Integrating MEditatioN inTO heaRt disease care (The MENTOR Study)

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Doctor of Philosophy

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2020

Certificate of Original Authorship

I, Angela Rao declare that this thesis, is submitted in fulfilment of the requirements for the award of Doctor of Philosophy, in the School of Nursing, Faculty of Health at the University of Technology Sydney.

This thesis is wholly my own work unless otherwise reference or acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

This document has not been submitted for qualifications at any other academic institution.

This research is supported by the Australian Government Research Training Program.

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Date: 18th June 2020

Acknowledgements

This thesis could not have been undertaken, or completed, without the support of many.

Firstly, to my supervision team, Louise Hickman, Michelle DiGiacomo and Jane Phillips. Your expertise, rigour and support have been imperative to my training as a researcher. Thank you for your kindness and selflessness in the support you have given me in bringing this thesis together. For this I am sincerely grateful, and will always remember the contribution you have made in enabling me to reach this milestone.

To Mr Robert Zecchin, for your ongoing support and allowing me to do what I love in a health care environment. To those who enabled the research to go ahead in the Local Health District, and supported data collection and analysis, thank you for going above and beyond for this project. And for all the participants who gave so generously their time and energy to support this project. Thank you.

To my family and friends. For always reminding me of my values and supporting me in this journey to explore mind body therapies and spirituality within a conventional research environment. And to be there when a laugh is needed or to put perceived stressors into perspective.

A special mention must be made to Victor and Wendy Zammit for planting the seed of a PhD in my head, and who could see my potential far earlier than I could. Victor, you said it first!

Because of all the wonderful support from my community, I am able to look forward with excitement at what lies ahead.

Thank you again for your love and support.

Format of thesis

This thesis has adhered to a thesis by compilation format.

Anthology of Publications

1. **Rao, A.,** Newton, P., DiGiacomo, M., Phillips, J.L., & Hickman, L.D. 2019. 'Meditation for the secondary prevention of depression and anxiety in heart disease. A systematic review' *Mindfulness* vol. 10 (1), p. 1-14 [IF: 3.692].

2. **Rao, A.,** Zecchin, R., Newton, P.J., Phillips, J.L., DiGiacomo, M., Denniss, A.R., & Hickman, L.D. 2020. 'The prevalence and impact of depression and anxiety in cardiac rehabilitation: A longitudinal cohort study' *European Journal of Preventive Cardiology* vol. 27 (5), p. 478-489 [IF: 5.640]

3. **Rao, A.,** DiGiacomo, M., Phillips, J.L. & Hickman, L.D. 'Dipping the toe but not ready to jump: Health professional perspectives of integrating meditation into routine heart disease care' *Heart, Lung & Circulation* (under review)

Other Related Publications

4. **Rao, A.,** Newton, P.J, DiGiacomo, M., Hickman, L.D., Hwang, C., & Davidson, P.M. 2018. 'Optimal gender specific strategies for the secondary prevention of cardiovascular disease in women. A systematic review' *Journal of Cardiopulmonary Rehabilitation and Prevention* vol. 38 (5), p. 279-285 [IF: 1.815].

Conference presentations

Rao, A., Zecchin, R., Newton, P.J., Phillips, J.L., DiGiacomo, M., Denniss, A.R., & Hickman, L.D. (2019). 'The impact of depression and anxiety on cardiac rehabilitation programs: A cohort study of prevalence, predictors and adherence rates.' *Cardiac Society of Australia and New Zealand Annual Scientific Meeting*. 8th-11th August 2019, Adelaide, Australia (mini oral presentation).

Rao, A., Zecchin, R., Newton, P.J., DiGiacomo, M., Phillips, J.L., Denniss, A.R. & Hickman, L.D. (2019) 'Prevalence and predictors of depression and anxiety in a cardiac rehabilitation population and its impact on adherence: a cohort study' Australian Cardiac Rehabilitation Association Annual Scientific Meeting. 5th-7th August 2019, Sydney, Australia (oral presentation).

Rao A., DiGiacomo M., Phillips J.L, Hickman L.D. (2019). 'Health professional perspectives of the organisational barriers and facilitators to implementing meditation in heart disease clinical settings.' Australian Cardiac Rehabilitation Association Annual Scientific Meeting. 5th-7th August 2019, Sydney, Australia (oral presentation).

Rao, A., Zecchin, R., Newton, P.J., DiGiacomo, M., Phillips, JL. & Hickman, LD (2018). 'Who drops out of cardiac rehabilitation programs (2007-2017)?' *European Society of Cardiology Congress*, 25-29th August 2018, Munich, Germany (poster presentation).

Rao, A., Zecchin, R., Newton, P.J., DiGiacomo, M., Phillips, JL. & Hickman, LD (2018). 'The significance of depression and anxiety in heart disease' *Australian Cardiac Rehabilitation Association Annual Scientific Meeting,* 30th July -1st August 2018, Brisbane, Australia (poster presentation).

Rao, A., DiGiacomo, M., Newton, P.J., Phillips, J.L & Hickman, L.D (2018). 'Meditation and Secondary Prevention of Depression and Anxiety in Heart Disease: A Systematic Review.' *Sigma Theta Tau International 29th International Nursing Research Congress.* 27-29th July 2018, Melbourne, Australia (oral presentation).

Rao, A., Zecchin, R., Newton, P.J., DiGiacomo, M., Phillips, J.L. & Hickman, L.D. (2018) The significance of depression and anxiety in heart disease*, Cardiac Rehabilitation Association of*

Australia (NSW & ACT) AGM, 12th October 2018, Brisbane, Australia (invited oral poster presentation).

Rao, A., Zecchin, R., Newton, P.J., DiGiacomo, M., Phillips, J.L. & Hickman, L.D. (2018) 'Who drops out of cardiac rehabilitation programs?' *Cardiac Rehabilitation Association of Australia (NSW & ACT) AGM*, 12th October 2018, Brisbane, Australia (invited oral poster presentation).

Rao, A., Newton, P., DiGiacomo, M., Phillips, J.L. & Hickman, L.D. (2016) 'Meditation as a secondary prevention strategy for heart disease.' *Australian Cardiac Rehabilitation Association 2016 Annual Scientific Meeting*. 1-3rd August 2016, Adelaide, Australia (oral presentation).

Other Related Presentations

Rao, A., Lee, J., Agar, M (2017). Panel discussion: Conducting Clinical Trials. Practical Perspectives, *Centre for Cardiovascular & Chronic Care Summer School*, University of Technology Sydney, Australia (invited panel presentation).

Rao, A., Newton, P.J, DiGiacomo, M., Hickman, L.D., Hwang, C., & Davidson, P.M. (2016). 'Which gender specific cardiac rehabilitation models best reduce cardiovascular risk in women?' *21st International Council On Women's Health Issues Congress. Scale and Sustainability: Moving Women's Health Issues Forward*. 6-9th November 2016, Baltimore, Maryland, USA (oral presentation).

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Thesis Abstract

Background: Depression and anxiety symptoms after a cardiac event are often under-recognised and undertreated, reducing the ability of people living with heart disease to effectively manage their symptoms and to fully optimise the opportunities afforded by cardiac rehabilitation programs.

Aims: The Integrating MEditatioN inTO heaRt disease care (MENTOR) Project aimed to generate contextual knowledge to understand the capacity for meditation to improve the psychological well-being of people participating in a cardiac rehabilitation program.

Methods: A three-phased explanatory sequential mixed methods project, composed of four discrete yet interrelated studies. The MENTOR Project is underpinned by two complementary interrelated frameworks: 1) the World Health Organisation's Innovative Care for Chronic Conditions Framework; and 2) Bandura's Self-Efficacy Model.

Phase 1 identified the burden of depression and anxiety in cardiac rehabilitation programs, and included a longitudinal cohort study, and a systematic review of meditation's feasibility in reducing depression and anxiety symptoms. Phase 2 tested the feasibility and acceptability of a meditation intervention, and included a phase II RCT and semi-structured interviews of i) people living with heart disease's perspectives on participating in a meditation intervention; and ii) health professionals' perspectives of the barriers and facilitators to integrating this self-care strategy into existing cardiac rehabilitation programs. Phase 3 recommendations for meditation research and practice were generated during the meta-inference of the integrated data from Phases 1 and 2.

Results: Meta-inferences generated from the MENTOR Project found that a range of supports are required to integrate meditation at the patient, health organisation and health systems levels of heart disease care. Compared with the general population, moderate depressive symptoms were higher in people who attended cardiac rehabilitation programs (18% vs 5%). Anxiety and stress were the strongest predictors of moderate depression in people living with heart disease ($p<0.001$), and

depression was a strong predictor of anxiety ($p<0.001$). While cardiac rehabilitation contributed to modest reductions in depression and anxiety symptoms, these symptoms reduced the capacity for people living with heart disease to adhere to cardiac rehabilitation programs (depression: 24% vs 13%; $p<0.001$; anxiety: 32% vs 23%; $p<0.001$).

The preliminary phase II results suggest it is feasible to recruit people in a future phase III trial and may also increase cardiac rehabilitation attendance and adherence. Integrating a meditation intervention into cardiac rehabilitation was also considered to be acceptable to health professionals and people living with heart disease.

Conclusion: Better monitoring of depression and anxiety symptoms throughout cardiac rehabilitation programs is required, and the integration of psychological support strategies is warranted. An integrated approach to care that is inclusive of meditation has the potential of improving psychological well-being and the self-efficacy of people living with heart disease and increase their adherence to cardiac rehabilitation programs. Building the effectiveness and efficacy evidence of the role of mediation in cardiac rehabilitation is critical to ensuring that the relevant supports and processes are available to integrate this non-pharmacological strategy into existing programs. In the meantime, implementing the MENTOR Project recommendations at the patient, health organisation and health systems levels will do much to improve the psychological care of people living with heart disease in Australia.

Abbreviations

AMI	Acute Myocardial Infarction
bpm	Beats Per Minute
cm	Centimetres
CAD	Coronary Artery Disease
CD	Compact Disc
CI	Confidence Interval
DASS-21	Depression Anxiety Stress Scale
DSM-V	Diagnostic and Statistical Manual of Mental Disorders – Volume 5
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
ICD-10	International Classification of Diseases
kg	Kilograms
m	Metres
MD	Medical Doctor
METS	Metabolic Equivalent of Task
mmHg	Millimoles of Mercury
MSES-R	Mindfulness Self-Efficacy Scale - Revised
NSTEMI	Non ST Elevation Myocardial Infarction
NYHA	New York Heart Association Classification
PCI	Percutaneous Coronary Intervention
PPM	Permanent Pacemaker

RCT	Randomised Controlled Trial
RN	Registered Nurse
STAI	State Trait Anxiety Inventory
STEMI	ST Elevation Myocardial Infarction
V02	Maximal volume of oxygen delivered to the working muscles per minute
6MWT	Six Minute Walk Test

Glossary of terms

Acceptability	The probability that a method or intervention will be used by a specific population.
Acute myocardial infarction	Life threatening emergency occurring when a vessel supplying blood to the heart muscle is suddenly blocked completely by a blood clot. The lay term given to a myocardial infarction is a 'heart attack'.
Acute coronary syndromes	Umbrella term given for heart attacks and unstable angina.
Cardiac rehabilitation	The coordinated sum of activities required to influence favourably the underlying cause of cardiovascular disease, as well as to provide the best possible physical, mental and social conditions, so that the patients may, by their own efforts, preserve or resume optimal functioning in their community and through improved health behaviour, slow or reverse progression of disease.
Coronary heart disease	Or ischaemic heart disease, is the most common form of cardiovascular disease, most commonly occurring as an acute myocardial infarction and angina.
Depression	Or clinical depression, is characterised by depressed mood or anhedonia (loss of interest or pleasure) for at least two weeks, accompanied by significant functional impairment and additional somatic or cognitive symptoms.
Feasibility	An analysis and evaluation of a proposed project to determine if it is technically feasible; is feasible with the estimated cost; and will be profitable.

Generalised anxiety disorder	Excessive anxiety and worry about a number of activities or events that occurs for most days over a period of six months, accompanied by three of the following symptoms: i) restlessness; ii) fatigue; iii) difficulty concentrating or mind going blank; iv) irritability; iv) muscle tension; or vi) sleep disturbance. The anxiety is not attributed to a medical condition or medication, and causes clinically significant distress.
Heart disease	A group of disorders of the heart and blood vessels, including coronary heart disease, cerebrovascular disease, peripheral artery disease, rheumatic heart disease, congenital heart disease, deep vein thrombosis and pulmonary emboli.
High income countries	A country with an economy that has a World Bank Atlas defined gross national income of ≥ $12,056 US dollars in 2017.
Integrated care	An approach to strengthen people-centred health systems through the promotion of the comprehensive delivery of quality services across the life course, designed according to the multidimensional needs of the population and the individual and delivered by a coordinated multidisciplinary team of providers working across settings and levels of care. It should be effectively managed to ensure optimal outcomes and the appropriate use of resources based on the best available evidence, with feedback loops to continuously improve performance and to tackle upstream causes of ill health and to promote well-being through inter-sectoral and multi-sectoral actions.

Knowledge translation	A dynamic, iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve the health of all, provide more effective health services and products and strengthen the health care system.
Low income countries	Countries with an economy that has a gross national income per capita of ≤ $995 as calculated by the World Bank Atlas method in 2017.
Major depression	Depressed mood or anhedonia, exhibited for at least two weeks, in conjunction with two of the following: i) markedly diminished interest or pleasure in activities; ii) more than 5% change in body weight; iii) insomnia or hypersomnia; iv) psychomotor retardation or agitation; v) fatigue or loss of energy; vi) feelings of worthlessness or guilt; vii) diminished ability to concentrate or think; or viii) recurrent thoughts of death.
Medical model	An approach to health service delivery that is underpinned by the diagnosis and treatment of physical conditions.
Metabolic exercise test	Metabolic equivalent of task (MET), or the ratio of energy expenditure to body mass. One MET is defined as 3.5ml of oxygen/per kilogram/per minute, which is equivalent to the energy expended at rest.
Middle income countries	Countries with an economy that has a gross national income, as defined by the World Bank Atlas, of between $996 and $12055 US dollars in 2017.
Mild depression	Low level depression, in line with mild cut-off points for depression in validated standardised questionnaire scales

Minor 'subthreshold' depression	Low-level depression, with one core symptom (see major depression) present most of the day, every day, for at least two weeks, leading to a change in function or impairment in daily activities.
Moderate depression	Clinically significant depressive symptoms, in line with moderate cut-off points on validated, standardised questionnaire scales
Outpatient care	The period of follow up treatment after hospital discharge. It may involve participation in a defined and structured cardiac rehabilitation program, or care provided by a multidisciplinary team.
Percutaneous coronary intervention	Formerly known as 'angioplasty with stent', it is a non-surgical procedure involving the use of a catheter (thin flexible tube) to place a small structure (stent) to open up blood vessels in the heart that may have been narrowed by a plaque build-up (atherosclerosis).
Person-centred care	Health care delivery that priorities and is shaped around the needs and expectations of people, their families and their communities, rather than focus on diseases.
Secondary prevention	Treatment of people with established coronary heart disease cerebrovascular disease, or peripheral vascular disease, involving medical care, modification of behavioural risk factors, psychosocial care, education and support for self-management, that is delivered in various settings.

Sedentary Lifestyle	Sedentary lifestyle, or sedentary behaviour can be defined as an activity that is performed at or slightly above the resting metabolic rate (1-1.5 METS) that is equivalent to sitting or lying down.
Self-efficacy	A reflection of the perceived capabilities an individual has to improve their behaviour. One's perception, rather than their capability has a more prominent influence on behaviour.
Self-management	Refers to the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition.
Six minute walk test	A measure of functional capacity that measures (in metres) the total distance walked on a flat surface in six minutes.
State anxiety	An unpleasant emotional arousal in the face of threatening demands or dangers that includes a cognitive appraisal of the threat.
Trait anxiety	The stable tendency to attend to, experience and report negative emotions such as fears, worries and anxiety across many situations.

Chapter 1 Introduction

1.1 Epidemiology of heart disease

Heart disease accounts for one third of all global mortality, which equates to approximately 17.9 million deaths per year[1-3]. Heart disease encompasses a range of conditions, including: coronary heart disease, cerebrovascular disease, peripheral artery disease, rheumatic heart disease, congenital heart disease, deep vein thrombosis and pulmonary emboli[2]. In Australia, heart disease is the second highest cause of morbidity and mortality, accounting for 15% of the total burden of disease[4]. It is the leading cause of death in men and the second highest cause of death in women[5]. Since the middle of the last century, deaths from heart disease have been declining due to a combination of primary and secondary prevention strategies to reduce risk factors, enable better detection, and promote technological advances and care developments[6]. As a result, 75% of Australia's heart disease related deaths occur in older adults ≥75 years[4], and these rates are not expected to fall in the coming decades as the number of older people in the community continues to increase[5]. However, living longer and with heart disease now accounts for 7.7% of the total disability adjusted life years for Australian men (9.4%) and women (5.8%)[4].

Heart disease accounts for $(US) 863 billion dollars in global health care expenditure[7]. In Australia, the costs of heart disease care has increased by 48% over an eight year period and now accounts for the largest proportion (12%) of the nation's health care costs[8]. The greatest proportion of heart disease spending in Australia is for hospital admitted patient services (4.6 million), which also increased by 55% over the decade between 2000-09[8].

1.2 Preventing heart disease

Most people diagnosed with heart disease have modifiable risk factors[9]. Yet, few countries have successfully implemented preventative heart disease strategies that changes people's lifestyle and health behaviours[10]. As a result, hypertension; tobacco use; excessive weight and obesity; excessive alcohol consumption; and sedentary lifestyle contribute to between 68% and 80% of the global heart

disease burden[4, 10]. Whilst Australia has had an enviable reduction in smoking rates, it still remains the single most important risk factor for ill health and death[11]. Over 60% of Australians now overweight or obese, and 10% of people (≥ 14 years) have increased cardiovascular risk due to their levels of alcohol consumption[11]. Recent European Society of Cardiology and European Association for Cardiovascular Prevention and Rehabilitation guidelines have recommend introducing public health measures at the population level, including healthy lifestyle change, to reduce the risk of heart disease.

International and national heart disease guidelines[9, 10] recommend that people with established heart disease with a high level of cardiovascular risk require appropriate medical management, inclusive of a referral to cardiac rehabilitation programs and/or a structured secondary prevention service[12] and general practitioner (GP) follow up[10]. A range of secondary prevention strategies are required to optimise heart disease risk factor modification and self-management, including the initiation of healthy behaviours such as exercise and adherence to cardio-protective medications[12]. Effective discharge communication and follow up at cardiac rehabilitation programs is crucial for the promotion and reinforcement of self-management strategies and cardiovascular risk reduction[12].

1.3 Cardiac rehabilitation as a secondary prevention strategy

The Australian Cardiac Rehabilitation Association (ACRA) guidelines describe three levels of cardiac rehabilitation: inpatient rehabilitation; outpatient rehabilitation and long-term outpatient cardiac rehabilitation (refer Table 1.1). These guidelines recommend that outpatient (phase 2) cardiac rehabilitation services: 1) be offered to all eligible people living with heart disease; 2) include individualised clinical assessment; 3) provide a range of exercise and education sessions designed to facilitate return to or improvement in baseline functioning; 4) promote self-management; and 5) collect minimum datasets to support quality improvement[13].

Table 1.1: Phases of cardiac rehabilitation[14]

Phase	Description
Phase 1 (inpatient cardiac rehabilitation)	A program that delivers preventive and rehabilitative services to hospitalised patients following an index cardiovascular event, such as an acute myocardial infarction (AMI) or acute coronary syndrome.
Phase 2 (early outpatient cardiac rehabilitation)	Outpatient cardiac rehabilitation describes the provision of prevention and rehabilitation services in the outpatient setting after an acute cardiac event, most commonly in the first 3 to 6 months after the event, but can continue for up to 1 year after the event
Phase 3 or Phase 4 (long term outpatient cardiac rehabilitation)	A program that provides longer term delivery of preventive and rehabilitative services for patients in the outpatient setting

Cardiac rehabilitation is relevant and important for people who have experienced an: acute myocardial infarction (AMI), heart failure and cardiomyopathy, heart valve replacement or repair, permanent pacemaker or defibrillator insertion, heart transplantation or ventricular assisted devices[15]. National cardiac rehabilitation guidelines[13] also specify that cardiac rehabilitation is relevant for people with New York Heart Association (NYHA) class I and II (refer Table 1.2). In practice, people with NYHA classifications III and IV generally have increased severity of symptoms[16], are usually considered too unwell to participate in outpatient cardiac rehabilitation. However, people living with heart disease with a lower ejection fraction with NYHA classification class II to IV symptoms despite optimal heart failure therapy, who are stable for ≥6 weeks without a major heart disease hospitalisation or procedure within 6 months may be eligible for inclusion[17].

Table 1.2: New York Heart Association Classification and Associated Objective Assessment[18]

NYHA functional classification	Patient Symptoms	NYHA Class	Objective Assessment
Class I	No limitation of physical activity. Ordinary activity does not cause undue fatigue. Palpitation or dyspnoea (shortness of breath)	A	No objective evidence of heart disease. No symptoms and no limitation in ordinary physical activity.
Class II	Slight limitation of physical activity. Comfortable at rest Ordinary physical activity results in fatigue, palpitations or dyspnoea (shortness of breath).	B	Objective evidence of minimal heart disease. Mild symptoms and slight limitation during ordinary activity. Comfortable at rest.
Class III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitations or dyspnoea.	C	Objective evidence of moderately severe heart disease. Marked limitation in activity due to symptoms, even during less than ordinary activity. Comfortable only at rest.
Class IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.	D	Objective evidence of severe heart disease. Severe limitations. Experiences symptoms even while at rest

1.3.1 Cardiac rehabilitation assessment

Individualised assessment of the suitability of people living with heart disease for cardiac rehabilitation should occur either during hospitalisation or as soon as possible after they receive their diagnosis and/or are discharged home. This assessment ought to include an appraisal of the person's physiological, psychological and social circumstances and needs[13]. Cardiac rehabilitation services can be delivered using a number of different modes, including: as a face to face or as a tele-health intervention via phone or video[19]. Recommended assessment items include: i) demographic details and heart disease risk factor profile; ii) admitting diagnosis and cardiac interventions; iii) assessment of people individuals' understanding of their condition and co-morbidities; iv) medication management and adherence; v) cultural background and sensitivities; vi) heart disease symptoms including pain management and functional capacity. Explaining the structure of cardiac rehabilitation services, including exercise and education sessions is important for people to see the value in participating. The assessment information allows for the tailoring of the person's goals according to their needs and preferences[13]. As well as providing an opportunity for people living with

heart disease to receive advice and referral regarding smoking cessation, diet and nutrition, weight, blood pressure, cholesterol, diabetes, psychological health, obstructive sleep apnoea, alcohol, and illicit drug use. At the end of the assessment health professionals are encouraged to co-develop a secondary prevention action plan with the person living with heart disease[13]. The inclusion of family members and/or significant others in cardiac rehabilitation assessment process is recommended to promote adherence and facilitate synergistic lifestyle change[13].

There is a large body of available evidence on the effectiveness of cardiac rehabilitation programs on reducing cardiovascular deaths, readmissions, and improving functional capacity and quality of life[20]. The core focus of cardiac rehabilitation programs is the use of exercise to facilitate physical recovery, with secondary consideration given to risk factor management and lifestyle modification[21].

1.3.2 Structured exercise in cardiac rehabilitation programs

The recommended duration of attendance at structured exercise based cardiac rehabilitation programs vary with up to 12 sessions attended between four and twelve weeks[22], according to the person's pre-defined goals. People living with clinically stable heart disease ought to achieve 30 minutes or more of low to moderate intensity physical activity most days of the week, including resistance training[13]. High intensity interval training may also be recommended for individuals with a high level of pre-morbid fitness, and supervised use of high intensity interval training protocols is under consideration for people classified as NYHA class I to III patients who are clinically stable[23].

1.3.3 Completion of cardiac rehabilitation programs

Completion of cardiac rehabilitation programs is considered to be adherence to an individually tailored cardiac rehabilitation program, which is discussed at an initial assessment. Individual goals focus on lowering the person's cardiovascular risk profile, attendance and/or participation in an agreed number of exercise and/or education sessions or tele-health cardiac rehabilitation sessions[13]. On completion of the cardiac rehabilitation program, all participants have a discharge (functional

capacity) assessment, and referral to their general practitioner and/or cardiologist for ongoing[12, 13] monitoring of their heart disease.

1.3.4 Barriers to secondary prevention

In practice, however, the exposure of people living with heart disease to secondary prevention in hospital is not consistent with guideline recommendations, with only one quarter (27%) of acute coronary syndrome survivors receiving recommended secondary prevention medication, dietary or lifestyle advice and referral to cardiac rehabilitation programs[24]. Even following assessment and referral, cardiac rehabilitation program attendance rates are relatively low, with only a quarter (23%) of myocardial infarction, (56%) of coronary artery bypass graft and (10%) of people post percutaneous coronary angiogram completing a recommended cardiac rehabilitation program[25]. Lack of clinician referral has been identified as a significant barrier to participation in cardiac rehabilitation programs[14], with less than half (47%) of eligible people living with heart disease referred to cardiac rehabilitation[13]. Despite the evidence on the relevance and effectiveness of exercise based cardiac rehabilitation, few health professionals use standardised referral processes to cardiac rehabilitation programs[26, 27]. Standardised cardiac rehabilitation referral process have been recommended to address these poor participation rates[14], but is yet to be implemented fully in Australian due to a lack of funding and incentives for medical professionals to refer eligible patients onto these services[22].Despite cardiac rehabilitation being recommended in heart disease management guidelines[12], it is not included as cardiac service performance measures[14].

People living with heart disease also have varied levels of understanding around the relevance of rehabilitative processes after a cardiac event[28]. Technological advances in heart disease care such as percutaneous stenting and minimally invasive procedures, have also reduced perceptions and understanding of the risk of future harm[29].

1.3.5 Psychosocial health in cardiac rehabilitation

Whilst exercise is the foundation of cardiac rehabilitation programs, an integrated approach to care[30, 31] inclusive of psychological health is recommended to ensure that people living with heart disease are able to: understand and process new information needed to enact necessary lifestyle changes, and reduce the risk of future cardiac events. Integrating non-pharmacological strategies, such as collaborative, co-ordinated care programs and cognitive behavioural therapies have been demonstrated to assist people living with heart disease to self-manage their physical and psychological symptoms[32-35]. These programs are essential to improve self-management in the 20% of people living with heart disease who are also depressed[36].

1.4 Depression and anxiety

The management of prevalence of psychological symptoms in important as depression and anxiety is known to be high after an acute cardiac event[37, 38]. Depression is characterised by a depressed mood or anhedonia (loss of interest or pleasure) for at least two weeks, accompanied by significant functional impairment and additional somatic or cognitive symptoms[39]. Anxiety, is characterised by excessive anxiety or worry such as apprehension or expectation about a number of events or activities, that occurs on most days over a period of six months[39].

Depression and anxiety reduces the capacity of people living with heart disease to effectively self-manage their symptoms, and comply with medical recommendations for treatment[40]. Despite, the burden of depression and anxiety in this population, medical practitioners and health organisations continue to prioritise the physical management of heart disease[41] over psychological support and secondary prevention. However, targeted strategies to address depression and anxiety symptoms in people living with heart disease is minimal during hospitalisation and varies greatly across cardiac rehabilitation outpatient programs[42]. There is a need for health professionals and health organisations to integrate empirical non-pharmacological therapies to better manage depression and anxiety symptoms within existing heart disease care[36, 43]. Addressing the complex needs of people living with heart disease and their families is required to enhance their capacity to adhere to

recommended secondary prevention strategies and optimise their health and well-being[44]. Promoting self-efficacy is an important element of cardiac rehabilitation programs, and improving adherence to secondary prevention strategies.

1.4.1 Self-efficacy

Self-efficacy is defined as a reflection of perceived as opposed to actual capabilities, and that perceptions rather than ability or capability has a more prominent influence on behaviour[45]. Beliefs about self-efficacy influence, thoughts, feelings, motivation, intention and actions, including those related to health behaviour change[46]. That is, those with positive perceptions of their capacity to change their behaviour and manage their symptoms are more likely to attempt to change negative lifestyle patterns[46, 47]. Self-efficacy is proposed as the mechanism by which self-management is achieved, and is therefore essential to optimise the ability of people living with heart disease to manage their symptoms[48]. Self-efficacy is also purported to enhance the self-regulating process that facilitate health behaviour changes[49] required to reduce cardiovascular risk[50]. People living with heart disease and co-morbid depressive symptoms are likely to have negative perceptions of their quality of life, negative affect and mood, and reduced affective and cognitive processing[51]. Rumination, negative thoughts and negative recall bias that occurs in people with co-morbid depression results in negative interpretations of experiences[51]. These negative interpretations result in minimising successes and exaggerating failures, thereby reducing self-efficacy, including one's capacity to engage in exercise, and their ability to change health related behaviours[51].

Conversely, positive perceptions of self-efficacy are known to increase exercise self-efficacy, physical activity[52] and adherence to cardiac rehabilitation programs[53], particularly in people living with depression[54]. This may occur as increases in self-efficacy shifts people with co-morbid depression from disregarding behaviour change towards the process of contemplating change, initiating and maintaining new positive health behaviours[55]. Therefore, integration of non-pharmacological therapies, such as meditation, that have the capacity to improve depression and anxiety symptoms,

and perceptions of self-efficacy in people living with heart disease is essential to improving secondary prevention adherence and outcomes[56].

1.5 Self-management

Self-management is integral to effective primary and secondary heart disease prevention. Self-management is defined as the capacity for an individual to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes that accompany living with a chronic condition[57]. Efficacious self-management describes the ability for people living with heart disease to monitor their condition and to adapt cognitive, behavioural and emotional responses as required to maintain a satisfactory quality of life[57]. In doing so, a dynamic and continuous process of self-regulation is established[57]. The shift to a self-management paradigm is required as it enables people living with heart disease to move from focusing on illness in their 'psychological foreground' to maintaining wellness[48].

1.6 Meditation as a strategy to promote psychological health in cardiac rehabilitation

Meditation is a potential self-management strategy that may improve psychological well-being of people living with heart disease. As a novel non-pharmacological strategy, meditation offers the potential to address the emotional, mental and psychological components of health that contribute to overall health and well-being. Meditation includes "…practices that self-regulate the body and mind, thereby affecting mental events by engaging a specific attentional set"[58, p. 180]. Meditation is commonly classified into two types, concentrative and mindfulness meditation. Concentrative meditation types, such as Transcendental Meditation, Benson's Relaxation Response or guided imagery, involve a focus on a specific mental or sensory activity, such as a repeated sound, visualised image(s) or specific body sensations such as breath[58]. Mindfulness encourages a present-moment awareness of thoughts, feelings, and sensations without attachment or analysis of mental contents[58]. There is overlap between the two approaches, as concentrative practices incorporate mindfulness by allowing thoughts to pass without attachment, returning attention to the object of

concentrative awareness, whilst mindfulness encourages a return to an open, non-judgemental attentive set[58]. Whilst methods used to elicit state changes differ across practices, both approaches can mutually influence and enhance each other, producing similar changes towards an expanded awareness or consciousness[58, 59].

Integrating meditation into a cardiac rehabilitation program would provide opportunities for people living with heart disease to improve self-management of their depression and anxiety symptoms. By facilitating awareness and the integration of emotional experiences after a cardiac event, meditation has the potential to enable adaptive self-regulation of one's emotional responses, thereby challenging negative interpretations of experiences and promoting self-efficacy[51]. This shift can reduce depression and anxiety symptoms and generate positive health behaviour change[60]. As such, meditation potentially empowers people living with heart disease to reintegrate as functional, productive members of society, and may reduce illness exacerbations that require frequent use of acute care services. Integrated approaches to care that are affordable, sustainable, easy to use and adaptable are more likely to facilitate implementation across heart disease clinical settings and enable continuity of care[61]. Despite, these potentially positive outcomes, few cardiac rehabilitation services have integrated mediation into their program.

1.7 Thesis aim

The Integrating MEditatioN inTO heaRt disease care (MENTOR) Project aimed to generate contextual knowledge to understand the capacity for meditation to improve the psychological well-being of people participating in a cardiac rehabilitation program.

1.8 Research Questions

The MENTOR Projects objectives are detailed below:

I. What is the burden of moderate depression and anxiety symptoms in people living with heart disease attending cardiac rehabilitation programs?

II. Does completing cardiac rehabilitation programs reduce depression and anxiety symptoms?

III. Do depression and anxiety symptoms affect adherence to cardiac rehabilitation programs?

IV. What is the feasibility and acceptability of integrating meditation into a NSW cardiac rehabilitation program as a strategy for reducing depression and anxiety symptoms in people living with heart disease?

V. What are the research and practice implications for integrating meditation into heart disease care as a self-management strategy?

1.9 Significance

The MENTOR Project is innovative in that it seeks to generate new insights into the current gaps in the management of depression and anxiety in heart disease care in Australia. It will also contextualise the relevance of psychological risk factors to heart disease outcomes and the provision of secondary prevention services, including the delivery of non-pharmacological strategies in one Australian jurisdiction. Understanding the burden of psychological health in heart disease secondary prevention will help identify whether investigation of non-pharmacological adjuncts to manage these symptoms is warranted to maximise benefits to consumers and health organisations[4]. The MENTOR Project will generate new knowledge of the potential for meditation to be implemented alongside a conventional heart disease secondary prevention service in NSW, and inform future collaborative agendas for meditation research and practice as a strategy to improve health service delivery[62].

Findings of this research will enable heart disease clinicians and stakeholders to better understand and collaborate in meditation research and practice as a strategy to reduce the burden of depression and anxiety symptoms in people living with heart disease. Integration of patient and health professional perspectives into self-management strategy development and implementation will

enhance the quality of heart disease health service delivery. This will be achieved through the potential of the research to 1) enhance self-management of psychological health symptoms; 2) improve adherence to recommendations for heart disease secondary prevention; and 3) improve perceptions of self-efficacy required to optimise health behaviours.

1.10 Thesis Outline

This doctoral research project adopted an explanatory sequential mixed methods design guided by two interrelated conceptual frameworks, 1) The World Health Organisation Integrated Care for Chronic Conditions Framework[63], and 2) Bandura's Self-Efficacy Model[64]. The thesis consists of four discrete yet interrelated studies, presented in three phases, across seven chapters. The structure and content of these chapters are outlined in Table 1.3:

Table 1.3: Thesis navigation table

Sequence	Content	Chapter
Preliminary	Introduction to the MENTOR project	1
Phase 1	Study 1: Longitudinal cohort study of the prevalence, correlates and predictors of depression and anxiety in people attending NSW cardiac rehabilitation programs, and the impact of these symptoms on adherence.	2
	Study 2: Systematic review of randomised controlled trials and quasi experimental studies of meditation for the reduction of depression and anxiety symptoms	3
	Mixed methods design and conceptual framework	4
	Study 3: Phase II pilot randomised controlled trial to determine the feasibility of a meditation intervention for people living with heart disease delivered in the outpatient cardiac rehabilitation setting for the reduction of depression and anxiety symptoms	5
Phase 2	Study 4: Semi-structured interviews of key health professionals to understand their perspectives of the barriers and facilitators affecting meditation's integration as an adjunct health care strategy	6
Phase 3 Conclusion and recommendations	Data integration and meta-inference	7
	Recommendations for meditation research and practice, including the design of a future phase III randomised controlled trial	

1.11 Summary

People living with heart disease have experiences during and after a cardiac event are complex and multifaceted. This doctoral research project seeks to improve care for people living with heart disease by assessing the potential of integrating meditation into a cardiac rehabilitation setting to facilitate better long term heart disease health related outcomes.

Chapter 2 presents a longitudinal cohort study of the prevalence, correlates and predictors of depression and anxiety in people living with heart disease who have participated in a cardiac rehabilitation program. It will also identify the impact of cardiac rehabilitation on depression and

anxiety symptoms, and the effect of depression and anxiety on attending and completing a cardiac rehabilitation program.

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Chapter 2 The prevalence and impact of depression and anxiety symptoms in a NSW cardiac rehabilitation program: A longitudinal cohort study

2.1 Preface

Chapter 1 identified that heart disease is the leading cause of death internationally. It also highlighted the importance of cardiac rehabilitation programs in secondary prevention and their role in reducing heart disease morbidity and mortality. Chapter 1 also outlined the barriers to cardiac rehabilitation participation, the problem of low cardiac rehabilitation adherence rates and the relevance of integrated approaches to self-management as being vital to improving cardiovascular outcomes. One of the elements to emerge was how poor psychological health potentially impacts on cardiac rehabilitation participation rates and adherence to other recommended secondary prevention strategies. This chapter focuses on the burden of psychological health in people living with heart disease and the degree to which depression and anxiety impacts on their health, wellbeing and engagement with cardiac rehabilitation programs.

2.2 Publication reference

Rao, A., Zecchin, R., Newton, P.J., Phillips, J.L., DiGiacomo, M., Denniss, A.R., & Hickman, L.D. 'Prevalence and impact of depression and anxiety in cardiac rehabilitation: A longitudinal cohort study' *European Journal of Preventive Cardiology* vol. 27(5), p. 478- 489 [IF: 5.640]

2.3 Introduction

Depression and anxiety cost the global economy $1 trillion per year, which accounts for 10% of the global disease burden[1, 2], and increases heart disease health care costs[3]. The prevalence of co-morbid depression and anxiety in heart disease increases the risk of poorer prognosis and mortality after a cardiac event[4], with depression increasing the risk of mortality by more than two-fold[5, 6], and reduces compliance with medications and recommended treatments[7].

Depression and anxiety is under-recognised and undertreated in people living with heart disease, particularly in women[8]. Misdiagnosis of depression and anxiety commonly occurs during hospitalisation due to the protective function of denial in people living with heart disease[9], which accounts for the persistence of symptoms after discharge and on entry into cardiac rehabilitation programs. Milder forms of depression, characterised by anhedonia or depressed mood that persists daily for most of the time, for up to two weeks, and leads to a change in function, occurs in up to 30% of people after an acute cardiac event[10]. Whilst depressive symptoms are often considered transient in nature after a cardiac event[4], they can also worsen over time[11]. Major depression, occurs in between 11-20%[12, 13] of people living with heart disease, whereas generalised anxiety disorder , occurs at a rate of approximately 15%[14, 15]. Prevalence rates for moderate anxiety symptoms in people living with heart disease, defined by cut-off points on validated standardised questionnaires, are higher, occurring in approximately 30% of cases[16]. Presence of depression and anxiety places people living with heart disease at an even greater risk of further cardiovascular events, poorer quality of life[17], functional decline or disability[18], and reduces productivity[19].

Reduced adherence to recommendations for the management of risk factors such as hypertension, smoking, dyslipidaemia, diabetes, sedentary lifestyle, and weight management[20, 21] after a cardiac event is common. Low adherence to heart disease treatment recommendations is due to the complex interplay of physical, social, environmental and psychological components of heath, which are often not afforded the same priority as the treatment of physical symptoms[22]. Psychological health is also likely to mediate the bi-directional interaction between psychosocial risk factors and heart disease[22, 23]. Reducing depression and anxiety in people living with heart disease presents an opportunity to improve the impact of psychosocial risk factors on poorer cardiovascular outcomes[22]. Some efforts have been made to integrate psychological health within secondary prevention to improve psychological health management[2, 24, 25] . However, this has not led to widespread changes in the delivery of psychological health support in heart disease care. Assessment of the mental health status of people living with heart disease also varies greatly across clinical settings[26].

Structured clinical interview by a medical practitioner is the only well validated measure for the diagnosis of depression and anxiety. These clinical interviews enable the assessment of the persistence of symptoms that correspond with a major depressive disorder or anxiety disorder in accordance with DSM-V criteria[27]. However, cut-off scores used in clinical practice to define clinically significant depression, in many, but not all cases, also correspond to standard criteria for a diagnosis of depression and vice versa[28]. As such, understanding the prevalence of moderate psychological health symptoms, factors that increase vulnerability to poor psychological outcomes[29] and predictors of depression and anxiety symptoms will provide the evidence required for health organisations, clinicians and policy makers to better understand the impact of poor psychological health on cardiac rehabilitation service provision. It will also allow decision makers to plan for better coordination of services in order to optimise uptake and adherence to cardiac rehabilitation services, which is aligned with an integrated approach to care. Integrated approaches to the identification and management of moderate depression and anxiety symptoms in cardiac rehabilitation programs will provide opportunities for clinicians to reduce the impact of these symptoms on poor cardiovascular outcomes.

2.3.1 Rationale for Study 1 of the MENTOR Project

Study 1 aimed to identify the gaps in cardiac rehabilitation service delivery, quantifying the burden of depression and anxiety on an Australian heart disease population who ought to have completed these programs.

2.4 Objectives

To understand the burden of moderate depression and anxiety symptoms in people participating in a NSW cardiac rehabilitation program and if these symptoms affect cardiac rehabilitation adherence.

2.5 Methods

2.5.1 Study design

A retrospective longitudinal cohort study of Australian people living with heart disease who participated in cardiac rehabilitation programs in one local health district in metropolitan Sydney, between 2006 and 2017.

While the study population was dynamic with variable entry and exit dates, this design reflected clinical reality and allowed for the: i) exploration of ideas, such as clinical observations of depression and anxiety in heart disease outpatients; ii) identification of nuances in the data based on these clinical observations; and iii) verification of the magnitude of associations previously reported in the literature[30]. An additional benefit of the cohort design was the ability of the researcher to calculate depression and anxiety risk ratios at the point of participant entry[30].

This study is reported in accordance with the STROBE statement for cohort studies[30].

2.5.2 Setting

All participants attended an outpatient Cardiac Exercise and Assessment Program at one of two hospitals in a local health district over an 11 year period (2006-17) in metropolitan Sydney, Australia. This local health district provides outpatient cardiac rehabilitation for people with cardiac problems, including acute myocardial infarction, (AMI), coronary artery bypass grafts (CABG), coronary angioplasty (PTCA), percutaneous coronary interventions (PCI), valve surgery, heart failure, implantable devices and also people who have risk factors for developing heart disease. The service includes individual comprehensive clinical assessment, patient education about lifestyle change and self-management and a structured, supervised exercise program of six or 12 weeks duration that is led by specialised cardiac rehabilitation registered nurses.

2.5.3 Sample

Adults ≥ 18 years who had a recent admission to hospital (in the previous six months), with a cardiac condition, who had a cardiac diagnosis including an acute coronary syndrome or heart failure, or who were referred to cardiac rehabilitation for risk factor modification, were eligible for inclusion.

2.5.4 Data Collection

The cohort used in this study was generated from a 20 year dataset of people entering cardiac rehabilitation programs, which was generated by a research collaborator and maintained by clinical staff across the local health district. Clinical staff and the Nurse Unit Manager were responsible for the quality and consistency of input into the dataset across multiple sites. The variables used from this dataset are described below.

Variables

Demographic characteristics included gender (male, female), age, year of entry into cardiac rehabilitation, occupation, marital status (married, engaged or de-facto, divorced or separated, widowed, or single), or family history of heart disease in members under 55 years of age. The data collection form and data dictionary are included in Appendices 1 and 2.

Health Status: Short Form-36 (SF-36) Quality of Life measures (version 1). Subscales included general health perceptions (5 items); physical functioning (limitations in physical activities due to health problems) (10 items); role-physical (limitations in usual role activities because of physical health problems) (4 items); bodily pain (2 items); vitality (energy and fatigue) (4 items); social functioning (limitations in social activities due to physical or emotional problems) (2 items); role-emotional (limitations in usual role activities due to emotional problems) (3 items); general mental health (psychological distress and well-being) (5 items); and health transition (1 item)[31, 32]. Each SF-36 item was scored on a scale of 0 to 100 points, and an average score was obtained for each subscale on entry and on completion. The overall SF-36 score was also used. Higher scores reflected greater mental and physical self-rated health[31]. The SF-36 has been validated in stroke[33], heart valve

surgery[34], myocardial infarction patients[35], cardiac rehabilitation[36] and a variety of chronic illness populations[37-39].

Risk factors included smoking status at cardiac rehabilitation assessment, depression, diabetes, hypertension and lifestyle (active, sedentary). An active lifestyle was defined as more than 30 minutes of exercise (outside of work) >3 days per week.

Heart disease diagnosis included acute myocardial infarction (AMI), cardiothoracic surgery, percutaneous coronary angiogram (PTCA) and/or percutaneous coronary intervention (PCI), chest pain or angina or other diagnoses as specified in hospital discharge summary documents.

Current medications were categorised into key cardiac medication groups including self-reported blood pressure control or use of digoxin, beta-blocker agents, angiotensin converting enzyme (ACE) inhibitors, anti-arrhythmic agents, calcium antagonists, or nitrates.

Physiological Assessment included body mass index (BMI), exercise capacity, defined by metabolic equivalent of task (MET) levels or six-minute walk test results on entry, systolic blood pressure (SBP), diastolic blood pressure (DBP) and resting heart rate (HR) on entry into cardiac rehabilitation programs. Body mass index was classified according to the World Health Organisation classifications of underweight (<18.5), normal (18.5-24.9), overweight (25.0-29.9) and obese (>30)[40]. The metabolic equivalent of task (MET) is the ratio of energy expenditure to body mass, defined as 3.5ml of oxygen/per kilogram/per minute, which is equivalent to the energy expended at rest[41]. Metabolic equivalent of task (MET) testing has been used to measure the reductions in cardiovascular risk that are mediated by physical activity[42]. Exercise capacity testing in cardiac rehabilitation programs is also measured using a six minute walk, which is the number of metres walked in a six minute period[43]. Blood pressure, measured in millimetres of mercury (mmHg) is defined as optimal (<120/80); normal (≤ 120-129mmHg [systolic]; 80-84mmHg [diastolic]); high-normal (130-139mmHg [systolic]; 85-89mmHg [diastolic]); Grade 1 mild hypertension (140-159mmHg [systolic]; 90-99mmHg [diastolic]); Grade 2 moderate hypertension (160-179mmHg [systolic]; 100-109mmHg [diastolic]); Grade 3

severe hypertension (≥180mmHg/110mmHg) or isolated systolic hypertension (>140mmHg [systolic]; <90mmHg [diastolic])[44]. A normal resting heart rate is defined as 60 to 100 beats per minute[45].

