School of Nursing and Midwifery
Centre for Cardiovascular and Chronic Care

Home-Heart-Walk: Evaluation of an intervention to promote and monitor physical activity

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Declaration

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made.

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

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HuiYun Du

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Date

Acknowledgement

Looking back, when I arrived in Sydney in 2002, the mission was solely to complete a six-month English class. How did I end up writing this thesis? Seems to be series of flukes, and meeting of wonderful people who have inspired and motivated me at each step of the way.

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Anthology of publications and presentations associated with this thesis

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Du, H., Newton, P., Zechin, R., Dennis, R., Salamonson, Y., Currow, D., Macdonald, P., Wilkinson, A., & Davidson, P. (2011) Study protocol: Evaluation of an self-monitoring intervention of physical functional capacity to promote physical activity and self-management in people with stable chronic heart failure. BMC-*Trials* (**Impact factor 2.020**)

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Abstract

Chronic heart failure is a complex and multifaceted clinical syndrome and impacts adversely on health related quality of life and also increases the risk of hospitalisation and major acute coronary events. Self-care in chronic heart failure requires lifestyle changes, such as dietary modifications, fluid restriction, medication adherence and increasing physical activity. Enhancing self-care has been shown to result in better health outcomes and improved quality of life. Promoting better self-care is an important and effective strategy in chronic heart failure management. Exercise and physical activity are part of best practice recommendation. Despite compelling evidence to support the benefits of physical activity in improving functional capacity and quality of life, physical activity adherence remains low. Many people find following physical activity recommendations more difficult than following their medication regime, fluid restriction and diet. To date, the majority of interventions have focused on improving physical functioning of people living with CHF involving supervised, clinic based exercise programs although the benefits for home based programs is evident. Nevertheless, the impressive gains people have achieved through physical activity programs are often lost as many fail to maintain a physically active lifestyle after they complete the program.

Based upon a comprehensive literature review and theoretical framework, the Home-Heart-Walk has been developed. The Home-Heart-Walk is a novel theoretically informed self-monitoring intervention, sought to promote physical functioning in people living with chronic heart failure. This model is a self-administered intervention adapted from the standard six minute walk test. It comprised six months of weekly Home-Heart-Walk and monthly telephone follow-up. This doctoral project evaluated the effect of the Home-Heart-Walk in promoting physical functioning in a group people with chronic heart failure.

Participants were followed up at three months and six months. The primary outcome was the physical function domain of the Medical Outcome Study Short Form-36. Secondary outcomes included the Six Minute Walk Test (6MWT)

distance, European Heart Failure Self-care Behaviour Scale, Bandura's exercise self-efficacy, generic health related quality of life (Medical Outcome Study Short Form-36) and disease specific (Minnesota Living with Heart Failure Questionnaire) as well as Physical Activity Scale.

This thesis presents the conceptual underpinnings of a theoretically derived intervention, clinical trial methodology and the interim analysis of the first 67 participants who have completed the six-month study. All participants' data were analysed on the basis of the intention to treat principle. Despite there were no statistical or clinical significant difference observed between the intervention and the control group at six-month follow-up, there was a significant increase in the 6MWT distance over the six-month study period, in the intervention group (p=0.05). A trend of improved self-reported health related quality of life was also observed in the intervention group, with a slight decreased Minnesota Living with Heart Failure Questionnaire score (baseline: 45.4 [95% CI: 37.0-53.9]; three-month: 41.7 [95% CI: 32.6-50.9]) compared to the clinically meaningful deterioration (increased score) in the control group (baseline: 36.3 [95% CI: 27.8-44.7]; three-month: 43.9 [95% CI: 35.3-52.6]). The deterioration observed in control group was sustained at six-month follow-up. Similarly, score in self-care behaviour was also slightly decreased (improvement) (26.2 [95% CI: 23.4-29.0] to 24.0 [95% CI: 21.6-26.3]) compared to a slight increase (deterioration) in the control group (25.6 [95% CI: 22.9-28.5] to 26.5 [95% CI: 23.4-29.6]), over the study period.

While results from this interim analysis will not allow conclusion to be made on the effectiveness of the Home-Heart-Walk, they have provided preliminary data and insights into the challenge of promoting physical functioning in people living with chronic heart failure. This study highlights the challenges of achieving long-term physical activity adherence for people living with CHF. This has been demonstrated in recruitment challenges, and the refractory dimension of increasing physical activity.

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Abbreviations

Abbreviation	Full term
6MWT	Six Minute Walk Test
ACE	Angiotensin-converting enzyme
AICD	Automated implantable cardioverter defibrillator
ATS	America Thoracic Society
BN	Bachelor of nursing
CABG	Coronary artery bypass graft
CAD	Coronary artery disease
CCM	Chronic care model
CHD	Coronary heart disease
CHF	Chronic heart failure
CI	Confidence interval
COPD	Chronic obstructive airways disease
CVA	Cerebral vascular accident
CR	Cardiac rehabilitation
EHFScBS	European Heart Failure Self-care Behaviour Scale
EF	Ejection fraction
HF	Heart failure
HRQoL	Health related quality of life
ICC	Intraclass correlation coefficient
LV	Left ventricle
MACE	Major adverse cardiac event

Abbreviation	Full term
MET	Maximal exercise test
MI	Myocardial infarction
MLHFQ	Minnesota Living with Heart Failure Questionnaire
NHMRC	National Health and Medical Research Council
NSW	New South Wales
NYHA-FC	New York Heart Association – functional class
PASW	Predictive Analytics SoftWare (previously known as SPSS)
Peak VO2	Peak oxygen consumption
PCI	Percutanous coronary intervention
QoL	Quality of life
RCT	Randomised controlled trial
RV	Right ventricle
SD	Standard deviation
SF-36	Medical Study Outcome Short Form-36
SPSS	Statistical Package for the Social Sciences
US	United State of America
WHO	World health organization

Glossary

Terms	Definition
Acute heart failure	de novo acute heart failure or decomposition of chronic heart failure characterized by signs of pulmonary congestion, including pulmonary edema
Adherence	The extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.
Angina	A medical term used to describe a discomfort or chest pain felt by a patient. Angina can be the result of a spasm, narrowing or blockage of a coronary vessel depriving the heart muscle of blood and oxygen.
Body Mass Index	A statistical measure of the weight of a person scaled according to height.
Cardiac rehabilitation	Cardiac rehabilitation is a medically supervised program to help heart patients recover quickly and improve their overall physical, mental and social functioning.

Terms	Definition
Chronic care model	A well-established organizational framework for chronic care management and practice improvement
Chronic heart failure	A complex clinical syndrome with typical symptoms (eg, dyspnoea, fatigue) that can occur at rest or on effort that is characterised by objective evidence of an underlying structural abnormality OR cardiac dysfunction that impairs the ability of the ventricle to fill with or eject blood (particularly during exercise).
Compliance	A patient's adherence to a recommended course of treatment
Congestive Heart Failure	A clinical syndrome caused by heart disease, characterized by breathlessness and abnormal sodium and water retention, and resulting in edema. This term is used when there is congestion of pulmonary or systemic vascular beds. This term often used interchangeable with “chronic heart failure” (also known as “heart failure”)

Terms	Definition
Coronary Artery Bypass Grafts (CABGS)	A surgical procedure where a vein or an artery is rafted surgically to bypasses the blocked vessel or vessels to improve blood supply from the aorta to the heart muscle.
Diastolic heart failure	Diastolic CHF is the inability to fill the heart at normal filling pressures despite normal ventricular contraction
Dyspnoea	Short of breath, perceived difficulty breathing or painful breathing
Ejection fraction	The fraction of blood pumped out of the right and left ventricles with each heart beat. The term ejection fraction applies to both the right and left ventricles; Left ventricular ejection fraction (LVEF) Right ventricular ejection fraction (RVEF)
Exercise	Planned structured physical activity that is done to improve or maintain one of the physical fitness, they are, strength, flexibility, endurance
Feasibility	How reasonably practical it is to follow a designated procedure within a pre-specified time frame and within existing resources

Terms	Definition
Functional capacity	An individual's 'maximum potential to perform' those activities people do in the normal course of their lives to meet basic needs, fulfill usual roles, and maintain their health and well-being.
Health Behaviour	Undertaking methods to prevent or reduce the incidence of developing diseases
Health related outcome	Change in the health status of an individual, group or population which is attributable to a planned intervention or series of interventions, regardless of whether such an intervention was intended to change health status
Health related quality of life	The overall impact of a medical condition on the physical, mental, and social well-being of an individual

Terms	Definition
Heart failure	A clinical syndrome resulting from a cardiac disease which compromises ventricular systolic or diastolic function or both. Heart failure results when the heart is unable to generate a cardiac output sufficient to meet the demands of the body without unduly increasing diastolic pressure. Heart failure may be manifested by symptoms of poor tissue perfusion alone (e.g., fatigue, poor exercise tolerance, confusion) or by both symptoms of poor tissue perfusion and congestion of vascular beds (e.g., dyspnoea, chest rales, pleural effusion, pulmonary edema, distended neck veins, congested liver, peripheral edema).
Inactivity	Not engaging in any regular pattern of physical activity beyond daily functioning
Incidence	A measure of the risk of developing some new condition within a specified period of time
Maximal exercise test	A test performed until volitional exhaustion

Terms	Definition
Moderate activity	Physical activity during which there should be a moderate, noticeable increase in the depth and rate of breathing of the person, while still allowing comfortable talking
New York Heart Association – functional class	The New York Heart Association (NYHA) Functional Classification provides a simple way of classifying the extent of heart failure. It places patients in one of four categories based on how much they are limited during physical activity; the limitations/symptoms are in regards to normal breathing and varying degrees in shortness of breath and or angina pain
Peak oxygen consumption	The maximum capacity to transport and utilize oxygen during incremental exercise
Physical activity	Any bodily movement produced by skeletal muscles that result in energy expenditure using a method that is accurate and reproducible

Terms	Definition
Prevalence	The total number of cases of the risk factor in the population at a given time, or the total number of cases in the population, divided by the number of individuals in the population. It is used as an estimate of how common a disease is within a population over a certain period of time
Quality of Life	A generic term that measures the individual's perception of their life experience. It is a multidimensional concept measuring important aspects or domains of a person's life including physical functioning, psychological processes and social and economic concerns, as well as spiritual and existential aspects.
Self-care	A process of maintaining health through constructive behaviours
Self-efficacy	The level of confidence an individual has in their ability to perform the task for physical activity which can likely be translated to other self-care behaviours

Terms	Definition
Self-management	The involvement of a person with a chronic disease in activities that protect and promote health, monitoring and managing symptoms and signs of illness, managing the impacts of illness on functioning, emotions, and interpersonal relationships and adhering to treatment regimes
Self-monitoring	A complex concept involves monitoring, understanding, interpretation and response with appropriate actions to signs and symptoms
Sub-maximal exercise test	A exercise test, which measures individuals' work below maximum effort. In sub-maximal tests, extrapolation is used to estimate maximum capacity. Example of sub-maximal exercise test: the 6 minute walk test
Systolic heart failure	The inability of the heart to pump properly and remains the most common cause of CHF

Terms	Definition
Risk Factors	This refers to the factors which contribute to the development of cardiac disease. These factors can either be modifiable, obesity, physical inactivity, cigarette smoking, high fat diet, high cholesterol and hypertension. Non - modifiable risk factors include age, gender and family history
Vigorous activity:	Physical activity during which there should be a severely increase in heart rate, the depth and rate of breathing of the person

Chapter 1
The burden of chronic heart failure and the importance of self-care

1.1 Introduction

Chronic heart failure (CHF) is one of the most costly chronic syndromes in developed countries in both economic and human terms.[1] Currently, developed countries spend 1-2% of all healthcare expenditure on CHF.[2] As demographic transitions result in an increased number of elderly individuals in both developed and developing nations, the resources devoted to CHF care will likely further increase.[2] A range of innovative disease management approaches have been developed and evaluated in response to the increasing disease burden.[3, 4] This thesis presents the conceptual underpinnings, development and preliminary evaluation of an intervention designed to improve physical functioning through increased physical activity. This chapter describes the burden of CHF, physical functional capacity monitoring and the scope of home-based, self-management interventions.

1.2 Chronic heart failure

1.2.1 Heart failure

Heart failure is a complex clinical syndrome resulted from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood, and is commonly associated with hypertensive, coronary and/or valvular cardiovascular disease.[5] While the cardinal manifestations of heart failure are dyspnoea and fatigue, decreased exercise tolerance, and fluid retention leading to pulmonary congestion and peripheral edema may or may not be present.[6] Some people have exercise intolerance, but will not necessary experience fluid retention, while others may experience oedema with little change in exercise tolerance.[7] Not all people with heart failure have volume overload at the time of initial or subsequent evaluation. This has resulted in the terms “heart failure”, “congestive heart failure”, and “chronic heart failure” being used interchangeably. For the reasons listed above, the term “chronic heart failure” is preferred over “congestive heart failure”.[7]

1.2.2 Acute vs. chronic heart failure

Acute heart failure is often used exclusively to mean de novo acute heart failure or decompensation of CHF characterised by signs of pulmonary congestion, including pulmonary edema.[8] Acute decompensation of CHF is the most common form of heart failure presentations to hospital.[8] The study presented in this thesis focuses on the syndrome of CHF and not on aspects of acute heart failure. Therefore, unless stated, the term “heart failure” refers to the chronic state of heart failure. Chronic heart failure is associated with significant morbidity and mortality. In particular functional performance and the capacity to undertake physical activity influences Health related quality of life (HRQoL) is also a prognostic marker.[9, 10] In spite of considerable progress in the management of CHF in the preceding decades, the prognosis of CHF remains poor.[11] Increasing prevalence of CHF mandates a reform of how we deliver care and adopting an approach such as the Chronic Care Model (CCM).[12] The Chronic Care Model identifies the essential elements of a health care system that encourages high-quality chronic disease care.[13] There is an extensive body

of evidence demonstrating the benefits of multidisciplinary, coordinated home-based interventions in improving health related outcome and HRQoL, which is now a part of the standard care.[14] These interventions incorporate self-care, including exercise training, education and self-monitoring components to assist individuals adjust and cope with this debilitating syndrome.

1.2.3 Definition of chronic heart failure

A number of definitions for CHF exist. For the purpose of this study, CHF is defined according to the National Heart Foundation of Australia and Cardiac Society of Australia & New Zealand (2006). Chronic heart failure is:

"A complex clinical syndrome with typical symptoms (eg, dyspnoea, fatigue) that can occur at rest or on effort that is characterised by objective evidence of an underlying structural abnormality OR cardiac dysfunction that impairs the ability of the ventricle to fill with or eject blood (particularly during exercise). A diagnosis of CHF may be further strengthened by a beneficial clinical response to treatment(s) directed towards amelioration of symptoms associated with this condition." [5, p 550]

Once the diagnosis of CHF is established, symptoms are often used to characterise the severity of the disease, and to quantify the degree of functional limitation imposed. A system commonly used for this classification has been developed by the New York Heart Association (NYHA), and is presented in Table 1.1.

Table 1.1 New York Heart Association functional class

Class I	No limitation: ordinary physical exercise does not cause undue fatigue, dyspnoea or palpitations.
Class II	Slight impairment of physical activity: comfortable at rest but ordinary activity results in fatigue, palpitations.
Class III	Marked limitation of physical activity: comfortable at rest but less than ordinary activity results in symptoms.
Class IV	Unable to carry out any physical activity without discomfort: symptoms of CHF are present even at rest with increased discomfort with any physical activity.

Source: Kossman CE (ed) Diseases of the heart and blood vessels; nomenclature and criteria for diagnosis. (6th ed) Boston: Little Brown 1964:112.[15]

1.3 Burden of chronic heart failure

1.3.1 Incidence and prevalence

Chronic heart failure is a major and growing public health problem globally.[2, 16] Unfortunately, reliable epidemiological data for CHF is not readily available, with some exceptions.[17, 18] Much of the available data for Australia is extrapolated and modeled as described below. Therefore, it is useful to also review some international comparisons. Figure 1.1 presents the prevalence of CHF by sex and age in the United States of America (US).[19] The incidence of CHF approximately doubles with each advancing decade of age which is concerning given the ageing of the population.[19]

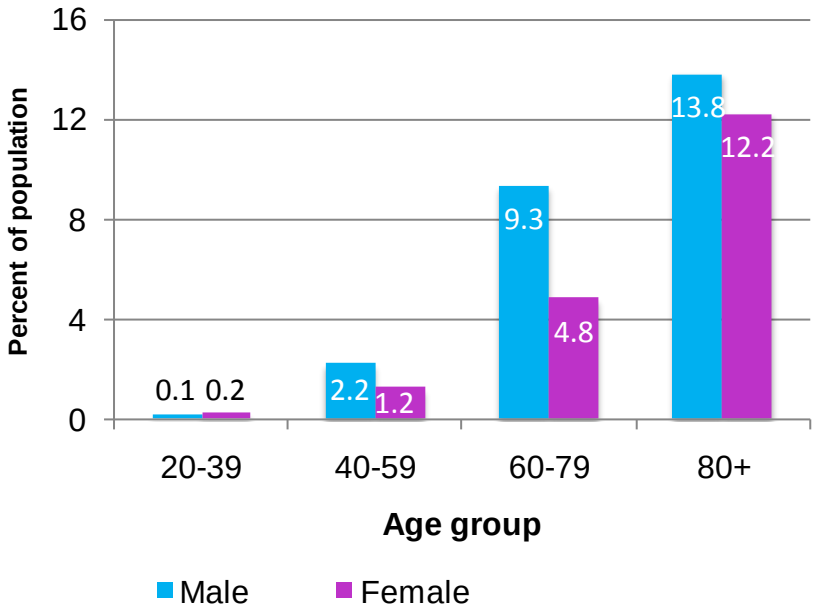

Figure 1.1 Prevalence of heart failure by sex and age
(National Health and Nutrition Examination Survey [NHNES]: 2005-2006). Source: National Centre for Health Statistics [NCHS] and National Heart, Lung and Blood Institute [NHLBI]. [19]

Chronic heart failure is estimated to affect 1% of the general population, 3-5% of people over the age of 65 years and 10% of people aged over 75 years in Western countries.[20] The Framingham Study provides population-based data, which reported between 6%-10% of the population, aged over 65 years experience CHF.[11] In Scotland, a national survey that covered 6% of the Scottish population revealed a prevalence of 7.1 in 1000 and an incidence of 2.0 in 1000.[21] Both the prevalence and incidence of CHF increase dramatically with age to 90.1 in 1,000 (prevalence) and 22.4 in 1,000 (incidence) among people aged 85 years or above.[21] These data not only represents treated people but also population-based screening, rendering a more robust estimation of prevalence. The 2009 update from the American Heart Association provide data of CHF incidence in relation to sex and age, which is presented in Figure 1.2.

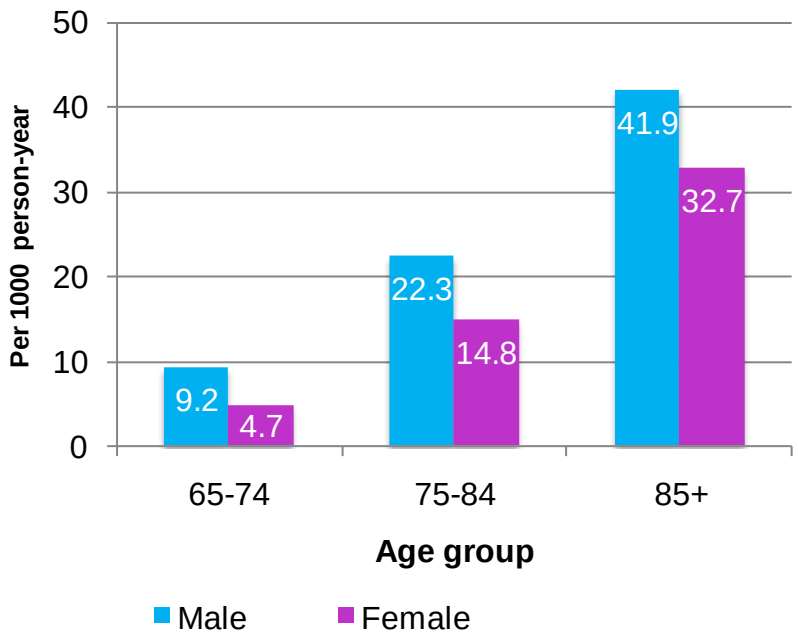

Figure 1.2 Incidence of heart failure by sex and age
(CHF based on physician review of medical records and strict diagnostic criteria) (1980-2003) Source: NHLBI. [19]

As discussed previously, in Australia, the estimation of heart failure prevalence and incidence has been primarily derived by extrapolation of overseas data until the last decade.[17, 18] It is estimated that about 10 to 15 per 1000 people have CHF in Australian population.[17] There was no population-based data for heart failure prevalence in Australia prior to the Canberra Heart Study.[17] In this study, 2000 residents (60 - 86 years of age) in Canberra were randomly selected. Of the 2000 residents, 1275 participants completed all the investigations (including echocardiography). It was identified that, 3.1% of the these participants in the 60-64 years age group have CHF, and 13.6% of participants in the 80-86 years group have CHF. In total 5.6% of the participants had diagnosed CHF and 0.6% were not previously diagnosed. The mean age of the participants was 69.4 years. Every year, an estimated 30,000 Australians receive a diagnosis of CHF. [22]

The ageing of the population globally is well documented.[23] By 2051, the estimated proportion of Australians aged over 65 years is expected to increase three fold.[23] Figure 1.3 shows the projected change in Australian's population over the next 50 years. Because CHF occurs mainly in those over the age of 65 years,[24] this projected ageing of the population will have significant effect on

the incidence of CHF in the future. Beside the ageing population, the introduction of thrombolytic therapy, percutaneous coronary interventions, and adjuvant treatments, [25] have improved survival after an acute cardiac event, which is another contributor to the predicted increase in the incidence of CHF.[24] These advances have seen a 12%-16% reduction in fatalities from an acute cardiac event in Australia between 1993-1994 and 1999-2000.[26] With an expected increase in the incidence of some risk factors, particularly obesity and diabetes, a rise in the incidence of cardiovascular disease is projected.[25]

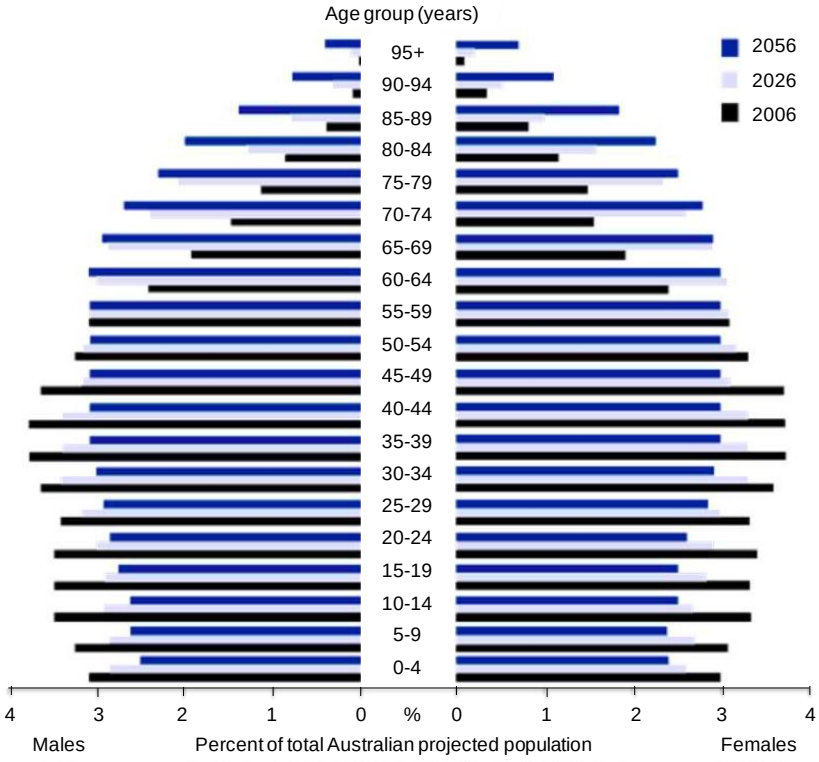

Figure 1.3 Australian population projections to 2056
Source Australian Bureau of Statistics, Population projections, Australia 2004-2101. 2005, (cat. No. 3222.0):Canberra.[23]

In addition to population ageing and improved survival after an acute coronary event, increased awareness, and advances in the diagnosis of CHF may also have contributed to the increase in disease prevalence. For example, it has only been in the last decade that echocardiography has been incorporated into the diagnosis of CHF to confirm structural heart disease in people with non-specific symptoms and signs of cardiac insufficiency. Echocardiography is now the gold standard for diagnosing CHF.[7, 27, 28]

1.3.2 Hospitalisation

Hospital admission

Chronic heart failure is the most common principal diagnosis among hospitalised adults aged 65 years or older.[29] From 1979 to 1999, hospitalisation for CHF rose 155%, to 962,000 per year in the US.[30] In 2006, the number of hospitalisations for people with CHF was 1,106,000 (Figure 1.4).[30]

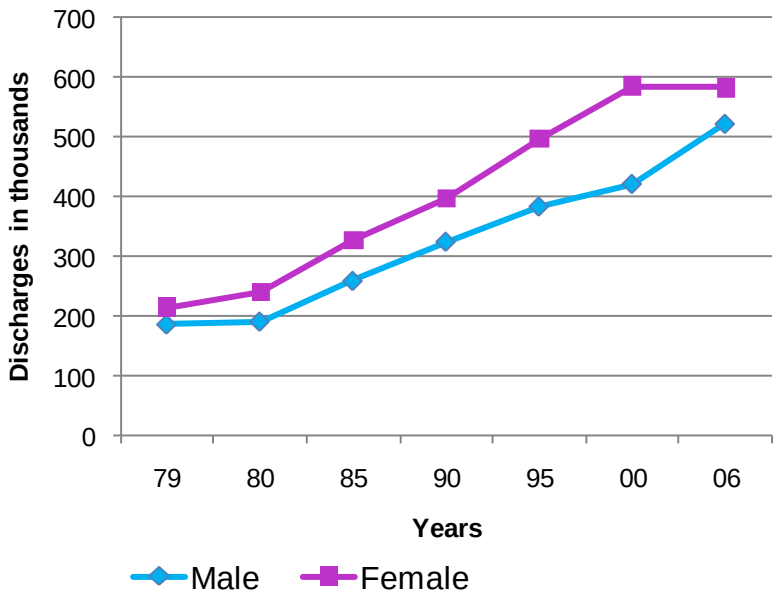

Figure 1.4 Hospital discharge for heart failure by sex
(United States: 1979-2006) Note: Hospital discharges include people discharged alive, dead, and "status unknown." Source: NHDS/NCHS, and NHLBI.

Readmission is often used as an outcome measure of disease management and an indicator of quality of care.[31-33] Readmission is also recognised as a predictors of mortality and increased disease burden.[20] Patterns of increased health care utilisation also heralds a new phase in the illness trajectory.[34, 35] As discussed above, CHF has emerged as a major public health problem, often characterised by progressive deterioration and frequent hospital admissions. It is estimated that the readmission rate for people discharged with CHF approaches 50% within six months of discharge.[36, 37] In a 10-year retrospective study of unplanned hospital readmissions to a regional Australian hospital, CHF was the third highest cause of unplanned readmissions (2.2% of all hospital admission) following Chronic Obstructive Pulmonary Disease (COPD) (3.8%) and complications associated with procedures (3.6%).[38] Over the 10-year study

period, the readmission rate of CHF did not decrease. The increasing rate of CHF hospital admission may also reflect change in hospital admission coding and reimbursement practices.[39]

1.3.3 Mortality of chronic heart failure

Despite the progress in the treatment of CHF, the prognosis for people with CHF is still poor, with a 5-year mortality rate in excess of 50% and ongoing symptomatic limitation.[40] Based on a 44-year follow up of the Framingham study and 20 year follow up of the offspring cohort, 80% of men and 70% of women under the age of 65 years living with CHF die within eight years.[41] The one-year mortality rate after CHF diagnosis was 20%.[41] In a population-based observational study in west London, a cohort of 220 individuals with newly diagnosed CHF was followed up for a median of 16 months. The survival rate was 81% at one month, 70% at six months, 62% at 12 months and 57% at 18 months.[42] In general, the mortality rate reported in population-based studies is higher than that reported in randomised controlled trials. The SOLVD study reported a 12% mortality rate at one year in the active treatment arm.[43, 44] Differences such as this, is often a result of recruitment criteria of the RCT, which generally results in a younger and more stable cohort that is not representative of the overall CHF population.[40-42] Improved survival without declining in its incidence,[45] which again highlights the growing disease burden of CHF in the context of a growing population.

In Australia, CHF was the underlying cause of 2,225 deaths in 2005, with 91% of these occurring among people aged 75 years and over. Chronic Heart Failure was also an associated cause of death in a further 14,466 cases for the same period.[22] However, the rate of death due to heart failure in Australia appears to be declining.[46, 47]

1.3.4 Heart failure with preserved ejection fraction

The nomenclature “heart failure with preserved ejection fraction”, is also known as “diastolic heart failure”. The use of “heart failure with preserved ejection fraction” is preferred because: “diastolic heart failure” suggests a single

operative mechanism, which is not present in every individual with CHF, whereas "heart failure with preserved ejection fraction" is observational of the phenotype without suggesting a predominant mechanism.[48] In addition, "heart failure with preserved ejection fraction" has been used in the most recent heart failure guideline updates for the above reason.[49, 50] Parallel to an increase in prevalence, incidence and hospitalisation rate, there has also been a change in the overall profile of people living with CHF. Studies have shown increases in the prevalence of CHF with preserved ejection fraction.[51] The Olmsted study showed the proportion of people with heart failure with preserved ejection fraction increased over the three consecutive five-year periods (15 years) (38% to 47% to 54%).[52] The proportion of people having CHF with preserved ejection fraction was found to be higher in community-based studies (average 54%) than clinical-based studies (average 40%).[52-54] Importantly, while survival has improved for people with CHF, these improvements are mostly in people with a reduced ejection fraction, but there has been no trend towards improvement in heart failure with preserved ejection fraction, which represents a significant proportion of people with CHF in community settings.[45] The increasing recognition of the presence of clinical heart failure with a normal ejection fraction has also led to heightened awareness of the limitations of evidence-based therapy for this condition.[7]

1.3.5 Health related quality of life

While the preceding discussion has highlighted the improved survival of people living with CHF, this does not necessarily equate to an improvement in HRQoL. Health related quality of life is more than the presence or absence of illness and, while life expectancy is prolonged, it is important that quality of life is added to the years. The syndrome of CHF is associated with debilitating symptoms, which have profound implications on an individual's HRQoL.[55] Compared to almost any other chronic condition, CHF affects people's HRQoL to a much greater extent in physical functioning, role limitation due to physical problems, social functioning, energy and general health perception.[56] The CONSENSUS study not only demonstrated the benefits of ACE inhibitors, but also suggested HRQoL

can be improved in people with this debilitating syndrome.[57] This finding has been replicated in a number of disease management interventions.[58-61]

1.3.6 Social cost of chronic heart failure

The burden of CHF not only has an impact on an individual's HRQoL but also on their families, carers, and the wider society.[31, 56, 62-64] In 2009, the direct and indirect cost associated with HF in the United States was $37.2 billion, of which approximately $23 billion was for hospital stays.[1, 25] The cost of CHF exceeds the costs for myocardial infarction or all types of cancer combined. A significant proportion of CHF costs are associated with hospitalisation, which accounts for 69% of treatment costs.[16, 65] It is estimated that each readmission costs close to $8000 per patient. In the United State of America (US), CHF has been reported to be second (following hypertension) cardiovascular reason for an office visit.[16, 65]

In Australia, although no direct cost analysis has been undertaken, it has been estimated that CHF may cost more than $1 billion annually.[66] In 2005-2006, there were over 41,000 Australians hospitalised for CHF.[22] Although admission rates for CHF appear to have stabilised, the contribution of CHF to total bed-days attributed to circulatory disease appears to be increasing.[67] In addition, it is speculated that there is an under reporting of CHF admission.[18] Therefore, many CHF related costs are not accounted for.[68] The failure to adequately identify patients with CHF is likely due to the absence of incentives to identify cases that may occur in systems of managed care or case mix driven systems.[18] The high number of hospitalisations is associated with increasingly high costs to the health care system, 70% of CHF related health care expenditure is associated with hospitalisation.[69] Many factors contribute to the high readmission rate in CHF, such as poor adherence to lifestyle change, fluid overload and acute decompensation.[70]

1.4 Chronic Care Model

1.4.1 Chronic care paradigm

The increasing prevalence of chronic conditions, such as CHF described above, mandates a shift of the health care system from a reactive acute focused system to a proactive Chronic Care Model. Wagner and colleagues [12] have developed a new paradigm for managing chronic conditions, known as the Chronic Care Model (CCM). This model has been endorsed by key bodies such as the World Health Organisation (WHO) and Australian General Practice Network.[12] The CCM has six key elements and the relationship between these is shown in Figure 1.5.

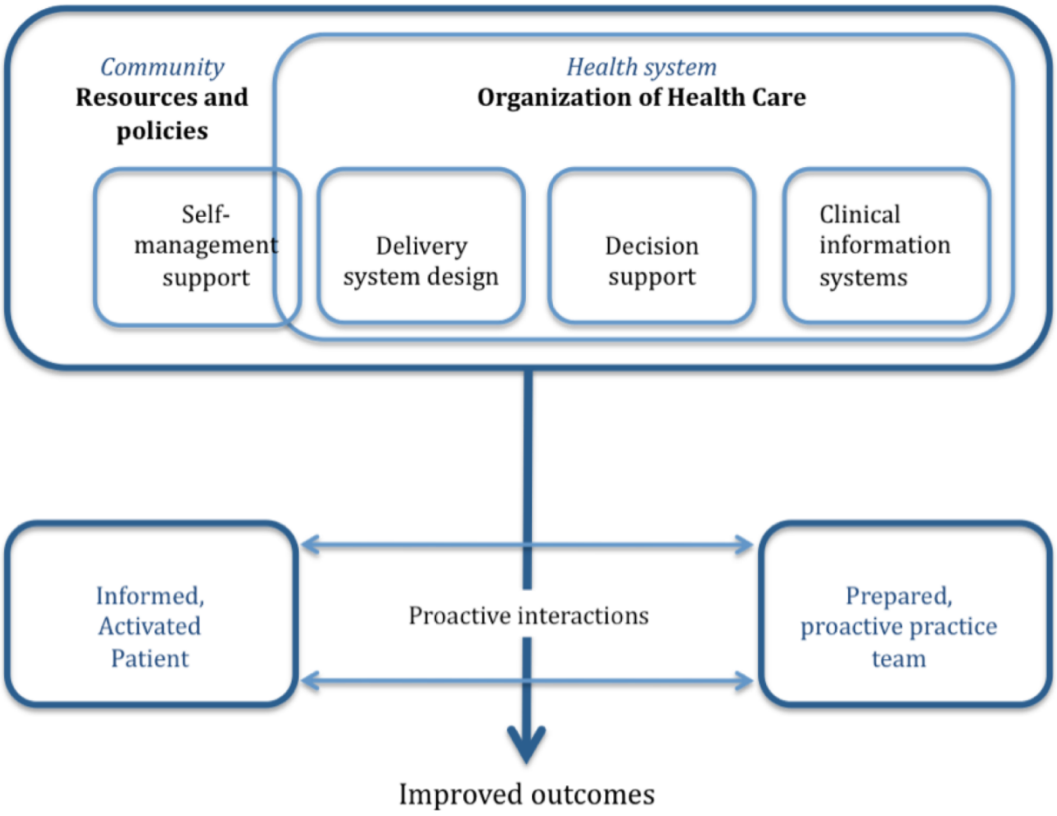

Figure 1.5 Chronic Care Model
Source: [12]

The six key elements are:

1. **Community focus** where health care services interface with the community.
2. **Health system** to support management of chronic conditions.
3. **Self-management support** incorporating a comprehensive behavioural strategy, which empowers and prepares people to manage their health and health care
4. **Delivery system redesign**, where roles and expectations are clarified. This assures the delivery of effective, efficient clinical care and self-management.
5. **Decision support** the search for more effective prevention and management strategies are essential.
6. **Clinical information systems**, allowing the tracking of patients.

The important aspects of the CCM are the partnership between the individual living with the chronic condition and the health care professional, with the emphasis on self-care.

1.4.2 Self-care

The terms self-care and self-management are widely used and many definitions co-exist in the literature. Self-care is a process of maintaining health through engaging in constructive behaviours.[71] Overall, self-care is an overarching concept including self-care undertaken by the person to stay well or managing chronic illness, with or without support from a healthcare practitioner.[72] In contrast, self-management is the cognitive process of self-care and the outcome of a collaborative partnership, among clinicians, individuals and others involved, such as health workers, carers and agencies.[73] The term self-management denotes the active participation of patients in their treatment.[73]

Self-care is pivotal to the management of chronic conditions. In chronic disease management, around 90% of the care a person with a chronic condition needs must come directly from the individual.[74]. Therefore, an individual's self-care

capacity is an important factor for achieving optimal outcomes. Self-care involves cognitive decision making based on the recognition of signs and symptoms, and processing these within the context of existing knowledge and prior experiences [71]. There is a growing body of evidence suggesting the benefits of self-care interventions in improving health related outcomes in people living with chronic conditions [75].

The central concept of self-care is self-efficacy, whereby an individuals' judgment and belief of their own ability for successful performance of a variety of behaviours. A person's self-efficacy influences their choice, behaviour and thought, and it is predictive of one's behaviour.[76-78] The concept of self-efficacy will be further discussed in Chapter Three.

1.4.3 Self-care in chronic heart failure

Self-care is a multidimensional construct with definitions varying as to who is involved, why self-care occurs and how self-care is accomplished.[72] Self-management is a critical process, involving cognitive decision making based on recognition of the signs and symptoms, and processing these within the context of existing knowledge and prior experiences.[71] Two principal factors of self-care are self-care knowledge, and resources.[79, 80] Self-care resources include internal and external factors that can mobilise an individual to cope with their chronic illness, which may assists individuals in monitoring changes over time, benchmarking their current condition within the context of a patient action plan, and may be a successful strategy for preventing acute decompensation and hospitalisation.[79, 80]

Figure 1.6 presents the Self-care for Chronic Heart Failure Model.[81] This model illustrates that self-monitoring and adherence to treatment recommendations, are two inter-related functional factors of self-care maintenance. Self-care management begins with recognizing signs and symptom (i.e., shortness of breath or oedema). This recognition is only essential if one is to make decisions in response to the signs or symptoms.[81] Evaluating the change, deciding to take action, implementing a treatment strategy (adherence to treatment

recommendation), and then evaluating the treatment implemented are components of the model.[81] In the next section, self-monitoring and adherence to treatment recommendations in CHF will be discussed further.

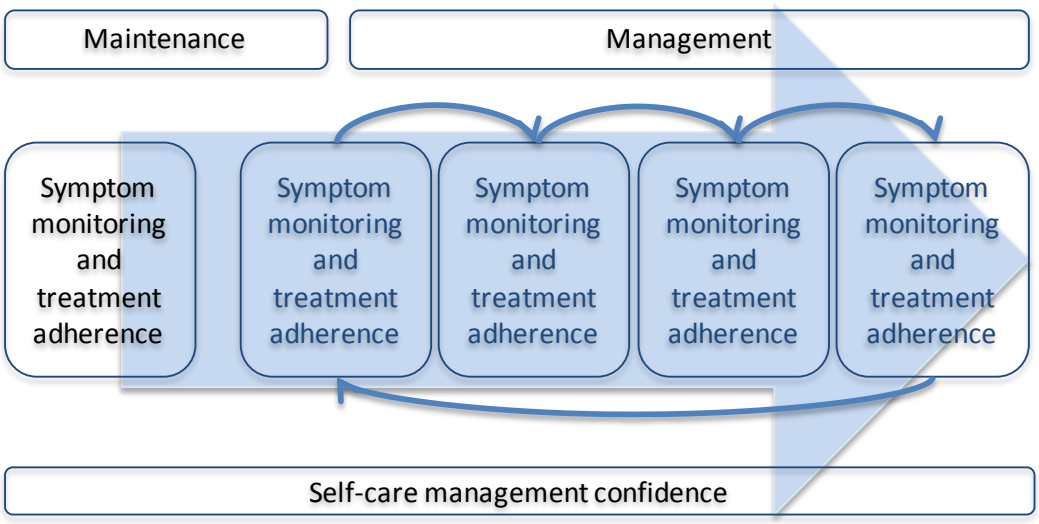

Figure 1.6 Chronic Heart Failure Self-care Model
Source:[81]

1.4.4 Adherence to treatment recommendation in chronic heart failure

Adherence is defined as "the extent to which a person's behaviour-taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider".[82 p 3] This definition has concluded that adherence not only applies to taking prescribed pharmaceuticals, but encompasses a number of other health-related behaviours.[82] What differentiates adherence from compliance is not only the patient's agreement to the recommendations, but the engaging of health professionals in a collaborative, respectful partnership.[82, 83] Adherence to treatment recommendations is a primary determinant of treatment success.[84] Adherence to treatment recommendations are associated with less intense relapses, decreased risk of dependence, and decreased risk of abstinence and rebound effect.[82, 85] Chronic disease management often requires complex multiple therapies which may place patients at increased risk if prescribed recommendations are not followed [86]. Therefore improved adherence may improve patient outcomes.

In CHF, adherence to physical activity recommendations is generally lower than adherence to medications, follow-up appointments, smoking and alcohol cessation.[87, 88] In a study of adherence in people living with CHF, the overall rate of compliance was 85.13%.[87] Higher levels of compliance (> 90%) were noted for follow-up appointments, medications, smoking, and alcohol cessation. Poor compliance was observed with dietary and exercise recommendations (71% and 53%, respectively).[87]

Although, as many as 80% of people with CHF believed that physical activity is an important health behaviour,[89] only 39% actually engage in any kind of physical activity.[90] A systematic review by van der Wal and colleagues,[88] suggested that in general medication adherence rate was approximately 70%. Compliance with diet and fluid restrictions ranged from 50% to 88% and compliance with daily weighing ranged from 12% in one study to 75% in another. In general, adherence to physical activity recommendations had a lower adherence rate of 39-59% compared to other aspects of treatment prescription. Following a recommended physical activity regimen has been demonstrated to reduce morbidity in this population,[91, 92] hence the need for strategies to improve physical activity adherence in CHF population. The concept of adherence will be discussed further in Chapter Three.

1.5 Physical activity in chronic heart failure

1.5.1 Physical activity

Physical activity is any bodily movement produced by skeletal muscles that results in an expenditure of energy.[93] Examples of physical activity are walking, gardening and vacuuming. Exercise is a form of physical activity that is planned, structured and performed to improve at least one aspect of physical fitness, that is strength, flexibility or endurance.[94] In contrast, 20 minutes of treadmill training is a form of exercise. Physical activity can be viewed as a broader construct where exercise is a subset. Randomised controlled trials have shown similar effects of lifestyle “physical activity” and “exercise” on increasing physical functioning level, improving fitness, and reducing blood pressure and body

fat,[95, 96] as well as in weight loss and cholesterol reduction.[95] In CHF, physical activity has been associated with increasing in peak oxygen consumption, amelioration of heart failure symptoms, as well as affects on peripheral adaptations and improving overall CHF outcomes.[94] The term "physical activity" has a stronger emphasis on continuity and a lifestyle approach compared to "exercise". Within the current literature, "physical activity" and "exercise" are often used interchangeably, which may confuse the interpretation of constructs.

The current physical activity recommendations have taken into consideration the "lifestyle physical activity" approach, as they recommend 30 minutes of moderate activity (such as brisk walking) most days of the week.[94] These activities can be accomplished in a single session or accumulated in multiple bouts, with each lasting at least 8-10 minutes. Importantly, it is said that these activities include leisure, occupational, or household activities that are part of everyday life.[93, 94, 97] For the development of physical activity interventions, the European Association of Cardiovascular Prevention and Rehabilitation has stated, structured out-patient cardiac rehabilitation (CR) is crucial for the development of a life-long approach to prevention. This includes clinical and non-clinical based programs and in community settings.[98] However, to date, most CR programs are limited to facility-based activities and accessing these programs is challenging.

Benefits of physical activity

In Australia, insufficient physical activity is second only to tobacco smoking as the modifiable behavioural risk factor most associated with the burden of disease. [99] Each year in Australia, 8000 deaths with annual direct costs attributed to physical inactivity is conservatively estimated at $377 million.[100] Many people with CHF have limited daily physical activity, which while often is a result of symptoms and decreased functional capacity, has also been shown to be due to a fear of injury associated with physical activity in older age.[101, 102] A systematic review of physical activity in CHF reported no deaths in over 60,000 patient-hours of exercise training.[103] The risk of a major or fatal cardiac event

occurring among people attending cardiac rehabilitation programs in America is estimated to be one for every 117,000 and 750,000 hours of participation in physical activity respectively.[104] It is well established that the benefits of moderate-intensity physical activity outweigh the risks.[101, 102]

There is Level I evidence available supporting the benefits of physical activity in people with well-compensated, clinically stable CHF.[94] Physical activity is associated with an increase in peak oxygen consumption (peak VO_2), favorably altering a number of established atherosclerotic risk factors.[93, 105] Endurance physical activity could potentially reduce both systolic and diastolic blood pressure by approximately five to seven mmHg systolic and diastolic.[106, 107] Moderate-intensity aerobic physical activity for > 12 weeks has been shown to increase HDL level by 4.6% and reduce triglycerides by 3.7%, as well as reducing insulin resistance and glucose intolerance. Amelioration of CHF symptoms, affects on peripheral adaptations and improving CHF outcome overall also results from physical activity.[94] In the recently completed HF-ACTION Trial,[61] the largest exercise study in people with CHF to date, 2331 people with CHF (NYHA II-IV, ejection fraction<35%) were randomised to receive either usual care or usual care plus 12 weeks of supervised and ongoing home based aerobic training. After adjusting for predetermined prognostic factors, exercise training was associated with a statistically significant 15% decrease in all-cause mortality and CHF hospitalisations (p=0.03). The position statement on exercise training and CHF by Exercise & Sports Science Australia,[61] state that individually prescribed and carefully supervised exercise testing and prescription, undertaken by appropriately trained health professionals can safely and effectively reduce the burden of disease and improve prognosis and HRQoL in medically stable CHF patients.

Barriers to physical activity

Despite the well-known benefits of physical activity, many people do not regularly perform sufficient physical activity because of a range of barriers. Table 1.2 presents a range of barriers to physical activity. While these were identified in a general population, they are particularly important in people with CHF.

Increased self-efficacy and confidence can aid in overcoming these intrinsic factors.[14, 85] Extrinsic factors must also be considered in order to promote physical activity.

Table 1.2 Barriers to physical activity

Intrinsic barriers	Extrinsic barriers
○ Lack of time ○ Lack of energy ○ Lack of motivation ○ Illness/injury ○ Feeling uncomfortable ○ Perceived lack of skill ○ Fear of injury/illness	○ Lack of accessible facilities ○ Lack of safety ○ Lack of child care ○ Lack of a partner ○ Insufficient programs ○ Lack of support from family and friends ○ Lack of transportation

Source: Canadian Fitness and Lifestyle Research Institute. Barriers to physical activity.[102]

Lower perceived health status has been associated with less exercise and overall activity in older adults.[108] By age 75 years, one in three men and one in two women engage in *no* regular physical activity.[93] In CHF, there are actual and perceived barriers to physical activity. First, impaired physical functional capacity associated with CHF and the condition-related symptoms such as dyspnoea and fatigue make it challenging for the person to perform adequate physical activity.[109] Second, fear of injury or another cardiac event has been identified as a barrier to physical activity. For example, in one study nearly half of the participants over 80 years of age reported fear of falling as a reason for not participating in physical activity programs.[110] A majority (63%) of people with CHF has expressed a feeling of lack of skills for physical activity,[90] which emphasised the need for strategies to assist individuals to gain confidence in simple physical activity. Over-emphasis on vigorous physical activity in guidelines can lead to a lack of confidence, motivation and self-efficacy due to perceptions of unachievable intensity and goals for CHF patients,[13] and can induce fear of injury and a perception of a lack of skills. Third, the further the distance of the facility from the home of the individual, the less likely the person will

participate.[102] In the CHF population, which is comprised predominantly of elderly persons, transportation is another barrier. Other reported common barriers in the CHF population include negative thoughts, such as perceived lack of control over self, lack of motivation,[111] lack of resources, lack of information, and safety issues.[102, 112]

It is widely known that motivation drives sustainable adherence. However, motivation is one of the most difficult elements for the health care system to sustain in the long term [82]. The concept of adherence and the study underlying theoretical underpinnings will be discussed in Chapter Three.

