio (*WHO STEPS on measurement*)	H: ____cm W: ____ cm	Give patient measuring tape to take home for consecutive measurements. Recommend taking first thing in the morning before breakfast (as cited in World Health Organization (2009).
Activity / Exercise	None / light / moderate / heavy	Comments: _____

Dietary intake	Daily intake	Breakfast	
		Morning tea	
		Lunch	
		Afternoon tea	
		Dinner	
		Dessert	
		Snacks/Other (i.e., Meal supplements)	

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<u>**Section 3**</u>: **Assessment**

Salivary cortisol assay (Researcher to demonstrate collection to participant before collecting sample).
Note: Patient pack to include 1 salivette, 1 reply paid envelope, 1 plastic zip lock bag and written instructions.

<u>**Visit**</u>	**Sample taken** *(Please tick if taken and date)*	**Sample received by laboratory** *(Please tick and date)*	**Salivary cortisol**
Day of discharge	☐ / / **2012/2013**	☐ / / **2012/2013**	_____**ug/dl**

Cardiac Self-Efficacy Questionnaire (CSE) – Attach completed tools to this document

<u>**Visit**</u> **Total score**	**Score: Control symptoms (CS)**	**Score: Maintain Functioning (MF)**	<u>**Actions**</u>
Day of discharge	_____	_____	_____ _____ _____ _____

State -Trait Anxiety Inventory (STAI) – Attach completed tools to this document

Visit	**State Score**	**Trait Score**	**Actions**
Day of discharge	State Anxiety:_____	Trait Anxiety:_____	_____ _____ _____

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Cardiac Depression Scale (CDS) – Attach completed tools to this document

Visit	**Score**	**Actions**
Day of discharge		_____ _____ _____

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Section 4: Access site assessment

Please indicate on diagram below with a circle and/or attach photo of site if available and patient consent given. Participants to draw / shade in how they view their access site. Please give participant 3 diagrams to take home for follow-up (present in patient packs.)

Access-site assessment tool (O'Grady, 2007, p. 2).

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Access Site Assessment	
Access site: Femoral artery / Radial artery / Brachial artery / Combination (i.e., radial for angiogram and femoral for PCI) (*Please Circle*)	
Haematoma (now on assessment)	a. Yes / No (*Please circle*)
	b. Haematoma diagnosed pre-enrolment: Yes/No (See medical chart notes for documentation if haematoma observed)
If yes:	Size ___:___cm (new diagnosis) Size of pre-diagnosed haematoma: ____:____cm
Description:	_____ _____ _____ _____
Action(s): New haematoma or pre-diagnosed requiring attention	_____ _____ _____ _____
Bleeding	New: Yes / No
	Pre-enrolment bleeding: Yes/No (Refer to documentation in medical notes)
If yes	a. New: Amount of blood present _____ml b. Pre-enrolment documented bleed: _____ml or c. Pre-enrolment bleed: Volume not documented (please circle)
Description	_____ _____ _____ _____ _____
Action(s)	_____ _____ _____ _____ _____
Bruising	Yes / No
	Pre-enrolment documented bruising: Yes / No
Size of bruise	New bruising: **Length**:_cm **Width**:_cm a. Pre-enrolment documented: **Length** _____cm **Width**: _____cm b. Pre-enrolment bruise: Size not documented (please circle)
Colour(s)	
Action(s)	_____ _____

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Bruit	Diagnosed pre-enrolment and documented in patient's medical notes (*Please circle*) Yes / No
	New Bruit: Yes / No
If new bruit:	Action:_____ _____ _____ _____ _____ _____
Site Pain	**New**: Yes / No (*Please circle yes or no*) **Pain rating**: 0 1 2 3 4 5 6 7 8 9 10 (0 = Nil pain, 10 = Most severe)
	Pre-reported pain (To RN/Doctor): Yes/No (*Please circle*) **Pain rating**: 0 1 2 3 4 5 6 7 8 9 10 (0 = Nil pain, 10 = Most severe)
If patient experiencing pain: Describe pain and RN actions taken.	**Action**:_____ _____ _____ _____ _____ _____ _____
Arterial sheath removal	**Type of pressure**: Digital / Femstop / TR Band/ Radistop/ Other _____ (*Please circle*)
Time to haemostasis	Minutes
Complication (s) related to sheath removal (i.e., vasovagal episode, bleed, haematoma post removal) (in hospital) Yes / No (*Please circle*)	
Complication(s) detail	_____ _____ _____
Closure device	Yes / No (*Please circle*)
Type of closure device	_____
Closure device complication(s) (in hospital – see medical notes) Yes / No/N/A (*Please circle*)	
Complication (s) detail	_____ _____
Access Site Inflammation / Signs of Infection	
Heat at site	Yes / No
Redness	Yes / No
Ooze	Yes / No

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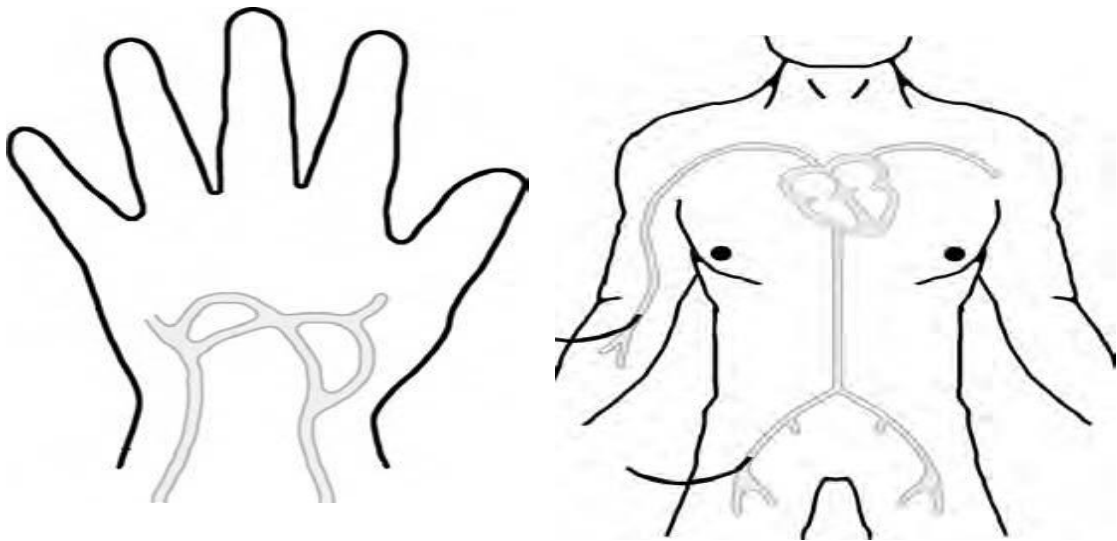| Odour	Yes / No
Signs of inflammation / infection noted pre-enrolment: Yes / No	
Description	_____ _____

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Wound Assessment and Management Tool

Assessment and Continuation Chart
How to use the Continuums

STEP ONE - THE WOUND HEALING CONTINUUM

The Wound Healing Continuum is an aid to understanding the type of tissue present in a wound and how it should progress. Thought of as a continuum of colour changes (see the diagram below) from black to pink, it correlates with the healing of the wound. Not all wounds progress across the whole spectrum (for example not all wounds will have a black stage).

THE WOUND HEALING CONTINUUM

BLACK	BLACK/YELLOW	YELLOW	YELLOW/RED	RED	RED/PINK	PINK
6	5	4	3	2	1	0

Using the Wound Healing Continuum

Identify the colour of the wound that is furthest to the left of the continuum. For example, if the wound contains yellow slough and red granulating tissue it would be defined as a yellow/red wound. The management plan would focus on removal of the yellow sloughy tissue and promotion of the red granulation tissue. As this objective is achieved, so the patient can progress along the wound healing continuum towards the right and therefore pink/healing status.

STEP TWO - THE WOUND INFECTION CONTINUUM

The Wound Infection Continuum is an aid to understanding the level of bacteria present in the wound. There are four criteria which work from left to right with the most severe, Spreading Wound Infection on the left (see diagram below). The continuum moves right, through Local Infection, Critical Colonisation to Colonisation.

Spreading infection can be a life threatening condition. Local signs and symptoms associated with a spreading soft tissue infection include; spreading redness [greater than 2cm around the wound margin], very high exudate levels, pain, malodour, heat in the surrounding tissues and blistering. Localised infection is characterised by less than 2cm of redness around the wound margin symptoms similar to spreading infection may also be present but to a lesser degree. Critical Colonisation is characterised by delayed healing, malodour and raised exudate levels; slough may also be present. However the wound will not present as if locally infected.

A Colonised Wound is the normal healing state of a wound healing by secondary intention; a reduction in the wound size over a two week period would suggest an acceptable level of colonisation.

SPREADING INFECTION	LOCAL INFECTION	CRITICAL COLONISED	COLONISED
3	2	1	0

Using the Wound Infection Continuum

The Wound Infection Continuum is a simple sliding scale which can be used as an aid to clinical decision-making regarding the level of bacterial colonisation of a wound. A patient may never move to the furthest point on the right (Colonisation) on the continuum during their entire treatment.

However, lower bacterial levels found in colonised wounds generally lead to better healing. The status of a wound which has a Spreading Infection, a Localized Infection or a Critically Colonised wound should be considered when developing a wound management plan.

STEP THREE - THE WOUND EXUDATE CONTINUUM

The Wound Exudate Continuum is an aid to quantifying wound exudate. The viscosity as well as the volume of the exudate can be an important indicator of a wound's status. The gradings are High, Medium and Low for both and this allows wound exudate to be categorised by a score (see diagram below). For example, a low volume of medium viscosity would be a Low/Med category and would score 4, placing it in the Low Exudate portion of the continuum.

Any wound assessed as having both high viscosity and high volume of wound exudate would score a full 10 points and be regarded as giving serious concern. It is likely that such a wound indicates a Spreading Infection, a sinus or a fistula formation or some other cause for concern. Any wound scoring 6 points would be regarded as requiring regular review. It may be that this finding is entirely consistent with the treatment applied e.g. the liquefying of wound slough. The wound may previously have been scored in the Red Zone and as such a score of 6 would indicate an improvement.

Using the Wound Exudate Continuum

When reviewing the wound, the exudate on the dressing and present in the wound should be assessed along with information relating to the number of dressing changes required over a 48-hour period.

VOLUME	VISCOSITY		
	HIGH 5	MEDIUM 3	LOW 1
HIGH 5			
MEDIUM 3			
LOW 1			

Where a wound previously scored as 2-4 points and is observed to be in the Amber Zone (scoring 6 points) it may be showing early signs of Critical Colonization or the development of outright infection and should be treated appropriately.

Source: Wounds UK (2010). *Applied wound management: Assessment and continuation chart.*

Retrieved from http://www.wounds-uk.com/pdf/content_8973.pdf

Wound Assessment and Management Tool

Applied Wound Management
Assessment and Continuation Chart

Patient Identity	Date	Chart completed by		
Patient Address	Unit No.	GP/Consultant		
	D.O.B / /	Consent to images (circle appropriate)	YES	NO
	Location	Date next assessment required		

Front   Back

**INITIAL ASSESSMENT -
TYPE AND LOCATION OF WOUND**

Type of wound/s

Location of wound/s

Wound pain present - YES ☐   NO ☐

CONTINUAL ASSESMENT - THE HEALING ZONE
Please enter a cross from the total scoring of the two step continuums to see the overall healing progress of the wound.

Asesment 1 Asesment 2 Asesment 3 Asesment 4 Asesment 5 Asesment 6 Asesment 7 Asesment 8 Asesment 9 Asesment 10

wound healing and wound infection continuums

High 9
8
7
6
5
4
3
2
1
Low 0

HEALING ZONE

Source: Wounds UK (2010). *Applied wound management: Assessment and continuation chart*. Retrieved from http://www.wounds-uk.com/pdf/content_8973.pdf

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<u>Wound Assessment and Management Tool</u>

Source: Wounds UK (2010). *Applied wound management: Assessment and continuation chart*.

Retrieved from http://www.wounds-uk.com/pdf/content_8973.pdf

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Section 5: **Neurovascular check (Bilateral assessment)**

Neurovascular Chart					
Name:		**Ward:**	**Hospital no:**		
Consultant:			**Procedure/Injury:**		
Area for observation:			**Frequency of Observations:**		
Date:			Right	Left	Comments
Time:					
Pain Score (1–10):					
Colour	Normal				
	Pale*				
	Cyanotic*				
	Mottled*				
Warmth	Hot*				
	Warm				
	Cold*				
	Cool*				
Pulses	Name of pulse:				
	Strong				
	Weak*				
	Absent*				
Capillary refill greater than 2 seconds (yes/no)					
Movement					
Dorsi flexion	No movement*				
	Movement, no pain				
	Movement with pain*				
Plantar Flexion	No movement*				
	Movement, no pain				
	Movement with pain*				
Toe extension	No movement*				
	Movement, no pain				
	Movement with pain*				
Toe flexion	No movement*				
	Movement, no pain				
	Movement with pain*				
Sensation					
Web space First and second toe	No sensation*				
	Tingling/numbness*				
	Full sensation				
Web space third and fourth toe	No sensation*				
	Tingling/numbness*				

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	Full sensation			
Sole of foot/toes	No sensation*			
	Tingling/numbness*			
	Full sensation			
Arch of foot (medial)	No sensation*			
	Tingling/numbness*			
	Full sensation			
Initials				

Always compare with the unaffected limb. If both limbs are affected, use a separate chart for each limb.

*These may be signs of abnormalities, take appropriate action, document and inform a member of the medical team. Document all actions taken in the space below.

Changes present now: Yes ☐ No ☐ *(Please tick)*
Affected limb(s): Right upper/Right lower/Left upper/Left lower *(Please circle)*

Actions:_____
_____
_____
_____
_____
_____
_____
_____

Judge, N. L. (2007). Neurovascular Assessment. *Nursing Standard, 21*(45), 39–44.

Neurovascular complications pre-enrolment: Yes/No (Please circle)
Details:_____
_____
_____
_____

Section 6: Vital Signs (All participants: Day of discharge from hospital)

Vital signs	Reading
Blood Pressure (BP)	/ mmHg
Heart Rate (HR)	beats per minute (bpm)
Temperature	°C (Taken above in access site assessment)
Respirations	Respirations per minute (rpm)
Oxygen Saturation	_____ %
ECG *(Please tick)*	
Photocopy ECG from medical chart (Taken ≤24 hrs)	**Normal Sinus Rhythm ☐**
	Sinus bradycardia ☐ Sinus tachycardia ☐ Sinus Arrhythmia ☐
	Atrial Fibrillation ☐ Atrial Flutter ☐
	Paced Rhythm ☐ Sinus rhythm 1st Degree Heart Block ☐

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	Sinus rhythm 2nd Degree Heart Block ☐ **Complete heart block** ☐
	Other Rhythm ☐ (*Please document the rhythm in space provided*) _____

Section 7: Chest pain assessment, education & management plan

	Details	**Action(s)**
Chest Pain / Discomfort	**Yes / No**	_____ _____ _____ _____

a. If no, below not applicable: N/A (Please circle)

b. If yes, follow this pathway in conjunction with specific risk protocol (i.e., XXX or

XXX):

	Description
Pain **Sensation(s)** (*Please circle*)	a. Pain b. Pressure c. Heaviness d. Tightness e. Other (*Describe in patients own words*) _____ _____
Pain location	a. Chest b. Neck c. Jaw d. Arm/s e. Back f. Shoulders g. Other *Other details*: _____
Pain severity	0 1 2 3 4 5 6 7 8 9 10 (*please circle*) ***Note:*** 0 = Nil pain; 10 = Most excruciating
Pain symptoms	a. Nausea b. Cold sweat c. Dizziness d. Short of breath e. Other *Other details (Patient's description):* _____ _____ _____
Response to rest	Does the pain respond well to rest (i.e., Is it getting better) **Yes/No** (*please circle*)
Duration of the pain	a. Greater than 10 minutes Yes/No b. Patient's description ____minutes
Response to nitroglycerin (GTN)	Has the patient self-administered GTN? Yes / No Has the patient been instructed by the RN to administer GTN? Yes/No

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| Action(s) | _____ |
| | _____ |

National Heart Foundation of Australia. (2010). *Chest Pain Action Plan.*

- Supply the participant with a copy of the NHFA's, '*My Heart, My Life'.* Donated kindly by the NHFA. Advise they are to bring this with them to their follow-up if they are in face-to-face group Yes/No /N/A*(Please circle).*

Section 8:
Morisky Medication Adherence Scale (MMAS – 8)

Visit	**Morisky Medication Adherence Scale (MMAS – 8 Item)**
Day of discharge:	Score:

*Use of the ©MMAS is protected by US copyright laws. Permission for use is required. A license agreement is available from: **Donald E. Morisky, ScD, ScM, MSPH, Professor, Department of Community Health Sciences, UCLA School of Public Health, 650 Charles E. Young Drive South, Los Angeles, CA 90095–1772.**

Patient's understanding of medications, behaviour, compliance and education:

Do you know what medications you are taking? **Yes / No** *(Please circle)*

If yes, can you tell me what medications you are taking without looking at them or a list? Yes/No

Ask participant to name the medication, dose, frequency and what they are for.

Current medications:
Recommended discharge medications for ACS patients Aroney. C., Aylward, P., Kelly,

A., Chew, D., & Clune, E. (2006). Guidelines for the management of acute coronary

syndromes: on behalf of the Acute Coronary Syndrome Guidelines Working Group.

Medical Journal of Australia, 184(8): S1-S30.

<table>
<tr><td></td><td colspan="2"></td><td>Randomisation no:</td></tr>
</table>

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Medication	Dose / Tablets	Frequency	Medication purpose *Please document in patient's own words*
Statin **Name given by patient:**			
NSAID **Name given by patient:**			
ACE inhibitor **Name given by patient:**			
Anti-platelet agent: **Name given by patient:**			
β-Blocker **Name given by patient:**			
Nitrates **Name given by patient:**			
Warfarin **Name given by patient:**			
Aldosterone Antagonists **Name given by patient:**			

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Medication	Dose / Tablets	Frequency	Medication purpose *Please document in patient's own words*
Insulin/oral hypoglycaemics **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications: **Name given by patient:**			

	Randomisation no:

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Section 9: Cardiac Rehabilitation (CR)

1a. Have you been seen by the CR team?	Please tick: **Yes ☐ / No ☐**
1b. If yes, have you been enrolled in a course?	Please tick: **Yes ☐ / No ☐**
1c.If yes, what are you expecting of this program?	Document:_____ _____
1d.If no, did anyone else speak with you about this?	Please tick: **Yes ☐ / No ☐**
1e.If yes please circle:	Nurse / Doctor / Allied health/ Family / Other _____
1f. If yes, what are you expecting of this program?	Document: _____ _____ _____
1g.If no, what do you think CR may involve (i.e., what do you expect it may be about?)	Document: _____ _____

Event notification	Please tick Yes or No	Communication source
Cardiologist	Yes ☐ No ☐	Telephone ☐ Writing ☐
GP	Yes ☐ No ☐	Telephone ☐ Writing ☐
Family/Next of Kin _____	Yes ☐ No ☐	Telephone ☐ Writing ☐
Ethics: XXX HREC/MS HREC/ QUT HREC/XXX DON (via Research Director of Nursing)	Yes ☐ No ☐	Telephone ☐ Writing ☐
Data Entry and Cleaning		
Data Entered	Yes ☐ No ☐	
Date Entered	/ / 2012/2013	Signature:
Data Cleaned	Yes ☐ No ☐	
Date Cleaned	/ / 2012/2013	Signature:

End of Assessment: Day of discharge from hospital.