Psychological Assessment consisted of the *Depression, Anxiety and Stress as measured by the Depression Anxiety Stress Scales (DASS-21)* [46]. The DASS is a set of three self-report scales designed to measure the negative emotional states of depression, anxiety and stress. The depression sub-scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest/involvement, anhedonia, and inertia. The anxiety sub-scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect. The stress sub-scale is sensitive to levels of chronic non-specific arousal. It assesses difficulty relaxing, nervous arousal, and being easily upset/agitated, irritable/over-reactive and impatient[46]. All scales of the DASS-21 have been shown to have high internal consistency and to yield meaningful discriminations in a variety of settings[46]. The DASS-21 has also been validated in chronic obstructive pulmonary disease[47], older adults with pain[48] and adolescent mental health populations[49]. The term 'moderate depression' was used to define moderate to extremely severe depressive symptoms, indicated by a DASS-21 subscale score of ≥14. 'Moderate anxiety' was used to describe to moderate to extremely severe anxiety symptoms, defined by a DASS-21 subscale score of ≥10. 'Moderate stress' was used to describe moderate to extremely severe stress symptoms, defined by a DASS-21 subscale score of ≥19.

Cardiac rehabilitation program participation rates included days to pre-assessment at cardiac rehabilitation and drop out. People who dropped out of cardiac rehabilitation programs due to reasons other than non-motivation or lack of attendance/contact were excluded from this analysis, given that these people may simply have been referred to anther program or re-hospitalised.

2.5.5 Data collection procedure

This study involved retrospective data collection from a Sydney metropolitan cardiac rehabilitation administrative dataset. Nursing staff routinely conduct a comprehensive assessment for people living with heart disease after hospital discharge and prior to the commencement of the exercise component of the cardiac rehabilitation program. During this interview, nursing staff complete a case report form that includes medical history, co-morbidities, and heart disease risk factors, based on medical records and self-report. People living with heart disease are instructed to complete a DASS-21 questionnaire and a six minute walk test or exercise stress test, depending on the facility (refer Appendix 3). The program is completed at the completion of 12 sessions, at 6 or 12 weeks, depending on the preferences of people living with heart disease. Six minute walk test or an exercise stress test is repeated to measure improvements in functional capacity. Physical (blood pressure and heart rate) and psychological (DASS-21) outcomes are repeated to measure progress and to determine that people living with heart disease have returned to their usual level of functioning before experiencing their cardiac event. Registered nurses then enter this information into the Excel spreadsheet based cardiac rehabilitation administrative dataset.

This database was independently developed by the Nurse Unit Manager of the Cardiac Education and Assessment Program and collection of this data involved no patient contact. De-identified data was exported from an Excel spreadsheet to SPSS Version 23 by the researcher, then uploaded to Cloudstor online cloud platform for data cleaning and analysis.

2.5.6 Data storage

Data was stored on Cloudstor online cloud platform and accessed via password protected servers at the University of Technology Sydney. All records will be kept for 5 years after the completion of the study and electronic files will be permanently deleted upon completion of the term. Researchers ensured that patients were not identifiable in journal publications or presentations.

2.5.7 Data Analysis

Data collected at baseline assessment, prior to the commencement of the cardiac rehabilitation exercise program and at completion of the program's 12 sessions at six or 12 weeks were included in the analysis. A total of 4784 participants completed the DASS-21 questionnaire on entry into cardiac rehabilitation programs over the eleven year period. Therefore 81% of the total sample was included in questions related to the DASS-21, with 19% of the total sample considered as missing data and excluded from these analyses. Independent t-tests and Mann Whitney U tests were used to analyse continuous data and chi-squared tests and Fishers exact tests were used for categorical outcomes in univariate non-parametric analyses. Scores derived from psychometric measures for depression, anxiety and stress, and quality of life, were all measured on continuous scales on entry and at completion of cardiac rehabilitation programs. Statistical significance was set at $p<0.05$.

To determine predictors of moderate depression or anxiety, factors with $p<0.1$ were entered into stepwise backward logistical regression models using likelihood ratio tests. Analyses were completed in consultation with a biostatistician from Western Sydney Local Health District. Change in depression and anxiety DASS-21 subscale scores were not significantly different between the two sites, therefore both sites were combined into a single model for multivariate analyses. Missing data in multivariate analyses was limited to approximately 12% of cases which was considered acceptable. Receiver operating curves determined that the sensitivity/specificity of the depression and anxiety models was AUC=0.923 and AUC=0.860 respectively, indicating that we were not able to reject the hypothesis that the fit of the models was good, and the likelihood of a type I or type II error was low.

2.5.8 Ethics

Ethical approval for use of the dataset was obtained from Western Sydney Local Health District Human Research Ethics Committee (AU RED LNR/17/WMEAD/24) and ratified by the University of Technology Sydney Human Research Committee (ETH 17-1604).

2.6 Results

This study sample was drawn from a cohort of 5908 patients from two hospitals in one local health district in Sydney, Australia, and a total of 4784 participants completed the DASS-21 questionnaire on entry into cardiac rehabilitation programs.

2.6.1 Profile of adults entering cardiac rehabilitation programs

Participants had a mean age of 61 years, were predominately male (77%), married, engaged or in a de-facto relationship (74%), employed (44%) and admitted for cardiothoracic surgery (30%) (Refer table 2.1). A greater proportion of these adults also had risk factors for heart disease including hypertension (63%), hypercholesterolaemia (88%), sedentary lifestyle (60%) and were overweight (mean BMI=29) (refer Table 2.2).

Table 2.1: Demographic profile of adults on entry into cardiac rehabilitation programs (2006-2017)

Variables		N	%
Socio-demographic profile		**(5908)**	**(100)**
Sex	Male	4533	77
	Female	1374	23
Marital status	Married/engaged/de-facto	4317	74
	Divorced/ separated	639	11
	Widowed	466	8
	Single	443	7
Occupation	Employed	2561	44
	Unemployed/ government benefits	551	9
	Retired	2241	38
	Student/home duties	280	5
	Not known	215	4
Family history of heart disease		2165	37
Diagnoses	AMI	1657	28
	Cardio-thoracic surgery	1749	30
	PTCA and/or stent insertion	1211	21
	Chest pain or angina	321	5
	Other	968	16
		N	**Mean (SD)**
Age		5904	61(12)

Table 2.2: Cardiovascular and psychosocial risk factors on entry into cardiac rehabilitation programs (2006-2017)

Risk factors		N (5908)	% (100)
Smoking status	Current smoker	1401	24
	Ex-smoker	2707	46
	Never smoked	1770	30
Sedentary lifestyle		3515	60
Self-reported depression		1128	19
Diabetes		1974	33
Hypercholesterolemia		5165	88
Hypertension		3679	63
Physiological Assessment		**N**	**Mean (SD)**
Body Mass Index		5653	29 (6)
METs level		4416	8 (3)
6MWT		1079	321 (119)
Systolic blood pressure		5567	117 (18)
Diastolic blood pressure		5559	69 (10)
Heart rate		5571	73 (14)
Participation rates		N	**Mean (SD)**
Days to pre-assessment		5421	30 (26)
Health Status (SF-36)		**N**	**Mean (SD)**
General Health		4297	62 (21)
Physical Functioning		4296	58 (24)
Role-physical		4297	32 (39)
Bodily pain		4297	66 (25)
Vitality		4297	55 (22)
Social functioning		4297	66 (28)
Role-emotional		4297	55 (45)
Mental health		4297	72 (19)
Health transition		4296	29 (22)
SF-36 total score		4297	109.41 (17.17)
Psychological assessment (DASS-21)		**N**	**Mean (SD)**
Depression subscale		4784	7 (8)
Anxiety Subscale		4780	7 (7)
Stress Subscale		4780	8 (9)
DASS-21 total score		4788	23 (22)

2.6.2 Moderate depression, anxiety and stress (DASS-21) symptoms on entry into cardiac rehabilitation programs

Symptoms of moderate to extremely severe depression were prevalent in approximately 18% (n=867) of adults who entered cardiac rehabilitation programs. A higher proportion of participants (28%, n=1333) reported having moderate to extremely severe anxiety, and approximately 13% of adults (n=637) reported having symptoms of moderate to extremely severe stress on entry into cardiac rehabilitation programs (refer Table 2.3).

Table 2.3: Socio-demographic factors associated with depression, anxiety and stress on entry into cardiac rehabilitation programs (2006-2017)

Variable		Normal to mild depression	Moderate to extremely severe depression		Normal to mild anxiety	Moderate to extremely severe anxiety		Normal to mild stress	Moderate to extremely severe stress	
Socio-demographic factors		**N (%)**	**N (%)**	**p value**	**N (%)**	**N (%)**	**p value**	**N (%)**	**N (%)**	**p value**
		3917 (100)	**867 (18)**		**3447 (72)**	**1333 (28)**		**4143 (87)**	**637 (13)**	
Sex	Male	3085 (79)	642 (74)	0.002	2754 (80)	969 (73)	<0.001	3252 (79)	471 (74)	0.010
	Female	832 (21)	225 (26)		693 (20)	364 (27)		891 (21)	166 (26)	
Marital status	Married, engaged or de-facto	2978 (76)	565 (65)	<0.001	2621 (76)	918 (69)	<0.001	3087 (75)	452 (71)	<0.001
	Divorced/separated	368 (9)	150 (17)		325 (10)	193 (15)		419 (10)	99 (16)	
	Widowed	292 (8)	64 (8)		248 (7)	108 (8)		324 (8)	32 (5)	
	Single	273 (7)	86 (10)		247 (7)	112 (8)		305 (7)	54 (8)	
Occupation	Employed	1947 (50)	328 (38)	<0.001	1715 (50)	558 (42)	<0.001	2015 (49)	258 (41)	<0.001
	Unemployed/ Benefits	268 (7)	155 (18)		268 (7)	194 (15)		304 (7)	118 (19)	
	Retired	1464 (37)	295 (34)		1314 (38)	444 (33)		1564 (38)	194 (31)	
	School/ home duties	143 (4)	44 (5)		107 (3)	80 (6)		154 (4)	33 (5)	
	Not known	78 (2)	38 (5)		66 (2)	50 (4)		88 (2)	28 (4)	
Family history of heart disease		1409 (36)	367 (43)	0.001	1224 (36)	551 (42)	0.001	1509 (37)	266 (42)	0.029
		Mean (SD)	**Mean (SD)**		**Mean (SD)**	**Mean (SD)**		**Mean (SD)**	**Mean (SD)**	
Age		61.1 (12.0)	59.2 (12.3)	<0.001	61.3 (11.9)	59.4 (12.6)	<0.001	61.0 (12.1)	58.9 (12.0)	<0.001
Heart disease diagnoses		**N (%)**	**N (%)**		**N (%)**	**N (%)**		**N (%)**	**N (%)**	
Diagnoses	AMI	1144 (29)	238 (28)	<0.001	1039 (30)	342 (26)	<0.001	1213 (29)	168 (26)	<0.001
	Cardiothoracic surgery	1272 (33)	211 (24)		1127 (33)	355 (27)		1324 (32)	158 (25)	
	PTCA/ PCI	855 (22)	176 (20)		752 (22)	277 (21)		901 (22)	128 (20)	
	Chest pain/angina	163 (4)	69 (8)		133 (4)	99 (7)		174 (4)	58 (9)	
	Other	482 (12)	173 (20)		395 (11)	260 (19)		530 (13)	125 (20)	

Table 2.4: Cardiovascular risk factors and medication use associated with depression, anxiety and stress on entry into cardiac rehabilitation programs

Variable		Normal to mild depression	Moderate to extremely severe depression	p value	Normal to mild anxiety	Moderate to extremely severe anxiety		Normal to mild stress	Moderate to extremely severe stress	
Risk factors		**N (%) 3917 (100)**	**N (%) 867 (18)**	**p value**	**N (%) 3447 (72)**	**N (%) 1333 (28)**	**p value**	**N (%) 4143 (87)**	**N (%) 637 (13)**	**p value**
Smoking	Current smoker	826 (21)	251 (29)	<0.001	747 (22)	330 (25)	0.068	902 (22)	175 (28)	0.001
	Ex-smoker	1221 (31)	252 (29)		1070 (31)	401 (30)		1266 (30)	205 (32)	
Sedentary lifestyle		2198 (56)	576 (66)	<0.001	1924 (56)	848 (64)	<0.001	2382 (58)	390 (61)	<0.001
Self-reported depression		573 (15)	362 (42)	<0.001	513 (15)	420 (32)	<0.001	671 (16)	262 (42)	<0.001
Diabetes		1181 (30)	315 (36)	<0.001	1016 (30)	477 (36)	<0.001	1272 (31)	221 (35)	0.042
Hypercholesterolaemia		3496 (89)	777 (90)	0.509	3094 (91)	1176 (89)	0.106	3692 (90)	578 (91)	0.454
Hypertension		2403 (61)	563 (65)	0.049	2130 (62)	832 (62)	0.681	2555 (62)	407 (64)	0.302
Days to pre-assessment [mean (SD)]		29 (25)	32 (26)	0.109	29 (24)	31 (30)	0.256	29 (25)	32 (26)	0.086
Physiological Assessment		**Mean (SD)**	**Mean (SD)**		**Mean (SD)**	**Mean (SD)**		**Mean (SD)**	**Mean (SD)**	
Body Mass Index		29 (5)	30 (6)	<0.001	29 (5)	29 (6)	0.045	29 (6)	30 (6)	0.001
Pre-assessment MET level		8 (3)	7 (2)	<0.001	8 (3)	7 (3)	<0.001	8 (3)	7 (3)	0.001
Six minute walk test pre-assessment (metres)		336 (114)	316 (111)	0.040	344 (115)	308 (107)	<0.001	336 (113)	306 (111)	0.011
Resting SBP (mmHg)		149 (27)	144 (26)	0.434	117 (17)	116 (18)	0.050	117 (18)	117 (17)	0.793
Resting DBP (mmHg)		69 (10)	70 (10)	0.333	69 (10)	69 (10)	0.531	69 (10)	70 (10)	0.172
Resting HR (mmHg)		72 (13)	75 (13)	<0.001	72 (13)	75 (14)	<0.001	73 (13)	75 (14)	0.001
Medications		**N (%)**	**N (%)**		**N (%)**	**N (%)**		**N (%)**	**N (%)**	
BP control		2436 (92)	571 (92)	0.949	2157 (92)	846 (92)	0.978	2590 (93)	413 (91)	0.978
Digoxin use		122 (3)	45 (5)	0.003	97 (3)	70 (5)	<0.001	138 (3)	29 (5)	0.119
Beta-blocker use		2849 (73)	631 (73)	0.991	2529 (74)	949 (71)	0.130	3020 (73)	458 (72)	0.555
ACE inhibitor use		2304 (59)	501 (60)	0.551	2055 (60)	746 (56)	0.020	2428 (59)	373 (59)	0.927
Anti-arrhythmic use		296 (8)	56 (7)	0.269	245 (7)	107 (8)	0.272	309 (8)	43 (7)	0.531
Calcium antagonist use		457 (12)	122 (14)	0.047	396 (12)	182 (14)	0.037	479 (12)	99 (16)	0.004
Nitrates use		275 (7)	103 (12)	<0.001	228 (7)	150 (11)	<0.001	296 (7)	82 (13)	<0.001
Cholesterol control		3482 (91)	763 (90)	0.656	3089 (91)	1153 (89)	0.007	3681 (91)	561 (90)	0.117

Table 2.5: Health status and psychological risk factors associated with depression, anxiety and stress symptoms on entry to cardiac rehabilitation programs (2006-2017)

Variable		Normal to mild depression	Moderate to extremely severe depression	p value	Normal to mild anxiety	Moderate to extremely severe anxiety		Normal to mild stress	Moderate to extremely severe stress	
Health status (SF-36 subscale scores)		**Mean (SD)**	**Mean (SD)**	**p value**	**Mean (SD)**	**Mean (SD)**	**p value**	**Mean (SD)**	**Mean (SD)**	**p value**
General Health		65.99 (18.86)	43.84 (19.93)	<0.001	66.99 (18.80)	49.43 (20.47)	p<0.001	64.66 (19.73)	44.66 (19.75)	<0.001
Physical Functioning		60.59 (23.44)	46.99 (23.60)	<0.001	62.37 (22.92)	47.38 (23.45)	p<0.001	59.87 (23.67)	46.89 (23.34)	<0.001
Role-physical		35.13 (40.00)	17.60 (31.40)	<0.001	37.56 (40.62)	17.63 (30.89)	p<0.001	34.11 (39.77)	17.92 (31.68)	<0.001
Bodily pain		68.94 (24.28)	51.57 (24.79)	<0.001	70.42 (24.14)	54.11 (24.21)	p<0.001	68.22 (24.47)	50.05 (24.79)	<0.001
Vitality		59.14 (20.34)	34.34 (18.89)	<0.001	60.20 (20.59)	40.72 (19.93)	p<0.001	57.64 (21.14)	35.34 (19.37)	<0.001
Social functioning		71.07 (43.68)	44.21 (24.79)	<0.001	72.57 (26.37)	50.21 (26.05)	p<0.001	69.57 (27.06)	44.42 (25.44)	<0.001
Role-emotional		61.22 (43.68)	23.61 (36.85)	<0.001	63.54 (43.13)	31.32 (40.86)	p<0.001	58.74 (44.31)	26.36 (38.19)	<0.001
Mental health		77.20 (15.87)	49.62 (18.41)	<0.001	77.89 (16.24)	58.05 (19.64)	p<0.001	75.96 (16.76)	47.74 (18.59)	<0.001
Health transition		26.69 (21.34)	38.73 (21.22)	<0.001	26.51 (21.31)	34.70 (21.97)	p<0.001	27.45 (21.34)	38.01 (22.77)	<0.001
SF-36 pre-assessment total		113.40 (15.06)	90.71 (13.97)	<0.001	114.64 (4.98)	95.85 (15.01)	p<0.001	112.16 (15.77)	90.67 (14.69)	<0.001
Psychological assessment (DASS-21)		**N (%)**	**N (%)**		**N (%)**	**N (%)**		**N (%)**	**N (%)**	
Depression	Normal to mild	-	-	-	3423 (94)	670 (50)	<0.001	3752 (91)	161 (25)	<0.001
	Moderate to extremely severe	-	-	-	204 (6)	663 (50)		391 (9)	476 (75)	
Anxiety	Normal to mild	3423 (83)	204 (24)	<0.001	-	-	-	3340 (81)	107 (17)	<0.001
	Moderate to extremely severe	670 (17)	663 (76)		-	-	-	803 (19)	530 (83)	
Stress	Normal to mild	3752 (96)	391 (45)	<0.001	3340 (97)	803 (60)	<0.001	-	-	-
	Moderate to extremely severe	161 (4)	476 (55)		107 (3)	530 (40)		-	-	-
		Mean (SD)	**Mean (SD)**		**Mean (SD)**	**Mean (SD)**		**Mean (SD)**	**Mean (SD)**	
DASS-21 total		14.67 (12.18)	58.23 (21.90)	<0.001	12.62 (10.90)	48.22 (23.15)	<0.001	16.00 (13.33)	65.12 (20.73)	<0.001

2.6.3 Factors associated with moderate to extremely severe depression, anxiety or stress (DASS-21 scores) on entry into cardiac rehabilitation programs

Factors associated with depression, anxiety and stress symptoms on entry into cardiac rehabilitation programs are described in Tables 2.3, 2.4 and 2.5. A significantly greater proportion of people with at least moderate depression, anxiety or stress symptoms were male (79%), married, engaged or in a de-facto relationship (74%), or employed (48%) with a mean age of 60 years (SD ± 12). Heart disease risk factors were increasingly prevalent in people with these symptoms including sedentary lifestyle (58%), hypertension (62%) and hypercholesterolaemia (11%), lower exercise capacity testing scores (METS: mean= 8 [SD ± 12]; 6MWT: mean= 331 metres [SD± 114]), and borderline obesity (BMI: mean = 29 [SD ± 13]).

2.6.4 Change in depression anxiety and stress symptoms at completion of cardiac rehabilitation

Nine percent of people with moderate depression on entry had only normal to mild depressive symptoms on completion. However, 5% of adults with moderate depression on entry who completed cardiac rehabilitation programs remained moderately depressed ($p<0.001$). Similarly, 15% of people with moderate anxiety on entry had only normal to mild anxiety symptoms on completion, whilst 8% of these people remained moderately anxious ($p<0.001$). Eight percent of people with moderate stress on entry had only normal to mild stress on completion compared with 3% of people who remained moderately stressed ($p<0.001$) (refer Table 2.6). The mean reductions in DASS-21 depression, anxiety and stress subscale scores on completion were all 1.93 points ($p<0.001$).

Table 2.6: Change in depression, anxiety and stress scores on completion of cardiac rehabilitation (2006-2017)

DASS-21 subscale scores		Normal to mild		Moderate to extremely severe		
On entry		N	%	N	%	p value
		Depression on completion				
Depression	Normal or mild	2437	83	94	3	p<0.001
	Moderate to extremely severe	261	**9**	143	**5**	
		Anxiety on completion				
Anxiety	Normal to mild	2097	71	150	5	p<0.001
	Moderate to extremely severe	451	**15**	239	**8**	
		Stress on completion				
Stress	Normal to mild	2575	88	60	2	p<0.001
	Moderate to extremely severe	221	**8**	81	**3**	

2.6.5 Depression, anxiety and stress symptoms and dropout from cardiac rehabilitation programs

People with symptoms of moderate depression (24% vs 13%), anxiety (32% vs 23%) or stress (18% vs 10%) symptoms on entry into cardiac rehabilitation programs were significantly more likely to drop out compared with adults with only normal to mild symptoms (all $p<0.001$) (refer Table 2.7).

Table 2.7: Association between depression, anxiety and stress symptoms and dropout from cardiac rehabilitation programs (2006-2017)

DASS-21 subscale		Dropout				
		yes		no		
		N	%	N	%	p value
		714	100	2564	100	
Depression	Normal to mild	540	76	2220	87	<0.001
	Moderate to extremely severe	174	**24**	344	**13**	
Anxiety	Normal to mild	482	68	1965	77	<0.001
	Moderate to extremely severe	231	**32**	599	**23**	
Stress	Normal to mild	587	82	2303	90	<0.001
	Moderate to extremely severe	126	**18**	261	**10**	

2.6.6 Predictors of depression on entry into cardiac rehabilitation programs

Independent predictors of moderate depression on entry into cardiac rehabilitation programs are described below in Table 2.8. Moderate anxiety increased the risk of moderate depression reflected in higher DASS-21 scores by 4.395 times ($p<0001$). Similarly, prevalence of moderate stress symptoms increased the risk of moderate depression by 4.527 times ($p<0.001$). Better role-emotional functioning and mental health (SF-36 subdomain scores) reduced the risk of moderate depression on entry by 0.944 times ($p<0.001$). Higher health transition scores slightly increased the risk of moderate depression on entry into cardiac rehabilitation programs by 1.018 times ($p<0.001$).

Table 2.8: Predictors of depression on entry into cardiac rehabilitation programs

Factor		Odds ratio	Lower	Upper	p value
Anxiety	Moderate to extremely severe	4.395	3.363	5.744	<0.001
Stress	Moderate to extremely severe	4.527	3.315	6.181	<0.001
Role-emotional		0.994	0.990	.0997	<0.001
Mental health		0.944	0.935	0.952	<0.001
Health transition		1.018	1.012	1.025	<0.001

2.6.7 Predictors of anxiety on entry into cardiac rehabilitation programs

Moderate depression and stress were the strongest predictors of moderate anxiety, increasing the risk of by 3.167 times ($p<0.001$) and 5.577 ($p<0.001$) times respectively. Increasing age and quality of life also slightly reduced the risk of moderate anxiety ($p<0.001$) (refer Table 2.9). A diagnosis of chest pain increased the risk of anxiety by 1.945 times ($p=0.006$). Other diagnoses, such a heart transplantation or left ventricular assisted device insertion, for example, increased the risk of anxiety by 1.553 times ($p= 0.006$) whilst a percutaneous coronary intervention increased the risk by 1.358 times ($p= 0.043$).

Table 2.9 Predictors of anxiety on entry into cardiac rehabilitation

Factor		Odds ratio	Lower	Upper	p value
Depression	Moderately to extremely severe	3.167	2.411	4.161	<0.001
Stress	Moderate to extremely severe	5.577	4.006	7.765	<0.001
Age		0.989	0.981	0.997	0.009
Quality of life (SF-36)		0.9443	0.936	0.950	<0.001
Diagnoses	Acute myocardial infarction	-			<0.001
	PCI/ stent	1.358	1.010	1.826	0.043
	Chest pain	1.945	1.209	3.129	0.006
	Other	1.553	1.131	2.131	0.007

2.7 Discussion

This longitudinal cohort study indicates that the prevalence of moderate depression and anxiety symptoms in Australian people attending the cardiac rehabilitation program of one local health district is high. One in five people in this cohort had moderate to extremely severe psychological health symptoms on entry into cardiac rehabilitation programs. These findings indicate that the prevalence of moderate depression in people living with heart disease is slightly higher when compared with the general population where the lifetime prevalence of depression is between 10-16%[50, 51]. The prevalence of moderate anxiety symptoms is similar to the general population with more than a third of those with generalised anxiety disorder also suffering from depression[52].

In this study, people with moderate depression and anxiety symptoms were significantly less likely to adhere to cardiac rehabilitation programs. This is also reflected in a US study which found that people with anxious depression have higher relapse rates and poorer response rates to antidepressant medication treatment[53]. Other studies have found that people with co-morbid depression are two times less likely to adhere to antidepressant medication[7], and the risk of non-attendance and non-completion of cardiac rehabilitation in people with major depressive disorder is doubled compared with those without major depression[54].

Further, these findings indicate that depression, anxiety and stress are independent, yet interrelated[55]. Moderate anxiety or stress quadrupled the risk of moderate depression on entry into cardiac rehabilitation. Similarly, moderate depression tripled the risk of moderate anxiety, and moderate stress increased the risk of moderate anxiety by over five times. Previous findings also suggest that depression is a strong predictor of anxiety over and above coronary artery disease severity, antidepressant use or clinical characteristics[56], and anxiety after an acute cardiac event is predictive of developing depression in the following six months[17, 57].

A diagnosis of chest pain increased the risk of anxiety on entry into cardiac rehabilitation, which is consistent with previous findings in recently diagnosed heart failure patients[58]. However no link between depression and chest pain was established, confirming difficulties in determining a causal relationship between these two factors[59].

In this study, being older improved overall quality of life and reduced the risk of moderate anxiety, whilst better role functioning due to emotional health and mental health reduced the risk of moderate to extremely severe depression. This confirms that people living with heart diseases' perception of poor mental health is a useful indicator of undiagnosed depression[60]. It also suggest that moderate depression and anxiety symptoms reduces the motivation, intention and capability of adults living with heart disease to engage in physical exercise[61]. Depression and anxiety dampens positive exercise intentions despite receiving health professional support and improving risk awareness in the initial assessment[62]. Depression and anxiety symptoms also negatively impact people living with heart diseases' perceptions of self-efficacy as the cardiac rehabilitation program continues[63], by reducing their ability to effectively manage negative affective states[64].

Better general health at the initial cardiac rehabilitation assessment when compared with the previous year also increased the risk for moderate depressive symptoms on entry into cardiac rehabilitation programs. Self-reported better general health in the presence of moderate depressive symptoms could indicate that depressive symptoms are persistent, despite improvements in health as a result of treatment of their cardiovascular condition. Decreased medication adherence in depressed patients may be attributable to a perception of no additional benefit or 'feeling worse' whilst perceptions of disability, incapacitation, and de-masculinisation in men may contribute to reduced adherence to exercise based programs [65, 66]. These findings indicate that success in heart disease secondary prevention, including adherence to cardiac rehabilitation programs may depend on the interaction between the

body and the mind, which needs to be better reflected in the assessment and management of depression and anxiety, as well as psychosocial risk factors that impact psychological health and quality of life[23].

Comprehensive screening, referral and treatment of co-morbid depression and anxiety symptoms after a cardiac event is essential given the current findings. American Heart Association and National Heart Foundation of Australia guidelines recommend screening for people living with heart disease and co-morbid depression in heart disease using the Patient Health Questionnaire-Version 2 (PHQ-2), and Patient Health Questionnaire- Version 9 (PHQ-9) for those meeting diagnostic criteria[13] to identify those at risk of poorer cardiovascular prognosis and mortality[67]. The PHQ-2 elucidates the frequency of depressed mood and anhedonia, in alignment with the DSM-V criteria. Whilst the PHQ-2 is promoted as a 2-item tool to increase routine depression screening, it requires supplementation with the PHQ-9 in those who screen positive to determine the presence of a depressive disorder[68]. International cardiac rehabilitation guidelines additionally recognise the impact of anxiety in people living with heart disease, and recommend screening all patients for both depression and anxiety symptoms [69-71]. The Hospital Anxiety and Depression Scale (HADS), for example, has been identified as the most commonly used screening tool for anxiety and depression in 248 cardiac rehabilitation programs across South America, US and Canada [67], and the most efficient method for screening and utilisation of adjunct psychological strategies in the cardiac rehabilitation setting [72]. The DASS-21 has additional utility in that it has been translated into over 50 languages and dialects, increasing accessibility for its use in non-English speaking populations, where depression and anxiety rates are known to be high[73]. Despite these recommendations[13], screening and referral procedures for depression are not standard practice during hospitalisation for a cardiac event, and omission of screening varies between 29-68% in cardiac rehabilitation programs[67].

Screening practices alone are insufficient to modify depression outcomes, and further research is required to understand the impact of referral and compliance with treatment of poor psychological health[67]. Poor compliance with external referral for psychological treatment suggests that people may feel more comfortable receiving adjunct psychological support within cardiac rehabilitation programs[66]. However, the availability of comprehensive cardiac rehabilitation programs that include strategies for psychological health vary internationally. Calls for the development and testing of an effective referral and treatment approach that goes beyond process-oriented screening practices towards collaborative care is required to better enhance psychological outcomes in heart disease clientele[67]. Indeed, collaborative care approaches for depression initiated during the hospitalisation process have demonstrated improved depression, cognitive symptoms of depression, mental health related quality of life and anxiety in people living with heart disease[74].

It is unknown whether treating depression definitively improves heart disease outcomes[75]. The use of antidepressant medication as a first line of treatment has been inconsistent in reducing depression, and largely disappointing in improving prognosis in cardiac rehabilitation programs[76, 77]. However, RCTs of psychosocial interventions highlight that whilst treating depression is inconsistent in improving mortality[24, 78, 79], it may reduce depressive symptoms and social isolation[24], and cardiac event recurrence[25]. As such, National Institute for Clinical Excellence (NICE)[80] and American Heart Association[4] guidelines recommend the integration of psychosocial interventions such as cognitive behavioural therapy (Class I, Level A evidence) or meditation[81] as adjunct or alternative treatments for those unable to tolerate antidepressant drugs or who prefer a non-pharmacological approach. These interventions could address identified needs to calm thoughts, alleviate physical discomfort[66], and improve cognition, behaviour and affect that are associated with low perceived social support[24]. However, to date there is not broad consensus or support between Australian clinicians involved in heart disease care on how adjunct strategies might be best integrated into clinical practice to improve

depression and anxiety outcomes or whether adjunct strategies should be incorporated within existing heart disease care. Further research is required to best identify how clinicians might proactively implement comprehensive patient centred strategies to best reduce depression and anxiety in heart disease secondary prevention and reduce cardiovascular risk.

2.7.1 Limitations

There are a number of limitations in this cohort study. It is possible that there is overlap between the constructs of depression, anxiety and stress, and that the current results reflect a syndrome of negative affectivity, or a chronic experience of negative emotions, rather than a relationship between two distinct symptoms or conditions[82]. However, the DASS-21 depression, anxiety and stress subscales are considered to align with facets of diagnostic criteria for mood disorders, panic disorder, and generalised anxiety disorder respectively[83, 84]. The anxiety subscale also correlates with symptoms of other anxiety disorders, apart from generalised anxiety and obsessive compulsive disorders[83]. People with high negative affectivity also have the tendency to be attuned to somatic symptoms, possibly misinterpreting these ambiguous sensations as physical illnesses[82]. Both these factors introduce the possibility of a response bias and is a limitation of the current findings. However, whilst the DASS-21 anxiety subscale contains some somatic items that could be experienced for reasons unrelated to emotion, such as breathlessness, the depression subscale does not contain somatic items, reducing the possibility of artificial score inflation[83]. Caution is required when interpreting the results of the anxiety subscale given its inclusion of somatic content, whilst the depression subscale is considered reliable in differentiating patients with and without depression in the presence of co-morbidity[83].

The true prevalence of moderate to extremely severe depression and anxiety after cardiac rehabilitation is possibly higher given that depression and anxiety symptom scores were not available for those who did not complete cardiac rehabilitation programs. Use of convenience sampling reduces generalizability of the findings to the broader cardiac rehabilitation

population. Analyses on disease severity, complications, and differential diagnoses (such as panic disorder in patients with chest pain) could not be completed due to the limited data available in this administrative dataset. Use of self-reported data and heterogeneity of the sample due to the inclusion of some risk factor modification patients without a definitive heart disease diagnosis may reduce the validity of the findings. A major limitation of the dataset is that it does not capture language spoken at home, or country of birth, which makes it difficult to report the proportion people living with heart disease who were of Aboriginal and Torres Strait Islander descent or were from culturally and linguistically diverse backgrounds.

This study involved an open cohort[30], where the study population was dynamic with variable entry and exit dates. However, this was not determined to be detrimental due to the relatively short time in which the participants were followed and that the demographic and some baseline clinical characteristics remained unchanged during this time.

2.8 Conclusion

This chapter has identified that moderate, clinically significant depression and anxiety symptoms are experienced by many people entering into cardiac rehabilitation programs. Comprehensive, pro-active screening, referral and treatment of moderate depression and anxiety symptoms within cardiac rehabilitation programs is required to decrease the severity and impact of depression and anxiety symptoms and to improve adherence to recommendations for heart disease risk factor management, thereby reducing future cardiovascular risk. Chapter 3 will explore the use of meditation as a non-pharmacological self-management strategy in cardiac rehabilitation programs, and whether it demonstrates the capacity to reduce depression and anxiety symptoms.

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Chapter 3 The role of meditation in reducing depression and anxiety symptoms in adults with heart disease: A systematic review

3.1 Chapter preface

Chapter 2 highlighted the importance of recognising moderate depression and anxiety symptoms in people living with heart disease and the strong bidirectional effect that these symptoms have on each other. These findings indicated that people with moderate depression, anxiety or stress symptoms were less likely to adhere to cardiac rehabilitation programs, which supported and validated the need for adjunct psychological strategies to better meet the needs of people living with heart disease. This chapter will detail a systematic review of meditation interventions designed to reduce depression and anxiety symptoms in people living with heart disease who have recently experienced a cardiac event who have enrolled in an outpatient cardiac rehabilitation program.

This systematic review was published in Mindfulness in 2018, an international high ranking peer-reviewed journal [IF:3.015] that explores the latest research findings, best practices, foundations, mechanisms of action, and cross-cultural use of Mindfulness, as well as training of clinicians, industry personnel, institutional staff in mindful provision of services.

3.2 Publication reference

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3.3 Introduction

Heart disease is the leading cause of death in both low, middle and high income countries[1, 2]. Evidence targeting sustainable non-pharmacological interventions to optimise modifiable heart disease risk factors is an international priority[3]. The American Heart Association recommends the use of meditation as an adjunct to guideline-directed cardiovascular risk

reduction[4]. Calls for further research for meditation's effectiveness in large phase III trials are required to facilitate the implementation of mediation into heart disease clinical settings[4, 5].

Depression is an independent risk factor for further cardiac events[6], whereas comorbid depression and anxiety are significantly associated with increased heart disease morbidity and mortality[6, 7]. After an acute cardiac event or hospitalisation, rates of depression and anxiety are high, which persists on entry into cardiac rehabilitation programs[8]. It is essential that clinicians identify and work with people who have recently experienced an acute cardiac event to ensure that those with depression or anxiety are able to improve their chances of both mental and physical recovery. Specific psychological stressors for people who have recently experienced a cardiac event generally occur between the first few weeks after the event to up to six months post discharge. These may manifest as existential anxiety, characterised by lingering fears of recurrence or progression of the disease, uncertainty and vulnerability[9], high incidence of post-coronary bypass depression[10], as well as adjustment to reductions in physical function and quality of life[11]. Whilst there are recommended pathways for referral of people hospitalised for a cardiac event who display depression and anxiety symptoms, depressive symptoms are often mistaken as cardiac in nature, and optimal treatment for these people is often overlooked during the inpatient phase[12]. How people living with heart disease can be best supported in this period of their heart disease trajectory is seldom explored outside an exercise based program[13], leaving avenues for mind-body therapies such as meditation to address their unmet psychological support needs.

Meditation is a means of generating self-awareness and acceptance, which can facilitate adaptive affective regulation, behaviour change, and alleviation of depression and anxiety symptoms[14]. Skills attained through meditation such as grounding and centering provide opportunities for regeneration and allow the individual to integrate stressful experiences, such as hospitalisation and cardiac interventions, thereby optimising self-management. Meditation may also lead to earlier detection of stress-ruminative thoughts and physiological arousal,

enabling opportunities to engage in more effective coping responses[15]. Whilst the predominant focus of secondary prevention has been towards the modification of physiological risk, meditation can empower individuals by identifying the role they play in addressing the emotional component of their illness[16].

Understanding and interpreting the philosophy underlying meditation practices from a Western frame of reference is challenging[17]. This is because meditation is culturally embedded, and there are philosophical differences between meditation approaches that align with different Eastern traditions. As such, different meditation techniques cannot be fully understood unless they are considered in the context of a spiritual tradition, in a specific historical time period, or contained in a text in accordance with the philosophy of an individual[17]. Meditation practices derived from Eastern origins have also undergone changes as they were adapted to Western cultural contexts. For example, Vipassana (silent meditation), which has origins in the Theravada tradition of Buddhism, has been adapted to the Western context as 'insight meditation'[18, 19]; while Transcendental Meditation is based on the teachings of Maharishi Mahesh Yogi as a part of Vedantic Hinduism[17]. The most notable adaptation of meditation practices for the Western context has been undertaken by Jon Kabat Zinn who developed Mindfulness Based Stress Reduction (MBSR), which subsequently evolved into Mindfulness Based Cognitive Therapy (MBCT)[20, 21] as well as other mindfulness practices. With popularisation of meditation into Western mainstream, 'mindfulness' now broadly defines a variety of meditation practices with or without links to their traditional Eastern origins[22].

Meditation and deep breathing are the two most commonly utilised mind-body therapies in cardiac rehabilitation programs for psychological and emotional well-being[23]. Mindfulness meditation has demonstrated effectiveness in meta-analytic reviews in reducing risk for relapse in successfully treated depressed patients[15], and for coping with distress and disability across a broad range of chronic illnesses[24], thereby supporting its use as an adjunct secondary prevention strategy. Meditation has also demonstrated capacity to improve a range of health

outcomes in heart disease populations during hospitalisation and in the post-operative period, and there is strong evidence supporting the integration of mind-body therapies generally into cardiac rehabilitation programs[25-28]. However, the potential for meditation to be implemented in the outpatient cardiac rehabilitation setting, at a time when these adults desire additional support and are amenable to behaviour change is less clear. Implementing innovative strategies to reduce depression and anxiety in heart disease populations is particularly important at this time point, as it occurs in the context of their psychosocial and socioeconomic circumstances; and is conducted in a setting that is supported by conventional medicine, which is likely to encourage participants and improve adherence[29] to meditation as an adjunct cardiac risk reduction strategy.

3.4 Aim

To identify whether meditation reduces depression and anxiety symptoms in people living with heart disease

3.5 Methods

3.5.1 Study design

A systematic review of RCT and quasi-experimental studies conducted in accordance with the PRISMA Statement.

3.5.2 Eligibility criteria

The populations included in this review were people with modifiable risk factors for heart disease, coronary heart disease, valvular disease, or heart failure (hypertension, angina, atrial fibrillation, or breathlessness), and/or have undergone a surgical procedure (cardiac bypass surgery-coronary, aortic or valvular; pacemaker or defibrillator insertion or pericardial window) and/or an interventional procedure (coronary angiogram, percutaneous coronary intervention, ablation or other procedure); who participated in a clinic or outpatient disease management program after a recent inpatient hospitalisation. Interventions included meditation techniques that fit the operational definition, as previously described (refer

Chapter 1). Guided imagery has been included as it is an inherent component of some meditation practices that incorporate aspects of spirituality[30], and is in alignment with the goals of some meditation practices to achieve heightened awareness[31, 32]. Comparison groups were identified as conventional cardiac rehabilitation programs offered in mainstream outpatient healthcare settings or clinic-based programs or interventions. Outcomes were depression and/or anxiety.

Exclusion criteria were interventions involving yoga, qigong, predominately exercise-based interventions and/or multicomponent interventions that did not discretely analyse the meditation component; relaxation interventions that did not include a meditation component (such as biofeedback, autogenic training, and progressive muscle relaxation), and paediatric populations. Visualisation or mental rehearsal practices (for example, for peak performance) were excluded as they are a relaxation practice that is independent of meditation. Non-English articles and abstracts were excluded.

3.5.3 Information sources

This systematic review was completed in accordance with the PRISMA Statement. Databases searched included MEDLINE, AMED, CINAHL, Embase, PsycInfo and the Cochrane Database of Systematic Reviews between 1975 and 27th September 2017. Reference lists were also searched for additional articles.

3.5.4 Search Strategy

The keywords and search terms used in MEDLINE and CINAHL (Refer Appendix 4).

3.5.5 Study Selection and data collection process

Titles and abstracts were screened for eligibility and all duplicates were removed by the researcher. Uncertainties around articles for inclusion were resolved by consensus. The full-text article related to one abstract was obtained. Significant heterogeneity between intervention content, designs and outcomes precluded the use of meta-analysis and results were synthesised in a narrative review. To classify the elements of included interventions, each

line of text describing the interventions were coded by the researcher. Each element was listed in a table until all were included. Common elements were then identified and tallied across interventions.

3.5.6 Risk of Bias

A Cochrane Risk of Bias Table was used to report the risk of bias within and across studies[33].

3.6 Results

3.6.1 Study Selection

The initial search generated 780 articles, which after a process of review, elimination and hand searching, were reduced to nine articles for inclusion (Refer Figure 3.1).

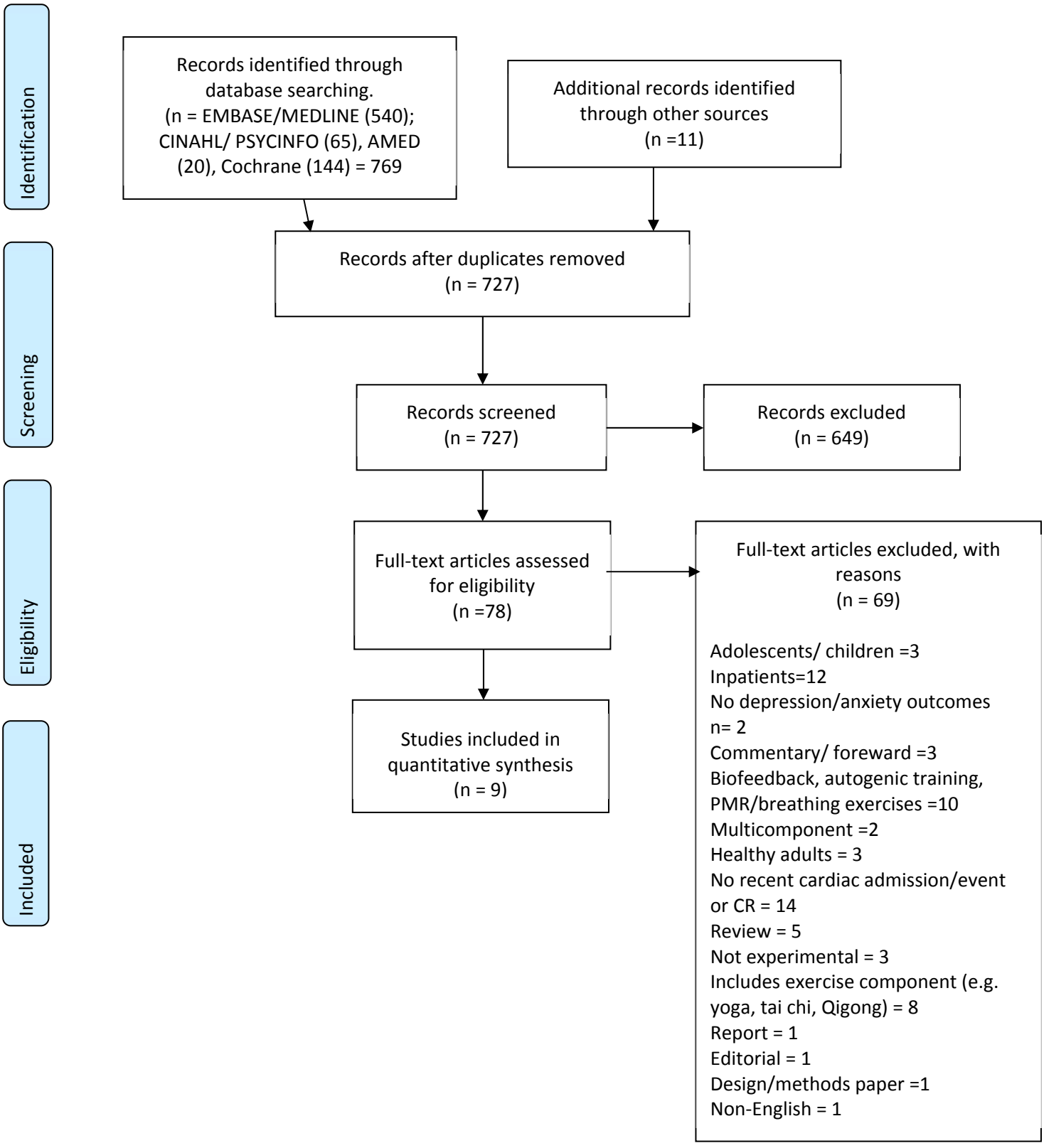

Figure 3.1: PRISMA 2009 Flow Diagram

3.6.2 Study Characteristics

Of these nine studies, four studies were phase II RCTs and five studies were pre and post-test designs. The majority of the 9 included studies were conducted in high-income countries (n=7) including the United States (n=6) and the Netherlands (n=1), whilst the remainder (n=2) were conducted in India (n=1) and Iran (n=1), which are considered low-income countries. The mean number of participants was 53 (SD ± 33), with a mean age of 60 years (SD ± 6). Just over two-thirds of the participants were male (67%), with one study including only men[34].

