School of Physiotherapy and Exercise Science

Faculty of Health Sciences

The impact of community-based, nurse-supported heart failure management on self-care behaviour, psychosocial and clinical outcomes

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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 acknowledgement has been made.

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

The research presented and reported in this thesis was conducted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007) – updated in March 2014. The proposed research study received human research ethics approval from the Curtin University Human Research Ethics Committee (EC00262), Approval Number HR12/2014; Curtin University Human Research Ethics Committee (EC00262), Approval Number HR181/2014 and Royal Perth Hospital Research Ethics Committee (15-081), Approval Number REG 14-090.

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Abstract

Background: Chronic heart failure (CHF) results in a significant health and economic burden to contemporary Australian society. Over the next decade the incidence of CHF is anticipated to increase markedly, due to an ageing population and the improved management of acute heart failure, highlighting the importance of developing innovative, evidence-based models of care to optimise CHF management.

Nurses play an integral role in supporting patients with CHF, and in a community setting are often at the 'front-line' of patient management. Clinical care provided by nurses can vary depending on the nurse's qualification and their associated scope of practice. Registered nurses provide education to patients on the aetiology of CHF, support for self-care including medication adherence, fluid management and lifestyle modifications, and act as a conduit between the patient and doctor. Nurse practitioners, take on the same role as registered nurses but have a broader scope of practice, which include titrating select CHF medications and requesting tests.

In order to support the growing population of patients with CHF, alternative models of community-based heart failure management which utilise the clinical skills of nurses are urgently required.

Aims: The aim of this thesis was to investigate the effects of two different models of community-based nurse-led CHF care, on patient self-care, quality of life and clinical outcomes.

Methods: Two discrete studies were conducted. Study 1 evaluated the effects of a community-based, nurse practitioner-led clinic, providing education and follow-up support to patients with CHF, compared with a control group of patients who didn't have access to community-based care. Study 2 was a randomised controlled trial of the effects of a nurse-supported telemonitoring intervention for patients with CHF. The intervention in the latter study was informed by a systematic review and subgroup meta-analysis of different telemonitoring strategies from prior studies in patients with CHF, and participants' feedback of their experience of the telemonitoring program was evaluated through a post-intervention questionnaire.

Results: In Study 1, participants who received nurse-practitioner support had better self-care behaviour ($p<0.05$), mental component summary of the Short Form-36 ($p<0.05$) and heart failure-specific quality of life ($p<0.05$). All-cause hospitalisations were delayed ($p<0.05$) and length of stay was shorter ($p<0.05$) in the group receiving nurse practitioner support, but there were no differences in CHF-related admissions.

In Study 2, participants who received the telemonitoring intervention achieved significantly higher compliance with the *a priori* primary outcome of weighing themselves at least 6 days a week, compared with the usual care control group (intervention: 41/91, 45% vs control: 23/93, 25%; $P<0.01$).

The majority of participants agreed or strongly agreed that the telemonitoring program was easy to use (61/67, 91%), easy to navigate (51/65, 78%), useful (59/65, 91%), and made them feel more confident in managing their weight (57/67, 85%). Themes arising from participants' feedback included that the telemonitoring program increased support for early intervention of clinical deterioration, improved compliance to daily weighing, provided a sense of reassurance, and improved self-care and accountability.

Conclusions: Community-based, nurse-led models of care improved self-care in patients with CHF. Telemonitoring appears to be a valuable adjunct to traditional approaches to patient management, providing support to patients remotely and increasing compliance and confidence with self-care behaviours. Further research involving implementation science approaches are required to support embedding these models of care into clinical services that are sustainable to help meet the challenges of managing patients with CHF into the future.

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List of publications and presentations related to this thesis

Research papers:

1. **Chen SH**, Boyd J, Randall S, Maiorana A. Association between community-based nurse practitioner support, self-care behaviour and quality of life in patients with chronic heart failure. Australian Journal of Advanced Nursing. 2021; 38(3). DOI https://doi.org/10.37464/2020.383.147

2. Ding H, **Chen SH**, Edwards I, Jayasena R, Doecke J, Layland J, Yang I, Maiorana A. The effects of different telemonitoring strategies in chronic heart failure care: a systematic review and subgroup meta-analysis. Journal of Medical Internet Research: 2020; 22(11) e20032.

3. Ding H, Jayasena R, Maiorana A, Dowling A, **Chen SH**, Karunanithi M, Layland J, Edwards I. Innovative Telemonitoring Enhanced Care Programme for Chronic Heart Failure (ITEC-CHF) to improve guideline compliance and collaborative care: protocol of a multicentre randomised controlled trial. BMJ Open. 2017; 7(10):e017550. doi: 10.1136/bmjopen-2017-017550.

4. Ding H, Jayasena R, **Chen SH**, Maiorana A, Dowling A, Layland J, Good N, Karunanithi M, Edwards I. The Effects of Telemonitoring on Patient Compliance With Self-Management Recommendations and Outcomes of the Innovative Telemonitoring Enhanced Care Program for Chronic Heart Failure: Randomized Controlled Trial. Journal Medical Internet Research 2020;22(7): e17559.

5. **Chen SH**, Edwards I, Jayasena R, Ding H, Karunanithi M, Dowling A, Layland J, Maiorana A. Patient Perspectives on Innovative Telemonitoring Enhanced Care Program for Chronic Heart Failure (ITEC-CHF): Usability Study. JMIR Cardio. 2021; 5(2):e24611. doi: 10.2196/24611. PMID: 34519663; PMCID: PMC8479597.

Conference presentations:

1. **Chen SH**, Maiorana A, Davidson P, Leslie G, A randomised controlled trial of nurse-supported telehealth for people with heart conditions. Oral presentation at the Cardiology Journal Club Presentations Fiona Stanley Hospital (Western Australia), Perth, Australia, 16 Oct 2015.

2. **Chen SH**, Maiorana A, The impact of a nurse practitioner-led, community-based heart failure management service on self-care behaviour. Oral presentation at the Australian Cardiovascular Health and Rehabilitation Association Research Conference 27th Annual Scientific Meeting (Western Australia), Perth, Australia, 7-9 August 2017.

3. **Chen SH**, Maiorana A, The impact of a nurse practitioner-led, community-based heart failure management service on self-care behaviour. Paper presentation at the 2018 Allied Health Research Forum (Western Australia), Perth, Australia, 10 May 2018.

4. **Chen SH**, Maiorana A, Telemonitoring of body weight improves quality of life in patients with chronic heart failure. Oral presentation at the Australian Cardiovascular Health and Rehabilitation Association Research Symposium (Western Australia), Perth, Australia, 18 July 2018.

5. **Chen SH**, Maiorana A, Improved daily weighing compliance with telemonitoring in patients with CHF. E-Poster presentation at the SMHS Research Showcase. (Western Australia), Perth, Australia, 28 November 2019.

List of Awards and Research Grants:

1. School of Physiotherapy – Department of Health Top-up Scholarship, Perth, Australia, March 2015.

2. SPARK Co-Lab Medical Innovation Scholarship, Perth, Australia, Jun 2017.

3. Best Student Presentation Award. South Metropolitan Health Service Research Showcase 2019.

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List of Abbreviations

6MWT	Six-Minute Walk Test
ACE	angiotensin-converting enzyme
AF	atrial fibrillation/atrial flutter
ARNI	angiotensin receptor neprilysin inhibitor
BP	blood pressure
CAD	coronary artery disease
CDS-SF2	cardiac depression scale
CHF	chronic heart failure
CIs	confidence intervals
CKD	chronic kidney disease
COPD	chronic obstructive pulmonary disease
CRF	case report forms
D/A	depression and anxiety
ECG	electrocardiogram
ED	emergency department
EF	ejection fraction
EQ-5D	Five-dimension EuroQol health related quality of life questionnaire
GP	general practitioner
HFmrEF	heart failure with a mildly-reduced ejection fraction

HFpEF	heart failure with preserved ejection fraction
HFrEF	heart failure with reduced ejection fraction
HQoL	health-related quality of life
HR	heart rate
HREC	human research ethics committee
HTN	hypertension
ICD	implantable cardioverter defibrillator
ICD-10-CM	international classification of diseases, tenth revision, clinical modification
IHD	ischaemic heart disease
IRR	incidence rate ratio
ITEC-CHF	innovative telemonitoring enhanced care program for chronic heart failure
KCCQ	Kansas City Cardiomyopathy Questionnaire
LVEF	left ventricular ejection fraction
MCS	mental component summary
mHealth	mobile health.
MI	myocardial infarction
MLHFQ	Minnesota Living with Health Failure Questionnaire
MMH	Manage My Health
NYHA	New York Heart Association

PC	personal computer
PCB	project control board
PCS	physical component summary
PWG	project working group
QOL	quality of life
RCT	randomised controlled trial
RR	risk ratio
SCHFI	Self-care Heart Failure Index
SD	standard deviation
SF-36	Short Form-36
SGLT-2	sodium-glucose cotransporter-2
T2DM	type 2 diabetes mellitus
TAM	technology acceptance model
UC-CHF	usual care - chronic heart failure
VIC	Victoria
WA	Western Australia

Chapter 1 - Introduction

1.1 General introduction

Chronic heart failure (CHF) is a chronic condition resulting from cardiovascular disease of varying aetiologies and is characterised by an impaired capacity of the heart to pump blood efficiently throughout the body.[1] Common causes of CHF are myocardial infarction, hypertension, heart valve defects, coronary artery disease and viruses, however, there are many other less common causes.[2] In the contemporary context, CHF is characterised based on whether left ventricular ejection fraction (LVEF) is impaired or not; heart failure with reduced ejection fraction (HFrEF) is typically considered as a LVEF of less than 40%, and heart failure with preserved ejection fraction (HFpEF) is typically considered as a LVEF of greater than or equal to 50%. LVEF that ranges from 40 to 49% has been termed heart failure with mildly-range ejection fraction (HFmrEF).[2]

Chronic heart failure is a major public health burden and is increasing worldwide. In Australia, it is estimated that 2.1% of the population have CHF.[3] Chronic heart failure accounts for almost one in 50 deaths, equating to one person dying of heart failure every three hours.[4]

The prevalence of CHF is expected to rise dramatically in Australia over the next decade due to an ageing population and improved survival from acute cardiovascular events.[5] Even though advances in medical treatment have led to increased survival following CHF diagnosis, the death rate for CHF patients remains high; 3648 deaths occurred in 2019.[4] It has been estimated that approximately 325,000 Australians (4.5 % of the population aged ≥ 45 years) were afflicted with this complex syndrome.[6]

From an economic perspective, CHF is one of the most costly health care problems faced by the Australia health care system. In 2015 -2016, there were approximately 173,000 admissions where cardiomyopathy or heart failure were the primary diagnoses, representing an estimated hospitalisation rate of 1.6% of all hospital admissions.[1] In 2017, the health care costs of CHF amounted to $3.1 billion per year.[7] Chronic heart failure patients are at high risk of relapse and much of the high health-care cost of CHF relates to readmissions.[8, 9] Therefore government, health care

providers, health insurers and patients need to explore new opportunities for improving the effectiveness and efficiency of CHF care.

Over the past three decades, an increased understanding of the pathophysiology, in addition to evidence-based pharmacologic interventions such as angiotensin-converting enzyme (ACE) inhibitors and β-adrenoceptor antagonists, and more recently angiotensin receptor neprilysin inhibitor (ARNI) and sodium-glucose cotransporter-2 (SGLT-2) have advanced the prognosis, quality of life and survival of patients with CHF.[7, 9-13] Despite these improvements, high morbidity, mortality and readmission rates associated with CHF remain.[9, 14] Factors contributing to this include poor compliance with medication, inadequately controlled ischemic heart disease or hypertension, ineffective discharge planning or follow-up and suboptimal self-management.[9, 14, 15] There are also many other barriers such as lack of awareness and continuing education for health professionals, time constraints, poor communication between different specialties, and cost factors.[16, 17] As a consequence, non-pharmacologic interventions have become an essential element in the management of the patient with CHF, as an adjunct to medical therapy.[18, 19] Nurses play an important role in supporting and encouraging patients in performing self-care in managing CHF.[20] Because self-care activities can be demanding for some patients, the collaboration between patients and nurses is important for illness adaptation, self-care success, and quality of life improvement,[1, 20] and many patients benefit from the support and encouragement nurses can provide.

The overarching objective of this thesis was to evaluate different models of nurse-supported management of patients with CHF, focusing on patients with HFrEF, and is comprised of two discrete studies:

Study 1 evaluated the effects of a community-based, nurse practitioner-led CHF management clinic on self-care behaviour and quality of life. An age and gender-matched group of patients with CHF, but who were not offered community-based, nurse-supported heart failure management, were recruited as a control group.

Study 2 involved a randomised, controlled trial of nurse-supported telemonitoring of patients with CHF. Participants randomised to the telemonitoring intervention were provided with a computer tablet, blue-tooth enabled weighing scales and access to

CHF self-management software which allowed a nurse to monitor the patients' health and compliance with body weight measurements remotely. The telemonitoring intervention was patient-centred, providing patients with education and support for self-management and had a strong focus on coordination of care through the feedback of clinical information to help participants implement timely medical follow-up for episodes of clinical deterioration. Participants in the control group received usual care through their cardiologist, general practitioner or other support services. Participants feedback on the usability of the telemonitoring intervention to determine the benefits and barriers to using the telemonitoring intervention for CHF management was also evaluated.

1.2 Aims and Hypotheses

The specific research aims and hypotheses were:

Study 1

Aim 1: To evaluate the effects of a community-based, nurse practitioner-led clinic, involving education and follow-up support, compared with usual care.

Hypothesis 1: A community-based nurse practitioner-led clinic involving education and follow-up support will improve self-care behaviour and quality of life in patients with CHF, compared with usual care.

Study 2

Aim 2: To evaluate the effects of a nurse-supported telemonitoring intervention, compared with usual care.

Hypothesis 2a: Nurse-supported telemonitoring will improve weight monitoring compliance in patients with CHF, compared with usual care.

Hypothesis 2b: Nurse-supported telemonitoring will improve self-management skills, self-care behaviour and quality of life in patients with CHF, compared with usual care.

Hypothesis 2c: Nurse-supported telemonitoring will improve clinical outcomes by reducing the rate and length of hospital readmissions in patients with CHF, compared with usual care.

Aim 3: To evaluate patients' feedback following participation in the nurse-supported telemonitoring program.

This aim was not hypothesis driven.

1.3 Thesis structure

This thesis is presented as a thesis by publications. This format was selected for its many benefits such as writing the thesis efficiently, disseminating the research findings in a timely manner and refining my writing skills throughout my higher degree research journey. The publication strategy reflected the goal of reaching a diverse audience, spanning multiple professional areas including nursing, cardiology and digital health.

Five manuscripts arising from the project, published in peer-reviewed journals, are presented in the thesis as chapters. Chapter 3 describes outcomes from a community-based, nurse practitioner-led CHF clinic. Chapters 4-7 relate to remote telemonitoring in patients with CHF; Chapter 4 is a systematic review and sub-group meta-analysis of telemonitoring in CHF, Chapter 5 is a protocol paper for a randomised, controlled trial of nurse-supported telemonitoring in patients with CHF, the *Innovative telemonitoring enhanced care program for chronic heart failure (ITEC-CHF)*, Chapter 6 describes the main outcomes from the ITEC-CHF study and Chapter 7 reports usability and patient feedback from the ITEC-CHF study. Tables and figures have been embedded within the text. References are presented at the conclusion of each chapter.

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Chapter 2 - Literature review

2.1 Chronic heart failure

2.1.1 Definition

Chronic heart failure (CHF) is a chronic cardiovascular disease characterised by an inability of the heart to fill with or eject blood due to structural or functional cardiac abnormalities. The National Heart Foundation of Australia[1] defines CHF as a condition that develops after the heart has been damaged or weakened due to medical events such as: 1) previous myocardial infarction (MI); resulting in scar tissue in the myocardium that impedes function; 2) hypertension (HTN); 3) a primary disease of the heart muscle, i.e. cardiomyopathy; 4) coronary artery disease (CAD) causing narrowing of the arteries that supply blood to the heart; 5) infection of the heart valves or heart muscles, i.e. endocarditis or myocarditis or; 6) cardiac valve disease, from rheumatic fever or other illnesses. Other causes of heart failure include drugs such as chemotherapy and methamphetamine, pregnancy (peripartum cardiomyopathy) and congenital heart conditions.

2.1.2 Clinical characteristics of chronic heart failure

Chronic heart failure is characterised by periods of relative clinical stability, interrupted by episodes of acute exacerbation when cardinal signs and symptoms are more evident. These symptoms can be quite diverse and may include new or worsening shortness of breath, palpitations, exercise intolerance (including fatigue and weakness), swelling of the ankles or legs, cough, weight gain, abdominal distension, nocturia and cool extremities.[1-7] Symptoms of CHF vary markedly between individuals, depending on factors such as treatment adherence and the individual's capacity to compensate for inadequate cardiac function.

Due to improvements in contemporary medical therapy and support systems for patients with CHF, many patients today experience longer periods of stability between exacerbations and experience less symptom burden. However, there continues to be a need for further development in treatment and management strategies to optimise patient outcomes.

2.2 Burden of chronic heart failure

Chronic heart failure places a heavy burden not only on patients and their families but also on society, due to the pressure it puts on healthcare resources. Despite advancements in CHF management strategies, pre-discharge education, post-discharge education and follow-up care [8-10], CHF remains a condition that has a significant negative physical, psychological and social impact on patients.[11-13]

2.2.1 Prognosis in patients with chronic heart failure

The natural history of CHF is clinical deterioration over time with worsening symptoms and more frequent and severe episodes of decompensation as the disease progresses, eventually resulting in death from progressive heart failure, cardiac arrhythmia or end-organ failure.[7] Encouragingly, over the past 20 years, due to an evolving understanding of the pathophysiological mechanism of CHF, and improvement in treatment and management strategies, the prognosis of CHF while still poor has improved, with one, five, and 10-year survival rates increasing by 6.6% (from 74.2% in 2000 to 80.8% in 2016), 7.2% (from 41.0% in 2000 to 48.2% in 2012), and 6.4% (from 19.8% in 2000 to 26.2% in 2007), respectively.[4] Accordingly, more people are living with CHF, highlighting the importance of new strategies to help them live well, despite their condition.

2.2.2 Impact of chronic heart failure on hospitalisation and readmissions

In Australia, it is estimated that 2.1% of the population have CHF.[14] While CHF can affect individuals at any age, it is most common in older people,[15-17] with most cases occurring in people over the age of 65.[15, 18] In the United States, CHF is the leading cause of hospital admission among patients over 65 years of age, and in total is responsible for over 1 million hospital admissions annually.[19] This increases the demands on health resources, places a burden on the healthcare system, and increases healthcare expenditure.[20] In addition to primary hospitalisations, CHF is

responsible for high readmission rates, with up to 25% of patients being readmitted within 30 days after discharge from hospital [21], and 50% of patients readmitted within 6 months.[21] Many of these readmissions are preventable, attributed to factors such as insufficient patient education, poor compliance with prescribed medications, and inability to maintain self-care behaviours.[22]

2.2.3 Impact of chronic heart failure on quality of life

Chronic heart failure symptoms may impair activity tolerance, cause depression, stress, and emotional disturbance, and as a consequence, negatively impact patients' quality of life (QOL).[12].[23] Providing support to patients that help them optimise their QOL is considered a core component of CHF management because patients experiencing emotional distress are less likely to perform effective self-care.[8] This has become increasingly important as the treatment options for CHF have improved, and life expectancy has increased.

Quality of life can be assessed using instruments (questionnaires) that are either generic or disease-specific.[24] Generic instruments involve general health questions applicable to a wide range of groups, age, diseases and cover a wide range of QOL domains,[25, 26] such as the Short Form 36 (SF-36).[27] Disease-specific instruments are specifically designed for heart failure-related QOL. The Minnesota Living with Health Failure (MLHF) Questionnaire[25, 27] and the Kansas City Cardiomyopathy Questionnaire (KCCQ)[28] are the most frequently used disease-specific instruments. In QOL research, it is recommended that both a generic and a disease-specific instrument be combined to synergise the advantages inherent in each instrument.[25]

2.3 Chronic heart failure management

Historically, CHF management focussed predominantly on acute care.[29] However, there has been a changing focus towards more proactive and preventative

management models to help patients maintain optimal health between periods of decompensation and reduce the incidence and severity of these episodes.[30, 31]

The National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand have outlined CHF management guidelines.[1] The guidelines highlight the importance of an approach that combines pharmacological and non-pharmacological treatment strategies for patients with CHF. Chronic heart failure is managed pharmacologically by a combination of ACE inhibitors/angiotensin II receptor blockers or angiotensin receptor neprilysin inhibitors, beta-blockers, vasodilators, aldosterone antagonists and diuretics and more recently, sodium-glucose cotransporter-2 (SGLT-2) inhibitors.[1-3, 32-34] Non- pharmacological strategies such as regular physical activity, salt and fluid restrictions, and daily weighing to monitor for fluid retention, are important adjuncts to pharmacotherapy in comprehensive CHF management.

The goals of CHF management are to reduce mortality and rehospitalisation rates and improve the quality of life for patients with CHF through individualised patient care. The Cochrane Review, "Disease management interventions for heart failure", identified three types of CHF disease management models; (1) clinic-based approaches, (2) case management, and (3) multidisciplinary.[29] Nurses play a pivotal role in all these models. Successful CHF clinics may be predominantly nurse-led and generally require an ongoing commitment of resources, the application of established clinical practice guidelines, an appropriate infrastructure, and a culture of quality assessment.[1, 29] Case management, which is usually specialist nurse-driven, may include education pre/post-discharge, specialist nurse home visits, scheduled telephone calls for symptom management, and instruction on when to seek help.[1, 29] Nurses are key drivers in the multidisciplinary care team for CHF management which are comprised of coordinated interventions and communications including patient–caregiver education regarding their disease, medication and diet, nurse clinic visits, regular telephone calls, individualised follow-up plan, and access to physician, dietician, pharmacist, social worker and physiotherapist/exercise physiologist.[1, 29]

2.3.1 The role of nurses in the management of chronic heart failure

As described above, nurses (and nurse practitioners) play a critical role in CHF management and are responsible for much of the education provided to patients and their carers.[1] Important education topics include disease awareness and understanding, the role of medications, lifestyle issues, self-management strategies and encouraging a healthy diet and regular exercise.[35] Nurse practitioners are nurses with an advanced scope of practice and are uniquely credentialed to apply case management for patients with CHF.[36] This extends to making decisions about medication titration and requesting blood tests as well as supporting patients in a holistic approach to managing their health, including co-morbidities.[36] Heart failure education should commence while the patient is hospitalised. However, the opportunity for education may be limited due to competing clinical demands during the inpatient period, and the short duration of time some patients spend as an inpatient. This highlights the importance of further opportunities to provide CHF education after hospital discharge to empower CHF patients to make informed decisions about actions to take and those to avoid for effective self-care.[37] An important element of CHF education is conveying information to improve self-care behaviours,[38,39] because appropriate self-care can reduce disease exacerbations, enhance quality of life, and lower costs for patients with CHF.[40, 41] Self-care in CHF is described further in the next section.

Nurses often take a focal role in case management of patients with CHF through close monitoring of patients post-discharge. This may involve face-to-face clinics, home visits, telephone calls or telehealth.[29] Similarly, nurses complement medical management in clinic-based approaches and are often the first line of assessment when patients attend the clinic.[42, 43] Nurses are well-suited as primary educators because they can build trusting relationships by spending more time communicating with patients and their families.[44, 45]

Nurse-led and nurse practitioner-led programs of care have been successfully applied to improve clinical outcomes in patients recently hospitalised with CHF.[40, 46-52] Systematic reviews and meta-analyses of randomised controlled studies of nurse-led post-discharge programs involving components such as self-care education, physical

examinations, psychosocial support, and education on heart failure management have been found to improve clinical outcomes. [46, 47, 49, 50, 52] For example, Ruppar et al. [52] found that self-care interventions that emphasised medication adherence achieved a significant reduction in mortality and hospital readmissions in patients with CHF. A recent systematic review showed that advanced practise, nurse-led CHF management interventions demonstrated a decrease in mortality and length of hospitalisation whilst having positive effects on cost-benefit and improving the quality of life of patients with CHF.[50] Similarly, another meta-analysis showed that comprehensive nurse-led discharge planning plus post-discharge support for patients with CHF significantly reduced readmission rates and may improve health outcomes such as survival and QOL without increasing costs.[47] These data together suggest that nurse-led or nurse practitioner-led programs can improve QOL, reduce readmissions and mortality rates in CHF patients, and have potential cost-saving benefits.[40, 46-51]

2.4 Self-care in patients with chronic heart failure

2.4.1 Definition of self-care

Orem's Self-Care Deficit theory identifies self-care as a learned, goal-oriented activity of individuals:

> *"It is behavior that exists in concrete life situations directed by persons to self or to the environment to regulate factors that affect their own development and functioning in the interest of life, health, or well-being"* [53]

Accordingly, self-care involves activities performed intentionally by individuals, families and communities to promote health and prevent disease.[54] In the context of CHF management, self-care involves a variety of actions including medication adherence, regular exercise, vaccinations, diet modification (restricting sodium, fat, cholesterol, and alcohol), abstinence from smoking and illicit drugs, and fluid restrictions and daily weighing to monitor fluid balance.[1, 2, 55, 56,5,48] Monitoring weight is a key component in the self-care of CHF because rapid fluctuations in weight reflect fluid imbalance which may highlight that other aspects of self-care are not being

adhered to, or that the patient's heart failure is worsening. If neglected and untreated, fluid retention can lead to worsening symptoms and unplanned hospitalisation.[1, 2, 55, 56] When rapid weight gain occurs (increases by 2 kg over 2 days) in an individual with CHF, they should self-initiate some form of adjustment.[1] For this adjustment to occur, they must have the knowledge to inform their action i.e. that an increase in diuretic dose, as advised by their treating clinician, will reduce fluid retention (outcome expectation), as well as the confidence that this action is the correct response to the weight gain (efficacy expectation).[57]

Effective CHF self-care also depends on a patient's competency to recognise, understand and report signs and symptoms of clinical deterioration to healthcare providers.[21, 58] A variety of health care strategies have been developed to provide support for patients to achieve this, including outpatient clinics, regular follow-up phone calls, home visits, and assistance from support groups and community health volunteers.[8-10] In addition, CHF self-care can be supported by providing education, using a patient-centred care approach,[38, 54] lifestyle modification programs, supporting patient education, and providing social and emotional support.[8, 11]

The effectiveness of CHF management programs for improving self-care has been investigated in several systematic reviews.[40, 46, 54,47] Buck et al. investigated the outcomes, context and components of dyadic self-care interventions.[59] The review, which included 18 papers published between 2000 and 2016, found that self-care is related to the adaptation of behaviour and lifestyle. Outcomes of dyadic interventions were categorised into four groups: behavioural outcomes (carer tasks, self-care), cognitive outcomes (knowledge, perceptions control, readiness to care), affective outcomes (strain, social support, depression), and the utilisation of healthcare services (hospitalisations). Dyadic interactions in the context of CHF are important in relation to the experiences of stress, support and a sense of security of patients and caregivers. The systematic review reported a number of limitations of these studies, including small sample sizes, poor quality of studies, methodological weaknesses, mixed intervention effects, significant lack of reliable and detailed information, and unclear descriptions of the dose and amount of CHF intervention delivered. A second systematic review sought to identify strategies that assisted with accommodating self-care recommendations into daily life.[54] The authors reported that healthcare providers,

including nurses, need to understand that patients perceive self-care as an adaptation to their behaviours to maintain their quality of life. Furthermore, it was recommended that healthcare providers adopt individualised strategies for patients based on their different experiences, knowledge and self-care skills. The review demonstrated that negative emotions caused by CHF, such as depression and anxiety negatively affect patients' ability to engage in self-care. Therefore, the emotional reactions of patients and their personal experiences with CHF symptoms should be explored to optimise self-care strategies, and nurses can play a critical role in this process.[60, 61] A further conclusion drawn by this review is that individualised CHF management, such as a case-management approach, should be adopted to improve CHF self-care and quality of life.[54] Highlighting the importance of patient-centred support for the efficacy of self-care interventions, an integrative review of 19 randomised controlled trials found that studies that augmented standard education with cognitive behavioural strategies demonstrated significant improvement in knowledge and self-care among patients with CHF. The review concluded that standard education alone is not sufficient to improve self-care. This finding highlights the importance of augmenting standard CHF education by incorporating other approaches such as cognitive behavioural intervention, peer support and social support which nurses are well-placed to facilitate given that they are commonly the intermediary between the patient and their family, and other members of the multidisciplinary team. Another systematic review of nine randomised controlled trials that examined the effectiveness of self-care interventions in patients with CHF[47] concluded that cognitive status, health literacy, depression, and self-efficacy or self-confidence were all important to self-care capacity among patients with CHF, and attention to these factors is important. Accordingly, nurse-led CHF management programs should consider these factors to tailor the best CHF management to patients. In addition, knowledge alone is insufficient to improve self-care or decrease clinical events and/or symptom burden. Thus, augmenting education with interventions that will enhance self-confidence and empower patients effectively promotes optimal self-care and reduces symptom burden.

CHF self-care strategies should include enhancing patients' understanding of CHF illness, the involvement of a family member in the care process, and providing patients with psychological and social support.[62] Over 60% of the included studies included in

the systematic review showed that effective follow-up care or support provided by healthcare providers had a significant positive impact on self-care, with the role of the nurse central to this process. The review suggested that the effectiveness of CHF strategies is decreased when healthcare providers focus on simply delivering information during follow-up visits or prioritising treatment goals over the goals, preferences, values or cultural beliefs of patients.[62]

Despite the comprehensive efforts made to improve self-care, the two most common reasons for unplanned hospitalisation in patients with CHF continue to be non-adherence to prescribed medication and not seeking medical care in a timely fashion.[63-67] Indeed, it has been estimated that up to 70% of hospitalisations due to CHF are preventable, with ineffective CHF self-care a significant contributing factor. Accordingly, new strategies to support self-care are warranted that combine traditional approaches to CHF management with innovative nurse-led strategies and new technologies which allow nurses to focus on the patient's continuing therapeutic care through support, education and action.

2.5 Telemonitoring in patients with chronic heart failure

Digital health technology is a rapidly evolving area of healthcare which offers significant potential to complement traditional CHF management approaches. Telemonitoring is a form of digital health which draws on digital technology to help the healthcare provider monitor the patient remotely, such as in their own home. This can enable patients with chronic illnesses such as CHF to remain at home while improving healthcare access and reducing healthcare costs.[66, 68, 69]

Telemonitoring involves the remote assessment of real-time physiological data and can be used to guide clinical decision-making. There are four main approaches to telemonitoring in CHF: i) structured telephone support, ii) stand-alone telemonitoring devices, iii) implantable/invasive remote monitoring systems, and iv) wearables.[70] Telemonitoring allows healthcare providers to be alerted when measurements exceed a predetermined threshold so that support can be provided to patients in a timely

manner. This provides an opportunity for early clinical intervention to prevent further exacerbation of a condition.

Telemonitoring can be applied to case management of CHF and as a mechanism for supporting a nurse-led self-care model. As described in previous sections, many patients require a degree of support to effectively self-manage chronic conditions such as CHF.[71] If alerted early, nurses or other healthcare providers can intervene when a person's health is declining, potentially preventing costly escalations in care, including hospitalisation.

Daily weight monitoring is a strong case in point, as it is a sentinel for fluid retention, which may reflect poor medication compliance (especially for diuretics), lack of adherence to fluid restriction or clinical deterioration. However, weight monitoring is often inconsistent amongst patients[72-74], so there is a clear need to provide support for daily weight monitoring in the care of CHF.

Several systematic reviews and meta-analyses have been performed that highlight the benefits of nurse-led telemonitoring in CHF. These studies showed that nurse-led telemonitoring is associated with a reduced risk of all-cause mortality and CHF-related hospitalisations.[56, 69, 75-77] There are also additional benefits of improved QOL, reduced cost of management and improved self-care among CHF patients enrolled in telemonitoring programs targeted at body weight.[78-81]

Telemonitoring in CHF is addressed in more detail through a systematic review and sub-group meta-analysis in Chapter 4 of this thesis.

To provide context to the impact of the COVID-19 pandemic on the adoption of telemonitoring, it's important to understand the timeline of events leading up to the thesis submission. Here's an explanation of the pre-COVID project and the subsequent thesis submission:

Pre-COVID Project (Before the Pandemic):

- The research project, which served as the foundation for the thesis, was conducted before the COVID-19 pandemic emerged.

- At that time, the world was operating in a relatively normal healthcare environment, and the use of telemonitoring in CHF management was gradually gaining attention but had not yet reached its peak adoption.[82]
- Data collection, analysis, and thesis preparation were conducted in this pre-COVID environment.

Thesis Submission (During/After the COVID-19 Pandemic):

- The COVID-19 pandemic had a profound and transformative impact on healthcare practices, including the use of telemonitoring.[83, 84]
- As the thesis was being prepared for submission, the world was experiencing the effects of the pandemic, including lockdowns, restrictions on in-person healthcare visits, and the need to minimise the risk of virus transmission.

The COVID-19 pandemic has accelerated the adoption of telehealth and telemonitoring technologies for heart failure management.[85, 86] Due to the need to minimize in-person healthcare interactions and reduce the risk of virus transmission, both patients and healthcare providers turned to telehealth solutions.[87] This rapid adoption has transformed the way heart failure is managed, making remote monitoring, teleconsultations, and telemedicine a more common component of care delivery.[82-84]

The COVID-19 pandemic has driven a significant shift in heart failure management, with the increased use of telehealth and telemonitoring at the forefront.[82] This transformation has not only improved access to care but has also paved the way for a more data-driven, patient-centred, and adaptable approach to heart failure management.[84, 88] It is likely that these changes will continue to shape the field in the post-pandemic era.

2.6 Summary

This chapter has provided an overview of the key constructs and epistemological underpinnings of nurse-led management modalities for people with CHF.

Nurses are integral to the care of patients with CHF. While studies to date demonstrate that nurse-led CHF management programs can improve patient outcomes, there remains a need to explore targeted approaches to nurse-led CHF management that investigate innovative models of CHF care.

The current thesis explored two such models where nurses worked independently in a community setting to support patients with CHF;

1. A nurse practitioner service involving mixed modes of care provision (face-to-face, telephone and home visits).

2. A nurse-led telemonitoring program that provided CHF patients with support based on changes in body weight, a sign of non-adherence with self-care guidelines and an early indicator of clinical deterioration.

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Chapter 3 - Study 1: Association between community-based nurse practitioner support, self-care behaviour and quality of life in patients with chronic heart failure

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Declaration of candidate contribution

The following Chapter was published as a first authorship by the PhD candidate. The candidate contributed to the formulation of the study, contacting and engaging participants (via phone call, mail and e-mail), providing information about the study and seeking informed consent, scheduling and conducting home visits, data collection including linked data, analysing data, interpreting results, and drafting the manuscript. Critical revision and approval of the final manuscript were conducted by all authors.

Sheau Huey Chen | PhD Candidate

Professor Andrew Maiorana | Primary supervisor and senior author

For more information on the candidate's level of contribution, please refer to Appendix 22 – Chapter 3: Co-Authorship Contribution Form

3.1 Background

Chronic heart failure (CHF) is a major public health burden, affecting 2-3% of the population with prevalence rising steeply to over 20% in people aged over 65 years.[1] Episodic exacerbations and rehospitalisation are common in patients living with CHF and contribute significantly to the high health-care costs associated with the disease.[2] However, many readmissions are considered preventable with better self-management such as following sodium and fluid restrictions, adhering to evidence-based medication, undertaking regular exercise, and knowing when to seek medical support in the event of changes in clinical status.[3, 4]

Co-morbidities are also common in patients with CHF, and these often complicate care and increase the risk of adverse events, especially in older patients.[5] For example, the high incidence of concomitant conditions including frailty,[6] type two diabetes, renal dysfunction, anaemia, cognitive deterioration, and depression can all make the management of patients with CHF particularly challenging and contribute to the high rates of hospitalisation.[6, 7]

Many patients with CHF are managed in a primary care setting and may lack a structured system of care to help manage their condition including effective self-management.[8] Accordingly, there is a need to design and evaluate strategies, with patient education at the core, to improve self-management behaviour of patients with CHF that targets both CHF and other co-morbid conditions, an approach that has been shown in various settings to improve clinical outcomes.[7] Patient self-management in community-based disease management programs that monitor patients at regular intervals shows promise in delaying disease progression and improving quality of life for patients with CHF.[9]

Even though self-management is a patient action, it is most effective when implemented with support and education from health care professionals.[10] Nurse practitioners are qualified registered nurses who have been trained and completed postgraduate qualifications in clinical practice in a selected specialisation. They are credentialed through registration with the Nursing and Midwifery Board of Australia to apply an advanced scope of practice, including diagnosing and treating a wide range

of health conditions; designing and implementing therapeutic regimens; initiating referral to other health professionals; ordering and interpreting pathology and radiology tests; prescribing and reviewing medications.[11] Nurse practitioners can play an important role in educating and supporting patients in performing self-care[12] and have prescriptive privileges in Australia including renewing, adjusting or prescribing medications as necessary.[11] In the case of CHF, this extends to making decisions about patient management such as medication titration in response to changing clinical status[13] and supporting patients in a holistic approach to managing their health, including co-morbidities.

3.2 Aim

The aim of this study was to evaluate the effects of a community-based CHF management program, delivered by nurse practitioners, on self-care behaviour, quality of life and hospitalisation outcomes derived from linked hospital morbidity data.

3.3 Methods

This study compared the effects of a community-based, CHF management program delivered by nurse practitioners, the SmartHeart Living Well with Heart Failure Service (SmartHeart), with usual care. We undertook a pragmatic trial to compare the effects of SmartHeart, with a control group who received standard post-discharge CHF care but did not have access to a specialised nurse practitioner CHF clinic.

This study was registered with the Australian New Zealand Clinical Trials Registry (Number 12614000421639). Ethics approval was obtained from the Human Research Ethics Committees at Royal Perth Hospital (REG 13–171) and Curtin University (HR12/2014). All participants in the study provided written informed consent.

3.3.1 Participants

Participants in the intervention group were recruited from patients who attended the SmartHeart service following a tertiary hospital admission and consented to take part in the study. Control participants were patients admitted to the same tertiary hospital following the cessation of the SmartHeart Service (Figure 3.1). The Control Group received usual care, including follow-up by a General Practitioner (GP) or Cardiologist. Inclusion criteria for both groups were a hospital admission due to CHF as documented by International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnoses codes[14], a left ventricular ejection fraction of less than 40% and New York Heart Association Functional Class I-III. Patients were excluded from the study if they were unwilling or unable to provide informed consent, had been diagnosed with a terminal illness such as cancer and had an estimated life expectancy of less than one year, or had significant cognitive impairment or physical disability that was likely to impact on their capacity to engage in self-care behaviours.