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FOLLOW-UP   Date__/__/2012/2013

DAY 5–7 POST-DISCHARGE
*Use 'My Heart, My life as a guide

a.
Patient deceased **Yes/No** *Find out pre-telephone follow-up/face-to-face visit* (circle). Cause of death:

_____
_____
_____

b. Firstly, to ask participant if they require urgent medical attention (i.e., CP, access site etc)

Details:
_____
_____
_____

Section 1: Assessment

Cardiac Self-Efficacy Questionnaire (CSE) – Attach completed tools to this document

Visit	**Score: Control symptoms (CS)**	**Score: Maintain Functioning (MF)**	**Actions**
	_____	_____	_____ _____ _____

State -Trait Anxiety Inventory (STAI) – Attach completed tools to this document

Visit	**State Score**	**Trait Score**	**Actions**
	State Anxiety:_____	Trait Anxiety:_____	_____ _____ _____ _____

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Cardiac Depression Scale (CDS) – Attach completed tools to this document

<u>Visit</u>	<u>Score</u>	<u>Actions</u>
		_____ _____

<u>**Section 2:**</u> Access site assessment

Please note: Not all questions applicable due to telephone assessment

Access site assessment	Digital photograph ☐			
	Diagram ☐	e-mail ☐ MMS ☐	Australia Post ☐	Posted ☐ Received ☐

Please indicate on figure below with a circle and/or attach photo of site if available and

patient consent given. Patients may also post or e-mail these figures via mail (Please

remind participants to complete and forward in reply-paid envelope and figures supplied

in packs).

Access site assessment tool (O'Grady, 2007, p. 2).

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Access Site Assessment	
Haematoma (new)	Yes / No
If yes	Size ___:___cm
Researcher's description	_____ _____ _____ _____ _____ _____
Action	_____ _____ _____
Haematoma present on day of discharge?	1. Yes/No 2. If yes or no, document changes compared to now (Patient's description if telephone follow-up): _____ _____ _____ _____ _____ _____ _____ _____ _____
Haematoma between day of discharge and follow-up now?	Yes/No If yes, how was this managed (i.e., patient and medical management) If no: Circle N/A _____ _____ _____ _____
Bleeding now	Yes/No (Please circle)
If yes	Amount of blood present _____ml; b. Participant unsure of volume (telephone follow-up) c. N/A
Description	_____ _____ _____ _____ _____ _____
Action	_____ _____

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	_____ _____ _____ _____
Day of discharge bleed? (review / compare DCF notes from visit 1 bleed)	Yes/No If yes, compare to now: _____ _____ _____
1. Bruising present on day of discharge	a. Yes / b. No (please circle)
a. Yes	If bruising present on day of discharge, document changes/site as observed now: _____ _____ _____ _____ _____ _____
b. No	If nil bruising on day of discharge, is there bruising present now? a. Yes / b. No (please circle)
a. New bruising (document observations)	_____ _____ _____ _____
Size of bruise	**Length**: _____cm **Width** _____cm or b. N/A (if nil bruise)
Action	_____ _____ _____ _____ _____
New Bruit (heard with stethoscope _**face-to-face group only**_)	Yes / No
If yes:	Action:_____ _____

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	_____ _____ _____
If previous bruit, listen and document status	Present / No longer present / N/A(please circle)
If present	Action:_____ _____ _____
Site Pain (now)	Yes / No (*please circle yes or no*)
Site pain description	Pain rating: 0 1 2 3 4 5 6 7 8 9 10 (0 = Nil pain, 10 = Most severe)
If yes	Participants description and researcher's actions: _____ _____ _____ _____ _____

Access Site Inflammation / Signs of Infection	
Heat at site	Yes / No
Redness	Yes / No
Ooze	Yes / No
Odour	Yes / No
Description (if signs of infection/inflammation now)	_____ _____ _____
Actions	_____ _____ _____ _____
Access site inflammation/infection changes between day of discharge to now, day 5–7 (Yes/No)	
a. Access site inflammation/infection changes, description and patient/medical management; or b. N/A (please circle) _____ _____	

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_____
_____
_____
_____

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Intervention patients: Circle *N/A* for Standard care group participants:

Haematoma education and management given (What to look for/to do) ☐

    a. Understood: Patient able to verbalise and demonstrate actions Yes/No/N/A (please

circle)

Notes:_____

_____

_____

Bleeding education and management given (What to do if bleed occurs) ☐

    a. Understood: Patient able to verbalise and demonstrate actions Yes/No/N/A (please

circle)

Notes:_____

_____

_____

Bruising education and management given (What to look for/Colour/Extent) ☐

    b. Understood: Patient able to verbalise and describe Yes/No/N/A (please
        circle)

Notes:_____

_____

_____

Access site inflammatory changes (Heat/redness/swelling/odour/ooze and type of ooze)

    a. Understood. Patient able to verbalise and explain actions. Yes/No/N/A (please

circle)

Notes:_____

_____

_____

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Wound Assessment and Management Tool

Applied Wound Management – Assessment and Continuation Chart (Wounds UK, 2010).

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Section 3: Neurovascular check (Bilateral assessment)

Neurovascular Chart				
Name:	**Ward:**	**Hospital no:**		
Consultant:		**Procedure/Injury:**		
Area for observation:		**Frequency of Observations:**		
Date:		Right	Left	Comments
Time:				
Pain Score (1–10):				
Colour	Normal			
	Pale*			
	Cyanotic*			
	Mottled*			
Warmth	Hot*			
	Warm			
	Cold*			
	Cool*			
Pulses	Name of pulse:			
	Strong			
	Weak*			
	Absent*			
Capillary refill greater than 2 seconds (yes/no)				
Movement				
Dorsi flexion	No movement*			
	Movement, no pain			
	Movement with pain*			
Plantar Flexion	No movement*			
	Movement, no pain			
	Movement with pain*			
Toe extension	No movement*			
	Movement, no pain			
	Movement with pain*			
Toe flexion	No movement*			
	Movement, no pain			
	Movement with pain*			
Sensation				
Web space First and second toe	No sensation*			
	Tingling/numbness*			
	Full sensation			
Web space third and fourth toe	No sensation*			
	Tingling/numbness*			
	Full sensation			
Sole of foot/toes	No sensation*			
	Tingling/numbness*			
	Full sensation			

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Arch of foot (medial)	No sensation*			
	Tingling/numbness*			
	Full sensation			
Initials				

Always compare with the unaffected limb. If both limbs are affected, use a separate chart for each limb.

*These may be signs of abnormalities, take appropriate action, document and inform a member of the medical team. Document all actions taken in the space below.

Changes present between day of discharge to now, day 5–7 post-discharge: Yes/No *(please circle)*

Changes present now: Yes ☐ No ☐ *(Please tick)*

Affected limb(s): Right upper/Right lower/Left upper/Left lower/N/A *(Please circle)*

Actions:_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Neurovascular Assessment Tool (Judge, 2007, p. 43).

Neurovascular assessment education (Intervention group only): Yes/No/N/A *(please circle)*

c. Patient able to verbalise understanding Yes/No/N/A *(please circle)*

d. Patient able to demonstrate assessment: Tingling/numbness/capillary refill/ pulse/heat Yes/No/N/A

Notes: _____

_____

_____

Section 4: Vital Signs

*Take vital signs on all participants at day 5–7 post discharge in face-to-face clinic. Standard care group to be asked if they have taken or had recent measurements and to document below.

Vital signs	Reading
Blood Pressure (BP)	____/____mmHg
Heart Rate (HR)	beats per minute (bpm)
Temperature	°C (taken on access site assessment)
Respirations	Respirations per minute (rpm)
Oxygen Saturation	_____ %

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ECG (*Please tick*)	**Normal Sinus Rhythm** ☐
(*Use Omron ECG*)	**Sinus bradycardia** ☐ **Sinus tachycardia** ☐ **Sinus Arrhythmia** ☐
	Sinus tachycardia ☐
	Atrial Fibrillation ☐ **Atrial Flutter** ☐
	Paced Rhythm ☐ **Sinus rhythm 1ˢᵗ Degree Heart Block** ☐ **Sinus rhythm 2ⁿᵈ Degree Heart Block** ☐ **Complete heart block** ☐
	Other Rhythm ☐ (**Please document the rhythm in space provided*)_____
Patient's rhythm on discharge from hospital	Document: _____ _____ _____
Rhythm Change	Yes / No (*Please circle*)
Action(s)	_____ _____ _____ _____ _____ _____
Have you visited or spoken to your GP; cardiology clinic/cardiologist; or hospital ward prior to this visit for any concerns? **Prompt for researcher:** Did they call any health info lines such as: • NHF, QLD Health	Yes / No
If yes, what were the concerns?	_____ _____ _____ _____ _____ _____ _____

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Section 5: Chest pain assessment, education & management plan

	Details	**Additional notes**
Chest Pain / Discomfort leading up to clinic	**Yes / No**	Day 1: _____ _____ Day 2: _____ _____ Day 3: _____ _____ Day 4: _____ _____ Day 5: (CP prior to clinic if face-to-face group) _____ _____ Day 6: (CP prior to clinic if face-to-face group) _____ _____ Day 7: (CP prior to clinic if face-to-face group) _____ _____
CP at clinic/time of follow-up? *If yes, follow pathway below*	**Yes / No**	Action/Comments:_____ _____ _____ _____ _____

If no CP, circle: N/A
If yes, follow the pathway alongside specific hospital risk protocol

	Description
Pain Sensation(s) *(Please circle)*	a. Pain b. Pressure c. Heaviness d. Tightness e. Other *(Describe in patients own words)* _____ _____
Pain location	a. Chest b. Neck c. Jaw d. Arm/s e. Back f. Shoulders g. Other *Other details*: _____
Pain severity	0 1 2 3 4 5 6 7 8 9 10 (*please circle*) *Note:* 0 = Nil pain; 10 = Most excruciating
Pain symptoms	c. Nausea b. Cold sweat c. Dizziness d. Short of breath e. Other

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	Other details (Patient's description): _____ _____ _____
Response to rest	Does the pain respond well to rest (i.e., Is it getting better) **Yes/No** (*please circle*)
Duration of the pain	a. Greater than 10 minutes Yes/No b. Patient's description _____ minutes
Response to nitroglycerin (GTN)	Has the patient self-administered GTN? Yes / No Has the patient been instructed by the RN to administer GTN? Yes/No
If telephone follow-up: **Call Ambulance**	Has the ambulance (000) been called by patient/family/RN/other? **Yes/No** (*please circle*) **Other:** _____ Why did RN/Other call ambulance? (*Document*) _____ _____ _____ _____ _____
Action(s)	_____ _____ _____ _____

NHFA (2010).

Intervention group participants only
- Discuss with the participant their chest pain management plan. Go through chest pain management plan with the patient in 'My heart, my life'. Supplied on day of discharge in patient's study pack.

- Chest pain action plan shown (in face-to-face clinic) to patient with recommendations to follow:
  Yes □ / No □ / N/A □

  If no, explain:
  _____
  _____

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Section 6: Medication adherence
MMAS – 8

Visit	Morisky Adherence Scale (MMAS – 8 Item)
Day 5–7:	Score:

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Patient's understanding of medications, behaviour, compliance and education:

- Do you know what medications you are taking? **Yes / No** *(Please circle)*

- Can the participant identify cardiac (predominantly) and other medications, what they are for, when to take, dose without seeing the medication/a list or prompting? **Yes/No**

- Have there been any changes to your medications since we last spoke? **Yes / No**

- If yes, ask the patient to tell you what the changes are in their own words and document in chart below? **Yes / No**

- **If changes were made, who made them?** GP/Cardiologist/Emergency centre doctor/ Nurse practitioner/ Patient *(please circle)*

Current medications **Add changes only – Do not ask patient to go through all medications at day 5–7):**

Recommended discharge medications for ACS patients (Aroney, Alyward, Kelly, Chew, & Clune, 2006, p. S23)

Medication	Dose / Tablets	Frequency	Medication purpose *Please document in patient's own words*
Statin **Name given by patient:**			
NSAID **Name given by patient:**			

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Medication	Dose / Tablets	Frequency	Medication purpose *Please document in patient's own words*
ACE inhibitor **Name given by patient:**			
Anti-platelet agent: **Name given by patient:**			
β-Blocker **Name given by patient:**			
Nitrates **Name given by patient:**			
Warfarin **Name given by patient:**			
Aldosterone Antagonists **Name given by patient:**			
Insulin/oral hypoglycaemics **Name given by patient:**			
Other medications			

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Medication	Dose / Tablets	Frequency	Medication purpose *Please document in patient's own words*
Name given by patient:			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications: **Name given by patient:**			

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Intervention group participants

- Medications discussed with intervention group participant (Use 'My heart, my life' as a guide):
- **Yes ☐ / No ☐ / N/A ☐**
  If no, explain:
  _____
  _____

- Verbal and/or written information given to face-to-face participant: **Yes ☐ / No☐ / N/A ☐**
  If no, explain:
  _____
  _____

Section 7: Cardiac Rehabilitation (CR)

Have you been approached by the CR team prior to this visit? (***i.e., In hospital / via telephone***)	**Please tick: Yes ☐ / No ☐** **Comments**: _____ _____ _____
If yes, what regarding the programme was discussed?	**Comments:**_____ _____ _____ _____ _____
Both groups of patients (even if SCG not aware) Will you attend CR?	**Yes ☐ / No ☐**
Why / why not? Details (*Please make comments for both yes and no responses*)	_____ _____ _____ _____
If not approached by CR, or approached, but no appointment arranged, make appointment below:	If in SCG, make appointment at end of follow-up at 3 months if still not enrolled or contact not made with participant.

a. Appointment date for CR: / / 2012/2013
b. Appointment time for CR:_____ am / pm (***Please circle am or pm***)
c. Team member spoke with:_____
d. Supply CR business card with details for participant ☐ (***Please tick box when completed***)
e. Cardiac rehabilitation notified in writing of study enrolment ☐

i. Patient's expectations of CR (Both groups):

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_____
_____
_____

j. Do you think it is important to attend a cardiac rehabilitation (CR) course: Yes ☐ / No ☐

Reason (Why/why not):
_____
_____
_____

Intervention group only: CR and Activity
k. CR education on importance given (Hospital brochure and *My heart, my life* as a guide):
Yes ☐ / No ☐

If no, document why not given**:**
_____
_____

m. **Activity education given** post-PCI specific (i.e., Hospital brochure and/or *My Heart, my life* as a guide): Yes ☐ / No ☐

n. Current status on modifiable risk factors

Modifiable and Cardiac Risk Factors	Details	Additional Information
Hypertension *Review BP at beginning of clinic. Standard care asked via telephone if they have taken or had a recent reading taken.*	Yes / No/N/A	For guidelines on hypertension see Chapter 3 Australia's Health (Australian Institute of Health and Welfare [AIHW], 2010). Is / has blood pressure becoming / become more under control **with/without** medications? **Comments**:_____ _____ _____ _____
Cholesterol (*if a measurement requested by doctor*)	mmol/L	See Chapter 3 Australia's Health (AIHW, 2010).
Smoking	Number per day/wk:	N/A (non-smoker)
Alcohol consumption	____Standard drinks per day/wk/month/year	Or N/A (non-drinker) (please circle) Or Social Drinker (please circle)
Stress	Yes / No	
Diabetes	Type 1 / Type 2/ N/A	Control of blood glucose levels (i.e., what are

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		current readings like and description): **mmol/L**:_____ **Description**:_____ _____
Activity (ies)/ Exercise (post-discharge)	None / light / moderate / heavy	Comments (why /why not recommenced or commenced) _____ _____ _____ _____

Dietary intake	Daily intake		
		Breakfast	
		Morning tea	
		Lunch	
		Afternoon tea	
		Dinner	
		Dessert	
		Snacks/Other (i.e., Meal supplements)	

o. Tell me, how do you feel about having a blockage/blockages and stents (i.e., cardiovascular disease)? (**Prompts**: *Are they concerned? Do they feel they are cured?)*
_____
_____

p. Do you have anything you would like to change with respect to your current lifestyle (i.e., dietary choices) and behaviours (i.e., highly stressful occupation) *(Please circle)*: Yes / No

Why/why not and what they are? (Comment below)

<table>
<tr><td>Randomisation no:</td></tr>
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Reason:_____
_____
_____

q. Would you know a. What to do if you had a complication such as a bleed Yes/No?; b. How to manage it; and c. Who to contact if you needed to (post-PCI)? *(Stagger questions. Please document participant's responses)*
_____
_____
_____

r. Who do you turn to for support?
_____

s. Are there any personal issues that we have not covered that you would like to share with me? Yes/No (and document response)
_____
_____
_____

Section 8: Participant Questions *(Questions asked of the researcher by participants)*

Visit	Question(s) asked and Response(s)
Day 5–7 post-discharge	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Event notification (add to excel spreadsheet)	Please tick Yes or No	Communication source
Cardiologist	Yes ☐ No ☐	Telephone ☐ Writing ☐
GP	Yes ☐ No ☐	Telephone ☐ Writing ☐
Family/Next of Kin _____	Yes ☐ No ☐	Telephone ☐ Writing ☐
Ethics: XXX HREC/MS HREC/ QUT HREC/ XXX DON (via Research Director of Nursing)	Yes ☐ No ☐	Telephone ☐ Writing ☐
Data Entry and Cleaning		
Data Entered	Yes ☐ No ☐	
Date Entered	/ / 2012/2013	Signature:
Data Cleaned	Yes ☐ No ☐	

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| Date Cleaned | / / 2012/2013 | Signature: |

***NOTE** – Arrange time and date for next follow-up call at 1 month post-discharge from hospital:
a. Date: / / 2012/2013 b. Time: am/pm

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Follow-up visit: 1 Month post-discharge   **Date__/__/2012/2013**

a. Patient deceased **Yes/No** (**To find out pre-telephone follow-up/face-to-face visit*)
(please circle)

b. Cause of death:_____

Section 1b: Tests
Salivary cortisol assay

Visit	Reminder to take sample (SMS / Telephone call) *(Add to excel)*		Sample taken *(Please tick Yes or No if taken)*		Sample received by laboratory *(Please tick)* *(Add to excel)*		Salivary cortisol
1 Month post-discharge	Yes ☐	No ☐	Yes ☐	No ☐	Yes ☐	No☐	____ug/dl

Notes:
_____
_____

Cardiac Self-Efficacy Questionnaire

Visit: 1 Month	Score: Control symptoms (CS)	Score: Maintain Functioning (MF)	Actions
	_____	_____	_____

State -Trait Anxiety Inventory (STAI)

Visit: 1 Month	State Score	Trait Score	Actions
	State Anxiety: _____	Trait Anxiety: _____	_____ _____

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Cardiac Depression Scale (CDS)

Visit: 1 Month	**Score**	**Actions**
		_____ _____

Section 2: Chest discomfort and Hospitalisation

Question	**Participant's response(s)**
1. How are you feeling after 1 month of having your procedure? *(ask patient to describe)*	_____ _____ _____ _____ _____ _____
2a. Have you had any chest heaviness/pain since we last spoke? **Yes/No** *(Circle)* 2b. If yes, what did you do? (i.e., actions taken)	_____ _____ _____ _____ _____ _____ _____ _____

3a. Do you have any CP / Discomfort now? **Yes/No** *(Circle)*

3b**. If YES:**
3c. **Cease participant questions** ☐ *(Please tick)*

3d. **Follow: Assess CP (Follow NHFA CP Action Plan)** ☐
3e. Circle <u>N/A</u> for participants without CP

	Description
Pain **Sensation(s)** *(Please circle)*	a. Pain b. Pressure c. Heaviness d. Tightness e. Other *(Describe in patients own words)* _____ _____ _____ _____
Pain location	a. Chest b. Neck c. Jaw d. Arm/s e. Back f. Shoulders g. Other

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	Other details: _____
Pain severity	0 1 2 3 4 5 6 7 8 9 10 (*please circle*) ****Note:*** 0 = Nil pain; 10 = Most excruciating
Pain symptoms	a. Nausea b. Cold sweat c. Dizziness d. Short of breath e. Other ***Other details (Patient's description):*** _____ _____ _____ _____
Response to rest	Does the pain respond well to rest (i.e., Is it getting better) **Yes/No** (*please circle*)
Duration of the pain	a. Greater than 10 minutes **Yes/No** b. Patient's description _____ minutes
Response to nitroglycerin (GTN)	Has the patient self-administered GTN? **Yes / No** Has the patient been instructed by the RN to administer GTN? **Yes/No** Did the GTN reduce/eliminate the patient's CP? **Yes/No**
Telephone follow-up Ambulance called	Has the ambulance (000) been called by patient/family/RN/other? **Yes/No** (*please circle*) **Other:** _____ Why did RN/Other call ambulance? (*Document*) _____ _____ _____ _____ _____ _____ _____
Action(s)	_____ _____ _____ _____ _____

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3. Notify cardiologist, and GP of actions taken. Document event and actions taken in DCF "Actions" ☐ *(Tick) (document in excel)*	
4a. Have you been readmitted to hospital for your heart since we last spoke? **Yes / No** *(Circle)* 4b. If **yes**, what was Your diagnosis? (***Please document in participant response area)***	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
5a. Have you been readmitted to hospital for any other reason since we last spoke? **Yes / No** *(Circle)* 5b. If **yes**, please document in participant response area.	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Access site assessment: Please note not all assessment items applicable due to telephone follow-up.

