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Trial of a family-based education program for patients with heart failure and their carers in rural Thailand

Nittaya Srisuk

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Trial of a family-based education program for patients with heart failure and their carers in rural Thailand

Submitted by Nittaya Srisuk RN

A thesis submitted in total fulfilment of the requirements of the degree of Doctor of Philosophy

School of Nursing, Midwifery and Paramedicine
Faculty of Health Sciences
Australian Catholic University

September 2016
Candidate’s statement of originality

This thesis contains no material published elsewhere or extracted in whole or in part from a thesis by which I have qualified for or been awarded another degree or diploma.

No parts of this thesis have been submitted towards the award of any other degree or diploma in any other tertiary institution.

No other person’s work has been used without due acknowledgment in the main text of the thesis.

All research procedures reported in the thesis received the approval of the relevant ethics/safety committees.

Signed:

__________________________

Ms Nittaya Srisuk

Student ID No: S00140131

Date
Contribution to jointly published work

It is acknowledged that I collaborated within a research team and as such have been mentored and supported by this team’s members and others at Australian Catholic University for my research training and work.

The body of work for this program of research was conceptualised by me and undertaken for my PhD, and is therefore my own intellectual property.

It is acknowledged that while a number of researchers contributed in part to the publications included in this thesis, the actual research undertaken and preparation of the manuscript for publication were solely my own work.

It is acknowledged that all co-authors of jointly published papers included in this thesis provided their consent for the inclusion of each paper in this thesis and that the co-authors accept my contribution to the paper as so described in the statement of contribution to jointly published work by others. All other work included in this thesis not part of published papers or those accepted for publication are entirely my own work, except where duly acknowledged.

My contribution and the contribution of others to each of the published papers included in this thesis are outlined in the following statements.
Statement of contribution to jointly published work – Chapter Two


Nittaya Srisuk
- Conception and design of the literature search and data extraction
- Drafting the article and revising it for critically important intellectual content
- Approval of the final version for publication and submission of the article to the journal for publication

Jan Cameron
- Advised on conception of study
- Made critical revisions to draft versions for important intellectual content

Chantal F. Ski
- Advised on conception of study
- Made critical revisions to draft versions for important intellectual content

David R. Thompson
- Advised on conception of study
- Made critical revisions to draft versions for important intellectual content

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Statement of contribution to jointly published work – Chapter Three


Nittaya Srisuk
Conception and design of the literature search and data extraction
Drafting the article and revising it for critically important intellectual content
Approval of the final version for publication and submission of the article to the journal for publication

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David R. Thompson
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Publications by the candidate

Chapter Two: Literature review paper


Chapter Three: Protocol paper

Presentations by the candidate

Published abstract

Oral presentation

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Abstract

Introduction

Heart failure is a major public health problem, affecting over 26 million people worldwide. It is associated with a high rate of mortality, symptom burden and diminished quality of life. Best practice guidelines for the management of chronic heart failure recommend that patients and carers/family members are educated about heart failure self-care. Effective heart failure self-care has the potential to improve health outcomes. Studies conducted in Thailand addressing heart failure self-care are limited and none have investigated the potential benefits of education programs on the health outcomes of both parties within the dyad: the patient with heart failure and their carer.

Aims

The primary aim of this research was to examine the effectiveness of a family-based education program for patients with heart failure and their carers in rural Thailand. The research comprises a series of studies, each with specific aims: i) to investigate current heart failure family-based education provision – a global review, ii) to develop a family-based heart failure education program, and iii) to evaluate the effectiveness of this program in rural Thailand.

Methods

After completing a systematic review of the literature, a study protocol for development and evaluation of a culturally specific family-based education program was developed. A randomised controlled trial was then conducted in rural Thailand to examine the effectiveness of the program. For patients, the primary outcome was heart failure knowledge as measured by the Dutch Heart Failure Knowledge Scale (DHFKS). The main outcome for carers was perceived control over managing patients’ heart failure symptoms as measured by the Control Attitudes Scale-Revised (CAS-R). Secondary outcomes for patients were self-care as measured by the Self-Care of Heart
Failure Index (SCHFI) and health-related quality of life as measured by the Minnesota Living with Heart Failure (MLHF) questionnaire. For carers, additional outcomes were heart failure knowledge as measured by the Dutch Heart Failure Knowledge Scale (DHFKS) and health-related quality of life as measured by the Short Form 12-Item (SF-12) Health Survey. In total, 100 dyads from two public hospitals in Thailand were randomly assigned in a 1:1 ratio in blocks of 10 to the intervention (family-based education program) or usual care (control) group. The education group received usual care in addition to a family-based education program, which consisted of face-to-face education and counselling sessions, a manual, a DVD, and telephone support. Data were collected at baseline, three months, and six months.

**Results**

The systematic review identified six trials reported in nine papers. A dearth of HF studies was found that specifically developed and evaluated an education intervention for both patient and carer. There was a wide variation in the quality of the studies.

A family-based HF education program, underpinned by adult learning theory, was developed in strict adherence to CONSORT guidelines. This comprised a culturally specific heart failure manual and DVD that were reviewed for content and cultural validity by a Thai cardiologist and heart failure nurses; minimal changes were recommended.

Patients and carers in the education group (those who received the heart failure manual and DVD) had higher knowledge scores than the usual care group at three and six months ($p < 0.01$). Patients in the education group had better self-care maintenance, confidence, and quality of life scores than the usual care group ($p < 0.05$) at three and six months, as well as better self-care management scores ($p < 0.05$) at six months. Carers in the education group had higher perceived control over managing patients’ heart failure symptom scores than the usual care group ($p < 0.05$) at three months.
Conclusion

This is the first randomised controlled trial to evaluate a family-based heart failure education program developed for patients and their carers in rural Thailand. The education program improved heart failure knowledge (in patients and carers), patients’ self-care behaviours and emotional dimension of quality of life, and carers’ perceived control over managing patients’ heart failure symptoms. This program provides evidence supporting the positive influence of self-care education by engaging family members/carers. Despite the lack of access to heart failure disease management programs in rural Thailand, it may be possible to improve patient engagement in self-care through educational programs that can be easily introduced, guided and followed-up by a Thai nurse, and which are predominantly self-administered (i.e. manual and DVD) in the patient’s home.
Chapter One: Introduction

1.1 Overview

The purpose of this chapter is to provide a rationale for this research that investigates patients with heart failure (HF) and their carers in rural Thailand. It begins with a brief overview of HF, before focusing on the burden of this condition from both a national (i.e. Thailand, where this research was undertaken) and international perspectives. Discussion will focus on long-term HF management and the pivotal role of self-care, successful patient education approaches, and the essential role of the carer in assisting patient engagement in HF self-care. Furthermore, the evidence gap in HF patient education in Thailand will be explored along with Eastern cultural adaptations essential to the development of an educational self-care program. The chapter concludes with the research study aim, objectives, questions, and organisation of the thesis.

1.2 Definition and classification of HF

Heart failure is a complex syndrome characterised by symptoms such as shortness of breath at rest or during exertion and/or fatigue, signs of fluid retention such as pulmonary congestion or ankle swelling, and objective evidence of an abnormality in the structure or function of the heart at rest (McMurray et al., 2012). Classification of HF can be identified as HF with preserved (HFpEF; previously termed diastolic dysfunction) or reduced (HFrEF; previously termed systolic dysfunction) ejection fraction, terminologies used to explain differences in myocardial functioning (De Keulenaer & Brutsaert, 2007). The most common causes of HF are coronary artery disease, hypertension, and antecedent myocardial infarction as well as diabetes (Center for Disease Control, 2015; Lindenfeld et al., 2010; Go et al., 2014). An ageing population and advanced treatments for patients with cardiovascular disease have seen the prevalence of HF rapidly increase over the past decade (Liu & Eisen, 2014).

In 1928 the New York Heart Association (NYHA) published a classification of HF based on clinical severity and prognosis (Criteria Committee of the New York Heart Association, 1994).
(Table 1). This function classification system provides a simple way of classifying the severity of HF to assist when identifying the best course of treatment. This classification system relates symptoms to the degree of physical limitation experienced during daily activities (Criteria Committee of the New York Heart Association, 1994).

**Table 1: Criteria of NYHA function classification for patients with HF**

<table>
<thead>
<tr>
<th>Class</th>
<th>Patient symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>No limitations. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or angina pain.</td>
</tr>
<tr>
<td>II</td>
<td>Slight physical limitations. Ordinary physical activity results in fatigue, palpitation or dyspnea, or angina pain.</td>
</tr>
<tr>
<td>III</td>
<td>Marked physical limitations. Less than ordinary activity causes fatigue, palpitation or dyspnea, or angina pain.</td>
</tr>
<tr>
<td>IV</td>
<td>Inability to perform any physical activity without discomfort. If any physical activity is undertaken, discomfort is increased.</td>
</tr>
</tbody>
</table>

1.3 **The burden of heart failure internationally and in Thailand**

Heart failure is reaching epidemic proportions. Over 26 million people worldwide suffer from HF and it is expected to continue to escalate, making it a significant global public health problem (Ambrosy et al., 2014). Despite improvements in the pharmacological treatment of HF, mortality rates remain high; HF contributes to over 280,000 deaths per year in the United States (Mozaffarian et al., 2015). Hospital admissions for HF have also steadily increased, recognised now as one of the most common reasons for the elderly being admitted to hospital
(Yancy et al., 2013). Subsequently, the ramifications of HF as a substantial economic burden to healthcare systems are clear. It is the most expensive cardiovascular diagnosis billed to Medicare (Australian Institute of Health and Welfare, 2015; Torio & Andrews, 2013), and in light of the predicted escalating incidence, HF will continue to be a substantial drain on healthcare budgets into the future. In 2012 HF costs in the United States exceeded $30 billion, and they are expected to increase by 130% to reach $70 billion in 2030 (Mozaffarian et al., 2015).

The prevalence of HF in Australia is not dissimilar to that in Europe and the USA; between 350,000 and 400,000 Australians present annually with symptomatic HF (Chan et al., 2015). It is one of the most common reasons for hospitalisation and general practitioner consultation among elderly Australians (National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand, 2011). More than 45,000 Australians were hospitalised with HF in 2009 (AIHW, 2012). Estimates of the annual direct cost of managing HF are close to AU$900 million, with acute hospitalisations costed at AU$1.8 billion and total direct costs equating to approximately AU$2.7 billion (Chan et al., 2015). Australia’s population has been forecasted to increase to 43 million by 2056 with approximately one-quarter predicted to develop HF (National Heart Foundation of Australia, 2013).

Similarly, the increasing burden of cardiovascular disease in Thailand is substantial and a leading cause of death (Kaufman, Chasombat, Tanomsingh, Rajataramya, & Potempa, 2011). Accurate epidemiological statistics describing the burden of HF in Thailand are not available. The strongest evidence for the burden of HF is drawn from the Thai Acute Decompensated Heart Failure Registry (Thai ADHERE), a multi-centre open-label registry that is a collation of data from 18 cardiac centres in Thailand (Laothavorn et al., 2010). This registry provided evidence that HF is a major disabling cardiovascular health problem and economic burden. The Thai ADHERE epidemiological data collected between 2006 and 2007 identified 2041 HF-related admissions among 1612 patients. Also, in comparison with other HF registries, such as the US ADHERE, the Euro-Heart Failure Survey I (EHFS I), and the Euro-Heart Failure Survey II (EHFS II), Thai patients with HF were found to be younger, with an average age of 64 years compared with 73 years for the US ADHERE, 71 years for the EHFS I and 69.7 years for the EHFS II. In
addition, Thai patients had more severe clinical features such as dyspnoea (97%), fatigue (36%), peripheral oedema (60%), pulmonary rales (85%) and pulmonary congestion by chest X-ray (93%), and a high 6% in-hospital mortality rate. Clinical presentations and initial investigations on (re)admission included dyspnoea (97%), fatigue (36%), peripheral oedema (59%), pulmonary rales (84%) and pulmonary congestion by chest X-ray (93%) (Laothavorn et al., 2010). It is suggested that causes of these severe clinical presentations are associated with patients’ poor compliance or inadequate education (Laothavorn et al., 2010). Of significance is compelling evidence of systematic review of randomised controlled trials (RCTs) from studies conducted in Westernised countries that HF education may improve quality of life and prevent unplanned hospital readmissions (Ditewig, Blok, Havers, & van Veenendaal, 2010; McAlister, Stewart, Ferrua, & McMurray, 2004; Wakefield, Boren, Groves, & Conn, 2013).

1.4 Management of heart failure

The general features of evidence-based treatments for HF consist of both pharmacological and non-pharmacological interventions, such as angiotensin converting enzyme (ACE) inhibitors, beta blockers, mineralocorticoid/aldosterone receptor antagonists, diuretics, implantable devices and surgical procedures (McMurray et al., 2012; National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand, 2011; Yancy et al., 2013). These treatment modalities have the potential to alleviate HF symptoms and improve the patient’s quality of life (Chen, Yin, & Krucoff, 2012; Shah, Desai, & Givertz, 2010). However, it is beyond the scope of this thesis to explain pharmacological treatment modalities, instead the focus will be to examine patient education, which is considered pivotal to the long-term management of this chronic condition.

Widely accepted HF practice guidelines for non-pharmacological interventions have been developed by the European Society of Cardiology (McMurray et al., 2012), the American College of Cardiology (Yancy et al., 2013), and the Canadian Cardiovascular Society (Malcom et al., 2008). In Australia, guidelines for prevention, detection, and management among people with HF have been developed on behalf of the National Heart Foundation of Australia (Krum et al.,
These guidelines provide explicit links between recommendations and supporting scientific knowledge intended to guide healthcare management and prevention of HF. All guidelines are directed towards improving quality of life, reducing unplanned hospital readmission and HF symptoms. Key to achieving all three is the promotion of an individual’s self-care abilities. One way to deliver such a message is increasing HF knowledge and building patient self-care skills through patient education. Nurses are considered a primary educator with a pivotal role in delivering HF education to patients and their family members/carers (Albert et al., 2014; Lupon et al., 2008; Martensson, Stromberg, Dahlstrom, Karlsson, & Fridlund, 2005).

Systematic reviews, including meta-analyses, have provided solid evidence that nurse-led multidisciplinary approaches to HF management can reduce the rate and cost of hospital readmissions (Gonseth, Guallar-Castillon, Banegas, & Rodriguez-Artalejo, 2004; Lambrinou, Kalogirou, Lamnisos, & Sourzi, 2012; McAlister et al., 2004), improve quality of life (Jovicic, Holroyd-Leduc, & Straus, 2006; Wakefield et al., 2013), and reduce associated mortality (Gonseth et al., 2004). Nurse-led approaches to HF disease management include delivering interventions through various modalities such as specialist nurse-led clinics, multi-component outpatient HF clinics, home-based disease management programs (DMPs), and telephone support (Lambrinou et al., 2012; Phillips, Singa, Rubin, & Jaarsma, 2005; Wakefield et al., 2013). These treatment modalities are considered the gold standard for non-pharmacological disease management for HF in Westernised countries (Krum, Jelinek, Stewart, Sindone, & Atherton, 2011; McMurray et al., 2012; Yancy et al., 2013), yet are not routinely provided in Thailand. A meta-review of evidence for HF DMP, which included 15 meta-analysis studies (Savard, Thompson, & Clark, 2011), demonstrated that most of the programs reviewed had three or four components (mean of 1.13). The most common components of nurse-led HF DMP trials appear to be education, home visits and phone support. This meta-review highlights the complexity and heterogeneity of HF DMP, making it difficult to draw firm conclusions as to which one element is the most effective. Nonetheless, patient education appears to be the foundation of all these heterogeneous approaches (Savard et al., 2011). Significant improvements in health
outcomes are evident when patient education has been applied, and these include: increased HF knowledge, HF self-care behaviours, quality of life (Boyde, Turner, Thompson, & Stewart, 2011; Ditewig et al., 2010); and decreased HF readmissions (Ditewig et al., 2010; Jovicic et al., 2006; Savard et al., 2011). However, it is still unclear which single intervention or component confers the most effect (Clark & Thompson, 2010; Wakefield et al., 2013; Savard et al., 2011).

1.5 Patient education – the foundation of HF disease management

Patient education aims to improve patient knowledge and skills in an effort to increase self-efficacy and positively influence attitudes towards self-supporting health behaviours. Engagement in appropriate lifestyle behaviours can result in significant health improvements (Rankin, Stallings, & London, 2005). With respect to understanding the HF disease trajectory, increased knowledge can empower patients to adhere to treatment regimens and motivate them to make the necessary adaptations and lifestyle changes appropriate to their circumstance, which is likely to improve an individual’s self-confidence, sense of control, and mastery (Moser & Riegel, 2001).

Heart failure has an enormous impact on patients’ physical functioning, psychosocial well-being and daily life activities (Hoekstra et al., 2013; Holland, Rechel, Stepien, Harvey, & Brooksby, 2010). International practice guidelines regarding non-pharmacological HF interventions recommend that patients with HF, and their carers, should be educated on the topics presented briefly in Table 2 (Heart Failure Society of America, 2010; Malcom et al., 2008; McMurray et al., 2012; National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand, 2011). The American Heart Association state of science statement promoting self-care provides details of the essential characteristics of these behaviours (Riegel et al., 2009). One of the vital components of this statement relates to the interventions that promote self-care skill where knowledge is underlined as an essential requirement in achieving successful self-care behaviours. Understanding the implications of HF can help patients achieve several objectives including: reducing the possibility of non-adherence to pharmacotherapy regimens and recommended lifestyle changes; monitoring behaviours; improving clinical
Patient education has received significant research attention resulting in several systematic reviews of RCTs and qualitative studies examining the effectiveness of patient education on HF health outcomes (Barnason, Zimmerman, & Young, 2012; Boren, Wakefield, Gunlock, & Wakefield, 2009; Boyde et al., 2011; McAlister et al., 2004; Wakefield et al., 2013). Although the evidence is compelling as to the importance of patient education, most studies investigating patient education have been conducted in the United States and Europe where the characteristics of the population and the culture are often quite different from those in Asia, including Thailand (and especially rural Thailand). The evidence gap in HF education in Thailand will be discussed further on.

**Table 2: Summary of recommended HF education topics and self-care behaviours**

<table>
<thead>
<tr>
<th>Education topic</th>
<th>HF self-care behaviours</th>
</tr>
</thead>
<tbody>
<tr>
<td>General advice</td>
<td>Etiology, cause, and prognosis of HF, signs and symptoms of HF</td>
</tr>
<tr>
<td>Symptom monitoring</td>
<td>Monitoring signs and symptoms, recognising signs and symptoms, self-monitoring, knowing when to notify healthcare provider</td>
</tr>
<tr>
<td>Medication</td>
<td>Understanding dose and effects, recognising the common side effects of each drug prescribed, what to do in case of skipped dose, self-management, drugs to avoid, importance of drug adherence, immunisation against influenza and pneumococcal disease</td>
</tr>
<tr>
<td>Weight control</td>
<td>Recording daily weight and recognising rapid weight gain, knowing how to report sudden increase or decreases in weight</td>
</tr>
</tbody>
</table>
Sodium restriction  Restricting sodium intake to 2000 mg/day

Fluid  Monitoring fluid intake and when to increase or decrease

Smoking and alcohol consumption  Quitting smoking, limiting alcohol intake and rationale

Exercise  Exercising and rehabilitation, sexual activity

Travel  Knowing what to prepare when travelling and places to avoid

1.6 Incorporating the principles of adult learning in the development of a family-based education program

Because patient education is recognised as the foundation of the long-term management of HF, it is important for patient educational approaches to be underpinned by a theoretical framework (Syx, 2008). For this particular research, development of a family-based education program for patients with HF and carers in rural Thailand, Knowles’ (1984) adult learning theory was deemed the most appropriate theory. This theory was developed to assist those who design and develop learning interventions specifically for adult learners, who constitute the centre of the process of tailored education (Knowles, Holton III, & Swanson, 2005).

Patients with HF require knowledge and skills to facilitate their understanding of treatment plans and assimilate self-care behaviours into their daily routines. They are expected to manage their own care and collaborate with their healthcare teams to improve their quality of life and stay out of hospital. However, the HF education approach that achieves the best outcomes is yet to be clearly identified (Boyde et al., 2011; Cameron, Worrall-Carter, Driscoll, New, & Stewart, 2007). Patient-centred care is care that is directed towards the patient, not the disease. It enhances growth in patient knowledge and in their capacity to successfully manage
their own care (Greene, Tuzzio, & Cherkin, 2016). Knowles (1984, p. 12) suggests five principles to be applied to adult learning:

1. Self-concept: as a person matures, his self-concept moves from a dependent personality to a self-directed human being.

2. Experience: as a person matures he accumulates a growing reservoir of experience that becomes an increasing resource for learning.

3. Readiness to learn: as a person matures his readiness to learn becomes oriented increasingly to the developmental tasks of his social roles.

4. Orientation to learning: as a person matures his time perspective changes from one of postponed application of knowledge to immediacy of application, and accordingly his orientation towards learning shifts from subject-centredness to problem centredness.

5. Motivation to learn: as a person matures the motivation to learn is internal.

The first principle behind the theory is that adult learning is self-concept, that is, adults are independent, autonomous, and direct their own learning (Knowles, 1984). When they assimilate knowledge and skills to produce change, they are actively applying the principles of self-direction (Brookfield, 1986). It is possible to achieve self-direction by including self-reflection among the learning strategies or mutual goal setting between healthcare providers and patients or carers (Brookfield, 1986).

The second principle in adult learning theory is experience, that is, previous life experiences are a rich resource for adult learning (Knowles, 1984). Previous learning and the experiences of adults have a subsequent influence on learning strategies. It is proposed that adults create knowledge by transforming previous experience (Kolb, Boyatzis, & Mainemelis, 2001). In relation to HF, experience is highlighted as a key factor that influences self-care decisions and behaviours (Cameron, Worrall-Carter, Page, & Stewart, 2010; Riegel, Lee, & Dickson, 2011; Zavertnik, 2014). Evidence has shown that patients who have more experience tend to perform self-care more effectively and have a lower risk for hospital readmission than
newly diagnosed HF patients (Carlson, Riegel, & Moser, 2001). In a descriptive study involving 143 elderly patients with HF, which aimed to examine differences in self-care skills between novices (diagnosis of HF less than two months) and patients more experienced in living with HF, the findings revealed that experienced patients reported significantly higher self-care maintenance and self-care management SCHFI scores than novices (Cameron et al., 2010). Another prospective cohort study involving 146 patients with moderate and advanced HF found that novice patients (SCHFI score less than 40) reported poorer self-care on all aspects (self-care maintenance, self-care management, and self-care confidence) compared with experienced patients (Lee et al., 2015). In a systematic review and meta-synthesis of qualitative studies involving 1377 patients, experience in living with HF was a critical factor in developing an adequate self-care behaviour skill level (Harkness, Spaling, Currie, Strachan, & Clark, 2014).

The third principle in adult learning theory is that adults must be ready to learn (Knowles, 1984). Many factors influence adults’ readiness to learn including developmental stage, personal beliefs or attitudes, cultural influences and perceived threats to health (Merriam, 2001). Patients with HF respond negatively when they are ‘told what to do’ or are given too much information when they are anxious (Riegel & Carlson, 2002). Other factors that impact on patients’ readiness to learn and engagement in HF self-care include age-related and biomedical conditions, knowledge deficits, gender-specific barriers, socioeconomic conditions and the healthcare system (Holden, Schubert, & Mickelson, 2015; Jerant, von Friederichs-Fitzwater, & Moore, 2005; Riegel & Carlson, 2002; Riegel et al., 2010).

The fourth principle behind adult learning is ‘orientation to learning’, that is, adults learn best through problem-solving or contextual learning (Knowles, 1984). Educational interventions that relate to immediate problems are more likely to enhance learning strategies (C. C., Doak, L. G., Doak, & Root, 1996). In the context of HF, worsening symptoms such as shortness of breath and ankle swelling fit the contextual discussions on fluid or sodium restriction and the importance of daily weighing. For example, a RCT examined the effects of a sliding scale diuretic titration protocol as one of the successful problem-solving-oriented programs (Prasun, Kocheril, 2019).
Klass, Dunlap, & Piano, 2005). In this study, patients were randomised to either the usual care group \( (n = 31) \) or the flexible diuretic titration group \( (n = 35) \). The patients in the latter group were trained to monitor and assess their fluid-related symptoms using a self-directed diuretic titration protocol and subsequently adjust their diuretic dose in relation to these symptoms. After three months, this group demonstrated significant improvement in 6-minute walking distance and quality of life, while this was not observed in the usual care group. Moreover, the patients in the diuretic titration group demonstrated significantly fewer emergency department visits compared with those in the usual care group (Prasun et al., 2005). In previous cardiac educational interventions, problem solving has been adopted using combinations of the following components (DeWalt et al., 2006; Prasun et al., 2005; Wang et al., 2014):

1. providing scenarios and asking patients how they would deal with problems;
2. inviting patients to repeat what they have learnt;
3. testing their recall, comprehension and application of the educational materials provided.

The fifth principle behind adult learning is ‘motivation to learn’, which acknowledges that there are internal rather than external factors that motivate adults to learn (Knowles, 1984). That is, the individual makes their own choice to engage in learning activities. The Health Belief Model (Janz & Becker, 1984) and Model of Self Care of Chronic Illness (Connelly, 1993) support this view, as adults need to perceive the benefit or value of behaviour change in order to embrace it. Patients with more severe clinical symptoms of HF are more likely to be motivated to engage in self-care behaviours than those with fewer symptoms (Davis, Himmelfarb, Szanton, Hayat, & Allen, 2015). Riegel and Carlson (2002) investigated the factors associated with facilitators and barriers of patients with HF to perform self-care and found that the most important factor that motivated patients to practice self-care was a desire to stay out of hospital (Riegel & Carlson, 2002). These five principles were applied in the development of the HF education program in the current study (see Chapter Three).

Even though adult learning theory is widely accepted it should be noted that both the individual learner and the situation in which the learning occurs will impact on the learning
experience. In terms of patients with HF, individual differences such as gender, race, and culture have been shown to greatly influence learning and engagement in HF self-care. For example, a mixed method study involving 27 adults (eight women) that investigated gender-specific barriers and facilitators studying self-care found that women have more difficulty interpreting their HF symptoms than men (Riegel et al., 2010b). A secondary analysis of a cross-sectional study involving 2082 patients (1306 men, 776 women) from the United States, Australia, and Thailand compared gender differences in HF self-care (SCHFI) (Lee et al., 2009). Overall, the findings revealed that men who are newly diagnosed with HF demonstrated difficulty to perform all aspects of self-care (self-care maintenance, self-care management, and self-care confidence), whereas women only had difficulty performing self-care management. Generally, women with diastolic HF had poorer self-care maintenance and self-care confidence. In contrast to the entire population, a sub-group analysis of Thailand found that men had poorer self-care confidence than women (Lee et al., 2009). This may be due to the culture of Thailand, in which men and women are expected to play difference roles (Pinyuchon & Gray, 1997). Eastern versus Western cultural contexts and differences between healthcare systems were a primary consideration in the development of the HF family-based education program for patients and their carers for application in rural Thailand, details of which are presented in Chapter Three.

1.7 Heart failure self-care

The goal of self-care in HF is to encourage patients with HF to develop self-care skills during any stage of this chronic condition. The most widely used self-care theory in HF is the situation-specific theory of HF self-care that provides a framework for understanding and evaluating the competencies of patients with HF (Riegel & Dickson, 2008). This theory describes the process patients adopt in coping with HF, in which the healthcare provider and family are essential sources of support (Riegel & Dickson, 2008). Self-care in HF is described as a natural decision-making process involving the behaviour choices patients make to maintain physiological stability, self-care maintenance, and the responses executed when symptoms
occur (Riegel et al., 2004). Self-care confidence has been acknowledged to influence the relationship between HF self-care and health outcomes – high levels of confidence result in better engagement in self-care maintenance and management and consequently better health outcomes. The key behaviours in HF self-care are maintenance and management. To sustain their physiological stability, patients with HF are required to adhere to a complex daily medication regimen with multiple tablets at different times throughout the day, and to ‘body watch’ for signs of oedema, increasing fatigue, or shortness of breath. These behaviours are considered self-care maintenance. Self-care management is an active process consisting of four stages: symptom recognition, symptom evaluation, treatment implementation, and treatment evaluation. This is a decisional process through which, in the event of recognition of deleterious changes in HF symptoms, the patient considers taking an appropriate course of action to reduce the symptom, such as taking an additional diuretic, reducing fluid intake, resting, or reporting the change to a healthcare professional (Riegel & Dickson, 2008).

Recently, the situation-specific theory of HF self-care has been revised and updated (Riegel, Dickson, & Faulkner, 2015). Table 3 shows the differences between the original situation-specific theory of HF self-care and the updated and revised version. Three major updates to this theory are:

1. ‘Symptom perception’ has been added to the self-care process. Symptom perception refers to symptom monitoring and recognition in addition to body listening, symptom interpretation, and labelling. This concept arises from difficulties patients experience recognising and interpreting HF symptoms. Difficulties due to age-related impairment and the complex nature of HF symptoms, which occur in a cluster, are the main reasons for adding symptom perception to the theory. The authors expect that understanding this mechanism will assist healthcare providers to better help patients recognise and interpret their HF symptoms.

2. Each self-care process (maintenance, symptom perception, and management) involves autonomous and consultative self-care behaviours; independent behaviours
and decisions or those influenced by healthcare or care providers’ suggestions. This indicates that carers play an important role in HF self-care. Consequently, carers may experience an increase burden, both physically and mentally, particularly if they have their own illnesses and lack of social and professional support. However, it appears that there are only a few studies on developing the intervention addressing an HF carer’s health outcome (Stromberg, 2013).

3. Self-care maintenance, symptom perception, and management are influenced by the individual’s decision-making process. Patients make decisions about HF self-care under different circumstances every day and, consequently, self-care is not maintained consistently over time. That is, patients who are experts in self-care may fail at any time. Moreover, several factors impede patient engagement in self-care, including personal factors (e.g. cultural beliefs, health literacy, socioeconomic circumstances), problematic factors (e.g. comorbidity, lack of knowledge, poor physical functioning, cognitive impairment), and environmental factors (e.g. lack of social support, living in rural areas) (Riegel & Moser, 2015). As a result, these barriers may impede engagement in self-care with sub-optimal adherence to self-care behaviours (Riegel et al., 2009).

Table 3: Differences between the original situation-specific theory of heart failure (HF) self-care (2008) and the revised version (2015)

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Naturalistic decision-making processes that influence actions that maintain physiologic stability, facilitate the perception of symptoms,</td>
</tr>
</tbody>
</table>
and direct the management of those symptoms. symptoms when they occur (management).

<table>
<thead>
<tr>
<th>Self-care process</th>
<th>1. Maintenance: captures treatment adherence and healthy behaviours</th>
<th>1. Self-care maintenance: reflects behaviour used to maintain physiologic stability-symptom monitoring and treatment adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Example of activities:</strong> taking medications, exercising, and following a salt-restricted diet</td>
<td><strong>Example of activities:</strong> following the advice of providers to follow the treatment plan and live a healthy lifestyle</td>
</tr>
<tr>
<td></td>
<td>2. Management, or the response to symptoms when they occur</td>
<td>2. Self-care management refers to the decision-making response to symptoms when they occur, including five stages: 1) symptom monitoring, 2) symptom recognition, 3) symptom evaluation, 4) treatment implementation, 5) treatment evaluation</td>
</tr>
<tr>
<td></td>
<td><strong>Example of activities:</strong> recognising a status change (e.g. new swelling), evaluating the change in status, deciding to take action, implementing a treatment strategy (e.g. taking an extra diuretic dose),</td>
<td></td>
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and evaluating the treatment implemented

3. Symptom perception: involves both the detection of physical sensations and the interpretation of meaning. Specifically, symptom perception involves body listening, monitoring signs, as well as recognition, interpretation, and labelling of symptoms

**Example of activities:** “you have to listen to your body, you have to listen to what it tells you; if the ring gets real tight then I’ll know I’m holding fluid”

| Naturalistic decision making characteristics of self-care | All three processes involve both autonomous and consultative elements | Confidence as a mediator and/or a moderator of the relationship between self-care and outcomes rather than a core component of self-care itself |

**1.7.1 Self-care adherence: the ultimate goal**

Importantly, appropriate engagement in HF self-care has the potential to decrease HF readmissions, healthcare costs, and improve patients’ health-related quality of life (HRQoL) (McAlister et al., 2004; Jovicic et al., 2006; Ditewig et al., 2010). Successful adherence to self-care management contributes to a 56% reduction in the risk of all-cause mortality, readmission, or emergency room admission compared with those with inadequate self-care (Lee, Moser,
Lennie, & Riegel, 2011). However, self-care is not an easy process to master, with only 10.3% of patients with HF being experts in self-care, and the ramifications of non-adherence to self-care are well documented (Riegel, Vaughan Dickson, Goldberg, & Deatrick, 2007). One large study involving 2082 patients from the United States, Australia, Mexico, and Thailand found that self-care was inadequate (Riegel et al., 2009).

Patients with HF are expected to recognise and interpret insidious changes in HF symptoms. They are also expected to confidently decide on an appropriate course of action to reduce the severity of given HF symptoms (for instance, shortness of breath and a sudden weight increase of two kilograms), thereby reducing their risk of being readmitted to hospital (Davidson, Inglis, & Newton, 2013). Unfortunately, most patients lack the skills to translate self-care into practice. A longitudinal survey of self-care behaviour in 88 patients found that self-care maintenance (e.g. daily weighing) improved over time, but this improvement did not contribute to decision making about self-care management (e.g. adjustment of diuretic dose) (Goodman, Firouzi, Banya, Lau-Walker, & Cowie, 2013). A study of medical records in 2587 hospitalised patients regarding the factors associated with delays in seeking medical care found that patients who had experienced fewer than three acute HF symptoms were more likely to seek prompt medical care than patients who experienced three or more HF symptoms (Goldberg et al., 2008). Those patients typically endured increasing symptoms over four days to a week before going to hospital. It is believed that symptom interpretation and detection among patients is complex. Jurgens (2006) defines this process as somatic awareness, assuming that the variability and severity of HF symptoms has the potential to impair patients’ symptom interpretation and the development of a reliable cognitive experience (Jurgens, 2006). Riegel et al. (2010a, p. 93) hypothesise that a lack of ability to detect and interpret HF symptoms is caused by “poor interoception – the process by which sensory nerve receptors receive and process stimuli that originate inside the body”. A study was conducted to test this hypothesis. Patients were divided into either the younger group (<73 years) or the older group (>73 years) and were stimulated using a 6-minute walk test. Shortness of breath was compared, 1) by the patient’s ability to perceive exertion, and 2) by the gold standard rating scale as recorded by a
trained registered nurse. This hypothesis was supported by the results of the study, which found that younger patients had a higher ability to detect and interpret internal physical symptoms than older patients. Older patients who had poor interoception because of a loss of cortical function in the brain had less ability to perceive HF symptoms (Riegel et al., 2010a).

While physiological factors such as age-related symptom recognition impede detection and interpretation of HF symptoms, non-compliance with HF self-care on other aspects is also largely reported. A cohort study of 501 patients revealed that compliance with diet was 83%, fluid restriction was 73%, exercise was 39%, and weighing was 35% (van der Wal et al., 2006). Another cohort study of 557 patients found that non-adherence to HF medication regimens throughout the follow-up period (1.1 year) was approximately 50% (Fitzgerald et al., 2011). As a result, patients were at increased risk of mortality and hospital readmission. In a prospective study conducted by van der Wal et al. (2010), examining the association between non-adherence with HF self-care recommendations and health outcomes in 830 patients, adherence was measured at one month and 18 months. Findings revealed that non-adherence to only one recommendation placed patients at higher risk of mortality or readmission (HR 1.40: \( p = 0.01 \)). More specifically, non-adherence with daily weighing was associated with increased risk for mortality (HR 1.57: \( p = 0.02 \)), and non-adherence with daily weighing, sodium restriction, and fluid restriction, and non-adherence with exercise both had a higher risk of readmission (HR 1.38: \( p < 0.05 \) [overall] and HR 1.55: \( p < 0.01 \) [exercise]) (van der Wal et al., 2010). The evidence clearly shows that patients with HF struggle to comply with self-care regimens. However, a large body of data has found that social support from carers or family members enhances self-care and HF health outcomes (van der Wal et al., 2010).

### 1.7.2 The essential role of the carer in patient engagement in HF self-care

As discussed above, patient engagement in self-care is often sub-optimal and compounded by multiple comorbidities, cognitive impairment, functional limitations and psychosocial distress. These factors limit their ability to assimilate knowledge, impacting on their self-efficacy and motivation to translate what they have learnt into self-care skills (Dickson, Buck, & Riegel, 2011; Riegel et al., 2015). Hence, carers have a critical role in
supporting the patient in self-care and the long-term management of HF (Clark et al., 2014; Deek et al., 2015). An informal carer can be defined as someone who provides care with daily activities and/or medical administration to a recipient without pay (AIHW, 2015). As such, an informal carer can be a spouse, other family member, friend or neighbour.

The tasks that informal carers often assist with include maintaining activities of daily living such as bathing and dressing; instrumental activities of daily living such as shopping, transportation, housekeeping, and finances; and HF-related activities such as diet and fluid restrictions, medication compliance, recognition of signs and symptoms of worsening HF, and contacting health professionals for advice (Buck et al., 2015; Clark et al., 2014; Holden, Schubert, & Mickelson, 2015; Sethares, Sosa, Fisher, & Riegel, 2014; Wu et al., 2013). Patient health outcomes including HRQoL, rehospitalisation, adherence to HF treatment, and optimal engagement in self-care are strongly associated with the existence of carers (Arestedt, Saveman, Johansson, & Blomqvist, 2013; Vellone et al., 2014; Wu et al., 2013). A study investigating the role of social support in HF self-care involving 333 patients reported that patients with high levels of social support had significantly higher self-care scores than those with low or moderate levels of social support (Gallagher, Luttik, & Jaarsma, 2011). A systematic review of 15 studies examining the impact of social support on depressive symptoms in patients reported that 11 found that social support was able to reduce depressive symptoms (Graven & Grant, 2013). In contrast, a systematic review of 17 studies examining the relationship between social support and HF health outcomes (Luttik, Jaarsma, Moser, Sanderman, & van Veldhuisen, 2005) found that, of these, four studies reported that a lack of social support predicted future hospital readmission and mortality (Luttik et al., 2005a). The evidence of the critical role carers play in supporting HF patients is compelling. However, it is inevitable that carers will experience both positive and negative health outcomes.