Concentrative meditation types were used in four studies, including guided imagery[35-37] and Transcendental Meditation[38]. Mindfulness-Based Stress Reduction or Mindfulness meditation were used in five studies[34, 39-42], with one of these studies categorising participants into mindfulness only or combined mindfulness and concentrative meditation techniques according to Spirituality Scale scores[41]. The mean frequency of group meditation interventions was 11 sessions (SD ± 7; n = 5 studies), and the mean duration of these sessions was 68 minutes (SD ± 27; n = 5 studies). Four studies did not utilise group meditation practices. The average amount of personal instruction received across studies was 3 sessions (SD ± 3; n = 5 studies), with a mean duration of 45 minutes (SD ± 27; n = 4 studies). Home practice was utilised at an average of 1.3 sessions (SD ± 0.8; n = 9 studies); with a mean duration of 23 minutes (SD ± 9; n = 6 studies). The mean intervention period across studies was 9.5 weeks (SD ± 4.8; n = 8 studies). In one study the intervention period was unclear [42] (refer Table 3.1). Time since the cardiac event ranged between 1 week and 12 months. Individual data around time since admission or cardiac event was not reported in any of the included studies.

3.6.3 Setting

Interventions took place across a number of settings, including a university medical centre (tertiary care)[40], an outpatient clinic[34], or in an outpatient cardiac rehabilitation centre[35, 36, 41, 42]. The setting was not clearly defined in three studies[37-39].

3.6.4 Intervention delivery

A variety of methods were used for intervention delivery that included an initial session delivered by the researcher[38], followed by self-administered home practice with an audiotape or CD[38, 40, 41]; investigator delivered (who was also a registered nurse)[35]; use of professional health educators [38], phone delivery of sessions by health care professionals and graduates of a mindfulness training program[40]; use of a certified clinical psychologist with 10 years' experience in mindfulness/Vipassana meditation and 5 years supervision experience[39]; a licensed psychotherapist[37]; a music therapist trained and supervised by the study investigator, who has extensive experience eliciting the relaxation response[36]; or was not specified[34, 42].

3.6.5 Control and/or Comparison Groups

Usual care was clearly defined in seven of the nine studies. Usual care was described as a conventional cardiac rehabilitation program in one study that included exercise and peer support[35], or was not specified[42]. Usual care also included one month follow-up with a cardiologist[34]. In one study, a waitlist control was used where participants were offered relaxation or meditation training at the end of the study[37]. Comparison groups included a 10 minute phone call regarding defibrillator concerns[40]; a self-help booklet based on group psycho-education sessions[39], maintenance of a regular diet as suggested by the medical team, 30 minutes of regular exercise, and a single[34], or weekly health education class for heart disease risk factor modification[38]. Two studies did not include a control or comparison group[36, 41].

Table 3.1: Summary Table of Meditation Interventions

Author	P	Age mean (SD)	M/ F (%)	O	Measure	N	Intervention	Comparison	Frequency Duration	IP	Before mean (SD):	After mean (SD), or differences between groups over time	Results
Paul-Labrador, Polk [38] **US**	Metabolic syndrome Stable CHD	67.4 (0.42)	84 (82)/ 19 (18)	D, TA	CES-D STAI	103 52 IG 51 CG	**Transcendental meditation** mental procedure; sitting comfortably with eyes closed. Calming of ordinary thinking processes, towards a psychophysiological state of restful alertness [43]. Introductory lecture, personal interview, group meetings, daily home practice.	Health education, daily home assignment	F: 2x daily HP; 2 x IL; PI x 1; Pin x 1; 3 x GM; then GM 2 x weekly/ 4 weeks; then GM weekly/ 12 weeks D: HP not stated; 90 mins IL; 10-15 min PI; 60-90 min Pin; 90 min GM.	16 weeks	CES-D IG: 6.8 (7.1) CES-D CG: 12.2 (10.7) STAI (T): IG: 14.4 (10.1) STAI (T): CG: 17.8 (11.7)	CES-D: IG 7.1 (6.9) CES-D: CG: 11.2 (10.0) STAI (T): IG: 12.8 (7.9) STAI (T): CG: 15.8 (11.4)	No significant reduction in depression (p= 0.053) or trait anxiety (p= 0.31) between groups at 16 weeks
Salmoirago-Blotcher, Crawford [40] **US**	ICD out-patients	64.6 (2.40)	31 (69)/ 14 (31)	A	HADS	46 24 IG 22 CG	Adapted **Mindfulness based stress reduction**: 1) **body scan** – attention to bodily sensations and cognitions; 2) training in **breathing awareness. sitting meditation** with **mindful** eating, drinking, attention to sounds, visual objects, thoughts & emotions); daily HP with CD	10 minute scripted weekly phone call addressing possible defibrillator concerns	F: weekly phone call; daily HP D: 30 mins phone call; 20 mins HP	8 weeks	HADS IG: 5.5 (4.1) HADS CG: 6.4 (4.1)	HADS: beta=-1.15 (95% CI: 0.046, -2.344)	No significant reduction in anxiety between groups (p=0.059) at 8 weeks

Parswani, Sharma [34] **India**	Male CHD out-patients	48.93 (2.35)	30 (100) male	A, D	HADS	30 15 IG 15 CG	**Mindfulness based stress reduction (body scan, sitting meditation, mindful** walking, eating, **3 minute breathing space** –resting awareness of inner experience, focus and **awareness of the breath**, body)	Treatment as usual with one health education session; maintain diet and 30 mins regular exercise	F: weekly GM; daily HP D: 60-90 mins GM; 30 mins HP	8 weeks	HADS A IG:7.87 (3.11) HADS A CG:7.67(3.65) HADS D IG: 6.13(2.03) HADS D CG: 4.93(2.49)	HADS A IG: 3.27 (1.27) HADS A CG: 7.53 (3.33) HADS D IG: 3.33 (1.59) HADS D CG: 5.47 (2.39) Between groups/ time: HADS-A: t=-4.63; HADS-D: t=-2.9	Reduced anxiety (p=0.001), depression (p=0.01) between groups at 8 weeks.
Nyklíček, Dijksman [39] **Netherlands**	PCI	55.85 (0.64)	88 (82) / 19 (18)	A, D	SAD-4	114 57 IG 57 CG	Adapted **Mindfulness Based Stress Reduction**, (mindfulness of bodily sensations, emotions and thoughts in an upright position, discussion of experiences during home practice), **psycho-education** (role of behaviour, bodily sensations, emotions, thoughts in psychological distress, role of mindfulness and non-judgemental acceptance of thoughts and emotions in stress reduction)	Self-help booklet based on group training	F: weekly GM; daily HP D: 90-120 mins GM; 30 mins HP	6 weeks	SAD-4: IG: 4.03 (0.49) SAD-4: CG: 3.01(0.49)	SAD-4: IG: 2.42 (0.41) SAD-4: CG: 2.80 (0.42) Between groups/ time t (102)= 3.46	Improved depression and anxiety between groups at 6 weeks ($p<0.01$); Younger adults more likely to have greater decreases in anxiety/ depression vs older adults (p=0.001).

Collins and Rice [35] **US**	CVD (MI and/or CABG)	59.17 (0.35)	39 (78)/ 11 (22)	SA, ,A	STAI	50 24 IG 26 CG	Progressive muscle relaxation and **guided imagery** (mental journey to a pleasant relaxing setting using the senses; think of the heart as healed and strong); daily home practice with audiotape	CR, monitored supervised exercise training, CHD risk factor modification education, peer support	F: Pin x 1 (initial study visit); daily HP D: Pin not stated; HP not stated	6 weeks	STAI (S) IG: 33.50 (8.41) STAI (S) CG: 32.78 (9.85)	STAI (S) IG: 32.05 (9.34) STAI (S) CG: 31.48 (8.59) Between groups/ time: STAI (S): t(42)= 0.21	No significant reduction in state anxiety (p>0.05), or anxiety between groups at 6 weeks (p>0.05).
Luskin, Reitz [37] **US**	NYHA class I-III heart failure	66 (9)	13 (39)/ 20 (61)	D, A	GDS STAI	33 14 IG 15 CG	**Guided imagery** (conscious shifting of attention from stressful experiences to an area around one's heart), **visualisation** of positive emotion or memory, holding of that feeling/emotion within the heart; **stress education** (discussion of secondary gain, practice of **deep breathing,** pausing before making a decision, review of stress management research	Waitlist. Invited to attend 1 day training at end of study.	F: 8 weekly GM; daily HP x 4 weeks; then 2x daily HP x 4 weeks D: 75 mins GM; 15 mins HP	10 weeks	GDS IG: 8.3 (6.0) GDS CG: 5.3 (6.3) STAI IG: 40.2 (8.0) STAI CG: 36.4 (9.9)	GDS IG: 5.5 (3.0) GDS CG: 6.0 (6.8) STAI: IG: 35.9 (7.1) STAI: CG:36.6 (11.1)	Reduced depression between groups at 10 weeks (p=0.02). No significant reduction in anxiety between groups at 10 weeks (p>0.05).

Mandel [36] **US**	CR patients	58	9 (60)/ 6 (40)	D, A	CES-D STAI	15	**Deep breathing, guided imagery** (comfortable place), **visualisation** for muscle relaxation, comforting word or phrase, positive affirmations	n/a	F: 1 x Pin; daily HP D: 60 mins Pin; 31.5 mins HP	4 months	STAI (S): 44.14 (14.35) STAI (T): 40.27 (11.79) CES-D: 18.33 (12.5)	Post Pin: STAI (S): 35.36 (12.06) 2 weeks: CES-D: 15.5 (12.31) STAI (T): 35.75 (11.95) 4 months: CES-D: 11.0 (10.42) STAI (T): 34.00 (9.97)	Within group differences: Improved state anxiety post Pin (p=0.002). No significant reductions in depression (p=0.67/0.07) or trait anxiety (p=0.31/0.44) at 2 weeks/ 4 months
Delaney, Barrere [41] **US**	CVD	64.4 (11.4)	15 (37)/ 26 (63)	D, A	CES-D STAI	41	**Mindfulness meditation,** present moment awareness, setting aside worrisome thoughts, **attention to breathing, guided visualisation** of a small circle of light from the head to the heart and chest area, recall a situation of feeling loved or loving, connecting to a higher power, sending and receiving of loving energy, **prayer/reflection**	n/a	F: Pin x 1; PI x 1 at 2 weeks; 3 x week HP D: 15 mins Pin; 12-60 min HP	1 month	CES-D: 19.49 (5.3) STAI (S): 24.03 (2.4)	CES-D: 18.75 (4.2) STAI (S): 24.90 (3.2)	Within group differences: No significant reductions in depression (p=0.33) or anxiety

							in a **perceived healing environment**						(p=0.19) at 1 month.
Delui, Yari [42] **Iran**	CVD and comorbid depression referred to CR	45-60 years not stated	27 (60)/ 18 (40)	D, A	BDI Zung Self Rating Anxiety Scale	45 15 IG 15 PMR 15 CG	**Mindfulness meditation** (details not stated); routine CR.	Jacobsen's PMR or no intervention CG	F: 10 sessions after CR; 3 x week HP D: 25 mins after CR; HP not stated	Not stated	BDI IG: 21.93±7.226 BDI: PMR: 21.60±7.491 BDI: CG: 23.27±6.984 Zung: IG: 36.87±6.323 Zung: PMR: 36.33±7.326 Zung: CG: 35.73±6.193	BDI IG v PMR: 7.60 (1.64) BDI IG v CG: 5.73 (1.64) Zung IG v PMR: 3.07 (1.95) Zung IG v CG: 3.13 (1.95)	Significantly reduced depression v PMR (p<0.001) and v CG (p=0.03) post intervention No significant reductions in anxiety vs PMR (p=0.27) or CG (0.25) post intervention

Key: P, Population; SD, Standard Deviation; *, Where reported; M, Male; F, Female; O, Outcome; N, Number; IP, Intervention period; US, United States; RCT, Randomised controlled trial; CHD, Coronary Heart Disease; D, Depression, TA, Trait Anxiety; CES-D, Centre for Epidemiological Studies Depression Scale; STAI, State Trait Anxiety Inventory; IG, Intervention Group; CG, Control Group; F, Frequency; HP, Home Practice; IL, Introductory Lecture; PI, Personal instruction; Pin, Personal interview; GM, Group Meeting; D, Duration; min, Minutes; STAI (T), Trait anxiety; ICD, Implantable Cardioverter Defibrillator; A, Anxiety; HADS, Hospital Anxiety and Depression Scale; v, Versus, HADS A, Hospital Anxiety and Depression Scale Anxiety Subscale; HADS-D, Hospital Anxiety and Depression Scale Depression Subscale; PCI, Percutaneous Coronary Intervention; SAD-4, Symptom Anxiety Depression Index- 4; CR, Cardiac Rehabilitation; CVD, Cardiovascular Disease, MI, Myocardial infarction, CABG, Coronary artery bypass graft; STAI (S), State anxiety; n/s, not significant; NYHA, New York Heart Association; GDS, Geriatric Depression Scale; n/a, not applicable; BDI, Beck Depression Inventory

3.6.6 Risk of Bias Assessment

All nine meditation studies have an inherently high risk of bias due to the inability to blind study participants and intervention delivery personnel (n=9). Apart from this unavoidable risk other identified reasons for bias included incomplete or no randomisation in quasi-experimental designs (n= 3)[36, 37, 41]; lack of allocation concealment procedures (n=3)[36, 37, 41]; blinding of outcome assessors for patient reported outcomes (n= 3)[35, 36, 41]; and/or incomplete outcome data for measures taken at greater than 6 weeks (n= 3)[34, 36, 38] (refer Table 3.2).

Table 3.2: Assessment of Risk of Bias

Author/Year	Selection Bias		Performance Bias	Detection Bias		Attrition Bias		Reporting Bias
	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessors pt. reported	Blinding of outcome: mortality	Incomplete outcome data short term outcomes 2-6 weeks	Incomplete outcome data>6 weeks long term	Selective reporting
Collins and Rice [35]	Low risk Prospective quasi experimental Random assignment within sites	Unclear risk No information provided	High risk Unable to blind participant or practitioner	High risk Individually instructed by investigator during initial study visit.	n/a	Low risk 5% IG; 4% CG	n/a	Low risk
Luskin, Reitz [37]	High risk "incomplete randomisation"	High risk Not considered	High risk Unable to blind participant or practitioner	Unclear risk Not reported	n/a	Low risk 12% overall attrition Equal attrition between groups (6%)	n/a	Low risk
Paul-Labrador, Polk [38]	Low risk Block randomisation via a computerised program'	Unclear risk No information provided	High risk Unable to blind participants or interventionists. Study personnel blinded	Low risk "…outcome data collected and analysed by personnel blinded to treatment status"	n/a	n/a	High risk 18% overall attrition 13% IG; 23% CG	Low risk
Mandel [36]	High risk Non-randomised design	High risk Not considered in study design	High risk No binding used	High risk No blinding used. Author did not interact with patients during the intervention.	n/a	n/a	High risk 42% attrition	Low risk
Delaney, Barrere [41]	High risk Quasi-experimental study. No randomisation	High risk Not considered in study design	High risk No blinding used	High risk No blinding used	n/a	Low risk 34.2% attrition. Attrition analysis: no significant differences between study completers and non-completers.	n/a	Low risk

Salmoirago-Blotcher, Crawford [40]	Low risk "…sequence of group assignments randomly permuted in blocks of several sizes"	Low risk "A programmer will generate random allocation sequence and upload table containing sequence of group assignments to an Access database".	High risk No blinding used	Low risk "… research coordinator administered study questionnaires, experienced instructors blinded to study outcomes conducted intervention"	n/a	n/a	Low risk 4% attrition from intervention group, retention rate 93%	Low risk
Parswani, Sharma [34]	Low risk 'Randomly assigned… using computer generated random tables'	Unclear risk No information provided	High risk; Unable to blind participants or interventionists; no information provided for study personnel	Unclear risk No information provided	n/a	n/a	High risk >20% attrition 20% IG; 33% CG at 3 month follow up	Low risk
Delui, Yari [42]	Unclear risk 'randomly selected using medical records at our centre'	Unclear risk No information provided	High risk Unable to blind participant or practitioner	Low risk Unclear if rehabilitation nurses BP blinded to group assignment. 'Post-test measures conducted by individual blinded to treatment condition'.	n/a	Unclear risk Data seems complete (n=45). Numbers eligible, recruited, dropped out not specified	n/a	Low risk
Nyklíček, Dijksman [39]	Unclear risk "randomised"	Unclear risk No information provided	High risk; Unable to blind participants or interventionists; no information provided for study personnel	Unclear risk No information provided	n/a	Low risk <20% attrition 12% IG; 14% CG Missing data imputed	n/a	Low risk
Total	4 low risk 2 unclear risk 3 high risk	1 low risk 5 unclear risk 3 high risk	9 high risk	3 low risk 3 unclear risk 3 high risk	9 n/a	4 low risk 1 unclear risk 4 n/a	3 high risk 1 low 5 n/a	9 low risk

3.6.7 Outcomes

Whilst none of these studies were adequately powered, significant improvements in depression and/or anxiety were demonstrated over half (5/9) of the identified phase II meditation studies. Populations with significant improvements in depression and/or anxiety included people with congestive heart failure (n=33), coronary heart disease or cardiovascular disease (n=85), metabolic syndrome with comorbid CHD (n= 103), CVD with comorbid depression (n=45), recipients of a percutaneous coronary intervention (n= 114), or male recipients of an automatic implantable cardioverter defibrillator (AICD) (n= 52). Significant interventions included guided imagery (2 studies), Mindfulness-Based Stress Reduction (2 studies), or Mindfulness meditation (1 study) (refer Table 3.1).

Depression

Four studies demonstrated statistically significant between-group differences in depression. A further three studies did not show improvements in depression after using meditation, and two studies did not assess depression outcomes. Three of the studies that generated significant between-group differences in depression utilised a mindfulness meditation approach such as Mindfulness Based Stress Reduction[34, 42], or an adapted version of Mindfulness Based Stress Reduction[39], whilst one other successful study used concentrative meditation techniques, including guided imagery[37].

Anxiety

The results for state anxiety were equivocal. One out of two studies evaluating meditation's effectiveness for state anxiety generated statistically significant within-group differences using guided imagery[36]. None of the two studies that utilised concentrative meditation approaches such as guided imagery[36] or Transcendental Meditation[38] were successful in demonstrating improvements within or between groups in trait anxiety. Two studies that generated statistically significant improvements in overall anxiety between groups both used either Mindfulness Based Stress Reduction[34] or an adapted version of Mindfulness Based Stress Reduction[39]. However, a further five

studies that utilised either an adapted version of Mindfulness Based Stress Reduction[40], mindfulness[41, 42] or guided imagery [35, 37] did not demonstrate improvements in overall anxiety within or between groups.

Elements of meditation interventions

The elements of meditation interventions that facilitate improvements in depression and/or anxiety outcomes are highlighted in Appendix 5. All included studies advised participants to adhere to daily home meditation practice. Three out of four studies that included focused attention to body parts or a 'body scan' generated significant results in depression, anxiety[34, 39] and state anxiety[36]. However, one of these studies did not produce significant results for trait anxiety[36]. Four out of five studies that utilised group meetings demonstrated statistically significant improvements in depression[34, 37, 39, 42] and/or anxiety[34, 39]. However, two of these studies did not generate significant improvements in anxiety[37, 42].

Mindfulness as a potential mediator of meditation efficacy for depression and anxiety symptoms

Interestingly, two studies that used adapted mindfulness meditation also generated statistically significant improvements in mindfulness[39, 40]. In one of these two studies, increases in mindfulness were found to mediate the improvements in depression in anxiety symptoms between the intervention and comparison group in adults <60 years[39].

3.7 Discussion

There were no phase III randomised controlled trials to determine the effectiveness of meditation for the secondary prevention of depression and anxiety for people who have recently experienced a cardiac event or hospitalisation. Based on the results of this review, there is evidence to suggest that meditation can improve depression and may improve state anxiety symptoms in adults living with heart disease. However, the current study suggests that the capacity for meditation to improve trait anxiety among people living with heart disease is limited. Whilst there is no definitive evidence, common elements of effective meditation interventions that may influence depression and/or state

anxiety outcomes include: focused attention to body parts or 'body scan', and group meetings (particularly among those who are depressed).

This review identified that 67% of participants were male, and there were no meditation studies specifically designed for women. These results are consistent with the AHA consensus statement, reflecting the underrepresentation of women with heart disease in clinical trials and reduced referral rates to outpatient secondary prevention programs[44]. This is significant given that women have higher rates of heart disease morbidity and mortality compared to men[45] and experience poorer outcomes after a cardiac event [46]. Collaborative group-based approaches such as meditation may also address the unique psychosocial support needs of women alongside conventional exercise-based programs[47].

Findings of this review are consistent with previous systematic reviews of meditation that have demonstrated small, consistent improvements in anxiety, stress and depression in clinical[14] and chronic illness populations[48]; vascular disease[49]; and quality of life in heart failure patients[50]. However, it is difficult to determine meditation efficacy given an unknown dose-response relationship, mechanism of effect and significant heterogeneity within and between study designs[41]. Measures of self-efficacy have also been recommended to determine the degree to which participants can adapt and integrate new relaxation strategies into their lifestyle and identify areas where further training is required[51].

One study found mindfulness to be a mechanism of change, which could indicate that mindfulness practices positively affect anxiety by improving cognitive flexibility[52]. Focusing on the breath, an element common to a variety of meditation practices, involves aspects of cognitive flexibility such as maintaining *attention* to the breath, *inhibiting* focus to other thoughts when the mind wanders and *switching* attention back to the breath[52]. Thus, focusing on the breath and the 'body scan', which again draws *attention* to the sensation of different body parts, is likely to assist in the development

of practices that enhance cognitive flexibility and are challenging skills for people with generalised anxiety disorder to develop[52].

Risk of bias in meditation studies is frequently high given the inability to blind the participant or practitioner[25]. There will always be an element of provider-participant interaction that contributes to a risk of bias, however, this should not overshadow positive findings of robust study designs and the potential for translation of findings into practice. One way around bias appraisal has been to implement a modified Jadad scale with a maximum score of 4 rather than 5, with no points assigned to information provided with regards to participant blinding[53]. Controlled trial designs may require minimising therapeutic interaction between participant and provider to accurately assess meditation efficacy, however, this may reduce ecological validity and thereby reduce the potential treatment effect[36]. Various factors, such as levels of anxiety, depression, stress, recent life events and personality[54], may also determine which elements of meditation (for example guided imagery vs mindfulness) might be most suitable in initiating meditation practice, which requires exploration in future qualitative or mixed methods designs.

A few studies have explored the effect of age as a covariate for meditation effects. One study determined that people living with heart disease who were younger (<60 years) benefited most from meditation[39]. Such differences in outcome measures could be a floor effect, that is, older people with cardiovascular disease are more likely to report higher baseline quality of life compared to younger adults, and lower levels of psychological distress[51]. Younger females, in particular, are likely to benefit from meditation as an adjunct secondary prevention strategy given increased openness to complementary therapies and higher baseline levels of psychological distress[51, 55, 56].

A floor effect was also identified in one study as a reason for non-significant within-group changes in depression post-intervention[41]. Baseline state anxiety in two studies[35, 41] was also lower than the suggested 39-40 STAI state subscale cut-off score for clinically significant symptoms[57]. Baseline mean scores in two other non-significant studies indicated mild trait anxiety on the STAI trait subscale[38],

and less than clinically significant anxiety on the HADS[40, 58] which may have contributed to non-significant results in these studies. The capacity of meditation interventions to capture changes in trait anxiety using the STAI may be limited given that the purpose of the trait subscale is to determine anxiety as a longstanding characteristic, and is less responsive to change[57]. Meditation interventions delivered over longer periods of time, with longer follow-up periods may be required to capture changes in trait anxiety, such as heightened sensory awareness and shifts in the relationship between thoughts, feelings, and sense of self that are often seen in experienced meditators[59].

3.7.1 Implications for practice

Utilising a novel approach such as meditation addresses a clearly identified need to reframe cardiac rehabilitation service provision from a conventional prescriptive approach to an integrated disease management model[60]. Small group meditation instruction also provides an opportunity for peer support and trust building, provides a safe environment for relaxation and promotes positive interaction between care provider and participant, which is vital to maintain health behaviour change[61].

Meditation also has the potential to reduce health care utilisation and costs[62], however formal cost-benefit analyses are required for confirmation, and to ensure effective resource utilisation[63]. It is also important to consider people living with heart diseases' preferences and determine the specific demographic and clinical characteristics of cardiac rehabilitation participants that are most likely to adhere to and benefit from a meditation intervention.

3.7.2 Implications for research

Future well designed, methodologically rigorous studies with sufficient detail around intervention content and setting are required to allow for replication, and reporting of these studies should adhere to the CONSORT statement. Consensus processes are required to develop a standardised taxonomy for the reporting of meditation intervention elements to better identify which elements are most effective in reducing cardiovascular risk[64]. The inclusion of data such as time since

admission or cardiac event and stratification of depression and anxiety rates by gender and type of cardiac procedure is required in the reporting of future studies to shed light on which cardiac populations would most benefit from a meditation intervention. Gender differences in receptivity to meditation and its effectiveness also needs to be considered in future research. Multicomponent interventions need to discretely analyse the meditation component of their intervention. Research designs targeted to adults living with heart disease with a minimum of mild depression or anxiety symptoms may lead to better outcomes attributable to meditation interventions. Strategies to control for secondary relaxation effects associated with meditation and practitioner interaction effects[52], such as a relaxation comparison group, are required in future phase III meditation intervention designs.

3.7.3 Limitations

This review is limited by the small number of methodologically strong studies, and lack of availability of any phase III RCT's that were solely evaluating meditation effects. Some of the included meditation intervention descriptions were brief, limiting conclusions drawn around the optimal elements of meditation interventions that may improve outcomes, as well as replication and generalisability of the findings. The authors acknowledge the potential for confounding factors to affect the results of individual studies included in the review.

3.8 Conclusion

This chapter demonstrated the feasibility of meditation for the reduction of depressive symptoms in people living with heart disease who attend outpatient cardiac rehabilitation programs. However, meditation may not assist with trait anxiety symptoms in adults living with heart disease. Key findings indicate that a phase III trial is required to better understand the effectiveness of meditation in addressing the psychological health support needs of people living with heart disease, and to support the integration of meditation into existing cardiac rehabilitation programs. Chapter 4 will detail the thesis objectives, mixed methods design of the MENTOR Project and the conceptual frameworks underpinning this thesis.

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Chapter 4 Design, mixed methods approach and conceptual framework of the MENTOR Project

4.1 Introduction

The longitudinal cohort study presented in Chapter 2 confirmed that the prevalence of moderate depression and anxiety symptoms in people living with heart disease in one local health district in New South Wales (NSW), is similar to that reported in the international literature[1-5]. The systematic review described in Chapter 3 established that the highest level of evidence[6] (Level II) for the use of meditation for people living with heart disease had been generated by nine feasibility and acceptability studies[7]. The data generated by these pilot studies suggests that while meditation may help improve depressive symptoms in a heart disease population, it does not necessarily assist with their trait anxiety symptoms. This systematic review also identified the key elements that could be used to guide the integration of future meditation interventions for this population[7]. Despite the paucity of high level evidence, in 2017, the American Heart Association recommended that meditation offered to people living with heart disease who are depressed and/or anxious as an adjunct primary and secondary heart disease prevention strategy. These same guidelines stressed the importance of future phase III trials[8] for building the evidence for meditation as a strategy for helping to reduce depression and anxiety for people living with heart disease.

Given this recommendation, the Integrating MEditatioN inTO heaRt disease care (MENTOR) Project set out to better understand if a meditation intervention is feasible and acceptable to people living with heart disease, as well as to clinicians and health service managers in the Australian context.

This chapter outlines the conceptual framework and methods for the MENTOR Project and provides a rationale for the choice of a mixed methods design. It also details how the Project's four studies were integrated to generate a series of recommendations for the integration of meditation into Australian cardiac rehabilitation programs.

4.2 Thesis Objectives

The MENTOR Project objectives were to:

I. Understand the burden of moderate depression and anxiety symptoms in people participating in a NSW cardiac rehabilitation program and if these symptoms affect cardiac rehabilitation adherence;
II. Identify whether meditation reduces depression and anxiety symptoms in people living with heart disease;
III. Determine the feasibility and acceptability of integrating a meditation intervention into an existing NSW cardiac rehabilitation program for the reduction of depression and anxiety symptoms in people living with heart disease;
IV. Explore health professionals' perceptions of integrating meditation into secondary prevention heart disease care; and
V. Generate recommendations regarding the integration of meditation into existing NSW cardiac rehabilitation programs.

4.3 Design

The MENTOR Project uses an explanatory sequential mixed methods design to: understand the feasibility and acceptability of integrating meditation into established cardiac rehabilitation programs; and its capacity to improve psychological health in people living with heart disease. This doctoral project was conducted across three phases, in four discrete, yet interrelated studies, as depicted in Figure 4.1.

4.3.1 MENTOR Project Phase 1

As described in Figure 4.1, phase 1 of the MENTOR Project includes two studies:

- Study 1: A longitudinal cohort study of people entering outpatient cardiac rehabilitation over an eleven year period (2006-2017) (Reported in Chapter 2); and
- Study 2: A systematic review of meditation interventions designed to reduce depression and anxiety symptoms (Reported in Chapter 3).

The methods for Studies 1 and 2 were presented in Chapters 2 and 3, respectively, while the methods for Studies 3 and 4 are described in this chapter.

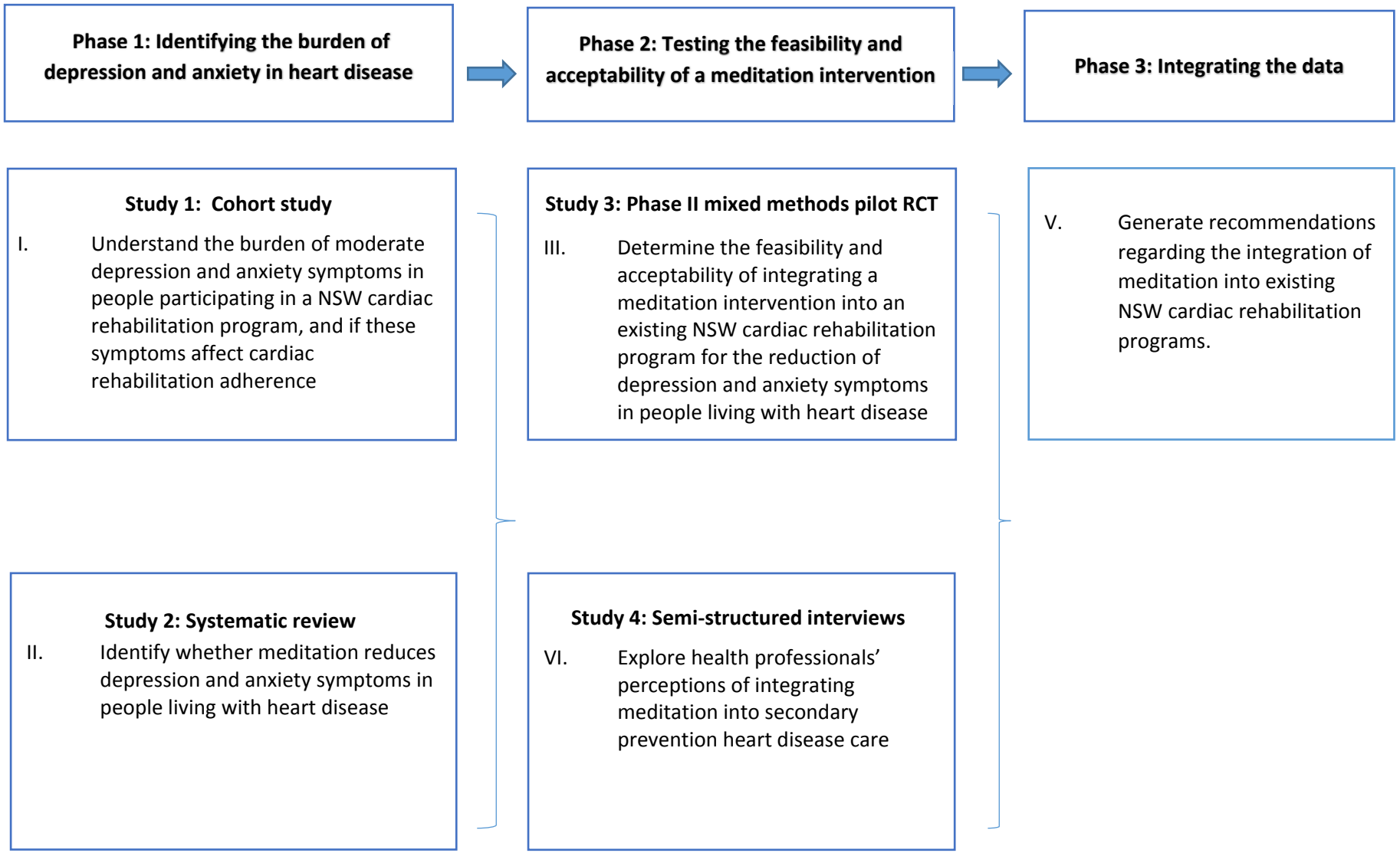

Figure 4.1: The MENTOR Project's phases and study designs

4.4 Setting and participants

The specific settings, participants and sites involved are detailed in the MENTOR Project are described below.

4.4.1 Setting

The setting for the MENTOR Project was a cardiology service of one local health district in metropolitan Sydney, New South Wales, Australia. This cardiac service included two inpatient wards and the cardiac rehabilitation outpatient department. This local health district reflects the multicultural landscape of Australia, with 1.5% of residents identifying as Aboriginal, and nearly half (45%) speaking a language other than English at home[9, 10]. This local health district is also known to have a level of socio-economic disadvantage that is higher than the national average, and areas of extreme disadvantage[9, 10].

4.4.2 Participants

The participants in this Project included two distinct populations, namely:

- adults (≥18 years) who were attending an outpatient cardiac rehabilitation program following a cardiac event (Studies 1 and 3); and
- health professionals including nursing, medical and allied health professionals working in heart disease clinical settings and managers of relevant national or international health organisations who had publicly listed profiles (Study 4).

4.5 Application of the Medical Research Council Framework to the MENTOR Project

The Medical Research Council Framework was used to plan the MENTOR Project's program of research[11, 12] to inform the development of a complex intervention (integrating meditation into cardiac rehabilitation), using best available evidence and relevant theory[12]. The MENTOR Project therefore complied with Medical Research Council Framework recommendations for a phased approach to the testing of complex interventions in pilot studies. A phased approach was required to address

uncertainties in research design prior to conducting exploratory and definitive evaluations in a phase III trial[12].

The Medical Research Council Framework for complex interventions assisted with planning and operationalisation of the four included studies of the MENTOR Project with respect to identifying existing evidence, modelling processes and outcomes (Phase I), and assessing feasibility in a pilot study (Phase II), as detailed below.

Phase I

Identifying existing evidence: A systematic review of meditation for people living with heart disease was undertaken to determine its feasibility in reducing their depression and anxiety symptoms, and to identify the common elements of meditation interventions that may facilitate improvements in depression and anxiety outcomes in this population[7] (Study 2) This systematic review informed the design of the phase II RCT (Study 3).

Modelling processes and outcomes: A retrospective longitudinal cohort study was undertaken to identify gaps in the delivery of heart disease secondary preventative care, with specific focus on the management of depression and anxiety symptoms (Study 1). A descriptive qualitative study involving health professionals was undertaken to understand the barriers and facilitators that affect the integration of meditation into cardiac rehabilitation programs (Study 4).

Phase II

Assessing feasibility: A mixed methods parallel group pilot randomised controlled trial was undertaken to assess the feasibility and acceptability of a meditation intervention designed to reduce depression and anxiety symptoms in people living with heart disease (Study 3). A descriptive qualitative sub-study involving the intervention participants sought to understand their intervention experiences. Meta-inferences of the quantitative and qualitative data were generated to assess the feasibility of integrating meditation into a cardiac rehabilitation setting and to inform the design of a future definitive phase III trial.

4.6 The MENTOR Project Phase 2: Testing the feasibility and acceptability of the intervention

A prospective mixed methods parallel group phase II RCT was undertaken to determine the feasibility and acceptability of a meditation intervention to reduce depression and anxiety symptoms in people attending cardiac rehabilitation. This study used a mixed methods explanatory sequential core design whereby qualitative data was embedded within the quantitative component[13]. An explanatory sequential core design was necessary to generate contextual data regarding the feasibility of meditation as an intervention to inform the design of a larger phase III trial[13]. Using a mixed methods explanatory sequential core design strengthened the ability of the phase II RCT to: i) check adherence to the intervention procedures and factors that may explain variance in adherence, as well as other moderating factors [14]; ii) obtain participant feedback to better understand the outcomes and inform future interventions[13]; and iii) counteract publication biases against studies that do not generate statistical significance and are deemed ineffective by clarifying negative results and informing future research[15].

4.6.1 Phase II pilot randomised controlled trial with post-intervention participant interviews (Study 3)

The pilot RCT was designed to test the feasibility and acceptability of the proposed methods and procedures to be used in an adequately powered Phase III RCT[16]. A pilot II RCT was also required to obtain the necessary preliminary data to power a Phase III RCT and to support any future funding applications[16]. Additional factors that influenced the use of a pilot RCT design were the constraints of completing a RCT within the researcher's doctoral project timeframe and the funding required to undertake a Phase III trial.

The disadvantages of a pilot RCT design are its limitations in determining the effectiveness of meditation as an adjunct therapy to enhance depression and anxiety symptom self-management capabilities.

Eligibility Criteria

Participants included adults aged 18 years and older who have had a recent admission to hospital with a cardiac condition, or who have a cardiac diagnosis including acute coronary syndrome or heart failure, who were referred to cardiac rehabilitation (NYHA classification I or II). These people additionally:

- Had at minimum mild to severe depression (DASS-21 score ≥5), and/or anxiety (DASS-21 score ≥4). Participants receiving psychological support and/or medication for their depression and/or anxiety were eligible for inclusion.
- Willing to give informed consent, and participate in a 6 week group meditation program, adhere to daily home meditation practice using provided resources (CD) and be followed up for 3 months;
- Level of English literacy to allow completion of study instruments with minimal assistance.

Patients with cognitive impairment, unstable angina, psychotic illness, congenital heart disease or were otherwise considered unsuitable for exercise based cardiac rehabilitation were excluded.

Modification to inclusion criteria

Early in the pilot trial, it was identified that the current staffing of cardiac rehabilitation and periods of staff shortages produced a limitation in the ability to assess risk factor modification patients. A decision was made by members of the research team in collaboration with cardiac rehabilitation staff to only recruit patients considered most in need (high priority) of completing the cardiac rehabilitation programs. These high priority patients included: people experiencing an acute or chronic cardiac event, including STEMI, NSTEMI, insertion of defibrillator or pacemaker; undergoing a PCI; diagnosed with coronary artery disease; and post coronary artery bypass patients. Patients considered low priority, with an admitting diagnosis of syncope, atrial fibrillation, increased risk factors such as uncontrolled hypertension and co-morbid diabetes were excluded. Heart failure patients were accepted upon referral from the hospital's heart failure service to cardiac rehabilitation, and were not approached directly on the inpatient wards.

Participant identification and consent

The researcher generated inpatient lists from the participating sites two cardiology wards with the assistance of cardiac rehabilitation staff or administrative staff from the cardiology wards. Participants entering cardiac rehabilitation programs were then approached at pre-assessment to determine interest in participating in a meditation intervention or were recommended to the researcher by cardiac rehabilitation nursing staff. Participants were approached by the researcher in-person and given brief information about the meditation intervention. Interested participants were given full details of the study, and formal written consent was obtained from the participant.

Voluntary participation was emphasised, including participants' freedom to withdraw at any time. Participants' appointments or hospital procedures were prioritised, in addition to consultations with health professionals and meal times. Whilst relatives may have been present in some instances, respect for privacy was maintained and a second time for approach was always offered to patients in this instance. Recruitment always occurred within cardiac rehabilitation and cardiology wards' daytime hours (7am and 5pm).

Intervention

This intervention was informed by Study 2 of The MENTOR Project, a systematic review of RCTs of meditation delivered in the outpatient (Phase 2) cardiac rehabilitation setting[7], the researcher's understanding of a variety of meditation practices and informal consultation with meditation experts. The researcher also had prior knowledge of the demographics of the patient population and setting, as this hospital is situated within the same local health district as the two hospitals included in Study 1.

This meditation intervention consisted of 6 weekly group sessions of 16 minutes in duration in addition to conventional cardiac rehabilitation.

Intervention content: Prior to the first meditation, a short explanation of the steps involved in the meditation was explained to participants, and participants had an opportunity to share what brought them to the group and what they hoped to gain by using meditation. Participants were reassured that initially, chatter that occurs within the mind can be difficult to 'quieten', and that this is part of the

process, but would become easier over time as practice continued and the group progressed. Before each subsequent meditation session, the researcher facilitated a short 1-2 minute per person 'check in' to identify any issues or challenges participants are having with the practice or during the week.

An audio CD was created by the researcher that combined her own voice and a 16 minute breathing meditation by called Seashells by Deuter[17]. This meditation was used to guide participants through the 'concentrative' components of the intervention, including a guided deep breathing practice and a 'body scan' that sequentially drew focused attention to the relaxation of major muscle groups. This was followed by an open focus that included peaceful ambient music designed to calm the mind and facilitate a deeper meditative state or altered state of consciousness[17]. At the end of the meditation, participants sat in silence with the researcher for 2 to 3 minutes before being gradually guided back to normal awareness. In addition to in-person groups, participants were asked to practice meditation at home daily, excluding the day of the group meditation session.

Delivery personnel: Group meditation sessions were facilitated by the researcher, a registered nurse with over 14 years' experience in meditation practice, including completion of a three day meditation retreat and an 8 week Mindfulness Based Stress Reduction Course, and 12 years of fortnightly participation in a private meditation group.

Method of communication, intensity and complexity: The intervention was comprised of six face-to-face, weekly meditation groups that lasted 16 minutes, with 3 additional minutes of introductory and concluding instruction. Participants were given a copy of the intervention audio on CD, USB stick, or via online link. Participants not using the Youtube link for home practice were given a weekly log sheet to record frequency and duration of meditation sessions for each day of the week (refer Appendix 6). The Youtube user analytics were recorded automatically each time the participant accessed the link online.

Home practice: Daily home practice meditation practice consisted of digital audio (USB, CD, Youtube link) that was identical to the content and time used in the weekly group meditation sessions,

including an introduction and conclusion to each session. The conclusion brought participants back to normal awareness and was recorded in the researcher's voice. Participants were asked to complete one home practice session daily on the days they were not attending the face-to-face group session.

Environment: Face-to-face group sessions were held in a private room in close proximity to the participating hospital's cardiac gym. In keeping with usual meditation practice, the lights were dimmed, doors closed, blinds were drawn shut, and a 'do not disturb' sign was placed on the door to minimise interference. Participants were seated on couches or padded chairs. Home practice was advised to occur in a quiet space, such as the bedroom or outdoors in a space that was uninterrupted and could be made comfortable with a chair, pillows or a bed.

Usual care

Participants allocated to the control group attended the six week/12 session outpatient cardiac rehabilitation program. These participants were also offered a meditation CD or USB for home practice at the end of the trial period. There were no alterations to cardiologist or other outpatient follow-up appointments or medications unless advised by the relevant health professional. There were no restrictions imposed on use of other complementary and alternative therapies. Participants were followed-up at 6 weeks.

Measurements

Study measures included:

Baseline interview

Clinical and socio-demographic data included New York Heart Association (NYHA)[18] classification, clinical history, risk factor profile, medication use, age, marital status, country of birth, living arrangements, number of children, education status, work status, health care utilisation (general practitioner visits and hospitalisation), caregiver status and participation in any current meditation, spiritual practices (including church attendance) or other complementary therapies.

Charlson Comorbidity Index[19] was used to calculate the burden of co-morbidity over a period of one year based on the presence of a range of 22 co-morbid conditions. Each condition is assigned a weighted score of 1, 2, 3 or 6 in accordance with prognosis. Co-morbidity burden is calculated based the number of conditions and the impact of prognosis[20]. The Charlson Co-morbidity Index has been used widely in cardiovascular disease[21, 22] and has been validated in acute coronary syndromes[23] and ischaemic stroke populations[24].

The *Social Readjustment Rating Scale (SRRS)* is a 43-item scale used to measure additional psycho-social factors found to increase risk for anxiety, depression, stress and heart disease[25]. The SSRS included yes/no dichotomous answers to questions ascertaining the presence of stressful life events in the past 12 months, and has been validated in adolescents[26], male psychiatric patients[27] and healthy adults[25, 27, 28]. The impact of psychosocial stressors as described in this scale have yet to be applied to cardiac populations. New weights were assigned to the SRRS items in line with Scully, Tosi [25] revisions. The Holmes and Rahe [29] prediction model asserts that a score ≤150 points indicates a relatively low amount of life change and low susceptibility to stress-induced health breakdown, defined as the onset of illness or disease due to the onset of 'psychophysiological reactions'[29, p. 215]. A score of 150-300 points indicates a 50% chance of a major health breakdown in the next two years; and a score >300 points increases the risk of a health breakdown to approximately 80%[29].

Depression, Anxiety, Stress Scale (DASS-21) is a set of three self-report scales each with seven items designed to measure the negative emotional states of depression, anxiety and stress. The depression sub-scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest/involvement, anhedonia, and inertia[30]. The anxiety sub-scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect. The stress sub-scale is sensitive to levels of chronic non-specific arousal. It assesses difficulty relaxing, nervous arousal, and being easily upset/agitated, irritable/over-reactive and impatient. All scales of the DASS have been shown to have high internal consistency and to yield meaningful discriminations in a variety

of settings, including the cardiac rehabilitation setting[31]. The DASS-21 has also been validated in chronic obstructive pulmonary disease[32], older adults with pain[33] and adolescent mental health populations[34].

Hospital Anxiety and Depression Scale (HADS): contains two sub-scales (14 items) that were used to measure depression and anxiety, as well as an overall combined score. Higher scores indicated greater psychological morbidity[35]. A cut-off point of 8 was used to indicate clinically significant morbidity for the depression and anxiety sub-scales[36]. HADS has good internal consistency in previous studies of cardiac, medically ill populations and distressed patients [37], and was determined to be appropriate for patient reported outcomes and screening in cardiac rehabilitation populations [38]. The HADS was used in addition to the DASS-21 due to its increased sensitivity to changes in depression and anxiety. Some of the DASS-21 items relating to breathlessness and palpitations could occur as a result of a recent heart event and may be unrelated to emotion[39]. However, the DASS-21 was used in our profiling study (Study 1) and its use here allowed for comparison of the baseline data for RCT participants to the cardiac rehabilitation cohort over 11 years. This will allow for assessment of generalisability of the findings of the intervention to the cardiac rehabilitation population.