Access site assessment	Digital photograph ☐			
	Diagram ☐	e-mail ☐	Australia Post ☐	Posted ☐ Received ☐

 Access site assessment
**Please indicate on diagram below with a circle and/or attach photo of site if available and patient consent given. Patients may also post or e-mail these diagrams. Please remind participants to complete diagram and forward in reply-paid envelope supplied in packs).

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Access site assessment tool (O'Grady, 2007, p.2).

Access Site Assessment	
Haematoma	Yes / No
If yes	Size ___:___cm
Description	_____ _____ _____ _____ _____
Action	_____ _____ _____ _____ _____ _____ _____ _____
Haematoma 3 – Present day of discharge (Yes/No)	
Haematoma 3 – Changes (i.e., complications) present from day of discharge to day 5–7 post discharge? (Yes/No)	
Haematoma 3 – Changes (i.e., complications) present from day 5–7 to now at 1 month? (Yes / No)	
Haematoma 3 – Management of changes (document details) (i.e., did they see a GP/Cardiologist/self etc?) or N/A (Circle) _____ _____ _____	
Haematoma 3 – Changes present now? Yes/No	
Haematoma 3 – Description of new changes (Patient description as telephone follow-up for all	

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participants. Document below and actions)		
		_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	
1.	Bruising day of discharge	Yes/No (see notes DCF at day of discharge for details)
2.	New bruising present day 5–7 post-discharge	Yes / No (please circle)
a.	Yes	If bruising present day 5–7 post discharge, document changes/site as observed now (*in photograph, diagram and patient's description)*: _____ _____ _____ _____ _____ _____
b.	No	If nil bruising day 5–7 post-discharge, is there bruising present now (*in photograph, diagram and patient's description)*? A. Yes / B. No (circle)
A. New bruising (document observations i.e., *colours)*		_____ _____ _____ _____ _____ _____
Size of bruise		**Length**: cm **Width**: cm
Action		_____ _____ _____ _____ _____ _____

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Site pain	Yes / No (*please circle yes or no*)
Site pain score	Pain rating: 0 1 2 3 4 5 6 7 8 9 10 (0 = Nil pain, 10 = Most severe)
If yes, patient's description of pain and researchers actions	Participants description and researcher's actions: _____ _____ _____ _____
Bleeding between follow-up and 1 month post-discharge follow-up	Yes / No (Please circle) If yes, how was this managed (i.e., how did the patient manage this? Did they see a doctor?; Did a family member hold pressure?; Call an ambulance?) _____ _____ _____ _____ _____
Bleeding now	Yes/No (Please circle)
If yes	Amount of blood present _____mls (ask patient)
Description	_____ _____ _____ _____
Action	_____ _____ _____ _____ _____

Access Site Inflammation / Signs of Infection	
Heat at site (new)	Yes / No
Redness (new)	Yes / No
Ooze (new)	Yes / No
Odour (new)	Yes / No
New changes: Description	_____ _____ _____ _____ _____
New changes: Management	_____ _____

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	_____ _____ _____ _____ _____ _____ _____
Access site inflammation/infection changes from day of discharge to 5–7 days post-discharge?	**Yes/No** (please circle) If yes, what are the changes, description and management? _____ _____ _____ _____ _____ _____ _____ _____
Access site inflammation/infection from day 5–7 to now at 1 month post-discharge?	**Yes/No** (please circle) If yes, what are the changes, description, and management? _____ _____ _____ _____

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Wound Assessment and Management Tool

Applied Wound Management
Assessment and Continuation Chart

Patient Identity	Date	Chart completed by
Patient Address	Unit No.	GP/Consultant
	D.O.B / /	Consent to images (circle appropriate) YES NO
	Location	Date next assessment required

Front **Back**

**INITIAL ASSESSMENT –
TYPE AND LOCATION OF WOUND**

Type of wound/s

Location of wound/s

Wound pain present – YES ☐   NO ☐

CONTINUAL ASSESMENT – THE HEALING ZONE
Please enter a cross from the total scoring of the two step continuums to see the overall healing progress of the wound.

Assesment 1 Assesment 2 Assesment 3 Assesment 4 Assesment 5 Assesment 6 Assesment 7 Assesment 8 Assesment 9 Assesment 10

wound healing and wound infection continuums

High 9
8
7
6
5
4
3
2
1
Low 0

HEALING ZONE

Source: Wounds UK (2010). *Applied wound management: Assessment and continuation chart*.
Retrieved from http://www.wounds-uk.com/pdf/content_8973.pdf

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Section 3: Neurovascular check (Bilateral assessment)
Neurovascular assessment 3 – Changes from assessment day of discharge to follow up day 5–7 (Yes/No)

Neurovascular assessment 3 – Changes from assessment day 5–7 to now (diagnosed between this time (Yes/No)

Neurovascular Chart				
Name:		**Ward:**	**Hospital no:**	
Consultant:			**Procedure/Injury:**	
Area for observation:			**Frequency of Observations:**	
Date:			Right	Left	Comments
Time:					
Pain Score (1–10):					
Colour	Normal				
	Pale*				
	Cyanotic*				
	Mottled*				
Warmth	Hot*				
	Warm				
	Cold*				
	Cool*				
Pulses	Name of pulse:				
	Strong				
	Weak*				
	Absent*				
Capillary refill greater than 2 seconds (yes/no)					
Movement					
Dorsi flexion	No movement*				
	Movement, no pain				
	Movement with pain*				
Plantar Flexion	No movement*				
	Movement, no pain				
	Movement with pain*				
Toe extension	No movement*				
	Movement, no pain				
	Movement with pain*				
Toe flexion	No movement*				
	Movement, no pain				
	Movement with pain*				
Sensation					
Web space **First and second toe**	No sensation*				
	Tingling/numbness*				
	Full sensation				
Web space **third and fourth toe**	No sensation*				
	Tingling/numbness*				
	Full sensation				
Sole of foot/toes	No sensation*				
	Tingling/numbness*				
	Full sensation				

Arch of foot (medial)	No sensation*			
	Tingling/numbness*			
	Full sensation			
Initials				
Always compare with the unaffected limb. If both limbs are affected, use a separate chart for each limb. *These may be signs of abnormalities, take appropriate action, document and inform a member of the medical team. Document all actions taken in the space below.				
Actions:_____ _____ _____ _____ _____ _____ _____				

Neurovascular Assessment Tool (Judge, 2007, p. 43).

Neurovascular assessment 3 – New changes present at 1 month post discharge (i.e., now) – Limb(s) (upper or lower): Right upper / Right lower / Left upper / Left lower / N/A (*Please circle*)

Section 4: Patient's understanding of medications, behaviour, compliance and education:

- Do you know what medications you are taking? **Yes / No** (*Please circle*)

- Have there been any changes to their medications? **Yes / No**

- **If yes**, who made the changes? **GP/Cardiologist/Emergency centre doctor/Nurse practitioner/ Patient** (*Please circle*)

- Can the participant identify cardiac (predominantly) and other medications, what they are for, when to take, dose without seeing the medication/a list or prompting? **Yes/No**

- Ask participant to name the medication, dose, frequency and what they are for.

Current medications:

Visit	**Morisky Medication Adherence Scale (MMAS – 8 Item)**
1 Month post-discharge:	Score:

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Recommended discharge medications for ACS patients (Aroney et al., 2006, p. S23)

Medication	Dose	Frequency	Medication purpose *Please document in patient's own words*
Statin **Name given by patient:**			
NSAID **Name given by patient:**			
ACE inhibitor **Name given by patient:**			
Anti-platelet agent: **Name given by patient:**			
β-Blocker **Name given by patient:**			
Nitrates **Name given by patient:**			
Warfarin **Name given by patient:**			
Aldosterone Antagonists **Name given by patient:**			
Insulin/oral hypoglycaemics **Name given by**			

Medication	Dose	Frequency	Medication purpose *Please document in patient's own words*
patient:			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications: **Name given by patient:**			

Section 4: Nurse-researcher led questions

At 1 month Post-PCI Cardiac Rehabilitation; Cardiology and Lifestyle   **(*Check participant has taken/will take saliva sample and post today).**
Questions and Responses
1a. Are you currently attending CR? **Yes/No (**If no, go to question 1c)**   1b. Attendance confirmed with CR team member **Yes / No / N/A**   1c. If **no**, ask participant reasons for not attending and if an appointment has been made and rescheduled to attend? *(Document comments below)*   _____   _____   _____
1d. Rescheduled appointment confirmed with CR team member Yes (rescheduled) / No (not rescheduled) / N/A (please circle)   1e. If **not attending CR**, please no proceed to question 3.

2a. How are you finding this program? *(Document comments below)*

_____
_____
_____
_____

2b. Is it fulfilling your expectations? (i.e., is it what you thought it would be, or different)? **Yes/No**
If **no**, ask participant to explain. *(Document comments below)*

_____
_____
_____
_____

3a. Have you been for follow-up with your cardiologist since your procedure? **Yes/No**
(Please circle)

3b. If **yes**, what did you discuss about your cardiovascular health since your procedure?

_____
_____
_____
_____

3c. If **no**, ask reason why:

_____
_____
_____

4. Are you making lifestyle/behavioural adjustments? (Do they still feel they need to/do not need to?) (e.g. Making dietary changes, going to a gym, stopped/stopping smoking, diabetes under control, controlling your stress/stressors) **Yes/No**. Why/why not and what are they?

_____
_____
_____
_____
_____

5. **Modifiable risk factors/Cardiac risk factors**		
Modifiable, and Cardiac Risk Factors	**Details**	**Additional Information**
Hypertension *Review BP at beginning of clinic. Standard care asked via telephone if they have taken or had a recent reading taken.*	Yes / No	For guidelines on hypertension see Chapter 3 Australia's Health (Australian Institute of Health and Welfare [AIHW], 2010). Is / has blood pressure becoming / become more under control **with/without** medications? **Comments**:_____ _____ _____
Cholesterol (*if a measurement requested by doctor*)	mmol/L Reading not available □	See Chapter 3 Australia's Health (AIHW, 2010).
Smoking	Number per day:	N/A (non-smoker)
Alcohol consumption	Standard drinks per day/wk/month/year: _____	N/A (non-drinker) (please circle) Social drinker (please circle)
Stress	Yes / No	
Diabetes	Type 1 / Type 2 / N/A	Control of blood glucose levels (i.e., what are current readings like and description): **mmol/L**:_____ **Description**:_____ _____ _____
Weight	kg	
BMI	kg/m^2	• **Note**: Require height and weight for calculation
Hip to Waist ratio (*WHO STEPS on measurement*)	W:____ cm H: _____cm	Instruct patient over telephone how to take measurement if in Standard Care Group.
Activity (ies)/ Exercise (post-discharge)	None / light / moderate / heavy	Comments (why /why not recommenced or commenced) _____ _____
Dietary intake	Daily intake Nil changes made since last follow-up □	Breakfast	
		Morning tea	

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	(please tick)	Lunch	
		Afternoon tea	
		Dinner	
		Dessert	
		Snacks/Other (i.e., Meal supplements)	

6a. Who do you turn to for support?
_____

6b. Are there any personal issues that we have not covered that you would like to share with me?
_____
_____
_____
_____

NOTE – Arrange time and date for 3 month follow-up call:

    a.   Date: / /2012/2013 b. Time: am/pm

Section 5: Participant Questions *(Questions asked of the researcher by participants)*

Visit	Question(s) asked and Response(s)
1 month post-discharge	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Event notification (document in excel spreadsheet)	Please tick Yes or No	Communication source
Cardiologist	Yes ☐ No ☐	Telephone☐ Writing ☐
GP	Yes ☐ No ☐	Telephone☐ Writing ☐
Family/Next of Kin _____	Yes ☐ No ☐	Telephone☐ Writing ☐
Ethics: XXX HREC / MSEC / QUT ETHICS / XXX DON (via Research Director of Nursing)	Yes ☐ No ☐	Telephone☐ Writing ☐
Data Entry and Cleaning		
Data Entered	Yes ☐ No ☐	
Date Entered	/ / 2012/2013	Signature:
Data Cleaned	Yes ☐ No ☐	
Date Cleaned	/ / 2012/2013	Signature:

Follow-up: At 3 Months post-discharge   Date__/__/2012/2013

a.Patient deceased **Yes/No** (*find out pre-telephone follow-up*) **(please circle)**
Cause of death:
_____

Section 1b: Tests
Cardiac Self-Efficacy Questionnaire (CSE)

Visit	**Score: Control symptoms (CS)**	**Score: Maintain Functioning (MF)**	**Actions**
3 months post-discharge	_____ _____	_____	_____ _____ _____

State -Trait Anxiety Inventory (STAI)

Visit	**State Score**	**Trait Score**	**Actions**
3 months post-discharge	State Anxiety:_____	Trait Anxiety:_____	_____ _____ _____ _____

© Spielberger, Gorsuch, Lushene, Vagg & Jacobs (1983).

Cardiac Depression Scale (CDS)

Visit	**Score**	**Actions**
3 months post-discharge		_____

Section 2: Chest Pain identification & Hospitalisation

Question	**Participant's response(s)**
1. How are you feeling after 3 months of having your procedure? (*ask patient to describe*)	_____ _____ _____ _____

2a. Have you had any chest heaviness/pain since we last spoke? **Yes/No** *(Circle)* 2b. If **yes**, what did you do? *(Please document response)*	_____ _____ _____ _____
3a. Do you have any CP / Discomfort now? 3b**. If YES:** **1. Cease participant questions ☐ *(Please tick)*** **2. Assess CP, and Follow NHFA CP Action Plan ☐**	

If no CP: N/A (please circle)

Description	
Pain **Sensation(s)** *(Please circle)*	a. Pain b. Pressure c. Heaviness d. Tightness e. Other *(Describe in patients own words)* _____ _____ _____
Pain location	a. Chest b. Neck c. Jaw d. Arm/s e. Back f. Shoulders g. Other *Other details*: _____
Pain severity	0 1 2 3 4 5 6 7 8 9 10 *(please circle)* ***Note:** 0 = Nil pain; 10 = Most excruciating
Pain symptoms	a. Nausea b. Cold sweat c. Dizziness d. Short of breath e. Other *Other details (Patient's description):* _____ _____ _____ _____
Response to rest	Does the pain respond well to rest (i.e., Is it getting better) **Yes/No** *(please circle)*
Duration of the pain	b. Greater than 10 minutes Yes/No c. Patient's description _____minutes
Response to nitroglycerin (GTN)	Has the patient self-administered GTN? **Yes / No** Has the patient been instructed by the RN to administer GTN? **Yes/No**
Telephone follow-up Ambulance called	Has the ambulance (000) been called by patient/family/RN/other? **Yes/No** *(please circle)* **Other:** _____

	Why did RN/Other call ambulance? *(Document)* _____ _____ _____ _____ _____ _____
Action(s)	_____ _____ _____ _____ _____ _____

** Notify cardiologist, and GP of actions taken. Document event and actions taken in DCF "Actions" ☐ *(Tick) (document in excel)*

1a. Have you been back to hospital for your heart since we last spoke? **Yes / No** *(Circle)* 1b. If **yes**, what was your diagnosis? *(Please document in participant response area)*	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
2a. Have you been readmitted to hospital for any other reason since we last spoke? **Yes / No** *(Circle)* 2b. If **yes**, please document in participant response area.	_____ _____ _____ _____ _____ _____

Section 2: Access site assessment
Please note: Not all questions applicable due to telephone assessment

Access site assessment	Digital photograph ☐			
	Diagram ☐	e-mail ☐	Australia Post ☐	Posted ☐ Received ☐

**Please indicate on figure below with a circle and/or attach photo of site if available and patient consent given. Patients may also post or e-mail these figures via mail (Please remind participants to complete and forward in reply-paid envelope and figures supplied in packs).

Access Site Assessment	
Haematoma	Yes / No
If yes	Size ___:___cm
Description	_____ _____ _____ _____ _____ _____ _____ _____
Action	_____ _____ _____ _____ _____ _____ _____ _____ _____

Haematoma 4 – Present day of discharge (Yes/No)	
Haematoma 4 – Changes (i.e., complications) present from day of discharge to day 5–7 post discharge? (Yes/No)	
Haematoma 4 – Changes (i.e., complications) present from day 5–7 post-discharge to 1 month post discharge? (Yes/No)	
Haematoma 4 – Changes (i.e., complications) present from review at 1 month to now at 3 months? (Yes / No)	
Haematoma 4 – Description of complications/changes or improvements (Patient words as telephone follow-up only) N/A (please circle for those unaffected) _____ _____ _____ _____ _____ _____ _____ _____ _____	

Bleeding (new)	Yes / No
If yes	Amount of blood present _____ml; b. N/A
Description	_____ _____ _____ _____ _____ _____ _____ _____
Action	_____ _____ _____ _____ _____ _____

Bleeding between 5–7 days and 1 month follow-up? Yes/No (Please circle) Bleeding between 1 month and 3months at home? Yes/No (Please circle and document below)	
If yes, how was this managed (i.e., how did the patient manage this? Did they see a doctor? Have a family member hold pressure? Call an ambulance?) _____ _____ _____ _____	
1.New bruising present 1month post-discharge	a. Yes / b. No (Please circle)
c. Yes	If bruising present 1 month post discharge, document changes/site as observed now (***in photograph, diagram and patient's description)***: _____ _____ _____ _____ _____ _____ _____
d. No	If nil bruising 1 month post-discharge, is there bruising present now (***in photograph, diagram and patient's description)***? A. Yes/ B. No (Please circle)
e. Have there been any changes prior to this follow up and how do they compare to the site now?	
B. New bruising (document observations)	_____ _____ _____ _____ _____ _____
Size of bruise	Length: cm Width: cm
Action	_____ _____ _____ _____ _____ _____ _____
Site Pain	Yes / No (*please circle yes or no*)
Site pain description	Pain rating: 0 1 2 3 4 5 6 7 8 9 10 (0 = Nil pain, 10 = Most severe)
If yes	Participant's description and researcher's actions: _____ _____ _____

	_____
Bleeding	Yes / No
If yes	Amount of blood present _____ml (ask patient)
Description	_____ _____ _____ _____ _____
Action	_____ _____ _____ _____ _____

Access site assessment tool (O'Grady, 2007, p.2).

Access Site Inflammation / Signs of Infection	
Heat at site (new)	Yes / No
Redness (new)	Yes / No
Ooze (new)	Yes / No
Odour (new)	Yes / No
Description	_____ _____
Actions	_____ _____
Access site inflammatory / infection changes from day of discharge to day 5–7 (Yes/No)	
Access site inflammatory / infection changes from day 5–7 to 1 month (Yes/No)	
Access site inflammatory / infection changes from 1 month to now 3 months (Yes/No)	
Access site description: _____ _____ _____ _____ _____	

Wound Assessment and Management Tool

Applied Wound Management – Assessment and Continuation Chart (Wounds UK, 2010).

Section 3: Neurovascular check (Bilateral assessment)

Neurovascular assessment			
Neurovascular assessment 4: Changes between assessment day of discharge to follow up day 5–7	Yes/No (please circle)		
Neurovascular assessment 4: Changes between assessment day 5–7 to 1 month (Yes/No)	Yes/No (please circle)		
Neurovascular assessment 4: Changes between assessment day 1 month to 3 month (Yes/No)	Yes/No (please circle)		

Neurovascular Chart				
Name: Ward:		**Hospital no:**		
Consultant:		**Procedure/Injury:**		
Area for observation:		**Frequency of Observations:**		
Date:		Right	Left	Comments
Time:				
Pain Score (1–10):				
Colour	Normal			
	Pale*			
	Cyanotic*			
	Mottled*			
Warmth	Hot*			
	Warm			
	Cold*			
	Cool*			
Pulses	Name of pulse:			
	Strong			
	Weak*			
	Absent*			
Capillary refill greater than 2 seconds (yes/no)				
Movement				
Dorsi flexion	No movement*			
	Movement, no pain			
	Movement with pain*			
Plantar Flexion	No movement*			
	Movement, no pain			
	Movement with pain*			
Toe extension	No movement*			
	Movement, no pain			
	Movement with pain*			
Toe flexion	No movement*			
	Movement, no pain			
	Movement with pain*			
Sensation				
Web space First and second toe	No sensation*			
	Tingling/numbness*			
	Full sensation			
Web space third and fourth toe	No sensation*			
	Tingling/numbness*			
	Full sensation			
Sole of foot/toes	No sensation*			
	Tingling/numbness*			

	Full sensation			
Arch of foot (medial)	No sensation*			
	Tingling/numbness*			
	Full sensation			
Initials				

Always compare with the unaffected limb. If both limbs are affected, use a separate chart for each limb.