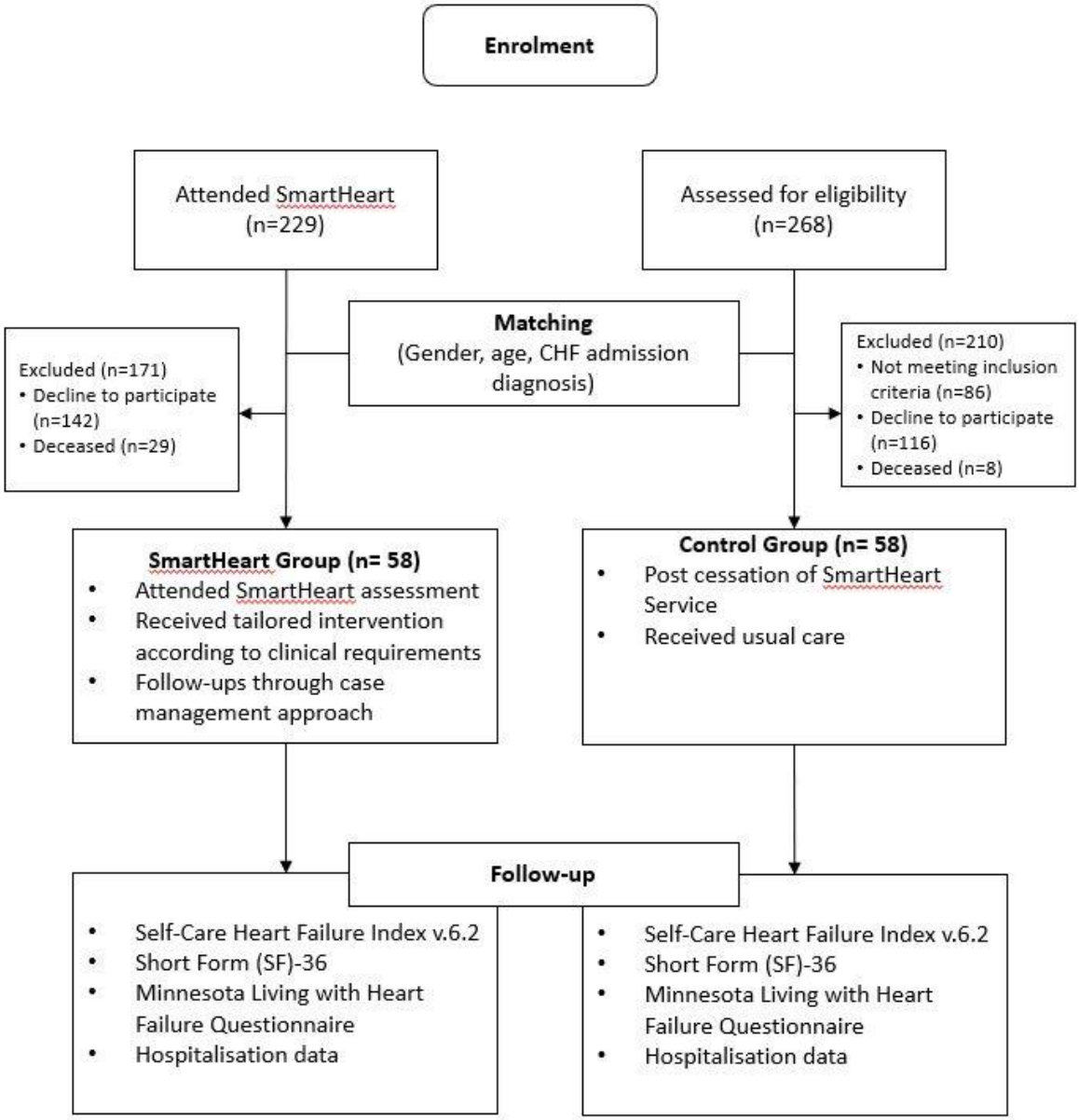

Figure 3.1. Participant enrolment, group allocation and follow-up.

3.3.2 SmartHeart Intervention

Referral to SmartHeart occurred following tertiary hospital admission for CHF. SmartHeart was conducted in a multidisciplinary university clinic for 12 months and was designed to help patients understand their condition and its treatment to enhance self-care and maximise their utilisation of support services. At the patients' initial appointment, a nurse practitioner conducted a clinical assessment and patients were

provided with education in self-management strategies and healthy lifestyle including the provision of an individualised CHF management plan, based on the Cardiac Society of Australia and New Zealand CHF Management Guidelines,[13] addressing medication adherence, diet, physical activity and maintaining fluid balance. Patients and their families received CHF education to support the patients in establishing an effective self-care regimen including adhering to prescribed medication with a flexible diuretics regime, restricting the intake of fluids and sodium and monitoring and early reporting of signs and symptoms characteristic of clinical deterioration such as weight gain, increased breathlessness and oedema. Comorbidities were documented and follow up care for these conditions was arranged as indicated. At each visit, the nurse practitioner obtained an interim history and performed a general assessment on the patient including titration of patient medication as required with close monitoring of blood chemistry following medication adjustment in accordance with the advanced scope of practice afforded nurse practitioners. This enabled the nurse practitioners to tailor care according to clinical requirements and arrange subsequent follow-up appointments to suit patients' healthcare needs and goals through a case management approach. This included the option of clinic appointments, telephone follow-up, home visits and clinics conducted through a mobile health service.[15] Frequency of visits was determined by the nurse practitioner based on the patient's clinical status. If the nurse practitioner identified that treatment wasn't consistent with guidelines, or there were signs of clinical deterioration (i.e. fluid retention, worsening symptoms), patients' GP and/or Cardiologist were consulted, and treatment was amended in accordance with best practice guidelines. When patients were stable and well informed about self-management, they were discharged from the service for ongoing care by their GP and/or Cardiologist, independent of SmartHeart. Discharge from the service routinely occurred within six months of the initial appointment. Participants were enrolled from February 2013 to September 2014.

3.3.3 Assessments

Demographic and clinical characteristics were collected from a medical record review. Several questionnaires described below were administered by an independent nurse

researcher after participants in the intervention group had engaged with, and been discharged from, the SmartHeart service approximately 12 months after patients' initial SmartHeart appointment (344.9±79.7 days; mean ± SD), to evaluate the enduring effect of the program on self-care behaviour and quality of life. In the control group, questionnaires were administered approximately six months after discharge following patients' index hospital admission (181.9±131.4 days). Participants were followed up from September 2014 to August 2015.

Self-care behaviour was assessed by the Self-Care Heart Failure Index v.6.2 (SCHFI).[16] This questionnaire contains 22 items measured on a 4-point self-reported Likert scale divided into three subscales: self-care maintenance, self-care management, and self-confidence. The scores for each subscale range from 0 to 100 points. Higher scores reflect greater self-care behaviour and scores ≥70 points for each subscale indicate appropriate self-care behaviour.[16]

Generic quality of life (QOL) was assessed using the Short Form (SF)-36 questionnaire which provides information about individuals' multidimensional psychosocial health and includes a physical component summary (PCS) and mental component summary (MCS), comprising wellbeing and personal evaluations of health that is suitable for use in CHF trials when used in combination with disease-specific questionnaires.[17] PCS and MCS outcome measures are scored from 0 to 100, with 100 representing optimal health and 0 representing the poorest health on the scale.[17]

The Minnesota Living with Heart Failure Questionnaire (MLHFQ) was employed to assess disease-specific QOL. This tool measures the physical, emotional, social and mental dimensions of quality of life as it relates to CHF using a 6-point Likert scale.[18] MLHFQ is a 21-item scale, with a scoring range of zero for no impairment, to 105 for maximum impairment. It provides a total score (range 0–105, from best to worst QOL), as well as scores for two dimensions, physical (eight items, range 0–40) and emotional (five items, range 0–25).[19]

3.3.4 Clinical outcomes

Hospitalisation data were collected from the Western Australian Hospital Morbidity Database. This health administrative data set records all hospital admissions in private and public hospitals, in both rural and metropolitan areas, in the state of Western Australia, providing a robust method for data linkage. Clinical outcomes included were hospitalisation due to all-causes and due to a primary diagnosis of CHF.

To ensure consistency between the SmartHeart Group and Control Group, patients start date for clinical outcome follow-up was derived from the date of discharge following their index hospital admission. The index hospital admission in the SmartHeart Group was defined as the admission that preceded their referral to SmartHeart. For the Control Group, the index hospital admission was the admission that resulted in the invitation to participate in the Control Group. Hospitalisation data were calculated from 30 days post-discharge of the index hospitalisation in both groups to enable sufficient time for those in the SmartHeart Group to commence the SmartHeart service. Readmission rates, length of stay, and emergency department presentations were subsequently reviewed for the 12-month period commencing at this time point, for both groups (Figure 3.2).

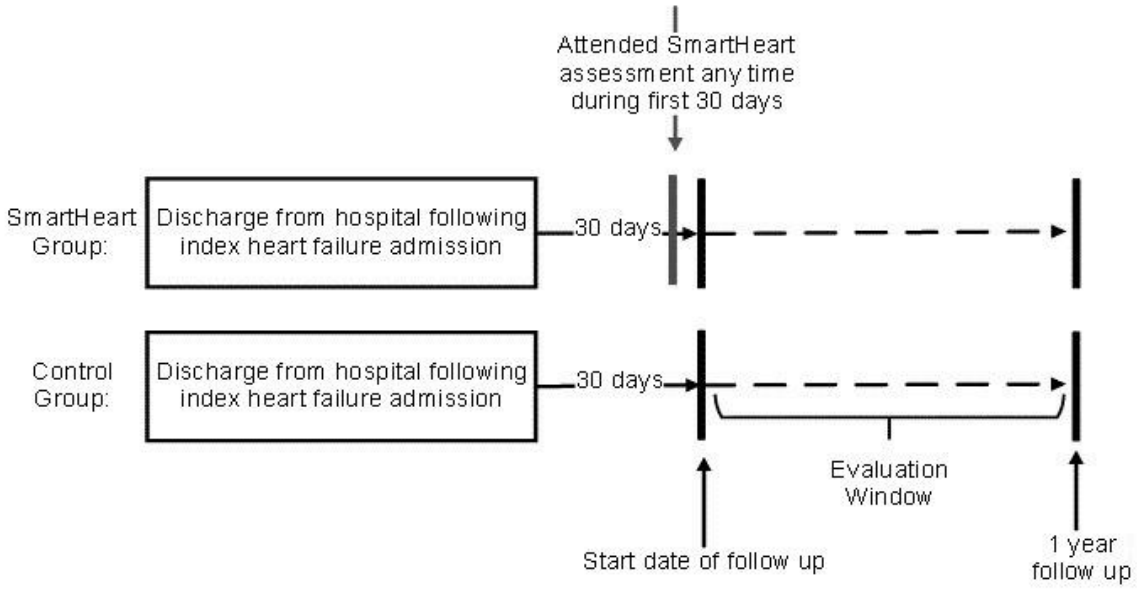

Figure 3.2. Timeline of participant follow-up.

3.3.5 Statistical analyses

Data analysis was conducted using SPSS v25 software. Descriptive statistics were computed for sample demographics and reported using frequency distributions and percentages for categorical variables and mean and standard deviation for continuous variables. Differences between the control and intervention groups' total scores and individual question responses were analysed using paired t-tests. Pearson $\chi 2$ test was used to test for differences in categorical variables and the t-test or Mann-Whitney test for continuous variables. The Kaplan–Meier product-limit method was used to describe time to clinical events (rehospitalisation due to CHF and all causes). The log-rank test was used to compare differences in time to the event between the groups. $P<0.05$ was considered statistically significant.

3.4 Results

The study sample comprised of 58 participants in the SmartHeart Group and 58 participants in the Control Group. Participants in each group were well matched for gender, age, CHF severity, prescribed medication, and demographics. The majority of participants in each group had at least moderate heart failure (NYHA Class II-III) (Table 3.1). More than two-thirds of the participants were receiving government benefits (aged-pension, disability or sickness benefits) and over a third in each group lived alone.

Table 3.1 Participant characteristics of the SmartHeart versus Control Group.

		SmartHeart	Control
Demographic data		**N = 58**	**N = 58**
Age		69.9 ± 13.2	67.9 ± 12.2
Female gender		19 (32.8%)	20 (34.5%)
Social status	Lives alone	20 (34.5%)	25 (43.1%)
	Lives with spouse	30 (51.7%)	31 (53.4%)
	Lives with children	5 (8.6%)	2 (3.4%)
	Lives with extended family	3 (5.2%)	0
Employment status	Employed	13 (22.4%)	8 (13.8%)
	Unemployed	4 (6.9%)	6 (10.3%)
	Receiving Government benefits	41 (70.7%)	44 (75.9%)
Baseline medical data			
LVEF		26.3%	22.7%
NYHA class 1		18 (31.0%)	17 (29.3%)
NYHA class 2		28 (48.3%)	30 (51.7%)
NYHA class 3		12 (20.7%)	11 (19.0%)
NYHA class 4		0	0
IHD		43 (74.1%)	35 (60.3%)
Non-IHD		15 (25.9%)	23 (39.7%)
AF		37 (63.8%)	31 (53.4%)
T2DM		29 (50.0%)	20 (34.5%)
Pacemaker		10 (17.2%)	8 (13.8%)
ICD		12 (20.7%)	10 (17.2%)
Medications			
ACE inhibitor		38 (65.5%)	32 (55.2%)
Angiotensin II blocker		13 (22.4%)	12 (20.7%)
Beta-blocker		46 (79.3%)	37 (63.8%)
Loop inhibitor		40 (69.0%)	45 (77.6%)
Aldosterone antagonist		24 (41.4%)	25 (43.1%)
Digoxin		14 (24.1%)	7 (12.1%)
Warfarin		10 (17.2%)	11 (19.0%)

All data presented as n (%) or mean ± SD unless specified otherwise. LVEF = Left ventricular ejection fraction; NYHA = New York Heart Association; IHD = Ischaemic heart disease; AF = atrial fibrillation / atrial flutter; T2DM = Type II Diabetes Mellitus; ICD = Implantable cardioverter defibrillator; ACE = angiotensin-converting enzyme.

Awareness of self-care behaviour was significantly higher in the SmartHeart compared with the Control Group for all three subscales; self-care maintenance, self-care management and self-care confidence ($p<0.05$) (Table 3.2).

There was a higher rating for the MCS component of the SF-36 in the SmartHeart Group, but no difference in PCS (Table 3.2).

For the disease-specific MLHFQ, participants in the SmartHeart Group rated their overall QoL significantly better than the Control Group. Similarly, there was a significantly better rating of physical ($p<0.05$) and emotional ($p<0.05$) functioning in the SmartHeart, compared with the Control Group (Table 3.2).

Table 3.2 Self-care and quality of life questionnaire outcomes of participants in the SmartHeart versus Control Group.

	Smart Heart	Control	p-Value
SCHFI			
Maintenance	76.7 ± 10.9	52.1 ± 16.1	p< 0.05
Management	82.0 ± 13.3	46.4 ± 16.4	p< 0.05
Confidence	88.7 ± 14.6	40.6 ± 21.0	p< 0.05
SF-36			
PCS	47.4 ± 12.8	45.4 ± 12.4	NS
MCS	81.7 ± 23.8	61.6 ± 22.0	p< 0.05
MLHFQ			
Total score all items	28.4 ± 14.6	49.6 ± 21.6	p< 0.05
Physical items	13.9 ± 7.6	22.0 ± 9.6	p< 0.05
Emotional items	5.4 ± 4.1	11.3 ± 6.0	p< 0.05

All data presented as mean ± SD. SCHFI = Self-Care Heart Failure Index; PCS = Physical Component Summary; MCS = Mental Component Summary; MLHFQ = Minnesota Living with Heart Failure Questionnaire.

SmartHeart participants had delayed, and fewer overall, rehospitalisation events compared to participants in the Control Group over the 12-month follow-up period; 43 participants in the Control Group compared with 36 participants in the SmartHeart Group were hospitalised at least once over 12 months of follow-up ($p<0.05$) (Figure 3.3).

Mean length of stay for all-cause hospitalisations was significantly lower ($p<0.05$) in the SmartHeart Group, leading to a lower total number of days of hospitalisation ($p<0.05$). Analysis of all-cause hospitalisation, excluding rehabilitation admissions, revealed that mean length of stay tended to be lower in the SmartHeart Group, achieving borderline statistical significance ($p=0.05$) compared with the Control Group (Table 3.3).

Table 3.3 Hospital readmissions and Emergency Department presentations over one year of follow-up in the SmartHeart versus Control Group.

	SmartHeart (n = 58)	Control (n = 58)	p-value
ED presentations			
Participants with 0 presentations, n (%)	24 (41.4)	26 (44.8)	NS
Participants with 1 presentation, n (%)	12 (20.7)	15 (25.9)	NS
Participants with 2 presentations, n (%)	7 (12.1)	8 (13.8)	NS
Participants with ≥ 3 presentations, n (%)	15 (25.9)	9 (15.5)	NS
Total ED presentations	89	93	NS
Hospital admissions			
Chronic heart failure related			
Number of admissions, n	23	24	NS
Mean length of stay (days)	1.8 ± 6.4	2.8 ± 5.9	NS
Total (days)	102	163	NS
All-cause			
Number of admissions, n	131	113	NS
Mean length of stay, all-cause (days)	9.0 ± 11.5	20.1 ± 21.6	p< 0.05
Total (days)	416	664	p< 0.05
All-cause, excluding rehab. admissions			
Number of admissions, n	130	106	NS
Mean length of stay (days)	8.2 ± 11.2	14.9 ± 16.6	(p=0.05)
Total (days)	401	493	(p=0.05)

All data presented as n (%) or mean ± SD unless specified otherwise.

ED = Emergency Department.

There were no differences in the number of CHF-related hospital admissions or length of stay due to a CHF admission. Similarly, neither the total number of Emergency Department presentations nor the number of participants with zero, one, two or at least three Emergency Department presentations differed between groups.

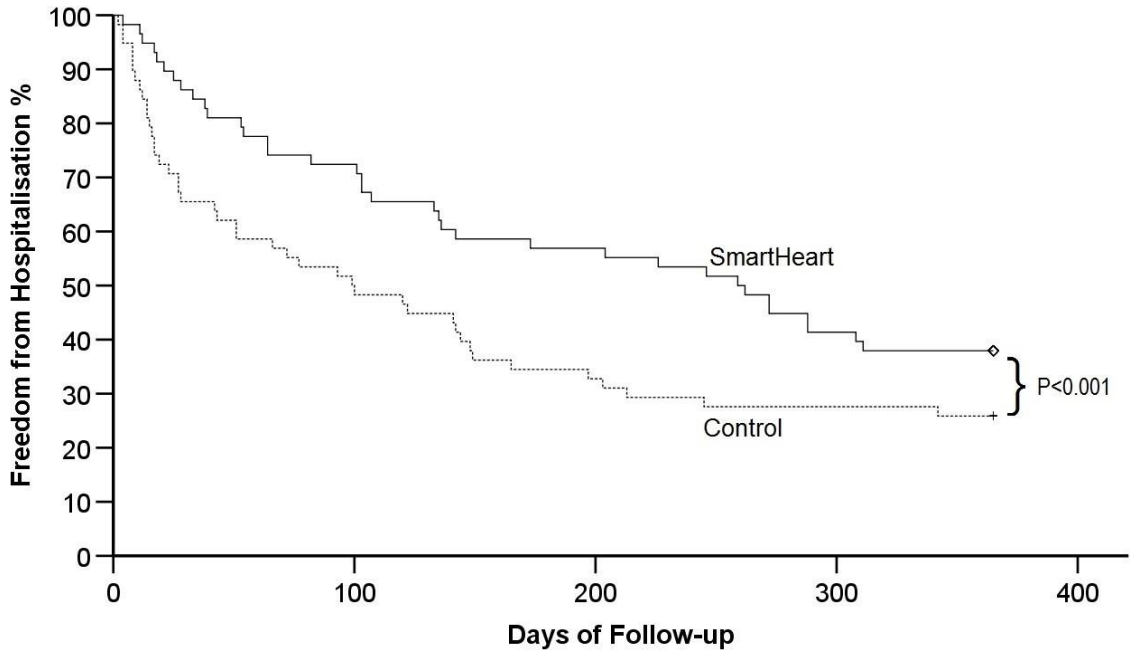

Figure 3.3 All cause hospital admission in the SmartHeart and Control Groups.

3.5 Discussion

In this evaluation of the effect of a community-based, nurse practitioner-led CHF management service, we observed significantly higher awareness of CHF self-management strategies and better quality of life in patients who had received nurse practitioner support compared with a well-matched cohort of patients who did not attend the clinic. While this was not associated with a reduction in CHF-related admissions, participants receiving the SmartHeart intervention had lower all-cause hospitalisations than the Control Group, suggesting improved management of the comorbidities commonly experienced by patients with CHF.

Patients receiving the SmartHealth intervention had better self-care across the subscales of ‘management’, ‘maintenance’, and ‘confidence’. Education was a core component of the nurse practitioner service and was provided via written material, through face-to-face consultations and by phone call follow-ups between nurse practitioners and patients. Patient education is an important facilitator of self-management, through improved awareness of signs and symptoms, and better adherence to a healthy lifestyle and medical treatment.[20] Patients with CHF frequently lack the knowledge, confidence, and support to be actively involved in their own care, and their adherence to behaviours important for long-term health is often suboptimal.[15] Notably, in the current study, the higher level of self-care behaviour in the SmartHeart Group compared with Controls, was sustained for at least six months following the completion of the SmartHeart program, highlighting that a time-limited intervention can have ongoing benefits. Improved self-care behaviour has previously been associated with an improved ability to recognise and respond appropriately to adverse signs and symptoms of CHF,[21] which in turn has been associated with reduced emergency department visits[22] and hospital admissions.[21] In the current study, better self-care metrics did not translate to a reduction in CHF-related hospitalisations. The lack of a significant effect may reflect the relatively small sample size and limited power to detect a significant difference. We also excluded hospital admissions in the first month following hospital discharge, which is known to be the period that patients are at highest risk of readmitting,[23] which would likely have reduced the sensitivity of the project to detect a change in CHF admissions. Nevertheless, it is apparent that evidence-based strategies should be tailored to patient’s individual needs, while communicating best practice standards for CHF disease management.

The study observed that patients with CHF who received nurse practitioner support experienced significantly better psychosocial outcomes and had better self-management strategies than those who did not. These findings are comparable with other studies which have found that patients who have attended a nurse-delivered CHF program feel more capable of dealing with disease-related symptoms and experience a better QoL than those who did not participate in such programs.[20] The results of our study validate the contribution of a nurse practitioner-led self-management intervention in attaining better patient outcomes including improved self-

care behaviour and QOL. The results also suggest that the community-based intervention encouraged patients' maintenance of self-care behaviours, highlighting the value of nurse practitioner-patient engagement.

While there was no difference between groups in all-cause or CHF-specific hospitalisations during the 12-month follow-up period, participants who engaged in the SmartHeart program had delayed rehospitalisation, a shorter mean length of stay and lower overall days of hospitalisation due to all causes. Higher self-care maintenance has previously been found to be associated with reduced all-cause hospitalisation length of stay in a nurse-led CHF clinic.[24] Together, these findings provide support for community-based CHF clinics as a valuable adjunct to medical care in the management of CHF and the advanced skills of nurse practitioners are well suited in this context. The lower total days of hospitalisation observed in the SmartHeart Group were due predominantly to lower admissions to rehabilitation settings due to post-fall complications which were more prevalent in the Control Group. The high rate of rehabilitation-related admissions may reflect the mean age of participants in the study (almost 70) who may be at increased risk of frailty due to the effect of long-term chronic illness, impaired mobility, cognitive impairment, and medication.[25] CHF and frailty often co-exist and patients with both are likely to have worse outcomes including falls, hospitalisation, and mortality.[7]

3.6 Limitations of the study

There are several limitations to this study that warrant highlighting. The objective of the study was to conduct a pragmatic trial to evaluate the efficacy of a 'real world' nurse practitioner-led CHF program, compared with standard post-discharge care which did not include the provision of formal post-discharge education and support for CHF self-management. The Control Group was recruited post-cessation of the nurse practitioner-led CHF program due to the time-limited nature of funding for the SmartHeart service. Furthermore, because the SmartHeart program was delivered using a flexible approach according to what the nurse practitioners deemed most appropriate for individual patients, it is not possible to determine which specific aspects

of nurse practitioner care contributed to the observed outcomes, nor whether similar outcomes would have been achieved by registered nurses. Another potential limitation relates to the difference in the length of time that had elapsed between the index admission and the evaluation of self-care behaviour and QoL, which was approximately 12 months in the SmartHeart group compared with approximately six months in the Control Group. However, this supports the sustainability of the SmartHeart intervention.

3.7 Conclusions

The current study shows that a nurse practitioner-delivered model of chronic disease management results in better self-care behaviour, improved quality of life and reduced hospital admissions, compared with usual care in patients with CHF. These findings are particularly relevant to older patients with co-morbidities, many of whom are managed in a primary care setting. Based on these findings, programs of this nature should be more widely available to help address the challenges of managing patients with CHF in primary healthcare.

3.8 Implications for research, policy, and practice

Nurse practitioner-delivered models of CHF management should be more widely available to help address the challenges of managing patients with CHF in primary care. Future randomised controlled trials, that are adequately powered to evaluate the effects of nurse practitioner support on CHF hospitalisations and mortality, are required to more comprehensively investigate the effects of nurse practitioner management of CHF in a community setting.

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Chapter 4 - Effects of different telemonitoring strategies on chronic heart failure care: systematic review and subgroup meta-analysis

The following chapter has been published in a peer-reviewed journal: Journal of Medical Internet Research. Ding H, Chen SH, Edwards I, Jayasena R, Doecke J, Layland J, Yang I, Maiorana A. The effects of different telemonitoring strategies in chronic heart failure care: a systematic review and subgroup meta-analysis. Journal of Medical Internet Research: 2020; 22(11) e20032. doi: 10.2196/20032

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Declaration of candidate contribution

The following chapter was published as a shared co-first authorship between Dr Hang Ding and the candidate, Sheau Huey Chen. Both were accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of

the work were appropriately investigated and resolved. The candidate was one of the two researchers who individually extracted information from articles for cross-checking and performing parallel independent assessments of the manuscripts. After reviewing an initial tranche of articles together, the two researchers reached consensus on what to extract from the articles. The candidate contributed to the literature review process including allocating the article to subtopics, developing and validating the review protocol, searching the literature, screening for inclusion, assessing quality, extracting data, analysing and synthesising data, and reporting the findings. All authors contributed to the conception and design, and the analysis and interpretation of data.

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For more information on the candidate's level of contribution, please refer to Appendix 23 & 24 – Chapter 4: Co-Authorship Contribution Form

4.1 Overview

Chronic heart failure (CHF) is a severe chronic disease[1] affecting over 26 million people worldwide.[2] Despite advances in modern medical therapy[3] and multidisciplinary clinical care[4], CHF continues to manifest a poor quality of life[5], frequent hospitalisations[6,7], low survival rates[8], and high health care expenditure. [2] Telemonitoring has been extensively studied as an innovative approach to enable care providers to remotely monitor patients at home and provide timely intervention in the event of clinical deterioration. Over the past two decades, many enabled care programs have been developed and evaluated, and several reviews have demonstrated the potential of using telemonitoring interventions to reduce mortality[9-11] and hospitalisations[9,11] in CHF care. However, the outcomes from individual randomised controlled trials (RCTs) are heterogeneous, with nonsignificant effects obtained in several large and well-designed RCTs[12-14]. Owing to these mixed outcomes, the use of telemonitoring in CHF care has been questioned[15,16] and has not yet been embraced in clinical recommendations.[17,18]

Mixed outcomes in telemonitoring studies have been attributed to insufficient support from cardiologists, unsatisfactory patient compliance[19,20], low predictive power for clinical deterioration[14], and improvements in usual care.[14,18] However, these findings were limited to narrative analyses of individual telemonitoring studies. Several reviews have evaluated specific approaches to CHF care, including mobile health (mHealth)[21-23]; structured telephone[11,18], videophone, and interactive voice response devices[24]; education alone; pharmacist interventions; and clinical support by various care providers[25]. These reviews provide valuable insight into the effectiveness of specific types of interventions but do not explain the mixed outcomes across telemonitoring interventions involving different components of care.

To address the existing knowledge gap, we conducted a systematic review and meta-analysis using a novel approach of evaluating the effect of different non-invasive telemonitoring strategies on reduced all-cause mortality and hospitalisation to identify which strategies were associated with these outcomes.

4.2 Aim

The aim of this systematic review and subgroup meta-analysis was to identify non-invasive telemonitoring strategies attributing to improvements in all-cause mortality or hospitalisation outcomes for patients with chronic heart failure.

4.3 Methodology

4.3.1 Literature Search

This review was performed according to the Cochrane Collaboration methodological guidelines.[26]. We conducted a literature search in the PubMed, EMBASE, CINAHL, and Cochrane Library databases, covering the publication period from January 1990 to February 2020. The publications were required to be:

(1) relevant to telehealth, telemedicine, telemonitoring, telecare, internet, mobile, smartphone, remote monitoring, or home monitoring;
(2) involving patients with CHF;
(3) in the English language.

An information specialist officer at the Commonwealth Scientific and Industrial Research Organization (Brisbane, Australia) and an expert librarian at Curtin University, Western Australia, Australia helped develop the bibliographies and conduct the database search (for a more complete description of our search strategy, see Table 4.1).

Table 4.1 Databases and search strategy in the literature search.

	Bibliographic databases	Access date	Search strategy	Filters / limiters applied	Number of records retrieved
Record identification and Screening	PubMed	18/02/2020	((((("telemedicine"[MeSH Terms] OR "telemedicine"[All Fields] OR "telehealth"[All Fields]) OR ("telemedicine"[MeSH Terms] OR "telemedicine"[All Fields]) OR telemonitoring[All Fields] OR telecare[All Fields] OR ("internet"[MeSH Terms] OR "internet"[All Fields]) OR mobile[All Fields] OR ("smartphone"[MeSH Terms] OR "smartphone"[All Fields]) OR "remote monitoring"[All Fields] OR "home monitoring"[All Fields]) AND "heart failure"[All Fields]) AND	("1990"[PDAT] : "2020"[PDAT])) AND "english"[Language]	1421
	EMBASE	18/02/2020	telehealth':ab,ti OR 'telemedicine':ab,ti OR 'telemonitoring':ab,ti OR 'telecare':ab,ti OR 'internet':ab,ti OR 'mobile':ab,ti OR 'smartphone':ab,ti OR 'remote monitoring':ab,ti OR 'home monitoring':ab,ti AND 'heart failure':ab,ti AND [1990-2018]/py	Limiters - Published Date: 19900101-20200218; English Language; Peer Reviewed; Publication Type: Journal Article	1590
	Cinahl	18/02/2020	(Telehealth or telemedicine or telemonitoring or telecare or internet or mobile or smartphone or "remote monitoring" or "home monitoring") AND TX "heart failure"	Limiters - Published Date: 19900101-20200218; Human; Publication Type: Journal Article	489
	Cochrane Library	18/02/2020	(Telehealth or telemedicine or telemonitoring or telecare or internet or mobile or smartphone or "remote monitoring" or "home monitoring") AND TX "heart failure"	Limiters - Published Date: 19900101-20200218	370
	Total				3870
	Records after duplicates removed				1632

Two investigators (HD and SC) independently reviewed the articles obtained. Disagreements between the two investigators were resolved by a third reviewer (AM or IE).

4.3.2 Scope of telemonitoring

In this review, we employed a hierarchical structure considering that telehealth encompasses telemonitoring, as well as eHealth care processes and communication, telemedicine, and mHealth.[27]. We then defined the scope of telemonitoring as “the use

of information technology to monitor patients at a distance," as described by Meystre.[28] Finally, we included a telemonitoring intervention in the analysis if it involved "the transfer of physiological data such as blood pressure, weight, electrocardiographic signals, or oxygen saturation through technology such as telephone lines, broadband, satellite, or wireless networks".[27]

4.3.3 Inclusion and Exclusion Criteria

This review focused on non-invasive telemonitoring interventions evaluated through an RCT. The inclusion criteria were: (1) studies evaluating telemonitoring for CHF for at least 3 months, (2) prospective RCTs comparing telemonitoring-based care with usual care, and (3) full peer-reviewed journal articles reporting outcomes of all-cause mortality or all-cause hospitalisation. The exclusion criteria were: (1) articles reporting preliminary analysis outcomes; (2) studies with a sample size less than 50 (Table 4.2), because, compared with large studies, small studies are often associated with a lower level of reporting quality[29], are more likely to be heterogeneous[30], and overestimate outcome effects[31]; and (3) telemonitoring via implantable devices, as these interventions often involve a different care paradigm to non-invasive devices and have been the subject of dedicated reviews.[32,33]

Table 4.2 The list of excluded studies with the reason for exclusion.

Study	Reason for exclusion
Kashem A, Droogan MT, Santamore WP, et al. Web-based Internet telemedicine management of patients with heart failure. *Telemed J E Health.* 2006;12(4):439-447. doi:10.1089/tmj.2006.12.439	Ongoing trial, overestimated outcome effects.
Kashem A, Droogan MT, Santamore WP, Wald JW, Bove AA. Managing heart failure care using an internet-based telemedicine system. *J Card Fail.* 2008;14(2):121-126. doi:10.1016/j.cardfail.2007.10.014	Ineligible study design.

4.3.4 Telemonitoring strategies extracted

We extracted 18 telemonitoring strategies according to three categories: technology applications (6 strategies), care objectives (7 strategies), and care support methods (5 strategies) (Table 4.3).

Table 4.3 Extracted telemonitoring strategies for the subgroup meta-analysis on telemonitoring interventions for chronic heart failure (CHF).

Strategies	**Descriptions**
Technology Applications	
Mobile health system (or combining with mobile health applications)	A mobile health system was used in the telemonitoring program; and the system involved a set of software applications mainly designed for mobile devices such as smartphones, personal digital assistants, and tablet computers.
PC-based system	A PC-based system was used in the telemonitoring program; and the system involved a set of software applications mainly designed for personal computers (PC).
Weight scale	A device enabling participants to measure body weight and transfer the data to care providers in the telemonitoring program.
Blood pressure monitor	A device enabling participants to measure blood pressure and transfer the data to care providers in the telemonitoring program.
ECG monitoring device	A device enabling participants to record ECG and transfer the data to care providers in the telemonitoring program.
Heart rate monitor	A device enabling participants to measure heart rate and transfer the data to care providers in the telemonitoring program.

Care Objectives	
Education	The telemonitoring program included a care objective/component involving CHF education. The education content could be provided via video clips, animation, and/or text messages.
Daily weight monitoring	The telemonitoring program contained a care objective/component to assist the participants in daily weight monitoring. The assistance could be delivered via automated messages, telephone calls, and/or follow-up by care providers.
Diet	The telemonitoring program contained a care objective/component for improving dietary behaviour recommended for CHF.
Medication support	Clinical support was provided to optimally adjust medication therapy and/or support participants to adhere to the medication recommendations for CHF.
Exercise	Clinical interventions such as automated messages or follow-up by care providers were integrated in the CHF care program to assist participants in conducting exercise according to clinical recommendations.
Depression and anxiety	A care objective/component was specifically provided to address depression and anxiety in participants through the telemonitoring program.
Monitoring symptoms	Participants used telemonitoring applications to record their CHF-related symptoms. Accordingly, care providers reviewed the recorded symptoms and provided interventions.
Care Support Methods	
Collaborative care	Interventions and/or support for collaborative care were provided in the telemonitoring program, such as collaborative reviews, referrals, and communication for follow-up.

Physician support	Physicians were included in the telemonitoring program to provide clinical intervention to the participants.
Nurse support	Nurses were included in the telemonitoring program to provide clinical intervention to the participants.
Call centre support	A call centre was included in the telemonitoring program to provide support to the participants.
Automated system	Automated systems were used to automatically monitor the participants' data and provide reminders, alerts and/or notifications to the participants.

4.3.5 Review Outcomes

The risk ratio (RR) of all-cause mortality and the incidence rate ratio (IRR) of all-cause hospitalisation in the RCTs were analysed. The RR and IRR values in each RCT were calculated from the event counts of mortality and hospitalisation. For each strategy, we divided the RCTs into two subgroups: RCTs that applied the strategy in the telemonitoring intervention (subgroup 1) and RCTs that did not apply the strategy (subgroup 2). We then compared the two subgroups (subgroup 1 vs subgroup 2) and examined whether the difference between the two groups in the RR and IRR outcomes was statistically significant.

4.3.6 Meta-analysis

In the meta-analysis, we used a random-effects model with the DerSimonian–Laird estimator[34,35], and report the RR, IRR, and 95% CI for each group. For RCTs with no events in one arm, we applied a continuity correction of 0.5. The heterogeneity of RCTs in each subgroup was examined by the Q test and I2 statistic.[36,37] The statistical significance of heterogeneity was determined by a relaxed P value of .10 (PH<.10).[38] The I2 values of 25%, 50%, and 75% were used to reflect a low, moderate, and high

level of heterogeneity, respectively.[37] To evaluate the risk of bias, a regression test was used to analyse the asymmetry of a funnel plot of the RR or IRR results in a subgroup.[36] The regression test was used to examine whether the outcomes of individual RCTs were related to the corresponding sampling variances.[39] A significant regression (PF<.05) indicated a significant risk of bias. The difference between the two groups (subgroup 1 vs subgroup 2) was evaluated by a Wald-type test[36], and statistical significance was determined if the corresponding two-sided P value was less than .05 (PC<.05). A mixed-effects model[36] was also used to evaluate the effects of potential confounders, including sex, age, or the severity measure of left ventricular ejection fraction (LVEF). The meta-analysis methods and tests were performed using RStudio Version 1.1.383[40] associated with the “metafor” meta-analysis package (version 2.0).[36]

4.3.7 Risk of Bias

A summary of the methodological risk of bias of the included studies was conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions[26] by two investigators (HD, SC) using the risk of bias tool in the Cochrane Collaboration’s review-writing software RevMan 5.3. This involved reporting the following individual elements for the included RCTs: random sequence generation, allocation sequence concealment, blinding of participants and personnel, blinding of outcome assessment, completeness of outcome data, and selective outcome reporting. Each item was judged as being at a high, low, or unclear risk of bias. Studies were deemed to be at the highest risk of bias if they were scored at a high or unclear risk of bias for either the sequence generation or allocation concealment domains.[26]

4.4 Results

4.4.1 Participant characteristics

The literature search results are presented in Figure 4.1. We found 3870 records from the bibliographic search and 56 records from three existing systematic reviews[9,11,41] and a manual search, resulting in a total of 3926 records. After removing duplicates, we obtained 1632 articles for screening. In the screening process, we excluded 1553 articles because of the absence of inclusion criteria and consequently obtained 79 articles for a full-text assessment. We then excluded 53 articles according to the inclusion and exclusion criteria, and one article because of its poor completion rate recognized by the authors.[42] Finally, this review included 26 RCTs. Among them, 25 RCTs provided all-cause hospitalisation events and 21 RCTs provided mortality events.

Among the assessment elements of bias risk, the blinding of participants and personnel was the least used method in the RCTs included (Figure 4.2). There were 11 RCTs that did not blind participants and personnel (Figure 4.3). Nine RCTs did not report their blinding status and only six RCTs used a blinding approach. The blinding of outcome assessment was the least reported element, and 14 RCTs (54%) had “unclear risk of bias.”