Mindfulness Self-Efficacy Scale Revised (MSES-R): assessed the change in levels of perceived efficacy before, during and after meditation[40]. Whilst this intervention was not strictly mindfulness meditation, elements of this modified meditation, such as focusing on the breath, and relaxation of muscle groups through focused attention to body parts was in alignment with mindfulness practices. This instrument was therefore suitable for use for this intervention in this population. The MSES-R is a 22 item self-report questionnaire containing 6 subscales of self-efficacy: emotional regulation (involuntary or subconscious emotional response), equanimity (normalising difficulties and preventing reactivity), social skills (social ability in terms of broader social interaction), distress tolerance (inhibiting avoidance of experiential discomfort), taking responsibility (normalising difficulty and preventing reactivity), and interpersonal effectiveness (ability to connect with others in the intimate domain of

relationships)[40]. It has high internal consistency (Chronbach's alpha = 0.86), and good test-re-test reliability (r = 0.88). The MSES-R has a good inverse relationship with the DASS-21, has good discriminant validity and it discriminates well scorers who report having a mental illness from those who do not[40].

Health status: The first question of the 36 Item Short Form Survey 'in general would you say your health is excellent, very good, good fair or poor' was used to determine health status[41]. This question is a single item with a 5 point Likert scale that assess the extent to which participants agreed or disagreed that their overall health status had changed over time, with higher scores indicating better health[41]. It has been used widely used in cardiovascular[42-44], and in community populations[45, 46].

Home practice: Home practice of meditation was tracked using Google analytics attached to a private Youtube account. Each participant was assigned a separate Youtube link to the meditation audio. This Youtube link was an exact replication of the audio CD given to participants for home practice who did not have online access or had preferences for CD use. Data collected were frequency and duration of meditation sessions in minutes. Log sheets collected for participants not using the Youtube link included the date, and a yes/no column for use of the meditation home practice CD. A timeline for the collection of study measures is detailed in Figure 4.2.

Study measures	Baseline	6 weeks
Socio-demographic questionnaire	***X***	
Charlson Comorbidity Index	***X***	
SRRS	***X***	
DASS-21	***X***	***X***
MSES-R	***X***	***X***
HADS	***X***	***X***
GQOL	***X***	***X***
Health status	***X***	***X***
Google analytics (home practice)		***X***

Figure 4.2: Time-points for collection of study measures

4.6.2 Data collection

Prior to data collection the trial was registered on the Australia and New Zealand Clinical Trial Registry[47]. Medical records were accessed via a hospital online platform which was password-protected and accessible by hospital staff only. Therefore, data collection from medical records only occurred in the presence of a hospital employee. Paper records of patient medical history, personal details, date of entry into cardiac rehabilitation and number of cardiac rehabilitation sessions attended were obtained on-site from discharge summaries and an online review of medical records.

Baseline questionnaire data was collected from patients on entry into cardiac rehabilitation programs at pre-assessment if the patient was to commence cardiac rehabilitation the following day (or Monday for patients recruited on Friday). If there was more than 24 hours to cardiac rehabilitation program commencement, baseline measures were completed by a researcher on the morning of the first cardiac rehabilitation session. Volunteers and cardiac rehabilitation staff were informed of the need for the researcher to collect data prior to the commencement of exercise based cardiac rehabilitation. A sign was placed on patient folders informing staff to refer the patient to the researcher prior to commencing exercise.

To minimise potential response bias, participants were given the questionnaires and the researcher was present only to answer questions as needed to ensure that participants understood the questions and meaning of certain words. However, participants had the option of having the questions read out to them by the researcher if this was their preferred option. This was considered important for participants with English as a second language who had sufficient English communication skills, and for people who may have had lower levels of literacy. In these instances, the questions were read by the researcher to the participant who then selected the appropriate response without prompting.

Participants who were not using the online Youtube link were asked to complete a log sheet of the number of home meditation sessions completed, including date, duration and location of their meditation practice. The log sheets were collected by the researcher on a weekly basis at the group

sessions (refer Figure 4.3). If participants chose to exit the intervention after commencement, their de-identified baseline data were kept by the researcher for data analysis.

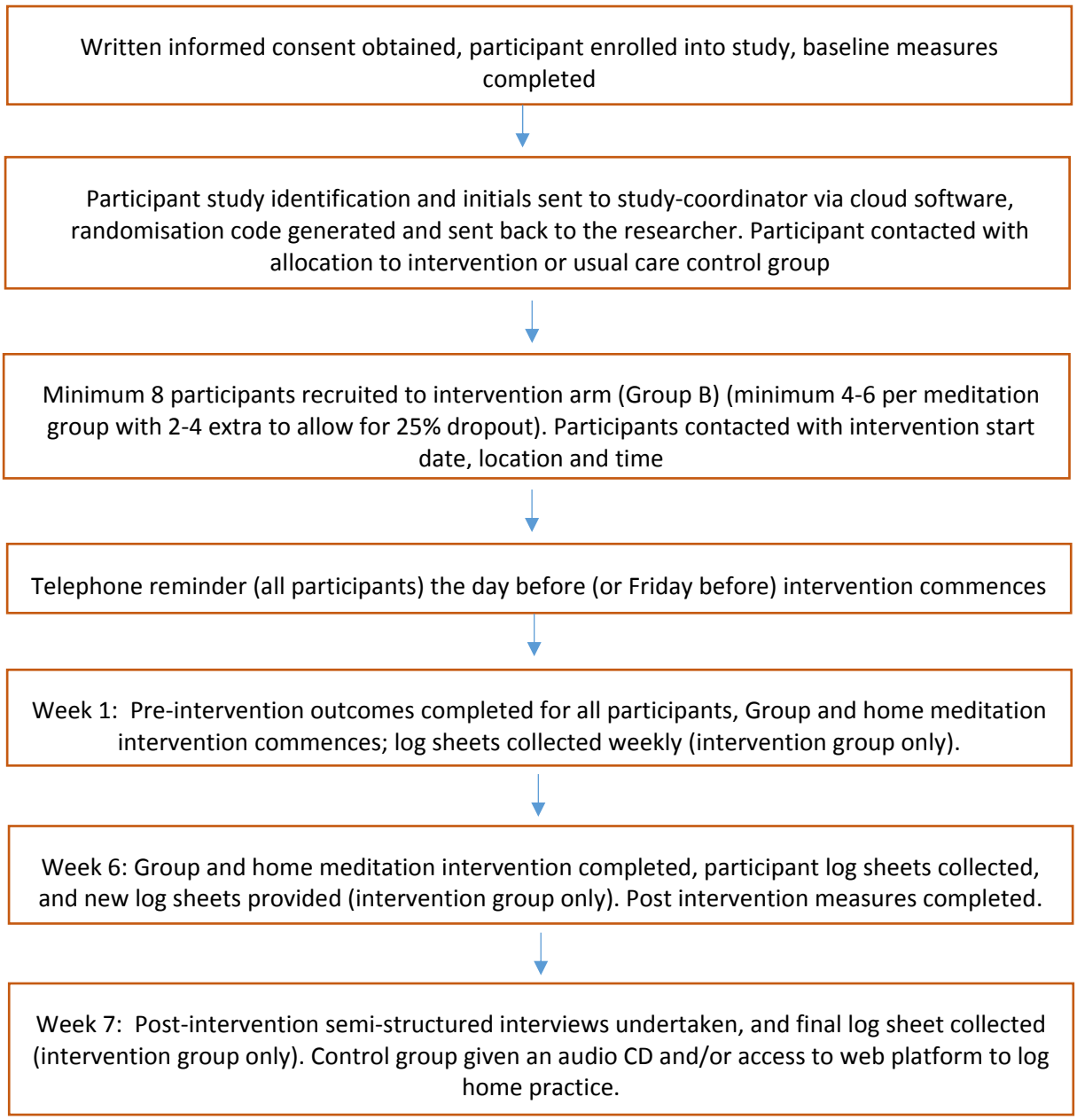

Figure 4.3: Participation flowchart

4.6.3 Data analysis

Data were analysed using descriptive and inferential statistics. All analyses were based on intention to treat. Independent t-tests were used for continuous data and Chi Squared tests were used for categorical outcomes in univariate analyses. Scores derived from psychometric measures for depression, anxiety and stress, mindfulness self-efficacy and social readjustment were all measured on continuous scales. Non-parametric tests, such as the Mann Whitney U test, was applied for comparing means in non-normally distributed variables. Data analysis was completed after consultation with a

biostatistician from the University of Technology Sydney, who was blinded to treatment allocation and had no part in the implementation of the intervention or endpoint assessment.

4.6.4 Semi-structured interviews with cardiac rehabilitation participants and health professionals (Studies 3 and 4)

Studies 3 and 4 included descriptive qualitative components to generate contextual knowledge to inform the feasibility and acceptability of meditation as an adjunct strategy for people living with heart disease. These data were collected from the perspectives of the participants in the phase II RCT as well as from health professionals across the cardiac and cardiac rehabilitation sectors. Semi-structured interviews were undertaken to understand i) people living with heart diseases' perspectives of meditation as an adjunct strategy for the reduction of depression and anxiety symptoms (Study 3); ii) health professionals' perspectives of the pragmatic design and delivery considerations involved in meditation's integration (collected in Study 4 and reported in Study 3); and iii) health professional perspectives of the barriers and facilitators to integrating meditation in heart disease clinical settings (Study 4).

4.6.5 Sampling procedures and participant recruitment

Patient recruitment: qualitative data from post intervention semi-structured interviews were embedded within the phase II RCT design, and a convenience sample of participants who had completed 6 weeks of a meditation intervention was recruited[48].

Health professional recruitment: In Study 4, the largest qualitative component of the MENTOR project, participants were recruited using *purposive* and *snowball sampling*. Purposive sampling allowed the researcher to intentionally select participants with experience with the key concepts being explored[49]. Snowball sampling refers to locating an initial source then utilising the networks of the individual to recruit additional participants in a multistage process[50]. The respondents then recruit others themselves which is comparable to a snowball rolling down a hill[51]. Snowball sampling was considered the most appropriate form of convenience sampling to obtain the necessary number and diversity of participants in a timely manner and at minimal cost[50]. Whilst non-probability sampling is considered to

be the gold standard for recruiting participants who are likely to be representative of the population of the sample as a whole, snowball sampling also had the distinct advantage of enabling access to time-poor high level health professionals who the researcher may not otherwise had access to[50]. The disadvantage, or potential bias of undertaking a snowball recruiting strategy could be an overrepresentation of participants of similar characteristics[50]. To counter this, a list of all participants screened and recruited was created to enable visual representation of the sample, gender, age range and professional roles (refer Appendix 7). This was viewed by the researcher and a member of the supervision team to ensure that a diversity of participants were included. The recruitment process continued until it was deemed by the supervision team that a diverse sample with a balance of participants from all levels of cardiovascular health were included.

The project adhered to Curtis, Gesler [52] sampling strategy guidelines, as summarised below:

i) *The sampling strategy was directly related to the WHO Innovative Care for Chronic Conditions Framework and research questions:* Health professionals with roles at the clinical, health organisational and health systems levels of health care with the leadership and clinical expertise to influence organisational change were included for their capacity to identify organisational barriers and facilitators to meditation's integration in heart disease settings.

ii) *The sample should be likely to generate rich contextual data on the barriers and facilitators to meditation implementation in clinical contexts:* Health professionals and academics with nursing, medical and allied health backgrounds with extensive experience in their area of specialisation were recruited to provide adequate depth and insight to best answer the research questions specific to Study 4. Efforts were made to invite and include health professionals at all levels of cardiovascular health service delivery to ensure that information on all aspects of the research question were generated, including negative cases to ensure validity[53].

iii) *The sample enables clear inferences (or enables meta-synthesis) to be drawn from the data:* During the interview process, the researcher's understanding of participants' meanings and

experiences were fed-back to participants to ensure clarity and accurate interpretation. Qualitative data analysis was an iterative process with the supervision team. The first three transcripts were viewed by the supervision team to ensure that the researchers' interview technique was sound, and that the findings were data driven.

iv) *The sampling strategy must be ethical:* The sampling strategy included processes for obtaining consent and ensured that participants understood that there were no implications for not participating or withdrawing from the research. No incentives were offered to encourage participation. Obtaining data from health professionals about meditation was not considered to include information of a personal nature that could potentially cause distress.

v) *Feasibility of the sampling plan is ensured:* The feasibility of the researcher in conducting health professional interviews was considered. The researcher did not have previous experience in conducting qualitative research, however, she had previous experience in group facilitation, and well developed empathic communication skills that ensured sensitivity to nuances that were highlighted by participants during the course of the interviews. In Study 4, accessing publicly listed e-mails of heart disease health professionals through relevant cardiovascular conference websites, relevant health organisations and the NSW/ ACT Cardiac Rehabilitation [54] directory ensured accessibility to relevant health professionals and recruitment feasibility [50]. This included an online search of e-mails for keynote speakers at the 2017 Australian Cardiac Rehabilitation Association Conference, Perth, the 2017 Heart Foundation Women's Health Forum, Sydney and the 2017 Cardiac Rehabilitation Association Conference (CRA). Recommendations for other health professionals within health organisations were obtained during the snowball sampling process, and a publicly listed e-mail search was undertaken to increase participant recruitment until data saturation was achieved. In some instances, as a consequence of the snowball process direct e-mail contact was given for a relevant health professional to the researcher. Additionally, cardiovascular health professionals in one Sydney metropolitan hospital were recruited by the researcher introducing herself to the cardiology and cardiac rehabilitation

Nurse Unit Managers. Nurse Unit Managers were asked to inform their nursing, medical and allied health staff on these wards of the nature of the study, which would enable snowball (word of mouth) recruitment. Posters were displayed on cardiac rehabilitation and cardiology wards and waiting rooms with information about the study and researcher contact details. Interested participants were asked to contact the researcher via e-mail or telephone.

4.6.6 Qualitative Data Collection

The majority of interviews were conducted by the researcher. To mitigate bias, one semi-structured interview in Study 4 was conducted by an experienced qualitative researcher who was a member of the research team. This was due to a pre-existing relationship between the researcher and one health professional, who was also aware that the researcher was seeking to integrate meditation into heart disease care. In Study 3, all interviews were conducted by either an experienced qualitative researcher or other members of the research team to avoid response bias associated with the facilitator of the meditation groups. In Study 3, short semi-structured interviews were used to generate descriptive accounts of participants' experiences. In Study 4, semi-structured interviews were used to generate in-depth responses to pre-set open-ended questions[55]. Interview guides were used to ensure consistency in issues explored [55] (refer Text box 4.1 and 4.2). The interview guides were based on identified gaps in the literature, and previous research on barriers and facilitators to meditation in clinical care[56, 57]. In Study 4, the interview guide was pilot tested on one participant and refined during the interview process and discussed with the research team.

Patient data collection: Interviews were conducted face to face at the outpatient department of a NSW hospital or via telephone. Field notes containing the key points from each interview were transcribed by the interviewer and sent to the researcher for coding and analysis. Data were collected between 16th August and 12th December 2018.

Health professional data collection: Interviews were conducted individually via telephone, face-to-face at the University of Technology Sydney, a private area of the participant's workplace or at a heart

disease conference venue with no one else present. Data were collected between 18th May 2017 and 29th March 2018. Interview sessions were of 20-60 minutes duration, unless more times was needed as determined by the participant. The interviews were based on topics including participants' previous exposure to meditation and their perspectives of the potential role of meditation as a secondary prevention strategy that could be promoted within health care settings. Interviews were recorded on an audio recorder.

Reflexive accounts of the interviews were documented at the completion of each interview. These accounts contained notes on the tone of the interview, nuances made with respect to different topics and contextual details such as the dynamic between the researcher and the participant within the interview setting. These reflexive accounts enabled the researcher to report any instances of participant bias due to shared interest in the topic being discussed, and enabled the researcher to reflect on the need to remain objective by distancing her own experiences and assumptions and remaining neutral when phrasing questions. These accounts were referred to during the process of transcription and data analysis to ensure accurate interpretation and representation of the data. Data collection and analysis was an iterative process that occurred concurrently such that the researcher, in conjunction with her supervision team could establish what was known and areas where further depth was required[53]. Data collection ceased when it became clear that no new information was being elicited and data saturation was achieved.

Text box 1: Post-intervention participant interview guide

Participant interview guide

1. What was your experience of trying meditation in the clinical setting?
2. What aspects of meditation did you enjoy? Was there any part of meditation that you didn't like?
3. What influenced your decision to try meditation?
4. Do you think you will continue to practice meditation at home?
   a) Why or why not? (Prompt - any factors that would support you to continue meditation at home and that would challenge it?)
5. Was anyone else involved in your meditation practice? If so, did they use meditation independently or did you practice meditation together?

Text box 2: Health professional interviews: Semi-structured interview guide

Health professional interviews: Semi-structured interview guide

Meditation can be described as a variety of practices where the individual trains or regulates the mind, and includes techniques designed to encourage relaxation, well-being and emotional balance. Some examples of meditation practice include mindfulness, guided imagery and transcendental meditation.

1. Have you, or someone that you know, had any experience with meditation?
2. Can you tell me about any situation where you have been involved in the oversight organisation of or delivery of meditation services within a health setting?
    a. If not, do you think that introducing meditation as a part of care could be beneficial?
    b. In what format would you perceive this to be best delivered, for example, as a part of an inpatient care pathway, inpatient cardiac rehabilitation, outpatient follow up care with their clinician or as a part of outpatient rehabilitation services?
    c. Why do you think this format would be best? Are there any other options that have not been considered?
3. What are the organisational behaviours that you perceive facilitate or support a people who may like to use meditation for their health?
    a. What are the organisational behaviours that you perceive facilitate or support a staff member who may like to use meditation for their health?
4. To what level or extent do you think that organisational behaviours or culture may prevent a person from trying meditation?
    a. To what level or extent do you think that organisational behaviours or culture may prevent a staff member from trying meditation?
5. Can you tell me what you think would facilitate or enable meditation to be implemented in clinical settings?
6. What do you see as some of the key challenges to implementing meditation in clinical settings?
    a. What solutions may assist in addressing these challenges?
7. Can you foresee any perceived risks in implementing meditation in clinical settings?
8. Do you think patients or colleagues would be willing to disclose personal use of meditation practices? Why or why not?

4.6.7 Reflexivity

The researcher was an experienced perioperative registered nurse employed as a clinical trials nurse at the site where the phase II RCT was conducted. She is a 35-year-old Australian female of Indian descent with an interest in spirituality, but without religious affiliation. The researcher has practiced meditation regularly over a period of 14 years and finds value in meditation for emotional balance, healing and clarity and as a means to increase sensitivity to a higher level of consciousness or 'inner knowing'. In conjunction with the medical treatment of illness, the researcher believes that inherent in the physical body, is an innate capability to promote healing, yet stressors of daily life impact on one's

ability to optimise their ability to manage their health and well-being. As such, she believes that meditation can be a valuable process for some people who require additional support. The researcher recognises that skills in meditation practice to promote health and well-being are cumulative and occur over time and with practice. However, she also realises that meditation may not be of interest for all people living with heart disease and is respectful of the values and choices of each individual.

The researcher was constantly aware of her perspective of meditation during the interview process and ensured that neutrality in tone, posture and language was maintained. The researcher presented as open to participants' perspectives during interviews and withheld her own point of view. A key role of the research team was to challenge the lead author's interpretations in light of her known stance on meditation. Whilst participants were told the purpose of the research, information about the researcher's experience in meditation was not discussed until the completion of the interview to maintain neutrality. During the process of reviewing the first transcript in Study 4, the researcher had an opportunity to minimise researcher bias in subsequent interviews by ensuring that questions were phrased more simply, yet remained open-ended. She also ensured that double-barrelled questions were not used and the possibility of predetermining the direction of a probable answer was avoided.

4.6.8 Data Analysis

In Study 3, qualitative analysis occurred as part of a mixed methods pilot RCT in accordance with Halcomb and Davidson [58] in a series of six steps. This method of analysis was chosen as the interviews were relatively short in duration and did not require closeness between the researcher and the interview data[58]. Firstly, interviews were audiotaped and notes were taken concurrently by the interviewer to ascertain their impressions of each interaction. Key points were noted using reflective journaling immediately after the interview and sent to the researcher for analysis. The summary and field notes were checked against the audio recording to ensure they accurately reflected the interaction. Data were then analysed to elicit common themes between interactions, and preliminary findings were reviewed in an iterative process with the research team. Finally, the data was rechecked

to reduce and refine themes and illustrative examples were used to demonstrate the meaning of each theme from a participant perspective[58].

In Study 4, the qualitative data was analysed using an inductive approach and thematic analysis[59]. Thematic analysis involves searching across a data set to find recurrent patterns of meaning[59]. It differs to discourse analysis or interpretive phenomenological analysis or grounded theory as it is not bound to a theoretical framework[59]. The research question did not determine the need for implied theoretical commitments as this data was obtained to generate contextual knowledge of health professionals' perspectives of the organisational barriers and facilitators that affect the capacity for meditation to be implemented in heart disease care. Thematic analysis was considered a useful approach to reflect and untangle the surface of reality[59].

An *inductive approach* (or bottom-up) was utilised to ensure that the themes identified were purely derived from the data[60, 61]. This involved coding the data without fitting it into a pre-existing coding frame, within themes generated from previous research, or the researchers preconceived ideas[59]. One possible outcome of utilising this approach is that the themes generated may not directly correlate with the questions asked of the participants[59]. However, a specific research question may emerge during the coding process[59].

The six steps involved in the Braun and Clarke [59] method of thematic analysis as applied to Study 4 are detailed below:

Step 1: Becoming familiar with the data

Transcription of verbal data

Data was transcribed verbatim by the researcher or with the use of a professional transcription service. All transcriptions were read along with the corresponding voice recording to ensure accuracy of the data and to accurately ascertain meaning. The entire dataset was then re-read to search for patterns and meaning[59].

Step 2: Generating initial codes

Initial codes were generated using NVivo version 11 to organise data into meaningful groups. Coding was data driven, where initial themes that were selected were dependent upon the data contained across the entire dataset. Many codes were generated, with quotes assigned to each code containing surrounding text to ensure meaning was not lost.

Step 3: Searching for themes

Codes generated by the researcher were then formatted into Microsoft Word tables. This enabled the selection of the most relevant quotes within each code and ordered structuring of each quote so that the code could be combined with other codes to form an overarching theme. A mind map was also used to cluster groups of codes to identify potential themes and collate the relevant codes in groups prior to identifying an overarching theme.

Step 4: Reviewing themes

Categories that were identified as 'potential themes' were refined to ensure that the collated quotes within each category fit and the 'potential theme' formed a coherent pattern. Subcategories that did not contain enough coherent data were broken down and fit into separate themes, set aside or discarded. Alternatively, subcategories were collapsed into a larger existing or new 'potential theme' to synthesise and better reflect the key ideas contained within the data, and to ensure coherence and identifiable distinctions between central concepts[59]. The remaining 'potential themes' were refined for coherence.

Step 5: Defining and naming themes

Key points generated from the groups of data were discussed with the research team to generate the key themes and corresponding sub-themes, and ensure that the themes generated broadly reflected the data contained across the dataset. A thematic analysis table was generated to assist with visual representation of the integrity between the themes and corresponding subthemes, and to enable further organisation of the data in a collaborative, iterative process between the researcher and her supervision team. Data was further refined to reflect themes that were to be presented in the

analysis. Of key assistance to the researcher's progress during this phase was supervisory advice to 'look at the lens used' or 'what was underpinning the ideas presented'. Also of importance in this phase was to identify how the selected concepts and subthemes fit into the four overarching themes presented[59]. To ensure that themes answered the broader research question, data reflecting health professional perspectives with respect to meditation intervention design and delivery collected in Study 4 were synthesised with semi-structured interview data from Study 3 to address meditation's feasibility in heart disease clinical settings, and reported in Study 3. The themes generated became clearer after this process and repetition between themes was identifiable and removed.

Step 6: Producing the report

The data analysis is presented in the format of thesis chapter and a draft manuscript for publication. Choices were made to further reduce content to ensure compliance with manuscript guidelines with respect to length. The content was taken 'to a higher level', and the most illustrative quotes were selected for inclusion in the manuscript that added depth to the analysis. Weight assigned to quotes and subthemes within the data were addressed within the manuscript. This ensured that the selection of quotes best reflected the consensus of the majority whilst teasing out important points of difference or nuance contained within each theme and subtheme.

4.7 Defining mixed methods research

Mixed methods research by definition, involves the collection, analysis and synthesise of qualitative and quantitative data to enhance the breadth and depth of understanding of a defined phenomenon[14]. Mixed methods has been proposed as the third research paradigm, sitting midway on a continuum between qualitative and quantitative research methodologies[62]. A mixed methods research design is required in circumstances where the overarching research questions cannot be answered by qualitative or quantitative research methodologies alone[49]. Mixed methods research is an approach to knowledge generation in theory and practice that considers multiple viewpoints, perspectives and standpoints[63]. As such, it is methodologically eclectic by comparison with mono-

method research, by including the use of both qualitative and quantitative research designs and inductive and deductive approaches to reasoning[49, 62].

Essential components of a mixed methods design include: i) comprehensive collection and meticulous analysis of both quantitative and qualitative data to answer specific research questions and hypotheses; ii) mixing or combining the results from different types of data (data integration); and iii) selection of explicit research designs that inform procedures for guiding the study; and contextualising these procedures within philosophy and/or theoretical frameworks[13]. Rather than fitting different methods to specific content, mixed methods research emphasises matching methods to different research questions or problems[13].

4.7.1 Rationale for mixed methods in the MENTOR project

Mixed methods is used when it is necessary to generate a broader understanding of the context in which health care decision making takes place[64]. Primarily because it expands upon the general question of what works, asking "…what works with whom, by whom, in what contexts?"[65, p. 110]. Mixed methods research is increasingly valued in the conduct of health services research due to its harnessing of the strengths of both qualitative and quantitative methodologies in the exploration of research questions[15]. Complex problems in a dynamic health system require comprehensive multilevel exploration of patient, health professional and organisational perspectives in order to generate solutions that can be readily adapted for local health care contexts[15]. The MENTOR Project required a mixed methods design in order to generate new knowledge about the burden of anxiety and depression in Australians living with heart disease and the feasibility of integrating meditation into existing outpatient cardiac rehabilitation programs.

This mixed methods design provided the opportunity to elaborate, enhance and/or clarify the results from one method with the findings from another method (*'complementarity'*) to determine whether integrating a novel strategy such as meditation into cardiac rehabilitation could be successful and sustainable across different cardiac rehabilitation contexts[63]. This use of different methods will expand

the breadth and range of inquiry to generate answers to the MENTOR Projects' the five research questions[63]. If the American Heart Association vision of integrating meditation into cardiac rehabilitation programs is to be realised, then obtaining a contextual understanding of the barriers and facilitators to achieving this across different healthcare settings will be vital. Combining the strengths of qualitative and quantitative approaches will assist in determining these cross-contextual patterns[66]. This insight could not be achieved with an experimental approach which would only provide numerical information about the feasibility of an intervention, which would be insufficient to determine what works *(complementarity)*[14, 67]. Drawing up the strengths of both quantitative and qualitative research offsets each method's weaknesses to provide a more comprehensive generation of contextual knowledge of the capacity for meditation to be integrated into cardiac rehabilitation programs and to improve the psychological health of people living with heart disease *(completeness)*[67]. The integration of the data generated by each of the MENTOR Project's four studies and the meta-inference will ensure that the research questions are addressed.

Pragmatism

A pragmatic approach was considered necessary because understanding the role of meditation within a scientific paradigm requires that it be taken out of its original Eastern frame of reference into one that can be readily understood by investigators[68]. While the scientific method used to understand meditation processes and analyse the effectiveness of various meditation approaches has the benefit of being objective, there are several downsides to this positivist reductionist[13] Western approach. Namely, that positivism does not value the intuitive, nor the concept of higher states of consciousness that underlie Eastern meditation practices[69].

There is also a tendency in Western adaptations of meditation to extract the primary characteristics of meditation from a variety of traditions to arrive at a generic definition, that ultimately separates Western adaptations of meditation from their Eastern spiritual origins[68]. This does not mean that meditation research cannot be done, but rather that a pragmatic approach be taken to the conduct of

meditation research and the philosophical and spiritual underpinnings surrounding the Western adaptations of different meditation approaches.

4.7.2 Philosophical assumptions

As this mixed methods research was focussed on understanding the role of meditation for people living with heart disease, a pragmatic worldview was considered the most appropriate overarching paradigm to situate this project[49]. Pragmatism, put simply, refers to identifying 'what works'[13]. However, this is an overly simplistic understanding of pragmatism, that negates the more important factor of why to conduct research in a particular way[70]. The roots of pragmatism originated from Dewey's concept of experience, where he sought to reorient philosophy away from the abstract to towards concerns of human experience[70]. Dewey understood the need for interpretation of experiences, which were divided into habit, or inquiry, which he defined as the process of self-conscious decision making[70]. As opposed to philosophical discussions on the nature of reality based on metaphysics, Dewey's rooting of interpretation of experiences in the contextual, emotional and social underpinned his process-based approach to knowledge, which emphasises the process of inquiry[70].

In the course of conducting research as a form of inquiry, the mind-set of the researcher is influenced by emotions, preferences and feelings in identifying a particular problem[70]. However, the thoughts and standards that are applied to them are subject to the social context in which the research is conducted, and any statements made about the implications of our research are exposed to the judgement of others who may not share the same belief or standards[70]. This is particularly relevant in the conduct of meditation and mind-body research, where concepts such as 'consciousness' are not readily appreciated as having implications for health and well-being[68]. Pragmatism also acknowledges the role that the values of the researcher plays in the interpretation of data[66].

Philosophically and methodologically speaking, pragmatism offers a useful middle ground, seeking to close the gap between post-positivism and constructivism by acknowledging the value of those different approaches in guiding choices as to how different research communities conduct research[70].

Quantitative methodology is commonly underpinned by post-positivism, which claims that the world exists apart from our understanding[70]. Conversely, qualitative methodology is often underpinned by a constructivism, which claims that the world is created by our conceptualisation of it[70]. As such, pragmatism is a "…practical and outcome-oriented method of inquiry that is based on action and leads, iteratively, to further action and the elimination of doubt…"[62, p. 17]. Pragmatism also emphasises that research inherently involves decisions about which goals are most meaningful, and which methodological combinations will best enable researchers to answer specific research questions[62, 70]. Pragmatism focuses on real life research problems, with priority given to the purpose of the study over the use of particular research designs[14].

4.8 Conceptual Frameworks applied to the MENTOR Project

The MENTOR Project was underpinned by two complementary and interrelated conceptual frameworks: i) the World Health Organisation Innovative Care for Chronic Conditions Framework[71]; and ii) Bandura's Self-Efficacy Model[72]. These two frameworks, and their application to the MENTOR Project are described below:

4.8.1 WHO Innovative Care for Chronic Conditions Framework

The WHO Innovative Care for Chronic Conditions Framework was chosen as it underscores the need for systems level redesign to better meet the needs of adults living with chronic illnesses, including heart disease. The Innovative Care for Chronic Conditions Framework centres on the person living with a chronic illness and their healthcare needs, and highlights the need to reframe health service provision away from a biomedical approach towards a holistic approach that is patient-centred [73].

The Innovative Care of Chronic Conditions Framework is guided by a set of principles that apply to the micro, meso and macro levels of the framework. These guiding principles include the need for: i) evidence based decision making to inform and optimise care of chronic conditions; ii) a population focus that is planned and proactive, rather than an acute reactive focus to the organisation of health services; iii) a prevention focus that facilitates health behaviour change, and reduces the long term

burden and impact of chronic conditions; iv) focus on quality that ensures the efficient and effective use of health resources; v) integration that blurs the lines between health system levels and includes multiple perspectives to facilitate coordinated and continued care that transcends disease specific boundaries; and vi) flexibility and adaptability to withstand economic and political transitions, and increases in health care demands[71]. The Integrated Chronic Care Framework also contains building blocks that enable health systems to adapt to situational pressures[71]. These building blocks are delineated at the patient (micro), health organisational and community (meso), and health systems (macro) levels, and are described below.

Patient interactional (micro) level: Successful heart disease management requires positioning people living with heart disease and their families at the centre of care, who enter a partnership with health organisations and their communities[71]. This collaboration enables people living with heart disease to become informed about prognosis and strategies to manage symptoms, motivated towards health behaviour change, and prepared with the necessary behavioural skills to manage their condition[71]. The health care team delegates roles according to strengths and capabilities, rather than by their position within the health organisational hierarchy.

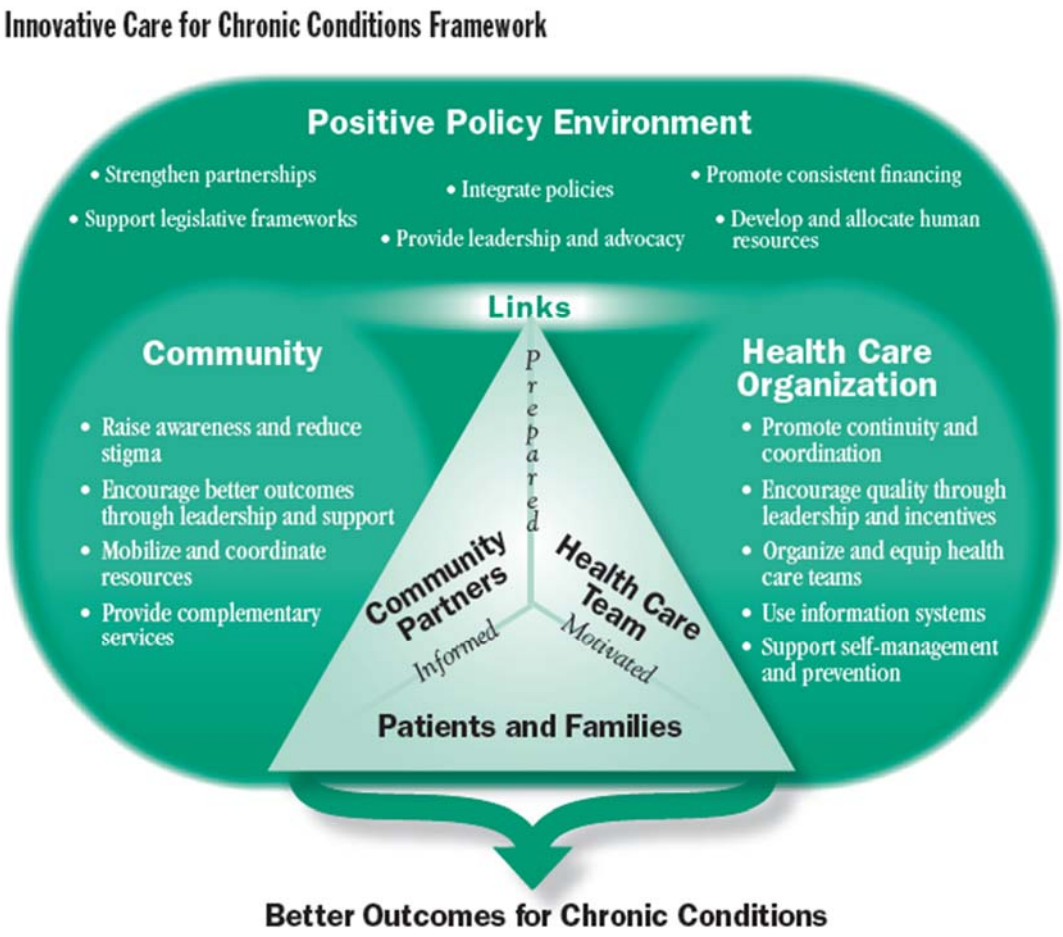

Figure 4.2: WHO Innovative Care for Chronic Conditions Framework[73]

Health Care Organisation (meso) level: Proactive management of chronic conditions requires effective team care and planned interactions, self-management support bolstered by effective use of community resources, integrated decision support and supported information technology, in order to strengthen the patient-provider relationship to achieve better health outcomes[74]. This happens through improving health care providers' expertise and skill in shared decision making and facilitating behavioural interventions, supporting and educating patients and families about self-management over time, making care delivery more team based and planned, and making better use of information systems[71, 74]. A quality improvement culture that supports innovative self-management practices and provides incentives to improve health outcomes is also essential[71]. Establishing formal and informal

community links to promote and provide complementary services that fill a gap in the prevention and management of chronic illnesses may also enhance patient outcomes[71].

Policy (macro) level: includes leadership and advocacy that advances care for chronic conditions, for example, through media engagement to raise the profile of chronic illnesses and the increasing burden and impact of these conditions. Advocating for policies that promote consistent, structured financing and reduced health system fragmentation may increase options for the funding of innovative therapies. Mandatory continuing education that specialises in chronic illness management and allocation of human resources to provide self-management support may better address unmet needs. Strengthening interdisciplinary partnerships, including non-government organisations and charitable providers may also influence care for chronic conditions.

4.8.2 Bandura's Self-Efficacy Model

Self-efficacy is defined as a reflection of perceived as opposed to actual capabilities, and claims that perceptions rather than ability or capability has a more prominent influence on behaviour[75]. Attaining competence involves an iterative process of continued improvement of multiple subskills to best manage dynamic circumstances that surround people in their everyday lives[72]. Effectively dealing with one's environment requires utilising and organising cognitive, social and behavioural skills into courses of action[72]. Bandura's Self-Efficacy Model addresses how people judge their capabilities, and how self-efficacy influences peoples motivations and behaviours[72]. It centres on the premise that one's sense of personal efficacy has the capacity to manifest and regulate events in their lives[72]. That is, confidence in one's ability to change their circumstances and impact outcomes is an essential component of positive behaviour change[76].

Bandura [77] proposes that expectations of personal efficacy are created and strengthened by different psychological and cognitive processes. These expectations are divided into efficacy expectations and outcome expectancies [77]. Efficacy expectations are defined as the belief that one can execute the behaviour required to produce the desired outcome, whereas outcome expectancy refers to the

estimation that a particular behaviour will lead to certain outcomes[77]. This is an important distinction, as whilst one can believe that taking a particular course of action will produce a certain outcome, if they are doubtful about their ability to perform a certain task, this information will not change their behaviour[77] (refer Figure 4.3).

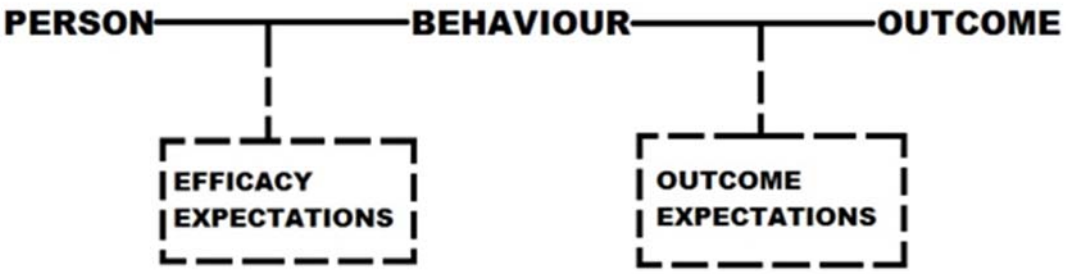

Figure 4.3: Bandura's self-efficacy Model: Difference between efficacy expectations and outcome expectations[77]

Expectations of self-efficacy are derived from four key information sources: i) enactive attainment, ii) vicarious experiences; iii) verbal persuasion; and iv) physiological state (refer Figure 4.4). *Enactive attainment* can be described as the personal mastery of performance outcomes. That is, repeated success in an activity increases expectations of mastering that activity, with repeated success providing a buffer to subsequent negative experiences in the same activity. Behavioural improvements then translate to other areas of activity outside the initial success. Enactive attainment can also be achieved thorough modelling behaviour, performance desensitisation, performance exposure (graduated exposure) and self-directed mastery experiences[77]. *Vicarious experiences* describes the process of viewing others performing a task without adverse consequences, as a means of forming positive expectations that they might also be able to successfully perform the task (modelling behaviour)[77]. Vicarious experiences rely on inferences from social comparison, and alone are a less reliable source of information compared with personal accomplishments[77]. Observing behaviours and tasks completed by a variety of sources is more likely to positively influence perceptions of self-efficacy[77]. *Verbal persuasion* describes the process of being led, by suggestion, into believing that they are able to accomplish a task or cope successfully in areas where they have been overwhelmed in the

past. Persuasive experiences are not as strong as personal experience of mastery and dissuasion can occur from negative personal experiences[77]. Verbal persuasion, in the form of corrective performance promotes self-efficacy, however attainment of self-efficacy also requires conditions to facilitate effective performance and enable mastery[77]. *Physiological state* refers to emotional arousal that occurs during stressful situations that can provide useful information regarding personal competency in coping with these situations. Physiological arousal state is used, in part, to judge anxiety and vulnerability to stress, with high arousal debilitating performance and reducing self-efficacy. However, behaviour change closely aligns with the level of self-efficacy change, regardless of which component is used to improve it[72].

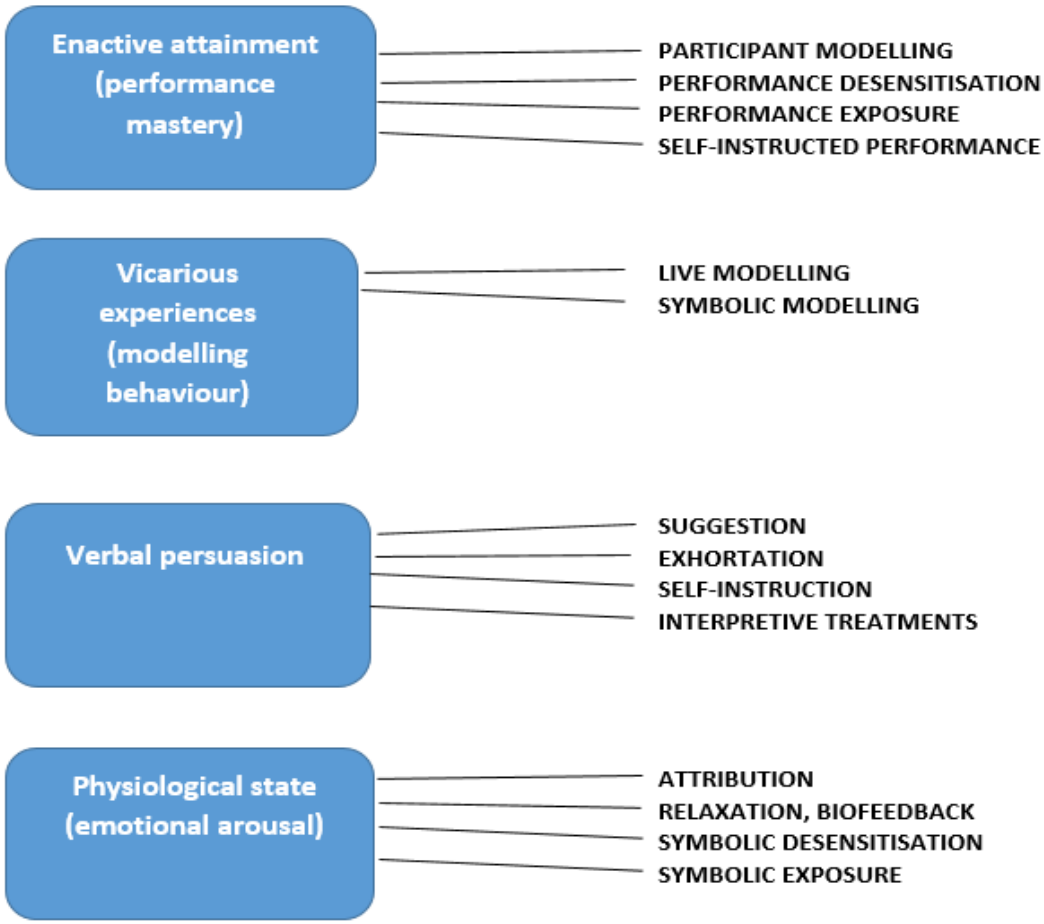

Figure 4.4: Bandura's Self Efficacy Model: Sources of efficacy information[77]

4.8.3 Application of Bandura's Self-Efficacy Model in the MENTOR Project

The theoretical relevance of Bandura's self-efficacy to the MENTOR Project is in the relationship between self-efficacy and health behaviours[76]. The social context of heart disease care, that is, the experience of the hospitalisation process, can support or impede the capacity for people living with heart disease to act in ways that optimise health behaviours. As such, recovery from a cardiac event involves both the impact of 'interactive (social) efficacy' and the contribution of an individual's perception of self-efficacy to the development of health promoting habits[72]. An important component of recovery from a cardiac event is physical self-efficacy, where perceptions of limited capacity to resume activities leads to a slower psychological recovery and exacerbates depression and anxiety symptoms[72]. This is evident in the reluctance of people living with heart disease to engage in physical, social or sexual activities due to fears of a recurrent cardiac event[78, 79]. Higher prevalence of depression and anxiety symptoms also decreases adults living with heart diseases' functional status and quality of life[80], and consistently reduces exercise self-efficacy over time[81]. Self-efficacy has also been shown to mediate the relationship between depression and social support with adherence to recommended treatments in adults with heart failure[82]. As such, integrating adjunct strategies to improve self-efficacy and co-morbid depression and anxiety symptoms is necessary to build confidence to commence and adhere to cardiac rehabilitation programs, and to support self-management[81].

The relevance of incorporating non-pharmacological self-management approaches, such as meditation, into heart disease care as a means of promoting self-efficacy and facilitating positive health behaviour change, is that it provides opportunities for people living with heart disease to increase their capacity to better manage their psychological health symptoms. Meditation is purported to be a mechanism by which people living with heart disease and co-morbid depression, anxiety and stress symptoms can attain competence in better managing these symptoms, which in turn may enhance their capacity to adhere to recommended heart disease secondary prevention recommendations, including attendance and adherence to cardiac rehabilitation programs. As such,

exploring the potential relationship between the mind and the body, including the role of thoughts, emotions and feelings[76, 83, 84], and the interaction this may have with the experience of people living with heart disease[76] is essential to optimising heart disease secondary prevention services, including those services that enhance self-management capacity and self-efficacy[83].