1.6 Self-monitoring in chronic heart failure

Self-monitoring by people with chronic conditions has been linked to improved body awareness, better communication with health professionals and in an improved sense of self-efficacy in self-managing CHF.[113, 114] Bandura[78] maintains that the individual is an active participant in the management of their condition. Self-monitoring is a complex concept involving monitoring, understanding, interpretation and response with appropriate actions to signs and symptoms. Riegel et al.[115] describe in the Heart Failure Self-care Model (Figure 1.6), people's decision making regarding symptoms require the individual to recognise that a body cue or symptom is related to the illness, be able to respond with appropriate action to address the symptom, and then evaluate the effectiveness of the action taken.

The recognition and sensitivity to physical sensations secondary to physiological change is an important aspect for consideration in CHF management. Symptoms such as dyspnoea and fatigue are subjective. Symptom monitoring can be impaired by poor sensitivity or awareness of body sensations. Jurgens [116] suggested that variability in the type and severity of symptoms might be partially responsible for people's difficulty developing a reliable cognitive meaning upon which to make decisions about seeking care. Therefore, interventions that facilitate objective measurement of progress of physical functional status may be potentially useful in reducing delay in seeking health care. [116]

It is generally recognised that people with CHF need to learn to live with the condition, which requires life style modification.[75, 80, 117] Individual health related outcome is closely related to their self-care ability. It is expected improved self-care ability will lead to improved HRQoL.[80] Most studies evaluating effects of CHF programs focused on physical functioning, readmission rate, as study endpoints.[118, 119] It is also important to directly assess the effect of the intervention on an individual's self-care ability.[118, 119] In our Home-Heart-Walk study, we have assessed participant's self-care behaviour using the European Heart Failure Self-care Behaviour Scale [118] before and after the intervention (the Home-Heart-Walk).

1.6.1 Monitoring of physical functional capacity

Due to the symptom burden of CHF, deconditioning related to ageing and comorbidities there is often a low tolerance for physical activity.[120, 121] This is of a concern given the proven benefits of increasing physical activity in improving cardiovascular outcomes. As a consequence of deconditioning, there is a reduced capacity for performing physical activities that involve dynamic movement of large skeletal muscles because of the onset of symptoms such as dyspnoea or fatigue.[122, 123] Physical functional capacity depends on the ability of the heart to augment its output to the exercising muscles, and the ability of these muscles to utilise oxygen from the delivered blood. People with CHF often have a reduced peak VO_2 of 10-20 ml/kg/min compared with 30-40 ml/kg/min in healthy middle aged individuals.[122] This commonly results in activity intolerance, affecting the individuals' daily function and their HRQoL.

In advanced age, the maximum heart rate declines by approximately one beat per minute, each year.[124] In addition, as people age, the heart relies on greater enhancement of preload, and is less able to reduce left ventricular end-systolic volume.[122] In the CHF population, beside the normal cardiac changes associated with ageing, changes in physical functional capacity is also mediated by dilatation of the left ventricle and/or valvular problems.[122]

Physical functional capacity is often expressed by peak oxygen consumption (peak VO_2). Peak oxygen consumption represents the highest rate of oxygen uptake achieved.[125]. Frances and colleagues suggests a peak VO_2 of 14ml/kg/min is the threshold for prediction of mortality at 24 months.[125] Peak VO_2 has also been adapted by the American Heart Association/American College of Cardiology (AHA/ACC) consensus statement on the selection and treatment of candidates for heart transplantation.[126] Patients with a peak VO_2 less than 14mkl/kg/min have decreased survival rate after heart transplantation (48%), compared to patients with a peak VO_2 ≥14ml/kg/min (94%). Francis and colleagues [125] identified from 267 people with CHF, not only the prognostic value of peak VO_2 but also suggested the VE/VCO_2 is more independent than age and ventricular function.[125] Therefore, to monitor physical functional capacity, maximal exercise testing is considered the gold standard, although a sub maximal exercise test is often the more frequently used test because it is simple, safe and well tolerated by people undertaking the test.[127-129] When assessing the application of maximal or sub-maximal exercise tests in this population, there is a need to appraise the strengths and limitations of each of these approaches.

Maximal exercise testing

Maximal exercise testing (MET) is an objective assessment of functional ability in people with CHF.[125] The key measurement during maximal exercise testing is peak VO_2. The value of MET is its ability to assess the integration of cardiac adaptations, and skeletal muscle, pulmonary, and endothelial dysfunctions more than other traditional prognostic indicators for CHF.[130, 131] The Olmsted County study of 22,193 residents in Olmsted County, with a follow up period of 6.3 ±2.0 years[132] demonstrated an increase in 1 MET work load was associated with a 20% reduction in the risk of all-cause mortality in men and a 25% risk reduction in women.[132] An increase in 1 MET was also associated with a 17% reduction in the risk of cardiac events in men and 23% in women. [132] The reliability, reproducibility and prognostic value has been well studied. There is little doubt about the value of maximal exercise testing in measuring

functional capacity when the test is undertaken properly. However, during maximal exercise testing, unless individuals are able to attain a peak VO_2 without fatiguing first or being limited by musculoskeletal impairments or other problems, the results of the test are invalid.[133] An individual with CHF population are predominantly elderly and likely have multiple co-morbidities with varied degree of exercise limitation resulting in their MET performance being likely limited by pain, fatigue and other problems like musculoskeletal impairment rather than exertion. Moreover, the requirement for equipment and well-trained health care professionals is costly and labor intensive. This further limits its use, especially in community settings.[127]

Sub-maximal exercise testing

Sub-maximal exercise testing overcomes many limitations of maximal exercise testing, and is often the choice of exercise testing in many clinical settings including cardiac rehabilitation for a range of pragmatic considerations.[127, 133, 134] Compared to maximal exercise tests, sub-maximal exercise tests have a lower level of intensity and often does not require the use of high technology.[127, 133] The obvious disadvantage of sub-maximal exercise tests is the inability to assess peak VO_2 as accurately as maximal exercise testing, as well as the inferior measurement of cardiopulmonary function. However, sub-maximal intensity makes it an ideal intervention for people with limited physical functional capacity who are unable and are less likely to undertake maximal physical activity.[127] Compared to maximal tests, the application of sub-maximal exercise tests is less well developed. Given the large number of patient types and individuals who could benefit from a non-maximal exercise test, it is timely to evaluate the potential of a novel approach to this type of test.

The Six Minute Walk Test

One of the most commonly used sub-maximal exercise tests is the Six Minute Walk Test (6MWT).[127] The 6MWT measures the distance that people walk on a flat, hard surface during a period of six minutes. It is a self-paced exercise test, where subjects are allowed to stop and rest during the test and resume walking when they feel comfortable to do so,[135] and is used in clinical settings as a

one-time measurement intervention in patients with moderate to severe heart or lung disease.[136, 137] The 6MWT also has a predictive value in respect of morbidity and mortality.[138, 139] In spite of the criticisms that have been reported in relation to the 6MWT, including training effect and inter-rater reliability,[127] it is a simple, safe and inexpensive test in monitoring physical functional capacity[127]. There is little variation in the distances covered in a 6MWT between normal subjects and people with mild CHF, despite noticeable differences in their maximal exercise capacity.[140] This suggests this simple test may be more applicable to people with moderate to severe functional limitations.[140] Although the six-minute walk test is less discriminating than the measurement of maximal oxygen consumption, a reliable, valid test provides important prognostic information and may be a better reflection of an individual's daily physical activity level.[127] The reliability, responsiveness, and prognostic value of this test will be discussed further in Chapter Four.

1.7 Physical activity programs in chronic heart failure

As previously described, the benefits of physical activity in people with CHF are well established. In a large systematic review of exercise training in CHF, the authors concluded exercise training was safe and effective.[103] A review of randomised controlled trials in CHF exercise training identified nine peer reviewed original articles. [103] Exercise intervention in these nine trials differed by type of activity, duration and intensity. The mean follow-up time of the nine trials was 705 days. During the mean follow-up period, there were 22% death in exercise group and 26% in control group. Exercise training also reduced hospital admission in the exercise group compared to the control group. [103]

Of note, the trials mentioned in the above review had younger participants than those in community populations of CHF.[103, 141] The mean age of the participants was 60.5 years (exercise group) and 59.7 years (control group), where the mean age of people with diagnosed CHF in the community is 74-75years.[141] Exercise in older adults can be different as they are likely to have more morbidities and functional impairment that impose limitations on the type, duration and intensity of exercise that they can tolerate. In addition, many of

those older adults are living in community settings. Long-term benefits of physical activity are often limited by low adherence to recommendations because of a range of barriers. Interventions that promote self-efficacy and increase adherence to physical activity recommendations are more likely to assist people to gain the benefits of physical activity. A review of the current literature on physical activity interventions in CHF will be presented in Chapter Two particularly as they pertain to HRQoL.

1.8 Achieving long-term adherence of physical activity

Theoretical models have made important contributions to our understanding of human health behavior. Models such as the Health Belief Model,[142] Theory of Planned Behavior;[143] the Transtheoretical Model of behavior change;[144] and Social Cognitive Theory [145] have been popular in research into health behavior change.

Interventions that facilitate an initial change in behaviour have been automatically expected to assist in maintenance of that change. Yet, repeated findings have shown, those who successfully initiate a change in their behavior frequently fail to maintain that behavior pattern. These findings lead some to suggest that "relapse remains the norm, regardless of the behaviour in question" (p. 77). Whether implicitly or explicitly, the same cognitive processes that underlie the behavior change have been assumed to be the same as those that underlie behavior maintenance. Much of the research based on these models has focused on initiation of behaviour change, with little guidance offered as to how the processes that governs the initiation and *maintenance* of behaviour change might differ.

Sustaining behaviour change is difficult, which is why motivation to consolidate the change is needed. Despite a person's desire to change, and regardless of their willingness to take action, without a strong commitment, and adequate self-efficacy, they are not likely to experience long-term success.[146, 147] Therefore, an approach that addresses not only intrinsic individual related factors but also their condition and health system related factors can be useful.

The Exercise Self-efficacy Model is such an approach; which will be discussed in more depth in Chapter Three.

1.8.1 Potential of home-based self-monitoring interventions to improve adherence

People with CHF tend to be elderly and have multiple co-morbidities, increasing the complexity of CHF management. Inadequate monitoring and adherence to a prescribed treatment regimen are frequent precipitants of exacerbation and recurrence of symptoms that compromise an individual's ability to engage in daily activity and negatively impact on their HRQoL. Studies demonstrate people with CHF want to maintain their independence for as long as possible and look to health professionals to help maintain them in their homes.[148] Home-based interventions have been studied in a number of controlled trials which have yielded generally promising results in improved patient outcomes.[149-152] Even a home based intervention that only consisted of a single home visit (to optimise medication management, identify early clinical deterioration and intensify medical follow-up and caregiver vigilance) was associated with reduced frequency of unplanned readmission plus out of hospital deaths within six months of discharge from the hospital compared with usual care.[150]

Using a diary (monitoring daily weight) was associated with more telephone calls and clinic visits to their primary care giver, and longer mean length of follow up, more days alive and time out of hospital compared to participants who did not use the diary [153]. However, adherence to daily weighing and diary use decreased over the 12 month study follow up period, again underscoring the importance of monitoring and reinforcement.[153] Jovicic and colleagues suggest that scheduled telephone calls and home visits may increase implementation of diary use and self-monitoring and may be a particularly useful adjunct for people at high risk of re-admission.[154] Individually and collectively, studies suggest that improved monitoring and supervision of high-risk patients post-hospital discharge may improve their compliance with prescribed medication and facilitate early detection of clinical deterioration. [155-158]

1.9 The Home-Heart-Walk

Within the context of the increasing burden of CHF, and based on self-efficacy theory and the evidence that self-monitoring interventions can be effective, the Home-Heart-Walk was developed. This doctoral thesis builds upon the candidate's BN (Hons) thesis.[159] The Home-Heart-Walk adapted the 6MWT protocol to a home-based self-monitoring intervention for physical functional capacity and undertook preliminary testing in a cardiac rehabilitation population.[160] These participants were recovering from acute coronary syndrome events. The Home-Heart-Walk assists individuals to self-monitor physical functional capacity and encourages recognition and response to functional change. This is a novel approach as it combines the theoretical elements of the self-efficacy theory and a self-monitoring concept which enables not only feedback to the individual but also the clinician.

1.10 Aims of the Home-Heart-Walk study

The Home-Heart-Walk study is an approach to support self-management in people with CHF. It has four discrete yet interrelated aims. ***Firstly,*** it seeks to promote physical functioning through improved physical activity level using a method that is accurate and reproducible; ***secondly,*** it provides a measurement whereby individuals and their clinicians can monitor their condition; ***thirdly,*** it is designed to assist in self-care behaviour, and ***fourthly*** to improve HRQoL.

This randomised controlled trial seeked to evaluate the impact of the Home-Heart-Walk on the following aspects of health related outcomes:

- Physical functioning (subjective and objective)
- Self-care beahviour;
- Physical activity level and self-efficacy
- Self-reported HRQoL

1.11 Significance of the study

Approximately 50% of people given specific advice about long-term health care do not follow it.[82] Neither the severity of the disease nor symptoms appear to

influence adherence. Adherence does not appear to be solely dependent upon the efficacy of the intervention but rather influenced by logistic factors such as the duration of the treatment, cost, inconvenience and support provided to individuals. Almost all health care interventions require adherence and persistence.[82] Therapeutic regimes requiring active participation, particularly those involving changes in personal habits, are more likely to have high dropout rates. From a preventive standpoint the critical issue facing exercise and health research no longer relates to the possible benefits of exercise but rather the facilitation of exercise adherence.

The efficacy of physical activity programs is limited by individual's adherence. The health benefits of physical activity are lost through dropout at approximately the same rate as those acquired through adherence.[82, 89, 101] This suggests that an adherence enhancement program for people with CHF is an appropriate area for research. Improvement in adherence is dependent upon knowledge of the determinants, which influence behaviour. There is a need to validate the findings of current research in this area for the target population of CHF. Especially the use of nurse-coordinated models of intervention to improve health outcomes, including home based programs.[62, 151, 161-165]

A key element of these programs is promotion of self-care. Home-based exercise programs have demonstrated short-term benefits. Long-term effect is often limited by program adherence.[62, 101] The Home-Heart-Walk seeks to promote key aspects associated with self-efficacy. With the known epidemic of chronic disease if this simple intervention is effective, it may positively impact on chronic disease management programs. Significantly, this model of intervention seeks to address well-known barriers to physical activity in people with CHF, particularly inability in accessing transport, severe functional limitations, weather, safety issues and lower self-efficacy for exercise. Further, in vulnerable populations, particularly the elderly, this model of intervention may overcome the challenges in safety and accessibility which can all affect an individual's capacity to engage in structured physical activity programs. This approach is novel in that it

extrapolates an inexpensive, valid and reliable assessment tool, with predictive power, to be self-administered by the patient in a community-based setting.

1.12 Structure of this theses

In ***Chapter One***, the significance of the growing burden of CHF, as well as the importance of self-management in the CHF population has been highlighted. Population ageing has accelerated the shift of focus of the health care system from an acute care model towards a Chronic Care Model that emphasises self-management. This approach is increasingly advocated in the policy, clinical and research context.[166] In the context of chronic disease management, new innovations have emerged in order to improve patient self-management and to meet the needs of the growing burden of chronic conditions. The rationale, utility and the significance of the Home-Heart-Walk was also introduced as a means to promote self-management and improve CHF patient outcomes by better monitoring physical functional capacity and early recognition of signs and symptoms. The significance of the study to nursing has been discussed, and the operational definitions of key terms to be used in the study have been provided.

Chapter Two will provide a review of randomised controlled trials of physical activity interventions in CHF. It reviews the effectiveness of physical activity interventions to improve HRQoL in the CHF population and the impact of low adherence on long-term benefits, with particular attention on characteristics of interventions, to inform future research.

Chapter Three discusses the rationale for the theoretical framework chosen for the Home-Heart-Walk study. In details, the construct of exercise self-efficacy is explored and the relevance to the Home-Heart-Walk intervention.

Chapter Four provides a description of the development of the Home-Heart-Walk study. Evaluation of the correlation between the Home-Heart-Walk and the standard 6MWT and its reliability is provided in this chapter. Part of this material was developed as part of the BN (Hons). However, it was decided that it was appropriate to include this to provide the reader with information regarding the derivation of the Home-Heart-Walk intervention. As will be discussed the proof

of concept was demonstrated in normal volunteers and participants in cardiac rehabilitation following acute coronary syndrome event. This study extends the concept of the Home-Heart-Walk into the CHF population.

Chapter Five provides a critical description and justification of the study method. Study management and ethical issues are also discussed.

Chapter Six reports the study findings. Comparability of the intervention and control group is provided first, followed by comparison of changes over the six-month study period. Lastly an analysis of the effect of the intervention is provided in this chapter.

Chapter Seven discusses the findings, strengths and limitations of the study and the challenges in improving physical functioning in people living with CHF.

Chapter Eight summaries the Home-Heart-Walk study and identifies implications for policy, practice and research.

References are provided at the end of each chapter. Every reasonable effort has been made to acknowledge the owners of copyright material. I would be pleased to hear from any copyright owner who has been omitted or incorrectly acknowledged.

Copies of the data collection form, copies of ethics approval from the Curtin University [HR 170/2008] and St Vincent's Hospital, Sydney [08/SVH/77] participant information sheet and consent form are provided in the appendixes at the end of the thesis.

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Chapter 2
Physical activity interventions in chronic heart failure to promote health related quality of life

2.1 Introduction

As described in Chapter One, CHF is a prevalent and debilitating condition and is most common in the elderly. Major symptoms include breathlessness and restricted activities of daily living due to reduced functional capacity, which in turn impacts adversely on HRQoL. Other important symptoms are fatigue and lethargy in addition to swelling of the feet and ankles.[1, 2] The symptoms and functional capacity are used to classify the severity of CHF, using the NYHA-FC. Whilst disease severity is based upon symptoms, diagnosis is based on objective measures, for example echocardiography.[3] Like many chronic diseases, there is a poor correlation between symptoms and the degree of cardiac impairment and also between symptoms and disease prognosis.[1, 4]

Over the last decade, physical activity has been considered as safe in stable CHF populations, the benefits are well described and Level 1 evidence is available in practice guidelines.[5-8] There have been an extensive number of studies in the literature evaluating the effectiveness of physical activity interventions in CHF management.[8] A systematic review of exercise training in CHF reviewed 81 studies undertaken by Smart and Marwick concluded exercise training is safe and effective in patients with CHF.[9] The effectiveness of physical activity intervention is often limited by low program adherence.[10] Many individuals consider that adhering to physical activity recommendations is harder compared to implementing strategies related to medications, dietary modifications or fluid restriction.[11] After completing physical activity programs, the adherence to physical activity recommendation decreases rapidly after program completion.

There is a growing body of evidence demonstrating the benefits of multidisciplinary, coordinated interventions in improving health related outcome and HRQoL. [12] Specific to promoting physical activity in people with CHF, there are supervised, centre based programs; unsupervised, community based programs; home-based interventions; or interventions incorporated with tele-monitoring.[13] The type of interventions, and follow-up time varies from study to study. To date there is consensus about the positive effect of exercise training

on physical capacity.[8, 9] However, the impact on HRQoL is less certain. This is particularly the case when comparing different strategic approaches.[8] Methodological challenges in reporting HRQoL data such as treatment of missing data and failing to use intention to treat analysis can be problematic.[8, 14] A strategy to support self-care and promote maintenance of physical activity requires further development.

2.2 Objectives of the review

Randomised controlled trials (RCTs) are the most valid source of evidence for identifying the effects of an intervention.[15, 16] This review of randomised controlled trials of physical activity interventions in CHF population was undertaken to determine implications for program adherence, self-care and effects on HRQoL. This review differs to other similar reviews in that rather than focusing on whether physical activity interventions are effective, and how effective; we are putting more attention on the differences between interventions, variable effects and potential explanations. This is in an attempt to explore evidence for informing further development of interventions in promoting physical functioning and long-term maintenance.

2.3 Methods

2.3.1 Criteria for selecting studies for this review

Type of studies

Randomised controlled trials, with either parallel group or cross-over design where the follow-up was six month or more after the start of the intervention.

Types of participants

Individuals greater than or equal to 18 years of age, with CHF due to any aetiology. Both systolic and heart failure with preserved ejection fraction were included in this review.

Types of interventions

Physical activity based program either along or as a component of comprehensive management program (programs including component such as health education and psychological support, telephone intervention). The intervention group is the group receiving the physical activity based interventions. Interventions can be centre-based, community or home-based; supervised or unsupervised. Interventions involving an initial centre-based physical activity program, followed by community-based program were also included. The comparison group or the control group consisted of people with

CHF, not receiving the physical activity program. This group of people should not participate in any other formal regular physical activity programs while they were in the study. Studies were excluded, if the comparison group (control group) also received an intervention other than usual care, and the study aim was to compare physical activity intervention with another type of intervention.

Types of outcome measures

Primary outcome

Health related quality of life (HRQoL) assessed by a validated outcome measure.

Secondary outcome

Physical functioning as measured by the Six Minute Walk Test, peak VO_2 or other valid measures (i.e, walk test, maximal exercise test).

2.3.2 Search Methods for identification of studies

The literature search was conducted using databases PubMed, Medline, CINAHL, Cochrane library, EMbase, EBM reviews, and PsychINFO, under the supervision of a health librarian. A filter for RCT were used when available on database. In addition, reference list of relevant articles were manually searched. The following terms were used:

1. heart failure
2. ventricular dysfunction
3. cardiomyopathy
4. ventricular dysfunction or LV dysfunction or RV dysfunction or ventricular systolic dysfunction or ventricular diastolic dysfunction
5. exercise therapy
6. exercise
7. exercise movement techniques
8. physical fitness
9. motor activity
10. rehabilitation
11. resistance or aerobic or endurance or strength

2.4 Data collection and analysis

2.4.1 Study selection

A search of the literature from 2000 to October 2010, was conducted by the first reviewer and a medical librarian independently using electronic search engines. The final search results were deduplicated within EndNote. Two independent reviewers then screened the retrieved articles independently using predetermined inclusion criteria. Articles were first screened by reviewing title and key words. Disagreement of included articles was resolved by consensus. Potential full text publications were reviewed by two independent individuals for assessment of eligibility for inclusion. Disagreement of study inclusion was resolved by consensus. A summary of the selected articles is provided below (Table 2.1).

2.5 Results

2.5.1 Description of studies

The systematic literature search using search strategy described previously, yielded 1372 publications, and 182 full text publications were retrieved for potential inclusion. After reviewing the title and abstract of the 182 publications, a total of 18 publications were included in the review, and 164 publications excluded. Within the 164 excluded studies, there were 60 studies excluded as the follow-up duration was less than six months. Twenty-six studies had no CHF control group; four studies had an inappropriate population (not CHF population, or subgroup of CHF); 58 studies reported irrelevant outcomes as to this review; and 16 studies were not randomised controlled trials. The study selection process is summarised in the flow diagram shown in Figure 2.1.

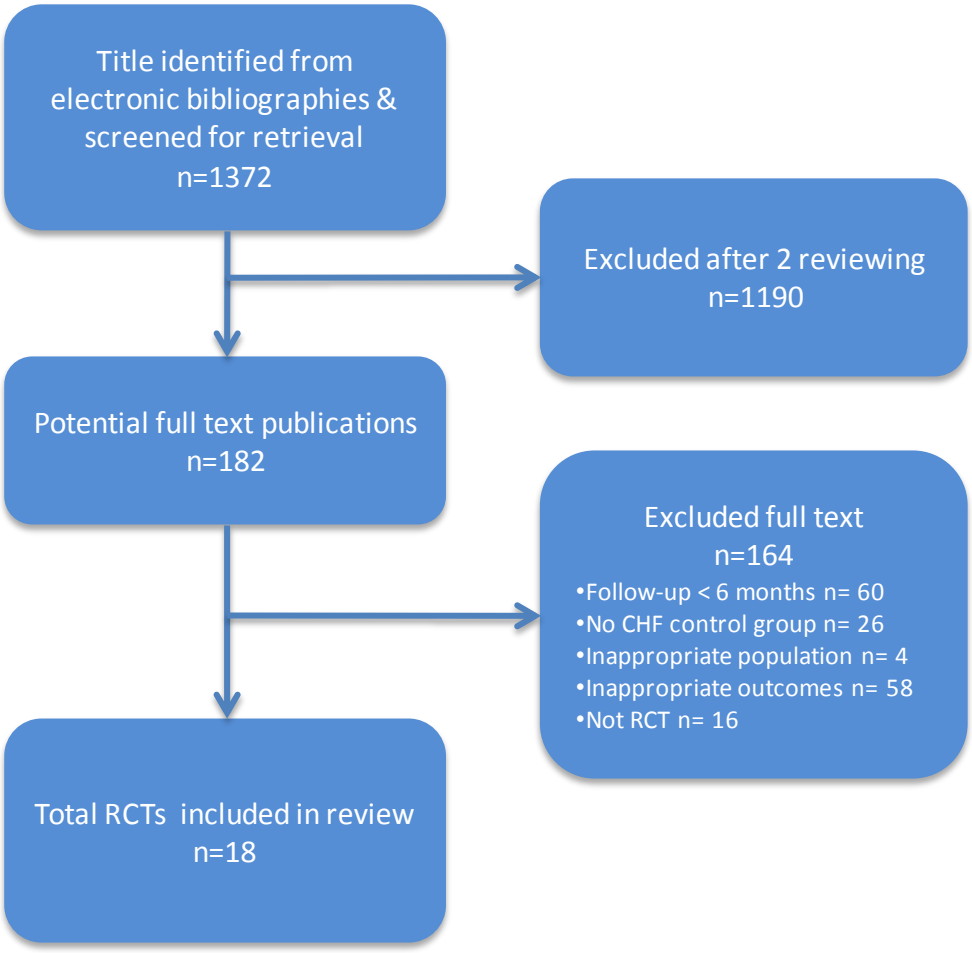

Figure 2.1 Study selection process

Table 2.1 Summary of included studies

Article	Participant	Intervention/ follow-up duration	Relevant outcome	Intervention	Control	Measured program adherence	Delivered by / Site	Outcome
Austin, J. 2005	NYHA-FC: II-III Systolic n=200 Male=86, Female=114	6 months / 6 months	HRQoL (MLHFQ, Eq-D5); Mortality; Re-hospitalisation; NYHA; 6MWT; Borg scale	8 weekly monitoring of clinical status and cardiac rehabilitation program, followed by 16 weeks community based regimen	8 weekly monitoring of clinical status	No	Nurse/ Clinic	Cardiac rehabilitation was associated with improvement of HRQoL; NYHA classification, 6MWT distance. Between group difference ($p<0.001$). As well as fewer admission ($p<0.01$); HRQoL (MLHFQ) improved in both groups.
Austin, J. 2008	NYHA-FC: II-III Systolic n=200 Male=86, Female=114	6 months / 6 months	HRQoL: MLHFQ; Eq-D5; Mortality; Re-hospitalisation; NYHA; 6MWT; Borg scale	8 weekly monitoring of clinical status and cardiac rehabilitation program, followed by 16 weeks community based regimen	8 weekly monitoring of clinical status	No	Nurse/ Clinic	Sustained long-term improvement in HRQoL was in both intervention and control group. Control group had decreased walking distance ($p<0.05$). No significant differences between groups in survival.

Article	Participant	Intervention/ follow-up duration	Relevant outcome	Intervention	Control	Measured program adherence	Delivered by / Site	Outcome
Belardinelli, R. 1999	NYHA-FC: II-IV Systolic n=99 Male=88 Female=11	14month/ 26month	HRQoL (MLHFQ); Mortality; Re-hospitalisation; PeakVO_2 Thallium scintigraphy	8 weeks of 3session/week exercise training, followed by 12 month maintenance program (2 session/week)	Usual care	Yes	Not stated Cardiologist present at exercise training session	Exercise training was associated with imoproved HRQoL; peak VO_2 (p<0.01); lowered mortality (p=0.01) and hospital readmission (p=0.02), compared to control group.
Bocalini, D. 2008	NYHA-FC: II-III Systolic n=42 Male=37 Female=5	6 month/ 6 month	HRQoL (WHOQoL) Sit and reach Sit and stand 800m walking test	3 weekly sessions over 6 months	Standard care	Yes	No stated/ clinic	Physical exercise was associated with improvement in physical functional capacity (p<0.001); HRQoL (p<0.001); no significant change in control group

Article	Participant	Intervention/ follow-up duration	Relevant outcome	Intervention	Control	Measured program adherence	Delivered by / Site	Outcome
Davidson, P. 2010	NYHA-FC: I-III Systolic n=104 Male=65 Female=40	3 month/ 12 month	HRQoL (MLHFQ); Mortality; Re-hospitalisation; NYHA; 6MWT; Heart failure needs assessment questionnaire; Medication usage	Multidisciplinary program. Weekly program and counseled to undertake a home-based exercise program tailored to individual	Usual care	No	Nurse/ Clinic and home	Intervention was associated with less hospital admission. Also associated with improved HRQoL (p<0.01); 6MWT distant (p=0.01) at 3-month follow-up, but improvement was not sustained at 12-month follow-up.
de Mello Franco, F. 2006	NYHA-FC: II-III Systolic n=36 Male=29 Female=7	8 month/ 8 month	HRQoL (MLHFQ); PeakVO_2;	Clinic supervised sessions (3/week) followed by home-based at same intensity	Follow-up only	No	Not stated/ Clinic and home	Intervention was associated with improved peak VO_2(p<0.05); HRQoL(p<0.05), which was maintained during home-based program.
Dracup, K. 2007	NYHA-FC: II-IV Systolic n=173 Male=123 Female=50	12 month/ 12 month	HRQoL (MLHFQ); Re-hospitalisation; Depression; PeakVO_2 6MWT	4 weekly home-based exercised training	Maintained usual level of daily activity; no systematic exercise program	No	Nurse/ Home	No significant difference between intervention and control groups, in functional status, HRQoL, or psychological states over 6-month. Intervention group had lower multiple hospitalisations (p=0.018)

Article	Participant	Intervention/ follow-up duration	Relevant outcome	Intervention	Control	Measured program adherence	Delivered by / Site	Outcome
Flynn, K. 2009	NYHA-FC: II-IV Systolic n=2331 Male=1670 Female=661	3 years/ 3 years	HRQoL (KCCQ);	Supervised aerobic training, 3 sessions/week; followed by home-based training, 5 times/week	Usual care	No	Exercise physiologist/ Clinic and home	Exercise training led to greater improvement in HRQoL (p<0.001), compared to the control group.
Giannuzzi, P. 2003	NYHA-FC: II-III Systolic n=90	6 month/ 6 month	HRQoL (Likert scale); PeakVO_2; NYHA; 6MWT	30mins bicycle ergometer 3 session/week or more; and home-based exercise training	Avoid physical activity that cause dyspnoea or fatigue	Yes	Not stated/ Clinic and home	Exercise training was associated with improved ejection fraction (p<0.01); work capacity (p<0.001); peak VO_2 (p<0.006); walking distance (p<0.001); and HRQoL (p<0.01). compared to control group (NS).
Giannuzzi, P. 1997	NYHA-FC: I-II Systolic n=70	6 month/ 6 month	HRQoL (Likert scale); Echo; EDV; ESV; Work capacity	2 sessions/week, cycle ergometer for 2 month, followed by home-based program	No formal exercise training, only education and psychological support	No	Not stated/ Clinic and home	Exercise training was associated with increased work load (p<0.01); ejection fraction improved in intervention group (p<0.01) compared to control (NS)

Article	Participant	Intervention/ follow-up duration	Relevant outcome	Intervention	Control	Measured program adherence	Delivered by / Site	Outcome
Gottilib, S. 1999	NYHA-FC: II-III Systolic n=33 Male=22 Female=3	6 month/ 6 month	HRQoL (MLHFQ, SF-36) Peak $VO_{2;}$ NYHA; 6MWT	3 sessions/week aerobic training	Usual care no training	Yes	Exercise physiologist and nurse/ clinic	Exercise training was associated with improved peak VO_2(p<0.05); 6MWT distance (p<0.05); No significant improvement in HRQoL (MLHFQ) but greater than 5 points decrease in score in intervention group.
Klocek, M. 2005	NYHA-FC: II-III Systolic n=42 Male=42 Female=0	6 month/ 6 month	HRQoL (PGWB, SSA-P); Peak VO_2; Echo; Oxygen consumption	1: 3 sessions/ week exercise training with constant workload 2: exercise training with progressive/increasing workload	No training	No	Physician, CR staff/ clinic	Exercise training was associated with decreased symptoms (p<0.01); emotional distress (p<0.01); peripheral circulatory symptoms (p<0.01); and dizziness (p<0.01); Improvement in HRQoL was greater in progressive load group than constant load group, HRQoL correlated positively with peak VO_2 in progressive load group (r=0.56, p<0.05).

Article	Participant	Intervention/ follow-up duration	Relevant outcome	Intervention	Control	Measured program adherence	Delivered by / Site	Outcome
Koukouvou, G. 2004	NYHA-FC: II-III Systolic n=26 Male=26 Female=0	6 month/ 6 month	HRQoL (MLHFQ, QLI, LSI); Depression; Peak VO_2; METs; EPQ;	Supervised training program: various upper and lower body training modalities.	No formal exercise training	Yes	Not stated/ clinic	Exercise training was associated with improved peak VO_2 (p<0.05); significant decrease in anxiety and depression was also observed
McKelvie, R. 2002	NYHA-FC: I-IV Systolic n=181 Male=143 Female=34	12 month/ 12 month	HRQoL (MLHFQ); Peak VO_2; NYHA; 6MWT;	Clinical based for 3 months (twice a week), followed by 9 months of home-based program	Continue usual activity, not discouraged from regular physical activity	No	Not stated/ Home	Exercise training was associated with increased 6MWT distance; 6MWT distance also increased in control group, no between group differences (Not Significant). Peak VO2 improved in intervention group at 4 month (p=0.026); but not sustained as 12-month follow-up No significant change in HRQoL in both group.

Article	Participant	Intervention/ follow-up duration	Relevant outcome	Intervention	Control	Measured program adherence	Delivered by / Site	Outcome
Nilsson, B. 2008	NYHA-FC: III Systolic n=80 Male=63 Female=17	4 month/ 12 month	HRQoL (MLHFQ); 6MWT	32 hours exercise; 4 hours individual counseling	Usual care without supervised exercise	No	Physio/ clinic	Exercise was associated with improved 6MWT distance (p<0.001); HRQoL (p<0.005); Improvement was sustained at 12-month follow-up.
Passino, C. 2006	NYHA-FC: I-IV Systolic n=85 Male=74 Female=11	9 month/ 9 month	HRQoL (MLHFQ); BNP; Peak VO_2	30mins a day, 3 sessions/week, bicycle, supervised	Continue usual activity	No	Physio/ Clinic	Exercise training was associated with increased work load (p<0.001); peak VO_2 (p<0.001); ejection fraction (p<0.01); and HRQoL (p<0.01); compared to controlled group (NS).
Wall, H. 2009	NYHA-FC: II-III Systolic n=19 Male=11 Female=8	12 month/ 12 month	HRQoL (CHFQ); METs; Walk time; Max HR	3 supervised sessions followed by home-based training	Usual care with follow-up	No	Not stated/ Clinic and home	Control group had lower perceived fatigue level at follow-up (p=0.015); At 12-month, no significant difference between intervention and control in perceived functional capacity.

Article	Participant	Intervention/ follow-up duration	Relevant outcome	Intervention	Control	Measured program adherence	Delivered by / Site	Outcome
Witham, M. 2005	NYHA-FC: II-III Systolic n=82 Male=45 Female=11	6 month/ 6 month	HRQoL (Guyatt chronic heart failure questionnaire); Depression; 6MWT; Functional limitation profile	Gentle seated exercise program; 0-3 months supervised; followed by home-based program	Usual care	No	Physio/ Clinic	No change between groups in HRQoL and 6MWT distance. Intervention group had increased physical activity level measured by accelerometry
Willenheimer, R. 2001	NYHA-FC: II-III Systolic n=37 Male=26 Female=11	4 month/ 6 month	HRQoL; Dyspnoea; Fatigue; Peak VO_2	Cycle ergometer interval training; 3 sessions/ week	No training	Yes	Physio/ Clinic	Both intervention and control had decreased physical activity level

2.6 Effect of interventions

This review will focus on the effect of interventions on HRQoL and physical functioning.

2.6.1 Health related quality of life

As one of the inclusion criteria, all of the studies reported validated HRQoL measure. The majority of studies reported disease specific quality of life, using the Minnesota Living with Heart Failure Questionnaire (MLHFQ); EuroQoL (EQ-D5); Kansas City Cardiomyopathy Questionnaire (KCCQ); Psychological General Wellbeing index (PGWB); Quality of Life Index (QLI); Chronic Heart Failure Questionnaire (CHFQ). The study done by Gottlieb (1999), changes in HRQoL was only reported in the intervention, with no comparison to the control group.[17]

Pooling across all studies, regardless of which measurement tool was used, there was evidence of a significant improvement in HRQoL. Ten out of the 18 studies demonstrated a significant improvement in the HQRoL score compared to control group.[18-28] In Davidson and colleagues' study, the mean MLHFQ total score improved significantly from baseline to three-month follow-up (-16.2 for intervention,-15.5 for control), this improvement was not sustained at 12-month follow up.[22] On the other hand, in a study of 173 individual with CHF demonstrated no significant between group difference at follow-up, in HRQoL score.[29] In this particular study, both intervention and control group has decreased MLHFQ score (lower score dictates better perceived HRQoL) from baseline to six-month follow-up.[29] The mean total score for MLHFQ in the intervention group decreased from 46.7 at based to 35.7, at six-month follow-up; compared to 49.2 to 43.2 for the control group.[29] Although, the improvement observed in the control group was less compared to intervention group, there was a clinical meaningful change (>5 points change).[30-32] In this study, the intervention involved a home-based exercise program, and both groups received a pedometer to be used for during waking hours to measure their daily physical activity level.[29] Similar findings were observed in other studies involving home or community based interventions.[19, 23, 24, 33, 34]

The common aspect of these studies was that, the control groups also received some form of education, monitoring, counseling, or disease management program;[34] information or psychological support,[24] where the intervention group had exercise program in addition. The findings from this review may have suggested the effectiveness of interventions such as monitoring and education in improving HRQoL. This is supported by a analysis of activities of home-based heart failure nurse specialists,[35] and by other studies,[35-37] which suggested home visit, regular contact with participants are important, not only to enable assessment of treatment adherence and safety but also allow contact with participants in vulnerable stages of their illness trajectory.[35]

2.6.2 Physical functioning

Physical functioning is closely related to the prognosis in people with CHF.[38, 39] It is evident that regular physical activity can improve physical functioning and HRQoL in people with CHF.[40-42] Nevertheless, the long-term effect of physical activity program is often limited by poor program adherence.[11, 43] The majority studied in this review have demonstrated an improvement in physical functioning in the intervention group. The 6MWT was one of the most commonly used measurement for physical functioning.[44] In the study by Davidson and colleagues (2010),[22] the 6MWT distance increased by 107 meters which not only achieved statistical significance (p<0.001) but also a clinically meaningful change, as reported previously in the literature (43m-54m).[45-48] Similar findings were observed in another group of CHF individuals (n=200), where the 6MWT distance increased by 45 meters in the intervention group and decreased in the control group.[18] While in other studies, the change in the 6MWT distance was statistically significant; they were not clinically meaningful changes (difference of 22m-41m).[25, 29, 33, 49] Only Witham and colleagues, observed no improvement of 6MWT distance in both the intervention and control groups,[49] in a study involving clinic and home based components of a gentle seated exercise program. Although the 6MWT distance stayed unchanged over the study period, the authors has found an increase in

the physical activity level in the intervention group, measured by accelerometer.[49]

A similar pattern was found in studies using Peak VO_2 as a measure of physical functioning. Findings from those studies supported a moderate correlation between 6MWT distance and Peak VO_2, which has been reported in the literature (between 0.56-0.88).[44] Regardless of the measure used; it appeared the effect of the studied interventions observed immediately after program completion was often not sustained at long-term follow-up.[18, 29, 43, 50] These findings highlight the challenge of promoting longer-term maintenance of physical active behaviour.[19] Future research into alternative strategy in promoting physical activity, physical functioning is needed.

2.7 Program adherence

Adherence to exercise over time in healthy individuals is relatively low, estimated to fall to less than 50% adherence after 12 months.[43, 51, 52] Exercise adherence has been examined in individuals attending cardiac rehabilitation programs and might be similar to what would be expected in CHF population. Individuals with CHF have reported to have difficulty following exercise recommendations. Evangelista and colleagues found 61% of patients with CHF considered adhering to a physical activity regimen to be more difficult relative to following other recommendations.[11] While 80% people with CHF believe physical activity is important, only 39% reported undertaking regular physical activities.[53]

Out of the 18 studies, five provided information regarding program adherence. The methodology of assessing intervention fidelity ranged from the use of accelerometer, dairy use and to home visit by a nurse.[2, 20, 21, 24, 33] The remaining studies did not provide data regarding adherence assessment. There is generally a lack of uniformity with regarding how adherence was measured and what it is.[43] Bellardinelli and colleague defined adherence as the percentage of sessions attended. The average of sessions attended by participants range from 72% to 100% in their study.[20] Similarly to the study done by Bocalini and

colleague, the mean frequency of the training program was 89%±4%.[21] Whereas Mckelvie and colleague provided more detailed information, that 43% participants in their study attended 80% or more sessions, and 70% attended 55% or more session.[33]

Low adherence in research studies is challenging because of the corresponding impact of psychological, behavioural, and systems factors; as well as can causing a dilution effect and undermining the treatment effect.[54] Therefore uniformity in the definition and method of measuring adherence can be important in the interpretation of study results. In summary, CHF programs to date appear to have devoted little attention to the issue of adherence.[43] This is concerning given the importance of adherence to the physical activity recommendation and its benefits.

2.8 Exercise setting

The setting in which exercise training is conducted appears to play a role in level of adherence and its effectiveness.[43] The results from the literature appeared to be divisive. King and colleagues suggested in their study of 269 healthy, but sedentary middle-aged women and men, the adherence were higher in the home-based group compared to those in the supervised training group.[55] McKelvie and colleague found that adherence to home training in a CHF sample was lower relative to adherence during the supervised phase. The conflict between these two studies could be due to the difference on lifestyle, imposed by the characteristic of study participants, such as age, health status, employment status.[33, 55] Physical activity intervention in CHF management, exercise training program commonly conducted in a supervised, clinic environment. In recent decades, there are increasing home-based or community based intervention are considered as effective as clinic based programs, if not superior.[29, 56-58] Because of the lack of attention and reporting on program adherence in current literature,[43, 52] it is difficult to suggest the difference between clinic based and community or home-based programs on long-term adherence. This is an area requiring further research.[43]

2.9 Implications for program development

The review of the interventions in this chapter has provided several observations which are salient for intervention development. The result of this review supports that an intervention combining clinic based and community and home-based intervention is likely to be effective in improving HRQoL. This review has also underscored the issue of attrition and the importance of adherence in promoting physical activity. It has emphasised the importance of incorporating strategies in the home to promote adherence with direction and assistance of health professionals. Another important challenge was that many interventions were found to be effective in these reviewed studies, but the effect was often not sustained in the longer-term. Implementing strategies to promote longer-term adherence is important. Witham and colleague concluded in their study, in the absence of increase in 6MWT distance, the improved physical activity level in the intervention group suggested it was likely a result of behavioural changes brought about by participation in the program, telephone follow-up, keeping a diary and the setting of walking targets.[49] Improvement observed in both intervention and control groups in some studies may support monitoring and social interaction of participants with health care professional is an effective method in CHF management. To be able to inform future research and intervention development, more evidence is needed regarding what program characteristics are more likely to determine program effects. Current reviews are often limited by inadequate reporting in trials.[59]

Another issue to be considered in this review is the distinction between exercise and physical activity. Although for some this distinction can be considered arbitrary, in the case of CHF not only is exercise important but also the promotion of physical activity, which is the capacity of the individual to undertake activities of daily living and maintain functional status. In addition, inadequate adherence and monitoring to a prescribed treatment regimen (i.e. physical activity recommendations, medication) frequently precipitates exacerbation and recurrence of symptoms that compromise an individual's HRQoL. Self-monitoring may improve adherence with prescribed medication and

other recommendations such as physical activity.[60-63] As discussed in the previous chapter, self-monitoring can be complex and support is required to assist people to improve their self-care capacity. Therefore, implementing interventions to assist self-monitoring may have a capacity to increase adherence to health recommendations in the longer term. The Home-Heart-Walk is an innovative approach developed to promote physical activity and physical functioning based using the principles of self-monitoring.

2.10 Conclusion

This chapter has provided a review of exercise interventions to promote exercise in CHF management. These data were used to inform conceptual elements of the intervention that are described in Chapter Three and as an endpoint assessment for the intervention. This review shows that exercise training may promote physical functioning and HRQoL in people living with CHF. The effectiveness of the interventions study appeared to be dependent on the sub-components of intervention (i.e. exercise training only, exercise training, education, psychological support, and self-monitoring), as well as length of follow-up. This review also suggested that individuals with CHF require ongoing support on self-care to maintain the benefits they have gained from formal CHF management programs. Given the variation in interventions across studies, and lack of reported program adherence, it was not possible to provide definitive recommendation on which model is more effective in promoting physical functioning and adherence. There is a need to examine more home-based exercise programmes and how such programs can be effectively integrated alongside current models of service delivery in terms of clinical effectiveness. As well as further study needs to consider interventions to enhance the long-term maintenance of physical activity regimen.

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Chapter 3
Conceptual framework and rationale for the Home-Heart-Walk

3.1 Introduction

Previously, the advantages of physical activity in people with stable CHF have been discussed.[1] Despite the strong evidence of benefits for being physically active, promoting and maintaining physical activity, particularly among older adults remains a challenge.[2]

The European Association of Cardiovascular Prevention and Rehabilitation promotes structured out-patient cardiac rehabilitation for the development of a life-long approach to prevention of cardiovascular conditions.[3] This includes clinical and non-clinical based programs and in community settings.[3] Ongoing physical activity is necessary to sustain health benefits in the longer term. During supervised physical activity programs, verbal persuasion and encouragement from a health care professional may facilitate program adherence. In spite of the well-known evidence on physical activity, adherence to long term lifestyle change after completion of clinic-based programs is low.[4-6] Approximately 50% of older adults who initiate a physical activity regime discontinue within three months.[5, 6]

Two questions commonly posed are: What motivates people to pursue an active lifestyle? And what makes someone continue a physical activity regime while others fail to do so? In this chapter, the concept of adherence to treatment recommendations will be first explored, followed by a summary of theoretical models that are commonly used in explaining health behaviours and informing intervention development. Finally, the theoretical framework supporting the Home-Heart-Walk will be discussed.

3.2 Adherence to treatment recommendation

In Chapter One, the notion of adhering to treatment recommendation has been defined. Briefly, it is "the extent to which a person's behaviour-taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider".[6 p. 3]

The terms "adherence" and "compliance" are often used interchangeably in the literature. The differences between the two terms have been discussed for more than 10 years.[7] The term "adherence" implies that people freely choose to undertake the recommended behaviour, have input to their management plans, and have collaborative partnership involvement in developing and adjusting their plans.[2] In contrast the term "compliance" implies behaviour characterised by the extent to which people obey and follow instructions from their health-care providers faithfully.[2] In short, the term "adherence" implies active involvement, while "compliance" implies a passive role. Because of this important difference, the term "adherence" is preferred in the context of improving outcomes for chronic conditions and is used in this thesis.