*These may be signs of abnormalities, take appropriate action, document and inform a member of the medical team. Document all actions taken in the space below.

Actions:_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Neurovascular Assessment Tool (Judge, 2007, p. 43).

Section 4 – Patient's understanding of medications, behaviour, compliance and education:

Medication Adherence

Visit	Morisky Medication Adherence Scale (MMAS – 8 Item)
3 months post-discharge:	Score:

*Use of the ©MMAS is protected by US copyright laws. Permission for use is required. A license agreement is available from: **Donald E. Morisky, ScD, ScM, MSPH, Professor, Department of Community Health Sciences, UCLA School of Public Health, 650 Charles E. Young Drive South, Los Angeles, CA 90095–1772.**

- Do you know what medications you are taking? **Yes / No** *(Please circle)*

- Have there been any changes to your medications since we last spoke? **Yes / No**

- If yes, ask the patient to tell you what the changes are in their own words and document in chart below? **Yes / No**

- **If changes were made, who made them?** GP/Cardiologist/Emergency centre doctor/ Nurse practitioner/ Patient *(please circle)*

- Ask participant to name the medication, dose, frequency and what they are for.

Current medications:

Recommended discharge medications for ACS patients (Aroney, Alyward, Kelly, Chew, & Clune, 2006, p. S23)

Medication	Dose	Frequency	Medication purpose *Please document in patient's own words*
Statin **Name given by patient:**			
NSAID **Name given by patient:**			
ACE inhibitor **Name given by patient:**			
Anti-platelet agent: **Name given by patient:**			
β-Blocker **Name given by patient:**			
Nitrates **Name given by patient:**			
Warfarin **Name given by patient:**			
Aldosterone Antagonists **Name given by patient:**			

Medication	Dose	Frequency	Medication purpose *Please document in patient's own words*
Insulin/oral hypoglycaemics **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications **Name given by patient:**			
Other medications: **Name given by patient:**			

Section 5: Nurse-researcher led questions

At 3 months Post-PCI Cardiac Rehabilitation; Cardiology and Lifestyle

Questions and Responses

1a. Did you attend your/most of your entire CR course? **Yes/No/N/A** *(Circle)(N/A = Did not attend from start)*

1b. Attendance confirmed with CR team member **Yes / No** *(Circle)*

1c. If **no**, ask participant reason(s) for not attending *(Document comments below)*
_____

1d. If **yes**, please go to question 2.

2. How did you find this program after attending? Did it meet your expectations? **Yes/No** (i.e., More knowledgeable; motivated to make changes etc..)
_____
_____

2a. If no, why not?
_____
_____

3. Have you been for follow-up with your cardiologist since your procedure? **Yes/No** *(Please circle)*

3a. If **yes**, what did you discuss about your cardiovascular health since your procedure?
_____
_____
_____

3b. If **no**, ask reason why:
_____
_____

4. Are you making lifestyle/behavioural adjustments (e.g. Dietary changes, exercising, ceased smoking, diabetes under control) **Yes/No** *(Please circle) Why/Why not?(Document below)*
_____
_____
_____
_____
_____
_____
_____

5. Risk factors

Modifiable, and Cardiac Risk Factors	Details	Additional Information
Hypertension *Reviewed BP at beginning of clinic. Standard*	Yes / No	For guidelines on hypertension see Chapter 3 Australia's Health (Australian Institute of Health & Welfare [AIHW], 2010).

care asked via telephone if they have taken or had a recent reading taken.		Is / has blood pressure becoming / become more under control **with/without** medications? **Comments**:_____ _____ _____ _____ _____
Cholesterol (*if a measurement requested by doctor)*	mmol/L Not available ☐	See Chapter 3 Australia's Health (AIHW, 2010).
Smoking	Number per day:	Non-smoker (please circle)
Alcohol consumption	Standard drinks per day/week/month/year:	Non-drinker (please circle) Social drinker (please circle)
Stress	Yes / No	
Diabetes	Type 1 / Type 2	Control of blood glucose levels (i.e., what are current readings like and description): **mmol/L**:_____ **Description**:_____ _____ _____ _____
Weight	kg	
BMI	kg/m^2	Note: Require height and weight for calculation.
Hip to Waist ratio (*WHO STEPS on measurement*)	W: _____cm H:_____cm	Instruct patient over telephone how to take measurement.
Activity (ies)/ Exercise (post-discharge)	None / light / moderate / heavy	Comments (why /why not recommenced or commenced) _____ _____ _____ _____ _____
Dietary intake	Daily intake	Breakfast	
		Morning tea	
		Lunch	

		Afternoon tea	
		Dinner	
		Dessert	
		Snacks/Other (i.e., Meal supplements)	

6. Who do you turn to for support?_____

6b. Are there any personal issues that we have not covered that you would like to share with me?
_____
_____
_____
_____

7. How did you find this follow-up clinic? (Ask of intervention group participants) *(Document responses)* (**Prompts**: was it helpful?; Not at all?; A little) (***Ask for an example of where they applied what they learnt at clinic in their post-discharge period and up to 3 months***).
_____
_____
_____
_____
_____

Alerts:

Issue(s)	Notes and Action(s)
	_____
	_____
	_____
	_____
	_____
	_____
	_____

Section 6: Participant Questions *(Questions asked of the researcher by participants)*

Visit	Question(s) asked and Response(s)
3 months post-discharge	_____ _____ _____ _____ _____ _____ _____ _____

Event notification (add to excel spreadsheet)	Please tick Yes or No	Communication source
Cardiologist	Yes ☐ No ☐	Telephone ☐ Writing ☐
GP	Yes ☐ No ☐	Telephone ☐ Writing ☐
Family/Next of Kin _____	Yes ☐ No ☐	Telephone ☐ Writing ☐
Ethics: XXX HREC/ MS HREC/QUT HREC/ XXX DON (via Research Director of Nursing)	Yes ☐ No ☐	Telephone ☐ Writing ☐
Data Entry and Cleaning		
Data Entered	Yes ☐ No ☐	
Date Entered	/ / 2012/2103	Signature:
Data Cleaned	Yes ☐ No ☐	
Date Cleaned	/ / 2012/2013	Signature:

Letter of study completion and summary of results (Add to excel spreadsheet)	Please tick Yes or No
Patient	Yes ☐ No ☐
GP	Yes ☐ No ☐
Cardiologist	Yes ☐ No ☐
NOTE: If patient a standard care group participant and not been contacted throughout 3 months by CR centre, contact the hospital at which they underwent their procedure to arrange for referral.	Yes ☐ No ☐

*Thank participant for their time and volunteering in this study. Advise participant they will receive certificate of appreciation in the mail with a summary of key findings on completion of the study.

Chest Pain Action Plan

Chest Pain Action Plan – National Heart Foundation of Australia (NHFA) (2009).

*Reproduced with permission from www.heartattackfacts.com.au © 2011 National Heart Foundation of Australia.

Appendix Q: Wound Healing Continuum – Access Site Assessment Tool

Assessment and Continuation Chart
How to use the Continuums

STEP ONE - THE WOUND HEALING CONTINUUM

The Wound Healing Continuum is an aid to understanding the type of tissue present in a wound and how it should progress. Thought of as a continuum of colour changes (see the diagram below) from black to pink, it correlates with the healing of the wound. Not all wounds progress across the whole spectrum (for example not all wounds will have a black stage).

THE WOUND HEALING CONTINUUM

| BLACK | BLACK/YELLOW | YELLOW | YELLOW/RED | RED | RED/PINK | PINK |
| 6 | 5 | 4 | 3 | 2 | 1 | 0 |

Using the Wound Healing Continuum

Identify the colour of the wound that is furthest to the left of the continuum. For example, if the wound contains yellow slough and red granulating tissue it would be defined as a yellow/red wound. The management plan would focus on removal of the yellow sloughy tissue and promotion of the red granulation tissue. As this objective is achieved, so the patient can progress along the wound healing continuum towards the right and therefore pink/healing status.

STEP TWO - THE WOUND INFECTION CONTINUUM

The Wound Infection Continuum is an aid to understanding the level of bacteria present in the wound. There are four criteria which work from left to right with the most severe, Spreading Wound Infection on the left (see diagram below). The continuum moves right, through Local Infection, Critical Colonisation to Colonisation.

Spreading Infection can be a life threatening condition. Local signs and symptoms associated with a spreading soft tissue infection include; spreading redness [greater than 2cm around the wound margin], very high exudate levels, pain, malodour, heat in the surrounding tissues and blistering. Localised infection is characterised by less than 2cm of redness around the wound margin symptoms similar to spreading infection may also be present but to a lesser degree. Critical Colonisation is characterised by delayed healing, malodour and raised exudate levels; slough may also be present. However the wound will not present as if locally infected.

A Colonised Wound is the normal healing state of a wound healing by secondary intention; a reduction in the wound size over a two week period would suggest an acceptable level of colonisation.

| SPREADING INFECTION | LOCAL INFECTION | CRITICAL COLONISED | COLONISED |
| 3 | 2 | 1 | 0 |

Using the Wound Infection Continuum

The Wound Infection Continuum is a simple sliding scale which can be used as an aid to clinical decision-making regarding the level of bacterial colonisation of a wound. A patient may never move to the furthest point on the right (Colonisation) on the continuum during their entire treatment.

However, lower bacterial levels found in colonised wounds generally lead to better healing. The status of a wound which has a Spreading Infection, a Localized Infection or a Critically Colonised wound should be considered when developing a wound management plan.

STEP THREE - THE WOUND EXUDATE CONTINUUM

The Wound Exudate Continuum is an aid to quantifying wound exudate. The viscosity as well as the volume of the exudate can be an important indicator of a wound's status. The gradings are High, Medium and Low for both and this allows wound exudate to be categorised by a score (see diagram below). For example, a low volume of medium viscosity would be a Low/Med category and would score 4, placing it in the Low Exudate portion of the continuum.

Any wound assessed as having both high viscosity and high volume of wound exudate would score a full 10 points and be regarded as giving serious concern. It is likely that such a wound indicates a Spreading Infection, a sinus or a fistula formation or some other cause for concern. Any wound scoring 6 points would be regarded as requiring regular review. It may be that this finding is entirely consistent with the treatment applied e.g. the liquefying of wound slough. The wound may previously have been scored in the Red Zone and as such a score of 6 would indicate an improvement.

Where a wound previously scored as 2-4 points and is observed to be in the Amber Zone (scoring 6 points) it may be showing early signs of Critical Colonization or the development of outright infection and should be treated appropriately.

Using the Wound Exudate Continuum

When reviewing the wound, the exudate on the dressing and present in the wound should be assessed along with information relating to the number of dressing changes required over a 48-hour period.

	VISCOSITY		
VOLUME	HIGH 5	MEDIUM 3	LOW 1
HIGH 5			
MEDIUM 3			
LOW 1			

Source: Wounds UK (2010). *Applied wound management: Assessment and continuation chart*.

Retrieved from http://www.wounds-uk.com/pdf/content_8973.pdf

Applied Wound Management
Assessment and Continuation Chart

Patient Identity	Date	Chart completed by		
Patient Address	Unit No.	GP/Consultant		
	D.O.B / /	Consent to images (circle appropriate)	YES	NO
	Location	Date next assessment required		

Front   Back

INITIAL ASSESSMENT - TYPE AND LOCATION OF WOUND

Type of wound/s

Location of wound/s

Wound pain present - YES ☐   NO ☐

CONTINUAL ASSESMENT - THE HEALING ZONE

Please enter a cross from the total scoring of the two step continuums to see the overall healing progress of the wound.

Asesment 1 Asesment 2 Asesment 3 Asesment 4 Asesment 5 Asesment 6 Asesment 7 Asesment 8 Asesment 9 Asesment 10

wound healing and wound infection continuums

High 9
8
7
6
5
4
3
2
1
Low 0

HEALING ZONE

Applied Wound Management – Assessment and Continuation Chart (Wounds UK, 2010).

Applied Wound Management – Assessment and Continuation Chart (Wounds UK, 2010).

Appendix R: Neurovascular Assessment Tool

Neurovascular Assessment Tool (Judge, 2007, p. 43).

Neurovascular Chart				
Name: **Ward:** **Consultant:** **Area for observation:**		**Hospital no:** **Procedure/Injury:** **Frequency of Observations:**		
Date:		Right	Left	Comments
Time:				
Pain Score (1–10):				
Colour	Normal			
	Pale*			
	Cyanotic*			
	Mottled*			
Warmth	Hot*			
	Warm			
	Cold*			
	Cool*			
Pulses	Name of pulse:			
	Strong			
	Weak*			
	Absent*			
Capillary refill greater than 2 seconds (yes/no)				
Movement				
Dorsi flexion	No movement*			
	Movement, no pain			
	Movement with pain*			
Plantar Flexion	No movement*			
	Movement, no pain			
	Movement with pain*			
Toe extension	No movement*			
	Movement, no pain			
	Movement with pain*			
Toe flexion	No movement*			
	Movement, no pain			
	Movement with pain*			
Sensation				
Web space **First and second toe**	No sensation*			
	Tingling/numbness*			
	Full sensation			
Web space **third and fourth toe**	No sensation*			
	Tingling/numbness*			
	Full sensation			
Sole of foot/toes	No sensation*			
	Tingling/numbness*			

	Full sensation			
Arch of foot (medial)	No sensation*			
	Tingling/numbness*			
	Full sensation			
Initials				

Always compare with the unaffected limb. If both limbs are affected, use a separate chart for each limb.

*These may be signs of abnormalities, take appropriate action, document and inform a member of the medical team. Document all actions taken in the space below.

Changes present now: Yes ☐ No ☐ *(Please tick)*

Affected limb(s): Right upper/Right lower/Left upper/Left lower *(Please circle)*

Actions:_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Appendix S: Permissions For Assessment Tools

mind garden

www.mindgarden.com

To whom it may concern,

This letter is to grant permission for the above named person to use the following copyright material for his/her thesis or dissertation research.

Instrument: *State-Trait Anxiety Inventory for Adults*

Authors: *Charles D. Spielberger, in collaboration with R.L. Gorsuch, G.A. Jacobs, R. Lushene, and P.R. Vagg*

Copyright: *1968, 1977 by Charles D. Spielberger*

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Sincerely,

Robert Most
Mind Garden, Inc.
www.mindgarden.com

Greetings Katina, and thank you for your interest in using the copyrighted Morisky Medication Adherence Scale, 8-Items (MMAS-8). Since you are a student, I will waive the license fee for use of the instrument, provided that your reference our research and send me a summary of your findings upon completion of your research. I have attached for you the documents regarding the copyright agreement, waiver of licensure fee and coding instructions for the MMAS-8. I hope this information is helpful and look forward to receiving your signed agreement and results of your investigation. Please send me (fax or email) at your earliest convenience the signed agreement form and your project results when completed. I have attached relevant manuscripts for your background reading.

Sincerely,

Dmorisky

Donald E. Morisky, Sc.D., M.S.P.H., Sc.M.
Professor and Program Director, Doctoral Training in the Social and Behavioral
Determinants of HIV/AIDS Prevention
Department of Community Health Sciences
UCLA School of Public Health

email: dmorisky@ucla.edu

Date: Thu, 16 Jun 2011 14:21:41 +1000
Subject: Permission

Dear Professor Hare,

I am writing to you seeking permission to use the 'Cardiac Depression Scale' to assess cardiac patients in my study for depression. With your written permission (the form of an e-mail will suffice), may I please use this scale for the purpose of participant assessment in my study? Please feel free to contact me at any time via e-mail or alternately via telephone if you have any questions.

Kind regards,
Katina

Katina Corones – PhD Candidate
School of Nursing & Midwifery | Victoria Park Rd, Kelvin Grove Campus| Queensland University of Technology | Kelvin Grove, QLD, 4059, Australia

---

Sent: Thursday, 16 June 2011 6:00
Subject: Re: Permission

Ok Katina.
We should send you some extra info when I get back from Europe.

Prof DL Hare

Hello Katina

Please find attached some documentation for your use.

Best wishes
Carol-Lynn

PA to Prof. David L Hare

Subject: Re: Permission request Cardiac Self-efficacy
Questionnaire

Katina,

You are welcome to use our scale as long as you cite our
original paper in Psychosomatic Medicine.

Mark Sullivan, MD, PhD
Psychiatry and Behavioral Sciences
University of Washington

Good Morning Katina,

Further to your below e-mail, please accept this as our permission for you to utilise the Applied Wound Management Assessment and Continuation Chart for your participants.

Kind regards

Lorraine Knowles

Vi Guyan
Operations Director
HealthComm UK T/A Wounds UK

Dear Ms Judge,

I am a PhD Candidate seeking permission to use two figures from the following journal article in my PhD studies to assess patients and in my Thesis:

Neurovascular assessment' (2007), Nursing Standard, 21(45), pp. 39–44.

The figures consist of the following:
1. Location of peripheral pulses – p.41; &
2. Neurovascular Assessment Tool – p.43.

Please feel free to contact me at any time during business hours via telephone or alternately, you may e-mail at any time. My contact details are as listed below.

Kind regards,
Katiana

Katina Corones – PhD Candidate
School of Nursing & Midwifery | N Block, Victoria Park Rd, Kelvin Grove Campus|
Queensland University of Technology | Kelvin Grove, QLD, 4059, Australia

Dear Katina
Many thanks for your e-mail. I am more than happy for you to reproduce and use these two diagrams.

Kind regards
Nicola

Nicola Whiteing

MSc, PG Dip HE, BSc (hons), RN, RNT, ANP

Senior Lecturer in Advanced Practice

Department of Applied Biological Sciences

School of Community & Health Sciences

City University, London

Katina

Approval has been granted.

Please use the action plan located at: http://heartattackfacts.com.au/Action-plan.aspx

The following acknowledgement must be included directly below the action plan within the document.

Reproduced with permission from www.heartattackfacts.com.au © 2011 National Heart Foundation of Australia.

Regards

Roberto Pietrobon | National Health Content Unit Manager

Heart Foundation, Level 12, 500 Collins Street, Melbourne VIC 3000

Hi Katina,

My apologies for the late reply.

Yes, you can use our printed material for your education purposes. Please just acknowledge the source of those pictures by stating SOURCE: SARSTEDT AUSTRALIA PTY. LTD. underneath the pictures.

Thanks.
Shirley

Appendix T: Saliva Sample Instruction Sheet

The 'REALITY CHEC' Project©

Saliva sample – Instruction sheet
* Please take the sample at the same time your first sample was taken at: _____ am/pm.

Step1: **Figure 1.** Open the lid of the tube.

Step 2: **Figure 2.** Remove the swab from the tube (Please do not to touch the inside of the tube).

Adapted from "Salivette®: Hygenic saliva collection for diagnostics and monitoring," by SARSTEDT Australia, 2008, p.2. Copyright 2008, by SARSTEDT AG & Co. Reprinted with permission.

1

SALIVA_SAMPLE_INSTRUCTION_SHEET_V1_2012_JULY_TRCP©

Step 3: Figure 3. Place the swab inside your mouth and chew it for approximately 1 minute (60 seconds).

Step 4: Figure 4. Place the swab back into the container and put the lid back on the tube.

Step 5: Package and post - Please put the tube in the plastic zip lock bag given to you in your pack and then place it into the pre-paid, pre-addressed envelope. When you have packaged it per the instructions, please post it to Queensland University of Technology immediately.

References

SARSTEDT. (2008). Salivette®: Hygenic saliva collection for diagnostics and monitoring. In Salivette® (Ed.) (pp. Saliva sample instructions). Australia: SARSTEDT Australia PTY. LTD.

Adapted from "Salivette®: Hygenic saliva collection for diagnostics and monitoring," by SARSTEDT Australia, 2008, p.2. Copyright 2008, by SARSTEDT AG & Co. Reprinted with permission.