1.8 Carer health outcomes

Although carers are considered a pillar of support in the HF care dyad, unfortunately they too often experience adverse effects, such as physical and emotional distress, poor quality of
life, and carer burden and strain (Bakas, Pressler, Johnson, Nauser, & Shaneyfelt, 2006; Pressler et al., 2009; Trivedi, Piette, Fihn, & Edelman, 2012). On the other hand, some studies have also found that carers experience positive effects when they are given attention, recognised, included in the care of patients, and encouraged (Mårtensson, Dracup, & Fridlund, 2001). More specifically, studies have found that including carers in discharge planning subsequently produces better quality of life and satisfaction (Bull, Hansen, & Gross, 2000a, 2000b). Even so, interventions addressing carers’ health outcomes are limited, an evidence by our systematic review reported in the following chapter. Only a limited number of HF studies (four) have developed and tested educational interventions that include informal carers. Two studies delivered education to patients and measured outcomes in both dyads (Srisuk, Cameron, Ski, & Thompson, 2016). Including carers is challenging for healthcare providers, who must find appropriate approaches that enhance their roles without adding burdens. One important aspect to consider when developing an intervention is cultural perspective, that is, healthcare providers must take into account the meaning and function of the family and the roles of social support and caring in different cultures (Stromberg, 2013).

1.9 Cultural context and its influence on HF self-care in Thailand

Cultural beliefs and behaviours influence individuals’ perception of disease aetiology, illness, and disease labels (Turner, 1996). Understanding diversity in cultures has the potential to facilitate healthcare provider interpretation of attitudes, values, beliefs, and behaviours, not only during illness but also in health (Davidson et al., 2007). Previous studies have demonstrated that sociocultural factors impact significantly on patients’ behaviours, in particular, HF self-care (Becker, Gates, & Newsom, 2004; Howie-Esquivel, Bibbins-Domingo, Clark, Evangelista, & Dracup, 2014; Jiang, Wu, Che, & Yeh, 2013). Culturally appropriate educational interventions have the potential to improve patients’ self-care behaviours (Davidson et al., 2007; Deek et al., 2015; Dickson & Riegel, 2009; Howie-Esquivel et al., 2014), thereby improving HF health outcomes.
The population structure of Thailand has changed to that of an ageing population, which is growing at a similarly rapid rate to developed countries (World Health Organization, 2012). By 2040, Thailand’s ageing population is expected to increase to 17 million, accounting for one-quarter of the entire population (Department of Economic and Social Affairs & Population Division, 2001). Thus, one in every four Thais will be a senior citizen. However, in Thailand, as in much of Asia, the family and adult children in particular have traditionally played the predominant role in providing old age care and support. Although demographic and socio-economic factors have changed dramatically in Thailand over recent decades, family members remain the foundation of support for elderly people (Knodel & Chayovan, 2008). Elderly people in Thailand are more likely to rely on family members and less likely to live alone than elderly people in Westernised countries (Australian Bureau of Statistics, 2013; Knodel, Prachuabmoh, & Chayovan, 2013; Vespa, Lewis, & Kreider, 2013). Furthermore, the elderly people in Thailand play an important role in supervising and conveying the folkway of life and culture through the younger generations. Living with older parents, showing them respect, and taking care of them are considered to be normal aspects of family life and are highly commended in Thailand (Knodel et al., 2013; Pinyuchon & Gray, 1997; Thanakwang, 2009). Importantly, elderly people who perceive that they have greater social support are more likely experience higher quality of life (Thanakwang, Ingersoll-Dayton, & Soonthorndhada, 2012; Thanakwang & Soonthorndhada, 2011). Attesting to the crucial role of family in social support of elderly Thai people, data on 24,664 elders indicate that information and emotional support are significantly associated with perceptions of good health and psychological well-being (Thanakwang, 2009).

The culture of Thailand is complex. It is a Buddhist country, and religion has a major influence on the daily lives of Thai people, shaping many aspects of individual behaviour. A phenomenological study of the day-to-day experience of living with HF in Thailand demonstrated the influence of cultural context on patients’ self-care behaviours (Chiaranai, 2014). For example, to assist them in coping with HF, patients in Thailand employ karma, a Buddhist belief, as a tool to rationalise their HF experiences (Chiaranai, 2014). Specifically, the participants in this study practised kreng jai, a cultural desire not to disrupt the happiness of
others (even at the expense of efficiency) or burden them. As a result, their own quality of life might have been affected (Chiaranai, 2014). Patients with HF in Thailand’s rural areas have less education, inadequate knowledge, and limited healthcare resources. As a result, they experience and manage their HF symptoms within the context of traditional Thai culture and religious beliefs (Netchang, 2012). Consequently, a large proportion of patients with HF in Thailand are rehospitalised via the emergency department, and approximately 55% of these require intensive care (Laothavorn et al., 2010). As the evidence clearly suggests, patients and carers in Thailand are in need of an HF education program.

1.10 The evidence gap in HF education in Thailand

Patient educational interventions are vital in terms of supporting patients and their families to decrease HF complications and maximise health outcomes. In Thailand, HF DMPs do not exist and there is limited access to advanced practice HF nurses, and access to advanced treatment in tertiary hospitals is geographically and fiscally problematic. For example, in the Thai healthcare system, the doctor-to-patient ratio is 0.3 per 1000 population and the nurse-to-patient ratio is 1.5 per 1000 population, both lower than countries in the Eastern Mediterranean, Southeast Asia, and Western regions (Pagaiya & Noree, 2009). Moreover, only 16.5% of doctors and 28% of nurses work in rural areas (Pagaiya & Noree, 2009). Therefore, it is necessary for Thai healthcare providers to consider alternative methods of engaging patients and their carers residing in rural areas in Thailand throughout the trajectory of their HF illness. Approximately 10% of Thai nurses are engaged in advanced practice (Wongpratoom, Srisuphan, Senaratana, Nantachaipan, & Sritanyarat, 2010), indicating that Thailand has only a small number of clinical HF nurse specialists. Typically, in Westernised countries, there are larger numbers of HF advanced practice nurses who play an important role in co-ordinating DMPs and ensuring adherence to evidence-based best practice guidelines (Davidson, Driscoll, Clark, Newton, & Stewart, 2008; Driscoll, Srivastava, Toia, Gibcus, & Hare, 2014). Ultimately, such nurse-led HF programs have demonstrated a reduction in unplanned HF readmissions and mortality rates (Phillips et al., 2005; Stewart et al., 1999; D. R. Thompson, Roebuck, & Stewart, 2005; Whittingham & Pearce, 2011).
In Thailand, patients with HF demonstrate poor self-care compared with patients in the United States, Mexico, and Australia (Riegel et al., 2009a; Figure 1). Possible explanations of poor self-care in Thailand include lack of community awareness, low understanding of HF (Riegel et al., 2009a), inadequate self-care knowledge (Laothavorn et al., 2010) and limited access to HF DMPs (Atherton et al., 2012). Despite the evidence that social support is also important in Thailand, as discussed above, to date no studies have investigated the effectiveness of a family-based education program for patients with HF and their carers in Thailand. One unpublished study undertaken as a doctoral thesis (Netchang, 2012) investigated factors that correlated with the carer’s quality of life using the Thai translation of the quality of life index. This study examined a model that selected family carer and elderly patient characteristics to predict quality of life among 201 rural Buddhist Thai family carers of patients with chronic diseases, including HF (Netchang, 2012). The results revealed that patients and spousal carers who participated in religious activities had fewer chronic health conditions, better functional status, higher perceived social support, and higher perceived rewards of caregiving. They were also more likely to experience greater satisfaction and overall quality of life. Recommendations from the study included the need to educate both the patient and the carer in order to improve knowledge, self-care skills and quality of life (Netchang, 2012). Unlike in Westernised countries, Thailand’s healthcare system does not routinely provide education programs for patients and carers in the community. Hence, the imperative need to develop education programs to support patients with HF and their carers to enhance their overall health and well-being.
The majority of HF educational clinical trials have been undertaken in Westernised countries and comprise considerable differences in patient characteristics, settings, interventions, sample sizes, follow-up periods, and outcome measures. Five studies involving Thai patients with HF have been conducted on the application of education models to improve knowledge, self-care, and HF symptoms (Intharacha, 2005; Ritklar, 2011; Thongyim, 2001; Tungwichitsakun, 2006; Wongpiriyayothar, Piamjariyakul, & Williams, 2011). However, these studies had many limitations, such as the use of quasi-experimental designs (four studies), differing theoretical frameworks for developing the educational strategies, and varied settings (ranging from home-based to outpatient clinic settings). It is, therefore, difficult to make confident comparisons between the study findings. Moreover, none of these studies included carers as described previously, delivered the education program in community settings, or examined changes in the HRQoL in both patient and carer as an outcome of the education intervention. In light of these limitations and the increasing prevalence of HF in Thailand, further research is required to identify the potential benefits of HF education in rural Thai communities. The present study will overcome these limitations and offer a significant

**Figure 1:** Comparison of self-care adequacy across developed and developing countries (Riegel et al., 2009a)
contribution to the incomplete body of knowledge regarding the effectiveness of education-based intervention for patients with HF and their carers in Thailand.

1.11 Research aim and objectives

The aim of the research is to examine the effectiveness of a family-based education program for patients with HF and carers in rural Thailand. The specific objectives of this research are as follows, to:

- Investigate current family-based education provision for patients with HF and carers;
- Develop a family-based education program for patients with HF and carers in rural Thailand; and
- Implement and evaluate this family-based education program in rural Thailand.

1.12 Research questions

This research explores a selection of separate, but related, questions around family-based education for patients with HF and carers. The research questions for Chapter Two to Chapter Four are as follows:

Chapter Two [research paper]
Research question:
What is the effect of a family-based education on the health outcomes of patients with HF and their carers?

Chapter Three [research paper]
Research question:
Does family-based education for patients with HF increase knowledge, self-care behaviour, and quality of life?

Chapter Four [paper under review]
Research question:
Is there a significant difference in knowledge, self-care behaviours, and quality of life between patients with HF randomised to receive the family-based education or usual care?

H₁: Patients with HF receiving the family-based education program will have significantly higher knowledge, self-care behaviours, and quality of life compared to patients with HF receiving usual care.

Is there a significant difference in perceived control over managing patients’ HF symptoms, knowledge, and quality of life between carers randomised to receive the family-based education or usual care?

H₁: Carers of patients with HF receiving the family-based education program will have significantly higher knowledge, self-care behaviours, and quality of life compared to carers of patients with HF receiving usual care.

1.13 Organisation of the thesis

This thesis is divided into five chapters, an abstract, a reference list, and appendices. The thesis contains three manuscripts: two of which have been published in peer-reviewed scientific journals; the other is under review.

This chapter, Chapter One, provides an introduction to the burden of HF internationally and from a Thai perspective. Concerning the economic burden and substantial human cost of HF, this chapter explains how patient education programs focused on HF self-care have developed as a model of service to reduce the cost of care and unplanned hospital admissions, and improve patients’ quality of life. Reasons for including carers of patients with HF in the education program are provided. Finally, the chapter presents an evidence gap of HF education in Thailand.

The literature review published in Chapter Two examines the literature regarding family-based HF education. The review considers six RCTs reported in nine papers. Studies were included if the study population consisted of patients with HF and their carers. The type of education program was defined as any structured education program, regardless of content,
format, or duration. The program was required to be delivered by an HF health professional to the patient and carer or to the carer alone. This systematic review highlighted the knowledge gap regarding the effectiveness of family-based education in the HF context. Of note, a small number of studies was identified and a diverse range of educational approaches and outcome measures were used.

The study protocol published in Chapter Three describes the methods used to determine the effectiveness of the impact of a family-based education program on health-related outcomes of Thai patients with HF and carers. The chapter outlines the research design selected for testing the education program as well as the family-based education protocol, the sample, and the setting of the study. The tools for measuring the study outcomes included HF knowledge, patient self-care behaviour, patient quality of life, carer perceived control over managing patients’ HF symptoms, and carer quality of life. Also, the details of the data collection procedure and the method used to analyse the study data, as well as its ethical implications, are outlined.

Chapter Four discusses the implementation and evaluation of the HF family-based education. An RCT was undertaken to assess changes in patient and carer outcomes mentioned previously. One hundred dyads completed baseline assessment and 83 dyads completed the study. Findings demonstrated significant improvement for the education group on all measures except carers’ quality of life. A manuscript of this study has been submitted to the peer-reviewed Journal of Advanced Nursing for consideration for publication. The feedback from participants regarding the satisfaction of conducting this research is provided.

The concluding chapter, Chapter Five, discusses the findings of this thesis as it has been presented in the three articles reporting the HF family-based education program. Firstly, a brief revision of the research subject and rationale elaborated on in Chapter One, followed by a review of the HF family-based education program and key findings. The development of the research protocol and HF family-based education, which consisted of an HF manual, a DVD, and telephone support using a teach-back method, are outlined. Overall findings of the research program and its contribution to new knowledge important to the future provision of HF family-
based education are described. Lastly, important limitations are discussed and recommendations for future research are made.
Chapter Two: Systematic review

2.1 Chapter introduction

Patients with HF experience marked to severe physical and mental limitations and often rely on family members or friends for assistance (Joo, Fang, Losby, & Wang, 2015). Social support from family members is associated with better patient health outcomes such as enhanced quality of life (Luttik et al., 2005a), improved medical adherence (Aggarwal, Pender, Mosca, & Mochari-Greenberger, 2015; Gallagher et al., 2011; Wu, Moser, Chung, & Lennie, 2008), decreased depression (Graven & Grant, 2013; Park, Fenster, Suresh, & Bliss, 2006), fewer hospital readmissions (Luttik et al., 2005a; Wu et al., 2013). Carers also play a critical role in assisting patients with HF perform self-care (Buck et al., 2015; Cameron, Rhodes, Ski, & Thompson, 2016; Rosland, Heisler, Choi, Silveira, & Piette, 2010; Sayers, Riegel, Pawlowski, Coyne, & Samaha, 2008; Stromberg, 2013; Vellone et al., 2015). Furthermore, the role of carer has been recognised in international practice guidelines for HF management programs, which recommend that carers be included in educational processes (Lindenfeld et al., 2010; Malcom et al., 2008; McMurray et al., 2012; National Heart Foundation of Australia, 2013).

Patient education is a standard procedure for assisting patients to acquire appropriate knowledge that will positively influence their attitude towards developing and engaging in HF self-care behaviours (Falvo, 2010). Enhanced self-care skills and behaviours have been found to produce positive health outcomes, such as reducing hospital readmissions (Feltner et al., 2014; Sahebi, Mohammad-Aliha, Ansari-Ramandi, & Naderi, 2015) and mortality rates (Lee et al., 2011), and improving quality of life (Britz & Dunn, 2010; Yves, Marvelin, Mei, Supawadee, & Jason, 2014). There is compelling evidence for the positive benefits of HF education in regards to health outcomes. In a systematic review and meta-analysis of 19 RCTs (McAlister et al., 2004) nurse-led educational interventions reduced all-cause hospitalisation rates by 15% (RR 0.84, 95% CI 0.75–0.93) and HF-related hospitalisation rates by almost 25% (RR 0.73, 95% CI 0.66–0.82) (McAlister et al., 2004). In 2006, a systematic review of 21 RCTs examined the effects of HF DMPs on hospital readmission and mortality, a key finding was that patient education was a
foundational component of these DMPs (Yu, Thompson, & Lee, 2006). More than half ($n = 11$) of the DMPs significantly reduced the number of hospital readmissions by 29–85% (mean ± SD = 44.5 ± 14.4%; RR: 0.56 ± 0.14). In addition, four of these DMPs significantly reduced the mortality rate by 28–78% (mean ± SD = 57.6 ± 21.9%; RR: 0.42 ± 0.22) (Yu et al., 2006). Later in the same year, a systematic review of six RCTs involving 857 patients indicated that HF education that was primarily focused on self-management decreased all-cause hospital readmission (OR 0.59; 95% CI 0.44–0.80, $p = 0.001$) and HF readmission (OR 0.44; 95% CI 0.27–0.71, $p = 0.001$) (Jovicic et al., 2006). A subsequent systematic review (Boren et al., 2009) of HF self-management education examined the education content and techniques used for improving self-care behaviours: 35 clinical trials that had randomised 7413 participants for either usual care or educational intervention were examined. The educational interventions were found to significantly improve patients’ knowledge, symptom monitoring skills, compliance with prescribed medications, and quality of life (Boren et al., 2009). In 2011, a systematic review of HF education (19 RCTs that involved 2686 patients) examined outcomes of HF knowledge, self-care behaviours, HF hospital readmission, mortality rate, or quality of life, and 15 studies showed significant improvement in at least one outcome measure (Boyde et al., 2011). Recently, the effectiveness of patient-centred self-care education primarily aimed at increasing HF knowledge, self-care behaviours, quality of life and decreasing readmission was reported in the Joanna Briggs Institute Database of Systematic Reviews (Yves et al., 2014). Six studies were included in the review. Four studies examined patient-centred self-care education in reducing hospital readmissions, with one study demonstrating statistical significance at the one-month and six-month follow-up. Quality of life improved in five studies, with one study showing statistical significance between baseline and the 12-month follow-up. Only one study measured HF knowledge and self-care behaviours, demonstrating statistical significance at 12 months for HF knowledge and at one month and three months for self-care behaviours (Yves et al., 2014).

Although it is clear that patient education is a critical component of DMPs and may have a positive benefit when delivered, there seems to be no clear evidence pointing to best patient
education approaches. Systematic reviews were unable to determine the best component of HF education regardless of frequency, duration, intensity, delivery, or type of education (Boren et al., 2009; Boyde et al., 2011; Jovicic et al., 2006; McAlister et al., 2004). Factors that may have influenced the outcome of HF education were also varied in each review (Clark & Thompson, 2010; Savard et al., 2011). Moreover, the studies included in the review did not always significantly improve outcome measures (Boyde et al., 2011; Jovicic et al., 2006), indicating that there is still room for research in the area.

Given the importance of carers of patients with HF, but with little data to guide the development of an HF family-based education program to achieve optimal outcomes, the following systematic review was undertaken to explore the question:

What is the effect of a family-based education program on the health outcomes of patients with HF and their carers?

Meta-analysis will be conducted if a group of studies are sufficiently homogeneous in terms of subjects involved, interventions, and outcomes to provide a meaningful summary (Haidich, 2011). However, meta-analysis was not possible, therefore a narrative review was applied.

The systematic review has been published in Patient Education and Counseling (Srisuk et al., 2016) and is presented below.
Review

Heart failure family-based education: a systematic review

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\textbf{ABSTRACT}

Objective: To systematically review evidence for the efficacy of family-based education for heart failure (HF) patients and carers.

Method: A systematic review was conducted. Databases CINAHL, MEDLINE Complete, Cochrane, PubMed, Web of Science, EMBASE, PsycINFO, and Scopus were searched between 1 January 2005 and 1 May 2015. Randomised controlled trials included HF patient and carer dyads or carers alone. The primary outcome was HF knowledge. Secondary outcomes included self-care behaviour, dietary and treatment adherence, quality of life, depression, perceived control, hospital readmissions, and carer burden.

Result: Six trials reported in nine papers were included. Wide variation in the quality of the studies was found. Two studies only examined HF knowledge; a significant improvement among patients and carers was reported. Other significant findings were enhanced patient self-care, boosted dietary and treatment adherence, enriched patient quality of life, improved perceived control among patients but not carers, and reduced carer burden.

Conclusion: Modest evidence was found for family-based education among HF patients and carers. Methodological shortcomings of trials signify the need for empirically sound future research. Practice implication: Family-based HF education needs to include strategies that are tailored to the HF patient and carer, and sustainable in nature.

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1. Introduction

Heart failure (HF) is a major chronic health problem [1] associated with high rates of mortality [2], symptom burden [3], rehospitalisation [4] and diminished quality of life [5]. Annually, HF consumes a substantial portion of the healthcare budget [6]. The prevalence of HF is approximately 2–3% of the population and, notably, hospitalised HF patients remain a significant burden on the healthcare sector, representing 1–2% of all hospitalisations [7].

The management of HF is complex with the majority of ongoing care provided outside of the hospital system. Most commonly, HF patients and their families require substantial education regarding engagement in self-care. As a consequence, theory-driven self-care education is aimed at promoting, on a daily basis, self-monitoring of symptoms and engagement in appropriate strategies to address symptom changes [8–10].

In the context of HF, self-care is defined as a process involving the choice of behaviours patients adopt to sustain their health and respond appropriately when changes in symptoms occur [11]. The key behaviours in HF self-care are maintenance strategies and management decisions. Maintenance behaviours include daily weighing, monitoring for increased shortness of breath and adherence to medication regimes and have been revealed as instrumental in sustaining physiological stability, thereby preventing hospital readmissions [12,13]. Self-care management requires patients to recognise and evaluate deleterious changes in HF symptomatology, initiate remedial actions such as taking an additional diuretic, reducing fluid intake or resting, and report any negative changes to a healthcare professional [14]. These strategies have been shown to reduce the risk of clinical decompensation, thereby reducing emergency department admissions [15].

However, despite evidence attesting to self-care aiding clinical stability and improving quality of life [12,13,16,17], many HF patients struggle to assimilate such knowledge into everyday activities [18]. Self-care is complex and challenging due to the numerous and often simultaneous daily activities and tasks faced by the patient. Complexity is a challenge also experienced by the carer, who takes on several roles including health care administrator, treatment navigator, advocate for quality of life, and expert in the lived and ongoing experience of HF in the context of community and family [19–21]. Carers typically provide practical direct care, such as assisting with daily weighing, exercises, dietary sodium reductions and contacting health care professionals for advice. In addition, carers also provide indirect care, such as providing motivation and emotional support [20]. High rates of depression [21], mortality [22,23], hospital readmissions [24,25] and a diminished quality of life [26,27] have been identified in HF patients who lack support. Subsequently, informal carers have become recognised as a vital source of support for HF patients and in reducing a major burden on health services. The potential contribution from carers toward achieving positive HF health outcomes is now recognised in international clinical guidelines [28–30], with best practice guidelines recommending that family members be included in care planning discussions and educational strategies [28–31].

In order to promote optimal well-being in HF patients and reduce the burden on the healthcare system, family-based education is deemed essential, though little evidence is available to attest to its effectiveness or to guide its structure, content and delivery. The aim of this study, therefore, was to systematically review the evidence pertaining to family-based education for HF patients and carers.

2. Method

The development of this systematic review was guided by the criteria of the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement [32,33]. A protocol for the systematic review was developed through consensus among the co-authors and can be supplied upon request.

2.1. Search method

The search strategy aimed to identify published literature sources in the English language from 1 January 2005 to 1 May 2015 inclusive. Electronic databases searched included CINAHL, Cochrane Library, EMBASE, MEDLINE Complete, PsychINFO, PubMed, Scopus, and Web of Science. The following search terms were used: "heart failure" OR "congestive heart failure" OR "chronic heart failure" AND "family support" OR "family support intervention" OR "family education" OR "dyadic intervention" OR "family-focused intervention" OR "family member" OR "family caregiver" OR "informal caregiver" OR "family carer" OR "partner" AND "randomised controlled trial". The reference lists of returned articles were searched to snowball for additional studies. The full search algorithm used to identify potential studies in the electronic database is included in Appendix A.

2.2. Types of studies

Studies included in this review were randomised controlled trials (RCTs), such as HF patient and carer education compared with a control condition such as usual HF care, which provide the highest level of evidence in the literature [34]. The setting of the education program was either inpatient or outpatient. Exclusion criteria were studies in which education targeted the HF patient alone.

2.3. Types of participants

Participants included HF patients and their carer. Patients were those with a confirmed diagnosis of HF regardless of severity and aged 18 years or older. Carers were those living in the same household as the patient, or someone of the patient’s own designation as ‘carer’ aged 18 years or older.
2.4. Types of education program

We included any structured education program, regardless of content, format, or duration. The program was required to be delivered by a HF professional to either the patient and carer, or carer only. Usual care included standard medical care without any form of structured education or counselling.

2.5. Outcomes

The primary outcome was HF knowledge in patients and carers. Secondary outcomes were patient self-care behaviour, dietary and treatment adherence, quality of life, depression, perceived control and hospital readmissions, and among carers were quality of life, anxiety and depression, and carer burden.

2.6. Selection of studies

All studies were screened for eligibility by two independent reviewers (NS, JC) who reviewed titles, abstracts and full text. Any disagreements were resolved by discussion and, if necessary, a third reviewer (CF) was consulted.

2.7. Data extraction and analysis

The Cochrane Collaboration data extraction form was used by the first reviewer to obtain data from the full text articles. The extracted data was then reviewed by a second reviewer. Data obtained included general information, study eligibility, population and setting, methods, risk of bias assessment, participants, intervention group, outcomes, result, applicability and any additional information not captured by the data extraction form. As per study selection two reviewers (NS, JC) worked independently and disagreements were resolved through consensus, or in consultation with a third reviewer.

2.8. Quality and bias assessment

The methodological quality of included studies was assessed using the PEDro scale for RCTs [35] by both reviewers, independently. The PEDro scale is based on the Delphi list [36] and includes two additional items that measure the percentage of subjects allocated to group and the reported between-group statistical comparisons.

Risk of bias was assessed using the Cochrane Collaboration assessment of bias tool [37]. Domains assessed included: sequence generation, allocation concealment, blinding of outcomes assessment, incomplete outcome data, selective outcome reporting, and other sources of bias (e.g., conflict of interest). Responses on each domain were assessed as “low,” “unclear” or “high” risk of bias [37].

3. Findings

The initial search yielded 745 citations. After removing duplicates, 485 publications remained. Studies were excluded for the following reasons: intervention was not family-based education (n=378); conference abstracts (n=17); not randomised controlled trials (n=90). One RCT study was excluded on the basis that it was a pilot study with randomisation to two family-based education approaches, without a control group. Thus, a total of six studies reported in nine publications (three studies reported their findings in two publications) were included in this systematic review (Fig. 1).

3.1. Study characteristics

The six studies comprised 438 HF patient/carer dyads and 230 carers. The average age of the patients and carers was 73 and 62 years respectively. Study sample sizes ranged from 61 to 155 dyads, and from 72 to 128 carers (for carer only studies). Of the three studies [38-41] that reported carer demographics, 80% were female. In three studies more than half of the carers were either a spouse or partner of the patient [39,41-43] and in two studies half
the carers were siblings of the patient [38-41]. Ethnicity was reported in two studies: in one 58% of participants were African American [42,43], in the other 80% were Caucasian [44].

3.1.1. Quality assessment and bias

There was wide variation in the quality of studies as assessed by the PEDro scale. Only one study met eight of the 11 PEDro quality assessment criteria [42,43], one study met six [44] and four studies met four of the quality criteria [38-41,45,46] (Fig. 2). Overall, studies specified the eligibility criteria. Each publication described the study design as an RCT, but only two studies indicated that allocation was concealed [42-44]. None of the studies reported blinding of subjects and/or therapist administering the treatment, whereas two studies had blinded the assessor collecting outcome data [42-44]. Three studies stated that they had conducted an intention to treat analysis [38,40,42-44]. All studies reported the results of between group statistical comparisons, but only one reported effect size of the treatment [42,43]. Using the Cochrane Collaboration tool for assessing risk of bias all (n=6) studies were assessed as ‘low’ on two of the six items: incomplete outcome data, and selective outcome data (Table 1). Four of the studies were assessed as low risk of bias for random sequence generation [38-40,42,43,45,46], all studies were assessed as ‘unclear’ risk of bias for blinding of participants and personnel, and four studies [38-41,45,46] were assessed as ‘unclear’ risk of bias for allocation concealment. Key reasons for this assessment were a lack of detail in describing the method of blinding of outcome assessment and allocation concealment.

3.2. Types of studies

Most (n=5) of the studies were parallel RCTs comparing the intervention group with a usual care group [38-41,44-46] and one was a 3-arm RCT comparing a treatment arm with an active control arm and an alternative active treatment [42,43].

3.3. Types of participants

The studies included adults with a primary diagnosis of HF (Table 2). Five studies reported HF disease severity based on the New York Heart Association (NYHA) classification and included persons with mild to severe functional limitations (NYHA grade II-IV) [39-41,46]. Ejection fraction threshold was not used as an inclusion or exclusion criterion in any of the studies; three reported echocardiography findings [38-40,42,43]. Only one study reported comorbidity using the Charlson comorbidity index [42,43]: mean of 3.1. Another study reported the number and list of comorbidities: patients had a mean of 4.5 comorbidities, predominantly hypertension, diabetes and atrial fibrillation [39,45,46].

3.4. Theoretical basis for education interventions

Overall, the education programs were heterogeneous (Table 2) and only two were specifically guided by an education theory. One study [45,46] used the concepts of Stiefberger et al. [47] to assist dyads in recognising and modifying factors that contribute to physical and emotional distress. The other study [42,43] used self-determination theory (SDT) [48] and social cognitive theory (SCT) [49] to guide HF patients and their carers on improving dietary sodium. Another study used the European Society of Cardiology clinical practice guidelines for HF to develop education sessions [39,40], and another developed the education program from the results of a preliminary qualitative study [38].

![Fig. 2. PEDro quality assessment.](image-url)
3.5. Delivery of the education interventions

Four studies delivered the education program to both the patient and caregiver [41–46] and two studies delivered it to the caregiver only [38–40]. In three studies, the education was delivered in group sessions with 8–12 participants [38–41]. One study provided individualised telephone support and education [43]. In three studies education was delivered by nurses [41,44–46], in two by a multidisciplinary team [38–41], and in one by a nurse and a dietitian [42,43].

In three studies educational booklets were used in combination with other multimedia sources such as CD-ROM, PowerPoint and DVD [38,42,43,45,46]. One study used a written report depicting a graph of the patient’s dietary sodium intake as a means of providing individualised feedback regarding their dietary and medication adherence, in addition to sending participants a newsletter containing educational messages [42,43]. Three studies reported follow-up education using telephone reinforcement [38,41–43]; however, only one of these stated that the follow up was scripted. Also, one study had two differing forms of education: patient family education (PFE) and family partnership intervention (FPI). Across the six studies, the duration of the intervention ranged from 5 to 24 weeks.

3.6. Comparators

In general, description of the comparator arm was ‘usual care’ with limited explanations such as usual post-hospital discharge care, where family members were not incorporated into the process of care (Table 2). In addition to usual hospital care, the control group in some studies received an information brochure and newsletter regarding the study progress [42,43].

3.7. Outcomes

In four studies that delivered education to both patients and caregivers [41–46], only two measured outcomes in both dyads [44–46]; and in two in patients alone [41–43]. In one study where education was delivered to caregivers alone, only caregiver outcomes were measured [38]. In the remaining study, education was delivered to caregivers but outcomes were measured in both partners [39,40].

3.7.1. Primary outcome for patients

3.7.1.1. Knowledge. Only one study examined HF knowledge in patients and found significant improvements [42,43] using the Atlanta Heart Failure Knowledge Test (AHFKT), which demonstrated good internal reliability (Cronbach’s alpha > 0.84). This study had two education interventions (PFE and FPI) and the percentage of correct knowledge responses increased immediately in both groups after the education session. However, in each group, mean knowledge scores were lower at four and eight months than at baseline (p < 0.01). Analysis of covariance (ANCOVA) demonstrated significant group differences at four months (F(2, 28) = 3.17, p < 0.05) in the AHFKT scores by group and using the baseline knowledge score and education level as covariates; at four months both education programs resulted in higher AHFKT scores than achieved by the usual care group.

3.7.2. Primary outcome for caregivers

3.7.2.1. Knowledge. Only one study examined HF knowledge among caregivers and found improvements after a group-based multidisciplinary education program [39,40]. Knowledge was assessed using a questionnaire developed by the researcher, approved by three HF experts and tested on 19 family members of HF patients. Reliability was deemed good (Cronbach’s alpha > 0.83). Knowledge of HF increased at two weeks after the education in both the intervention and control groups. The education group had a 1.1 point higher knowledge score (16 ± 1.9) than the control group two weeks after the education program was completed (14.9 ± 2.1, p < 0.01), and a 1.7 point higher knowledge score (16.5 ± 1.3) than the control group (14.8 ± 1.8, p < 0.01) at six months after the second assessment.

3.7.3. Secondary outcomes for patients

3.7.3.1. Self-care. Two studies examined self-reported changes in patients’ self-care but only one found improvements. To assess changes in self-care, one study used the European Heart Failure Self-Care Behavior Scale (EHFScBS) [45,46] and the other an investigator-designed self-care behaviour questionnaire [41] where internal reliability of these instruments was reported as adequate (Cronbach’s alpha > 0.72 and > 0.80, respectively). Contrasting findings were reported by these two studies. One [45,46] reported no group difference in patients’ self-care behaviour using the EHFScBS mean score changes from baseline to three and six months. The other [41] reported a mean 20 (+42) point increase in patient self-care behaviour scores one month after the group education session with carers, compared with a 1 (±2.4; t = 22.1, p < 0.01) point mean increase in patient self-care behaviour scores in the control group.

3.7.3.2. Dietary and treatment adherence. Only one study examined dietary and treatment adherence among patients and found improvements [42,43]. In this study, patients’ motivation for a low-sodium diet and HF medication adherence was reported in one study using the Treatment Self-Regulation Questionnaire (TSRQ) which was found to have adequate reliability (Cronbach’s alpha > 0.7). Across all three groups the proportion of patients scoring high in autonomous motivation for diet increased over time but this difference was only statistically significant, with a moderate effect size, in the FPI group (FPI: p = .01, ES = 0.7). In contrast, the controlled regulation scores for dietary adherence
<table>
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<tr>
<th>Study design</th>
<th>Participants</th>
<th>Baseline characteristics of participants</th>
<th>Education intervention</th>
<th>Outcomes and instruments</th>
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<tr>
<td>Parallel group randomized controlled trial. Controlled described as traditional in-hospital care, outpatient education and support focused on the patient’s needs. The partner is not systematically involved in the follow-up and education.</td>
<td>Inclusion (diagnostic): A dyad consisting of a patient diagnosed with HF and partner living in the same household. HF diagnosis based on the European Society of Cardiology guidelines, NYHA functional class II-IV, recently discharged from hospital (i.e., 2-3 weeks) after an HF exacerbation. Exclusion: dementia or other severe psychiatric illnesses, drug abuse, difficulties in understanding or reading the Swedish language, undergoing cardiac surgery, including cardiac transplant, or participating in other studies.</td>
<td>Total n = 155 dyads Intervention n = 84 Control n = 71 Patient intervention group: age mean (SD): 34 (11), female n (%) 52 (38.8), NYHA n (%) II-IV. Patient control group: age mean (SD): 34 (11), female n (%) 52 (38.8).</td>
<td>Education intervention delivered to both patient and caregiver consisting of: twice (±1 h) face to face nurse led counseling and educational sessions for HF care with CD-ROM program and written teaching material. Each session included problem solving skills to assist the dyad in recognizing and modifying factors that contribute to emotional and behavioral distress, with a focus on changing thoughts and behaviors and implementing strategies for self-care. The dialogue guide used during the sessions included an opportunity for the dyad to discuss their mutual and individual life situation, receive information, raise questions, discuss difficulties and subject of joy, and deal with emotional and practical support and self-care. Length: 12 weeks.</td>
<td>Patients: QoL-SF 36 Depression: BDI-II Control Attitudes Scale: CAS Self-care: EBS/SRS Cost of care: Partners: QoL-SF 36 Depression: BDI-II Control Attitudes Scale: CAS</td>
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<td>Three-armed randomized controlled trial. Controlled described as provision of an educational brochure and usual care from health care providers. Patient teaching regarding general overview of HF, medications and diet. Family members included if available. A newsletter mailed at ±5 months with an update on the study progress.</td>
<td>Inclusion (patient): diagnosis of HF confirmed in the medical record, age 30-78 years, NYHA functional class II-IV, English fluency, telephone access, home HF medications, no contraindication for low-sodium diet, adequate renal function as evidenced by glomerular filtration rate &gt;30 mL/min/1.73 m², history of exacerbation (patient). Exclusion (patient): significant loss of the past 6 months, significant anemia, HF secondary to untreated condition, planned cardiac surgery, impaired cognition, psychiatric diagnosis, and uncontrolled visual/hearing problems. Inclusion (family member): primary person helping with HF self-care and interacting with the HF patient ≥1 times/week, ≥10 years of age, willing to participate, and without conditions that would impair the ability to participate in the intervention session, such as impaired cognition or psychiatric diagnosis.</td>
<td>Total n = 117 dyads Intervention group I n = 42 Intervention group II n = 77 Patient intervention group I: age mean (SD): 55.0 (10.5), female n (%) 57.8, NYHA n (%) II-IV, III-IV, IV; EF ≤30%, medications: ACEI/ARB 100%, Beta-blocker 100%, diuretic 100%. Patient intervention group II: age mean (SD): 55.0 (10.5), female n (%) 57.8, NYHA n (%) II-IV, III-IV, IV; EF ≤30%, medications: ACEI/ARB 100%, Beta-blocker 100%, diuretic 100%. Patient control group: age mean (SD): 55.0 (10.5), female n (%) 57.8, NYHA n (%) II-IV, III-IV, IV; EF ≤30%, medications: ACEI/ARB 100%, Beta-blocker 100%, diuretic 100%.</td>
<td>Education intervention delivered to both patient and family members. Patient education intervention (PEI): Educational session ±1 h overview of HF, symptoms of fluid overload, ways to reduce sodium intake, medication adherence and self-management activities such as daily weighing. 2 months later dyads attended a second 1 h group session using active learning activities to reinforce sodium restrictions and medication adherence. Written and media resources also provided. Participants also received regular feedback from a trained facilitator regarding their dietary sodium intake and medication adherence. Telephone booster educational session ±4 months. At ±4 ±5 month they received a newsletter containing strategies to lower dietary sodium, new seasonal recipes, and reinforcement of medication taking behaviors. Patient-family partnership intervention (PFPI): received same educational protocol as PEI, with an additional 2h</td>
<td>Patients: Heart failure knowledge: AHIFT Dietary sodium: 24 h-urine analyzed for Na, creatinine, and urea. Medication adherence: MEMS and MMS. Motivation for health behavior (medication and low-sodium diet adherence): TSRI. Perceived condition: PCS.</td>
</tr>
<tr>
<td>First author, year, country</td>
<td>Study design</td>
<td>Participants</td>
<td>Baseline characteristics of participants</td>
<td>Education intervention</td>
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<td>Ermadile et al., 2014 [30]</td>
<td>Parallel group randomized controlled trial. Control described as routine hospital care</td>
<td>Total n = 100 caregivers: Intervention n = 50, Control n = 50</td>
<td>Patients’ intervention group: age years (range): 40-49, 50-60, 61-70, 71-80, 81-90, mean (SD): 63.5 (7.5), median (IQR): 63, female: 75%, male: 25%.</td>
<td>Telephone education intervention delivered to caregiver consisting of one education session (2 h) over four weeks with a family caregiver. The group sessions used multimedia training covering topics related to the caregiver’s role in family and societal health development according to the World Health Organization’s guidelines. The sessions focused on emotional support, symptom management, and communication skills.</td>
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Incision (family member): living in the same household as the patient or otherwise someone of the patient's own choice. Age 18y of patients with CHF who had been treated in hospital.