There are different theoretical perspectives that attempt to explain the nature of adherence.[6] The biomedical perspective believes patient-related factors, such as personality and socio-demographic background, influence adherence behaviour,[8] while individuals' views about their management are largely ignored. The behavioural and communication perspectives emphasises the importance of positive and negative reinforcement as the mechanism that influences adherence, and encourages health professionals to improve communication skills.[9] In contrast, cognitive theories focus on patient conceptualisation of factors related to health.[10, 11] In addition, variable environmental factors and cognitive responses of individuals to illness can also influence adherence.[6]

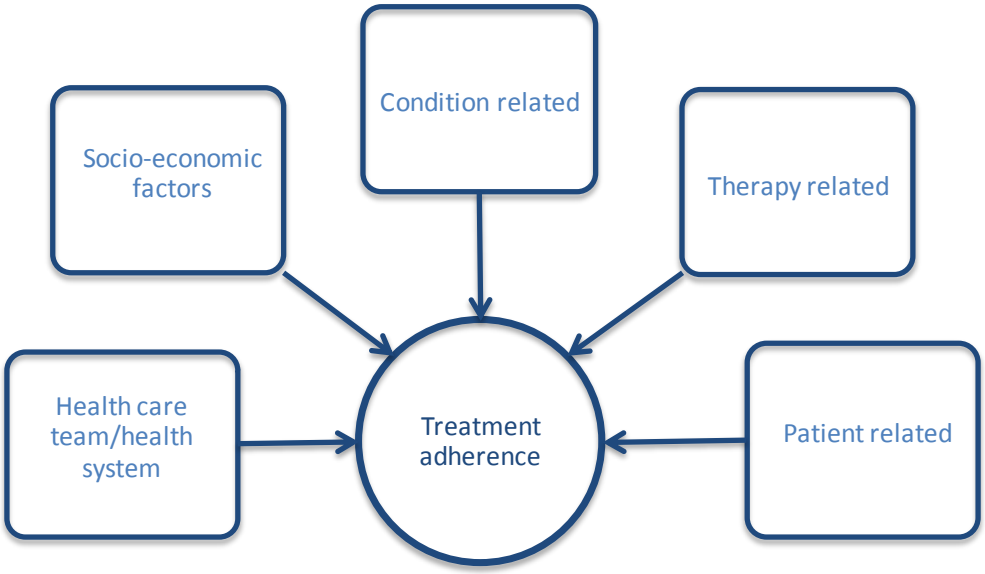

Figure 3.1 Dimensions of treatment adherence (World Health Organisation)
Source: [6]

The World Health Organisation has categorised factors impacting on adherence into the following five dimensions:

1. Health care team/health system: the patient-healthcare professional partnership has a significant influence on patient adherence to treatment recommendations. Inadequate feedback, consultation and follow-up from health care providers, affects self-management ability and self-efficacy, thereby affecting adherence to treatment recommendations.[12]

2. Socio-economic factors: although there is no consistent evidence of socio-economic factors as independent predictors of adherence, socioeconomic factors place the patient in the position of choosing between priorities (e.g. their own needs versus the needs of other family members).

3. Therapy-related: the complexity of the intervention, structure of the intervention, previous intervention failure, and the immediate benefit from the intervention can influence patient adherence. Lack of feedback and positive reinforcement to continue the recommended intervention is associated with low adherence rate (behavioural perspective).[6]

4. Patient-related: knowledge of the illness, motivation, confidence and self-efficacy are patient-related factors.[13]

5. Condition-related: severity of the illness and symptoms the patient is experiencing are condition-related factors that challenge adherence to health recommendations. Co-morbidities, such as depression, also play an important role in modifying treatment adherence behaviour.[6]

As low adherence rates are rarely the result of a single factor, interventions to improve adherence require a consideration of all the factors mentioned above. Long term physical activity adherence is difficult for many people, but for people living with CHF, maintaining a physical activity regime is especially problematic.[14, 15] The adherence to recommended physical activity levels are reported to be as low as 40% in people with coronary heart disease.[6, 16-18] In developed countries, for chronic disease in general, the adherence rates average just 50%, while the number is lower in developing countries.[6, 19] Symptoms of CHF, such as dyspnoea and fatigue, can severely limit exercise participation. People often require assistance to continue physical activity on their own, but few effective strategies are available.[7] The adherence of physical activity recommendation of people living with CHF in community settings is largely unknown.[20, 21] The process of adherence facilitation is derived from the Social Learning Theory which predicts that successful adherence to a new behavior is facilitated by setting goals, monitoring the behavior they wish to change, and developing a supportive relationship with their health care provider.[21]

3.3 Theoretical models

Theories and models of health behaviour have been used to predict, explain and understand not only health behaviour, but also provide a basis upon which interventions to improve the health of people can be developed and evaluated. Current research suggests that theoretically informed programs are more effective in changing health behaviour than those that are not theoretically informed.[22] Four of the most commonly used models are described and discussed below within the context of physical activity. They are: the Health

Belief Model;[23] the Theory of Reasoned Action;[24] Transtheoratical Model,[25-27] and the Self-efficacy Theory.[28, 29]

3.3.1 The Health Belief Model

The Health Belief Model (Figure 3.2) assumes that the individual makes a rational decision regarding personal susceptibility to the consequences of not doing physical activity.[23] In this model, individuals weigh the "pros" and "cons" of physical activity. Symptom perception or health communication, termed 'cues to action', may also prompt performance of the behaviour.[30] This 'perceived threat' construct differs the Health Belief Model from other models.[30]

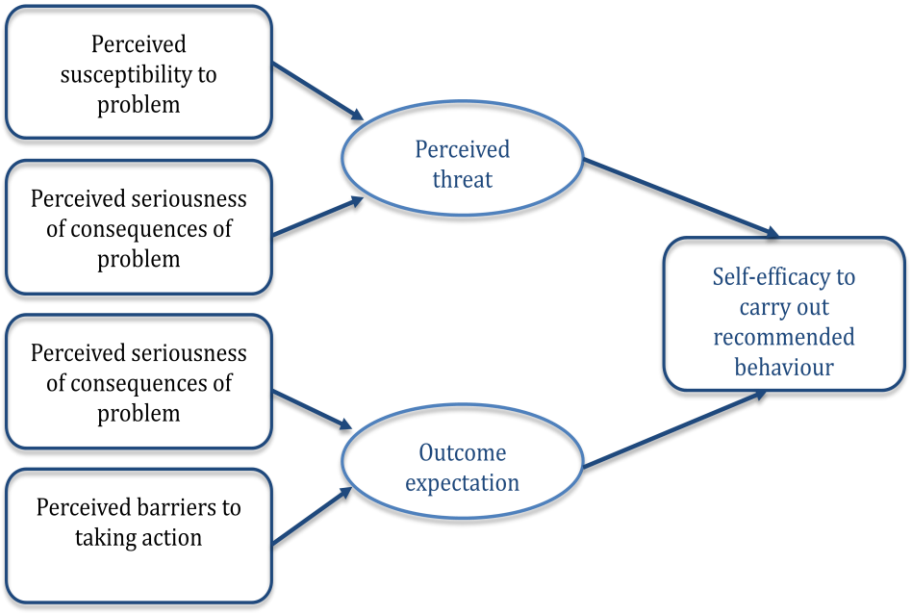

Figure 3.2 The Health Belief Model
Source: [23]

This model is most frequently employed in the context of health service uptake issues such as adherence with medical treatment.[31, 32] In 1988, self-efficacy was added to the original beliefs of the construct of the Health Belief Model.[33] In a meta-analysis of the Health Belief Model, although correlations between the model and behaviour were statistically significant, small effect sizes (all r's <0.21) and lack of homogeneity suggested weak predictive validity.[34] Although the Health Belief Model was found to have informed 20% of health behaviour research,[35] it focuses primarily on predicting a single behavioural outcome, and does not address the issue of maintaining behaviour change.[30] Therefore,

the Health Belief Model is not the most suitable potential model to address the adherence issue, which the Home-Heart-Walk study is focusing on.

3.3.2 The Theory of Planned Behaviour

The Theory of Planned Behaviour (Figure 3.3) is an extension of the Theory of Reasoned Action.[24] The Theory of Reasoned Action is considered as a versatile and situation specific model. Developed by Fishbein and Azjen,[36, 37] this model aims to predict behaviour based upon the individual's intention to perform a specific predict behaviour.[24, 36] In this model, an individual's behaviour intention is influenced by a person's attitude towards performing the behaviour and by the subjective norm.[36, 37] Studies that have applied this model to exercise behaviour found that personal attitudes and beliefs are more important determinants of behaviour than subjective norms.[37] While the Health Belief Model is health focused, the Theory of Reasoned Action has a level of generalisation that can be applied outside the health sphere and has better predictive value.

Meta-analyses have provided support for use of the Theory of Planned Behaviour in predicting a range of health behaviours, with correlations ranging from r=0.64 (41% of the variance) for behavioural intentions to *r*=0.58 (34% of the variance) for health behaviours. [38] This model fails to account for the intention-behaviour gap; that is, the model explains a larger proportion of the variance in intention rather than behaviour, providing only a partial account of how motivation is translated into action.[39] The Theory of Planned Behavior model has limitations in distinguishing between the initiation of a behaviour and maintenance of a behaviour over time.[30, 39]

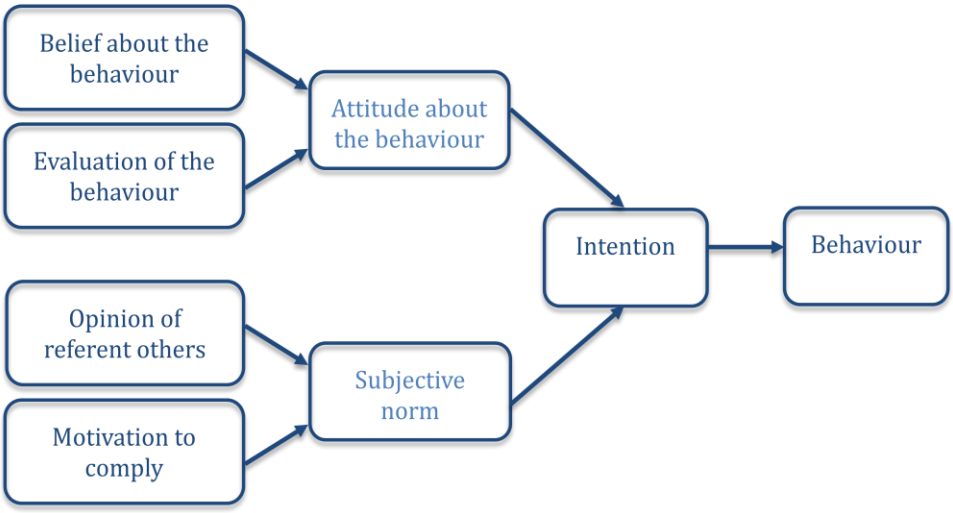

Figure 3.3 The Theory of Reasoned Action
Source: [24]

3.3.3 The Transtheoretical Model

The Transtheoretical Model (Figure 3.4) is a model of intentional change. It is a model that focuses on the decision making of the individual.[25-27] The Transtheoretical Model is an integrative model of behaviour change. This model assumes that different factors are important at different stages and involves emotions, cognitions, and behaviour.[40] The central organizing construct of the model is the Stages of Change. According to the Transtheoretical Model, a person can move from stage I to stage III only via stage II. Casual factors are hypothesised to influence the stage transitions.[40] Additional stages and explanatory variables can be included in this model as well as backwards transitions to non-adjacent stages.[40] The Transtheoretical Model implies that interventions should be matched to the participant's stage by targeting the variables (i.e. the processes of change) that are assumed to influence the transition from one stage to the next.[25-27] Almost one-third of health behaviour research between 2000 and 2005 utilised the Transtheoretical Model, with application to a wide range of health behaviours.[35]

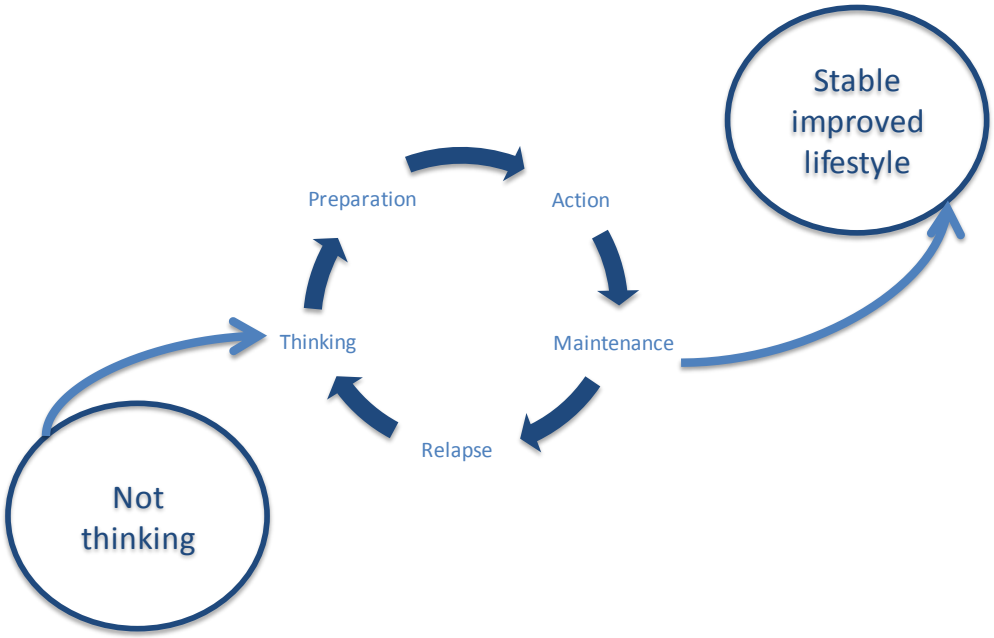

Figure 3.4 The Transtheoratical Model
Source: [27]

Including maintenance as a separate stage in this model would suggest its suitability as a theoretical basis for the Home-Heart-Walk study. However, the primary focus of the Transtheoretical Model has been to recognise that people differ in their readiness to take action.[41] Hence, research efforts have focused on delineating the processes through which people become ready to initiate a change in their behaviour. Although a distinction is made between people in the action and maintenance stages of the Transtheoretical Model, the basis for this distinction rests solely on the length of time a behaviour has been adopted (six months or more), which has been suggested to be somewhat arbitrary.[42] The Transtheoretical Model believes the set of cognitive and behavioural processes that are predicted to facilitate *initial* action are similarly predicted to help *maintain* that action over time.[41] In summary, the Transtheoretical Model, in effect, is no different to the continuum models previously discussed.

3.3.4 Self-efficacy Theory

The above theories have explored important aspects of behaviour changes. Each of the models above has emphasised the importance of individuals' attitudes and beliefs, which are congruent with the concept of self-efficacy. Adherence to treatment recommendation is more than behaviour change, but also behaviour

maintenance. Besides attitudes and beliefs, the Self-efficacy Theory takes into consideration the physical environment and habit, which can influence long-term adherence. It was also developed for the specific health behaviour of physical activity. Self-efficacy Theory was developed as part of a larger theory, the Social Leaning Theory, which has progressed into the Social Cognitive Theory.[11, 29] Below, Social Cognitive Theory, Self-efficacy Theory and Exercise Self-efficacy Model will be discussed in details.

3.4 Social Cognitive Theory

Social Cognitive Theory illustrates how individuals do not simply respond to environmental influences, but actively seek and interpret information. Individuals "function as contributors to their own motivation, behaviour, and development within a network of reciprocally interacting influences"[11] (p196). Figure 3.5 illustrates Badura's Triadic Reciprocal Determinism. According to Bandura, human functioning is the result of the interaction of all three factors. As embodied in his Triadic Reciprocal Determinism. Furthermore, the influencing factors are not equal strength, nor do they all occur concurrently.

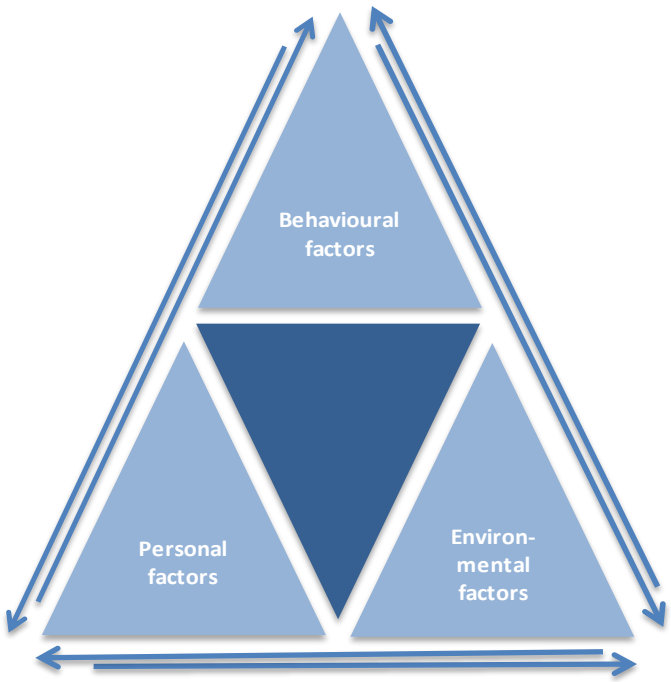

Figure 3.5 Bandura's triadic reciprocal determinism
Source: [43]

3.4.1 Self-efficacy Theory

The relationship between the construct of self-efficacy and adherence to health recommendations is derived from Social Cognitive Theory.[28, 29] Self-efficacy is the degree of confidence an individual has in his/her ability to perform behaviour under a number of specific circumstances.[29] The Self-efficacy Theory (Figure 3.6) was developed by Albert Bandura.[29] This theory has been suggested as suitable to explain why some people manage to change habits that promote cardiac health in the long-term.[44, 45] It was developed to explain the gap between ability and performance.[29] Self-efficacy Theory believes social modeling antecedents, that social consequences are especially powerful and assumes people who are confident in their ability to perform a particular behavior in a situation are more likely to perform the activity.[29] The Self-efficacy Model has been shown to be a powerful predictor of performance.[46-48]

It is a cognitive mechanism that mediates behaviour, influences participation in various activities and determines the amount of effort and degree of persistence in pursing the activity despite aversive stimuli.[11] The construct of self-efficacy can be complex. Adherence to a supervised exercise program (e.g. cardiac rehabilitation) does not necessarily equate with adherence to physical activity recommendations more broadly. Similarly, confidence in one's own ability to perform a certain level of physical activity does not mean that this level of activity will be maintained in the longer term. In order to develop conceptually congruent interventions, understanding these relationships is important.[49] A recent systematic review by Ashford and colleagues,[50] has assisted in elucidating which constructs contribute to promoting self-efficacy.

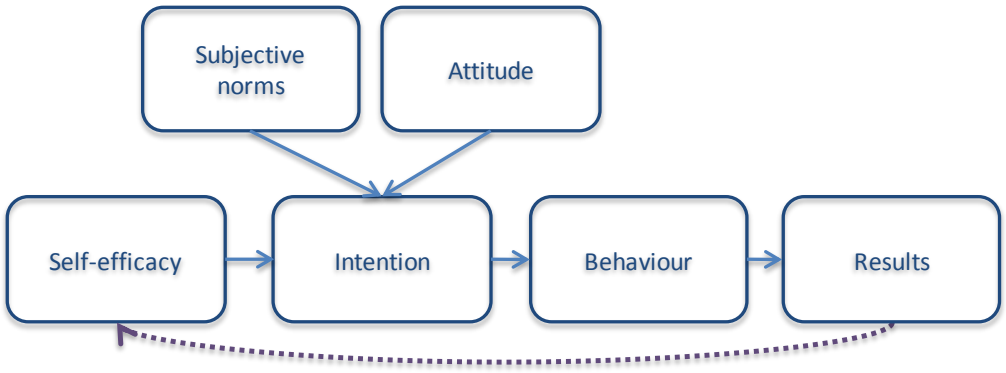

Figure 3.6 Bandura's Self-efficacy Theory
Source: [29]

Proxy efficacy

When initially diagnosed with CHF, people often find they have little control over their condition and are unsure about their ability to start a physical activity regime independently. In this situation, developing self-care strategies is important.[29] An individual's confidence in the skills and abilities of their helper or 'proxy agent' (e.g. health care providers) to function effectively on one's behalf is referred to as proxy efficacy.[51] Proxy efficacy is often helpful in the early stages of behaviour change as a person begins to initiate a new behaviour, and is closely associated with adherence to a guided and supervised program, such as cardiac rehabilitation program. While proxy efficacy is helpful, high proxy efficacy may compromise development of independent capabilities, leading to dependency on the proxy agent and/or be associated with a lower task efficacy.[51, 52]

Task efficacy

Task efficacy is an individual's confidence in his/her ability to perform the elemental aspects of a task.[29] For example, after completing cardiac rehabilitation, an individual may start to doubt his/her ability to undertake physical activity independently, which is low task efficacy. Therefore, it is important for the health care provider to support this transition in order to promote the maintenance of physical activity post program completion.[51]

Self-regulatory efficacy

The balance between the pros and cons greatly influences an individual's readiness for adopting physical activity. Yet, even when the perceived pros outweigh the cons, many people who start a regime often quit after a short period of time.[53] To maintain a physical activity regime, good proxy efficacy, supported transition, and high task efficacy is not enough. An individual's confidence in maintaining improved physical activity in the face of personal, social and situational challenges is necessary for improvements in the longer term. This confidence is an individual's self-regulatory efficacy.[51, 54, 55] We must therefore ask, how can self-efficacy for exercise be improved? Bandura[29] points out that it is important to help individuals understand that behaviour changes are in the interest of outcomes they personally desire, and consistent with the goals they value. In relation to exercise self-efficacy, four determinants can be learned and used to promote maintenance of physical activity. Understanding these factors is important in leveraging behaviour change and maintenance.

3.4.2 Exercise self-efficacy

Self-efficacy and previous levels of physical activity are thought to be important for behaviour maintenance in older adults.[56] In a longitudinal study by McAuley and colleagues,[57] participants' exercise self-efficacy at two years (following completion of a six-month exercise program) predicted physical activity behaviour at five years. An individual's exercise self-efficacy determines their choice (for example, whether to participate in an exercise program or not), effort (how much effort they are willing to put in) and thoughts (e.g. why should I exercise, what is the usefulness of the exercise and should it be continued). Four determinants influence an individual's level of self-efficacy. These are *past performance*, *vicarious experience*, *verbal persuasion* and *physiological arousal*. The concept of exercise self-efficacy is summarised in Figure 3.7 and described below.

Past performance-past performance is the most important determinant of self-efficacy.[29] Successful past performance dictates higher self-efficacy and

minimises perception of barriers to physical activity. Providing opportunities to gain successful experiences with physical activity is important in assisting individuals to build confidence.

Vicarious experiences-also known as “modelling.” This is a process of comparison between oneself and someone else. Modelling is a powerful influence when a person is particularly unsure of his/her ability.[29]

Verbal persuasion-Once an individual begins to exercise, receiving positive feedback regarding performance can help maintain and promote exercise self-efficacy. Self-monitoring is a good strategy for those who exercise on their own to monitor performance and provide evidence regarding physical activity accomplishments.[57, 58]

Physiological arousal-A person's perceptions of his/her physiological response to physical activity, can markedly alter their self-efficacy. Some level of shortness of breath during a fast walk can be interpreted by those with low self-efficacy negatively as a sign of their own inability or a trigger of another cardiac event. Those with high self-efficacy can also interpret it positively as a normal response to physical activity.[29]

Self-efficacy plays an influential role in the adoption and maintenance of exercise behaviour in older adults. Manipulation of the variables of exercise self-efficacy has been shown to increase adherence to regular physical activity in older adults more than health education or instruction alone. [39]

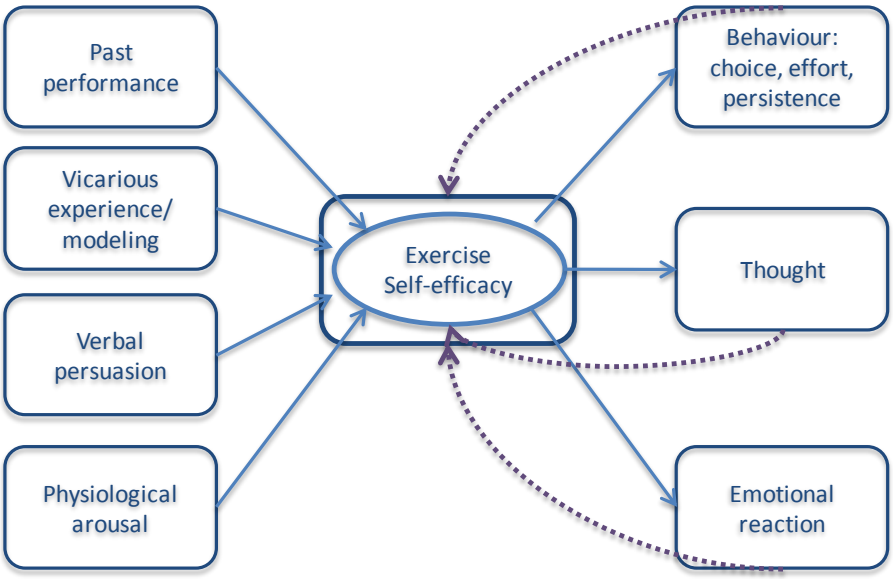

Figure 3.7 Exercise Self-efficacy Model
Source: [29]

3.5 The construct of self-efficacy in intervention development

Explicitly or implicitly, all the other theories discussed above, particularly the Self-efficacy Theory, recognize that behaviour maintenance is a self-regulated, dynamic social learning process.[39, 59] Individuals experience successes and failures as they attempt to maintain a specific behaviour. Within this process, goal adjustment, self-monitoring and self-regulation of their behaviour are based upon their experience; at the same time they are influencing people's experience. Interventions based on the Exercise Self-efficacy Theory, should attempt to facilitate the process of goals adjustment, self-monitoring and self-regulation of behaviour, in order to promote physical activity maintenance.

In this behaviour maintenance process, individuals set their goal, and regulate their behaviour to achieve the set goal. While carrying out the behaviour, individuals monitor how they feel, what they can or cannot do, and seek feedback from others. But more commonly, people determine whether they are successful by comparing what they have achieved with their initial set goal. Based upon what they have achieved and their experience, individuals decide whether they are satisfied with their performance, and self-regulate their behaviour accordingly.[2] Facilitating a realistic goal is important in behaviour

maintenance. This is because heightening expectations may encourage people to initiate a change, but over time may have the paradoxical effect of reducing the chance that the behaviour will be maintained.[39, 60] Therefore, physical activity intervention should be achievable to the targeted population, facilitate realistic goal setting and encourage maintenance.

Encouraging behaviour adherence is also important to exploring the barriers for behaviour maintenance. As mentioned previously, fear of falling is one barrier to physical activity in elderly populations.[61] Lowered confidence to balance oneself and prevent falling leads to avoidance of any physical activity that is perceived as a risk to falling. One study has found increased physical activity levels, nine months after completion of a 12 week fall prevention program in the elderly.[62] This is an example of facilitating physical activity by overcoming barriers and improving task efficacy. Research has also found, that programs promoting walking have higher adherence rates (25-35% drop out rate) compared to those based on vigorous exercise, such as running (50% dropout rate), and providing a variety of exercises can also promote physical activity by preventing boredom.[63, 64] Other studies have found positive effects on physical activity adherence through telephone support.[65-68]

In summary, intervention should be easily undertaken and able to overcome some of the barriers of physical activity to promote the individual's confidence.

As there is no 'one size fits all' physical activity program, counselling the individual is critical in developing an individualised regime to promote program adherence. Courneya and McAuley [56] have written extensively about cognitive strategies for altering self-efficacy. They recommend targeting various "incentive" aspects of physical activity, such as its health benefits to build motivation, as well as affective states and enjoyment, which also play a role in activity maintenance.[56] The Home-Heart-Walk was developed based on the above conceptual framework.

3.6 Conceptual framework for the Home-Heart-Walk program

As physical functional capacity is closely related to the prognosis of people with CHF, the Home-Heart-Walk allows regular monitoring of physical functional capacity at community settings, without the presence of a health care professional. The Home-Heart-Walk is based on the concept of self-efficacy positioned within the Social Cognitive Theory. The Home-Heart-Walk itself targets the four factors influence individuals exercise self-efficacy. As well as it also take into consideration of the other three components within the Social Cognitive Theory (Self-observation, Self-evaluation and Self-reaction). It aims to improve physical functioning through facilitating participation in physical activity; as well as to improve self-care behaviour. Figure 3.8 presents the theoretical framework of the Home-Heart-Walk study.

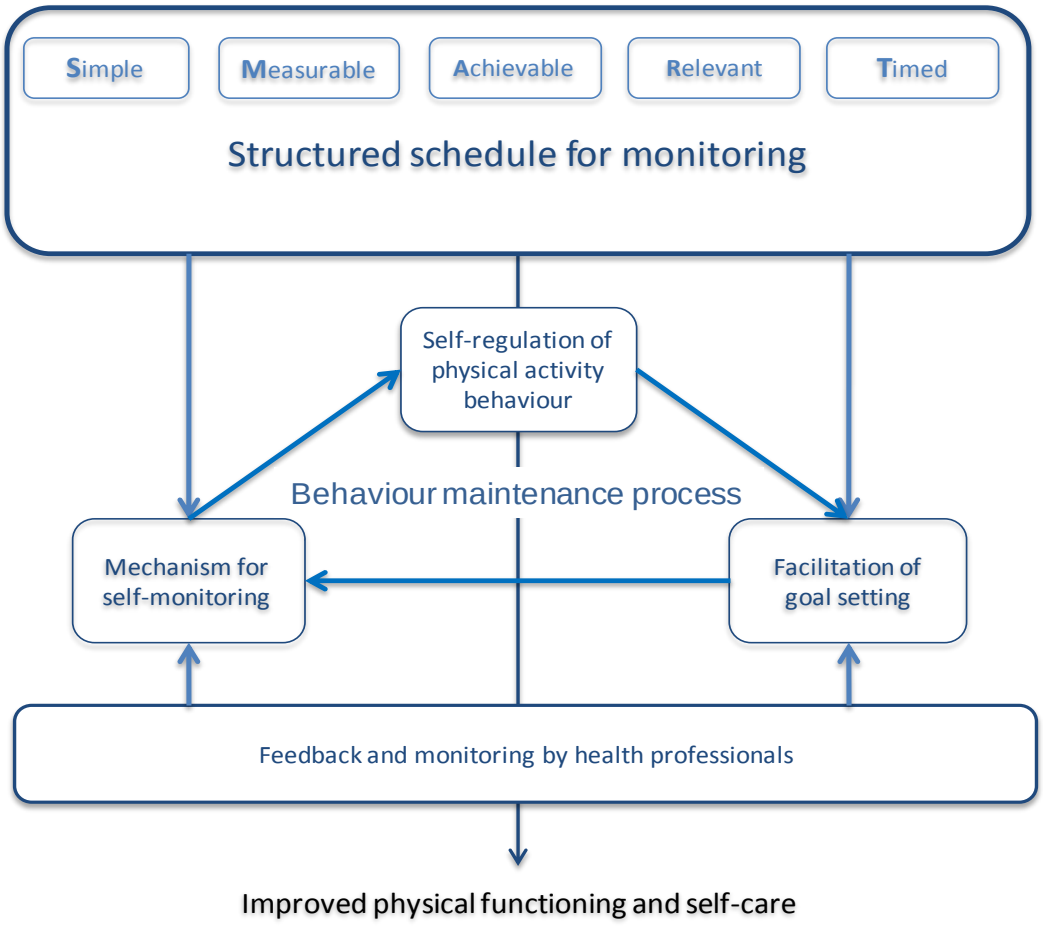

Figure 3.8 Conceptual framework of the Home-Heart-Walk program

3.7 Home-based and self-administered monitoring intervention

In recent years, there has been increasing attention on using self-monitoring interventions to improve health outcomes.[69, 70] The six-minute walk test (6MWT) has been commonly used in clinical settings especially CR programs to measure functional capacity.[71] However, the monitoring of functional capacity is still limited in a clinical-based environment. The Home-Heart-Walk is a self-administered intervention adapted from the standard Six Minute Walk test. In this study, it comprised six months of weekly self-administered, adapted 6MWT and monthly telephone follow-up. Table 3.1 presents how the Home-Heart-Walk program addresses each of the four determinants of exercise self-efficacy.

3.7.1 Improving physical functioning

The Home-Heart-Walk aims to improve physical functioning in people living with CHF through facilitating physical activity using a simple, low intensity self-administered intervention. Although physical activity guidelines provide patients with directions for exercise, when the progress of daily exercise is not monitored, the importance and usefulness of daily exercise is likely to be overlooked, as people do not receive positive reinforcement for engaging in such activity.[70] Bandura [29] suggests that once regular activity has been initiated and the benefits become apparent through personal performance and positive physiological and psychological response, adherence becomes more likely.

The Home-Heart-Walk promotes physical functioning through two aspects. First, the activity of the Home-Heart-Walk is self-paced walking, which set a good exemplar to individuals as an achievable physical activity. It is achievable to people even with very limited physical functional capacity.[71] It can be undertaken in both indoor and outdoor settings, addressing weather and safety issues. Therefore, it facilitates the development of confidence in undertaking physical activity, especially for the elderly. Secondly, the Home-Heart-Walk provides immediate feedback on an individual's performance. It facilitates goal setting, which was one important aspect of the dynamic behaviour maintenance process.

Table 3.1 Exercise self-efficacy and the Home-Heart-Walk program

Determines of exercise self-efficacy	The Home-Heart-Walk program
1. Successful performance	Simple, specific program protocol and sub-maximal intensity nature ensure the program to be an achievable physical activity for people with chronic heart failure. The Home-Heart-Walk involves a self-paced and timed (6 minutes) walking. The sub-maximal intensity nature of this intervention promotes more individuals who are not able to undertake higher intensity physical activity due to physical limitation, to engage in something simple. Therefore, promoting confidence in physical activity.
2. Vicarious experience/modelling	Modeling and coaching from health care professionals make the program even easier to comprehend. Health care professionals encourage the individual to undertake the Home-Heart-Walk, one to one at the beginning of the program. Equipment (timer, lap counter, rope for measure walking track) for undertaking this simple walking intervention is provided to the individual.
3. Verbal persuasion	Measurable intervention, immediate feedback on performance. In the Home-Heart-Walk intervention, each time an individual completes the walk, the distance is recorded by the individual in a diary. The distance walked provides the individual immediate feedback on their progress and physical status, therefore promoting self-monitoring and encouraging physical activity by monitoring progress.
4. Physiological arousal	Follow-up discussion with health care professionals, re-interpretation of symptoms, provide reassurance to individuals, ensure individuals safety and provide professional monitoring of physical functional capacity. Health care professional assists individual interpret Home-Heart-Walk distance, guide individual to a better recognition of changes in physical status, better self-management.

3.7.2 Assisting in self-care

Monitoring physical functional capacity is an important aspect of CHF management, as it is closely linked to an individual's prognosis. Redelmieier and colleagues,[72] surveyed a group of 104 chronic obstructive pulmonary disease (COPD) patients on their walking ability relative to how it had been a few months earlier. A poor correlation between actual and perceived changes in walking ability was found. More than half of the patients who perceived themselves as subjectively improved had actually experienced an objective worsening of their performance.[72] This finding suggests that patients do not have perfect memory of their past functional status, and this is not unusual. In CHF, the

apparent severity of a patient's symptoms may fluctuate widely, although the patient's cardiac function may be unchanged.[73, 74] This variability suggests that symptoms are an unrealistic guide to the degree of physical limitation. As many people with CHF are living and managed in community, self-management becomes very important in the prognosis of their condition. Assistance is often needed for better self-care in people living with CHF. The Home-Heart-Walk program is a self-monitoring program that not only provides feedback to individuals on condition, but also can be used to inform clinicians of progress and variation in performance over the trajectory of CHF. It encourages individuals to become more actively involved in the management of their condition.

3.8 Conclusion

Improved self-care capacity can improve health outcomes. Two important aspects of self-care in CHF population are self-monitoring and adherence to treatment recommendations (medication, lifestyle). Self-monitoring and adherence are two interrelated concepts. Self-monitoring includes monitoring, interpretation and response. Therefore, better self-monitoring dictates better self-care behaviour. Using a self-monitoring intervention to improve self-care behaviour is not new, but an objective self-monitoring of physical functioning that also facilitates improvement in physical functioning is a novel approach. In this chapter, four commonly used theoretical models have been briefly introduced, within which the importance of self-efficacy was emphasised, and led to the exploration of Self-efficacy Theory and the Exercise Self-efficacy Model. The Home-Heart-Walk program theoretical framework was developed based on the Self-efficacy Theory. It seeks to assist in the self-monitoring of physical functional capacity and promote physical activity adherence. In the next chapter, the development of the Home-Heart-Walk program will be detailed.

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Chapter 4
Development and preliminary evaluation of the Home-Heart-Walk

4.1 Introduction

Previous chapters have outlined the burden of CHF and challenges in management, in the context of the Chronic Care Model (CCM).[1, 2] Self-monitoring and adherence to treatment recommendation are two important aspects of self-management for people living with CHF.[3] To support an individual's self-management of their CHF, interventions that promote adherence to physical activity recommendation, and assist in self-monitoring are recommended. After exploring the construct of exercise self-efficacy, as well as the barriers and facilitators to physical activity adherence (Chapter Three); the idea of using the simple self-monitoring intervention to monitor physical functional capacity for promoting physical activity adherence and self-management was gradually formed.

Promoting an active lifestyle has the potential to positively reorient the trajectory of functional decline in people with CHF.[4-8] Based on the exercise self-efficacy theory[9, 10] discussed in the previous chapter, the Home-Heart-Walk was developed to promote physical functioning through 1) assist in self-monitoring of physical functional capacity and 2) promote adherence to physical activity recommendations through the four determinants of exercise self-efficacy.

The Home-Heart-Walk consists of a weekly self-administered, modified 6MWT, and regular telephone follow-up. A comparison of maximal and sub-maximal exercise test; as well as the rationale of choosing the 6MWT was presented in Chapter One. This chapter seeks to first provide a literature review of the 6MWT. As well as, to briefly outline the results from an evaluation of feasibility and reliability of the Home-Heart-Walk that was completed as part of the candidate's BN (Honors) thesis.[11]

4.2 Maximal exercise test vs. sub-maximal exercise test

The advantages and disadvantages of maximal exercise test and sub-maximal exercise test were compared in Chapter One. That comparison has highlighted the usefulness of the sub-maximal exercise test in populations where maximal exercise testing is contraindicated or in people whose physical capacity is limited because of pain or fatigue rather than exertion.[12-14] One of the most commonly used sub-

maximal exercise tests is the 6MWT. In comparison with maximal exercise tests, the application of sub-maximal exercise tests is less well developed. Given the large number of patient types and individuals who could benefit from a non-maximal exercise test, it is timely to evaluate the potential one of the most commonly used sub-maximal exercise tests. The next section outlines the utility and effectiveness of the 6MWT from a literature review and its potential to be a self-administered intervention.

4.3 The Six Minute Walk Test: a review of the literature

4.3.1 The Six Minute Walk Test

The Six Minute Walk Test was first developed to evaluate functional capacity, in the 1960s, by Balke.[15] This simple walk test measures the distance walked during a defined period. The duration of the test was initially 12 minutes. Subsequently, three minute walk test, six minute walk test and twelve minute walk test [16] have been tested for their correlation to the gold standard of graded, symptom limited exercise tests, such as treadmill exercise tests.[17, 18] Their reproducibility are similar.[17] However, when the duration of a walk test is less than four minutes, the result is not sensitive enough for statistical evaluation of differences in distance walked.[19] The 6MWT has now become a sensible compromise and is currently the most commonly used walk test.[20] Earlier studies by Guyatt *et al.* [21] and Lipkin *et al*. [22] have demonstrated the ability of the 6MWT to differentiate individuals with the most compromised heart failure from the less severe cases according to the New York Heart Association (NYHA) functional class classification.[23, 24]

Peak oxygen uptake, functional capacity and the Six Minute Walk Test

As discussed in Chapter One, functional capacity, expressed by peak oxygen consumption (peak VO_2) during maximal exercise testing,[25] is a strong indicator of the severity of CHF,[26] as well as an independent predictor of mortality.[13] In people with advanced conditions, maximal exercise testing may be contraindicated due to significant impairment in functional capacity.[13] The 6MWT is a simple and safe exercise test,[22, 27-29] with strong correlation to an individual's peak VO_2 (r=0.56 to r=0.88).[29] Studies suggested that in people whose physical functional

capacity is severely impaired, an exercise test of a sub-maximal nature could be reflective of the results obtained from a maximal exercise test.[29, 30]

Prognostic value of the Six Minute Walk Test

There is no consensus regarding the prognostic value of the 6MWT due to a "ceiling effect", where the test result plateaus at a particular level precluding detecting further significant improvement, both clinically and statistically.[31] The 6MWT has perhaps its greatest application in the CHF population, where functional capacity is impaired and periods of de-compensation are common. Most studies examining the prognostic value of the 6MWT have been conducted amongst people with CHF. Studies suggest that the 6MWT distance is not an independent prognostic indicator, but rather a complement or substitute for the peak VO_2 or NYHA-functional class.[28] Although, the 6MWT may not be a standard, independent prognostic indicator, compared with peak VO_2 assessed during maximal exercise testing; it certainly provides valid and important information regarding an individual's functional capacity.[28, 32-36]

4.3.2 Practical application of the Six Minute Walk Test: methodological considerations

In current literature, the 6MWT protocol can vary from study to study.[20] Two key variances in 6MWT protocol were related to using encouragement and learning effect.[20]

Learning effect is often observed, when individual has performed a test previously.[35] Study has shown, the distance walked during the 6MWT tends to increase (+19 metres when the two tests are done 30 minutes apart) and over the first five walks.[37] It is believed that a change greater than 10% of the average of two consecutive can be considered as an expression of a real variation of functional capacity.[35, 38] Practice 6MWTs were recommended when using it to evaluated intervention effect over time.[27, 29, 39, 40] The use of encouragement during the 6MWT can also affect the distance walked. The majority of studies have used standard encouragement as in the American Thoracic Society (ATS) 6MWT guideline,[18, 24, 35, 41] while others have not.[18, 24, 42] Despite that, the reproducibility of the 6MWT result, with or without encouragement, are similar.[43]

Should encouragement be used during the walk test, is dependent on the nature and purpose of the study.[44]

4.3.3 Reliability of the Six Minute Walk Test

Reliability refers to the ability to measure the same result on repeated tests.[44] The intraclass correlation coefficient (ICC) is a measure of reliability.[44] An ICC of greater than 0.75 is considered adequate and 0.90 is considered excellent.[44] In the current literature, studies have suggested the 6MWT is a reliable intervention, with an ICC between 0.75-0.97.[27, 41, 45] Only one study reported a significant difference between the distance of two consecutive 6MWTs, leaving these authors to conclude that the 6MWT distance to be not reproducible in their study.[44] In this particular study, the period between the two 6MWT was unknown, it is also not known if a learning effect was another contributing factor to the result of this study. Despite the variations among the 6MWT protocol in each study, such as whether there was a practice test or encouragement was used, existing data suggests that the 6MWT is a reliable measurement of functional capacity.

4.3.4 Validity of the Six Minute Walk Test

Validity describes the relationship between an attribute under evaluation and other established characteristics.[44] The 6MWT has been evaluated against other assessment tools such as the NYHA-functional class and measures of HRQoL, including the disease specific Minnesota Living with Heart Failure Questionnaire (MLHFQ)[41], and the Medical Outcome Study Short Form-36 (SF-36).[44] The 6MWT has been shown to have a weak and inverse correlation (r=-0.39) with the MLHFQ, and likewise, an inverse correlation (r=-0.45) between the 6MWT distance and the NYHA scale (p=0.058).[41] The correlation between the 6MWT distance and the SF-36 physical function domain was 0.623 (p<0.001).[44] Questionnaires examining HRQoL are subjective, multidimensional self-report tools, consisting of domains other than physical functioning. The physical function domain of the SF-36 is better in reflecting physical activity; therefore, a weak correlation between the 6MWT and HRQoL in general and stronger correlation between the 6MWT and SF-36 physical function domain are expected. These studies suggest the 6MWT is a valid

measurement tool for physical functional capacity and is not representative of other aspects of HRQoL.

4.3.5 Responsiveness of the Six Minute Walk Test

The responsiveness or sensitivity of a test represents the ability to measure change over time or the ability to measure the effectiveness of intervention.[40] In a systematic review, the changes in the 6MWT distance before and after the intervention was significant in four out of the seven non-pharmacological interventions, and only significant in nine out of the 39 pharmacological interventions.[16] The majority of the pharmacological trials, showing no significant changes in the 6MWT distance, were done in assessing the effectiveness of angiotensin-converting enzyme inhibitors and beta-blockers.[46, 47] These data underscore the importance of choosing outcome variables that are most responsive to the study question being addressed.

4.4 Six Minute Walk Test as a self-administered intervention

Self-monitoring of functional capacity in CHF has been limited by the application of an empirical tool.[12, 20, 48] Although pedometers and accelerometers has been shown to be motivational to people's daily physical activity,[49] there are a couple of practical issues[49, 50], such as adherence with pedometer wear protocol; identification and treatment with extreme value, and estimating physical activity level with difference in pedometer wearing time, which requires further research.[50]

High levels of subjectivity affect the description of fatigue and shortness of breath is common in many heart conditions. The 6MWT is a widely acceptable self-paced sub-maximal exercise test in conditions, such as moderate to severe CHF where maximal exercise testing is contraindicated or where access to equipment is limited.[20] Compared to maximal exercise tests, the 6MWT is likely to be less intimidating in older people, particularly women.[40] In people with severe CHF, the 6MWT provides prognostic information on morbidity and mortality, reflecting physical function aspect of HRQoL in measuring impairment.

As discussed before, the reliability, validity and responsiveness of the 6MWT have been extensively tested in clinical settings. Therefore, as part of this thesis it has been postulated that the 6MWT could potentially be adapted as a self-administered test. This approach will allow a two-pronged approach. Firstly, as a therapeutic intervention to improve functional activity and secondly provide utility as a therapeutic index.[11] In addition, the variability in the type and severity of symptoms might be partially responsible for people's difficulty developing a reliable cognitive meaning upon which to make decisions about seeking care through monitoring performance over time and against a negotiated baseline level. Therefore, a self-administered 6MWT allows objective measurement of progress of physical functional status can be potentially useful in reducing delay in seeking health care and improve self-management capacity.[51]

4.5 The Home-Heart-Walk program

The use of a sub-maximal exercise test potentially best meets the needs of people with functional limitations and the needs of older adults, whose functional capacity are limited. However, the sub-maximal exercise tests and their applications have been less well developed and is an important area for future research.[40]

Based on the literature review outlined in the previous section, the 6MWT appeared to be a feasible self-administered test.[20] Considering the characteristics of the CHF population, the Home-Heart-Walk intervention was developed, which is a home-based, self-administered, modified 6MWT (Figure 4.1). As a self-administered tool, a lap counter and a timer with a countdown function is also used to assist individual's undertaking the Home-Heart-Walk. A comparison between the 6MWT according to the ATS 6MWT guideline[43] and the Home-Heart-Walk is presented in Table 4.1.

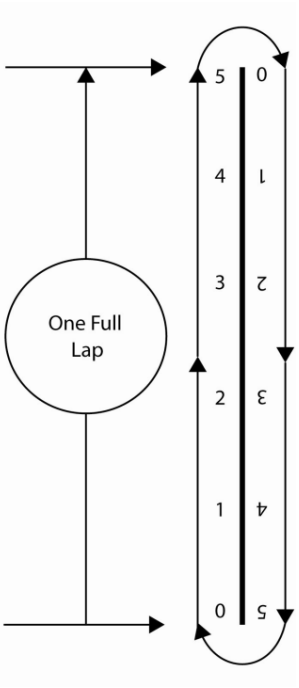

Figure 4.1 Illustration of the Home-Heart-Walk track

Table 4.1 Comparison of the 6MWT and the Home-Heart-Walk protocol

The 6-Minute Walk Test	The Home-Heart-Walk
○ Flat, hard surface	○ Flat, hard surface
○ 30m walking track	○ 5m walking track
○ 6 minutes in duration	○ 6 minute in duration
○ Aim to cover as much distance as possible	○ Aim to cover as much distance as possible
○ Stop and rest is allowed	○ Stop and rest is allowed
○ Standard encouragement used	○ No encouragement used during test
○ Observer record result)	○ Individual record own result

4.5.1 Evaluation of the Home-Heart-Walk

Prior to this doctoral project-the Home-Heart-Walk study; correlation between the Home-Heart-Walk distance and the standard 6MWT was assessed as well as its feasibility and reliability.[52] Evaluation of the feasibility and reliability of the Home-Heart-Walk was part of the candidate's BN (Hons) project. The results of this study are briefly presented below. These are presented to show the extension of this concept as part of the PhD thesis.[52]

Phase 1: Correlation between the Home-Heart-Walk distance and the Six Minute Walk Test distance

The correlation between the Home-Heart-Walk distance and the 6MWT distance was assessed in a group of healthy volunteers (n=13; aged 23 to 59 years old), with no known heart disease, and no known conditions that would affect their ability to walk were invited to participate. Participants performed a clinician-supervised, standard 6MWT undertaken according to the ATS 6MWT guidelines,[43] followed 30 minutes later by the Home-Heart-Walk.

The distance walked on the standard 6MWT ranged from 538 to 776m (mean 652m, SD: 69m). The distance walked on the Home-Heart-Walk ranged from 358m to 695m

(mean 492m, SD: 78m). The correlation between the standard 6MWT and the Home-Heart-Walk test distance was r =0.81.[53]

After obtaining a satisfactory correlation between the Home-Heart-Walk distance and the standard 6MWT, the feasibility and reliability of the Home-Heart-Walk was evaluated in a group of people with coronary heart disease (CHD).

