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

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**Conflict of interest**

No conflict of interest has been declared by the authors.

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**Aim.** To evaluate a heart failure education program developed for patients and carers in Thailand.

**Background.** Heart failure is major health problem. This is the first trial of a family-based education program for heart failure patients and carers residing in rural Thailand.

**Design.** Randomized controlled trial.

**Methods.** One hundred 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.** Linear mixed-effects model revealed that patients and carers who received the education program had higher knowledge scores at three and six months than those who received usual care. Among those who received the education program, when compared with those who received usual care, patients had better self-care maintenance and confidence and health-related quality of life scores at three and six months and better self-care management scores at six months, whereas carers had higher perceived control scores at three months.

**Conclusion.** Addressing a significant service gap in rural Thailand, this family-based heart failure program improved patient knowledge, self-care behaviours and health-related quality of life and carer knowledge and perceived control.

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

## 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.

## 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 contrast to the significant increase of symptomatic HF in Southeast Asia (Lam 2015), patients' self care appears to be insufficient compared with those patients in North America and Australia (Riegel *et al.* 2009a). 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). There are three separate but linked concepts to self-care that encompass sequentially mastered processes. Self-care maintenance is considered as behaviours that help to stabilise HF symptoms, this includes adherence to treatment of HF and healthy behaviours. Symptom perception refers to symptom monitoring and recognition in addition to body listening, symptom interpretation and labelling of symptoms. Self-care management is the response to symptoms

when they occur. Each self-care process involves autonomous and consultative self-care behaviours; independent behaviours and decisions or those influenced by healthcare or care providers' suggestions (Riegel *et al.* 2016). 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, Casimir 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 where 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 with 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 with 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 with 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

patient 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). For this study, assuming a medium effect size (0.65) in the between-group differences on the Dutch Heart Failure Knowledge Scale (DHFKS) and allowing for a 20% attrition rate, the minimal sample size of 40 per group will have sufficient power (0.80). 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 New York Heart Association (NYHA) 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 family-based education program was designed as a six-month program comprising one face-to-face education counselling session, provision of a heart failure manual and DVD and



telephone follow-up. 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 DHFKS (van der Wal *et al.* 2005). The questionnaire consists of 15 items assessing HF knowledge: four items regarding general HF information, six items regarding HF treatment (diet, fluid restrictions and activity) and five items assessing symptoms and symptom recognition. In the present study internal consistency reliability for the patients measured by Cronbach alpha was 0.61 and for the carers was 0.34. It should be noted that this is the first study to administer the DHFKS among carers.

Carer perceived control over managing patients' HF symptoms was measured with the Control Attitudes Scale-Revised (CAS-R) (Moser *et al.* 2009). The CAS-R assess how much perceived control or how helpless individuals feel about managing their family member's heart

problems. Internal reliability of the CAS tested in 21 carers of patients with HF was .75 (Bakas *et al.* 2006) In the present study, Cronbach's alpha was .60.

Self-care behaviour was measured with the Self-Care of Heart Failure Index (SCHFI) (Riegel *et al.* 2009b). It contains three subscales: self-care maintenance, self-care management and self-care confidence. In the Thai context the tool was administered to 400 HF patients and found to be reliable: a Cronbach's alpha coefficient of .85 (Suwanno *et al.* 2009). For the three subscales, Cronbach's alpha ranged from .63 (SCHFI maintenance) to .91 (SCHFI confidence) (Suwanno *et al.* 2009). In the present study, Cronbach's alpha for the three subscale were .54 (SCHFI maintenance), .73 (SCHFI management) and .68 (SCHFI confidence).

Health-related quality of life was measured with the Minnesota Living with Heart Failure (MLHF) questionnaire (Rector & Cohn 1992). It 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 effect of HF treatment (Rector & Cohn 1992). The Thai version has been used in 422 HF patients and in pilot testing in sample of 30 had good reliability (Cronbach's alpha coefficient was .94 (Krethong *et al.* 2008). The MLHF was applied only to patients with HF and not the carers. In the present study reliability of the MLHF was .87.