Exclusion (family member): medical problems that make it impossible to participate, e.g. cognitive dysfunction.

Exclusion (patient): planned heart operation or other serious disease (e.g. cancer and renal failure), living in a nursing home, cognitive dysfunction, drug and alcohol abuse, language difficulties, participating in other studies.

Total n = 128 family caregivers intervention n = 65
Control n = 63

Patients intervention group:
- age years (mean): 68.3 (11)
- female n (57): 42 (40), NYHA (3): unknown = 32, II = 38, III = 18, IV = 9
- admission (mean): 55 = 237, 45-49% = 13, 50-59% = 21, 60-69% = 13, 70-79% = 2, 80% = 4
- medication n (5): ACE/AARB = 46 (14), Beta-blocker = 33 (13), diuretics = 62 (10)

Patients control group:
- age years (mean): 68.7 (6)
- female n (57): 27 (38), NYHA (3): unknown = 32, II = 38, III = 18, IV = 9
- admission (mean): 55 = 237, 45-49% = 13, 50-59% = 21, 60-69% = 13, 70-79% = 2, 80% = 4
- medication n (5): ACE/AARB = 46 (14), Beta-blocker = 33 (13), diuretics = 62 (10)

Family member intervention group:
- age years (mean): 64 (11)
- female n (57): 28 (46), relationship to the patient: married/living together = 57%, child = 32%, close friend = 16%, other = 8%

Family member control group:
- age years (mean): 65 (12.2)
- female n (57): 28 (46), relationship to the patient: married/living together = 57%, child = 32%, close friend = 16%, other = 8%

Inclusion (patient): aged 55+, had a diagnosis of NYHA classification II, III, or IV HF, functionally impaired in at least 1 ASL or IADL, requiring assistance of a family caregiver.

Exclusion (patient): planned discharge to a nursing home, inability to be interviewed and contacted post-discharge, receiving regular infusions or dialysis, NYHA class IV, independence in daily life, NYHA class III, independence in daily life, NYHA class II, independence in daily life.

Caregivers control group:
- age years (range): 46-75 (20-39)
- female n (57): 31 (48), NYHA (3): unknown = 32, II = 38, IV = 9, 50-59% = 15, 60-69% = 10
- overall relationship to the patient: daughter or sister = 9.6%, spouse = 9.6%

Pregnancy: 4.6%

Schwarz et al., 2008 A pilot randomized controlled trial. Randomized as usual post-hospital discharge care

Inclusion (patient): aged 55+, had a diagnosis of NYHA classification II, III, or IV HF, functionally impaired in at least 1 ASL or IADL, requiring assistance of a family caregiver.

Exclusion (patient): planned discharge to a nursing home, inability to be interviewed and contacted post-discharge, receiving regular infusions or dialysis, NYHA class IV, independence in daily life.

Caregivers control group:
- age years (range): 46-75 (20-39)
- female n (57): 31 (48), NYHA (3): unknown = 32, II = 38, IV = 9, 50-59% = 15, 60-69% = 10
- overall relationship to the patient: daughter or sister = 9.6%, spouse = 9.6%

Pregnancy: 4.6%

Inclusion (family member):
- living in the same household as the patient or otherwise someone of the patient's own choice. Age 18y of patients with CHF who had been treated in hospital.

Exclusion (family member):
- medical problems that make it impossible to participate, e.g. cognitive dysfunction.

Exclusion (patient):
- planned heart operation or other serious disease (e.g. cancer and renal failure), living in a nursing home, cognitive dysfunction, drug and alcohol abuse, language difficulties, participating in other studies.

Total n = 128 family caregivers, intervention n = 65
Control n = 63

Patients intervention group:
- age years (mean): 68.3 (11)
- female n (57): 42 (40), NYHA (3): unknown = 32, II = 38, III = 18, IV = 9
- admission (mean): 55 = 237, 45-49% = 13, 50-59% = 21, 60-69% = 13, 70-79% = 2, 80% = 4
- medication n (5): ACE/AARB = 46 (10), Beta-blocker = 33 (13), diuretics = 62 (10)

Patients control group:
- age years (mean): 68.7 (6)
- female n (57): 27 (38), NYHA (3): unknown = 32, II = 38, III = 18, IV = 9
- admission (mean): 55 = 237, 45-49% = 13, 50-59% = 21, 60-69% = 13, 70-79% = 2, 80% = 4
- medication n (5): ACE/AARB = 46 (10), Beta-blocker = 33 (13), diuretics = 62 (10)

Group member intervention group:
- age years (mean): 64 (11)
- female n (57): 28 (46), relationship to the patient: married/living together = 57%, child = 32%, close friend = 16%, other = 8%

Group member control group:
- age years (mean): 65 (12.2)
- female n (57): 28 (46), relationship to the patient: married/living together = 57%, child = 32%, close friend = 16%, other = 8%

Inclusion (patient): aged 55+, had a diagnosis of NYHA classification II, III, or IV HF, functionally impaired in at least 1 ASL or IADL, requiring assistance of a family caregiver.

Exclusion (patient): planned discharge to a nursing home, inability to be interviewed and contacted post-discharge, receiving regular infusions or dialysis, NYHA class IV, independence in daily life.

Caregivers control group:
- age years (range): 46-75 (20-39)
- female n (57): 31 (48), NYHA (3): unknown = 32, II = 38, IV = 9, 50-59% = 15, 60-69% = 10
- overall relationship to the patient: daughter or sister = 9.6%, spouse = 9.6%

Pregnancy: 4.6%
<table>
<thead>
<tr>
<th>First author, year, country</th>
<th>Study design</th>
<th>Participants</th>
<th>Baseline characteristics of participants</th>
<th>Education intervention</th>
<th>Outcomes and instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shafi E., et al., 2013 (41)</td>
<td>RCT, double-blind, randomized, controlled trial</td>
<td>64 patients</td>
<td>Age &lt; 55 years, BMI &gt; 35 kg/m², hospitalization score &gt; 1</td>
<td>Education intervention delivered to both patient and caregiver consisting of 4 sessions (8–12 participants)</td>
<td>May include self-care, self-care behaviors developed by Shehabe et al. (2015)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion (caregivers):</th>
<th>Family member of the patient, age &gt; 18 years</th>
<th>Total n = 64 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group:</td>
<td>n = 32 patients</td>
<td></td>
</tr>
<tr>
<td>Patients intervention group:</td>
<td>n = 32 patients</td>
<td></td>
</tr>
<tr>
<td>Patients control group:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caregivers intervention group:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caregivers control group:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 2 (Continued)**

ADL, activities of daily living; AHCPR, the Atlanta Heart Failure Knowledge Test; BDI-II, Beck depression inventory; CAS, Control Attitudes Scale; CES-D, Center for Epidemiological Studies Depression Scale; EHPIS/B, European Heart Failure Self-Care Behaviors Scale; EIS, European Society of Cardiology; HADS, Hospital Anxiety and Depression Scale; IADL, Instrumental Activities of Daily Living; NYHA, New York Heart Association; MMAS, Morisky Medication Adherence Scale; MLHR, Minnesota Living with HF questionnaire; PCS, Perceived Confidence Scale; PGCAS, Philadelphia Geriatric Center Caregiver Appraisal Scale; QoL, Quality of Life; SF-36, Short Form Health Survey; TBB, Treatment Beliefs Beliefs Questionnaire; TBR, Treatment Beliefs Reflections; TBS, Treatment Beliefs Summary; TSB, Treatment Self-Regulation Questionnaire; ZBI, Zerit Boxline Interview; ZDFR, 3 Day Food Record.
were significantly higher, indicating less self-control, in the usual care group at eight months (4.68 ± 1.72) than in either education intervention groups (PFE: 3.65 ± 1.82; FFF: 3.14 ± 1.66, p = .05, ES = .29). Across all three groups, autonomous motivation for adherence with HF medications increased from baseline to eight months (p < .01). Relative to the time effect, post-hoc analysis revealed a moderate effect size in the FFF group (p < .01, ES = .42), whereas a modest increase in the proportion of patients scoring high for autonomous motivation for medications was found in the PFE group (p = .06, ES = .28).

Medication adherence was assessed by the Medication Events Monitoring System (MEMS) and the Morisky Medication Adherence Scale (MMAS) in the same study [42,43]. The internal reliability of the MMAS was deemed good (Cronbach’s alpha = .72). Medication adherence rates were high at each assessment time point and across all three groups (>80%). In regard to HF medication adherence, there was no group, time or group–time interaction when controlling for age, gender, NYHA classification and comorbidity index. The FFF group demonstrated a significant decline in diuretic adherence compared with the usual care group at 8 month follow-up (mean difference 14.58, SE 5.67, p = .03).

3.7.3.3. Quality of life. Two studies examined quality of life among patients but only one found improvements. One study used the short-form 36-item health survey (SF-36) [45,46], the other the 21-item Minnesota living with HF questionnaire (MLHF) [44]. Internal reliability of the SF-36 was good (Cronbach’s alpha = .76) but was not reported for the MLHF. Quality of life using the MLHF significantly improved from baseline to the 90-day follow up (r = .38, p < .01) in both the groups receiving the Electronic Home Monitoring system intervention or usual care [44]. In contrast, the other study reported no significant differences in quality of life (SF-36) between the group receiving education and psychosocial support compared with the control group, at three or 12 months [45,46].

3.7.3.4. Depression. Two studies examined depression among patients and both found no improvement. One study used the Center for Epidemiologic Studies Depression Scale (CES-D) [44], and the other the Beck Depression Inventory II (BDI-II) [45,46]. Both studies reported good internal reliability of the instruments (Cronbach’s alpha > .90). Neither study observed statistically significant differences over time in depressive symptoms between the intervention and control groups.

3.7.3.5. Perceived control. Only one study examined perceived control, among patients, and found improvements using the Control Attitudes Scale (CAS), which had good internal reliability (Cronbach’s alpha > .80) [45,46]. Findings demonstrated that compared with the control group, the intervention group had significant improvements in perceived control at three months (p < .05) but not at 12 months.

3.7.3.6. Hospital readmissions. Two studies examined hospital readmission rates among patients [39,40,44]. One reported a trend for fewer HF readmissions over 18 months in the group-based multi-professional education program compared with usual care; however, this was not statistically significant (p = .08) [39,40]. The other study reported that 90-day readmissions were not significantly different between the education and control groups [44].

3.7.4. Secondary outcomes for carers

3.7.4.1. Quality of life. Two studies examined quality of life among carers and found no improvements. One study used the SF-36, with internal reliability reported as good (Cronbach’s alpha > .70) [45,46], and the other Carrillo’s Ladder of Life with internal reliability not reported [39,46]. In both studies, quality of life over time was not significantly different between the education and control groups.

3.7.4.2. Depression. Two studies examined anxiety and depression among carers and found no improvements. One study used the Hospital Anxiety and Depression Scale (HADS) [39,46], the other the BDI-II [45,46]. The reliability of each instrument was reported as good (Cronbach’s alpha .86, and .90, respectively). Over time, anxiety or depression was not statistically different between the education and control groups.

3.7.4.3. Perceived control. One study examined perceived control using the CAS among carers of dyads who received education and psychosocial support [45,46]. The internal reliability of the CAS was good (Cronbach’s alpha > .80) but there was no difference in score between the education and control groups at three and 12 months.

3.7.4.4. Carer burden. Two studies examined carer burden: one found it reduced in the intervention group [38], whereas the other study found no group difference [45,46]. One study used the Caregiver Burden Scale (CBS), reporting a Cronbach’s alpha of .91 [45,46], and the other the Zarit Burden Interview (ZBI), reporting a Cronbach’s alpha of .79 [38]. Following a face-to-face education and psychosocial support for dyads there were no significant group differences in carer burden using the CBS [44,46]. In contrast, the effects of a supportive group education for carers only resulted in statistically significant reductions in carer burden (ZBI) compared with the control group [38]. Mean burden scores of carers were significantly different at baseline, one, and three months in both the education (F = 145.49, p < .01) and control groups (F = 12.5, p < .01). In the education group, there was a 21 point decrease in carer burden scores from baseline to one month (r = 14.12, p < .01) and a mild increase from one to three months (r = 10.6, p < .01). In the control group, there was a 3.77 point increase in carer burden scores from baseline to post-intervention (r = −3.16, p < .01) and a 1.15 point increase from post-intervention to three months (r = −6.83, p = .10).

4. Discussion and conclusion

4.1. Discussion

This is the first systematic review of family-based education for HF patients and carers. Surprisingly, only six studies (reported in nine papers) met the inclusion criteria. Overall findings demonstrated that family-based education improved knowledge in both HF patients and carers with modest improvements in other health outcomes. However, it is difficult to draw any firm conclusions as to optimal strategies for HF education due to the heterogeneity found among the studies in terms of education strategies, intensity and duration and sample sizes. Although the literature acknowledges that carers play a pivotal role in supporting HF patients and exerts their inclusion in family-based education, there is a paucity of studies to evaluate its effectiveness. Only two studies delivered education to patients and measured outcomes in both dyads [44-46]. Carer outcomes were mixed: knowledge improved but psychosocial status (quality of life, perceived control, anxiety and depression) did not.

Our findings contrast with a systematic review and meta-analysis of family-based psychoeducation or interventions addressing family relationships for patients with chronic physical disease [50]. That review of 52 randomised controlled trials where
interventions were compared with standard treatment found overall improvements in patients’ physical and mental health and family members’ health. Although the effect size for these improvements was small the improvements were sustained over time. More importantly, relationship-focused family interventions had a greater effect than educational interventions [50]. Similar findings have been reported in two other systematic reviews of family-based interventions in adults with chronic disease [51,52]. From the literature it is apparent that carers play a critical role in improving health outcomes of patients with chronic disease. Furthermore, across the spectrum of chronic diseases expectations and needs of carers are similar; hence, in addition to disease-specific education strategies, those inclusive of family with a psychosocial focus are critical [53]. From the perspective of HF, our systematic review highlights the knowledge gap regarding the effectiveness of family-based education.

In our review, only two studies referred to a theoretical framework in the development of the education adopted [42,43,45,46]. Optimal education is best achieved when tailored to the information needs, preferences and abilities of each patient [54]. Patients with HF have differing learning needs influenced by factors such as prior HF experience, knowledge, ethnicity or cultural identity, socioeconomic status and health literacy [55]. By identifying individual needs along with potentially confounding factors that may limit the patient’s ability to assimilate learning, a better understanding of the person and situation is gained. In other words, education interventions that are tailored to learning needs, developed through a theoretical framework and take into account the nature of the target audience, setting, resources, goals, and constraints are likely to be more effective and better translated into practice [56]. A recent systematic review highlighted the importance of tailoring self-management interventions to individual need when delivered to HF patients [57]. Those with low education, income, literacy, and self-care ability are likely to benefit most from such interventions [57], and culturally and linguistically appropriate educational content and materials, and community awareness, are likely to enhance effectiveness [58].

The goal of education is to enhance knowledge in conjunction with developing an effective self-care skill set [31] as increased knowledge does not necessarily result in changed health behaviours [59]. Based on our findings, patient education significantly increased HF knowledge but conferred only modest improvements in other behavioural and psychosocial outcomes. Moreover, though patients and carers reported improvements in HF knowledge immediately after education, this was not sustained [42]. This indicates that further evidence is warranted in the application of theory-driven, multi-modality education strategies that not only improve knowledge over the longer term but also build self-care skills.

Telephone reinforcement is one strategy that may assist in overcoming limitations of dyadic group education. Telephone reinforcement may be a convenient supplement that could potentially address long-term learning needs and overcome geographical and health literacy barriers. The evidence for structured telephone support and telemonitoring is compelling, with improvements in HF self-care behaviours [60–62] and reduced HF hospital readmissions [63]. In our review, three studies reported follow-up education using telephone reinforcement [38,41–43]; however, only one of these stated that the follow-up was scripted [42,43]. Using a script during telephone support helps the investigator maintain consistency with the intervention condition and reduces potential bias by decreasing conversational time with participants [64]. Combining structured telephone support with HF education is likely to improve HF education and self-management.

An obvious limitation of this review is the small number of studies identified and the diverse range of educational approaches and outcome measures used, which precluded a meta-analysis being conducted. Comparisons regarding the effectiveness of the interventions may also be weakened due to heterogeneity of the populations and comparators in the studies reviewed. In order to reduce the risk of bias, only RCTs were included in this review as they provide the most reliable evidence as to the effectiveness of interventions [34]. In addition, blinding of allocation and outcome assessment were poorly described. These methodological shortcomings signify the need for more empirically robust research design features.

4.2. Conclusion

This systematic review of HF family-based education found improvements in knowledge in both patients and carers. However, only modest improvements in other outcomes were found. Most studies were marred by weak conceptualisation and methodological rigor. These findings highlight the need for future research to ensure well-designed robust studies of HF family-based education.

4.3. Practice Implications

• Though promising, more robust evidence is needed to demonstrate that HF family-based education is effective for HF patients and carers.
• Future studies need to address the methodological shortcomings of the studies identified in this review.
• Better-designed and conducted studies that are theory-driven are necessary to demonstrate the effectiveness of HF family-based education.

Conflict of Interest

There are no conflicts of interest.

Appendix A. Search strategy

1. (“heart failure” or “congestive heart failure” or “chronic heart failure”). mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures].
2. (“family support” or “family support intervention” or “family education” or “dyadic intervention” or “family focused intervention” or “family member” or “family caregiver” or “caregiver” or “informal care” or “informal caregiver” or “family carer” or “partner”). mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures].
3. “randomised” or “controlled trial” or “randomised controlled trial” or “clinical trial” or “experimental”.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures].
4. 1 and 2
5. 3 and 4

Limit 4 to (“300 adulthood < age 18 yrs and older”) or 320 young adulthood < age 18 to 29 yrs or 340 sixties < age 30 to 39 yrs or 360 middle age < age 40 to 64 yrs or 380 aged < age 65 yrs and older or “390 very old < age 85 yrs and older”).

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.pec.2015.10.009.
2.2 Update to Srisuk et al. (2016) systematic review

Following the publication of the systematic review (Srisuk et al., 2016) the search was updated to identify any more recent publications. One additional paper was found. Liljeroos, Agren, Jaarsma, Arestedt, & Stromberg (2015) published a 24-month follow-up of their original study (Agren, Evangelista, Hjelm, & Stromberg, 2012) that was included in our systematic review (Srisuk et al., 2016), which describes the long-term outcomes of dyadic education and psychosocial support (Liljeroos et al., 2015). In their follow-up study, patients with HF and their carers completed the questionnaire packages separately at 24 months. The results were evaluated based on an intention-to-treat analysis and on dyad level, with patients and carers combined and treated equally. The final sample comprised 44 dyads in the intervention group and 52 dyads in the control group, but only 37 dyads completed the 24-month follow-up.

The key finding was that at 24 months post-intervention there was no difference detected between the two groups in terms of health, depression, or perceived control. The authors acknowledge that some of the dyads in both groups may have completed follow-up at a nurse-led HF clinic, which is provided as standard care for all patients. Therefore, the intervention did not detect any changes and may have caused the low follow-up rate and, subsequently, the non-significant result. Other possible reasons were that the intervention was not directly tailored to the dyads’ needs and included insufficient information to build practical and psychological skills (Liljeroos et al., 2015). Alternatively, the study may have lacked ongoing reinforcement. The existing literature found that continuous support or reinforcement such as telephone follow-up has the potential to decrease hospital readmission and mortality rates, and increase quality of life, medical adherence and self-care behaviours (Inglis et al., 2010). Also, the dyad intervention should take into consideration the quality of the dyad relationship. Kitko et al. (2014) suggest that the success of dyadic intervention may depend on congruence of views about the illness. Patient and carer incongruence can affect illness management and place undue burden on the carer (Kitko et al., 2014).

Although the findings of the latest study (Liljeroos et al., 2015) involving family-based HF education demonstrated neutral long-term effects, they provide further evidence of the need
to identify the impact of family-based HF education in supporting patients with HF and their carers (Srisuk et al., 2016). Specifically, greater methodological rigour is required in future trials. In addition, patients and carers require continuous support in order to increase their perception of control and effectively perform self-care (Liljeroos et al., 2015).

2.3 Chapter Two summary

This systematic review has provided a comprehensive synopsis of family-based HF education and revealed a key area of neglect – the lack of inclusion of carers in educational programs to support patients with HF. In regards to the effectiveness of family-based HF education, the overall findings were that family-based education increased knowledge in both HF patients and carers, and other health outcomes showed moderate improvement. Of note, only two studies delivered education to patients and measured outcomes in both patients and carers. Vital is evidence that the included studies had insufficient methodological rigour to prove that family-based HF education improves patient and carer outcomes. In addition, all of the studies reviewed were conducted in Western countries or Iran. No prior studies have investigated the effectiveness of family-based HF education in Thailand. The next chapter will describe the study protocol and development of a family-based HF education program for patients and carers residing in rural Thailand.
Chapter Three: Methods

3.1 Chapter introduction

Chapter One provided a theoretical framework based on adult learning theory (Knowles, 1984) for the development and evaluation of the intervention. The findings of the published literature reviewed in Chapter Two demonstrated key characteristics of HF family-based education programs and their effects on patient and carer health outcomes. Only four studies developed and evaluated an HF education intervention for both the patient and their carer. Most importantly, a distinct evidence gap was identified: none of the studies conducted in Thailand examined the effectiveness of HF education for both patients and carers. To date, most HF educational clinical trials have been undertaken in Westernised countries with considerable cultural differences to Thailand. Only one published RCT of HF education, which used coaching by telephone, has been conducted in Thailand (Wongpiriyayothar et al., 2011). In this context, the challenges of teaching self-care must be taken into consideration, such as cultural differences (Clark et al., 2010; Davidson et al., 2007), barriers to effective self-care (Dickson, Deatrick, & Riegel, 2008; Riegel & Carlson, 2002), and the high likelihood of non-compliance (Aggarwal et al., 2015; Wu et al., 2013).

The aim of the current chapter is to present: i) the development of a family-based HF education program for patients and carers living in rural Thailand, and ii) a methodology for evaluating the intervention presented in the publication included in this chapter (Srisuk, Cameron, Ski, & Thompson, 2014).

3.2 Development of a family-based HF education program for patients and carers living in rural Thailand

Details of development of the HF family-based education program are outlined in the publication by Srisuk et al. (2014). This chapter extends on this by providing a comprehensive description of: i) the incorporation of adult learning theory in the education program, ii) development of the HF educational resources, iii) cultural adaptation and validation of the HF
manual and DVD, and iv) the perspective of HF family based-education on carers' health outcomes.

3.2.1 Adult learning theory applied to development of the HF educational program

The development of the HF education program for this study was guided by adult learning theory (Knowles, 1998) as discussed in Chapter One. Development of the educational intervention incorporated the five core principles of adult learning theory (Knowles, 1984): i) self-concept; ii) experience; iii) readiness to learn; iv) orientation to learning; and v) motivation to learn.

In the family-based education, the principle of ‘self-concept’ was incorporated during the education session and telephone contact primarily via self-reflection and mutual goal setting. To begin with, the investigator assessed patient and carer learning needs during the face-to-face education and counselling session and established with the patient and carer a short-term goal to be achieved. In addition, the HF manual and the DVD required patients to reflect on their HF symptoms by asking, “Which one of your HF symptoms is the hardest for you manage?” Self-concept, emphasising patient independence, was further developed during the telephone reinforcement, in which patients were encouraged to express their health concerns by being asked questions such as, “I want to be sure I was clear. Could you please tell me, in your words, how you should take the HF medication?”

The adult learning principle of ‘experience’ was incorporated into the educational program as part of the education and counselling session. Patients who had been diagnosed with HF less than two months prior were identified as novices (Riegel et al., 2004). Evidence suggested that newly diagnosed HF patients should be informed about basic matters, such as taking diuretics early in the morning and restricting fluid intake at night (Artinian, Magnan, Christian, & Lange, 2002). As such, patients’ experiences and coping strategies were explored at the beginning of the patient education and counselling session so that the intervention could be tailored to each individual’s unique situation. For example, they were asked, “What do you do to ease your suffering on a day-to-day basis?” Patients’ answers were assessed to see whether
they dealt properly with HF symptoms and, if not, the investigators gave them appropriate advice.

The principle of ‘readiness to learn’ was pre-identified in the volunteering of patients and carers willingness to: i) be involved as participants in this research project, and ii) work together as dyads to improve the self-abilities of the patient. In addition, patients and carers were evaluated on their readiness to learn during the ongoing intervention. Patients’ barriers to performing self-care were also explored during the counselling session.

The fourth principle behind adult learning is ‘orientation to learning’, that is, adults learn best through problem-solving or contextual learning (Knowles, 1984). The present study incorporated this principle into the counselling session and in the teach-back method in the telephone follow-up calls. Specifically, in the counselling session questions were asked to identify the problem-solving strategies of patients and their carers. For example, patients were asked, “Do you have any other problems besides your health that you are dealing with and want to share with us?” and “If so, how are you managing these?” The answers patients provided assisted investigators to scope their health concerns and approaches to self-managing their condition. The teach-back method assisted patients and their carers to retain knowledge via problem-solving or questioning of knowledge in the weekly, fortnightly and monthly telephone follow-ups, some example questions are presented in Srisuk et al. (2014) and Table 4.

The fifth principle of adult learning theory, ‘motivation to learn’, was incorporated into the educational program as part of the counselling session and in their introduction to the educational resources (HF manual and DVD). This was achieved via patients and carers being informed about the benefit of increasing their HF knowledge and how it would enable them to master self-care, thereby improving their quality of life and reducing the chance of unplanned hospital readmissions. The focus of the education was empowering patients and carers through understanding the benefits of increased HF knowledge and self-care.
Table 4 Examples of questions based on a teach-back method

<table>
<thead>
<tr>
<th>Topic</th>
<th>Example questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signs and symptoms of HF</td>
<td>I want to know how well I explained HF. Could you please tell me some of the symptoms of HF?</td>
</tr>
<tr>
<td>Medication</td>
<td>I want to be sure I was clear. Could you please tell me, in your words, how you should take the HF medication?</td>
</tr>
<tr>
<td>Fluid management</td>
<td>Just to see whether I covered it thoroughly. Could you please tell me what you need to watch when weighing yourself?</td>
</tr>
<tr>
<td>Diet</td>
<td>I would like to make sure I did a good job of explaining your diet. Could you please tell me the foods you should avoid?</td>
</tr>
<tr>
<td>Activity</td>
<td>I want to find out whether I explained it well enough. Could you please tell me when you need to call or visit your doctor?</td>
</tr>
</tbody>
</table>

3.3 Development of the HF educational resources: manual and DVD

According to previous studies that have investigated patient learning needs, patient preference is for more than one format of education (Boyde & Peters, 2014; Boyde et al., 2009; Veroff et al., 2012). Knowles (1998) suggests that visual representations can help learners to absorb and transfer knowledge. The DVD accompanying the HF manual for the present study was developed by the researcher. The contents of the DVD were based on the HF manual topics. The DVD is presented using a storyboard. In addition, at the beginning of, in the middle of, and at the end of the DVD the researcher emphasises and summarises the most important messages to reinforce these for the audience. The patient and their carer and/or family member were asked to openly discuss potential issues at the end of each chapter. The HF
manual was deliberately designed and developed using a reader-friendly approach to provide information about health promotion, disease prevention, treatment modalities, and self-care behaviours. In addition, the HF manual and the DVD act as support materials for patients with HF and their carers that they can access whenever necessary. Patients and their carers or family members were highly encouraged to read the HF manual and watch the DVD together.

The content the DVD and HF manual was informed by the recommended HF guidelines from Australia, America, and Europe (Heart Failure Society of America, HFSA, 2010; Krum et al., 2006; Malcom et al., 2008; McMurray et al., 2012; National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand, 2011) and additional advice from expert clinicians in Australia and Thailand. The reliable websites of the Heart Foundation and Heart Failure Association of the European Society of Cardiology were also used to guide the development of HF education resources (Heart Failure Association of the European Society of Cardiology, 2009; National Heart Foundation of Australia, 2012). More specifically, the HF manual was divided into nine chapters (as described in Srisuk et al., 2014) to emphasise key educational items. The use of chapters is an especially effective pedagogical technique for patients with low health literacy (Doak et al., 1996). The topics of each chapter are outlined in Table 5 and examples of the HF manual are shown in Appendix E. At the end of each chapter, patients are asked to answer questions and complete the activities to supplement the contents of the DVD. Medical terminology and jargon are avoided whenever possible. Also, the second-person pronoun ‘you’ is used to make the reader feel that they are communicating with the healthcare provider. For this reason, active rather than passive voice is used in both the HF manual and the DVD. Each HF manual chapter uses a different colour code. For example, signs and symptoms associated with worsening HF and indicating the need for emergency help are coded in red. The manual uses simple language and associates each point with local (i.e. of Thailand) pictures to reinforce understanding. Alternative choices for HF self-care behaviours are offered if patients have limited resources. For example, patients without weighing scales are advised to go to the nearest local public health clinic for regular weighing and close monitoring for the signs and symptoms of fluid congestion.
Table 5: Brief content of the HF manual and DVD by chapter

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Content</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>• Purpose of the HF manual and the DVD</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>• Introduction of HF self-care and its benefit</td>
<td></td>
</tr>
<tr>
<td>1. What is HF?</td>
<td>• Definition of HF</td>
<td>• My heart failure is caused by_______</td>
</tr>
<tr>
<td></td>
<td>• Causes of HF</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Symptoms of HF</td>
<td>• Which one is the hardest for you to manage?</td>
</tr>
<tr>
<td>2. How does heart failure make you feel?</td>
<td>• Shortness of breath</td>
<td>• How can family members help you?</td>
</tr>
<tr>
<td></td>
<td>• Swollen ankles, legs or stomach</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Coughing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Heart going too fast</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Feeling tired</td>
<td>• HF self-care</td>
</tr>
</tbody>
</table>
• Feeling dizzy
• Feeling sad or worried

4. How can make your heart feel better?
• Managing fluid
• Managing salt
• Exercising
• Resting
• Lifestyle modifications
• Flu shots
• How much do you weigh when you feel well? ______kg (i.e. dry weight)
• How much do you weigh when you don't feel well? _______kg
• How much fluid you can have each day ____litres (talk with your doctor)
• Test your knowledge

5. My medicine
• Patient HF medicine
• Side effects of HF medicine
• Fill in the form about discussing what medicine to take with the healthcare professional in accordance with the classification of HF medicine
• List of questions to ask the healthcare professional

6. My health record
• Important patient medical details
• Weight chart and
• Fill out the weight chart every day
7. Your HF action plan

- Important ‘get help’ sign

  e.g. Get help NOW if you have:

  ✓ Severe shortness of breath
  ✓ Chest pain
  ✓ Tightness in your chest, neck, jaw, throat, shoulder, arms or back
  ✓ Have a racing or pounding heart
  ✓ Blackouts

Visit the hospital TODAY if you:

  ✓ Need to sit up to sleep
  ✓ Get swelling in legs
  ✓ Gain 2 kg in weight in two days
  ✓ Are not able to

- Discuss your plan with family members

- Discuss your plan with family members
3.3.1 Cultural adaptation and validation of the HF manual and DVD

The DVD storyboard and script were developed in Australia, and filming took place in Thailand. The manual and DVD were translated into Thai. The contents of both resources were based on HF guidelines from Western countries including Australia (HFSA, 2010; Malcom et al., 2008; McMurray et al., 2012; National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand, 2011), which were then adapted to fit the rural Thai cultural context. Topics included in the HF manual and DVD are described below.

3.3.1.1 Daily weighing

The guidelines recommended that patients weigh themselves daily. In this study, most of the patients were advised to watch for clinical signs of deterioration, such as increased shortness of breath or ankle swelling, and to go to the nearest health clinic as often as possible to be weighed, because access to personal scales is limited and adjusting their own diuretic doses is not endorsed.
3.3.1.2 Asking for help

In Western countries where HF DMPs exist it is recommended that patients seek follow-up assistance until they demonstrate independence and symptom stability. Patients are instructed to contact healthcare professionals immediately if their HF symptoms worsen. In this study, HF DMPs were not available. Instead, patients were encouraged to immediately ask for help, primarily from the carers, if they detected any signs of deterioration. However, in Thai culture, the disruption of others happiness, especially at night, is discouraged (Chiaranai, 2014; Pinyuchon & Gray, 1997), so the investigator needed to emphasise that it is essential to get help whenever HF symptoms worsen.

3.3.1.3 Alternative treatment

The Australian guidelines for the prevention, detection and management of HF mention the use of alternative therapies such as co-enzyme Q-10 and L-carnitine by prescription. However, in Thailand traditional medicines or herbs are widely used without prescription by patients and carers. Therefore, patients were advised to always consult with a doctor before taking any of these traditional medicines.

3.3.1.4 Annual immunisation against influenza

The Western guidelines, including in Australia, recommend that patient should be vaccinated against influenza and pneumococcal disease. In this study, patients were encouraged to have the immunisation if they could afford it, because annual immunisation against influenza is not routinely offered in Thailand.

3.3.1.5 Food

Patients were advised to avoid foods that are high in sodium and were given information on reducing dietary sodium; specific examples of foods to be avoided were provided in both written and pictorial form.

3.3.1.6 Daily activities
Heart failure rehabilitation programs are not routinely provided in Thailand. In this study, many of the participants were orchardists, which requires walking a long distance every day to harvest rubber tree fluid and fruit. Therefore, guidance regarding exercise was developed in consideration of the patient’s occupation, and included how to make appropriate adjustments. However, they were also encouraged to discuss with their healthcare provider any particular type of physical exercise they wanted to engage in.

### 3.3.1.7 Sexual activities

Western guidelines recommend that sexual activity and treatment options are discussed freely with both male and female patients. In Thai culture this would be considered inappropriate (Pinyuchon & Gray, 1997) and was therefore not included in the HF manual or DVD.

### 3.3.1.8 Psychosocial activities

Most Thai people are Buddhist. Buddhism has a strong influence on their ability to cope with psychological issues. Buddhist beliefs have been shown to be a resource that people use when they are facing problems or dealing with difficult life situations, including HF issues (Netchang, 2012; Rerkluenrit, Panpakdee, Malatham, Sandelowski, & Tanomsup, 2010). Therefore, the education program for the present study included religious engagement as one of the strategies for dealing with stress. For example, patients were advised to go to the temple for meditation and participate in religious activities that would foster spiritual support when feeling distressed.

Both the HF manual and the DVD were reviewed by a panel of HF experts in Thailand, which consisted of a cardiologist and HF nurses who had experience in caring for patients with HF. The experts gave some thoughtful recommendations for improving the HF family-based education program and the HF manual, such as adding the key messages for each chapter in the HF manual for reinforcement for the reader. In addition, minimal changes included rephrasing some of the sentences to make them culturally appropriate. The HF manual was tested for readability and comprehensibility by three Thai patient and carer dyads, who reported that
both resources were helpful for the transmission of knowledge and self-care skills and for assistance in coping with HF. They suggested adjusting the font size of the HF manual.

3.4 The perspective of HF family based-education on carers’ health outcomes

Interventions targeting the family can have different perspectives. Relationship-focused interventions primarily focus on skill building in order to encourage family relations while living with the burden of chronic illness management. Such programs usually involve didactic skill building in problem solving, family communication, conflict management, or cognitive restructuring (Chesla, 2010). In contrast, this study is considered to be psychoeducational, which aims to educate patients and family members about disease processes, requirements for care, and basic information about how individuals and families are affected by living with chronic illness. These interventions are largely directed toward increasing knowledge and skills in disease management, such as managing dietary restrictions in HF, and may address individual responses to the demands of HF and its care.

For this study, family members refer to the person who was most involved in the HF patient’s activities related to their self-care. The HF family-based education included dyad face-to-face education, the DVD, and the manual. The primary outcome of the program aims to increase HF knowledge in patients. The carer’s primary outcome is to perceive control of managing a family member’s HF. Secondary outcomes for patients are self-care and HRQoL. For carers, secondary outcomes are HF knowledge and HRQoL. Although the HF family-based education program was primarily developed for dyad, family functioning perspective was also taken into consideration. For example, the HF manual and DVD address the structure and function of the family by including information specifically designed to enhance communication within the family. In other words, the DVD encourages patients, primary carers, and family members to watch the DVD together and discuss the potential issues. The HF manual encourages carers and family members to avoid critical comments when encountering patient self-care behaviours that are not as good as they expected; rather, they were encouraged to discuss alternative choices that might help the patient better manage self-care.
3.5 Methodology for evaluating the intervention

The methodology for the development and evaluation of the HF family-based education is presented in the study protocol publication (Srisuk et al., 2014). This chapter extends on this by presenting the reasoning behind adherence to the Consolidated Standards of Reporting Trials (CONSORT) statement (Moher, Schulz, & Altman, 2001). The CONSORT statement, first developed and published in 1996 then revised in 2001, is a set of guidelines designed to help researchers report on findings from RCTs in a clear and transparent manner so that conclusions can be reliably made as to the efficacy of the interventions investigated (Moher, Schulz, & Altman, 2001). Randomised controlled trials are designed to provide the highest quality of evidence (Burns, Rohrich, & Chung, 2011); however, the need for the CONSORT guidelines arose because of documented deficiencies in clinical trial reports and evidence of bias, exaggerated treatment effects, and incomplete or inaccurate reporting (Bhandari, Richards, Sprague, & Schemitsch, 2002; Moher et al., 2012).

Five of the six studies included in the systematic review presented in Chapter Two did not abide by CONSORT guidelines, and indeed had methodological shortcomings. For example, only one study met eight of the 11 PEDro quality assessment criteria (Maher, Sherrington, Herbert, Moseley, & Elkins, 2003). Each publication described its study design as an RCT, but only two studies indicated that the allocation was concealed. Moreover, none of the studies reported blinding of subjects and/or therapists administering the treatment, and only two studies blinded the assessor collecting the data.

The methodology of the present study carefully applied the CONSORT statement to explanations and elaborations of RCTs of non-pharmacological treatments (Boutron, Moher, Altman, Schulz, & Ravaud, 2008). In addition, the CONSORT guidelines provide an item checklist for reporting trials (see Appendix F). As such, the CONSORT guidelines were followed and adhered to from the outset of this research to ensure robustness of the study methodology and to avoid methodological biases. This not only allowed for transparency in reporting, but also improved the methodology of the study. The following protocol publication (Srisuk et al., 2014) provides details of the methods that were used to develop and evaluate the HF educational
program along with the proposed data analysis. A brief description of the study setting is outlined below, which was not included in the publication, but is warranted at this stage to highlight the gap in HF services this study is trying to address.