Phase 2: Feasibility and reliability

The feasibility and reliability of the Home-Heart-Walk were evaluated in a group of 29 individuals (aged 49-80 years) with CHD, over a seven-day protocol.[52] On Day one and Day seven, individuals undertook the Home-Heart-Walk in the clinical setting. Participants and the research nurse recorded the result independently. Participants submitted their study diaries on Day seven, upon completion of the seven-day protocol. The inter-rater reliability was assessed by comparing Home-Heart-Walk results recorded by participants with the results recorded by the research nurse on Day one and seven. The reliability of the test was assessed by the two Home-Heart-Walk tests performed on Day one and by the repeated tests over the seven days.

The correlation between the distance recorded by the research nurse and the distance recorded by the participant, on Day 1 was 0.99 for the first walk undertaken and 0.99 for the second walk. On Day 7, a high positive correlation between the research nurse-recorded distance and the participant-recorded distance was again noted (r=0.99). Over the seven-day study period, the daily mean Home-Heart-Walk distance of the 29 participants ranged from 282 meters to 500 meters. The standard deviation of distance covered ranged between 9 and 39 meters. The reliability of the Home-Heart-Walk over the seven-day study period was encouraging with an ICC of 0.98.[52] There was not adverse event observed in phase one and phase two. No participants withdrew from the study specifically because of protocol-related issues. Participants reported the Home-Heart-Walk to be an enjoyable activity. It was also shown to be a tool for motivation and goal setting.

4.6 Discussion

Data reported in Phase 2 is consistent with the ICC reported in the 6MWT literature (ICC=0.75-0.97).[20, 41] The Home-Heart-Walk appears to be a potentially useful tool for promoting self-management and physical activity as it includes specific, measureable, relevant, and timed elements that are useful in promoting behavior change.[54] Several factors should be considered in interpreting these findings. First, participants were volunteers and therefore, more likely to be compliant with the study protocol. Moreover, those participants were participating in a cardiac rehabilitation program, where structured programs and equipment, such as a timer, were familiar to the study participants. Because of this sample selection bias, the results cannot be generalised to a wider population where level of self-efficacy and motivation vary. Despite these limitations, the results of these two studies suggest that the Home-Heart-Walk is a reliable test for promoting and monitoring physical activity in patients with CHD. Further evaluation of the Home-Heart-Walk is required-both in respect of safety and efficacy as well as refinement of the prototype.

4.7 Conclusion

Self-monitoring of physical functional capacity can be effective in promoting self-management in people with CHF. A self-monitoring intervention has the potential to improve adherence to physical activity. The Home-Heart-Walk program has been developed based on the exercise self-efficacy theory. A high feasibility and reliability suggested further evaluation of this self-monitoring intervention in groups with physical functioning limitation is necessary to assess its utility. After the completion of the Bachelor of Nursing (Hons) project, this present randomised controlled trial has been developed to evaluate the utility of the Home-Heart-Walk. The design and method of the randomised controlled trial will be detailed in the next chapter.

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Chapter 5
Study methodology

Australian New Zealand Clinical Trial Registry 12609000437268

5.1 Introduction

The previous chapters have described the background and rationale for the Home-Heart-Walk study. The findings from the literature review identified that interventions that facilitate physical activity adherence are needed to promote physical functioning and self-care in people living with CHF. The concept of adherence, the dynamic process of behaviour maintenance and the four common health behaviour theories and the usefulness in applying these theories in physical activity have also been discussed. The development of the Home-Heart-Walk was detailed in Chapter Four. A high (r=0.81*)* correlation between the Home-Heart-Walk and the standard 6MWT and a high reliability (ICC>0.9) found in a previous study, suggesting the Home-Heart-Walk is a safe and reliable self-administer intervention. In order to further evaluate the effectiveness of the Home-Heart-Walk in promoting physical functioning and self-care behaviour in people living with CHF a randomised control trial is needed.

This chapter will provide the rationale for the study design; study aims, and present a detailed description of all major study elements, including the study setting, participant recruitment, randomisation, and the required sample size. Details of the Home-Heart-Walk will be described. Primary and secondary outcome measures will be defined, and a description of the study instruments and their scoring presented. Finally, the statistical methods undertaken will be provided.

5.2 Rationale for study design

The primary aim of this study was to evaluate the effectiveness of the Home-Heart-Walk in improving physical functioning in people living with stable symptomatic CHF. A randomised controlled trial design was chosen, as this design minimises bias in treatment assignment, specifically selection bias and confounding factors.[1, 2] It also permits the use of probability theory to express the likelihood that any difference in outcomes between treatment groups merely indicates chance.[1, 3] The choice of this design was further strengthened by addressing another issue that is often noted as a limitation in program intervention research–lack of blinding.[4]

As the Home-Heart-Walk was a self-administered intervention, blinding of the participant and the researcher who conducted telephone follow-up was not possible. Blinding allocation is intended to reduce measurement bias by preventing the expectations of participants or researchers from influencing the outcome.[4] While blinded allocation of the participant and one of the researchers was not possible in this study, the researcher who undertook the assessment of three-month and six-month outcomes was blinded to treatment allocation. Hence, a single blinded randomised control study was undertaken.

5.3 Study hypothesis

The Home-Heart-Walk is a theoretically informed intervention, which sought to improve physical functioning and self-care behaviour in people living with stable symptomatic CHF. The overall aim of this study was to evaluate the effectiveness this Home-Heart-Walk intervention to improve physical functional capacity. The study null hypotheses of this study were:

1. There will be no observed improvement in physical functioning of participants in the intervention group, at six-month follow-up compared to participants in the control group
2. There will be no observed improvement in self-care beahviour of participants in the intervention group, at six-month follow-up compared to participants in the control group

5.4 Participants

5.4.1 Setting

Study participants were recruited from four hospitals in metropolitan Sydney; St Vincent's Hospital, Westmead Hospital, Blacktown Hospital and Mt Druitt Hospital.

In September 2009, as part of the Federal Government's proposal for reform of the Australian health system, Area Health Services in New South Wales were disbanded and replaced with 18 new Local Area Health Networks. These include eight networks covering the Sydney metropolitan region, and seven in rural and regional NSW. In addition, two specialist networks have been formed to focus on Children's and Paediatric Services, and Forensic Mental Health, and a third network will operate across the public health services provided by three Sydney facilities operated by St Vincent'sHealth [5]. Figure 5.1 shows the local health networks under the governance of NSW Health.

St Vincent's Hospital, Sydney is a 326 bed quaternary teaching hospital. At the time the study commenced, this hospital was part of the South Eastern Sydney and Illawarra Area Health Service. As a result of the National Health Reform, in 2011, St Vincent's Hospital, Sydney became part of St Vincent's and Mater Health Sydney (SV&MHS). The SV&MHS health network comprises St Vincent's Hospital, Sydney, St Vincent's Private Hospital, Sacred Heart Hospice, Mater Hospital, St Joseph's Hospital and St Joseph's Village. St Vincent's Hospital, Sydney is renowned for its clinical excellence in the care of patients with heart and lung conditions, in particular heart and lung transplantation and cardiothoracic medical care. It provides services to inpatients and outpatients from the local community and throughout the state of New South Wales. Figure 5.1 shows the location of St Vincent's hospital, Sydney.

Figure 5.1 Map of NSW health services

Westmead, Blacktown and Mt. Druitt Hospitals are three of five hospitals within the Western Sydney local health network. Westmead Hospital is a 975 bed specialised tertiary referral hospital for the western Sydney metropolitan area, which has a population of 1.5 million people and 15 local government areas. It also acts as the district hospital for the immediate surrounding community. Blacktown and Mt Druitt Hospitals work in partnership to provide health care to residents in the local government area. Because of high rates of cardiovascular and socioeconomic deprivation, a significant proportion of the population in the Western Sydney local health network are vulnerable to chronic diseases, in particular coronary heart disease.[6] Figure 5.1 shows the location of Westmead Hospital, Blacktown Hospital, and Mt Druitt Hospital.

5.4.2 Sample Size

The Medical Outcome Study Short Form-36 (SF-36): physical function domain was used as the primary outcome measure in this study. The rational of choosing the primary outcome measure will be provided in Chapter Seven.

Based on a previous heart failure study,[7] to detect a 12-point difference in physical function domain of the SF-36 with a standard deviation of 20 points, we estimated a sample size of 74 per group was needed with a 2-sided 5% significance level and 95% power (calculated using GPower program by a statistician). When taking into account a loss to follow-up of 10%, 166 participants (83 per group) were required to be enrolled in this study.

5.4.3 Selection criteria

The diagnosis of CHF was based on the Australian National Heart Foundation and the Cardiac Society of Australia and New Zealand guidelines.[8] Individuals with diagnosed CHF; with a previous hospitalisation for CHF; in New York Heart Association Functional Class (NYHA-FC) II or III and approved by their clinicians for physical activity were invited to participate. Table 5.1 provides a brief summary of the inclusion and exclusion criteria.

Table 5.1 Summary of inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
○ Have been previously hospitalised for heart failure	○ Unstable angina pectoris
○ NYHA-functional class II or III	○ Recent unexplained syncope
○ Approval of responsible clinician to participate in mild to moderate physical activity	○ Failure to give informed consent
○ Willing to give informed consent	○ Resting HR greater then 120
	○ Inability to perform 6MWT
	○ Significant cognitive impairment

The above exclusion criteria excluded patients who were not suitable for moderate exercise, who were at high risk of an adverse cardiac event, and who were cognitively unable to follow the study protocol and give informed consent.

5.5 Intervention description and program plan

5.5.1 The Home-Heart-Walk

The development of the Home-Heart-Walk program has been detailed in Chapter Four. The Home-Heart-Walk is a modified 6MWT. It is a home-based, self-monitoring tool for functional capacity, developed based on a 6MWT literature review.[9] According to the American Thoracic Society 6MWT guideline, a 30-meter long walking track is required. However, a 30-meter long walking track is rarely feasible in a home environment. In the Home-Heart-Walk, walking is performed alongside a five-meter length of walk track (marked in one-meter gradations) on a flat hard surface free of obstacles. A lap counter was used to assist the individuals to count the number of full laps walked during the test. A timer with a countdown function was used to time the six minutes.

A systematic process was undertaken in the development and preliminary evaluation of the Home-Heart-Walk. The Home-Heart-Walk intervention development process is outlined below:

1: First, a brain storming session was conducted among the research team members and two technology designers. Potential options for the Home-Heart-Walk ranged from low technology based, marking on the floor and manual calculation of distance; to higher technology based such as pods with sensors, participant mounted sensor and retractable reel.

2: The advantage and disadvantage of each option were discussed among the research team in following meetings.

3: A consumer consultation was also carried out with elderly individuals with CHF and two research team members.

4: The consumers' opinions were taken into consideration, and the Home-Heart-Walk options were reviewed and discussed within the research team.

Based on the opinions of consumers, and the nature of the project, a Home-Heart-Walk kit was developed for assisting participants in undertaking the Home-Heart-Walk in their home environment. Choosing the following option for the current project is base on the scope of a PhD project, as well as within the allocated resources and time.

There were total of four items in the participants' take-home kit.

1: the rope:

A 5-metre long rope is used to measure the distance at home. The 5mm polyester rope was chosen for its ability to stay straight on the floor, as well as for being soft and bright orange in color. The rope is marked in 1-metre gradations.

2: the timer:

The Leeda© countdown timer was used in this study to assist participants countdown the six minutes duration. This timer was chosen because of its accuracy, ease of use, audibility of the alarm and its portable feature. Other features available included having a flashing light and/or vibration at the end of the preset time.

Figure 5.2 Timer

3: the lap counter:

The handheld four-digit lap counter, manufactured by Tally©, was used in this study to enable participants to count the laps they walked. The Tally lap counter was chosen for this study because it is engineered to guarantee accurate and dependable service; it fits comfortably in the hand, and has a finger ring for added security against dropping. The white numbers on a black background were easy to read and simple to operate.

Figure 5.3 Lap counter

4: the participant booklet (Appendix 4):

This booklet was developed to assist individuals in undertaking the Home-Heart-Walk in their own home and included information on how to undertake the Home-Heart-Walk and a diary for recording the Home-Heart-Walk distance.

The Home-Heart-Walk program consisted of weekly walks over a six month period using the kit (as above), as well as regular (monthly) telephone follow-ups from a heart failure nurse.

Below are the instructions given to the intervention group participants to undertake the Home-Heart-Walk:

Preparation before the Home-Heart-Walk:

1. Wear comfortable shoes and clothing for your walk

2. Use your usual walking aids, such as your walking stick
3. Take your usual medications
4. Do not exercise prior to the walk
5. Do not have a heavy meal within 2 hours prior to the walk

To undertake the Home-Heart-Walk:

1. Stand at the starting line (one end of the rope) Always begin your walk at point “0” and walk towards point “5”
2. Set the timer to six minutes.
3. When you are ready, start the timer and walk.
4. Walk along the five metre rope, until you reach the end (point 5), then turn and head back to your starting point.
5. Try to cover as much distance as possible during the six minutes. Stop and rest if you need to, resume walking when you feel you are able to continue.
6. Use the lap counter to record how many laps you have walked over the six minutes.
7. Stop walk when your timer rings to indicate the end of the six minutes. Remember where along the rope you stopped (point “1”, “2”, “3”, “4” or “5”)
8. Record the laps you have walked and your level of exertion in the recording form.
9. These instructions were provided in the participant’s booklet, and were explained and demonstrated by the research nurse at the beginning of the study.

5.6 Program plan

Participants in the intervention group undertook the Home-Heart-Walk in their own home in addition to their usual care. The control group received usual care only plus a monthly phone call from the study nurse. Physical assessment occurred and study questionnaires were administered to all participants at baseline, three months and six months as outlined in Figure 5.4.

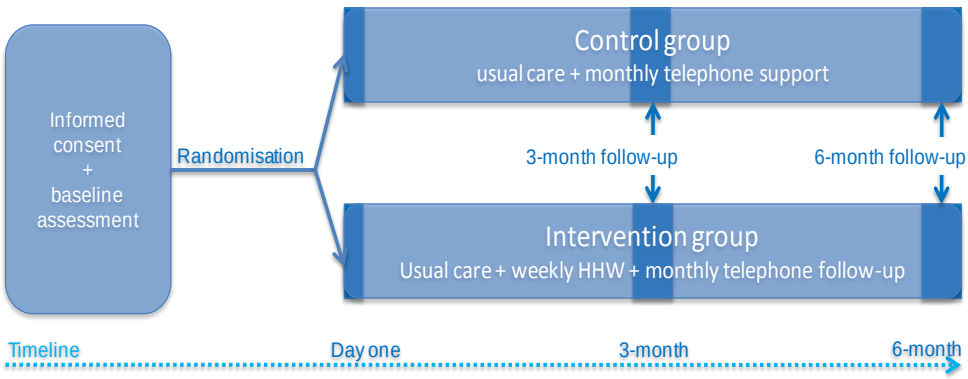

Figure 5.4 The Home-Heart-Walk study plan

After obtaining informed consent from participants, baseline assessment was completed, which included a physical assessment, a standard 6MWT, and received an information session from a cardiac nurse on HF self-management. All participants were provided with the Living well with chronic heart failure booklet from the National Heart Foundation.[10]

5.6.1 Intervention group

Participants randomised to the intervention group received detailed instructions and a demonstration by the research nurse on how to perform the Home-Heart-Walk (described in previous section). The research nurse then observed their competency in the technique. Participants were asked to perform the Home-Heart-Walk daily for the following week to gain proficiency. Within a week of starting the Home-Heart-Walk, on a pre-arranged day, the research nurse called participants to clarify their understanding, concerns of the procedure and to answer any other questions. Subsequently, participants in the intervention group were asked to undertake the Home-Heart-Walk at least weekly, and record the number of laps (whole and partially completed) in the Participant Booklet (Appendix 4). A monthly phone follow-up was also scheduled with the participant to obtain information on recent hospitalisations and cardiac related events that had occurred, as well as to discuss their Home-Heart-Walk progress.

5.6.2 Control group

Apart from an identical baseline information session, the control group also received a monthly telephone follow-up from the study nurse. The purpose of

this telephone call was to obtain information on recent hospitalisation and cardiac related event had occured during the month. There was no discussion regarding participants CHF condition and physical activity. Participants were advised to contact their CHF nurse or clinician for any enquires.

5.6.3 Usual care

Participants randomised to the control group received only usual care. The term "usual care" in this study means the care a person receives from their clinicians and the clinic they were attending. Usual care at the study sites did not include any form of formal physical activity program or community based CHF program or any other program that focused on health behaviour modification.

5.7 Recruitment and randomisation

5.7.1 Recruitment

Potential participants were identified at cardiac wards and outpatient cardiac clinics by clinical staff. The clinical staff explained the Home-Heart-Walk study in brief to individuals and if they were interested their details were provided to the research nurse. During the meeting with the research nurse, if identified as eligible, the purpose of the study and study protocol were explained to the individual. For individuals who were ineligible for the study, there was no change made to their routine care. Details on the number of participant included and reasons for exclusion will be provided in Chapter Six. The Participant information sheet (Appendix 2) was given to the individual and they were given the option of reviewing the sheet and speaking with the study nurse at a later date or if they chose, they could have consented to participate or declined at that time. If agreed to participate and provided informed consent, the participant underwent baseline assessment, which included a review of their medical record, resting blood pressure and heart rate for assessment of eligibility. A study log was maintained where all individuals screened was recorded and the reason for non-participation. These data provide a breakdown of the overall pool of patients that were assessed and the reason for non-participation.

5.7.2 Sequence generation

Prior to study commencement, the study statistician generated the allocation sequence of 83 “group 1” (intervention group) and 83 “group 2” (control group) using Predictive Analytics SoftWare (PASW) computer statistical software version 18.0 (PASW, Chicago, Illinois).

5.7.3 Allocation concealment

The Excel file containing allocation sequences was password protected and only accessible to an administrative assistant based external to the study sites and who was not involved in study recruitment.

5.7.4 Randomisation

Randomisation only occurred upon obtaining informed consent from participants and completion of baseline assessment. This was to ensure that baseline assessment was not affected by the research nurse and the participant knowing the treatment allocation.

Upon completion baseline assessment, the research nurse telephoned the administrative assistant with the name and date of birth of the participant. The Participant’s details were also recorded with their group allocation, which were only accessible by the administrative assistant. The research nurse was then informed of the participant’s allocation to treatment group.

5.7.5 Screening log

A screening log of all screened individuals was maintained at study sites by the site research nurse to keep track of potential participants, as well as to monitor reasons for non-participation.

5.8 Study measurements

5.8.1 Demographic information and physical assessment

Demographic information, clinical status, functional and general health status as well as their management capacity as shown in Table 5.2 was collected. A brief physical examination was carried out on all participants to collect the following

data: height; weight; waist circumference; hip circumference; heart rate; blood pressure; pulse oximetry; and a cardio-respiratory examination.

For all anthropometric measurements, the participant wore light clothing, and was asked to remove their shoes. Standing height was measured to the nearest 0.1cm using a calibrated stadiometer. Weight was measured to the nearest 0.1kg using a digital scale. Waist circumference was measured by using a narrow measuring tape and recorded to the nearest 0.1cm.

Table 5.2 Study measurements

Demographic profile:	Age, sex, marital status, social support, education, ethnicity
Clinical status:	Type, presumed cause and duration of CHF, NYHA functional class, current pharmacological and non-pharmacological treatment, waist and hip circumference, and existing most recent blood test results.
Functional/general health status:	The Six Minute Walk Test distance,[11] Most recent echocardiography report, National Lifestyle Prescription-Physical Activity Scale[12]and SF-36[13]
Self-care behaviour:	Bandura's exercise self-efficacy scale;[14] The European Heart Failure Self-care Behaviour Scale (EHScBs)[15] Minnesota Living With Heart failure Survey[16]

Measurement protocols were used to standardise the collection of blood pressure, height, weight waist circumference, and hip circumference.

5.9 Study outcome measurements

Medical Outcome Study Short Form 36

The Medical Outcome Study Short Form (SF-36) is a close-ended, multi-purpose, health survey with 36 questions assessing several domains of HRQoL.[17] It yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures and a preference-based health utility index. This instrument has undergone extensive validation in the cardiac population. The SF-36 has demonstrated high reliability of its physical function component in adults over 65 years.[13, 18, 19] The correlation between the physical function domain and the 6MWT distance ranges from 0.63 to 0.68.[20, 21] Scores for all dimensions were transformed on a scale of 0-100 according to the SF-36 scoring method,[22] where a high score indicates a better state of health or well-being.

Six Minute Walk Test

The Six Minute Walk Test has been discussed in detail in Chapter Four.[11] The Borg dyspnoea and fatigue level, heart rate and oxygen saturation were used before and after undertaking the test.[9] The 6MWT was administered by a research nurse blinded to treatment allocation to participants at baseline; three-month and six-month follow-up. The 6MWT was administered in clinical settings, on a pre-measured 30-meter long walking track. The participants' 6MWT distance was measured and recorded by the research nurse in accordance with the American Thoracic Society Guideline (Appendix 5).[11]

Physical activity scale

Physical activity levels were measured using the National Lifestyle Prescription (three 8-point Likert scale).[12] The aim of this questionnaire was to find out how many periods of 30 minutes of moderate (20 minutes of vigorous) physical activity an individual would do in a week. One hour of continuous moderate physical activity counts as two periods of 30 minutes. Each point dictates one session of physical activity. The score of each item was summed to provide a

total number of physical activity sessions that undertaken in a typical week.(i.e. score of 5=5 sessions of physical activity/week)

Bandura's Exercise Self-efficacy Scale

Bandura's exercise self-efficacy scale is an 18-item scale which asks participants to rate the strength of their belief in their ability to perform activities. The psychometric properties and validity of this scale has been assessed in studies of older people with chronic disease, including people with CHD. [23, 24] Strength of the participants' belief was recorded on a 10-point scale, ranging in 1-unit intervals from 0 ("cannot do"), through intermediate degrees of assurance, 5 ("moderately can do"), to complete assurance 10 ("certain can do").[14] The score of each item were summed to provide the total score reflecting individual's level of exercise self-efficacy.

The European Heart Failure Self-care Behaviour Scale (EHFScBS)

The European Heart Failure Self-care Behaviour Scale (EHFScBS) is a 12-item, self-administered questionnaire that measures self-care behaviour of people with CHF. Each item is scored from 1 (I completely agree) to 5 (I completely disagree), with the global score ranging from 12 (better self-care behaviour) to 60 (worse self-care behaviour). In this scale, a lower score indicates better self-care behaviour, and a higher score indicates less desirable self-care behaviour. Face-validity and concurrent validity were established through pooled data from six European countries.[25] Cronbach's alpha was 0.81.[15] This instrument has been demonstrated to be a valid, reliable and practical measurement of the self-reported self-care behaviour of people with CHF. It is specifically for evaluating the outcome of CHF management that focus on self-management behaviour.[15]

Minnesota Living with Heart Failure Questionnaire

The Minnesota Living with Heart Failure Questionnaire (MLHFQ) contains 21 questions which evaluates how much CHF has affected an individual's life in the previous four weeks.[16] This questionnaire consists of physical and emotional domains, with the sum of all item responses used to calculate a global score. In

the MLHFQ, the higher the score, the more influence/burden CHF has on the individual's life.The MLHFQ has been validated in the Australian population.[16, 26, 27] Its reliability and validity have been assessed in a number of clinical studies, with Cronbach's alpha ranging from 0.92-0.95.[16, 26, 28] For this instrument, there were 8 items constitute the physical domain, and 4 items for the emotional domain. Score for each domain were calculated as well as the total. Table 5.3 provides the timeline of study measurements.

5.10 All cause mortality and Major Adverse Cardiac Event

Information for all cause of mortality and major adverse cardiac event (MACE) were collected at three-month follow-up and six-month follow up. Major Acute Cardiac Event events included stroke, acute myocardial infarction and acute coronary syndrome events as well as planned and unplanned re-vasularisation procedures. It is recognised that the HHW is not powered to detect differences in mortality or hospitalisation and this data was collected for safety monitoring only, and is not included in data analysis.

5.11 Study endpoints

5.11.1 Primary endpoint

The SF-36 was used to assess the HRQoL.[13] Although the primary outcome was the physical functioning subscale of the SF-36, all eight subscales of the SF-36 were measured. Items relating to each subscale were coded, summed and transformed to a scale from 0 (worst possible health state) to 100 (best possible health state).

5.11.2 Secondary endpoints

Secondary endpoints included: distance walked on a 6MWT Test;[11] European Heart Failure Self-Care Behaviour Scale;[15] Minnesota Living with Heart Failure Questionnaire;[29] Physical activity scale;[12] and Bandura's Exercise Self-efficacy Scale.[14] These measures were administered at baseline, three and six-month follow-up.

5.12 Adverse event monitoring

For the purpose of this study a Serious Adverse Event (SAE) was defined as any untoward medical occurrence resulting in hospitalisation or prolongation of hospitalisation, was life-threatening, or resulted in death or disability.[30] Adverse events (AE) was defined as any untoward occurrences in study participants, potentially related to implementation of the study protocol. All SAEs were reported to the Coordinating Centre and the Human Research Ethics Committee within 24 hours and AEs within 7 days as required.

Table 5.3 Timeline of study measurements

Measure	Baseline	3 Months	6 months
Clinical history , physical assessment	X	X	X
Sociodemographic data	X		
Self-efficacy [14]	X	X	X
6MWT[11]	X	X	X
SF-36[13]	X	X	X
EHFScBS[15]	X	X	X
MLHFQ[29]	X	X	X
Physical activity scale[12]	X	X	X
Major Adverse Cardiac Event[30]		X	X

5.13 Data analysis

Data from this study was analysed according to intention to treat principle, using (state method) in order to provide unbiased assessment of treatment efficacy.[31] Survey data was coded and analysed using the Predictive Analytics SoftWare (PASW) computer statistical software version 18.0 (PASW, Chicago, Illinois). Continuous data with normal distribution was analysed using independent t test, and the Mann-Whitney U test was used for non-normally distributed data. Association between categorical data was analysed using Chi-square test. When comparing the change in the SF-36 subscale scores over time within groups; and between baseline and each follow-up point, paired *t* test and independent sample *t* test were used. A *p* value of <0.05 was considered

statistically significant and all tests were two tailed. Data analysis was supervised by a statistician who was not involved in screening, recruitment and follow-up of study participants.

5.13.1 Intention to Treat

Data was analysed based on the intention to treat principle.[32] The 'carry-forward' imputation method was used, where the missing value was replaced by the last observed value.[32] This is considered to be the most conservative strategy for demonstrating a significant difference between intervention and control groups, and gives the most unbiased estimate of the intervention effect.[32, 33] It is also considered to reflect the 'real world' implementation of a treatment policy or strategy, where non-adherence to intervention and study protocol are likely to occur in clinical practice.[34]

In spite the use of intention to treat analysis, biased estimates of treatment effects can still occur when there is a high percentage of participants drop out, or are lost to follow-up.[32] This is not uncommon for trials with long-term follow-up [33] and in which outcomes are measured at three or more points in time.[32] To aid the interpretation of study result and evaluate the effect of using intention to treat analysis, conducting a sensitivity analysis is recommended to compare findings based on intention to treat with those from other approaches to prevent misleading conclusions being drawn and inappropriate recommendations being made.[32] In this Home-Heart-Walk study, sensitivity analyses were performed using all available data regardless of compliance, and without imputation of mission data, as a comparison to the ITT primary analysis.

5.13.2 Data analysis

Survey data were coded and analysed using the PASW (version 18.0) computer statistical software. Statistical analysis was supervised by Dr Yenna Salamonson and Sunwon Chang (statistician). Descriptive statistics were used to summarise the baseline demographic, clinical, behavioural and psychological characteristics of the sample. Continuous data were summarised by using mean, median,

standard deviation and standard error of the mean scores, whilst categorical data were summairsed in terms of percentages. All tests were two-tailed with values of $p<0.05$ considered statistically significant. All continuous variables were also inspected visually (frequency histograms) and assessed statistically for normality using Kolmogore-Simimov goodness-of-fit test. Normality assumptions were made based on the tests result of a *p* value greater than 0.05.

Independent sample t-test was used for continuous variables, and Pearson's chi-square test for categorical data, to compare baseline and six-month follow-up, outcome measurements, between intervention and control groups. Paired sample t-test was used to compare changes over time in both groups, for outcome measures, from baseline, to three-month and six-month follow-up.

This thesis is based on an interim analysis of the first 67 participants enrolled to the HHW program, using the analysis method detailed above. This planned interim analysis will allow assessment of the quality of the data collected, and treatment effects; reassess sample size, and allow completion of the candidate's PhD within the allocated time frame. Interim analysis will be discussed further in Chapter seven.

5.14 Ethical issues

The study was conducted according to the principle of the declaration of Helsinki (version 2004) and the National Health and Medical Research Council Guidelines [35] for the ethical conduct of clinical research. Ethical approval was obtained from Curtin University [approval number HR 170/2008] and St Vincent's Hospital, Sydney [approval number 08/SVH/77]. New South Wales Health uses a single review of ethics application so the St Vincent's Hospital ethics approval covered all sites for this study. Copies of the relevant approval letters can be found in Appendix 1. The Home-Heart-Walk is registered on the Australian and New Zealand clinical trial registry (ANZCTR12609000437268).

5.14.1 Informed consent

Participants involved in this study were from a vulnerable population, all ethical considerations involving informed consent, freedom to participate/withdraw

from the study and any time and protection of their privacy in data reporting were observed. All questions and self-administered instruments used in the study were non-invasive. All participants were first approached by clinical staff at each of the sites. As the initial approach did not involve a direct personal approach from the research nurse, real or perceived coercion from researchers for potential participants to enroll was avoided.

A statement was also made to potential participants as well as in the Participant information sheet, that refusal to participate in this study would not alter the caring relationship between them and the study site where they were recruited. Participants were also advised during the study they had the option to withdraw from the study at any time without fear of penalty, and data collected would be only as specified in the approved ethics documents, and any dissemination of research study outcomes would not identify any individual participant.

5.14.2 Data Management

Data collected as part of the Home-Heart-Walk study was identified by a unique record number. All data collected in this study was filed and stored in a locked cabinet at each of the sites and will be stored for a period of seven years. Data will be destroyed by means of shredding. Only authorised study personnel have access to the study database which is password protected. Data collected in this study was only used for the purpose of this current study. Only de-identified, aggregated data will be published.

5.14.3 Study steering committee

A steering committee involving key stakeholders including the research team, nurse specialist, and clinicians was formed to monitor the study progress and protocol implementation. After the first 25 enrolled participants have completed the six-month follow-up, there was a meeting held within the committee to evaluate the safety and another issues related to the research program.

5.15 Conclusion

This chapter has detailed the methods used to evaluate the Home-Heart-Walk. The Home-Heart-Walk study is a novel approach to self-care in people living with CHF. Low adherence to health recommendations suggests the need to explore ways of better promoting adherence to clinical advice and develop innovative interventions for monitoring and managing people with CHF in community settings. If evaluated as being successful, it is likely that the Home-Heart-Walk protocol could be readily incorporated into the community based management of CHF. In particular it has the potential to reach a subgroup of the CHF population who have limited physical functional capacity and are not appropriate for higher intensity physical activity. At the same time, this self-monitoring intervention if shown to be beneficial would also assist in managing people living in areas where clinic-based, supervised programs are not easily accessible. Chapter Six will presents the study results.

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Chapter 6
Results

6.1 Introduction

The Home-Heart-Walk study was developed based on the Exercise Self-efficacy Model, which is derived from social cognitive theory.[1-4] This program sought to promote physical functioning and self-care through a self-monitoring intervention. Chapter Five presented the study design and methodology. Both the intervention and control group were assessed after randomisation (baseline), at three months and six months follow-up. As discussed previously this is an interim analysis.

As described in Chapter Five, data were analysed using intention to treat analysis.[5] In this chapter, the flow of participants through each stage of the study is presented first, followed by baseline demographic and clinical characteristics of all participants to establish comparability of study groups. Outcome measures are presented comparing the changes over time and between groups. Finally, a sensitivity analysis of the primary outcome is presented which investigated the likely effect of losses to follow-up and assist in explaining study findings.

6.2 Participants

Between October 2009 and April 2011, 5982 individuals were screened for eligibility, and 273 were identified as eligible to participate in the trial. Of these 5869 individuals who were excluded, 5654 did not meet inclusion criteria after a review of their medical records. Sixty two refused to participate, 98 individuals were participating in other studies at time of recruitment and 55 people were discharged before seen by the research nurse. During interview with the research nurse, if the individual was ineligible for the study due to acute conditions (e.g. recent syncope, angina) that were not already noted in their medical notes; it would be documented and the individual would be referred to the appropriate personnel. A total of 113 participants were enrolled in the Home-Heart-Walk study at time of data analysis. An interim analysis was undertaken of the first 67/113 (59%) participants who had completed the six-month study and the results from this interim analysis are presented in this chapter.

In the intervention group, there were six participants who did not continue the intervention but using intention to treat principles their last completed results were carried forward and included in the final analysis. Two participants became unwell after randomisation and consequently died before commencing the intervention. Two participants withdrew from the program after randomisation due to personal reasons and another participant had an urgent heart transplant. A total of 29/36 (81%) participants from the intervention group and 28/31 (90%) participants from the control group completed the six-month follow-up.

At the time of data analysis, there were 46/113 (41%) who had not completed the six-month study and therefore they were not included in the interim analysis. This process is presented in Figure 6.1

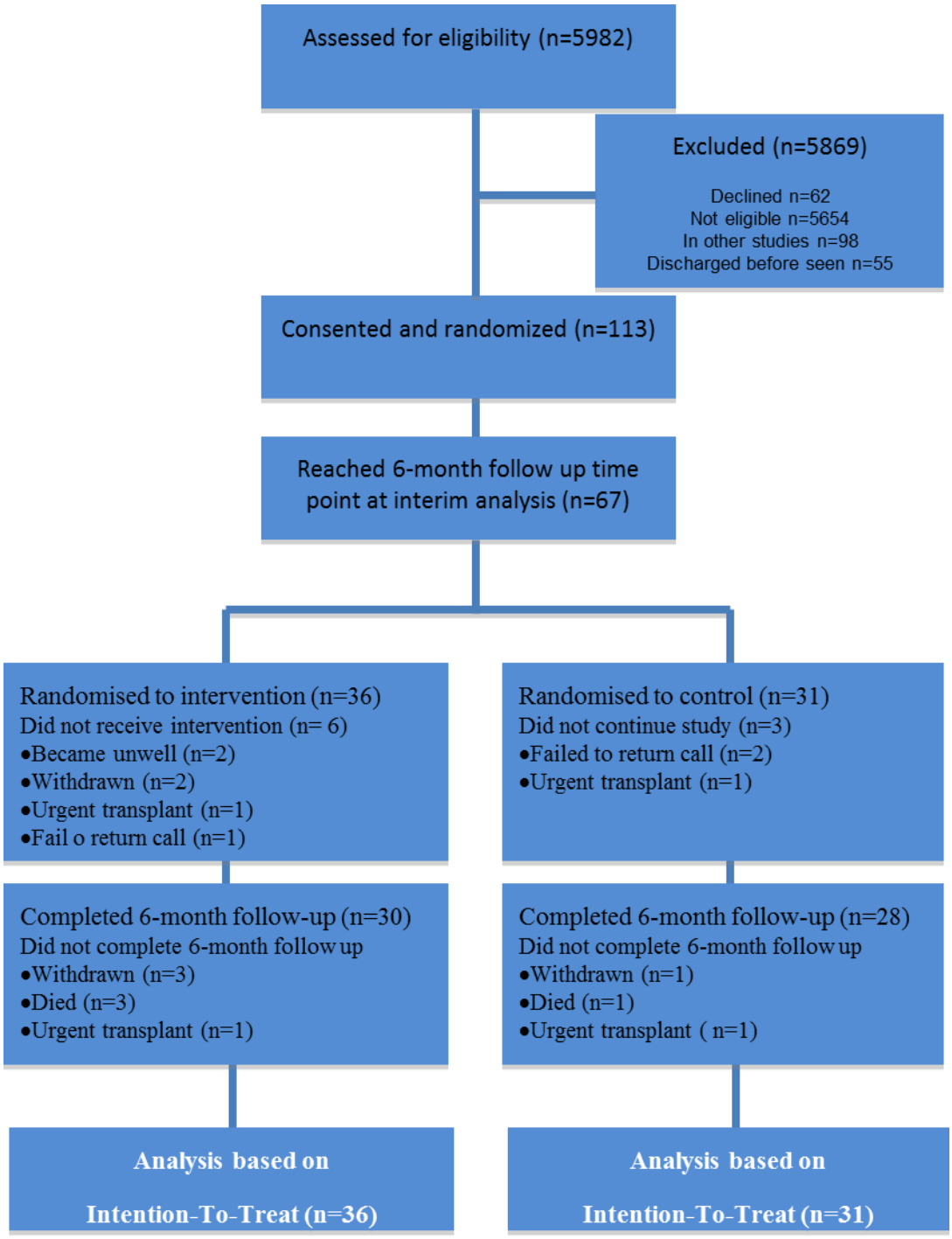


Figure 6.1 Flow of participants through the Home-Heart-Walk study

6.2.1 Baseline demographic characteristics, overall study cohort

Table 6.1 presents the baseline demographic characteristics of the 113 participants who were enrolled into the study by the end of April 2011. The comparability of those who have completed the program (n=67; 59%) and those who are still in the program (n=46; 41%) is also presented. The mean age of the overall cohort (n=113) was 61(SD 14) years old, ranging from 20 to 94 years. The majority of the study participants were male (80%) and over half (63%) were born in Australia. Most (81%) participants spoke only English at home. Close to a quarter (22%) of the participants was living alone, and 22% were in paid employment. There were no statistically significant differences in any of the baseline demographic characteristics.

Table 6.1 Baseline demographic characteristics of the total cohort

	Total (n=113)	**Analysed (n=67)**	**Not-analysed* (n=46)**
Age, mean (SD)	61 (14)	61 (15)	61 (13)
(Range)	(20-94)	(20-94)	(29-82)
Sex (Male), n (%)	90 (80)	55 (82)	35 (76)
Country of birth n (%)			
Born in Australia	71 (63)	47 (70)	24 (52)
Marital status			
Married/de facto, n (%)	65 (58)	39 (58)	26 (57)
Primary language spoken, n (%)			
English	92 (81)	55 (82)	37 (80)
In paid employment, n (%)	25 (22)	15 (22)	10 (22)
Living status, n (%)			
Living alone	25 (22)	12 (18)	13 (28)
Highest education level, n (%)+			
Up to high school	65 (61)	37 (62)	28 (61)
Trade/certificate/diploma	25 (24)	12 (20)	13 (28)
University	16 (15)	11 (18)	5 (11)

*had not completed six-month follow-up prior to interim analysis
+ calculated from 106 cases

6.2.2 Baseline clinical characteristics, overall study cohort

Table 6.2 presents the baseline clinical characteristic of the overall study cohort as well as comparing the participants who have completed the study to those who are still in the program.

There were more participants in the group included in the interim analysis that had dilated cardiomyopathy compared to those not included in the interim analysis (40 (60%) vs 21(46%); p = 0.011). This was the only difference in clinical characteristic between those included in the analysis and those that were not included in the analysis that reached statistical significance. Approximately half (48%) have had a previous myocardial infarction, and automated implantable cardioverter defibrillator (AICD) (50%). The mean left ventricular ejection fraction was 32% (SD 12%), and 66% of the study participants were in NYHA functional class II. At baseline the mean 6MWT distance was 375.8 (SD 50.4) meters.

There was a high prevalence of modifiable coronary risk factors in this group of study participants. The mean body mass index (BMI) was 32.0 kg/m^2. Nearly half (46%) had dyslipidaemia. The mean waist circumference was 102.9cm (SD 15.9) and mean waist hip ratio was 0.96 (SD 0.1) while the prevalence of diabetes was 28%. Approximately half (56%) reported not smoking in the past. The mean Charlson index of co-morbidity score was 5.0 (SD 2.5) in this group. There were no statistically significant differences observed between the completed participants and those who were still in the program.

Table 6.2 Clinical characteristics of the total cohort

	Total (n=113)	Analysed (n=67)	Not-analysed (n=46)
Aetiology of heart failure (%)			
Ischaemic	53 (47)	32 (48)	21 (46)
Idiopathic	19 (17)	10 (15)	9 (20)
Valvular	21 (19)	8 (12)	13 (28)
Dilated	61 (54)	40 (60)	21 (46) [+]
Hypertension	19 (17)	6 (9)	13 (28)
Other	22 (20)	10 (15)	12 (26)
Ejection fraction, mean (SD)	32.2 (12)	31.8 (10)	32.5 (13)
NYHA-FC (*n*%)			
II	75 (66)	42 (63)	33 (72)
III	38 (34)	25 (37)	13 (28)
Coronary risk factors			
Diabetes, n (%)	32 (28)	19 (28)	13 (28)
Hypertension, n (%)	44 (39)	21 (31)	23 (50)
High cholesterol, n (%)	51 (46)	29 (44)	22 (48)
History of smoking, n (%)	63 (56)	38 (60)	40 (60)
History of renal condition, n (%)	22 (20)	13 (19)	9 (24)
Waist circumference, mean (SD)	102.9 (15.9)	102.0 (16.8)	104.3 (14.5)
Body Mass Index, mean (SD)	32.0 (7.9)	31.9 (9.2)	32.3 (5.4)
Waist/hip ratio, mean (SD)	0.96 (0.1)	0.96 (0.1)	0.96 (0.1)
Family history, n (%)	49 (44)	26 (39)	23 (51)
Previous cardiac conditions/procedure, n (%)			
MI	54 (48)	31 (46)	23 (50)
PCI	29 (26)	15 (22)	14 (30)
CABG	33 (29)	18 (27)	15 (32)
AICD	57 (50)	34 (51)	23 (50)
Charlson Index, mean (SD)	5.0 (2.5)	4.7 (2.5)	5.39 (2.6)
Functional capacity*			
6MWT distance, meter mean (SD)	375.8 (50.4)	371.9 (107.1)	381.8 (101.9)

+p=0.011(between groups)

*n=105 (analysed n=63, not analysed n= 42) completed baseline 6MWT. n=8 refused to complete 6MWT due to fatigue, SOB, and other physical limitations.

NYHA-FC: New York Heart Association-Functional Class

6MWT: Six Minute Walk Test

MI: Myocardial Infarction

PCI: Percutaneous coronary intervention

CABG: Coronary artery bypass graft

AICD: Automated implantable cardioverter defibrillator

6.2.3 Baseline demographic characteristics of participants

The previous sections have presented all randomised participants regardless of whether they had completed the six-month study endpoint. From this section forward, all data presented are for the 67 participants who had reached their six-month follow-up at the time of data analysis.

Table 6.3 presents the baseline demographic characteristics of the 67 participants who had completed the study at the time of data analysis. The mean age of the 67 participants was 61 (SD 15) years old, ranging from 20 to 94 years. The majority of the participants were male (82%) and most (70%) were born in Australia. Most of the participants (82%) spoke only English at home. Close to a quarter (22%) of participants were in paid employment. There were 62% participants who had completed their formal education at the high school certificate level, 20% had a trade or certificate or diploma, and 18% had a university degree. There were also 10% of participants who did not provide information regarding their level of education.

Table 6.3 Baseline demographic characteristics of participants

	Total (n=67)	**Interventio n (n=36)**	**Control (n=31)**
Age, mean (SD)	61 (15)	63 (15)	59 (16)
(Range)	(20-94)	(37-94)	(20-86)
Sex (Male), n (%)	55 (82)	30 (83)	25 (81)
Country of birth n (%)			
Born in Australia	47 (70)	26 (72)	21 (68)
Marital status			
Married/de facto, n (%)	39 (58)	21 (58)	18 (58)
Language, n (%)			
English	55 (82)	29 (81)	26 (84)
In paid employment, n (%)	15 (22)	8 (22)	7 (23)
Living status, n (%)			
Living alone	12 (18)	5 (14)	7 (23)
Highest education level, n (%)*			
Up to high school	37 (62)	21 (64)	16 (59)
Trade/certificate/diploma	12 (20)	5 (15)	7 (26)
University	11 (18)	7 (21)	4 (15)

* n=60

6.2.4 Baseline clinical characteristics of participants

Table 6.4 presents the baseline clinical characteristics of participants. Among the 67 participants included in the interim analysis, the majority (60%) had dilated cardiomyopathy. The mean left ventricular ejection fraction was 33% (SD 13%) and 63% were in NYHA-FC II. Mean 6MWT distance was 371.9 (SD 107.1) meters.

Among these 67 participants, 46% have had myocardial infarction and half (51%) had an AICD. A quarter (27%) had had a previous coronary artery bypass graft, while 22% had had a previous percutaneous coronary intervention.

A similar high prevalence of coronary risk factors was observed in these 67 participants. Over half (60%) reported they had previously smoked. The mean body mass index was 31.9 (SD 9.2) kg/m^2, and the mean waist circumference was 102cm (SD 16.8). The prevalence of diabetes was 28%, and 44% for dyslipidaemia. The mean Charlson index of co-morbidity score was 4.7 (SD 2.5).

Table 6.4 Baseline clinical characteristics of participants

	Overall (n=67)	Intervention (n=36)	Control (n=31)
Aetiology of heart failure, n (%)			
Ischemic	32 (48)	20 (56)	12 (39)
Idiopathic	10 (15)	5 (14)	5 (16)
Valvular	8 (12)	5 (14)	3 (10)
Dilated	40 (60)	16 (44)	24 (77)[+]
Hypertension	6 (9)	2 (6)	4 (13)
Others	10 (15)	5 (14)	5 (16)
Ejection fraction, (mean ± S.D)	32.5 (13.2)	30.9 (12.4)	34.1 (14.1)
Atrial fibrillation, n (%)	5 (8)	3 (8)	2 (7)
NYHA-FC (%)			
II	42 (63)	22 (61)	20 (65)
III	25 (37)	14 (39)	11 (36)
Coronary risk factors			
Diabetes, n (%)	19 (28)	8 (22)	11 (36)
Hypertension, n (%)	21 (31)	11 (31)	10 (32)
High cholesterol, n (%)	29 (44)	12 (34)	17 (55)
History of smoking, n (%)	38 (60)	21 (58)	19 (61)
History of renal condition, n (%)	13 (19)	7 (19)	6 (19)
Waist circumference, mean(SD)	102.0 (16.8)	103.0 (16.3)	101.1 (17.6)
Body Mass Index, mean(SD)	31.9 (9.2)	31.1 (7.8)	32.9 (11.0)
Waist/hip ratio	0.99 (0.1)	0.97 (0.1)	0.95 (0.1)
Family history, n (%)	26 (39)	16 (44)	10 (32)
Previous cardiac conditions/procedures, n (%)			
MI	31 (46)	18 (50)	13 (42)
PCI	15 (22)	10 (28)	5 (16)
CABG	18 (27)	10 (28)	8 (26)
AICD	34 (51)	21 (58)	13 (42)
Charlson Index, mean (SD)	4.7 (2.5)	4.83 (2.6)	4.61 (2.4)
Functional capacity*			
6MWT, meter, mean (SD)	371.9 (107.1)	372.5 (111.2)	371.2 (104.1)

[+] p=0.006 (between groups)

* n=63. (intervention n=34, control n=29) 4 participants refused six minute walk test due to shortness of breath, low blood pressure, fatigue or other personal reason.

NYHA-FC: New York Heart Association-Functional Class

6MWT: Six Minute Walk Test

MI: Myocardial infarction

PCI: Percutaneous coronary intervention

CABG: Coronary artery bypass graft

AICD: Automated implantable cardioverter defibrillator

6.2.5 Comparability between intervention and control group

The baseline demographic characteristics of the intervention group and the control group are comparable. Less participants in the intervention group had dilated cardiomyopathy (44%) compared to the control group (77%) (p=0.006). Otherwise there were no between group differences for any other clinical characteristics.

6.3 Medication use in participants

Figure 6.2 presents the baseline medication used in the intervention and control groups. Beta blocker was the most used medication in both groups and followed by diuretics, angiotensin converting enzyme inhibitor and lipid lowering agents. Participants in the intervention group were more likely to be on anti-arrhythmic medications (25%) compared to participants in the control group (7%) (p=0.041).