General quality of life in carers was assessed with the Short-Form 12 health survey (SF-12) (Ware *et al.* 1996). 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 scores provide an indication of physical and emotional functioning, with higher scores indicating better HRQL. The reliability of the SF-12 in the present study was .86.

### **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. All patients and carers were informed that participation was optional and that their decision whether or not to participate would not affect their care. The dyads were assured of confidentiality and that a decision to withdraw from the study would not affect their future care.

### **Data analysis**

The data analysis used SPSS version 22 software and the significance level was set at 0.05. Basic descriptive analysis was conducted using chi-square test (proportions) for nominal variables and t-test and effect size (ES) for continuous normally distributed data. 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-effects 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 3). Where significant group by time interaction effects were found, mean pairwise comparison was conducted to identify differences between the groups at each time point. Missing data were handled according to instrument specific requirements. Data analysis was based on the intention-to treat-principle.

## **Results**

### **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 1). No significant differences in clinical or demographic variables 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 between education and usual care groups (Table 1).

### **Changes in HF knowledge**

Type III tests of fixed effects in the linear mixed model showed that HF knowledge changed significantly with time ( $F(2/87)=69.88, p < 0.001$ ) in patients. A significant interaction was found between education and usual care groups and over time ( $F(2/87)=43.16, p < 0.001$ ) (Table 2). The significant interactions were examined by conducting simple effect tests that compared the groups at each time point (Table 3). 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],  $p < 0.001$ ) and a 1.7-point higher score at six months (95% CI [0.64, 2.87],  $p = 0.002$ ). 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 ( $F(1/98)=17.70, p < 0.001$ ) with DHFKS scores changing significantly with time ( $F(2/31)=85.43, p < .001$ ) and a significant interaction between group and time ( $F(2/91)=29.40, p < 0.001$ ) (Table 2). At three months (Table 3), carers in the education group had a 2.6-point (95% CI [1.75, 3.41],  $p < 0.001$ ) 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],  $p < 0.001$ ) 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 ( $F(2/88)=22.74, p < 0.001$ ), self-care management ( $F(2/56)=16.26, p < 0.001$ ) and self-care confidence ( $F(2/93)=75.68, p < 0.001$ )

scores changed significantly with time. Moreover, there was significant interaction between groups and time for self-care maintenance ( $F(2/88)=17.09, p < 0.001$ ), self-care management ( $F(2/56)=7.70, p < 0.001$ ) and self-care confidence scores ( $F(2/93) = 10.69, p < 0.001$ ) (Table 2). At three months (Table 3), 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],  $p = 0.048$ ), 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],  $p = 0.048$ ) 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],  $p = 0.048$ ) 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],  $p = 0.013$ ), 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],  $p = 0.004$ ), 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 ( $F(2/91)=11.80, p < 0.001$ ) and there was significant interaction between groups and time ( $F(2/91)=6.53, p < 0.001$ ) (Table 2). At three months (Table 3), 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],  $p = 0.018$ ) and this was a medium effect size ( $ES=0.49$ ). At six months, there was no significant difference in the CAS-R scores.

### **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 ( $F(2/99)=5.01, p = 0.027$ ) (Table 2). At three months (Table 3), 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],  $p = 0.014$ ), 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],  $p = 0.015$ ), 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 findings of this research address a clinical practice gap in rural Thailand where HF management programs do not exist. Importantly, this novel approach to delivering patient education is amenable for implementation within the scope of existing nursing practice in rural Thailand. To distribute the program more broadly and influence hospital policy, hospital-based nursing administrators could be engaged to assist in and translating the evidence provided by this research to improve the quality of nursing care.

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 education reported significantly increased perceived control over managing patients' HF symptoms but not improved quality of life. This may be because most of the carers were children of HF patients and had a comparatively good quality of life, as indicated by the SF-12 scores. Another 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 having an adverse impact on quality of life.

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 disease management programs 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.

### Author Contributions:

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE\*):

- 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- 2) drafting the article or revising it critically for important intellectual content.