Participants who had not been previously exposed to structured HF education were recruited from outpatient clinics in the southern part of Thailand, Chumporn Province, at one provincial hospital and one community hospital. Chumporn Hospital is a 509-bed hospital and Lungsuan is a 120-bed hospital. These two outpatient clinics were selected because they treat patients from the rural community. In Thailand, advanced cardiac services are undertaken in tertiary hospitals located in cities with large populations. In the southern part of Thailand, cardiac catheterisation or heart surgery is performed in only three hospitals: Suratthani, Songkla, and Trang hospitals. Although Chumporn Hospital is a tertiary hospital there are no interventional cardiology services and it is serviced by only one cardiologist (Chumporn Hospital Profile, 2016). In 2010, the total population in Chumporn was 470,000 (Paudel, Lim, & Dureh, 2015). In 2007, on average, 1250 patients visited the outpatient clinics at Chumporn Hospital per day (Bureau of Information Ministry of Public Health, 2010).
Trial of a family-based education program for heart failure patients in rural Thailand

Nittaya Srisuk1*, Jan Cameron1, Chantel F Ski1 and David R Thompson1

Abstract

Background: Heart failure (HF) significantly impacts on the daily lives of patients and their carers. In Western society HF education programs have increased patient and carer knowledge and improved health-related quality of life. However, there is a paucity of such evidence in Asia. For example, to date no studies have been conducted in Thailand to investigate the potential benefits of a family-based education program on the health outcomes of HF patients and carers.

Methods: This randomised controlled trial will evaluate the effectiveness of an education program on knowledge, self-care and health-related quality of life of Thai HF patients and their carers. Assessments will be conducted at baseline, three and six months. Participants will be assigned by independent random allocation to an intervention (family-based education plus usual care) or a control (usual care) group. Analyses will be conducted on an intention-to-treat basis.

Discussion: This trial will be the first to evaluate the effectiveness of family-based education for HF patients and carers residing in rural Thailand. It attempts to advance understanding of family-based HF education and address the gap in service provision.

Trial registration: Thai Clinical Trial Registry TCCTR201405016013

Keywords: Family, Education, Self-care, Health-related quality of life, Heart failure, Thailand

Background

Over 23 million people worldwide suffer from heart failure (HF) [1]. Already at epidemic proportions, this significant global public health problem is predicted to escalate exponentially over the next decade [1]. For example, currently in the United States HF affects over five million people [2] and it is expected that by 2030 eight million will be diagnosed with HF [3]. Heart failure is now one of the most common reasons for hospital admissions in older people, resulting in a substantial economic drain on healthcare resources [4].

One way to redress the burden of HF is through implementation of multidisciplinary chronic disease models of care that have been shown to yield significant benefits, compared with usual care, in reducing readmissions and associated costs and improving patient quality of life [5]. Identified as a key component of these programs is patient education specifically directed at promoting self-care behaviours [6]. Most studies investigating HF patient education have been conducted in Europe [7-10], Australia [11-13] and North America [14-17]. This leaves a significant knowledge gap regarding the efficacy of such programs in Asia, for example Thailand.

The Thai Acute Decompensated Heart Failure Registry (Thai ADHERE) has recognised HF as a major cardiovascular health problem and economic burden [18]. Thai ADHERE epidemiological data were collected from 18 cardiovascular health centres across Thailand. Thai ADHERE found 2,061 HF admissions among 1,612 HF patients during 2006 to 2007. A large proportion of re-hospitalisations were admitted via the emergency department (77%), of which one quarter (25%) required a critical care bed. The absence of HF education programs was identified as a significant factor leading to the high numbers of Thai HF readmissions [18]. Evidence presented from studies conducted in Western countries has
demonstrated that many HF readmissions are preventable through patient education targeting self-care [6,19].

Patient education aims to improve knowledge and skills in order to positively influence attitudes and behaviours, thereby resulting in improved health outcomes [20]. Knowledge can improve an individual’s confidence and sense of control, and with respect to understanding the disease trajectory of HF, can motivate patients to adhere to treatment and lifestyle changes and necessary adaptations [21]. The evidence-base in support of patient education improving HF health outcomes is compelling [5,6,22], and has resulted in the inclusion of educational strategies as a key non-pharmacological component within evidenced-based HF practice guidelines [4,23,24].

The situation-specific theory of HF self-care provides a framework for understanding and evaluating the competencies of HF patients [25]. Self-care refers to a naturalistic decision-making process involving the choice of behaviours patients adopt in order to maintain physiological stability and responses executed when they occur [26]. Appropriate engagement in HF self-care has the potential to reduce HF readmissions and health care costs, and improve health-related quality of life [27]. In light of this, evidence has also revealed that patients with HF demonstrate difficulties in complying with the recommended self-care regimen [28]. Recently, and importantly, patient knowledge and social support from informal carers are fast being recognised as key to successful self-care [29-32].

The informal carer can be defined as a spouse/partner, family member, friend or neighbour who performs caring without pay, assisting the care recipient with daily activities and/or medicine administration [33]. The role of carers is crucial in HF self-care. A recent systematic review found that the social well-being of HF patients is strongly linked with carers’ support in performing HF self-care [29]. Social support has been found to be a vital resource for patients with HF and used as part of their everyday coping strategies [32]. Patient health outcomes, including health-related quality of life (HRQoL), rehospitalisation, adherence to HF treatment, and optimal engagement in self-care, are strongly associated with the existence of carers [34]. International guidelines now specify that carers be included in the educational processes that promote HF self-care [35-37], though the number of intervention studies that have focused on informal carers of HF are limited [38].

Although the evidence is compelling as to the importance of patient education promoting self-care, most studies investigating patient education have been conducted in Europe, Australia and North America where the characteristics of the population and the culture are often quite different from that in Asia, including Thailand, and especially in rural communities. In Thailand only one published randomised trial of education (coaching by telephone) in HF has been conducted [39], and only two other published studies have explored the notion of education improving knowledge, self-care and HF symptoms [40,41]. However, limitations of these studies include the use of quasi-experimental designs, small samples, differing theoretical frameworks for developing the educational strategies, and varied settings - home-based to outpatient clinic settings – for conducting them. Moreover, none of these studies included carers, or delivered the education program in the community, nor examined changes in HRQoL in both the patient and carer as an outcome of the education. In light of the incomplete body of knowledge regarding the effectiveness of an education-based intervention for HF patients and carers in Thailand, and the increasing prevalence of HF in Thailand, further research is warranted.

Cultural perspectives become paramount when adapting a Western-based intervention into an Asian country. For example, in Thailand the role of carer is crucial, and the Buddhist concept of karma strongly influences Thai people’s beliefs and their way of thinking and living. Although demographic and socio-economic aspects have changed dramatically in Thailand over recent decades, family members remain the pillar of support for elderly people [42]. Living with older parents, showing respect and taking care of them are considered a normal way of family life and are highly valued in Thailand. Therefore, providing an education program that involves both the patient and carer has the potential to enhance the quality of life for the patient with HF, and for their supporting family [43].

Aim
The aim of this research is to develop and evaluate a family-based education program for HF patients and their carers residing in rural Thailand.

Hypothesis
We hypothesise that a family-based education program is effective in improving HF knowledge, self-care behaviour and HRQoL for patients, and perceived control, HF knowledge and HRQoL for their carers living in rural Thailand.

Methods
Study design
This is a prospective single-blind randomised controlled trial of family-based education versus usual care for HF patients and their partners residing in rural Thailand. Ethics approval has been obtained from the Human Research Ethics Committees of the Australian Catholic University and Chumphon Hospital and informed consent will be obtained from all participants prior to enrolment. The trial will be conducted in accordance with
CONSORT (Consolidated Standards of Reporting Trials) guidelines ([44] See Figure 1).

The setting will be outpatient clinics at one provincial hospital and one community hospital in Chumphon province in the south of Thailand. These clinics were purposively selected on the basis that they are representative of HF patients and care in the rural community. Participants will be assigned by independent random allocation to an intervention (family-based education plus usual care) or a control (usual care) group.

**Participant eligibility**

Participants for this study will be a dyad consisting of a patient and their partner or family member that is identified as providing informal care. All participants will need to have sufficient comprehension to read Thai without the need for a translator. The patients will be aged 20 years or over, although with the increasing prevalence of HF in the elderly, it is envisaged that the majority will be above 50 years of age. The inclusion criteria for HF patients are: 1) a primary diagnosis of HF NYHA (New York Heart Association) class I to III confirmed by the treating doctor and determined by a history of typical signs and symptoms and physical examination [45]; and, where possible, objective evidence of cardiac dysfunction on echocardiogram; 2) at least one family member residing with them; 3) contactable by telephone at home; and 4) a DVD player at home. The inclusion criteria for carers are: 1) living in the same household as the HF patient or someone of the patient’s own choice; and 2) aged 20 years or over. Participants will be excluded if they reside in an urban area, have a documented history of dementia or severe psychiatric illness, are unable to continue to follow the protocol, and have severe symptoms indicative of acute heart failure.
[24,36] or complications from cardiac or disease or other life threatening comorbidities.

Recruitment
This trial will enroll a minimum of 100 dyads sourced from two rural hospitals in Thailand. Participants will be identified for enrollment by clinical staff based on inclusion criteria. Potential dyads will be approached at their regular outpatient appointment or contacted via telephone and verbally informed of the study. The dyads who agree to participate will receive a verbal and written explanation of the study by the investigator or the attending nurse, allowing them time to consider and freely participate.

Randomisation
The investigator will derive the random allocation from a computer-generated sequence of random numbers. Each dyad will be randomised at a 1:1 ratio in blocks of ten to either the control (usual care) or intervention (family-based education plus usual care) group. The random allocation will be sealed in an envelope and retained by technical staff at each hospital to give to the research assistants. Once participants have consented to the study and baseline data has been collected, the research assistant will open the sealed envelope indicating the group allocation. In this way, the research assistant collecting baseline data will be unaware of which group participants have been allocated to.

Intervention
Development of the HF education DVD and manual
A HF DVD and accompanying manual was developed by the principal investigator guided by adult learning theory [47] and studies that have investigated the individual learning needs of HF patients, especially in Asia [48-51]. Both the DVD and HF manual have been reviewed by a panel of HF experts in Australia and verified for content and cultural validity by a panel of HF experts in Thailand. The DVD and HF manual have been tested for readability and comprehensibility by three HF patients and carer dyads, who reported both resources to be helpful in gaining knowledge and self-care skills as well as assisting in coping with HF.

The DVD contains nine chapters that explain key aspects in learning to live with and adjust to HF. Chapter headings are: 1) What is HF?; 2) How does HF make you feel?; 3) When you feel sick what should you do?; 4) How you can make your heart feel better?; 5) Your medicine; 6) Your health record; 7) Your HF action plan; 8) Tips for your family and friends; and 9) Conclusion. The DVD was developed in an easy and simple mode for patients and carers to readily absorb the information, using pictures that reflect the Thai cultural context. At the end of each chapter, a reflective question is asked to encourage the patient and their carer to interact and discuss openly potential issues (e.g. which of the symptoms is the hardest for me to manage?).

The written manual is based on the DVD chapters and combines information for both patient and their carers. The manual contains more detail than the DVD, including written material, pictures and health record forms. The HF manual is divided into easily recognisable, colour-coded chapters that correspond to the nine DVD chapters. Both patient and carer will be asked to read each chapter within the manual and also help each other to complete the reflective questions or activities at the end of each section.

Intervention group
Treatment fidelity will be used to guide the implementation of the educational program which consists of five processes including: design, training, delivery, receipt, and enactment [52,53]. The dyads in the intervention will receive their usual care plus a single individualised patient-carer education session. Education sessions will be conducted in the teaching room of the outpatient clinic. Dyads will receive the HF manual and a 45 to 60 minute education session focused on HF self-care. At the end of the session they will receive instructions about using the DVD and manual with their primary carer and/or family members. In addition, the intervention group will receive scripted telephone calls for 15 minutes per week in the first month, fortnightly in the second month, and once a month for the third to sixth month. The purpose of the telephone call is to reinforce, support and counsel each dyad about the HF information provided and assess any ongoing learning needs. The principal investigator will use the teach-back method [54] with each telephone call and give the dyad an opportunity to ask questions. The teach-back method is a technique used by educators to recall, deliver messages, encourage, and check for understanding, with participants asked to repeat the information that has been imparted to them [54]. This technique has been used to assess learning and promote self-care in patients with chronic conditions [54-56]. Specifically, in patients with HF, the teach-back method has been found to be an effective approach used in evaluating and educating patients’ self-care abilities [57,58].

Control group
The control group will receive usual care provided by a clinic and that includes: routine follow-up, physical and laboratory examinations, and general medical advice. The care of the HF patient will receive any additional information if requested. In addition, the control group will receive weekly telephone calls for the first month, fortnightly for the second month, and once a month for
the third to sixth month. To reduce the potential of patient contact acting as a confounding variable, the control group will also receive matched telephone calls, although the content of these calls will differ to that of the intervention group by being of a generic nature. Thus the telephone calls for the control group will not contain information based on the family support intervention; instead they will discuss in general terms how the patient and carer are feeling. If the patient's condition has deteriorated significantly they will be advised to go and see their doctor. In consideration of the principle of fairness, at the end of the six month follow-up period participants in the control group will be offered a copy of the HF DVD and accompanying manual.

Data collection
Before randomisation all dyads will complete baseline questionnaires. Outcome measures will be collected at three and six months at the outpatient clinic or via telephone interview. Data will be collected by research assistants who are not aware of study group allocation. Questionnaires will take approximately 45 to 60 minutes to complete.

Primary outcome measures
The primary outcome will be HF knowledge as measured by the Dutch Heart Failure Knowledge Scale (DHFKS) in patients. The carers’ primary outcome will be perceived control about managing their family member’s HF as measured by the Control Attitudes Scale (CAS).

Secondary outcome measure
Secondary outcomes for patients will be self-care as measured by the Self-Care of HF Index (SCHI) and HRQoL as measured by the Minnesota Living with HF (MLHF) questionnaire. For carers, secondary outcomes will be HF knowledge as measured by the Dutch Heart Failure Knowledge Scale (DHFKS) and HRQoL as measured by the Short-Form 12-item (SF-12) health survey.

Participant descriptive data
Participant clinical and socio-demographic characteristics will also be collected, including number of social supports, education level; occupational status; health literacy (measured using a single question “How confident are you filling out medical forms by yourself?” [69]); cognitive assessment (measured using the Montreal Cognitive Assessment [68]); comorbid illness burden (measured using Charlson Comorbidity Index [61]); vital signs; cardiac related history including cardiovascular risk factors and length of time living with HF; New York Heart Association functional classification [62]; and HF current treatment.

Summary of outcome measure
Knowledge
The Dutch Heart Failure Knowledge Scale (DHFKS) [63] is a self-report questionnaire consisting of 15 multiple choice items related to: HF in general (4 items), HF treatment (6 items related to diet, fluid restrictions and activity), symptoms and symptom recognition (5 items). The scale has a minimum score of 0 (no correct answer) and a maximum score of 15 (all answers correct), higher scores indicate better knowledge. The tool developed in the Netherlands and tested on 902 HF patients, was found to be reliable (Cronbach’s α .62) and valid [58]. The scale has been shown to be sensitive in differentiating between patients who had and who had not received education and counselling (p < .01) and has been widely used in clinical settings to evaluate patients’ HF knowledge [22,64,65].

Self-care
The Self-Care of Heart Failure Index (SCHI) [66] is an instrument that measures HF self-care behaviours and skills through self-report. The SCFI comprises 15-items with a four-point Likert response scale. It contains three subscales: self-care maintenance, self-care management, and self-care confidence. Self-care maintenance measures symptom monitoring and compliance with HF treatment in order to prevent worsening symptoms such as checking ankles for swelling and eating a low salt diet. Self-care management measures the capability to recognise changes in HF symptoms, assess the meaning of the changes, and make a judgment on appropriate treatment actions. For example, if a patient experiences weight gain of more than 2 kg in two or three days, an appropriate action would be to take an extra diuretic. Self-care confidence measures perceived control to perform self-care in each phase such as how confident they feel in recognising symptom changes when they occur. Scores from each of the three self-care subscales are transformed to 100-point scales; higher scores reflect better self-care. Self-care management scores are only computed for those patients reporting HF symptoms of ankle swelling or trouble breathing in the previous three months [66]. The SCFI was selected because it is a reliable measure of self-reported self-care skills and behaviours [66] and has been extensively validated among HF populations around the world. The SCFI has also been reliably translated into Thai [67]. In the Thai context the tool was administered to 400 HF patients and found to be reliable: Cronbach’s alpha coefficient of 0.85 [67].

Health-related quality of life
The Minnesota Living with Heart Failure (MLHF) questionnaire (MLHF) [68] is a disease-specific measure of HF HRQoL assessing patients’ perceptions as to the
influence of HF on physical, socioeconomic, and psychological aspects of their life. The MLHF consists of 21 questions focused on patients’ perceptions concerning the effects of HF on their physical functioning, such as shortness of breath, fatigue, and peripheral edema and their emotional life such as memory loss, loss of self-control, and side effects of HF treatment [68]. Patients respond to the 21 items using a 6-point Likert scale (0 = none; 5 = very much). The total score ranges from 0 to 105; a lower score reflects better HRQoL. Internal consistency reliability of the MLHF using Cronbach’s alpha coefficient was .91 [69]. The Thai version has been used in 622 HF patients, and in pilot testing in a sample of 30, had good reliability with a Cronbach’s alpha coefficient of 0.94 [70].

The Short-Form 12-item (SF-12) health survey [71] is a generic measure of HRQoL that will be used in this study as a combination of generic and disease-specific measures has been recommended. The SF-12 [72] is a shortened version of the original SF-36 [73] and consists of 12 items with a 5-point Likert scale (1 = all of the time, 5 = none of the time). The 12 items include the self-assessment of health, physical functioning, physical role limitation, mental role limitation, social functioning, mental health, and pain. The summary score provides an indication of physical and emotional functioning, with higher scores indicating better HRQoL. The Thai version of the SF-12 has been used with 98 HF patients, reliability in this population was 0.83 [74].

Perceived control about managing family member’s heart problems
The Control Attitudes Scale (CAS) family version will be used only for the caregivers of patients with HF in this study [75,76]. The CAS family version consists of eight items scale with a 5-point response scale (1 = strongly disagree, to 5 = strongly agree). The items address how much perceived control or how helpless individuals feel about managing their family member’s heart problems. Higher scores indicate greater perceived control. Internal reliability of the CAS tested in 21 caregivers of patients with HF was 0.75.

Instrument translation
There are three research tools which will be translated into Thai language: the brief screening questions for detecting in adequate health literacy, the DHFKs, and the CAS. The investigator will use the World Health Organisation [77] model process of translation and adaptation of instruments to guide the questionnaire translation.

Data analyses and sample size calculation
Data collected will be entered into the Statistical Package for the Social Sciences (SPSS Inc.). Descriptive statistics will be used to analyse demographic data. The sample size calculation is based on changes in HF knowledge. In a previous study investigating HF knowledge as the primary outcome [22]), a sample size of 50 per group and allowing for a 10% attrition rate, had adequate power (0.80) with a two-sided 95% significance to detect a difference of two-points on the DHFKs between the intervention and control conditions in mean post-test versus pre-test changes on the DHFKs and 93% power to detect clinically significant difference in MLHF scores of 6-points. For this study, assuming a medium effect size (0.65) in the between-group differences on the DHFKs and allowing for a 20% attrition rate, the minimal sample size of 40 per group will have sufficient power (0.80). An independent t-test will be used to test the overall differences of the DHFKs, SCHFI, CAS, MLHF and SF-12 within the groups and between the control group and the intervention group at baseline and over three and six months. Two-way repeated measures analysis of variance (ANOVA) will be used to test the difference between groups and change overtime in each group of the main outcomes (DHFKs, SCHFI, CAS, MLHF and SF-12). Treatment failure and withdrawal will be considered on an intention-to-treat basis, with the aim of providing a more realistic estimate of the difference between the two groups.

Process evaluation
Ongoing monitoring of program activity in both the intervention and control group will be regularly conducted. Participants will be interviewed when the principal investigator performs a telephone follow-up. Participants in the control group will be asked how satisfied they are with regular telephone contact. The investigator will pilot test the DVD and HF manual in six HF patients and caregivers prior to implementation of intervention, to ensure their usability and refine if necessary. Participants in the intervention group will be asked how satisfied they are with the DVD and the HF manual and telephone follow-up. At the end of the program participant satisfaction will be measured using a visual analogue scale and participants will be invited to offer additional comments. Completion of activities in the HF manual will be assessed by viewing participants’ HF manual at the six-month assessment. This process assessment is integral to identifying cultural and social facilitators of, and barriers to, the process of lifestyle behaviour change to improve HF risk as a result of this educational intervention.

Discussion
This trial will test the effectiveness of a family-based education program for HF patients and their carers residing in rural Thailand. Patient education is rapidly becoming recognised as a key component of HF management. Unfortunately, most trials of such programs have been undertaken in Western countries which have considerable
differences to Asian countries in terms of, for example, patient characteristics, settings, interventions, and outcome measures. This is the first trial of such a program in rural Thailand taking into account cultural and societal factors.

The trial will not only provide evidence pertaining to the effectiveness of education programs for Thai HF patients, but it will be the first to include family members. We hypothesise that a family-based education program will improve HF knowledge, self-care and HRQoL in patients and carers in rural Thailand. This will be assessed via the implementation of a HF manual and DVD specifically developed to meet the knowledge requirement of HF patients and carers.

Abbreviations
HF: Heart Failure; THAI: Thai Acute Decompensated Heart Failure Registry; MRFQ: Minnesota Living with Heart Failure questionnaire; SF-12: Short-Form 12-item Health Survey; ANOVA: Analysis of Variance.

Competing interests
The authors declare that they have no competing interests.

Authors’ contributions
NK, JC, CSF and OWR were involved in the conception and design of study, and drafting of the manuscript. All authors read and approved the final manuscript.

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3.6 Chapter Three summary

This study addresses an important gap in the management of HF in Thailand with the development of a culturally relevant, theory-driven, family-based education program. In Chapter Three the development and methods of the family-based education program have been presented. In addition, the methodology for the conduct of RCTs to evaluate this program has been described. The procedures for data collection, the study protocol, and the ethical considerations were also described in the research paper (Srisuk et al., 2014). In order to examine the effects of the HF education program, outcome variables in both the patient and their carer were measured at baseline, then three and six months after the commencement of the education program. Chapter Four presents the findings of the HF education intervention at each time point.
Chapter Four: Results

4.1 Chapter introduction

Although it has been recommended that patients with HF and their carers be educated on self-care, few studies have specifically set out to examine this in patient and carer dyads. Chapters One and Two of this thesis confirmed the evidence gap in HF family-based education in the West, and even more so in the East, in countries such as Thailand (Srisuk et al., 2016). The protocol for the RCT of an HF family-based education for patients and their carers was presented in Chapter Three. It is hypothesised that a family-based education program will be effective in improving HF knowledge, self-care behaviour, and quality of life of patients, and perceived control, HF knowledge, and quality of life of their carers in rural Thailand. The current chapter reports on the findings of the RCT that was designed to answer the following research questions:

Is there a significant difference in knowledge, self-care behaviours, and quality of life between patients with HF randomised to receive the family-based education or usual care?

H$_{1}$: Patients with HF receiving the family-based education program will have significantly higher knowledge, self-care behaviours, and quality of life compared to patients with HF receiving usual care.

Is there a significant difference in perceived control over managing patients’ HF symptoms, knowledge, and quality of life between carers randomised to receive the family-based education or usual care?

H$_{1}$: Carers of patients with HF receiving the family-based education program will have significantly higher knowledge, self-care behaviours, and quality of life compared to carers of patients with HF receiving usual care.

These findings have been submitted to the Journal of Advanced Nursing and are presented in a word version. Chapter Four will also present: i) supplementary data analysis on the DHFKS administered to carers, and ii) findings from the process evaluation. These data were
not submitted to the journal, but are relevant to the thesis because they demonstrate further academic contribution in analysis and evaluation of the education program.
Randomized controlled trial of family-based education for patients with heart failure and their carers (Paper 3)

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No conflict of interest has been declared by the authors.

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Abstract

Aim. To develop and evaluate a family-based education program for patients and carers living at home with heart failure in rural Thailand.

Background. Heart failure is major health problem and according to best practice guidelines, patients and carers should receive individualized education and counselling that emphasize self-care skills to improve health outcomes. However, only a few family-based studies, conducted in the West, have evaluated such programs for patients and carers, and none have been conducted in Asia.

Design. Randomized controlled trial.

Methods. One hundred consecutive patient-carer dyads attending cardiac clinics in southern Thailand from April 2014-March 2015 were randomized to usual care (n=50) or a family-based education program (n=50) comprising face-to-face counselling, a heart failure manual and DVD.
and telephone support. Assessments of heart failure knowledge, health-related quality of life, self-care behaviours and perceived control were conducted at baseline, three and six months.

**Results.** Patients and carers who received the education program had higher knowledge scores at three and six months \((p < .01)\) than those who received usual care. Among those who received the education program, when compared to those who received usual care, patients had better self-care maintenance and confidence and health-related quality of life scores \((p < .05)\) at three and six months, and better self-care management scores \((p < .05)\) at six months, whereas carers had higher perceived control scores \((p < .05)\) at three months.

**Conclusion.** A culturally and linguistically-appropriate family-based education programme for patients with heart failure and carers improved patients knowledge, self-care behaviours and emotional health-related quality of life, and carer knowledge and perceived control.

**SUMMARY STATEMENT**

**Why is this research or review needed?**

- Heart failure is a significant health problem and clinical guidelines emphasize the importance of including patients and carers/family members in education, particularly regarding self-care behaviours, to improve health outcomes.
- Despite guidelines recommending their inclusion, few studies have reported the effect of such education on patients and their carers.
- There are no reported studies examining the effects of education on knowledge and self-care behaviour among patients with heart failure and their carers in Thailand.

**What are the key findings?**

- A family-based education program for patients with heart failure and carers improved patient knowledge, self-care behaviours and emotional health-related quality of life.
- It also improved carer knowledge and perceived control in managing patient symptoms but not health-related quality of life.
• Both patients and their carers retained improved knowledge at three and six months after the program finished.

**How should the findings be used to influence policy/practice/research/education?**

• This family-based education program could be feasibly rolled out across Thailand and incorporated into routine discharge care planning.

• Nurses can improve health outcomes in patients with heart failure and their carers by delivering education through a variety of media that is culturally and linguistically-appropriate in promoting self-care skills.

• Future research should consider collecting other outcome data such as hospital readmission and mortality rates.

**Keywords:** heart failure, family-based, education, nursing, randomized controlled trial, Thailand
Introduction

Heart failure (HF) is a major public health problem affecting nearly 26 million people worldwide (Ambrosy et al. 2014). In Asia, given its recent dramatic socioeconomic development, the epidemiology of HF is similar to that in Western Europe and North America (Mendez & Cowie 2001). In Thailand, for example, where patients with HF are typically younger, present with more severe signs and symptoms and require more advanced medical care, the importance of patient education is acknowledged (Laothavorn et al. 2010). This is supported by systematic reviews which suggest that appropriate HF education targeting patient engagement in self-care behaviours is likely to improve patient health outcomes (McAlister et al. 2004, Ditewig et al. 2010).

Background

Self-care is an integral part of successful HF management (Phillips et al. 2005, Yu et al. 2006, Jaarsma et al. 2013a) and has been defined as a naturalistic decision-making process that the patient adopts to sustain their health and respond appropriately to HF symptoms (Riegel et al. 2004). Engagement in HF self-care has the potential to reduce HF readmissions and health care costs and improve patients’ health-related quality of life (McAlister et al. 2004, Holland et al. 2005, Boren et al. 2009, Wakefield et al. 2013, Yves et al. 2014). However, educational interventions are not always successful in improving patient health outcomes and self-care behaviours (Riegel & Moser 2015). Reasons include the lack of attention in adopting a patient-centred approach, the absence of behavioural tactical skill building, the intervention dose being short-term, and the content of the intervention having not been developed with consideration of cultural norms (Dickson et al. 2015). In addition, patients often require the assistance of family members for support in developing self-care skills even though they are not specifically included in educational interventions (Riegel & Carlson 2002, Yu et al. 2008, Holden et al. 2015).
Though family members are considered ‘informal carers’ as they do not receive financial remuneration for the support they provide, their input is extensive, primarily consisting of assisting with various activities of daily living (bathing, dressing, shopping, transportation, housekeeping, and finances) and activities related to HF self-care (diet and fluid restrictions, medication compliance, symptom recognition, and contacting health professionals for advice) (Buck et al. 2015). It is contested that 45% to 70% of HF patients have instrumental support from a caregiver (Buck et al. 2013); thus self-care occurs in a dyadic context. There is growing evidence for the instrumental role that carers play in improving HF health outcomes (Clark et al. 2008, Stromberg 2013, Spaling et al. 2015, Vellone et al. 2015), which has been translated into international practice guidelines (Malcom et al. 2008, Krum et al. 2011, McMurray et al. 2012, Yancy et al. 2013). However, there has been limited translation of these into practice; despite carers having unique insights into the manifestation of HF at home, they are largely absent from educational and disease management efforts (Clark et al. 2014, Srisuk et al. 2015). Many educational programs do not reach their full potential because the family context in which patients perform self-care has often not been taken into consideration (Dunbar et al. 2008). Consequently, carers often experience adverse psychosocial health outcomes, for example depression, burden, and poor quality of life (Ågren et al. 2011, Pressler et al. 2013, Burke et al. 2014). Thus, the testing of family-based interventions designed to improve HF self-care have been recommended which take into account the influence of factors such as culture (Dunbar et al. 2008).

The importance of the family context is perhaps greater in non-Western cultures. Invariably, studies conducted to date have focused on Western populations and there is a dearth of studies examining these issues among non-Western ones. The cultural perspective becomes paramount when adapting a Western-based intervention for a Southeast Asian population (Jaarsma et al. 2013b, Deek et al. 2016). For example, in Thailand younger family members predominantly provide care and support to their elders (Thanakwang & Soonthorndhada 2011). Living with older parents, showing them respect and taking care of them are ancient customs of family life and are highly prized in Thailand (Thanakwang 2009).
Yet, despite these cultural norms, to date, no studies conducted in Thailand have adopted a family-focused framework by including carers in the delivery of education and evaluating outcomes in patient and carer dyads. Consequently, the dearth of education programs developed specifically with cultural perspectives may help explain why patient engagement in HF self-care in Thailand is particularly poor compared to that in other developing nations and in Westernised countries (Jaarsma et al. 2013b).

Only one randomized trial of an education program examining the impact of face-to-face coaching with telephone support has been conducted in Thailand (Wongpiriyayothar et al. 2011). Over eight weeks, the intervention group had significantly decreased dyspnea severity and higher scores in physical functioning compared to the control group (Wongpiriyayothar et al. 2011). However, study limitations included the use of quasi-experimental designs, small samples, educational strategies based on differing theoretical frameworks and varied settings. Furthermore, no study included carers.

The study

Aims

The aim of this study was to develop and evaluate a family-based education program for patients with HF and their carers residing in rural Thailand. We hypothesized that compared to usual care, a family-based education program would: i) improve patient HF knowledge, self-care behaviours and health-related quality of life; ii) improve carer perceived control over managing patients’ HF symptoms, HF knowledge and health-related quality of life; and iii) maintain these changes over six months.

Design

This study was a randomized controlled trial (RCT) with follow-up assessment after three and six months (Trial registration: Thai Clinical Trial Registry TCTR20140506003). The study protocol has been reported elsewhere (Srisuk et al. 2014). Figure 1 depicts a summary of the study
design and participant flow based on the CONSORT (Consolidated Standards of Reporting Trials) reporting guidelines (Boutron et al. 2008). The trial was conducted in two public hospitals in southern Thailand.

**Participants**

The sample consisted of 50 dyads per group as determined by a previous study that investigated HF knowledge as the primary outcome (Delaney et al. 2013). Details of the sample-size calculation are reported elsewhere (Srisuk et al. 2014). Each dyad consisted of a patient diagnosed with HF and a family member, or someone of the patient’s choice, who had been nominated as an informal carer. Inclusion criteria for patients were: 1) aged 20 years or over; 2) a primary diagnosis of HF with NYHA (New York Heart Association) functional class I to III as confirmed by the treating doctor and/or patient history (Ho et al. 1993) and where possible, objective evidence of cardiac dysfunction on an echocardiogram; 3) residing with at least one family member; 4) being contactable by telephone at home; and 5) having a DVD player at home. Inclusion criteria for carers were: 1) living in the same household as the patient with HF; 2) aged 20 years or over. In addition, each dyad had to be able to read and understand Thai without a translator. Dyads were excluded if either member had a documented history of dementia, severe psychiatric illness or life-threatening comorbidities.

**Groups**

*Family-based education program*

The education group received usual care and face-to-face patient and carer education, a counselling session with trained nurses and a HF manual and DVD. The education session was conducted in the hospital out-patient clinic teaching room and lasted 40 to 60 minutes. The nurse who led the session was trained by the researcher and assessed to be competent prior to implementing the education. At the end of the session, dyads received instructions about using the manual and DVD. In addition, scripted telephone calls were delivered for 15 minutes per week in the first month, per fortnight in the second month and once a month in the third to
sixth months. The principal investigator and research assistant who delivered the intervention used the teach-back method (Peter et al. 2015) with each telephone call and gave each dyad the opportunity to ask questions. Teach-back has been found to be an effective method for evaluating patient comprehension of educational efforts and assimilation of self-care behaviours (White et al. 2013, Peter et al. 2015).

The education materials provided to each dyad were developed by the researcher and guided by adult learning theory principles (Knowles 1998) and studies that had investigated the individual learning needs of HF patients, especially in Asia (Kato et al. 2012, Yu et al. 2012, Jiang et al. 2013). Content was developed from relevant HF media and websites endorsed in Australia and adapted for cultural relevance by using pictures and text that reflected the Thai cultural and linguistic context. Both the HF manual and DVD had been translated into the Thai language at a level equivalent to schooling at primary level only. The manual and DVD were checked by HF experts in Australia and verified for content and cultural validity by a panel of HF experts (cardiologist and HF nurses) in Thailand. The manual and DVD had been tested for readability and comprehensibility by three patients with HF and carer dyads who reported both resources to be helpful for gaining knowledge and self-care skills as well as providing assistance for coping with HF. A sample of HF patients was also given the opportunity to review and their comments, in regard to formatting of text, were also included.

The manual contained nine chapters that explained key aspects of learning to live with HF and included pictures and health records as well as text. The DVD contained matched content. The HF manual was divided into easily recognizable, colour-coded chapters that corresponded to the nine DVD chapters. Patients and carers were asked to read each manual chapter after having watched the corresponding DVD chapter and also to help each other complete the reflective questions and activities. The manual and DVD incorporated skills building by providing the patient with a variety of activities such as self-appraisal, role-modeling, teaching problem solving, and learning self-monitoring skills.

Usual care group
The usual care group received standard medical and nursing care from the hospital, including physical and biomedical examinations at outpatient clinics and general medical advice (usually a brief discussion on current health status). To reduce the potential of patient contact acting as a confounding variable, this group received equivalent contact with research personnel to the education group; this involved general health discussion and was not HF-specific. Further details of both groups are reported elsewhere (Srisuk et al. 2014).

Data collection

Demographic and clinical variables were obtained at baseline from interviews and medical records. Comorbidities (Charlson et al. 1987), health literacy (Chew et al. 2008) and cognitive function (Nasreddine et al. 2005) were also assessed at baseline to identify any potential confounding variables.

Outcome measures

Outcome measures were assessed at baseline, three, and six-months. The primary outcome was HF knowledge in patients and perceived control in carers. Secondary outcomes for patients were self-care and health-related quality of life. For carers, secondary outcomes were HF knowledge and quality of life.

Knowledge was measured with the Dutch Heart Failure Knowledge Scale (DHFKS) (van der Wal et al. 2005). Carer perceived control over managing patients’ HF symptoms was measured with the Control Attitudes Scale-Revised (CAS-R) (Moser et al. 2009). Self-care behaviour was measured with the Self-Care of Heart Failure Index (SCHFI) (Riegel et al. 2009b). Health-related quality of life was measured with the Minnesota Living with Heart Failure (MLHF) questionnaire (Rector & Cohn 1992). General quality of life in carers was assessed with the Short-Form 12 health survey (SF-12) (Ware et al. 1996).

Validity and reliability of instruments
To enhance validity and reliability of the data, instruments with good psychometric properties were used. The psychometric properties of the DHFKS, CAS-R, SCHFI, MLHF, and SF-12 have been shown to be satisfactory in previous HF studies (Bakas et al. 2006, Krethong et al. 2008, Suwanno et al. 2009, Chiaranai & Salyer 2010, Delaney et al. 2013). Specifically, the SCHFI, MLHF and SF-12 were used in Thai populations and demonstrated good reliability (Suwanno et al. 2009, Krethong et al. 2008, Chiaranai Salyer 2010).

Procedure

The dyads were recruited from April 2014 to March 2015. Dyads who met the inclusion criteria were identified by a full-time nurse who had access to their medical records. Potential dyads were approached at their regular outpatient appointments or contacted via telephone and verbally informed of the study. Eligible dyads who agreed to participate in the study were randomized using a computer-generated sequence of random numbers at a 1:1 ratio in blocks of ten to either the control group or the intervention. Random allocations were supplied to the research assistants in a sealed envelope by a technical staff member. The technical staff member was not a member of the research team. Group allocation was only revealed after participants consented to the study and baseline data had been collected. The assessor who collected the outcome data was blinded to dyad groups. The nurses who delivered the intervention were not involved in the data collection processes.

Ethical considerations

Ethics approval (2013 310 AV) for conducting this trial was obtained from the Research Ethics Committees of the university in Australia and local hospitals in Thailand.

Data analysis

The data analysis used SPSS version 22 software, and the significance level was set at .05. Basic descriptive analysis was conducted using the chi-square test (proportions) for nominal variables and the t-test (mean and standard deviation (SD); and effect size (ES) for continuous normally distributed data. According to CONSORT statement (Boutron et al. 2008), it is not necessary to
test for baseline differences between groups in trials because any differences will be due to chance. However, it appears that reporting of baseline group differences persists in publications (Knol et al. 2012). Although it is acknowledged that any significant differences in baseline group characteristics will have no implications for the validity of the study findings, it was decided to examine baseline group differences for descriptive purposes. The differences in the outcome variables (DHFKS, SCHFI, MLHF, CAS-R and SF-12) between the two groups over time were analyzed using a linear mixed model. The within patient covariance structure was set as unstructured. The type III fixed effect test was used to determine significance. There were no significant differences in the DHFKS, SCHFI, MLHF, CAS-R and SF-12 scores between the intervention and control groups at baseline (See Table 4). If significant group by time interaction effects were found, the mean pairwise comparison was conducted to compare the mean differences between the groups at each time point. Missing data were handled according to scale requirement. Data analysis was based on the intention-to treat-principle.