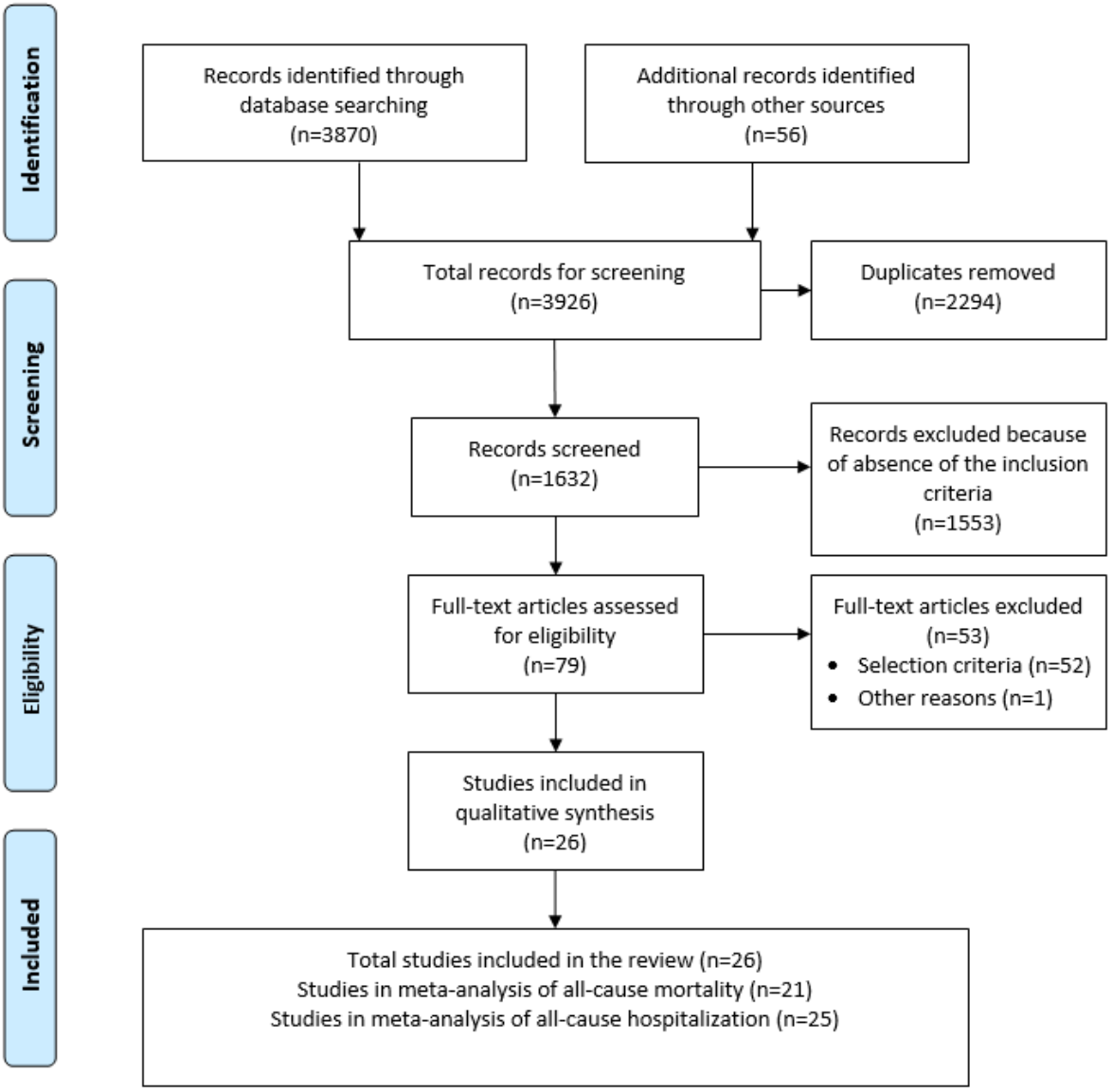

Figure 4.1 The PRISMA flow diagram of study selection

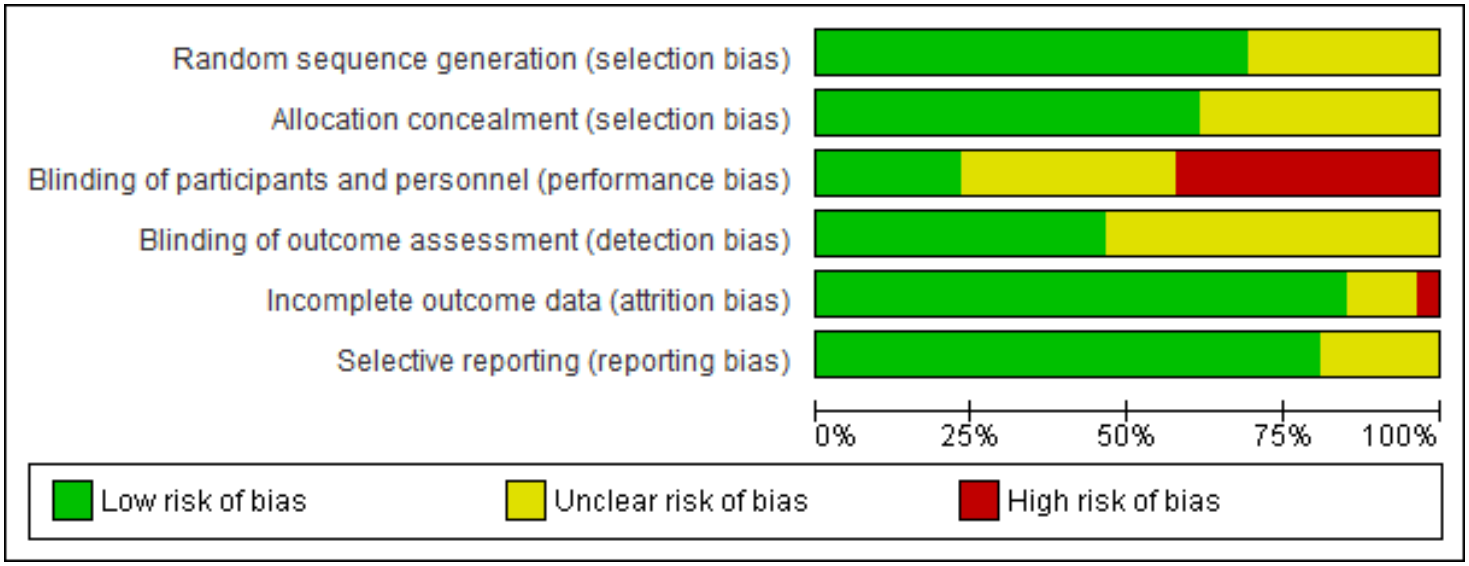

Figure 4.2 Risk of bias assessment. Authors' judgments about each methodological quality item are presented as percentages across all included studies.

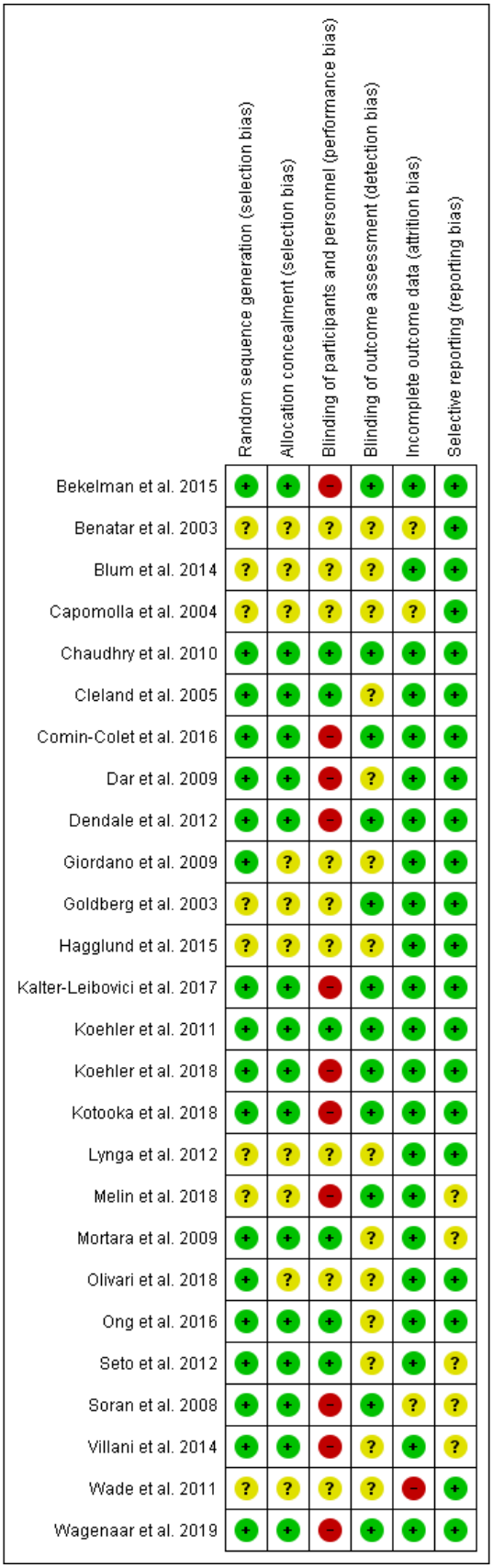

Figure 4.3 Risk of bias summary. Authors' judgements about each risk of bias item are summarized for each included study.

4.4.2 Participant characteristics

The 26 RCTs included 11,450 participants. The participants' characteristics are shown in Table 4.4. The median age was 67.4 years and the median rate of male participants was 73.15% (8376/11,450). The participants generally had a significantly reduced (<40%) LVEF, with a median LVEF of 29.6%, and they experienced mild to moderate levels of symptoms, with a median New York Heart Association functional class score of 2.6. The median trial size of the RCTs was 290 participants and the median follow-up duration was 12 months.

Table 4.4 Participants' characteristics in 26 randomised controlled trials included in the subgroup meta-analysis.

Characteristic	Median (IQR)
Age (years)	67.40 (65.08-72.75)
Trial size (N)	290 (180-675)
Follow-up duration (months)	12 (6-12)
Male (%)	73.15 (66.00-79.95)
LVEFa (%)	29.60 (27.00-35.93)
NYHAb class score	2.6 (2.3-2.8)

NYHA = New York Heart Association; LVEF = Left ventricular ejection fraction

4.4.3 Telemonitoring strategies

We extracted 18 telemonitoring strategies from the 26 RCTs, as shown in Table 4.5. Some strategies were commonly used, such as telemonitoring weight scales (26/26, 100% RCTs), call-centre support (24/26, 92%), and daily weight monitoring (25/26, 96%). Strategies that were not commonly used included nurse support (2/26, 8%), intervention for depression and anxiety (3/26, 12%), and exercise (3/26, 12%). The telemonitoring programs in the RCTs generally contained multiple strategies, with a mean of 8.7 strategies per care program.

Table 4.5 Telemonitoring strategies and randomised controlled trials included in the meta-analysis.

Reference	N	Care support method			Care objective									Technology application					
		Automated Alerts	Nurse Support	Call Center Support	Physician Support	Collaborative Care	Education	Daily Weight Monitoring	Diet	Medication	Exercise	Depression and Anxiety	Monitoring Symptoms	PC[a] app	Mobile health	Telemonitoring Weight	Blood Pressure Monitor	Heart Rate Monitor	ECG[b] Monitor
[44]	384	0	0	1	1	1	1	1	1	1	0	1	1	0	0	1	1	1	0
[45]	216	0	0	1	1	0	0	0	0	1	0	0	0	0	0	1	1	1	0
[46]	156	0	0	1	0	0	0	1	0	1	0	0	0	0	1	1	1	1	0
[47]	133	1	0	1	1	0	1	1	1	1	1	0	1	1	1	1	1	1	0
[12]	1653	0	0	1	1	0	1	1	0	0	0	0	1	0	0	1	0	0	0
[48]	248	0	0	1	1	0	0	1	0	0	0	0	0	0	0	1	1	1	1
[49]	178	1	0	1	1	1	0	1	0	1	0	0	1	0	1	1	1	1	0
[50]	182	0	0	1	1	0	0	1	0	1	0	0	1	0	0	1	1	0	0
[51]	160	0	1	1	1	1	0	1	1	0	1	0	0	0	1	1	1	1	0
[52]	460	0	1	1	1	0	1	1	1	1	0	0	1	0	1	1	1	0	1
[53]	280	0	0	1	1	0	0	1	0	0	0	0	1	0	1	1	0	0	0
[54]	72	1	0	1	1	0	1	1	0	1	0	0	1	0	1	1	0	0	0
[55]	1360	0	0	1	1	1	0	1	1	1	0	0	0	1	0	1	1	1	0
[56]	1538	0	0	1	1	1	1	1	0	1	0	0	1	0	1	1	1	1	1
[13]	710	0	0	1	1	0	0	1	0	0	0	0	1	0	1	1	1	0	1
[57]	181	0	0	1	1	0	0	1	0	0	0	0	0	0	0	1	1	1	0
[58]	319	1	0	1	0	0	0	1	0	1	0	0	0	0	0	1	0	0	0
[59]	72	1	0	1	1	0	1	1	1	1	0	0	1	0	1	1	0	0	0
[60]	261	0	0	1	1	0	1	1	0	0	0	0	1	0	1	1	1	1	1
[61]	339	0	0	1	1	0	0	1	0	0	0	0	0	0	0	1	1	1	1
[14]	1437	0	0	1	0	0	1	1	0	0	0	0	1	0	0	1	1	1	0
[62]	100	1	0	1	1	0	0	1	0	1	0	0	1	0	1	1	1	0	1
[63]	315	0	0	1	1	1	1	1	0	1	0	0	1	0	0	1	0	0	0
[64]	80	0	0	0	1	0	0	1	0	0	0	1	1	0	1	1	1	0	1
[65]	316	0	0	1	0	0	1	1	0	1	1	0	0	0	0	1	1	0	0
[66]	300	1	1	0	0	1	1	1	0	1	0	0	1	0	0	1	1	1	0
Total	11, 450	7	3	24	21	7	12	25	6	16	3	2	17	2	13	26	20	14	8

aEd = education; bMeds = medication; cEx = exercise; dD/A = depression and anxiety; ePC = personal computer; fmHealth = mobile health; gBP = blood pressure; hHR = heart rate; iECG = electrocardiogram.

4.4.4 Overall effectiveness of telemonitoring

There were 21 RCTs (n=10,536) with event counts of all-cause mortality and 25 RCTs (n=9912) with event counts of all-cause hospitalisation. The outcomes of mortality (RR) and hospitalisation (IRR) with 95% CIs are shown in Figure 4.4 and Figure 4.5, respectively. Overall, telemonitoring interventions were found to be more effective than usual care in reducing all-cause mortality (RR=0.85, 95% CI 0.76-0.94, P=.01) and all-cause hospitalisations (IRR=0.90, 95% CI 0.81-0.99, P=.04). The outcomes of both RR and IRR were heterogeneous (P_H=.001), with a low-to-moderate level of heterogeneity (I^2=35.3%) in the RR outcomes and a moderate-to-high level of heterogeneity (I^2=73.2%) in the IRR outcomes. In the funnel plot–based test, the risk of bias was significant for both RR (z=1.89, PF=.001 and IRR outcomes (z=3.33, PF=.001). We also used the mixed-effects model to adjust for sex, age, or LVEF but did not find significant differences in these results.

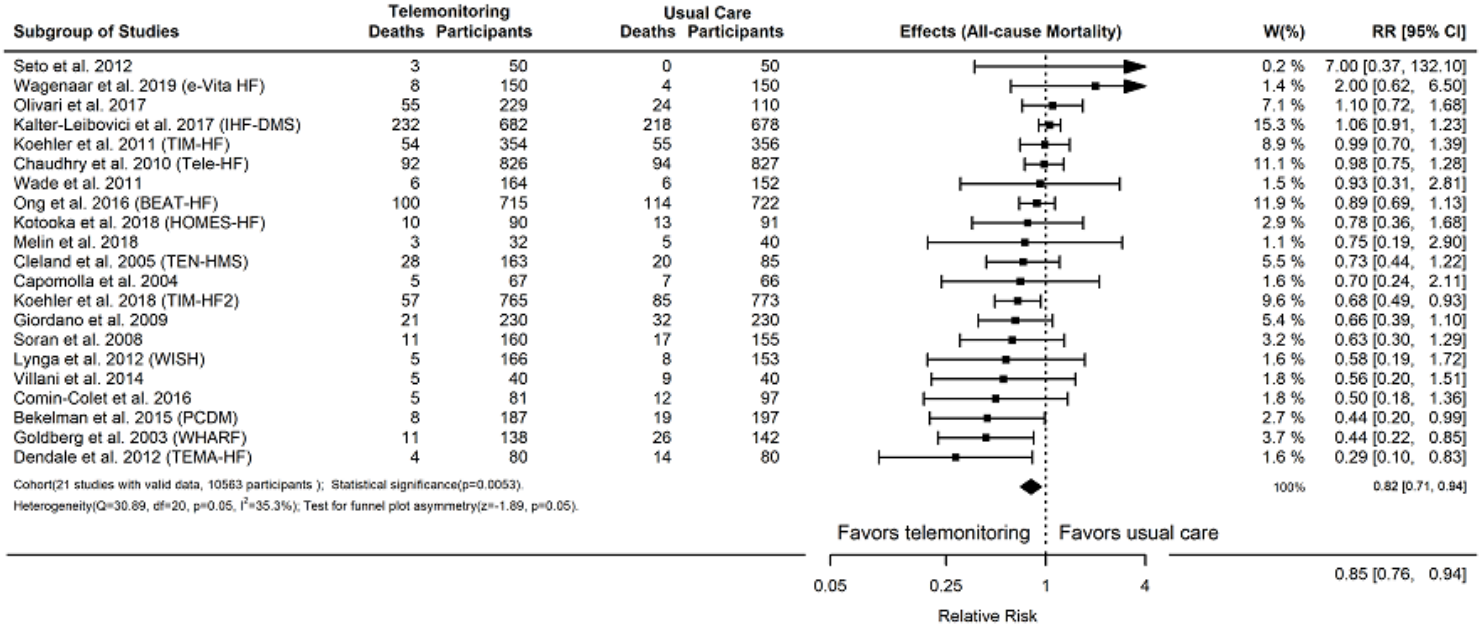

Figure 4.4 Event counts and effectiveness of telemonitoring interventions on all-cause mortality. There were 20 randomised controlled trials (N=10,263) with mortality event counts in the subgroup meta-analysis. RR: relative risk.

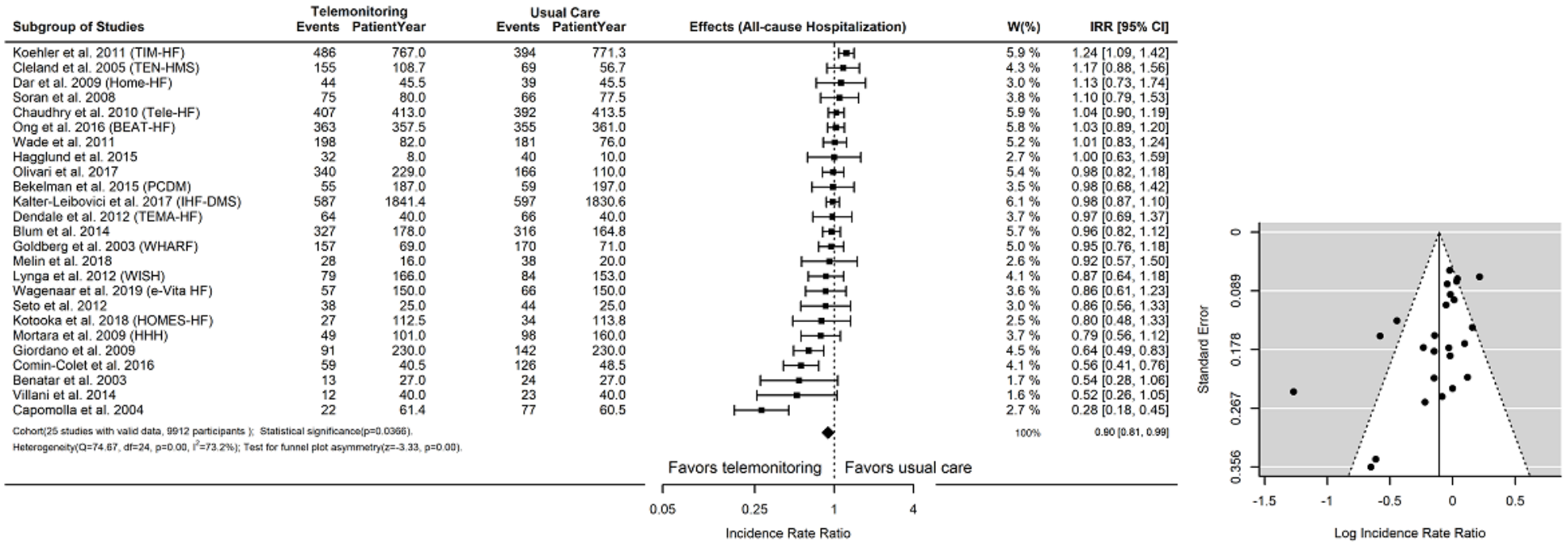

Figure 4.5 Event counts and effectiveness of telemonitoring interventions on all-cause hospitalisation. There were 24 randomised controlled trials (N=9612) with hospitalisation event counts in the subgroup meta-analysis. IRR: incidence rate ratio.

4.4.5 Subgroup comparison of telemonitoring strategies

The subgroup of RCTs that provided medication support (subgroup 1, 15 RCTs, n=4563, IRR=0.83, 95% CI 0.72-0.95) was found to be associated with a significantly (P=.01) lower IRR of all-cause hospitalisation than the comparison subgroup of RCTs that did not apply this strategy (subgroup 2, 10 RCTs, n=5349, IRR=1.02, 95% CI 0.93-1.12), as shown in Tables 4.6-4.8, and Figure 4.6. Within the subgroup of RCTs that provided medication support, the telemonitoring interventions were found to be more effective than usual care in reducing hospitalisations (15 RCTs, n=4563, IRR=0.83, 95% CI 0.72-0.95, P=.01). The IRR outcomes in both subgroups were heterogeneous (Figure 4.6 and Figure 4.7). The outcomes in the comparison subgroup of RCTs that did not apply this strategy were associated with the risk of bias.

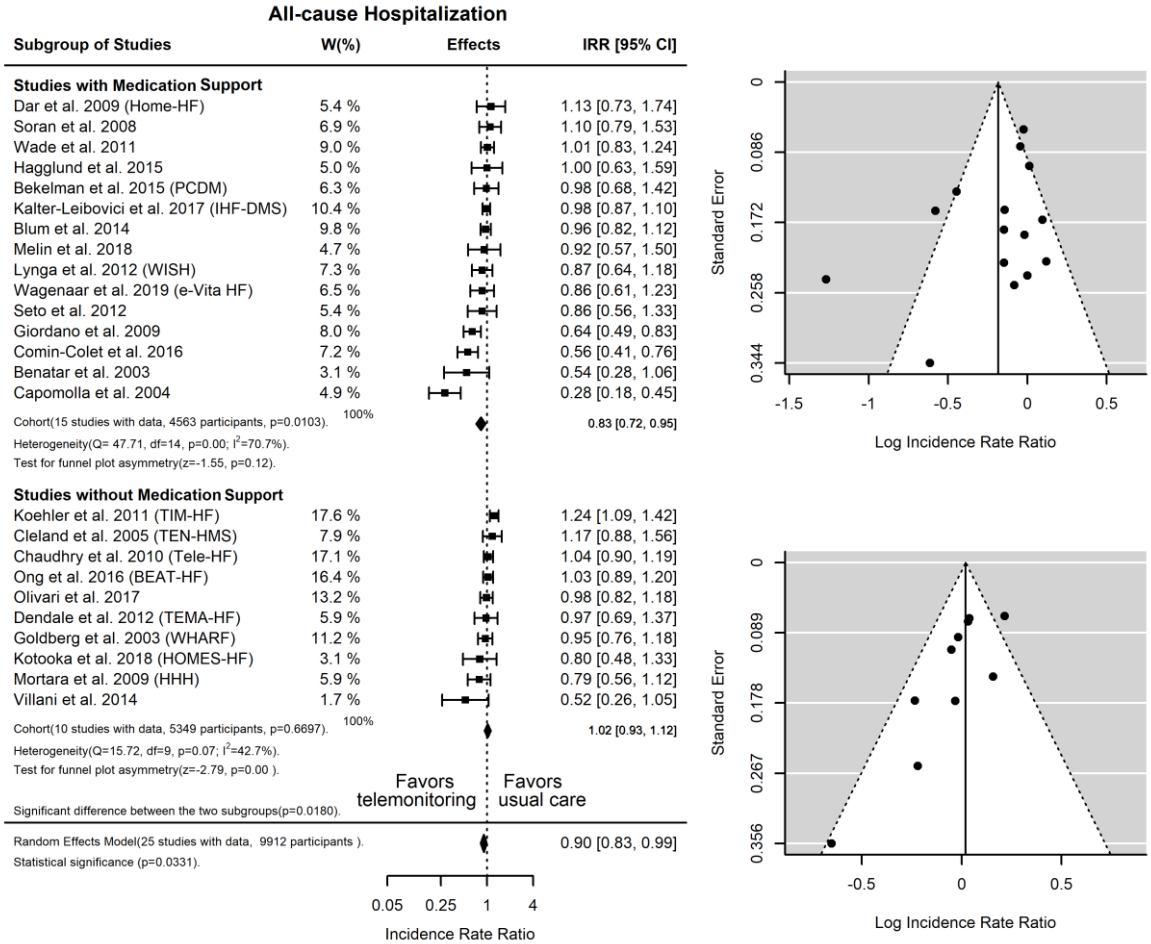

Figure 4.6 Effectiveness of the strategy of providing medication support on reducing the risk of all-cause hospitalisation. The subgroup of randomised

controlled trials (RCTs) that provided medication support was compared with the subgroup of RCTs that did not provide medication support.

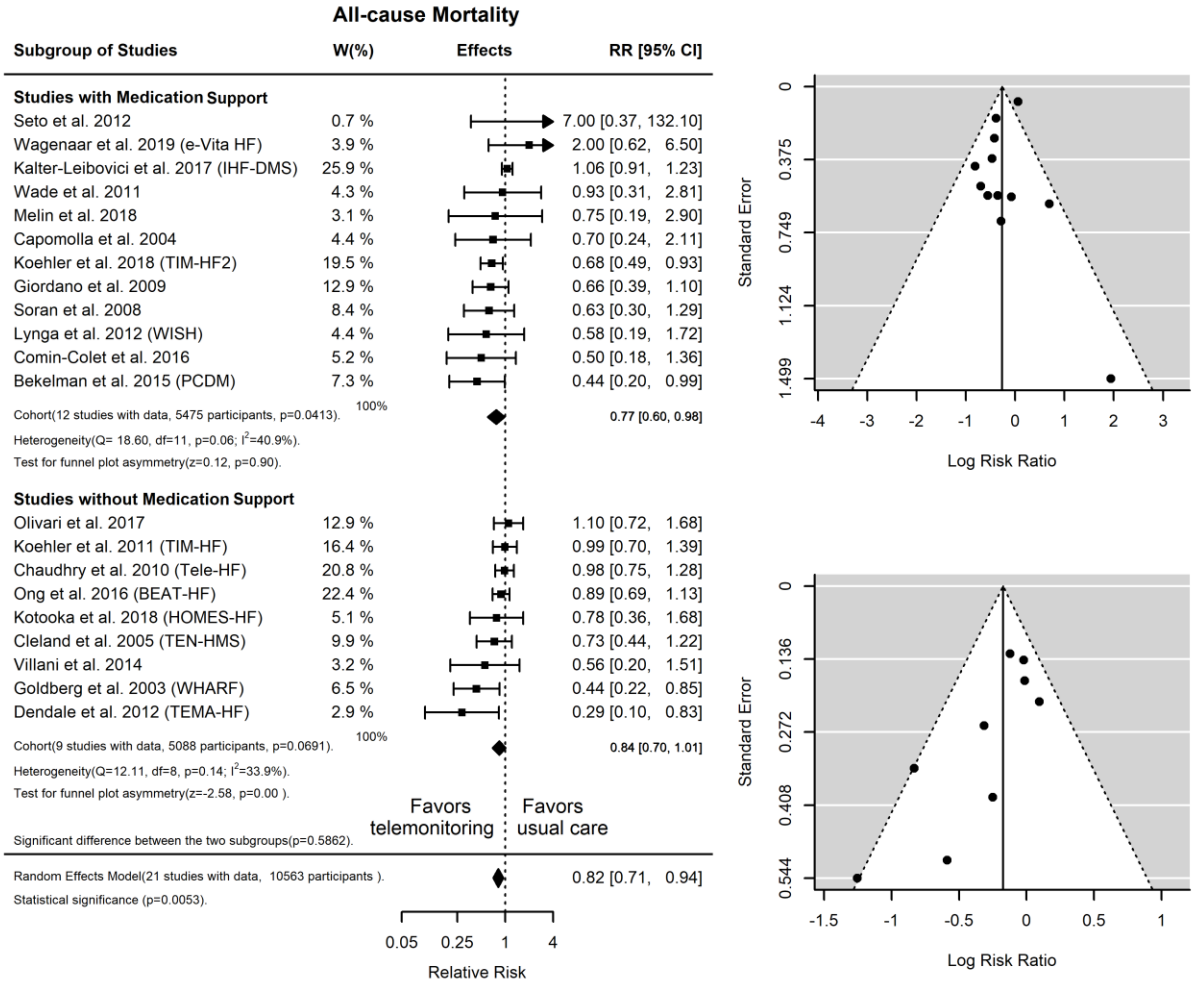

Figure 4.7 Effectiveness of the strategy of providing medication support on reducing the risk of all-cause mortality. The subgroup of randomised controlled trials (RCTs) that provided medication support were compared with the subgroup of RCTs that did not provide medication support.

Similarly, the subgroup of mHealth (subgroup 1, 12 RCTs, n=2662, IRR=0.79, 95% CI 0.64-0.96) was associated with a significantly (P=.03) lower IRR of all-cause hospitalisation than the comparison subgroup (subgroup 2, 13 RCTs, n=7250, IRR=1.00, 95% CI 0.94-1.06), as shown in Tables 4.6, Table 4.7, Table 4.8 and Figure 4.8. Within the mHealth subgroup, the telemonitoring interventions were found to be significantly more effective than usual care in reducing all-cause hospitalisations (subgroup 1, 12 RCTs, n=2662, IRR=0.79, 95% CI 0.64-0.96, P=.03). The IRR

outcomes in the mHealth subgroup were heterogeneous and were associated with a risk of bias.

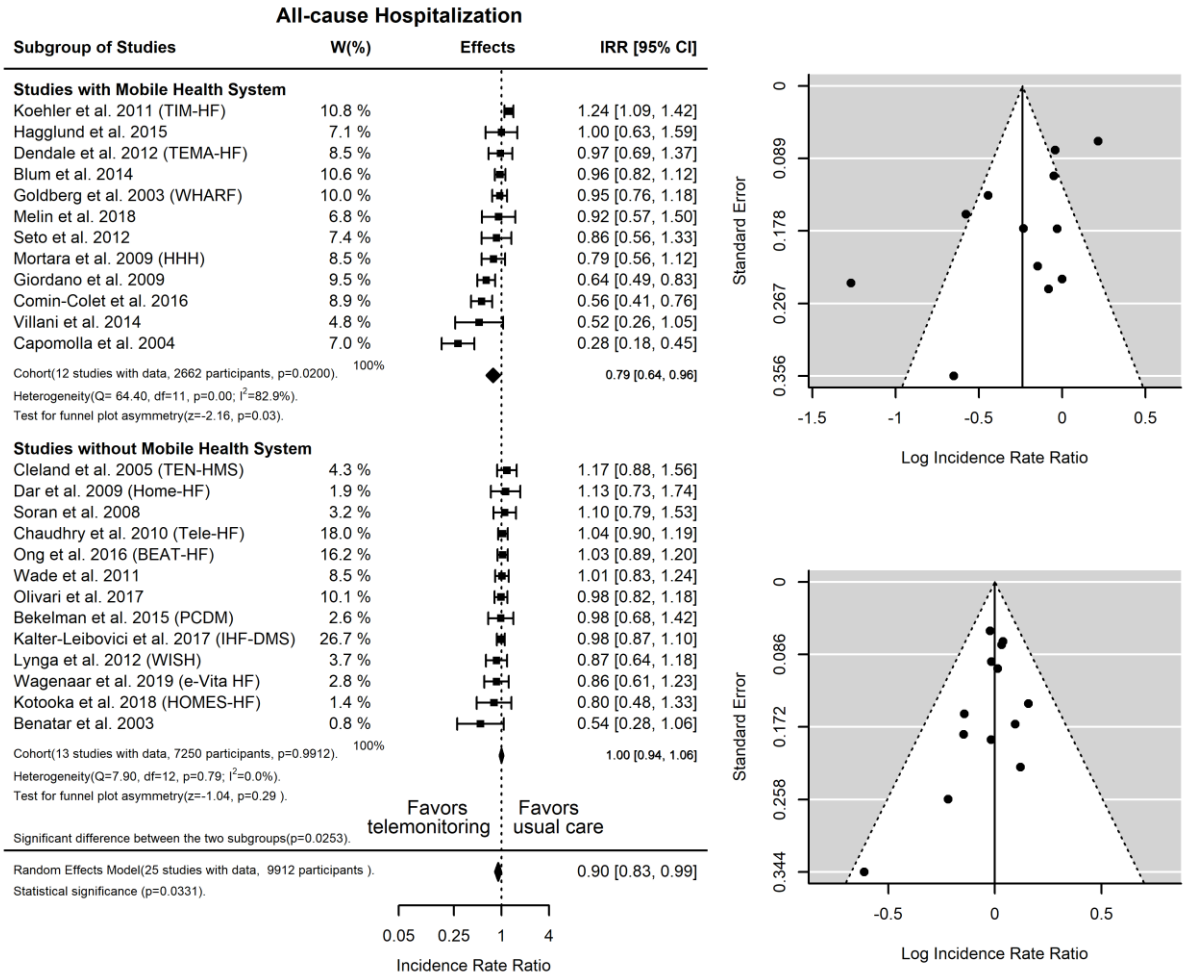

Figure 4.8 Effectiveness of the strategy of combining with mobile health (mHealth), or applying a mHealth system, on reducing the risk of all-cause hospitalisation. The subgroup of randomised controlled trials (RCTs) that applied the mHealth strategy was compared with the subgroup of RCTs that did not apply the strategy.

Table 4.6 Subgroup meta-analysis to examine the effect of telemonitoring strategies on all-cause hospitalisation for randomised controlled trials (RCTs) that applied the strategy in the telemonitoring intervention (subgroup 1).

Strategies	RCTs (N participants)	Effect IRR[a] (95% CI)	*P* value	Heterogeneity Q (*P* value)	I^2	Funnel test *Z* (*P* value)
Technology application						
PC[b]-based system	2 (1493)	0.54 (0.16-1.81)	.32	25.07 (<.001)	96.0%	0.00 (<.001)
Blood Pressure Monitor	19 (7201)	0.87 (0.77-0.98)	.02	72.50 (<.001)	75.2%	–3.30 (.001)
ECG[c] Monitor	7 (2198)	0.91 (0.73-1.12)	.37	27.56 (<.001)	78.2%	–2.01 (.04)
Telemonitoring Weight Scale	25 (9912)	0.90 (0.83-0.99)	.03	74.67 (<.001)	67.9%	–3.24 (.001)
Heart Rate Monitor	13 (5353)	0.85 (0.74-0.97)	.02	44.39 (<.001)	73.0%	–2.92 (.003)
Mobile Health System	12 (2662)	0.79 (0.64-0.96)	.02	64.40 (<.001)	82.9%	–2.16 (.03)
Care objective						
Education	10 (5103)	0.86 (0.72-1.02)	.10	39.11 (<.001)	77.0%	–1.82 (.07)
Daily Weight Monitoring	24 (9696)	0.91 (0.83-1.00)	.05	71.77 (<.001)	68.0%	–2.90 (.004)
Monitoring Symptoms	16 (6617)	0.86 (0.74-0.99)	.04	68.81 (<.001)	78.2%	–2.38 (.02)
Medication	15 (4563)	0.83 (0.72-0.95)	.01	47.71 (<.001)	70.7%	–1.55 (.12)
Diet	6 (2569)	0.75 (0.56-1.02)	.07	31.76 (<.001)	84.3%	–1.07 (.29)
Exercise	3 (609)	0.67 (0.35-1.29)	.24	24.38 (<.001)	91.8%	–1.70 (.09)
Depression and Anxiety	2 (464)	0.77 (0.42-1.40)	.39	2.47 (.11)	59.5%	0.00 (<.001)
Care support method						
Call Center Support	23 (9532)	0.91 (0.83-1.00)	.06	71.15 (<.001)	69.1%	–2.83 (.005)
Physician Support	20 (7384)	0.88 (0.78-0.99)	.03	72.83 (<.001)	73.9%	–2.72 (.01)
Automated Alerts	7 (1174)	0.72 (0.53-0.96)	.03	23.59 (<.001)	74.6%	–0.25 (.80)
Collaborative Care Support	6 (2697)	0.89 (0.75-1.07)	.22	12.32 (.03)	59.4%	–0.21 (.83)
Nurse Support	3 (920)	0.80 (0.61-1.03)	.08	3.99 (.13)	49.9%	1.90 (.06)

[a]IRR = incidence rate ratio; [b]PC = personal computer; [c]ECG = electrocardiogram.

Table 4.7 Subgroup meta-analysis to examine the effect of telemonitoring strategies on all-cause hospitalisation for randomised controlled trials (RCTs) that did not apply the strategy in the telemonitoring intervention (subgroup 2).

Strategies	RCTs (N participants)	Effect		Heterogeneity		Funnel test Z (*P* value)
		IRR[a] (95% CI)	*P* value	Q (*P* value)	I^2	
Technology application						
PC[b]-based System	23 (8419)	I0.94 (0.86- 1.01)	.13	48.12 (<.001)	54.3%	–2.68 (.007)
Blood Pressure Monitor	6 (2711)	1.00 (0.91- 1.10)	.99	1.78 (.87)	0.0%	–0.53 (.59)
ECG[c] Monitor	18 (7714)	0.90 (0.81- 0.99)	.05	45.19 (<.001)	62.4%	–2.46 (.01)
Heart Rate Monitor	12 (4559)	0.96 (0.85-1.08)	.55	26.57 (<.001)	58.6%	–1.70 (.09)
Mobile Health System	13 (7250)	1.00 (0.94-1.06)	.99	7.90 (.79)	0.0%	–1.04 (.30)
Care objective						
Education	15 (4809)	0.93 (0.84- 1.03)	.21	34.76 (<.001)	59.7%	–2.53 (.01)
Daily Weight Monitoring	1 (216)	N/A[d]	N/A	N/A	N/A	N/A
Monitoring Symptoms	9 (3295)	0.97 (0.91- 1.04)	.44	5.85 (.66)	0.0%	–1.13 (.26)
Medication	10 (5349)	1.02 (0.93-1.12)	.67	15.72 (.07)	42.7%	–2.79 (.01)
Diet	19 (7343)	0.96 (0.88-1.04)	.35	37.33 (<.001)	51.8%	–2.98 (.003)
Exercise	22 (9303)	0.94 (0.86-1.01)	.12	48.04 (<.001)	56.3%	–2.58 (.01)
Depression and Anxiety	23 (9448)	0.91 (0.83-0.99)	.05	71.60 (<.001)	69.3%	–2.94 (.003)
Care support method						
Call Center Support	2 (380)	0.74 (0.47-1.16)	.19	1.59 (.20)	37.2%	0.00 (<.001)
Physician Support	5 (2528)	0.98 (0.90-1.06)	.65	1.78 (.77)	0.0%	–1.05 (.29)
Automated Alerts	18 (8738)	0.98 (0.91-1.05)	.61	33.10 (.01)	48.6%	–2.39 (.02)
Collaborative Care Support	19 (7215)	0.90 (0.81-1.01)	.08	61.24 (<.001)	70.6%	–3.35 (.001)
Nurse Support	22 (8992)	0.92 (0.84- 1.01)	.10	64.19 (<.001)	67.3%	–3.32 (.001)

[a]IRR = risk ratio of mortality; [b]PC = personal computer; [c]ECG = electrocardiogram; [d]N/A = not applicable due to insufficient data.