Self-efficacy plays a mediating role in successful emotional regulation, defined as the capacity to effectively manage negative affective states[85]. Improving perceptions of self-efficacy in the management of depression and anxiety symptoms may be possible by introducing meditation practices designed to improve emotional regulation[85] and cognitive flexibility[86]. Emotional regulation describes conscious or unconscious strategies used to process emotional experiences, such as avoidance coping, reappraisal, and rumination[85]. Emotional regulation is particularly relevant to people living with heart disease and comorbid depression and anxiety who experience difficulties in adaptation[85]. Whilst the mechanism of action for meditation and emotional regulation is uncertain, clarity of internal experiences has been identified as partly mediating the relationship between mindfulness states (attention and acceptance) and the regulation of negative affect[87]. This may occur by recognition of awareness itself, and the sensory phenomena that accompanies it without need to engage or identify with any stimuli[88]. As such, meditation may result in recognising that the "…'mind' contains but is not identical to its contents…" and that "…we are not our thoughts, feelings or experiences"[88, p.563]. Recognition of awareness enables the individual to consciously attend to habitual, conditioned thoughts, emotions and actions that are in alignment with one's personal values and facilitate adaptive behaviours[88, 89]. As such, meditation facilitates personal autonomy[88]. Embracing experiences in this way may reduce the need to directly control or change experiences, thereby promoting adaptive behaviour, enhancing well-being and reducing negative affective and emotional states[88].

Cardiac rehabilitation programs provide individualised support in the initial cardiac rehabilitation assessment, and some programs may include a lifestyle change component. However, people living

with heart disease and co-morbid depression and anxiety symptoms do not necessarily experience improvements in their self-efficacy capabilities before, during and after cardiac rehabilitation programs compared with people without depressive symptoms[81]. As such, these people are less likely to engage and adhere to cardiac rehabilitation programs or undertake the activities required to improve self-efficacy. The contribution of a meditation intervention to reducing the burden and impact of depression and anxiety in people living with heart disease occurs by the capacity for meditation practice to influence the belief or understanding that meditation may reduce their depression and anxiety symptoms (outcome expectancy), and that participating in a meditation intervention will equip them with the necessary skills to meditate independently and manage their depression and anxiety symptoms as they arise (efficacy expectation).

Adjunct therapies, such as meditation, are required within cardiac rehabilitation programs to provide opportunities for people living with heart disease and comorbid depression and anxiety to reduce the burden and impact of these symptoms in attaining self-efficacy and mastery over cardiac rehabilitation activities *(enactive attainment).* Group meditation sessions provide an avenue for deeper connection and rapport with other participants and may be a source of additional encouragement from the meditation facilitator for the development of their meditation practice. As such, meditation, offers an additional benefit for people who need extra support for self-management, confidence building and encouragement to improve health behaviours and attain better quality of life *(verbal persuasion).* The MENTOR project may also provide a context for *vicarious experiences* by identifying the problem of co-morbid depression and anxiety symptoms, and providing an opportunity for these people to observe others with similar or increasingly difficult challenges in managing their psychological health symptoms utilise meditation to support self-management. The possibility of experiencing a relaxation effect during meditation and reducing emotional arousal *(physiological state)* may improve one's perceptions of their capabilities in participating and adhering to cardiac rehabilitation programs, and gain confidence in a new coping strategy to self-manage their depression and anxiety symptoms.

4.9 The MENTOR Project's mixed methods design

An explanatory sequential mixed methods design was considered necessary to generate contextual knowledge of the role of meditation in improving psychological health of adults living with heart disease[48]. The MENTOR Project involved the sequential collection of qualitative and quantitative data, with emphasis given to the quantitative data.

The first phase of the MENTOR Project involved the collection of longitudinal cohort data in Study 1 (QUAN) while the Systematic Review (Study 2) involved the collection of data from RCTs (QUAN + qual). During Phase 2, qualitative data from the Study 3 phase II RCT (QUAN + qual) and semi-structured interviews of health professionals in Study 4 (QUAL) were connected sequentially with findings from the quantitative phase. As such, the population selected in the quantitative phase was used to guide the collection of the qualitative data in the second phase. Qualitative data on health professional perceptions of meditation intervention design and delivery features collected in Study 4 was reported in the Study 3 phase II RCT to inform feasibility. Data presented in the respective four studies were analysed separately then integrated in the third phase at the conclusion of the project[90]. Details of the four studies across the three phases of this sequential mixed methods research project are described below and depicted in Figure 4.3.

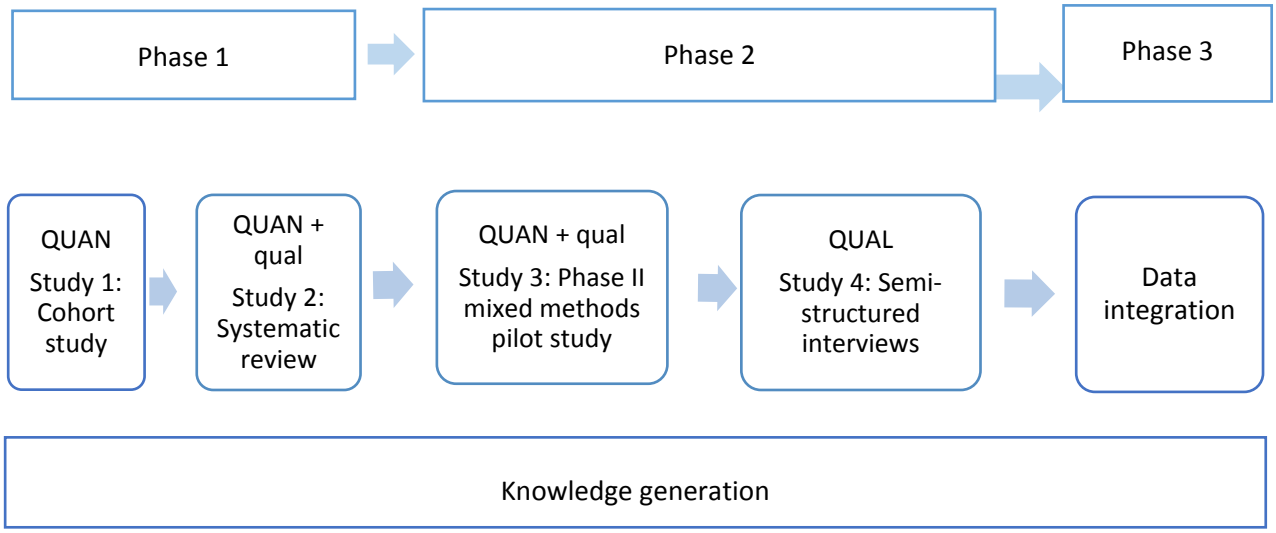

Figure 4.5: Sequential mixed methods design of the MENTOR Project

4.10 Data integration

In the MENTOR Project data integration involved the intentional process of bringing the qualitative and quantitative data together to address common research questions[91]. The meaningful integration of multiple data sources produced a 'whole' that is greater than the individual quantitative and qualitative results[92]. The integration of the MENTOR Project data took into account the following four key considerations[13]:

Intent of the integration

To connect the results from Phase 1 and Phase 2 so that both quantitative (Studies 1, 2 and 3) and qualitative data (Studies 2, 3 and 4) were used to best answer the overarching research questions.

Integration data analysis procedures

Firstly, the data generated from the NSW specific cardiac rehabilitation data (Study 1), international data (Study 2) and local data (Study 3) was analysed. Secondly, qualitative data from Studies 2, 3 and 4 was analysed for cohesion with quantitative outcomes data in the Study 3 phase II RCT, and to provide explanations for the quantitative results. Finally, integration of the data was undertaken to answer the mixed methods research questions.

Findings from qualitative data in Study 4 were connected sequentially with the results from Studies 1, 2 and 3 to understand how the context (organisational barriers and facilitators) could affect meditation implementation outcomes[13]. Quantitative and qualitative data from each of the four included studies were integrated at the completion of all four studies to best answer the mixed methods research questions.

Representation of integration results

The connected sequential integration is presented in joint displays linking the threads of data across qualitative and quantitative data to best answer the overarching first five research questions (refer Appendix 8). Joint displays are a means of identifying analytical relationships between quantitative and qualitative results to generate a more complete understanding of the phenomena studied[93]. Side-by-side joint display tables are used as a visual means to simultaneously display qualitative and quantitative data, in order to draw new insights and inferences beyond the data collected in the individual studies alone[91, 94].

Each joint display table addresses the research question and includes: details of the domains that align with each research question, quantitative and/or qualitative data from all four studies that was relevant to answering each domain, the degree of data convergence and the mixed methods inference for each domain[91]. Relevant results from the MENTOR Project's four studies were categorised into domains and applied to each research question, then assessed for data convergence. During this step, the researcher considered whether the quantitative and/or qualitative data confirmed, contradicted or enhanced each other[95]. Examining areas of convergence and divergence between two forms of data was necessary to shed light on insights that might otherwise have gone unnoticed[64]. The 'confirm' label was applied where two or more data sources were positively aligned and confirm the results of the other[95]. A 'contradictory' label was applied when two or more forms of data were incongruous, and generated additional questions about the validity of the data and the nature of the questions being asked[95]. Data was 'enhanced' when data generated from two separate methodologies provided

similar answers to a research question that was presented in different formats. For example, in instances where different measurement scales were used to measure a similar construct or elaborations generated from qualitative data that supported quantitative results[95]. The 'mixed' label was applied where results from two forms of data was neither confirmatory, nor contradictory, and suggested that further research is warranted[95].

Interpretation of the integration results

Interpretation of the integrated data was achieved through data consolidation, where quantitative and qualitative data were reviewed together and consolidated narratively to obtain new perspectives and insights[96]. Knowledge generated from Phase 1 (Studies 1 and 2) and Phase 2 (Studies 3 and 4) were connected using meta-inferences to answer research questions I to V. Meta-inferences were used to inform recommendations for future research and practice, and the outcomes of this final stage of the mixed-methods analysis are reported in Chapter 7.

4.10.1 Addressing the challenges of using a mixed methods design in the MENTOR Project

Skills of the researcher

Conducting a mixed methods design required skill development beyond the ability to narratively synthesise data and quantitatively analyse data using descriptive statistics and univariate analyses. In order to complete this doctoral Project, the researcher's capabilities were developed to include competence in the following areas: study design, protocol and clinical research forms development, project and data management, cleaning and recoding of variables for questionnaire scoring, and the completion of multivariate analyses. Qualitative skill development was also required including the design of a topic guide, interview techniques, reflexivity and self-reflection and qualitative data analysis and integration[49].

To address these challenges, the researcher was supported by the qualitative and mixed methods research expertise of her supervision team[64]. She was also supported externally by Dr Karen Byth, a statistician at a Sydney Local Health District to develop the skills required to conduct the multivariate analyses.

Considerations that needed to be addressed when conducting this sequential mixed methods project included: i) the timeframe involved in the conduct of a clinical trial; ii) time taken to transcribe and analyse qualitative data within the PhD timeframe; and iii) limited resources for the conduct of a clinical trial. As such, a sequential mixed methods design was utilised to allow for sequential collection[62] and analysis of quantitative and qualitative data whilst minimising delays in collecting multiple forms of data. This design also enabled a single researcher to collect multiple forms of data. These considerations were addressed in the MENTOR Project by: i) consultation with the Nurse Unit Manager of Cardiac Rehabilitation and Assessment Programs in one Sydney Local Health District to ensure site availability for the duration of the research project; ii) collaboration with the research team to assist with collection of interview data; iii) creation of GANTT charts to ensure that the project outcomes were SMART[97] (specific, measurable, achievable, relatable, and able to be conducted within the timeframe of the PhD) with consideration of time required for data analysis and integration. Protocols were drafted, reviewed and submitted as early as practicable and frequent communication with the Local Health District Research and Education Network staff and UTS ethics committee staff was necessary to ensure ethics submissions complied with Local Heath District and university requirements. A separate UTS low-negligible risk ethics application was submitted to allow purposive and snowball sampling using e-mail recruitment to allow for timely completion of semi-structured interviews.

4.10.2 Data storage

Hard copies of quantitative data included completed case report forms. These case report forms were collected and stored under the participant's identification number in a filing system on a shelf in a locked storeroom in the cardiac rehabilitation gym. The storeroom door was also secured by a second locked door separating it from the outpatient cardiac rehabilitation gym. A hard copy of the master log linking the participant data with their identification number and personal details was stored

separately. A source document was generated linking the identifiable data to the study code and held separately on a password protected server only accessible by the researcher.

All data was entered on to Research Electronic Data Capture (REDCap) cloud software using a unique participant code. REDCap is a secure web application specifically designed to support online or offline data collection for research studies and operations[98]. Digital files were then extracted into SPSS Statistical package version 24 for analysis and accessed at the University of Technology Sydney. Data was cleaned and checked (range checking and double data entry checking) prior to statistical analysis.

Qualitative data from semi-structured interviews stored on digital files were de-identified during transcription, coded and analysed for the purpose of extracting information relating to participants' experiences and perceptions. Audio digital recording of the interviews allowed for verbatim transcription by the researcher which reduced the risk of missing important points or nuances from the data and enabled active listening. De-identified data was uploaded to Cloudstor online cloud platform and stored behind password protected servers at the University of Technology Sydney.

From the time of publication, the Information Technology department will to be contacted to permanently delete files from the Local Health District servers. All paper records will remain on site at the hospital where the study is being conducted and digital records will be stored on the REDCap online platform for 15 years after the completion of the study. Paper based data will be destroyed by means of shredding and electronic files will be permanently deleted upon completion of the term.

4.10.3 Ethics and Governance Procedures

This research was undertaken according to the National Statement on Ethical Conduct of Human Research (2007), and the Australian Code for the Responsible Conduct of Research (2007). Human Research Ethics Committee approvals, and Scientific Committee approvals were obtained for Studies 1, 3 and 4. Ethical approval was obtained from one Sydney Local Health District (Study 1: AU/RED/LNR/17/WMEAD/24; Study 3: AU/RED/HREC/17/WMEAD/495; Study 4:

AU/RED/LNR/17/WMEAD/69) and ratified by the University of Technology Sydney (Study 1: ETH 17-1604; Study 3: ETH-18-2337; Study 4: ETH 17-1605) (Refer Appendix 9).

Site Specific Assessment (governance) approvals were also obtained for Studies 3 and 4 (Study 3: AU/2/F951312; Study 4: AU/RED/LNR SSA/17/XXXX/70).

Study Four was registered with the Australian and New Zealand Clinical Trial Registry (ANZCTR: U1111-1213-2716).

4.11 Conclusion

This chapter outlined the mixed methods design of the MENTOR Project. It identified the participants, setting and context for the MENTOR Project, described the conceptual frameworks used to underpin and operationalise the four included studies, and detailed the methods for Studies 3 and 4. Next, Chapter 5 contains Study 3, a mixed methods phase II RCT of a meditation intervention for people attending an outpatient cardiac rehabilitation program, with post intervention follow-up. It includes the analysis of both quantitative (descriptive statistics and multivariate analyses), and qualitative (thematic analysis) outcomes. Chapter 6 contains Study 4, a descriptive qualitative study of health professionals involved at levels of heart disease care who will be involved in the meditation integration process. Study 4 will identify the barriers and facilitators that affect meditation's integration in heart disease care.

4.12 References

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Chapter 5 The feasibility and acceptability of meditation for the reduction of depression and anxiety symptoms in people attending cardiac rehabilitation programs: A phase II RCT

5.1 Chapter preface

Chapter 4 detailed the design, mixed methodology and conceptual frameworks underpinning the MENTOR project. Chapter 5 reports the findings of a phase II randomised controlled trial designed to reduce depression and anxiety symptoms in people attending cardiac rehabilitation programs, and explores their perceptions of meditation as an adjunct therapy in post intervention interviews. Better understanding the feasibility and acceptability of meditation as a potential adjunct strategy for heart disease psychological symptom management is an important next step. This phase II RCT was designed to determine the feasibility and acceptability of meditation and evaluate a meditation intervention in one hospital in metropolitan Sydney. Given that there is currently no phase III trial of meditation effectiveness internationally, and no current meditation services available to people living with heart disease who look for adjunct self-management approaches, a phase II pilot intervention conducted in a Sydney metropolitan hospital that will inform the development of an adequately powered (phase III) randomised controlled trial is warranted.

5.2 Introduction

Meditation has been identified as a low cost accessible adjunct to conventional therapies, and has demonstrated a possible benefit to the reduction of cardiovascular risk[1]. As such, exploring the relevance and use of meditation to enable people living with heart disease to better manage their depression and anxiety symptoms within cardiac rehabilitation programs is required.

Study 1 identified that moderate depression and anxiety were prevalent in 18% and 28% of cardiac rehabilitation participants respectively. Further, anxiety and stress quadrupled the risk for depression after a cardiac event, whilst depression and stress increase the risk of anxiety by up to three times. The burden of depression in heart disease makes the timeliness of targeted interventions that meet the psychological support needs of adults after an acute cardiac event an

essential element of care, especially as it has implications for poor self-management[2]. Depression is also associated with reduced quality of life, earlier and more severe cardiac events and increased mortality [3-5].

Implementing a meditation intervention in a heart disease outpatient clinical setting is *timely* given American Heart Association recommendations for meditation use as a risk reduction strategy[1], and increasing patient preferences for adjunct meditation use. Meditation is used to manage symptoms of depression, anxiety and stress in 17.8%, 29.2% and 21.6% of the general population respectively [6]. Similarly, 23.9% of people living with heart disease symptoms or diagnosed heart disease are using mind-body therapies, with meditation among the top four strategies used for the management of cardiac symptoms[7]. Almost half of these people (48.6%) were willing to participate in a clinical trial of an alternative therapy[7].

5.3 Rationale for a Phase II trial

The proposed phase II trial recognises the increasing evidence for the role of depression and anxiety as independent risk factors for heart disease *and* the bi-directional nature of depression and anxiety symptoms[8]. This study will contribute to the broader body of knowledge of meditation for people living with heart disease and will contribute to understanding the pragmatic aspects of meditation's integration, and the design and outcomes for a phase III trial to reduce psychological aspects of cardiovascular risk and improve self-management. It is a small step in addressing the critical need for health professionals to formalise the importance of psychosocial and psychological support within a biomedical model[9, 10].

A pilot study is a necessary first step in exploring the feasibility of an innovative, novel application of a meditation intervention and is used to identify modifications needed in a larger hypothesis testing study[11]. This is required to avoid unintended negative consequences in an expensive, larger study, and to begin the iterative process of development, determining feasibility, evaluation and implementation[12, 13]. As such, this study was conducted as a smaller version of the main study to

explore if the components of the intervention could successfully work together[14]. This study was not designed to definitively determine safety, efficacy and effectiveness[11]. Rather, the reason for conducting a pilot study was essentially process oriented, with consideration of recruitment and randomisation retention[12]. Inclusion of a control group will allow for a more realistic examination of these factors, as well as blinded assessment procedures, and intervention implementation, all of which could differ in an uncontrolled study design[11]. The strengths of this pilot study is that the sample population is representative of the target population in a larger phase III trial[12]. Further, a feasibility design allows for consideration of process, resource, management and scientific aspects related to the success of implementing a meditation intervention[12]. *Process* considerations addressed recruitment rates, screening to randomisation ratio and retention rates; and *resource* considerations refer to predetermining fiscal and time constraints that could occur in a larger study. *Management* aspects deal with human resources[12], such as the meditation practitioner, research assistance needed, and site clinician involvement, for example, with access and provision of people with heart diseases' medical history, and pragmatic data management considerations in compliance with Good Clinical Practice (GCP) guidelines[15] and the National Statement on Ethical Conduct in Human Research[16]. *Scientific* considerations include the estimation of a dose-response relationship. This is notoriously difficult in meditation research where there is not a known cause-effect pathway, however a feasibility design will allow the researcher to determine the whether the number of sessions will be sufficient to detect patterns suggestive of a potential treatment effect that could be further explored in a larger study.

5.4 Objectives

To determine the feasibility and acceptability of integrating a meditation intervention into an existing NSW cardiac rehabilitation program for the reduction of depression and anxiety symptoms in people living with heart disease.

5.5 Methods

5.5.1 Trial Design

This was a mixed methods, open label, parallel group, phase II randomised controlled pilot study with a qualitative sub-study. Participants were randomly assigned by an independent statistician in a 1:1 computer generated block randomisation sequence to cardiac rehabilitation or meditation and cardiac rehabilitation. There was no alteration to cardiologist or other outpatient follow up appointments or medications unless advised by the relevant health professional, nor restrictions to the use of other complementary and alternative therapies. Participants were followed up at 6 weeks.

Post-intervention interviews of participants allocated to the meditation intervention were conducted via phone or in small groups after their final group meditation session. Semi-structured interviews were used to: 1) understand participants' experiences of meditation on their psychological health symptoms; and 2) explore the barriers and enablers to participation and adherence to group and home practice sessions.

5.5.2 Intervention

This meditation intervention consisted of 6 weekly group sessions of 16 minutes duration in addition to conventional cardiac rehabilitation.

Group sessions: An audio CD was created by the researcher that combined her own voice and an online YouTube breathing meditation[17]. This meditation was use to guide participants through concentrative meditation practices including guided deep breathing, and a 'body scan' that sequentially drew focused attention to the relaxation of major muscle groups. This was followed by an open focus that included peaceful ambient music designed to calm the mind and facilitate a meditative state[17].

Daily home meditation practice: Digital audio (USB, CD or Youtube link) that was identical to the content used in the weekly group meditation sessions was provided by the researcher. This digital medium also included an introduction to the session and a conclusion to the session that brought

participants back to normal awareness, which was recorded in the researcher's voice. The duration of the home practice sessions also replicated that of the group sessions. Participants not using the Youtube link for home practice were given a weekly log sheet to record the frequency and duration of mediation sessions for each day of the week (refer Appendix 6).

Usual care

Participants allocated to the control group attended the six week/ 12 session outpatient cardiac rehabilitation program. Cardiac rehabilitation consisted of an individual health assessment, one hour of a personalised exercise program, including treadmill, exercise bike, arm ergometer and walking, and an optional weekly psychosocial health session with a pastoral care worker of one hour duration. These participants were also offered a meditation CD or USB for home practice at the end of the trial period.

5.5.3 Study measures

Details about the included study measures are described in Chapter 4 Methods. Outcome assessments at baseline interview included:

1. Clinical and socio-demographic data;

2. Charlson Comorbidity Index[18];

3. Social Readjustment Rating Scale (SRRS)[19];

4. Depression, Anxiety, Stress Scale (DASS-21)[20];

5. Hospital Anxiety and Depression Scale (HADS) [21];

6. Mindfulness Self-Efficacy Scale Revised (MSES-R)[22];

7. Health Status (single item SF-36)[23, 24]; and

8. Google analytics attached to private Youtube meditation links.

5.5.4 Outcomes

Evaluation of between group differences (where relevant) at six weeks in:

1. Recruitment rate, screening, randomisation ratio and attrition rate
2. Patterns of adherence at weekly group sessions, home practice, and mean duration of home practice sessions; qualitative interview responses.
3. Variance of outcome measures for depression (HADS and DASS-21 depression subscales) at 6 weeks.
4. Improvement in symptoms of depression, anxiety (DASS-21, HADS subscales), self-efficacy (MSES-R) and health status at 6 weeks.

5.5.5 Sample Size

The pilot sample size was determined based on the pragmatics of recruitment and the necessities for examining feasibility[11]. This pilot study aimed to recruit 30 participants, 15 to the control arm (Group A), and 15 to the intervention arm (Group B), which is an acceptable number for pilot and feasibility studies[25].

Stopping rule

A stopping rule was employed based on the feasibility of recruitment (refer Figure 5.4). The target recruitment rate was approximately two patients per week, or eight patients per month to a total of 60 patients in 10 months (with a buffer of 2 months included). However, to allow for an interim analysis during the timeframe of the researcher's PhD, this target was modified to 30 patients in a seven month period (May-November 2018).

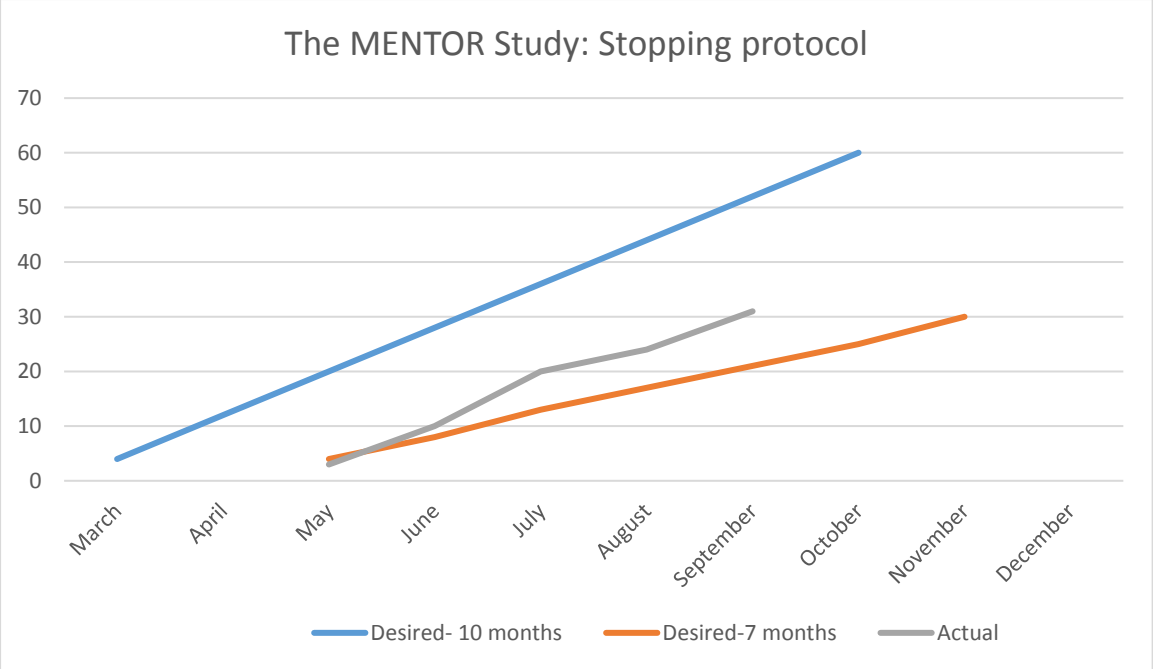

Figure 5.1: Stopping rule

Interim Analyses

Results presented for questionnaire data at baseline and six weeks are an interim analysis required for the completion of the researcher's PhD project.

5.5.6 Data analysis

Data was analysed using descriptive and inferential statistics. All analyses were on the basis of intention to treat. Independent t-tests were used for continuous data and chi squared tests were used for categorical outcomes in univariate analyses. Scores derived from psychometric measures for depression, anxiety and stress, mindfulness self-efficacy and social readjustment were all measured on continuous scales. Non-parametric tests, such as the Mann Whitney U test was applied for comparing means in non-normally distributed variables. Data analysis was completed after consultation with a biostatistician from the University of Technology Sydney, who was blinded to treatment allocation and had no part in the implementation of the intervention or endpoint assessment.

5.6 Interim results

At the time of writing up this thesis, 31 patients had been recruited into the control and intervention arms of this feasibility trial. The results that are reported here are an interim analysis.

5.6.1 Recruitment feasibility

Between 15th May and 26th September 2018, 377 patients were screened for eligibility, 31 participants were randomised and 15 completed the intervention (refer Figure 6.6). One fifth (18%) of patients meeting the eligibility criteria were randomised. The trial recruitment rate averaged 1.63 patients/week or 6.53 patients/month. The screening to randomisation ratio was 1: 8.

Of 175 patients excluded for not meeting eligibility criteria, only 13 (7.4%) were excluded due to low depression or anxiety subscale scores, and 11 out of 15 patients recruited had at least mild depressive symptoms (DASS-21 depression subscale score ≥5). Nineteen participants (11%) were from non-English speaking backgrounds with limited English language skills. The major reason for non-participation was due to patients attending cardiac rehabilitation at a second site (n=17), or the participant being non-contactable (participants not returning the phone call [n=23]; wanting to be contacted after the recruitment period [n= 1] or no phone number was provided [n= 2]).

5.6.2 Participant characteristics

The majority of participants at the mid-point of the trial are male (71%) and married (80%) (Refer Table 5.1). Twenty-nine percent were born Syria or Afghanistan, with 40% of participants speaking both English and a second language at home. Just under a half (45%) had a university degree.

At baseline, participants had on average high normal depressive symptoms (DASS-21 [D]: mean 9.10; SD ±9.21), borderline moderate anxiety symptoms (DASS-21 [A]: mean 9.73; SD ± 5.32) and high normal stress levels (DASS-21 [S]: mean 11.93; SD ±7.15). There were no significant differences between intervention and control group at baseline in terms of their demographic, clinical characteristics, psychological health status or meditation use (refer Table 5.2).

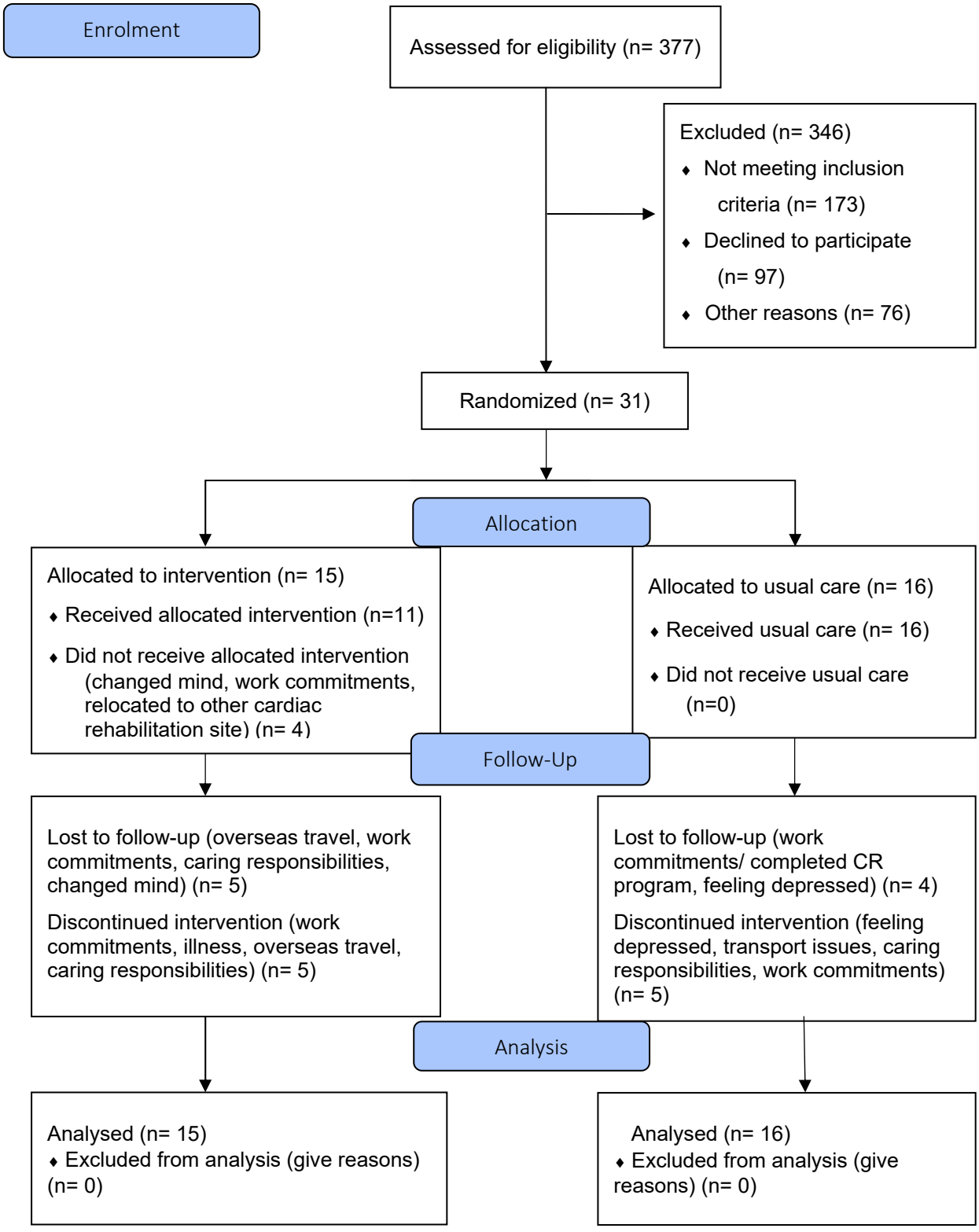

Figure 5.2: CONSORT 2010 Flow Diagram

Table 5.1: Baseline Demographic Characteristics

Demographics		Control (n= 16)	100%	Intervention (n= 15)	100%
Age (mean SD)		62.5	2.5	58.4	2.2
		N	**%**	**N**	**%**
Sex	Male	12	75	10	67
	Female	4	25	5	33
Country of birth	Australia	4	25	4	27
	UK	2	13	0	0
	New Zealand	1	6	1	7
	China/ Hong Kong	0	0	1	7
	India	1	6	2	13
	Philippines	4	25	2	13
	Other	4	25	5	33
Language spoken at home	English	8	50	5	33
	Other	3	19	3	20
	English/Other	5	31	7	47
Marital Status	Single	1	6	1	6
	Married	12	76	13	88
	De-facto	1	6	0	0
	Separated	1	6	0	0
	Divorced	1	6	0	0
	Widowed	0	0	1	6
Living arrangements	Living alone	2	12	0	0
	Living with a spouse, carer or relative	14	88	14	100
Current occupation	Paid employment	7	44	4	50
	Home duties	2	12	1	7
	Retired/ pensioner	7	44	6	43
Highest level of education	≤ Intermediate/ School Certificate	1	7	3	19
	Leaving/ Higher School Certificate	1	7	1	7
	Apprenticeship/ Trade Certificate	3	21	2	13
	Diploma	3	21	1	7
	University Degree	6	44	7	47
	Other	0	0	1	7

Table 5.2: Baseline heart disease diagnoses, co-morbidities, medications, and meditation use

Diagnoses/ co-morbidities		Control (n = 16)	100%	Intervention (n = 15)	100%
AMI		8	50	9	60
CAD		14	88	12	80
NYHA classification	I	12	75	9	64
	II	3	19	5	36
	III	1	6	0	0
Charlson Index [mean(SD)]		3.3	1.1	3.1	0.9
Heart failure		1	6	0	0
Heart valve problem		1	6	1	7
Permanent Pacemaker		1	6	1	7
Implantable Cardioverter Defibrillator		0	0	0	0
Percutaneous coronary intervention		14	93	13	87
Stroke		1	6	1	7
Hypertension		10	63	9	60
Hypercholesterolaemia		9	56	7	47
BMI [mean [SD])		28.6	7.4	26.7	4.7
Type I diabetes		0	0	1	7
Type II diabetes		4	25	7	47
Self-reported depression		5	33	2	13
Severe angina on admission		8	62	8	73
Cardiac arrest		2	15	0	0
Smoking status	Never smoked	7	44	7	47
	Ex-smoker	7	44	7	47
	Current Smoker	2	12	1	7
Alcohol	Abstinence/Rarely	11	73	11	73
	<once /week – twice/week	1	7	3	20
	3-4 times/ week	0	0	0	0
	≥ 5 times/ week	3	20	1	7
Walking	At least 10 minutes at a time	12	75	11	79
Medications		**Control**		**Intervention**	
ACEI		5	31	5	33
ARB		5	31	4	27
Beta blocker		8	50	7	47
Anticoagulant		1	6	0	0
Loop diuretic		2	12	3	20
Antiplatelet		15	94	15	100
Lipid lowering agent		16	100	14	93
Nitrate		2	12	4	27
Other vasodilator		1	6	0	0
Antidepressant		3	19	0	0
Meditation use		**Control**		**Intervention**	
Meditation use (ever)		6	38	4	27
Current meditation use		2	13	2	13

5.6.3 Mediation sessions and home meditation practice

80% of participants in the intervention group completed an average of 3.13 (SD ± 2.56) group meditation sessions. Home practice sessions were completed by 8 out of 15 (53%) participants, who completed an average of 7.2 (SD ± 11.1) sessions. This is supported by qualitative data where four interviewees who adhered to home practice reported completing these sessions a few (1 or 2-3) times per week. Of 11 participants who completed online Youtube meditation home practice, the mean total time spent in meditation home practice was 61.82 minutes (SD ± 148.50). Time spent on average in daily meditation home practice per session was reduced (approx. 2.32 mins) relative to the duration of the meditation intervention (16 mins).

Table 5.3: Between group differences at baseline and six weeks for major outcomes

Variable	Baseline				p value	6 weeks				p value
	Control		Intervention			Control		Intervention		
	n	Mean (SD)	n	Mean (SD)		n	Mean (SD)	n	Mean (SD)	
DASS-21 [D]	16	9.62 (9.22)	15	8.53 (6.07)	0.984	12	6.67 (7.15)	10	7.60 (8.88)	0.973
DASS-21 [A]	15	9.73 (3.76)	15	9.73 (6.67)	0.515	12	6.33 (5.71)	10	7.00 (6.82)	0.920
DASS-21 [S]	15	11.87 (4.37)	15	12.00 (9.31)	0.677	12	10.33 (6.49)	10	7.00 (6.81)	0.425
HADS [A]	16	6.13 (2.90)	14	6.35 (4.13)	0.900	10	5.80 (3.65)	10	4.80 (3.55)	0.542
HADS [D]	16	5.56 (3.60)	14	3.50 (3.37)	0.048	12	5.50 (3.03)	10	4.50 (3.66)	0.318
HADS total	16	11.69 (5.25)	14	9.86 (6.25)	0.465	10	11.5 (6.43)	10	9.30 (6.87)	0.420
MSES-R global	15	57.93 (8.06)	14	55.29 (7.995)	0.512	11	60.73 (6.92)	10	57.20 (8.26)	0.338
MSES-R emotional regulation	16	17.44 (3.74)	14	16.29 (4.25)	0.378	12	17.33 (3.06)	10	17.10 (3.73)	1.000
MSES-R equanimity	16	8.38 (3.58)	14	6.00 (3.72)	0.066	12	9.33 (4.03)	10	6.50 (2.76)	0.077
MSES-R social skills	16	7.69 (2.39)	14	8.79 (2.29)	0.282	12	8.83 (1.59)	10	7.90 (2.23)	0.283
MSES-R distress tolerance	16	7.81 (1.91)	14	7.79 (2.72)	0.769	11	7.64 (1.50)	10	7.40 (2.32)	0.886
MSES-R taking responsibility	16	8.25 (1.34)	14	7.93 (2.30)	0.882	12	7.83 (2.33)	10	9.20 (1.40)	0.099
MSES-R interpersonal effectiveness	15	8.40 (2.44)	14	8.50 (2.59)	0.982	12	9.50 (1.62)	10	9.10 (1.52)	0.545
Health status	16	2.94 (0.85)	14	3.29 (0.99)	0.438	13	3.15 (0.90)	10	3.50 (0.97)	0.407

P values are derived from Mann Whitney U tests were used given non-parametric data.

Key: [A], Anxiety subscale; [D], Depression Subscale; DASS-21, 21 Item Depression, Anxiety, Stress Scale; [S]Stress Subscale; HADS, Hospital Anxiety Depression Scale; MSES-R, Mindfulness Based Self-Efficacy Scale – Revised.

5.6.4 Indication of symptom improvement

Both intervention and control groups experienced improvements in psychological health symptoms, however none of these results demonstrated statistical significance. Mean differences between intervention and control groups did not favour the intervention group for DASS-21 depression and anxiety outcomes (refer Table 5.3). However, the mean difference in DASS-21 stress subscale scores was increased in the intervention group compared to the control group at 6 weeks (mean difference: 5.00 vs 1.54; p = 0.425). Mean differences in HADS depression subscale scores favoured the control group, whereas mean differences in HADS anxiety subscale scores favoured the intervention group (mean difference: 1.55 vs 0.33; p = 0.542). Larger decreases in HADS total scores were also gained in the intervention group (mean difference: 0.59 vs 0.19; p = 0.420). Control and intervention groups experienced equivocal, small improvements in quality of life, which were not statistically significant.

This study was unable to demonstrate a statistically significant effect for meditation over and above an exercise based cardiac rehabilitation program at 6 weeks. However, these results suggest that there are aspects of anxiety, stress, emotional regulation, and taking responsibility that might produce additional benefit over and above the benefits of exercise that may encourage better self-management of depression and anxiety symptoms.

5.6.5 Ancillary analyses

Attendance at cardiac rehabilitation programs was also tracked as part of usual care. The control group attended a total of 152 (79%) sessions of a possible 192 sessions. The intervention group attended 161 (89%) of a possible 180 sessions. The mean number of exercise based cardiac rehabilitation sessions attended was increased in the intervention group (mean: 10.7 sessions; 95% CI: 9.0-12.5) compared with the control group (mean: 9.5 sessions; 95% CI: 7.6-11.4) however the result was not statistically significant (p = 0.198). An increased proportion of participants in the intervention group (39%) also completed all 12 sessions compared with the control group (29%).

5.6.6 Strategies to promote engagement and improve adherence with meditation practice: Semi-structured interviews

A convenience sample of 10 out of 15 (67%) of participants allocated to the intervention group completed post-intervention semi-structured interviews. Six themes emerged from the content analysis (refer Text box 5.1).

Group meditation as enhancing the cardiac rehabilitation experience

Participants who benefited from the group experience felt that meditation group practice enhanced the cardiac rehabilitation program, in terms of increasing their social confidence, enabling a feeling of inclusion and enhancing the overall well-being benefit they felt as a result of the exercise program. A number of participants also supported the integration of meditation within cardiac rehabilitation sessions.

Text box 5.1: Illustrative Quotes: Participants

Group meditation as enhancing the cardiac rehabilitation experience

- *"They give twice a week, the exercise, I think they should give twice a week the meditation too. Because we do better then. Then together. More effective I think"* (Male, 73 years post AMI, PCI).

Meditation as a self-management strategy – integration into daily life

- *"Every now and again I'll be thinking what's going to happen at work tomorrow, or something, or if I'm anxious at the moment- early in the piece it was about my commercial driver's license. So I use those relaxation and breathing techniques in those cases…"I'll continue to use them (meditation techniques). I've got no problem with that. I just use it from my memory. It's just sort of automatic I suppose. When I feel the tension, or can't get off to sleep, it just sort of kicks in"* (Male, 72 years, post AMI).
- *"It doesn't work for me because I'd rather do a physical activity. "I need to move."* (Male, 65 years, post PCI).

Future intention to meditate

- *"Yes, that's one thing that I would like to do. I've tried it a couple of times. Meditation is something I'd like to get into. Keep up, and remind myself I need to relax"* (Female, 60 years, post AMI, PCI).

Developing self-awareness and maintaining calm

- *"I sort of felt good, I tend to over think things sometimes, and you know I found after sitting down and relaxing like that, I didn't sort of think everything was on top of me, I'm overthinking things"* (Female, 60 years, post AMI, PCI).
- *"You know if you're fighting the situation, stressing out about what's happened to you I think you put yourself in a worse* situation*…* (Male, 56 years, post AMI, PCI).
- *"…before I had the heart attack, my head is fast, my character is fast, I have to keep everything perfect. So I have a lot of stress. So I think this time is a good time point to control my character and activity or some things"* (Male, 73 years, post AMI, PCI).

Initial perceptions and experiences with meditation practice

- *"I told xx (facilitator) that "I was firmly entrenched in the 20th century and I told her I didn't want to end up wearing orange robes and sit there chanting and stuff. So I think I had a little bit of a, I suppose, a negative attitude towards it"* (Male, 72 years, post AMI).
- *"So I guess to improve for the better, I guess lifestyle or living, or whatever, I'm open to anything. So if this is going to improve my well-being, well, why not"* (Male, 56 years, post AMI, PCI).
- "*…a lot thought it was a waste of time, but I found it very helpful"* (Male, 71 years, after PPM insertion).
- *"To divert the mind from the outer world. To see the whole soul. I can't do it properly but I want to try to hold the soul and to see the soul."* (Female, 62 years, post AMI, PCI).

Recommending meditation practices

- *I've actually since, now that I think of it, one of the blokes at work, his sister has a heart attack, and we both live in the Blacktown area, and I told him of my experience, and I told him to get involved with the cardiac education program and take advantage of the meditation"* (Male, 72 years, post AMI).

Timing

- *"Fifteen minutes is alright. It's ok to concentrate for that time. To do it longer is hard."* (Female, 62 years, post AMI, PCI).

Questionnaires

- *"Most people don't want to show up their personal story. So I think without the query, so you have them mixed together one course, exercise and this course. If you do that then I think many people will come"* (Male, 73 years post AMI, PCI).

Environmental considerations

- *"The environment was appropriate, quiet, relaxing, and not noisy or distracting"* (Female, 67 years, post TAVI).
- *"Maybe a little bit of noise outside. We are where we are"* (Male, 56 years, post AMI, PCI).
- *"…the previous place I practiced my relaxation technique was, um, you could hear birds, and the wind blowing, and the trees, and I like that sort of stuff, Those are the things that would make me relax a bit more, open to it all, I think… So I found the room a bit sterile in that situation I suppose… people going past and doing all the hospital business*…." (Male, 72 years, post AMI).

Work commitments

- *"I could have attended meditation if it was at different hours. Outside of work hours"* (Female, 60 years, post AMI, PCI).

Integrating meditation into daily life

Most participants were positive in regards to their ability to integrate the intervention into their daily life. Meditation was perceived to be helpful to reduce stress in the workplace, and in life generally. Participants also report using meditation to aid sleep, forget problems, promote a general feeling of rejuvenation, and to reduce feelings of anger. Aspects of meditation that were perceived to be helpful were the background music of waves crashing (particularly for concentration) and the calming voice of the facilitator. Meditation was also perceived to reinforce techniques learned from other courses such as Cognitive Behaviour Therapy, with particular reference to breathing and general relaxation. Participants almost universally expressed readiness to apply meditation to practice outside of the program. One participant, however, preferred physical activity as a stress reduction strategy over meditation. The ability to draw on meditation in life circumstances indicated the ability to adapt meditation to everyday circumstances. Resources, such as the CD or downloading the meditation Youtube stream to a smartphone was also reported to promote continuity of meditation practice after the program ended. Other interviewees perceived that in theory they would like to use meditation outside of the group but were not currently applying meditation practices on a regular basis. One participant recognised that meditation could be beneficial however did not find it personally helpful. This participant was unable to complete any meditation sessions, which may indicate a lack of readiness or preference for meditation practices.

Developing self-awareness and maintaining calm

Participants described the experience of meditation as providing a sense of calm or peace and assisted with the development of self-awareness of their emotional states. Meditation aided participants to recognise the notion of being in one's head the need to shift their internal dialogue away from tendencies such as perfection, overthinking or denial of their health status and its impact on their lifestyle. In these instances, meditation assisted participants to adjust or slow down, particularly during an interim recovery period where they were unable to assume all normal activities.