Results

Reliability of instruments

The reliability of each instrument used in the study was adequate (Table 1), though it should be noted that this is the first study to administer the DHFKS among carers.

Characteristics of patients

One hundred and thirty-one patients diagnosed with HF were screened and assessed for eligibility to participate in the study; ten patients declined and 21 did not meet the inclusion criteria. There were no significant differences in age and gender between eligible (n=100) and ineligible (n=31) groups. The mean age of the HF patient was 62 years (SD=16.24); 53 were female. Half had a medium Charlson comorbidity index and were NYHA functional class II. Around half of the patients were prescribed gold standard pharmacotherapy: an angiotensin converting enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB), nearly two-thirds a
beta-blocker and three-quarters a diuretic (Table 2). No significant differences in clinical or demographic variables ($p \geq .05$) were identified between education and usual care groups.

**Characteristics of carers**

Carers were predominantly female and married and over one third a child of the patient with HF. The mean age of carers was 41 years ($SD=10.74$). No significant differences were identified in demographic variables ($p \geq .05$) between education and usual care groups (Table 2).

**Changes in HF knowledge**

Type III tests of fixed effects in the linear mixed model showed that HF knowledge changed significantly with time ($F(2/87)=69.88$, $p<.01$) in patients. A significant interaction was found between education and usual care groups and over time ($F (2/87)=43.16$, $p < .01$) (Table 3). The significant interactions were examined by conducting simple effect tests that compared the groups at each time point (Table 4). Patients in the education group had a 2.2-point higher DHFKS score than those in the usual care group at three months (95% CI [1.06, 3.34], $p < .01$) and a 1.7-point higher score at six months (95% CI [0.64, 2.87], $p < .01$). This represented a medium effect size at three ($ES=0.72$) and six ($ES=0.58$) months.

For carers, the fixed effect showed that there was a significant difference between the groups ($F (1/98)=17.70$, $p < .01$) with DHFKS scores changing significantly with time ($F (2/31)=85.43$, $p < .01$), and a significant interaction between group and time ($F (2/91)=29.40$, $p < .01$) (Table 3). At three months (Table 4), carers in the education group had a 2.6-point (95% CI [1.75, 3.41], $p < .01$) higher DHFKS score than the usual care group and this was a large effect size ($ES=1.25$). At six months, carers in the education group had a 2.4-point (95% CI [1.56, 3.19], $p < .01$) higher DHFKS score than the usual care group which was a large effect size ($ES=1.17$).

**Changes in patient self-care behaviours**

The fixed effects revealed that mean self-care maintenance ($F (2/88)=22.74$, $p < .01$), self-care management ($F (2/56)=16.26$, $p < .01$) and self-care confidence ($F (2/93)=75.68$, $p < .01$) scores
changed significantly with time. Moreover, there was significant interaction between groups and time for self-care maintenance ($F (2/88)=17.09, p < .01$), self-care management ($F (2/56)=7.70, p < .01$) and self-care confidence scores ($F (2/93) = 10.69, p < .01$) (Table 3). At three months (Table 4), patients in the education group had a 6.7-point higher self-care maintenance score than the usual care group (95% CI [0.06, 13.26], $p < .05$), which was a small effect size ($ES=0.35$). At six months, patients in the education group had a 6.1-point higher self-care maintenance score than the usual care group (95% CI [0.07, 12.14], $p < .05$) and this was a small effect size ($ES=0.29$). At three months, self-care management scores showed no statistically significant difference between the two groups. However, there was a statistically significant difference at six months with the education group showing a 4.8-point higher self-care management (95% CI [0.04, 9.51], $p < .05$) score, which was a small effect size ($ES=0.39$). At three months, patients in the education group had a 6.2-point higher self-care confidence score than those in the usual care group (95% CI [1.30, 11.03], $p < .05$), which was a small effect size ($ES=0.43$). At six months, patients in the education group had a 6.4-point higher self-care confidence score than those in the usual care group (95% CI [2.10, 10.66], $p < .01$), which was a small effect size ($ES=0.29$).

**Change in perceived control over managing patients’ HF symptoms**

The fixed effects revealed that carers’ perceived control over managing patients’ HF symptoms, as measured by the CAS-R, changed significantly with time ($F (2/91)=11.80, p < .01$), and there was significant interaction between groups and time ($F (2/91)=6.53, p < .01$) (Table 3). At three months (Table 4), carers in the education group had a 1.4-point higher CAS-R score than those in the usual care group (95% CI [0.25, 2.63], $p < .05$) and this was a medium effect size ($ES=0.49$). At six months, there was no significant differences in the CAS-R scores (95% CI [-0.20, 2.11], $p > .05$).

**Change in health-related quality of life**
The fixed effects revealed that the emotional dimension of health-related quality of life, as measured by the MLHF, showed significant differences between the patient groups ($F(2/99)=5.01, p < .05$) (Table 3). At three months (Table 4), patients in the education group had a 1.7-point lower MLHF emotional dimension score (lower scores indicate better quality of life) than those in the usual care group (95% CI [-3.05, -0.35], $p < .05$), which was a medium effect size ($ES=0.52$). At six months (Table 3), patients in the education group had a 1.5-point lower MLHF emotional dimension score than those in the usual care group (95% CI [-2.78, -0.313], $p < .05$), which was a medium effect size ($ES=0.53$).

Carers’ quality of life, as measured by the SF-12, was not significantly different between groups, time, or group by time for both the physical and emotional dimensions. The mean score of physical component of carers’ quality of life was 50.6 and mental component was 41.3. The physical component of the normative group in the same age range was 50.8 and the mental component was 51.7 (Gandek et al. 1998).

**Discussion**

This is the first randomised controlled trial to evaluate the effects of a family-based education program for patients with HF and their carers in Thailand. The findings indicate that a HF education program specifically tailored for the Thai culture was effective in improving HF knowledge, self-care maintenance and confidence and emotional health-related quality of life in patients, and knowledge and perceived control over managing patients’ HF symptoms in carers. These findings add to the evidence base for developing culturally-relevant, family-based educational interventions to improve health outcomes in this population.

The primary goal of HF education is to increase knowledge of HF and subsequently to develop skills in treatment adherence and daily monitoring and making decisions in the event of changes in clinical signs and symptoms (Dickson et al. 2015, Riegel & Moser 2015). In our study, knowledge levels increased in all patients and carers, but more so in the education group. These findings add to the evidence-base for applying family-based educational
interventions for this patient group (Dunbar et al. 2005, Duhamel et al. 2007, Lofvenmark et al. 2011, Dunbar et al. 2013). However, the benefits of educational interventions are not always realised, and it has been argued that efforts need to not only improve knowledge but also build appropriate tactical skills and behaviour changes (Stromberg et al. 2006, Dunbar et al. 2013). In our study patients and their carers maintained improvements in knowledge for up to six months, which may be explained by the use of multiple approaches to the delivery of education and counselling. Moreover, improvement in knowledge was accompanied by improvements in self-reported self-care behaviours.

Process evaluation was undertaken to examine the patient and carer satisfaction with the educational program and dyads expressed favourable views. They felt the manual helped them gain more knowledge about HF and its management. Specifically, carers expressed that the program made them aware of the key role they play in HF self-care, especially in meal preparation for patients.

Our findings corroborate others that included carers and demonstrated improvements in patient self-care behaviours arising from education (Shahriari et al. 2013, Zamanzadeh et al. 2013). In contrast, Agren et al. (2012) found that education and psychosocial support for patients with HF and their partners had no significant impact on patients’ self-care. Their intervention also included face-to-face counselling and was similar to ours regarding the duration of sessions and the type of teaching materials (Agren et al. 2012). However, they used no reinforcement from telephone follow-up or the teach-back method. The situation-specific theory of HF self-care anticipates that even those who are normally successful in self-care may fail at any time due to contextual and environmental circumstances without ongoing support (Riegel et al. 2015). For example, some patients may suffer cognitive impairment which may impede their ability to remember and practice self-care (Dickson et al. 2008), and affirms the need for sustained educational efforts.

Social support is a key factor in assisting patients with HF to maintain positive self-care behaviours (Coyne et al. 2001, Murberg & Bru 2001) and inconsistent HF self-care management
is often due to a lack of social support (Riegel et al. 2011). Thus, it is recommended that educational efforts be developed with a dyadic approach if acceptable levels of engagement in HF self-care are to be attained (Lyons 2015). Unfortunately, few studies have investigated the effectiveness of HF education programs that include carers and none have been conducted in Thai populations (Srisuk et al. 2015).

Our study shows that carers who received the family-based education reported significantly increased perceived control over managing patients’ HF symptoms but not improved quality of life. The possible reason may be that in the traditional Thai family, caregiver burden is shared among all family members (Vithayachockitikhun 2006, Limpawattana et al. 2013), thereby not impacting adversely on quality of life. Other studies support the perspective that educational interventions may improve carer psychological wellbeing. For example, a systematic review of 52 studies examining family-based education for adults with other chronic diseases indicated that relationship-focused family interventions have the potential to decrease carer’s perceived burden, alleviate depression and anxiety, and improve quality of life and self-efficacy (Hartmann et al. 2010). Carers contribute significantly to patient self-care, including monitoring of appropriate patient behaviours. This can lead to added burden and stress for the carer when the person with HF decides on actions and behaviours which are not consistent with treatment recommendations (Clark & Dunbar 2003). There is an assumption that if HF education directed at the patient only is successful in improving their engagement in self-care, the patient will be more independent and this has the potential to reduce carer burden and improve their psychological well-being (Agren et al. 2010, Cameron 2015). However, the evidence for this proposition is scant and does not acknowledge the important role that carers and family members contribute to patient engagement in HF self-care, underlining the need for greater evidence of family-based educational interventions that successfully improve health outcomes among both members of the dyad.

Studies have demonstrated that self-care behaviours among Thai patients with HF are particularly poor when compared with patients in developed countries (Riegel et al. 2009a).
However, consideration must be given to the different health care systems and cultural contexts of Thailand and Western countries. In Thailand, HF DMPs are not routinely provided, the availability of HF specialists is limited, especially in rural hospitals (Pagaiya & Noree 2009), there is a lack of access to HF nurses (Wongkpratoom et al. 2010), and most elderly Thai people receive support and care primarily from their family. Thus, in this cultural context, a dyadic approach to education appears critical (Moser et al. 2012).

Limitations
A potential limitation of this study is the use of the DHFKS to assess knowledge in carers as, though the instrument has been shown to be valid at assessing change in knowledge among patients with HF (van der Wal et al. 2005), it has not been validated among carers. An examination of the internal reliability of the DHFKS administered to carers found the Kuder-Richardson (KR20) coefficient was low at baseline (.34), which did not improve even after deletion of items with very low inter-item correlations. After consultation with the authors of the scale (van der Wal et al. 2005) we examined the individual change in responses to each item over time (not reported). The findings of the individual item analysis using Cochran's Q test indicated that there were statistically significant improvements for each item on the DHFKS in the intervention group, but only for four items in the control group. This supports the reported findings of the linear mixed model. A potential explanation for the very low baseline KR20 coefficient is that carers were dealing with a prohibitive amount of novel information, and were unused to a structured test regarding HF knowledge, hence they randomly responded to the questions (Carver 1974). However, after receiving the family-based education as well as two further exposures to the questionnaire, the internal reliability improved at three (.64) and six (.59) months. This indicates the DHFKS was able to successfully discriminate between individuals who had improved HF knowledge as a consequence of the education. Further psychometric evaluation of the DHFKS when administered to carers is warranted.

Future research is needed to replicate these findings and, ideally, be sufficiently powered to examine other health outcomes such as hospital readmission and mortality rates.
Conclusion

This trial of a family-based education program improved HF knowledge, self-care behaviours and emotional health-related quality of life in patients, and HF knowledge and perceived control in carers in rural Thailand. The study needs to be replicated and extended but provides sufficient evidence to suggest that the intervention could be feasibly rolled out across Thailand. Nurses are well-placed to assist patients and carers better manage HF by teaching them self-care via education, counselling and telephone support. This program has the potential to be successfully incorporated as part of routine post-discharge care.
Figure 2 Study design and participant flow
### Table 1 Reliability coefficient

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of item</th>
<th>Cronbach’s alpha</th>
<th>Number of responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dutch Heart Failure Knowledge Scale (patients)</td>
<td>15</td>
<td>0.62</td>
<td>100</td>
</tr>
<tr>
<td>Dutch Heart Failure Knowledge Scale (carers)</td>
<td>15</td>
<td>0.40</td>
<td>100</td>
</tr>
<tr>
<td>Self-Care of Heart Failure Index</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Self-Care maintenance</td>
<td>5</td>
<td>0.54</td>
<td>100</td>
</tr>
<tr>
<td>Self-Care management</td>
<td>6</td>
<td>0.73</td>
<td>100</td>
</tr>
<tr>
<td>Self-Care confidence</td>
<td>4</td>
<td>0.68</td>
<td>100</td>
</tr>
<tr>
<td>Minnesota Living with Heart Failure questionnaire</td>
<td>21</td>
<td>0.87</td>
<td>100</td>
</tr>
<tr>
<td>Control Attitudes Scale-Revised</td>
<td>8</td>
<td>0.60</td>
<td>100</td>
</tr>
<tr>
<td>Short Form 12 Health Survey</td>
<td>12</td>
<td>0.86</td>
<td>100</td>
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</table>
Table 2 Sample characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (n=100)</th>
<th>Family-based education (n=50)</th>
<th>Control (n=50)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, mean ± SD</td>
<td>61.9±16.2</td>
<td>65.2±14.1</td>
<td>58.74±17.7</td>
<td>0.05</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>53 (53)</td>
<td>28 (56)</td>
<td>25 (50)</td>
<td>0.69</td>
</tr>
<tr>
<td>Marital status, n (%)</td>
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<td></td>
<td></td>
<td>0.44</td>
</tr>
<tr>
<td>Married</td>
<td>62 (62)</td>
<td>31 (62)</td>
<td>31 (62)</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>12 (12)</td>
<td>8 (16)</td>
<td>4 (8)</td>
<td></td>
</tr>
<tr>
<td>Divorce</td>
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<td>0 (0)</td>
<td>1 (2)</td>
<td></td>
</tr>
<tr>
<td>Widower</td>
<td>24 (24)</td>
<td>11 (22)</td>
<td>13 (26)</td>
<td></td>
</tr>
<tr>
<td>Education, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uneducated</td>
<td>34 (34)</td>
<td>26 (32)</td>
<td>8 (16)</td>
<td>0.17</td>
</tr>
<tr>
<td>Primary school</td>
<td>38 (38)</td>
<td>14 (28)</td>
<td>24 (48)</td>
<td></td>
</tr>
<tr>
<td>Secondary school</td>
<td>19 (19)</td>
<td>8 (16)</td>
<td>11 (22)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diploma</td>
<td>Bachelor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>---------</td>
<td>----------</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7 (7)</td>
<td>2 (4)</td>
<td>5 (10)</td>
<td></td>
</tr>
<tr>
<td>Number of family members, n (%)</td>
<td>37 (37)</td>
<td>16 (32)</td>
<td>19 (38)</td>
<td></td>
</tr>
<tr>
<td>3-5</td>
<td>61 (63)</td>
<td>34 (68)</td>
<td>29 (58)</td>
<td></td>
</tr>
<tr>
<td>6-10</td>
<td>2 (2)</td>
<td>0 (0)</td>
<td>2 (4)</td>
<td></td>
</tr>
<tr>
<td>&gt;10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| HL, n (%)     |          |          | 0.58     |
| Not confident | 39 (39)  | 21 (42)  | 18 (36)  |
| Moderate confident | 26 (26)  | 14 (28)  | 12 (24)  |
| Confident     | 26 (26)  | 14 (28)  | 12 (24)  |
| Extremely confident | 9 (9)     | 1 (2)    | 8 (16)   |

| NYHA class, n (%) |          |          | 0.44     |
| I                | 7 (7)    | 5 (10)   | 2 (4)    |
| II               | 50 (50)  | 23 (46)  | 27 (54)  |
| III              | 43 (43)  | 22 (44)  | 21 (42)  |

<p>| HF medicine, n (%) |          |          |          |</p>
<table>
<thead>
<tr>
<th></th>
<th>Low comorbidity</th>
<th>Medium comorbidity</th>
<th>High comorbidity</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACEI/ARB</td>
<td>55 (55)</td>
<td>63 (63)</td>
<td>76 (76)</td>
<td>0.32</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>23 (40)</td>
<td>31 (62)</td>
<td>40 (80)</td>
<td>0.84</td>
</tr>
<tr>
<td>Diuretic</td>
<td>32 (52)</td>
<td>32 (64)</td>
<td>36 (72)</td>
<td>0.48</td>
</tr>
<tr>
<td>Aldosterone antagonist</td>
<td>37 (37)</td>
<td>22 (44)</td>
<td>25 (50)</td>
<td>0.67</td>
</tr>
<tr>
<td>Digoxin</td>
<td>15 (30)</td>
<td>22 (44)</td>
<td>22 (44)</td>
<td>0.21</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CCI n (%)</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Low comorbidity</td>
<td>45 (45)</td>
<td>50 (50)</td>
<td>5 (5)</td>
<td>0.16</td>
</tr>
<tr>
<td>Medium comorbidity</td>
<td>25 (50)</td>
<td>21 (42)</td>
<td>4 (8)</td>
<td></td>
</tr>
<tr>
<td>High comorbidity</td>
<td>20 (40)</td>
<td>29 (58)</td>
<td>1 (2)</td>
<td></td>
</tr>
</tbody>
</table>

|Duration of HF, mean ± SD     | 22.8±18.3       | 22.0±19.1          | 23.5±17.6        | 0.68    |
|LVEF%, mean ± SD              | 50.5±12.9       | 50.7±13.0          | 50.3±13.1        | 0.06    |
|MoCa, mean ± SD               | 26.5±2.4        | 26.2±2.48          | 26.8±2.3         | 0.13    |

**Carers**

<p>|Age, mean ± SD                | 41.1±10.74      | 39.0±10.5          | 43.2±10.7        | 0.05    |
|Gender, n (%)                 |                 |                    |                  | 0.37    |
|Women                         | 73 (73)         | 34 (68)            | 39 (78)          |         |</p>
<table>
<thead>
<tr>
<th>Education, n (%)</th>
<th>0.13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uneducated</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Primary school</td>
<td>23 (23)</td>
</tr>
<tr>
<td>Secondary school</td>
<td>27 (27)</td>
</tr>
<tr>
<td>Diploma</td>
<td>23 (23)</td>
</tr>
<tr>
<td>Bachelor</td>
<td>22 (22)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relationship to the patients, n (%)</th>
<th>0.09</th>
</tr>
</thead>
<tbody>
<tr>
<td>27 (27)</td>
<td>12 (24)</td>
</tr>
<tr>
<td>Spouse</td>
<td>39 (39)</td>
</tr>
<tr>
<td>Daughter or son</td>
<td>26 (26)</td>
</tr>
<tr>
<td>Sibling</td>
<td>8 (8)</td>
</tr>
<tr>
<td>Parent</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HL, n (%)</th>
<th>0.22</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not confident</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Moderate confident</td>
<td>30 (30)</td>
</tr>
<tr>
<td>Confident</td>
<td>32 (32)</td>
</tr>
<tr>
<td>Extremely confident</td>
<td>36 (36)</td>
</tr>
</tbody>
</table>
Table 3 Means (SEs) and the type III tests of fixed effects on patient with HF and carer outcomes

<p>| Variables          | Baseline | | 3 Months | | 6 Months | | The type III tests of fixed effects, p value |
|--------------------|----------|----------------|----------|----------|----------|----------------------------------|----------------|----------------|-----------------|-----------------|-----------------|------------------|------------------|------------------|------------------|
|                    | Family-based education | Control | Family-based education | Control | Family-based education | Control | Group | Time | Group × Time |
| DHFKSpt            | 7.4 (0.5)  | 8.3 (0.5)  | 10.9 (0.6)  | 8.7 (0.6)  | 10.9 (0.6)  | 9.1 (0.6)  | .06  | .00  | .00  |
| SCmaint            | 22.1 (3.2) | 26.7 (3.2) | 34.3 (3.3) | 27.7 (3.3) | 31.4 (3.0) | 25.3 (3.0) | .36  | .00  | .00  |
| SCcon              | 23.5 (2.9) | 25.2 (2.9) | 37.2 (2.4) | 31.1 (2.9) | 39.0 (2.1) | 32.6 (2.9) | .12  | .00  | .00  |
| SCmanag            | 30.6 (2.9) | 35.6 (2.9) | 38.6 (2.5) | 37.1 (2.9) | 42.6 (2.4) | 37.8 (2.9) | .86  | .00  | .00  |
| MLHF               | 50.2 (2.5) | 53.0 (2.5) | 50.3 (2.2) | 53.0 (2.2) | 52.0 (2.0) | 55.0 (2.0) | .19  | .00  | .96  |
| MLHFemo            | 11.8 (0.9) | 13.0 (0.9) | 11.5 (0.7) | 13.2 (0.7) | 12.1 (0.6) | 13.6 (0.6) | .03  | .06  | .62  |
| MLHFphy            | 19.8 (1.1) | 19.9 (1.1) | 19.3 (1.0) | 19.3 (1.0) | 19.6 (0.9) | 20.0 (0.9) | .87  | .03  | .76  |
| DHFKSc             | 7.8 (0.4)  | 8.3 (0.4)  | 11.9 (0.4) | 9.4 (0.4)  | 12.0 (0.4) | 9.6 (0.4)  | .00  | .00  | .00  |
| CAS-R              | 25.4 (0.7) | 25.6 (0.7) | 27.5 (0.6) | 26.1 (0.6) | 27.3 (0.6) | 26.4 (0.6) | .19  | .00  | .00  |</p>
<table>
<thead>
<tr>
<th></th>
<th>PCS</th>
<th></th>
<th>PCS</th>
<th></th>
<th>PCS</th>
<th></th>
<th>PCS</th>
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<th>PCS</th>
<th></th>
<th>PCS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>52.0(1.6)</td>
<td>49.8 (1.6)</td>
<td>52.1 (1.5)</td>
<td>49.3(1.5)</td>
<td>52.1 (1.5)</td>
<td>49.5 (1.5)</td>
<td>.09</td>
<td>.89</td>
<td>.66</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MCS</td>
<td>42.4(1.4)</td>
<td>42.2 (1.4)</td>
<td>42.0 (1.1)</td>
<td>41.0(1.1)</td>
<td>41.4 (1.1)</td>
<td>41.0 (1.1)</td>
<td>.18</td>
<td>.06</td>
<td>.08</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DHFKSpt, Dutch Heart Failure Knowledge Scale in patients; SCmaint, Self-care maintenance; SCcon, Self-care confidence, SCmanag, Self-care management; MLHF, Minnesota Living with Heart Failure questionnaire; MLHFe, Minnesota Living with Heart Failure emotion dimension; MLHFphy, Minnesota Living with Heart Failure physical dimension; DHFKSc, Dutch Heart Failure Knowledge Scale in carer; CAS-R, Control Attitudes Scale-Revised; PCS, Physical Component Summary; MCS, Mental Component Summary.
Table 4 Pairwise comparison of patient with HF and carer outcome variables at each time point

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean difference at baseline [95% CI]</th>
<th>p value</th>
<th>Mean difference at 3 months [95% CI]</th>
<th>p value</th>
<th>Mean difference at 6 months [95% CI]</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHFKSpt</td>
<td>-0.9 [-1.9, 0.1]</td>
<td>0.08</td>
<td>2.2 [1.0, 3.3]</td>
<td>0.00</td>
<td>1.7 [0.6, 2.9]</td>
<td>0.00</td>
</tr>
<tr>
<td>SCmaint</td>
<td>-4.5 [-10.8, 1.8]</td>
<td>0.16</td>
<td>6.7 [0.1, 13.2]</td>
<td>0.05</td>
<td>6.1 [0.1, 12.1]</td>
<td>0.05</td>
</tr>
<tr>
<td>SCcon</td>
<td>1.7 [-7.4, 4.0]</td>
<td>0.56</td>
<td>6.2 [-1.3, 11.0]</td>
<td>0.01</td>
<td>6.4 [2.1, 10.6]</td>
<td>0.00</td>
</tr>
<tr>
<td>SCmanage</td>
<td>-5.0 [-10.8, 0.8]</td>
<td>0.09</td>
<td>1.5 [-6.5, 3.5]</td>
<td>0.56</td>
<td>4.8 [0.0, 9.5]</td>
<td>0.05</td>
</tr>
<tr>
<td>MLHF</td>
<td>-2.8 [-7.8, 2.1]</td>
<td>0.26</td>
<td>-2.7 [-7.1, 1.6]</td>
<td>0.22</td>
<td>-3.0 [-7.1, 1.0]</td>
<td>0.14</td>
</tr>
<tr>
<td>MLHFemo</td>
<td>-1.2 [-2.9, 0.5]</td>
<td>0.17</td>
<td>-1.7 [-3.0, -0.3]</td>
<td>0.01</td>
<td>-1.5 [-2.8, -0.3]</td>
<td>0.02</td>
</tr>
<tr>
<td>MLHFphy</td>
<td>-0.1 [-2.2, 2.0]</td>
<td>0.92</td>
<td>0.0 [-2.0, 2.0]</td>
<td>0.99</td>
<td>-0.4 [-2.2, 1.4]</td>
<td>0.68</td>
</tr>
<tr>
<td></td>
<td>Mean Difference</td>
<td>Standard Error</td>
<td>95% CI</td>
<td>t-Value</td>
<td>p-Value</td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>-----------------</td>
<td>----------------</td>
<td>--------------</td>
<td>---------</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td>DHFKScarer</td>
<td>-0.5 [-1.3, 0.3]</td>
<td>0.20</td>
<td>2.6 [1.7, 3.4]</td>
<td>0.00</td>
<td>2.4 [1.6, 3.2]</td>
<td>0.00</td>
</tr>
<tr>
<td>CAS-R</td>
<td>-0.2 [-1.5, 1.1]</td>
<td>0.74</td>
<td>1.4 [0.2, 2.6]</td>
<td>0.02</td>
<td>1.0 [-0.2, 2.1]</td>
<td>0.10</td>
</tr>
<tr>
<td>PCS</td>
<td>2.2 [-1.0, 5.3]</td>
<td>0.18</td>
<td>2.8 [-0.1, 5.7]</td>
<td>0.06</td>
<td>2.5 [-0.4, 5.5]</td>
<td>0.09</td>
</tr>
<tr>
<td>MCS</td>
<td>0.2 [-2.5, 3.0]</td>
<td>0.87</td>
<td>1.0 [-1.2, 3.1]</td>
<td>0.40</td>
<td>0.4 [-1.7, 2.5]</td>
<td>0.71</td>
</tr>
</tbody>
</table>

Mean difference = Mean score of the family-based education group - mean score of the control group; DHFKS, Dutch Heart Failure Knowledge Scale; SCmaint, Self-care maintenance; SCmanage, Self-care management; SCcon, Self-care confidence; MLHF, Minnesota Living with Heart Failure questionnaire; MLHFeemo, Minnesota Living with Heart Failure emotion dimension; MLHPhy, Minnesota Living with Heart Failure physical dimension; CAS-R, Control Attitudes Scale-Revised; PCS, Physical Component Summary; MCS, Mental Component Summary.
References


4.2 Additional analyses from the randomised controlled trial

The following two sections (4.3 and 4.4) provide further academic contribution in analysis and evaluation of the education program i) supplementary data analysis on the DHFKS administered to carers, and ii) details on process evaluation for the RCT.

4.3 Psychometric evaluation of the DHFKS administered to carers

4.3.1 Introduction

In the present study, HF knowledge of patients and their carers was assessed using the DHFKS – a self-report questionnaire consisting of 15 multiple-choice items (further details of the DHFKS are described in Chapter Three; Srisuk et al., 2014). This instrument was developed in the Netherlands and tested on 902 HF patients; findings identified sufficient internal reliability (Cronbach’s alpha 0.62; van der Wal, Jaarsma, Moser, & van Veldhuisen, 2005). A potential limitation of this study that warrants greater investigation and discussion was the use of the DHFKS to assess knowledge in carers, as it was not originally designed for carers. Further supplementary analyses were conducted to examine the psychometrics of this scale for carers, which are presented below.

4.3.2 Aims

1. To examine the internal reliability of the DHKS administered to both patients and carers.
2. To examine changes in responses to each item of the DHFKS over six months.

4.3.3 Methods

To address the first aim, the internal reliability of the DHFKS was examined in both patients and carers. The coefficient alpha, Kuder–Richardson formula 20 (KR20), was used to assess the overall reliability of the scale as well as inter-item correlations. The KR20 reliability is useful for calculating reliability when the items in a test are dichotomous. The KR20 and Cronbach’s alpha are identical except for the way that the item variances are calculated; however, the interpretation of the reliability coefficient also differs. Frisbie (1988, p. 29) states that “most published standard test yield scores that have reliabilities more than 0.08 are
considered good. In contrast, the KR20 tends to yield score reliabilities that average about 0.50” (Frisbie, 1988, p. 29). Frisbie further states that:

*Experts in education measurement have agreed informally that the reliability coefficient should be at least 0.85 if the scores will be used to make decisions about individuals and if the scores are the only available useful information. (This ought to be a very rare circumstance.) However, if the decision is about a group of individuals, the generally accepted minimum standard is .65. Usually, we can tolerate reliabilities around .50 for scores from teacher-made tests if each score will be combined with other information-test scores, quiz scores, observations to assign a grade for quarter or semester works* (Frisbie, 1988, p. 29).

To address the second aim, individual change in responses to each item was assessed using Cochran’s Q test within each group (i.e. education versus usual care) and over time based on the proportion of correct responses across the three time points. In the education group there were 43 carer responses with matched data over the three time points; there were 40 matched responses in the usual care group.

### 4.3.4 Findings

The sub-analyses regarding the internal reliability of the DHFKS yielded KR20 coefficient of reliability of 0.61 for patients and 0.40 for carers at baseline, which according to Frisbie (1988), is not acceptable. After consultation with the authors of the scale (van der Wal et al., 2005), it was agreed that items with very low inter-item correlations should be deleted and reliability re-examined (see Table 6). Deletion of these two items did not improve the KR20 coefficient (KR20 = 0.45). After further expert consultation with DHFKS authors it was suggested that carer responses be examined via individual change in responses to each item over time and this analysis is presented below.
### Table 6: Item-total statistics of the DHFKS in carers

<table>
<thead>
<tr>
<th>Questions</th>
<th>Scale mean (item deleted)</th>
<th>Scale variance (item deleted)</th>
<th>Corrected item (total correlation)</th>
<th>KR20 coefficient (item deleted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How often should patients with severe HF weigh themselves?</td>
<td>7.90</td>
<td>3.60</td>
<td>0.28</td>
<td>0.28</td>
</tr>
<tr>
<td>• every week</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• now and then</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• every day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Why is it important that patients with HF should weigh themselves regularly?</td>
<td>7.71</td>
<td>3.40</td>
<td>0.27</td>
<td>0.27</td>
</tr>
<tr>
<td>• because many patients with HF have a poor appetite</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• to check whether the body is retaining fluid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• to assess the right dose of medicines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. How much fluid are you allowed to take at home each day?</td>
<td>7.77</td>
<td>3.67</td>
<td>0.13</td>
<td>0.32</td>
</tr>
<tr>
<td>• 1.5 to 2.5 L at the most</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• as little fluid as possible</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• as much fluid as possible</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Which of these statements is true?</td>
<td>7.11</td>
<td>3.84</td>
<td>0.20</td>
<td>0.31</td>
</tr>
<tr>
<td>• When I cough a lot, it is</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
better not to take my HF medication

- When I am feeling better, I can stop taking my medication for HF
- It is important that I take my HF medication regularly

5. What is the best thing to do in case of increased shortness of breath or swollen legs?
   - call the doctor or the nurse
   - wait until the next check-up
   - take less medication

6. What can cause a rapid worsening of HF symptoms?
   - a high-fat diet
   - a cold or the flu
   - lack of exercise

7. What does HF mean?
   - that the heart is unable to pump enough blood around the body
   - that someone is not getting enough exercise and is in poor condition
   - that there is a blood clot in the blood vessels of the heart
8. Why can the legs swell up when you have HF?

- because the valves in the blood vessels in the legs do not function properly
- because the muscles in the legs are not getting enough oxygen
- because of accumulation of fluid in the legs

9. What is the function of the heart?

- to absorb nutrients from the blood
- to pump blood around the body
- to provide the blood with oxygen

10. Why should someone with HF follow a low-salt diet?

- salt promotes fluid retention
- salt causes constriction of the blood vessels
- salt increases the heart rate

11. What are the main causes of HF?
- a myocardial infarction and high blood pressure
- lung problems and allergy
- obesity and diabetes

12. Which statement about exercise for people with HF is true?
- it is important to exercise as little as possible at home to relieve the heart
- it is important to exercise at home and to rest regularly in between
- it is important to exercise as much as possible at home

13. Why are water pills prescribed to someone with HF?
- to lower the blood pressure
- to prevent fluid retention in the body
- because then they can drink more

14. Which statement about weight increase and HF is true?
- an increase of over 2 kg in 2 or 3 days should be reported to the doctor at
the next check-up

- in case of an increase of over 2 kg in 2 or 3 days you should contact your doctor or nurse
- in case of an increase of over 2 kg in 2 or 3 days you should eat less

15. What is the best thing to do when you are thirsty?

- suck an ice cube
- suck a lozenge
- drink a lot

Compared with baseline, the individual changes in responses to each item on the DHFKS among the education group indicated a significant increase in HF knowledge on 13 items (1, 2, 3, 5, 6, 7, 8, 10, 11, 12, 13, 14, and 15) (see Table 7) at the six-month follow-up. Compared with baseline, at the six-month follow-up the usual care group significantly increased their HF knowledge on only four items (2, 6, 10, and 15). There were two items (4 and 9) in which responses did not change over time in both groups and these were related to selecting a true statement from a choice of three regarding medications and the function of the heart.

**Table 7:** Number/proportion of correct responses within each group and changes across time on the DHFKS

<table>
<thead>
<tr>
<th>Questions</th>
<th>Group Baseline</th>
<th>Three months</th>
<th>Six months</th>
<th>P value</th>
</tr>
</thead>
</table>


1. How often should patients with severe HF weigh themselves?
   - every week
   - now and then
   - every day

<table>
<thead>
<tr>
<th></th>
<th>Control (n = 40)</th>
<th>Interventio (n = 43)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>21 (52)</td>
<td>4 (9)</td>
</tr>
<tr>
<td></td>
<td>29 (72)</td>
<td>23 (53)</td>
</tr>
<tr>
<td></td>
<td>29 (72)</td>
<td>20 (46)</td>
</tr>
<tr>
<td>P-value</td>
<td>0.08</td>
<td>0.00</td>
</tr>
</tbody>
</table>

2. Why is it important that patients with HF should weigh themselves regularly?
   - because many patients with HF have a poor appetite
   - to check whether the body is retaining fluid
   - to assess the right dose of medicines

<table>
<thead>
<tr>
<th></th>
<th>Control (n = 40)</th>
<th>Interventio (n = 42)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15 (37)</td>
<td>14 (33)</td>
</tr>
<tr>
<td></td>
<td>20 (50)</td>
<td>33 (79)</td>
</tr>
<tr>
<td></td>
<td>23 (57)</td>
<td>32 (73)</td>
</tr>
<tr>
<td>P-value</td>
<td>0.03</td>
<td>0.00</td>
</tr>
</tbody>
</table>

3. How much fluid are you allowed to take at home each day?
   - 1.5 to 2.5 L at the most
   - as little fluid as possible
   - as much fluid as possible

<table>
<thead>
<tr>
<th></th>
<th>Control (n = 40)</th>
<th>Interventio (n = 43)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11 (27)</td>
<td>11 (26 )</td>
</tr>
<tr>
<td></td>
<td>11 (27)</td>
<td>22 (51)</td>
</tr>
<tr>
<td></td>
<td>11 (27)</td>
<td>27 (63)</td>
</tr>
<tr>
<td>P-value</td>
<td>1.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

4. Which of these statements is true?
   - When I cough a lot, it is better not to take my HF medication
   - When I am feeling better, I can stop taking my medication for HF
   - It is important that I take my HF medication regularly

<table>
<thead>
<tr>
<th></th>
<th>Control (n = 40)</th>
<th>Interventio (n = 43)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>37 (92)</td>
<td>40 (93)</td>
</tr>
<tr>
<td></td>
<td>39 (97)</td>
<td>43 (100)</td>
</tr>
<tr>
<td></td>
<td>36 (90)</td>
<td>43 (100)</td>
</tr>
<tr>
<td>P-value</td>
<td>0.24</td>
<td>0.05</td>
</tr>
</tbody>
</table>
5. What is the best thing to do in case of increased shortness of breath or swollen legs?
   - call the doctor or the nurse
   - wait until the next check-up
   - take less medication

   Control (n = 40) | Interventio (n = 43)
   --- | ---
   39 (97) | 37 (86)
   39 (97) | 43
   37 (92) | 43
   0.14 | 0.00

6. What can cause a rapid worsening of HF symptoms?
   - a high-fat diet
   - a cold or the flu
   - lack of exercise

   Control (n = 40) | Interventio (n = 43)
   --- | ---
   4 (10) | 3 (7)
   6 (15) | 11 (26)
   12 (30) | 17 (39)
   0.00 | 0.00

7. What does HF mean?
   - that the heart is unable to pump enough blood around the body
   - that someone is not getting enough exercise and is in poor condition
   - that there is a blood clot in the blood vessels of the heart

   Control (n = 40) | Interventio (n = 43)
   --- | ---
   18 (45) | 24 (56)
   23 (57) | 35 (81)
   22 (55) | 31 (72)
   0.05 | 0.01

8. Why can the legs swell up when you have HF?
   - because the valves in the blood vessels in the legs do not function properly

   Control (n = 40) | Interventio (n = 43)
   --- | ---
   29 (72) | 25 (58)
   33 (82) | 43
   31 (77) | 42 (98)
   0.22 | 0.00
• because the muscles in the legs are not getting enough oxygen
• because of accumulation of fluid in the legs

9. What is the function of the heart?
• to absorb nutrients from the blood
• to pump blood around the body
• to provide the blood with oxygen

Control (n = 40)

Intervention (n = 43)

10. Why should someone with HF follow a low-salt diet?
• salt promotes fluid retention
• salt causes constriction of the blood vessels
• salt increases the heart rate

Control (n = 40)

Intervention (n = 43)

11. What are the main causes of HF?
• a myocardial infarction and high blood pressure
• lung problems and allergy
• obesity and diabetes

Control (n = 40)

Intervention (n = 43)

12. Which statement about exercise for people with HF is true?
• it is important to exercise as little

Control (n = 40)
as possible at home to relieve the heart
• it is important to exercise at home and to rest regularly in between
• it is important to exercise as much as possible at home

13. Why are water pills prescribed to someone with HF?
• to lower the blood pressure
• to prevent fluid retention in the body
• because then they can drink more

14. Which statement about weight increase and HF is true?
• an increase of over 2 kg in 2 or 3 days should be reported to the doctor at the next check-up
• in case of an increase of over 2 kg in 2 or 3 days, you should contact your doctor or nurse
• in case of an increase of over 2 kg in 2 or 3 days, you should eat less

15. What is the best thing to do when you are thirsty?
• suck an ice cube
4.3.5 Discussion

This is the first study to administer the DHFKS to carers. Results showed that the internal reliability of the DHFKS was low (0.40) at baseline but improved at three and six months. After receiving the family-based education intervention as well as being exposed to questions more than once (3 and 6 months), the DHFKS was able to successfully discriminate between the carers in the education and usual-care groups, that is, who did and did not receive the HF education respectively. A potential explanation for the very low baseline KR20 coefficient is that carers had very poor knowledge and had to deal with an excessive amount of new information or were simply not used to structured testing with regards to HF, thus their random responses to the questions (Carver, 1974).