Table 4.8 Comparison of the effect of telemonitoring strategies on all-cause hospitalisation and all-cause mortality between subgroup 1 and subgroup 2.

Strategies	All-cause hospitalisation *P* value	All-cause mortality *P* value
Technology application		
Blood Pressure Monitor	.08	.46
ECG[a] Monitor	.98	.89
Heart Rate Monitor	.19	.92
Mobile Health System	.03	.01
Care objectives		
Education	.45	.92
Monitoring Symptoms	.13	.40
Medication	.02	.59
Diet	.13	.33
Exercise	.33	.28
Depression and Anxiety	N/A[b]	.09
Care support method		
Call Center Support	.37	.73
Physician Support	.14	.35
Automated Alerts	.05	*P*=.99
Collaborative Care Support	.92	.28
Nurse Support	.29	.66

[a]ECG = electrocardiogram; [b]N/A = not applicable due to insufficient data for comparison.

In the analysis of all-cause mortality, the mHealth subgroup (subgroup 1, 10 RCTs, n=3711, RR=0.67, 95% CI 0.53-0.85) was also associated with a significantly (*P*=.01) lower RR than the comparison subgroup (subgroup 2, 11 RCTs, n=6852, RR=0.95, 95% CI 0.84-1.07), as shown in Tables 4.9, Table 4.10 and Figure 4.9. Within the mHealth subgroup, the telemonitoring interventions were significantly more effective than usual care in reducing all-cause mortality (subgroup 1, 10 RCTs, n=3711, RR=0.67, 95% CI 0.53-0.85, *P*<.001). No significant heterogeneity was detected in both the mHealth subgroup and the comparison subgroup. A significant risk of bias (P_F=.01) was found in the comparison subgroup.

In the subgroup comparison of RR and IRR outcomes, we also used the mixed-effects model to adjust for sex, age, or LVEF but did not find significant improvements in these RR and IRR analysis results.

Table 4.9 Subgroup meta-analysis to examine the effect of telemonitoring strategies on mortality in randomised controlled trials (RCTs) that applied the strategy in the telemonitoring intervention (subgroup 1).

Strategies	RCTs (N participants)	Effect		Heterogeneity (*P* value) and Funnel Test (*P* value)		Funnel test Z (*P* value)
		RR[a] (95% CI)	*P* value	Q (*P* value)	I^2	
Technology application						
PC[b]-based System	2 (1493)	1.05 (0.90-1.21)	.52	0.52 (.47)	0.0%	0.00 (<.001)
Blood Pressure Monitor	16 (7924)	0.83 (0.71-0.98)	.03	24.22 (.06)	38.1%	–1.03 (.30)
ECG[c] Monitor	7 (3475)	0.82 (0.66-1.01)	.07	7.88 (.24)	23.8%	0.66 (.51)
Telemonitoring Weight Scale	21 (10563)	0.82 (0.71-0.94)	.005	30.89 (.05)	35.3%	–1.89 (.06)
Heart Rate Monitor	11 (6258)	0.82 (0.67-1.00)	.05	19.66 (.03)	49.1%	–1.69 (.09)
Mobile Health System	10 (3711)	0.67 (0.53-0.85)	.001	11.58 (.23)	22.3%	–0.27 (.78)
Care objectives						
Education	9 (6308)	0.81 (0.70-0.93)	.004	7.00 (.53)	0.0%	–1.37 (.17)
Daily Weight Monitoring	21 (10563)	0.82 (0.71-0.94)	.005	30.89 (.05)	35.3%	–1.89 (.06)
Monitoring Symptoms	14 (7640)	0.78 (0.66-0.92)	.004	17.33 (.18)	25.0%	–0.48 (.63)
Medication	12 (5475)	0.77(0.60-0.98)	.04	18.60 (.06)	40.9%	0.12 (.90)
Diet	6 (2569)	0.67 (0.43-1.03)	.07	12.60 (.02)	60.3%	–3.05 (.002)
Exercise	3 (609)	0.56 (0.28-1.13)	.11	2.49 (.28)	19.5%	1.57 (.12)
Depression and Anxiety	2 (464)	0.48 (0.26-0.90)	.02	0.12 (.73)	0.0%	0.00 (<.001)
Care support method						
Call Center Support	19 (10183)	0.81 (0.70-0.93)	.005	28.23 (.05)	36.2%	–2.52 (.01)
Physician Support	17 (8191)	0.78 (0.66-0.92)	.005	28.47 (.02)	43.8%	–2.43 (.01)
Automated Alerts	6 (1102)	0.82 (0.48-1.39)	.46	5.68 (.33)	11.9%	1.67 (.09)
Collaborative Care Support	7 (4235)	0.70 (0.48-1.01)	.06	18.75 (<.001)	68.0%	–1.14 (.26)
Nurse Support	3 (920)	0.69 (0.29-1.67)	.42	5.76 (.05)	65.3%	0.23 (.81)

[a]RR = risk ratio; [b]PC = personal computer; [c]ECG = electrocardiogram.

Table 4.10 Subgroup meta-analysis to examine the effect of telemonitoring strategies on mortality in randomised controlled trials (RCTs) that did not apply the strategy in the telemonitoring intervention (subgroup 2).

Strategies	RCTs (N participants)	Effect		Heterogeneity		Funnel test Z (*P* value)
		RR[a] (95% CI)	*P* value	Q (*P* value)	I^2	
Technology application						
PC[b]-based System	19 (9070)	0.79 (0.68-0.91)	.002	23.55 (.17)	23.6%	–1.08 (.28)
Blood Pressure Monitor	5 (2639)	0.71 0.49-1.03)	.08	6.08 (.19)	34.3%	–1.80 (.07)
ECG[c] Monitor	14 (7088)	0.80 (0.66-0.97)	.03	21.59 (.06)	39.8%	–2.91 (.004)
Heart Rate Monitor	10 (4305)	0.81 (0.65-0.99)	.04	10.50 (.31)	14.3%	–0.59 (.55)
Mobile Health System	11 (6852)	0.95 (0.84-1.07)	.40	11.01 (.35)	9.2%	–1.67 (.09)
Care objectives						
Education	12 (4255)	0.82 (0.65-1.04)	.11	20.66 (.03)	46.8%	–0.89 (.37)
Monitoring Symptoms	7 (2923)	0.89 (0.69-1.13)	.35	8.88 (.18)	32.4%	–2.26 (.02)
Medication	9 (5088)	0.84 (0.70-1.01)	.07	12.11 (.14)	33.9%	–2.58 (.01)
Diet	15 (7994)	0.84 (0.73-0.96)	.02	16.50 (.28)	15.2%	–0.34 (.73)
Exercise	18 (9954)	0.83 (0.72-0.96)	.01	26.24 (.07)	35.2%	–1.46 (.14)
Depression and Anxiety	19 (10099)	0.84 (0.73-0.96)	.02	26.97 (.07)	33.3%	–1.42 (.17)
Care support method						
Call Center Support	2 (380)	1.01 (0.29-3.54)	.98	2.63 (.10)	62.0%	0.00 (<.001)
Physician Support	4 (2372)	0.90 (0.71-1.13)	.37	2.42 (.49)	0.0%	0.34 (.74)
Automated Alerts	15 (9461)	0.81 (0.70-0.94)	.008	25.03 (.03)	44.1%	–3.76 (<.001)
Collaborative Care Support	14 (6328)	0.87 (0.77-0.99)	.04	11.76 (.54)	0.0%	–1.01 (.31)
Nurse Support	18 (9643)	0.85 (0.74-0.96)	.02	23.23 (.14)	26.8%	–2.36 (.02)

[a]RR = relative risk; [b]PC = personal computer [c]ECG = electrocardiogram.

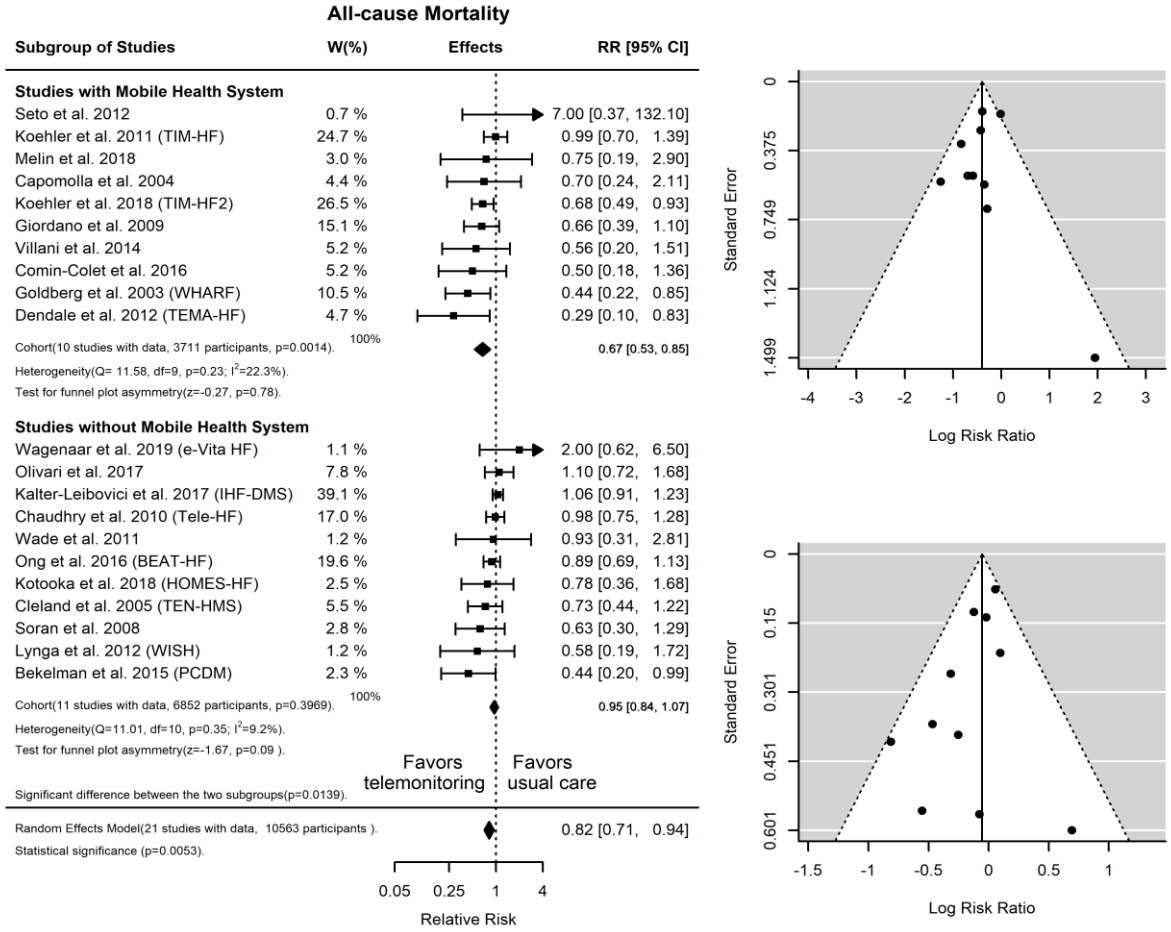

Figure 4.9 Effectiveness of the strategy of combining with mobile health (mHealth), or applying an mHealth system, on reducing the risk of all-cause mortality. The subgroup of randomised controlled trials (RCTs) that applied the mHealth strategy were compared with the subgroup of RCTs that did not apply the strategy.

4.5 Discussion

In this systematic review and meta-analysis, we evaluated 18 telemonitoring strategies in 26 RCTs. In addition to a traditional meta-analysis for overall effectiveness, we used a subgroup comparison method to analyse the effects of different telemonitoring components on clinical outcomes. We found that the telemonitoring strategy of providing medication support was associated with reduced all-cause hospitalisation, whereas mHealth systems were associated with both reduced all-cause hospitalisation and reduced all-cause mortality. Therefore, our review provides unique

insight into specific telemonitoring strategies associated with improved clinical outcomes, which will help inform future telemonitoring interventions.

The positive findings related to the medication support strategy underscore the importance of medication therapy in telemonitoring interventions for CHF care. Strong evidence supports the role of modern pharmacological therapy in CHF management for delaying CHF deterioration[66,67], and reducing mortality and hospitalisations.[18,67] However, the therapeutic benefits are often limited by suboptimal patient adherence[68] and this limitation is not addressed by traditional face-to-face consultations.[25] Our findings suggest that the use of telemonitoring improves the efficacy of medication therapy, possibly through frequent reinforcement of compliance, leading to reduced episodes of clinical deterioration requiring hospitalisation. Further research on optimizing medication therapy and underlying care processes in telemonitoring interventions is warranted to improve clinical outcomes in CHF care.

Using the subgroup comparison method, we also found that the strategy of providing telemonitoring interventions through an mHealth system was associated with a significant improvement in both all-cause mortality and hospitalisation (or corresponding RR and IRR) outcomes. These positive findings could be supported by several unique advantages of using mHealth for general chronic disease care, including ease of use, portability, and real-time communication.[69-71] These advantages have been shown to improve the underlying care processes of patients' self-management[72], care engagement[73,74], and medication adherence in CHF.[75] Therefore, our positive findings support delivering telemonitoring interventions through mHealth platforms, consistent with the increasing trend in using smartphones and computer tablets for the primary and secondary prevention of chronic disease.[76,77]

Three recent reviews of mHealth in CHF management have resulted in inconsistent outcomes and, consequently, were unable to conclude significant clinical benefits.[21,23,78] In contrast to these traditional reviews, each intervention program in our mHealth subgroup combined both telemonitoring and mHealth interventions. Our positive finding indicates that simple mHealth apps without telemonitoring (enabling care providers to provide timely clinical intervention), such as apps only focusing on self-management or education, were insufficient to improve clinical outcomes.

Similarly, this finding suggests that telemonitoring programs focusing on clinical assessment and intervention, but not delivered through a mHealth environment, fail to engage patients with CHF in self-management to the same extent as those provided via mHealth. Therefore, our finding warrants future research on comprehensive care programs combining telemonitoring and mHealth to improve both timely clinical intervention and patient engagement in CHF care.

As a part of our evaluation, we also conducted a traditional meta-analysis to evaluate the overall effectiveness of all of the telemonitoring interventions in the RCTs included in this review. We found that telemonitoring interventions were more effective than usual care in reducing both all-cause mortality and all-cause hospitalisations. This finding adds evidence to support telemonitoring interventions for CHF care generally. In our review, invasive telemonitoring interventions and small RCTs were excluded. These exclusions may have refined the selection of telemonitoring studies, leading to significant findings, in contrast to the three previous mHealth reviews with inconclusive findings.[21,23,78]

It is also important to note that several strategies such as daily weight monitoring, call centre support, and exercise contained limited numbers of RCTs in the subgroup or comparison group. The evaluation of these strategies was therefore limited by our subgroup comparison method. However, these strategies should not be overlooked, and further research on their contributions to CHF care, such as improving patient adherence to daily weight monitoring and level of exercise, remains essential to continuously improve telemonitoring outcomes in future studies.

4.6 Limitations

Because the objective of our review was to evaluate different telemonitoring strategies, our meta-analysis did not rigorously exclude RCTs with a risk of bias, although we did exclude studies with small sample sizes. In addition, this review was an exploratory study, and hence we did not adjust the P value in the multiple comparisons of the telemonitoring strategies.

4.7 Conclusion

The issues of mixed mortality and hospitalisation outcomes have deterred the adoption of telemonitoring in CHF care. To address this issue, this review extensively investigated strategy-related factors associated with improvements in the outcomes and found that the strategies of (1) providing medication support and (2) combining telemonitoring interventions through mHealth were associated with a significant improvement in all-cause mortality or hospitalisations. Importantly, these findings emphasize the importance of prioritizing medication therapy and patient engagement through mHealth apps in future telemonitoring interventions for CHF care.

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Chapter 5 - Study 2: Innovative telemonitoring enhanced care programme for chronic heart failure (ITEC-CHF) to improve guideline compliance and collaborative care: protocol of a multicentre randomised controlled trial

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Declaration of candidate contribution

For this co-authored manuscript, the candidate contributed to the design of the clinical study, writing and critical revision of the manuscript. In the collaborative effort of crafting this manuscript, the candidate's involvement ensured the robustness and relevance of the investigation given the candidate played a multifaceted role encompassing several key aspects of the research process including design refinement through the process writing of the protocol paper. The candidate engaged in in-depth reviews of the content, ensuring the accuracy of research methodology, adherence to research standards, and alignment with the study's objectives.

Sheau Huey Chen | PhD candidate

Professor Andrew Maiorana | Primary supervisor

For more information on the candidate's level of contribution, please refer to Appendix 25 & 26 – Chapter 5: Co-Authorship Contribution Form

5.1 Introduction

Congestive heart failure (CHF), a life-threatening chronic disease, is a global pandemic.[1] It affects over 26 million people[2] with annual direct costs of over US$65 billion globally.[3] Despite advances of modern medicine, patients with CHF continue to experience poor survival (30%–50% at 5 years[4, 5]), debilitating symptoms such as dyspnoea and fatigue,[6] poor health-related quality of life (HQoL)[7] and episodic clinical exacerbations with high risks of hospitalisation.[8, 9]

To effectively manage CHF, evidence-based guidelines are available internationally.[10, 11] A consistent recommendation of guidelines is self-management, such as fluid restrictions and daily weighing to monitor fluid balance.[12] Patient compliance with such clinical guidelines is essential to optimise health outcomes,[13] but is often suboptimal.[14, 15] For example, 12%–75% of patients in usual care were found to adhere to the cardinal recommendation of daily weighing.[15, 16] Non-compliance is likely due to a variety of factors including time constraints[17], insufficient knowledge[18] and limited clinical support.[19] Importantly, patients who are non-compliant with self-management guidelines often fail to effectively engage with clinicians for timely interventions,[16] resulting in increased risks of mortality[20] and hospital readmissions.[21, 22]

Telemonitoring applications are an evolving strategy to improve CHF care, which have the potential to support patients in self-management.[23-25] However, the effect of telemonitoring on patient compliance with guideline-advocated self-management has not been extensively studied. To our knowledge, only four randomised controlled trials (RCTs) have compared patient compliance between a telemonitoring intervention and usual care group.[26-29] These trials were limited by small sample sizes (n≤100) or short-duration follow-up (≤3 months). Furthermore, their outcomes are inconsistent, with two trials reporting improved patient compliance[26, 27] and two reporting no benefit.[27] Because of the limited and inconsistent evidence, no meta-analysis studies or reviews have been able to conclude the effectiveness of using telemonitoring to improve patient compliance. These facts highlight the need for further research to substantiate patient compliance in telemonitoring studies for CHF care.

To address the issue of patient non-compliance, we have designed an Innovative Telemonitoring Enhanced Care Programme for CHF (ITEC-CHF). This programme focuses on assisting patients with CHF in complying with the daily weight management recommended by the guidelines. To minimise weight monitoring burdens and technical difficulties, the programme proposes a novel 'zero-touch' design, meaning that the participants are not required to interact with the technology other than stepping onto a scale for weight measurement as in usual care, and they do not need to learn extra knowledge and skills to receive the telemonitoring intervention. The programme is also integrated with existing best-practice clinical workflows and action plans to streamline the intervention and make it seamless for care providers.

To evaluate the programme, we will conduct a multicentre RCT. The objective of the trial is to examine the hypothesis that the ITEC-CHF improves patients' compliance, and associated health and economic outcomes. This trial will examine patient compliance with an innovative telemonitoring programme across different care settings. It will also add essential clinical evidence to support the use of telemonitoring applications in the community.

5.2 Methods

5.2.1 Trial design

A prospective open two-arm multicentre RCT has been designed. In the trial, patients with CHF will be recruited at two trial sites: (1) Frankston Hospital and Rosebud Hospital in Victoria (VIC), Australia, and (2) Royal Perth Hospital and Fiona Stanley Hospital in Western Australia (WA).

The participants in the trial will be individually randomised to receive either ITEC-CHF or usual care (UC-CHF) for at least 6 months. The allocation ratio of the randomisation is 1:1. The randomisation is stratified by the two trial sites (VIC and WA) to ensure the allocation ratio in each site. According to a recommended method[30], a series of random allocation assignments with permuted blocks have been generated and sealed in opaque envelopes by two research scientists in a research organisation in

the study. The block sizes will be kept confidential to prevent potential predictions of the assignments. Data analysts generated the randomisation sequence and will be blinded throughout the trial using de-identified patient data. It will be difficult to effectively blind the participants and care providers to telemonitoring interventions, but we will attempt to avoid unnecessary discussions about the allocations and hypothesised outcomes with the participants and care providers throughout the trial.

The trial flow diagram is presented in Figure 5.1. Through the trial, project nurses at the trial sites will use their electronic patient administration systems to screen patients with CHF from medical records of patient presentations at the local hospitals and emergency departments (EDs). They will also screen patient records at heart failure outpatient clinics, and community healthcare services. The nurses will then record eligible candidates, and accordingly, send an invitation letter to the candidates. One week later, project nurses will follow up with the candidates via a telephone call. If a candidate is willing to participate in the trial, the project nurses will arrange a face-to-face interview. During the interview, project nurses will explain the trial processes and requirements in detail and conduct formal written consent with the candidates who agree to participate in the trial. Participants recruited will be interviewed by the project nurses for a baseline assessment. Each participant will then be randomised into either ITEC-CHF or UC-CHF group. At the 6-month time point, all participants will be assessed again. After the 6-month assessment, if the participants are willing to continue, they can stay in the trial to receive a 12-month assessment. Finally, the project nurses will collect the trial data for the research analysis. Participants will be enrolled from January 2015 to October 2017.

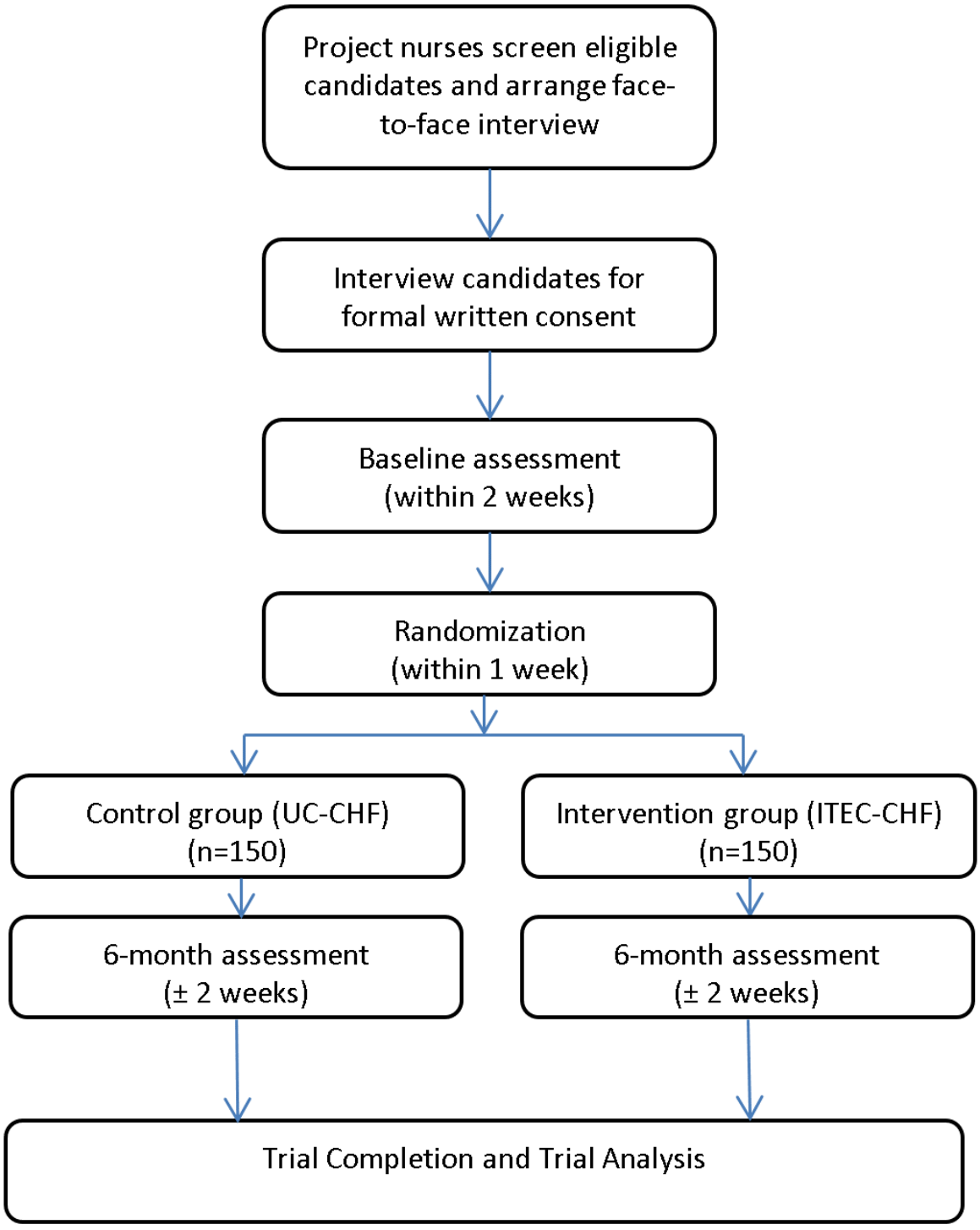

Figure 5.1 Proposed trial CONSORT flow diagram of the two-arm randomised controlled trial to compare the ITEC-CHF program with usual care.

5.2.2 Inclusion and exclusion criteria

Patients will be eligible to participate in the trial, if they satisfy all the following inclusion criteria: (1) CHF diagnosed by a clinician with an ejection fraction ≤40%, (2) able to weigh themselves safely, (3) at least 18 years of age, (4) have a regular personal general practitioner (GP) or agree to use a designated GP, (5) with a permanent residential address and (6) without significant cognitive impairments. Patients will be excluded if they meet any of the following criteria: (1) expected survival <12 months, such as patients with documented palliative care in medical records, (2) end-stage renal failure on dialysis, (3) long-term nursing home resident or (4) participating in any other clinical trial.

5.2.3 Trial interventions

Usual care

Participants in the UC-CHF group will receive a standard package of paper-based diary and booklets at baseline, including the 'Living Well with Chronic Heart Failure' resource produced by the Heart Foundation of Australia (HFA). They will then attend standard CHF clinics and primary care physicians and undertake traditional CHF self-management through the trial period. Each participant will also be provided with an electronic weighing scale (ForaCare, W550, Moorpark, CA, USA), and asked to use the weight scale according to the self-management recommendation of the HFA. Project nurses will visit the participants to download the weight data from the weight scale at scheduled times, approximately every 3 months.

Enhanced care

The ITEC-CHF will combine usual care and an additional telemonitoring service. The telemonitoring service consists of three major components: remote weight monitoring, structured telephone support and nurse-led collaborative care. The service is integrated with a telephone call centre (MePACS, VIC, Australia)[31] and a nurse care service according to their workflows in usual care.

The integrated care model of the ITEC-CHF is shown in Figure 5.2. In the model, participants are provided with an electronic weighing scale (ForaCare, W550), and a computer tablet (Samsung, Galaxy Tab A, Seoul, Korea). They are asked to use the scale to measure their body weight daily, immediately after wake-up, following voiding, without shoes, in light clothing and before the next dose of medication. The measured weight entry is recorded in the scale, and then automatically transmitted to the tablet via a wireless Bluetooth function embedded in the scale. The tablet is preloaded with an Android application (Medtech Global, Melbourne, Australia). This application receives the weight entry and uploads the entry to a proprietary software package, called ManageMyHealth (MMH) (Medtech Global). A web application in MMH automatically monitors uploaded weight entries in real time to generate alerts and triage the alerts to project nurses and the telephone call centre. The rules to generate and triage the alerts are given in Table 5.1. They were designed in accordance with the HFA guidelines for the prevention, detection and management of CHF in Australia.[10]

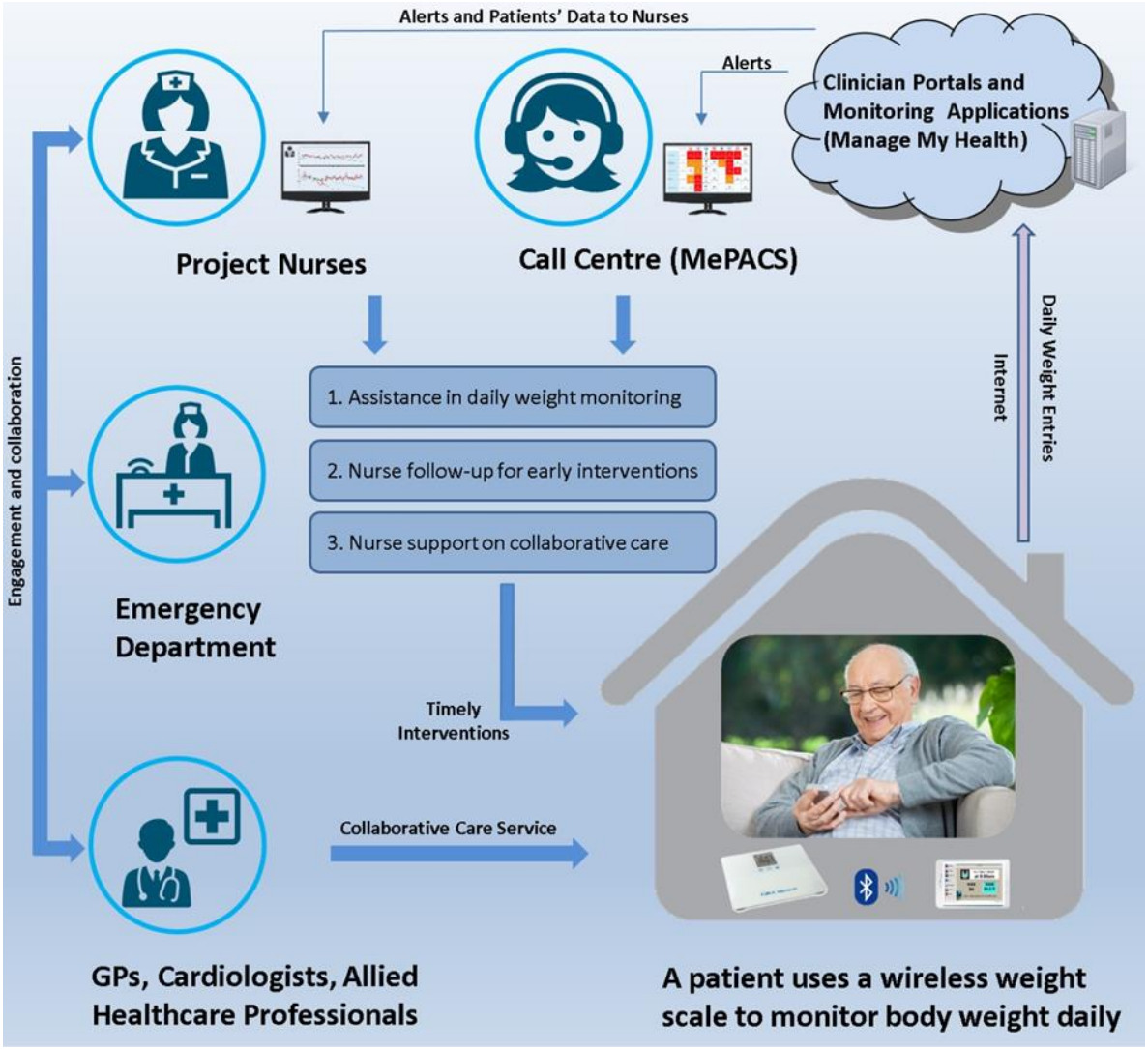

Figure 5.2. The care model of the ITEC-CHF program is integrated in usual care. The integration includes: 1) remote weight monitoring, 2) structured telephone support, and 3) nurse-led collaborative care.

Table 5.1 Alerts generated, and associated interventions provided in the ITEC-CHF program.

Care Provider	Conditions	Response Time	Interventions
Call Centre (MePACS)	No weight entry detected before 10AM.	In real-time, 24 hours, 7 days a week.	Operators at MePACS call the patients to remind them to weigh. If needed, they call nurses to follow-up.
	Technical issues, such as low level of battery power.	In real time, 24 hours, 7 days a week.	Operators at MePACS call the patients to solve the issues and call nurses to follow-up if needed.
Project Nurses	Fluctuation of 2 kg in 2 days.	In real time, 24 hours, 7 days a week.	Nurses call patients for further assessment and help process the CHF action plan.
	Fluctuation of 5 kg in 28 days (unintentional weight loss/gain)	Work days.	Nurses follow up with the patients and engage with CHF clinics for further clinical assessments.
	Fluctuation of 1 Kg over 24 hours.	In real time, 24 hours, 7 days a week.	A questionnaire will be automatically triggered on the table to assess clinical symptoms. If the participant has any of the symptoms assessed, the nurses will be notified to follow up with the patient for intervention.

Operators at the call centre will respond to the alerts in real time (24 hour, 7 days a week). If a participant does not weigh before 10 AM, a call operator will call the participant to remind him/her to weigh. During the call, if the participant needs clinical support such as advice for assessing CHF symptoms or managing diet, the call operator will arrange a nurse follow-up. The project nurses will subsequently follow up with the participant via a telephone call or home visit if needed. The call operators also provide technical support through the trial, such as updating the tablet application and arranging home visits to change batteries in the scales.

The project nurses provide structured interventions according to three types of alerts: rapid weight fluctuation (±2 kg in 2 days), slow weight fluctuation (±5 kg in 28 days), and low-risk weight fluctuation (±1 kg over 24 hours). If a participant has rapid weight fluctuation, a project nurse will be alerted. The nurse will then call the participant to assist him/her in assessing critical symptoms, and activating the CHF action plan if indicated, such as attending their GP, CHF clinic or presenting to an emergency department (ED). For an alert of slow weight fluctuation, the project nurses will assist the participant in assessing CHF symptoms and arranging clinical reviews at the participants' GP or CHF clinics. The option to present to an ED may also be applied if this is clinically indicated. If a participant's body weight fluctuation exceeds ±1 kg (but is less than ±2 kg) over 24 hours, a questionnaire will be automatically triggered and sent to the participant's computer tablet. The user interface of the questionnaire is shown in Figure 5.3. If the participant reports any of the clinical conditions in the questionnaire or does not respond to the questionnaire, the project nurses will follow up with the participant for a clinical assessment.

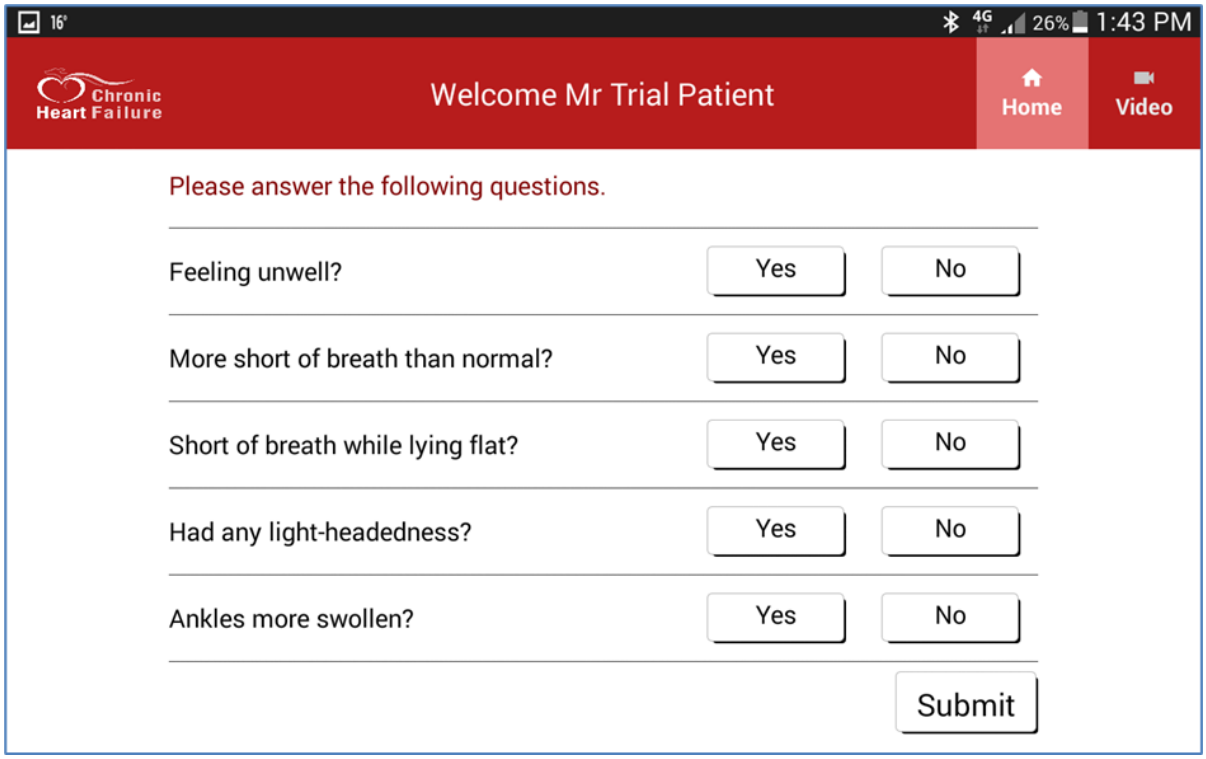

Figure 5.3 User interface of the questions sent in the event of a low-level alert.

5.2.4 Primary and secondary outcomes

The outcome measures of the trial are given in Table 5.2. The primary outcome will be patient compliance with daily weight monitoring as evaluated by weight entries, recorded on the electronic scales provided to both the ITEC-CHF and UC-CHF groups. Based on a published study,14 we define that a participant is compliant with daily weight monitoring if he/she performed weight monitoring at least 4 days a week. The rate of compliant days with weight monitoring (days with at least one body weight entry) per week for each participant during his/her trial period will also be computed, and the histogram of the rate will be analysed. The secondary outcomes will include compliance with other guideline recommendations assessed by Heart Failure Compliance Questionnaire[32] (health maintenance, medication, diet and exercise), health outcomes including HQoL (European Quality of Life Five Dimension, EQ-5D[33]), risk factors, functional capacity (6 min walk test[34]), psychological states (Cardiac Depression Scale, CDS-SF2[35]) and frailty scale (Canadian Frailty Index[36]), and health economic outcomes related to the use of healthcare resources such as hospital

readmissions and GP/ED visits. Patients' characteristics and assessment records will be collected by the project nurses. For the evaluation of hospital readmissions and ED presentations, the data will be extracted from the electronic patient administration systems of the hospitals in the trial.