\* <http://www.icmje.org/recommendations/>

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**Table 1 Sample characteristics**

Variable	Family-based education (n=50)	Control (n=50)	$\chi^2$	P
<b>Patients</b>				
Gender				
Women	28 (56)	25 (50)	0.16	.689
Marital status			2.69	.441
Married	31 (62)	31 (62)		
Single	8 (16)	4 (8)		
Divorce	0 (0)	1 (2)		
Widower	11 (22)	14 (28)		
Education			6.43	.170
Uneducated	26 (32)	8 (16)		
Primary school	14 (28)	24 (48)		
Secondary school	8 (16)	11 (22)		
Diploma	2 (4)	5 (10)		
Bachelor	0 (0)	2 (4)		
Number of family members			6.63	.582
3-5	16 (32)	19 (38)		
6-10	34 (68)	29 (58)		
>10	0 (0)	2 (4)		
HL			5.98	.112
Not confidence	21 (42)	18 (36)		
Moderate confident	14 (28)	12 (24)		
Confident	14 (28)	12 (24)		
Extreme confident	1 (2)	8 (16)		
HF medicine				
ACEI	23 (40)	32 (52)	1.00	.316
Beta blocker	31 (62)	32 (64)	0.00	1.000
Diuretic	40 (80)	36 (72)	0.49	.482

Aldosterone antagonist	22 (44)	25 (50)	0.16	.686
Digoxin	15 (30)	22 (44)	1.54	.214
NYHA			1.63	.443
I	5 (10)	2 (4)		
II	23 (46)	27 (54)		
III	22 (44)	21 (42)		
CCI			3.63	.162
Low comorbidity	25 (50)	20 (40)		
Medium comorbidity	21 (42)	29 (58)		
High comorbidity	4 (8)	1 (2)		
<b>Carers</b>				
Gender				
Women	34 (68)	39 (78)	0.81	.368
Education			7.11	.130
Uneducated	1 (2)	4 (8)		
Primary school	10(20)	13(26)		
Secondary school	12(24)	15(30)		
Diploma	11(22)	12(24)		
Bachelor	16(32)	6(12)		
Relationship to the patients			6.45	.092
Spouse				
Daughter or son	12 (24)	15 (30)		
Sibling	21 (42)	18 (36)		
Parent	16 (32)	10 (20)		
	1 (2)	7 (14)		
HL			4.43	.218
Not confidence	0 (0)	2 (4)		
Moderate confident	13 (26)	17 (34)		
Confident	15 (30)	17 (34)		
Extremely confident	22 (44)	14 (28)		

	Mean (SD)	Mean (SD)	t	P
<b>Patients</b>				
Age (years)	65(14)	59(18)	-2.01	.057
Duration of HF (month)	22(19)	23(18)	0.41	.684
LVEF%	51(13)	50(13)	-0.15	.883
MoCa	26(2)	27(2)	1.87	.132
<b>Carers</b>				
Age (years)	39(10)	43(11)	1.98	.053

HL, Health Literacy; NYHA, New York Heart Association; ACEI, Angiotensin-Converting-Enzyme Inhibitor; ARB, Angiotensin II Receptor Blockers; CCI, Chalon Comorbidities Index; LVEF, Left Ventricular Ejection Fraction; MoCa, Montreal Cognitive Assessment