Further investigation was conducted to examine the carers’ individual responses on each item of the DHFKS over time. This demonstrated that carers in the education group responded correctly to 13 out of 15 items on the DHFKS compared with carers in the control group, who responded correctly to only four of the knowledge items. These findings are aligned with our findings of the linear mixed model regarding changes in carer knowledge. However, as two items failed to distinguish between the control and intervention group, future research examining the psychometric properties of the DHFKS in culturally diverse groups of carers is warranted.

4.4 Process evaluation of the family-based education

4.4.1 Introduction

Process evaluations within trials help investigators explore the implementation, receipt, and setting of an intervention and help in the interpretation of the outcome results. This
process may be examined through the views of participants in the intervention (Oakley, Strange, Bonell, Allen, & Stephenson, 2006).

### 4.4.2 Aims

In the present study, process evaluation was undertaken to: i) gain an understanding of patient and carer satisfaction with the HF education program, and ii) evaluate adherence to the intervention.

### 4.4.3 Methods

The methods for the process evaluation were described in greater detail in Chapter Three (Srisuk et al., 2014). In summary, the methods for obtaining ratings of satisfaction with participation in all aspects of the trial were conducted on completion of the program. Participants either had a face-to-face interview or a telephone interview in which comments from patients and their carers regarding their satisfaction in participation of the study were collected by the study nurse. At the face-to-face interview a visual analogue scale was used to assess their satisfaction in study participation. Satisfaction scores ranged from 0 (not satisfied at all) to 10 (extremely satisfied). An independent sample t-test was conducted to compare the satisfaction scores for the education and usual care group. To assess adherence, patients in the education group were asked to bring their HF manual to the hospital on completion of the study so that the research nurse could evaluate whether activities listed at the end of each chapter had been completed.

### 4.4.4 Results

#### 4.4.4.1 Patient and carer satisfaction

Eighty-three patients and 83 carers completed the satisfaction survey. The overall satisfaction score for patients was 8.01 (standard deviation, SD = 0.74) and for carers was 7.81 (SD = 0.44). There was a statistically significant difference in patients’ satisfaction scores among the education group (M = 8.45, SD = 0.58) compared with the usual care group (M = 7.55, SD = 0.57; t (81) = 7.02, p < 0.01). Carers’ satisfaction scores were significantly higher in the
education group (M = 8.01, SD = 0.44) than the usual care group (M = 7.77, SD = 0.42; t (81) = 2.48, p < 0.05).

Overall, patients and carers reported positive comments with regards to their participation in the study. Dyads in the usual care group were thankful for the telephone calls, even though they were only asked general health questions such as, “How are you?” Carers in the usual group reported that the communications with the research nurse made them feel safe, and that they were being cared for by a healthcare provider.

4.4.4.2 Patient and carer perceptions of the family-based education intervention

Dyads in the education group expressed favourable responses with the education they had received. They felt the HF manual helped them gain more knowledge about the condition and its management. Patient ID 13 reported: “I gained more knowledge reading this book that the nurse gave to me. There is something that I never knew before. I never thought that I should do exercise, but actually I can”. The pictures used in the HF manual were perceived to be relevant and represent some of their previous experiences with HF symptoms. Patient ID 52 said: “I found that I even had exactly the same swollen leg as he had in the book”. Participants thought that the colour coding of the HF manual made it more interesting and easy to absorb, and the information in the manual was supported by the DVD. The participants stated that they were eager to learn through the audio-visual education and the DVD made them feel confident in dealing with life-threatening conditions. Patient ID 63 said: “I like watching and listening more than reading because my vision is impaired . . . you know my children were watching that DVD with me . . . and I think it was not that hard to follow some of the suggestions”.

This format allowed them to recall information when necessary and assisted in self-monitoring of the patient. The carers expressed that the education program made them aware of the key role they play in HF self-care, especially in meal preparation for patients. The most critical feedback about the DVD was technical – the sound volume was deemed inadequate and the dubbing of the nurse’s voice-over needed to be more animated.

4.4.4.3 Intervention adherence – completion of the manual
Twenty-seven patients out of 43 (63%) who completed the study returned the HF manual for evaluation of activities completed; 16 (37%) reported they forgot to bring the HF manual to the hospital appointment. The manual was reviewed by the research nurse with patients and their carers for completion of activities. When activities had not been completed the research nurse asked politely for any reasons why they had not been completed. The numbers of participants who responded to each activity in the HF manual are reported in Table 8. The HF manual comprised 12 activities for completion. Eighteen patients answered the question “Which symptom is the hardest for you to manage?” Patients who did not answer this question said that it was difficult to tell which one was the hardest HF symptom to manage because they felt uncomfortable throughout the day every day; however, two patients stated that they felt fear when experiencing shortness of breath. One of the activities with the poorest rate of completion was the daily weight chart, with only two patients recording this information. All other patients replied that they did not have a scale at home and, indeed, this is not something readily accessible in Thailand. Seven patients completed the medication section, which asked them to discuss with healthcare providers what HF medications they took. The main reason patients did not complete this section was that they felt uncomfortable and disrespectful asking busy healthcare workers for such information when they had limited time.

Two activities in the HF manual were specifically for carers to complete. Twenty carers answered the question, “What are the signs and symptoms of HF that carers can help patients to monitor?” The top answer was ankle swelling (90%), followed by shortness of breath (85%), cough (50%), and anxiety (15%). Almost all carers (80%) completed the carer section, which asked them, “What can carers do to help the patient?” The top answer was providing emotional support (81%), followed by preparing a low-sodium meal (63%), drug administration (62%), monitoring signs and symptoms of HF (59%), and help with physical activities (36%).

Table 8: Number of participants who responded to the questions and activities on the HF manual

<table>
<thead>
<tr>
<th>Questions and activities</th>
<th>Number of participants completed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. My HF is caused by__
2. Which one is the hardest for you to manage?
3. How can family members help you?
4. How much do you weigh when you feel sick? ____kg
5. How much fluid you can have each day? _____L (talk with your doctor)
6. How do you know when you have extra fluid in your body?
7. Complete the HF knowledge test
8. Fill in the form asking the patients to discuss with a healthcare professional what medicine they take in accordance with the classification of HF medicine
9. List of questions to ask the healthcare professional
10. Fill out the weight chart every day

**Carer activities**

11. What are the signs and symptoms of HF that carers can help patient to monitor?
12. What can carers do to help the patient?

- Emotional support 18
- Preparing a low-sodium meal 14
- Drug administration 13
- Monitor signs and symptoms of HF 11
- Help with physical activities 8

4.4.5 Discussion regarding the process evaluation

The process evaluation using the participants’ descriptions demonstrated that patients and carers were satisfied with the program. Both members of the dyad, irrespective of treatment group allocation, perceived positive benefits from the continued telephone support. The education group felt the whole program provided additional information for their healthcare concerns, provided continuous care, and provided additional time to discuss their health concerns with a healthcare professional. This suggests that dyads normally believe that
healthcare professionals do not have enough time to talk with patients or their families in the hospital setting as everyone is “in a rush and busy”. These findings are aligned with a previous qualitative study, which found that patients and carers experience difficulty understanding treatment plans and are in need of extra time with healthcare professionals (Burke et al., 2014).

The surprising feedback was that dyads in the usual care group also felt supported by the telephone follow-up they received, even though they were asked a very general question, “How are you?”, rather than any specific HF queries or provision of information. Dyads in the usual care group were thankful for the telephone calls, as communication with the research nurse made them feel safe, and that they were being cared for by a healthcare provider. Therefore any contact from the research nurse throughout the illness trajectory was deemed to be helpful and may have had a positive impact on health outcomes.

In terms of the responses to activities in the HF manual, findings demonstrated a low completion rate among patients, whereas carers were more diligent in completing the activities. Reasons for low response rates in patients were related to lack of health equipment, such as weighing scales, and lack of time to talk to a healthcare professional. This finding is consistent with a previous study that demonstrated approximately 45% of participants with HF involved in a self-monitoring program using a weight and symptom diary did not use the diary (Eastwood, Travis, Morgenstern, & Donaho, 2007).

4.4.6 Limitations to the process evaluation

Due to scholarship requirements, I was unable to reside in Thailand and was therefore reliant on the research nurse to collect the process evaluation information. The research nurse had a clinical role and found that, due to the large numbers of patients visiting the outpatient clinics, she did not have adequate time to discuss each activity in detail. Instead, the reasons dyads did not complete the set activities could only be discussed in general terms.

4.4.7 Conclusions

Data gathered through different methods of process evaluation provided a rich source of information regarding patients’ and carers’ perceptions and experiences of the family-based HF
education program. The key findings confirmed that as a result of the intervention patients and carers felt more knowledgeable and self-confident in managing HF. In Thailand, where HF management programs do not exist, ongoing support from healthcare providers regarding the long-term management of this chronic and complex syndrome is warranted and needed.

4.5 Chapter Four summary

This chapter presented the results of an RCT that evaluated a family-based HF education program conducted in rural Thailand. The study hypothesised that in the education group patients and carers would have significantly higher HF knowledge and quality of life, patient self-care behaviours would be improved, and carer-perceived control of managing patients’ HF symptoms would be higher in comparison with the usual care group. The findings of the study supported this hypothesis. Additional findings related to process evaluation, such as participant feedback providing useful information for future studies and identifying that the HF family-based education program addressed a significant gap in terms of patient and carer educational needs and support in rural Thailand. The next chapter will discuss the findings and how they fit with previous studies and the associated literature, the strengths and limitations of the study, the implications for nursing practice, and recommendations for future research endeavours.
Chapter Five: Discussion and conclusions

5.1 Chapter introduction

The purpose of Chapter Five is to synthesise the findings of this research described in the preceding chapters, highlight the original contributions made to existing knowledge, suggest avenues for further research, and present conclusions. Chapter Five begins with a brief re-cap on the key area of investigation and the rationale that instigated this research. This is then followed by a review of research objectives and key findings. Key findings from each chapter will be summarised in terms of the research objectives and then integrated into a comprehensive discussion of the overall contribution of this research to the existing HF literature. This will be followed by limitations of the current research, implications for clinical practice, and avenues for future research.

5.2 Overview

Patients with HF present a multifaceted management challenge to healthcare providers. Heart failure is a complex, debilitating, and progressive syndrome associated with high rates of hospital admissions and readmissions, high mortality rates, and poor quality of life (Erceg et al., 2013; Moleerergpoom et al., 2013; Mozaffarian et al., 2015). The human and economic burdens of HF internationally, and in Thailand specifically, are clear, as outlined in Chapter One. Disease management programs for HF have received significant research attention in Western countries, as they have been shown to decrease hospital readmissions and thereby reduce healthcare costs (Feltner et al., 2014; Gwadry-Sridhar, Flintoft, Lee, Lee, & Guyatt, 2004; Holland et al., 2005; McAlister, Lawson, Teo, & Armstrong, 2001; McAlister et al., 2004). The foundation of these HF DMPs is patient education. Several systematic reviews of trials and qualitative studies examining the effectiveness of patient education on HF health outcomes provide compelling evidence of the effectiveness of HF education in improving health outcomes (Boren et al., 2009; Boyde et al., 2011; Cameron et al., 2007). However, there is a knowledge gap in HF patient education programs in Thailand, where only one trial has been conducted (Wongpiriyayothar et al., 2011). Despite evidence for the essential role that carers play on a
daily basis in supporting patients (Buck et al., 2015; Vellone et al., 2015), and even recommendations in best practice guidelines that they be included in educational processes (HFSA, 2010; Malcom et al., 2008; McMurray et al., 2012; National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand, 2011), it appears that most carers are not routinely included in education programs (Clark et al., 2014; Srisuk et al.;2016, Stromberg, 2013). Moreover, Thailand is a country where the family has a much stronger influence in society than in Western culture (Subgranon & Lund, 2000). Thus, the present research focused on the family and cultural context surrounding the development and evaluation of a family-based HF education program in rural Thailand.

5.3 Research purpose

The purpose of this research was to examine the effectiveness of a family-based education program for patients and carers in rural Thailand. The specific objectives were to:

- investigate family-based education provisions for patients with HF and carers;
- develop a family-based education program for patients with HF and carers in rural Thailand; and
- implement and evaluate this family-based education program in rural Thailand.

5.3.1 Research objective 1: To investigate family-based education provisions for patients with HF and carers

A systematic review of HF family-based education provided a comprehensive synthesis of the available literature (Srisuk et al., 2016). This systematic review highlighted a dearth of HF studies focusing on education and including both the patient and family or carer. Furthermore, patient and carer HF knowledge was found to improve with educational interventions; however, only modest improvements were achieved in other outcome measures, including enhanced patient self-care, increased dietary and treatment adherence, enriched patient quality of life, improved perceived control among patients but not carers, and reduced carer
burden (Srisuk et al., 2016). Of significance, the majority of studies reviewed were marred by weak conceptualisation and methodological rigour (Srisuk et al., 2016).

The finding that education improves HF knowledge in both patients’ and carers’ is encouraging as there is the potential for this to subsequently yield improvements in HF self-care. This proposition is supported by the situation-specific theory of HF self-care (Riegel & Dickson, 2008; Riegel et al., 2015). This theory describes the process patients adopt in coping with HF in which the healthcare provider and family are essential sources of support, and knowledge is the underlying key factor influencing patient decisions about self-care.

Most of the educational interventions in the studies included in the review were not underpinned by an educational theory. Only two studies were: one (Agren et al., 2012) guided by health promotion theory, and the other (Dunbar et al., 2008) a combination of self-determination and social cognitive theory. The rationale for underpinning educational interventions with an appropriate theory is that didactic approaches, in which the patient is the passive recipient, may not achieve the optimal outcome for patients (Parsons, 1975; Shattell, 2004; Wright, Wiles, & Moher, 2001). For example, adult learning theory highlights the importance of the educator and the learner playing equal roles (Knowles, 1998). The role of educator is to motivate, inform, support, coordinate, and facilitate patients to achieve their goal. This is enhanced if the educator creates an environment that allows the patient to feel comfortable asking questions and discussing sensitive topics freely (Svavarsdóttir, Sigurðardóttir, & Steinsbekk, 2016). Specifically, in regards to HF education programs, a systematic review of patient-centred self-care education defined patient-centred care as “the provision of care that is respectful and responsive to a patient’s preferences, needs, and values, and perceives patients as leaders of their clinical care” (Yves et al., 2014, p. 192). Indeed, this approach increased HF knowledge, self-care behaviours, and quality of life, and reduced hospital readmissions (Malcom et al., 2008; McMurray et al., 2012; National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand, 2011; Syx, 2008; Yancy et al., 2013).
Despite the fact that there remains an appreciable knowledge gap in the literature regarding a gold standard approach to HF educational strategies, some evidence suggests that knowledge, behaviour, and symptom management improve when education is individualised and tailored to patients’ learning needs (Aidemark, Askenäs, Mårtensson, & Strömberg, 2014; Boyde & Peters, 2014). This process is acknowledged in the theory of andragogy (Knowles, 1998). However, none of the studies included in the systematic review had specifically assessed the learning needs of patient and carers combined.

To summarise the findings from the systematic review, the true potential of HF family-based education warrants further investigation of issues such as appropriate theoretical basis and educational approaches tailored to patients’ needs including, in this case, cultural and linguistic characteristics. These essential cultural adaptations are discussed below in reference to the development of the family-based education program for patients with HF and their carers residing in rural Thailand.

5.3.2 Research objective 2: To develop a family-based education program for patients with HF and their carers in rural Thailand

The context and format in which HF education is delivered should be a key consideration and should be tailored to the individual in order for the recipient to successfully develop skills in self-care management (Riegel et al., 2004). For example, when educational interventions employ differing teaching modalities and are tailored to individual needs, patient self-care behaviours and management of HF symptoms significantly improve (Bloom, 1956; Boyde & Peters, 2014; Fredericks et al., 2010; Riegel et al., 2004). Boyde et al. (2013) utilised both an HF booklet and DVD designed according to the learning goal to teach patients self-care skills, thereby helping them move to the upper level of cognitive learning. By doing so, patients were encouraged to become active and independent in the learning process, i.e. by setting their own goals. Much like in the Boyde et al. (2013) study, patients and carers in the present study were encouraged to identify the topics of learning that were most relevant to them, via the counselling session, and then to seek the relevant information in the manual and DVD. Four studies in our systematic review reported the use of various modalities in presenting HF
information, including an educational booklet, a DVD, a CD-ROM, PowerPoint, and telephone reinforcement (Agren et al., 2012; Dunbar et al., 2013; Etemadifar, Bahrami, Shahriari, & Farsani, 2014; Shahriari, Ahmadi, Babaee, Mehrabi, & Sadeghi, 2013). It was evident that, regardless of treatment modality, the content must be culturally and linguistically appropriate – as was achieved in this study.

Cultural background will influence an individual’s perception of their chronic illness (Turner, 1996). Most of the theoretical models of chronic illness acknowledge culture as an important factor in the development of educational interventions (Dunbar et al., 2008; Riegel et al., 2015; Riegel et al., 2012). That is, every nurse and patient interaction has a cultural dimension (Shattell, 2004). Riegel et al. (2009) compared patient engagement in self-care in developed and developing countries and found significant differences; specifically, patients in Thailand demonstrated far fewer self-care skills (Riegel et al., 2009). It is crucial for healthcare providers to consider cultural diversity in the development and application of patient education. In our systematic review (Srisuk et al., 2016) only two studies mentioned that they considered cultural differences when developing and implementing the education intervention (Etemadifar et al., 2014; Shahriari et al., 2013). Culture is central to building self-care skills in minority groups (Becker et al., 2004). Therefore, in our study (Srisuk et al., 2014) a culturally specific education program was developed. For example, the HF education resources (i.e. HF manual and DVD) were translated into Thai and then adapted to fit the rural Thai cultural context. Further, both the HF manual and the DVD were tested for content validity by HF experts in Thailand. Minor changes included adding the key messages for each chapter to the HF manual for reinforcement for the reader and rephrasing some of the sentences to make them culturally appropriate. The HF manual was tested for readability and understanding by three Thai patient and carer dyads, who reported both resources to be helpful for the transmission of knowledge and self-care skills and for assistance in coping with HF.

Further, many educational programs do not reach their full potential because the family context in which HF patients perform self-care has not been taken into consideration (Dunbar et al., 2008). As a consequence, carers may experience adverse health outcomes such as
depression or poor quality of life (Bakas et al., 2006; Chung et al., 2010; Pressler et al., 2013).
Thus, considerations of family and culture were taken into consideration in the development of the present intervention designed to improve HF self-care. For example, the HF manual and DVD addressed the structure and function of the family by including information specifically designed to enhance communication within the dyad, i.e. the HF manual encourages carers to avoid critical comments when encountering patient self-care behaviours that are not as good as they expected; rather, carers were encouraged to discuss alternative choices that might help the patient better manage self-care.

5.3.3 **Research objective 3: To implement and evaluate the effectiveness of a family-based education program in Thailand**

One of the primary objectives of this research was to address a significant treatment gap in Thailand – poor quality of HF self-care (Riegel et al., 2009). The findings of this study have demonstrated the potential of improving patient engagement in self-care through the implementation of a family-based education program that can be readily taught by Thai nurses. The family-based HF education program was effective, with demonstrated improvements in patient HF knowledge, self-care behaviours and emotional quality of life, and in carer HF knowledge and perceived control over managing patient HF symptoms. Those in the education group had significantly higher scores on HF knowledge than those in the usual care group at three and six months. Also, patients in the education group had significantly higher scores on self-care maintenance, confidence, and quality of life (emotional dimension only) than those in the usual care group at three and six months. Additionally, three months after the intervention, carers in the education group had significantly higher scores in perceived control over the management of patient HF symptoms than those in the usual care group. This is the first study of HF education for patients and their carers conducted in Asia, and the findings contrast with those from a previous HF dyadic study that measured outcomes in both patients and carers in Western countries. Schwarz et al. (2008) found that telemonitoring education for patients and carers produced no significant differences in patients’ depressive symptoms and quality of life, or carers’ mastery of coping with problems (Schwarz et al., 2008). Similarly, Agren et al. (2012)
found that education and psychosocial support for patients with HF and their carers had no significant effect on patients’ self-care, depressive symptoms, or quality of life, or on carers’ burden, perceived control, or quality of life (Agren et al., 2012). In contrast with these results, the present study found that HF family-based education can enhance health outcomes in patients and carers, perhaps especially those in collectivist cultures (Deek et al., 2015; Moser et al., 2012).

Although RCTs are the preferred method to evaluate treatment efficacy, by identifying statistical differences between treatment and control groups, also of importance is whether such differences are clinically meaningful (Ogles, Lunnen, & Bonesteel, 2001). In other words, statistical significance does not necessarily indicate meaningful or clinically significant differences between groups or individuals. Cohen’s $d$ is most useful for assessing magnitude of effects and can be used to make treatment decisions. A Cohen’s $d$ score of zero means that the treatment and comparison agent have no differences in effect. A Cohen’s $d$ greater than zero indicates the degree to which one treatment is more efficacious than the other. A conventional rule is to consider a Cohen’s $d$ of 0.2 as small, 0.5 as medium, and 0.8 as large (McGough & Faraone, 2009). This approach to treatment selection urges clinicians to base treatment choices on the best evidence from systematic research on the efficacy and adverse effects of treatment alternatives (Faraone, 2008). In the present study, the results show statistically significant differences in outcomes between the intervention and usual care groups, including patient HF knowledge, self-care maintenance, and self-care confidence, and quality of life (emotional dimension). The effect size of the difference in knowledge was medium at both three and six months. There was also a moderate significant effect on the emotional dimension of patient quality of life at three months and six months. However, the size of the effect on carer HF knowledge was large at both three and six months. These differences in knowledge need to be evaluated for clinical significance; for example, did changes in knowledge reduce hospital readmissions? However, other studies (Delaney et al., 2013; Gwadry-Sridhar et al., 2005) have reported that a 2-point change in scores is clinically meaningful (Delaney et al., 2013). It is important that the evaluation of the outcomes of treatments consider not only their statistical
significance, but also whether the treatments are meaningful for patients (Johnson, Dow, Lynch, & Hermann, 2006). While the $P$ value tells the researcher whether an effect of the treatment exists, it does not reveal the size of the effect (Sullivan & Feinn, 2012).

This is the first study of its kind in Thailand, in which researchers directed the HF education to both patients and their carers. The findings demonstrate that HF family-based education improved carers’ knowledge and perceived control over managing patents’ HF symptoms (only at three months), but not carers’ own quality of life. Thus, this extends previous associated literature by identifying that patient education can significantly increase HF knowledge in carers, but confer only modest improvements in other behavioural and psychosocial outcomes. Thus, the findings are aligned with those from a previous HF dyadic study – Agren et al. (2012) found that psychosocial support intervention conferred a neutral effect in carers, that is, the carers’ quality of life appeared stable over time. It is possible that the use of a general versus disease-specific family HRQoL instrument may also explain the neutral outcome of carers’ quality of life. General instruments provide the overall impact of disease on quality of life. By contrast, disease-specific instruments aim to assess a particular condition and its effect on related groups (L. E. Thompson, Bekelman, Allen, & Peterson, 2015). In light of this, future research should consider the use of disease-specific instruments, developed specifically for carers, for instance, the Family Caregiver Quality of Life (FAMQOL) for HF (Nauser, Bakas, & Welch, 2011).

5.4 Strengths of the study

A number of factors contributed to the strength of this study:

1. To our knowledge this is the first study to assess the effect of a family-based education program in patients with HF and their carers in rural Thailand. The study has contributed to the literature by examining and determining whether a culturally appropriate, tailored HF family-based education program delivered to patients and their carers or family members has favourable health outcomes; in particular, enhanced HF knowledge and self-care among patients and carers. The evidence from this study addresses a gap
between theory and practice, and supports the view that HF family-based education is both important to patients with HF and their carers and needed in rural Thailand.

2. The education program was underpinned by educational theory. The framework for this study was based on adult learning theory, which informed the development of the HF family-based education program (i.e. education and counselling session, HF manual and DVD, and telephone follow-up). The results of the current study showed that the theory-based HF family-based education program was effective in significantly improving health outcomes such as HF knowledge, self-care behaviour, and perceived control over managing patients’ HF symptoms. Furthermore, a transparent description of the educational intervention in Chapter Three illustrates how the theory was applied in developing the HF family-based education intervention.

3. A variety of educational resources have been specifically designed and implemented in this study. These resources include face-to-face education and counselling sessions, an HF manual and DVD, and telephone reinforcement. These educational resources, which were previously not available in Thailand to patients with HF, were added to the patients’ usual care. The results demonstrated that this type of education was well received by patients and carers, as evidenced by the process evaluation undertaken in which patients and carers engaged in utilising the educational resources provided and reported they were useful. Using this multi-component educational resource for carers and patients with HF enhanced their knowledge and ability to engage in HF self-care, and created a learning environment that encouraged dyads to discuss managing HF symptoms. Importantly, this program can easily be taught to clinical nurses to deliver.

4. The use of an RCT study design with careful adherence to CONSORT guidelines in reporting the study and comprehensive process evaluation. The random allocation of participants to the education or usual care groups reduced selection bias, and thus posed less threat to external validity (Peters, Langbein, & Roberts, 2015). The study adhered to CONSORT guidelines including ensuring the research assistant who collected all outcome measures was blinded to study group allocation. In addition, methods of
process evaluation were implanted to enure intervention adherence and participant satisfaction. As evident from the systematic review conducted (Srisuk et al., 2016), interpretation of previous randomised control design studies of family-based education interventions has been limited due to methodological quality.

5. The high participation and low withdrawal rates of participants in the study. This might be due to the telephone calls participants received encouraging them to complete the education program. In addition, a characteristic of culture in South-East Asian countries, including Thailand, where people have learned to respect all people in positions of authority may have contributed to participants’ high cooperation (Bankston & Hidalgo 2006). Similarly, a previous study conducted in this region demonstrated a high participation rate (Chien, Thompson, Lubman, & McCann, 2016; McCann, Songprakun, & Stephenso, 2016). Furthermore, the high retention rate could also be due to the fact that limited tailored support is provided to Thai families in this situation; therefore, participants might have perceived the intervention could be beneficial to them.

5.5 Limitations of the study

This is the first study to use the DHFKS with carers. It was found that the KR20 coefficient of reliability was low at baseline, which may have reflected random responses in dealing with large amounts of novel information and the structured questionnaire. Thus, the authors who developed the DHFKS (van der Wal et al., 2005) were contacted to discuss the most appropriate psychometric evaluation. As a result, supplementary analyses were performed to assess the validity of this measure via individual item analysis using Cochran's Q test in this new population. These analyses identified significant improvement in HF knowledge in the education group compared with the usual care group after six months, which suggests the intervention was successful.

The clinical setting of the counselling session for verbal delivery of HF education will be discussed as another potential research limitation. Most hospitals, and certainly those in Thailand, are hectic environments, which can make it difficult for patients and carers to focus.
Despite the fact that the education session was conducted in the teaching room, keeping the room quiet was difficult. As a result, the learners could lose their concentration at any time. The ideal setting for further research may be the home setting, or home visiting. Home-based interventions have been found to reduce mortality, morbidity, and rehospitalisation, as well as improve physical and mental characteristics in patients with HF (Aguado et al., 2010; Siabani, Driscoll, Davidson, & Leeder, 2015; Stewart, Vandenbroek, Pearson, & Horowitz, 1999; D. R. Thompson, Roebuck, & Stewart, 2005). With respect to the education and counselling session, patients and carers may feel more comfortable to ask questions and speak freely in their own home (Jaarsma et al., 2009; Kline, Scott, & Britton, 2007). However, for the current study, providing the education at the outpatient clinic was the only feasible option.

Another limitation of the HF education program is the participants need to have some reading ability. Participants who were not able to read Thai were excluded. In terms of the level of comprehensive reading skills, patients and carers were assessed indirectly on education level and health literacy in order to consider them when delivering the education. However, it should be noted that the manual was used as a supplement to the DVD.

The researcher also recognises the limitations associated with the generalisability of the study findings, which cannot be generalised to all Thai patients with HF living in the community. The study sample was selected from two hospitals in southern Thailand, which may have important cultural and behavioural differences to people living in urban areas of Thailand; for example, the southern part of Thailand is a more rural-oriented lifestyle. Furthermore, the findings may not be generalisable to patients with HF in other cultures. Differences in medical care, access to health services and cultural lifestyles limit the generalisability of the findings beyond this study, that is, to patients with HF living in rural areas of Thailand.

5.6 Implications for practice

Limited access to healthcare services has always been a problem in rural Thailand. In response to this gap, the present study developed and implemented a theory-driven family-based education program in rural Thailand. The education program directed at both patients
with HF and their carers included a face-to-face education and counselling session, provision of an HF manual and DVD, and telephone support for three months. The findings of this research indicate that this culturally relevant, family-based HF education program was effective in improving four health-related outcomes, including patient and carer HF knowledge, patient self-care behaviours, patient quality of life (emotional dimension), and carer-perceived control. This novel approach to delivering patient education is amenable for implementation within the scope of nursing practice in rural Thailand and could address a clinical practice gap where HF management programs do not exist. Importantly, this research provides evidence that implementation of such a program can be easily delivered to those most in need. For example, in establishing their outpatient clinic, one rural hospital in another province in Thailand has already expressed an interest in utilising this family-based HF education program. It is anticipated that, on completion of this PhD, the research will be promoted to other clinicians, hospital administrators, and government bodies to increase the transferability of the family-based intervention more broadly. This will be achieved through conference presentations, publications in peer-reviewed journals, and the Thai Trial Registry. In addition, further funding will be sought to extend on the trial, addressing some of the cultural issues and study limitations discussed above.

In Thailand, programs such as this can be incorporated into existing course structures to better prepare nursing students to meet the needs of a significant proportion of Thailand’s patient population currently with limited access to healthcare. In addition, to distribute the program more broadly, nursing education institutions could offer a course for working nurses who manage patients with heart disease in hospitals, primary care units, or healthcare centres.

In a similar vein, findings from this research have the potential to influence hospital policy. This could be achieved via hospital-based nursing administrators translating the evidence provided by this research to improve the quality of nursing care. For example, nurse administrators may support primary care nurses in applying this family-based education by arranging team training on program implementation and providing a budget for the HF manual, DVD, and telephone contact. Importantly, as the program needs an advanced practice nurse or
HF specialist nurse to deliver the intervention, hospital administrators should encourage registered nurses to train for the role of HF specialist in a nursing education institution. The reasons that the program requires HF specialist nurses is because they need to have a deeper understanding of HF syndrome and its treatment, be able to work independently, and have an ability to manage patients' psychosocial aspects of being chronically ill and help them adapt to self-care behaviour (Wilkinson & Whitehead, 2009). By doing so, the program may be less accessible to general cardiac nurses, but patients and carers will have the potential to receive the most effective HF care.

5.7 Future research

Teaching HF self-care without building critical skills may not be sufficient to generate long-term behaviour changes (Dickson et al., 2014; Harkness et al., 2014; Riegel & Moser, 2015). Future studies should consider including cognitive behavioural strategies as an intervention to focus on developing problem-solving skills and other critical skills that have been found to effectively promote HF self-care in the longer term (Dickson et al., 2014). Utilising behavioural strategies for future educational programs may require training nurses in motivational interviewing (Brodie, Inoue, & Shaw, 2008; Riegel, Masterson Creber, Hill, Chittams, & Hoke, 2016), goal setting (Brennan & Elkins, 2014), and strategies that enhance patient self-efficacy (Gary, 2006; Shao, Chang, Edwards, Shyu, & Chen, 2013).

In addition, the cultural relevance of the SCHFI (Riegel et al., 2004), which was administered only to patients, requires some discussion. The self-care maintenance scale had satisfactory reliability for this study, but on reflection some of the questions were not culturally relevant; for example, the daily weighing (most Thai patients do not have access to scales) and water pills adjustment (Thai patients are not recommended to adjust their own diuretic). Future studies conducted in Thailand should consider investigating the cultural relevance of the SCHFI.

5.8 Conclusions
This research makes a new contribution to knowledge regarding a family-based HF education program specifically relevant to rural Thailand. This is the first study of its kind to examine the impact of HF family-based education for patients with HF and theirs carers in rural Thailand. This study confirmed that harnessing the support of family members and including them in an HF education program resulted in favourable improvements in HF knowledge, patients’ self-care behaviours, and carers’ perceived control over managing patients’ HF symptoms. The evidence provided from this study has substantially assisted in narrowing the evidence gap between theory and practice, i.e. between recommended HF self-care and achievable HF self-care in rural Thailand. The findings of this study have the potential to translate into clinical practice via dissemination through university and hospital education programs to impact on not only clinical practice, but also on the lives of those in most need, patients with HF and their carers with limited access to healthcare education and services in rural Thailand.
References

NB: The references cited in the publications are not included in this reference list as each contains its own references.


National Heart Foundation of Australia (2012). Heart failure. Retrieved from http://www.heartfoundation.org.au/search/eyJyZXN1bHRfcGFnZSI6Iiwvc2VhcmNoXC8iLmJrZXI3b3JkcyI6ImhlYXJ0IGNcWx1cmUifQ


Appendices

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Appendix A: Research portfolio

Appendix A.1 List of manuscripts and statement of contributions

**Published works by the candidate**


Title: Heart failure family-based education: a systematic review

Status: Published in Patient Education and Counseling

Statement of contribution of others:

I acknowledge that my contribution to the above paper is 60%.

Nittaya Srisuk

I acknowledge that my contribution to the above paper is 20%.

Dr Jan Cameron

I acknowledge that my contribution to the above paper is 10%.

Association Professor Chantal F Ski

I acknowledge that my contribution to the above paper is 10%.

Professor David R Thompson
**Protocol paper**

**Title:** Trial of a family-based education program for heart failure patients in rural Thailand.

**Status:** Published in *BMC Cardiovascular Disorders*

**Statement of contribution of others:**

I acknowledge that my contribution to the above paper is 70%.

Nittaya Srisuk

I acknowledge that my contribution to the above paper is 10%.

Dr Jan Cameron

I acknowledge that my contribution to the above paper is 10%.

Association Professor Chantal F Ski

I acknowledge that my contribution to the above paper is 10%.

Professor David R Thompson
Unpublished works by the candidate

Srisuk, N., Cameron, J., Ski, C. F., & Thompson, D. R. Manuscript submitted for publication to the *Journal of Advanced Nursing*. 
Study 1

Title: Randomized controlled trial of family-based education for patients with heart failure and their carers

Status: Submitted for publication to the Journal of Advanced Nursing

Statement of contribution of others:

I acknowledge that my contribution to the above paper is 60%.

Nittaya Srisuk

I acknowledge that my contribution to the above paper is 20%.

Dr Jan Cameron

I acknowledge that my contribution to the above paper is 10%.

Association Professor Chantal F Ski

I acknowledge that my contribution to the above paper is 10%.

Professor David R Thompson
Fw: JAN-2016-0194 - Randomized controlled trial of family-based failure and their carers

Nittaya Srisuk
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From: onbehalfof+disclainr+wiley.com@manuscriptcentral.com <onbehalfof+disclainr+wiley.com@manuscriptcentral.com> o
Sent: Tuesday, 26 April 2016 10:11 PM
To: Nittaya Srisuk: zomwhan@hotmail.com
Subject: JAN-2016-0194 - Randomized controlled trial of family-based education for patients with heart failure and their carers

26-Apr-2016

JAN-2016-0194 - Randomized controlled trial of family-based education for patients with heart failure and their carers

Dear Ms Srisuk,

Thank you for submitting your paper to JAN. I apologise for the delay in sending you a decision, this is due to a large volume of obtaining peer reviews for your paper. We have received one review and are awaiting responses to our latest invitations to revi

I will continue to monitor the situation.

With thanks and best wishes,

Di Sinclair
Managing Editor
Journal of Advanced Nursing
A.2 List of peer-reviewed conference presentations

National conference abstracts and presentations by the candidate relating to the thesis


Appendix B: Ethics approval

B.1 Human Research Ethics Committee

Human Research Ethics Committee

Committee Approval Form

Principal Investigator/Supervisor: Professor David Thompson
Co-Investigators: Associate Professor Chantal Ski, Dr Jan Cameron
Student Researcher: Ms Nittaya Srisuk

Ethics approval has been granted for the following project:
A trial of a family-based education program to support heart failure patients and carers in rural Thailand
(Supporting heart failure patients and carers in rural Thailand)
for the period: 19/03/2014-31/12/2014
Human Research Ethics Committee (HREC) Register Number: 2013 310V

Special Conditions of Approval
Prior to commencement of your research, the following permissions are required to be submitted to the ACU HREC:
Written permissions from Chumphon Hospital and Parknern Lungsuan Hospital

The following standard conditions as stipulated in the National Statement on Ethical Conduct In Research Involving Humans (2007) apply:

(i) that Principal Investigators / Supervisors provide, on the form supplied by the Human Research Ethics Committee, annual reports on matters such as:
   • security of records
   • compliance with approved consent procedures and documentation
   • compliance with special conditions, and

(ii) that researchers report to the HREC immediately any matter that might affect the ethical acceptability of the protocol, such as:
   • proposed changes to the protocol
   • unforeseen circumstances or events
   • adverse effects on participants

The HREC will conduct an audit each year of all projects deemed to be of more than low risk. There will also be random audits of a sample of projects considered to be of negligible risk and low risk on all campuses each year.