Table 5.2 Trial outcome measures and assessment tools and data resources.

Primary Outcome	
Compliance with daily weight monitoring	Daily weight entries recorded in participant's scale and MMH
Secondary Outcomes	
Other guideline recommendations to the CHF management	Heart Failure Compliance Questionnaire (health maintenance, medication, diet, and exercise)
Health/Clinical Outcomes	Variation of body weight (mean and SD of weekly weight entries)
	Functional capacity (6-minute walk test)
	Health-related quality of life (EQ-5D)
	Psychosocial status (CDS, short version)
	Frailty scale (Canadian Frailty Index)
Health Economic Outcomes	Number of hospital readmissions, and length of stay (mean, SD)
	Number of ED visits, and length of stay (mean, SD)
	Number of GP visits

CHF = congestive heart failure; ED = emergency department; GP = general practitioner; MMH = Manage My Health.

5.2.5 Strategies of participant retention

Prior to the trial recruitment, we will discuss the importance of participant retention within the recruitment and care teams. During the trial, each participant recruited will be provided with a telephone contact in the information package. Through the contact, the participants can contact project nurses for trial-related support. A structured procedure will be in place to guide project nurses to document the participants' enquiries and ensure timely responses and/or follow-ups. Moreover, the project nurses will visit each participant every 3 months, to discuss any concerns or issues related to the trial and change the batteries in the weight scale.

5.2.6 Participant discharge

Participants will be discharged from the trial under the conditions of 1) mortality, 2) elective withdrawal, and 3) full completion of the program. When discharging participants, project nurses will document the conditions in case report forms (CRF) with the date and causes in detail.

5.2.7 Data security and storage

All trial files, including the master list, CRF, and clinical assessment forms, will be stored securely, either in password-protected computer files or in locked filing cabinets in a secure area at Peninsula Health or Curtin University. Access to these files will only be granted to study personnel trained in confidentiality and privacy procedures at the hospitals in the study. All trial data provided for research analysis will be de-identified, including patient characteristics, primary and secondary outcomes, and data entries through the healthcare and telemonitoring systems in the study.

All the trial files and data will be stored securely for a minimum of 5 years after completion of the study and, finally, be securely destroyed according to the Privacy Policy provided by the National Health and Medical Research Council of Australia.

5.2.8 Sample size

Compliance with daily weight monitoring was used to calculate the sample size. The null hypothesis is that the percentage of "compliant" participants in the ITEC-CHF group is not higher than in the UC-CHF group. To reject the null hypothesis, we assumed a compliance rate of 80% in ITEC-CHF and 65% in UC-CHF. We also assumed an attrition rate of 10%. A two-tailed test with a power of 90% and an Alpha of 0.05 was used to calculate the same size to achieve statistical significance.[37] The power calculation resulted in the study needing at least 143 participants in each group. Accordingly, we rounded the calculated sample size, and made the trial size of 150 patients in each group, for a total of 300 participants. With this sample size, we have a likelihood of 90% to yield statistical significance.

5.2.9 Statistical analysis

All participants recruited and randomised into the two trial groups will be included in the final comparative analysis according to the intention-to-treat design. A Chi-square test will be used to compare categorical variables between the ITEC-CHF and UC-CHF groups, such as sex, and compliance (compliant patients vs noncompliant patients). ANOVA will be applied to analyse continuous variables such as age and weight variations. A Cox proportional hazards model will be performed to analyse the risks of hospital readmission and ED visits. The analysis will be adjusted for confounding variables including sex, age and trial sites. The confidence interval of 95% will be estimated. A p-value less than 0.05 will be considered as statistical significance for all tests. The statistical analysis will be conducted using SPSSv23. Missing data at the case level will be imputed using a multiple imputation method in the SPSS.

5.2.10 Trial management

A Project Working Group (PWG) will be composed of the chief investigators, research scientists or project managers from the organizations of the project. The PWG will convene monthly (with additional meetings if needed) and take overall responsibility for the conduct of the trial, such as managing the trial progress, reviewing adverse events in CRF, resolving technical issues, and monitoring trial data. If necessary, the committee will advise and make changes in the clinical trial protocol. The PWG will be independent from project sponsors and free from competing interests.

A project control board (PCB) will be composed of a) CHF clinical champions, b) chief investigators, c) researchers, and d) project managers. The PCB will convene monthly to govern the project and ensure that the project meets all requirements outlined in the project plan. The major responsibilities of the PCB will include 1) reviewing the study plan, 2) providing reports to the project sponsors and ethics committees, 3) deciding budget and administration, 4) resolving contractual issues, and 5) maintaining IT and telemonitoring systems in the trial. The PCB will also work with independent management committees for safety and quality of care at corresponding hospitals, to assess the severity of incidents and adverse effects. The PCB will have the capacity to terminate the trial in the event of slow recruitment, safety concerns, or overwhelming evidence of benefit.

A Clinical Trial Advisory Committee, composed of chief investigators and research scientists, will convene monthly. The committee will implement and maintain quality assurance and quality control systems to ensure the trial in compliance with the protocol and applicable policies. The committee will also arrange at least one audit during the trial. An arranged audit team will check the overall quality and completeness of the data, examine source documents, and ensure that the trial complies with the requirements outlined by the trial protocol, ethics applications and hospital policies. The audit process will be independent from chief investigators and project sponsors.

5.3 Discussion

Daily weight monitoring is a Class I recommendation in the management of CHF[11] to help maintain fluid balance. Fluid retention is an early sign of acute CHF deterioration, a flag for poor compliance with prescribed medication (especially diuretics) and non-adherence with fluid and salt restrictions. Early identification of abnormal weight fluctuations caused by fluid accumulation allows clinicians to work with the patient to improve their compliance and provide timely interventions. This potentially reduces the burden of heart failure in terms of reducing preventable hospitalisations and preventing clinical deteriorations amongst patients with CHF.[22, 38, 39]

In usual care, patients often have difficulties using paper-based diaries to record daily weight entries and analyse recorded weight entries in association with observed symptoms in order to seek clinical interventions. Weight monitoring in isolation also requires patients to have the knowledge and skills to effectively identify symptoms, make decisions about their clinical relevance, and act on these. To overcome these difficulties, this study proposes the ITEC-CHF program to automatically detect abnormal weight fluctuations and provide active clinical support through a call centre and project nurses. Compared with the traditional management of CHF, this program has the potential to dramatically simplify the daily weight monitoring and management and does not require special knowledge or skills. While engaging with the patients for interventions of abnormal weight fluctuations, the project nurses have opportunities to assess patients' health, and issues of compliance with other recommendations, such as diet, fluid restriction, medication, exercise, and collaborative care. We anticipate that this will allow the nurses to actively engage with patients and provide a broad range of clinical interventions for the management of CHF. Through the improved compliance and clinical support, it is expected that patients will actively engage with well-established multidisciplinary clinical services for further treatment or care such as titration of diuretic medication.

The efficacy of the program will be evaluated through a multicentre RCT. The evaluation is focused on the improvement in patient compliance and associated outcomes. To accurately evaluate the compliance with daily weight monitoring, objective weight data will be obtained from both intervention and control groups. A

validated questionnaire will also be used to assess participant compliance with other important self-management behaviours, as recommended by CHF guidelines.[10] In addition to compliance, the questionnaire will also assess barriers to self-management of CHF more broadly. This will help in the refinement of telemonitoring to support CHF care in future clinical practice.

If the efficacy is validated, use of the ITEC-CHF program will not only improve the patient compliance and health outcomes, but also provide an easy way for care providers to effectively and efficiently engage with patients for collaborative care, especially for patients in rural and remote areas. Based on the ITEC-CHF program, other telemonitoring devices such as ambulatory electrocardiogram, glucose meters and blood pressure monitors can also be easily integrated to provide broader interventions for CHF patients with cardiac conditions and comorbidities including diabetes and hypertension. Therefore, validation of the system for weight compliance would support further exploration of telemonitoring for improving CHF care, as well as other chronic conditions.

The study is limited to the 6-month intervention. The 6-month duration is potentially insufficient to reflect real long-term effects of the program through the ongoing management of CHF. Recent studies, in fact, have already demonstrated an issue of declined patient adherence overtime.[40, 41] Therefore, extra caution will be exercised when interpreting the outcomes of this study.

5.4 Ethics and dissemination

The ethics application for the trial site in VIC has been approved by Peninsula Health Human Research Ethics Committee (HREC Reference: HREC/14/PH/27), and the ethics applications for Royal Perth Hospital and Fiona Stanley Hospital have been approved by Royal Perth Hospital Human Research Ethics Committee (Reference: 15-081) and the Curtin University Human Research Ethics Committee (Reference: HR 181/2014). The trial has been registered in the Australian New Zealand Clinical Trials Registry (Trial ID: ACTRN12614000916640).

We will report the primary and secondary outcomes regardless of the magnitude and direction of interventional effects or differences between the two trial groups. The report will be disseminated through publication in an appropriate journal, approximately 6 months after finishing data collection.

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Chapter 6 - Study 2: The effects of telemonitoring on patient compliance with self-management recommendations and outcomes of the innovative telemonitoring enhanced care program for chronic heart failure: randomised controlled trial

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Declaration of candidate contribution

For this co-authored manuscript, the candidate contributed to the study execution as the clinical research nurse for the two Western Australian sites. This role involved participant screening and recruitment, technical support related to the hardware and software employed in the study, and the provision of clinical support as determined by the alert systems outlined in the study protocol. The candidate was also responsible for data acquisition, liaising with participants as required throughout the study, scheduling and conducting home visits, data analysis and interpretation and the writing and critical revision of the manuscript. The candidate played a crucial role in data cleaning and preparation, addressing issues such as missing data, outliers, and data transformation. The attention to detail and data hygiene enhanced the quality and reliability of the dataset, making it feasible for in-depth analysis. Additionally, the candidate's contribution extended to providing practical recommendations based on the research findings. These recommendations were not only rooted in data but also considered the real-world applications and implications of the study.

Sheau Huey Chen | PhD Candidate

Professor Andrew Maiorana | Primary supervisor

For more information on the candidate's level of contribution, please refer to Appendix 27 & 28 – Chapter 6: Co-Authorship Contribution Form

6.1 Introduction

Chronic heart failure (CHF) is a severe chronic disease that affects more than 26 million people worldwide.[1] It significantly reduces the health-related quality of life and increases the risk of hospitalisation and mortality.[1] To improve health outcomes, it is recommended that patients with CHF undertake self-management, such as daily monitoring of body weight to assess fluid balance and seek early clinical support in the event of symptoms, which may indicate decompensation. This has been consistently outlined by evidence-based clinical guidelines for CHF[2, 3] and is practically supported by CHF clinics and rehabilitation programs in standard care. Despite these clinical efforts, patient compliance with self-management recommendations is often suboptimal for activities such as body weight recording, fluid restrictions, and medication adherence.[4] Time constraints[5], limited knowledge[6], and insufficient ongoing clinical support[7] are some of the reported barriers to the self-management of CHF. Poor compliance with self-management recommendations often leads to delays in essential treatment[4] and increases the risk of mortality and hospitalisation.[8]

In recent years, there has been significant research interest in telemonitoring as an innovative approach to remotely assist patients with CHF in self-managing their health.[9] However, to date, only 2 studies, to our knowledge, have evaluated patient compliance with weight monitoring in a randomised controlled trial (RCT).[10, 11] Although they demonstrated a higher rate of compliant participants in the telemonitoring arm (telemonitoring vs usual care: 88.6% vs 70.9%[10] and 91.7% vs 67.4%[11]), the studies relied on self-report, which is known to be influenced by recall bias.[12] In addition, the definition of compliance was loosely defined based on terms such as most of the time or all of the time and, hence, was not sufficiently accurate to reflect the daily weight monitoring recommendation. Moreover, patient adherence to telemonitoring systems has often been found to be low, even in large, well-designed RCTs (55%[13] and 55.4%[14]). This has led to an ongoing debate about the practicality of using telemonitoring to improve CHF care.[13-15] Therefore, further rigorous research for evaluating patient compliance is needed in telemonitoring studies for CHF care.

We evaluated an innovative telemonitoring enhanced care program for CHF (ITEC-CHF) in an open multicentre RCT. The ITEC-CHF program focused on assisting

patients in daily weight monitoring and engaging with nurse-supported care in the event of weight fluctuations. This study aimed to examine whether the ITEC-CHF program improved patient compliance with weight monitoring as well as other self-management behaviours and health outcomes.

6.2 Methods

6.2.1 Study Design

The protocol for the ITEC-CHF study has been previously published.[15] Images of the user interface and the Bluetooth-enabled scales are provided in Figure 6.1 and 6.2. In this study, patients with CHF were recruited from 2 trial sites in Australia: one in Victoria (VIC) and one in Western Australia (WA). The trial sites were at 2 hospitals in VIC and WA, respectively. This study complies with the Declaration of Helsinki. All participants provided written informed consent. The clinical trial protocol was approved by the Human Research Ethics Committee at Peninsula Health, VIC (HREC reference: HREC/14/PH/27), and Royal Perth Hospital, WA (reference: 15-081 and reference: HR 181/2014), Australia. Participants were enrolled from January 2015 to October 2017. The latest data collection of hospitalisations and emergency department (ED) presentations was conducted in September 2018.

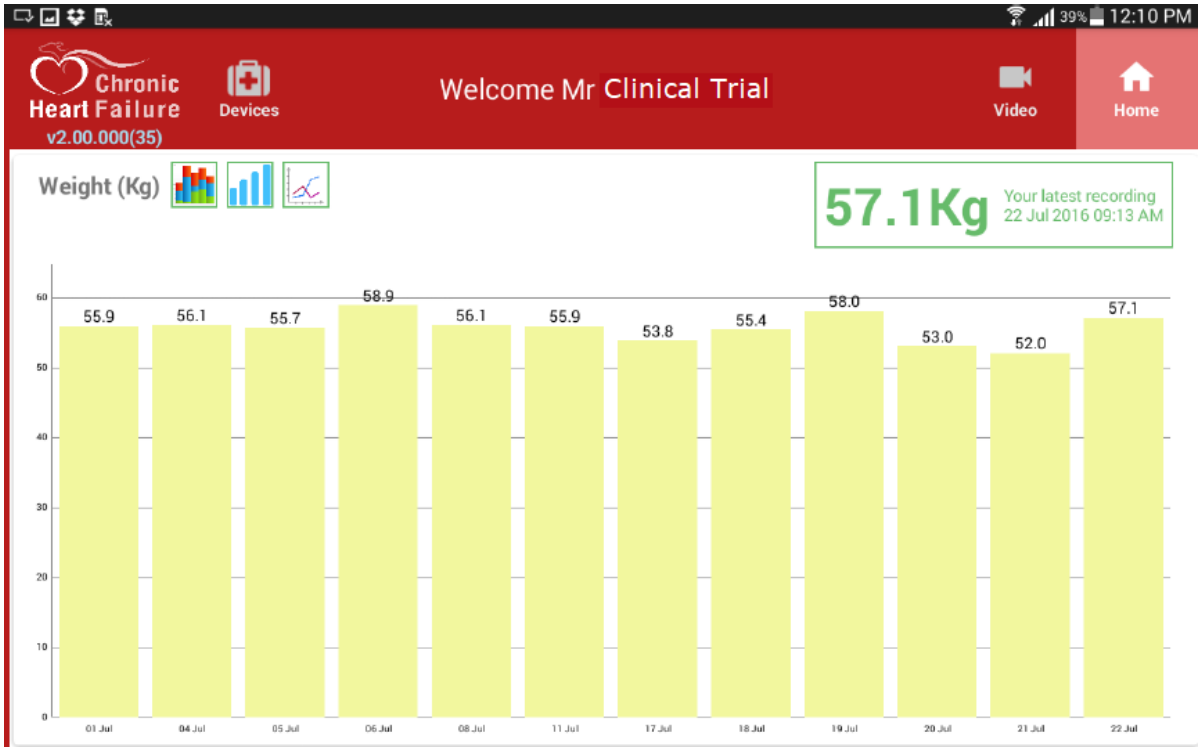

Figure 6.1 User interface.

Figure 6.2 Bluetooth-enabled scales.

6.2.2 Randomisation and Masking

Participants in the trial were individually randomised with an allocation ratio of 1:1 to receive either ITEC-CHF or usual care (control) for 6 months. Randomisation was stratified by the 2 trial sites (VIC and WA) to ensure that the allocation ratio was consistent at each site. A block method was used to achieve a balanced number of participants between the ITEC-CHF and control groups throughout the trial. The random allocation assignments were sealed in opaque envelopes. Data analysts generated the randomisation sequence and were blinded to the trial because of the use of deidentified patient data.

6.2.3 Inclusion and Exclusion Criteria

The inclusion criteria were as follows: patients (1) with CHF with reduced ejection fraction (EF; ie, EF≤40%), (2) able to weigh themselves safely, (3) aged at least 18 years, (4) having a regular personal general practitioner (GP) or agreeing to use a designated GP, (5) with a permanent residential address, and (6) without significant cognitive impairments. The exclusion criteria were as follows: (1) patients with expected survival <12 months, (2) patients with end-stage renal failure on dialysis, (3) long-term nursing home residents, or (4) patients participating in any other clinical trial.

6.2.4 Interventions

At baseline, control participants were provided with a standard package of a paper-based diary and the Living Well with Chronic Heart Failure booklet, produced by the Heart Foundation of Australia. They were instructed to maintain their usual CHF care, as provided by clinics specialized in CHF and primary care physicians, and to undertake CHF self-management as previously instructed. Each participant was also provided with an electronic weight scale (FORA TN'G W550; ForaCare) and asked to use the scale to measure their body weight daily, immediately after waking, following voiding, without shoes, in light clothing, and before taking medication. Approximately

every 3 months, project nurses visited the participants to download the weight entries from the weight scale.

Participants in the ITEC-CHF group received the same resources as those in the control group, in addition to the ITEC-CHF program. The ITEC-CHF consists of 3 major components: remote body weight monitoring, structured telephone support, and nurse-led collaborative care. The service was integrated with a telephone call centre (MEPACS, VIC, Australia) and community nurse care services at the trial sites in VIC and WA. Each participant was provided with an electronic weight scale and a computer tablet (Galaxy Tab A, Samsung). Participants were asked to weigh themselves using the procedure described for the control group. After the measurement, the weight entry was automatically transmitted from the weight scale to the tablet via a wireless Bluetooth function. The tablet was preloaded with an Android app (Medtech Global). This app received the weight entry and uploaded the entry to a software package called Manage My Health (MMH; Medtech Global). A rule-based decision support system (a web app) in MMH automatically monitored the uploaded weight entries in real-time. In response to the weight data generated by telemonitoring, 6 types of alerts were possible: (1) rapid weight fluctuation (an increase or decrease of 2 kg over 2 days), (2) slow weight fluctuation (an increase or decrease of 5 kg over 28 days), (3) low-risk weight fluctuation (an increase or decrease of 1 kg over 24 hours), (4) missed weight measurement, (5) low level of tablet battery, and (6) tablet connection lost. In the event of a rapid weight fluctuation, project nurses were alerted, and they called the participant to assist him or her in assessing symptoms and activating their CHF action plan, such as attending their GP, visiting a CHF clinic, or presenting to an ED as indicated. For an alert of slow weight fluctuations, the project nurses assisted the participants in assessing CHF symptoms and arranging clinical reviews at the participants' GP or CHF clinics as indicated. For low-risk fluctuations, a questionnaire was automatically triggered and sent to the participant's computer tablet to help him or her determine the need for further clinical follow-up. Finally, the generated alerts were distributed to project nurses and/or the MEPACS call centre in the ITEC-CHF program. Call operators at the centre responded to the alerts in real time (24 hours, 7 days a week), focusing on reminding participants to weigh themselves if they had not done so before 10 AM, helping assess CHF symptoms and manage diet, and

arranging a nurse follow-up if needed. The project nurses reviewed their alert requests on weekdays and followed up with the participants via a telephone call. Some participants were unable to monitor their body weight for a short period, such as when they were hospitalised for medical treatment, travelled away from home, or experienced unresolved technical issues. Under such conditions, they were required to notify the call centre, and weight monitoring was skipped. If a participant notified the call centre to skip the monitoring for a period, the telemonitoring intervention was then switched off during the skipped period, and the call centre did not receive any alerts from the participant and provide intervention until the skipped period ended. Monitoring days that were skipped were still included in the per-protocol analysis for the ITEC-CHF group (described in the Primary and Secondary Outcomes section).

6.2.5 Primary and Secondary Outcomes

The primary outcome was in compliance with weight monitoring. The monitoring frequency was calculated as average weight monitoring days per week during the 6-month assessment period (monitoring frequency=weight monitoring days/180 days×7 days/week [for 6 months: 6 months×30 days/month=180 days]). A weight monitoring day was determined if at least one weight entry was practically recorded on the weight scale on that day, irrespective of time. In total, 2 frequencies were employed in the examination. One was that the participant monitored their weight on at least four days per week. This frequency reflects the compliance threshold of most of the time, as previously applied in questionnaire-based assessments.[4, 12] The other frequency was at least 6 days per week, which more closely aligns with the advice for patients to monitor their weight daily.

Secondary outcomes included patient compliance with weight monitoring based on a per-protocol analysis (only undertaken in participants who completed the trial) and an analysis of other guideline recommendations assessed by the Heart Failure Compliance Questionnaire[12], health-related quality of life (five-dimension EuroQol, EQ-5D[16]), 6-min walk test distance[17], psychological state (cardiac depression scale short form 2[18]), frailty (clinical frailty index[19]), and clinical outcomes of CHF-related and

all-cause hospitalisations and ED presentations. CHF-related events were determined by using the International Classification of Diseases, Tenth Revision, Clinical Modification, diagnosis codes in Table 6.1.[20] Furthermore, we reported the alerts provided in ITEC-CHF and days when ITEC-CHF participants requested to skip weight monitoring.

Table 6.1 International Classification of Diseases, Tenth Revision, Clinical Modification, diagnosis codes used to determine heart failure–related hospitalisations and emergency department presentations.

ICD-10-CM	Description
I25.5	Ischaemic cardiomyopathy.
I42	Cardiomyopathy.
I42.0	Dilated cardiomyopathy.
I42.6	Alcoholic cardiomyopathy.
I42.7	Cardiomyopathy due to drugs and other external agents.
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified.
I50	Heart failure.
I50.1	Left ventricular failure, unspecified.
I50.2	Systolic (congestive) heart failure.
I50.4	Combined systolic (congestive) and diastolic (congestive) heart failure.
I50.9	Heart failure, unspecified.
I50.20	Unspecified systolic (congestive) heart failure.
I50.21	Acute systolic (congestive) heart failure.
I50.22	Chronic systolic (congestive) heart failure.
I50.23	Acute on chronic systolic (congestive) heart failure.
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure.
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure.
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure.
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure.

6.2.6 Statistical Analysis

In the evaluation, a chi-square test was applied to analyse continuous variables such as age, and a Fisher exact test was used to compare categorical variables such as sex and subgroups of participants under a given weight monitoring frequency (participants who achieved a given monitoring frequency vs participants who did not achieve the monitoring frequency). The Wilcoxon signed-rank test was used to compare compliance scores from questionnaire-based assessments. An analysis of covariance model[21] was used to evaluate the improvement or change in the outcome variables between the 2 groups with an adjustment for baseline. The Andersen-Gill model[22] with an adjustment for sex and age was used to analyse the hazard of hospitalisations and ED presentations. The 95% CI was estimated for the hazard function in each group. A P value<.05 was considered statistically significant. The analysis was conducted using RStudio version 1.1.383 (RStudio Inc)[23] with the R package of survival version 2.43-3. The intention-to-treat principle was applied to the analysis of the primary outcome of patient compliance with weight monitoring. It was also applied to the analysis of the hazards of hospitalisation and ED. In the intention-to-treat analysis, all participants in the RCT were included. A per-protocol analysis was also applied to weight monitoring as a secondary outcome, only including participants who did not discontinue in the trial. A complete case analysis, which restricts the analysis to individuals with complete data, was used to analyse improvements in questionnaire-based assessments and 6-min walk distances.

6.3 Results

A total of 6587 patients were screened for eligibility. Among them, 6403 patients were excluded because of failure to meet the inclusion criteria (n=5998), declined (n=306), or for other reasons (n=99), such as losing contact with the patient (Figure 6.3). Finally, 184 patients were randomised to the ITEC-CHF (n=91) and control (n=93) groups. During the 6-month intervention period, 24 participants in the ITEC-CHF group discontinued (palliative care or dialysis: n=2; deaths: n=2; and withdrawals: n=20), and

12 participants in the control group discontinued (lost to follow-up: n=1; deaths: n=1; and withdrawals: n=11). According to the intention-to-treat principle, all randomised participants (ITEC-CHF: n=91; control: n=93) were included in the analysis of the primary outcomes of patient compliance with weighing. They were also included in the analysis of the hazards of hospitalisation and/or ED presentation.

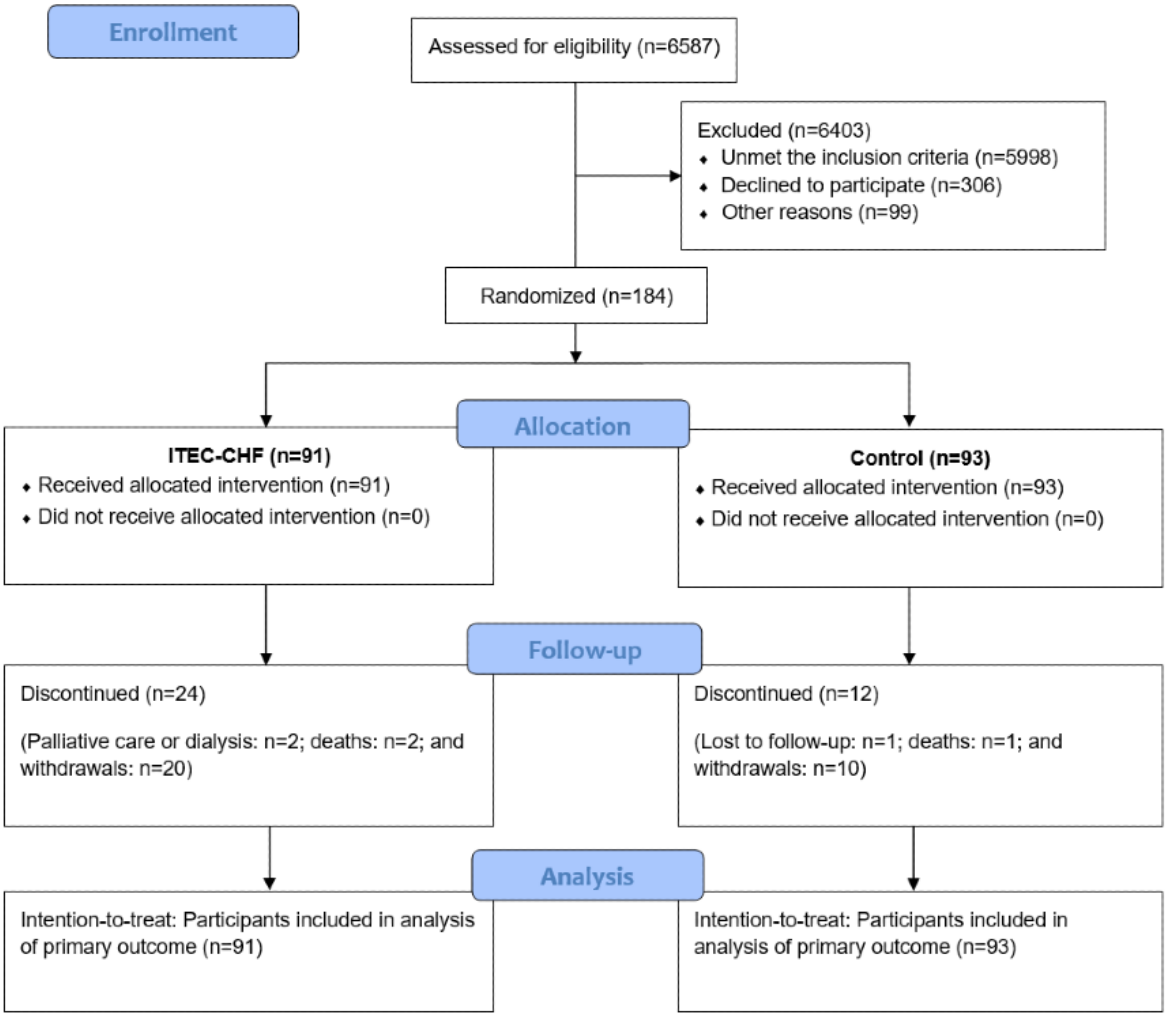

Figure 6.3 CONSORT flow diagram for the ITEC-CHF: innovative telemonitoring enhanced care program for chronic heart failure.

6.3.1 Baseline Characteristics of the Participants

There were no significant differences between the characteristics of the ITEC-CHF and control groups at baseline (Table 6.2). The mean ages of the participants in the ITEC-CHF and control groups were 69.5 (SD 12.3) years and 70.8 (SD 12.4) years,

respectively. Participants were predominantly male, and a high proportion of participants were diagnosed with type 2 diabetes, chronic obstructive pulmonary disease, or asthma. Common medications included angiotensin-converting enzyme inhibitors, beta-blockers, loop diuretics, and/or aldosterone receptor antagonists.

Table 6.2 Patient baseline characteristics.

Characteristic[a]	Victoria		Western Australia		Total	
	ITEC-CHF[b] (n=42)	Control (n=42)	ITEC-CHF (n=49)	Control (n=51)	ITEC-CHF (n=91)	Control (n=93)
Age (years), mean (SD)	69.8 (13.4)	69.6 (11.7)	69.2 (11.5)	71.8 (13.0)	69.5 (12.3)	70.8 (12.4)
Gender, n (%)						
Male	28 (67)	36 (86)	38 (78)	39 (77)	66 (73)	75 (81)
Weight (kg), mean (SD)	87.7 (24.1)	86.9 (19.1)	88.6 (18.3)	83.3 (19.4)	88.2 (21.0)	84.9 (19.3)
BMI (kg/m2), mean (SD)	31.2 (8.9)	30.2 (9.5)	31.6 (10.2)	29.1 (6.6)	31.4 (9.6)	29.6 (8.0)
NYHA[c] class, mean (SD)	1.9 (0.6)	2.0 (0.6)	2.1 (0.4)	2.3 (0.5)	2.0 (0.5)	2.2 (0.6)
LVEF[d] (%), mean (SD)	29.4 (6.5)	25.5 (23.7)	29.0 (7.5)	28.6 (7.9)	29.1 (7.1)	27.4 (15.9)
Chronic condition, n (%)						
Type 1 diabetes	1 (2)	3 (7)	0 (0)	1 (2)	1 (1)	4 (4)
Type 2 diabetes	9 (21)	19 (45)	19 (39)	16 (31)	28 (31)	35 (38)
COPD[e] or asthma	11 (26)	5 (12)	12 (25)	15 (29)	23 (25)	20 (22)
Chronic renal disease	4 (10)	10 (24)	6 (12)	10 (20)	10 (11)	20 (22)
Medical treatment, n (%)						
ACEI[f]	24 (57)	24 (57)	45 (92)	49 (96)	69 (76)	73 (79)
Beta-blockers	30 (71)	38 (91)	46 (94)	47 (92)	76 (84)	85 (91)
Digoxin	5 (12)	6 (14)	10 (20)	8 (16)	15 (17)	14 (15)
Loop diuretic	28 (67)	26 (62)	42 (86)	48 (94)	70 (77)	74 (80)
Aldosterone receptor antagonist	18 (43)	17 (41)	32 (65)	39 (77)	50 (55)	56 (60)

[a]There were no statistical differences between the characteristics of ITEC-CHF and control; [b]ITEC-CHF: innovative telemonitoring enhanced care program for chronic heart failure; [c]NYHA: New York Heart Association Functional Classification; [d]LVEF: left ventricular ejection fraction; [e]COPD: chronic obstructive pulmonary disease; [f]ACEI: angiotensin-converting enzyme inhibitor.

6.3.2 Skipped Monitoring Days in the Innovative Telemonitoring Enhanced Care Program for Chronic Heart Failure

There were 1312 participant monitoring days when weight monitoring was skipped. Being away from home or travelling was the major reason for skipped monitoring, occurring on 515 participant monitoring days (39.3% of total skipped days) in 41 participants. Technical issues (Table 6.3) resulted in skipped monitoring on 390 participant monitoring days (29.7%) in 27 participants. Hospitalisations and ED presentations caused skipped monitoring on 232 participant monitoring days (17.7%) in 18 participants, whereas health conditions such as being unwell, falling, surgery, and chemotherapy led to 136 skipped participant monitoring days (10.4%) in 11 participants. The skipped days were regarded as noncompliant with daily weighing in the analysis of the primary outcome.

Table 6.3 The percentage of technical issues in the innovative telemonitoring enhanced care program for chronic heart failure group.

Technical issues	Value, n (%)
Bluetooth connectivity	203 (52.1)
Network connectivity	61 (15.6)
Weighing scale connectivity	49 (12.6)
CHF[a] app	34 (8.8)
Call centre system/support	23 (5.9)
Weighing scale battery	18 (4.6)
Tablet battery	2 (0.4)

[a]CHF: chronic heart failure.

6.3.3 Primary Outcome and Related Analysis Results

Applying the intention-to-treat analysis to the primary outcome of weight monitoring at least four days a week on average over the duration of the trial, the proportion of

compliant participants in the ITEC-CHF group did not achieve statistical significance compared with that of the control group (ITEC-CHF: 67/91, 74% vs control: 56/93, 60%; P=.06). However, ITEC-CHF was associated with significantly more participants who monitored their body weight on average for at least 6 days per week over the duration of the trial than the control (ITEC-CHF: 41/91, 45% vs control: 23/93, 25%; P≤.005; Table 6.4).

Comparison of participant compliance with daily weight monitoring between the innovative telemonitoring enhanced care program for chronic heart failure (ITEC-CHF) and the control groups in Table 6.4. Under the conventional weight monitoring standard of at least 4 days per week, there was no significant difference between the ITEC-CHF and the control groups (P=.06). Under a stricter weight monitoring criterion of at least 6 days per week, more participants in the ITEC-CHF group were found to achieve this criterion than those in the control group (P=.005).

Table 6.4 Compliance with daily weight.

Compliance[a]	ITEC-CHF[b], n (%)	Usual care, n (%)	*P* value
Participants who monitored body weight at least 6 days per week	41 (45)	23 (25)	.005
Participants who monitored body weight at least 4 days per week	67 (74)	56 (60)	.06

[a]Compliance with daily weight monitoring.

[b]ITEC-CHF: innovative telemonitoring enhanced care program for chronic heart failure.

6.3.4 Secondary Outcomes

Applying a per-protocol analysis by excluding participants who discontinued the study (ITEC-CHF: 24/91 and control: 12/93), the difference in weight monitoring compliance was significant for weight monitoring at least 4 days a week (ITEC-CHF: 65/67, 97%

vs control: 56/81, 69%; P<.01) and at least 6 days a week (ITEC-CHF: 41/67, 61% vs control: 23/81, 28%; P<.01).

In the complete case analysis, 147 participants (ITEC-CHF: 66 and control: 81) completed the Heart Failure Compliance Questionnaire at baseline and 6-month assessments (Table 6.5). ITEC-CHF was associated with a significantly improved score in the domains of health maintenance (P<.01), medication adherence (P<.01), and diet (P<.01). No significant differences were found in the category of exercise (P=.10), smoking (P=.48), or alcohol use (P=.32).

In the EQ-5D assessment, no significant differences were found in the change in category of mobility (P=.44), self-care (P=.26), usual activities (P=.59), discomfort (P=.46), and anxiety or depression (P=.38). The mean change in the overall score of EQ-5D was also not significantly different (ITEC-CHF: 4.05, SD 15.95 vs control: 1.10, SD 14.24; P=.13).

No significant effects were found for the 6-min walk test distance, frailty, and depression.

No significant differences were found in all-cause hospitalisations (ITEC-CHF: 73 vs control: 58; hazard ratio [HR] 1.18; P=.49) or emergency department (ED) presentations (ITEC-CHF: 36 vs control: 45; HR 0.83; P=.55), chronic heart failure (CHF)–related hospitalisations (ITEC-CHF: 15 vs control: 8; HR 1.98; P=.24), CHF-related ED presentations (ITEC-CHF: 4 vs control: 5; HR 0.98; P=.98), or unplanned hospitalisations (ITEC-CHF: 41 vs control: 39; HR 1.06; P=.86).

Table 6.5 Secondary outcomes of self-management behaviours, quality of life, 6-min walk test, frailty, and depression.

Compliance[a]	Baseline				6 months				Difference from baseline				*P* value
	ITEC-CHF[b]		Usual care		ITEC-CHF		Usual care		ITEC-CHF		Usual care		
	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)	
Health maintenance score	90(99)	3.83(0.48)	93(100)	3.77(0.61)	67(74)	3.88(0.33)	81(87)	3.60(0.96)	66(73)	0.06(0.49)	81(87)	−0.20(1.03)	0.04
Medications score	90(99)	3.68(0.79)	93(100)	3.73(0.81)	67(74)	3.70(0.78)	81(87)	3.69(0.74)	66(73)	0.08(0.54)	81(87)	−0.04(0.87)	0.05
Diet score	90(99)	2.56(1.11)	93(100)	2.81(1.10)	67(74)	2.97(1.02)	81(87)	2.81(1.05)	66(73)	0.35(1.05)	81(87)	−0.01(1.07)	0.008
Exercise score	90(99)	1.83(1.19)	93(100)	2.04(1.30)	67(74)	1.85(1.33)	81(87)	1.83(1.34)	66(73)	−0.03(1.02)	81(87)	−0.21(1.06)	0.1
Smoking score	90(99)	0.53(1.43)	93(100)	0.45(1.26)	67(74)	0.39(1.18)	81(87)	0.37(1.13)	66(73)	−0.14(1.51)	81(87)	−0.11(1.14)	0.48
Alcohol use score	90(99)	0.57(1.27)	93(100)	0.70(1.47)	67(74)	0.45(1.07)	81(87)	0.68(1.44)	66(73)	−0.06(1.19)	81(87)	0.02(1.15)	0.32
EQ-5D[c]													
Mobility score	90(99)	1.63(0.84)	93(100)	1.86(0.90)	66(73)	1.71(0.95)	81(87)	1.98(1.03)	65(71)	0.12(0.72)	81(87)	0.11(0.81)	0.44
Self-care score	90(99)	1.21(0.53)	93(100)	1.33(0.66)	66(73)	1.22(0.54)	81(87)	1.30(0.64)	65(71)	0.03(0.39)	81(87)	−0.04(0.62)	0.26
Usual activities score	90(99)	1.74(0.94)	93(100)	1.74(1.01)	66(73)	1.65(1.01)	81(87)	1.68(0.92)	66(73)	−0.06(0.73)	81(87)	−0.07(0.79)	0.59
Discomfort score	90(99)	1.86(0.94)	93(100)	2.00(0.98)	66(73)	1.86(1.01)	81(87)	2.02(0.97)	65(71)	0.00(0.77)	81(87)	0.02(0.85)	0.46
Anxiety/depression score	90(99)	1.87(0.91)	93(100)	1.82(0.91)	66(73)	1.85(0.92)	81(87)	1.79(0.94)	65(71)	−0.05(0.74)	81(87)	−0.01(0.68)	0.38
Your health today score	90(99)	70.22(18.54)	93(100)	68.74(17.95)	66(73)	75.97(20.95)	81(87)	70.02(18.62)	65(71)	4.05(15.95)	81(87)	1.10(14.28)	0.13
6-min walk test													
Walked distance (m)	89(98)	367.24(122.93)	93(100)	350.45(108.96)	62(68)	396.77(131.68)	77(87)	367.19(130.88)	61(67)	17.16(54.23)	77(83)	10.23(70.04)	0.4
Frailty													
Frailty score	90(99)	3.07(1.01)	93(100)	3.42(1.13)	63(69)	2.89(1.29)	81(87)	3.22(1.31)	64(70)	−0.19(0.94)	81(87)	−0.23(0.90)	0.54
Depression													
Sleep score	89(98)	3.30(2.10)	91(98)	3.74(1.93)	64(70)	3.40(2.04)	81(87)	3.80(2.00)	65(71)	0.12(1.59)	80(86)	0.01(1.72)	0.5
Spirits score	89(98)	2.26(1.39)	91(98)	2.48(1.58)	64(70)	2.28(1.63)	81(87)	2.53(1.54)	65(71)	0.18(1.27)	80(86)	0.02(1.10)	0.48
Tearful score	89(98)	2.12(1.80)	91(98)	2.36(1.89)	64(70)	2.08(1.77)	81(87)	2.47(1.84)	66(73)	−0.03(1.30)	80(86)	0.09(1.22)	0.3
Frustrated score	89(98)	3.04(2.02)	91(98)	3.23(1.78)	64(70)	2.89(1.95)	81(87)	2.89(1.76)	66(73)	−0.03(1.48)	80(86)	−0.21(1.26)	0.42
Pleasure score	89(98)	2.39(1.42)	91(98)	2.59(1.59)	64(70)	2.23(1.60)	81(87)	2.46(1.57)	66(73)	−0.02(1.33)	80(86)	−0.06(1.04)	0.4

[a]Compliance with self-management behaviours was assessed using the Heart Failure Compliance Questionnaire.