Challenges with meditation practice

One participant described difficulties with deep breathing and concentration as challenges in developing their meditation practice. Inability to hold the breath for a longer than usual period of time was perceived to be difficult. This indicates that individual attention to breathing training may be required for some participants as a part of developing a successful meditation practice, or reassurance to breathe at one's own pace. Difficulties in concentrating were described as a period of time required to convert the mind from work, and resulted in a temporary raise in blood pressure.

Initial perceptions and experiences with meditation practice

The majority of interviewees had no previous experience with meditation. Participants' initial perceptions of meditation were either ambiguous or cautious. All who participated, despite their own reservations (or the reservations of others) were open minded and were willing to try meditation. The spiritual aspect of meditation also motivated one participant to engage in meditation practices.

Recommending meditation practices

All interviewees said they would recommend meditation to others with or without a heart condition. These recommendations were independent of participation in cardiac rehabilitation and/or were used to encourage others with a heart condition to engage in cardiac rehabilitation programs.

Engagement and adherence

Timing

One half of these participants described the process of participating in meditation alongside the delivery of cardiac rehabilitation programs as convenient. The frequency and duration was considered acceptable for participants. This aligns with health professional perspectives of the optimal duration for meditation practices, which is considered to be no longer than 30 minutes, with an intervention duration of no more than 3 months. However, other participants found work commitments as a barrier to participating or completing the meditation program. Those who were unable to complete the meditation program had a desire to do so, and would recommend

meditation to be held outside of working hours to facilitate attendance and adherence. Caring responsibilities, juggling multiple health professional referrals and taking time to integrate lifestyle changes also delayed and/or inhibited participation in meditation.

Questionnaires

Participants did not express personal reservations about completing questionnaires. However, some of these participants acknowledged that questionnaires necessary for a clinical trial as a deterrent for others who were unwilling to disclose personal information about their mental health status. These participants encouraged a format for meditation that was integrated into the standard cardiac rehabilitation program to promote broader uptake.

Environmental considerations

There was some ambivalence in perspectives of meditating in a hospital environment. All participants were able to experience a meditative state in the outpatient hospital setting. However, some participants found that the hospital environment produced some limitations to a deeper meditation practice.

One of these participants acknowledged that a natural setting would be more conducive to meditation practice. Two participants reported a need for more comfortable chairs. One of these participants reported that the low back chairs available in the room did not provide security, and the participant felt that it could have fallen backwards.

5.6.7 Heath professional perspectives – intervention design and delivery: Semi-structured interviews

Health professional perspectives were obtained for the purpose of informing the design of a future phase III trial. A total of 18 health nursing, medical, allied health professionals or health managers completed these interviews. Key themes are detailed below (refer Text Box 5.2).

Risk for adverse events

The majority of participants perceived that the risk for distress for patients engaging in meditation programs in clinical settings was minimal. Other participants attributed minimal risk to how meditation was implemented in clinical settings. These participants emphasised creating a safe space for meditation practice and valued the strategies to reduce and manage distress that were embedded in the design of mindfulness based programs.

Modification of structured programs

The majority of health professionals agreed that modification of structured 8 week programs, for example was required for pragmatic purposes to enable participant adherence and engagement in meditation programs. However, there was some variation in perspectives on the optimal depth and duration of meditation sessions. Participants considered lighter forms of meditation (in terms of depth) that were less likely to produce distress as most appropriate for application in clinical settings. The majority of participants using mindfulness based practices considered 30 minutes as the optimal duration of meditation sessions. The need to adapt meditation practices to the changing health care needs of patients as they progressed through their recovery was a driver for modifying the duration of meditation sessions. This was noted by other participants, who perceived that mediation could be suitable for a specific recovery period before participants were ready to return to usual activities. One participant promoted longer (hour and a half) sessions as run in Mindfulness Based Stress Reduction programs that combined theoretical aspects and group interaction with meditation practices. A few participants, however, promoted the use of short meditation techniques within secondary prevention programs to promote feasibility and minimise the impact on existing program delivery. This perspective differed to other participants who were concerned about the dilution of meditation practices, and reduction in clinical benefits for patients in a shorter time frame.

Text box 5.2: Illustrative quotes: Health professional perspectives of meditation intervention design features and delivery methods

Risk for adverse events

- *When I think of risks, I think of adverse patient outcomes and I can't think of any risks like that. If the patients decide that it's not for them or they decide that they don't like it and it's not achieving the desired outcomes, then I think they just disengage, but I don't think it has any risks to their physical or mental wellbeing* (P006, female, RN).
- *I think, pre-emptive or proactive is always better than reactive. So the way you set the group up is incredibly important. And I think the mindfulness based stress reductions and the MBCT groups all of them generally have given this some consideration…* (P011, male, RN).
- *…So I think you need to be mindful that you are creating a safe space for people to be going a place... going somewhere...* (P004, female, MD).

Modification of structured programs

- *I'm not concerned with the four sessions... The nature of the groups too is, as I run them, the meditation is light, it's not an hour and a half…Yeah, so the actual practices within this, as I say, there's nothing longer than say, about half an hour. That would be the maximum* (P011, male, RN).
- *Well I think you could start out really gently and like, if it says you've got a six week cardiac program, there's no reason why you couldn't start each session with just five minutes of sitting quietly and doing a little body scan* (P010, female, GP).

Adaptation of meditation content for home practice

- *…So what I've tried to do is divide it into both formal practice, which is where you actually have a formal meditation practice, which might be as simple as 10 minutes… And then on top of that, as you remember, having these informal practices that come in, so that you can attune yourself, and reconnect with what this is all about, during the day* (P001, male, project manager).
- *…The first one being the body scan, which I've record in my voice. Which I think is important. And it just ties back into what they have done more intensively you know, in that little period that we've done together* (P010, female, GP).

Delivery personnel

- *I think all members of the health care team ideally, have some knowledge of the technique. I think if it's isolated to professionals such as psychologists or social workers who are traditionally sort of led those sort of interventions, if that's the case it's never going to get broad uptake, particularly within the Australian model the majority of cardiac rehabilitation programs are delivered and coordinated by nurses, it seems that that is a logical step…* (P005, female, RN).
- *I think again, if you were in a service that had a clinical psychologist, you'd be absolutely using them as your leverage point to raise the profile and the benefits of doing this, but where you don't have that luxury it would be working with whose available* (P014, female, RN)**.**
- *Some patients are a little bit resistant to getting referred to a psychologist. You know because to some patients it can have some connotations that they're to particularly comfortable with. Whereas they might be more comfortable being referred to, for meditation by you know by some other service provider* (P015, male, allied health).

Method of communication

- *Because I think if you want to make it something that people want to come and do again, not just as a one-off exercise, then you want to make sure that they have a little bit of background around it, first of all, and then if they understand why it is that you're doing it, then they're more likely to commit to it and engage in it more fully* (P006, female, RN).

Flexible delivery options for meditation practice using technology

- *You know when you hold their hands, shake their hand there is a human element there that is so hard to replicate without being in the person's presence. However, having said that, once that's established, then tele-health and these other forms of communication can work very well…But you've got to get to that point of trust.* (P008, male, MD)
- *… But if you just given them the app without any introduction, then it is less likely that they will use it. So you need to kind of (give) them confidence, and interest and motivation, then they will go on hopefully to use an app or…* (P009, female, RN)

Benefits of group meditation practice

- *I do like the group dynamic…. And that's one of the positives about the MBSR you, go on this journey with the others in your group. It's quite transformative and I like that about it* (P010, female, GP).
- *You're getting instruction, and everyone's closing their eyes and doing it and trying to zone out and do their own thing. There's a learning experience and there's a discipline that comes with that* (P016, male, Director).

Environment

- *So the inpatient, particularly in the cardiology setting where length of stay is short and it's busy and in a busy setting, it's challenging* (P005, female, RN).
- *I'm envisaging a meeting room that we have away from where all the patient care areas are, not too far, but it's (far) away enough that you're not going to be disturbed. You could close the door. You could draw the blinds, dim the lights, and set the mood in that manner and you could do things that I've found have worked like putting on the background music to just mean that people are completely focused in that environment that you're creating for them there* (006, female, RN)

Need for a champion

- *…it often needs someone to really drive it. Some sort of concerted lobbying and getting key stakeholders within the health system on board. You know to bring about the changes in the way that things are done and the services that are offered for patients* (P015, male, allied health).
- *...Look, I think it's going to be challenging to keep people motivated if you're asking the clinicians at the point of care to deliver it, then their motivation levels might vary. Whereas if you have someone else that takes on that role and it's theirs that they own, then I think that would potentially mean that they would commit to it more fully and really want to see it succeed.* (P006, female, RN).

Challenges to meditation implementation

- *This is not founded on anything, I think that there are some people who are very set in their ways, and may not be as open to exploring new techniques or new adjuncts to what they say is something that works perfectly well, and why would you change it?* (P014, female, RN).
- *…You can't expect them to be positive, but at least they should be, you know, not working against it. Because if you have too much of that it's going to be hard to do a study and definitely hard to implement it. Because sometimes, even if you have a positive study, if people are still negative towards the intervention it will not happen* (P009, female, RN).
- *You know some people are already out the door before it's even suggested you might want to do rehab. And then there are...a lot of people have to go back to work and families, and there's financial issues. So that would be…time and money. That's what it comes down to.* (P002, manager)

Adaptation of meditation content for home practice.

Participants identified the need to maintain consistency in meditations between home and group sessions and preferred shorter frequent home practice sessions to promote adherence and integration.

Delivery personnel

Whilst participants had diverse perspectives towards the professions best placed to deliver meditation in clinical settings they were generally open to interdisciplinary collaboration. Nursing, allied health professions, and volunteer peer leaders were perceived as most suited to implementing mediation due to the therapeutic nature of their clinical (and non-clinical) roles, and the flexibility within these roles to deliver meditation practices whilst working within their scope of practice. Other participants favoured psychologists as ideal meditation facilitators given their ability to manage complex psychological health issues. Prestige associated with the role of the clinical psychologist was perceived as increasing the credibility of meditation. Psychologists also worked cohesively with nursing staff in cardiac rehabilitation, which translated well into meditation program facilitation. Other participants were cautious with respect to patient referral to a psychologist, due to stigma attached to addressing mental health concerns. There was also variation in medical perspectives towards their role in promoting and/or implementing meditation practices. Some medical professionals perceived meditation to be outside the scope of their responsibilities, and highlighted workload capacity as underlying reluctance to extend their role to include meditation. However, they were willing to delegate referral and delivery of meditation programs to other health disciplines within secondary prevention. Other medical professionals, however, were keen to implement meditation for their patients.

Method of communication

A range of strategies were identified by participants to promote adherence and engagement in meditation practices that accounted for the differences in patient learning styles, including information provision, benefits of group and individual meditation sessions, and flexible delivery

using technology. Participants were supportive of introducing theoretical aspects of meditation provided in educational material and experiential learning processes to support meditation skill development. However, some participants highlighted that the language, theoretical concepts and the background of specific meditation practices needed to be kept simple to account for different levels of health literacy, and possible minor changes in cognition. Extensive reading material was considered inappropriate for implementation in the secondary prevention context.

Benefits of group and individual meditation sessions

There was a general consensus among participants with experience in delivering meditation practices of the benefits of group based learning. Participants recognised the benefits of group meditation practice in providing a context for shared learning, deeper meditation practice, supported skill development and promoting adherence to meditation. However, it was also recognised that meditation groups may not meet the needs of all patients who required or preferred one-on-one sessions.

Flexible delivery options for meditation practice using technology

Online approaches to patient engagement with meditation including tele-health and online patient forums were identified as means of improving adherence to meditation programs. Online applications were supported broadly by participants as a means of supporting adherence and continuity of care. However technological approaches were not to be seen as replacing the value of the therapeutic encounter and developing the patient-provider relationship. Other participants suggested that rapport could be developed online with the caveat that the health professional delivering the meditation program was facilitating those online introductory sessions, and by providing opportunities for feedback for example, through a diary or online patient forums.

Environment

The general perception was that implementing meditation in the inpatient clinical environment was antithetical to the core business of hospitals, which produced logistical challenges. Participants

identified the need to address limitations of the clinical environment including noise, lighting and privacy.

Need for a champion

The need for an external champion was considered important for the sustainability of meditation programs where competing demands in clinical care could lead to health professional complacency. Internal champions with pre-existing clinical relationships was also perceived as conducive to the introduction of meditation.

Referral to meditation practices

Conflicting views on how to implement a referral pathway for meditation were discussed. A patient-driven referral to approach (opt-in) was preferred by the majority of participants which reflected a need to empower patients with the decision making process. The need for health professional endorsement of meditation programs to facilitate patient engagement was a driver for some participants' preference for an opt-out approach to meditation program referral. An opt-out referral process was considered necessary by other participants to provide opportunities for patients to experience the benefits from meditation programs, which implied that health professional endorsement of meditation programs was required to increase acceptability and facilitate patient engagement with meditation practices.

Challenges to meditation implementation

Challenges in the clinical environment with respect to the promotion of meditation, including health professional resistance to change and time were discussed. Underlying health professional reluctance to promote meditation was negativity based on a lack of familiarity of what it involved and what it could offer for their patients, and the task oriented nature of clinical roles. Limitations to successful meditation implementation that were a direct result of time included: limited opportunities for patient education and engagement, which was largely due to fast patient turnover and other patient priorities; and limited opportunities to plan implementation, including

consideration of the structure of group sessions and organising an appropriate space that did not interfere with existing outpatient programs.

5.7 Discussion

These interim analysis suggest that it is feasible to conduct a parallel group randomised controlled trial of meditation within the cardiac rehabilitation setting, in terms of recruitment, completion rates, and acceptability of study measures. There was a good screening to randomisation ratio from patients recruited directly from cardiology wards or outpatient cardiac rehabilitation intake. Interim analyses did not generate a statistically significant difference for the benefits of meditation over and above cardiac rehabilitation. However the study was not designed to demonstrate statistical significance, and these results are unsurprising given the relatively small sample size. Qualitative data suggests that participants found the intervention beneficial for their depression and anxiety symptoms, and enhanced their experience of the cardiac rehabilitation program. Further, they were able to integrate meditation practices into their daily life, and initial negative perceptions of meditation practices or its potential benefits did not inhibit participation, and were positively shifted during the process of the six week intervention.

Health professionals recognised the feasibility of integrating meditation within existing heart disease programs, with due consideration given to the value of psychologists, nurses, allied health professionals, pastoral care and peer leaders as possessing the relevant skill set for meditation facilitation. Integration of flexible delivery approaches for meditation after a facilitated introduction was considered necessary to promote engagement and sustainability of meditation practices. Exploration of the adaptability of online approaches to specific heart disease populations and contexts was also warranted, however other strategies for patient engagement require consideration in areas of socio-economic disadvantage, lower levels of health literacy, and reduced access and competence with technological approaches. Careful consideration of the language around which meditation is described and focus on the physiological benefits of meditation practices

is required when engaging patients in meditation practices to ensure that these practices best address identified patient support needs and align with the goals of health service delivery.

5.8 Implications for the design of a phase III trial

This interim analysis has provided insights into the feasibility of conducting a larger phase III meditation trial. The intervention did not document any harms, and the intervention is teachable. Health professional and participant data also suggest that implementing meditation in the heart disease clinical setting is feasible, and meets the psychological support needs of adults during the process of their recovery after a cardiac event. Specific consideration given to pragmatic aspects of clinical trial design are detailed below.

5.8.1 Delivery

Qualitative participant and health professional perspectives highlighted an existing stigma or privacy attached to addressing mental health concerns. This is consistent with the literature which suggests that some patients may be reluctant to utilise external referral to psychologists for psychological health symptom management, with preference for strategies to address psychological health to be delivered within cardiac rehabilitation programs [26]. In order to achieve optimal psychological health outcomes for patients, delivery of meditation programs within conventional cardiac rehabilitation outpatient programs is feasible and recommended.

Whilst health professionals valued both group and individual meditation practices, delivery of one to one sessions is not pragmatic in the cardiac rehabilitation clinical environment with a large volume of patients. However, external referral of patients not suitable for group processes to a psychologist, who may be trained in cognitive behaviour therapy techniques and/or an external trained meditation practitioner is warranted in these situations, according to patient preferences. External engagement with local community centres and collaboration with experienced and trained meditation practitioners is required to promote long term adherence and provide opportunities for those limited by work commitments to engage in meditation practice. Delivery of meditation practices within the outpatient setting after hours is another long term option that can be explored.

5.8.2 Adherence

Quantitative and qualitative data suggests that adherence to home practice twice a week is feasible, in addition to weekly group meditation sessions. This endpoint will be used as an outcome measure for adherence to home practice in a larger study design. A participant who was recruited at the intervention site who moved to a different site within the same cardiac rehabilitation service, and was allocated to the intervention group did not receive the online link for the meditation intervention, and was not present in the weekly groups to check adherence to home practice. A follow up phone call in week 2 of the intervention is warranted for those patients who move to a different cardiac rehabilitation site within the same service to ensure they have the necessary resources to complete home practice.

Use of Google analytics was feasible to track patient adherence to meditation practice, and participants did not express difficulties with using an online platform. The relatively short time spent on average in meditation home practice sessions relative to the duration of the meditation intervention confirms that some participants may have chosen to download the Youtube file the first time they completed home meditation practice. This would prevent analysing the duration of meditation during subsequent home practice sessions. Use of weekly log sheets for all patients, including those who use online versions is also warranted to confirm meditation use in instances where downloading data may underestimate the frequency and duration of online sessions completed.

Qualitative data confirmed that transportation was a limitation for some eligible participants to program attendance. External funding or collaboration with the not for profit sector is required to enable participation for participants with limited transport options or financial limitations. Qualitative feedback also suggests that the private room used was suitable for most participants, however, in a larger study, efforts will be made to find a similar room that is closer to natural surroundings further away from the inpatient wards.

5.8.3 Timing

Meditation sessions were offered at 9am to accommodate the majority of patients who preferred to attend cardiac rehabilitation exercise classes early or for those with work commitments. It was also the optimal time slot to accommodate the needs of cardiac rehabilitation staff to ensure commencement of exercise for new patients between 7-9am prior to the exercise sessions for maintenance group patients. This time was also implemented to ensure that patients were not too relaxed and less motivated to complete their cardiac rehabilitation exercise session at the completion of their meditation session. However, qualitative data confirms that this did not appear to be a deterrent for those patients who completed their exercise session after attending weekly meditation practice. Qualitative participant and health professional data suggests that the optimal duration of meditation sessions in a larger trial design will maintain the 16 minute session format, with the total duration of the session, including introductory check in, not exceeding 30 minutes. This is considered respectful of participant's time, and will allow for the timely collection of outcome data.

5.8.4 Engaging diverse populations

Over half of adults living with heart disease who participated in this meditation study spoke a language other than English, or combined English with a second language at home. While adults living with heart disease with sufficient English literacy were able to use the English version of the DASS-21, use of the DASS-21 translations in their native language will enable better comprehension of question items, and reduced time to complete the questionnaire. In the absence of funding for the use of interpreter services, the use of Google translator will also be sufficient to enable basic understanding of key concepts in a larger study.

5.8.5 Intervention design

In a larger phase III trial, inclusion criteria will be refined to include adults living with heart disease who have experienced an acute or chronic cardiac event, including STEMI, NSTEMI, insertion of defibrillator or pacemaker, patients undergoing a PCI, diagnosed coronary artery disease and post

coronary artery bypass patients, in adherence with necessary modifications that occurred during this study. Given the ability to meet the recruitment rate, stricter exclusion criteria in a larger trial with a DASS-21 depression subscale score of ≥5 for all participants is warranted. Lack of significant change in depression scores may be attributable to experimental inclusion criteria, where patients with low or no depression were excepted where they had at least mild anxiety symptoms. It is possible that the HADS has increased sensitivity compared with the DASS-21, which is supported by its frequent use in clinical trials for assessment and treatment in the US[27]. HADS may be appropriate for use as an alternative measurement tool for primary outcomes in a larger study design.

A larger study will also allow for analysis of a third control arm, where those patients not electing to attend cardiac rehabilitation will be asked if they are willing to be contacted for 6 week and 3 month follow up. This will allow for better understanding of the effect of meditation compared to heart disease usual care.

5.9 Limitations

As part of being part of an intervention, both groups had interaction with study personnel in addition to the social environment of group exercise based cardiac rehabilitation exercise programs. Some participants became reluctant to complete intervention questionnaires at multiple time points. Whilst they complied with repeat questionnaires at intervention commencement the decision was made by the researcher to eliminate the six week completion of cardiac rehabilitation time point for those allocated in the intervention group. This was due to the completion of meditation after the completion of 6 weeks exercise based cardiac rehabilitation, which was the time point used for the 6 week post intervention follow up. In the current study, the mean time to completion of 6 week meditation and the differences between the 6 week follow up point are reported for the intervention and control group. This may have impacted on the results of the final analyses, with those in the control group who were assessed strictly at the 6 week time point having a better chance of determining the full benefit attributed to cardiac rehabilitation. In the intervention group, this benefit may have dropped off slightly given that exercise completed one or

two weeks prior for some patients. However, in this instance, the results demonstrate the capacity for meditation to sustain the benefits of exercise based cardiac rehabilitation on psychological health symptoms. In a larger study, a three month or 12 week follow up time point may be a better indicator of true between group differences. However consideration also needs to be given to the possibility of a false positive result for those patients who have been allocated to the maintenance program (continued exercise beyond the intervention period according to need). However, the number of patients attending maintenance programs was found to be similar between the intervention and control groups.

Limitations were also present in the subjective measurement of New York Heart Association functional classification, particularly between functional classes II and III[28]. However this was circumnavigated by referral of heart failure patients from heart failure clinical nurse specialists and the capacity for patients to undergo pre-exercise testing by completing a six minute walk test. Whilst peak V02 testing is advocated at pre-assessment, this was not available at the cardiac rehabilitation service where the trial was conducted. This was not considered to impact the main outcomes for this pilot study. However, in a larger study across multiple cardiac rehabilitation sites, pre assessment V02 testing will be used where this is usual care for functional exercise capacity (METS) testing.

Given the small numbers, we were not able to demonstrate an additional effect of meditation over and above the benefits of completing cardiac rehabilitation programs. However, what the data does indicate is that a greater proportion of adults in the intervention group adhered to cardiac rehabilitation compared with usual care. This is significant given that attendance at cardiac rehabilitation is known to be low. Integrating meditation into cardiac rehabilitation programs therefore has the potential to increase adherence to conventional recommendations for treatment.

5.10 Implications for research

This study was designed as a feasibility study to understand if meditation could be successfully integrated into existing cardiac rehabilitation programs. Further research in a phase III three arm

design to compare the effect of meditation in addition to usual cardiac rehabilitation, cardiac rehabilitation alone and standard hospital care without cardiac rehabilitation is required to understand the impact of meditation in heart disease secondary prevention. The transferability of this protocol to other cardiac rehabilitation settings is dependent on how cardiac rehabilitation services are provided and the staffing levels of each service. Programs that commence patients in blocks rather than patient driven entry points will be conducive to research in meditation and will not encounter difficulties in assessment time points encountered with continuous enrolment. However, it was considered unethical to delay the commencement of exercise based cardiac rehabilitation due to the established link between increased wait times with poorer adherence[29], poorer fitness[30, 31] and psychological health outcomes[32]. However, this meditation intervention is transferable to other cardiac rehabilitation settings. Previous experience with meditation practices or health professional qualification and willingness to establish a personal meditation practice and mentorship or training to successfully implement this protocol is advised. However, training in formal meditation practices, whilst helpful, is not a pre-requisite to implementing this meditation protocol as the depth of meditation practices contained in this study are light and produce nil to minimal risk of distress that might occur with deeper analysis in cognitive mindfulness based practices or deeper forms of meditation practice. There is also a need for cost-effectiveness analyses of meditation in heart disease clinical settings in a larger study design. While this meditation intervention did not incorporate patient co-design, which is an important element of clinical trial design, participant perspectives with respect to intervention timing, delivery, adherence, and the inclusion of people who are from non-English speaking backgrounds will be integrated into the design of a future fully powered RCT.

5.11 Ethical approval and trial registration

This study was registered with the Australian and New Zealand Clinical Trial Registry (ANZCTR: U1111-1213-2716). Ethical approval was obtained from Western Sydney Local Health District (HREC: AU/RED/HREC/17/WMEAD/495) and ratified by the University of Technology Sydney UTS-18-2337)

5.12 Conclusion

This study confirms the feasibility of a larger multi-site phase III trial to determine the benefits of meditation for the reduction of depression and anxiety symptoms over and above the benefits of cardiac rehabilitation programs. Next, chapter 6 contains Study 4, a descriptive qualitative study of health professionals involved at all levels of heart disease care who will be involved in the meditation integration process. Study 4 will identify the barriers and facilitators that affect meditation's integration into heart disease care.

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Chapter 6 Study 4: 'Dipping the toe in but not ready to jump': Health professional perspectives of integrating meditation into routine heart disease care

6.1 Preface

Chapter 5 reported the results of a phase II RCT of a meditation intervention for the reduction of depression and anxiety symptoms in people living with heart disease. Results suggested that meditation delivered in the cardiac rehabilitation setting was considered to be feasible and acceptable to people living with heart disease and health professionals. This phase II RCT also found that meditation may improve participant attendance and adherence to conventional exercise based cardiac rehabilitation programs. This chapter presents the findings from semi-structured interviews with health professionals. These interviews explore the feasibility and acceptability of integrating meditation into routine heart disease care and the organisational factors that may affect this integration. Understanding health professional perspectives of the feasibility and acceptability of meditation will contribute to informing the design of a future phase III trial.

6.2 Introduction

Depression in adults living with heart disease is at least twice as prevalent as that experienced by the general population[1] . Moderate depressive symptoms are experienced by 15% of adults living with heart disease[2]. The interplay between sub-optimal psychological outcomes and cardiovascular risk remains poorly understood[3]. However, the role of health professionals in the identification of psychological risk and support of concurrent self-management strategies is recognised[1]. There is also growing acknowledgement of the importance of non-pharmacological therapies, such as Cognitive Behavioural Therapy[4], collaborative care, and exercise-based cardiac rehabilitation[5] programs in supporting psychological health in adults living with heart disease[1, 2, 6]. The recently revised American Heart Association Meditation and Cardiovascular Risk Reduction scientific statement adds significant support to the use of meditation as a primary and secondary preventative heart disease strategy[7].

Despite this endorsement, there is little evidence of its effectiveness or how to successfully integrate meditation into usual clinical heart disease care.

Integrating meditation into heart disease care is a complex social process that is interconnected with the context where it takes place[8].

Context is important, as it encompasses a myriad of unique factors such as a provider's perception of the evidence supporting an intervention, local and national policies describing how to integrate the intervention within existing health organisations and health systems, and attributes of the individuals involved in the implementation process[8]. The World Health Organisation Innovative Care for Chronic Conditions Framework[9] provides a theoretical framework for the consideration of contextual factors that impact on the capacity of an organisation to integrate mediation into heart disease care. Exploring the perspectives of health professionals involved in the prevention and management of heart disease is therefore essential to understanding the organisational and systems-level factors that impact on the integration of meditation within usual clinical care[10].

6.3 Objective

To investigate health professionals' perceptions of integrating meditation into secondary prevention heart disease care

6.4 Methods

6.4.1 Study Design

Descriptive qualitative study, using semi-structured interviews. Reporting of this study adhered to the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist[11]. The methods for this study are reported in Chapter 4.

6.5 Findings

Of the 48 eligible participants contacted, 18 health professionals consented to be interviewed. Reasons for non-participation included non-respondents (n= 22), scheduling difficulties (n= 4), time constraints (n=1), or the topic was considered to be outside their area of specialisation (n=1).

Participants were predominately female (n= 11; male n= 7), and aged between approximately 40 and 60 years. Participants included: nurses (38%), medical doctors (28%), allied health professionals (17%), and individuals in health management roles (17%). These participants were from a wide variety of practice settings and locations across NSW, Australia and overseas. The average duration of each interview was 49.6 (SD± 19.5) minutes.

Three key themes were generated from the data: i) Convincing the establishment; ii) Building the evidence for meditation in heart disease care; and iii) Finding an organisational fit for meditation in heart disease care. These themes, subthemes and concepts are described in Table 6.1, and are discussed along with relevant supporting quotes in the following section.

Table 6.1: Development of themes, subthemes and concepts

Theme	Subtheme	Concept
Convincing the establishment		Role of medical training on a siloed approach to care
		Perceived vested interest in maintaining biomedical health structure
Building the evidence for meditation in heart disease care		Perceptions of the role and value of meditation
	Perceived lack of evidence	Preliminary evidence and acceptability
		Devaluation of meditation
		Need for definitive evidence
Finding an organisational fit for meditation in heart disease care	Driving organisational change	Top down, bottom up approach
		Finding mutually beneficial outcomes
		Justifying resource allocation
	Integrating meditation into secondary prevention pathways	Lack of a meditation referral pathway
		Meditation guideline development
	Accreditation or training to facilitate meditation referral	

6.5.1 Convincing the establishment

Meditation was perceived by participants to sit outside the existing health service operating parameters that prioritises the delivery of evidence-based medical care. Participants suggested that the current siloed health care system reflected the historical and deeply embedded bio-medical disease model of care that continues to operate within many areas of specialist health care.

> *…but I think you know, it is about the system and the way it has evolved. It has become so siloed. You know the fact that we're siloed between the physical health streams, to then take that leap and join up physical and mental health is another. You know, it is a big piece of work. Doesn't mean it shouldn't. You know, it's got to happen (Participant 002).*

Consequently, the current health care structure was not geared to adequately identify and address the psychological support needs of increasingly complex patients, like people living with heart disease. It was suggested that there was still a significant way to go in convincing many health professionals of the link between psychological health and heart disease outcomes.

> *Not so much I think because that they didn't see the importance (of meditation), but it was more that they didn't understand the importance, and it really comes out of their training…. I think it comes back to the training that people receive as they go through medical school. But I see that changing (Participant 001).*

Many suggested that self-management action plans and ongoing support were perceived to be outside the scope of usual medical care. In part, they attributed the current focus on acute care to medical education and training programs that reinforced hegemony. The unintended consequence of conventional medical education and training was that it limited medical professionals' ability to conceptualise meditation as an integrated element of self-care.

> *You know, I definitely think there is a part of the medical community that sort of disregards that area because it's non-pharmacological, which is sort of sad, but*

that's the reality…so you know I think sort of the barriers are convincing clinicians that these interventions do help the patient (Participant 012).

Participant's suggested that there was vested interest in maintaining the structure of health service delivery for the promotion of medical care, which was not inclusive of meditation.

I think there's a lot to be said for meditation and Pilates and indeed yoga…but we get structured by our AMA (Australian Medical Association) friends I suspect, and some old thinking (Participant 016).

Participants acknowledged that the closed hierarchical structure of cardiovascular health care was largely driven by the medical profession which made it difficult to promote non-pharmacological interventions and develop new and innovative models of care.

And I think especially for non-pharmacological interventions, we don't really have this strong (incentives) for implementation …For example with drugs you have drug representatives knocking on the doors…but for non-pharmacological interventions, for example, exercise, even if we know it's effective, it's harder to implement than providing a beta-blocker or some other new medication. So, I think you need to be aware of the hidden barriers there are with non-pharmacological interventions treatment in general (Participant 009).

The above excerpt highlights some participants' perspectives of the potential role of financial incentives in enabling cardiologists to prioritise pharmacological treatments. That is, opportunities were available for cardiologists to receive funding or other subsidies to test pharmaceutical drugs that were not as readily available for the testing of non-pharmacological interventions, including meditation.

We're just finding at the moment that there's you know, it's quite challenging to get new services up and running. But… you know. The bean counters at the

hospital are sort of mindful of how much funding is being generated for how much investment in terms of staff and other resources… (Participant 015).

Health executives were also incentivised to prioritise medical therapies that attracted government funding for the organisation. A direct result of funding limitations was an organisational culture that limited opportunities for allocation of resources or time to support the implementation of meditation programs.

Given this reality, there was still quite a long way to go to convince 'the establishment' that meditation had a primary and secondary role to play in heart disease care.

6.5.2 Building the evidence for meditation in heart disease care

Participants' were divided on the value and role of meditation, which was largely due to their perceptions about the level of evidence and the relative importance that evidence plays in patient decision making.

Some participants perceived that meditation had a role to play in heart disease secondary prevention because of the positive effects it had on adults living with heart disease, particularly those who were open to using meditation. These participants identified meditation's feasibility, given that it was a low cost and relatively safe non-pharmacological strategy.

…many people attribute their heart attack or heart disease to stress… So people are actually quite receptive to a (meditation) technique. And you know there are a lot of non-pharmacological techniques where the evidence is not very strong but the uptake is high (Participant 005).

Others considered the perceived benefits derived from meditation were more subjective benefits rather than objective, as exemplified in this quote.

If they think it would be of benefit to them, who am I to say that it won't? It's a bit like when patients come to me with 'natural therapies'. I know nothing about

what they are doing with their 'natural therapies' and I say 'As long as you don't stop taking my pills…' (Participant 008).

Other participants either doubted that meditation could tangibly improve patient outcomes, or considered that meditation was a bit too 'out there'. Many considered that there was insufficient empirical evidence to support its integration in heart disease care. While a proportion of participant perceptions were determined by the value they placed on different types of meditation and its supporting evidence.

…but you know…would you recommend something like transcendental meditation, which has very limited research over a MBSR (mindfulness based stress reduction) based approach which has a huge body of literature that supports it (Participant 001).

Some participants were more likely to endorse and implement mindfulness or Mindfulness Based Stress Reduction techniques due to greater perceived acceptability and the widespread adaptation of mindfulness based practices into Western clinical settings. These participants relied on the positive findings from preliminary studies to support their views about the role of meditation in secondary prevention, while others were much more hesitant.

…I would hypothesize that it (meditation) can help people be better able to regulate their emotional reactions to situations. So it improves emotion regulation. It clearly helps to evoke the relaxation response in the body…However, I can't say that I absolutely know for sure that I know that is the situation (Participant 018).

Some participants were reluctant to make definitive conclusions about meditation's efficacy because of reputational risk and uncertainty as to whether promoting meditation was a clinical responsibility.

And my challenge has been, because I'm not an expert in that field (meditation), so if you go in and look into the literature, it seems a bit of a hodgepodge. So you have mindfulness-based, and you have meditation, and you have other things that I may not even know about (Participant 007).

Other participants highlighted inconsistencies in meditation research that reduced health professionals' capacity to evaluate meditations' efficacy within and across different meditation traditions. This created ambivalence about the value of meditation in clinical practice.

Perceived lack of evidence

The majority of participants were not ready to openly endorse the broad implementation of meditation practices in heart disease clinical care because they perceived that meditation is not underpinned by high level evidence. Additionally, some participants were uncertain about the level of the existing evidence.

So if you want it (meditation) funded by government, you need really good evidence that it does something… mostly that evidence is not there, and it is not universally true …the amount of evidence that meditation actually makes a difference is pretty low. (Participant 003).

The perception of a lack of evidence to support prioritisation of meditation within clinical care leads it to being devalued as a primary or secondary prevention strategy. This perception was both enhanced and driven by government funding bodies which did not support meditation research and practice.

So they might say the same thing about meditation, well what's the problem for the patient not to be exposed to meditation. What evidence can you show us that if we change things, things will improve for either the patients or the profession?

Data, give us data, that's the other thing they will want. Evidence. And without that, you can't move (Participant 002).

As participants operated within a culture of evidence based practice, all of their clinical decisions were informed by the available evidence, patient preference and their own clinical experience. To translate meditation research into practice, participants suggested that effectiveness and efficacy data from adequately powered phase III randomised controlled trials was required to change their practices. The above excerpt implies that self-report of positive meditation outcomes in clinical research that focused on patient reported outcomes was perceived to be less definitive.

6.5.3 Finding an organisational fit for meditation in heart disease care

Successfully navigating organisational change was required to find a fit for meditation within the current structure of health service delivery. Participants described the key facilitators for integrating meditation into heart disease care as i) aligning with health organisational objectives and ii) integrating meditation into secondary prevention pathways to create opportunities for meditation programs.

Driving organisational change

Successfully influencing health executives by operating within the health organisational structure was required to create a fit for mediation.

…if it is a radical departure from how things are being done, then unless you start from the top down, it's going to be enormously difficult. Or you start from the bottom up, you wait for 20 or 30 years until those people then, hopefully you've survived, and find this valid….. I think that that is important, but I think the other approach is the drip approach, where they have some personal experience, they have patients who do this, and clearly derive some benefit. And this happens often enough (Participant 001).

An integrated approach encompassing top down executive support was required to drive organisational change, yet health professionals perceived that their relative influence was small. Health professional driven bottom up change at the point of care was also described as necessary, and enabled some participants to work quietly within their scope of practice whilst not compromising the integrity of their primary role.

> *There is definitely a lot more accountability, and a lot emphasis on trying to eliminate variation in care, and a lot of it's based on readmissions, information that's provided to people before they leave hospital. They're really big on trying to decrease readmissions, they're really big on trying to improve quality of life, they're really big on patient experience* (Participant 014).

> *I think the best funding source there would be, in the area of mental health, which is a very, very popular area funding at the moment in the current landscape...I think there is a lot of opportunity from government to get funding because it will increase productivity in the workplace. And reduce hospital admission times and all sorts of things. So the government will be approachable* (Participant 012).

Participants suggested that a multi-strategy approach was required to generate health organisations support for the integration of meditation programs into existing services. These strategies included: identifying mutually beneficial outcomes between the meditation service provider and the relevant health organisation, such as couching meditation within state government mandated key performance indicators (KPIs), and promoting meditation within a person-centred model of care or for mental health. Participants implied that health executives could be motivated to support meditation as a part of addressing KPIs and had some flexibility as to what strategies could assist this process.

> …having a very strong structure, you can then, have the freedom to actually do a lot of- do lot. But you need an organization that supports it. Without an organisation... you're not going to get very far (Participant 004*).*

Participants described a safety net that is inherent in a large organisation, which could provide support for meditation where services provided aligned with the goals of meditation. Participants perceived it as essential to understand and function within clearly delineated roles in order to successfully integrate meditation within existing departments and programs. Resource allocation was also discussed.

> *So, if you went at it from those angles, putting together, some sites won't look at anything unless you've got a business case. And evaluation is the other thing, so most places will want to know what your evaluation strategy was. What would be your metrics, what would be your evaluation strategy?* (Participant 014)

Participants generally considered the need to justify allocating resources to establish meditation programs. These participants perceived that demonstrating the potential for meditation programs to reduced health expenditure was required to generate executive support for meditation.

> *And obviously if there's (Activity-based funding) attached to that then that strengthens the case. In the public health system it's the way the hospital gets income from the government for the work that it's doing and the services that it's providing for patients (Participant 015).*

Understanding the language and internal processes of health organisational operating systems for resource allocation were important facilitators to leveraging health organisational resources. Sustainability of meditation programs and increased funding for the organisation through numbers of patients serviced were strong incentives for health organisational change.

Integrating meditation into secondary prevention pathways

Cardiac rehabilitation was identified by the majority of participants as the best fit for the delivery of meditation programs within the heart disease care trajectory. The creation of secondary prevention pathways for meditation was perceived to better enable adults living with heart disease to become aware of and access meditation within cardiac rehabilitation programs.

> *…And I thought it was interesting because it (Heart Foundation Survivor survey) doesn't look at meditation, but it talks about stress management. And it's (stress management) actually a part of the cardiac rehab program. Now I don't know what that looks like…So again, what strategies they used for that I don't know, but, you know that there's a place for it in there… (Participant 002).*

Participants identified the potential to incorporate meditation within the stress management component of cardiac rehabilitation service delivery. However, the extent to which stress management techniques were applied across different clinical settings was unknown, and implementation was left to the discretion of the health professional. Other participants focused more on the potential role of meditation for depression in cardiac rehabilitation programs.

Many participants also identified that there was no existing pathway for referral for meditation programs within heart disease secondary prevention.

> *But I think you need to streamline the path of entry. I don't know where you would refer patients for this sort of thing. And I'll be really frank with you. If I don't, the chances are that a lot of people don't… (Participant 008).*

Reduced prioritisation of non-pharmacological approaches to heart disease secondary prevention, including cardiac rehabilitation, was perceived to underpin the lack of existing referral pathways for meditation within heart disease clinical care.

I mean it's not something that perhaps is considered a core component of cardiac rehabilitation- but yeah it probably is seen as, you know, perhaps a bit of an add-on....That's not to say that you couldn't change that perception. But I would say that at the moment it's not seen that way…I think if you know if it's seen as an essential component then it would be promoted to patients more strongly and they would be more strongly encouraged to get involved (Participant 015).

Whilst the majority of participants supported the introduction of a referral pathway for meditation, lack of inclusion of meditation within cardiac rehabilitation guidelines was perceived to drive health professional reluctance to refer patients to meditation.

…I mean it's making it available and having enough of the clinicians being prepared to refer. You know, and not say 'whatever you do, do not go down there' kind of thing (Participant 003).

Other participants highlighted the need to reduce health professional misconceptions about meditation to facilitate referral. Opportunities for community referral were also discussed.

So I think getting support across the health care team, particularly I think within general practice is something to think about as well. Because what you've got to remember is that you know about that's where the majority of care happens in primary care, essentially engaging practice nurses and general practitioners. Or just letting them know about the techniques and the purpose might be useful (Participant 005).

Participants identified the appropriateness of community referral to meditation programs due to an increasing emphasis on outpatient services and continuity of care. Strategies to facilitate meditation implementation within cardiac rehabilitation were also addressed.

So it is about you know getting, you know, people within the system on side. Because when you try and do it from the outside…even as the (a Non-Government Organisation) we are sort of on the outside, because there's the Cardiac Society, the College of Physicians, we sit outside that, so you kind of need to have people on the inside who are chipping away internally (Participant 002).

Some participants recognised the potential to collaborate with peak bodies to generate support for research and practice that would enable the positioning of meditation within national cardiac rehabilitation guidelines.

Accreditation or training to facilitate meditation referral

Participants' perspectives on formal accreditation and training were divided into two groups: those who recognised the role of formal accreditation and training in facilitating referral to meditation; and those who perceived that health professional experience in meditation practices was sufficient to ensure competence in delivery.

I would suggest that we would be more comfortable if they had some form of credentialing. You know, if someone, if a service provider sort of came on recommendation and they didn't have credentialing then that might be acceptable. But you know if they had neither and we really didn't know much about the veracity of the service they provide, we would probably be a little reticent to refer. And that's fairly consistent with referral to other service providers as well (Participant 015).

Meditation was perceived by the majority of participants be underdeveloped as a professional practice. Lack of widespread formal accreditation processes and responsibility to fulfil a duty of care underpinned the need for discernment when accepting referrals for meditation practitioners.

…there are a number of health professionals, psychologists or psychiatrists, or social workers, who might have done, gone to a day workshop, and think yeah

yeah, I get it, and then, they start teaching it, or teaching what they think is the practice, and it's actually counterproductive (Participant 001).

The need to maintain integrity and build the credibility of meditation practices in health care was a driver for some participants' expression of caution with respect to adequate health professional training. What constituted adequate training in meditation was also discussed.

…so I would say if someone's got their own regular practice that they've had for several months and they are willing to sort of follow a standardized protocol which we know is safe, then they are the best people to do it (Participant 018).

Some participants perceived that a formal qualification in meditation alone did not guarantee the necessary competence in implementing meditation practices, rather that mentorship and sustained personal meditation practice was needed. Protocols in clinical settings were favoured in order to maintain duty of care to the patient.

6.6 Discussion

As the first Australian study to explore health professional perceptions of the barriers and facilitators to implementing meditation in heart disease clinical settings this study has highlighted the importance of building the meditation evidence before proceeding to implementation. It is evident that it will be challenging to fully embed meditation into heart disease care without substantive effectiveness evidence. Despite meditation being recommended in the American Heart Association guidelines, there is still a need for definitive phase III meditation trials to increase health professionals' support for meditation practices, which is consistent with previous systematic review findings[7, 12, 13]. While most health professionals considered meditation was a useful self-management strategy that supported behaviour change, particularly in adults who identified the role of stress in heart disease, the lack of evidence presented a barrier to integrating it into routine heart disease care.

Without sufficient evidence it was also evident that meditation would not be afforded priority within the existing dominant biomedical model of care focused on curative outcomes. The low priority given to meditation in the acute health care setting is not surprising when there are currently consistently low cardiac rehabilitation referral and participation rates[14, 15] and physician referral predicts cardiac rehabilitation attendance[16]. Findings suggest that some medical professionals have a vested interest in maintaining the current health service delivery status quo. However, there are other medical professionals who support meditation as an adjunct approach to care, yet are limited in their roles to implement meditation practices.

The WHO Innovative Care for Chronic Conditions Framework describes the need for health organisations to provide the necessary tools and training to enable health professionals to engage in productive interactions with adults living with heart disease that facilitate self-management and health behaviour change[9]. Current findings suggest that the majority of health professionals are open to exploring future research and practice in meditation as a secondary prevention strategy for adults living with heart disease. Health professional education on the role of meditation in heart disease care after a cardiac event is required to reduce any misperceptions on what meditation can and cannot do for adults living with heart disease. Caution is needed to avoid endorsing meditation practices as a 'panacea'[17] for the complex interplay of physiological factors involved in heart disease maintenance. Rather, information about the value of meditation to conventional care to better promote adherence and alleviate psychological stress is warranted.

Health professionals and meditation practitioners need to affiliate with national accreditation bodies to improve the minimum standards of experience and training required to implement meditation in heart disease clinical care. Care needs to be taken within the framework of accreditation for meditation practitioners to value the experience and skills of health professionals or others within the health system from a range of meditation traditions. Practitioners need to adapt meditation to simple practices that are evidence based and appropriate for use within the heart disease clinical context. Mindfulness[18] or Mindfulness Based Cognitive Therapy (MBCT) [19] guidelines could assist

secondary prevention specific meditation training and implementation within heart disease clinical care.

Information systems that facilitate referral of adults living with heart disease to meditation programs to support self-management are currently not in place in heart disease care. Changes in delivery systems design[20] could involve strengthening secondary prevention pathways that are inclusive of meditation and psychological health within cardiac rehabilitation programs. A consensus process is required to understand how to best guide the development of a referral pathway for meditation practitioners within the existing pathway of heart disease clinical care in Australia. Aligning with the relevant heart disease national organisations and promoting meditation research and practice within these organisations, including meditation guideline development, is considered essential to driving the case for meditation as a secondary prevention strategy within heart disease care. Leveraging support for meditation from open-minded cardiologists involved with external organisations is required to create opportunities to increase the focus on secondary prevention, including meditation, and directly influence patient care at a higher level.