Within one month of the conclusion of the project, researchers are required to complete a Final Report Form and submit it to the local Research Services Officer.

If the project continues for more than one year, researchers are required to complete an Annual Progress Report Form and submit it to the local Research Services Officer within one month of the anniversary date of the ethics approval.

Signed: ....
Date: 18/03/2014
(Research Services Officer, McAuley Campus)
B.2 Chumporn Hospital
บันทึกข้อความ
ส่วนราชการ โรงพยาบาลลำบุกน้ำแดง
ที่ 0027.012/0 วันที่ 4 เมษายน 2557
เรื่อง อนุมัติให้ดำเนินการวิจัย

เรียน หัวหน้ากลุ่มการพยาบาล

ตามที่ นางสาวนิตยา ศรีสุริยา นิติบัณฑิตเปรียญทางการศึกษา Australian Catholic University มีความประสงค์แสดงความไว้วางใจว่า "ขอให้โปรแกรมการให้ความรู้โดยใช้กระบวนการเป็นฐานในการให้ความรู้ทุกวิชาการทุกกลุ่มและผู้สูงอายุในประเทศไทย" นั้น

โรงพยาบาลหลังสวน จึงมีความเห็นสมควรสนับสนุนให้ดำเนินการวิจัยตามขอบเขตที่กำหนดไว้โดยมีข้อเสนอแนะดังนี้

1. ประสานงานกับหน่วยงานที่เกี่ยวข้องในการเก็บข้อมูล
2. ประสานงานกับผู้ว่าราชการ แล้วให้กับโรงพยาบาลหลังสวน

จึงเรียนมาเพื่อโปรดทราบ

[ลายเซ็น]

นายแพทย์ นุทธิรา ศิริศักดิ์วุฒิ
(ผู้อำนวยการโรงพยาบาลหลังสวน)
Appendix C: Informed consent information sheet

C.1 Patient participant consent form (English)
Carer Participant Consent Form

Title of project: Supporting heart failure patients and carers in rural Thailand

Research Supervisor: David Thompson
Student Researcher: Nittaya Srisuk

I ...................................................... (the participant) have read and understood the information provided in the Carer Participant Information Letter. Any questions I have asked have been answered to my satisfaction. I agree to participate in this research to be conducted over a 6-month period involving education and a series of follow-up telephone calls, realising that I can withdraw my consent at any time without adverse consequences.

I agree that research data collected for the study may be published or may be provided to other researchers in a form that does not identify me in any way.

Name of participant...........................................................................................................

Signature............................................................... DATE ..............................................

Signature of Research Supervisor................................................................. DATE.....................

Signature of Student Researcher................................................................. DATE.....................
C.3 Patient participant consent form (Thai)
C.4 Carer participant consent form (Thai)

เอกสารสินสมการเข้าร่วมโครงการวิจัย (สำหรับผู้คุ้มครอง)
(informed consent form)

ชื่อเจ้า

บอกเล่าชื่อ

วันประสานเข้าร่วด

รายการ

โครงศัก

ได้ทราบและเห็นชอบโครงการวิจัย ที่กิจกรรมนี้มีการให้คุณคู่ได้รับการศึกษาในที่มีการหัวใจ
สมทบและผู้ดูแลในประเทศ ตลอดจนประโยชน์และเสี่ยงที่เกิดขึ้นจากการค้น

จากวิจัย และได้รับการให้คำแนะนำในการที่จะต่อสู้

จากการค้น

โดยคุณคู่จะได้รับบัตรไปรับเงิน

เพื่อใช้เป็นเรื่องต่างๆ ของคุณคู่ และจะเป็นเรื่องต่างๆ ผู้คุ้มครองได้รับ

ผลประโยชน์จากโครงการวิจัย

ชื่อเจ้า

(.............................................)

ชื่อ...

(.............................................)

ชื่อ...

(.............................................)

ชื่อ...

(.............................................)

หมายเหตุ สิ่งที่ให้สินสมการเข้าร่วมโครงการวิจัย ไม่มีผลต่อสิทธิ์ใดๆของคุณคู่ในการรับ

ค่าตอบแทนของผู้คุ้มครอง

จากวิจัยได้รับการและเห็นชอบโครงการวิจัยตลอดจนประโยชน์ของการวิจัย รวมทั้งสิ่งที่คุณคู่จะได้รับ ที่คุณคู่จะได้รับการค้น

จากวิจัย และได้รับการให้คำแนะนำในการที่จะต่อสู้

โดยคุณคู่จะได้รับบัตรไปรับเงิน

เพื่อใช้เป็นเรื่องต่างๆ ของคุณคู่ และจะเป็นเรื่องต่างๆ ผู้คุ้มครองได้รับ

ผลประโยชน์จากโครงการวิจัย

ชื่อเจ้า

(.............................................)

ชื่อ...

(.............................................)

ชื่อ...

(.............................................)

ชื่อ...

(.............................................)
Patient Participant Information Letter

Project name: Supporting heart failure patients and carers in rural Thailand

Principal Investigator: Professor David Thompson
Student Researcher: Nittaya Srisuk
Student's degree: PhD

Dear Participant,

This letter invites you to take part in a study aimed at supporting heart failure patients and their carers in Thailand. My name is Nittaya Srisuk, as a nursing student I am undertaking a PhD at the Australian Catholic University. My supervisor is Professor David Thompson.

What is the study about?

The aim of this research is to develop and evaluate a family-based education program in patients with HF and carers in rural Thailand. It is important to assist patients and carers with strategies to self-manage some of the symptoms associated with heart failure. Education and support may increase patient and carer knowledge and improve health.

I want to trial a patient education program developed for patients with heart failure. You may live alone or with family, we also wish to involve your main carer/family member in supporting you to manage your condition.

What will I be asked to do?

It is your choice if you participate or not. If you choose to participate, you will be asked to:

1. Participate in 1 interview.

The interview will be at a time and place that suits us both. We will arrange this after you return the consent form. At this interview you will be asked to provide some details about yourself, your health and medical conditions. Five short questionnaires also need to be completed that ask about your memory and brain function (cognition), your knowledge of heart failure, how you currently manage your heart failure, how heart failure affects you every day, and how you have been feeling emotionally and physically in
the past week. These questionnaires will take 40-50 minutes to complete. Once this information has been collected you will be randomly allocated to receiving your routine medical care or your routine medical care with the addition of the education intervention. You are not able to choose the group you are allocated. If you are selected to receive the intervention you will be asked to attend an education session in the clinic. Your nominated carer will need to attend this with you. This education session will last 45-60 minutes. You will also be given a booklet and a DVD about heart failure. These are for you to take home and use with your family. You will be given instructions about how to use them.

2. **Participate in telephone calls.**
   No matter which group you have been allocated, you will be called seven times over a three month period. I will need to speak with both yourself and your nominated carer. The calls will not be audio taped but I will write down what we talk about in the telephone call. You will be asked if you want a written copy of your interview record so that you can check it.

3. **Participate in 2 further interviews.**
   You will be asked to complete some of the questionnaires that were completed in the first interview. These will need to be collected at three and six months following the initial interview. These may be administered in the clinic, posted to you, or I can ask the questions over the phone.

*Are there any risks involved?*

There are no unforeseen risks in this study as you will continue to receive your usual care. If you are allocated to the usual care group you will be offered an education session and HF pamphlet at the end of the study.

You can stop the any of the interviews at any time for any reason. What you talk about in the interview is your choice. If I ask you a question that you do not want to answer, I will respect your right to privacy.

*What are the benefits of the study?*

The main benefit to you is that you may gain a better understanding about managing your HF. I can also link you with helpful contacts, such as counseling, if you wish.
Not much is known about benefits of educational programs for heart failure patients and carers in Thailand. This study will help the community to be more aware of the issue.

**You do NOT have to participate in the study - it is YOUR choice.**

You can also change your mind and withdraw from the study at any time over the 6-month period. For example, you can stop during a telephone call.

There are no bad consequences to you if you choose not to participate or to withdraw from the study.

**What will be done with my information and the results of the study?**

This study is strictly confidential. Questionnaires will not use your name.

Questionnaires and interview records will be kept in a locked cabinet at the Australian Catholic University for 5 years after the research.

Your name and personal information will NOT be included in any public documents. All data will be de-identified and aggregate data only will be reported. You can have a copy of your written interview record if you wish.

A copy of my thesis will be held at the Australian Catholic University in Melbourne. On your request a summary of the findings of my research will be mailed to you. These findings may also be published in an academic journal.

**What if I have a complaint or any concerns?**

The study has been approved by the Human Research Ethics Committee at Australian Catholic University. If you have any complaints or concerns about the project, you should contact:

**Mail:** Chair, HREC  
c/o Office of the Deputy Vice Chancellor (Research)  
Australian Catholic University  
Melbourne Campus  
Locked Bag 4115  
FITZROY, VIC, 3065

**Phone:** 03 9953 3150

**Fax:** 03 9953 3315

**Email:** res.ethics@acu.edu.au
Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

_I am interested in this study. What should I do?_

_It is your decision if you participate or not. If you have any questions before you make your decision you can talk to your Advocacy Organisation._

If you decide that you want to participate, you or your legally appointed guardian (if you have one) may sign both copies of the Consent Form. Keep one copy for your own records. Return the other to me in the paid return envelope provided. You can also contact Nittaya or David on:

**Nittaya Srisuk (Student Researcher)**
Ph: +66 8 1538 6625  
Email: nnsris002@myacu.edu.au

**David Thompson (Supervisor)**
Ph: 0011 61 3 9953 3680
Cardiovascular Research Centre  
Australian Catholic University  
486 Albert St, East Melbourne  
VIC 3002

Yours sincerely,

Nittaya Srisuk  
Student Researcher  

Professor David Thompson
Principle Supervisor
Carer Participant Information Letter

Project name: Supporting heart failure patients and carers in rural Thailand

Principle Investigator: Professor David Thompson
Student Researcher: Nittaya Srisuk
Student’s degree: PhD

Dear Participant,

This letter invites you to take part in a study aimed at supporting heart failure patients and their carers in Thailand. My name is Nittaya Srisuk, as a nursing student I am undertaking a PhD at the Australian Catholic University. My supervisor is Professor David Thompson.

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The aim of this research is to develop and evaluate a family-based education program in patients with HF and carers in rural Thailand. It is important to assist patients and carers with strategies to self-manage some of the symptoms associated with heart failure. Education and support may increase patient and carer knowledge and improve health.

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   The interview will be at a time and place that suits us both. We will arrange this after you return the consent form. At this interview you will be asked to provide some details about yourself, your health and medical conditions. Three short questionnaires also need to be completed that ask about your memory and brain functioning (cognition), your knowledge of heart failure, how you have been feeling emotionally and physically in the past week and whether you feel in control in managing the family member’s heart
problems. These questionnaires will take 30-40 minutes to complete. Once this information has been collected the person with heart failure will be randomly allocated to receiving their routine medical care or their routine medical care with the addition of the education intervention. You are not able to choose the group you are allocated. If you are selected to receive the intervention you will be asked to attend an education session in the clinic. This education session will last 45-60 minutes. You will also be given a booklet and a DVD about heart failure. These are for you to take home and use. You will be given instructions about how to use them.

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   No matter which group you have been allocated, you will be called seven times over a three month period. I will need to speak with both yourself and the person with heart failure. The calls will not be audio taped but I will write down what we talk about in the telephone call. You will be asked if you want a written copy of your interview record so that you can check it.

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   You will be asked to complete some of the questionnaires that were completed in the first interview. These will need to be collected at three and six months following the initial interview. These may be administered in the clinic, posted to you, or I can ask the questions over the phone.

**Are there any risks involved?**

There are no unforeseen risks in this study as you the person with failure will continue to receive their usual care. If you are allocated to the usual care group you will be offered an education session and HF pamphlet at the end of the study.

You can stop any of the interviews at any time for any reason. What you talk about in the interview is your choice. If I ask you a question that you do not want to answer, I will respect your right to privacy.

**What are the benefits of the study?**

The main benefit to you is that you may gain a better understanding about managing your HF. I can also link you with helpful contacts, such as counseling, if you wish.
Not much is known about benefits of educational programs for heart failure patients and carers in Thailand. This study will help the community to be more aware of the issue.

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You can also change your mind and withdraw from the study at any time over the 6-month period. For example, you can stop during a telephone call.

There are no bad consequences to you if you choose not to participate or to withdraw from the study.

What will be done with my information and the results of the study?

This study is strictly confidential. Questionnaires will not use your name.

Questionnaires and interview records will be kept in a locked cabinet at the Australian Catholic University for 5 years after the research.

Your name and personal information will NOT be included in any public documents. All data will be de-identified and aggregate data only will be reported. You can have a copy of your written interview record if you wish.

A copy of my thesis will be held at the Australian Catholic University in Melbourne. On your request a summary of the findings of my research will be mailed to you. These findings may also be published in an academic journal.

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**Mail:** Chair, HREC  
c/o Office of the Deputy Vice Chancellor (Research)  
Australian Catholic University  
Melbourne Campus  
Locked Bag 4115  
FITZROY, VIC, 3065

**Phone:** 03 9953 3150  
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Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

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If you decide that you want to participate, you or your legally appointed guardian (if you have one) may sign both copies of the Consent Form. Keep one copy for your own records. Return the other to me in the paid return envelope provided. You can also contact Nittaya or David on:

**Nittaya Srisuk (Student Researcher)**
**David Thompson (Supervisor)**

Ph: +66 8 1538 6625
Email: nnsris002@myacu.edu.au

Ph: 0011 61 3 9953 3680
Cardiovascular Research Centre
Australian Catholic University
486 Albert St, East Melbourne
VIC 3002

Yours sincerely,

Nittaya Srisuk
Student Researcher

Professor David Thompson
Principle Supervisor
C.7 Participant information letter (Thai)

เอกสารข้อมูลผู้เข้าร่วมโครงการวิจัย

(Participant Information Sheet)

๑. โครงการวิจัยมีชื่อ และจะต้องลงข้อมูลเกี่ยวกับผู้ร่วมการวิจัยในแบบฟอร์มที่มีการระบุเพื่อเห็นตัวผู้เข้าร่วมโครงการวิจัยแบบฟอร์มที่มีการระบุในเอกสารนี้

๒. ผู้เข้าร่วมโครงการวิจัยต้องมีดังนี้
   □ อายุ
   □ ชั้นศึกษา
   □ สถานที่ที่มารู้จัก คุณสมบัติทางด้านสังคมของผู้เข้าร่วมโครงการวิจัยกรณี 272 นมผู้ครูทางด้านภาษาคู่ชุมชน

๓. วัตถุประสงค์ของโครงการวิจัย

เพื่อศึกษาและประเมินผลการเปลี่ยนแปลงที่เกิดขึ้นในระดับการเรียนรู้ในกลุ่มผู้เข้าร่วมโครงการวิจัย (อนุบาล)

๔. เมื่อผู้เข้าร่วมโครงการวิจัยได้รับข้อมูลหลัก

ท่านจะได้รับข้อมูลการเข้าร่วมโครงการวิจัยในแบบฟอร์มที่มีการระบุข้อมูลการเรียนรู้ และเป็นผู้สมัครผู้ที่มีการเข้าร่วมโครงการวิจัย

- ผู้เข้าร่วมโครงการวิจัยที่มีการระบุข้อมูลการเข้าร่วมโครงการวิจัย
- ผู้เข้าร่วมโครงการวิจัยที่มีการระบุข้อมูลการเข้าร่วมโครงการวิจัย

ท่านมีสิทธิร่วมโครงการวิจัยในแบบฟอร์มที่มีการระบุข้อมูลการเข้าร่วมโครงการวิจัย 100 คน ระยะเวลาการเข้าร่วมโครงการวิจัยประมาณ 180 วัน

หากผู้เข้าร่วมโครงการวิจัยที่มีการระบุข้อมูลการเข้าร่วมโครงการวิจัย

- ครั้งที่ 1
- ครั้งที่ 2
- ครั้งที่ 3
- ครั้งที่ 4
- ครั้งที่ 5

โดยผู้เข้าร่วมโครงการวิจัยต้องเข้าร่วมโครงการวิจัยแบบฟอร์มที่มีการระบุข้อมูลการเข้าร่วมโครงการวิจัย 3 ครั้ง ที่มีโครงการวิจัยเป็น 3 ครั้ง ที่มีการระบุตัวอย่างผู้เข้าร่วมโครงการวิจัย 3 ครั้ง (ชั้นวัยประถม ชั้นปฐมวัย)

- ผู้เข้าร่วมโครงการวิจัยที่มีการระบุข้อมูลการเข้าร่วมโครงการวิจัย

ท่านมีสิทธิเข้าร่วมโครงการวิจัยในแบบฟอร์มที่มีการระบุข้อมูลการเข้าร่วมโครงการวิจัย 100 คน ระยะเวลาการเข้าร่วมโครงการวิจัย 100 วัน สิทธิในการเข้าร่วมโครงการวิจัย 100 คน

- ผู้เข้าร่วมโครงการวิจัยที่มีการระบุข้อมูลการเข้าร่วมโครงการวิจัย

ท่านมีสิทธิเข้าร่วมโครงการวิจัยในแบบฟอร์มที่มีการระบุข้อมูลการเข้าร่วมโครงการวิจัย 100 คน ระยะเวลาการเข้าร่วมโครงการวิจัย 100 วัน สิทธิในการเข้าร่วมโครงการวิจัย 100 คน

๕. ต้องการขอeyJxYXNudCB0aGUgaW5yaWstepvngYW5jaVRvbWwyIHRoZSB0aGUgYm9yZSB0aGlzIGl0ZW0gaW50ZXJhbA==

- การตอบแบบสอบถาม
- การเปรียบเทียบ
- การรักษาสุขภาพ
- การวิเคราะห์ข้อมูล
218

(Illegible text)

ใจการรักษาหัวใจ

 lacked

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Appendix D: Questionnaires used in the research program

D.1 Patient questionnaires
### ลำดับที่ 1 แบบสอบถามข้อมูลส่วนบุคคล

ต่อไปนี้ โปรดเลือกคำตอบในข้อถามต่อไปนี้ หรือติบติในข้อต่อไปนี้เพื่อคอมใหญ่ส่วนบุคคลของผู้ส่ง

1. อาชีพ ..........
2. เพศ ชาย หญิง
3. สถานภาพสมรส แต่งงาน โสด หย่า หย่าเจ็บ แยกกันอยู่
4. จำนวนสมาชิกในครอบครัว .............คน
5. สถานะ โสด พิการ อายุเรียกว่า อื่นๆ
6. ระดับการศึกษาสูงสุด ระดับประถมศึกษา ระดับมัธยมศึกษา ระดับปริญญาตรี ปริญญาโท ปริญญาตรี ปริญญาโท
7. อาชีพ นักศึกษา
8. รายได้ต่อเดือน
   - เน้นราคา 3,000 บาท
   - 5,001-10,000 บาท
   - 16,001-20,000 บาท
   - 20,001-30,000 บาท
ส่วนที่ 1: แบบสอบถามข้อมูลล้วนบุคคล

9. ระยะเวลาของการที่มีผู้ดูแลสุขภาพที่ไม่เสี่ยง...............ปี
10. ประวัติการรักษา

- ใช้ ตั้งแต่ แต่เป็นระยะเวลา............... หรือ ไม่เคยรักษาเป็นระยะเวลา...........

- ไม่รู้
ข้อมูลที่เกี่ยวข้องกับการวินิจฉัยที่ 2 สำหรับการรักษาที่

1. V/S BP.................mmHg Pulse....................................../min
   Temp.................C RR................................./min

2. ผลการตรวจดีเอ็นเอที่หัวใจ ค่าประสิทธิภาพการปั่นวัสดุของหัวใจ (Ejection Fraction) =......%

3. วัตถุประสงค์ในการรักษาหรือข้อมูลเกี่ยวกับ O ไว้  O ไม่ไว้

4. อาการ𝚔າcriptionsที่เกี่ยวข้องที่ได้รับในปัจจุบัน

2.1.................................................................
2.2.................................................................
2.3.................................................................
2.4.................................................................
2.5.................................................................
2.6.................................................................
2.7.................................................................
2.8.................................................................

3. NYHA functional class.................................................................
4. Charlson Comorbidity Questionnaire

1. Myocardial infarction
   O No  O Yes  Score  1  0
One or more instances of definite or probable MI (enzyme changes):

2. Congestive Heart Failure
   O No  O Yes  Score  1  0
History of exertional or paroxysmal nocturnal dyspnea with symptomatic
response to dig, diuretics or after load reducers:

3. Peripheral Vascular Disease:
   O No  O Yes  Score  1  0
Current: intermittent claudication, gangrene, acute arterial insufficiency, or
untreated thoracic or abdominal aneurysm (6cm or more) or history of arterial bypass:

4. Cerebrovascular Accident:
   O No  O Yes  Score  1  0
CVA with minor or no residual or transient ischemic attack (TIA):

5. Chronic Obstructive Pulmonary Disease:
   O No  O Yes  Score  1  0
Asthma, emphysema, chronic bronchitis, or chronic obstructive lung disease
(dyspnic at rest or with activity)

6. Ulcer Disease:
   O No  O Yes  Score  1  0
Peptic ulcer disease requiring treatment (including hx of bleed):

7. Diabetes requiring medication (oral or insulin)
   O No  O Yes  Score  1  0
, not treated by diet alone
8. Connective tissue disease:  
<table>
<thead>
<tr>
<th></th>
<th>O No</th>
<th>O Yes</th>
<th>Score</th>
<th>1</th>
<th>0</th>
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</table>
Systemic lupus erythematosus, polymyositis, mixed connective tissue disease, Polyynalgia rheumatica, or moderate to severe Rheumatoid Arthritis:

9. Alzheimer's Disease, or another form of dementia:  
<table>
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<tr>
<th></th>
<th>O No</th>
<th>O Yes</th>
<th>Score</th>
<th>1</th>
<th>0</th>
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<td></td>
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</tbody>
</table>

10. Chronic hepatitis or Cirrhosis:  
<table>
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<th></th>
<th>O No</th>
<th>O Yes</th>
<th>Score</th>
<th>1</th>
<th>0</th>
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</tr>
</tbody>
</table>
without history of portal HTN or variceal bleeding

11. Hemiplegia:  
<table>
<thead>
<tr>
<th></th>
<th>O No</th>
<th>O Yes</th>
<th>Score</th>
<th>1</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>
Hemiplegia or paraplegia as a result of CVA or other condition:

12. Diabetes with end-organ damage:  
<table>
<thead>
<tr>
<th></th>
<th>O No</th>
<th>O Yes</th>
<th>Score</th>
<th>1</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
retinopathy, neuropathy or nephropathy:

13. Moderate or severe renal disease  
<table>
<thead>
<tr>
<th></th>
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<th>O Yes</th>
<th>Score</th>
<th>1</th>
<th>0</th>
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</tbody>
</table>
(serum creatinine<3 mg%, with uremia, on dialysis, or history of transplant:

14. Leukemia or polycythemia vera  
<table>
<thead>
<tr>
<th></th>
<th>O No</th>
<th>O Yes</th>
<th>Score</th>
<th>1</th>
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</thead>
<tbody>
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<td></td>
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</table>

15. Lymphoma  
<table>
<thead>
<tr>
<th></th>
<th>O No</th>
<th>O Yes</th>
<th>Score</th>
<th>1</th>
<th>0</th>
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</tbody>
</table>

16. Cancer  
<table>
<thead>
<tr>
<th></th>
<th>O No</th>
<th>O Yes</th>
<th>Score</th>
<th>1</th>
<th>0</th>
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</tbody>
</table>
other than skin cancer, leukemia, or lymphoma (Solid Tumor)

Without metastasis but first treated less than 5 years ago

17. Cirrhosis with history of portal HTN  
<table>
<thead>
<tr>
<th></th>
<th>O No</th>
<th>O Yes</th>
<th>Score</th>
<th>1</th>
<th>0</th>
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<tbody>
<tr>
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</tbody>
</table>
Or variceal bleeding
### 18. AIDS

<table>
<thead>
<tr>
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<th>O Yes</th>
<th>Score</th>
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</thead>
<tbody>
<tr>
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</tbody>
</table>

### 19. Cancer (Solid Tumour) with metastasis

<table>
<thead>
<tr>
<th></th>
<th>O No</th>
<th>O Yes</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 O</td>
</tr>
</tbody>
</table>

Charlson: Total Score

Comorbidity CATEGORY (Score of 1-2=1; 3-4=3; 5 or more = 5)
ส่วนที่ 3 แบบสอบถามความมั่นใจในการให้ข้อมูลทางการแพทย์

โปรดติ๊กเครื่องหมาย X ด้านข้างต่อไปนี้ถ้าความรู้สึกของคุณมากที่สุด 1 หมายถึงไม่มั่นใจในการรับแบบฟอร์มทางการแพทย์ และ 4 มั่นใจมากที่สุด

<table>
<thead>
<tr>
<th>ไม่มั่นใจ</th>
<th>มั่นใจมากที่สุด</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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</tbody>
</table>
คำถามที่ 4 แบบสอบถามความรู้เกี่ยวกับภาวะแทรกซ้อนเหตุการณ์

โปรดทำการส่งแบบฝึกหัดดังนี้ที่เห็นดีที่สุด

1. ผู้ที่มีภาวะแทรกซ้อนเหตุการณ์ภาวะจิตเวชเช่น
   ก. รู้ทัน
   ข. บอก
   ค. หาย

2. เกณฑ์ที่ทำให้ผู้ที่มีภาวะแทรกซ้อนเหตุการณ์มีอาการต่อไปนี้
   ก. ผู้ที่มีภาวะแทรกซ้อนเหตุการณ์มีอาการต่อไปนี้
   ข. ผู้ที่มีภาวะแทรกซ้อนเหตุการณ์มีอาการต่อไปนี้
   ค. ผู้ที่มีภาวะแทรกซ้อนเหตุการณ์มีอาการต่อไปนี้

3. ผู้ที่มีภาวะแทรกซ้อนเหตุการณ์มีอาการต่อไปนี้
   ก. ที่มีความต้องการมีสุขภาพดี
   ข. ที่มีความต้องการมีสุขภาพดี
   ค. ที่มีความต้องการมีสุขภาพดี

4. จึงให้แสดงผลลัพธ์การว่าผู้ที่มีภาวะแทรกซ้อนเหตุการณ์มีอาการต่อไปนี้
7.

8.

9.

10.

11.
7. ภาวะที่มีผลเสียต่อจุดประสงค์ในผลผลิตของหัวใจ

8. อาการบุคคลที่มีภาวะทำใจล้มเหลว ถูกตรวจพบหรือ

ก. เลือกผลผลิตที่มีไม่สามารถทำงานได้อย่างมีประสิทธิภาพ

ข. กลับเหิรัดจากได้รับการจัดทำไม่ได้รับหลัก

ค. ถูกตรวจความเสี่ยงของความรุนแรง

9. หัวใจของที่มีภาวะทำใจล้มเหลว

ก. ดูไข้หวัดอาจร่างเกี่ยวกับ

ข. หน้าท้องเป็นโรคหรือโรคต่าง ๆ ของร่างกาย

ค. ให้ออกซิเจนแก่หัวใจ

10. ผลผลิตที่มีภาวะทำใจล้มเหลว ถูกตรวจพบหรือที่มีผลผลิตที่มี

ก. เลือกผลผลิตที่มีได้รับการจัดทำหรือแก้ไข

ข. เลือกผลผลิตที่มีคุณสมบัติเป็นหลักเกี่ยวกับ

ค. เลือกผลผลิตที่มีคุณสมบัติ

12

230
11. สำเนาตัวอย่างที่ดีที่ท่านให้ยักยิ่งกว่าในฝั่งใต้ คือจังหวะ
ก. กลับเนื้อหัวใจตามและความส่วนใหญ่ต่ำ
ข. โรคปกคลุมภูมิKEN
ค. ความตื่นเต้นและไวรัสบางวัน

12. ภาวะลดักล่าด่านที่ดีของผู้ที่มีภาวะหัวใจอักเสบ จัดเกณฑ์สุทธิต้อง
ก. ผู้ที่มีภาวะหัวใจอักเสบที่ดีคงคลื่น尥ปลายที่หน้า สั้นเพื่อให้หัวใจได้สึก
ข. ผู้ที่มีภาวะหัวใจอักเสบที่ดีคงคลื่น十七条ลายและที่ต้นอย่างยาวนาน
ค. ผู้ที่มีภาวะหัวใจอักเสบที่ดีคงคลื่น十七条ลายให้มากที่สุดก่อนจะยืนไปได้

13. ผู้ที่มีภาวะหัวใจอักเสบที่ดีคงคลื่นเรียบหรรษาหัวใจส่วนว่างใหญ่
ก.  เชื่อมความต้านโรค
ข. เยื้องกลับมาระบายตัวในร่างกาย
ค. เยื้องกลับมาระบายตัวได้มากขึ้น

14. จัดเกณฑ์สุทธิต้อง
ก. หากน้ำหนักตัวเพิ่มขึ้นมากกว่า 2 กิโลกรัมภายใน 2-3 วันควรรายงานแพทย์ในการไปพบตามนัด
ตรวจไป

ข. หากน้ำหนักตัวเพิ่มขึ้นมากกว่า 2 กิโลกรัมภายใน 2-3 วัน ควรไปโรงพยาบาลหรือคลินิกแพทย์
แล้วจึงได้

ค. หากน้ำหนักตัวเพิ่มขึ้นมากกว่า 2 กิโลกรัมภายใน 2-3 วัน ควรตรวจรับประทานยา

15. หากผู้ที่มีภาวะท้องว่าง มีอาการกระหายน้ำ ควรปฏิบัติตามข้อดังต่อไปนี้

ก. ออกมาอาเจริญ

ข. ออกแก่หรือกระเพาะที่ระดับเก้า

ค. ดื่มน้ำเพิ่มมากขึ้น
ต่อเนื่องจากตารางข้างบน

<table>
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<tr>
<th>เลข</th>
<th>คำถาม</th>
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<th>ผลการตอบ</th>
<th>ผลการตอบ</th>
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</tr>
</thead>
<tbody>
<tr>
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<td>หมายเหตุเกี่ยวกับอาการทางใจ</td>
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<td>ไม่ได้</td>
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<td>ไม่ได้</td>
</tr>
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<td>ไม่ได้</td>
<td>ไม่ได้</td>
</tr>
<tr>
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<td>6</td>
<td>อื่นๆ</td>
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</tbody>
</table>

ข้อมูลเพิ่มเติม:

- รายละเอียดที่เกี่ยวกับอาการทางใจในวันนี้
- อาการทางใจในวันนี้
- อาการทางใจในหน้าผากหรือหน้าอก
- อาการทางใจในกล้ามเนื้อ
- อาการทางใจในลิ่ว
- อื่นๆ
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<th>มูลค่า</th>
<th>หน่วย</th>
<th>ปริมาณ</th>
<th>ผลผลิต</th>
<th>ผลผลิตสุทธิ</th>
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<tbody>
<tr>
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<td>รายการหน้า</td>
<td>๑</td>
<td>ครั้ง</td>
<td>๑</td>
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<td>รายการสำนักงาน</td>
<td>๑</td>
<td>ครั้ง</td>
<td>๑</td>
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<td>ครั้ง</td>
<td>๑</td>
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<td>ครั้ง</td>
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<td>13</td>
<td>รายการอื่นๆ</td>
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<td>ครั้ง</td>
<td>๑</td>
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<tr>
<td>14</td>
<td>รายการอื่นๆ</td>
<td>๑</td>
<td>ครั้ง</td>
<td>๑</td>
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</tbody>
</table>

หมายเหตุ: ตัวอักษร '๑' หมายถึง ปี
คำถามที่ 6 แบบสอบถามเกี่ยวกับคุณภาพของชีวิตของผู้ที่มีภาวะแทรกซ้อน

คำถาม: คุณมีแนวโน้มที่จะต้องการทราบว่าภาวะแทรกซ้อนนี้มีผลกระทบต่อการดับเนินชีวิตและความสุขของคุณในช่วง 1 (lemon) มากเท่าใด

1. ไม่มี หมายถึง คุณไม่เกี่ยวข้อง หรือไม่มีสิ่งที่เกี่ยวข้องกับคุณ
2. มากเพียงใด แต่ไม่ค่อนข้าง 2-5 ครั้งใน 1 เดือน
3. มากกว่า 2-5 ครั้งใน 1 เดือน
4. มากกว่า 2-5 ครั้งต่อสัปดาห์
5. มากกว่าที่สุด หมายถึง พบรับหรือทุกครั้ง

<table>
<thead>
<tr>
<th>ลำดับ</th>
<th>คำถาม</th>
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<th>มากที่สุด</th>
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<td>เลิกการงานที่ค่อนข้างถาวร หรือไม่ก็ตาม</td>
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<tr>
<td>2.</td>
<td>คือประสงค์จะอยู่ที่นี่ช่วงกี่ปี</td>
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</tr>
<tr>
<td>3.</td>
<td>ทำให้คุณเสียชีวิตไปได้ลึกลับ</td>
<td>0</td>
<td>1</td>
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<td>4</td>
</tr>
<tr>
<td>4.</td>
<td>ทำให้คุณทำตามที่คุณคุ้นหรือคุณกำลังบินได้</td>
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<td>ทำให้คุณเสียเวลาอย่างหน่อย</td>
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</tr>
<tr>
<td>7. ทำให้ท่านมีความคุ้นเคยในการทำกิจกรรมที่มีผลต่อสุขภาพ การมีกิจกรรมที่มีผลต่อสุขภาพและการมีกิจกรรมที่มีผลต่อสุขภาพ</td>
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<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
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<td>8. ทำให้ท่านทำงานหรือประกอบอาชีพได้อย่างลำบาก</td>
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<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>9. ทำให้ท่านทำงานด้วยอุปกรณ์ทางกายภาพหรือให้ท่านทำงานแต่ละขั้นตอนได้อย่างลำบาก</td>
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<tr>
<td>10. ทำให้ท่านมีการกระทำทางเพศเกินกว่าลำบาก</td>
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<td>5</td>
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<tr>
<td>11. ทำให้ท่านรับประทานอาหารที่ชอบได้ยาก</td>
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<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>12. ทำให้ท่านใช้ยาในลำบาก</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>13. ทำให้ท่านใช้ยาหรือพืชสมุนไพรบางอย่าง</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>14. ทำให้ท่านไปทำสุขภาพที่โรงพยาบาล</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>15. ทำให้ท่านมีการใช้ยาในการรักษาโรค</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>16. ทำให้ท่านมีการกระทำทางเพศเกินกว่าลำบาก</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>17. ทำให้ท่านมีการกระทำทางเพศเกินกว่าลำบาก</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>18. ทำให้ท่านมีการกระทำทางเพศเกินกว่าลำบาก</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>19. ทำให้ท่านมีการกระทำทางเพศเกินกว่าลำบาก</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>20. ทำให้ท่านมีการกระทำทางเพศเกินกว่าลำบาก</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>21. ทำให้ท่านมีการกระทำทางเพศเกินกว่าลำบาก</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
D.2 Carer questionnaires

แบบสอบถามในการวิจัย

แบบสอบถามผู้ที่มีผลกระทบด้านสมรรถภาพฯ 6 ลำดับดังนี้

ลำดับที่ 1 แบบสอบถามชื่อมูลส่วนบุคคล
ลำดับที่ 2 แบบสอบถามความมั่นใจในการให้ข้อมูลทางการแพทย์
ลำดับที่ 3 แบบสอบถามความรู้ที่เกี่ยวกับการทัศนคติสุขภาพ
ลำดับที่ 4 แบบสอบถามความสามารถในการจัดการปัญหาที่เกิดขึ้นกับผู้ป่วยที่มีปัญหาทางสรีรวิทยา
ลำดับที่ 5 แบบสอบถามส่วนจุติความชีวิต
# ลำดับที่ 1 แบบสอบถามข้อมูลส่วนบุคคล

ตั้งแต่ตน โปรดให้คำแนะนำในช่วงว่าง หรือคำหรือลายมือ / หน้าชื่อที่ตรงกับข้อมูลส่วนบุคคลของผ่าน

<table>
<thead>
<tr>
<th>ลำดับ</th>
<th>รายการ</th>
<th>รายละเอียด</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>อายุ</td>
<td>ปี</td>
</tr>
<tr>
<td>2.</td>
<td>เพศ</td>
<td>ก / ผู้หญิง</td>
</tr>
<tr>
<td>3.</td>
<td>สถานภาพสมรส</td>
<td>แต่งงาน / โสด / หย่า / แยกกันอยู่</td>
</tr>
<tr>
<td>4.</td>
<td>จำนวนนกวัชในครอบครัว</td>
<td>คน / คน / คน / คน</td>
</tr>
</tbody>
</table>
ท้ายที่ 2 แบบสอบถามความมั่นใจในการให้ข้อมูลทางการแพทย์

โปรดตีความหมาย X ดังนี้ที่ตรงกับความรู้สึกของคุณมากที่สุด 1 หมายถึงไม่มั่นใจในการกรอกแบบฟอร์มทางการแพทย์ และ 4 มั่นใจมากที่สุด

ตัวอย่างความมั่นใจในการกรอกแบบฟอร์มทางการแพทย์ดังต่อไปนี้:

<table>
<thead>
<tr>
<th>ไม่มั่นใจ</th>
<th>มั่นใจมากที่สุด</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
ลำดับที่ 3 แบบสอบถามความรู้เกี่ยวกับภาวะแทรกซ้อนเหตุ

1. ผู้ที่มีภาวะแทรกซ้อนเหตุ ควรทำให้เกิดความตระหนักรู้
   ก. ทุกอาการ
   ข. บางอาการ
   ค. ทุกอาการ

2. เกณฑ์ที่ควรให้ผู้ที่มีภาวะแทรกซ้อนเหตุ สามารถติดตามความต้องการได้
   ก. ผู้ที่มีภาวะแทรกซ้อนเหตุรับประทานอาหารได้ปกติ
   ข. ควรเฝ้าระวังการมีภาวะแทรกซ้อนหรือไม่
   ค. ประเมินว่าได้รับยาตามที่เห็นชอบหรือไม่

3. ผู้ที่มีภาวะแทรกซ้อนเหตุควรได้รับ การประกอบอาหารให้เหมาะสม
   ก. 1 ิิตตัวร่วง ถึง 2 ิตตัว
   ข. น้อยที่สุดเท่าที่จะเป็นไปได้
   ค. มากที่สุดเท่าที่จะเป็นไปได้
4. ข้อตกลงต้องมีข้อกำหนดการรับผิดชอบของผู้ให้ที่มีภาระผูกพันต่อ
ก. ความตกลงว่าจะประทานฯตามที่มี
ข. สามารถตกลงว่าจะประทานฯตามที่มีภาระผูกพันต่อ
ค. ภาระที่ต้องรับผูกพันต่อในส่วนนี้ของบริษัทฯแห่งนี้