Appendix U: The REALITY CHEC Project© – Risk Protocols

THE 'REALITY CHEC' PROJECT

ADMINISTRATION and RESEARCH PROTOCOL

RESEARCH ISSUES

- REGULAR SUPERVISORY TEAM DEBRIEFING
- Assistant Director of Nursing (ADON); Director of Nursing (DON); SITE CONTACT (S) & RESEARCH TEAM
- RESEARCH MANAGER & RESEARCH TEAM
- CARDIOLOGY DIRECTOR UPDATES

ADMINISTRATION

- Reporting event
- Meet with:
  - Nursing Director of Research;
  - Administration manager;
  - Medical records manager;
  - DON;
  - ADON; &
  - Site contact.

SUPPORTING DOCUMENTATION

- Keep appropriate documentation (hard copies) at all times (i.e. detailing room allocation and times)

1

THE 'REALITY CHEC' RISK PROTOCOL
MEDICAL EMERGENCIES
XXXX HOSPITAL

MEDICAL EMERGENCY

- CALL A CODE: # XXXX
- Commence:
  - BASIC LIFE SUPPORT (BLS)
  - ADVANCED LIFE SUPPORT (ALS)

PATIENT TRANSFER

- REFERRAL TO:
- EMERGENCY CENTRE
- INTENSIVE CARE (ICU)
- WARD

Post-event procedures

- DOCUMENTATION IN:
  - Patient's medical chart
  - Data collection form (DCF)
- NOTIFICATION
  - Next of Kin notification
  - GP and Cardiologist
  - Human Research Ethics Committee (HREC): Queensland University of Technology (QUT), and XXX
  - One week post: Follow-up call
  - Assess emotional status and offer counseling/psychology referral if concerns.

1

Version 2, January, 2012©

THE 'REALITY CHEC' PROJECT
RISK PROTOCOL
EMOTIONAL DISTRESS
TELEPHONE FOLLOW-UP

STEP 1

- REASSURE PATIENT

Step 2

- Option 1: Call ambulance 000
- (a. Have patient call if capable or friend/family if present)
- (b. Call for patient if no-one present and incapable of calling)

- Option 2:
- Contact general practitioner (GP) at time of follow-up
- Arrange for appointment based on assessment

Step 3

- DOCUMENTATION IN:
- Data collection form
- Medical chart

- Notification:
- Cardiology director and GP
- Next of kin
- Follow-up: Next day post event

1

THE 'REALITY CHEC' RISK PROTOCOL
MEDICAL EMERGENCIES TELEPHONE FOLLOW-UP

MEDICAL EMERGENCY

- Assess the situation
- Reassure patient
- Get patient to dial for ambulance (000)If patient unable to call for ambulance have:
- 1. Family/friend (if present)
- 2. Researcher to dial 000 for patient (if no one present)

Action(s)

- Actions:
- 1. If bleed/haematoma - Application of pressure (by patient or person(s) present)
- 2. If chest pain - Follow National Heart Foundation of Australia (NHFA) Chest Pain Action Plan (Page 2 of this protocol)

Post-event procedures

- Data collection form (DCF)
- Next of kin notification (if not present)
- General practitioner (GP) and cardiologist
- Human research ethics committes (HREC):
- ▮ Ethics Committee; ▮ HREC Queensland University of Technology (QUT)
- **One week post**: Follow-up call. Assess emotional status and offer QUT counseling/psychology referral if concerns.

1

Version 1, JUNE, 2012©

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Chest Pain Action Plan - National Heart Foundation of Australia (NHFA) (2009).
*Reproduced with permission from www.heartattackfacts.com.au © 2011 National Heart Foundation of Australia.

THE 'REALITY CHEC' RISK PROTOCOL
MEDICAL EMERGENCIES
XXXX HOSPITAL

MEDICAL EMERGENCY

- CALL A CODE: # XXXX
- Commence:
  - BASIC LIFE SUPPORT (BLS)
  - ADVANCED LIFE SUPPORT (ALS)

PATIENT TRANSFER

- **REFERRAL TO:**
- EMERGENCY CENTRE
- INTENSIVE CARE (ICU)
- WARD

Post-event procedures

- **DOCUMENTATION IN:**
  - Patient's medical chart
  - Data collection form (DCF)
- **NOTIFICATION**
  - Next of Kin notification
  - GP and Cardiologist
  - Human Research Ethics Committee (HREC): Queensland University of Technology (QUT), and XXXX
  - One week post: Follow-up call
  - Assess emotional status and offer counseling/psychology referral if concerns.

1

Version 2, January, 2012©

THE 'REALITY CHEC' RISK PROTOCOL
MEDICAL EMERGENCIES
XXXXXX HOSPITAL

MEDICAL EMERGENCY

- CALL APPROPRIATE CODE (XXX)
- Commence:
  - BASIC LIFE SUPPORT (BLS)
  - ADVANCED LIFE SUPPORT (ALS)

NOTIFICATION

- Notify Dr XXX
- Speed dial to mobile phone within XXX
- CALL: XXX
- Pager: XXX

- **If not available, contact: Cardiology registrar blue team.

Post-event procedures

- Patient's medical chart
- Data collection form (DCF)
- Next of kin notification
- General practitioner (GP) and cardiologist
- Human research ethics committee (HREC):XXXX XXXX Ethics Committee; Queensland University of Technology (QUT); Nursing Director of Research.
- **One week post**: Follow-up call. Assess emotional status and offer counselling/psychology referral if concerns.

1

Version 3, June, 2012©

THE 'REALITY CHEC' PROJECT

STEP 1

- REASSURE PATIENT

Step 2

- 1. Acute psychiatric episode/Emotional distress:
  - **Contact**: XXXX Emergency Centre (XX)(XX) XXXX XXX to arrange referral to XXX Hospital (XX).

- **2. General concerns/anxiety**
  - **Procedure-related**: Cardiologist, ▮▮▮▮
- **Anxiety**: General Practitioner (GP); Queenlsand University of Technology (QUT) Clinic; Pastoral care (PC).
  - Contact with PC, GP and/or QUT to be made via telephone and e-mail.

Step 3

- **DOCUMENTATION**:
  - Data collection form (DCF)
  - Medical chart

- Notify cardiologist and GP
- Notify next of kin

- **Follow-up**: Next day post event

1

Appendix V: Nurse-led Clinic – Sample of slide presentation

THE 'REALITY CHEC' PROJECT

Ms K. Corones, PhD Candidate
Queensland University of Technology

YOUR HEART & PROCEDURE

- **What has just happened to me?**
  - Procedure on your heart:
    - Percutaneous coronary intervention (PCI)
    - Balloon angioplasty/Stent/Both/Other
    - Very serious surgery

  - **Why?**
    - To open up one or more blockages or narrowings in your heart (Coronary heart disease [CHD] or blood clot)
    - Coronary heart disease: A chronic disease; life long; you have not been cured

EMOTIONS

- Why are we doing these questionnaires about personal feelings and emotions?
  - Anxiety, depression and CHD have a strong association

  - Want to make sure that we can detect anxiety or depression early on and offer treatment if required

- Feeling a range of emotions after your heart attack or heart procedure is: ***VERY NORMAL***

Emotions: Anxiety, teary, upset, angry, short temper, sad

EMOTIONS

- If you would like to speak with someone about how you are feeling, *please let me know today* or alternately you may want to contact your General Practitioner (GP)

- Others: Beyond Blue; Lifeline; QUT Psychology Clinic

- If these emotions present at a later time and are causing you distress, please contact your GP, Beyond Blue or Lifeline.

- Who do you turn to for support? Is there a friend or family member that is always there for you?

YOUR WOUND SITE

Have you removed your dressing?
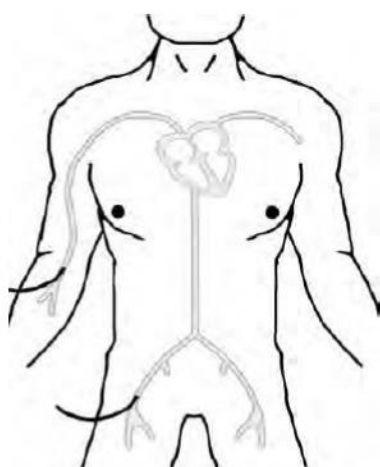
Figure 1.1. and 1.2. Adapted from "A nurse's guide to caring for cardiac intervention patients," by E. O'Grady, 2007, p. 2. Copyright 2007 by Wiley. Reprinted with permission.

CHEST PAIN

- You may experience chest pain (Angina) even after you have this procedure

- Do you know what to do?
  - What would you do?

- National Heart Foundation of Australia
  - Chest pain action plan (Put this magnet on your fridge)
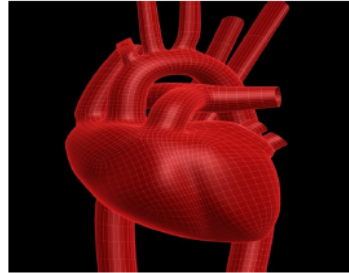
  Let's discuss your plan together ☺

CARDIAC REHABILITATION

What can I expect?

Exercise program: A tailored exercise program

Education:
- Your heart and health after surgery
- Medications
- Diet
- Lifestyle and behaviour changes
- Support: Patient and family

CARDIAC REHABILITATION

Q. What health professionals may I see there?
Pharmacist, Dietician, Nurses, Exercise
physiologists, Cardiologist

Q. Do other patients attend?
Yes. Patients (and families) like yourself and those
who have had open heart surgery

LET'S GET YOU ENROLLED NOW ☺

Appendix W: Phase One – Participant Information and Consent Form (PICF) and Ethical Approval

QUT Queensland University of Technology Brisbane Australia	**PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT**

The 'REALITY CHEC' Project©

QUT Ethics Approval Number 1200000332

RESEARCH TEAM

Principal Researcher:	Katina Corones – PhD Candidate	07 3138 8208	k.corones@student.qut.edu.au
Associate Researcher:	Dr Karen Theobald – Supervisor	07 3138 3904	k.theobald@qut.edu.au
	School of Nursing – Faculty of Health – Queensland University of Technology (QUT)		

DESCRIPTION

This project is being undertaken as part of a PhD project by Ms Katina Corones.

The purpose of this project is to study and follow-up patients like yourself who have undergone a procedure to clear blockages in your heart in the early post-discharge period.

The main aim of the research is to evaluate if the intervention provided to patients who have a procedure to clear blockages in their heart can reduce emotional distress early in the post-discharge period and encourage the maintenance of long-term positive health behaviours.

The research team requests your assistance because the literature has shown a need for more regular patient follow-up within this time frame. There can be a long time between the day you are discharged from hospital until you see the specialist and/or your GP and start your cardiac rehabilitation program. Therefore, we look to investigate the support and care given during the post-discharge period surrounding this procedure.

PARTICIPATION

If you agree to participate you will be contacted on 3 occasions over the next 3 months. The nature of this follow-up will depend on which one of two groups you are assigned to. Detailed information is given below.

Day of discharge from hospital:

- If you consent to participate in this study, we will collect general demographic information; Medical history; Physical assessment; Undertake questionnaires concerning your emotional health; Photograph of your procedure wound(s).
    - Physical assessment: These will involve the measurement of your vital signs. This will include blood pressure, pulse, temperature and respirations. Your wound(s) will also be reviewed by the researcher for any complications. Following this, a photograph of your wound(s) will be taken and/or a diagram will be filled out. This photograph will be used to view wound healing process and to compare over time. The photograph(s) may be used to educate healthcare professionals, however, it will not contain any identifiable personal information. Lastly, physical assessment will also review and measure any chest pain/chest related discomfort you may have.
    - Saliva sample: A saliva sample will be taken to assess your stress levels. An instruction leaflet with pictures will be provided.
    - Questionnaires: These will ask questions such as: "How confident are you that you can maintain your usual activities at work?"; and "Do you sometimes forget to take your heart pills?"(Morisky, Ang, Krousel-Wood, & Ward, 2008; Sullivan, LaCroix, Russo, & Katon, 1998).
- Information will also be collected from your hospital medical records.
- This will take approximately 20–30 minutes.

Instructions on taking a saliva sample (You will be given a leaflet with pictures and instructions on how to take the sample):
1. Remove the swab from the tube (please do not touch the inside of the tube);
2. Place the swab inside your mouth and chew it for approximately 1 minute (60 seconds);
3. Place the swab back into the container and put the lid back on the tube.

After the researcher collects the information detailed above, *you will be randomly assigned to one of two groups*.

The two groups include the following:

- At 3 months post-discharge (you will be contacted via telephone).
  - This will take approximately 30–45 minutes.
  - You will be asked questions about your physical health, undertake questionnaires concerning your emotional health, medications and coping. You will also be asked questions regarding your post-procedural health and well-being.

PLEASE NOTE: The two saliva samples will be processed at a laboratory at the University to assess for stress and anxiety. Sample one will be taken on the day you sign the consent form and sample two will be taken at 1 month post-discharge. You will be reminded and given written information on when and how to take the second sample at home.

Your participation in this project is voluntary. If you do agree to participate you can withdraw from participation at any time during the project without comment or penalty. If you decide to withdraw from the study, the information you have provided (i.e. Saliva sample or questionnaires) may not be withdrawn. Importantly, this information will remain anonymous. Your decision to participate or withdraw will in no way impact upon your current or future relationship with QUT;

EXPECTED BENEFITS

It is expected that this project will benefit you directly in that:

Intervention group:
- You will be provided with support should anxiety or depression be detected throughout the course of the study.
- You will receive direct referral to a cardiac rehabilitation program.
- Education on post-discharge cares and management of your procedure will be reinforced.
- You will receive information on your medications with the importance of taking these reinforced.
- In participating, you should have the knowledge and skills to detect possible post-discharge complications early on.
- You will have the knowledge to care for yourself or others after the procedure and make positive choices when considering lifestyle and health related issues.

Standard care group:
- You will be provided with support should anxiety or depression be detected throughout the course of the study.
- Early detection of post-discharge complications.
- Ability to ask questions of your procedure and the post-discharge period and concerns.

RISKS

The research team has identified the following possible risk in relation to participating in this study – emotional issues associated with talking about your experience.

It should be noted that if you do agree to participate you can withdraw from participation at any time during the project without comment or penalty.

QUT provides limited free counseling for research participants of QUT projects, who may experience discomfort or distress as a result of their participation in the research. Should you wish to access this service please contact the Clinic Receptionist of the QUT Psychology Clinic on 07 3138 0999. Please indicate to the receptionist that you are a research participant.

CONFIDENTIALITY

All comments and responses will be treated confidentially. The names of individual participants will not be identified in the thesis and subsequent publications. Furthermore, the names of individual participants will not be disclosed to any person outside the research team.

CONSENT TO PARTICIPATE

We would like to ask you to sign a written consent form (enclosed) to confirm your agreement to participate.

QUESTIONS / FURTHER INFORMATION ABOUT THE PROJECT

Please contact the research team members named above to have any questions answered or if you require further information about the project.

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE PROJECT

QUT is committed to researcher integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the project you may contact the QUT Research Ethics Unit on 07 3138 5123 or email ethicscontact@qut.edu.au. The Research Ethics Unit is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

Thank you for helping with this research project. Please keep these sheets for your information.

QUT Queensland University of Technology Brisbane Australia	**CONSENT FORM FOR QUT RESEARCH PROJECT**

The 'REALITY CHEC' Project©

QUT Ethics Approval Number 1200000332

RESEARCH TEAM

Principal Researcher:	Katina Corones – PhD Candidate	07 3138 8208	k.corones@student.qut.edu.au
Associate Researcher:	Dr Karen Theobald – Supervisor	07 3138 3904	k.theobald@qut.edu.au
	School of Nursing – Faculty of Health – Queensland University of Technology (QUT)		

STATEMENT OF CONSENT

By signing below, you are indicating that you (please tick boxes):

☐ Have read and understood the information document regarding this project.

☐ Have had any questions answered to your satisfaction.

☐ Understand that if you have any additional questions you can contact the research team.

☐ Understand that you are free to withdraw at any time, without comment or penalty.

☐ Understand that you can contact the Research Ethics Unit on 07 3138 5123 or email ethicscontact@qut.edu.au if you have concerns about the ethical conduct of the project.

☐ Agree to the release of your medical records to the principal researcher <u>only</u> for the purpose of this study.

☐ Understand that any personal information (such as medical records, names) will be de-identified.

☐ Understand that the project will include taking digital photographs of the procedural wound(s).

☐ Understand that the digital photographs of the procedural wound(s) will be used in the thesis, subsequent publications and presentations for the purpose of health education.

☐ Understand that digital photographs of the procedural wound(s) may be presented to healthcare professionals and patients for the purpose of health education.

☐ Understand that the project will include taking two saliva samples in total.

☐ Agree to participate in the project.

Name _____

Signature _____

Date _____

WITNESS

Name _____

Signature _____

Date _____

MEDIA RELEASE PROMOTIONS

From time to time, we may like to promote our research to the general public through, for example, newspaper articles. Would you be willing to be contacted by QUT Media and Communications for possible inclusion in such stories? By ticking this box, it only means you are choosing to be contacted – you can still decide at the time not to be involved in any promotions.

☐ Yes, you may contact me about inclusion in promotions.

☐ No, I do not wish to be contacted about inclusion in promotions.

Please return this sheet to the investigator.

Phase One PICF and Ethical Approval

Human Research Ethics Committee
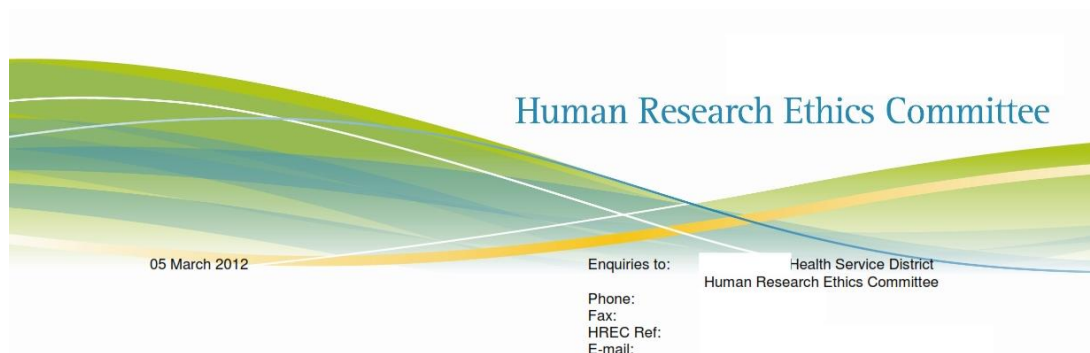
05 March 2012

Enquiries to:

Health Service District
Human Research Ethics Committee

Phone:
Fax:
HREC Ref:
E-mail:

Ms Katina M Corones
Queensland University of Technology
School of Nursing and Midwifery, Kelvin Grove Campus
Nursing Block, Level 6, Room 603
Kelvin Grove QLD 4059

Dear Ms Corones

HREC Reference number: HREC/1
Protocol title: The REALITY CHEC Project - A Three-Arm, Randomised Controlled Clinical Trial Of A Post-Discharge Intervention For Percutaneous Coronary Intervention (PCI) Patients Within Seven Days Post-discharge.

Thank you for submitting the above research protocol to the   Human Research Ethics Committee for ethical and scientific review. This protocol was first considered by the Human Research Ethics Committee (HREC) at the meeting held on 8 November 2011

I am pleased to advise that the HREC has granted approval of this research protocol.

You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until separate authorisation from the District CEO or Delegate of that site has been obtained.

A copy of this approval must be submitted to the District Research Governance Office(r)/Delegate of the relevant institution with a completed Site Specific Assessment (SSA) Form for authorisation from the CEO or Delegate to conduct this research at the   Hospital.

The documents reviewed and approved include:

Document	Version	Date
Application		
Data Collection Form:	9	September 2011
Protocol: Study Protocol	9	
Recruitment Flyer	5	
Participant Withdrawal of Consent	2	
Information and Consent: Image release	3	
Investigator CV		04 October 2011
Risk Management: Letter		12 October 2011
Response to Request for Further Information		13 February 2012
Protocol: Reality Chec	5	06 February 2012
Patient Information Sheet/Consent Form	6	06 February 2012

Please note the following conditions of approval:
1. The Coordinating Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that might affect

health • care • people

Queensland Government

continued ethical acceptability of the protocol. Serious Adverse Events must be notified to the HREC as soon as possible. In addition the Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Coordinating Principal Investigator, including duration of treatment and outcome of the event.

2. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review. Major amendments should be reflected in a revised online NEAF (accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised NEAF, the cover letter and all relevant updated documents, with *tracked changes*, must also be submitted to the HREC office as per standard HREC SOP. (Further advice on submitting amendments is available at

3. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.

4. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.

5. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) should be submitted electronically (track changes) and in hard copy (final clean copy) to the Research Ethics Manager. These should include a cover letter from the Coordinating Principal Investigator or Study Co-ordinator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.

6. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.

7. The Coordinating Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.

   This HREC approval is valid for 3 years from the date of this letter.

8. If you require an extension for your study, please submit a request for an extension in writing outlining the reasons. Note: One of the criteria for granting an extension is the compliance with the approval's conditions including submission of progress reports.

9. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO / ICMJE 2008 definition) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers (WHO Recommendation / ICMJE policy). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. http://www.anzctr.org.au/

Should you have any queries about the HREC's consideration of your protocol please contact the Ethics Secretariat on

Please note that the _____ HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice.* Attached is the HREC Composition with specialty and affiliation with the Hospital (Attachment I).

Office	Postal	Phone	Fax

The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the following websites:

Once authorisation to conduct the research has been granted, please complete the Commencement Form (Attached) and return to the   Human Research Ethics Committee.

The   HREC wishes you every success in your research.

Yours sincerely,

Chair
         Health Service District
Human Research Ethics Committee
Centres for Health Research

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PC
Phone:
Email:

7th March 2012
Please quote our reference:

Ms Katina Corones
QUT School of Nursing and Midwifery
Nursing Block, Level 6
KELVIN GROVE   QLD   4059

Dear Ms Corones

RESEARCH PROPOSAL: *A RandomisEd Controlled Clinical TriAL Of A Post-DIscharge Educational IntervenTion to Reduce Anxiety and Enhance Self-Efficacy (SE) In Percutaneous CoronarY Intervention (PCI) Patients WitHin Five to SEven Days Post-disCharge*
Data Collection Form Version 9 September 2011
Chest Pain Action Plan – National Heart Foundation of Australia (2009)
Information for Prospective Participants Recruitment Flier Version 5
Image Release: Research Participants Version 3   Participant Information Version 6 dated February 2012

I am pleased to advise that the   Human Research Ethics Committee has reviewed the abovenamed research proposal and at its meeting on 23rd February 2012 granted ethical approval. Thank you for your response to the Committee's feedback. I am now able to confirm full approval.

If your project involves inpatients or the use of hospital facilities, it will be necessary for you to obtain the approval of the Director of Medical Services of that hospital before commencement.

It is a strict condition of approval that any departure from the protocol detailed in the proposal submitted for approval be reported immediately to the Committee. If there is any change to the status of the project, this should be reported also.

Approval for the project is given subject to your agreement to   requirements for the monitoring of research (see overleaf), which have been based on the Australian Health Ethics Committee guidelines. Please note the requirement to submit a report annually or at the completion of the project, as appropriate.

With best wishes

Yours sincerely

Executive Officer

Ms Katina Corones – RN, Full-time PhD Candidate
School of Nursing, Queensland University of Technology (QUT)
Level 6 N Block, Room 603
Victoria Park Rd, Kelvin Grove Campus
Kelvin Grove Q 4059

26 April 2012

Dear Ms Corones

Study/Project: "A Randomised Controlled Clinical Trial Of A Post-Discharge Educational Intervention to Reduce Anxiety and Enhance Self-Efficacy (SE) In Percutaneous Coronary Intervention (PCI) Patients Within Five to Seven Days Post-discharge".

The   Institute Research Committee reviewed the above study on 17 April 2012 and approval for the conduct of this study was granted.

Documents reviewed and approved include:

- HREC Initial Application for Ethics Approval for Research Involving Humans (including accompanying documentation)

This approval is valid for the duration of the project. Please note the following conditions of approval.

- Any departure from the protocol detailed in your proposal must be reported immediately to the Committee.
- When you propose a change to an approved protocol, which you consider to be minor, you are required to submit a written request for approval to the Chairperson. Such requests will be considered on a case by case basis and interim approval may be granted subject to ratification at the next meeting of the Committee.
- Where substantive changes to any approved protocol are proposed, you are required to submit a full, new proposal for consideration by the Research Committee.
- You are required to provide a written report on the progress of the approved project annually.
- Please inform the Committee of publications, conference presentations, education and quality improvement outcomes from this study. The Committee may also choose to conduct an interim audit of your research.

In line with   Research Project Governance Policy and Procedures, once the study commences, you are required to provide the   Research Committee and   HREC with the following:

- Amendments and Serious Adverse Event notifications as required;
- Project updates, annually and at project conclusion;
- Abstracts, presentations and publications as they occur;
- Meta-data from study dataset on completion.

This project also requires approval by   Health Human Research Ethics Committee and all conditions of that approval are to be adhered to.

Please accept our best wishes for the success of this study.

Yours sincerely

Chair
          Medical Institute Research Committee

Ethics Application Approval -- 1200000332

https://outlook.qut.edu.au/ . . .

JQJ9lQBUL5N8GBwBA9uc81xqQS7COUnH18FazAAg9myv0AABA9uc81xqQS7COUnH18FazABaX%2fHatAAAJ[

9/10/2012 2:47:20 PM]

Reply Reply to All Forward

Sent: Monday, 16 July 2012 9:58 AM

To: Katina Corones; Karen Theobald; Robyn Clark

Cc: XXXX

Dear Ms Katina Corones

Project title: A RandomisEd controlled clinical triAL of a post-
dIscharge

educational IntervenTion to reduce anxiety and enhance self-efficacY in

percutaneous Coronar intervention patients witHin five to sEven days

post-disCharge – The 'REALITY CHEC' Project

Ethics category: Human – Administrative Review

QUT approval number: 1200000332

(HREC approval

number: HREC/11/QXXX/526;

HREC approval number: 1125)

QUT clearance until: 31/12/2014

This email is to advise that your administrative review application has

been reviewed by the Chair, University Human Research Ethics Committee

and confirmed as meeting the requirements of the National Statement on

Ethical Conduct in Human Research.

Your application has received QUT administrative review approval based

on the approval gained from the XXXXX Human Research Ethics

Committee(HREC), approval number XXXXX. We note this HREC has awarded

the project ethical clearance until 31/12/2014.

VARIATIONS

The XXXX HREC should be considered the lead HREC in terms of the

ethical review of this project. As such, all variations must first be

approved by the XXXX HREC before submission to QUT for ratification

(please submit to QUT using our online variation form:

http://www.research.qut.edu.au/ethics/humans/applications.jsp#amend)

MONITORING

Please ensure you also provide QUT with a copy of each adverse event

report

and progress report submitted to XXXX HREC.

When your project has been completed please advise us by email at your

earliest convenience.

For information regarding the use of social media in research, please go

to:

http://www.research.qut.edu.au/ethics/humans/faqs/index.jsp

Please do not hesitate to contact the unit if you have any queries.

Regards

XXXX on behalf of the Chair UHREC

Research Ethics Unit | Office of Research

Level 4 | 88 Musk Avenue | Kelvin Grove

p: +61 7 3138 5123

e: ethicscontact@qut.edu.au

w: http://www.research.qut.edu.au/ethics/

Appendix X: Phase Two – Intervention Group and Healthcare Professional Interview Questions

Interviewer to state: Commencement of participant interviews for The 'REALITY CHEC' Project©

Date and Time:

Participant ID:

Disclaimer: No names will be used throughout the course of this interview.

Questions

Clinic effectiveness/impact - Participant feedback

1. Tell me about the nurse-led clinic you attended with me.
2. Tell me about any lifestyle or personal changes that you made after attending the nurse-led clinic?
3. What can be done to enhance this clinic/program?
4. What in general did this clinic offer you that you did not know before attending?
5. If there is one thing you could change/add to encouraging patients like yourself in this nurse-led program, what would it be?

Clinic & Emotions

6. How would you describe your emotions surrounding the procedure?
7. How did you feel emotionally when you were discharged home?
8. Tell me about your emotional status after attending the nurse-led clinic the first week after you were discharged home?

Clinic & Cardiac Rehabilitation (CR)

9. Tell me about your experience attending the CR program?
10. Did you attend? Why did you/did you not attend?
11. If you had been to CR in the past, how long ago was this?
12. If this is not your first time attending CR, tell me what did you gain from cardiac rehabilitation this time?
13. **First time attendees:** How important to you was it to attend CR?
14. What would you say to patients who do not attend the program to encourage them?
15. What can we do/offer in this nurse-led clinic do to encourage those to visit/re-visit the course?

16. Who encouraged you to attend?
17. How/did this clinic encourage you to attend the CR course?

Clinic & Medications

18. How are you managing at home with your medications and regime?

19. Were there any changes you made to your medication regime after attending the nurse-led clinic?

Clinic, Complications, Education & Management

20. Tell me how you felt in terms of managing any complications before and after the clinic?

21. Did you suffer any complications after attending the clinic/after hospital discharge?

22. If complication(s) experienced, what information offered to you did you refer to in order to manage this?

Thank participant for their time. Advise Coles/Myer voucher to be posted via mail.

End of interview

Phase Two – Healthcare Professionals Semi-Structured Interview Questions

<u>Healthcare professionals (HCP) - Interview</u>

Commencement of Healthcare professional interview for The 'REALITY CHEC' Project

Date & Time:

Study ID:

Disclaimer: Names of participants and sites will not be used throughout the course of this interview.

Explain intervention and nurse-led clinic to HCP's

Firstly give a brief verbal overview of the clinic and then:

1. Show slide presentation
2. Show HCP's questionnaires asked of participants
3. Access site assessment – Explanation of what is undertaken.
4. Vital signs and physical assessment – Head to toe (Explanation of what is undertaken)

Questions:

1. Describe your impression of the educational value of the slide presentation offered at the nurse-led clinic?
   a. Please explain in detail the positives of this intervention from a HCP's perspective and elaborate why.
   b. Please discuss the negatives in detail and give your professional opinion of what could be added to improve the study.
2. Please explain how you feel about the time involved to undertake the clinic.
3. Explain your feelings about the screening questionnaires undertaken by participants.

<u>Anxiety reduction and SE increase</u>

Comment on the education intervention in respect of the ability to decrease patient anxiety.

<u>Cardiac rehabilitation (CR) referral</u>

This program encourages CR attendance and aims for 100 % referral. Identify where in the presentation that this is made clear. Is this message of encouragement clear in

the presentation? How can we better refer/encourage those who have attended the program in the past who decline referral to revisit the program again?

Medication adherence

As seen, patients' medications are discussed with focus placed on anti-hypertensives, anticholesterolaemics (cholesterol lowering medications) and platelet aggregation inhibitors (the "blood thinners"), complications (briefly) and the importance of adherence and keeping adequate stock at home (i.e. Never running short of clopidogrel!). Do you think this message is clear/clear enough? If yes, how is this message conveyed (or made clear to participants)? If no, what can be done to enhance the presentation and/or encourage adherence? Could this be presented in a different way or format perhaps? Please provide details.

Complication identification and management

As you would have seen, the clinic and presentation aims to provide patients with light education on post-operative complications (post-op) and management. They consist of: 1. Chest pain; 2. Haematomas; infection and wound care. Activity is touched on briefly here in the prevention of complications.

Firstly, are the messages of complication identification and management clear in this presentation; and

Secondly, if yes, how is it made clear to you?

If not, please provide recommendations so that we can improve the program.

Thank participant for undertaking session. Present with Coles/Myer voucher for their input.

<center>End of session.</center>

Appendix Y: Phase Two Ethical Approval and Consent

Dear Ms Katina Corones

Project title: A randomised controlled clinical trial of a post-discharge Educational intervention to reduce anxiety and enhance self-efficacy in Percutaneous Coronary intervention patients within five to seven days Post-discharge - The 'REALITY CHEC' Project

Ethics category: Human - Administrative Review

QUT approval number: 1200000332

                        (Metro XXX HREC approval number: HREC/11/QXXX/526;

                         XXX approval number: 1125;

                        Institute XXX)

QUT clearance until: 31/12/2014 (as per Metro XXX HREC approval)

This email is to advise that your administrative review application has been reviewed by the Chair, University Human Research Ethics Committee and confirmed as meeting the requirements of the National Statement on Ethical Conduct in Human Research.

Your application has received QUT administrative review approval based on the approval gained from the Metro XXX Human Research Ethics Committee (HREC), approval number HREC/11/QXXX/526. We note this HREC has awarded the project ethical clearance until 31/12/2014.

VARIATIONS

The Metro XXX HREC should be considered the lead HREC in terms of the ethical review of this project. As such, all variations must first be approved by the Metro XXX HREC before submission to QUT for ratification (please submit to QUT using our online variation form: http://www.research.qut.edu.au/ethics/humans/applications.jsp#amend)

MONITORING

Please ensure you also provide QUT with a copy of each adverse event report and progress

report submitted to Metro XXX HREC.

When your project has been completed please advise us by email at your earliest

convenience.

For information regarding the use of social media in research, please go to:

http://www.research.qut.edu.au/ethics/humans/faqs/index.jsp

Please do not hesitate to contact the unit if you have any queries.

Regards

Janette Lamb on behalf of the Chair UHREC

Research Ethics Unit | Office of Research

Level 4 | 88 Musk Avenue | Kelvin Grove

p: +61 7 3138 5123

e: ethicscontact@qut.edu.au

w: http://www.research.qut.edu.au/ethics/

Document Submission and Approval Form

Our reference
Your reference REALITY CHEC

14th March 2013

Correspondence: from Katina Corones dated 12th March 2013

Study Title: *A RandomisEd Controlled Clinical TriAL Of A Post-DIscharge Educational IntervenTion to Reduce Anxiety and Enhance Self-Efficacy (SE) In Percutaneous CoronarY Intervention (PCI) Patients WitHin Five to SEven Days Post-disCharge*

Investigators: Katina Corones

Details of documents reviewed:

- Amendment

The document/s listed above were received, reviewed and approved.

Phase Two - Participant Consent

QUT Queensland University of Technology Brisbane Australia	**PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT**

The 'REALITY CHEC' Project©

QUT Ethics Approval Number 1200000332

RESEARCH TEAM

Principal Researcher:	Katina Corones – PhD Candidate	07 3138 8208	k.corones@student.qut.edu.au
Associate Researcher:	Dr Karen Theobald – Supervisor	07 3138 3904	k.theobald@qut.edu.au
	School of Nursing – Faculty of Health – Queensland University of Technology (QUT)		

DESCRIPTION

This project is being undertaken as part of a PhD project by Ms Katina Corones.

The purpose of this project is to study and follow-up patients like yourself who have undergone a procedure to clear blockages in your heart in the early post-discharge period.

The main aim of the research is to evaluate if the intervention provided to patients who have a procedure to clear blockages in their heart can reduce emotional distress early in the post-discharge period and encourage the maintenance of long-term positive health behaviours.

The research team requests your assistance because the literature has shown a need for more regular patient follow-up within this time frame. There can be a long time between the day you are discharged from hospital until you see the specialist and/or your GP and start your cardiac rehabilitation program. Therefore, we look to investigate the support and care given during the post-discharge period surrounding this procedure.

PARTICIPATION

If you agree to participate you will be contacted on 4 occasions over the next 3.5 months. The nature of this follow-up will depend on which one of two groups you are assigned to. Detailed information is given below.

Day of discharge from hospital:

- If you consent to participate in this study, we will collect general demographic information; medical history; physical assessment; undertake questionnaires concerning your emotional health; photograph of your procedure wound(s).
  - **Physical assessment:** These will involve the measurement of your vital signs. This will include blood pressure, pulse, temperature and respirations. Your wound(s) will also be reviewed by the researcher for any complications. Following this, a photograph of your wound(s) will be taken and/or a diagram will be filled out. This photograph will be used to view wound healing process and to compare over time. The photograph(s) may be used to educate healthcare professionals, however, it will not contain any identifiable personal information. Lastly, physical assessment will also review and measure any chest pain/chest related discomfort you may have.
  - **Saliva sample:** A saliva sample will be taken to assess your stress levels. An instruction leaflet with pictures will be provided.
  - **Questionnaires:** These will ask questions such as: "How confident are you that you can maintain your usual activities at work?"; and "Do you sometimes forget to take your heart pills?"(Morisky, Ang, Krousel-Wood, & Ward, 2008; Sullivan, LaCroix, Russo, & Katon, 1998).
- Information will also be collected from your hospital medical records.
- This will take approximately 20–30 minutes.

Instructions on taking a saliva sample (You will be given a leaflet with pictures and instructions on how to take the sample):

1. Remove the swab from the tube (please do not touch the inside of the tube);
2. Place the swab inside your mouth and chew it for approximately 1 minute (60 seconds);
3. Place the swab back into the container and put the lid back on the tube.

After the researcher collects the information detailed above, *you will be randomly assigned to one of two groups*.

The two groups include the following:

Intervention group:

Face-to-face clinic and follow-up over 3.5 – 6 months of having your procedure.

Follow-up times will consist of:

- At 5-7 days post-discharge (You will visit the principal researcher at the clinic)
    - The clinic assessment will take approximately 45–60 minutes.
    - You will receive education concerning your medications, post-procedural cares and activity, and cardiac rehabilitation program. You may also ask questions if you have any concerns regarding your post-discharge health and well-being.
    - You will also undergo a physical assessment, undertake questionnaires concerning your emotional health, medications and coping. You will also be asked questions concerning your procedure and post-procedural health and well-being.
- At 1 month post-discharge from hospital (You will be contacted via telephone)
    - This will take approximately 30–45 minutes.
    - You will be asked questions about your physical health, undertake questionnaires concerning your emotional health, medications and coping. You will also be asked questions regarding your post-procedural health and well-being.
    - You will take a photo of your procedure wound(s) or colour/draw on a picture provided and forward to the principal researcher in the pre-paid, addressed envelope provided.
    - You will also have the opportunity to ask any questions regarding your health and well-being.
    - A saliva sample will be taken by you and you will post this back to QUT in the packaging provided. You will be instructed on how to take this by the principal researcher on the day you are discharged from hospital. This must be taken at the same time that the first sample was taken (For example, if your first sample was taken at 2pm on the day of discharge from hospital, you will take this second sample at 2pm).
- At 3 months post-discharge (you will be contacted via telephone)
    - This will take approximately 30–45 minutes.
    - You will be asked questions about your physical health, undertake questionnaires concerning your emotional health, medications and coping. You will also be asked questions regarding your post-procedural health and well-being.
    - You will also have the opportunity to ask any questions regarding your health and well-being.
- At 3.5 months (14 weeks) to 6 months post-discharge – An in-depth telephone interview
- You will be contacted by Ms Katina Corones via telephone and undertake a telephone interview which will take approximately 45 minutes to 1 hour maximum.
- You will be asked questions about the clinic you attended with Ms Katina Corones after your procedure

Standard care group:

Routine hospital and post-discharge follow-up.

Telephone follow-up over 3 months of having your procedure.

Follow-up times will consist of:

- At 5-7 days post-discharge (you will be contacted via telephone);
    - This will take approximately 30–45 minutes.
    - You will be asked questions about your physical health, undertake questionnaires concerning your emotional health, medications and coping. You will also be asked questions regarding your post-procedural health and well-being.
- At 1 month post-discharge from hospital (you will be contacted via telephone);
    - This will take approximately 30–45 minutes.
    - You will be asked questions about your physical health, undertake questionnaires concerning your emotional health, medications and coping. You will also be asked questions regarding your post-procedural health and well-being.
    - You will take a photo of your procedure wound(s) or colour/draw on a picture provided and forward to the principal researcher in the pre-paid, addressed envelope provided.

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- A saliva sample will be taken by you and you will post this back to QUT in the packaging provided. You will be instructed on how to take this by the principal researcher on the day you are discharged from hospital. This must be taken at the same time that the first sample was taken (For example, if your first sample was taken at 2pm on the day of discharge from hospital, you will take this second sample at 2pm.)
- At 3 months post-discharge (you will be contacted via telephone).
  - This will take approximately 30–45 minutes.
  - You will be asked questions about your physical health, undertake questionnaires concerning your emotional health, medications and coping. You will also be asked questions regarding your post-procedural health and well-being.