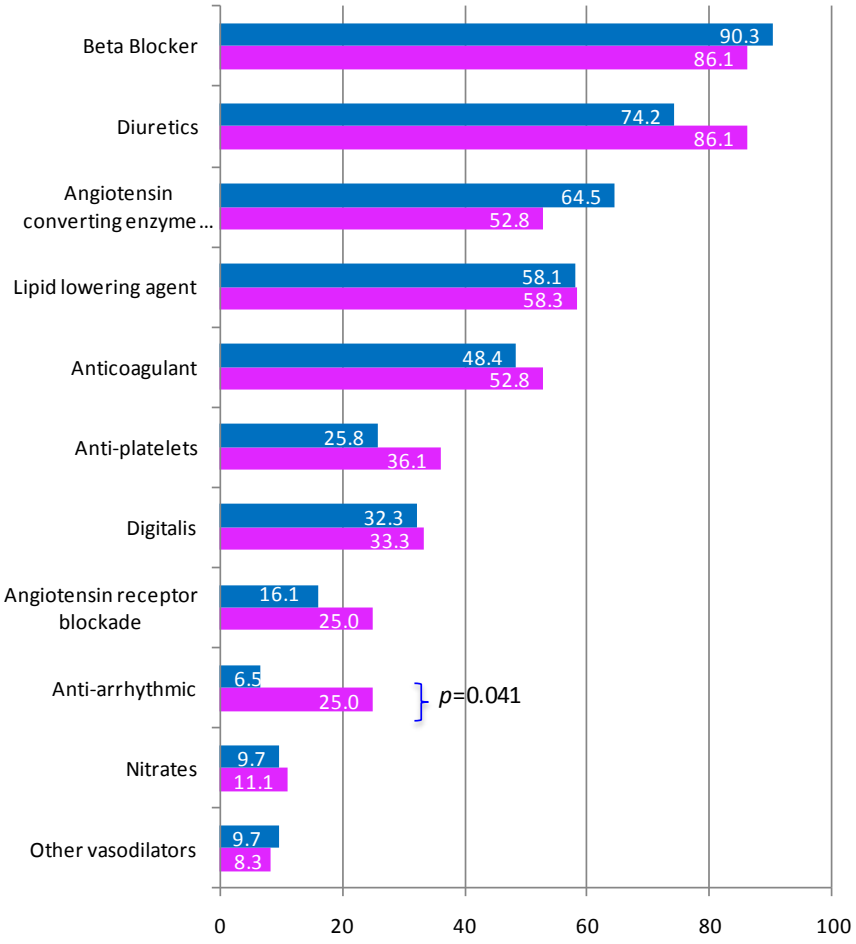


Figure 6.2 Baseline medication use
Data is presented in percentage.

6.4 Baseline outcome measures

Table 6.5 presents the baseline HRQoL and psychosocial characteristics of the overall study participants who had completed six-month follow-up. Health related quality of life was measured by the SF-36 [6] and Minnesota Living with Heart Failure Questionnaire (MLHFQ).[7]

The highest mean score on the SF-36 was in the pain domain (69.6 [95% CI: 62.7-76.5]) followed by role emotion (69.0 [95% CI: 61.8-75.3]), social functioning (67.9 [95% CI: 61.0-74.8]), and the general health domain had the lowest mean score (42.3 [95% CI: 37.1-47.4]). The mean score of the physical function domain was 54.0 (95% CI: 48.4-59.6) among this group of participants. In the disease specific quality of life measure-the MLHFQ, the total mean score was 40.4 (95% CI: 35.3-47.1). The participants' mean score in the emotional domain (8.7 [95% CI: 7.0-10.2]) was lower compared to physical domain (18.7 [95% CI: 16.1-21.3]). There was no statistically significant difference in the participant's HRQoL scores between the intervention group and the control group. The baseline self-care behaviour was measured by the European Heart Failure Self-care Behaviour Scale (EHFScBS). The mean score was 25.9 (95% CI: 24.1-27.9).

Exercise self-efficacy was measured by Bandura's Exercise self-efficacy scale.[8] The mean exercise self-efficacy score was 75.7 (95% CI: 66.2-85.3). Participants' physical activity level was measured by the National lifestyle prescription-physical activity scale.[9] On average this group of participants undertook 6.3 (95% CI: 5.3-7.6) sessions of physical activity. There were no statistically significant differences between the intervention group and the control group. Table 6.5 provides the full baseline outcome measures.

Table 6.5 Baseline outcome measures

Measurements	Overall (n=67)	Intervention (n=36)	Control (n=31)
SF-36, mean (95% CI)			
Physical functioning	54.0 (48.4-59.6)	53.0 (44.4-60.3)	55.2 (47.7-64.2)
Role physical	55.7 (49.4-62.7)	52.9 (43.2-62.7)	59.1 (50.3-69.0)
Pain	69.6 (62.7-76.5)	69.9 (60.0-79.9)	69.3 (59.2-79.4)
General health	42.3 (37.1-47.4)	42.5 (35.0-50.0)	42.0 (34.5-49.5)
Vitality	45.1 (39.4-51.1)	44.4 (35.6-53.2)	45.8 (38.3-54.0)
Social functioning	67.9 (61.0-74.8)	62.8 (52.6-73.1)	73.8 (64.5-83.1)
Role emotion	69.0 (61.8-75.3)	67.4 (57.4-76.0)	70.7 (60.4-81.0)
Mental health	65.6 (60.3-71.0)	61.8 (54.0-69.6)	70.0 (62.6-77.4)
6MWT distance, meters, mean (95% CI)	371.9 (344.9-398.9)	372.5 (333.7-411.3)	371.2 (331.6-410.8)
Exercise self-efficacy Scale, mean (95% CI)	75.7 (66.2-85.3)	75.5 (62.2-88.8)	76.0 (61.6-90.4)
Physical activity level, Sessions/week, mean (95% CI) *	6.3 (5.3-7.6)	5.8 (4.3-7.2)	7.2 (5.5-9.0)
EHFEcBS, mean (95% CI)	25.9 (24.1-27.9)	26.2 (23.4-29.0)	25.6 (23.0-28.5)
MLHFQ, mean (95% CI)			
Physical	18.7 (16.1-21.3)	20.7 (17.0-24.4)	16.3 (12.6-20.0)
Emotional	8.7 (7.0-10.2)	9.3 (6.9-11.3)	7.9 (5.5-10.0)
Total	40.4 (35.3-47.1)	44.6 (37.0-53.9)	35.3 (27.8-44.7)

*One session = 20mins vigorous activity or 30mins moderate/mild activity
SF-36: Medical Outcome Study Short Form-36
6MWT: Six Minute Walk Test
EHFScBS: European Heart Failure Self-care Behaviour Scale
MLHFQ: Minnesota Living with Heart Failure Questionnaire

6.5 Outcome measures

6.5.1 Primary endpoint

Medical Outcome Study Short Form-36: physical function domain

Figure 6.3 shows the mean score of the overall study cohort from baseline to three-month, and six-month. Overall the study participants demonstrated a small but non-significant decrease in the mean score of SF-36, physical function domain, from baseline (54.0 [95% CI: 48.4-59.6]) to three-month follow-up (53.4 [95% CI: 47.8-59.1]) and to six-month follow-up (52.5 [95% CI: 46.5-59.3]).

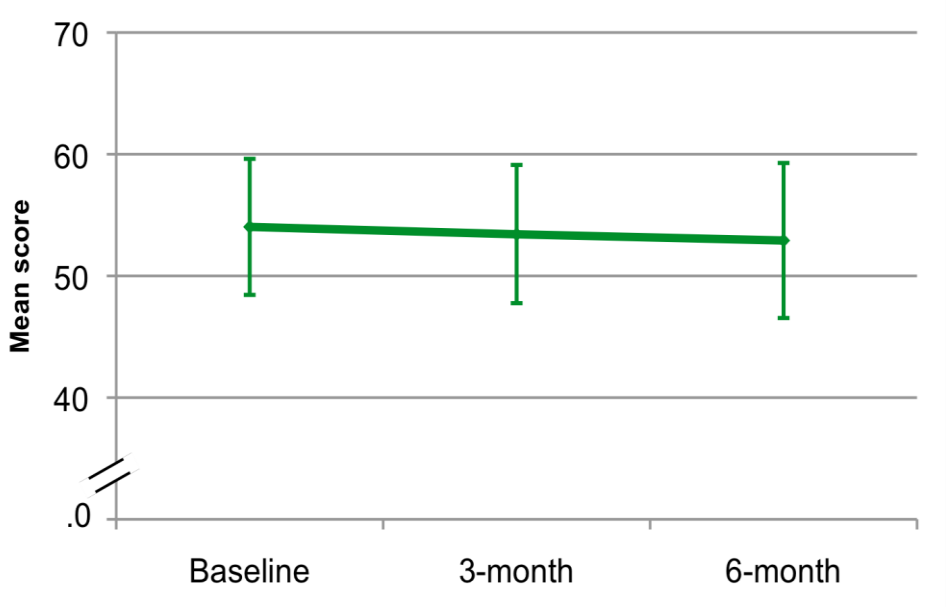


Figure 6.3 Physical function domain of SF-36 (n=67)
Data presented as mean and 95% confidence interval.

Figure 6.4 shows the mean scores of each group over the six-month study period. There was a small, non-significant increase in the intervention group's (n=36) mean score from baseline (52.4 [95% CI: 44.4-60.3]) to three-month (53.2 [95% CI: 44.8-61.6]) then a small, non-significant decrease at six-month follow-up (50.9 [95% CI: 41.8-59.3]). The control group's (n=31) mean score stayed relatively the same from baseline (55.2 [95% CI: 47.7-64.2]) to three-month (53.8 [95% CI: 45.7-61.7]) to six-month (54.5 [95% CI: 45.9-65.4]). None of these changes were statistically significant.

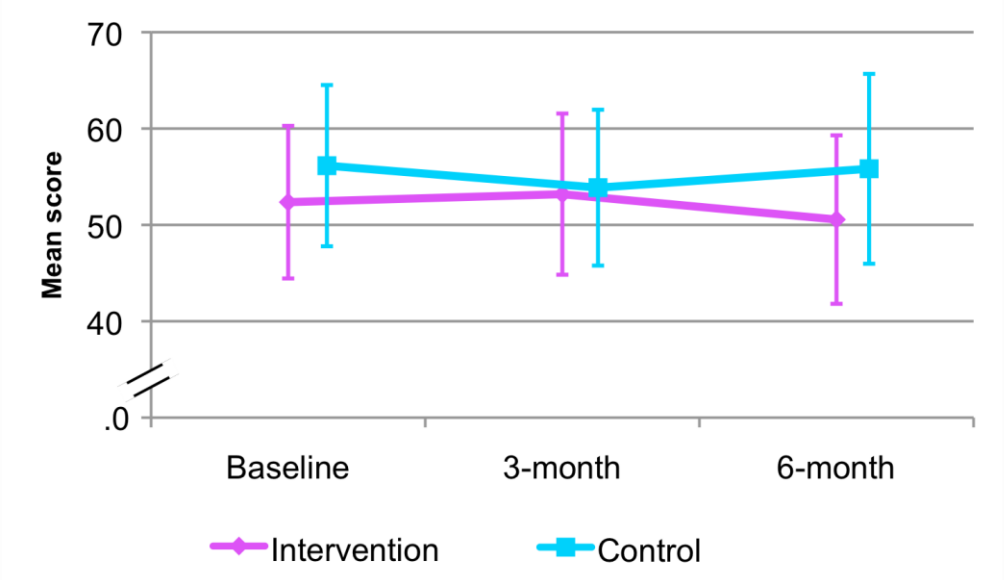


Figure 6.4 Physical function domain from baseline to six-month, by group
Data presented as mean and 95% confidence interval.

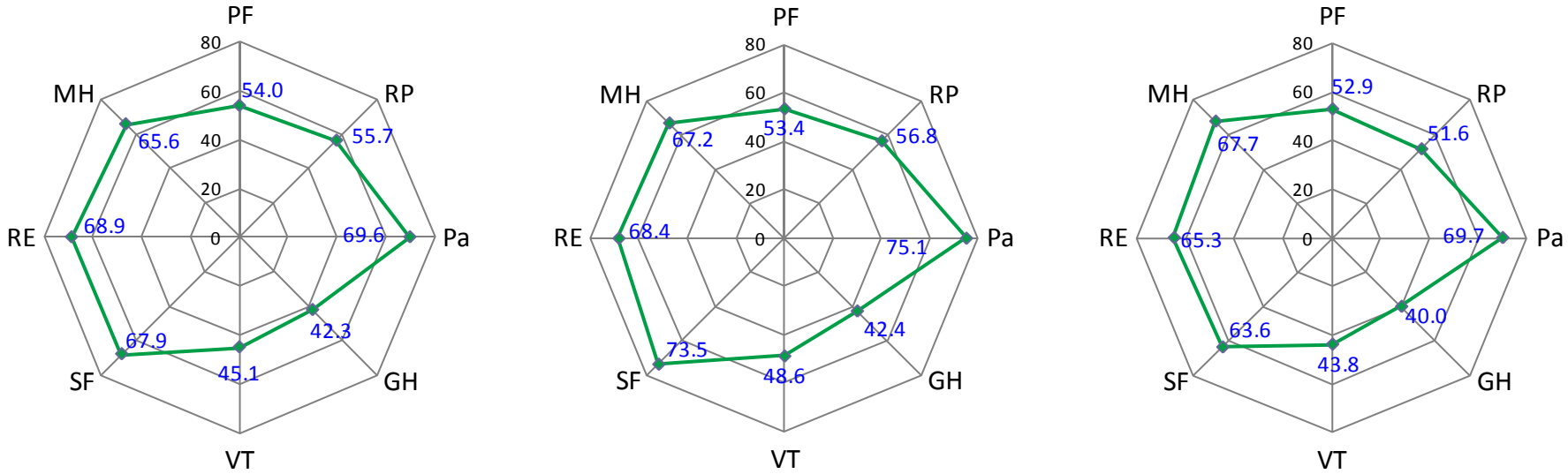
6.5.2 Secondary outcome measures

Health related quality of life

Medical Outcome Study Short Form-36

Figure 6.5 presents the mean scores of the overall study participants in each of the eight SF-36 domains, over the study period. There were no statistically significant changes in any of the eight domains of SF-36, from baseline to three-month and to six-month follow-up.

Figure 6.6 presents the mean score changes by study group. Again no statistically significant difference was observed between the mean score of the intervention group and control group. In the intervention group (n=36), the participants' score in vitality (44.4 to 49.8) and social function (62.8 to 72.2) increased more than five points from baseline to three-month follow-up. An increased score was also seen in the role physical domain (mean of 53.0 to 56.3), pain domain (69.6 to 73.0), and the mental health domain (61.8 to 65.8). These increased scores were not sustained at six-month follow-up as shown in Figure 6.6. There were no observed changes in other domains.



Baseline **3-month** **6-month**

Figure 6.5 Medical Outcome Study Short Form-36 from baseline to six-month (n=67)
Data presented as mean.

PF: Physical Function **RP**: Role Physical **Pa**: Pain **GH**: General Health

VT: Vitality **SF**: Social Function **RE**: Role Emotion **MH**: Mental Health

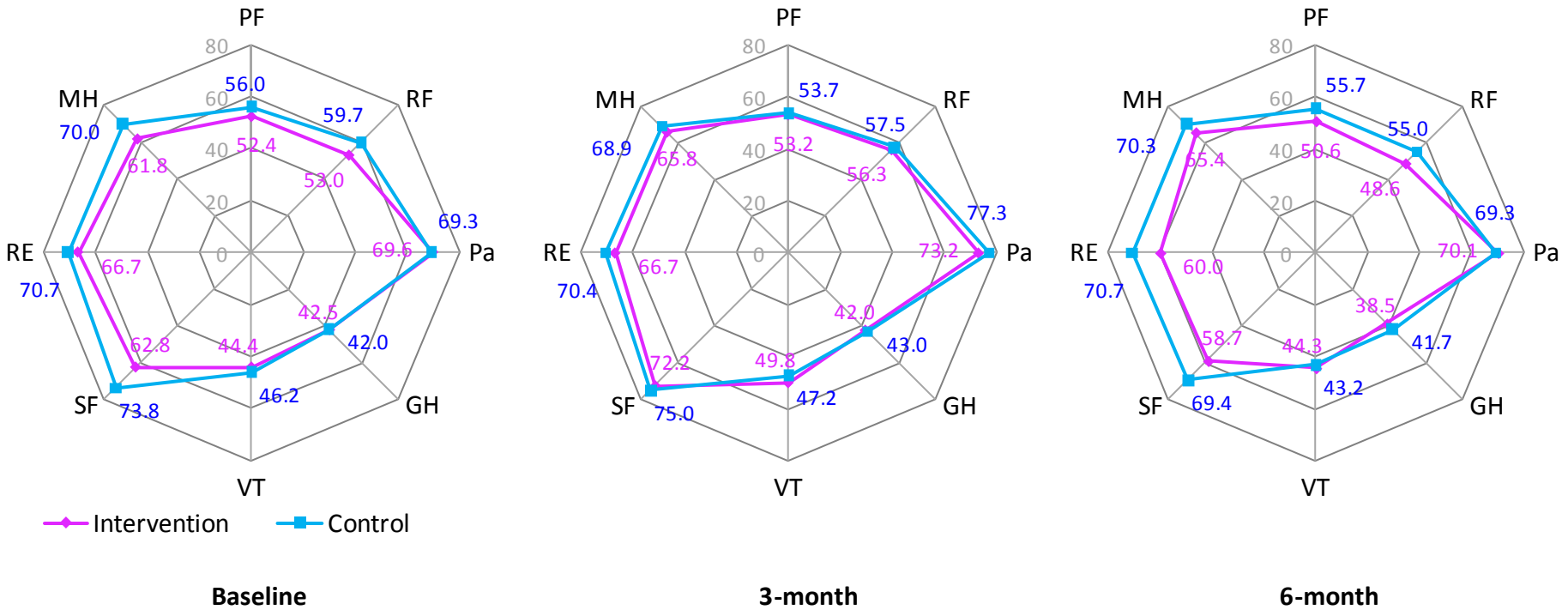


Figure 6.6 Medical Outcome Study Short Form-36 from baseline to six-month

Data presented as mean.

PF: Physical Function **RP**: Role Physical **Pa**: Pain **GH**: General Health

VT: Vitality **SF**: Social Function **RE**: Role Emotion **MH**: Mental Health

Minnesota Living with Heart Failure Questionnaire

The Minnesota Living with Heart Failure Questionnaire (MLHFQ)[7] and Medical Outcome Study Short Form-36 (SF-36)[6] were used to measure HRQoL in our study. In the MLHFQ, the higher the score, the more influence/burden CHF has on the individual's life.[7] Over all, there was a slight, non-significant increase in the total score of the MLHFQ, from baseline (41.2 [95% CI: 35.3-47.1]) to three-month follow-up (42.8 [95% CI: 36.6-49.0]) and to six-month follow-up (43.1 [95% CI: 37.3-49.0]). This is presented in Figure 6.7

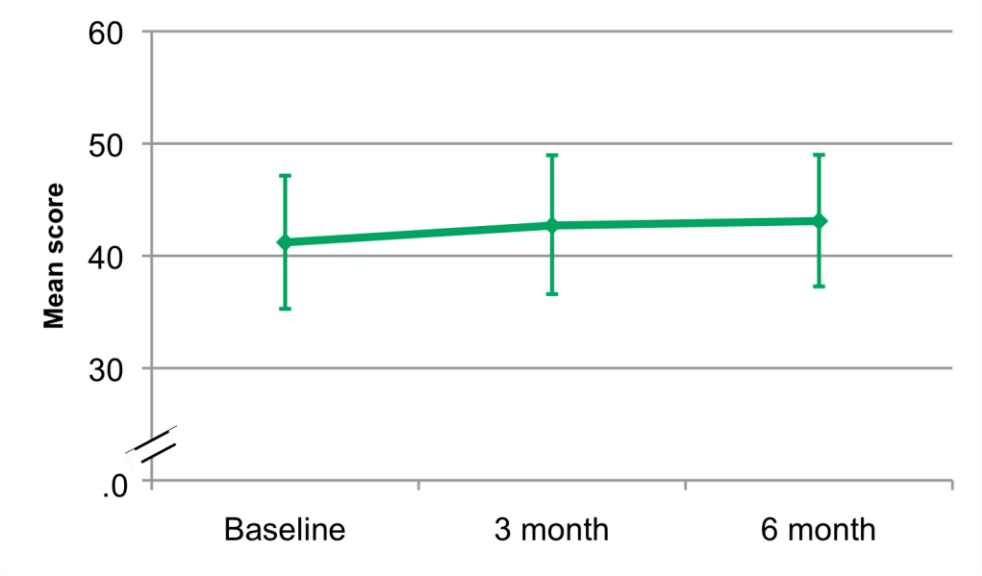


Figure 6.7 Minnesota Living with Heart Failure Questionnaire, total score (n=67)
Data presented in mean and 95% confidence interval

Figure 6.8 shows the total score of the MLHFQ of intervention and control group. For the intervention group, the total score at baseline was 45.4 (95% CI: 37.0-53.9) and it decreased to 41.7 (95% CI: 32.6-50.9) at three-month time. At six-month follow-up the mean total score of MLHFQ was 44.2 (95% CI: 36.3-52.1). The mean total score of control group at baseline was 36.3 (95% CI: 27.8-44.7) at baseline; 43.9 (95% CI: 35.3-52.6) at three-month follow-up and 41.9 (95% CI: 32.7-51.1) at six-month follow-up.

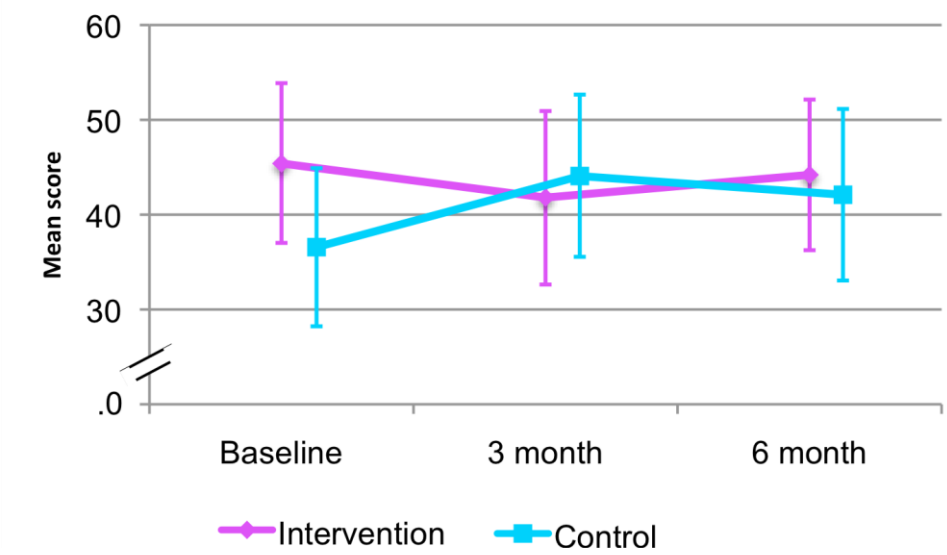


Figure 6.8 Minnesota Living with Heart Failure Questionnaire total score
Data presented in mean and 95% confidence interval.

Figure 6.9 presents the changes in physical and emotional domains over time. The mean score of the physical domain, for this study group was 18.7 [95% CI: 16.1-21.3] at baseline, which increased slightly to 19.4 [95% CI: 16.7-22.1] at three-month follow-up. The mean score for the physical domain was almost the same at six-month follow-up (19.2 [95% CI: 16.6-21.9]). For the emotional domain, there was also a slight increase from baseline (8.6 [95% CI: 7.0-10.2]) to three-months 9.1 [95% CI: 7.4-10.9] and to six-month follow-up (9.6 [95% CI: 7.8-11.3]).

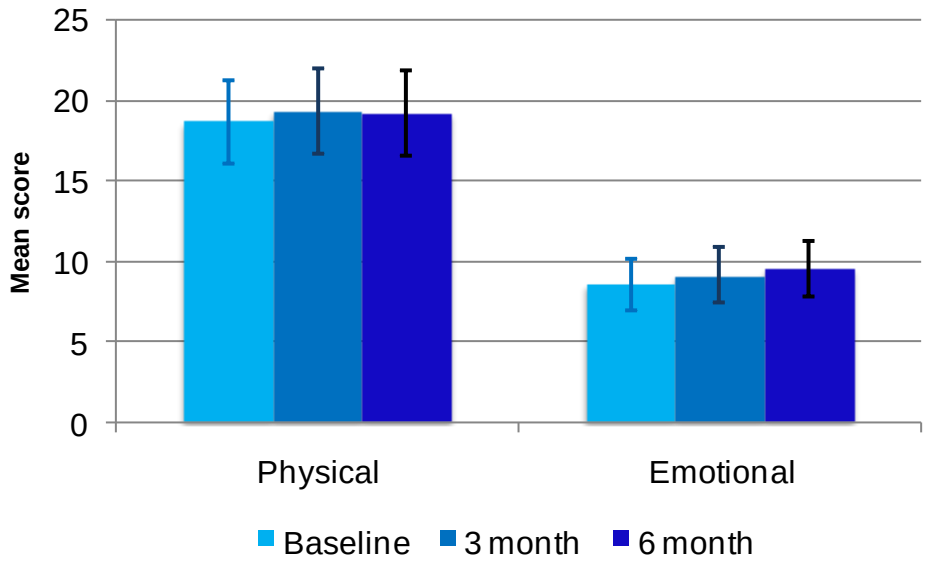


Figure 6.9 Minnesota Living With Heart Failure Questionnaire-physical & emotional domains (n=67)
Data presented as mean and 95% confidence interval

Figure 6.10 presents physical domains score from baseline to six-month, by group. In the intervention group, there was a slight, non-significant decrease in the physical domain from baseline (20.7[95% CI: 17.0-24.4]) to three-month (19.0 [95% CI: 15.2-22.8]). At six-month the mean score was 19.6 (95% CI: 16.0-23.3).

Among participants in the control group, mean score of the physical domain increased slightly from baseline (16.3 [95% CI: 12.6-20.0]) to three-month (19.8 [15.8-23.7]). At six-month follow-up the mean score decreased slightly to 18.8 (95% CI: 14.8-22.7). Again, there were no statistical significant changes.

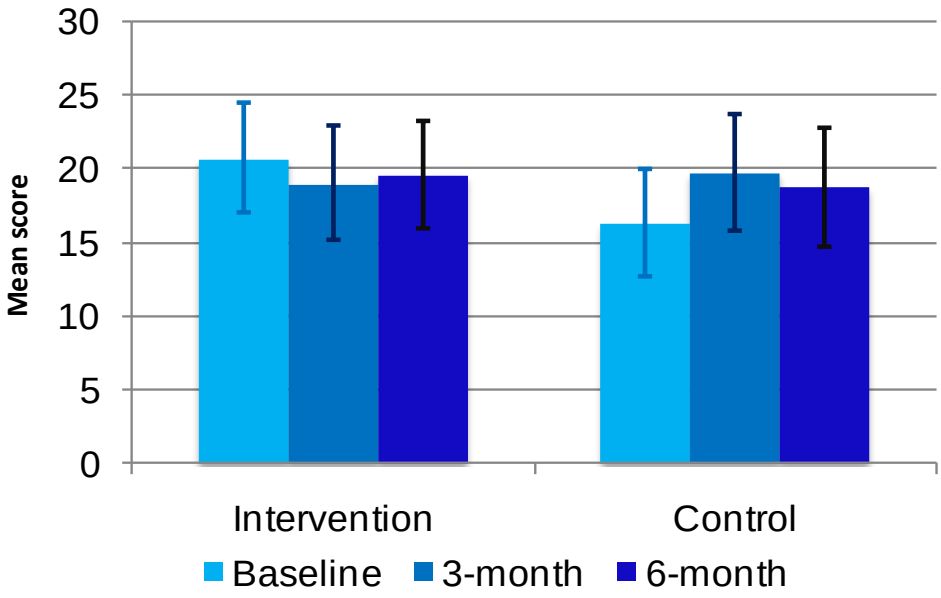


Figure 6.10 Minnesota Living With Heart Failure Questionnaire-physical domain

Data presented as mean and 95% confidence interval

Figure 6.11 presents the mean scores of the emotional domain for the intervention group and the control group. There was a slight, non-significant decrease from baseline (9.3 [95% CI: 6.9-11.7]) to three-month (8.5 [95% CI: 5.9-11.1]), for the intervention group. The mean score of the emotional domain increased, although not significantly to 9.8 (95% CI: 7.4-12.1) at six-month follow-up. Among participants in the control group, the baseline mean score of the emotional domain was 7.8 (95% CI: 5.5-10.0) and 9.9 (95% CI: 7.4-12.4) at three-month follow-up. At six-month follow-up the mean score decreased to 9.3 (95% CI: 6.7-12.0), which was not statistically significant.

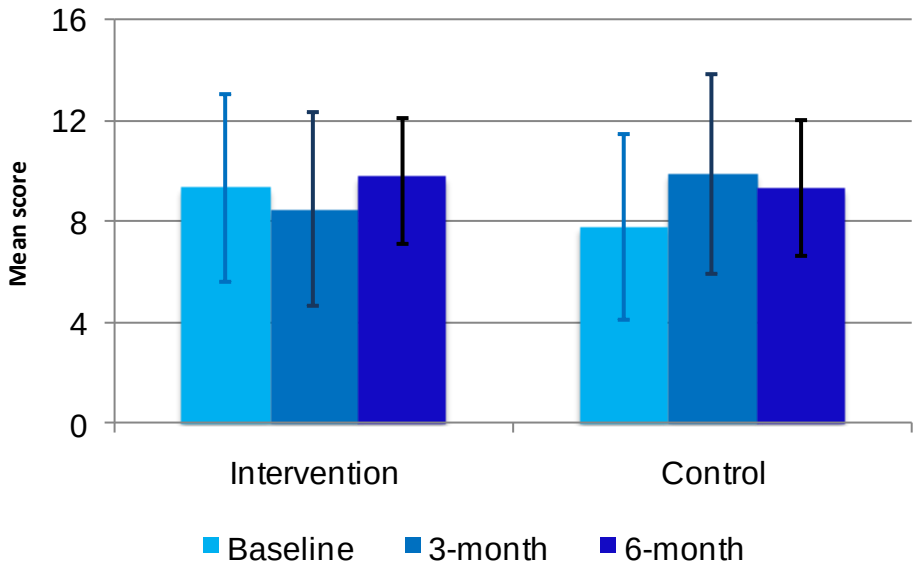


Figure 6.11 Minnesota Living With Heart Failure Questionnaire-Emotional domain

Data presented in mean and 95% confidence interval.

Six Minute Walk Test distance

Figure 6.12 presents the mean 6MWT distance of study participants over the six-month study period. There was a non-significant increase in the mean 6MWT distance from baseline (371.9m [95% CI: 344.9-398.9]) to six-month (379.1m [95% CI: 352.5-405.8]). The distance stayed relatively the same at three-month, 370.1m (95% CI: 340.6-399.6).

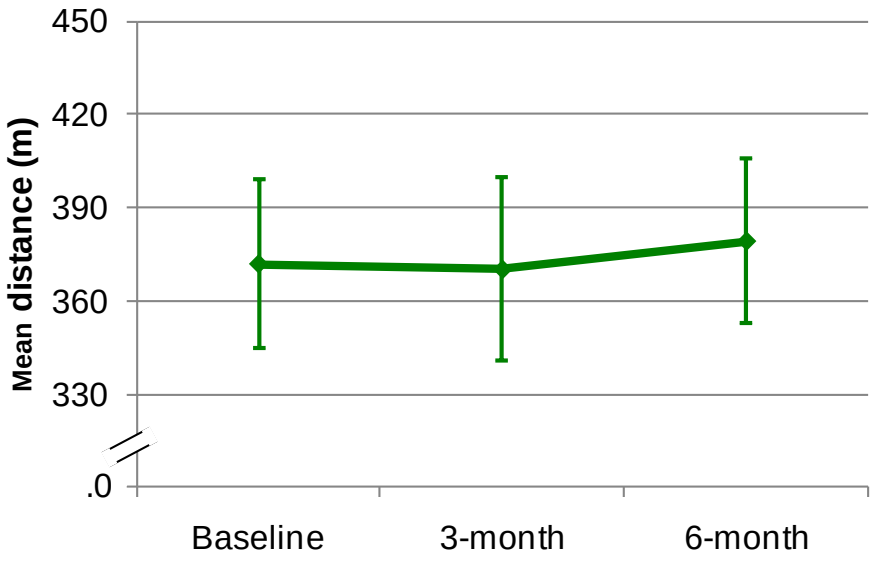


Figure 6.12 Six Minute Walk Test distance (n=67)
Data presented as mean and 95% confidence interval.

Figure 6.13 presents the mean 6MWT distance over the six-month study period by study groups. The mean 6MWT distance of the control group decreased from baseline (371.2m [95% CI: 331.6-410.8]) to three-month (356.7m [95% CI: 309.2-404.2]) and increased at six-month to approximately the same as at baseline (373.3m [95% CI: 334.1-412.6]). While the intervention group demonstrated a steady increase in the mean 6MWT distance over the six-months. The mean distance of the intervention group was 372.5m (95% CI: 333.7-411.3) at baseline. The distance increased at three-month (381.6m [95% CI: 343.0-420.1]) and at six-months (384.1[95% CI: 346.1-422.2]). The change in mean 6MWT distance from baseline to six-months in the intervention group was statistically significant (p=0.05).

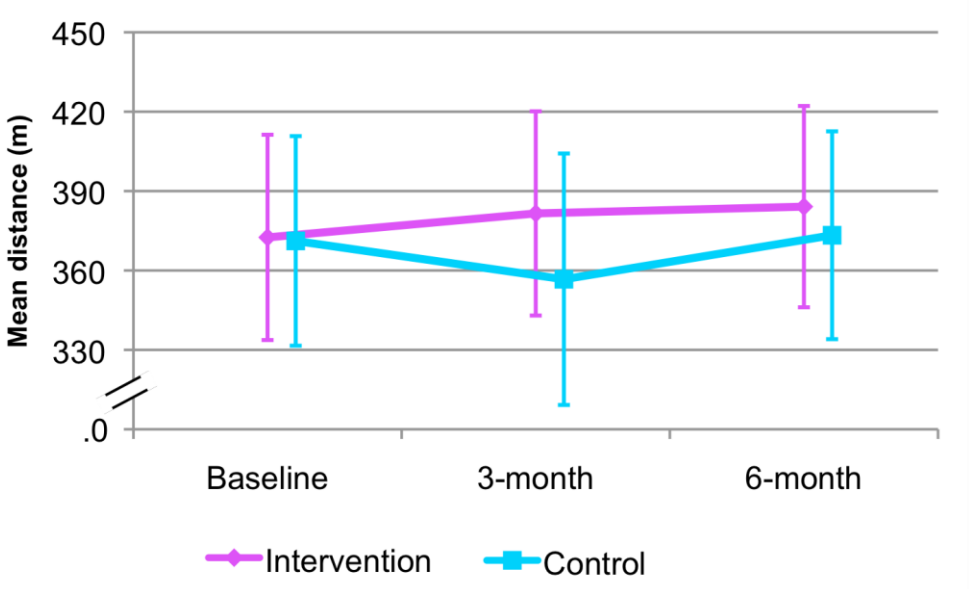


Figure 6.13 Six Minute Walk Test distance by group
Data presented as mean and 95% confidence interval.

Heart failure self-care behaviour

Heart failure self-care behaviour was measured by using the European Heart Failure Self-care Behaviour Scale.[10] In this scale, a lower score indicates better self-care behaviour, and a higher score indicates less desirable self-care behaviour.[10] Figure 6.14 presents the mean score of the overall study participants (n=67). At baseline the mean score was 25.9 (95% CI: 24.0-27.9), which decreased to 25.3 (95% CI: 23.3-27.4) at three-month follow-up and there was a slight, non-significant decrease at six-month follow-up (25.1 [95% CI: 23.3-27.0]).

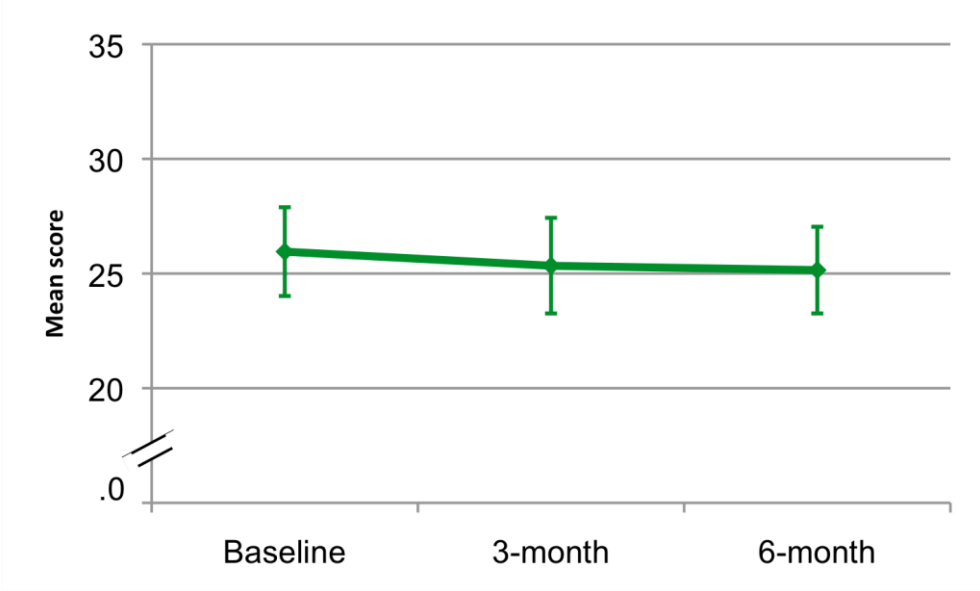


Figure 6.14 European Heart Failure Self-care Behaviour score from
Data presented as mean and 95% confidence interval.

Figure 6.15 presents the mean score over time, by study groups. In the control group, there was a non-significant improvement in the participants' mean self-care behaviour score from baseline (25.6 [95% CI: 22.9-28.5]) to three-month follow-up (25.8 [95% CI: 22.3-29.2]), and to six-month follow-up (26.5 [95% CI: 23.4-29.6]). In the intervention group, the mean self-care behaviour score 26.2 (95% CI: 23.4-29.0), which was decreased at three-month follow-up (25.0 [95 % CI: 22.3-27.6]). At six-month follow-up the mean score was 24.0 (95% CI: 21.6-26.3). This observed change in both intervention and control group was not statistically significant.

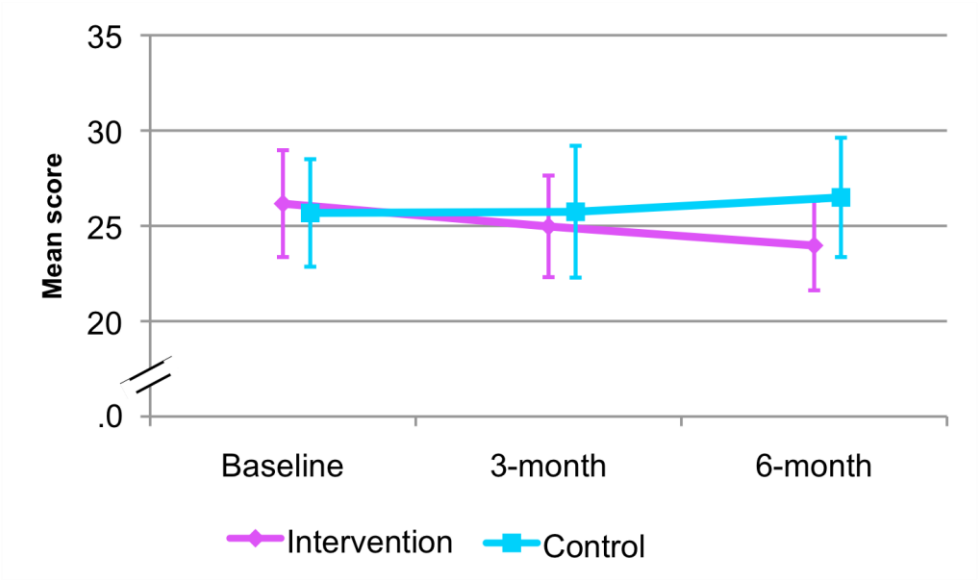


Figure 6.15 European Heart Failure Self-care Behaviour score
Data presented as mean and 95% confidence interval.

Exercise self-efficacy

Figure 6.16 presents the overall mean score of the study participants over six-month study period. There was a small, non-significant decrease in the mean self-efficacy score from baseline (75.7 [95% CI: 66.2-85.3]) to three-month (74.9 [95% CI: 66.3-83.5]), then to six-month (71.5 [95% CI: 62.5-81.9]).

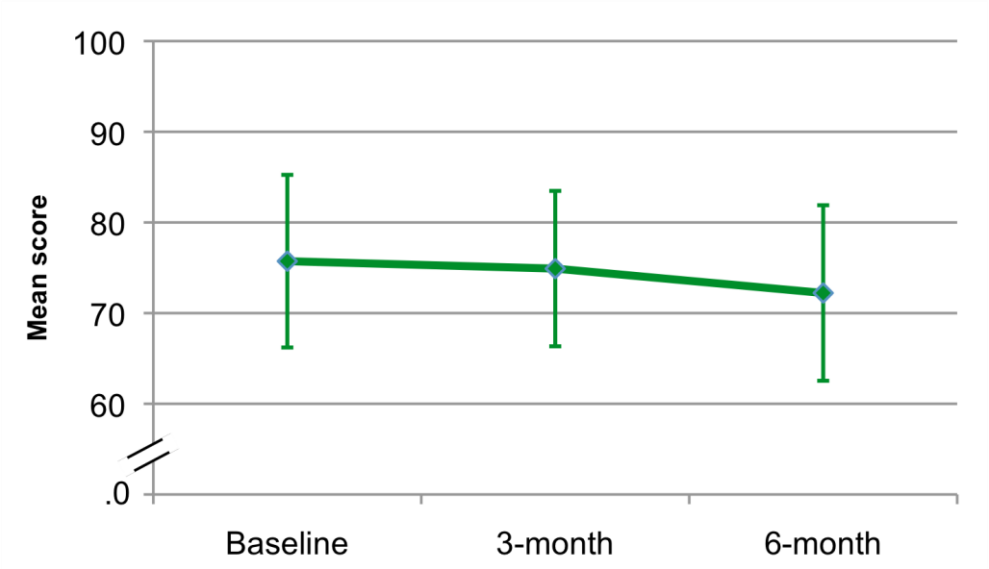


Figure 6.16 Exercise Self-efficacy Scale from baseline to six-month (n=67)
Data presented as mean and 95% confidence interval.

Figure 6.17 present the change over time, by study groups. There was a small, non-significant improvement in the control group's mean self-efficacy score from baseline (76.0 [95% CI: 61.6-90.4]) to three-month (79.1 [95% CI: 64.8-93.4]). However this improvement was not sustained at six months (73.5 [95% CI: 59.8-90.4]). In the intervention group, there was a steady, non-significant decrease from baseline (75.5 [95% CI: 62.2-88.8]) to three-month (71.4 [95% CI: 60.7-82.2]), then to six-month (69.8 [95% CI: 56.8-82.7]).

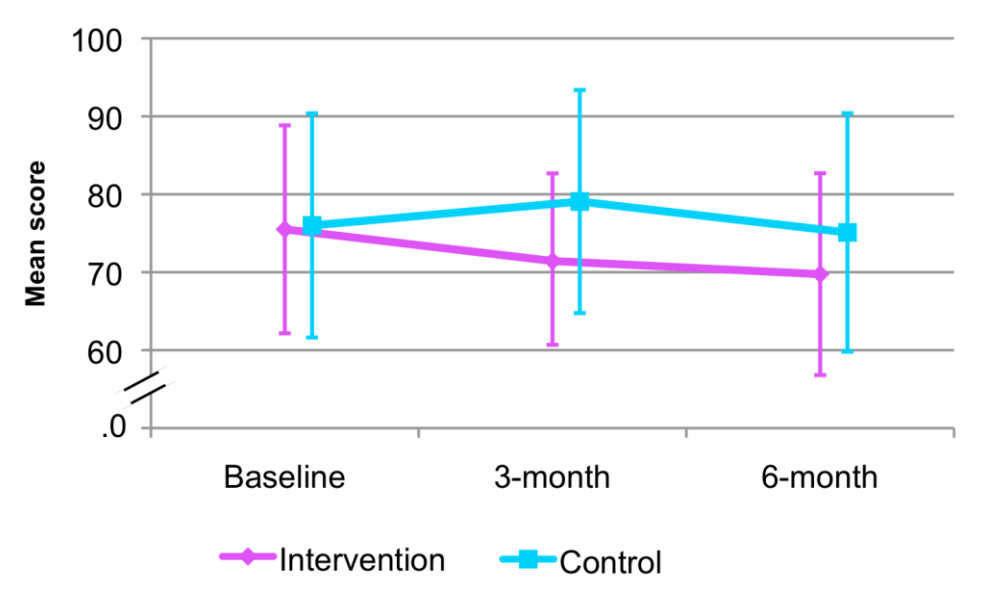


Figure 6.17 Exercise Self-efficacy Scale from baseline to six-month
Data presented as mean and 95% confidence interval

Physical activity level

Figure 6.18 present the physical activity level (in sessions) of study participants over the six-month study period. Twenty minutes of vigorous physical activity or 30 minutes of moderate/mild physical activity was considered as one session.

At baseline on average, participants undertook 6.4 (95% CI: 5.3-7.6) sessions of physical activity in a typical week, which increased to 6.6 (95% CI: 5.5-7.8) sessions per week at three-month follow-up. At six-month follow-up the mean number of physical activity sessions undertaken by participants in a typical week was 6.7 (95% CI: 5.3-8.1). Overall there was a small, non-significant change in the number of physical activity sessions undertaken by the participants each week.

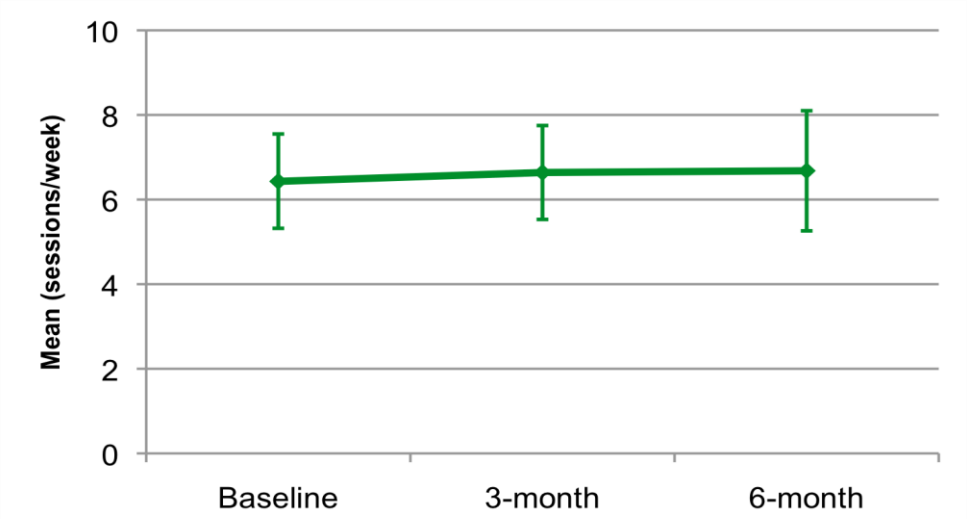


Figure 6.18 Physical activity level from baseline to six-month (n=67)
Data presented as mean and 95% confidence interval.

Figure 6.19 presents the mean number of sessions per week over the six-month study period, by group. Participant in the control group level of physical activity steadily decreased from baseline (7.2 [95% CI: 5.5-9.0]) to three-month (7.0 [95% CI: 5.1-8.7]), and at six-month follow-up (6.4 [95% CI: 4.5-8.3]). While in the intervention group, the mean number of sessions was almost the same from baseline (5.8 [95% CI: 4.3-7.2]) to three-month (6.4 [95% CI: 4.9-7.9]), and there was an increase at six-month follow-up (7.0 [95% CI: 4.8-9.2]). The changes observed in both groups over the six-month study period were not statistically significant.

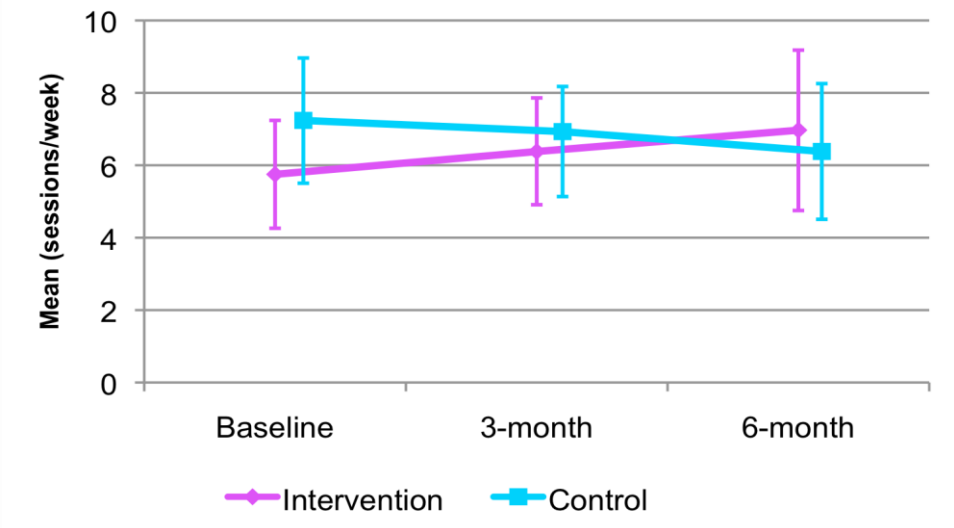


Figure 6.19 Physical activity level from baseline to six-month
Data presented as mean and 95% confidence interval

6.5.3 Summary of outcome measures at six-month follow-up

Outcome measures at each study point have been presented in detail in the previous sections. At six-month follow-up, the intervention group demonstrated a statistically significant increase in the mean 6MWT distance and also demonstrated a trend of improved self-care behaviour, although these changes did not reach statistically significance in this analysis.