[b]The innovative telemonitoring enhanced care program for chronic heart failure (ITEC-CHF) was associated with significant improvements in the subcategories of health maintenance, medication adherence, and diet in the compliance assessment.

[c]EQ-5D: five-dimension EuroQol

6.5 Discussion

6.5.1 Principal Findings

In this study of an innovative telemonitoring program (ITEC-CHF), facilitated by community nurses with call centre support, we observed no significant differences in the weight monitoring frequency of at least 4 days a week but observed a significantly higher proportion of the intervention group achieving a weight monitoring frequency of at least 6 days per week compared with the control group receiving usual care. To our knowledge, this is the first study to use objective measures of weight monitoring and the intention-to-treat principle to comprehensively evaluate patient compliance with daily weighing in patients with CHF.

The higher weight monitoring frequency of at least 6 days per week reflects better compliance with the recommendation in contemporary clinical guidelines for patients with CHF to weigh themselves daily as a self-management strategy to maintain fluid balance and identify signs of oedema.[2, 3] This criterion for compliance is stricter than that applied to weight monitoring in previous studies of most of the time (or at least 4 days per week) and was limited by a questionnaire-based assessment of compliance, which is prone to bias.[4, 12]

In the intention-to-treat analysis, 45% of participants randomised to ITEC-CHF achieved a monitoring frequency of at least 6 days per week over the 6-month follow-up period of the trial. This figure was influenced by the relatively high proportion of participants who discontinued the trial from the intervention group and provides valuable insight into factors that are pertinent to telemonitoring in clinical practice. In the early stages of the trial, there were relatively frequent technical issues with the telemonitoring system, which may have led to the withdrawal of some participants. It has previously been reported that learning how to use telemonitoring technology is perceived as burdensome and creates anxiety in some patients, especially those who are older.[24] This may be further exacerbated in the event of technical issues. Technical issues also resulted in increased reliance on technical support, which would have increased the cost of telemonitoring, although this was not assessed in this study, highlighting the need for future telemonitoring studies with a health economics

component. These issues highlight the importance of telemonitoring systems being seamless and reliable to not create an unnecessary burden on patients and their carers or health service providers.[25] Therefore, they underscore the need to improve the reliability and user experience of telemonitoring systems[26] for use in clinical CHF care.

In participants who completed the trial (the cohort in which the per-protocol analysis was conducted), compliance with weight monitoring in ITEC-CHF was high; 97% of participants monitored themselves for at least 4 days a week over the 6-month duration of the trial, and 61% of participants monitored themselves at least 6 days a week. In the ITEC-CHF group, 390 participant monitoring days were skipped because of technical issues, meaning that the difference in weight monitoring compliance between the ITEC-CHF and control groups is likely to be underestimated. These positive findings regarding weight monitoring compliance in participants who adhered to the program are likely to be underpinned by the multifactorial support mechanisms provided. This is further supported by a substantial number of alerts reported in this study, which included the automated generation of reminder alerts on 715 patient days when a weight recording was not received by 10 AM as well as contact made by the call centre and project nurses. These findings not only demonstrated the effectiveness of ITEC-CHF in supporting weight management but also indicated a strong need for such support in ongoing CHF care.

The ITEC-CHF group experienced a significant improvement in health maintenance compared with usual care, as measured by the Heart Failure Compliance Questionnaire. This positive result was consistent with a finding of improved self-care maintenance reported in 2 other RCTs of telemonitoring in CHF.[27, 28] Similarly, there was a significant improvement in adherence to medication and diet recommendations in the ITEC-CHF group, but not in the control group. These findings imply increased engagement with the heart failure nurses that occurred following the alerts generated through the telemonitoring intervention. These interactions created the opportunity for teachable moments, enabling nurses to provide informal education to reinforce self-management practices. It has previously been acknowledged that patients often benefit from ongoing support in CHF care to effectively manage their health conditions through the reinforcement of self-management strategies.[29] It is also possible that

merely being monitored was sufficient to enhance adherence to more desirable patterns of care because of a surveillance effect.[30] Nevertheless, the combination of telemonitoring with nursing support resulted in improved self-management activities, although it is often difficult for researchers to identify which component of the ITEC-CHF program drove these improvements.

There were no significant effects of ITEC-CHF on hospitalisations and ED presentations, although it should be noted that the study was underpowered for this analysis. We observed that CHF-related events were not the major cause of hospitalisations (23/131, 17.5%) or ED presentations (9/81, 11%). CHF is a complex condition, more prevalent in older people, and associated with a range of comorbidities. Telemonitoring in the context of this study focused exclusively on daily weight recordings. This finding implies a need to extend telemonitoring intervention for comorbidity and critical non-CHF–related health conditions to more comprehensively address the range of health issues faced by patients with CHF. To date, the effectiveness of telemonitoring in improving hospitalisation and mortality remains inconclusive.[13, 14] However, it has been shown that reduction in health services utilization, including unscheduled hospitalisations and length of stay, can be achieved for broader chronic disease management by monitoring a range of vital signs using telemonitoring enhanced care coordination.[31, 32] Further research to understand the underlying principles that impact hospitalisations and ED presentations related to a specific primary diagnosis such as CHF remains essential in future studies.

There are several limitations of this study that warrant discussion. First, the study was limited to a 6-month intervention, which may have been insufficient to translate to meaningful changes in clinical characteristics of patients. In addition, a relatively high number of participants discontinued their involvement in the trial, which has the potential to bias the analysis of some secondary outcomes where the intention-to-treat principle could not be applied. High rates of discontinuation in the ITEC-CHF group suggest a potential bias in the per-protocol analysis. Participants who discontinued in the ITEC-CHF group were unlikely to be random because some were because of deteriorating health (palliative care or dialysis) and because some were deceased, as shown in Figure 6.3. Therefore, we did not use the multiple imputation approach outlined in the trial protocol.[15] The study did not achieve the target sample size

(n=300), proposed in the trial protocol[15]; this might have compromised the power to detect significant effects in the analysis of the primary outcome. There are several reasons for the smaller than proposed sample size. We experienced technical issues with the telemonitoring software that were not apparent during an extensive testing phase before study commencement, which delayed recruitment. This highlights the challenges that arise in a real-world environment that may not be present in a testing scenario. We also experienced slower than anticipated recruitment; some patients were reluctant to engage in a model of care involving technology, whereas others were concerned about their ability to weigh themselves safely because of frailty and were therefore excluded from the trial. A substantial number of patients reported as having CHF did not have an echocardiogram documented in their medical records and were therefore excluded because they failed to meet the inclusion criteria of an EF of <40%. Finally, a high proportion of patients who were residents of nursing homes were excluded on this basis. These issues highlight that the clinical complexity of many patients with CHF, who are often older with multiple comorbidities, may complicate their ability to engage with telemonitoring and underpin the importance of telemonitoring models being developed that are reliable, easy to use, and accessible for patients across the clinical spectrum of CHF. Finally, the patient compliance rate in usual care (25% for at least 6 days per week and 60% for at least 4 days per week) was likely to be influenced by the provision of weight scales to participants, which kept a record of their weight recordings and, accordingly, might have resulted in a Hawthorne effect[33], reducing the difference between the ITEC-CHF and control groups.

6.6 Conclusions

The ITEC-CHF study is the first to report the effects of telemonitoring on weight monitoring compliance using an objective measure of weight recordings in patients with CHF. The proportion of participants in the ITEC-CHF program achieving a weight monitoring frequency of at least 6 days per week was higher than that in usual care controls. Furthermore, ITEC-CHF resulted in significant improvements in CHF self-management related to health maintenance, medication adherence, and diet. Among

participants who completed the study, there was a high level of compliance with weight monitoring, underscoring the importance of telemonitoring platforms that are seamless to reduce the risk of patients disengaging with the technology. Although telemonitoring and digital health more broadly offer significant potential for supporting patients in self-managing chronic conditions such as heart failure, further research is required to refine these evolving strategies to achieve effective care outcomes.

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Chapter 7 - Innovative Telemonitoring Enhanced Care program for CHF (ITEC-CHF): Usability and Patient Perspectives

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Declaration of candidate contribution

The following Chapter was published as a first authorship by the PhD candidate. The candidate contributed to the study execution as the clinical research nurse. She was

responsible for participant recruitment, data acquisition, analysis and interpretation and writing and critical revision of the manuscript.

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For more information on the candidate's level of contribution, please refer to Appendix 29 – Chapter 7: Co-Authorship Contribution Form

7.1 Introduction

Chronic heart failure (CHF) is a complex disease that is expensive to manage and affects approximately 2%-3% of the adult population[1], with a prevalence that continues to increase.[2] Daily weight monitoring and symptom control are cornerstones of CHF management[3]; hence, innovative strategies that are both effective and acceptable to patients are required to support traditional approaches to manage these aspects of care. Recent studies have reported that remote monitoring can improve health outcomes and reduce costs associated with CHF care by providing real-time physiological information to healthcare providers that can be acted on quickly, reducing the potential for progressive clinical deterioration and more complex care requirements.[4, 5] These contemporary telemonitoring systems have the advantage of being delivered by portable devices, enabling patients to be monitored in real-time from anywhere with access to the internet.[6] However, positive findings of the efficacy of telemonitoring in CHF management are not ubiquitous, with several studies identifying patients who are resistant to change.[7-9]

The mixed results from telemonitoring studies may, in part, reflect the willingness or readiness of patients with CHF to engage with telemonitoring technology and to adhere to its use.[10-12] Because the prevalence of CHF increases with age, a high proportion of patients with CHF are over 75 years of age. This is a subset of the population in whom digital literacy has historically been low. However, the characteristics of the “over 75 years” demographic in modern times is different than that in prior generations, with increased life expectancy[13] and rapidly improving digital literacy[12] highlighting the need for new research in this area.

Although several recent studies have investigated the perceptions of telemonitoring in other clinical cohorts, such as patients with chronic kidney disease, chronic obstructive pulmonary disease, or hypertension[10, 11, 14, 15], there are few contemporary studies describing the perceptions of telemonitoring in patients with CHF. Remote monitoring in patients with CHF has specific objectives and unique challenges. For example, rapid fluctuations in body weight (>2 kg in 48 hours) may be the result of a variety of precipitating factors such as poor adherence to fluid and salt restrictions or noncompliance with medication, which can be rectified through modification of self-

care behaviours, or it may be attributed to cardiac deterioration warranting urgent medical support.[16] This increases the complexity of telemonitoring and emphasizes the importance of integrated clinical support in telemonitoring ecosystems[16, 17], highlighting the importance of user-friendly technology.[18-20]

The Innovative Telemonitoring Enhanced Care program for CHF (ITEC-CHF) was the first such program to incorporate telemonitoring supported by a 24-hour call centre and first-line nurse-led CHF intervention in community care settings in Australia .[21, 22] To minimize weight monitoring burdens and technical difficulties, the program introduced a novel “zero-touch” design, meaning that the participants were not required to interact with the technology other than stepping onto a scale for weight measurement as in usual care, and they did not need to have extra knowledge or skills to receive the telemonitoring intervention (Figure 7.1).[21, 22] The objective of this study was to assess perceptions of telemonitoring among patients with CHF who participated in the ITEC-CHF study and to evaluate the usability of this model of care.

Figure 7.1 ITEC-CHF Telemonitoring System. ITEC-CHF: Innovative Telemonitoring Enhanced Care Programme for Chronic Heart Failure.

7.2 Methods

7.2.1 Study Setting and Design

A detailed description of the protocol for the ITEC-CHF study has been previously published.[22] Participants were recruited from the Frankston Hospital and Rosebud Hospital in Victoria, Australia, and Royal Perth Hospital and Fiona Stanley Hospital in Western Australia. Between January 2016 and December 2017, a total of 91 participants enrolled in the ITEC-CHF trial were mailed a survey and provided with a self-addressed and stamped envelope to return the survey at the end of the 6-month intervention. The survey consisted of two parts (see Appendix 20-21). Part 1 was designed to evaluate the usability of the ITEC-CHF telemonitoring system and consisted of 9 questions, which were scored on a 5-point Likert scale (1=strongly disagree; 2=disagree; 3=neither agree nor disagree; 4=agree; and 5=strongly agree). The 9 Likert scale questions addressed the following concepts adapted from the technology acceptance model (TAM) and attitude toward technology use: (1) ease of use, (2) participants' confidence with managing CHF, (3) participants' ability to navigate the technology, and (4) perceived usefulness.[23-26] These questions assessed the participants' perceptions of telemonitoring and their comfort with using the technology involved. The TAM is an information technology framework for understanding users' adoption and use of emerging healthcare technologies.[25, 26] The model states that usefulness and ease of use are two essential elements in describing participants' attitudes when using new technology.[26] A number of studies support the validity of the TAM and its satisfactory explanation of end-user system usage.[23, 24, 27] Part 2 of the survey involved 3 open-ended questions to provide the participants with an opportunity to express more detailed opinions about the ITEC-CHF telemonitoring system. The open-ended questions addressed perceived benefits and perceived barriers, as well as sought participants' suggestions about improving the system. The estimated time to complete all questions was approximately 15 minutes.

7.2.2 ITEC-CHF Telemonitoring System

Eligible participants for the survey were required to have completed the ITEC-CHF intervention. The detailed protocol for this study has been published[22], but it is summarised as follows:

Participants were provided with electronic weighing scales (W550; ForaCare), and a computer tablet (Galaxy Tab A; Samsung). They were asked to weigh themselves on the provided scales daily. The measured weight entry was recorded in the weighing scale and then automatically transmitted to the tablet via a wireless Bluetooth function embedded in the scales. The tablet was preloaded with an Android application (MedTech Global) that received the weight entry and uploaded it to a proprietary software package, ManageMyHealth (MedTech Global). A web application in MMH automatically monitored the uploaded weight entries in real time to generate alerts and triage those alerts to project nurses and the call centre. The alerts were designed in accordance with the National Heart Foundation of Australia's Guidelines for the Prevention, Detection, and Management of Chronic Heart.[17]

The telemonitoring intervention consisted of three components: remote weight monitoring, structured telephone support, and nurse-led collaborative care. Telemonitoring was integrated with a personal assistance call service (MePACS) and a nurse care service according to their workflows in usual care.

Operators at the call centre responded to the alerts in real time (24 hours, 7 days a week). In cases where the participant required clinical support, such as advice for assessing CHF symptoms or managing fluid and salt restriction, the call operator arranged a nurse follow-up.

The project nurses provided structured interventions according to three types of alerts: rapid weight fluctuation (±2 kg in 2 days), slow weight fluctuation (±5 kg in 28 days), and low-risk weight fluctuation (±1 kg over 24 hours). If a participant's body weight fluctuation exceeded ±1 kg (but less than ±2 kg) over 24 hours, a questionnaire was automatically triggered and sent to the participant's computer tablet. If the participant reported any of the clinical conditions in the questionnaire or did not respond to the questionnaire, the project nurses contacted the participant for a clinical assessment.

However, if the response to the questionnaire determined the participant was asymptomatic, the alert was cancelled automatically to minimize unnecessary alerts to the project nurses.

7.2.3 Inclusion and Exclusion Criteria

The study's inclusion criteria were as follows: patients (1) with CHF diagnosed by a clinician with an ejection fraction ≤40%, (2) who were able to weigh themselves safely, (3) who were at least 18 years of age, (4) who have a regular personal general practitioner (GP) or agree to use a designated GP, (5) who have a permanent residential address, and (6) without significant cognitive impairment. The exclusion criteria were as follows: (1) patients with expected survival <12 months, (2) patients with end-stage renal failure on dialysis, (3) long-term nursing home residents, or (4) patients participating in any other clinical trial. All participants provided written informed consent.

7.2.4 Statistical Methods

Statistical analyses were performed using SPSS software (version 26.0; SPSS Inc.). Descriptive statistics (mean and SD, frequencies, and percentages) were used to characterize the study population and described participants' perceptions of the usability of ITEC-CHF.

Open-ended questions were transcribed and imported into NVivo version 12 (QSR International) to facilitate the coding and to maximize the effectiveness and efficiency in sorting and merging the data according to themes reflecting common views and experiences. These were collated and supported by deidentified quotes from participants. Thematic analysis was performed to identify themes related to participants' perceptions of the perceived benefits and perceived barriers, as well as their suggestions about improving the system, thus capturing participants' understandings and allowing an in-depth analysis of the data.[24] Data were described,

summarized, and then interpreted in relation to broader implications. The first author (SC), who is a nurse researcher with experience in research on CHF telemonitoring, familiarized herself with the data by reading the participants' responses several times, while taking notes. Points of interest were noted while reading and re-reading the transcripts. Following the production of an initial set of codes, a thematic map was developed, which presented themes and subthemes. Accounts were then re-read to ensure that coding was checked and that nothing had been overlooked. Themes and subthemes were then allocated. The last author (AM), who is an experienced researcher in the fields of cardiac rehabilitation and heart failure management, cross-checked the set of themes and was fully involved in the data interpretation and write-up for dissemination.

7.3 Results

7.3.1 Overview

The survey response rate was 77% (67/91 surveys; Table 1). There were no significant differences between the demographics or clinical characteristics of the participants who completed the survey and the overall cohort who completed the ITEC-CHF study.

Table 7.1 Demographics and clinical characteristics of study participants.

Characteristic		Completed survey (n=67)	Completed ITEC-CHF (n=91)
Mean age, years		69.8 ± 12.4	69.5 ± 12.3
Gender, n (%)			
	Male	49 (73)	66 (73)
	Female	18 (27)	25 (27)
Highest education achieved, n (%)			
	Less than high school	9 (13)	10 (11)
	High school	28 (42)	41 (45)
	Trade or technical training	8 (12)	12 (13)
	College/university		23 (25)
	undergraduate	19 (28)	
	Postgraduate	3 (4)	5 (5)
BMI		32.1 ± 10.6	31.4 ± 9.6
NYHA, n (%)			
	I	5 (7)	8 (9)
	II	50 (75)	68 (75)
	III	11 (16)	14 (15)
	IV	1 (1)	1 (1)
LVEF, %		28.7 ± 7.7	29.1 ± 7.1
Other medical conditions, n (%)			
	CHD	46 (68)	58 (64)
	COPD or asthma	16 (24)	23 (25)
	CKD	7 (10)	10 (11)
	T2DM	22 (33)	28 (31)

BMI, body mass index; NYHA, New York Heart Association Functional Class, LVEF, left ventricular ejection fraction; CHD, coronary heart disease; COPD, chronic obstructive pulmonary disease; CKD, chronic kidney disease; T2DM, type 2 diabetes mellitus. P = NS for all comparisons.

For the broad concepts of ease of use, confidence, navigability, and usefulness described in the TAM, 91% (61/67) of participants “agreed” or “strongly agreed” that the telemonitoring system was easy to use, 85% (57/67) “agreed” or “strongly agreed” that the technology improved their confidence in managing their CHF condition, 78% (51/65) “agreed” or “strongly agreed” that the technology was easy to navigate, and 91% (59/65) “agreed” or “strongly agreed” that the telemonitoring was useful. A few participants indicated that they “disagreed” or “strongly disagreed that the telemonitoring system was easy to use (3%), that the technology improved their confidence in managing their CHF condition (2%), that the technology was easy to navigate (2%), and that the telemonitoring was useful (2%).

Table 7.2 presents the information related to the 9 questions that were rated on a 5-point Likert scale. Each indicator was evaluated across multiple questions.

Survey Question	n	Strongly Disagree %	Disagree %	Neither Agree Nor Disagree %	Agree %	Strongly Agree %	Mean Response (SD)
Ease of use							
The weighing scale was easy to use	67	1.5	1.5	4.5	13.4	79.1	4.7 (0.8)
The touch screen tablet was easy to use	67	0	4.5	11.9	25.3	58.2	4.4 (0.9)
The information given to me in how to weigh myself using the device was easy to understand	67	0	0	3.0	37.3	59.7	4.6 (0.6)
Confidence							
The technology helped me to manage my chronic heart condition	67	0	3.0	3.4	49.3	34.3	4.1 (0.8)
I feel more confident about managing my chronic heart failure after taking part in this research project	67	0	0	3.4	50.8	35.8	4.2 (0.7)
Navigability							
I found the weight reminders helpful on the touch screen tablet	56	0	0	19.6	39.3	41.1	4.2 (0.8)
I found the symptom questions easy to respond to on the touch screen tablet	65	0	4.6	20.0	30.8	44.6	4.2 (0.9)
Usefulness							
When I forgot to weigh myself, I found the reminder calls helpful	63	1.6	1.6	9.5	27.0	60.3	4.4 (0.9)
When my weight changed, I found the call from the Chronic Heart Failure nurse helpful	65	1.5	0	4.6	35.4	58.5	4.5 (0.7)

7.3.2 Themes and Subthemes Analysed

Participants provided feedback, including a range of benefits and barriers to using telemonitoring. Eight key themes related to the ITEC-CHF program emerged from responses to the open-ended questions. Quotes from participants are provided to support each theme.

Increased Support for Early Intervention of Clinical Deterioration

Clinicians were able to view patient health data easily and quickly, which enabled early detection of clinical deterioration. This meant that problems were detected quickly, and participants were able to receive an early intervention.

> *Weight fluctuation detected early and see GP same day.*

Improved Compliance to Daily Weighing

The telemonitoring system helped participants get into a routine and inform them when a change occurred in their weight that was outside the predetermined limits.

> *Information exchange. Motivation to try and be healthy.*

> *Learning about weight changes and fluid balance.*

A Sense of Reassurance

Participants indicated they felt reassured that a clinician was behind the scenes reviewing their data.

> *Staff are competent.*

> *Safety net that someone is watching.*

Improved Self-care and Accountability

Participants felt accountable for their self-management because they were being monitored and would receive a reminder if they missed weighing themselves. This was reported as having had a positive effect on compliance to their self-management regime.

Weight measurement helped me with trying to maintain my health status.

Made me personally more accountable of fluid management.

Encouraging to weigh regularly. Help keep an eye on my diet.

Supportive of Self-Management

The ITEC-CHF environment helped participants feel supported in self-managing their condition while reflecting on the telemonitoring system in self-care.

Weighing reminders from MEPACS.

Don't feel alone. Familiar with nurses.

Reassuring that help is on hand.

Technical Difficulties

Some concerns expressed by participants were related to the technology, mainly due to Bluetooth connectivity issues in the early stages of the trial.

When machine doesn't register (scales).

Computer tablet not registering weight measured from scales.

Flexibility of Telemonitoring System

Some participants suggested they would have liked greater flexibility to be able to weigh themselves later than 10 AM to suit their lifestyle. This feedback was provided by participants who are employed, including those who work a night shift, to have the flexibility of the cut-off time to weigh in extended.

Sunday mornings when woken by MEPACS.

Extend time to midday.

Extend time limit.

System Not Suitable for All Patients

Participants who had lifestyles involving frequent travelling found continuous telemonitoring unsuitable. In addition, some participants reported difficulty in answering the questions on the computer tablet in a timely manner.

> *Not suitable when going away on holiday.*
>
> *Not enough time to answer symptoms questions.*

7.4 Discussion

7.4.1 Principal Findings

In this evaluation of the perceptions of telemonitoring among patients with CHF, the majority of participants “agreed” or “strongly agreed” that the intervention was feasible and helpful in their care. This included being easy to use (91% agreement) and helpful in improving their confidence in self-management (85% agreement). These findings are consistent with those reported from studies in other cohorts of people with chronic diseases that have evaluated perceptions of telemonitoring[10, 11, 14, 15], but these results also provide new insights into the perceptions of patients with CHF.

Feedback from participants in this study highlights the importance of minimal user burden and ensuring user-friendly technology for telemonitoring to be acceptable to patients. High rates of satisfaction were observed with all the aspects of usability surveyed. Participants reported that the ITEC-CHF program was easy to use, easy to navigate, useful, and increased their confidence in managing their weight. Similarly, patients with chronic kidney disease were found to be highly accepting of using telemonitoring because they perceived it as being interactive and applicable in managing their condition.[10] In patients with hypertension, high levels of acceptability in using telemonitoring that relates to user-friendly technology has been previously reported.[11] User acceptance is especially important if telemonitoring is to be widely adopted; this is an important objective in the COVID-19 era when remotely delivered

health care is increasingly being utilized to avoid subjecting patients to the risk of infection.

Compliance with care provider instructions and being self-disciplined in health management activities and self-care were two themes that were expressed by a high proportion of participants using the ITEC-CHF system. Compliance with self-care activities, such as diet, exercise, and medication adherence, are important factors in managing chronic conditions such as CHF given that successful disease management is, in part, dependent on patients' ability and willingness to carry out self-care activities.[17] Moreover, confidence in undertaking self-management activities, particularly the ability to reliably self-identify symptoms associated with clinical deterioration and take appropriate action in a timely manner is an important component of chronic disease management.[28] The observation that telemonitoring is beneficial for weight surveillance represents an important clinical outcome given that fluctuations in body weight are a reliable way of detecting fluid imbalance, which can be associated with poor self-care compliance or disease exacerbation.[29-31]

However, the acceptance of telemonitoring was not ubiquitous for participants in the current study. For example, the technology in its current form may not suit patients who travel frequently. Several participants also indicated that greater flexibility in the telemonitoring system would reduce disruption to their lives, especially during holidays and on weekends. It was suggested by some participants that having the ability to alter the time before an alert was sent (ie, changing it to after 10 AM) would reduce the psychological burden of the alert system during these periods. This is an important consideration because previous studies have found that insufficient flexibility in telemonitoring models may hinder the ongoing use of the system.[32-36]

Participant feedback also highlighted the importance of engaging consumers with a lived experience of CHF in the co-design of telemonitoring to ensure that it is simple and easy to engage with by the end user. Participants stressed the importance of a system that is robust, with easily accessible technical support—a finding consistent with observations in other clinical groups.[37, 38] This is critical because technical problems are known to be a significant impediment to the uptake and adherence to telemonitoring.[30-32] From the ITEC-CHF trial, it was evident that technical issues led to

disengagement from the system when encountered by some participants.[22] Patients with CHF often have multiple competing comorbid health issues to manage in their lives, so a seamless system of telemonitoring takes on additional importance.

7.4.2 Limitations

There are several limitations to the study that warrant highlighting. First, the results from the usability of the ITEC-CHF program were based on a relatively small sample size, so larger studies are required to provide results from a sample that is more representative of the broader population of patients with CHF, to confirm these findings. Second, there was no baseline data of participants' perceptions of the usability of the system to provide a comparison for user satisfaction measured at the end of the study. However, this design would have its own limitations because participants would lack the experiential insight derived from being involved in the trial to answer some of the questions at baseline. Third, the findings are based on the experiences of participants who completed the trial and who are, therefore, likely to have a more favourable view of the telemonitoring system than those who dropped out. In future studies, it is essential to consider including a control or comparison group that does not use the system during the study. This approach would facilitate a more comprehensive evaluation by establishing a baseline for comparison against the group using the system. This comparative analysis would contribute to a more thorough assessment of changes in user satisfaction between those who have utilised the system and those who have not. Finally, the single-group ITEC-CHF usability design precluded the assessment of the feasibility of randomisation procedures, attrition, outcome measures, and acceptability in a control arm.

7.5 Conclusions

In this study evaluating the usability of a telemonitoring program in patients with CHF, a high overall usability rating was achieved, and the telemonitoring system was generally well accepted by users as an adjunct to their routine self-management activities. Participants in the study expressed that they were confident in using the ITEC-CHF system and reported many perceived benefits, including quick identification

of early signs of clinical deterioration, which allows for faster response to manage the symptoms of CHF. Future trials that are powered to assess whether telemonitoring affects rehospitalisation and mortality rates are required to determine whether these characteristics of telemonitoring translate to an improvement in clinical outcomes for patients with CHF.

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Chapter 8 - General Discussion

8.1 Overview

Chronic heart failure (CHF) has a major impact on patients' lives, due to cardinal symptoms such as fatigue and shortness of breath on exertion. Moreover, CHF leads to an increased requirement for clinical care, reduces patients' independence and in advanced cases, the ability to effectively undertake activities of daily living. Ultimately, this can adversely affect quality of life. Accordingly, the symptoms of CHF, and its treatment, can affect physical, personal and psychosocial well-being.

People with CHF have to learn to make adjustments in their lives to meet the new self-care requisites associated with CHF and this is most successful when done under the guidance of health care professionals.[1-3] For example, nurses play a pivotal role in providing education, advice and support to improve the ability of patients with CHF to perform self-care. Patient education on topics including the causes of CHF, medications used to manage and treat its symptoms, and lifestyle modifications such as fluid and dietary restrictions and physical activity can help demystify CHF for patients and their families and improve compliance with self-care actions. Moreover, clinical surveillance by nurses provides an opportunity to reinforce self-care activities, identify non-compliance and clinical deterioration early in its course, and take actions to rectify this to reduce more serious complications. The current thesis describes two distinct nurse-led interventions for managing CHF; i) an independent community-based, nurse practitioner-led clinic ('SmartHeart') operating out of a university, and ii). a telemonitoring program linked via a central call centre to nursing support. This chapter provides a summation of the thesis. It revisits the aims and discusses the strengths and limitations of the research undertaken.

Among the nursing profession, nurse practitioners have an advanced scope of practice, including: designing and implementing therapeutic regimens; initiating referral to other health professionals; ordering and interpreting pathology and radiology tests; prescribing and reviewing medications.[4] This makes them well credentialed to provide the specialised care required by patients with CHF. The intervention in the SmartHeart nurse practitioner-led CHF clinic (Study 1) involved the

provision of CHF support including clinical assessment, an individualised CHF management plan and education in self-management strategies in an independent university-based clinic.

The intervention in the innovative telemonitoring enhanced care program for chronic heart failure (ITEC-CHF) (Study 2) involved three distinct components: remote weight monitoring, structured telephone support, and nurse-led collaborative care. Participants were provided with electronic weighing scales and a computer tablet, and asked to measure their body weight daily. The service was integrated with a telephone call centre with operators who were available 24 hours, 7 days a week. If the participant needed clinical support, nurse follow-up was arranged by the call operators. The clinical research nurses associated with each site followed up with the participant via a telephone call or home visit as appropriate.

Participants in the usual care group in each study received standard care through the trial period, as available in their local health care environment at the time of the studies. This was predominantly through cardiologists or general practitioners. The usual care group in the SmartHeart study consisted of patients admitted to the same tertiary hospital following the cessation of the university-based clinic. The usual care group in the ITEC-CHF study were recruited at the same time as the intervention group and randomised to the control arm of the study. They were provided with a standard package of a paper-based diary and the Living Well with Heart Failure booklet, produced by the National Heart Foundation of Australia, (in accordance with best practice) and advised to undertake CHF self-management as instructed in their usual care.

8.2 Description of findings

The findings from this project highlight the important roles nurses can have in the ‘front line’ of community-based care of patients with CHF.

The evaluation of the SmartHeart clinic (Chapter 3) revealed enhanced self-care and improved psychosocial health in the intervention group.[2] The higher level of self-care

behaviour in the intervention group compared with usual care, was sustained for at least six months following the completion of participants' involvement in the SmartHeart program, highlighting that a time-limited intervention can have ongoing benefits. Compared with usual care, the intervention group also experienced significantly lower rates of all-cause hospitalisation, although no difference was evident in CHF-related hospitalisations. It is relevant to note that patients with CHF are often older and can have a complex mix of both cardiac and non-cardiac conditions, such as diabetes, obesity, osteoarthritis and renal dysfunction, all of which can lead to adverse health outcomes that increase hospitalisations.[3, 4] The nursing support providing through the clinic may have helped manage such conditions. This finding is consistent with those from systematic reviews that concluded that nursing case management reduces unplanned hospital readmissions.[5, 6] Moreover, a previous study found that only 12% of patients understand their CHF discharge instructions[7] highlighting the importance of post-discharge care. Study 1 in this thesis highlights the value of community-based nurse practitioners in providing education and support to address this shortcoming of CHF management.

As a precursor to Study 2, the thesis includes a systematic review and subgroup meta-analysis of the effectiveness of different non-invasive telemonitoring strategies on reduced all-cause mortality and hospitalisation (Chapter 4), to identify which strategies were associated with these outcomes.[8] The review found that telemonitoring strategies involving mobile health (mHealth) and medication support were associated with improvements in all-cause mortality or hospitalisation outcomes.[8] Multi-arm studies were included in the systematic review and meta-analysis using a carefully considered approach. In these cases, we treated each arm of a multi-arm study as an independent comparison, which allowed us to incorporate data from these studies while avoiding issues of double-counting. Data from each arm were treated as a separate data point, ensuring that the analysis accounted for all relevant data while maintaining statistical integrity. This method was employed to ensure that the unique information from multi-arm studies was appropriately integrated into the review and meta-analyses, contributing to a comprehensive and accurate synthesis of the available evidence. A protocol for the systematic review and meta-analyses was not published before the research was conducted. While protocols are typically valuable

for outlining the methodology and promoting transparency, in this case, the study proceeded without a pre-published protocol. Instead, the research followed a structured approach to ensure a systematic and rigorous review process, including defining objectives, search strategies, inclusion and exclusion criteria, data extraction methods, and statistical analysis techniques in adherence to established standards and guidelines. Consistent with the findings of the meta-analysis, the telemonitoring strategy in Study 2 was delivered through a small mobile tablet provided to the participants in the intervention group. The device was used to facilitate weight monitoring, through 'pairing' with a set of blue-tooth enabled scales (also provided to participants). These devices were easily transportable and several participants continued the intervention while on holiday away from home. The findings of Study 2 (Chapter 6) are also consistent with those of the meta-analysis. The ITEC-CHF intervention resulted in a significant improvement in CHF self-management, specifically related to medication adherence, in addition to health maintenance, and diet.[9] Software installed on the tablet was utilised to detect a change in body weight, outside pre-determined limits (e.g. >2kg over 48 hours). When a weight fluctuation occurred, a clinical assessment questionnaire was generated by the telemonitoring software (MMH), and if indicated based on the participant's response, a CHF nurse was notified and contacted the participant for clinical review and follow up action. This included medication support such as reinforcing adherence to prescribed medications, and encouraging participants to enact flexible diuretic regimens, if these were in place. In the event that the participant's clinical status warranted care beyond the scope of the CHF nurse, they were referred for medical follow-up according to a predetermined clinical management algorithm.

Compliance was higher with daily weight monitoring in the setting of telemonitoring support (Chapter 6), compared with usual care.[9] While no differences were evident between the Telemonitoring and Usual Care groups for all-cause hospitalisation, Emergency Department presentations, CHF-related hospitalisation, or unplanned readmissions, the study wasn't powered to assess these outcomes. Future studies with the statistical power to assess clinical outcomes as a result of similar telemonitoring interventions are therefore required. A usability evaluation (Chapter 7) of the telemonitoring intervention revealed that the intervention was rated highly on

usability and was well accepted by patients who perceived the benefits of the intervention were complementary to their routine self-management strategies.[10]

The results from this study support future investment in innovative nurse-led CHF educational programs which will promote high-quality CHF care. In terms of the implications for practice, this study identified several opportunities for practice which could be implemented in telemonitoring-enabled care. As health care services evolve to utilise virtual care more extensively, bio-metric information will need to become more accessible to clinicians managing the complexities of CHF. By accessing routine health data using telemonitoring in this care model, clinical decisions were able to be made in a timely fashion, potentially mitigating the risk of clinical deterioration to more serious medical events.

Chronic heart failure can have an ongoing impact on a patient's psychosocial health. The SmartHeart clinic in Study 1 resulted in improved health-related quality of life whereas there were no significant differences in health-related quality of life in response to the telemonitoring intervention evaluated in Study 2. This may have been influenced, at least in part, by the level of interpersonal interaction between the nurse practitioners and participants in the SmartHeart project, compared with the telemonitoring intervention, which was largely 'hands off' with the nurses only alerted when there were weight fluctuations meeting the predetermined criteria. In Study 2, the effect of telemonitoring on daily weighing, an important aspect of self-care was found to have a high level of compliance with weight monitoring in addition to a significant improvement in CHF self-management related to health maintenance, medication adherence, and diet.

8.3 Overall Strengths

This work has several strengths. Firstly, it highlights the diversity of nursing roles and how the different scope of practice between nurse practitioners and registered nurses can be applied in different settings to support patients with CHF. In Study 1, nurse practitioners used their advanced scope of practice to provide case-management in an independent community clinic. In Study 2, the CHF nurse role at the different sites

was held by registered nurses who provided clinical advice to patients and acted as an intermediary between the patient and the healthcare system. In clinical practice, there is broad variability in the role and scope of nurses involved in supporting patients with CHF across Australia depending on the availability of nursing personnel, ranging from enrolled nurses in some regional and remote locations, to registered nurses and nurse practitioners being employed increasingly outside the hospital setting, such as in practice nurse roles complementing medical care in general practice. In the telemonitoring model, the nurse support could be provided by either registered nurses or nurse practitioners. While the telemonitoring was led by registered nurses in Study 2, having a nurse practitioners employed in the role with their advanced scope of practice would provide greater opportunity to action episodes when patients' clinical status is fluctuating, improve access for vulnerable groups with limited access to services, and integrate services for patients across the care continuum including access to alternative referral pathways.