PLEASE NOTE: The two saliva samples will be processed at a laboratory at the University to assess for stress and anxiety. Sample one will be taken on the day you sign the consent form and sample two will be taken at 1 month post-discharge. You will be reminded and given written information on when and how to take the second sample at home.

Your participation in this project is voluntary. If you do agree to participate <u>you can withdraw from participation at any time</u> during the project without comment or penalty. If you decide to withdraw from the study, the information you have provided (i.e. Saliva sample or questionnaires) may not be withdrawn. Importantly, this information will remain anonymous. Your decision to participate or withdraw will in no way impact upon your current or future relationship with

EXPECTED BENEFITS

It is expected that this project will benefit you directly in that:
Intervention group:

- You will be provided with support should anxiety or depression be detected throughout the course of the study.
- You will receive direct referral to a cardiac rehabilitation program.
- Education on post-discharge cares and management of your procedure will be reinforced.
- You will receive information on your medications with the importance of taking these reinforced.
- In participating, you should have the knowledge and skills to detect possible post-discharge complications early on.
- You will have the knowledge to care for yourself or others after the procedure and make positive choices when considering lifestyle and health related issues.
- You will be posted a $25.00 Coles/Myer voucher for offering your input to the study, after the final interview has been completed.

You will assist in broadening the knowledge and insight of health professionals practicing in the cardiology field.
Standard care group:

- You will be provided with support should anxiety or depression be detected throughout the course of the study.
- Early detection of post-discharge complications.
- Ability to ask questions of your procedure and the post-discharge period and concerns.

RISKS

The research team has identified two following possible risk in relation to participating in this study
1. Emotional issues associated with talking about your experience
2. You may be inconvenienced as you will be required to provide up to one hour of your time for the interview.

It should be noted that if you do agree to participate you can withdraw from participation *at any time* during the project without comment or penalty.

QUT provides <u>limited free counseling</u> for research participants of QUT projects, who may experience discomfort or distress as a result of their participation in the research. Should you wish to access this service please contact the Clinic Receptionist of the QUT Psychology Clinic on 07 3138 0999. Please indicate to the receptionist that you are a research participant.

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You will be provided with contact details on request.

CONFIDENTIALITY

All comments and responses will be treated confidentially. The names of individual participants will not be identified in the thesis and subsequent publications. Furthermore, the names of individual participants will not be disclosed to any person outside the research team.

CONSENT TO PARTICIPATE

We would like to ask you to sign a written consent form (enclosed) to confirm your agreement to participate.

QUESTIONS / FURTHER INFORMATION ABOUT THE PROJECT

Please contact the research team members named above to have any questions answered or if you require further information about the project.

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE PROJECT

QUT is committed to researcher integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the project you may contact the QUT Research Ethics Unit on 07 3138 5123 or email ethicscontact@qut.edu.au. The Research Ethics Unit is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

Thank you for helping with this research project. Please keep these sheets for your information.

QUT Queensland University of Technology Brisbane Australia	CONSENT FORM FOR QUT RESEARCH PROJECT

The 'REALITY CHEC' Project©

QUT Ethics Approval Number 1200000332

RESEARCH TEAM

Principal Researcher:	Katina Corones – PhD Candidate	07 3138 8208	k.corones@student.qut.edu.au
Associate Researcher:	Dr Karen Theobald – Supervisor	07 3138 3904	k.theobald@qut.edu.au
	School of Nursing – Faculty of Health – Queensland University of Technology (QUT)		

STATEMENT OF CONSENT

By signing below, you are indicating that you (please tick boxes):

☐ Have read and understood the information document regarding this project.

☐ Have had any questions answered to your satisfaction.

☐ Understand that if you have any additional questions you can contact the research team.

☐ Understand that you are free to withdraw at any time, without comment or penalty.

☐ Understand that you can contact the Research Ethics Unit on 07 3138 5123 or email ethicscontact@qut.edu.au if you have concerns about the ethical conduct of the project.

☐ Understand that interviews will be recorded and transcribed

☐ Understand that all recorded and transcribed data will be de-identified

☐ Understand that interviews may be transcribed by a paid professional transcriber

☐ Agree to the release of your medical records to the principal researcher only for the purpose of this study.

☐ Understand that any personal information (such as medical records, names) will be de-identified.

☐ Understand that the project will include taking digital photographs of the procedural wound(s).

☐ Understand that the digital photographs of the procedural wound(s) will be used in the thesis, subsequent publications and presentations for the purpose of health education.

☐ Understand that digital photographs of the procedural wound(s) may be presented to healthcare professionals and patients for the purpose of health education.

☐ Understand that the project will include taking two saliva samples in total.

☐ Understand that you will be posted a Coles/Myer voucher after the final interview has been completed.

☐ Agree to participate in the project.

Name _____

Signature _____

Date _____

WITNESS

Name _____

Signature _____

Date _____

MEDIA RELEASE PROMOTIONS

From time to time, we may like to promote our research to the general public through, for example, newspaper articles. Would you be willing to be contacted by QUT Media and Communications for possible inclusion in such stories? By ticking this box, it only means you are choosing to be contacted – you can still decide at the time not to be involved in any promotions.

☐ Yes, you may contact me about inclusion in promotions.

☐ No, I do not wish to be contacted about inclusion in promotions.

Please return this sheet to the investigator.

Phase Two Consent – Healthcare Professionals

<table>
<tr><td colspan="2">QUT Queensland University of Technology
Brisbane Australia</td><td>PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT</td></tr>
<tr><td colspan="3" align="center">The 'REALITY CHEC' Project©
<small>QUT Ethics Approval Number 1200000332</small></td></tr>
</table>

RESEARCH TEAM

Principal Researcher:	Katina Corones – PhD Candidate	07 3138 8208	k.corones@student.qut.edu.au
Associate Researcher:	Dr Karen Theobald – Supervisor	07 3138 3904	k.theobald@qut.edu.au
	School of Nursing – Faculty of Health – Queensland University of Technology (QUT)		

DESCRIPTION

This project is being undertaken as part of a PhD project by Ms Katina Corones.

The purpose of this project is to provide an early post-discharge educational intervention to participants in the first 5-7 days after undergoing percutaneous coronary intervention (PCI).

Feedback is critical to ensure the usefulness of an educational program. Therefore, the research team seeks input from cardiovascular health professionals on the usefulness and suitability of the nurse-led educational clinic.

PARTICIPATION

If you agree to participate:

- You will be required to make one appointment at time suitable for you to experience the nurse-led educational intervention and then you will be asked to undertake an interview with Ms Katina Corones.

Who can be involved?
Inclusion criteria:

- Any healthcare professional in the cardiovascular specialty area
- Healthcare professionals undertaking post-PCI care and education
- Healthcare professionals undertaking post-discharge care and education
  - This may include:
    - Cardiologists
    - Ward Clinical Nurse Manager
    - Registered and Clinical Nurses (CN's)
    - Cardiac rehabilitation team members

How long? This will take approximately 1 hour of your time maximum.

Part 1: Procedure

- You will be given a brief verbal overview of the nurse-led clinic intervention.
- Katina will then instruct you through the educational package/intervention.
- You will be shown all research questionnaires undertaken by participants.

Part 2: Interview

- You will be asked a series of semi-structured questions regarding feedback about the nurse-led educational intervention.

  - What questions will be asked of me? (*See examples below*)

    - Please explain in detail the positives of this intervention from a HCP's perspective and elaborate why.
    - Comment on the educational intervention in respect of the ability to decrease patient anxiety.

Your participation in this project is voluntary. If you do agree to participate <u>you can withdraw from participation at any time</u> during the project without comment or penalty. If you decide to withdraw from the study, the information you have provided (i.e. interview data collected) may not be withdrawn. Importantly, this information will remain anonymous. Your

decision to participate or withdraw will in no way impact upon your current or future relationship with QUT or UnitingCare Health™.

EXPECTED BENEFITS

It is expected that this project will benefit you directly in that:

- You will be contributing to the future health and well-being of PCI patients as well as their own personal knowledge.
- You will be posted a $25.00 Coles/Myer voucher for offering your input to the study, after the final interview has been completed.

RISKS

The research team has identified the following possible risk in relation to participating in this study:

- Participants may be inconvenienced as they will be required to provide up to 1 hour of their time.

It should be noted that if you do agree to participate you can withdraw from participation *at any time* during the project without comment or penalty.

QUT provides limited free counseling for research participants of QUT projects, who may experience discomfort or distress as a result of their participation in the research. Should you wish to access this service please contact the Clinic Receptionist of the QUT Psychology Clinic on **07 3138 0999**. Please indicate to the receptionist that you are a research participant.

CONFIDENTIALITY

All comments and responses will be treated confidentially. The names of individual participants will not be identified in the thesis and subsequent publications. Furthermore, the names of individual participants will not be disclosed to any person outside the research team.

CONSENT TO PARTICIPATE

We would like to ask you to sign a written consent form (enclosed) to confirm your agreement to participate.

QUESTIONS / FURTHER INFORMATION ABOUT THE PROJECT

Please contact the research team members named above to have any questions answered or if you require further information about the project.

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE PROJECT

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Thank you for helping with this research project. Please keep these sheets for your information.

The 'REALITY CHEC' Project©

QUT Ethics Approval Number 1200000332

RESEARCH TEAM

Principal Researcher:	Katina Corones – PhD Candidate	07 3138 8208	k.corones@student.qut.edu.au
Associate Researcher:	Dr Karen Theobald – Supervisor	07 3138 3904	k.theobald@qut.edu.au
	School of Nursing – Faculty of Health – Queensland University of Technology (QUT)		

STATEMENT OF CONSENT

By signing below, you are indicating that you (please tick boxes):

☐ Have read and understood the information document regarding this project.

☐ Have had any questions answered to your satisfaction.

☐ Understand that if you have any additional questions you can contact the research team.

☐ Understand that interviews will be recorded and transcribed

☐ Understand that all recorded and transcribed data will be de-identified

☐ Understand that interviews may be transcribed by a paid professional transcriber

☐ Understand that you are free to withdraw at any time, without comment or penalty.

☐ Understand that you can contact the Research Ethics Unit on 07 3138 5123 or email ethicscontact@qut.edu.au if you have concerns about the ethical conduct of the project.

☐ Understand that any personal information will be de-identified.

☐ Understand that you will be given a Coles/Myer voucher after undertaking the interview

☐ Agree to participate in the project.

Name _____

Signature _____

Date _____

WITNESS

Name _____

Signature _____

Date _____

MEDIA RELEASE PROMOTIONS

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Appendix Z: Summary of Post-discharge Angina

Table Z.1. **Summary of Post-discharge Angina as a Percentage of the Sample**

Time	Study Participants % (*n*)
Time 1–2	36.4% (12)
Time	- (0)
Time 2–3	39.4% (13)
Time 3	- (0)
Time 3–4	30.3% (10)
Time 4	- (0)

Note. Time 1-2 = Between day of discharge and day 5-7 follow-up; Time 2 = Day 5-7 follow-up;
Time 2-3= Between day 5-7 and 1 month follow-up; Time 3 = 1 month; Time 4 = 3 months.

Appendix A1: Participant demographics

Table A1.1 General demographics – Intervention versus Standard Care Group

Condition (Intervention or standard care group)			Frequency	Percent	Valid Percent	Cumulative Percent
Gender						
Standard care group	Valid	Female	3	15.0	15.0	15.0
		Male	17	85.0	85.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	Female	3	23.1	23.1	23.1
		Male	10	76.9	76.9	100.0
		Total	13	100.0	100.0	
Country of birth						
Standard care group	Valid	Australia	17	85.0	85.0	85.0
		Other	3	15.0	15.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	Australia	11	84.6	84.6	84.6
		Other	2	15.4	15.4	100.0
		Total	13	100.0	100.0	
Primary Language Spoken						
Standard care group	Valid	English	18	90.0	90.0	90.0
		Other	2	10.0	10.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	English	13	100.0	100.0	100.0
Marital Status						
Standard care group	Valid	Not married	4	20.0	20.0	20.0
		Married	16	80.0	80.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	Not married	3	23.1	23.1	23.1
		Married	10	76.9	76.9	100.0
		Total	13	100.0	100.0	

Table A1.2 Participant Education

Condition (Intervention or standard care group)			Frequency	Percent	Valid Percent
Standard care group	Valid	Secondary or less	11	55.0	55.0
		Post-secondary education	9	45.0	45.0
		Total	20	100.0	100.0
Intervention	Valid	Secondary or less	7	53.8	53.8
		Post-secondary education	6	46.2	46.2
		Total	13	100.0	100.0

Table A1.3 Education

Condition (Intervention or standard care group)			Cumulative Percent
Standard care group	Valid	Secondary or less	55.0
		Post-secondary education	100.0
		Total	
Intervention	Valid	Secondary or less	53.8
		Post-secondary education	100.0
		Total	

Appendix A2: Participant Risk Factors – Intervention versus Standard Care Group

Condition (Intervention or standard care group) Risk factor			Frequency	Percent	Valid Percent	Cumulative Percent
Age						
Standard care group	Valid	Yes	20	100.0	100.0	100.0
Intervention	Valid	Yes	13	100.0	100.0	100.0
Gender						
Standard care group	Valid	No	4	20.0	20.0	20.0
		Yes	16	80.0	80.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	No	3	23.1	23.1	23.1
		Yes	10	76.9	76.9	100.0
		Total	13	100.0	100.0	
Family history						
Standard care group	Valid	No	7	35.0	35.0	35.0
		Yes	13	65.0	65.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	No	3	23.1	23.1	23.1
		Yes	10	76.9	76.9	100.0
		Total	13	100.0	100.0	
Hypertension						
Standard care group	Valid	No	8	40.0	40.0	40.0
		Yes	12	60.0	60.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	No	6	46.2	46.2	46.2
		Yes	7	53.8	53.8	100.0
		Total	13	100.0	100.0	
Chronic kidney disease (CKD)						
Standard care group	Valid	No	20	100.0	100.0	100.0
Intervention	Valid	No	13	100.0	100.0	100.0

Condition (Intervention or standard care group) Risk factor			Frequency	Percent	Valid Percent	Cumulative Percent
Atrial fibrillation (new or previous history)						
Standard care group	Valid	No	16	80.0	80.0	80.0
		Yes	4	20.0	20.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	No	10	76.9	76.9	76.9
		Yes	3	23.1	23.1	100.0
		Total	13	100.0	100.0	
Family history hypercholesterolaemia						
Standard care group	Valid	No	7	35.0	35.0	35.0
		Yes	13	65.0	65.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	No	6	46.2	46.2	46.2
		Yes	7	53.8	53.8	100.0
		Total	13	100.0	100.0	
Hypercholesterolaemia						
Standard care group	Valid	No	6	30.0	30.0	30.0
		Yes	14	70.0	70.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	No	1	7.7	7.7	7.7
		Yes	12	92.3	92.3	100.0
		Total	13	100.0	100.0	
Smoking Status smoke						
Standard care group	Valid	No	16	80.0	100.0	100.0
	Missing	666 (N/A)	4	20.0		
	Total		20	100.0		
Intervention	Valid	No	12	92.3	100.0	100.0
	Missing	666	1	7.7		
	Total		13	100.0		

Condition (Intervention or standard care group)		Risk factor	Frequency	Percent	Valid Percent	Cumulative Percent
Alcohol consumption						
Standard care group	Valid	No	8	40.0	40.0	40.0
		Yes	12	60.0	60.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	No	4	30.8	30.8	30.8
		Yes	9	69.2	69.2	100.0
		Total	13	100.0	100.0	
Risk factor Stress						
Standard care group	Valid	No	10	50.0	50.0	50.0
		Yes	10	50.0	50.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	No	6	46.2	46.2	46.2
		Yes	7	53.8	53.8	100.0
		Total	13	100.0	100.0	
Diabetes Mellitus						
Standard care group	Valid	No	18	90.0	90.0	90.0
		Yes	2	10.0	10.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	No	11	84.6	84.6	84.6
		Yes	2	15.4	15.4	100.0
		Total	13	100.0	100.0	
Body Mass Index (BMI)						
Standard care group	Valid	No	5	25.0	25.0	25.0
		Yes	15	75.0	75.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	No	5	38.5	38.5	38.5
		Yes	8	61.5	61.5	100.0
		Total	13	100.0	100.0	
Activity						
Standard care group	Valid	Not active	1	5.0	5.0	5.0
		Active	19	95.0	95.0	100.0
		Total	20	100.0	100.0	
Intervention	Valid	Active	13	100.0	100.0	100.0

Appendix B1: Cohen's *d* – Effect Size Calculations Cardiac Self-Efficacy (CSE)

Effect Size (*d*): Cardiac Self-Efficacy (CSE) Intervention Group Participants

Intervention Group Participants: Cohen's *d*

$$d = \frac{m_A - m_B}{\sigma}$$

m_A = Mean of intervention group at Time 2 (2.48)

m_B = Mean of intervention group at Time 3 (2.11)

σ = Standard deviation of intervention group at Time 2 (0.62)

$$d = \frac{2.48 - 2.11}{0.62}$$

$$d = \frac{0.37}{0.62}$$

$$d = \mathbf{\underline{0.60}}$$

Overall, a moderately reducing effect was demonstrated on CSE in intervention group participants, *d* = 0.60.

Effect size (*d*): Cardiac Self-Efficacy (CSE) Standard Care Group Participants

d= $\underline{m_A - m_B}$

      σ

m_A = Mean of standard care group at Time 2 (2.35)

m_B = Mean of standard care group at Time 3 (2.45)

σ = Standard deviation of standard care group at Time 2 (0.53)

$d = \underline{2.35 - 2.45}$

      0.53

$d = - \underline{0.10}$

      0.53

$d =$ **-0.19**

Overall, receiving standard care alone did not demonstrate any effect on CSE in standard care group participants.

Appendix C1: Reliable Change Index (RCI) Calculations: Cardiac Self-Efficacy (CSE)

Step 1. Calculation of the Standard Error (SE)

$SE = S1 \sqrt{1 - rxx}$

S1 = Standard deviation of the sample pre-intervention (0.56)

rxx = Reliability of the CSE questionnaire (0.697)

$SE = 0.56 \sqrt{1 - 0.697}$

SE = 0.56 x 0.56

SE = **0.31**

Step 2. Calculation of the Standard Error of Difference (*Sdiff*) between the two test scores

$Sdiff = \sqrt{2\,(SE)2}$

$Sdiff = \sqrt{2\,(0.31)2}$

$Sdiff = \sqrt{2\,(0.09)}$

$Sdiff = \sqrt{0.19}$

$Sdiff = \textbf{0.44}$

Step 3. Calculation of Reliable Change Index (RCI)

Intervention group participant 082

X1: Individual pre-treatment score (3.13)

X2: Individual post-treatment score (1.88)

Sdiff: 0.44

RCI = (X2 – X1)

       S*diff*

RCI = 3.13 - 1.88

       0.44

RCI = **2.84**

A reliable change of 2.84 (> ±1.96) in CSE has occurred for intervention group participant 082 after attending the nurse-led clinic.

Standard care group participant 005

X1: Individual pre-treatment score (2.44)

X2: Individual post-treatment score (3.38)

Sdiff: 0.44

RCI = (X2 – X1)

      Sdiff

RCI = 2.44 - 3.38

       0.44

RCI = **2.14**

A positive reliable change of 2.14 (> ±1.96) occurred for CSE in intervention group participant 005 post nurse-led clinic attendance.

Step 4. Cut-off point 'c'

S1: Standard deviation for participants' pre-treatment (0.56)

S2: Standard deviation for a well-functioning sample (0.72)

M1: Pre-treatment mean for the sample (2.40)

M2: Mean of the well-functioning sample on CSE (3.04)

$c =$ <u>S1M2 + S2M1</u>

       S1 + S2

$c =$ <u>0.56 (3.04) + 0.72 (2.40)</u>

       0.56 + 0.72

$c =$ <u>1.70 + 1.73</u>

     1.28

$c =$ **<u>2.68</u>**

A cut-off point of 2.68 suggests that participants' score of $\geq$ 2.68 will fall within the normal distribution, thus, indicating clinically significant change.