Current findings suggest that generating evidence of cost-effectiveness is required to promote the sustainability of meditation programs for adults living with heart disease that are delivered in clinical settings. Provider incentives are required for health organisations to build the evidence for meditation and to promote its integration as an innovative strategy to support self-management[9]. To find a fit for meditation within the current health service model, health professionals need to demonstrate that meditation addresses key performance indicators, and can be presented in a business model that evaluates cost-effectiveness. Utilising a health services framework for implementation and evaluation could be a means of demonstrating sustainability in a collaborative approach to care[17].

6.7 Limitations

Purposive and convenience sampling approaches may introduce a self-selection bias, thereby reducing generalisability to the national heart disease clinical care population. Further research into heart disease clientele perspectives of the relevance and barriers and facilitators to meditation use in heart disease secondary prevention is warranted.

6.8 Conclusion

Health professional engagement and support at the clinician, health organisation and health systems levels is required to better establish the role and relevance of meditation in heart disease secondary prevention settings. A definitive phase III trial is required to establish the evidence for meditation in heart disease secondary prevention and to promote uptake, including the evaluation of cost-effectiveness and sustainability.

This chapter highlighted the need to identify strategies to generate health professional support for meditation research and practice to better meet the needs of adults with heart disease and comorbid depression and anxiety symptoms. Chapter 7 reports the final discussion chapter, including data integration and meta-synthesis of the results of Studies 1, 2 3 and 4 to generate recommendations for meditation research and practice (next steps) and will highlight considerations for the design of a future phase III RCT.

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Chapter 7 : Data integration, recommendations and conclusion

7.1 Preface

The MENTOR Project has identified the importance of understanding the psychological health status of people living with heart disease and suggests that integrating meditation into cardiac rehabilitation programs may help improve adherence to cardiac rehabilitation program behavioural change and life-style recommendations. In Chapter 2 the longitudinal cohort study (Study 1) set the scene for the MENTOR Project by identifying that a fifth of people living with heart disease experience poor psychological health. Study 1 highlighted the negative impact that depression, anxiety and stress have on people living with heart disease and their ability to adhere to cardiac rehabilitation programs following an acute cardiac event. The systematic review (Study 2) presented in Chapter 3, revealed that there was currently no phase III evidence that meditation reduces depression and anxiety symptoms in people living with heart disease[1, 2]. The design and conceptual frameworks underpinning the mixed methods MENTOR Project were described in Chapter 4. The interim results of the phase II randomised controlled trial of a meditation intervention for people living with heart disease with moderate depression and anxiety symptoms who are participating in a cardiac rehabilitation program (Study 3) were presented in Chapter 5. While no statistically significant between-group differences were found due to the small sample size of the preliminary phase II RCT results, there is evidence that integrating a meditation intervention into a cardiac rehabilitation program is: a) feasible with timely recruitment; b) acceptable to people living with heart disease; and c) likely to increase cardiac rehabilitation program participation and adherence with secondary prevention strategies. Chapter 6 presented the findings of semi-structured interviews (Study 4) with health professionals, which identified multiple facilitators and barriers to integrating meditation into secondary heart disease prevention at the patient, provider and systems levels.

This final chapter integrates the data from these four studies into a meta-inference in order to answer the MENTOR Project's five research questions. To illustrate the connections between the

quantitative results and the qualitative findings, joint display tables[3] are used to answer the research questions I to IV. Findings from the meta-inference are then used to generate a series of recommendations related to the integration of meditation into heart disease care, thereby answering research question V.

7.2 Findings

7.2.1 Research Question I: What is burden of moderate depression and anxiety symptoms in people living with heart disease attending cardiac rehabilitation programs?

Data from Studies 1, 2 and 3 were integrated to answer research question I.

Prevalence of depression and anxiety symptoms

The MENTOR Project found that people attending a cardiac rehabilitation program in one local health district in NSW, have: higher rates of moderate depression and anxiety symptoms; and that the severity of their symptoms is higher[4] than that reported by Australian and US populations[5, 6]. These findings are consistent with the international literature, which suggest that major depression is experienced by up to one fifth (15-22%)[7-11] of people who experience a cardiac event, while one third (37%)[12] also experience anxiety disorders.

Correlates of depression and anxiety symptoms

The Project participants were more likely to be: older working aged married men with a university degree[13]. This demographic profile is comparable with the general cardiac rehabilitation population[14]. While the study could not confirm the proportion of people living with depression and anxiety symptoms from culturally and linguistically diverse backgrounds in the longitudinal cohort, 58% of participants in the MENTOR Project's phase II RCT had a language other than English as their first language.

The cardiac rehabilitation participants with depression and anxiety also had a higher prevalence of cardiovascular risk factors, including: being overweight or obese; sedentary lifestyle patterns[15, 16]; and reporting a lower quality of life[17, 18] compared to the general population. A higher proportion of cardiac rehabilitation participants who were depressed had survived an acute myocardial infarction which is similar to the broader cardiac rehabilitation population[14].

Predictors of moderate depression and anxiety symptoms on entry

In the MENTOR project, anxiety and stress were the strongest predictors of moderate depression in people living with heart disease. Having anxiety and stress symptoms increased the risk of moderate depression on entry into cardiac rehabilitation programs by more than four times[13]. Symptoms of depression were also found to be a strong predictor of anxiety, which is consistent with the general heart disease population[19]. The burden of anxiety in heart disease is known to be significant as it has been found to predict incident coronary heart disease and cardiac mortality in healthy adults[20].

7.2.2 Research Question II: Does completing cardiac rehabilitation programs reduce depression and anxiety symptoms?

Data from Studies 1 and 3 were integrated to answer research question II.

The MENTOR Project confirmed that cardiac rehabilitation contributes to modest reductions in depression and anxiety symptoms[21]. It has been suggested that anxiety symptoms may be more amenable to change compared with moderate to severe depressive symptoms in exercise based cardiac rehabilitation programs[22]. This could be due to the opportunities provided in cardiac rehabilitation programs for people living with heart disease to attain performance mastery over activities, such as treadmill exercise[23], which may decrease anxiety and apprehension about their exercise capabilities[24] and their risk for a recurrent cardiac event[25]. People living with heart disease who have depression may perceive an inability to attain highly desired outcomes, such as exercise mastery or returning to usual activities, which may lead to despondency, self-deprecation and hopelessness about the future[25]. Monitoring depression and anxiety symptoms on entry and during

cardiac rehabilitation programs is required to optimise self-efficacy and self-management capabilities. Given the high prevalence of depression and anxiety, the integration of psychological support strategies in cardiac rehabilitation programs is warranted.

7.2.3 Research Question III: Do depression and anxiety symptoms affect adherence to cardiac rehabilitation programs?

Data from Studies 1 and 3 were integrated to answer research question III.

There is evidence that one quarter (28%) of people with depression and anxiety symptoms who commence cardiac rehabilitation in NSW withdraw from the program[13]. These cohort study and phase II RCT results confirm the association between depressive symptoms and high cardiac rehabilitation non-completion rates found in the US [26]. The association between anxiety symptoms and dropout from cardiac rehabilitation programs is also confirmed the same US study where withdrawal rates were higher in those with anxiety after an initial psychological assessment[26]. However US Medicare beneficiaries with major depressive disorder have been found to have higher cardiac rehabilitation completion rates[27].

Similar to the international evidence, the MENTOR Project also had high non-completion rates. The Project's high withdrawal rates reflect that people living with co-morbid depression and anxiety are more likely to have reduced perceptions of self-confidence and report lower levels of general activity[28, 29]. Depression is also associated with reduced exercise self-efficacy,[30] while anxiety contributes to lower self-efficacy expectations, which has been correlated with reduced activity levels[31] in people living with heart disease. Inaccuracies in illness perceptions are also associated with higher emotional distress (arousal), limited belief in the ability to reduce the risk of a future cardiac event and increased perceptions of their need to restrict activities[32], which likely includes exercise based cardiac rehabilitation. Novel strategies are required to support people with depression or anxiety symptoms to complete cardiac rehabilitation programs, yet may not provide an additional benefit for those with depressive disorders[27].

7.2.4 Research Question IV: Is it feasible and acceptable to integrate a meditation intervention into an existing cardiac rehabilitation program as a strategy for reducing depression and anxiety symptoms in people living with heart disease?

Data from Studies 1, 3 and 4 were integrated to answer research question IV.

The interim results from the MENTOR Project's phase II RCT supports emerging evidence that integrating meditation into cardiac rehabilitation is potentially feasible and acceptable to people living with heart disease as detailed below (refer Appendix 8 – joint display tables).

Feasibility

The MENTOR Project's interim results demonstrated a feasible screening to recruitment rate, with one fifth of all eligible people living with heart disease randomised to the phase II RCT. The screening to randomisation ratio was 1:8, suggesting that it will be feasible to recruit eligible participants into a future phase III meditation trial. These interim results also suggest that depression and anxiety symptoms did not deter all people living with heart disease from participating in a meditation intervention. Better understanding of the degree to which self-efficacy[33] impacted on participation rates is an important consideration for any future meditation trials in this population.

Recruitment rates in future trials could be increased further if known psychosocial barriers[34] to cardiac rehabilitation participation such as timing and location of the meditation sessions for people with work, family commitments and/or poor access to transportation are addressed.

Overall, one third of the phase II RCT trial participants did not complete the intervention. These non-completion rates are higher when compared with mindfulness based interventions involving non-cardiac populations (15%)[35], yet lower when compared with completion rates in mindfulness based interventions addressing mental health, which vary between 39.5-92%[36].

Integrating meditation into an existing cardiac rehabilitation program appears to have increased cardiac rehabilitation attendance and meditation practice at home, which is a positive finding, given

that completion of cardiac rehabilitation programs is known to be low[37, 38]. These preliminary trial findings support existing evidence that relaxation training, that more broadly encompassed meditation, significantly increased cardiac rehabilitation program adherence in a US population[39]. Meditation appears to be a feasible and acceptable self-management strategy that facilitates better adherence to secondary prevention recommendations. The mechanisms leading to this outcome are poorly understood[40], but may be related to meditation's relaxation effect, providing an empowering experience that increases people's self-efficacy and belief that they can take positive action to avert further heart disease events and/or damage[41].

It is also possible that people with moderate depression and anxiety symptoms who are willing to participate in a meditation intervention reflect a sub-group of people who although have poorer mental health status have positive health help seeking behaviours[42]. Positive perceptions of the benefits of a meditation intervention might also be attributed to a desire to counter hopelessness by engaging in a novel strategy[1, 41]. Another possible explanation is that referrals in accordance with national and international cardiac rehabilitation guidelines[43] are likely to produce the greatest benefit and reflects a good use of available cardiac rehabilitation resources because they target people living with co-morbid depressive symptoms.

Acceptability

The MENTOR Project found that people living with heart disease considered a meditation intervention acceptable in the cardiac rehabilitation setting. While there is no available level I evidence of meditation's effectiveness in reducing depression and anxiety symptoms in people living with heart disease, emerging Phase II trial evidence suggests that meditation reduces depression and state anxiety symptoms[1, 44]. However, there is less evidence that meditation reduces trait anxiety. Meditation is perceived by people living with heart disease and health professionals as an acceptable strategy to support mental health, which is consistent with the findings from previous systematic reviews[36, 44, 45] and meta-analyses[46]. People living with heart disease were also confident

in recommending meditation to others, while health professionals considered the risk of adverse events to be low, which made integrating meditation into existing cardiac rehabilitation programs acceptable, if there were sufficient resources.

The National Health and Medical Research Council of Australia has prioritised mental health for the allocation of research funding[47], which lends support to conducting meditation research that focuses on depression and anxiety symptoms in people living with heart disease. The MENTOR Project findings suggest that integrating meditation into heart disease care may reduce depression and anxiety symptoms and is likely to improve this populations self-efficacy and self-management capabilities, including adherence to cardiac rehabilitation programs and recommended lifestyle changes[48].

However, the MENTOR Project confirmed what is widely known that health services continue to prioritise acute episodic care over more integrated chronic care models[49, 50]. Health executives required convincing of the need to prioritise integrated models of care that are inclusive of mental health and meditation, and health professionals who perceived that meditation lacks evidence were unlikely to change their perspectives without definitive evidence from a phase III trial. Focus on managing acute presentations over a preventive approach also presented a barrier to integrating Mindfulness Based Cognitive Therapy within the UK National Health System[50].

Identifying mutually beneficial outcomes

The MENTOR Project recognised that demonstrating cost-effectiveness and aligning meditation with health organisation mandated key performance indicators, such as improving people living with heart diseases' experience of health care and quality of life, is required to integrate meditation into heart disease care. Structuring quality improvement efforts in alignment with organisational goals, for example by improving patients' experience of health care[51] may counter barriers presented by organisational agendas that base decision making on output, performance, and short term outcomes[50]. Having an organisational strategic plan for Mindfulness Based Cognitive Therapy

implementation has also been positively correlated with widespread availability of Mindfulness Based Cognitive Therapy services; support for practitioners in terms of training, supervision, and dedicated time for implementation; sufficient and appropriate referrals; adequate understanding of Mindfulness Based Cognitive Therapy techniques by those who referred patients; and sufficient administrative support and physical space to implement mindfulness practices[50].

Integrating meditation into secondary prevention pathways

The MENTOR Project found that there is no existing pathway to refer people living with heart disease to meditation programs, which is consistent with the literature[50]. Health professionals recognised cardiac rehabilitation as the ideal forum for promoting meditation in heart disease care. Meta-analyses and international guidelines have also recognised cardiac rehabilitation as suitable for the integration of psychological health within heart disease secondary prevention[52, 53]. In the MENTOR Project, community based meditation programs are recognised as an option to promote continuity of care for people living with heart disease who require ongoing psychological health support on completion of their cardiac rehabilitation program. Both health professionals and people living with heart disease recommend providing opportunities for cardiac rehabilitation activities, including meditation outside of working hours to facilitate better attendance and engagement. Community based meditation programs might be one way to address this need (whereas cardiac rehabilitation exercise programs only open between 7am and 3pm), and is supported by the American Heart Association Scientific Statement for meditation's integration within both primary and secondary heart disease prevention[44].

Meditation intervention design and delivery

With respect to meditation intervention design and delivery, the MENTOR Project found the ideal duration of meditation practices to be approximately 15 minutes per session. Successfully modifying meditation practices for people living with heart disease or in cardiac rehabilitation programs requires consideration of the ability of beginners in meditation practices to maintain their

concentration, participant and cardiac rehabilitation program related time limitations and participants' physical conditions and cardiac symptoms. For example, a small number of people living with heart disease who may experience difficulties in adhering to deep breathing practices likely require additional reassurance. The use of online technology was considered acceptable to both health professionals and people living with heart disease as a self-management adjunct that supports greater adherence to meditation practices delivered in cardiac rehabilitation programs that includes a home practice component, which is consistent with the literature[36].

Psychological health assessment

One fifth (19%) of baseline psychological health (DASS-21) data was missing for all cardiac rehabilitation participants, suggesting that either the DASS-21 may not have been administered to all cardiac rehabilitation participants; or that the data was collected but not entered into the cardiac rehabilitation database. Health professionals need to consider the optimal means of collecting psychological health information that meets their informational needs and the preferences of people living with heart disease. This recommendation is in line with national cardiac rehabilitation guidelines Core Component 4.8 Assessment of Psychological Status[54]. It might also be helpful, despite English literacy, to administer the DASS-21 in the native language of culturally and linguistically diverse cardiac rehabilitation participants to facilitate ease with the reporting psychological health symptoms.

Obtaining data on ethnicity and Aboriginality is important to enable the reporting of the proportion of people from culturally and linguistically diverse backgrounds who participate in meditation interventions designed to reduce depression and anxiety in people living with heart disease. The MENTOR Project also determined that the preferences of people living with heart disease for psychological health support require assessment prior to engaging with the multidisciplinary team. Determining preferences for meditation is important given the reluctance of some people living with heart disease to engage with medical professionals about mental health concerns[55].

Accreditation and training requirements of meditation facilitators

The health professionals involved in the MENTOR Project supported the integration of meditation into a cardiac rehabilitation program but acknowledged that additional training in meditation techniques and/or an established meditation practice was required if it was to be effective. These finding are consistent with requirements for Mindfulness Based Cognitive Therapy implementation in the UK that include in-depth training, mentorship and a personal meditation practice[50]. Training health professionals and support staff in meditation practices is particularly important given the cost constraints in health care, and the need to demonstrate cost-effectiveness to support the integration of meditation into cardiac rehabilitation programs.

7.2.5 Research Question V: What are the research and practice implications for integrating meditation into heart disease care as a self-management strategy?

The MENTOR Project determined that while there is no evidence of meditation's effectiveness (Level I evidence)[56], it is recommended by the American Heart Association as being a low risk, relatively low-cost, but potentially effective secondary prevention strategy[44]. There is also growing support from health professionals that meditation ought to be promoted to people living with heart disease as a secondary prevention strategy[44, 46, 50, 57]. Given the health service cost implications of implementing meditation within into cardiac rehabilitation, there is a need to generate definitive evidence about effectiveness in this population. The MENTOR Project findings are consistent with the international literature[46] and the American Heart Association Scientific Statement, which suggests that meditation may be integrated into heart disease care for those who are interested in lifestyle change, with the understanding that the benefits of meditation interventions need to be confirmed in a phase III trial[44]. Building the evidence for meditation while providing opportunities for its integration is in keeping with the principles of evidence based practice whereby clinician's integrate their professional expertise, patient's preference(s) with the available evidence to arrive at

recommended management. The same principles apply to co-designing an individualised self-management plan for people living with heart disease[58].

The MENTOR Project suggests that meditation may enhance self-regulation via attention control, regulation of emotions, and increasing self-awareness[59]. Having an 'awareness of awareness' enables people living with heart disease to consciously attend to conditioned behavioural patterns, and adapt these patterns of behaviour[40]. Meditation involves a process of heightening awareness and non-reactivity, thereby reducing the intensity of negative emotional experiences[40]. As such, meditation promotes self-efficacy and may reduce anxious tendencies by reducing the need to directly control outcomes[25, 40]. Meditation may also promote self-efficacy by reducing depressive tendencies to ruminate on negative events[25, 40]. Providing opportunities for people living with heart disease to engage in positive health behaviours, including cardiac rehabilitation programs is critical to improving their self-efficacy.

The final stage of the integration of the MENTOR Project data involves examining the findings in accordance with the World Health Organisation's Innovative Care for Chronic Conditions Framework[60]. This meta-inference has identified a range of actions required at the: micro (patient); meso (health organisation and community); and macro (health systems) levels to ensure that meditation is more widely integrated into cardiac rehabilitation programs, as summarised below.

Micro

Self-management support

Meditation provides opportunities for people living with heart disease to address their lifestyle risk factors and to optimise their ability to better manage their health behaviours, whilst supporting them to take ownership of the secondary self-management practices required to minimise the impact of heart disease on their health and well-being. However, achieving this requires good self-efficacy as people with low self-efficacy are more likely to decline to participate in secondary preventive practices[25, 61]. Meditation may increase the perceived ability of people living with heart

disease to manage and modify their health behaviours by reducing emotional arousal and increasing cognitive flexibility[40, 62]. Reducing negative affective processes during meditation such as rumination, may also facilitate positive efficacy expectations in people living with heart diseases' ability to manage any depression and anxiety symptoms. In turn, positive self-efficacy builds confidence in attaining mastery in other self-management domains, including participation in, and completion of cardiac rehabilitation programs[63].

Meso

Building the evidence

Reducing the burden of depression and anxiety is essential to improving the self-management capabilities of people living with heart disease. The MENTOR Project demonstrated that people living with co-morbid depression and anxiety symptoms who meditated were able to reduce their symptom burden and were more likely to participate in and adhere to cardiac rehabilitation program recommendations. Whilst, it yet to be confirmed, it is postulated that these observed improvements may be related to improving the self-regulating behaviours of people living with heart disease through regular meditation[64]. However, these positive observations need to be confirmed in a definitive phase III trial.

> *Recommendation 1: To build the effectiveness evidence supporting the integration of meditation into existing cardiac rehabilitation programs as a secondary prevention strategy for improving psychological wellbeing.*

> *Recommendation 2: That a reduction in moderate depressive symptoms be used as the primary outcome measure for a future multi-site phase III RCT of a cardiac rehabilitation based meditation intervention for people with acute coronary syndrome or who have experienced a recent acute myocardial infarction.*

Delivery systems design

Organised, integrated systems of care are required to facilitate proactive and productive interactions between people living with heart disease and health professionals[60]. While health professionals are committed to providing psychological support and advocate for the inclusion of psychological support to promote self-management within cardiac rehabilitation programs, workload and time constraints reduce their capacity to deliver these programs[57]. Multidisciplinary stepped care approaches that provide opportunities to address psychological health at different stages of the cardiac rehabilitation encounter, beyond entry, are required to facilitate effective engagement and support psychological symptom self-management[65]. Integrated care approaches need to be designed to promote continuity so that people living with heart disease continue to develop their self-management skills during and at the completion of cardiac rehabilitation programs[57].

The MENTOR Project findings suggest that changes in delivery systems design[49] ought to involve developing a formal referral pathway for cardiac rehabilitation programs that are inclusive of meditation to provide psychological support for people living with heart disease. Leveraging support from peak national organisation, including National Heart Foundation of Australia[66], The Australian Cardiac Rehabilitation Association[54], and the Cardiac Society of Australia and New Zealand[67] is required to strengthen guideline recommendations about the role of meditation in line with the American Heart Association position statement[44]. Integrating this recommendation into national guidelines would lend weight to organisations to integrate meditation into their existing cardiac rehabilitation programs.

> *Recommendation 3: To work with peak national organisations to develop a collaborative, integrated model of cardiac rehabilitation model that is inclusive of meditation as a psychological support strategy.*

Recommendation 4: That the peak Australian organisations integrate the recommendations of the American Heart Association about meditation into the relevant national guidelines.

The recent allocation of $355 million in federal government funding[68] towards heart disease prevention, offers an opportunity to promote the National Heart Foundation of Australia recommendations[66] and build cardiac rehabilitation programs participation rates through the creation of standardised referrals processes[69].

Recommendation 5: That the peak heart disease organisations advocate as part of new Federal Government funding for agreed cardiac rehabilitation referral pathways.

Development of meditation research and practice requires extensive collaboration between secondary prevention settings and general practitioners who are motivated and supported to focus on preventative care[70]. Greater focus on preventive outpatient care would enable better integration of meditation into the ambulatory care setting and is likely to improve care for people living with heart disease and co-morbid depression and anxiety symptoms. However, ensuring that there is adequate financial support to cover transportation and parking costs for socio-economically disadvantaged heart disease populations is key to supporting their participation in cardiac rehabilitation programs.

An effectiveness trial is required to demonstrate whether meditation enhances people living with heart diseases' psychological health outcomes and is cost-effective. While Mindfulness Based Cognitive Therapy programs have demonstrated capacity as a protective mechanism for at risk patients, as an alternative to antidepressant medication, these programs were unable to demonstrate cost-effectiveness[71]. Implementation of formal Mindfulness Based Cognitive Therapy programs[71] alongside antidepressant treatment in cardiac rehabilitation may not be pragmatic, particularly in areas of socioeconomic disadvantage, due to the added costs of these programs,

which range from $600 AUD per person[72, 73]. If meditation is demonstrated to be an effective and low-cost intervention, there may also be opportunities for it to be delivered by an external provider with meditation experience and training as part of an existing cardiac rehabilitation program. Alternatively, there may be opportunities to identify health professionals or meditation practitioners who could implement meditation without additional cost, or at minimal cost to the organisation.

> *Recommendation 6: If mediation is found to be cost-effective, organisations will need to develop a sustainable model to promote the integration of meditation into cardiac rehabilitation programs.*

The MENTOR Project recognised that positioning meditation within National Health and Medical Research Council priority area of mental health is essential to obtaining future research funding to enable the development of meditation research and practice[47]. Exploring meditation as a strategy to address mental health also aligns with the 2013-20 Mental Health Action Plan[74], which highlights the need for health systems to close the gap between mental health treatment and prevention needs and available services. However, reduced funding allocation to mental health relative to the proportion of disability adjusted life years attributed to mental health presents a challenge in securing funding for meditation research[47].

> *Recommendation 7: To invest in high quality research which builds the evidence that meditation improves mental health outcomes for people living with heart disease.*

Meditation aligns with two NSW Health Service Agreement Key Performance Indicators: Integrated care service measures (potentially preventable hospitalisations) and improving admitted patients' overall experience of care[51]. An integrated care Key Performance Indicator that meditation might address is the reduction of chronic cardiac admissions, and unnecessary cardiac admissions or readmissions[51]. Unnecessary hospitalisations may be reduced by empowering people living with heart disease with skills to alleviate their anxiety symptoms such that 1) hypervigilance is reduced; 2)

they have the clarity of focus to manage their symptoms through preventative measures in the community; and 3) they have a greater awareness of their body to differentiate between cardiac and somatic symptoms and are able to seek earlier preventative treatment[51]. However, evidence of reductions in hospital readmissions will need to be demonstrated as a secondary outcome in a future phase III RCT.

> *Recommendation 8: To highlight the potential for meditation to address health organisations' Key Performance Indicators to promote its integration of within cardiac rehabilitation programs.*

Clinical information systems

Better clinical information systems are required for coordinated, integrated and evidence-based health care[60]. NSW cardiac rehabilitation services require the ability to identify and view those people accessing heart disease care who require additional support to manage their psychological health symptoms. Cardiac rehabilitation databases should also include information on ethnicity, including those who are from culturally and linguistically diverse backgrounds or who are of Aboriginal and Torres Strait Islander descent. Information on ethnicity will enable clinicians to tailor the delivery of information to meet the needs of specific cardiac rehabilitation populations. It will also enable clinicians to monitor symptoms in people living with heart disease over time and their adherence to lifestyle changes. These systems will enable health professionals to proactively, rather than reactively, support self-management of psychological health symptoms[60].

The MENTOR Project findings clearly indicate the need to advocate for consistent screening, referral and treatment of both moderate depression *and* anxiety symptoms at a national level. This aligns with the goals of the Australian Cardiac Rehabilitation Association and the National Heart Foundation, who are working towards implementing five core components for assessment within cardiac rehabilitation programs, including depression and anxiety screening and general practitioner or psychological counselling referral[54].

Currently, the majority of Australian cardiologists consider mental health concerns such as depression and anxiety to be in the realms of general practice, and do not use National Heart Foundation of Australia and American Heart Association recommended screening tools such as the PHQ-2 and PHQ-9[11, 75] to screen for depression[76]. Australian cardiologists do consider, however, that they are the next point of contact for their patients after the GP to initiate depression screening, and recognise that screening for depression is within their scope of practice[76] and aligned with a comprehensive approach to care. Cardiologists who preferred to manage depression in people living with heart disease pharmacologically are more likely to disregard the importance of non-pharmacological strategies in heart disease care[76]. However, cardiologists who ask about depressive symptoms are more likely to believe that depression is an important contributor to heart disease and monitor depressive symptoms[76].

Minimising the emphasis given to moderate depressive symptoms that coincide with a cardiac event is unjustified, as depression in people living with heart disease may have precipitated in the months preceding the cardiac event, or long before a definitive heart disease diagnosis[77]. Assessment of depression using standardised, validated questionnaires with cut-off scores have clinical utility, as whilst many are not used to definitively diagnose depression or anxiety, high symptom scores are often, but not always indicative of a subsequent disorder[78, 79]. Subthreshold or minor depression is clinically relevant as a significant risk factor for major depression, has shown similar levels of impairment to a diagnosed major depressive disorder, and warrants attention as a benchmark for targeted interventions or for treatment[80]. Whilst anxiety symptoms are often considered transient in nature, evidence suggests that both depression and anxiety are chronic fluctuating conditions with single measures insufficient in providing information on the nature and course of the burden of disease over time[81]. However, that moderate anxiety symptoms and existential anxiety might also be exacerbated by the hospitalisation process and the experience of an acute cardiac event cannot be disregarded[82].

Recommendation 9: Better recognition and treatment of depression and anxiety symptoms in people living with heart disease at the initial cardiac rehabilitation assessment, during and at the completion of cardiac rehabilitation programs is required to optimise self-management.

Decision support

Health professionals do not have opportunities to attain skills that enable them to effectively collaborate with people living with heart disease to support self-management with other members of the multidisciplinary team[60]. Person-centred guideline-based treatments for the management of co-morbid psychological health symptoms within cardiac rehabilitation services is required[48]. The American Heart Association position statement supporting the use of meditation in heart disease care needs to be endorsed and integrated into relevant decision support tools and local policies so that meditation can be effectively integrated into existing cardiac rehabilitation programs.

Organise and equip health care teams

Health professionals require expertise in behavioural interventions, including meditation that have potential to improve the self-management capabilities of people living with heart disease and increase their capacity for health behaviour change[60]. Health professional education is required to address misperceptions of what meditation is, what is involved in the process of meditation, and any adjunct role that meditation may have in future heart disease care. Health professional education and consultation is a useful first step to identifying whether people with co-morbid psychological health support needs could benefit from referral to meditation programs to better manage their symptoms.

One strategy to address the educational needs of health professionals is to design meditation education and practice development sessions that meets the criteria for Continuing Professional Development. Providing opportunities for health professionals to experience meditation through a Continuing Professional Development module may support those who are seeking to improve their

health and well-being and reduce burnout[83, 84] whilst meeting professional registration criteria. Promoting meditation use in both people living with heart disease and health professionals may contribute to the development of a positive meditation culture that supports the development of meditation research and practice within health organisations[50]. Developing a personal meditation practice is also a necessary pre-requisite for those who may be interested in using meditation to support psychological health in people living with heart disease.

Medical professional education and training: Clarity and reassurance is needed when engaging with medical professionals that meditation programs to support the psychological support of people living with heart disease will: i) be an adjunct to existing programs; ii) facilitate health behaviour change to support self-management; and iii) may increase adherence to heart disease secondary prevention recommendations. Integrating self-management interventions, including meditation, into medical education and training may demonstrate benefits in i) addressing the stressors of performance based medical training, ii) improving positive coping skills and role conflict resolution and; iii) improving spirituality and empathy[85]. Including meditation in medical professional education and training may have a dual benefit of reducing depression and anxiety symptoms in both medical professionals and people living with heart disease whilst building the evidence base for future meditation research and practice[85]. Meditation may also increase the qualilty of person-centred care for people living with heart disease and improve satisfaction with the delivery of medical care[86].

> *Recommendation 10: That meditation experts develop an online Continuing Practice Development meditation training module for health professionals, group education sessions, and individual mentorship and support.*

Effective communication is required to promote information exchange, open questioning and shared decision making with people living with heart disease[60]. Collaboration is required between health professionals working in heart disease acute care and secondary prevention to introduce comprehensive health assessments that are inclusive of psychological health support needs and

preferences for meditation use. Respect for the psychological health support preferences of people living with heart disease, including their receptivity to meditation, exemplifies an integrated approach that places individuals at the centre of care[49]. However, careful consideration of the optimal means of collecting psychological health information that aligns with people living with heart diseases' preferences for psychological support is essential given that some people are reluctant to accept external referral to manage their psychological health, yet may be open to improving their self-management capabilities within cardiac rehabilitation programs[55].

Obtaining data on ethnicity and Aboriginality is important to facilitate inclusion of people from culturally and linguistically diverse backgrounds in meditation interventions designed to reduce depression and anxiety in people living with heart disease. It might also be helpful, despite English literacy, to administer the DASS-21 in the native language of culturally and linguistically diverse cardiac rehabilitation participants to enable people living with heart disease to accurately report psychological health symptoms.

> *Recommendation 11: Assess the psychological support preferences of people living with heart disease, including meditation, at cardiac rehabilitation assessment, to determine their suitability for participating in meditation programs.*

Community resources

*C*ommunity resources are rarely integrated into the care of people living with heart disease, leaving a broad range of resources untapped[60]. The MENTOR Project identified the need to create community links to ensure that psychological support continues for people living with heart disease beyond cardiac rehabilitation, and that people living with heart disease who are developing a meditation practice are supported. A 'champion'[50] who will undertake concerted lobbying of relevant stakeholders, and facilitate collaboration between meditation researchers and external organisations is required to ensure the sustainability of meditation programs delivered in heart

disease care. Collaboration across the health sector is required to build a network of health professionals who are competent in facilitating meditation practices, and/or experienced, trained or accredited meditation practitioners. External engagement with community organisations such as Openground[73] and Insight Meditation Australia[87] is also required to strengthen partnerships that will enable the integration of meditation into cardiac rehabilitation programs. .

Chronicity of depression and anxiety symptoms in heart disease continue at the primary care level, highlighting the relevance of meditation as a potentially sustainable symptom management adjunct that can be continued within the community and home setting[81]. The NSW Integrated Care Strategy[51] highlights potential additional avenues for funding of meditation programs, including planning and innovation funds designed to foster innovation in local areas. This type of funding would most likely be used in primary care or community based approaches to the integration of meditation practices[88].

A user-pays model may be another means to circumnavigate resource limitations within health organisations. A user-pays model enables health organisations and communities to contract a trained meditation provider to deliver meditation programs within these settings. However, user-pays models present challenges in areas of socio-economic disadvantage, such as the local health district included in the MENTOR Project[89], which is likely to limit access to meditation programs[70]. To successfully build the evidence for meditation, links between cardiac rehabilitation, community health professionals (for example, general practitioners and advanced practice nurses) and trained meditation providers are required to facilitate continuity of care, better support psychological health and optimise health behaviour change in people living with heart disease.

> *Recommendation 12: Collaborate with community organisations and external meditation providers to build a network of meditation practitioners who are able to deliver meditation programs.*

Macro

Reorientating Policy

Health policy systems at the state and federal levels are focused on delivering acute, episodic care as opposed to a model of continuous, integrated chronic care. Many of Australia's current health care policies are perpetuating a narrow biomedical focus and emphasise cost minimisation rather than promoting new models of care that address the growing burden of chronic conditions in the community[60]. Failing to address the chronicity of symptoms associated with non-communicable diseases and identify the psychological health and self-management support needs of people living with heart disease will lead to fragmented care and additional health care costs[60].

Fragmented financing

Fragmented financing can occur across different budget streams. For example, funding sources for inpatient heart disease care may differ from outpatient or community health funding, preventing coordinated care for people living with heart disease across care settings[60]. Reduced financing for outpatient services, including cardiac rehabilitation may limit access to meditation for people living with heart disease as an important low risk, low cost psychological support strategy.

Misaligned provider incentives

Cardiologists are reimbursed for expensive therapies, however they care not compensated proportionally to the volume and costs of services delivered. As a result, reimbursement is reduced for the provision of services that support self-management and health behaviour change[60].

To successfully integrate meditation into cardiac rehabilitation and improve the psychological health of people living with heart disease, a multifaceted, person-centred approach is required[49]. Successful integration should be underpinned by evidence based decision-making that is focused on disease prevention, and a focus on quality that includes the effective use of resources. Integrating meditation into cardiac rehabilitation programs also requires the flexibility and adaptability to

withstand situational pressures within the health organisational environment, and enable active collaboration between health organisations, communities, people living with heart disease and the health policy environment[60].

7.3 Conclusion

Evidence from the MENTOR Project suggests that an integrated approach is required to enable people living with heart disease to reduce their psychological health symptoms. This Project also demonstrated the feasibility and acceptability of integrating meditation into an existing cardiac rehabilitation program. It may also enable people living with heart disease to better regulate their health behaviour choices, and increase participation in cardiac rehabilitation programs.

While there is a need for definitive evidence, meditation is likely to be a low-cost, and low risk intervention that is unlikely to cause harm. Additionally, meditation may be able to benefit some people living with depression and anxiety symptoms by supporting their self-management capabilities. As it is feasible, and considered ideal for cardiac rehabilitation programs to integrate meditation as a psychological support strategy while building the evidence of its effectiveness.

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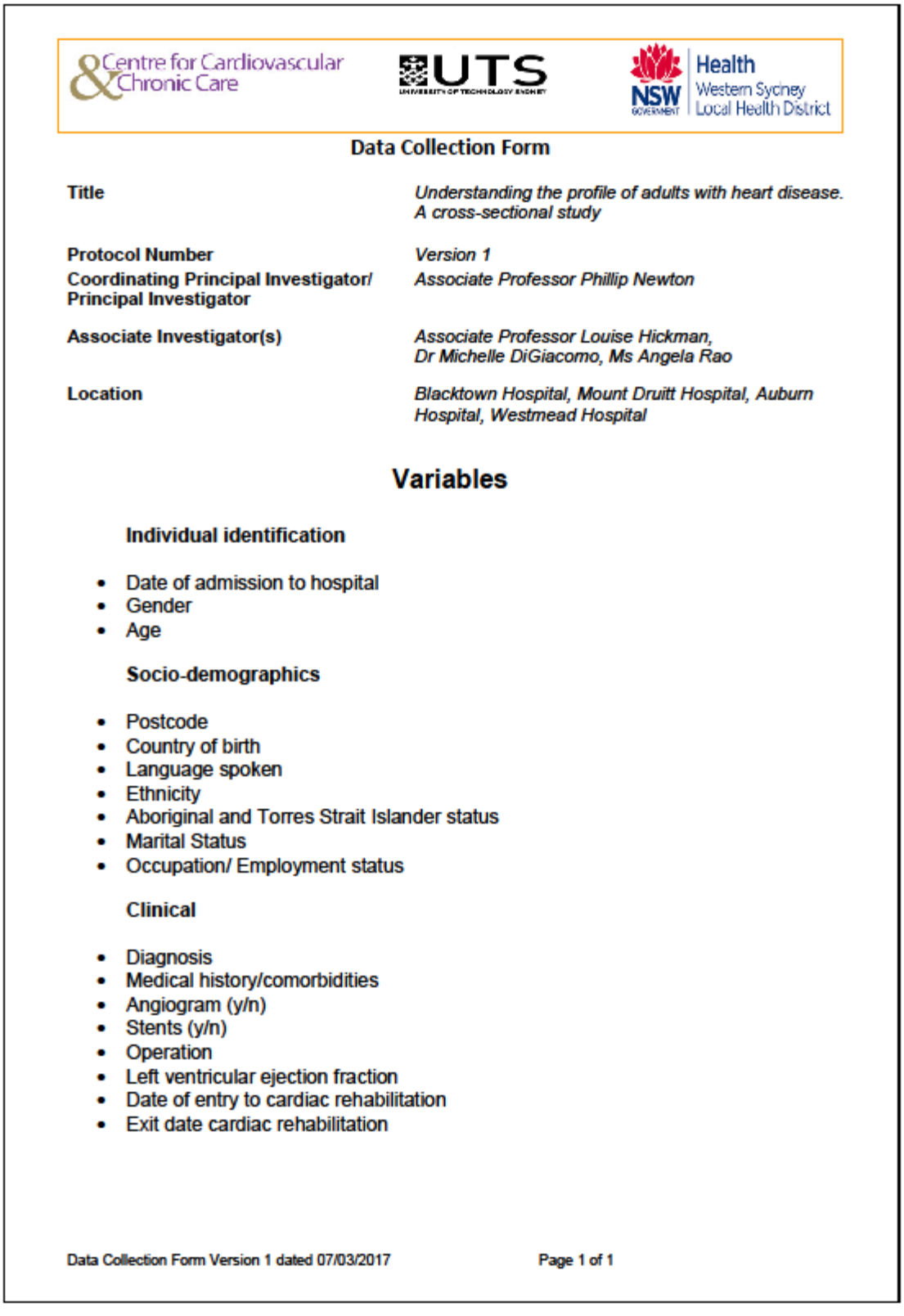
Appendices

Appendix 1: Study 1 Data Collection Form



Centre for Cardiovascular & Chronic Care

UTS UNIVERSITY OF TECHNOLOGY SYDNEY

NSW GOVERNMENT Health Western Sydney Local Health District

Data Collection Form

Title	*Understanding the profile of adults with heart disease. A cross-sectional study*
Protocol Number	*Version 1*
Coordinating Principal Investigator/ Principal Investigator	*Associate Professor Phillip Newton*
Associate Investigator(s)	*Associate Professor Louise Hickman, Dr Michelle DiGiacomo, Ms Angela Rao*
Location	*Blacktown Hospital, Mount Druitt Hospital, Auburn Hospital, Westmead Hospital*

Variables

Individual identification

- Date of admission to hospital
- Gender
- Age

Socio-demographics

- Postcode
- Country of birth
- Language spoken
- Ethnicity
- Aboriginal and Torres Strait Islander status
- Marital Status
- Occupation/ Employment status

Clinical

- Diagnosis
- Medical history/comorbidities
- Angiogram (y/n)
- Stents (y/n)
- Operation
- Left ventricular ejection fraction
- Date of entry to cardiac rehabilitation
- Exit date cardiac rehabilitation

Data Collection Form Version 1 dated 07/03/2017 Page 1 of 1

Risk factors/ Health Education

- BP (on entry and at 6 weeks)
- Medications
- Medication compliance
- Lipid profile : Cholesterol HDL, LDL triglycerides
- Genetics (family history)
- Obesity
- Diabetes
- Exercise
- ETOH (Y/n)
- BMI
- Waist circumference
- Sedentary lifestyle (on entry and at 6 weeks)
- Smoking status
- Depression, anxiety, stress scale (DASS-21) on entry, post cardiac rehabilitation
- Cardiac rehabilitation completion
- Drop out reason
- Estimated 6 minute walk test (pre, post cardiac rehabilitation and at 6 months)
- METs (exercise stress test pre and post CR)
- Number of standard CR groups attended
- Number of psychological groups attended
- SF-36
- PHQ 2; PHQ-9

Appendix 2: Study 1 Data Dictionary

Variable	Label	Values
Site	site	1, Site 1; 2, Site 2
POSTCODE	postcode	None
AGE	age	None
SEX	sex	1, male; 2, female
DIAGNOSIS_GP	diagnosis group	1, AMI; 2, CTCx; 3, PTCA/Stent; 4, Chest Pain/angina; 5, Other
DEPRESS	depression yes/no	1, yes; 2, no
DAY_PRETEST	days since event/diagnosis to attendance at pre-program assessment	None
RESTSBP	resting systolic blood pressure	None
RESTDBP	resting diastolic blood pressure	None
RESTHR	resting heart rate	None
MAXHR	maximum heart rate during functional capacity test	None
MAXSBP	maximum systolic blood pressure	None
SIXMWT	six minute walk test at assessment (on entry)	None
PREMET	metabolic exercise stress testing on entry	None
HEIGHT	height	None
WEIGHT	weight	None
PRE_BMI	body mass index on entry	None
WAIST	waist circumference in cms	None
MSGP	marital status group	1, married, engaged, de-facto; 2, divorced/separated; 3, widowed; 4, single; 5, not known
DIAB_GRP	diabetes group	1, yes; 2, no
DIAB_CONGRP	diabetes control	1, yes; 2, no
BPGP	blood pressure group	1, yes; 2, no
CONTROL	blood pressure control	1, yes; 2, no
SMOKE_GP	smoking status	1, yes; 2, no
SMOKE_STOP	stopped smoking on entry to CR	1, yes; 2, no
CHOLGP	hypercholesterolaemia	1, yes; 2, no
CHOLLEVEL	cholesterol level	None
TRIGLEVEL	triglyceride level	None
CHOL_CNTRL	cholesterol control	1, yes; 2, no

FHXGP	family history of premature heart disease (<55yrs for male & female)	
ACTIVE_GP	lifestyle: active or sedentary prior to event (active= 30 mins 3 times/week)	1, active; 2, sedentary
DIGGP	digoxin use	1, yes; 2, no
BBGP	beta blocker use	1, yes; 2, no
ACEIGP	ace inhibitor use	1, yes; 2, no
ANTI_ARRYTHMIC	anti-arrythmic use	1, yes; 2, no
CA_ANTAG	calcium atagonist use	1, yes; 2, no
NITRATES	nitrates use	1, yes; 2, no
WORK_GP	occupation	1, Employed; 2, Unemployed/on Centrelink benefits; 3, Retired; 4, school/ home duties
WALK	minutes walking when walking at home most days	None
DROPOUT	dropout group	1, yes; 2, no
EXERCISE_DAYS	number of days exercising in the clinic not including the pre or post ax days	None
Year	year of program attendance	None
SFQuestion_1-36	SF-36 question 1-36 on entry	None
SFPreTotal		None
Pre_GH	general health subscale score on entry	None
Pre_PF	physical function subscale score on entry	None
Pre_RP	role physical subscale score on entry	None
Pre_BP	bodily pain subscale score on entry	None
Pre_VT	vitality subscale score on entry	None
Pre_SF	social function health subscale score on entry	None
Pre_RE	role-emotional subscale score on entry	None
Pre_MH	mental health subscale score on entry	None
Pre_HT	health transition subscale score on entry	None
PRE_D	DASS depression subscale score at pre assessment	None
PRE_A	DASS anxiety subscale score at pre assessment	None
PRE_S	DASS stress subscale score at pre assessment	None

POST_D	DASS depression subscale score at post assessment	None
POST_A	DASS depression subscale score at post assessment	None
POST_S	DASS depression subscale score at post assessment	None
PRE_DASS	DASS sum total score at pre-assessment	None
POST_DASS	DASS sum total score at post-assessment	None
PRE_DMod		None
Post_DMod		None
Change_D		None
PrePost_D4grp		None
PRE_AMod		None
Post_AMod		None
PRE_SMod		None
Post_SMod		None
heightmsq	Height in metres squared	None
BMI_rec	Body mass index recoded	None

Appendix 3: Cardiac Rehabilitation Case Report Form

Patient: MRN:
Age: Sex: DOB
Associated Diagnoses:
Author
Attachments

Progress Note <Show Structure> <Use Free Text>

CEAP Pre/Assessment

Date of CEAP Entry: _

Email Address: _

Contact Numbers: _

Cardiologist/Surgeon: _

GP: _

Entry Diagnosis: _

Complications: _

Past Medical Hx: _

Date of Discharge/Referral: _

COB: _ **Language: _** **Interpreter Y/N _**

Risk Factors: _

STOP BANG (OSA): _ CPAP Y/N Referral made Y/N

Smoking: Y / N / EX

CO (ppm):

Diabetes Y/N Treatment: _ CDACC Referral Y/N

Lipids:

TC: _ HDL: _ LDL: _ Trigs: Ratio: Non-HDL C: _

Obesity:

Height: _ Weight: WC: _ BMI: _ %BF: _
%SMM: _

Hypertension: Y/N

Family Hx of Premature CAD/other Y/N

Sedentary: Y/N ETOH:

Vocation: _ **Marital Status: _**

Social Situation:

Appendix 4: Systematic Review Search Strategy

1: Heart/
2: heart*.mp.
3: angina.mp. or Angina Pectoris
4: coronary.mp. or Coronary Disease/
5: Myocardial Infarction/
6: Patients/
7: cardio* or MH Cardiovascular Diseases/
8. Heart Valve Diseases/ or valvular disease.mp.
9: cardiac.mp.
10: cardiovascular risk factors.mp.
11. Hypertension/ or hypertension.mp.
12: Myocardial Revascularization/ or revascularization.mp.
13: meditation.mp. or Meditation/
14: Relaxation Therapy/ or mindfulness based stress reduction.mp.
15: mindfulness.mp or Mindfulness/
16: guided imagery or "Imagery (Psychotherapy)"/
17: vipassana.mp.
18: zen.mp.
19: Breathing Exercises/ or pranayama.mp.
20: transcendental meditation.mp.
21: qigong.mp or Qigong/
22: depression
23: anxiety
24: 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12
25: 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21
26: 22 OR 23
27: 24 AND 25 AND 26

Appendix 5: Study 2: Elements of Meditation Interventions

Meditation elements	Non-significant		Significant	
	depression	anxiety	depression	anxiety
Concentrative meditation	(Paul-Labrador et al., 2006) (trait anxiety)	(Collins & Rice, 1997); (Paul-Labrador et al., 2006) (trait anxiety); (Luskin, Reitz, Newell, Quinn, & Haskell, 2002)	(Luskin et al., 2002)	
Mindfulness based stress reduction (MBSR)	(Mandel, 2007)	(Mandel, 2007) (trait anxiety); (Salmoirago-Blotcher et al., 2013)	(Nyklíček, Dijksman, Lenders, Fonteijn, & Koolen, 2014; Parswani, Sharma, & Iyengar, 2013)	(Mandel, 2007) (state anxiety); (Nyklíček et al., 2014; Parswani et al., 2013)
Mindfulness	(Delaney, Barrere, & Helming, 2011)	(Delaney et al., 2011; Delui, Yari, Khouyinezhad, Amini, & Bayazi, 2013)	(Delui et al., 2013)	
Home practice	(Delaney et al., 2011; Paul-Labrador et al., 2006)	(Mandel, 2007; Paul-Labrador et al., 2006) (trait anxiety); (Collins & Rice, 1997; Delaney et al., 2011; Luskin et al., 2002)	(Delui et al., 2013; Luskin et al., 2002; Nyklíček et al., 2014; Parswani et al., 2013)	(Nyklíček et al., 2014; Parswani et al., 2013); (Mandel, 2007) (state anxiety)
Diary/ log book re: home practice	(Delaney et al., 2011; Paul-Labrador et al., 2006)	(Mandel, 2007; Paul-Labrador et al., 2006) (trait anxiety); (Collins & Rice, 1997; Delaney et al., 2011; Luskin et al., 2002)	(Nyklíček et al., 2014; Parswani et al., 2013)	(Nyklíček et al., 2014; Parswani et al., 2013); (Mandel, 2007) (state anxiety)
Guided imagery peaceful scene	(Delaney et al., 2011)	(Collins & Rice, 1997; Delaney et al., 2011) (Mandel, 2007) (trait anxiety)		(Mandel, 2007) (state anxiety)
Guided imagery –suggested images	(Delaney et al., 2011)	(Delaney et al., 2011; Luskin et al., 2002); (Mandel, 2007) (trait anxiety);	(Luskin et al., 2002)	(Mandel, 2007) (state anxiety)
Guided imagery –health/heart imagery	(Delaney et al., 2011)	(Collins & Rice, 1997; Delaney et al., 2011; Luskin et al., 2002)	(Luskin et al., 2002)	
Focused attention –body parts or body scan		(Salmoirago-Blotcher et al., 2013); (Mandel, 2007) (trait anxiety)	(Nyklíček et al., 2014; Parswani et al., 2013)	(Mandel, 2007) (state anxiety); (Nyklíček et al., 2014; Parswani et al., 2013)
Muscle relaxation		(Collins & Rice, 1997); (Mandel, 2007) (trait anxiety)		(Mandel, 2007) (state anxiety)
Controlled yoga breathing/ deep breathing		(Collins & Rice, 1997; Luskin et al., 2002); (Mandel, 2007) (trait anxiety)	(Luskin et al., 2002)	(Mandel, 2007) (state anxiety);
Focus on breathing	(Delaney et al., 2011)	(Delaney et al., 2011; Luskin et al., 2002; Salmoirago-Blotcher et al., 2013)	(Luskin et al., 2002; Parswani et al., 2013);	(Parswani et al., 2013)
Mantra/word repetition	(Paul-Labrador et al., 2006)	(Mandel, 2007; Paul-Labrador et al., 2006) (trait anxiety)		(Mandel, 2007) (state anxiety)

Psychoeducational sessions			(Luskin et al., 2002; Nyklíček et al., 2014)	(Nyklíček et al., 2014)
Other educational sessions	(Paul-Labrador et al., 2006)	(Collins & Rice, 1997); (Paul-Labrador et al., 2006) (trait anxiety)	(Parswani et al., 2013)	(Parswani et al., 2013)
Instruction sheet		(Mandel, 2007) (trait anxiety)		(Mandel, 2007) (state anxiety)
Introductory session –how to use the technique	(Paul-Labrador et al., 2006)	(Mandel, 2007; Paul-Labrador et al., 2006) (trait anxiety); (Collins & Rice, 1997; Luskin et al., 2002; Salmoirago-Blotcher et al., 2013).	(Luskin et al., 2002; Parswani et al., 2013)	(Parswani et al., 2013); (Mandel, 2007) (state anxiety);
Cognitive restructuring			(Nyklíček et al., 2014)	(Nyklíček et al., 2014)
Transcendental meditation	(Paul-Labrador et al., 2006)	(Paul-Labrador et al., 2006) (trait anxiety)		
Group meetings	(Paul-Labrador et al., 2006)	(Paul-Labrador et al., 2006) (trait anxiety) (Delui et al., 2013; Luskin et al., 2002)	(Delui et al., 2013; Luskin et al., 2002; Nyklíček et al., 2014; Parswani et al., 2013)	(Nyklíček et al., 2014; Parswani et al., 2013)
Personal instruction (1:1)	(Delaney et al., 2011; Paul-Labrador et al., 2006)	(Delaney et al., 2011; Salmoirago-Blotcher et al., 2013); (Mandel, 2007; Paul-Labrador et al., 2006) (trait anxiety); (Collins & Rice, 1997) (state anxiety).	(Parswani et al., 2013)	(Parswani et al., 2013); (Mandel, 2007) (state anxiety)
Sitting meditation		(Salmoirago-Blotcher et al., 2013)	(Nyklíček et al., 2014; Parswani et al., 2013)	(Nyklíček et al., 2014; Parswani et al., 2013)
Audiotape/CD	(Delaney et al., 2011)	(Collins & Rice, 1997; Delaney et al., 2011; Delui et al., 2013; Salmoirago-Blotcher et al., 2013); (Mandel, 2007) (trait anxiety)	(Delui et al., 2013; Parswani et al., 2013)	(Parswani et al., 2013); (Mandel, 2007) (state anxiety)
Trained facilitator*	(Paul-Labrador et al., 2006)	(Luskin et al., 2002; Salmoirago-Blotcher et al., 2013); (Mandel, 2007; Paul-Labrador et al., 2006) (trait anxiety)	(Luskin et al., 2002; Nyklíček et al., 2014)	(Mandel, 2007) (state anxiety); (Nyklíček et al., 2014)
Phone delivered intervention		(Salmoirago-Blotcher et al., 2013)		
Background music	(Delaney et al., 2011)	(Delaney et al., 2011); (Mandel, 2007) (trait anxiety)		(Mandel, 2007) (state anxiety)

***trained and/or qualified in intervention delivery, and/or qualified health professional with extensive experience in the specific meditation technique**

Appendix 6: Study 3 Daily Meditation Practice Log Sheet

Meditation home practice log

Name: _____

Week starting: _____

Day	Yes	No
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Appendix 7: De-identified Participant Screening and Recruitment Table

Name	High Level	Clinician	Patient	Researcher meditation	Pro meditation	International	Date contacted	Date interviewed
A	Y	Y				Y	29/06/2017	02/08/2017
B		Y						
C		Y		Y	Y	Y		
D				Y	Y	Y		
E	Y						Contacted	responded
F	Y						Contacted	
G		Y					29/06/2017	
H		Y					04/07/2017	agreed
I		Y					29/06/2017	
J		Y						
K								
L								
M						Y		
N								
O		Y						
P	Y	Y						
Q				Y				
R	Y?	Y					03/08/2017	
S		Y					retired	
T		Y					03/08/2017	
U	Y?							
V		Y				Y	27/06/2017	08/08/2017
W	Y							
X	Y				Y		contacted	28/07/2017
Y					Y			completed
Z	Y						27/06/2017	29/07/2017
AA		Y			Y			18/08/2017
BB		Y						

Name	High Level	Clinician	Patient	Researcher meditation	Pro meditation	International	Date contacted	Date interviewed
CC		Y						
DD								
EE								
FF								
GG	Y							
HH		Y						
II	Y						29/06/2017	
JJ							27/06/2017	24/07/2017
KK		Y					contacted	
LL								
MM							29/06/2017	
NN				Y			29/06/2017	
OO		Y			Y		04/07/2017	18/08/2017
PP		Y					04/07/2017	16/08/2017
QQ		Y					04/07/2017	
RR								
SS								
TT		Y					04/07/2017	
UU		Y					04/07/2017	declined
VV		Y					04/07/2017	No further response after initial emails
WW		Y		Y	Y		03/08/2017	
XX		Y					03/08/2017	
YY	Y?	Y		Y		Y	03/08/2017	
ZZ	Y	Y					03/08/2017	
AAA		Y					01/02/2018	No response
BBB		Y					01/02/2018	done
CCC		Y					09/03/2018	
DDD		Y (MD)					09/03/2018	
EEE		Y (MD)					09/03/2018	

Name	High Level	Clinician	Patient	Researcher meditation	Pro meditation	International	Date contacted	Date interviewed
FFF		Y					09/03/2018	
GGG		Y					09/03/2018	
HHH		Y					09/03/2018	
III		Y					09/03/2018	
JJJ		Y					09/03/2018	
KKK		Y					09/03/2018	Responded 14/03/18. Booked for 29/3 @ 2pm
LLL		Y					09/03/2018	
MMM		Y					14/03/2018	Booked for 22/3 @2pm

Appendix 8: Joint display tables

Research Question I: What is the burden of moderate depression and anxiety symptoms in people living with heart disease attending cardiac rehabilitation programs?						
Study	**Longitudinal cohort study**	**Systematic review**	**Phase II RCT**	**Semi-structured interviews – Health Professionals**	**Data convergence**	**Meta-inference**
Domain	**QUAN**	**QUAN + Qual**	**QUAN + qual**	**QUAL**		
Prevalence						
Prevalence of depression and anxiety symptoms	The DASS-21 results revealed moderate depression (18%) and anxiety (28%) symptoms occurred in adults who attended cardiac rehabilitation.	In accordance with questionnaire cut-off scores, depressive symptoms were moderate and clinically significant in half of the participants in Phase II studies that reported depressive symptoms (4/8 studies; 222/401 participants). Borderline moderate or moderate anxiety symptoms were prevalent in over one third of	In accordance with the trial inclusion criteria, one third (29%) of all trial participants had moderate depressive symptoms, while almost half (47%) had moderate anxiety symptoms at baseline.	Not Applicable	Confirmed	Compared with the general population, adults attending cardiac rehabilitation programs have higher rates of moderate depression and anxiety symptoms.

		participants in Phase II studies (3/8 studies; 166/477 participants).				
Correlates						
Demographic characteristics	Cardiac rehabilitation participants with moderate depression and anxiety symptoms were significantly more likely to be: - Male (p = 0.002) - Age $\bar{X}$= 59 (SD ± 12) years (p<0.001) - In a relationship (p<0.001); and - Employed (p<0.001).	- Male (67%); - Age $\bar{X}$= 60 years (SD ± 7)	Phase II RCT participants were predominately: - Male (71%) - Age $\bar{X}$= 61.3 (SD ± 9.1) years - Married (81%) - Employed (47%) - University education (45%) - Born in South East Asia (61%) (e.g. India (10%), Philippines (20%) and Syria or Afghanistan (29%); and - Spoke a language other than English (19%) or English and a second language at home (39%).	Not applicable	Confirmed	The age, gender, relationship and educational status of adults with depression and anxiety symptoms who attended cardiac rehabilitation programs in one local health district are comparable with the general cardiac rehabilitation population[1]. While the proportion of adults living with heart disease from culturally and linguistically diverse backgrounds who attended cardiac rehabilitation programs within the local health district could not be confirmed, 58% of trial participants' first language was a language other than English.

Cardiovascular risk factors	A greater proportion of cardiac rehabilitation participants with moderate depression and anxiety symptoms: - led a sedentary lifestyle (p<0.001); - had lower exercise capacity (p<0.001); and - were obese (depression p<0.001) or borderline obese (anxiety p= 0.045). A greater proportion of cardiac rehabilitation participants with moderate depression had an AMI (p<0.001); while participants with moderate anxiety were more likely to have had cardiothoracic surgery and/or diabetes (both p<0.001).	Could not be determined	The cardiovascular risk factor profile of the trial participants was similar to the broader cardiac rehabilitation population of this local health district: - Hypertension (61%) - Hypercholesterolaemia (52%) - Overweight (BMI : X= 27.6 [SD ±6.1]) - Type I diabetes (3%) - Type II diabetes (35%). However, the trial participants were more likely to have had a recent AMI (55%); or a percutaneous coronary intervention (90%).	Could not be determined	Confirmed	Cardiac rehabilitation participants with depression and anxiety have a higher prevalence of overweight or obesity and sedentary lifestyle patterns compared to the general population[2, 3]. A higher proportion of depressed participants had an AMI which is comparable to the general cardiac rehabilitation population[1].
Health status	Cardiac rehabilitation participants with moderate depression and anxiety had significantly reduced quality of life in the following SF-36 domains (p<0.001): • General Health X= 43.84 (SD ± 20) [D]; X= 49.43 (SD ± 21) [A] • Physical function X = 46.99 (SD ± 24) [D]; X= 47.38 (SD ± 24) [A] • Role-physical X = 17.60 (SD ± 31) [D]; X= 17.63 (SD ± 31) [A] • Bodily pain X = 51.57 (SD ± 25) [D]; X= 54.11 (SD ± 24) [A] • Vitality X =34.34 (SD ± 19) [D]; X = 40.72 (SD ± 20) [A]	Could not be determined	In accordance with the first question on the SF-36 health survey, nearly half (47%) of adults attending cardiac rehabilitation with depression and anxiety symptoms who participated in the trial described their health status as 'good'. X= 3.1 [SD ± 0.92]	Could not be determined	Confirm	People living with heart disease with depression and anxiety symptoms have a lower quality of life compared with the general heart disease population[4, 5].

	• Social functioning X= 44.21 (SD ± 25) [D]; X= 50.21 (SD ± 26) [A] • Role-emotional X= 23.61 (SD ± 37) [D]; X= 31.32 (SD ± 41) [A] • Mental health X= 49.62 (SD ± 18) [D]; X=58.05 (SD ± 20) [A] Health status (SF-36) was characterised as 'good' (p<0.001). X= 3.65 (SD ± 0.9) [D]; X= 3.52 (SD ± 0.9) [A]					
Predictors						
Predictors of moderate depression and anxiety symptoms	Despite the high prevalence of depression and anxiety in women with heart disease reported in the literature, gender did not predict depression and anxiety (DASS-21) in this cohort. However, anxiety (OR: 4.395; 95% CI: 3.363-5.744); and stress (OR: 4.572; 95% CI: 3.315-6.181) increased the risk of depression by over four times. Depression quadrupled the risk of anxiety (OR: 5.577; 95% CI: 4.006-7.765), while stress tripled anxiety risk Stress (OR: 3.167; 95% CI: 2.411-4.161) (both p<0.001). Age (OR: 0.989; 95% CI: 0.981-0.997, p=0.009) reduced anxiety risk; while chest pain (OR: 1.945; 95% CI: 1.209-3.129, p=0.006) increased anxiety risk.	Not applicable	Not applicable	Not applicable	Confirm	Anxiety and stress were the strongest predictors of moderate depression in people living with heart disease. Depression is a strong predictor of anxiety, which is consistent with the general heart disease population[6].

	Other diagnoses such as a valve replacement (OR: 1.553; 95% CI: 1.131-2.131, p=0.007) increased anxiety risk.					

Research Question II: Does completing cardiac rehabilitation reduce depression and anxiety symptoms?						
Study	**Longitudinal cohort study**	**Systematic review**	**Phase II RCT**	**Semi-structured interviews - Health professionals**	**Data convergence**	**Meta-inference**
Domain	**Quantitative data**	**Quantitative data**	**QUAN + Qual**			
Change in depression and anxiety symptoms on completion of cardiac rehabilitation	Cardiac rehabilitation reduced moderate depression and/or anxiety symptoms in a greater proportion of people living with heart disease (p<0.0001). - Mean reductions in DASS-21 depression and anxiety subscale scores: $\bar{X}$= 1.93 (SD ± 6.2) [D] $\bar{X}$= 1.93 (SD ± 5.5) [A]	Could not be determined	There was no significant reduction in depression and anxiety symptoms (DASS-21 and HADS) in trial participants allocated to usual care (cardiac rehabilitation) compared with the intervention (meditation + cardiac rehabilitation). **Control group:** mean differences **Depression** DASS-21 [D]: 0.95; p = 0.973 HADS [D]: 0.06; p = 0.318 **Anxiety** DASS-21 [A]: 3.40; p = 0.920 HADS [A]: 0.33; p = 0.542 This pilot trial was not powered to detect statistically significant differences.	Not applicable	Mixed	Cardiac rehabilitation contributes to modest reductions in depression and anxiety symptoms. Anxiety symptoms may be more amenable to change compared with moderate to severe depressive symptoms in exercise based cardiac rehabilitation programs[7]. Monitoring depression and anxiety symptoms on entry and during cardiac rehabilitation programs is required. Given the burden of depression and anxiety, the integration of psychological support strategies in cardiac rehabilitation programs is warranted.

Research Question III: Do depression and anxiety symptoms affect adherence to cardiac rehabilitation programs?						
Study	**Longitudinal cohort study**	**Systematic review**	**Phase II RCT**	**Semi-structured interviews – Health professionals**	**Data convergence**	**Meta-inference**
Domain	**QUAN**	**QUAN**	**QUAN + qual**	**QUAL**		
Completion of cardiac rehabilitation programs	- One quarter (28%) of people with moderate depression or anxiety symptoms dropped out of cardiac rehabilitation programs compared with one fifth (18%) of those with normal to mild symptoms ($p<0.001$).	Could not be determined	- A lower proportion of participants allocated to usual care completed all 12 cardiac rehabilitation sessions (29% vs 39%). This dropout rate is similar to that reported in this local health district cardiac rehabilitation population.	Could not be determined	Confirm	One quarter of people with depression or anxiety who start cardiac rehabilitation programs drop out. Novel strategies are required to support people with moderate depression or anxiety symptoms to complete a cardiac rehabilitation program.

Research Question IV. Is it feasible and acceptable to integrate a meditation intervention into an existing cardiac rehabilitation program as a strategy for reducing depression and anxiety symptoms in people living with heart disease?						
Study	**Longitudinal cohort study**	**Phase II RCT**		**Semi-structured interviews - health professionals**	**Data convergence**	**Meta-inference**
Domain	**QUAN**	**QUAN + qual**		**QUAL**		
Participant screening and recruitment	Not applicable	**Screening to recruitment rates were acceptable** Almost a fifth (18%) of screened trial participants meeting the eligibility criteria were randomised (1:8 Screening to randomisation ratio). During the trial, the recruitment rate averaged 6.53 participants/month.	Not applicable	Not applicable	Confirm	The screening to randomisation rate and recruitment rate suggests that it will be feasible to recruit eligible adults living with heart disease into a future Phase III meditation trial.
Barriers to participation in meditation	Not applicable	Trial participants randomly allocated to a meditation intervention who withdrew identified barriers to participation as: - **work commitments** - caring responsibilities - transport - feeling depressed - overseas travel - juggling multiple health professional referrals; and	**Some participants were unable to attend meditation as cardiac rehabilitation program hours (7am-11am) did not fit in with their existing work commitments.** *"I could have attended meditation if it was at different hours. Outside of work hours"* (Female, 60 years, post AMI, PCI)	Health professionals recognised that work and family commitments presented barriers to adults living with heart diseases' participation in cardiac rehabilitation based meditation programs. *"You know some people are already out the door before it's even suggested you might want to do rehab. And then there are...a lot of people have to go*	Enhance	Psychosocial factors, particularly work and family commitments, prevent many adults living with heart disease from participating in cardiac rehabilitation. - Providing opportunities for cardiac rehabilitation

		- taking time to integrate lifestyle changes **One third of eligible adults living with heart disease declined to participate in the trial due to transport related issues.** - 5/66 transport issues; - 17/66 participants preferred to attend cardiac rehabilitation at a site that was closer to their home, which limited their ability to participate in meditation.		*back to work and families, and there's financial issues. So that would be…time and money. That's what it comes down to"* (Participant 002).		activities, including meditation outside of working hours is required to facilitate better attendance and engagement.
Cardiac rehabilitation – attendance rates and adherence to the suggested lifestyle strategies	Not applicable	- Trial participants allocated to the meditation intervention had better: cardiac rehabilitation sessions attendance rates (89% vs 79%) and four fifths (80%) of intervention participants attended half of the meditation sessions. Half (53%) of meditation intervention participants practiced their meditation at home. Overall, one third (32%) of trial participants dropped out, including one sixth (16%) from the meditation arm.	Cardiac rehabilitation participants who were allocated to a meditation intervention reported adhering to meditation home practice a few times per week (1 or 2-3 times/week).	Could not be determined	Enhance	The addition of meditation to an existing cardiac rehabilitation programs increases cardiac rehabilitation attendance and meditation practice at home which is important as adherence to cardiac rehabilitation programs is known to be low[8, 9]. Meditation appears to be a feasible self-management strategy for adults that facilitates better

						adherence to secondary prevention recommendations. Drop-out rates from meditation studies in cardiac rehabilitation are high due to known barriers in cardiac rehabilitation program attendance.
Acceptability	Not applicable	- 80% of meditation intervention participants completed an average of X= 3.13 (SD ± 2.56) group sessions, suggesting the meditation intervention was deemed acceptable by participants (n = 15).	**Participants perceived meditation as acceptable and would recommend meditation practices to others who have had a cardiac event.** *'…one of the blokes at work, his sister has (sic) a heart attack, and we both live in the Blacktown area, and I told him of my experience, and I told him to get (sic) involved with the cardiac education program and take advantage of the meditation"* (Male, 72 years, post AMI). **Some participants who initially had negative perceptions of meditation, or were exposed to the negative perceptions of meditation from others were not discouraged from trying meditation.**	**Some health professionals perceived that meditation had a role to play in heart disease care for those who were open to using it, due to its feasibility as a low cost, relatively safe non-pharmacological intervention.** *"…many people attribute their heart attack or heart disease to stress… So people are actually quite receptive to a (meditation) technique. And you know there are a lot of non-pharmacological techniques where the evidence is not very strong but the uptake is high"* (Participant 005).	Enhance	Many adults living with heart disease considered a meditation intervention conducted in the cardiac rehabilitation setting to be acceptable.

			"I told xx (facilitator) that "I was firmly entrenched in the 20th century and I told her I didn't want to end up wearing orange robes and sit there chanting and stuff. So I think I had a little bit of a, I suppose, a negative attitude towards it (meditation)" (Male, 72 years, post AMI). "*…a lot thought it was a waste of time, but I found it very helpful"* (Male, 71 years, after PPM insertion). **Most participants were open-minded about participating in meditation to improve their health.** *"So I guess to improve for the better, I guess lifestyle or living, or whatever, I'm open to anything. So if this is going to improve my well-being, well, why not"* (Male, 56 years, post AMI, PCI). **Health professionals perceived that the risk of adverse events is low.** *"When I think of risks, I think of adverse patient outcomes and I can't think of any risks like that. If the patients decide that it's not*			

			for them or they decide that they don't like it and it's not achieving the desired outcomes, then I think they just disengage, but I don't think it has any risks to their physical or mental wellbeing" (Participant 006).			
Duration of meditation sessions	Not applicable	**Adults living with heart disease completed on average a little less than one home practice session per week.** Total time spent in meditation home practice was X= 61.82 (SD ± 148.50) minutes.	**The optimal duration of meditation practices in cardiac rehabilitation programs was identified as between 15 and 30 minutes.** *"Fifteen minutes is alright. It's ok to concentrate for that time. To do it longer is hard."* (Female, 62 years, post AMI, PCI). **It is acceptable to replicate and adapt the content of meditation sessions for home practice.** *…The first one being the body scan, which I've record in my voice. Which I think is important. And it just ties back into what they have done more intensively you know, in that little period that we've done together* (P010, female, GP).	**Modification of the duration of formal meditation sessions was considered appropriate.** *"I'm not concerned with the four sessions... The nature of the groups too is, as I run them, the meditation is light, it's not an hour and a half…Yeah, so the actual practices within this, as I say, there's nothing longer than say, about half an hour. That would be the maximum"* (P011, male, RN).	Enhance	The ideal duration of meditation practices is likely to be approximately 15 minutes when adapted for adults living with heart disease.
Flexible delivery using technology	Not applicable	Almost three quarters (73%, n=11) of trial participants completed their home meditation practice using the private Youtube link.	**Health professionals considered flexible delivery approaches using technology were**	Could not be determined	Enhance	The use of online technology to facilitate adherence to a meditation

			acceptable after an introductory session. *You know when you hold their hand, shake their hand there is a human element there that is so hard to replicate without being in the person's presence. However, having said that, once that's established, then tele-health and these other forms of communication can work very well…But you've got to get to that point of trust* (Participant 009).			program was considered acceptable.
Integrating meditation into cardiac rehabilitation to reduce depression and anxiety symptoms	Not applicable	Preliminary evidence suggests that meditation may be helpful in reducing depression and anxiety symptoms in adults living with heart disease. While there were no statistically significant differences in depression and anxiety symptoms between the trial participants allocated to the control or intervention arm this study was not powered to detect statistically significant differences. A larger adequately phase III trial is required.	**Some participants have integrated meditation into their daily lives, and described the intervention as helpful for their psychological health and well-being.** *"Every now and again I'll be thinking what's going to happen at work tomorrow, or something, or if I'm anxious at the moment- early in the piece it was about my commercial driver's license. So I use those relaxation and breathing techniques in those cases…"I'll continue to use them (meditation techniques). I've got no problem with that. I just use it from my memory. It's just sort of*	**Heath professionals' suggested that couching meditation within an integrated care model that is inclusive of mental health is required to generate health executive support for meditation programs.** *I think the best finding source would be, in the area of mental health, which is a very, very popular area (for) funding at the moment in the current health landscape…I think there is a lot of opportunity from government to get funding because it will increase*	Mixed – further research is required	Meditation is perceived as an acceptable strategy to support mental health, which is consistent with the findings from systematic reviews[10] and meta-analyses[11].Whether meditation reduces the burden of depression and anxiety in adults living with heart disease requires further research in a

			automatic I suppose. When I feel the tension, or can't get off to sleep, it just sort of kicks in" (Male, 72 years, post AMI). **Meditation was helpful for developing self-awareness and maintaining calm.** *"I sort of felt good, I tend to over think things sometimes, and you know I found after sitting down and relaxing like that, I didn't sort of think everything was on top of me, I'm overthinking things"* (Female, 60 years, post AMI, PCI). **Some participants who did not adhere to this meditation intervention perceived that meditation was beneficial for relaxation and expressed a desire to use meditation in the future.** *"Yes, that's one thing that I would like to do. I've tried it a couple of times. Meditation is something I'd like to get into. Keep up, and remind myself I need to relax"* (Female, 60 years, post AMI, PCI).	*productivity in the workplace. And reduce hospital admission times and all sorts of things. So the government will be approachable* (Participant 012). **Medical professionals driving the health care system require convincing of the need to restructure health delivery towards an integrated model of care that is inclusive of meditation** *…but I think, you know, it is about the system and the way it has evolved. It has become so siloed. You know the fact that we're siloed between the physical and mental health streams, then to take that leap and join up the physical and mental health is another. You know, it's a big piece of work. Doesn't mean it shouldn't. You know, it's got to happen (*Participant 002). **Mindfulness based practices were endorsed based on the mainstream appeal of these techniques and the preliminary evidence available to support its use**		definitive phase III trial. Health executives require convincing of the need to prioritise integrated models of care, that are inclusive of meditation, which is consistent with the literature[12], However, health professionals who perceive that meditation lacks evidence are unlikely to change their perspective without definitive data from a phase III randomised controlled trial.

				"…but you know…would you recommend something like transcendental meditation, which has very limited research over a MBSR (mindfulness based stress reduction) based approach which has a huge body of literature that supports it" (Participant 001) **Other health professionals considered that there was insufficient empirical evidence to support meditation's integration in heart disease care** *"So if you want it (meditation) funded by government, you need really good evidence that it does something… mostly that evidence is not there, and it is not universally true …the amount of evidence that meditation actually makes a difference is pretty low" (Participant 003).*		
Finding a fit for meditation in heart disease care - Integrating meditation	Not applicable	Adults admitted to cardiology wards and/or entered cardiac rehabilitation in one local health district were directly approached and informed about the opportunity to participate in a	Could not be determined	**There is no standardised referral pathway for meditation within heart disease secondary preventive care.**	Confirm	There is no existing pathway to refer people living with heart disease to meditation programs, which is

into secondary prevention pathways		meditation study by the nurse researcher.		*"But I think you need to streamline the path of entry ('Meditation'). I don't know where you would refer patients for this sort of thing ('meditation'). And I'll be really frank with you. If I don't ('know'), the chances are that a lot of people don't… (know how to refer people onto meditation')" (Participant 008).* **Integrating meditation into secondary prevention pathways was required to find a fit for meditation in heart disease care** *"…And I thought it was interesting because it (Heart Foundation Survivor survey) doesn't look at meditation, but it talks about stress management. And it's (stress management) actually a part of the cardiac rehab program. Now I don't know what that looks like…So again, what strategies they used for that I don't know, but, you know that there's a place for it in there…" (Participant 002).*		consistent with the literature[12]. However, health professionals recognised cardiac rehabilitation as the ideal forum for promoting meditation in heart disease care. Community based meditation programs are also an option to promote continuity of care for adults living with heart disease who require ongoing psychological health support on completion of their cardiac rehabilitation program.

				Community referral was considered appropriate due to an increasing emphasis on outpatient services and continuity of care *"So I think getting support across the health care team, particularly I think within general practice is something to think about as well. Because what you've got to remember is that you know about that's where the majority of care happens in primary care, essentially engaging practice nurses and general practitioners. Or just letting them know about the techniques and the purpose might be useful" (Participant 005).*		
Finding a fit for meditation in heart disease care – identifying mutually beneficial outcomes	Not applicable	Not applicable	Not applicable	**Couching meditation in state mandated key performance indicators is required to find a fit for meditation in heart disease care** *"There is definitely a lot more accountability, and a lot emphasis on trying to eliminate variation in care, and a lot of it's based on readmissions,*		Demonstrating cost-effectiveness and aligning meditation with health organisation mandated key performance indicators, such as improving adults living with heart

				information that's provided to people before they leave hospital. They're really big on trying to decrease readmissions, they're really big on trying to improve quality of life, they're really big on patient experience" (Participant 014). **Demonstrating cost-effectiveness for meditation is also required to find a fit for meditation in heart disease care** *So, if you went at it from those angles, putting together, some sites won't look at anything unless you've got a business case. And evaluation is the other thing, so most places will want to know what your evaluation strategy was. What would be your metrics, what would be your evaluation strategy? (Participant 014)*		diseases' experience of health care and quality of life, is required to integrate meditation into heart disease care.
Psychological health assessment	A fifth (19%) of DASS-21 data was missing for adults living with heart disease who attend cardiac rehabilitation	Whilst there were no significant differences in depression and anxiety symptoms between trial participants allocated to the control or intervention, the phase II trial was not powered to detect statistically significant differences.	**A proportion of participants were hesitant to disclose personal information regarding their mental health, or considered the disclosure of mental health information as a deterrent for other adults living**	Could not be determined	Mixed	While the DASS-21 is being successfully implemented in a local health district's cardiac rehabilitation program, health professionals need to

	programs in one local health district. It is difficult to determine if participants elected not to answer these psychological health questions; or that the DASS-21 was administered to all cardiac rehabilitation participants; or that the data was collected but not entered into the cardiac rehabilitation database.	**Depression** DASS-21 [D] (p = 0.973); HADS [D] (p= 0.318) **Anxiety** DASS-21 [A] (p = 0.920); HADS [A] (p = 0.542) **Mindfulness-based self-efficacy** (p = 0.338) **Health status** (p = 0.407) Equanimity, a component of mindfulness-based self-efficacy was increased in the intervention group vs control group and approached statistical significance (p=0.077). The proportion of missing psychological health data from adults attending cardiac rehabilitation who participated in a meditation intervention was low: at baseline (3%), but increased on completion (36%).	**with heart disease who may be interested in meditation.** *"Most people don't want to show up their personal story. So I think without the query, so you have them mixed together one course, exercise and this course. If you do that then I think many people will come"* (Male, 73 years post AMI, PCI).			consider the optimal means of collecting psychological health information that meets their informational needs and the preferences of adults living with heart disease. This recommendation is in line with national cardiac rehabilitation guidelines Core Component 4.8 Assessment of Psychological Status[13].
Engaging adults living with heart disease from culturally and linguistically diverse backgrounds	The local health district involved in this study has a high proportion of ethnically diverse residents[14, 15]. However, data on ethnicity and/or	- 40% of people living with heart disease with depression and anxiety symptoms who participated in the meditation trial spoke both English and a second language at home. - 11% (19/173) of people living with heart disease did not meet	Could not be determined	Could not be determined	Mixed	Obtaining data on ethnicity and Aboriginality is important to facilitate inclusion of adults from culturally and linguistically diverse

	language spoken at home was not available.	the trial eligibility criteria as they had insufficient English language skills.				backgrounds in meditation interventions designed to reduce depression and anxiety in adults living with heart disease. It might also be helpful, despite English literacy, to administer the DASS-21 in the native language of culturally and linguistically diverse cardiac rehabilitation participants.
Facilitator-accreditation and training	Not applicable	The researcher, an experienced registered nurse who had ≥14 years' experience in meditation and has completed Mindfulness Based Stress Reduction training facilitated the meditation sessions.	**Health professionals considered it necessary to utilise the multidisciplinary team to successfully integrate meditation into cardiac rehabilitation programs.** *I think all members of the health care team ideally, have some knowledge of the technique. I think if it's isolated to professionals such as psychologists or social workers*	**Health professionals were ideally placed to facilitate meditation if they:** **i) had an additional qualification; and/or** *…there are a number of health professionals, psychologists or psychiatrists, or social workers, who might have done, gone to a day workshop, and think yeah yeah, I get it, and then, they start teaching it, or teaching*	Mixed	Health professionals are considered as acceptable to implement meditation for adults living with heart disease, however, additional training in meditation techniques and/or an established meditation practice

			who are traditionally sort of led those sort of interventions, if that's the case it's never going to get broad uptake, particularly within the Australian model the majority of cardiac rehabilitation programs are delivered and coordinated by nurses, it seems that that is a logical step… (Participant 005). **While psychologists have unique skills to facilitate meditation, care is required to ensure that adults living with heart disease are willing to receive meditation training from a psychologist.** *I think again, if you were in a service that had a clinical psychologist, you'd be absolutely using them as your leverage point to raise the profile and the benefits of doing this, but where you don't have that luxury it would be working with whose available* (Participant 014). *Some patients are a little bit resistant to getting referred to a psychologist. You know because to some patients it can have some connotations that they're to particularly comfortable with.*	*what they think is the practice, and it's actually counterproductive (Participant 001).* **ii) had experience in meditation techniques.** *…so I would say if someone's got their own regular practice that they've had for several months and they are willing to sort of follow a standardized protocol which we know is safe, then they are the best people to do it* (Participant 018).		was considered important. Adults living with heart diseases' preferences for meditation require assessment prior to engaging with the multidisciplinary team.

			Whereas they might be more comfortable being referred to, for meditation by you know by some other service provider (Participant 015).			
						Random stratification based on demographic and clinical characteristics is not required in a phase III RCT.

Appendix 9: Ethics Approval Letters

UTS HREC Approval - ETH17-1604

Research.Ethics@uts.edu.au

Thu 6/07/2017 11:25 AM

To: Louise Hickman <Louise.Hickman@uts.edu.au>; Angela Rao <Angela.Rao@uts.edu.au>; Research Ethics <research.ethics@uts.edu.au>; Phillip Newton <Phillip.Newton@uts.edu.au>; Michelle DiGiacomo <Michelle.DiGiacomo@uts.edu.au>

Dear Applicant

[External Ratification: Western Sydney Local Health District HREC approval – AU/6/1B2B215 – 02/02/2017 - 31/12/2017]

The UTS Human Research Ethics Expedited Review Committee has reviewed your application titled, "Understanding the profile of adults with heart disease: A cross-sectional study.", and agreed that the application meets the requirements of the NHMRC National Statement on Ethical Conduct In Human Research (2007). I am pleased to inform you that your external ethics approval has been ratified with a recommendation that the researcher have a Data Transfer Agreement in place. Also noting that it was both a transfer of approval from UNSW and a ratification of approval from the AH&MRC. The Committee noted that the AH&MRC would remain the primary committee

Your approval number is UTS HREC REF NO. ETH17-1604
Approval will be for the period specified above and subject to the provision of evidence of continued support from the above-named Committee.

Please note that the ethical conduct of research is an on-going process. The National Statement on Ethical Conduct in Research Involving Humans requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually, and at the end of the project (if it takes more than a year).

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

You should consider this your official letter of approval. If you require a hardcopy please contact Research.Ethics@uts.edu.au.

To access this application, please follow the URLs below:
* if accessing within the UTS network: https://rm.uts.edu.au
* if accessing outside of UTS network: https://vpn.uts.edu.au , and click on " RM6 – Production" after logging in.

We value your feedback on the online ethics process. If you would like to provide feedback please go to: http://surveys.uts.edu.au/surveys/onlineethics/index.cfm

If you have any queries about your ethics approval, or require any amendments to your research in the future, please do not hesitate to contact Research.Ethics@uts.edu.au.

UTS HREC Approval - ETH17-1605

Research.Ethics@uts.edu.au

Thu 6/07/2017 11:28 AM

To: Angela Rao <Angela.Rao@uts.edu.au>; Louise Hickman <Louise.Hickman@uts.edu.au>; Research Ethics <research.ethics@uts.edu.au>; Michelle DiGiacomo <Michelle.DiGiacomo@uts.edu.au>

Dear Applicant

[External Ratification: Western Sydney Local Health District HREC approval – AU/6/96/CB210 – 01/03/2017 - 30/05/2018]

The UTS Human Research Ethics Expedited Review Committee has reviewed your application titled, "Implementing meditation in heart disease clinical settings: Patient and health care provider perspectives", and agreed that the application meets the requirements of the NHMRC National Statement on Ethical Conduct In Human Research (2007). I am pleased to inform you that your external ethics approval has been ratified with a recommendation that the researcher have a Data Transfer Agreement in place. Also noting that it was both a transfer of approval from UNSW and a ratification of approval from the AH&MRC. The Committee noted that the AH&MRC would remain the primary committee

Your approval number is UTS HREC REF NO. ETH17-1605
Approval will be for the period specified above and subject to the provision of evidence of continued support from the above-named Committee.

Please note that the ethical conduct of research is an on-going process. The National Statement on Ethical Conduct in Research Involving Humans requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually, and at the end of the project (if it takes more than a year).

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

You should consider this your official letter of approval. If you require a hardcopy please contact Research.Ethics@uts.edu.au.

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We value your feedback on the online ethics process. If you would like to provide feedback please go to: http://surveys.uts.edu.au/surveys/onlineethics/index.cfm

If you have any queries about your ethics approval, or require any amendments to your research in the future, please do not hesitate to contact Research.Ethics@uts.edu.au.

UTS HREC Approval - ETH18-2337

Research.Ethics@uts.edu.au

Fri 20/04/2018 11:46 AM

To: Angela Rao <Angela.Rao@uts.edu.au>; Louise Hickman <Louise.Hickman@uts.edu.au>; Michelle DiGiacomo <Michelle.DiGiacomo@uts.edu.au>; p.newton@westernsydney.edu.au <p.newton@westernsydney.edu.au>; Research Ethics <research.ethics@uts.edu.au>; Jane Phillips <Jane.Phillips@uts.edu.au>

Dear Applicant

[External Ratification: Western Sydney Local Health District Human Research Ethics Committee HREC approval – AU RED HREC/17/WMEAD/495 – 21 Months (until 31/12/2019)]

The UTS Human Research Ethics Expedited Review Committee has reviewed your application titled, "Implementing meditation into heart disease clinical settings. (The MENTOR Study)", and agreed that the application meets the requirements of the NHMRC National Statement on Ethical Conduct In Human Research (2007). I am pleased to inform you that your external ethics approval has been ratified with the following recommendations:

- The researchers should consider that contamination is possible as participants could potentially attend classes elsewhere or undertake meditation themselves in the control group;
- Evidence of ANZCTR registration needs to be provided;
- The participant material should include the UTS Logo and HREC number;
- The Committee recommended that the health care utilisation section of the UTS Assessment Questionnaire provide an option to associate frequency of visits for 'other' health services;
- On page 2 of the participant information sheet/consent form, the word meditation is misspelt as 'mediation'; and
- The Committee recommended that the inclusion/exclusion criteria include 'reliable' internet access as participants will be directed to online resources.
- It is a condition of approval that the researcher confirm funding and contractual arrangements with their Faculty and/or RIO as per the current delegations.

Your approval number is UTS HREC REF NO. ETH18-2337.

Approval will be for the period specified above and subject to the provision of evidence of continued support from the above-named Committee.

Please note that the ethical conduct of research is an on-going process. The National Statement on Ethical Conduct in Research Involving Humans requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually, and at the end of the project (if it takes more than a year).

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

You should consider this your official letter of approval. If you require a hardcopy please contact Research.Ethics@uts.edu.au.

Health
Western Sydney
Local Health District

Research Office File No: (5005)
HREC Ref: AU RED LNR/17/WMEAD/24
SSA Ref: AU RED LNR SSA/17/WMEAD/87 – *Westmead*
AU RED LNR SSA/17/WMEAD/88 – *Auburn*
AU RED LNR SSA/17/WMEAD/89 – *Blacktown*
AU RED LNR SSA/17/WMEAD/90 – *Mt Druitt*

23 March 2017

Prof Phillip Newton
Centre for Cardiovascular & Chronic Care
Faculty of Health - UTS
PO Box 123
ULTIMO NSW 2007

Dear Prof Newton

LNR Research Project: "Understanding the profile of adult with heart disease: A cross-sectional study"

Your request to undertake the above protocol as a Low and Negligible Risk (LNR) research project was reviewed by a subcommittee of members of the Scientific Advisory Committee (SAC) and the Human Research Ethics Committee (HREC). We are satisfied that your protocol meets the criteria for an LNR research project and does not require review by the full HREC.

The WSLHD HREC has been accredited by the NSW Ministry of Health as a lead HREC to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

This proposal meets the requirements of the National Statement and I am pleased to advise that the HREC has granted ethical approval of this LNR research project to be conducted at:

- Westmead Hospital – Chief Investigator Mr Robert Zecchin
- Auburn Hospital – Chief Investigator Mr Robert Zecchin
- Blacktown Hospital – Chief Investigator Mr Robert Zecchin
- Mt Druitt Hospital – Chief Investigator Mr Robert Zecchin

Research Office File No: (5045)
HREC Ref: AU RED LNR/17/WMEAD/69
SSA Ref: AU RED LNR SSA/17/WMEAD/70

1 June 2017

Mr Robert Zecchin
Department of Cardiac Education and Assessment Program
Westmead Hospital

Dear Mr Zecchin

LNR Research Project: 'Implementing meditation in heart disease clinical settings: Patient and health care provider perspectives'

Your request to undertake the above protocol as a Low and Negligible Risk (LNR) research project was reviewed by a subcommittee of members of the Scientific Advisory Committee (SAC) and the Human Research Ethics Committee (HREC). We are satisfied that your protocol meets the criteria for an LNR research project and does not require review by the full HREC.

The WSLHD HREC has been accredited by the NSW Ministry of Health as a lead HREC to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice.*

This proposal meets the requirements of the National Statement and
I am pleased to advise that the HREC has granted ethical approval of this LNR research project to be conducted at:

- Blacktown Mount Druitt Hospital
- University of Technology

The following documentation has been reviewed and approved by the HREC:

- LNR Application Form submission code AU/6/96CB210
- Scientific Protocol, version 2, dated 18 April 2017
- Participant Information and Consent Form – Patients, version 2, dated 18 May 2017
- Participant Information and consent Form – Clinicians, version 2, dated 18 May 2017
- Study Flyer, no version or date

Health
Western Sydney
Local Health District

Research Office File No: **(5398)**
HREC Ref: AU RED HREC/17/WMEAD/495
SSA Ref: AU RED

26 February 2018

Prof Philip Newton
Nursing Research Centre
Westmead Hospital

Dear Prof Newton

LNR Research Project: Implementing meditation in heart disease clinical settings: The MENTOR Study

Thank you for your correspondence addressing the matters raised in the HREC's letter dated 5 December 2017 following single ethical review of the above project at its meeting held on 28 November 2017.

This HREC has been accredited by the NSW Department of Health as a lead HREC to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research and the CPMP/ICH Note for Guidance on Good Clinical Practice.

This proposal meets the requirements of the National Statement and I am pleased to advise that the HREC has now granted ethical approval of this Single site research project to be conducted by you at:

- Blacktown Hospital – Principal Investigator Prof Philip Newton

The following documentation has been reviewed and approved by the HREC:

- NEAF submission code AU/1/E951311
- Protocol Version 2 dated 8 January 2018
- Participant Information and Consent Form Version 2 dated 8 January 2018
- UTS Assessment No version and date
- Mentor participant log sheet Version 1 dated 18 October 2017

Please note the following conditions of approval:

- The Chief Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.
- For clinical trials of implantable medical devices only – The Chief Investigator will confirm to the HREC that a process has been established for tracking the participant, with consent, for the lifetime of the device and will immediately report any device incidents to the Therapeutic Goods Administration (TGA).

HUMAN RESEARCH ETHICS COMMITTEE

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