**Table 2 Linear mixed model fixed effect on patients with HF and carer outcomes**

Variables	Baseline		3 Months		6 Months		The type III tests of fixed effects, p value		
	Family-based education Mean (SE)	Control Mean (SE)	Family-based education Mean (SE)	Control Mean (SE)	Family-based education Mean (SE)	Control Mean (SE)	Group	Time	Group × Time
<b>DHFKSpt</b>	7.4 (0.5)	8.3 (0.5)	10.9 (0.6)	8.7 (0.6)	10.9 (0.6)	9.1 (0.6)	0.055	< 0.001	< 0.001
<b>SCmaint</b>	22.1(3.2)	26.7 (3.2)	34.3 (3.3)	27.7(3.3)	31.4 (3.0)	25.3 (3.0)	0.361	< 0.001	< 0.001
<b>SCmanag</b>	30.6(2.9)	35.6 (2.9)	38.6 (2.5)	37.1(2.9)	42.6 (2.4)	37.8 (2.9)	0.863	< 0.001	< 0.001
<b>SCcon</b>	23.5(2.9)	25.2 (2.9)	37.2 (2.4)	31.1(2.9)	39.0 (2.1)	32.6 (2.9)	0.117	< 0.001	< 0.001
<b>MLHF</b>	50.2(2.5)	53.0 (2.5)	50.3 (2.2)	53.0(2.2)	52.0 (2.0)	55.0 (2.0)	0.186	< 0.001	0.956
<b>MLHFemo</b>	11.8(0.9)	13.0 (0.9)	11.5 (0.7)	13.2(0.7)	12.1 (0.6)	13.6 (0.6)	0.027	0.055	0.624
<b>MLHFphy</b>	19.8(1.1)	19.9 (1.1)	19.3 (1.0)	19.3(1.0)	19.6 (0.9)	20.0 (0.9)	0.872	0.026	0.755
<b>DHFKSc</b>	7.8 (0.4)	8.3 (0.4)	11.9 (0.4)	9.4 (0.4)	12.0 (0.4)	9.6 (0.4)	<0.001	< 0.001	< 0.001
<b>CAS-R</b>	25.4(0.7)	25.6 (0.7)	27.5 (0.6)	26.1(0.6)	27.3 (0.6)	26.4 (0.6)	0.187	< 0.001	0.002
<b>PCS</b>	52.0(1.6)	49.8 (1.6)	52.1 (1.5)	49.3(1.5)	52.1 (1.5)	49.5 (1.5)	0.087	0.887	0.660
<b>MCS</b>	42.4(1.4)	42.2 (1.4)	42.0 (1.1)	41.0(1.1)	41.4 (1.1)	41.0 (1.1)	0.615	0.239	0.621

Note. Type III tests of fixed effects

SE, standard errors

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; MLHFemo, 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.

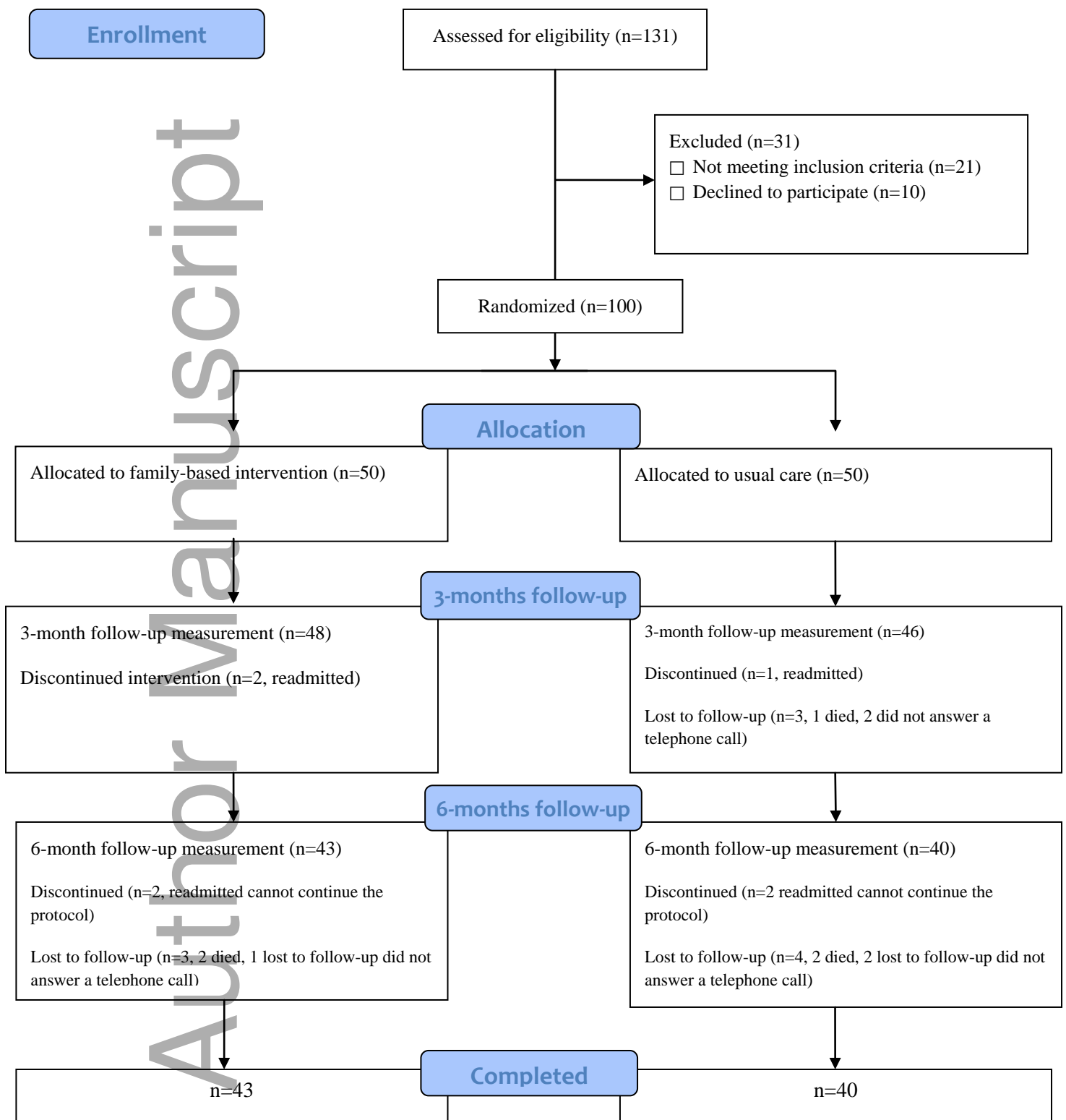
**Table 3 Mean difference in patient with HF and carer outcomes at baseline, 3-months and 6-months**