Appendix D1: Mean Cardiac Self-Efficacy (CSE) Ratings

Table D.1. **Summary of Means for Scores for the Cardiac Self-efficacy Scale (CSE) Items**

Group/CSE Measure	Time 1 *M(SD)*	Time 2 *M(SD)*	Time 3 *M(SD)*	Time 4 4 *M(SD)*
Intervention				
Weight	2.43 (1.13)	2.00 (1.15)	2.57 (1.27)	3.14 (0.90)
Diet	3.11 (1.17)	2.67 (1.32)	2.89 (0.60)	2.67 (1.12)
Physical activity	3.00 (1.13)	2.58 (0.79)	2.75 (1.14)	3.00 (1.13)
Work activities	2.67 (1.15)	3.00 (1.00)	3.33 (0.58)	3.33 (1.16)
Breathlessness	2.00 (1.41)	1.00 (0.00)	2.00 (0.00)	3.00 (0.00)
Calling doctor	3.08 (1.24)	3.50 (0.80)	2.92 (1.24)	3.17 (1.20)
Doctor understanding	2.92 (0.97)	3.00 (1.21)	3.00 (1.04)	3.00 (1.04)
Fatigue/medications	2.57 (1.27)	3.14 (0.90)	2.50 (0.71)	2.67 (0.58)
Fatigue and activity	2.71 (1.25)	3.14 (0.69)	2.57 (0.98)	3.00 (0.00)
Activity/ breathlessness	3.00 (0.71)	2.80 (0.84)	2.20 (0.84)	3.20 (0.45)
Social activities	2.80 (1.14)	3.10 (0.99)	2.60 (1.51)	2.80 (1.32)
Heart medications	3.75 (0.45)	3.75 (0.78)	3.25 (0.45)	3.58 (0.67)
CP and medications	2.75 (0.89)	3.25 (0.87)	2.50 (0.76)	2.75 (1.28)
CP and activity	2.75 (0.89)	3.00 (0.76)	2.25 (0.71)	3.13 (0.84)
Family activity	3.25 (0.75)	3.17 (1.03)	2.33 (1.37)	2.92(1.38)
Sexual activity	2.86 (1.46)	2.86 (1.46)	2.14 (1.57)	2.43 (1.51)
Standard care				
Weight	2.60 (0.91)	2.67 (0.62)	2.53 (1.13)	2.80 (1.15)
Dietary	3.07 (1.10)	3.13 (0.64)	3.27 (0.60)	3.27 (0.96)
Physical activity	2.94 (0.73)	2.67 (0.77)	3.00 (1.40)	3.33 (0.69)
Work activities	3.75 (0.50)	3.75 (0.50)	4.00 (0.00)	3.75 (0.50)
Breathlessness	4.00 (0.00)	4.00 (0.00)	3.00 (0.00)	3.00 (0.00)
Calling doctor	2.94 (1.44)	3.47 (0.62)	3.53 (0.87)	3.47 (1.01)
Doctor understanding	3.35 (0.49)	3.29 (0.72)	3.53 (0.62)	3.41 (1.07)
Fatigue/medications	2.67 (0.78)	2.00 (1.32)	3.67 (0.58)	4.00 (-)
Fatigue and activity	2.70 (0.95)	3.00 (0.82)	3.10 (1.29)	3.50 (0.85)
Activity /breathless	3.25 (0.96)	3.75 (0.50)	3.50 (0.58)	3.75 (0.50)
Activities at home	3.33 (0.97)	2.83 (1.10)	3.22 (0.81)	3.50 (0.86)
Heart medications	3.44 (0.98)	3.39 (0.78)	3.78 (0.43)	3.61 (0.78)
CP and medications	2.92 (0.90)	2.50 (1.10)	3.17 (0.84)	3.33 (1.23)
CP and activity	3.18 (0.75)	2.55 (1.13)	2.91 (0.94)	3.45 (0.82)
Family activity	3.44 (0.86)	2.94 (1.00)	3.39 (0.70)	3.61 (0.70)
Sexual activity	3.29 (0.73)	3.29 (0.99)	3.07 (1.07)	2.86 (1.35)

Note. CSE = Cardiac Self-Efficacy Scale. Time 1 = Baseline; Time 2 = Pre-intervention (day 5-–7); Time 3 = 1

month. Time 4 = 3 months. CP = Chest pain.

Appendix E1: State Trait Anxiety Inventory - Trait Anxiety Effect Size (*d*): Intervention Group Participants

$$d = \frac{m_A - m_B}{\sigma}$$

$$d = \frac{36.75 - 29.92}{14.10}$$

$$d = \frac{6.83}{14.10}$$

$$d = 0.48$$

$$d = \mathbf{\underline{0.50}}$$

Participation in the nurse-led clinic demonstrated a moderate effect on trait anxiety in intervention group participants over time (*d* = 0.50).

Trait Anxiety Effect Size (d): Standard Care Group Participants

$$d = \frac{m_A - m_B}{\sigma}$$

$$d = \frac{30.95 - 29.47}{9.43}$$

$d = \dfrac{1.48}{9.43}$

$d = 0.156$

$d = \mathbf{\underline{0.16}}$

Randomisation to the standard care group alone demonstrated no effect on trait

anxiety ($d = 0.16$).

Appendix F1: Reliable Change Index Intervention Group Participants For Trait Anxiety

S1: Standard deviation of the sample pre-intervention (9.45)

S2: Standard deviation of the well-functioning sample (9.19)

rxx: Reliability of the STAI-Y2 Form (0.91)

SE: Standard error of measurement for the STAI-Y2 Form (2.835)

S*diff*: Standard error of difference between the two test scores (4.01)

Reliable Change Index (RCI): Intervention Group Participants

X1: Individual pre-treatment score (46)

X2: Individual post-treatment score (30)

S*diff*: 4.01

Calculation 1: Participant 010

$$RCI = \frac{(X2 - X1)}{S\textit{diff}}$$

$$RCI = \frac{30 - 46}{4.01}$$

RCI = **-3.99**

A negative reliable change of -3.99 occurred in participant 010 over time after participation in the intervention.

Calculation 2: Participant 006

X1: Individual pre-treatment score (31)

X2: Individual post-treatment score (20)

S*diff:* 4.01

RCI = (X2 – X1)

$\qquad$ S*diff*

RCI = 20 - 31

$\qquad$ 4.01

RCI = **-2.74**

A negative reliable change of -2.74 occurred for intervention group participant 006.

Calculation 3: Participant 066

X1: Individual pre-treatment score (31)

X2: Individual post-treatment score (20)

S*diff:* 4.01

RCI = (X2 – X1)

$\qquad$ S*diff*

RCI = 24 - 41

$\qquad$ 4.01

RCI = **-4.24**

A negative reliable change of -4.24 occurred for intervention group participant 066.

Calculation 4: Participant 020

X1: Individual pre-treatment score (32)

X2: Individual post-treatment score (24)

S*diff*: 4.01

RCI = $\frac{(X2 - X1)}{Sdiff}$

RCI = $\frac{24 - 32}{4.01}$

RCI = **- 1.99**

A negative reliable change of -1.99 was evidenced for participant 020.

Calculation 5: Participant STA006

X1: Individual pre-treatment score (53)

X2: Individual post-treatment score (27)

S*diff*: 4.01

RCI = $\frac{(X2 - X1)}{Sdiff}$

RCI = $\frac{27 - 53}{4.01}$

RCI = **- <u>6.48</u>**

A negative reliable change of -6.48 occurred for trait anxiety for participant 106

post-intervention.

Appendix G1: Standard Care Group Participants: Reliable Change Index (RCI) Calculations For Trait Anxiety

Calculation 1: Participant 039

X1: Individual pre-treatment score (45)

X2: Individual post-treatment score (35)

S*diff*: 4.01

$$RCI = \frac{(X2 - X1)}{Sdiff}$$

$$RCI = \frac{35 - 45}{4.01}$$

RCI = **-2.50**

A negative reliable change of -2.50 was evidenced for participant 039 after randomisation to the standard care group.

Calculation 2: Participant 021

X1: Individual pre-treatment score (49)

X2: Individual post-treatment score (37)

S*diff*: 4.01

$$RCI = \frac{(X2 - X1)}{Sdiff}$$

RCI = <u>37 - 49</u>

4.01

RCI = **<u>-2.99</u>**

A negative reliable change of -2.99 was demonstrated for participant 021 after

randomisation to the standard care group.

Appendix H1: Summary of Means for Scores for the STAI Questionnaire: Trait Anxiety (Y2 Form)

Table H.1.   **Summary of Means for Scores for the STAI Questionnaire: Trait Anxiety (Y2 Form)**

Time	Intervention Group *M(SD)*	Standard Care Group *M(SD)*
Time 1	38.33 (13.28)	34.37 (8.84)
Time 2	36.75 (14.10)	30.95 (9.43)
Time 3	29.92 (12.66)	29.47 (8.13)
Time 4	31.25 (15.55)	25.37 (5.16)

Note. STAI = State-Trait Anxiety Inventory. Time 1 = Baseline; Time 2 = Pre-intervention (day 5-7); Time 3 = 1 month; Time 4 = 3 months.

Appendix I1: Cardiac Depression Scale (CDS) Intervention Group Participants:
Population Effect Size (ES)

$$d = \frac{m_A - m_B}{\sigma}$$

$$d = \frac{73.83 - 65.83}{30.32}$$

$$d = \frac{8}{30.32}$$

$$d = 0.263$$

$$d = \underline{\mathbf{0.26}}$$

Participation in the intervention demonstrated a small effect on depressive symptoms in intervention group participants over time ($d = 0.26$).

Cardiac Depression Scale (CDS) Standard Care Group Participants: Population

Effect Size (ES)

$d = \dfrac{m_A - m_B}{\sigma}$

$d = \dfrac{68.58 - 58.26}{28.10}$

$d = \dfrac{10.32}{28.10}$

$d = 0.367$

$d = \mathbf{\underline{0.37}}$

Receiving standard care alone demonstrated a small effect on depressive symptoms in standard care group participants ($d = 0.37$).

Appendix J1: Reliable Change Index (RCI) – Cardiac Depression Scale

Step 1. Calculation of the Standard Error

S1 = Standard deviation of the sample pre-intervention (28.13)

rxx = Reliability of the CDS questionnaire (0.79)

$SE = S1 \sqrt{1 - rxx}$

$SE = 28.13 \sqrt{1 - 0.79}$

$SE = 28.13 \sqrt{0.21}$

SE = 28.13 x 0.458

SE = **12.9**

Step 2. Calculation of the Standard error of difference between the two test scores (S*diff*)

$S\textit{diff} = \sqrt{2\ (SE)2}$

$S\textit{diff} = \sqrt{2\ (12.9)2}$

$S\textit{diff} = \sqrt{2\ (166.41)}$

$S\textit{diff} = \sqrt{332.82}$

$S\textit{diff} = $ **18.24**

Step 3. Calculation of Reliable Change Index (RCI)

Calculation 1: Intervention group participant 010

X1: Individual pre-treatment score (96)

X2: Individual post-treatment score (60)

RCI = $\frac{(X2 - X1)}{Sdiff}$

RCI = $\frac{60 - 96}{18.24}$

RCI = **<u>-1.97</u>**

A negative reliable change of -1.97 occurred for participant 010.

Calculation 2: Standard care group participant 013

X1: Individual pre-treatment score (157)

X2: Individual post-treatment score (59)

RCI = $\frac{(X2 - X1)}{Sdiff}$

RCI = $\frac{59 - 157}{18.24}$

RCI = **-<u>5.4</u>**

A reliable change of -5.4 was evidenced in participant 013.

Appendix K1: Mean Ratings for the Cardiac Depression Scale

Table K.1   **Summary of Means for Scores for the Cardiac Depression Scale (CDS)**

	Intervention Group	Standard Care Group
Time	*M(SD)*	*M(SD)*
Time 1	79.95 (19.60)	72.32 (22.42)
Time 2	73.83 (30.32)	68.58 (28.10)
Time 3	65.83 (27.96)	58.26 (17.78)
Time 4	73.17 (31.81)	53.37 (14.87)

Note. CDS = Cardiac Depression Scale. Time 1 = Baseline; Time 2 = Pre-intervention (day 5-7); Time 3 = 1 month; Time 4 = 3months.

Appendix L1: Effect Size Calculations for Medication Adherence (MMAS-8)

Intervention Group Participants: Cohen's *d* – Population Effect Size (ES)

$$d = \underline{m_A - m_B}$$

$$\sigma$$

$$d = \underline{7.71 - 7.71}$$

$$0.71$$

$$d = \underline{0}$$

$$0.71$$

$$d = \underline{\mathbf{0}}$$

Overall, the intervention had no effect on participant's medication adherence.

Standard Care Group Participants: Cohen's d – Population Effect Size (ES)

$$d = \underline{m_A - m_B}$$

$$\sigma$$

$$d = \underline{7.76 - 7.89}$$

$$0.60$$

d = $\underline{-0.13}$

    0.60

d = - 0.2166

d = **- 0.22**

A small effect was evidenced on standard care group participants.

Appendix M1: Summary of Mean Ratings for the MMAS-8

Table M.1. **Summary of Means for Scores for the Morisky Medication Adherence Scale (MMAS-8)**

Time	Intervention Group M(SD)	Standard Care Group M(SD)
Time 1	7.31 (1.12)	7.24 (1.20)
Time 2	7.71 (0.71)	7.76 (0.60)
Time 3	7.71 (0.71)	7.89 (0.47)
Time 4	7.88 (0.36)	7.97 (0.81)

Note. MMAS-8 = Morisky Medication Adherence Scale (8-Item). Time 1 = Baseline; Time 2 = Pre-intervention (day 5-7); Time 3 = 1 month; Time 4 = 3months.

Appendix N1: Femoral Arterial Access Site Images and Diagrams

Time 1: Baseline Digital Image_Participant_019

Time 2 (Day 5-7): Digital Image_Participant_019

Time 1: Baseline Digital Image_Participant_105

Time 3 (1 Month): Diagram_Participant_105

Time 1: Baseline_ Digital Image_Participant_010

Time 2 (Day 5-7): Digital Image_Participant_010

Time 3 (1 Month): Diagram_Participant_010

Instructions

- Please colour in/draw on either or both of the diagrams on pages 1 or 2 where you had your procedure.
- You can also write in your own words underneath the diagram how the wound feels and looks.

Figure 1.1. Adapted from "A nurse's guide to caring for cardiac intervention patients," by E. O'Grady, 2007, p. 2. Copyright 2007 by Wiley. Reprinted with permission.

Please write your description (in your own words):

At this time there is no evidence of having had the procedure at all. There is no bruising, no marks of the wound site and no lumps or lumps. All is as normal.

2

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Time 1: Baseline Digital Image_Participant_019

Time 2 (Day 5-7): Diagram _Participant_019

Time 3 (1 Month): Diagram_Participant_019

QUT

Queensland University of Technology
WOUND SITE(S) - The 'REALITY CHEC' Project© _2012_JULY_V1

Instructions

- Please colour in/draw on either or both of the diagrams on pages 1 or 2 where you had your procedure.
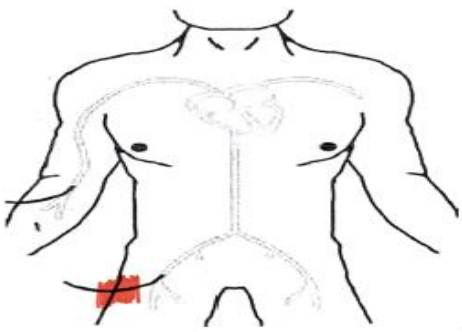- You can also write in your own words underneath the diagram how the wound feels and looks.
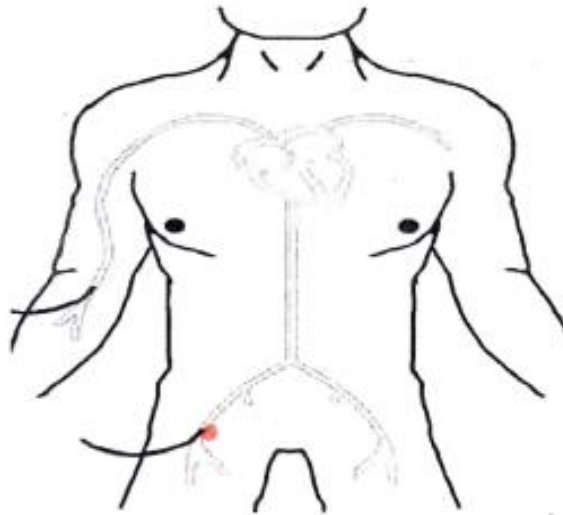
Figure 1.1. Adapted from "A nurse's guide to caring for cardiac intervention patients," by E. O'Grady, 2007, p. 2. Copyright 2007 by Wiley. Reprinted with permission.

Please write your description (in your own words):

The wound sight is clear except for a small red spot.
Trelina I took your advice + went across to St Andrews. A severe bout of flu - couldn't help me, gave me a script for Dinprices - which played up with the Bladder - complete rest 10 days 3.6.13. Went to see Dr Loo - he put me on Relide tabs 300 mg. I'm still feel evacuated when I exert myself with household jobs.

2

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Appendix O1: Phase Three Study Protocol

The 'REALITY CHEC' Project© – Study Protocol_2014_11_12_V1.1

Phase One:
Stress/Anxiety/Depression; Cardiac Self-efficacy (CSE); Chest pain assessment and management; CR commencement, adherence.

Randomised Controlled CLinical Trial (RCT)

Phase Two: At 6 months post intervention

Participant interviews
Open-ended, Semi-structured

Phase Three: Multi-centre study - Proposed electronic visual medium
Baseline visit: Day of hospital discharge

STAI: State Trait Anxiety Inventory
CDS: Cardiac Depression Scale
CSE: Cardiac Self-Efficacy Scale
MMAS-8: Morisky Medication Adherence Scale (8-Item)
CR: Cardiac rehabilitation

Day of hospital discharge
STAI; CDS; CSE; MMAS-8; Access site and neurovascular assessment; Cardiac rehabilitation (CR)

Day 3-5 post-discharge: Intervention group (n=110)
a. STAI; CDS ; CSE;
b. Access site and neurovascular assessment (digital photograph);
d. CP assessment and management;
e. Complications;
g. MMAS-8
h. Medication adherence and compliance;
i. CR referral and tracking;
j. RA & Participant questions.

Day 3-5 days post-discharge (n=110)
Standard care group
* SMS reminder day prior
*Limit contact with research team
a. Standard education and follow-up;
b. STAI; CDS; CSE; CP; Access site amd neurovascular assessment; Complications; MMAS-8; &
d. CR: Track attendance.

At day 3-5 post discharge (N=220)

Anxiety / Depression / General Self-efficacy Medication adherence
CR attendance; Complication(s); Readmission(s).

At 1,3,6, & 12 months
post-coronary angiography and PCI:
Screening: Anxiety and Depression; CR commencement; Cardiology review; Complication(s); Readmission(s).
*Reminder sms or email 2 days prior to questionnaire completion/follow-up.

At 1,3,6, & 12 months
STAI; CDS; CSE CP; Complications; MMAS-8; CR; & Participant questions.

At 1,3,6, & 12 months
STAI; CDS; CSE; CP; Complications; MMAS-8; CR.

Appendix P1: Morisky Medication Adherence Scale (MMAS-8 item)

©**Morisky Medication Adherence Scale (MMAS-8-Item). This is a generic adherence scale and the name of the health concern can be substituted in each question item.**

You indicated that you are taking medication for your (identify health concern, such as "high blood pressure"). Individuals have identified several issues regarding their medication-taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your [health concern] medication.
(Please circle the correct number)

	No=1	Yes=0
1. Do you sometimes forget to take your [health concern] pills?		
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your [health concern] medicine?		
3.Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?		
4.When you travel or leave home, do you sometimes forget to bring along your [health concern] medication?		
5.Did you take your [health concern] medicine yesterday?		
6.When you feel like your [health concern] is under control, do you sometimes stop taking your medicine?		
7.Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your [health concern] treatment plan?		

1. How often do you have difficulty remembering to take all your medications? (**Please circle the correct number**)

Never/Rarely **4**

Once in a while **3**

Sometimes **2**

Usually **1**

All the time **0**

From "Predictive Validity of a Medication Adherence Measure for Hypertension Control," by D.E. Morisky, A. Ang, and M. Krousel-Wood, 2008, *Journal of Clinical Hypertension*, *10*, pp.348–354. Copyright by D.E. Morisky. Reprinted with permission.

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