5. ข้อตกลงว่าปฏิบัติการในที่สุดตามที่ได้กำหนดใน]%% หรือก่อนการที่จะแจ้ง
ก. ใบประกอบการ ธ. ใบต่ออายุ X พ. ใบอนุญาตเวลาของไว้ได้
ข. ใบประกอบการธ. ใบต่ออายุ X พ. ใบอนุญาตเวลาของไว้ได้
ค. ใบประกอบการณ์หลัง

6. สำหรับที่สิ่งที่ให้ผู้ให้ที่มีภาระผูกพันต่อสิ่งที่จะแจ้งหรือจะแจ้ง
ก. รับใบประกอบการตามที่มีใบอนุญาต
ข. ใบอนุญาตเวลาก่อน
ค. ข้อควรรู้หลังจาก

7. ความหมายของการที่ให้ผูกพันต่อ คือข้อใด
14. ข้อที่ 14 ว่าด้วยคืนคืนก่อการณ์
ก. หากผู้ประสานงานยืนยันว่า 2 ศัพท์วิเคราะห์ใน 2-3 วันตรวจสอบแพทย์ในกรณีไปพบที่มี
คุณสมบัติ
ข. หากผู้ประสานงานยืนยันว่า 2 ศัพท์วิเคราะห์ใน 2-3 วัน ควรไปโรงพยาบาลหรือศูนย์บริการพยาบาล
แล้วนั้น
ค. หากผู้ประสานงานยืนยันว่า 2 ศัพท์วิเคราะห์ใน 2-3 วัน ควรดูอาการประณาม

15. หากผู้มีสิทธิ์มีความต้องการหรือข้อตกลงข้อใดข้อหนึ่งข้อใดที่ต้องการ
ก. ยอมไม่ได้
ข. ยอมแต่ต้องตกลงรายละเอียดที่ต้องการ
ค. ดื่มน้ำทนมากขึ้น
ค. เกลือทำให้หัวใจเต้นเร็ว

11. สามารถดูดซึมที่สุดที่ทำให้เกิดภาวะหัวใจถูกลมเหลว คือข้อใด
   ก. กลัมเบิร์ก
   ข. ไพรเมตหร์
   ค. คาเฟอีน
   ง. ไทมีน

12. ภาวะผู้ป่วยกล่าวพูดที่นั่งของผู้ที่มีภาวะหัวใจถูกลมเหลว จัดให้อยู่ในกลุ่ม
   ก. ผู้ที่มีภาวะหัวใจถูกลมเหลวเป็นบางกลุ่มอาจเรียกว่าเป็นโรคมีการผิดสูง เพื่อให้หัวใจได้พัก
   ข. ผู้ที่มีภาวะหัวใจถูกลมเหลวเป็นบางกลุ่มอาจเรียกว่าเป็นโรคมีการผิดสูงที่สำคัญ
   ค. ผู้ที่มีภาวะหัวใจถูกลมเหลวเป็นบางกลุ่มอาจเรียกว่าเป็นโรคมีการผิดสูงที่ชัดเจน

13. ผู้ที่มีภาวะหัวใจถูกลมเหลวจำเป็นต้องรับประทานยาจัดการป้องกันโรค
   ก. เพื่อลดความต้านทาน
   ข. เพื่อลดการเกิดการผิด
   ค. เพื่อให้สามารถเต้นไปได้มากขึ้น
14. ข้อใดกล่าวถูกต้อง

ก. หากน้ำหนักตัวเพิ่มขึ้นมากกว่า 2 ดิลีแตร์ภายใน 2-3 วันควรรายงานแพทย์ในกรณีให้พบตามบัตรตรวจออกไป

ข. หากน้ำหนักตัวเพิ่มขึ้นมากกว่า 2 ดิลีแตร์ภายใน 2-3 วัน ควรไปโรงพยาบาลหรือคลินิกเฉพาะ

ค. หากน้ำหนักตัวเพิ่มขึ้นมากกว่า 2 ดิลีแตร์ภายใน 2-3 วัน ควรติดตามวัคซีนประทานยา

15. หากคุณมีภาวะท้องขัดข้องมือจากการกระทำทางาน ควรปฏิบัติตามข้อใดดังต่อไปนี้

ก. อ่านหนังสือ

ข. อ่านเกี่ยวกับเรื่องมือระบบการเดิน

ค. ดื่มน้ำเพิ่มมากขึ้น


| เสนอแนะตามมาตรฐานในการจัดการสัญญาณภัยอันตรายดีเท็กซ์สัญญาณหัวใจ | ไม่เห็น
| ด้วย|
| มาตร|
| นี้หรือ|
| ไม่เห็น|
| เฉย|
| เห็น|
| ด้วย|
| มาตร|
| นี้หรือ|

| 1. ฉันสามารถจ่ายใหญ่ลูกสิทธิ์ของฉันเพื่อให้รักษาคุณภาพของโรคหัวใจได้อย่างมีประสิทธิภาพ ถ้าฉันมีมหิตาการรักษาที่เป็นอย่างดี | 1 2 3 4 5 |
| 2. ฉันสามารถจ่ายหนี้สิทธิ์ของฉันได้ด้วยการรักษาคุณภาพของโรคหัวใจได้อย่างดี | 1 2 3 4 5 |
| 3. เฉยฉันมีการวางแผนที่ดี ปัญหาดีที่สิทธิ์ของฉันเป็นโรคหัวใจจะสามารถส่งเสริมการรักษาได้ดี | 1 2 3 4 5 |
| 4. ฉันมีความสามารถของตนเองในการรักษาสิทธิ์ของฉันเป็นโรคหัวใจ | 1 2 3 4 5 |
| 5. ฉันไม่ได้รับการวางแผนที่ดี ฉันมีการส่งเสริมการรักษาสิทธิ์ของฉันเป็นโรคหัวใจ | 1 2 3 4 5 |
| 6. ฉันมีประสบการณ์ที่ดี ฉันมีสิทธิ์ของฉันเป็นโรคหัวใจ | 1 2 3 4 5 |
| 7. ฉันมีสิทธิ์ของฉันเป็นโรคหัวใจ | 1 2 3 4 5 |
| การสิทธิ์ของฉันเป็นโรคหัวใจ | 1 2 3 4 5 |
ลำดับที่ 5 แถบตอบสนองด้านกุญแจทองหนึ่ง

สุขภาพและความผิดปกติของกล้าม

แบบสอบถามนี้มีผลเสียด้านของกล้ามเนื้อที่มีความผิดปกติของกล้าม จึงขอให้ช่วยในการให้ความชัดเจนในด้านการครุภัณฑ์ได้ ใครสมบูรณ์ตรงตามความเป็นอยู่ของกล้ามเนื้อของคุณให้เขียนในที่เหมาะสม แบบสอบถามนี้

ให้แสดงผลตามดังนี้ไปโดยตรงถึงวิธีด้าน ดังนี้:

1. ยกข้อความ ลูกมือกล้ามเนื้อของกล้าม:

<table>
<thead>
<tr>
<th>กล้าม</th>
<th>ลูกมือ</th>
<th>ผ้า</th>
<th>หัวใจ</th>
<th>ผิว</th>
<th>ผัง</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ 1</td>
<td>☐ 1</td>
<td>☐ 1</td>
<td>☐ 1</td>
<td>☐ 1</td>
<td>☐ 1</td>
</tr>
</tbody>
</table>

2. ถ้าเป็นไปเป็นพจน์นั้นต้องการให้กล้ามเนื้อของคุณให้พิจารณาตามความต้องการด้านกล้ามเนื้อของกล้ามให้นำไปใช้ดูดังกล่าวด้านกล้ามเนื้อ:

- ใช้
- ไม่ใช้

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
- ไม่ใช้ดูดังกล่าวด้านกล้ามเนื้อ

- ใช้ดูดังกล่าวด้านกล้ามเนื้อ
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3. ที่มีความสูงต่ำมาก แต่แสดงมีความสูงฯ เช่นปั๊มน้ำค้าทำงาน
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6. คุณเคยมีปัญหาการเก็บรักษาเอกสารที่เกี่ยวข้องกับการติดต่อทางโทรศัพท์ของคุณอย่างไรบ้าง

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7. ให้จำนวนที่สูงที่สุดในกรอบด้านทิศเหนือที่เกี่ยวข้องกับการเก็บรักษาเอกสาร

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ขอขอบคุณที่ให้ความร่วมมือในการตอบคำถาม
Appendix E: Example of heart failure manual

E.1 Example of heart failure manual (English)

Heart Failure Manual

Faculty of Nursing Suratthani Rajabhat University
Australian Catholic University
Ms Nittaya Srisuk
Heart Failure Manual

The Heart Failure Manual handbook will provide you with information about heart failure to help you understand your condition, look after yourself, and stay out of hospital.

The development of this Heart Failure Manual has been guided by the best heart failure practice guideline.

Throughout this book you will find some activities and questions to guide you work with your doctor or nurse and test your knowledge about heart failure. Also, this book provides information for heart failure carers to help the carers understand heart failure treatment plan and communicate effectively with heart failure patient.
By reading this heart failure manual you are going to learn how to take care of yourself, and how to carry out self-care activities which will help you to feel better. We are strongly recommend that you and your family members or your carer should go through this book and work together thereby it easier to maintain the healthy lifestyle.

Heart failure usually gets worse over time. But there are many things you can do to feel better, stay healthy longer, and avoid the hospital.

Self-care means managing your health by doing certain things every day, like weighing yourself. It's about knowing which symptoms to watch for so you can avoid getting worse. When you practice good self-care, you know when it's time to call your doctor and when your heart failure has turned into an emergency.

Self-care involves choosing to manage your heart failure by take your medicine as prescribed, watch for signs that you are getting worse, limit salt, managing fluid, and try to exercise.

These things may seem hard to do. But your active input in the treatment plan is essential. Each part of this book will give you many tips and idea to make it easier for you to take control of your condition.
Heart failure is a serious heart problem and help from your doctor and nurse is really important. Work with them to help improve your heart and health.

**Lots of thing can hurt your heart including**

- Heart attack
- High blood pressure
- Too much fat in your blood
- Alcohol
- Lung disease
- Too much sugar (diabetes)

Activities; Ask you doctor for the cause (s) of heat failure. There may be special things you can do to care for yourself, based on the specific reasons for your conditions.

**Activity**

*My heart failure is caused by*

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

252
How does heart failure make you feel?

**Short of breath**
- Shortness of breath is caused by fluid accumulation and congestion in the lungs.
- Wet lungs cannot exchange oxygen easily.
  - In the early stages of heart failure you will probably only experience breathlessness after exercise,
  - but if your heart failure progresses you may feel breathless when resting as well.
- You may feel more breathless lying down because the fluid in your lungs moves with gravity, making more of your lungs wet (think of liquid in a bottle upright and then lying on its side).

**Coughing**
- In addition to breathlessness, some people with heart failure develop a cough or wheezing.
- This is usually due to fluid accumulation in the lungs, but can also be caused by lung conditions (such as chronic obstructive pulmonary disease (COPD) and asthma).
How does heart failure make you feel?

**Heart going too fast**

- When you have heart failure, your heart tries to compensate for its lack of pumping power by beating faster (tachycardia) in order to keep up the same flow of blood around your body.
- This increased heart rate may sometimes be irregular and cause palpitation which feels like your heart is racing or throbbing.

**Feeling tired**

- Heart failure reduces your heart’s pumping ability so less blood reaches your muscles.
- This lack of oxygen and nourishment cause your muscles to get tired much more quickly.
- Some patients find the tiredness overwhelming.
How does heart failure make you feel?

**Feeling sad or worried**

- Heart failure is a serious condition and the symptoms can leave you worn out and exasperated. In addition, breathlessness can feel constricting and make you feel uneasy and anxious. Symptoms may prevent you from participating in normal social activities, which can limit your social network. You may also depend on help from family and friends, which may make you feel that you are a burden on them.

- It is **very common for people with heart failure to feel depressed, uneasy or anxious.**

Which one is the hardest for you to manage?

____________________________

____________________________

____________________________
What you can do to improve your heart?

**Heart going too fast**
- Talk to your doctor if your heart is beating faster than usual

**Feeling tired**
- Try to increase your exercise each day to help your heart pump better
- Exercise also reduces stress and boosts your energy levels
- Rest in-between exercise
- Ask for help if you need

**Feeling dizzy**
- Stop and rest
- Stand up slowly when you have been sitting or lying down
- Talk to your health worker
When I feel sick what should I do?

**How to measure fluid?**

✓ Measure how much usual cup or glass holds and keep a record of how many you drink OR
✓ Fill a jug with your allowance each morning and drink from this during the day-allow water for tablet times

**If you get thirsty you can**

✓ Suck on a small amount of ice chips
✓ Remember to count these in your daily fluid

**What do I count as fluids or drinks?**

✓ Tea and coffee
✓ Fruit with lots of water
✓ Alcohol
✓ Ice
✓ Cola and other drink
When I feel sick what should I do?

Managing Salt
Eating salt in your food will affect the amount of fluid your body retains. Salt causes the body to retain fluid. Salt will also make you thirsty and then you will want to drink more fluid which makes it difficult for you to keep to your fluid limit.

You should not eat more than 2 grams of salt per day.
1 teaspoon salt = 2 grams of sodium.

Most of the salt in your diet is hidden in foods you eat. The examples of foods in high salt such as........

Message to heart failure patient
- Try adding herbs, spices or fruit juices (lemon/lime) to your meal to add more flavour.
- Remove the salt pot (shaker) from the table so that you are not tempted to add salt to your meal.
- Avoid processed foods which are high in salt such as ...(Thai food)
Test your knowledge

1. What is the main cause of heart failure
   a) Myocardial infarction and high blood pressure
   b) Obesity
   c) Diabetes

2. What happens when the pumping of the heart is poor?
   a) you feel hungry
   b) extra fluid builds up in your body
   c) extra fluid lost from your body

3. How much salt should you have each day
   a) As much as you can
   b) 1 teaspoon
   c) At least 5 teaspoons

4. How often should you weigh yourself
   a) Every day
   b) Once a week
   c) Whenever

5. What should you do if you feel thirsty
   a) Suck on an ice chip
   b) Have a large drink
   c) Have a large cool drink
Your heart failure medicine

Your doctor may give you a lot of medicines to take for your heart failure. Medicines for heart failure belong to the following groups.

Talk to your doctor or your nurse to fill the form

**ACE inhibitor or Angiotensin receptor blockers (ARB)**

ACE inhibitor or Angiotensin receptor blockers (ARB) increase the blood flow to your heart, reduce your blood pressure and make it easier for your heart to pump.

The medicine I take in this group is_________________________________________

**Beta blockers**

Beta blockers help your heart to pump slower and stronger.

The medicine I take in this group is_________________________________________

**Diuretics**

Diuretics help take extra fluid out of the body.

The medicine I take in this group is_________________________________________

**Aldosterone blocker**

Aldosterone blockers help stop fluid building up and make it easier for your heart to pump.

The medicine I take in this group is_________________________________________

**Digoxin**

Digoxin make your heart beat stronger and in a regular rhythm.

The medicine I take in this group is_________________________________________

**Other**

Other heart medicines I take_________________________________________
Part 6: My health record

Please write down important contact information in the space below.

Doctor treating me for heart failure

Name: ____________________________

Address: _________________________

Other doctor or nurses

_____________________________

_____________________________

Ambulance or emergency service phone number

_____________________________
Part 8: Tips for family and friends

Family and friends can play an important role in supporting a person with heart failure and helping them live as well as possible with disease. Many patients with heart failure continue to lead normal active lives and will not become sicker or disabled.

Provide support by learning about heart failure and the patients’ treatment plan

✓ Learning about heart failure and the patients’ treatment plan
✓ Watching for the changes in symptoms
✓ Follow a low sodium diet
✓ Become more active
✓ Remain dependent but safe

Helping with symptoms monitoring

✓ Telling any changes symptoms or condition that you notice such as shortness of breath, ankle and legs swelling
✓ Helping the patient weigh themself every day and keep a record
✓ Observing the number of pillows the patient use
Part 7: Tips for family and friends

**Helping with daily activities**
- Driving
- Living arrangement
- Stairs
- Cleaning
- Shopping and preparing food

**Other ways to provide support**
- Financial matter
- Talking with doctor or nurse
- Discussing advance care planning

**Message to heart failure patient’s carer**
- Your role will involve helping and supporting your partner or relative to adjust their lifestyle to fit with their new treatment plan.
- You are likely to have the largest impact on their success in following instructions from their healthcare team.
- Therefore, it is very important that you are involved, but you should aim to empower your partner or relative, while trying not to be over protective or dominate them.
Part 9 Conclusion

Many patients with heart failure continue to lead normal active lives and will not become sicker or disabled. Adherence to self-care is able to help you continue to enjoy a normal active lifestyle. Carers can best provide support by learning about heart failure and patient’s treatment plan. But because each person is an individual and has different goals, needs, and abilities, communication about how you can provide best support is important.
E.2 Example of heart failure manual (Thai)

คู่มือดูแลหัวใจวัยกลางแก่ ได้รับแรงบันดาลใจจากผู้จัดทำแนว  접근นี้จากประสบการณ์ในการปฏิบัติงาน และข้อมูลด้านบนของวิชาการที่พบว่าผู้ที่มีภาวะหัวใจล้มเหลวในประเทศไทย และในเขตภาคใต้ มีประสบการณ์ และความสามารถในการดูแล ตนเองอยู่ในระดับตอนช่วงต่ำเพื่อเป็นแบบอย่างกับผู้ที่มีภาวะหัวใจล้มเหลวในประเทศแบบตะวันตก ซึ่งผู้ที่มีสุขภาพชั่งเชิงภูมิปัญญาในแบบที่ต่าง ๆ ของทั่วไปยังคง การเข้ารับการรักษา ตัวสำคัญในโรงพยาบาลโดยไม่พอดี รวมทั้งผู้ที่มีคุณภาพชีวิตของผู้ป่วย

ผู้จัดทำข้อบังคับ คู่มือ ด.ช. ดาดตระการย์ ดร. David R. Thompson ดร. Jan Cameron ผู้ช่วยศาสตราจารย์ Chantal F. Ski ดร. Mary Boyde ซึ่งให้ความช่วยเหลือ ให้คำแนะนำและเป็นที่ปรึกษาในการจัดทำคู่มือเล่มนี้
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บทที่ 1: ภาวะหัวใจล้มเหลวคืออะไร?
ภาวะหัวใจล้มเหลวเป็นเหตุผลในโรคหัวใจที่พบบ่อยอย่างไรก็ตามภาวะหัวใจล้มเหลวไม่ได้หมายความว่าหัวใจหยุดเต้น แต่หมายถึงภาวะที่หัวใจไม่สามารถปัจจุบันส่งเลือดไปเลี้ยงส่วนต่าง ๆ ของร่างกายได้อย่างเพียงพอ และเป็นสาเหตุทำให้เกิดอาการตอบเหมือน มีอาการบิดบวม ช่วงระยะสั้นที่ยาวนานและยั่งยืน

หมายความถึงวิธีการคัดเลือกผู้มีภาวะหัวใจล้มเหลวที่มีภาวะหัวใจล้มเหลวที่ไม่สามารถรักษาให้หายขาดและควบคุมอาการของโรคผ่านการแพทย์ได้ จึงมีการทำให้ผู้ป่วยต้องพิจารณาการรักษาด้วยวิธีการรักษาที่อยู่บ้านรักษาการพิชิตโรคภัยไข้เจ็บต่าง ๆ
บทที่ 2: ภาวะหัวใจล้มเหลวมีอาการอย่างไร?

ภาวะหัวใจเต้นไม่ร่วงกระจายจากภาวะหัวใจล้มเหลว
ทำให้ทารนมีอาการ...
- หายใจล่าช้า ใจเต้นเพิ่มขึ้นเมื่อมีการออกแรง หรือเมื่อมี
 นอนน้ำ
- ระบบบริโภคอาหารช่วงเย็น เช่น เก้า ข้าหรือท้อง
- ไอ หายใจเพี้ยนเมื่อมีน้ำน้ำร้อน หรือต่อมกล้าม
- หน้ามึนเพิ่มขึ้นอย่างรวดเร็ว

ภาวะหัวใจล้มเหลวไม่สามารถมีบริบัติได้เลยมี
ประสิทธิภาพอาจทำให้ทารนมี...
- เจ็บ แผลหน้าอก
- หัวใจหัวใจเต้นเร็ว
- เรียบเสียรช์
- ผู้สีหัว⁺เหลืองและอ่อนเพลีย
ภาวะหัวใจล้มเหลวมีอาการอย่างไร?

交流合作的常见情况，包括站立、坐或躺下。

 devise treatment plan ข้อ 1.

 ทำาสาเหตุเกิดจากการนำาภัย หรืออาการรบกวนให้เข้า ทักเกณฑ์มากกว่า กลับเลื่อน

น้ำหนักเพิ่ม

 ต้องทำาไปผู้ป่วยที่มีการทำาใจล้มเหลว จะมีน้ำหนัก

 ที่เพิ่มขึ้นอย่างรวดเร็ว ซึ่งหมายถึงมีการพุ่งขึ้น

 น้ำในกระแสของเชื้อเพาะดูมีน้ำหนักด้วย

 เพิ่มขึ้นอย่างรวดเร็ว อย่างไรก็ตามหลังได้รับการรักษาที่เหมาะสม น้ำหนักส่วนนี้ก็

 จะลดลง

 ผู้ที่มีการทำาใจล้มเหลวมีความจำเป็นต้องสังเกตนาฬิกาหน้า

 มากกว่า 2 กิโลกรัม ภายใน 2 วันจะต้องรับไปพบแพทย์
ภาวะหัวใจสั่นเลือดมีอาการอย่างไร?

**เวียนศีรษะ**
- การที่หัวใจเบียบตัวส่งเลือดไปเลี้ยงสมองไม่เพียงพออาจทำให้ทำนองอาการเวียนศีรษะ
- อาการเวียนศีรษะในผู้ที่มีภาวะหัวใจสั่นเลือดอาจเกิดจากผลักน้ำหนักของอาหารที่เพิ่มได้ไม่ยอมใจก็ตาม อาการโชคดีหรือหัวใจเต้นเฉียบจำหว่า หรือการกระทำที่ไม่เกิดขึ้น ทำให้เป็นเหตุในการกระทำของอาการเวียนศีรษะในผู้ที่มีภาวะหัวใจสั่นเลือด

**เมื่ออาหาร**
- ผู้ที่มีภาวะหัวใจสั่นเลือดที่มีภาวะโรคต่างๆที่เป็นปัจจัยการที่ระดับ หรือในระบบทางเดินอาหาร และเปลี่ยนไปเสีย ระบบทางเดินอาหารไม่เพียงพอเป็นสาเหตุให้มีอาการท้องอืด เมื่ออาหาร คลื่นไหว้ถ้าจะมี

12
บทที่ 3: ต้องปฏิบัติตัวอย่างไรจึงจะช่วยให้หัวใจทำงานดีขึ้น?

อาการหายใจลำบาก
✓ หากมีสัญญาณหายใจลำบาก หายใจไม่เหมาะสมในเวลาลางกัน หรือมีอาการรุนแรง ให้หน่อยน้ำทำศีรษะสูง อาจใช้หมอหมอหนอนร้องสีผงให้สูงขึ้น
✓ หากอาการหายใจลำบาก หายใจไม่สะดวกในเวลาลางกัน หรือมีอาการมึนเมา ให้เป็นยาเบาลงหรือยาแก้ปวด หรือดื่มน้ำแก้ปวดเจ้าของไว้

ไม่
✓ หากมีอาการโยน หรือหายใจมีเสียงรัศมี ให้ทำปฏิบัติติ่มเติมกับแพทย์ เนื่องจากอาการหายใจลำบาก หายใจไม่เหมาะสม หรือมีอาการรุนแรง ให้สูงขึ้น
✓ หากมีอาการโยนไม่ได้ชิ้น หรือมีอาการโยนมากขึ้น ให้เป็นยาเบาลงหรือยาแก้ปวดเจ้าของไว้
✓ เลิกสูบบุหรี่

อาการเบาหวานข้อเท้า ขา หรือห้อง
✓ สอบถามแพทย์เจ้าของให้รักษาตามอาการของน้ำเป็นยาเบาลงไว้ตามหลักวิชา
✓ ควบคุมมีน้ำเป็นน้ำที่สุขภาพจะได้
✓ จัดการเป็นเวลาลางกันของอาการร่วมมัน
✓ ชักนำพิษภูริยา
ต้องปฏิบัติตัวอย่างไรจึงจะช่วยให้หัวใจทำงานเดี๋ยวนี้?

เบื้องหลัง
✓ รับประทานอาหารครั้งละน้อยๆ แต่บ่อยครั้ง
✓ บริโภคแอลกอฮอล์อย่างระมัดระวัง

วิธีการรักษาหรือเป็นกันมาก
✓ หากทานสิ่งเสี่ยงไม่สบายใจหรือเป็นกังวล สิ่งที่สำคัญคือการพูดคุย หรือแจ้งให้แพทย์และพยาบาลทราบถึงสิ่งที่ทำเป็นกังวล
✓ รับประทานยาตามคำสั่งของแพทย์อย่างเคร่งครัด การวิบัติทางกายยาจะขึ้นตามอาการที่เกิดขึ้น หากพบว่ามีอาการไม่อดทน ควรแจ้งให้แพทย์ทราบ
✓ ถึงแม้ว่าภาวะทวีคูณจะไม่สามารถรักษาได้ทั้งหมดก็ได้ การรู้จักดูแลตนเองแพทย์ หรือพยาบาลยังเป็นไปได้ที่จะทำการป้องกัน จงไปสู่การรักษาที่มีประสิทธิภาพเพิ่มมากขึ้น และต้องเตรียมให้ทุกๆ ประการที่จำเป็นต้องทำเดี๋ยวนี้
ปฏิบัติด้วยอะไรเมื่อมีอาการของภาวะของหัวใจล้มเหลว?

การจัดการเกี่ยวกับปริมาณน้ำที่ร่างกายควรได้รับ

ผู้ที่มีภาวะที่หัวใจล้มเหลวต้องให้มีความสำคัญเกี่ยวกับการจัดการ
น้ำที่ร่างกายควรได้รับในแต่ละวัน ซึ่งจะทำให้ทราบได้ว่า
เมื่อใดที่มีการน้ำเกินในร่างกาย

- น้ำหนักสูงเกินกว่าน้ำหนัก 1 กิโลกรัม
- ทราบน้ำหนักปกติ (น้ำหนักที่ควรของตัวทำแหวก) เพื่อใช้วัดปริมาณน้ำใน
  ภาวะน้ำเกิน

ปฏิบัติตัวอย่างไรเมื่อมีภาวะน้ำเกิน

- ต้องห้ามดื่มน้ำหรือเครื่องดื่มที่มีน้ำเชิง
- หากไม่ได้เครื่องดื่มน้ำให้แก่ท่าน วันละประมาณไม่เกินน้ำหนักได้ที่
  สถานีน้ำหนักหรือสถานีบริการสุขภาพใกล้บ้าน
- หากน้ำหนักของท่านเพิ่มขึ้นอย่างรวดเร็ว หรือเพิ่มขึ้น 2 กิโลกรัมภายใน 2-3 วัน
  ให้รีบไปโรงพยาบาล
- สอบถามกับแพทย์เจ้าของไข้ เป็นปริมาณน้ำที่ทำสำหรับที่ได้แก่แต่ละวัน
- ควบคุมการใช้สิ่งของแต่ละวัน และจำกัดปริมาณน้ำ โดยปกติผู้ที่มีภาวะหัวใจ
  ล้มเหลวสามารถดื่มน้ำได้รับและ 1-1.5 ลิตร
ปฏิบัติตัวอย่างไรเมื่อมีอาการของภาวะหัวใจสเมมหว่า?

การจัดการที่เหมาะสมกับบริบทนี้ที่ร่างกายควรได้รับ

ข้อความจากใจโดยผู้มีภาวะหัวใจสเมมหว่า

- คืนน้ำจากแก้วเล็ก
- วางแผนการดื่มน้ำตลอดทั้งวัน
- คืนน้ำเรื่อย หรือน้ำยันซึ่งจะทำให้คืนได้น้อยกว่าการคืนน้ำที่มีอุณหภูมิปกติ
- หากทำาเกิดไข หรือทองเลือด สามารถดื่มน้ำเพิ่มได้ประมาณ 100-300 ซีซี

กิจกรรม

น้ำหนักของท่านในการปกติ หรือทำาสิ่งที่ไม่ออกอัน ____________กก
(น้ำหนักเก่า)

น้ำหนักของท่านที่ทำาให้ทำาสิ่งที่อัน ____________กก

ปรับเวลาทำาสิ่งที่ทำาได้ในแต่ละวัน ____________ก

(สอบถามจากแพทย์เจ้าของ)
ภาวะปัญจิตตัวอย่างไรเมื่อมีอาการของภาวะหัวใจล้มเหลว?

ทำตามมาตรการล้างส่วนเสริมการทำงานของหัวใจโดยการรับประทานอาหารเพื่อสุขภาพหัวใจ ซึ่งได้แก่
✓ ผักและผลไม้
✓ รับประทานเอ็กซ์ตร้าฟิน ในปริมาณปกติ รับประทานเนื้อปลาให้มากขึ้น

ออกกำลังกาย
การออกกำลังกายอย่างสม่ำเสมอมีความสำคัญมากในผู้ที่มีภาวะหัวใจล้มเหลว ทำตามมาตรการปรึกษาแพทย์เจ้าของกิจของคุณเพื่อทราบวิธีการออกกำลังกายที่เหมาะสมที่สุดสำหรับคุณ
- การออกกำลังกาย 10-30 นาทีเป็นประจำเป็นการออกกำลังกายที่ดีสำหรับผู้ที่มีภาวะหัวใจล้มเหลว

การพักผ่อนระหว่างวัน
- สุขที่มีภาวะหัวใจล้มเหลวควรรับการพักผ่อนและพักผ่อนในช่วงระหว่างวัน

ปรับพฤติกรรม
- เลิกสุราหมวนและเลิกสูบบุหรี่เพื่อให้หัวใจทำงานอย่างมีประสิทธิภาพ
- จัดรูปแบบอันน่ารักให้หัวใจของคุณอยู่ในภาวะที่ดีจากการบริโภคอาหารที่เหมาะสมสำหรับท่าน

ข้อความจากใจของคุณที่มีภาวะหัวใจล้มเหลว
- การออกกำลังกายเป็นเวลาเท่าไหร่สามารถช่วยเพิ่มประสิทธิภาพการทำงานของหัวใจและลดอาการภูมิคุ้มกันจากการหัวใจล้มเหลว อย่างไรก็ตาม ทำตามที่แพทย์แนะนำอย่างง่ายที่สุด ควรปรึกษาแพทย์เจ้าของกิจของคุณเพื่อทราบวิธีการออกกำลังกายที่เหมาะสมสำหรับท่าน.
บทที่ 5: ยาของคน

การรับประทานยาตามคำสั่งของแพทย์อย่างเคร่งครัดตามรายชื่อให้การของภาวะท้องไส้
ผิดถังขี้จื้อป้องกันไม่ให้มีอาการดูน้อยและป้องกันการเจ็บป่วยจากการรับยา
โรงพยาบาลโดยไม่จำเป็น
- รับประทานยาทุกวัน
- กรณีการรับยาอย่างต่อเนื่อง ไม่ควรรู้จัก
ยาหมด
- จดบันทึกยาที่รับประทานและนำติดตัวไปด้วยทุก
ครั้งเมื่อไปโรงพยาบาล

อาการข้างเคียงของยาประกาศภาวะท้องไส้

- เรือนครีบ
- รู้สึกพุ่ง ไม่สบาย
- คันหรือฝีผี
- ไอ
หากเกิดอาการข้างเคียงกับผู้ที่รับยา หรือการรับยาไม่ตามคำแนะนำแพทย์

ข้อความจากใจกิติภูมิภาวะท้องไส้

- การรับประทานยาอย่างต่อเนื่อง ยาต้ม หรือยาเอง สมุนไพร ถ้ามีเหตุนี้อาจมีผล
ต่อน้ำสุขภาพท้องไส้ในระยะยาว ควรสอบถามแพทย์
- เจริญรู้จักดื่มน้ำเต้าแล้วเมื่อเกิดภาวะท้องไส้
กิจกรรม

สอบถามแพทย์หรือพยาบาล

ยาที่ฉันเคยมีผลข้างเคียงอย่างไรบ้าง?


เข้าใจว่าอย่างไร หากบริการแพทย์แจ้งผลข้างเคียงอย่างมาก?


เข้าใจว่าอย่างไร หากผลการรับประทานยา?


บทที่ 7: ข้อมูลทางสุขภาพของผู้ป่วย

ตารางผู้ป่วย

| วันที่ เดือน พ.ศ. | นำหนัก | วัยอิติปิตุศก
|
|------------------|--------|----------------|
|                  |        |                |
|                  |        |                |
|                  |        |                |
|                  |        |                |
|                  |        |                |
|                  |        |                |

ตามที่ท่านทราบแล้วว่าผู้ป่วยมีอาการท้องเจ็บและเหงื่อชูน้ำหนักเกินกว่าที่ควร ควรจึงนำหนักควบคุมใหม่ ควบคุมน้ำหนักسارสาระ และควรรักษาในเวลาเดียวกันทุกวัน ควรเพิ่มน้ำหนักขึ้นใหม่ให้กับ ปรับภายเก็บบริเวณผู้ป่วยกับวันที่ทำแน่น หากน้ำหนักเพิ่ม 2 กิโลกรัมภายใน 2-3 วันต้องรีบไปโรงพยาบาล
เคล็ดลับสำหรับผู้ดูแล

ให้ความช่วยเหลือในการเตรียมอาหาร
✓ ชุดอาหารและวางแผ่นผู้ป่วยเกี่ยวกับอาหารที่ผู้ป่วยชอบหรือไม่ชอบ โดยเป็นอาหารเจ้าหน้าที่เตรียม
✓ เตรียมอาหารลดเคลื่อนสำหรับผู้ป่วย
✓ อาหารลดเคลื่อนที่เตรียมไว้สำหรับผู้ป่วยตามน้ำภัย ไว้ในตู้เย็นสำหรับผู้ป่วยในกรณีที่ผู้ป่วยดีขึ้นเร็ววัน

ให้การสนับสนุนด้านจิตใจ
✓ ชุดดูแลผู้ป่วยเกี่ยวกับแผนการรักษา
✓ มีความร่วมมือกับผู้ป่วยในการวางแผนการรักษาและการปรับเปลี่ยนพฤติกรรมสุขภาพ
✓ ให้กำลังใจผู้ป่วยในการดูแลตนเอง
✓ ชุดดูแลผู้ป่วยเกี่ยวกับสภาพที่ผู้ป่วยต้านทานและเป็นกำลัง
✓ สนับสนุนให้ผู้ป่วยรู้จักเพื่อสุขภาพดีขึ้น หรือทำสิ่งที่ผู้ป่วยชอบ เช่นการช่วยดื่มทั้งหมด
บทที่ 9: สรุป

ผู้ป่วยที่มีอาการหัวใจเต้นเร็วอาจมีอาการที่มีลักษณะของความรู้สึกได้ตามปกติ พวกเขามักจะหายใจได้เงียบง่ายจากการปฏิบัติตามแผนการรักษา และการรักษาเริ่มเมื่ออาการดื้อ ควบคุมอาการของภาวะหัวใจเต้นเร็วจะเกิดอาการผิดปกติ พวกเขามักจะหายใจได้ตามปกติ โปรดดูว่ามีอาการเกิดonio โอกาสของการทำงานเต้นเร็วมีถึงระดับที่อาจนำไปสู่อาการภาวะหัวใจเต้นเร็วรวมถึงอักเสบทางที่ต้องรีบไปโรงพยาบาลได้ก่อน

อาการที่ต้องรีบไปโรงพยาบาลทันที

☑ ไม่สามารถนอนได้
☑ ไอมากในตอนกลางคืน
☑ หายใจลำบากมากขึ้น
☑ มีอาการปวด บริเวณเข่าท่า ขา หรือท้อง
☑ เนื้อเยื่อเป็นขึ้น 2 กิโลกรัมภายใน 2 ถึง 3 วัน
☑ เจ็บแน่นหน้าอก

ปฏิบัติตัวอย่างไรเพื่อให้หัวใจทำงานได้ดี?

☑ จำกัดปริมาณน้ำที่ดื่มทุกวันให้ได้รับไม่เกินตามแผนการรักษาของแพทย์
☑ อาหารที่มีเกลือสูง หรือมีรสเด็ด
☑ เลิกกินเครื่องดื่มที่มีแอลกอฮอล์
☑ รับประทานยาตามคำสั่งของแพทย์อย่างเคร่งครัด
☑ ไปพบแพทย์ตามนัด
Appendix F: CONSORT checklist

CONSORT 2010 checklist of information to include when reporting a randomised trial

<table>
<thead>
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<th>Section/Topic</th>
<th>Item No</th>
<th>Checklist item</th>
<th>Reported on page No</th>
</tr>
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<td>1</td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)</td>
<td>1</td>
</tr>
<tr>
<td>Introduction</td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
<td>5-7</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>Specific objectives or hypotheses</td>
<td>7-8</td>
</tr>
<tr>
<td>Methods</td>
<td>3a</td>
<td>Description of trial design (such as parallel, factorial) including allocation ratio</td>
<td>8</td>
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<tr>
<td></td>
<td>3b</td>
<td>Important changes to methods after trial commencement (such as eligibility criteria), with reasons</td>
<td>-</td>
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<tr>
<td>Participants</td>
<td>4a</td>
<td>Eligibility criteria for participants</td>
<td>8-9</td>
</tr>
<tr>
<td></td>
<td>4b</td>
<td>Settings and locations where the data were collected</td>
<td></td>
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<tr>
<td>Interventions</td>
<td>5</td>
<td>The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</td>
<td>9-10</td>
</tr>
<tr>
<td>Outcomes</td>
<td>6a</td>
<td>Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed</td>
<td>11</td>
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<tr>
<td></td>
<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
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<tr>
<td>Sample size</td>
<td>7a</td>
<td>How sample size was determined</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
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<tr>
<td>Randomisation:</td>
<td>8a</td>
<td>Method used to generate the random allocation sequence</td>
<td>12</td>
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<tr>
<td></td>
<td>8b</td>
<td>Type of randomisation; details of any restriction (such as blocking and block size)</td>
<td>12</td>
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<td></td>
<td>9</td>
<td>Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned</td>
<td>12</td>
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<tr>
<td>Implementation</td>
<td>10</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
<td>12</td>
</tr>
<tr>
<td>Blinding</td>
<td>11a</td>
<td>If done, who was blinded after assignment to interventions (for example, participants, care providers, those</td>
<td>12</td>
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*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org)*.