Variables	Mean difference at baseline [95% CI]	p value	Mean difference at 3 months [95% CI]	p value	Mean difference at 6 months [95% CI]	p value
DHFKSpt	-0.9 [-1.9, 0.1]	0.084	2.2 [1.0, 3.3]	< 0.001	1.7 [0.6, 2.9]	0.002
SCmaint	-4.5 [-10.8, 1.8]	0.158	6.7 [0.1, 13.2]	0.048	6.1 [0.1, 12.1]	0.048
SCmanage	-5.0 [-10.8, 0.8]	0.089	1.5 [-6.5, 3.5]	0.562	4.8 [0.0, 9.5]	0.048
SCcon	1.7 [-7.4, 4.0]	0.565	6.2 (1.3, 11.0)	0.013	6.4 [2.1, 10.6]	0.004
MLHF	-2.8 [-7.8, 2.1]	0.255	-2.7 [-7.1, 1.6]	0.221	-3.0[-7.1, 1.0]	0.139
MLHFemo	-1.2 [-2.9, 0.5]	0.173	-1.7 [-3.0,-0.3]	0.014	-1.5[-2.8,-0.3]	0.015
MLHFphy	-0.1 [-2.2, 2.0]	0.925	0.0 [-2.0, 2.0]	0.991	-0.4 [-2.2, 1.4]	0.683
DHFKScarer	-0.5 [-1.3, 0.3]	0.196	2.6 [1.7, 3.4]	< 0.001	2.4 [1.6, 3.2]	< 0.001
CAS-R	-0.2 [-1.5, 1.1]	0.739	1.4 [0.2, 2.6]	0.018	1.0 [-0.2, 2.1]	0.104
PCS	2.2 [-1.0, 5.3]	0.176	2.8 [-0.1, 5.7]	0.055	2.5 [-0.4, 5.5]	0.085
MCS	0.2 [-2.5, 3.0]	0.874	1.0 [-1.2, 3.1]	0.398	0.4 [-1.7, 2.5]	0.714

Note. Linear mixed-effects model pairwise multiple comparisons

These tests are based on the linearly independent pairwise comparisons among the estimated marginal means  
Mean difference = Mean score of the family-based education group minus 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; MLHFemo, Minnesota Living with Heart Failure emotion dimension; MLHFphy, Minnesota Living with Heart Failure physical dimension; CAS-R, Control Attitudes Scale-Revised; PCS, Physical Component Summary; MCS, Mental Component Summary.





**Figure 1 Study design and participant flow**



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