Table 6.6 presents a comparison of the outcome measures at six-month follow-between the intervention and control group. Between group effect mean differences with 95% confidence interval are also presented. In summary, among all the outcome measurements, the confidence intervals of each group overlaped. There was no observed statistically significant difference between the intervention group and control group, on mean score of any outcome measure at six-month follow-up, from this interim analysis.

Table 6.6 Summary of outcome measures at six-month follow-up

Measurements	Intervention (n=36)	Control (n=31)	Effect Mean Difference (95% CI)	p
SF-36, mean (95% CI)				
Physical functioning	50.6 (41.8-59.3)	55.7 (45.9-65.4)	-5.1 (-17.9, 7.7)	0.431
Role physical	48.6 (40.0-58.2)	55.0 (44.2-65.9)	-6.429 (-20.6, 7.5)	0.369
Pain	70.1 (61.9-78.2)	69.3 (58.1-80.6)	0.733 (-12.7, 14.1)	0.931
General health	38.5 (30.8-46.2)	41.7 (33.1-50.4)	-3.3 (-14.6, 8.0)	0.565
Vitality	44.3 (36.0-52.5)	43.1 (34.4-51.9)	1.1 (-10.7, 12.9)	0.849
Social functioning	58.7 (47.7-69.7)	69.4 (58.3-80.4)	-10.7 (-26.1, 4.7)	0.171
Role emotion	60.0 (50.6-69.3)	70.7 (60.2-81.2)	-10.7 (-24.5, 3.0)	0.124
Mental health	65.4 (57.2-73.6)	70.3 (62.2-78.5)	-4.9 (-16.3, 6.5)	0.394
6MWT distance (m), mean (95% CI))	384.1 (346.1-422.2)	373.3 (334.1-412.6)	10.8 (-43.0, 64.6)	0.810
Physical activity level, (sessions/week)* mean (95% CI)	6.5 (4.8-9.2)	6.1 (4.5-8.3)	0.4 (-2.1, 3.0)	0.431
EHFEcBS, mean (95% CI)	24.0 (21.6-26.3)	26.5 (23.4-29.6)	-2.5 (-6.3, 1.2)	0.182
MLHFQ, mean (95% CI)				
Physical	19.6 (16-23.3)	18.8 (14.8-22.7)	0.9 (-4.4, 6.1)	0.744
Emotional	9.8 (7.4-12.1)	9.3 (6.7-12.0)	0.5 (-3.0, 3.9)	0.795
Total	43.3 (36.3-52.1)	41.9 (32.7-51.1)	2.3 (-9.5, 14.1)	0.813

*One session = 30mins moderate/mild physical activity or 20mins vigorous physical activity

6.5.4 Correlates of the Six Minute Walk Test

Table 6.7 presents the correlates of the 6MWT at baseline and six-month. There was a strong moderate correlation between the baseline 6MWT distance and participants' NYHA functional class (r=0.514, p<0.001); age (r=-0.423, p=0.001); baseline exercise self-efficacy (r=0.420, p=0.001); baseline physical activity level (r=0.395, p=0.001) and status of arthritis (r=-0373, p=0.003). The correlation between the 6MWT and history of CVA/stroke (r=-0.245, p=0.053); the use of beta blocker(r=-0.086, p=0.503) history of chronic lung condition(r=-0.062, p=0.631) and body mass index (r=0.032, p=0.861), and were very mild to no correlation. Spearman's rho was calculated for dichotomous variables, which had similar results as to Pearson's correlation. These correlations were also consistent at baseline and at six-month follow-up assessment.

Table 6.7 Correlation between variables and the 6MWT distance

		6M: 6MWTD	3M: 6MWTD	Baseline 6MWTD	Baseline ESe	Baseline PA level	History of Lung Con	Age	Baseline BMI	Gender	CVA/ stroke	Arthritis	Beta Blocker	Baseline NYHA-II
6M: 6MWD	Pearson	1												
	Sig.													
	N	64												
3M: 6MWD	Pearson	.930	1											
	Sig.	.000												
	N	63	63											
Baseline: 6MWTD	Pearson	.965**	.913	1										
	Sig.	.000	.000											
	N	63	63	63										
Baseline ESe	Pearson	.402	.392	.420	1									
	Sig.	.001	.002	.001										
	N	63	62	62	66									
Baseline PA level	Pearson	.387**	.340	.395	.508	1								
	Sig.	.002	.006	.001	.000									
	N	64	63	63	66	67								
History of chronic lung condition	Pearson	-.065	.037	-.062	-.255*	-.254*	1							
	Sig.	.610	.774	.631	.039	.038								
	N	64	63	63	66	67	67							
Age	Pearson	-.449**	-.396	-.423	-.018	-.152	.089	1						
	Sig.	.000	.001	.001	.884	.219	.472							
	N	64	63	63	66	67	67	67						
Baseline BMI	Pearson	.052	-.143	.032	.030	-.128	-.230	-.218	1					
	Sig.	.779	.436	.861	.873	.485	.204	.230						
	N	32	32	32	31	32	32	32	32					
Gender	Pearson	-.129	-.161	-.146	-.138	-.147	-.170	-.187	-.005	1				
	Sig.	.311	.209	.255	.271	.234	.168	.129	.978					
	N	64	63	63	66	67	67	67	32	67				
History of CVA/stroke	Pearson	-.212	-.188	-.245	.081	.006	-.038	.171	-.181	-.086	1			
	Sig.	.092	.140	.053	.517	.960	.759	.167	.320	.487				
	N	64	63	63	66	67	67	67	32	67	67			
Arthritis	Pearson	-.370**	-.425**	-.373	-.290*	-.156	.050	.140	-.080	.000	.149	1		
	Sig.	.003	.001	.003	.019	.210	.690	.261	.665	1.000	.231			
	N	63	62	62	65	66	66	66	32	66	66	66		
Beta Blocker	Pearson	-.092	-.077	-.086	-.083	-.093	.220	-.244*	-.012	.264*	-.052	-.088	1	
	Sig.	.471	.551	.503	.507	.454	.074	.047	.947	.031	.679	.484		
	N	64	63	63	66	67	67	67	32	67	67	66	67	
Baseline: NYHA -II	Pearson	.498**	.524	.514	.294*	.162	.070	-.085	.020	-.123	-.023	-.067	-.160	1
	Sig.	.000	.000	.000	.016	.191	.572	.492	.913	.323	.852	.594	.197	
	N	64	63	63	66	67	67	67	32	67	67	66	67	67

6M: 6-month follow-up;
3M: 3-month follow-up;
6MWTD: Six minute walk test distance;
Ese: Exercise self-efficacy scale;
PA: physical activity;
Lung Con.: lung condition;
BMI: Body Mass Index;
CVA: Cerebrovascular accident;
NYHA-II: New York Heart Association FC- II.

6.6 Sensitivity analysis

Sensitivity analyses were performed using all available data regardless of compliance, and without imputation of missing data at six-month follow-up. Table 6.8 demonstrates the result of the primary outcome did not change when analysis of those who completed six-month follow-up (completer) was compared with the intention-to-treat primary analysis using the carry-forward imputation method. This is also illustrated in Figure 6.20.

Table 6.8 Sensitivity analysis of the primary endpoint

		Completer-only			**Intention-to-treat**		
Sensitivity analysis		**Intervention** (n=29)	**Control** (n=28)	**p**	**Intervention** (n=36)	**Control** (n=31)	**p**
Primary outcome SF-36 PF, mean (SD)		53.8 (26.4)	56.3 (26.9)	0.935	50.6 (25.9)	55.6 (26.6)	0.696
CI (95%)	Upper	43.7	45.8		41.8	45.9	
	Lower	63.8	66.7		59.3	65.4	

Completer: participants who have completed six-month follow-up assessment.
SF-36 PF= SF-36 physical function domain
SD= standard deviation
CI= confidence interval

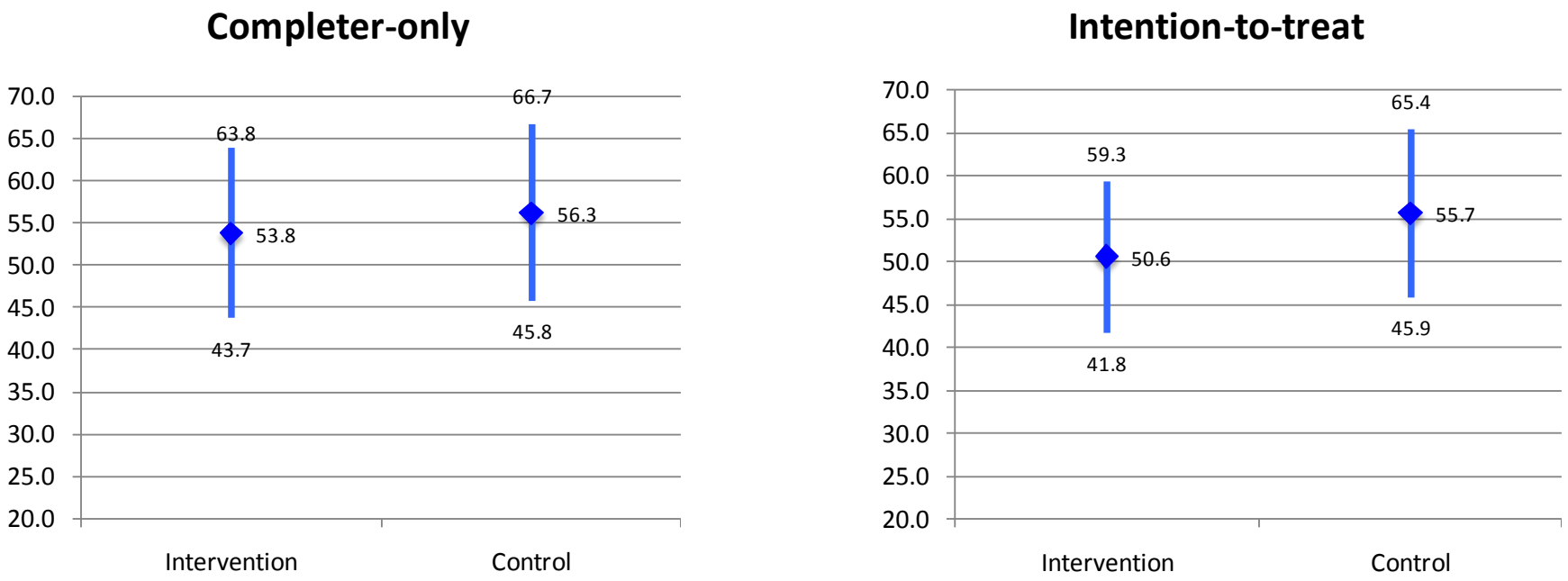


Figure 6.18 Sensitivity analysis
Data is presented in mean and 95% confidence interval

6.7 Study program adherence

The Home-Heart-Walk program is a self-administered monitoring program. Out of the 36 participants who were randomised to the intervention group, 30 participants received the intervention (Figure 6.1). At study completion, 17 participants provided evidence of undertaking the Home-Heart-Walk at their home (adherer), and 13 did not provide record of undertaking the self-monitoring intervention (non-adherer, including participants who verbally reported undertaking the intervention but did not providing record). A comparison between the baseline characteristic of the adherer and non-adherer demonstrated statistically significant differences on the mean age and Charlson Index of Co-morbidity.

The non-adherers were more likely to be younger (54 ± 15 years) compared to the adherers (68 ± 12 years) (p= 0.010). The non-adherers were also more likely to have less co-morbidities (3.4 ± 2.5) compared to the adherers (5.9 ± 1.9) (p = 0.004). Although, some participants did not provide a copy of the Home-Heart-Walk diary upon study completion, they did attend and complete the three-month and six-month follow-up. Comparison of baseline characteristics for the ten participants who did not complete six-month follow (non-completers) compared with the 57 participants who did complete the six-month follow-up (completers) found the NYHA-FC and the mean 6MWT distance at baseline to be statistically significant. There were 7/10 (70%) participants in NYHA-FC III among the non-completers, compared to 18/57 (32%) among the completers (p= 0.050). The mean distance walked at baseline, by non-completers was 269.4 (SD 102.5) meters compared to 386.8 (SD 100.1) meters for completers (p=0.003).

6.8 Adverse event

In this present study, there were three deaths and 31 rehospitalisations among the 67 participants, at the time of interim analysis. All of the events have been adjudicated by the investigators (PMD and PSM) and St Vincent's Hospital, Sydney Ethics Committee. None of these were attributable to the Home-Heart-Walk. As mentioned in Chapter Five, the Home-Heart-Walk is not powered to

detect differences in mortality or hospitalisation and this data was collected for safety monitoring only.

6.9 Conclusion

This chapter has presented the results of the first 67 participants in a RCT with six-month follow-up. Participants who undertook the Home-Heart-Walk program in addition to standard care (intervention group) were compared to participants who received standard care only (control group). Apart from an increased 6MWT distance in the intervention group at six-months, both groups had no significant change in any of the outcome measures (HRQoL, self-care behaviour, and exercise self-efficacy). The following Chapter will interpret and discuss the results presented in this chapter.

6.10 References

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Chapter 7
Impact of the Home-Heart-Walk Intervention

7.1 Introduction

The previous chapter has reported the preliminary findings from the Home-Heart-Walk study. As outlined previously, this study was undertaken to evaluate the effect of the Home-Heart-Walk on physical functioning of people living with CHF. Further the effect of this intervention on an individual's self-care behaviour, physical activity level and health related quality of life was examined. The study aims were achieved through a randomised controlled trial with two parallel groups. Individuals in the intervention group completed a six-month Home-Heart-Walk and individuals in the control group continued their usual care. All participants were followed up at three and six-months. The Six Minute Walk Test (6MWT), Medical Outcome Study Short Form-36 (SF-36), Minnesota Living with Heart Failure Questionnaire (MLHFQ), European Heart Failure Self-care Behaviour Scale (EHFScBS), Self-efficacy Scale and physical activity level were assessed at three-month and six-month follow-up.

In this chapter, the study findings will be discussed in the context of the existing literature, specifically addressing the Home-Heart-Walk aims. The Home-Heart-Walk was conducted within the limitation and time allocation of a doctoral thesis. It is challenging to provide a definitive discussion of a randomised controlled trial that has not achieved its targeted sample size. In spite of this, study results have elucidated some useful considerations in intervention development. The strength and limitations of the Home-Heart-Walk study will also be discussed in this chapter.

7.2 The Home-Heart-Walk study

Emerging from the literature reported in Chapter Two and Three was the importance of self-efficacy in mediating health behaviour, including physical activity. Physical activity intolerance, fatigue and dyspnoea are hallmark symptoms experienced by most people living with CHF.[1, 2] These symptoms frequently lead to decreased physical activity and physical de-conditioning that impair functional capacity and erode self-confidence that is necessary to initiate and maintain regular physical activity.[3, 4] Creative and alternative models for prompting physical functioning in people living with CHF are needed. The purpose of this present study was to evaluate a self-administered, adapted 6MWT [the Home-Heart-Walk] in its ability to promote physical functioning.

7.3 Participant characteristics

Despite an effort in recruiting a sample that was representative of the overall CHF population, the mean age of this group of participants was 61 years compared to 71 years of the average age of similar CHF studies.[5-8] There was also a high proportion (55/67, 82%) of male participants in our study. This likely reflects the targeting of the physical activity component and reticence for participants to consent to the study protocol.

The study participants were recruited from four hospitals in metropolitan Sydney. St Vincent's Hospital, Sydney, Westmead Hospital, Blacktown Hospital and Mt Druitt Hospital. In NSW, 74 % of the population was born in Australia.[9, 10] The sample for the Home-Heart-Walk study has a similar percentage (70%). Among the Home-Heart-Walk study participant, 24/67 (35.8%) was classified as obese (BMI>= 30kg/m^2). Although, this is higher compared to the general NSW population (18%),[9-11] it was comparable to other CHF studies.[5, 8, 12] It is considered that the sample reflects the sociodemographic characteristics of the broader sample from which they were drawn. The limitations of convenience sampling must be considered in the interpretation of the results.

7.4 Rationales for choice of primary outcome measure

Benefits of physical activity have been discussed in detail in Chapter One. In summary, firstly, prospective epidemiology studies of occupational and leisure-time physical activity have consistently documented a reduced incidence of cardiac events in those who are more physically active.[13] Secondly, physical activity improves physical functioning, which is an important domain of HRQoL.[14-17] Thirdly, physical activity is also useful in assisting other self-care behaviours in CHF, such as weight management, and lipid profile.[14-17] Although, the adherence to physical activity recommendations in CHF is largely unknown, the adherence of physical activity following cardiac rehabilitation are staggering with 60 to 80% of people failing to comply with physical activity recommendations post program completion.[18, 19] Hence, interventions which promote adherence to physical activity recommendation are likely to be useful in secondary prevention.[18, 19]

Regular physical activity increases cardiorespiratory fitness, and improves an individual's physical functioning.[1, 20-23] There are objective measurements of physical functioning, such as the maximal and sub-maximal exercise test.[24] There are also subjective measurements such as self-reported questionnaires.[25] In terms of objective exercise tests, as discussed in Chapter One, maximal exercise tests have a high intensity nature, which is not always well tolerated by people with severe functional limitation and are often replaced by sub-maximal exercise testing.[26] The reason we did not use the 6MWT as the primary outcome measure was that, the Home-Heart-Walk intervention itself was adapted from the 6MWT. There was a concern over the validity of the result, when using a test that is too similar to the study intervention. For the present study we have chosen to use the score of SF-36: physical function domain, as the primary outcome measure for physical functioning.

7.5 Impact of the Home-Heart-Walk

The aims of the Home-Heart-Walk study were to evaluate the impact of a self-monitoring intervention: the Home-Heart-Walk on the following aspects: 1)

physical functioning; 2) self-care behaviour; 3) exercise self-efficacy and physical activity level; and 4) health related quality of life. Overall, there were no statistical significant or clinical significant changes observed from baseline to six-month follow-up.

7.5.1 Physical functioning

Medical Outcome Study Short Form-36: Physical function

Physical functioning can be improved by regular physical activity. Measures of physical functional capacity have been used as indicators of habitual physical activity.[27] In Chapter One, it was proposed that by assisting people gain experience, skills and strategies with a simple physical activity and providing a tool for self-monitoring physical capacity could potentially improve an individual's physical functioning. Participants physical functioning was measured as the primary outcome by the physical function domain of the SF-36 and objectively by the 6MWT.

As mentioned previously, this study group was a younger group compared to other CHF studies with a disease management focus, where the mean age was 71 years.[5-8] In this group of CHF participants, the SF-36 physical domain score was lower compared to a general Australian population (n=3014, mean 84.6, 95% CI: 83.9-85.4), which was expected in people with CHF.[28] On the other hand, the baseline mean score of this study group was similar to other CHF studies.[1, 29-31]

Analysis of the change over time, and between group differences in these 67 participants who had completed the study at the time of interim analysis did not support the study hypothesis, although the final outcome of the study will not be known until all participants have completed the study. There was a small (2 points SD 15.5), non-significant change in the mean score of the physical function domain for the intervention group, and an even smaller, non-significant change (0.7 points SD 20.5) in the control group over the six month study period. These changes are not considered to be clinically meaningful (minimum of 5 points difference in score).[32, 33] This was different to the finding from a study done

by Collins and colleagues (2009), in a group of 27 CHF participants (mean age of 65 years), found 10.4 (SD 18.5) points increase in the physical function domain of the SF-36 in the exercise group, compared to 4.7 (SD 12.5) points decrease in the control group.[1] At the same time, the effect mean difference between exercise group and control group was also significant in Collin and colleague's study (p=0.025).[1] In their study, participants attended 12 weeks of three sessions/week supervised exerciser training, followed by 12 weeks weekly supervised exercise training. The author explained longer supervised training is required for older sedentary adults, as they may need longer time to adapt to the initial rigors of exercise training and to get full benefit from the program.[1] It is suggested that longer training programs may be useful in assist the individual in developing long term adherence.[34]

Although, we did not observe an improvement in the intervention group in our study, there was also no meaningful deterioration in either group. The Home-Heart-Walk was designed to be an intervention that can be easily incorporated into other home-based, multidisciplinary interventions. The impact of Home-Heart-Walk on physical functioning, physical activity level, in addition to a CHF management program requires evaluating in future research.

The Six Minute Walk Test

While an individual's subjective perception of their functioning is important, it may not accurately reflect their functioning objectively. This is because symptoms of CHF are not necessarily dependent on the severity of the condition.[35] In a study comparing hospital-based and home-based exercise training in people with CHF, found a 12.1 point of increase in SF-36 physical function domain, in the hospital based exercise group and a much smaller change in the home-based exercise group (4.8 point increase).[31] At the same time, the increase in the 6MWT distance was similar in both hospital based and home-based exercise groups.[31] The between group difference of physical function domain in the above mentioned study may reflects the effect of social interaction or close supervision in a hospital based exercise program, on

individual's perception of their physical functioning, which was supported by the similar changes in a objective measure, the 6MWT distance.[4]

In our Home-Heart-Walk study, despite no significant changes over time and between groups were observed in self-reported physical functioning (SF-36: physical function domain), a statistically significant improvement (12.2m, [95% CI 0.0, 23.0] *p*=0.05) in the 6MWT distance from baseline to six-month follow-up in the intervention group was seen. The change in the 6MWT distance in the control group was very small (increased 2.1m [95% CI -5.6, 9.8] *p*=0.574). While this is a good explanation of the study results and the change of 6MWT distance was statistically significant, a change of this size is not considered to be clinically meaningful (minimum meaningful change reported in literature was 43m-54m).[7, 36-38] However, it is important to note that the study results also shown there was a moderate strong correlation between individual's age (*r*=-0.423, *p*=0.001); arthritis status (*r*=-0.373, *p*=0.003) and NYHA function class (FC II, *r*=0.514, *p*=0.000). There was also a correlation between the participant's exercise self-efficacy level (*r=0*.420 *p*=0.001) and baseline physical activity level (*r*=0.395, *p*=0.001) and the 6MWT distance. Therefore, based on the characteristics of this group of participants with CHF, there was limited room for improvement in 6MWT distance. This is supported by findings from other CHF studies, which demonstrated similar changes in the 6MWT distance (range from 10m -23m).[39-43] In addition, in a CHF study of 60 participants, the authors noted the 6MWT was more responsive to change in deterioration than improvement.[7] Although, there were two CHF studies reported larger changes (95m; [95% CI 12m-178m] and 88m [95% CI:44m-132m]),[44, 45] they had relatively small sample size (n=28 and n=99) and larger confidence interval compared to other studies.[39-43]

Result of this study should be interpreted within the limitation of small sample size, and missing data. There were ten participants who did not return for follow-up. Therefore using carry forward imputation method, their 6MWT distance at baseline/three-month follow-up was imputed to six-month follow-up value. The limitations of this approach are recognised. The ten participants who did not

return for follow-up to the rest of the participant, they have a shorter baseline 6MWT distance (118m shorter), which could have affected the study results. It also reflects that they were a sicker group of patients. Issue with missing data will be discussed in detail in later section.

Impact of the Home-Heart-Walk on physical functioning

Unlike many other CHF studies, which found improvement in the intervention group while deterioration in the control group,[46-49] in our study, there were no deterioration observed in control group. Considering the disease trajectory of the CHF population,[50] this interesting finding warrant further discussion on why and how there was no observed deterioration in either group, as well as the difference from perceived physical functioning and objective measurement.

The results of multi-component physical activity programs in CHF are inconclusive as discussed in Chapter 2. While some studies demonstrated effect of intervention by observation of improvement in the study intervention group and deterioration in the control group,[46-48, 51] there are also many other studies had similar findings to our Home-Heart-Walk.[39, 49, 52, 53]

The similarity among Home-Heart-Walk and studies, which did not find between group differences was that, the care study control group received were more than just usual care, but involved the use of pedometer,[39] education session or psychological support, [39, 49] or telephone follow-up in the case of our study. It was discussed in Chapter Two, findings from the literature may suggest interventions such as monitoring and education can be effective on HRQoL, including perceived physical functioning. Cardiac rehabilitation programs involving exercise training, education and psychosocial support and its benefits are evident in the literature.[54-56] Thompson and colleagues [57] suggested in their review that the mechanisms through which rehabilitation is effective are unclear; programmes might exert a cardio-protective mechanism through exercise training, or might also be serial surveillance or social support.[57] The impact of study protocol for control group such as psychosocial support or telephone follow-up will be discussed further later in the context of “usual care”.

Whether these components had any impact on the perceived physical functioning of the participants in the control group, requires further investigation. Nonetheless, this study results should be interpreted within the limitation of a small sample size and interim analysis. At the time of data analysis, this trial was still recruiting. Because we have not achieved our target sample size (166), the results of the first 67 participants was ambiguous at this point of time to whether the Home-Heart-Walk have had any impact on participants' physical functioning.

7.5.2 Self-care behaviour

Measuring changes in self-care behaviours after intervention is considered an important performance indicator for CHF management programs.[58, 59] However, in RCTs this health outcome has been infrequently reported.[60, 61] A review of 14 instruments published in peer-reviewed journal, suggested there was only two disease-specific measures of self-care in CHF population.[62] They are the European Heart Failure Self-care behaviour scale (EHFScBS),[59] and the Self-care Heart Failure Index (SCHFI).[63] The author of the SCHFI acknowledges that the SCHFI only measures an individual's self-care response to two symptoms associated with CHF,[63] which limits its use. The EHFScBS use in the Home-Heart-Walk study is appropriate, as it is reliable and valid in evaluating outcomes of heart failure management programmes and it includes physical activity as an item. In this scale, a lower score indicates better self-care behaviour, and a higher score indicates less desirable self-care behaviour. The mean score at baseline for this study group was 25.9 (95% CI: 24.1-27.9), which was significantly lower compared to the CHF group in which this instrument was developed and tested (33.3).[59] The author of the EHFScBS suggested that prospective studies should be compared to define clinical meaningful changes.[64] In the literature the EHFScBS in CHF groups range from 24.2 to 38.[59, 65, 66] Lower score indicates that the participants in the Home-Heart-Walk had better self-care behaviour at baseline, which maybe a result of quality of care delivered at St Vincent's Hospital and they have been involved in CHF management programs. In

spite of this, there are ongoing discussions about how to define when self-care behaviour reaches a satisfactory level.[64]

As poor self-care behaviours are detrimental in the prognosis of people living with CHF,[67] there have been many investigations into interventions improving the self-care behaviour of people living with CHF.[58, 67] In our study there were no observed differences of the EHFScBS between intervention and control group at baseline. Although there was a slight improvement (-2.2 points SD 6.6) in the intervention group compared to a slight decline in self-care behaviour (1 point SD 5.7) in the control group, there was no statistically significant or clinically meaningful changes. This finding was similar to a study of 60 CHF participants (mean age 79 years), which also failed to demonstrate significant impact of the intervention on self-care behaviour (change of 2 points in score in 12-month).[68] Similar to the impact on physical functioning as discussed in previous section, it appeared to be interventions involves close supervision and intensive contact with health care professional have better effect on influencing participants self-care behaviour(n> 100; p<0.05 for these studies),[69, 70] compared to intervention only involved single education session and/or telephone follow-up.[58, 68, 71]

The Heart Foundation resource [72] on self-care suggests that not only evidence-based intervention, but incorporates input from patients and health professionals to target known limitations to accessing accurate and relevant information are important. Consideration of health literacy in promoting self-care, such as defining “low salt” and information on how to read food nutrition panels. Clark and colleagues [73] also identified symptom monitoring with timely use of health services is an important aspect in behavioural and lifestyle management in CHF. The Home-Heart-Walk was designed to assist individual with self-monitoring and promote early recognition of signs and symptoms to prevent deterioration. Although, result from this interim analysis did not support the hypothesis that participants in the intervention group will have improved self-care behaviour at follow up, the trend of improving in self-care behaviour was encouraging and worth further investigation at completion of the Home-

Heart-Walk study, when all participants have completed the study. Besides a known limitation of small sample size, study intervention related issues; such as supervision and client-health care provider interaction requires consideration.

7.5.3 Exercise self-efficacy and physical activity level

The role of self-efficacy in influencing health behaviour has been increasingly recognised.[19, 74, 75] It has been used as a theoretical construct to promoting self-care in CHF population.[74, 75] Exercise self-efficacy was measured by using the Bandura's Exercise Self-efficacy Scale.[76, 77] This 18-item exercise self-efficacy scale developed Bandura, has been shown to be a useful measure of exercise beliefs.[76, 77] Motivating people to do regular physical activity depends on several factors, among them perceived self-efficacy which has been found to be a major instigating force in forming intentions to exercise and in maintaining the behaviour for an extended time.[74, 78] The theory of self-efficacy in predicting initiating and maintaining a regular physical activity regime has been studied by many,[74-77, 79-82] In a study of 42 CHF participants, there was a significant improvement observed in the intervention group compared to the attention-control group (p=0.03), using a 5-point cardiac exercise self-efficacy scale.[83] Similar results were found in a TaiChi exercise program in a group of 100 people with CHF (p<0.001).[84] Although, the Home-Heart-Walk was a theoretically derived intervention, with strategies to overcome barriers to physical activity, we did not observe improved exercise self-efficacy in either the intervention or control group at this time. This observation also needs to be interpreted with in the context of an interim analysis. The mean exercise self-efficacy score of the study group at baseline was 75.7 (95% CI: 66.2-85.3). Overall, there was a slight decrease of physical activity self-efficacy of the intervention group. The score decreased by 3.8 points from baseline to six-month follow-up in the intervention group and 2.5 points in the control group. These changes in exercise self-efficacy score were not statistically significant.

Physical performance was found to depend on efficacy beliefs in people with chronic conditions.[85, 86] In heart disease, it was found that efficacy beliefs predicted both under-exercise and overexertion during programmed

exercise.[85] Therefore, with the observed slight decrease in exercise self-efficacy score of both the study groups, we would expect to also see a slight decrease in physical activity level in both groups. Nonetheless, while the number of mean physical activity sessions per week decreased slightly in the control group (mean: 7.2 sessions/week to 6.4 sessions/per week), there was a slight increase observed in the intervention group (mean: 5.8 sessions/week to 7.0 sessions/per week).

There are a few points should be considered. Firstly, self-efficacy is greatly influenced by an individual's experience.[87] In the CHF population, individuals' physical functioning is affected by condition severity and symptoms.[14, 79, 88] Hence, the perception of their own ability to undertake physical activity. Secondly, during the administration of this scale, many study participants found it difficult to relate to Item 2 of the scale "when I am feeling under pressure from work"; item 10 "after holiday" and item 16 "during holiday" to their current life. It is known that the majority (77.6%) of the participants were retired and reported that they had not had holiday in recent years, which may have affect the results. This exercise self-efficacy scale has been validated in an Australian cardiac rehabilitation population; its utility in CHF may also require further investigation.[77]

Another interesting and important point to considered is that, one study looking at the growth trajectories of exercise self-efficacy in older adults, suggested participating in physical activity intervention does not always lead to improvement in exercise self-efficacy.[89] This was supported by a number of other studies.[90-92] In a group of cardiac rehabilitation program in 273 individuals, while the risk of discontinuing regular exercise decreased in the intervention group, there was a decreased exercise self-efficacy score over the one year follow-up period, and across three assessment points, in both intervention and control group.[92] The hypothesis is, the target population of such studies are adults who are generally inactive, their exposure to physical activity was limited and initial efficacy estimations may have been hopeful overestimations.[89] In another word, they lack an appropriate frame of

reference for evaluating their capability to maintain a behaviour that have not yet undertaken.[89] Our study results demonstrated decreased self-efficacy scores in both group, but the increased physical activity in intervention group, appeared to provide preliminary evidence to support this hypothesis. If this is true, it has particular important implications for trials and interventions designed for older and inactive population. It is suggested in research study, exercise self-efficacy should be assessed frequently in the early stages of an intervention in order to determine strategies to increase efficacy.[89]

7.5.4 Health related quality of life

Although the primary outcome was the physical function domain of the SF-36, all eight domains were analysed. In CHF, numerous clinical indicators are employed to monitor people's health status over time, including physician assessment; exercise capacity; fluctuations in body weight; and biomarkers. Often, changes in an individual's own perceptions of their health status may not be readily apparent to the clinician or may not be reflected in these assessments.[93] As a result HRQoL measures are increasingly being used to provide complimentary and additional insight into the health status of a person.

Medical Outcome Study Short Form-36

The SF-36 was used in this study to assess HRQoL in study participants. The present study did not show significant changes in participant's SF-36 score, for each individual domain. The SF-36 was developed to gather information about the individuals' multidimensional health concepts and a measurement of the full range of health domains, including well-being and personal evaluations of health. It is the most widely and extensively used generic measure.[25, 29, 32] It is short and has found to be reliable and valid across numerous population samples.[25] However, there are reports of ceiling and floor effects in its use in chronic diseases compared to disease specific HRQoL instruments.[46] It has been found to be more sensitive to small degrees of impairment in quality of life. An advantage of using this generic instrument is the possibility to compare outcomes from this study across disease groups and different types of

intervention.[94] Yet, these general measures of HRQoL are likely to be insensitive to change that is related to CHF.[93, 95]

The incidence and prevalence of CHF in the elderly population is high.[96-98] This fact needs to be taken into account when using this SF-36. A study of older adults found that there were missing responses associated with the questions on work and vigorous activity, frequently regarded as not applicable by elderly people.[52] Hayes et al. [52] surmised that people under 75 years old could usually complete the SF-36 without difficulty, but those older than 75 years may need assistance, especially if they have poor physical and mental health. Participants in the Home-Heart-Walk study were aged between 20 and 94 years. The mean age of these study participants was 61 years. There were no difficulties in administering the SF-36 to study participants in our study. This maybe a result of having study personnel to administer the questionnaire.[99] On the other hand, it is suggested that an interview-administered SF-36 has a tendency to result in systematically higher ratings compared to postal questionnaire (self-administered).[99] This will also need to be taken into consideration when analysing and interpreting the final study results. Comorbidity associated with elderly patients can cause insensitivity to small clinical change.[56] Therefore, the SF-36 is suitable to be used in CHF population. Nevertheless, it is recommended that the SF-36 is to be used in conjunction with disease specific questionnaires.[95]

Minnesota Living with Heart Failure Questionnaire

The MLHFQ is a disease specific instrument for use in CHF.[100-102] It assesses the individual's perception of the effects of CHF on the physical, social economic and psychological aspects of their life.[102] This measure is easy to administer, short and easy to understand. The MLHFQ has been found to be valid in comparison with other health outcome scales. It is the most popular measure, and it is designed to be a self-assessment measure for use in clinical trials to assess the effects of drugs, devices or interventions.[101, 102] In the MLHFQ, the higher the score, the more influence/burden CHF has on the individual's life. The concern over the MLHFQ is that of the individuals' ability to separate symptoms

and impairments related to heart failure from other co-morbidities.[93] Using a disease specific as well as a non-disease specific instrument was strength of the study and was undertaken to focus on physical functioning.

Impact of the Home-Heart-Walk on health related quality of life

At baseline the total cohort of 67 participants had similar score in physical function of the SF-36 (54.0 Vs 57.8); general health (42.3 vs 42.1); vitality (45.1 vs 45.2); social function (67.9 vs 74.1); role emotion (69.0 vs 72.9); mental health (65.6 vs 62.9) compared to CHF normative data.[29] The score in role physical (55.7 vs 48.1); pain (69.6 vs 50.7) were relatively higher. [29] The score in the pain domain is almost the same compared score in the US general population (71.3) and slightly lower than the Australian general population (76.5).[103] This finding was similar to other CHF studies.[104] Comparing the intervention and control group, there were no significant difference between groups in all eight domains (p>0.05). Improvement of HRQoL using SF-36 [30, 105] have been demonstrated in research studies, which was not observed in the Home-Heart-Walk study, with no statistical significant (p<0.05) change over the six month study period or between groups. Two domains had clinical meaningful changes from baseline to three-month follow-up in the intervention group. These two domains were vitality (44.4 to 49.8) and social function (62.8 to 72.2) (minimum of 5 points change).[25, 28, 29, 32, 99] A trend in improvement was also observed in the intervention group from baseline to three-month follow-up, in role physical (mean of 53.0 to 56.3), pain (69.6 to 73.0), and mental health (61.8 to 65.8). Yet, these improvements were not sustained at six-month follow-up. Out study result contrary from Stewart et al [106] which suggested that the effects of multidisciplinary home-based interventions could be sustained for periods up to 18 months.

Similar findings were observed in MLHFQ scores. Although there was no statistically significant change, the deterioration (mean total score: baseline 36.3 to three-month 43.9 to six-month 41.9) observed in the control group was clinically meaningful (5 points change).[100-102] The improvement observed in intervention group from baseline to three-month follow-up (baseline 45.4 to three-month 41.7) is also noteworthy in the context of a chronic, progressive condition. Nonetheless, this improvement was not sustained at six-month follow-up (mean 44.2). These results vary from the findings by Bellardinelli and

colleagues (1999),[46] where the total score of MLHFQ in the intervention group (n=50) significantly improved compared to control group (n=49), from baseline to 26 month follow-up (p<0.001). However, in that study, the intervention involved 12 months moderate exercise training, with supervision.[46] Looking at the physical and emotional domain of the MLHFQ, the score of the intervention group in both physical and emotional domain stayed relatively the same (1 point change in physical domain; 0.5 point change in emotional domain). Among participants in the control group, there was a slight deterioration in physical domain from baseline, (16.3 [95% CI: 12.6-20.0]) to 19.8 [15.8-23.7] to 18.8 [95% CI: 14.8-22.7] and similar pattern found in the emotional domain.

Not surprisingly, in the current literature, some but not all studies have been able to demonstrate an improvement in quality of life from interventions targeting physical activity,[41, 47, 107] using the MLHFQ [41, 46, 108] and the SF-36.[30, 47] It is unclear whether these conflicting results are due to difference of the measures used, the mode of exercise or baseline characteristics of the study population. It appeared to be studies with longer program duration, close supervision, and/or group sessions were more likely to have reported improvement in HRQoL.[30, 46, 109, 110] As discussed previously, a lack of reporting of intervention characteristics, makes it difficult to compare and explore which ingredient of the intervention is effective.[57] It is possible the observed improvement in HRQoL in those studies may be due to social interaction or the presence of a health care professional in the program.[4, 57, 111] Nonetheless, the Home-Heart-Walk was not designed as a separate sole program, but to be used in conjunction with other home-based, multidisciplinary interventions.

7.6 Trial related factors for consideration

7.6.1 Usual care

In spite of non-significant differences between the intervention and the control group over the six-month study period, there was also no significant deterioration observed in either the intervention of control group. One

important point to consider is the nature of the usual care this group of individuals were receiving at the time of participating in the study. The declaration of Helsinki states that the "benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods".[112](section C, item 2) However, even in areas where high-level evidence is available to guide clinicians, substantial variability and inconsistency are present in usual care.[113, 114] An international survey has suggested that most individuals with CHF were appropriately investigated, but there are substantial variations in practice between countries.[115] The inconsistencies between physicians knowledge and the treatment that they deliver, suggests the improved organisation of care for heart failure is required for better outcomes.[115]

St Vincent's hospital, Sydney, where the first 67 participants of this study were recruited from, has an international reputation for innovation and are regarded as a centre of excellence for clinical care, research, teaching and medical leadership. The Heart and Lung clinic where most of the study participants were attending at the time of study is the longest running heart transplantation programs in Australia. The five year survival rate for patients past heart transplant was 76.8%, compared to the world benchmark of 68.3%.[116] The unit is also involved in cutting edge research and numerous clinical trials and has affiliations with Victor Chang Cardiac Research Institute and the Garvan Institute for Medical Research. The medication usage in this study group was comparable to other large CHF trials,[5] (Figure 6.2 in Chapter Six) showed high level use of beta blocker (88.%), ACE inhibitor/ARB (71.6%) and diuretics (80.1%), which has been introduced in CHF management in the last two decades, and suggested to have improved the clinical outcome of CHF.[97] Because of this group of study participants have already been on optimal CHF management at the time of the study, and have little room for further improvement. Hence, it is difficult to show the additive benefits of the Home-Heart-Walk, especially when the sample size is small.

Another issue with usual care in clinical trial is that, how usual is the usual care. In a study aimed to evaluate the effects of "usual care" on cardiovascular risk factors in a clinical trials suggested follow-ups with multiple examinations to collect trial information, may actually enhance quality of care.[117] This was also evident in our literature review of 18 RCT of physical activity interventions in CHF, where a number of studies failed to demonstrate between group difference.[39, 49, 52, 53] It is suggested that due to the large number of known and unknown differences in a complex intervention, differences and heterogeneity are inevitable.[118] Thompson and colleagues also identified that a lack of reporting in intervention characteristics is a challenge to unravel the active ingredients of an intervention in different populations and to determine what works for whom.[57, 111]

In this Home-Heart-Walk study, although we had no face to face contact with the participants in the control group until at three month and six month time, participants were telephoned monthly. A Cochrane systematic review indicated Structured telephone support and tele-monitoring are effective in improving HRQoL, reducing the risk of all-cause mortality and CHF-related hospitalisations in patients with CHF.[119] In our study, this monthly telephone call intended only to obtain information regarding rehospitalisation and cardiac events. When there were questions and concerns raised during the telephone call, participants were advised to contact their medical care provider for follow-up. Despite the neutral tone of the telephone call, it may have an effect on individual's health behaviour. In an "ideal" trial, participants would have not have been alerted to contact their clinician for follow-up in such situation. However, that would not be considered as ethical. Therefore, the above characteristic of been in the usual care group, may partially explain, the lack of observed between-group differences of the outcome measurements at six-month follow-up.

7.6.2 Missing data

Despite all effort in obtaining complete data, there were still missing data present in our study data set. Missing data presents several problems to the analysis including difficulties in variable selection, reduced power, and the

potential for bias in the interpretation of results.[120] Listwise deletion is the default method for dealing with missing data in most statistical software packages.[121] However, deleting these cases in a study with a small sample size can be problematic. It will reduce study power and possibly introduce bias into study results.[120]

In this study, missing values at six-month, due to participants not returning for follow up, were replaced by using carry-forward imputation method. Baseline missing values could be imputed by using either multiple imputation or treatment mean imputation. Among all the questionnaires there were 12 single values (12 items) missing at baseline. These missing values were caused by unanswered questions by participants. Because the number of missing values at baseline was very small, either using multiple imputation method or treatment mean imputation method would not make difference in the study result.[120, 122] In addition, multiple imputation requires information regarding adverse event and information on other variables, if inappropriate model was used in multiple imputation method, it could introduce more bias compared to treatment mean imputation.[122, 123] Therefore, after weighting the strengths and weaknesses of a range of approaches, for a small number of missing value, the treatment mean imputation was used to impute baseline missing values.

7.6.3 Follow-up adherence and regime adherence

The challenges of non-adherence in clinical practice have considerable relevance for conducting research because of the corresponding impact of psychological, behavioural, and system factors.[124] People's willingness to participate for studies evaluating the effects of investigational intervention, and their diligence, in following research protocol are fundamental to clinical research. There are two primary types of adherence in research, and they are 'follow-up adherence' and 'regime adherence'. Follow-up adherence refers to fulfillment of the scheduled sequence of assessment measures within a planned time period.[125] Whereas regimen adherence refers to following the assigned regimen consistently as study program protocol.[125]

The Home-Heart-Walk study was designed to have six-month follow-up. This is because six-month or above is what could be characterised as long term, and is considered as physical activity maintenance.[126] Ten participants (seven in the intervention group, and three in the control group) did not return for six-month follow-up, resulting in a dropout rate of 13%. Therefore, the follow-up adherence of this study was 87%. Those who did not complete study protocol were more likely have lower physical functioning level (shorter 6MWT distance [118m difference] and worse NYHA functional class), supporting that limited physical functioning as the barriers for attending clinical appointment/clinical based program.[19, 127-129] Because intention-to-treat analysis was pre-specified in the study protocol, baseline values were imputed for those participants who did not return for six-month follow-up.

Lasagna and Hutt [130] estimated that 25 to 50 % of research participants are not adherent to the study regime. Within the 30 people who started the Home-Heart-Walk program, there were 14 who did not provide a record of adhering to the self-monitoring program. Adherence was defined as completion of 80% of weekly Home-Heart-Walks during the six-month study period. The adherence rate of this study was 53%. Although, adherence can falter for many reasons, and low adherence can affect the analysis of treatment effect, understanding the addressing adherence-limiting factors are important in behavioural, and intervention development research.[130] In this present study, the non-adherers were more likely to be younger and with less co-morbidity. This analysis was pre-specified in the study protocol, and only included the first 67 participants. Because of the small sample size, we cannot suggest younger people with less co-morbidity were less likely to adhere to this self-monitoring intervention. In fact, Kinner and colleagues (2009) suggested in their study, that people who are older and with more comorbidities were less likely to adhere to the physical activity program in their study.[131] Whether this is because of the differences in lifestyle, imposed by participants' characteristics, such as age, employment status, requires further investigation. Another point to consider is that when a proportion of participants do not receive the assigned treatment (either

intervention group or control), a dilution effect, resulting in a decreased estimate of treatment effect, generally results. Although this is a limitation, it reflects the potential real world experience in which not all of the participants adhere to treatment recommendations. While dropout and non-adherence are seem to be an appealing explanation for lack of effect seen in this study, sensitivity analyses of completer only still showed no differences between groups.

7.7 Strengths

Using a RCT design is generally considered to produce the most robust evidence for the effectiveness of health interventions.[132] The RCT design reduces bias by controlling for factors, both known and unknown.[132] This study evaluated a novel and conceptually consistent method of promoting physical activity and self-monitoring. It is conceptually consistent as it uses specific, measurable, relevant and timed elements, informed by theoretical principles of self-efficacy. The study design has played close attention to the attitudes and preferences of study participants. This study has been conducted observing methodological rigour and adherence to ethical guidelines.[133] Wherever possible, standardised measuring devices have been used. As well as follow-up, the assessor was blinded to participants' allocation. Further, the sample was derived using formal sample size calculations to estimate the desired effect. Of note, the ease of administration and willingness to participate was not the same as in non-heart failure population, in which this concept was initially trialed.[134]

7.8 Limitation

Firstly, it is important to recognise that this is an interim analysis, due to time constraints of the PhD. Despite using a RCT design, research into behavioural interventions presents specific challenges. Interim analysis could precipitate protocol modification; it could suggest particular benefit or harm of the studies intervention and lead to early termination of the trial, which all could potentially introduce bias.[135] For this Home-Heart-Walk, the interim analysis also allowed the completion of the candidate's PhD thesis within the allocated resource and time frame.

The primary concern of this interim analysis is weakening blinding aspect of this trial. For this reason, the analysis was undertaking with a statistician who is not involved in the Home-Heart-Walk study. Results from this interim analysis are not discussed with the research nurses who are involved in ongoing study recruitment and assessment. Secondly, repeated data analysis increases the chance of observing a large statistical fluctuation, hence the observation of false positives.[135] These possible biases are especially important in a trial with multiple outcome measures and comparing treatment effect between groups. Interpretations and conclusions were taken with caution for the interim analysis, and will be for the final data analysis when the study is completed. Other limitations of this study are discussed below.

7.8.1 Sampling

Convenience sampling involves the use of the most conveniently available people as study participants.[136] The limitation associated with convenience sampling is that, the available people may not be representative to the population, and may carries risk of bias and erroneous findings.[136] In spite of this possibility the social, and demographic characteristics observed are typical of the population from which the sample is derived as discussed above.

Considering sampling methods is important in interpreting findings from research studies [137]. This study has evaluated the impact of Home-Heart-Walk program on people's physical functioning, exercise self-efficacy, self-care behaviour and HRQoL. The theoretical framework of this study is based on self-management and adherence to health recommendations. The research on interventions improving self-management and adherence to health recommendation are often biased by the participant characteristics. Participation in studies are voluntary, hence they are more likely to have higher motivation in managing their conditions. Interpretation of the study results need to take this sampling bias into consideration. However, a randomized controlled trial design was employed.