Secondly, the telemonitoring intervention in Study 2 was a program which was embedded into an existing call centre care model and not a pilot clinic or clinic model established for the sole purposes of this research, making this support system sustainable beyond the duration of the study. The implementation of the telemonitoring intervention was described in detail in Chapter 5. This protocol paper will be valuable to guide the implementation of telemonitoring in other settings that have access to a call centre, as well as to inform how to model new telemonitoring-enabled nurse-led chronic care delivery models in other settings.[11]

Another strength of Study 2 is that it was conducted across multiple sites (two in Western Australia and one in Victoria). Study 2 provides a framework for measuring outcomes across organisations and states. Whilst there were differences in health care systems such as funding, operational and regulatory arrangements between the two states[12]; a single centralised call centre was able to support care provision. The results are therefore likely to have greater generalisability to other settings than if the study was conducted in one state or city.

Lasty, the application of both quantitative and qualitative methods during the Study 2 provides a deeper insight than if either method had been used in isolation. Collecting

and analysing qualitative data is an essential component in studying health community needs, since not all information can be captured through collecting quantitative data. Qualitative data can cover issues such as patient non-compliance with self-reporting symptoms as a result of weight fluctuations, perceived risk and satisfaction. Analysing routinely collected data and combining it with other sources of information such as surveys, questionnaires, suggestion boxes, focus groups, participant observation and interviews are useful methods for gaining insight into patients' needs and expectations.

8.4 Limitations

Study-specific limitations have been discussed in the previous chapters. However, there are several overall limitations of this research that should be acknowledged. A limitation of Study 1 was that it was a pragmatic trial and not a randomised control trial. However, pragmatic trials optimise external validity and have the advantage of being able to evaluate an intervention's effectiveness in routine practice conditions and can be more readily implemented because they are more generalisable to 'real life'.[13, 14] The SmartHeart program in Study 1 involved multiple components, consistent with best-practice. Participants and carers were provided with support to increase their knowledge, attitude and self-management capabilities through educational resources, which included CHF management booklets, face-to-face education, discussions and the practising of skills, home visits and follow-up telephone calls. The control group was recruited several months after the intervention group, once the nurse practitioner-led program had ceased, to compare patient outcomes with and without the program in operation. While this time lag opens the possibility that other CHF management processes may have changed, the impact of this is likely to be minimal, given that no guideline updates or other changes to routine CHF management processes occurred during this time.

A limitation of Study 2 was the lack of statistical power to evaluate clinical outcomes. The primary outcome, daily weighing compliance, is behavioural in nature and it is unclear from the current study how the observed changes in weight monitoring translate to reduced risk of emergency department presentations or hospitalisation

(and the costs associated with these), nor mortality. Future studies that are powered to test the effect of body weight telemonitoring on clinical outcomes are warranted.

Secondly, in Study 2, patients were only eligible to enrol if they had received a recent echocardiogram, which limited the number of patients with CHF who were discharged from general medical wards where echocardiograms were not requested as frequently, despite having a clinical diagnosis of CHF. Despite this limitation, the overall participant population was heterogenous with a diverse background in aetiology and demographics.

A further limitation of Study 2 is that all devices including the computer tablet and weighing scales were provided to participants at no cost, with the computer tablets equipped with a monthly data plan. We recognise that the likelihood of this type of resource provision is uncommon as comprehensive clinical service delivery of this kind is difficult to fund at a larger scale. However, bring your own device (BYOD) models have already demonstrated positive results in telemonitoring studies.[15, 16] For instance, researchers at the Centre for Global eHealth Innovation have recently implemented several telemonitoring-models with success in clinical outcomes, quality of life, and patient self-care including BYOD models where study participants utilise their own devices including blood pressure cuffs, phones and weight scales.[15] This pragmatic approach has significant potential for telemonitoring support programs in a real world setting.

The study was conducted in a pre-COVID-19 era, which means it was undertaken in a different socio-economic, cultural, and technological context.[17] At that time, society was not as heavily reliant on technology for daily activities, communication, and work as it has become in the post-pandemic world.[18-20]

8.5 Future Research Directions

By the end of this project, a number of areas for further research have been identified, which can build on this research and enrich the relevant findings on the nurse-led models of care. Based on the limitations, the following part addressed some suggestions for future research and practice.

Future studies need to keep investigating the effect of co-design on the nurse-led models of care to identify to generalise the users' preferences. This will create meaningful engagement through creating awareness on the practical relevance of the research and valuing all stakeholder perspectives and experiences in the research process. This approach ensures a comprehensive understanding and application of co-designed interventions in nursing care, ultimately contributing to more effective and patient-centric healthcare practices. The findings from the current project are valuable for informing future research in the area of nurse-led CHF management. Nurse-led services exist on a continuum from the direct substitution of single medical tasks, through to comprehensive, advanced practice nursing models of care.[21] The range of nurse-led service models of care reflects the degree of professional autonomy exercised by nurses.[21-23] Research is important to optimise the ability of nurses to work to their full regulated scope of practice, and in doing so, increase flexible service delivery options, improve integration of care, promote self-care amongst patients, and reduce the demand for acute services. [21, 22, 24] Future experimental, pragmatic and mixed mode research will all be important for developing the evidence base to support the evolution of nurse-led clinical practice in the management of CHF, as well as other clinical conditions. Indeed, pragmatic randomised controlled trials of innovative nurse-led CHF management models that are embedded in usual clinical practice will be critical to inform the refinement of nurse-led and patient-centred care in real-world settings.

Future studies involving detailed health economics evaluations will be especially important to influence the decisions of health-care policy makers. The comparison of cost effectiveness data between new nurse-led initiatives with routine practice will provide policy makers with the information required to allocate resources and staff to optimise clinical care based on evidence.[25, 26] This is also the case for telemonitoring interventions. While telemonitoring has shown promise in this and other studies[8, 9, 15, 27-29], there remain barriers for its implementation into routine care, which are both bureaucratic and financial in nature. As with any new innovation, telemonitoring must operate within the financial constraints of health care services. Larger trials are warranted with the power to evaluate the effects of telemonitoring interventions on clinical outcomes and cost effectiveness. Importantly, cost effectiveness analyses

should be conducted that reports quality-adjusted life years as a measure of disease burden in order to understand the impact on both the quality and the quantity of life lived.

Ongoing advances in digital technologies have led to the design, development and deployment of different types of telemonitoring interventions.[30-33] Future research must consider the rapid changes in digital technologies in the context of nurse-led CHF management programs with particular emphasis on reaching patient populations with limited digital health literacy, so these patients are not further disadvantaged in the new age of digital technologies.

Interventions similar to those investigated in the current project could easily be applied to a variety of other chronic conditions, providing innovative solutions to address emerging priorities. Building on the experiences and lessons learned from the management of CHF patients, the models investigated in these studies could readily be modified to support patients with conditions such as chronic obstructive pulmonary disease, type 2 diabetes, and osteoarthritis.

Finally, more work needs to been done in understanding the parameters and impact of how the recent COVID-19 pandemic might have forced individuals and institutions to quickly adapt to technology, and this might have influenced user acceptance significantly.[34-36] Users' experiences, preferences, and expectations have evolved, making it important to recognise the limitations of the study's relevance to the current context as well as highlighting the need for the ongoing research and adaptation of strategies and solution due to the dynamic nature of technology acceptance in management of CHF patients.[37, 38] Future studies can explore how these changes have influenced user preferences, trust in technology, and the sustainability of technological interventions.

8.6 Summary and conclusions

The growing prevalence of CHF warrants a redesign of traditional care delivery methods. New and innovative approaches to care delivery are needed to monitor and treat this complex patient cohort, who are characterised by frequent emergency department presentations and hospitalisations, due to exacerbations of their condition,

which in many cases are potentially avoidable with better clinical surveillance. Nurse-led CHF management strategies can strengthen the interconnection between the clinician and the patient that can be of great value. With this support, patients are able to achieve more effective means to self-manage minor fluctuations in their health and detect more significant deterioration in their condition earlier for more timely clinical follow up.[15, 39] This may result in a decrease in hospital usage and in an better overall health status for patients with CHF.[15, 40]

With the rapid uptake of remote healthcare delivery in response to the COVID-19 pandemic, the potential of virtual health care solutions such as telemonitoring has become more widely recognised as an important adjunctive clinical service to improve support for best-practice management and the provision of equitable access to care. Increasingly, telemonitoring is being adopted and implemented as an efficient and cost-effective means for delivering and accessing quality health care services and outcomes.[8, 15] While telemonitoring continues to evolve, the results from this thesis demonstrate how telemonitoring can support patients with CHF through virtual assessments in a nurse-led care model by supporting patient self-care in the setting of a seamless transition of clinical information to the clinical team.

In closing, the project undertaken in this thesis demonstrates the important role that nurses play in the management of patients with CHF, and how this can be delivered effectively in a community setting through monitoring patients, managing their symptoms, providing education and counselling, and developing new approaches to improve clinical surveillance. We trust that the new knowledge generated will contribute to an improvement in the lives of people experiencing this complex but increasingly common condition.

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Appendices

Appendix 1 - Study 1: Ethic Approval (Curtin University)

Curtin University

Memorandum

To	Associate Professor Andrew Maiorana, Physiotherapy and Exercise Science
From	Professor Peter O'Leary, Chair, Human Research Ethics Committee
Subject	Protocol Approval **HR 12/2014**
Date	10 February 2014
Copy	Sheau Huey Chen Physiotherapy and Exercise Science Dr Sharon Chih Physiotherapy and Exercise Science

Office of Research and Development
Human Research Ethics Committee

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for providing the additional information for the project titled "*The impact of a nurse-led, community-based heart failure management service on self-management behaviour and psychosocial outcomes (Objective 1 & 2 only)*". The information you have provided has satisfactorily addressed the queries raised by the Committee. Your application is now **approved**.

- You have ethics clearance to undertake the research as stated in Objective 1 and 2 your proposal.
- The approval number for your project is **HR 12/2014.** *Please quote this number in any future correspondence*.
- Approval of this project is for a period of four years **10-02-2014** to **10-02-2018**.
- Your approval has the following conditions:
  i) Annual progress reports on the project must be submitted to the Ethics Office.
- **It is your responsibility, as the researcher, to meet the conditions outlined above and to retain the necessary records demonstrating that these have been completed.**

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 **Progress Report** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development annually.

Our website https://research.curtin.edu.au/guides/ethics/non_low_risk_hrec_forms.cfm contains all other relevant forms including:

- Completion Report (to be completed when a project has ceased)
- Amendment Request (to be completed at any time changes/amendments occur)
- Adverse Event Notification Form (If a serious or unexpected adverse event occurs)

Yours sincerely

[redacted]

Professor Peter O'Leary
Chair Human Research Ethics Committee

Appendix 2 - Study 2: Ethic Approval (Royal Perth Hospital – 1 of 2)

Government of **Western Australia**
Department of **Health**
South Metropolitan Health Service

Royal Perth Hospital
Human Research Ethics Committee

30 September 2015

A/Prof Andrew Maiorana
Advanced Heart Failure & Cardiac Transplant Service
Fiona Stanley Hospital

Dear Andrew

Project Title: The Chronic Heart Failure Telehealth Model of Care Study
HREC Reference: 15-081

The ethics application for the project referenced above has been approved by the RPH Human Research Ethics Committee (HREC).

Approved document:
• Participant Information Sheet & Consent Form (no version) • GP Letter (no version) • Patient Intake Form • Patient Assessment Questionnaire (EQ-5D-5L; Cardiac Depression Scale; Heart Failure Compliance Questionnaire; Short Form-12) • Participant Equipment Instruction Manual (electronic weight scale) • Participant Equipment Instruction Manual (electronic weight scale and touch screen tablet) • Physical capacity assessments (Six Minute Walk Test and Frailty Scale) • Health Adaptive Questionnaire • Participant Evaluation Fform • Telehealth Questionnaire

This approval is valid to **30 September 2018** and on the basis of compliance with the 'Conditions of HREC Approval for a Research Project' (attached).

The nominated participating site(s) in this project is/are:

- **Royal Perth Hospital**
- **Fiona Stanley Hospital**

If additional sites are recruited prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the HREC. Notification of withdrawn sites should also be provided to the HREC in a timely fashion.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate site authorisation has been obtained from the CE, or delegate, of the site following Site Specific Assessment by a Research Governance Officer.

The RPH HREC is registered with the Australian Health Ethics Committee and operates according to the NHMRC National Statement on Ethical Conduct in Human Research and International Conference on Harmonisation – Good Clinical Practice.

Southern Integrated Research Organisation (SIRO)
Locked Bag 100, PALMYRA DC WA 6961
Telephone: 08 6151 1180
Email: SMHS.REG@health.wa.gov.au
www.southmetropolitan.health.wa.gov.au

Appendix 3 - Study 2: Ethic approval (Royal Perth Hospital – 2 of 2)

Should you have any queries about the HREC's consideration of your project, please contact the HREC Administrative Officer on 6151 1180. The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the SIRO Research Ethics & Governance Unit or from the website http://smhs.hdwa.health.wa.gov.au/ServicesFacilitiesLocator/sa/ethics/aboutus.asp?v=0.

Yours sincerely

[redacted]

PROF FRANK VAN BOCKXMEER
CHAIRMAN
ROYAL PERTH HOSPITAL HUMAN RESEARCH ETHICS COMMITTEE

Appendix 4 - Study 2: Ethics approval (Curtin University)

Curtin University

Memorandum

To	A/P Andrew Maiorana, Physiotherapy
From	Professor Peter O'Leary, Chair Human Research Ethics Committee
Subject	Protocol Approval **HR 181/2014**
Date	10 September 2014
Copy	Prof Moyez Jiwa, Medical Education Prof James Boyd, Health Sciences Dr Delia Hendrie, Public Health Dr Jacquie Garton-Smith / Dr Lawrence Dembo, Royal Perth Hospital

Office of Research and Development
Human Research Ethics Committee

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for your application submitted to the Human Research Ethics Committee (HREC) for the project titled "*A randomised controlled trial of nurse-supported telehealth for people with heart conditions.*". The Committee notes the prior approval by Royal Perth Hospital HREC (EC00270) and has reviewed your application consistent with Chapter 5.3 of the *National Statement on Ethical Conduct in Human Research*.

- You have ethics clearance to undertake the research as stated in your proposal.
- The approval number for your project is **HR 181/2014.** *Please quote this number in any future correspondence*.
- Approval of this project is for a period of four years **09-09-2014** to **09-09-2018**.
- Annual progress reports on the project must be submitted to the Ethics Office.
- If you are a Higher Degree by Research student, data collection must not begin before your Application for Candidacy is approved by your Faculty Graduate Studies Committee.

- The following standard statement **must be** included in the information sheet to participants:

  This study has been approved by the Human Research Ethics Committee of (Royal Perth Hospital HREC) and Curtin University **181/2014.**

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 **Progress Report** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development annually.

Our website https://research.curtin.edu.au/guides/ethics/non_low_risk_hrec_forms.cfm contains all other relevant forms including:

- Completion Report (to be completed when a project has ceased)
- Amendment Request (to be completed at any time changes/amendments occur)
- Adverse Event Notification Form (If a serious or unexpected adverse event occurs)

[redacted]

Professor Peter O'Leary
Chair Human Research Ethics Committee

Appendix 5 - Study 1: Participant recruitment letter

Curtin University

School of Physiotherapy and Exercise Science

GPO Box U1987
Perth Western Australia 6845

Telephone +61 8 9266 9225
Facsimile +61 8 9266 4644
Email A.Maiorana@curtin.edu.au
Web curtin.edu.au

5 March 2023

Addressee's Name
Street Address
Suburb, State, Post Code

Dear

A team of researchers from Curtin University and Royal Perth Hospital are conducting a study to investigate how people manage their heart condition in the 6 to 12 months after being admitted to hospital with heart problems.

We are seeking people who have received support from the SmartHeart Service at Curtin University to take part in this study, hence this invitation to invite you to participate.

If you decide to take part, you will be asked to attend an appointment to confirm some questions about your medical history and complete 3 questionnaires. This process will take less than an hour and will be undertaken at Curtin University or Royal Perth Hospital, whichever is easiest for you. If you are unable to travel, we could also arrange to do this assessment at your home. You are welcome to have a family member with you at this appointment. More specific details of the study can be found in the attached Participant Information and Consent Form. We would encourage you to discuss your participation in the study with family, friends or your doctor if you wish.

One of the researchers will contact you within the next week to answer any questions you have and to see whether you would be interested in participating.

Kind regards,

[redacted]

Associate Professor Andrew Maiorana
Principal Investigator
SmartHeart Service Director
Ph. 1300 632 657

Appendix 6 - Study 1: Participant information sheet (1 of 2)

Curtin University

Faculty of Health Sciences

School of Physiotherapy

GPO Box U1987
Perth Western Australia 6845

Telephone +61 8 9266 4644
Facsimile +61 8 9266 3699
Web
http://www.physiotherapy.curtin.edu.au

PARTICIPANT INFORMATION SHEET

Project title: The impact of a community-based heart health service on self-management behaviour and psychosocial outcomes.

Principal Investigator: Associate Professor Andrew Maiorana, School of Physiotherapy & Exercise Science

This information sheet explains a study being undertaken at Curtin University and describes what will be involved should you decide to participate. Please read the information carefully and ask any questions you might have. You may also wish to discuss the study with a relative or friend.

BACKGROUND AND AIM

In early 2013, a new community-based program to help people manage their heart condition and stay out of hospital was established at Curtin University (known as SmartHeart). The SmartHeart program is led by nurse practitioner who provides comprehensive patient assessment, education and monitoring, regular liaison with General Practitioners and medical specialists and links patients to other services that will help them manage their health. The overall aim of this research is to evaluate the impact of the SmartHeart program. People attending the SmartHeart program will be compared to people with heart conditions who don't have access to SmartHeart (control group).

WHAT IS THE PURPOSE OF THE STUDY?

The specific objectives of this study are to determine whether nurse led, community-based care helps people with heart conditions manage their health and whether this improves their quality of life, self-management strategies, symptom recognition and reduces the risk of repeat hospital admissions

WHAT WILL HAPPEN?

1. Initially we will need to document your medical history and demographic information. Much of this will be recorded in your medical records, so we are requesting your permission to access these details. However, we may need to confirm some of this information or seek further information from you.

2. We will arrange an interview with you. At this interview we will to get you to fill out some questionnaires and to confirm the demographic information described above at point 1. The questionnaires will typically be undertaken at Curtin University. For people who are unable to travel to Curtin, one of the researchers will be able to visit you in your home if you wish.

Appendix 7 - Study 1: Participant information sheet (2 of 2)

There are three questionnaires that you will be asked to complete for the study. The first questionnaire measures your knowledge and confidence to undertake self-care activities to manage your heart condition. The second questionnaire poses 36 questions about how your heart condition impacts upon your physical and mental health. The third questionnaire measures how your heart condition affects your quality of life physically, mentally, emotionally and socially. If the researcher administering the questionnaires identifies that your mental health is being significantly impacted by your heart condition, we will advise you and offer you a referral to a Clinical Psychologist for follow up.

TIME COMMITMENT
The study typically takes less than an hour.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART?
This study only involves filling out questionnaires, so there are no risks to your health.

POSSIBLE BENEFITS
Whilst there may be no personal benefits to you from participating in this study, the information you provide may contribute to the future development of programs for the community-based management of heart conditions.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
You may decide to stop being a part of the research study at any time without explanation. You have the right to have your questions about the procedures answered. If you have any questions as a result of reading this information sheet, you should ask the researcher before the study begins.

WHAT ARE THE COSTS OF BEING IN THIS STUDY?
There are no financial costs associated with participating in the study.

PRIVACY AND CONFIDENTIALITY
The information gathered about you by the investigator or obtained during this study will be held by the investigator in strict confidence. All responses to the questionnaires and information provided by you will be stored in a locked cabinet or on a password protected computer. Only members of the research team will have access to this information. All the people who handle your information will adhere to traditional standards of confidentiality and will also comply with the Privacy Act 1988. If the results of the trial are published in a medical journal, as is intended, no reader will be able to identify individuals.

REFUSAL OR WITHDRAWAL
Participants have the right to refuse to take part in the study or to withdraw from the study at any time for any reason without prejudice or penalty.

FURTHER INFORMATION
This study has been approved by the Curtin University Human Research Ethics Committee (**Application 4591**). 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.

Appendix 8 - Study 1: Participant consent form

CONSENT FORM

Project title: The impact of a community-based heart health service on self-management behaviour and psychosocial outcomes.

Principal Investigator: Associate Professor Andrew Maiorana, School of Physiotherapy & Exercise Science

I, ... agree to participate in the above study. I have read and understood the attached information sheet and I have retained a copy of the signed document. I have been given the opportunity to ask questions about the study by the Investigator. I understand that I may withdraw from the study at any time without affecting any future medical treatment, or the treatment of the condition which is the subject of the study.

Signed ..... Date .....

Signature of Investigator ..... Date .....

Appendix 9 - Study 2: Participant information sheet (Royal Perth Hospital 1 of 4)

Royal Perth Hospital

PARTICIPANT INFORMATION SHEET

A randomised controlled trial of nurse-supported telehealth for people with heart conditions

Principal Investigator: Dr Andrew Maiorana, Cardiac Transplant Service, FSH

This information form explains a study being undertaken by Royal Perth Hospital, Fiona Stanley Hospital and Curtin University and describes what will be involved should you decide to participate in this research project. Please read the information carefully and ask any questions you might have. You may also wish to discuss the study with a relative or friend.

BACKGROUND

People with heart conditions can reduce the likelihood of future hospital admissions by good self-management of their condition such as taking their medication regularly and monitoring and reporting changes in their symptoms. Telehealth is a system that uses technology, such as the internet, computers and mobile and landline phones to help people manage their health.

Telehealth may be especially useful to support people with heart conditions, because it can be used to monitor changes in the person's condition and provide advice to the person on appropriate action to take, such as when to visit their GP or Cardiologist.

WHAT IS THE PURPOSE OF THE STUDY?

The specific objectives of this study are to determine whether Telehealth support will help people with heart conditions manage their health and whether this leads to an improved quality of life and lower risk of being readmitted to hospital.

Participants will be randomly allocated to one of two groups – as if by the toss of a coin with a 50/50 chance of being in each group. One group will receive **Telehealth follow up** and the other group will receive **usual heart care** provided by their GP, cardiologist or other healthcare provider, as well as being provided with literature on managing their heart condition.

WHAT WILL HAPPEN?

If you agree to take part in the study you will first be asked to attend an **initial appointment** at Royal Perth Hospital, Fiona Stanley Hospital or Curtin University, whichever is easiest for you. For people

Appendix 10 - Study 2: Participant information sheet (Royal Perth Hospital 2 of 4)

who are unable to travel, one of the researchers will be able to visit you in your home if you wish. The appointment will take about 1-2 hours.

The following will occur at the initial appointment:

1. We will review this Information Sheet, answer any questions you have and, if you agree to continue, ask you to sign the attached Consent Form.

2. You will be notified which group you have been allocated to; Telehealth or Usual Care.

3. We will document your medical history and demographic information. Much of this will be recorded in your medical records, so we are requesting your permission to access these details. We may need to confirm some of this information or seek further information from you, but obtaining the information already available in your medical record will save time and ensure accuracy.

4. You will be asked to complete 4-5 questionnaires for the study, depending on whether you are in the telehealth or usual care group. The first questionnaire measures your knowledge and confidence to undertake self-care activities to manage your heart condition. The second questionnaire poses questions about how your heart condition impacts upon your physical and mental health. The third questionnaire measures how your heart condition affects your quality of life physically, mentally, emotionally and socially. The fourth questionnaire relates to the strategies you employ in managing your health. A fifth questionnaire will be used in the telehealth group to find out opinions regarding telehealth. If the researcher administering the questionnaires identifies that your mental health is being significantly impacted by your heart condition, we will advise you and offer you a referral to a GP, Psychiatrist or Clinical Psychologist for follow up.

Study Period (12 months)

If you are allocated to the Telehealth group you will be linked to a secure online database that will be used to monitor your health. The database will be used to enter details about your health including recording body weight so it can be viewed and monitored by the study's nurse to help you manage your heart condition. This database can be accessed from your home by a computer tablet. A computer tablet will be provided to you for the 12 month duration of the study. A weighing scale will be provided to all participants through the study. At the end of the 12 month research period it will be necessary to return all the equipment to Curtin University, who have purchased it for the study.

Regardless of which group you are allocated to, you will be asked to attend **appointments at 6-months** and 12-months later so that the questionnaires can be repeated.

Participants allocated to the Telehealth group should continue to access their usual care, including seeing their Cardiologist and GP, as necessary.

Appendix 11 - Study 2: Participant information sheet (Royal Perth Hospital 3 of 4)

TIME COMMITMENT

The only time commitments in the **Usual Care Group** will be those outlined above for the initial, second and third assessment and completion of questionnaires (approximately one hour on each occasion).

People allocated to the **Telehealth Group** will also receive the following over a **12 month period**:
1. Heart health education and a **telehealth management plan** developed during an appointment with the project's nurse (approximately 1 hour). If a face to face appointment is not possible a telephone conference will be arranged. This can be combined with the initial appointment.

2. A **phone call when necessary** to support you in managing your heart condition and help you become familiar with using the database. Each phone call will last approximately 10 minutes (slightly longer if you are having any problems). Additional phone calls may be required.

The information entered into the database through a secure online portal will only be accessible by the researchers. The project's nurse will monitor your recorded details and use these to guide self-management and link you to your GP in the event of clinical deterioration.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISK OF TAKING PART?

The database employed in the study is protected by the latest online security so all information that you enter will be kept confidential and the risk of it being accessed by anyone without authority is very low.

All information provided by you will be kept confidential at all times. All responses to the questionnaires and information provided by you will be kept anonymous and stored in a locked cabinet or on a password protected computer. Only members of the research team will have access to the information provided in the questionnaires.

POSSIBLE BENEFITS

Participants in both the Telehealth and Usual Care Groups will be provided with literature on heart health self management. This literature is designed to assist people to better manage their heart condition. People in the Telehealth Group will get additional self management support. The impact of this type of support is yet to be determined but may also be helpful.

Appendix 12 - Study 2: Participant information sheet (Royal Perth Hospital 4 of 4)

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Participation in this study is voluntary. You do not have to participate and, if you decide to participate, you can stop at any time without explanation. Your decision to participate or not, or to later withdraw from the study, will in no way affect your current or future care at RPH.

WHAT ARE THE COSTS OF BEING IN THIS STUDY?

There are no financial costs associated with participating in the study. If you already have a internet connection that is suitable for the project you will be able to use this, otherwise a computer and internet connection will be provided to you. Similarly, if you require suitable scales, this will also be provided.

PRIVACY AND CONFIDENTIALITY

The information gathered about you by the investigator or obtained during this study will be held by the investigator in strict confidence. All the people who handle your information will adhere to traditional standards of confidentiality and will also comply with the Privacy Act 1988. If the results of the trial are published in a medical journal, as is intended, no reader will be able to identify individual patients.

WHAT IF SOMETHING GOES WRONG?

In the event that you suffer an expected or unexpected side effect or medical accident during this study that arises from your participation, you will be offered all full and necessary treatment by Royal Perth Hospital. The Ethics Committee has approved this study on the basis (amongst others) that the reported risk of such an event is either small or acceptable in terms of the risk you face as a result of your current illness.

CONTACT INFORMATION

If you have questions about this study, please contact Associate Professor Maiorana on 1300 632657.This study has been approved by the Royal Perth Hospital Ethics Committee. If you have any concerns about the conduct of the study or your rights as a research participant, please contact Prof Frank van Bockxmeer, Chairman of the RPH Ethics Committee, on (08) 9224 2244 and quote the ethics approval number (REG: 14-090).

Appendix 13 - Study 2: Participant consent form (Royal Perth Hospital)

Royal Perth Hospital

CONSENT FORM

A randomised controlled trial of nurse-supported telehealth for people with heart conditions

Principal Investigator: Dr Andrew Maiorana, Cardiac Transplant Service, RPH

I, ... agree to participate in the above study. I have read and understood the attached information sheet and I have retained a copy of the signed document. I have been given the opportunity to ask questions about the study by the Investigator. I understand that I may withdraw from the study at any time without affecting any future medical treatment, or the treatment of the condition which is the subject of the study.

Signed _____ **Date** _____

_____

Signature _____ **Date** _____

of person obtaining consent

Name _____

of person obtaining consent

Appendix 14 - Study 2: Participant information sheet (Fiona Stanley Hospital 1 of 4)

Government of **Western Australia**
Department of **Health**

FIONA STANLEY hospital

PARTICIPANT INFORMATION SHEET

A randomised controlled trial of nurse-supported telehealth for people with heart conditions

Principal Investigator: Dr Andrew Maiorana, Cardiac Transplant Service, FSH

This information form explains a study being undertaken by Royal Perth Hospital, Fiona Stanley Hospital and Curtin University and describes what will be involved should you decide to participate in this research project. Please read the information carefully and ask any questions you might have. You may also wish to discuss the study with a relative or friend.

BACKGROUND

People with heart conditions can reduce the likelihood of future hospital admissions by good self-management of their condition such as taking their medication regularly and monitoring and reporting changes in their symptoms. Telehealth is a system that uses technology, such as the internet, computers and mobile and landline phones to help people manage their health.

Telehealth may be especially useful to support people with heart conditions, because it can be used to monitor changes in the person's condition and provide advice to the person on appropriate action to take, such as when to visit their GP or Cardiologist.

WHAT IS THE PURPOSE OF THE STUDY?

The specific objectives of this study are to determine whether Telehealth support will help people with heart conditions manage their health and whether this leads to an improved quality of life and lower risk of being readmitted to hospital.

Participants will be randomly allocated to one of two groups – as if by the toss of a coin with a 50/50 chance of being in each group. One group will receive **Telehealth follow up** and the other group will receive **usual heart care** provided by their GP, cardiologist or other healthcare provider, as well as being provided with literature on managing their heart condition.

WHAT WILL HAPPEN?

If you agree to take part in the study you will first be asked to attend an **initial appointment** at Royal Perth Hospital, Fiona Stanley Hospital or Curtin University, whichever is easiest for you. For people who are unable to travel, one of the researchers will be able to visit you in your home if you wish. The appointment will take about 1-2 hours.

Appendix 15 - Study 2: Participant information sheet (Fiona Stanley Hospital 2 of 4)

The following will occur at the initial appointment:

1. We will review this Information Sheet, answer any questions you have and, if you agree to continue, ask you to sign the attached Consent Form.

2. You will be notified which group you have been allocated to; Telehealth or Usual Care.

3. We will document your medical history and demographic information. Much of this will be recorded in your medical records, so we are requesting your permission to access these details. We may need to confirm some of this information or seek further information from you, but obtaining the information already available in your medical record will save time and ensure accuracy.

4. You will be asked to complete 4-5 questionnaires for the study, depending on whether you are in the telehealth or usual care group. The first questionnaire measures your knowledge and confidence to undertake self-care activities to manage your heart condition. The second questionnaire poses questions about how your heart condition impacts upon your physical and mental health. The third questionnaire measures how your heart condition affects your quality of life physically, mentally, emotionally and socially. The fourth questionnaire relates to the strategies you employ in managing your health. A fifth questionnaire will be used in the telehealth group to find out opinions regarding telehealth. If the researcher administering the questionnaires identifies that your mental health is being significantly impacted by your heart condition, we will advise you and offer you a referral to a GP, Psychiatrist or Clinical Psychologist for follow up.

Study Period (12 months)

If you are allocated to the Telehealth group you will be linked to a secure online database that will be used to monitor your health. The database will be used to enter details about your health including recording body weight so it can be viewed and monitored by the study's nurse to help you manage your heart condition. This database can be accessed from your home by a computer tablet. A computer tablet will be provided to you for the 12 month duration of the study. A weighing scale will be provided to all participants through the study. At the end of the 12 month research period it will be necessary to return all the equipment to Curtin University, who have purchased it for the study.

Regardless of which group you are allocated to, you will be asked to attend **appointments at 6-months** and 12-months later so that the questionnaires can be repeated.

Participants allocated to the Telehealth group should continue to access their usual care, including seeing their Cardiologist and GP, as necessary.

Appendix 16 - Study 2: Participant information sheet (Fiona Stanley Hospital 3 of 4)

TIME COMMITMENT

The only time commitments in the **Usual Care Group** will be those outlined above for the initial, second and third assessment and completion of questionnaires (approximately one hour on each occasion).

People allocated to the **Telehealth Group** will also receive the following over a **12 month period**:
1. Heart health education and a **telehealth management plan** developed during an appointment with the project's nurse (approximately 1 hour). If a face to face appointment is not possible a telephone conference will be arranged. This can be combined with the initial appointment.

2. A **phone call when necessary** to support you in managing your heart condition and help you become familiar with using the database. Each phone call will last approximately 10 minutes (slightly longer if you are having any problems). Additional phone calls may be required.

The information entered into the database through a secure online portal will only be accessible by the researchers. The project's nurse will monitor your recorded details and use these to guide self-management and link you to your GP in the event of clinical deterioration.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISK OF TAKING PART?

The database employed in the study is protected by the latest online security so all information that you enter will be kept confidential and the risk of it being accessed by anyone without authority is very low.

All information provided by you will be kept confidential at all times. All responses to the questionnaires and information provided by you will be kept anonymous and stored in a locked cabinet or on a password protected computer. Only members of the research team will have access to the information provided in the questionnaires.

POSSIBLE BENEFITS

Participants in both the Telehealth and Usual Care Groups will be provided with literature on heart health self management. This literature is designed to assist people to better manage their heart condition. People in the Telehealth Group will get additional self management support. The impact of this type of support is yet to be determined but may also be helpful.

FSH site version 1 dated 27 March 2015 based on;
Master RPH Version 2 dated 20 August 2014

Appendix 17 - Study 2 Participant information sheet (Fiona Stanley Hospital 4 of 4)

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Participation in this study is voluntary. You do not have to participate and, if you decide to participate, you can stop at any time without explanation. Your decision to participate or not, or to later withdraw from the study, will in no way affect your current or future care at RPH.

WHAT ARE THE COSTS OF BEING IN THIS STUDY?

There are no financial costs associated with participating in the study. If you already have a internet connection that is suitable for the project you will be able to use this, otherwise a computer and internet connection will be provided to you. Similarly, if you require suitable scales, this will also be provided.

PRIVACY AND CONFIDENTIALITY

The information gathered about you by the investigator or obtained during this study will be held by the investigator in strict confidence. All the people who handle your information will adhere to traditional standards of confidentiality and will also comply with the Privacy Act 1988. If the results of the trial are published in a medical journal, as is intended, no reader will be able to identify individual patients.

WHAT IF SOMETHING GOES WRONG?

In the event that you suffer an expected or unexpected side effect or medical accident during this study that arises from your participation, you will be offered all full and necessary treatment by Royal Perth Hospital. The Ethics Committee has approved this study on the basis (amongst others) that the reported risk of such an event is either small or acceptable in terms of the risk you face as a result of your current illness.

CONTACT INFORMATION

If you have questions about this study, please contact Associate Professor Maiorana on 1300 632657.This study has been approved by the Royal Perth Hospital Ethics Committee. If you have any concerns about the conduct of the study or your rights as a research participant, please contact Prof Frank van Bockxmeer, Chairman of the RPH Ethics Committee, on (08) 9224 2244 and quote the ethics approval number (REG: 14-090).

FSH site version 1 dated 27 March 2015 based on;
Master RPH Version 2 dated 20 August 2014

Appendix 18 - Study 2: Participant consent form (Fiona Stanley Hospital)

Government of **Western Australia**
Department of **Health**

FIONA STANLEY hospital

CONSENT FORM

A randomised controlled trial of nurse-supported telehealth for people with heart conditions

Principal Investigator: Dr Andrew Maiorana, Cardiac Transplant Service, FSH

I, ... agree to participate in the above study. I have read and understood the attached information sheet and I have retained a copy of the signed document. I have been given the opportunity to ask questions about the study by the Investigator. I understand that I may withdraw from the study at any time without affecting any future medical treatment, or the treatment of the condition which is the subject of the study.

Signed _____ **Date** _____

Signature _____ **Date** _____

of person obtaining consent

Name _____

of person obtaining consent

FSH site version 1 dated 27 March 2015 based on;
Master RPH Version 2 dated 20 August 2014

Appendix 19 - Study 2: ITEC-CHF Equipment instruction manual

Royal Perth Hospital

FIONA STANLEY hospital

Curtin University

The Chronic Heart Failure Study

Equipment Instruction Manual

How to use the new electronic weight scale and touch screen tablet

medtech

Powered by Medtech Global products ManageMyHealth™ and VitelMed™

Contents

1. INTRODUCTION

"The Chronic Heart Failure Study" provides an opportunity to understand how technology can be used in the management of chronic heart failure in the community. It will also allow for the development of new ways of detecting changes in health status of people who have chronic heart failure so that their care team can be advised to take action at the right time to avoid unnecessary hospitalisation.

Changes in your weight are an important indicator of your chronic heart failure condition and it is important to keep track of your weight on a daily basis. Therefore, it is important that you weigh yourself each day and first thing in the morning after you wake up.

2. WHAT ARE YOU REQUIRED TO DO?

You are required to weigh yourself daily. You have been given the following equipment to support you to do this:-

1) 1 set of electronic weight scale (TNG 550)
2) 1 touch screen tablet (SAMSUNG TAB4 8")
3) 1 USB cable and 1 power adaptor – to charge the tablet battery

Taking your weight measurement should only take you less than 5 minutes a day.

Instructions for use of the electronic weight scales and touch screen tablet for taking your daily weight measurements are provided in this booklet. Please read the entire booklet before using the equipment to take your daily weight measurements.

3. IF YOU MISS TAKING A WEIGHT MEASUREMENT

If you miss weighing yourself first thing in the morning after you wake up, then an alert will be automatically sent to the MEPACS call centre.

Please note that a reminder prompt appears on your tablet device reminding you to weigh yourself before the designated time.

The MEPACS call centre operator will attempt to get in touch with you by telephone to remind about weighing. If the MEPACS operator is unable to get in touch with you after repeated calls, then MEPACS will get in touch with your nominated contacts to determine your current status. If there is no response from your contacts, MEPACS will follow the standard procedure and will send the police to your home.

If the MEPACS operator is able to reach you on the telephone and you are unwell, a decision will be made with you as to whether an ambulance is required to take you to the Emergency Department.

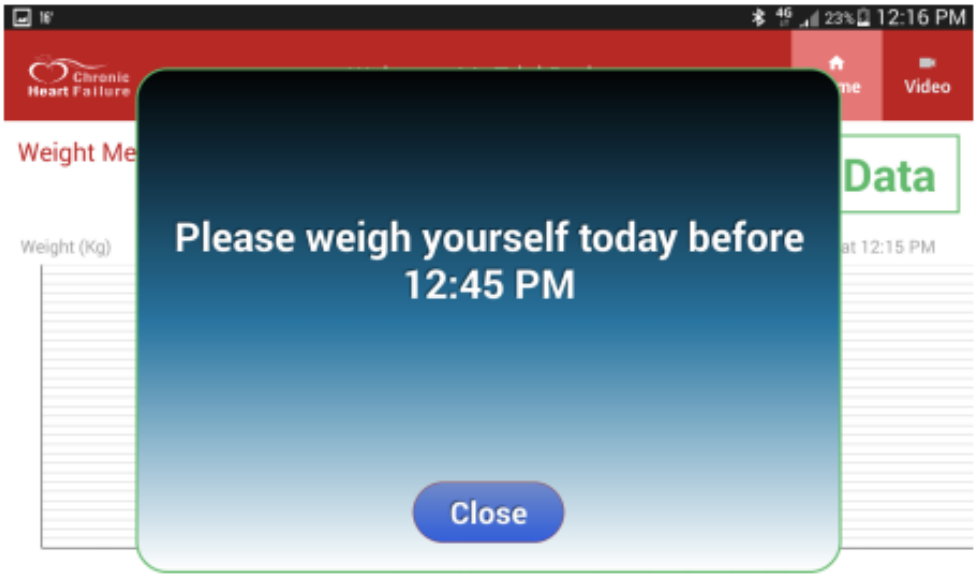
4. THINGS TO REMEMBER BEFORE TAKING YOUR DAILY WEIGHT MEASUREMENT

a) Each morning, the touch screen tablet will remind you that it is time to take your weight measurement.

b) So that the touch screen tablet can remind you to take your weight measurement, it must always be charged (that is, has enough battery life)

   - It is important that you leave the touch screen tablet plugged in to the charger connected to a PowerPoint, so that it is always charged.

c) When it is time to weigh yourself each morning, your touch screen tablet will remind you with a message like the one shown in the picture on the next page



Note: The weight measurement time shown here is an example only; the time may be different for you.

d) You will also receive a voice message from your touch screen tablet telling you to weigh yourself. Please ensure that you follow these instructions without fail:-

1) You weigh yourself each day and first thing in the morning after you wake up

2) You have been to the bathroom to urinate

3) You have-not had anything to eat or drink

   - If you forgot and have had something to eat or drink before taking your weight, then it's still important that you weigh yourself

4) You have removed your clothing and are naked while you take your weight measurement

5. STEPS FOR TAKING YOUR DAILY WEIGHT MEASUREMENT

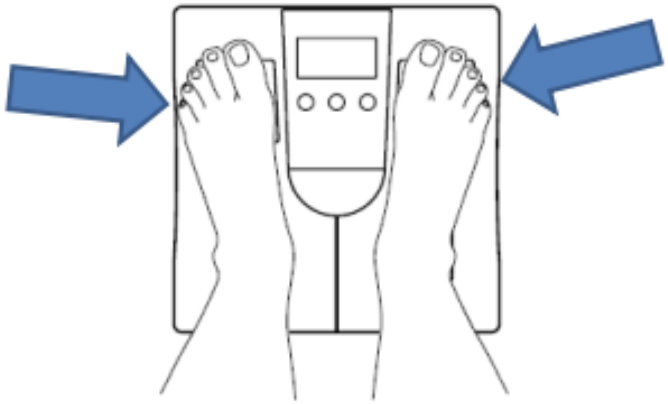
Follow these steps to take your daily weight measurement.

Step 1: Ensure the scales are placed on a hard surface.

Step 2: Step on the weight scales.

Step 3: Position your feet correctly on the foot marking on the scales.

Your feet should look like this when you are standing on the scales:-

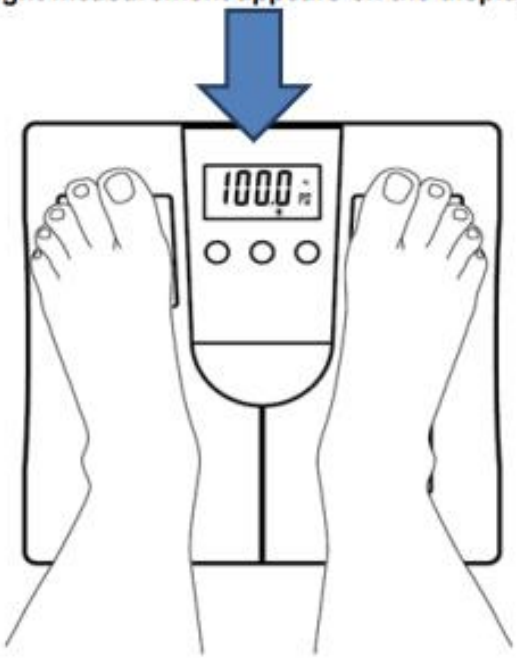


Make sure your feet are parallel to each other and your weight is evenly distributed.

Step 4: Stand as still as possible while the scale is measuring your weight.

- Continue to stand on the weighing scale until a measurement comes up on the display screen – this is shown in the picture below.
- Wait until the measurement value is read out loud by the scales.

Your weight measurement appears on the display screen

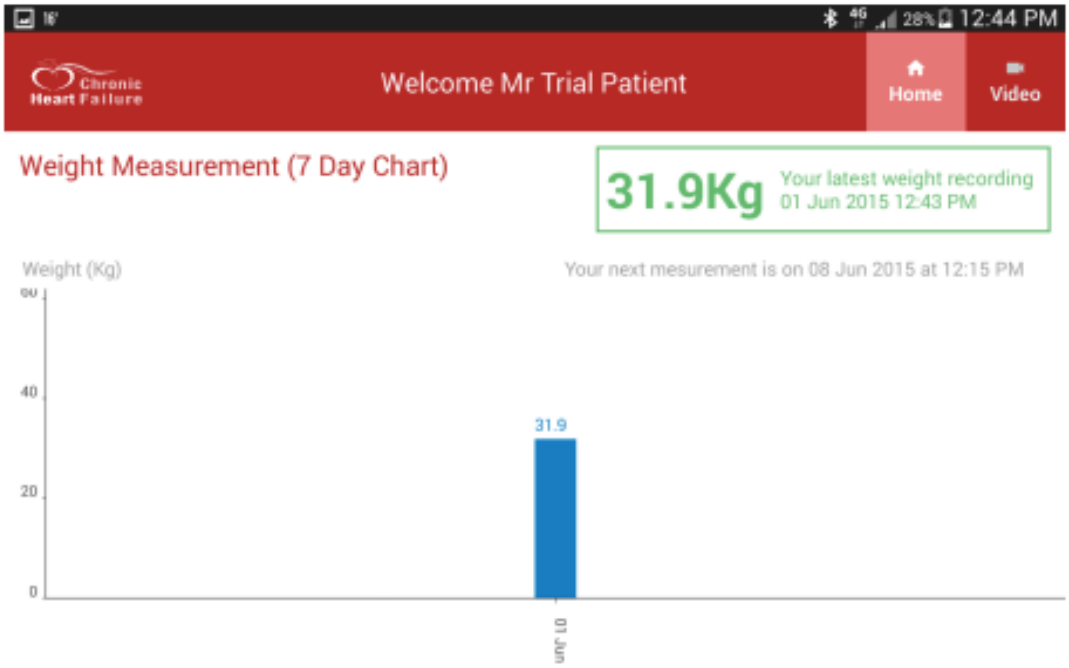


A few seconds following your weight measurement, you will hear a voice message coming from your touch screen tablet.

This voice will read your weight measurement out to you. For example:-

"Your weight is 31.9 kg."

Your weight measurement will also appear on the touch screen tablet as shown in the picture below:



You have now taken your weight measurement for the day.

Note: You must not weigh between 12 PM and 3.30 AM. The title bar in the tablet is blue and the application is inaccessible during this time.

➢ Upon logging in to the tablet, screen displays welcome message in blue colour as shown below during 12 PM to 3:30 AM.

6. USING THE TOUCH SCREEN TABLET TO RECEIVE OTHER MESSAGES AFTER YOU WEIGH YOURSELF

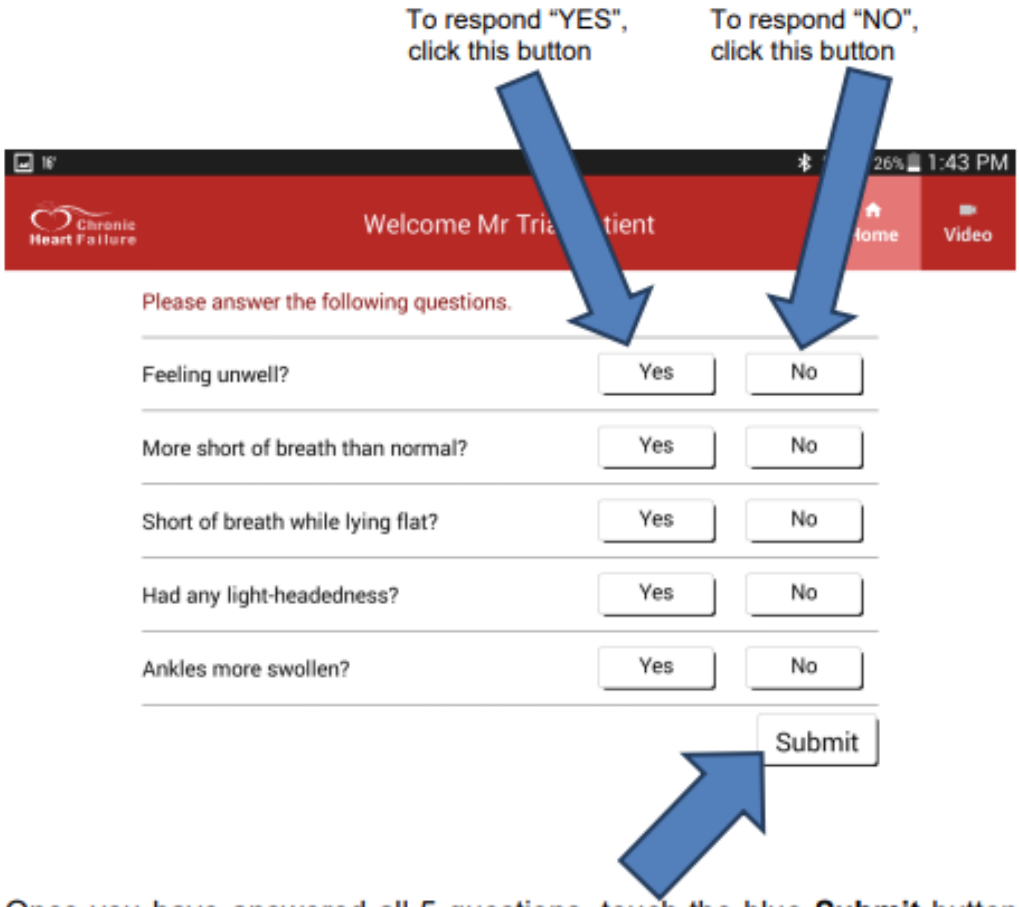
Other messages may come up on the touch screen tablet after you weight yourself each morning. For example, a message will appear on your touch screen tablet if your weight has decreased or increased in the past 24 or 48 hours.

Below is a list of examples of such messages and what you need to do in the event that these messages appear.

6.1 IF YOUR WEIGHT HAS VARIED BY 1KG IN THE PAST 24 HOURS

If your weight has increased or decreased by 1.0 kg in the last 24 hours, you will receive five (5) questions on your touch screen tablet - shown in the f picture below,

- Simply respond **YES** or **NO** to each question by touching the correct response on the touch tablet screen.



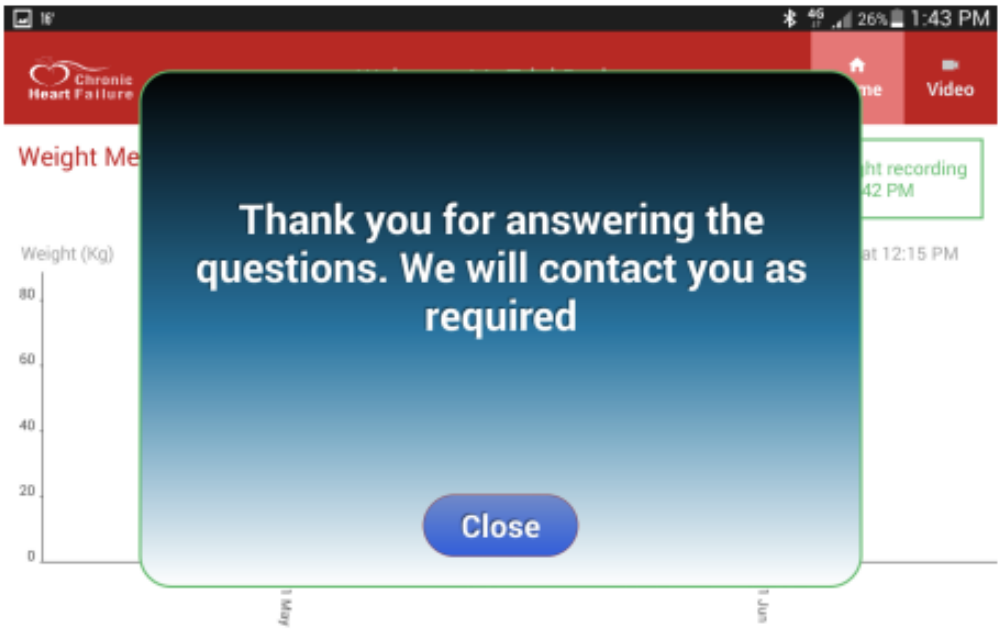
Once you have answered all 5 questions, touch the blue **Submit** button on the touch screen tablet as indicated by the blue arrow.

This will generate further instructions for you to follow.

6.2 IF YOU ANSWERED "YES/NO" TO ALL 5 QUESTIONS

Once you submit your responses to all 5 questions, you will receive the following message on the touch screen tablet:-

"Thank you for answering the questions, we will contact you as required"



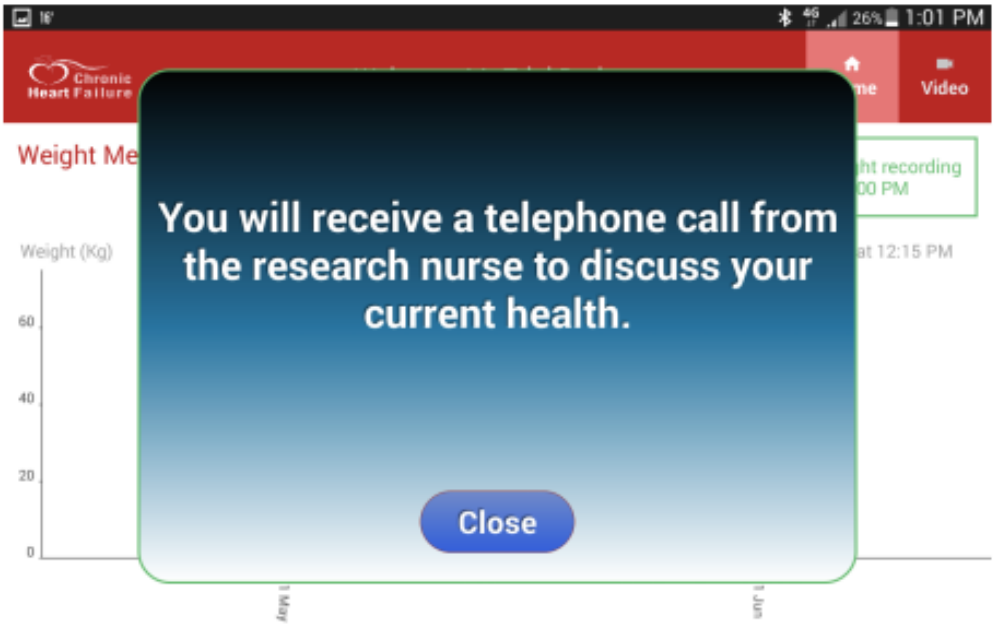
HOWEVER, PLEASE REMEMBER TO:-

- Restrict your fluids as advised
- Keep your salt intake low
- Take your meds as described
- Keep active

6.3 IF YOUR WEIGHT HAS VARIED BY 2.0KG IN THE PAST 24 HOURS

The touch screen tablet will send you the following message informing you that your weight has increased or decreased by 2.0 kg or more in the past 24 hours.

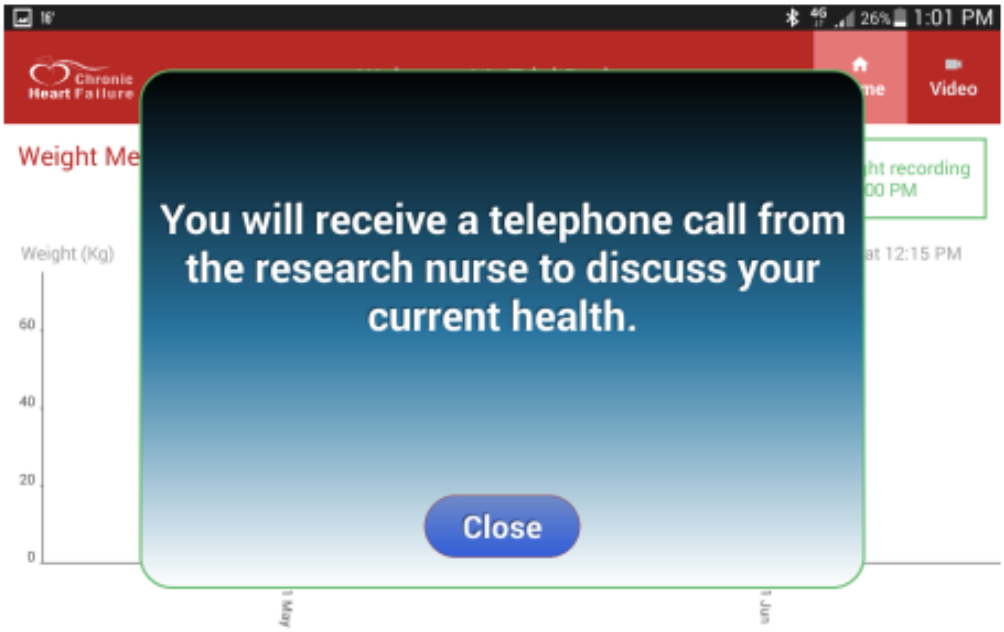
"You will receive a telephone call from the research nurse to discuss your current health."



6.4 IF YOUR WEIGHT HAS VARIED BY 2.0KG IN THE PAST 48 HOURS

The touch screen tablet will send you the following message informing you that your weight has increased or decreased by 2.0 kg in the last 48 hours.

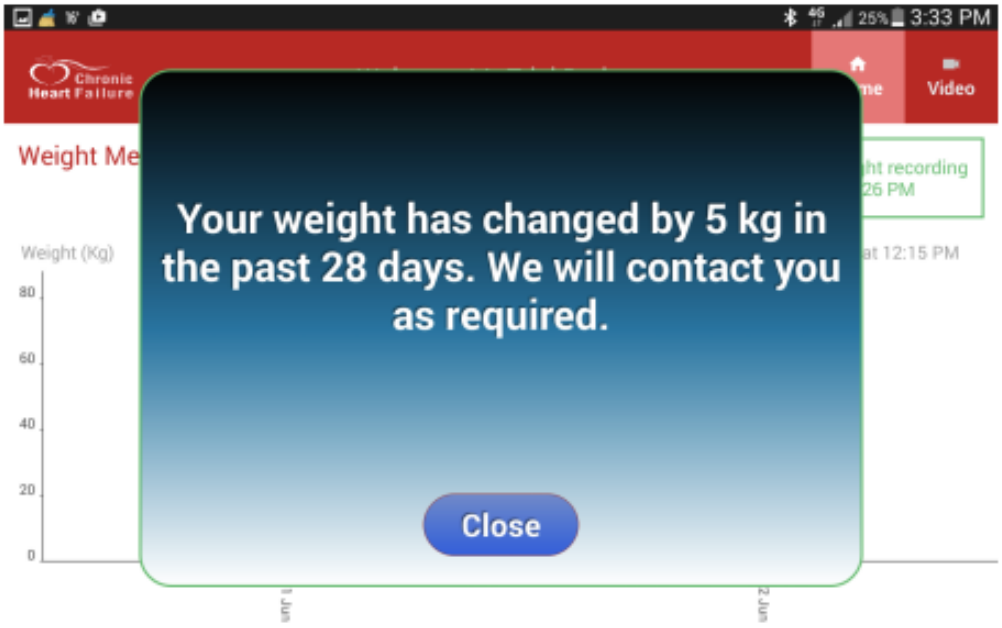
"You will receive a telephone call from the research nurse to discuss your current health."



6.5 IF YOUR WEIGHT HAS VARIED BY 5.0KG IN THE PAST 28 DAYS

The touch screen tablet will send you the following message informing you that your weight has increased or decreased by 5.0 kg in the last 28 days.

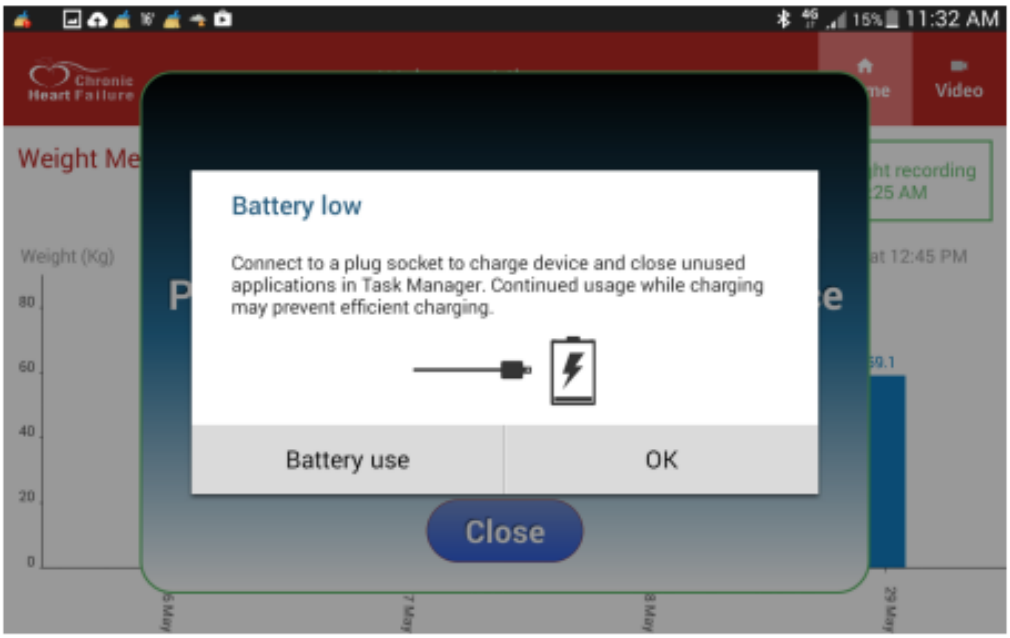
"Your weight has changed by 5 kg in the past 28 days. We will contact you as required."



6.6 LOW BATTERY REMINDERS

If the tablet battery level falls below 15%, you will receive a reminder on your touch screen tablet (as shown below) and a voice prompt.

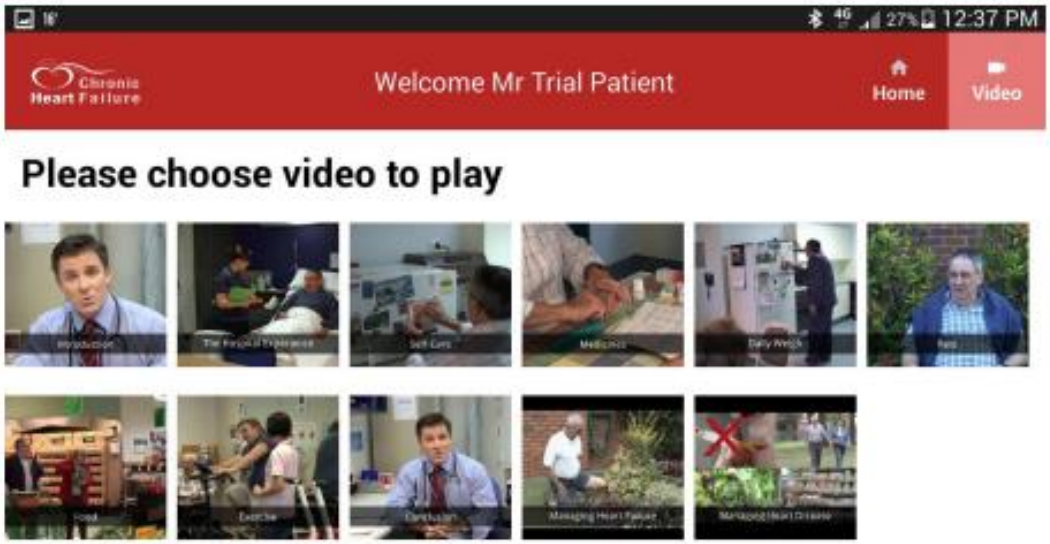
The tablet needs to be plugged in to a power source using the USB cable and power adaptor provided.



6.7 CHRONIC HEART FAILURE VIDEOS

You have the option to view Chronic Heart Failure videos on your touch screen tablet application. These resources will provide education and information about how to manage heart failure.

Tap on the 'Video' button and the following screen is displayed showing all of the videos that you are able to view.



The following is a list of videos which can be played,

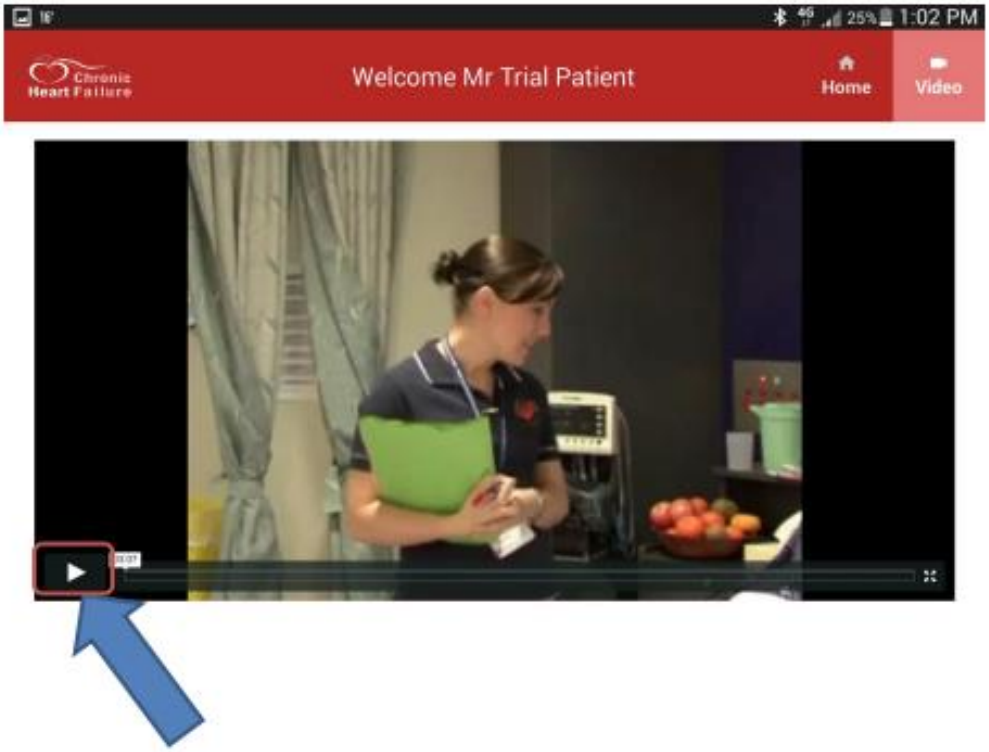
- 1 – Introduction
- 2 - The Hospital Experience
- 3 - Self-Care
- 4 - Medicines
- 5 - Daily Weigh
- 6 - Rest
- 7 - Food
- 8 - Exercise
- 9 - Conclusion
- 10 - Simple Steps for Managing Heart Failure
- 11 - Simple Steps for Managing Heart Disease

6.7.1 TO PLAY A VIDEO

To play any of the videos, simply tap on the corresponding video.

Once the video screen loads, tap the **Play** button to start playing the video.

Note: The selected video may take while to load the initial screen, after tapping on the video.



The "Play" button

6.7.2 TO STOP PLAYING A VIDEO

If you need to stop playing a video or you want to play a different video, simply tap the video button (as shown below):-

Pressing the video button will allow you to return to the list of videos. You can now either stop playing the currently playing video and/or choose to play another video.

Once viewing of the videos has been completed, press the 'Home' button to return back to the weight charts display. It is recommended to have the 'Home' view or the weight chart view all the times on your tablet display.

7. TROUBLESHOOTING GUIDE

7.1 TROUBLESHOOTING THE WEIGHT SCALES

Your scale takes four 1.5V AAA alkaline batteries. These will be supplied with your scale.

DISPLAY SCREEN SHOWS Lo MESSAGE

If the following message comes up on your scale, then the batteries needs to be replaced.

Technicians at MEPACS will be able to help you with the problem.

To speak to a technician, contact the MEPACS Helpdesk on **1800 451 300.**

Tell the Helpdesk operator that you are a participant in the Chronic Heart Failure Study and that you have a problem with your weight scales.

When you are speaking with the technician, you will be asked questions about your weight scale so they can determine what the issue is.

If your display screen is showing a **Lo** message, then your batteries will need replacing.

When speaking with the MEPACS Helpdesk operator, be sure to tell the operator that you are a participant in the Chronic Heart Failure Study and you are calling about a problem with your weight scale.

If any other error message comes up on the screen of your weight scales, contact the MEPACS Helpdesk on **1800 451 300** to report the problem.

DO NOT ATTEMPT TO REPLACE the battery without contacting the MEPACS Helpdesk.

The MEPACS Helpdesk will need to know if the batteries have gone flat in your weight scale and will assist you in replacing them.

7.2 TROUBLESHOOTING THE TOUCH SCREEN TABLET

If you cannot see anything on the screen of your touch screen tablet (that is, the screen is black or blank), then contact a technician at MEPACS to help you with the problem.

To speak to a technician, contact the MEPACS Helpdesk on **1800 451 300.**

Tell the Helpdesk operator that you are a participant in the Chronic Heart Failure Study and that you have a problem with your touch screen tablet.

When you are speaking with the technician, you will be asked questions about your touch screen tablet so they can determine what the issue is.

If you have any other issues with using the touch screen tablet, please contact the MEPACS Helpdesk on **1800 451 300** and report the problem.

7.3 RESET TABLET MANUALLY

The tablet does not register your weight reading, it may need a manual reset. Reset should be done during 4 am to 11:30 a.m. in the morning.

Manual reset can be done by pressing the Power button for more than 7 seconds to restart the tablet.

Click on Restart. Tablet should get restarted.

After Restart it brings you back to the application.

Now weigh again. Weight should get transferred to tablet. In case it doesn't not get transferred then please call MEPACS.

Appendix 20 - Study 3: Participant Evaluation Form (1 of 2)

The Innovative Telemonitoring Enhanced Care program for CHF (ITEC-CHF)
Participant Evaluation Form

Thank you for participating in the Chronic Heart Failure Study.
The study team would appreciate your feedback on your experiences as a participant of the Chronic Heart Failure Study. This will help us identify what worked well and what did not work so well. This information will be very helpful for our planning of future research studies.
Once you have completed the questions, please return the form to the research nurse.
Please indicate your rating of the following statements by circling the appropriate number, using the following scale:-
1=strongly disagree
2=disagree
3=neither agree nor disagree
4=agree
5=strongly agree

	Statement	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
1	The weighing scale was easy to use	1	2	3	4	5
2	The touch screen tablet was easy to use	1	2	3	4	5
3	The technology helped me to manage my chronic heart condition	1	2	3	4	5
4	I feel more confident about managing my chronic heart failure after taking part in this research project	1	2	3	4	5
5	I found the weight reminders helpful on the touch screen tablet	1	2	3	4	5
6	I found the medication reminders helpful on the touch screen tablet	1	2	3	4	5

Appendix 21 - Study 3: Participant Evaluation Form (2 of 2)

7	I found the symptom questions easy to respond to on the touch screen tablet	1	2	3	4	5
8	When I forgot to weigh myself, I found the reminder calls from MEPACS helpful	1	2	3	4	5
9	When my weight changed, I found the call from the Chronic Heart Failure nurse helpful	1	2	3	4	5
10	The information given to me in how to weigh myself using the device was easy to understand	1	2	3	4	5

1. What did you find most beneficial about participating in the study?

.....

.....

2. What did you find the most difficult about taking part in the study?

.....

.....

3. Do you have any suggestions on how we can improve the study to make it more helpful?

.....

.....

Appendix 22 – Chapter 3: Co-Authorship Contribution Form

Chapter 3: Chen SH, Boyd J, Randall S, Maiorana A. Association between community-based nurse practitioner support, self-care behaviour and quality of life in patients with chronic heart failure. Australian Journal of Advanced Nursing. 2021;38(3). DOI https://doi.org/10.37464/2020.383.147

Author 1: Chen SH 60%	• Participant recruitment and data collection. • Conception and design of analysis and interpretation of data. • Drafting the article and revising it critically for important intellectual content. • Final approval of the version to be published.
Author 2: Boyd J 5%	• Conception and design of analysis and interpretation of linked data. • Revising critically for important intellectual content. • Final approval of the version to be published.
Author 3: Randall S 5%	• Conception and design of analysis and interpretation of linked data. • Revising critically for important intellectual content. • Final approval of the version to be published.
Author 4: Maiorana A 30%	• Conception and design of analysis and interpretation of data • Revising critically for important intellectual content. • Final approval of the version to be published.

22/08/2023

Signed PhD candidate Date

Guarantor

I certify the fidelity of the above authorship and act as guarantor for all data

23/08/2023

Primary Supervisor Date

Appendix 23 – Chapter 4: Co-Authorship Contribution Form (1 of 2)

Chapter 4: Ding H, **Chen SH***, Edwards I, Jayasena R, Doecke J, Layland J, Yang I, Maiorana A. The effects of different telemonitoring strategies in chronic heart failure care: a systematic review and subgroup meta-analysis. Journal of Medical Internet Research: 2020; 22(11) e20032. doi: 10.2196/20032

*The candidate contributed equally with Ding, H as co-primary author of this paper.

Author 1: Ding H 35%	• Conception and design of analysis and interpretation of data. • Literature searching and analysis including allocating the article to subtopics, developing and validating the review protocol, searching the literature, screening for inclusion, assessing quality, extracting data, analysing and synthesising data. • Revising the manuscript critically for important intellectual content • Final approval of the version to be published.
Author 2: Chen SH 35%	• Literature searching and analysis including allocating the article to subtopics, developing and validating the review protocol, searching the literature, screening for inclusion, assessing quality, extracting data, analysing and synthesising data. • Drafting the manuscript and revising it critically for important intellectual content. • Final approval of the version to be published.
Author 3: Edwards I 5%	• Revising critically for important intellectual content. • Final approval of the version to be published.
Author 4: Jayasena R 5%	• Revising critically for important intellectual content. • Final approval of the version to be published.
Author 5: Doecke J 2%	• Revising critically for important intellectual content. • Final approval of the version to be published.
Author 6: Layland J 2%	• Revising critically for important intellectual content. • Final approval of the version to be published.
Author 7: Yang I 1%	• Final approval of the version to be published.
Author 8: Maiorana A	• Data analysis.

Appendix 24 – Chapter 4: Co-Authorship Contribution Form (2 of 2)

15%	• Drafting the article or revising it critically for important intellectual content • Revising critically for important intellectual content. • Final approval of the version to be published.

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Appendix 25 – Chapter 5: Co-Authorship Contribution Form (1 of 2)

Chapter 5: Ding H, Jayasena R, Maiorana A, Dowling A, **Chen SH**, Karunanithi M, Layland J, Edwards I. Innovative Telemonitoring Enhanced Care Programme for Chronic Heart Failure (ITEC-CHF) to improve guideline compliance and collaborative care: protocol of a multicentre randomised controlled trial. BMJ Open. 2017 Oct 8;7(10):e017550. doi: 10.1136/bmjopen-2017-017550. PMID: 28993389; PMCID: PMC5640081.

Author 1: Ding H 30%	• Design of project methodology including data analysis. • Drafting the article or revising it critically for important intellectual content • Final approval of the version to be published.
Author 2: Jayasena R 10%	• Design of project methodology • Revising critically for important intellectual content. • Final approval of the version to be published.
Author 3: Maiorana A 20%	• Design of project methodology • Revising critically for important intellectual content. • Final approval of the version to be published.
Author 4: Dowling A 5%	• Design of project methodology • Revising critically for important intellectual content. • Final approval of the version to be published.
Author 5: Chen SH 20%	• Design of project methodology • Revising critically for important intellectual content. • Final approval of the version to be published.
Author 6: Karunanithi M 3%	• Revising critically for important intellectual content. • Final approval of the version to be published.
Author 7: Layland J 2%	• Revising critically for important intellectual content. • Final approval of the version to be published.
Author 8: Edwards I 10%	• Design of project methodology • Revising critically for important intellectual content. • Final approval of the version to be published.

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Appendix 26 – Chapter 5: Co-Authorship Contribution Form (2 of 2)

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Appendix 27 – Chapter 6: Co-Authorship Contribution Form (1 of 2)

Chapter 6: Ding H, Jayasena R, **Chen S**, Maiorana A, Dowling A, Layland J, Good N, Karunanithi M, Edwards I. The Effects of Telemonitoring on Patient Compliance with Self-Management Recommendations and Outcomes of the Innovative Telemonitoring Enhanced Care Program for Chronic Heart Failure: Randomized Controlled Trial. J Med Internet Res. 2020;22(7): e17559.

Author 1: Ding H 40%	• Design of analysis and interpretation of data. • Drafting the article or revising it critically for important intellectual content. • Final approval of the version to be published.
Author 2: Jayasena R 5%	• Revising critically for important intellectual content.
Author 3: Chen S 40%	• Recruitment, intervention delivery and data collection. • Analysis and interpretation of data. • Drafting the article or revising it critically for important intellectual content.
Author 4: Maiorana A 20%	• Analysis and interpretation of data. • Revising critically for important intellectual content.
Author 5: Dowling A 15%	• Recruitment, intervention delivery and data collection • Revising critically for important intellectual content.
Author 6: Layland J 3%	• Revising critically for important intellectual content. • Final approval of the version to be published.
Author 7: Good N 1%	• Final approval of the version to be published.
Author 8: Karunanithi M 1%	• Final approval of the version to be published.
Author 9: Edwards I 5%	• Revising critically for important intellectual content. • Final approval of the version to be published.

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Signed PhD candidate Date

Appendix 28 – Chapter 6: Co-Authorship Contribution Form (2 of 2)

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Primary Supervisor Date

Appendix 29 – Chapter 7: Co-Authorship Contribution Form

Chapter 7: Chen SH, Edwards I, Jayasena R, Ding H, Karunanithi M, Dowling A, Layland J, Maiorana A. Patient Perspectives on Innovative Telemonitoring Enhanced Care Program for Chronic Heart Failure (ITEC-CHF): Usability Study. JMIR Cardio. 2021; 5(2):e24611. doi: 10.2196/24611. PMID: 34519663; PMCID: PMC8479597.

Author 1: Chen SH 60%	• Conception and design of analysis and interpretation of data • Drafting the manuscript and revising it critically for important intellectual content • Final approval of the version to be published.
Author 2: Edwards I 5%	• Revising critically for important intellectual content. • Final approval of the version to be published.
Author 3: Jayasena R 5%	• Revising critically for important intellectual content. • Final approval of the version to be published.
Author 4: Ding H 4%	• Revising critically for important intellectual content. • Final approval of the version to be published.
Author 5: Karunanithi M 1%	• Revising it critically for important intellectual content. • Final approval of the version to be published.
Author 6: Dowling A 3%	• Revising it critically for important intellectual content. • Final approval of the version to be published.
Author 7: Layland J 2%	• Revising it critically for important intellectual content. • Final approval of the version to be published.
Author 8: Maiorana A 20%	• Drafting the manuscript and revising it critically for important intellectual content • Final approval of the version to be published.

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