7.8.2 Sample size

In Chapter Five, the sample size calculation showed 166 participants were required to detect a difference of at least 20 points for the primary outcome measure. As previously explained in Chapter One, this thesis reports the results for the first 67 participants recruited for the Home-Heart-Walk study reaching the primary outcome. This interim analysis allows for timely submission of the thesis, and also establishes the potential for benefit or futility in a novel application of the Home-Heart-Walk. Conversely, the small sample size also limited data analytic options for this study. With a small number (67/113) of participants have completed the study, regression analyses were inappropriate in the statistician's view. Hence, the discussion cannot be definitive at this point of time.

7.8.3 Issue with self-reporting

The use of self-reported instruments could be a potential limitation of this study, because the risk of over reporting or under reporting from the participants and is likely to be evenly distributed between the randomised groups. However, this is inevitable with any kind of study using self-reporting instruments. Although the self-directed Home-Heart-Walk program appeared simple to follow, the risk of following the protocol incorrectly still exists. Inappropriate diary reporting may hinder inappropriate management planning by clinicians. If the Home-Heart-Walk measurements were to be used as an indicator of functional status, it requires careful assessment of individual's home environment and adequate self-management education to ensure accurate monitoring. Measurement biases are inherent in a range of test, whether administered by patients or health professionals. Including systems of checks and balances and interpreting test results, within the context of the total clinical picture, it is likely to eliminate adverse effects related to decisions made on incorrectly reported data. In this study, although the primary outcome was a self-reported physical functioning, the 6MWT distance was measured as a secondary outcome due to the close association of the intervention with this outcome. The results had also suggested

a correlation between the self-reported physical functioning and the 6MWT distance (r=0.492, p= 0.000).

In this study, the level of physical activity was also a self-reported measure. Options such as a pedometer were considered at the design stage of the study. Although pedometers and accelerometers has been shown to be motivational to people's daily physical activity,[138] there are a couple of practical issues in using pedometers in research study.[138, 139] Issues such a adherence with the pedometer protocol; the decreased number of individuals who would agree to participate due to additional burden of wearing pedometer; identification and treatment with extreme values, and estimating physical activity level with difference in pedometer wearing time.[139] For those reasons, we have decided to use a self-reported measure for participants' physical activity level. A focus of this study has been the use of the Home-Heart-Walk protocol as a self-monitoring tool.

7.8.4 Blinding

Blinding is difficult to achieve in a trial evaluating an intervention and, when feasible, relies on complex methods and specific designs. Although it was not possible to blind participants or the researcher to the intervention, blinded assessment of three-month and six-month outcomes was implemented in an attempt to ensure data was relatively free of any information bias. In addition staff from the research centre was not involved and they were remote to the study site. Attempts were also made to standardise telephone call delivery by the use of a protocol.

7.8.5 Contamination

Although, no participants assigned to the control group crossed over to the intervention group, and participants randomised to the intervention group were asked not to discuss the study with fellow CHF participants attending in the same heart failure clinic, it cannot be guaranteed that this did not occur. Similarly, the staff at the study sites were provided with a brief explanation of the study to facilitate recruitment, it cannot be assumed that staff did not undertake their

own exploration of self-monitoring while providing care and information to individuals attending the clinic.

7.9 Challenges in promoting physical functioning in CHF

As the burden of CHF is increasing, there is a need for innovative approaches and self-care interventions to better care for people living with this debilitating syndrome.[111, 140, 141] Thompson and colleagues stated, many cardiovascular disease management programs are multi-faceted and diverse in design with a multitude of contextual factors.[142] New approaches need to seek appropriateness, feasibility and effectiveness. The three major challenges facing nursing programs are to explore the strength of evidence; what works for who; when and why; and strategies to best evaluate complex interventions.[143] Despite the limitations of a small sample size and interim analysis, our results highlighted the challenges in promoting physical functioning in people living with CHF. Firstly, people with CHF are predominantly elder people, as demonstrated in our study their functional capacity (measured by the 6MWT) was strongly influenced by their age and status of arthritis. There would be little room for improvement in addition to optimal CHF management in their physical functioning. Therefore, it is challenging for interventions to demonstrate significant treatment effect on physical functioning in this group of people.[50, 144] Whereas measuring individual's perceived HRQoL has became a more important and appropriate assessment item in this context,[93] as well as improved daily physical level functioning.[16] It is more and more recognised that assessing an individual's perceived HRQoL is as legitimate and valid as the clinician's assessment and it is a central component of health care.[93] As Thompson and colleagues described, within the context of cardiovascular research, nurses are in a appositely position within cardiovascular health services to initiate, engage and lead collaborative research, which will result in rapid clinical changes and improved care for people living with CHF.[142] Therefore using appropriate and acceptable patient reported outcomes is also an important consideration.

7.10 Conclusion

Interventions to promote and monitor physical activity are important within the growing burden of chronic disease. In this study, it was expected that the study intervention would increase the physical functioning of participants in the intervention group, through improved self-monitoring and promoting self-care behaviours. The Home-Heart-Walk was directed toward helping individuals to become and remain motivated and confident with self-care in the context of their CHF condition. This interim analysis was not conclusive as the trial is ongoing.

Although, there was no observed improvement in the intervention on study outcome measures, alone with many other studies reported in the literature, it appears that self-efficacy is an important aspect for consideration in the development of intervention targeting physical function and self-care behaviour (such as adherence to physical activity recommendation); and program with a multidisciplinary in approach, tailored to the needs of the individuals with a theoretical foundation are more likely to be effective. The implications of the Home-Heart-Walk study on policy, practice and research will be discussed in the next chapter.

7.11 References

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Chapter 8
Conclusion: implications for policy, practice and research

8.1 Introduction

The previous chapters have provided a discussion of the importance of physical activity in improving health outcomes. This thesis has provided the rationale and conceptual model of a randomised controlled trial to evaluate the effect of the Home-Heart-Walk on physical functioning, self-care behaviour and HRQoL in a group of people with CHF. Preliminary findings from interim analysis have also been presented. As the final sample size of 166 has not been achieved at the time of the data analysis, it needs to be cautions when interpreting the findings. Although, no definite conclusion can be drawn from the interim analysis in regards to the effects of the intervention, the Home-Heart-Walk program is a novel approach to support self-management in people with CHF. This chapter provides a summary of this research and identifies implications for policy, practice and research, which should be viewed in the context of an interim analysis.

8.2 The Home-Heart-Walk program

Physical functioning is correlated with prognosis, survival and quality of life.[1-4] There has been an extensive literature that supporting the safety and benefits of physical activity in the management of CHF. In spite of these benefits, long term adherence to physical activity recommendation following program completion is a challenge to researchers and health care providers.[5, 6]

Extensive literature has identified that, there is significant improvement in health outcomes associated with exercise training (increased peak VO2, exercise duration, work capacity, and 6MWT distance).[7] Seven of the nine trials that measured this outcome all concluded that HRQoL improved with the introduction of exercise.[7] The review of psychological interventions suggested that a reduction in symptoms of depression and improvement in exercise capacity result from psychological interventions.[8] Research has repeatedly supported the utility of exercise interventions among adults with CHF. With exercise improving physical function capacity, decreasing symptoms, improving HRQoL and reducing hospital admission.[9-11]

The Home-Heart-Walk assists individuals to self-monitor physical functional capacity and encouraging recognition and response to functional change. This is a novel approach as it combined both the exercise self-efficacy model and a self-monitoring concept. As discussed in Chapter One, self-monitoring by people with chronic conditions has been linked to improved body awareness, better communication with health care professionals and in an improved sense of self-efficacy in self-care. The Home-Heart-Walk seeks to promote physical functioning through prompting physical activity using a method that is accurate and reproducible; as well as to provide a measurement whereby individuals and their clinicians can monitor their condition. It is believed that better self-monitoring assist people's self-care by facilitating decision making in symptoms recognition and taking appropriate action to address the symptoms. The Home-Heart-Walk is also designed to increase self-efficacy for physical activity, and to improve HRQoL. This Home-Heart-Walk study was a randomised controlled trial seeks to evaluate the effectiveness of the Home-Heart-Walk in a group of people living with CHF.

The study aims were tested through a randomised controlled trial with two parallel groups. Participants in the intervention group undertook the Home-Heart-Walk, which lasted for six months. Participants in the control group continued their usual care from their health care providers for the six-month study period. Participants from both groups were followed up at three months and six months time. In this interim analysis, an increase in the 6MWT distance in the intervention group from baseline to six-month follow-up was the only measure achieving statistical significance. Although, conclusion cannot be made based on this interim analysis of the first 67 participants, it has also provided preliminary data and suggested a trend of improved self-care behaviour and HRQoL in the intervention group.

8.3 Implications

This study has shed light on the method of promoting physical activity in people living with CHF. Findings of this study underscore the importance of understanding the difference between behaviour initiation and behaviour

maintenance. It is true for any health care intervention (e.g. smoking cessation, diet, medication, and physical activity), that the program is only successful if there is sufficient adherence to the program, as well as adherence after program completion. Not only in the CHF population, but other chronic conditions, failure not adhering with treatment recommendation is detrimental to the individual's prognosis.[5, 12] Yet, adherence is not only related to personal factors, but also condition related, health care system related, socio-economic related and therapy related factors.[12]

Studies show that 60% of people admit following physical activity recommendations is more difficult than following recommendations for medication regime, diet, and medical appointment schedule.[13] Therefore, the challenge facing health care provider is no longer on initiating physical activity regime, but maintaining physical activity over time. These findings from the present study have applications for policy, clinical practice, and research.

8.3.1 Implications for policy

This Home-Heart-Walk study was one of the six funded projects by the Australian Department of Health & Ageing as part of the Sharing Health Care Initiative.[14] Evidence in Australia and overseas suggests that self-management programs can assist people with chronic diseases to improve their HRQoL by equipping them with knowledge, skills and confidence to better manage disease related problems.[15-17] The Sharing Health Care Initiative was designed within the World Health Organisation's framework for Innovative Care of Chronic Disease. This approach was directed toward helping individuals to become and remain motivated and confident with self-care in the context of their CHF condition. This strategic initiative aimed to improve the HRQoL for people with chronic diseases, to encourage people to use the health care system more effectively and to enhance collaboration between individuals and their families, carers and health care professionals in the management of chronic disease.[14] It also aimed to expand the range and reach of quality chronic disease interventions to support self-care and to continue to build the evidence-base on the efficacy of chronic disease interventions.[14]

As part of this initiative, the Home-Heart-Walk program was developed based on the exercise self-efficacy theory and the evidence of self-monitoring intervention.[18] It was directed toward helping individuals to become and remain motivated and confident with self-care in the context of their CHF condition. This study has underscored the importance of strategies, processes and structures to increase physical activity and promote self-care in the community setting.

Contemporary policy and evidence in chronic illness also emphasises the importance of an integrated approach to care.[19] Based upon this thesis incorporating physical activity is a complex process and requires consideration of individual, provider and health care organisation factors. Ensuring policy frameworks provide infrastructure and support of physical activity programs is an important initiative. This was also reflected in a community workshop that was hosted by the Health Networks Brand,[20] where participants from the community expressed their feeling of a lack of home support, and their hope of support for ongoing physical activity after completion of hospital based exercise program.[20] In addition, it was suggested that telephone based programs should be available to people who are slightly unwell but not sick enough to go to hospital, in order to prevent deterioration and rehospitalisation.[20]

Primary and secondary CHF prevention programs are evidence based strategies to improve cardiovascular outcomes. In spite of the considerable amount of evidence demonstrating the benefits of physical activity in people with stable CHF, the maintenance of physical activity is challenging. The Chronic Care Model developed by Wagner [21] provides elements of a systematic approach, with responsive interventions and cross-sector interactions with the patients as the focus to promote high quality chronic disease management.[22]

Management of CHF occurs mainly in the community setting, even though it receives considerable attention in the acute setting.[23] This places a tremendous strains on the primary health section, in particular general practitioners.[24] The transition between the tertiary and primary sectors is being bridged by CHF disease specific programs. These programs have been

shown to have significant ability to reduce all-cause of mortality by 25%,[25] CHF hospitalisation by 30% [25] and all-cause hospitalisation by between 12 to 19%,[25, 26] These reductions were evidence despite the model of intervention. Further analysis of these data suggests enhancing patient self-care, follow-up monitoring by specialist staff and access to specialised CHF clinics appear to make the greatest contribution to these figures.[25] Creating resources and policies that foster partnerships within the community to meet the needs and engage community involvement of its individuals is paramount.[27] Engaging the community is dependent on increasing access to information, fostering awareness and access to appropriate health care personnel. The National Health and Medical Research Council acknowledges the importance of engaging community and recommending a national move towards the distribution of resources and the access and availability of material.[22, 27] Providing sufficient funds for community based care and mechanisms of access are an important focus of the health care reform agenda.[22]

These developments in primary care for people with chronic conditions has been facilitated by initiatives under the umbrella of the Primary Health Strategy.[28] These initiatives have identified and targeted areas such as better rewarding prevention; promoting evidence-based management of chronic disease; supporting patients with chronic disease to manage their condition; supporting the role GPs play in the health care team; as well as encouraging a greater focus on multidisciplinary team-based care.[28] The Primary Health Strategy initiatives aims to facilitate the delivery of better frontline care to families across Australia.[28]

8.3.2 Implications for clinical practice

The benefits of physical activity in the management of CHF, have been repeatedly supported by literature.[7] Only one large multicenter randomised controlled trial of exercise training in patients with CHF has been completed to date.[29] The Heart Failure: A controlled Trial Investigating Outcomes of Exercise Training trial demonstrated that exercise training is safe for individuals with CHF, but overall adherence was suboptimal.[29, 30] Findings presented in this study

are important for increasing our understanding of the adherence to physical activity in people with CHF, and the difficulties experienced by many people faced with the need to make lifestyle changes.[15, 31-33] A high proportion of patient with advanced CHF suffer from refractory symptoms such as pain, breathlessness, persistent cough, fatigue, and limitation in physical activity, anxiety, depression, sleeping problems, nausea and constipation.[34, 35] Symptom control in CHF poses specific challenges. Heart failure is a serious condition, and it is now recognised to be equivalent to malignant disease in terms of symptom burden and mortality,[36] yet, only a small number of people with CHF receive specialist care.[36]

In periods of clinical stability, routine chronic disease management may be sufficient in supporting people with CHF.[37] Whereas in advanced phases, declining in physical functioning requires increased an utilisation of hospital care; and a range of supportive and palliative care services.[36, 37] Therapy can be complex in CHF and symptom management presenting specific challenges.[36] The majority of people living with CHF are elderly and have multiple co-morbidities, therefore strategies for optimal symptom management need to accommodate both cardiovascular and non-cardiovascular conditions.[36] It should be incorporated as part of comprehensive management, across the whole disease trajectory.[36]

Theoretical models have helped us gain better understand of human health behaviour and informed intervention development. Models such as the Health Belief Model;[38] the Theory of Reasoned Action;[39] and the Transtheoretical Model,[40-42] have been used extensively in research. Despite their popularity, these models failed to differentiate between behaviour initiation and behaviour maintenance, as discussed in Chapter Three. These models have informed many research studies into intervention that promotes physical activity in people with chronic conditions. Due to the lack of focus on long-term adherence, few interventions had long-term impact on physical activity behaviour in people with CHF.[43, 44] These models were discussed in details in Chapter Three. The Exercise Self-efficacy Model,[45, 46] which is developed from the Social

Cognitive Theory, is a theoretical model that takes into account of personal, and external factors that affect individual's self-efficacy for physical activity; and it is focused on long-term adherence rather than initiation.[46, 47] Understanding what influences self-efficacy could be very beneficial in promoting health behaviour. Particularly, it is suggested in the literature that self-monitoring by people with chronic conditions has been linked to improved body awareness, better communication with health professionals and in improved sense of self-efficacy in self-managing heart failure.[48, 49] The management of CHF challenges nurses to expand and develop clinical practice and evidence based care. Expansion of home-based CHF nursing services is extending to incorporate medication initiation and titration, in particular beta-blockers and diuretics and facilitation of home-based exercise programs.[19, 50-57]

On both national and state levels management of chronic conditions is on the agenda and innovation and development of patient–centred models encouraged. Currently several coordinated care trials are under evaluation to create a template for this service delivery.[58] Findings from this Home-Heart-Walk study are potentially clinically important. First, despite a willingness to participate in a research study, there was evidence of ambivalence related to physical activity in some people. Many individuals who refused to participate in this study, expressed a lack of confidence in following the Home-Heart-Walk protocol as the reason. Second, the result from this study also highlighted the gap between intention and action, as the adherence rate to the six-month, weekly Home-Heart-Walk program in the intervention group was 53%, similar to adherence rate of physical activity interventions reported in the literature.[5, 13, 59] Third, more focus needs to be placed on strategies to assist people living with CHF to adhere to lifestyle recommendations. Lastly, the results of this study suggested a greater emphasis needs to be placed on assessing and supporting self-efficacy in order to increase the likelihood of long-term adherence to physical activity recommendation. There also a need for more exploration into interventions such as motivational interviewing and psychological support.

8.3.3 Implications for further research

As discussed in the previous chapter, this thesis presented the interim analysis of the first 67 participants who have completed the six-month study. The program adherence rate was 53%. Exploring whether the reasons for low adherence rate related to participating in structured, accountable exercise programs is necessary. A longer period between recruitment and follow-up may have uncovered differences between groups, and could be consider in future research designs. Researching ways to leverage/manipulate self-efficacy can enhance adherence and risk reduction, and should be considered in further research studies.

In as review of adherence to exercise training in heart failure, only eight out of the 14 reviewed trials reported information regarding assessment of exercise adherence.[5] Methodology ranged from the use of pedometers and heart rate monitors to home visit conducted by study nurses.[5] In a recent investigation of physical activity training in CHF, authors employed multiple strategies such as regular e-mail, and telephone contact, heart rate monitor, and exercise diaries, in an effort to determine the effects on physical activity adherence, in a sample of 30.[60] Despite intensive adherence efforts, only 50% of the sample exercised for longer than one hour per week at greater than 60% of maximum heart rate.[60]

In contrast to the extensively studied area of physical activity in CHF, the major CHF physical activity and exercise trials to date appear to have devoted relatively little attention to the issue of adherence.[5] As in the review, there is also an issue with how adherence is defined and measured.[5] While one study defined and presented adherence as percentage of sessions attended,[43] the other used graded the attendance (i.e. good adherence is attendant >80%).[61] Belardinelli (1999),[43] concluded that a long-term, supervised exercise programme improved the HRQoL by means of increased clinical care providing enhanced psychological support for the individuals. Oka and colleague (2005) found that a single exercise test and usual care did not improve self-efficacy in people with stable, mild to moderate heart failure, while participation in a

regular programme of exercise increased self-efficacy in adhering to walking thus enhanced HRQoL.[62]

Factors influencing adherence include individual, condition, system and therapy related factors. Many programs take into consideration of individual related factors, focused on intrinsic barriers, such as improved motivation, and have little emphasis on therapy related or system related factors. It is therefore, important that intervention development increases the focus on tailoring of the program to meet the needs of individual, and to overcome the extrinsic barriers of physical activity in the CHF population. The benefits of physical activity are not limited only to people with CHF. Although the Home-Heart-Walk program was evaluated in the CHF population in this study, its self-monitoring concept, and simple, achievable nature is potentially suited in many other chronic conditions, such as chronic obstructive pulmonary disease. Incorporating the Home- Heart Walk as a monitoring by health professionals and self-monitoring intervention within physical activity or other disease management programs, rather than as an independent intervention in clinical trials maybe be worthy for future exploration.

Based upon this thesis, it is apparent that further attention needs to be placed on promoting self-efficacy. This may be achieved by adding more targeted approaches such as motivational interviewing to the intervention design.

8.4 Conclusion

Chronic heart failure remains a great health burden to the individual, their carers and the wider society. Initiating lifestyle change has been suggested to maintain physical functioning, and improve prognosis. However, this will only be of benefit if the behaviours are maintained over prolonged periods of time. Thus, the challenge facing CHF management goes beyond simply motivating people with CHF to initiate physical activity regime, and extends to supporting them in maintaining these changes for a lifetime.

The benefits of physical activity in reducing cardiovascular risk have led to evidence based recommendations for patients with heart disease, including

those with CHF.[9, 63-66] Adherence to best practice recommendations is often suboptimal, particularly in those individuals, who experience high symptom burden, and feel less confident to undertake physical activity. Self-efficacy is the degree of confidence an individual has in his/her ability to perform a behaviour under a number of specific circumstances and is an important consideration in developing interventions.

The Home-Heart-Walk intervention provides an innovative, theoretically derived intervention to increase the nexus between clinic and home-based approaches [19, 55, 58]. It has also extended the process of developing a novel technique for self-monitoring. As the burden of chronic heart failure persists further development of innovative approaches to promoting and monitoring physical activity is warranted.

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Appendix 1 Ethics approval

memorandum

Curtin University of Technology

Office of Research and Development

Human Research Ethics Committee

TELEPHONE 9266 2784
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EMAIL hrec@curtin.edu.au

To	Professor Patricia Davidson, Centre for Cardiovascular and Chronic Care
From	A/Professor Stephan Millett, Chair, Human Research Ethics Committee
Subject	Protocol Approval HR 170/2008
Date	23 February 2009
Copy	Phillip Newton Centre for Cardiovascular and Chronic Care

Thank you for providing the additional information for the project titled "*Home Heart Walk: evaluation of an intervention to promote and monitor physical activity*". The information you have provided has satisfactorily addressed the queries raised by the Committee. Your application is now **approved**.

- You are authorised to commence your research as stated in your proposal.
- The approval number for your project is **HR 170/2008**. *Please quote this number in any future correspondence.*
- Approval of this project is for a period of twelve months **02-12-2008** to **02-12-2009**. To renew this approval a completed Form B (attached) must be submitted before the expiry date 02-12-2009.
- If you are a Higher Degree by Research student, data collection must not begin before your Application for Candidacy is approved by your Divisional Graduate Studies Committee.
- The following standard statement **must be included** in the information sheet to participants:

  This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 170/2008). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

The attached **FORM B** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development:
When the project has finished, or

- If at any time during the twelve months changes/amendments occur, or
- If a serious or unexpected adverse event occurs, or
- 14 days prior to the expiry date if renewal is required.
- An application for renewal may be made with a Form B three years running, after which a new application form (Form A), providing comprehensive details, must be submitted.

Regards,

A/Professor Stephan Millett
Chair Human Research Ethics Committee

St Vincent's Hospital
Charity, Care & Compassion

A facility of
St. Vincent's & Mater Health Sydney

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24 September 2008

Prof Patricia Davidson
School of Nursing and Midwifery
Sydney Campus of Curtin University of Technology
Curtin House
39 Regent St
Chippendale NSW 2008

Dear Patricia

SVH File Number: 08/077
Project Title: Evaluation of a modified, self-administered six minute walk test to improve health related outcomes in people with symptomatic heart failure
(HREC Ref: 08/SVH/77)

Thank you for submitting the above project for ethical and scientific review. The project was first considered by the St Vincent's Hospital HREC at its meeting held on 20 May 2008. This lead HREC has been accredited by NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that the Committee at an Executive meeting on **23 September 2008** has granted ethical approval of the above multi-centre project.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The project is approved to be conducted at the following NSW Public Health site(s):

- St Vincent's Hospital;
- Mt Druitt Hospital; and
- Blacktown Hospital.

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

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

- NEAF AB/3445/1;
- Protocol Version 1 dated 9 May 2008;
- Participant Information Statement and Consent Form Master Version 3 dated 22 September 2008; and
- Participant Booklet "The Home Walk Heart Program".

Please note the following conditions of approval:

1. This approval is valid for five years, and the Committee requires that you furnish it with annual reports on the study's progress beginning in **September 2009.**

Appendix 2 Participant Information & Consent form

St Vincent's Hospital
A facility of St Vincents & Mater Health Sydney

Curtin University of Technology

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

The Home-Heart-Walk Study

Invitation
You are invited to participate in a research study to improve the ability of people with chronic heart failure to exercise.

The study is being conducted by **Professor Patricia Davidson** (Curtin University of Technology), **Ms HuiYun Du** (Curtin University of Technology); **Dr Yenna Salamonson** (University of Western Sydney), **Dr Phillip Newton** (Curtin University of Technology); **Professor Peter MacDonald** (St Vincent's Hospital).

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'
Exercise capacity is closely related to the progress of your heart condition. By better monitoring your exercise capacity and staying active you can improve your symptoms, improve your heart condition and decrease the chance that you need to be admitted to hospital.

The Home-Heart-Walk program is a simple, weekly walking activity that involves walking around a five metre long rope for six minutes and recording the distance covered during the walk. It is a home-based, self-administered exercise program, specifically designed for people with chronic heart failure. This exercise program helps people to manage their heart condition by allowing them to monitor and keep a record of their physical exercise capacity, as well as to provide a simple effective and structured method to exercise. The Home-Heart-Walk has been demonstrated to be a reliable and enjoyable activity in a previous study. However, the effect of this Home-Heart-Walk program on improving the health related outcome in people with chronic heart failure is unknown. Therefore, this study aims to evaluate whether a home-based exercise program (the Home-Heart-Walk program) would improve the health related outcomes of people with chronic heart failure by providing a strategy to better monitor their exercise capacity and promote physical activity.

2. 'Why have I been invited to participate in this study?'
You are eligible to participate in this study because you have been admitted to hospital as a result of your heart condition in the previous six months and have been diagnosed with chronic heart failure which means that the heart is not working effectively as a pump. You will undergo screening for this study. If your doctor does not think that you are suitable for this study, for example if you become dizzy on the walking test, we will provide a detailed explanation of the reasons. We will also provide you with strategies to better monitor your condition.

3. **'What if I don't want to take part in this study or if I want to withdraw later?'**

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

New information about home based exercise programs being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. However, it may not be possible to withdraw your data from the study results if these have already had your identifying details removed.

4. **'What does this study involve?'**

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. This study will be conducted over 6 *months*.

- You will be one of 166 participants invited to participate in this study. Should you agree to participate, in addition to your standard care you receive from the cardiac clinic you are attending, you may also be enrolled in a home-based exercise program called the Home-Heart-Walk program.

The Home-Heart-Walk program:

The Home-Heart-Walk program is a home-based exercise program. To undertake the Home-Heart-Walk you will be asked to walk around a 5 metre long rope, on a flat, hard surface for 6 minutes. A lap counter and a timer will be provided to you to assist you record how far you have walked over the six minutes.

- We will also undertake a review of your medical record which will include documentation of your diagnosis, date of admission and discharge from hospital, and clinical details about your hospital admission that related to your heart condition. We will also need to contact your general practitioner (family doctor) and cardiologist to obtain information regarding your cholesterol and blood glucose levels. In a random number of cases the monthly telephone call will be audiotaped with your consent to ensure the quality of the telephone discussion. A brief report of the monthly telephone call will be faxed to your general practitioner and/or your cardiologist, with your consent.
- If you agree to participate you will be asked by a nurse researcher to respond to some questionnaires. The nurse researcher will assist you in completing the questionnaire although it is important that you answer the questions from your own perspective. Then you will receive one session on self-management of heart failure which last approximately one hour. You

will also be given the National Heart Foundation Consumer Resource Guide.

- After you have completed the initial questionnaires and had a session with a nurse researcher on self-management of health failure, you will be assigned to either the standard care that you are currently receiving OR the Home-Heart-Walk program in addition to the standard care. The method used to assign you to either group is called randomisation. This process is a bit like the flip of a coin where people are randomly assigned to one of the two groups. Neither the nurse researcher nor you can decide which group you will be put into. This is to ensure the two groups are similar to start with and to allow comparison between the Home-Heart-Walk program in addition to standard care.
- If you are assigned to the Home-Heart-Walk program group, the study nurse will explain to you how to undertake the Home–Heart-Walk. You will be asked to undertake the Home-Heart-Walk once for the first week. At the end of this week, you will meet with the study nurse at the clinic where you routinely visit, and you will be asked to undertake the Home-Heart-Walk. This will help us to ensure you are following the procedure correctly. This visit will also provide an opportunity for you discuss any issues related to the study that may have arisen in the previous week.
- After day 7 you will be asked to undertake the Home-Heart-Walk at your own home, ONCE A WEEK for 6 months. Every month, the nurse researcher will contact you via the telephone to discuss how you are going with managing your heart condition and also discuss your Home-Heart-Walk results.
- At 3 months, you will receive a questionnaire by post for you to complete (with postage paid envelope for returning the completed questionnaire). These questionnaires will be very similar to what you have completed when you first enrolled in this study. We will send out these questionnaires again to you after 6 months.
- If you are assigned to the standard care group, you will receive a telephone call from the nurse researcher every month to discuss how you are going with managing your heart condition. You will receive a questionnaire by post for you to complete (with postage paid envelope for returning the completed questionnaire). These questionnaires will be very similar to what you have completed when you first enrolled in this study. We will send out these questionnaires again to you after 6 months.

5. 'How is this study being paid for?'

The study is being sponsored by the Department of Health & Ageing. All of the money being paid by the sponsor to run the trial will be deposited into an account managed by Curtin University of Technology, Perth. Funds will then be transferred to the sites for administration of the study. No money is paid directly to individual researchers.

6. 'Are there risks to me in taking part in this study?'

If you are part of the group that will undertake the Home-Heart-Walk program there may be some additional risks associated with participation in the study. Anytime

you undertake physical activity there is a risk that you may experience worsening symptoms related to your heart failure. However the exercise program that we are asking you to undertake is no more strenuous then what you would do in a cardiac rehabilitation program. If at anytime during the study you develop chest pain or shortness of breath, you should immediately stop walking, sit down and follow your usual chest pain management plan. To further minimise the risk of the study, we also ask you to find a flat, hard area in your home that is free of clutter so you won't trip over anything when you are doing the Home-Heart-Walk.

7. 'What happens if I suffer injury or complications as a result of the study?'
If you suffer any injuries or complications as a result of this study, you should contact the study nurse as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the Home-Heart-Walk program, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

8. 'Will I benefit from the study?'
This study aims to improve the monitoring of physical capacity of people with heart failure, and to promote physical activity. It may improve future management and health outcomes of people with heart failure. It may also directly improve your physical capacity and your heart condition over the six month study period. However, it may not directly benefit you.

9. 'Will taking part in this study cost me anything, and will I be paid?
Participation in this study will not cost you anything. You will be reimbursed for your time and reasonable travel expenses that are related to the study.

10. 'How will my confidentiality be protected?'
Of the people treating you, only those named previously as the researchers of this study, and your treating doctor will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named previously and your treating doctor will have access to your details and results that will be held securely at the Centre for Cardiovascular and Chronic Care, Curtin University of Technology, Sydney.

11. 'What happens with the results?'
If you give us your permission by signing the consent document, we plan to discuss/publish the results in refereed journals, professional forums and presentation at conferences, to maximise the dissemination of knowledge from this study. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish after all participants have completed the study.

12. 'What happens to my treatment when the study is finished?'
If you wish to continue using the Home-Heart-Walk after the completion of the study, you should discuss this with your doctor. The study nurse will be unable to continue to make the monthly phone calls to you after you have completed the study.

13. 'What should I do if I want to discuss this study further before I decide?'
When you have read this information sheet, the study nurse will discuss it with you and answer any queries you may have. If you would like to know more at any stage, please do not hesitate to contact the study nurse whose contact details are provided at the end of this document.

14. 'Who should I contact if I have concerns about the conduct of this study?'
This study has been approved by St Vincent's Hospital HREC (Approval number 08/SVH/77) and Curtin University Human Research Ethics Committee (Approval number 170/2008). If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephone 08 9266 2784 or by emailing hrec@curtin.edu.au. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer in the Research Office who is the person nominated to receive complaints from research participants. You should contact them on 02 8382 2075 and quote *HREC Ref: 08/077*.

The conduct of this study at the St Vincent's Hospital has been authorised by St Vincent's Hospital. Any person with concerns or complaints about the conduct of this study may also contact the *Research Governance Officer* on 8382 2075 and quote reference number 5124

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

St Vincent's Hospital
A facility of St Vincents & Mater Health Sydney

Curtin
University of Technology

CONSENT FORM
[To be used in conjunction with a Participant Information Sheet]

The Home-Heart-Walk Study

1. I,.....
of.....
agree to participate as a subject in the study described in the participant information statement set out above ***(or: attached to this form).***

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the Curtin University of Technology and St Vincent's Hospital.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Professor Peter Macdonald on telephone.8382 2641, who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the, Executive Officer, St Vincent's Hospital Research Ethics Committee, Darlinghurst NSW 2010 (phone 8382 2075, email research@stvincents.com.au)

Signature of subject	**Please PRINT name**	**Date**
Signature of witness	**Please PRINT name**	**Date**
Signature of investigator	**Please PRINT name**	**Date**

St Vincent's Hospital
A facility of St Vincents & Mater Health Sydney

Curtin
University of Technology

The Home-Heart-Walk Study

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the (Curtin *University of Technology, Hospital or my medical attendants).*

Signature Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to

Professor Peter Macdonald
Department of Cardiology
St Vincent's Hospital
390 Victoria St
Darlinghurst NSW 2010

Appendix 3 Case Report Form

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The Home-Heart-Walk:

Evaluation of an intervention to promote and monitor physical activity

Please answer all questions. Most questions require you to tick a box(es) to indicate your answer. Choose the box(es) that best matches your answer.

Section one: general information		
1. Gender	Female ☐1	Male ☐0
2. Date of birth	DD/MM/YYYY	
3. Country of birth:		
4: Aboriginal or Torres Strait islander origin:	No ☐0	Yes, Aboriginal ☐1
	Yes, Torres Strait Islander ☐2	
5. Language spoken at home:	English ☐1	
	Other (*please specify*) _____ ☐0	
	Both English & other ☐2	
6. Address		
7. Post code		
8. Home telephone number:		
9. Mobile (*if available*)		
10. Next of kin telephone number:		
11. Email address (*if available*)		

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12. Contact details of a person who does not live with you	Address: Phone:

13. Marital status (*please tick one box only*)

Single	☐1
Married	☐2
Defacto	☐3
Separated	☐4
Divorced	☐5
Widowed	☐6

Living alone ☐1 Living with spouse, carer or relative(s) ☐2 Living with others ☐3

*please specify*_____

14. Current occupation

Paid employment ☐1 Home duties ☐2 Retired/pensioner ☐3

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		-										

15. Previous occupation: _____

16. Highest level of education (*please tick one box only*)

No school certificate or other qualifications	☐1
School or intermediate certificate (or equivalent)	☐2
Higher school or leaving certificate (or equivalent)	☐3
Trade/apprenticeship (e.g. hairdresser, chef)	☐4
Certificate/diploma (e.g. child care, technician)	☐5
University degree or higher	☐6

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Section two: health survey

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. (For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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

	Yes, limited a lot ▼	Yes, limited a little ▼	No, not limited at all ▼
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c. Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d. Climbing several flights of stairs	☐ 1	☐ 2	☐ 3
e. Climbing one flight of stairs	☐ 1	☐ 2	☐ 3
f. Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g. Walking more than a kilometre	☐ 1	☐ 2	☐ 3
h. Walking several hundred metres	☐ 1	☐ 2	☐ 3
i. Walking one hundred metres	☐ 1	☐ 2	☐ 3
j. Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

Centre Participant ID

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

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

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

	All of the time ▼	Most of the time ▼	Some of the time ▼	A little of the time ▼	None of the time ▼
a. Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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

None	Very mild	Mild	Moderate	Severe	Very severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

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

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks

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

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

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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

	Definitely true ▼	Mostly true ▼	Don't know ▼	Mostly false ▼	Definitely false ▼
a. I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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Physical activity

The aim of this scale is to find out how many periods of 30 minutes of moderate (20 minutes of vigorous) physical activity you would do in a week. One hour of continuous moderate physical activity counts as two periods of 30 minutes.

1. How many times a week do you usually do 20 minutes or more of vigorous-intensity physical activity that makes you sweat or puff and pant? (e.g. heavy lifting, digging, jogging, aerobics or fast bicycling)

0	1	2	3	4	5	6	7+	Score:

2. How many times a week do you usually do 30 minutes or more of walking? (e.g. walking from place to place for exercise, leisure or recreation)

0	1	2	3	4	5	6	7+	Score:

3. How many times a week do you usually do 30 minutes or more of moderate-intensity physical activity that increases your heart rate or makes you breathe harder than normal? (e.g. carrying light loads, bicycling at a regular pace or playing double tennis)

0	1	2	3	4	5	6	7+	Score:

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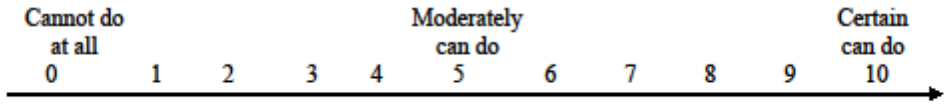
Please rate how sure you are that you can get yourself to exercise regularly (most days of the week). The scale ranges from 0 (I cannot do this activity at all) to 10 (I am certain that I can do this activity successfully). Remember that you may use any number between 1 and 10.



	Confidence (0-10)
When I am feeling tired	
When I am feeling under pressure from work	
During bad weather	
After recovering from an injury that caused me to stop exercising	
During or after experiencing personal problems	
When I am feeling depressed	
When I am feeling anxious	
After recovering from an illness that caused me to stop exercising	
When I feel physical discomfort when I exercise	
After a holiday	
When I have too much work to do at home	
When visitors are present	
When there are other interesting things to do	
If I don't reach my exercise goals	
Without support from my family or friends	
During a holiday	
When I have other time commitments	
After experiencing family problems	

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This scale contains statements about heart failure self-care. Respond to each statement by circling the number you think best applies to you. Note that the different answer alternatives constitute a scale ranging between the extremes of "I completely agree" (1) to "I don't agree at all" (5). Even if you feel uncertain about a particular statement, circle the number you feel is most true for you.

	I completely agree				I don't agree at all
1. I weigh myself every day	1	2	3	4	5
2. If I get short of breath I take it easy	1	2	3	4	5
3. If my shortness of breath increases I contact my doctor or nurse.	1	2	3	4	5
4. If my feet/legs become more swollen than usual I contact my doctor or nurse.	1	2	3	4	5
5. If I gain 2 kilo in one week I contact my doctor or nurse.	1	2	3	4	5
6. I limit the amount of fluids I drink (not more than 1½-2 l/day)	1	2	3	4	5
7. I take a rest during the day	1	2	3	4	5
8. If I experience increased fatigue I contact my doctor or nurse	1	2	3	4	5
9. I eat a low salt diet	1	2	3	4	5
10. I take my medication as prescribed	1	2	3	4	5
11. I get a flu shot every year	1	2	3	4	5
12. I exercise regularly	1	2	3	4	5

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The following questions ask how much your heart failure (heart condition) affects your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by	No	Very little				Very much
1. Causing swelling in your ankles or legs?	0	1	2	3	4	5
2. Making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. Making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. Making your working around the house or yard difficult?	0	1	2	3	4	5
5. Making your going places away from home difficult?	0	1	2	3	4	5
6. Making your sleeping well at night difficult?	0	1	2	3	4	5
7. Making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. Making your working to earn a living difficult?	0	1	2	3	4	5
9. Making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. Making you sexual activities difficult?	0	1	2	3	4	5

Continued on next page

Centre Participant ID

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Continued from previous page

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by	No	Very little				Very much
11. Making you eat less of the foods you like?	0	1	2	3	4	5
12. Making you short of breath?	0	1	2	3	4	5
13. Making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. Making you stay in a hospital?	0	1	2	3	4	5
15. Costing you money for medical care?	0	1	2	3	4	5
16. Giving you side effects from treatments?	0	1	2	3	4	5
17. Making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. Making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. Making you worry?	0	1	2	3	4	5
20. Making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21. Making you feel depressed?	0	1	2	3	4	5

Thank you for completing the survey!

Curtin University of Technology

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Section three: clinical information *(for researcher to complete)*

1. **Diagnosis:** _____

_____

_____

2. **Previous medical history**

	No$_0$	Yes$_1$	No data$_2$	How long (years) ago was this diagnosed?
Heart failure	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Myocardial infarction	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Pacemaker	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Coronary artery disease	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Hypertension	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
High blood cholesterol	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Angina	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Stroke / cerebro-vascular accident	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Vascular disease_____	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Valvular heart disease	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Aneurysm (abdominal, thoracic, leg)	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Renal disease	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Stomach ulcer	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Sleep apnea	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Asthma/Lung disease (*e.g. COPD*)	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Mental illness-depression	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Mental illness-others	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Diabetes type I	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Diabetes type II	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Arthritis-Rheumatoid	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Arthritis-Osteoarthritis	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Cancer	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___
Other serious condition_____	☐$_0$	☐$_1$	☐$_2$	if yes→___ ___

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3. Past procedure

	No$_0$	Yes$_1$	In what year
Coronary artery bypass operation	☐$_0$	☐$_1$	if yes→ ___ ___ ___ ___
Coronary angioplasty/stent	☐$_0$	☐$_1$	if yes→ ___ ___ ___ ___
Heart valve surgery	☐$_0$	☐$_1$	if yes→ ___ ___ ___ ___
Other cardiac surgery_____	☐$_0$	☐$_1$	if yes→ ___ ___ ___ ___

4. Family history

Family history of cardiovascular disease: Yes ☐$_1$ No ☐$_0$

If yes please specify:

5. Smoking status

Smoking status:
☐$_1$ Current smoker _____packs/day, since_____
☐$_2$ Ex-smoker _____packs/day for _____ years
☐$_0$ Non-smoker

6. Past admission (*in the past 12 months*)

	No$_0$	Yes$_1$	*if yes* →No. of times
Emergency department presentation			
HF related	☐$_0$	☐$_1$	___ ___
Non HF related	☐$_0$	☐$_1$	___ ___
Hospitalisation			___ ___
HF related	☐$_0$	☐$_1$	___ ___
Non HF related	☐$_0$	☐$_1$	___ ___

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7. Charlson index of comorbidity

Myocardial infarction	Yes ☐1 No ☐0		Diabetes	Yes ☐1 No ☐0	
Congestive heart failure	Yes ☐1 No ☐0		Hemiplegia	Yes ☐1 No ☐0	
Peripheral vascular disease	Yes ☐1 No ☐0		Mod/end organ damage	Yes ☐1 No ☐0	
Cerebrovascular disease	Yes ☐1 No ☐0		Any tumour	Yes ☐1 No ☐0	
Dementia	Yes ☐1 No ☐0		Leukemia	Yes ☐1 No ☐0	
Chronic pulmonary disease	Yes ☐1 No ☐0		Lymphoma	Yes ☐1 No ☐0	
Connective tissue disease	Yes ☐1 No ☐0		Mod/severe liver disease	Yes ☐1 No ☐0	
Ulcer disease	Yes ☐1 No ☐0		Metastatic tumour	Yes ☐1 No ☐0	
Mild liver disease	Yes ☐1 No ☐0		AIDS	Yes ☐1 No ☐0	

8. Left ventricular function

a. Left ventricular diastole (EDD): __ __ mm No data ☐0

b. Left ventricular systole (ESD): __ __mm No data ☐0

c. Intra ventricular septum diastole (ISD): __ __ mm No data ☐0

d. Intra ventricular septum systole (ISS): __ __ mm No data ☐0

e. Posterior wall diastole (PWD): __ __ mm No data ☐0

f. Posterior wall systole (PWS): __ __ mm No data ☐0

g. Regional wall motion abnormality: Yes ☐1 No ☐0 No data ☐2

h. Specify if yes: Anterior ☐1 Inferior ☐2 Lateral ☐3 No data ☐4

i. Ejection faction: _____% Date of measurement: DD-MM-YYYY

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9. Valvular

	No$_0$	Yes$_1$	No Data$_2$				
Aortic regurgitation	☐$_0$	☐$_1$	☐$_2$	*if yes* → Mild ☐$_1$	Modereate ☐$_2$	Severe ☐$_3$	Not recorded ☐$_4$
Mitral regurgitation	☐$_0$	☐$_1$	☐$_2$	*if yes* → Mild ☐$_1$	Modereate ☐$_2$	Severe ☐$_3$	Not recorded ☐$_4$
Tricuspid regurgitation	☐$_0$	☐$_1$	☐$_2$	*if yes* → Mild ☐$_1$	Modereate ☐$_2$	Severe ☐$_3$	Not recorded ☐$_4$
Pulmonary HT	☐$_0$	☐$_1$	☐$_2$	*if yes* → Mild ☐$_1$	Modereate ☐$_2$	Severe ☐$_3$	Not recorded ☐$_4$
Aortic stenosis	☐$_0$	☐$_1$	☐$_2$	*if yes* → Mild ☐$_1$	Modereate ☐$_2$	Severe ☐$_3$	Not recorded ☐$_4$
Mitral stenosis	☐$_0$	☐$_1$	☐$_2$	*if yes* → Mild ☐$_1$	Modereate ☐$_2$	Severe ☐$_3$	Not recorded ☐$_4$
Vegetation-greatest size	<1cm ☐$_1$	< 1-2 cm ☐$_2$	>2cm ☐$_3$				No data ☐$_0$
Valve with vegetation	aortic ☐$_1$	mitral ☐$_2$	other ☐$_3$ →please specify_____				No data ☐$_0$
Pericardial effusion	No ☐$_1$	<1cm ☐$_2$	1-2cm ☐$_3$	>2cm ☐$_4$			No data ☐$_0$

10. Echocardiographic evaluation

a. Aortic root size : __ __ mm No data ☐$_0$

b. Left atrial size: __ __ mm No data ☐$_0$

c. Rhythm: Sinus ☐$_1$ AF ☐$_2$ other ☐$_3$ *if other please specify*_____

No data ☐$_0$

11. New York Heart Association Functional class

Class I No limitation, ordinary physical exercise does not cause undue fatigue, dyspnoea or palpitations

Class II Slight impairment of physical activity, comfortable at rest but ordinary activity results in fatigue, palpitations.

Class III Marked limitation of physical activity, comfortable at rest but less than ordinary activity results in symptoms.

Class IV Unable to carry out any physical activity without discomfort, symptoms of CHF are present even at rest with increased discomfort with any physical activity.

Class I ☐$_1$ Class II ☐$_2$ Class III ☐$_3$ Class IV ☐$_4$

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12.Physical functional capacity

a. Peak oxygen consumption: _____ ml/kg/min No data ☐0

b. Anaerobic threshold:_____ ml/kg/min No data ☐0

c. The 6MWT distance: ___ ___ ___ . ___ metres No data ☐0

The 6MWT	Before	After
Blood pressure (Sitting)	___ ___ ___ / ___ ___ ___ mmHg	___ ___ ___ / ___ ___ ___ mmHg
Heart rate	___ ___ ___ beats / minute	___ ___ ___ beats / minute
Oxygen saturation	___ ___ ___ %	___ ___ ___ %
Dysponea (Borg scale)		
Fatigue (Borg scale)		

13. Etiology of heart failure

a. Ischemic Yes ☐1 No ☐0

b. Idiopathic Yes ☐1 No ☐0

c. Valvular Yes ☐1 No ☐0

d. Dilated Yes ☐1 No ☐0

e. Hypertension Yes ☐1 No ☐0

f. Others Yes ☐1 No ☐0 *please specify*_____

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14. Vitals

Weight	Current ___ ___ ___ . ___kg 12 months ago ___ ___ ___. ___ kg Highest ___ ___ ___ . ___ kg		
Height	___ ___ ___ . ___cm		
Waist circumference	___ ___ ___ . ___cm	Waist / hip ratio	
Hip circumference	___ ___ ___ . ___cm	____ . _____	
Heart rate	___ ___ ___ beats / minute		
Rhythm	SR ☐1 AF ☐2 PR ☐3 Other ☐4 *If other please specify*_____		
Oxygen saturation	___ ___ ___ %		
Chest auscultation	Clear ☐1	Rales ☐2	
Heart sound	S1/S2 ☐1 S3 ☐2 S4 ☐3 Systolic murmur ☐1 Diastolic murmur ☐2		
Pedal oedema	☐1 No edema ☐2 Barely discernable depression ☐3 A deeper expression [less than 5mm] accompanied by normal foot and leg swelling ☐4 An even deeper depression [more than 1 cm accompanied by severe foot and leg swelling		
Oedema:	No ☐0 Ankle ☐1 Calf ☐2 Knee ☐3 Higher than Knee ☐4		
JVP	Not elevated ☐0 <6cm ☐1 6-10cm ☐2 >10cm ☐3 No data ☐4		

		Sitting	Lying	HR
BP	1	S B P / D B P mmHg	S B P / D B P mmHg	
	2	S B P / D B P mmHg	S B P / D B P mmHg	

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15. Biochemistry (Admission)

Na ___ mmol/L	No data ☐0
K __ . __ mmol/L	No data ☐0
CL ___ . __ mmol/L	No data ☐0
Gluc __ . __ mmol/L	No data ☐0
Total bilirubin ___ umol/L	No data ☐0
Alk phos ___ iu/L	No data ☐0
GGT ___ U/L	No data ☐0
Total chol __ . __ mmol/L	No data ☐0
Trigl __ . __ mmol/L	No data ☐0
LDL __ . __ mmol/L	No data ☐0
HDL __ . __ mmol/L	No data ☐0
nt-proBNP ___ . __ pg/ml	No data ☐0
Plts ___ 10^9/L	No data ☐0
Hct __ . __ %	No data ☐0
INR __ . __	No data ☐0
Bicarbonate __ mmol/L	No data ☐0
Urea ___ . __ mmol/L	No data ☐0
Creatinine __ . __ umol/L	No data ☐0
Total protein __ . __ gm/dL	No data ☐0
ALT ___ U/L	No data ☐0
Troponin I __ ug/L	No data ☐0
HbA1c __ . __ %	No data ☐0
FT4 __ . __ pmol/L	No data ☐0
FT3 __ . __ pmol/L	No data ☐0
TSH __ . __ mlU/L	No data ☐0
RBC __ . __ 10^12/L	No data ☐0
Hb ___ g/L	No data ☐0
Albumin ___ mg/d	No data ☐0
WCC __ . __ 10^9/L	No data ☐0
Fibrinogen __ . __ g/L	No data ☐0
eGFR ___ mL/minBSAc	No data ☐0

Centre Participant ID

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Biochemistry (Discharge)

Na ___ mmol/L	No data ☐0
K __ . __ mmol/L	No data ☐0
CL ___ . __ mmol/L	No data ☐0
Gluc __ __ . __ mmol/L	No data ☐0
Total bilirubin ___ umol/L	No data ☐0
Alk phos ___ iu/L	No data ☐0
GGT ___ U/L	No data ☐0
Total chol __ __ . __ mmol/L	No data ☐0
Trigl __ __ . __ mmol/L	No data ☐0
LDL __ __ . __ mmol/L	No data ☐0
HDL __ __ . __ mmol/L	No data ☐0
nt-proBNP ___ . __ pg/ml	No data ☐0
Plts ___ 10^9/L	No data ☐0
Hct __ __ . __ %	No data ☐0
INR __ __. __	No data ☐0
Bicarbonate __ __ mmol/L	No data ☐0
Urea ___ . __ mmol/L	No data ☐0
Creatinine __ __ . __ umol/L	No data ☐0
Total protein __ . __ gm/dL	No data ☐0
ALT ___ U/L	No data ☐0
Troponin I __ __ug/L	No data ☐0
HbA1c __ __ . __ %	No data ☐0
FT4 __ __. __ pmol/L	No data ☐0
FT3 __ __ . __ __ pmol/L	No data ☐0
TSH __ __ . __ __ mlU/L	No data ☐0
RBC __ __ . __ __ 10^12/L	No data ☐0
Hb ___ g/L	No data ☐0
Albumin ___ mg/d	No data ☐0
WCC __ __ . __ 10^9/L	No data ☐0
Fibrinogen __ . __ g/L	No data ☐0
eGFR ___ mL/minBSAc	No data ☐0

Centre Participant ID

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16. Cardiac medication

a.	ACE inhibitors	Yes ☐1	No ☐0
b.	Antiarrhythmics	Yes ☐1	No ☐0
c.	Anticoagulatants	Yes ☐1	No ☐0
d.	Antiplatelets	Yes ☐1	No ☐0
e.	Angiotensin receptor blockers	Yes ☐1	No ☐0
f.	Beta blockers	Yes ☐1	No ☐0
g.	Diuretics	Yes ☐1	No ☐0
h.	Flexible diuretic regime	Yes ☐1	No ☐0
i.	Digitalis	Yes ☐1	No ☐0
j.	Lipid-lowering agents	Yes ☐1	No ☐0
k.	Nitrates	Yes ☐1	No ☐0
l.	Other vasodilators	Yes ☐1	No ☐0

Centre Participant ID

17. Current medications

☐0 None

Medication name	Dose	Frequency	Start date DD-MM-YYYY	End date DD-MM-YYYY	Continuing
(generic name preferred but use brand name for combination product)					
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0

Curtin University of Technology

Centre Participant ID

Section four: three-month follow up

1.Smoking status

Smoking status: ☐1 Current smoker _____packs/day, since_____
☐2 Ex-smoker _____packs/day for _____ years
☐0 Non-smoker

2.New York Heart Association Functional class

Class I No limitation, ordinary physical exercise does not cause undue fatigue, dyspnoea or palpitations
Class II Slight impairment of physical activity, comfortable at rest but ordinary activity results in fatigue, palpitations.
Class III Marked limitation of physical activity, comfortable at rest but less than ordinary activity results in symptoms.
Class IV Unable to carry out any physical activity without discomfort, symptoms of CHF are present even at rest with increased discomfort with any physical activity.

Class I ☐1	Class II ☐2	Class III ☐3	Class IV ☐4

3. Physical functional capacity

a. Peak oxygen consumption: _____ ml/kg/min No data ☐0

b. Anaerobic threshold:_____ ml/kg/min No data ☐0

c. The 6MWT distance: ___ ___ ___ . ___ metres No data ☐0

The 6MWT	Before	After
Blood pressure (Sitting)	/ mmHg	___ ___ ___ / ___ ___ ___ mmHg
Heart rate	___ ___ ___ beats / minute	___ ___ ___ beats / minute
Oxygen saturation	___ ___ ___ %	___ ___ ___ %
Dyspnoea (Borg scale)		
Fatigue (Borg scale)		

4. Vitals

Centre Participant ID

Weight	Current ___ ___ ___ . ___kg 12 months ago ___ ___ ___. ___ kg Highest ___ ___ ___ . ___ kg	
Height	___ ___ ___ . ___cm	
Waist circumference	___ ___ ___ . ___cm	Waist / hip ratio
Hip circumference	___ ___ ___ . ___cm	____ . _____
Heart rate	___ ___ ___ beats / minute	
Rhythm	SR ☐1 AF ☐2 PR ☐3 Other ☐4 *If other please specify*_____	
Oxygen saturation	___ ___ ___ %	
Chest auscultation	Clear ☐1	Rales ☐1
Heart sound	S1/S2 ☐1 S3 ☐2 S4 ☐3 Systolic murmur ☐1 Diastolic murmur ☐2	
Pedal oedema	☐1 No edema ☐2 Barely discernable depression ☐3 A deeper expression [less than 5mm] accompanied by normal foot and leg swelling ☐4 An even deeper depression [more than 1 cm accompanied by severe foot and leg swelling	
Oedema:	No ☐0 Ankle ☐1 Calf ☐2 Knee ☐3 Higher than Knee ☐4	
JVP	Not elevated ☐0 <6cm ☐1 6-10cm ☐2 10cm ☐3 No data ☐4	

		Sitting	Lying	HR
BP	1	S B P / D B P mmHg	S B P / D B P mmHg	
	2	S B P / D B P mmHg	S B P / D B P mmHg	

Centre Participant ID

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5.Biochemistry

Na ___ mmol/L	No data ☐0
K __ . __ mmol/L	No data ☐0
CL ___ . __ mmol/L	No data ☐0
Gluc ___ . __ mmol/L	No data ☐0
Total bilirubin ___ umol/L	No data ☐0
Alk phos ___ iu/L	No data ☐0
GGT ___ U/L	No data ☐0
Total chol ___ . __ mmol/L	No data ☐0
Trigl ___ . __ mmol/L	No data ☐0
LDL ___ . __ mmol/L	No data ☐0
HDL ___ . __ mmol/L	No data ☐0
nt-proBNP ___ . __ pg/ml	No data ☐0
Plts ___ 10^9/L	No data ☐0
Hct ___ . __ %	No data ☐0
INR __ . __	No data ☐0
Bicarbonate __ mmol/L	No data ☐0
Urea ___ . __ mmol/L	No data ☐0
Creatinine ___ . __ umol/L	No data ☐0
Total protein __ . __ gm/dL	No data ☐0
ALT ___ U/L	No data ☐0
Troponin I __ ug/L	No data ☐0
HbA1c ___ . __ %	No data ☐0
FT4 __ . __ pmol/L	No data ☐0
FT3 ___ . __ pmol/L	No data ☐0
TSH ___ . __ mlU/L	No data ☐0
RBC ___ . __ 10^12/L	No data ☐0
Hb ___ g/L	No data ☐0
Albumin ___ mg/d	No data ☐0
WCC ___ . __ 10^9/L	No data ☐0
Fibrinogen __ . __ g/L	No data ☐0
eGFR ___ mL/minBSAc	No data ☐0

Centre Participant ID

		-										

6. Cardiac medication

a. ACE inhibitors	Yes ☐1	No ☐0
b. Antiarrhythmics	Yes ☐1	No ☐0
c. Anticoagulatants	Yes ☐1	No ☐0
d. Antiplatelets	Yes ☐1	No ☐0
e. Angiotensin receptor blockers	Yes ☐1	No ☐0
f. Beta blockers	Yes ☐1	No ☐0
g. Diuretics	Yes ☐1	No ☐0
h. Flexible diuretic regime	Yes ☐1	No ☐0
i. Digitalis	Yes ☐1	No ☐0
j. Lipid-lowering agents	Yes ☐1	No ☐0
k. Nitrates	Yes ☐1	No ☐0
l. Other vasodilators	Yes ☐1	No ☐0

7. Did the Home-Heart-Walk program help you to increase your physical activity?

Please rate on the scale, how much the Home-Walk-Heart Program has helped you to increase your physical activity?

Not at all		A little bit			A good amount					Very much
0	1	2	3	4	5	6	7	8	9	10

Centre Participant ID

		-			

8. Current medications

☐0 None

Medication name (*generic name preferred but use brand name for combination product*)	Dose	Frequency	Start date DD-MM-YYYY	End date DD-MM-YYYY	Continuing
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0

Centre Participant ID

		-										

9. Admission (*between baseline and 3-month follow-up*)

	No$_0$	Yes$_1$	*if yes* → No. of times
Emergency department presentation			
HF related	☐$_0$	☐$_1$	___ ___
Non HF related	☐$_0$	☐$_1$	___ ___
Hospitalisation			___ ___
HF related	☐$_0$	☐$_1$	___ ___
Non HF related	☐$_0$	☐$_1$	___ ___

10. Major cardiac events (*between baseline and 3-month follow up*)

	No$_0$	Yes$_1$	No. of times	Admission NO.
Non-fatal AMI	☐$_0$	☐$_1$		
Non-fatal stroke	☐$_0$	☐$_1$		
ACS events	☐$_0$	☐$_1$		
Planned revascularization procedure	☐$_0$	☐$_1$		
Un-planned revascularization Procedure	☐$_0$	☐$_1$		
Death	☐$_0$	☐$_1$		

Curtin University of Technology

Centre Participant ID

Admission detail (*between baseline and 3-month follow up*) **Admission No.** ☐

Please attach discharge summary for each admission

Emergency admission ☐1 Elective admission ☐2 ED admission only ☐2

Time of admission __ __:__ __ Date of admission __ __/__ __/__ __ __ __

Date of discharge__ __/__ __/__ __ __ __

NYHA class:	I ☐1 II ☐2 III ☐3 IV ☐4 nt-pro BNP __ __ __. __ pg/L
BP:	S B P / D B P mmHg
HR:	___ ___ ___ beat/min
Chest auscultation	Clear ☐1 Rales ☐1
Pedal oedema	☐1 No edema ☐2 Barely discernable depression ☐3 A deeper expression [less than 5mm] accompanied by normal foot and leg swelling ☐4 An even deeper depression [more than 1 cm accompanied by severe foot and leg swelling
Oedema:	No ☐0 Ankle ☐1 Calf ☐2 Knee ☐3 Higher than Knee ☐4
Chest X-ray:	No ☐0 Yes ☐1 *if yes*, pulmonary oedema: Yes ☐1 No ☐0
ECG:	No ☐0 Yes ☐1 *if yes*: SR ☐1 AF ☐2 Ischaemic changes ☐3

Initial treatment: ☐1 Oxygen ☐2 IV GTN ☐3 CPAP ☐4 IV inotropes ☐5 IV diuretics ☐6 Other_____

Procedures:	No0	Yes1	Planned2	Unplanned3	if yes→Date
Coronary artery bypass operation	☐0	☐1	☐2	☐3	D D / M M / YYYY
Coronary angioplasty/stent	☐0	☐1	☐2	☐3	D D / M M / YYYY
Heart valve surgery	☐0	☐1	☐2	☐3	D D / M M / YYYY
Other procedure_____	☐0	☐1	☐2	☐3	D D / M M / YYYY

Precipitating factors for this admission:

1)
2)
3)
4)
5)

Curtin University of Technology

Centre Participant ID

Section five: six-month follow up

1. Smoking status

Smoking status: ☐1 Current smoker _____packs/day, since_____
☐2 Ex-smoker _____packs/day for _____ years
☐0 Non-smoker

2. New York Heart Association Functional class

Class I No limitation, ordinary physical exercise does not cause undue fatigue, dyspnoea or palpitations
Class II Slight impairment of physical activity, comfortable at rest but ordinary activity results in fatigue, palpitations.
Class III Marked limitation of physical activity, comfortable at rest but less than ordinary activity results in symptoms.
Class IV Unable to carry out any physical activity without discomfort, symptoms of CHF are present even at rest with increased discomfort with any physical activity.

Class I ☐1	Class II ☐2	Class III ☐3	Class IV ☐4

3. Physical functional capacity

a. Peak oxygen consumption: _____ ml/kg/min No data ☐0

b. Anaerobic threshold:_____ ml/kg/min No data ☐0

c. The 6MWT distance: ___ ___ ___ . ___ metres No data ☐0

The 6MWT	Before	After
Blood pressure (Sitting)	/ mmHg	___ ___ ___ / ___ ___ ___ mmHg
Heart rate	___ ___ ___ beats / minute	___ ___ ___ beats / minute
Oxygen saturation	___ ___ ___ %	___ ___ ___ %
Dyspnoea (Borg scale)		
Fatigue (Borg scale)		

Centre Participant ID

		-										

4. Vitals

Weight	Current ___ ___ ___ . ___kg 12 months ago ___ ___ ___. ___ kg Highest ___ ___ ___ . ___ kg	
Height	___ ___ ___ . ___cm	
Waist circumference	___ ___ ___ . ___cm	Waist / hip ratio
Hip circumference	___ ___ ___ . ___cm	____ . _____
Heart rate	___ ___ ___ beats / minute	
Rhythm	SR ☐1 AF ☐2 PR ☐3 Other ☐4 *If other please specify*_____	
Oxygen saturation	___ ___ ___ %	
Chest auscultation	Clear ☐1	Rales ☐1
Heart sound	S1/S2 ☐1 S3 ☐2 S4 ☐3 Systolic murmur ☐1 Diastolic murmur ☐2	
Pedal oedema	☐1 No edema ☐2 Barely discernable depression ☐3 A deeper expression [less than 5mm] accompanied by normal foot and leg swelling ☐4 An even deeper depression [more than 1 cm accompanied by severe foot and leg swelling	
Oedema:	No ☐0 Ankle ☐1 Calf ☐2 Knee ☐3 Higher than Knee ☐4	
JVP	Not elevated ☐0 <6cm ☐1 6-10cm ☐2 10cm ☐3 No data ☐4	

		Sitting	Lying	HR
BP	1	S B P / D B P mmHg	S B P / D B P mmHg	
	2	S B P / D B P mmHg	S B P / D B P mmHg	

Centre Participant ID

5. Biochemistry

Na ___ mmol/L	No data ☐0
K __ . __ mmol/L	No data ☐0
CL ___ . __ mmol/L	No data ☐0
Gluc __ . __ mmol/L	No data ☐0
Total bilirubin ___ umol/L	No data ☐0
Alk phos ___ iu/L	No data ☐0
GGT ___ U/L	No data ☐0
Total chol __ . __ mmol/L	No data ☐0
Trigl __ . __ mmol/L	No data ☐0
LDL __ . __ mmol/L	No data ☐0
HDL __ . __ mmol/L	No data ☐0
nt-proBNP ___ . __ pg/ml	No data ☐0
Plts ___ 10^9/L	No data ☐0
Hct __ . __ %	No data ☐0
INR __ . __	No data ☐0
Bicarbonate __ mmol/L	No data ☐0
Urea ___ . __ mmol/L	No data ☐0
Creatinine __ . __ umol/L	No data ☐0
Total protein __ . __ gm/dL	No data ☐0
ALT ___ U/L	No data ☐0
Troponin I __ ug/L	No data ☐0
HbA1c __ . __ %	No data ☐0
FT4 __ . __ pmol/L	No data ☐0
FT3 __ . __ pmol/L	No data ☐0
TSH __ . __ mlU/L	No data ☐0
RBC __ . __ 10^12/L	No data ☐0
Hb ___ g/L	No data ☐0
Albumin ___ mg/d	No data ☐0
WCC __ . __ 10^9/L	No data ☐0
Fibrinogen __ . __ g/L	No data ☐0
eGFR ___ mL/minBSAc	No data ☐0

Centre Participant ID

		-									

6. Cardiac medication

a.	ACE inhibitors	Yes ☐1	No ☐0
b.	Antiarrhythmics	Yes ☐1	No ☐0
c.	Anticoagulatants	Yes ☐1	No ☐0
d.	Antiplatelets	Yes ☐1	No ☐0
e.	Angiotensin receptor blockers	Yes ☐1	No ☐0
f.	Beta blockers	Yes ☐1	No ☐0
g.	Diuretics	Yes ☐1	No ☐0
h.	Flexible diuretic regime	Yes ☐1	No ☐0
i.	Digitalis	Yes ☐1	No ☐0
j.	Lipid-lowering agents	Yes ☐1	No ☐0
k.	Nitrates	Yes ☐1	No ☐0
l.	Other vasodilators	Yes ☐1	No ☐0

7. Did the Home-Heart-Walk program help you to increase your physical activity?

Please rate on the scale, how much the Home-Walk-Heart Program has helped you to increase your physical activity?

Not at all		A little bit			A good amount					Very much
0	1	2	3	4	5	6	7	8	9	10

Centre Participant ID

☐☐ - ☐☐☐☐☐☐☐☐☐☐					

8. Current medications

☐0 None

Medication name	Dose	Frequency	Start date DD-MM-YYYY	End date DD-MM-YYYY	Continuing
(generic name preferred but use brand name for combination product)					
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0
			___-___-_____	___-___-_____	☐0

Centre Participant ID

9. Admission (*between 3-month and 6-month follow up*)

	No$_0$	Yes$_1$	*if yes* → No. of times
Emergency department presentation			
HF related	☐$_0$	☐$_1$	___ ___
Non HF related	☐$_0$	☐$_1$	___ ___
Hospitalisation			___ ___
HF related	☐$_0$	☐$_1$	___ ___
Non HF related	☐$_0$	☐$_1$	___ ___

10. Major cardiac events (*between 3-month and 6-month follow up*)

	No$_0$	Yes$_1$	No. of times	Admission NO.
Non-fatal AMI	☐$_0$	☐$_1$		
Non-fatal stroke	☐$_0$	☐$_1$		
ACS events	☐$_0$	☐$_1$		
Planned revascularization procedure	☐$_0$	☐$_1$		
Un-planned revascularization Procedure	☐$_0$	☐$_1$		
Death	☐$_0$	☐$_1$		

Curtin University of Technology

Centre Participant ID

Admission detail (*between 3-month and 6-month follow up*) **Admission No.** ☐

Please attach discharge summary for each admission

Emergency admission ☐1 Elective admission ☐2 ED admission only ☐2

Time of admission __ __:__ __ Date of admission __ __/__ __/__ __ __ __

Date of discharge__ __/__ __/__ __ __ __

NYHA class:	I ☐1 II ☐2 III ☐3 IV ☐4	nt-pro BNP __ __ __. __ pg/L
BP:	S B P / D B P mmHg	
HR:	___ ___ ___ beat/min	
Chest auscultation	Clear ☐1	Rales ☐1
Pedal oedema	☐1 No edema ☐2 Barely discernable depression ☐3 A deeper expression [less than 5mm] accompanied by normal foot and leg swelling ☐4 An even deeper depression [more than 1 cm accompanied by severe foot and leg swelling	
Oedema:	No ☐0 Ankle ☐1 Calf ☐2 Knee ☐3	Higher than Knee ☐4
Chest X-ray:	No ☐0 Yes ☐1	*if yes*, pulmonary oedema: Yes ☐1 No ☐0
ECG:	No ☐0 Yes ☐1	*if yes*: SR ☐1 AF ☐2 Ischaemic changes ☐3

Initial treatment: ☐1 Oxygen ☐2 IV GTN ☐3 CPAP ☐4 IV inotropes ☐5 IV diuretics ☐6 Other_____

Procedures:	No0	Yes1	Planned2	Unplanned3	if yes→Date
Coronary artery bypass operation	☐0	☐1	☐2	☐3	D D / M M / YYYY
Coronary angioplasty/stent	☐0	☐1	☐2	☐3	D D / M M / YYYY
Heart valve surgery	☐0	☐1	☐2	☐3	D D / M M / YYYY
Other procedure_____	☐0	☐1	☐2	☐3	D D / M M / YYYY

Precipitating factors for this admission:

1)
2)
3)
4)
5)

Appendix 4 Participant booklet

The Home Heart Walk Program

Participant Booklet

St Vincent's Hospital | Curtin University of Technology

In this booklet you will find

How to prepare for your walk:

DO

Wear comfortable shoes and clothing for your walk

Use your usual walking aids, such as your walking stick

Take your usual medications

Don't

Exercise prior to the walk

Have a heavy meal within 2 hours prior to the walk

You will need an area with a flat, hard surface, free of obstacles, where you can place your 5 metre rope in a straight line, and walk along it without interruption.

How to complete your walk at home

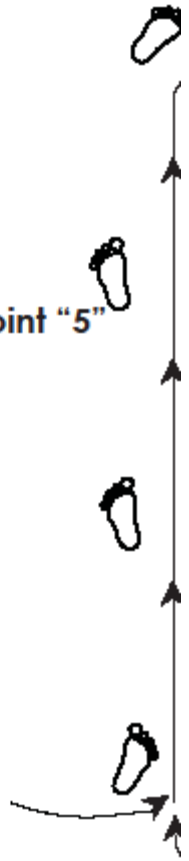
1. Stand at the starting line (one end of the rope)

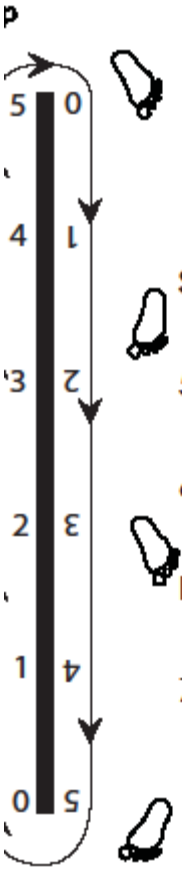
Always begin your walk at point "0" and walk towards point "5"

2. Set the timer to 6 minutes.

3. When you are ready, start the timer and walk.

4. Walk along the 5 metre rope, until you reach the end (point 5), then turn and head back to your starting point.





Try to cover as much distance as possible during the 6 minutes.

Stop and rest if you need to, resume walking when you feel you are able to continue.

5. You will need to remember how many laps you have walked over the six minutes.

6. Stop walk when your timer rings to indicate the end of the six minutes.

Remember where along the rope you stopped (point "1", "2", "3", "4" or "5")

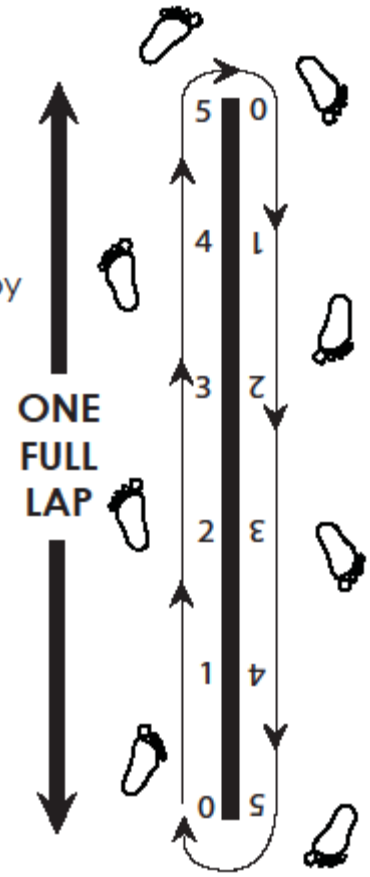
7. Record your distance and your level of exertion in the recording form (next page).

Please stop the walk if you begin to feel unwell or develop any chest pain, or unusual shortness of breath. Follow the action plan that your doctor or nurse gave you.

How to record the distance you walked

The distance covered during the Home-Heart-Walk will be calculated by 'Laps walked multiplied by the distance (in metres) per lap".

This calculation will be done by the nurse, so you only need to record the number of full laps you walked, and at which point you stopped in the unfinished lap.



6

One full lap - point "0" to point "5"

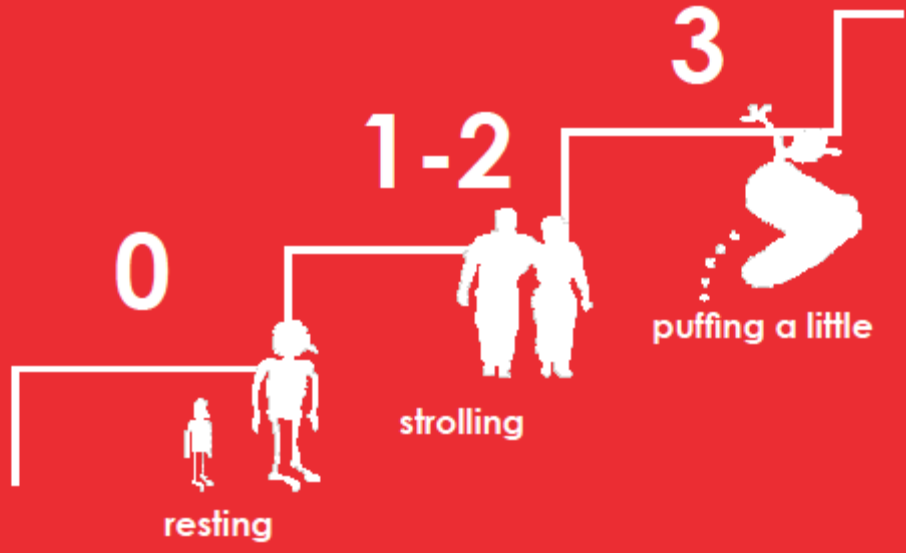
Example

Date	Distance covered in Home-Heart-Walk test
Day X	I walked 2 Full Laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap
Day Y	I walked Full Laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap Did not finish walk because I was feeling short of breath

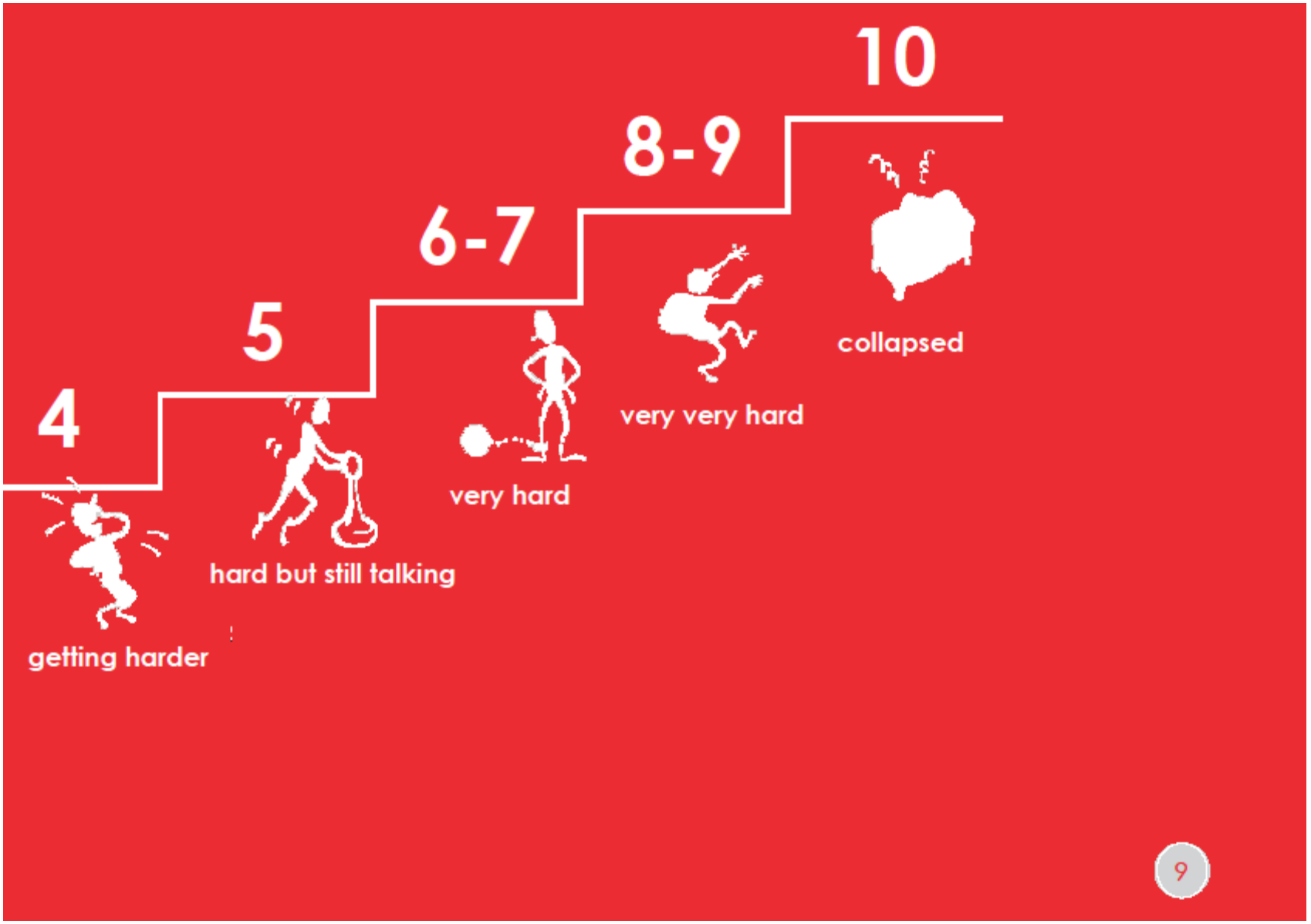
Please find the form on page 10 to record your distance walked

7

Effort Scale
(adapted from Borg scale)



8


10
8-9
6-7
5
4
collapsed
very very hard
very hard
hard but still talking
getting harder
9

Week One

Record your walk distance here

Date	Level of exertion (Before)	Distance covered	Level of exertion (After)
Example	*1*	I walked *2* full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	*4*
Day 1		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Day 2		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Day 3		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Day 4		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Day 5		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Day 6		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Day 7		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	

10

Record your walk distance here

Week & Date	Level of exertion (Before)	Distance covered	Level of exertion (After)
Week 2 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 3 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 4 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 5 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 6 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 7 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	

11

Record your walk distance here

Week & Date	Level of exertion (Before)	Distance covered	Level of exertion (After)
Week 8 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 9 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 10 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 11 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 12 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 13 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	

Congratulations! It is time for your 3 month follow-up! The researcher will contact you to arrange your appointment!

12

Record your walk distance here

Week & Date	Level of exertion (Before)	Distance covered	Level of exertion (After)
Week 14 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 15 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 16 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 17 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 18 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 19 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	

13

Record your walk distance here

Week & Date	Level of exertion (Before)	Distance covered	Level of exertion (After)
Week 20 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 21 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 22 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 23 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 24 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 25 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
Week 26 / /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	

14

Well done! It is time for your 6 month evaluation. The researcher will contact you to arrange your appointment!

Additional Home-Heart-Walk results

Record your walk distance here

Date	Level of exertion (Before)	Distance covered	Level of exertion (After)
/ /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
/ /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
/ /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
/ /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	
/ /		I walked full laps: and I stopped at 1 / 2 / 3 / 4 / 5 in the unfinished lap	

15

Thank you for completing the Home-Heart-Walk

Your appointments

3 Month Follow-up _____/_____/_____

6 Month Follow-up _____/_____/_____

Follow-up instructions

We are looking forward to seeing you again; please bring this booklet with you when you come to your follow-up appointment on the arranged date. Prior to each follow-up appointment, you should receive a questionnaire from us. The questionnaire is similar to the one you completed when you first enrolled in the study. Please complete the questionnaire and bring it with you.

Follow-up Record

Date	Weight	Hip Circumference	Waist Circumferance	The 6 Minute Walk Test
Baseline / /				
3 Month / /				
6 Month / /				

Comments and Suggestions

.....

.....

.....

.....

.....

.....

18 Your comments and suggestions will help us evaluate the Home-Heart-Walk Program.

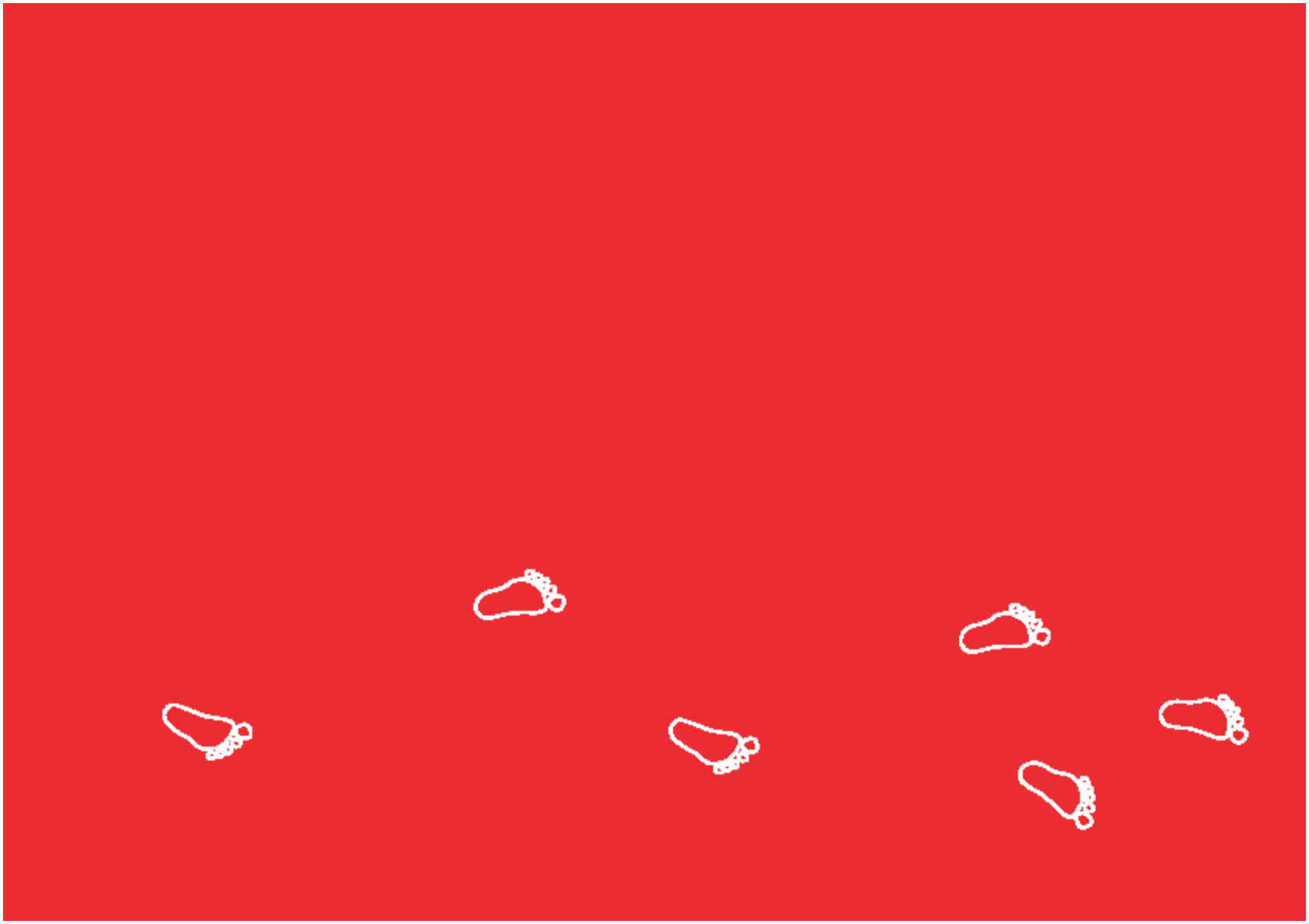
How to contact us

If you have any problems or enquiries while on the study, please contact the project supervisor.

Mailing address:
Centre for Cardiovascular & Chronic Care
Curtin University of Technology
39-47 Regent St, Chippendale, NSW, 2008

Professor Patricia Davidson
Office (02) 8399 7831
Mobile 0414 674 134

Hui Yun Du
Office (02) 8399 7836
Mobile 0423 844 323



Appendix 5 ATS guideline for the Six Minute Walk Test

Am J Respir Crit Care Med Vol 166. pp 111–117, 2002 DOI: 10.1164/rccm.166/1/111

INDICATIONS AND LIMITATIONS

The strongest indication for the 6MWT is for measuring the response to medical interventions in patients with moderate to severe heart or lung disease. The 6MWT has also been used as a one-time measure of functional status of patients, as well as a predictor of morbidity and mortality. The fact that investigators have used the 6MWT in these settings does not prove that the test is clinically useful (or the best test) for determining functional capacity or changes in functional capacity due to an intervention in patients with these diseases. Further studies are necessary to determine the utility of the 6MWT in various clinical situations.

CONTRAINDICATIONS

Absolute contraindications for the 6MWT include the following:

unstable angina during the previous month and myocardial infarction during the previous month. Relative contraindications include a resting heart rate of more than 120, a systolic blood pressure of more than 180 mm Hg, and a diastolic blood pressure of more than 100 mm Hg.

Patients with any of these findings should be referred to the physician ordering or supervising the test for individual clinical assessment and a decision about the conduct of the test.

The results from a resting electrocardiogram done during the previous six months should also be reviewed before testing. Stable exertional angina is not an absolute contraindication for a 6MWT, but patients with these symptoms should perform the test after using their antiangina medication, and rescue nitrate medication should be readily available.

SAFETY ISSUES

1. Testing should be performed in a location where a rapid, appropriate response to an emergency is possible. The appropriate location of a crash cart should be determined by the physician supervising the facility.

2. Supplies that must be available include oxygen, sublingual nitroglycerine, aspirin, and albuterol (metered dose inhaler or nebulizer). A telephone or other means should be in place to enable a call for help.

3. The technician should be certified in cardiopulmonary resuscitation with a minimum of Basic Life Support by an American Health Association–approved cardiopulmonary resuscitation course. Advanced cardiac life support certification is desirable. Training, experience, and certification in related health care fields (registered nurse, registered respiratory therapist, certified pulmonary function technician, etc.) are also desirable. A certified individual should be readily available to respond if needed.

4. Physicians are not required to be present during all tests. The physician ordering the test or a supervising laboratory physician may decide whether physician attendance at a specific test is required.

5. If a patient is on chronic oxygen therapy, oxygen should be given at their standard rate or as directed by a physician or a protocol.

Reasons for immediately stopping a 6MWT include the following:

1) chest pain

2) intolerable dyspnoea

3) leg cramps

4) staggering

5) diaphoresis, and

6) pale or ashen appearance.

Technicians must be trained to recognize these problems and the appropriate responses. If a test is stopped for any of these reasons, the patient should sit or

lie supine as appropriate depending on the severity or the event and the technician's assessment of the severity of the event and the risk of syncope.

The following should be obtained based on the judgment of the technician: blood pressure, pulse rate, oxygen saturation, and a physician evaluation. Oxygen should be administered as appropriate.

TECHNICAL ASPECTS OF THE 6MWT

Location

The 6MWT should be performed indoors, along a long, flat, straight, enclosed corridor with a hard surface that is seldom travelled. If the weather is comfortable, the test may be performed outdoors. The walking course must be 30 m in length. A 100-ft hallway is, therefore, required. The length of the corridor should be marked every 3 m. The turnaround points should be marked with a cone (such as an orange traffic cone). A starting line, which marks the beginning and end of each 60-m lap, should be marked on the floor using brightly coloured tape.

REQUIRED EQUIPMENT

1. Countdown timer (or stopwatch)

2. Mechanical lap counter

3. Two small cones to mark the turnaround points

4. A chair that can be easily moved along the walking course

5. Worksheets on a clipboard

6. A source of oxygen

7. Sphygmomanometer

8. Telephone

9. Automated electronic defibrillator

PATIENT PREPARATION

1. Comfortable clothing should be worn.

2. Appropriate shoes for walking should be worn.

3. Patients should use their usual walking aids during the test (cane, walker, etc.).

4. The patient's usual medical regimen should be continued.

5. A light meal is acceptable before early morning or early afternoon tests.

6. Patients should not have exercised vigorously within 2 hours of beginning the test.

MEASUREMENTS

1. Repeat testing should be performed about the same time of day to minimize intraday variability.

2. A "warm-up" period before the test should not be performed.

3. The patient should sit at rest in a chair, located near the starting position, for at least 10 minutes before the test starts. During this time, check for contraindications, measure pulse and blood pressure, and make sure that clothing and shoes are appropriate.

4. Pulse oximetry is optional. If it is performed, measure and record baseline heart rate and oxygen saturation (SpO2) and follow manufacturer's instructions to maximize the signal and to minimize motion artefact. Make sure the readings are stable before recording. Note pulse regularity and whether the oximeter signal quality is acceptable.

The SpO2 should not be used for constant monitoring during the exercise. The technician must not walk with the patient to observe the SpO2. If worn during the walk, the pulse oximeter must be lightweight (less than 2 pounds), battery powered, and held in place (perhaps by a "fanny pack") so that the patient does not have to hold or stabilize it and so that stride is not affected.

5. Have the patient stand and rate their baseline dyspnoea and overall fatigue using the Borg scale.

6. Set the lap counter to zero and the timer to 6 minutes. Assemble all necessary equipment (lap counter, timer, clipboard, Borg Scale, worksheet) and move to the starting point.

7. Instruct the patient as follows:

"The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway. Six minutes is a long time to walk, so you will be exerting yourself. You will probably get out of breath or become exhausted. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able.

You will be walking back and forth around the cones. You should pivot briskly around the cones and continue back the other way without hesitation. Now I'm going to show you. Please watch the way I turn without hesitation."

Demonstrate by walking one lap yourself. Walk and pivot around a cone briskly.

"Are you ready to do that? I am going to use this counter to keep track of the number of laps you complete. I will click it each time you turn around at this starting line. Remember that the object is to walk AS FAR AS POSSIBLE for 6 minutes, but don't run or jog.

Start now, or whenever you are ready."

8. Position the patient at the starting line. You should also stand near the starting line during the test. Do not walk with the patient. As soon as the patient starts to walk, start the timer.

9. Do not talk to anyone during the walk. Use an even tone of voice when using the standard phrases of encouragement.

Watch the patient. Do not get distracted and lose count of the laps. Each time the participant returns to the starting line, click the lap counter once (or mark the lap on the worksheet). Let the participant see you do it. Exaggerate the click using body language, like using a stopwatch at a race.

After the first minute, tell the patient the following (in even tones): “You are doing well. You have 5 minutes to go.”

When the timer shows 4 minutes remaining, tell the patient the following: “Keep up the good work. You have 4 minutes to go.”

When the timer shows 3 minutes remaining, tell the patient the following: “You are doing well. You are halfway done.”

When the timer shows 2 minutes remaining, tell the patient the following: “Keep up the good work. You have only 2 minutes left.”

When the timer shows only 1 minute remaining, tell the patient: “You are doing well. You have only 1 minute to go.”

Do not use other words of encouragement (or body language to speed up).

If the patient stops walking during the test and needs a rest, say this: “You can lean against the wall if you would like; then continue walking whenever you feel able.” Do not stop the timer. If the patient stops before the 6 minutes are up and refuses to continue (or you decide that they should not continue), wheel the chair over for the patient to sit on, discontinue the walk, and note on the worksheet the distance, the time stopped, and the reason for stopping prematurely.

When the timer is 15 seconds from completion, say this:

“In a moment I’m going to tell you to stop. When I do, just stop right where you are and I will come to you.” When the timer rings (or buzzes), say this: “Stop!” Walk over to the patient. Consider taking the chair if they look exhausted. Mark the spot where they stopped by placing a bean bag or a piece of tape on the floor.

10. Post-test: Record the postwalk Borg dyspnoea and fatigue levels and ask this: “What, if anything, kept you from walking farther?”

11. If using a pulse oximeter, measure SpO2 and pulse rate from the oximeter and then remove the sensor.

12. Record the number of laps from the counter (or tick marks on the worksheet).

13. Record the additional distance covered (the number of meters in the final partial lap) using the markers on the wall as distance guides. Calculate the total distance walked, rounding to the nearest meter, and record it on the worksheet.

Appendix 6 Permissions

Re: Permission to use Self-Efficacy scale

Albert Bandura [bandura@psych.stanford.edu]

Sent: Wednesday, 22 October 2008 8:52 AM

To: Hui Yun Du [H.Du@curtin.edu.au]

HuiYun

Permission granted.

Albert Bandura

On Wed, October 8, 2008 9:02 pm, Hui Yun Du wrote:
> Dear Professor Bandura:
>
>
>
> I am a postgraduate student undertaking a study titled "Home Heart
> Walk:
> evaluation of an intervention to promote and monitor physical
> activity'.
> This study will take place in three cardiology wards in Sydney South
> East Area Health Service and Sydney West Area Health Service. The Area
> Health Service Human Research Ethics Committee has approved the study.
>
>
>
> The study aims to evaluate a home-based exercise intervention (the
> Home-Heart-Walk) as a strategy to improve self-efficacy and promote
> physical activity in people with chronic heart failure. It is a
> randomized controlled trail. Patients will receive either usual care
> (standard care as area health service) or intervention (the
> Home-Heart-Walk program-6 months). The study will also explore the
> construct of self-efficacy and physical activity. Could I have your
> permission to use the exercise self-efficacy scale included in your
> 'Guide to constructing self efficacy scales'? I would be pleased to
> inform you of the results on completion of the study.
>
>
>
>
>
> Yours Sincerely
>
>
>
> HuiYun Du
>
>
>
>
>

From: Jaarsma, T [mailto:t.jaarsma@thorax.umcg.nl]
Sent: Wednesday, 13 August 2008 12:55 AM
To: Patricia Davidson
Subject: RE: Permission to use the European Heart Failure Self-Care Behaviour Scale

Dear Patricia

Please feel free to use the scale as you want. No special permission or fee is required.
We only ask proper referencing to:
Jaarsma T, Stromberg A, Martensson J, Dracup K. Development and testing of the European Heart Failure Self-Care Behaviour Scale. Eur J Heart Fail. 2003; 5:363-70

For your convenience I attach the UK English and US English versions.

Greetings

Tiny Jaarsma

Van: Patricia Davidson [mailto:P.Davidson@curtin.edu.au]
Verzonden: woensdag 30 juli 2008 9:25
Aan: Jaarsma, T
CC: Hui Yun Du; Yenna Salamonson; Phillip Newton
Onderwerp: Permission to use the European Heart Failure Self-Care Behaviour Scale

Hi Tiny

I am seeking permission for one of my doctoral students to use the European Heart Failure Self-Care Behaviour Scale in her doctoral project which is assessing a strategy to increase physical activity in patients with heart failure.

I would also appreciate you forwarding me a copy of the instrument so we can be absolutely sure we have the correct version.

Many thanks

Trish

Patricia Davidson RN PhD
Professor of Cardiovascular and Chronic Care
School of Nursing and Midwifery
Curtin University of Technology |Faculty of Health Sciences
Curtin House| 39 Regent St| Chippendale SYDNEY 2008
P: +61 2 83997831|**F** +61 2 83997834| **M**+61 (0) 414674134
Email: P.Davidson@curtin.edu.au
CRICOS Provider Code 00301J Perth 02637B Sydney

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Jul 26, 2011

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Licensed content title	Assessment of a Self-administered Adapted 6-Minute Walk Test
Licensed content author	HuiYun Du, Patricia Davidson, Bronwyn Everett, et al
Licensed content date	Jan 1, 2010
Volume Number	30
Issue Number	2
Type of Use	Dissertation/Thesis
Requestor type	Individual
Title of your thesis / dissertation	Home-Heart-Walk: Evaluation of an intervention to promote and monitor physical activity
Expected completion date	Aug 2011
Estimated size(pages)	300
Billing Type	Invoice
Billing Address	89, 86-88 Bonar street Wolli Creek, other 2205 Australia
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Appendix 7 Publications associated with this thesis