Faculty of Health

Family focused **A**pproach to i**M**prove Heart Failure care **I**n **L**ebanon Qualit**Y** (FAMILY) Intervention: A Randomized Controlled Trial

Hiba Deek

Centre for Cardiovascular and Chronic Care
Faculty of Health
University of Technology Sydney

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2. Certificate of Original Authorship

To the best of my knowledge, this thesis contains no material published elsewhere without gaining permission or making due acknowledgements. Everything presented in this thesis is the outcome of the work put together for the sole purpose of this PhD and not considered for any other awards or degrees. I confirm that everything in this thesis is written by me with the guidance of my supervisors; everything else borrowed or quoted is otherwise referenced or acknowledged appropriately.

Name: Hiba Deek

Signature of Student: *Hiba Deek*

Production Note:
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4. Anthology of Papers and Presentations

4.1 Publications/Submitted Papers Associated with this Thesis

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Deek, H., Hamilton, S., Brown, N., Inglis, S.C., Digiacomo, M., Newton, P., Noureddine, S., Macdonald, P.S. & Davidson, P.M. 2015, 'Family-centred approaches to health care interventions in chronic diseases: A quantitative systematic review', *Revised version submitted to Journal of Advanced Nursing, September, 2015*.

Deek, H., Noureddine, S., Newton, P. J., Inglis, S. C., Macdonald, P. S., & Davidson, P. M. (2015). A family focused intervention for heart failure self-care: Conceptual underpinnings of a culturally appropriate intervention. *Journal of advanced nursing*. Accepted August 4th, 2015. doi: 10.1111/jan.12768.

Deek, H., Noureddine, S., Newton, P. J., Inglis, S. C., Al Arab, G., Kabbani, S., Chalak, W., Timany, N., MacDonald, P. S., & Davidson, P. M. (2015). Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: protocol for block randomized controlled trial. *Nurse Researcher, accepted June 9th, 2015.*

Deek, H., Chang, S., Noureddine, S., Newton, P., Inglis, S., MacDonald, P. S., Al Arab, G., & Davidson, P. M. (2015). *Translation and Validation of the Arabic version of the Self-care of Heart failure Index (A-SCHFI)*. Under review/Journal of Cardiovascular Nursing.

Deek, H., Noureddine, S., Newton, P. J., Inglis, S. C., Al Arab, G., Kabbani, S., Chalak, W., Timany, N., MacDonald, P. S., & Davidson, P. M. (2015). Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: A randomized controlled trial. *Submitted to The* European Journal of Heart Failure.

4.2 Conference/ Forum Presentations

Deek, H., Chang, S., Newton, P.J., Noureddine, S., Inglis, S.C., Al Arab, G., Chalak, W., Timany, N., Macdonald, P.S., & Davidson, P.M. 'Family focused approach to improve heart failure care in Lebanon quality (FAMILY) intervention: Randomized controlled trial for implementing and educational family session. European Society of Cardiology, London: **August 31st, 2015.**

Deek, H., et al. Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: randomized controlled trial. Research Student Forum, University of Technology Sydney: **June 26th, 2015.**

Deek, H., Newton, PJ., Noureddine, S., Inglis, SC., MacDonald, PC., Davidson, PM. Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: A Randomized Controlled Trial. Australasian Cardiovascular Nursing College Conference 2015: **March 14th, 2015.**

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4.3 Awards Granted with Oral Presentations

Deek, H., Newton, PJ., Noureddine, S., Inglis, SC., MacDonald, PC., Davidson, PM. Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: A Randomized Controlled Trial. The Joanna Briggs Institute Australasian Cardiovascular Nursing College Certificate of Commendation Award for Best Clinical Research Paper presentation 2015: **March, 2015.**

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7 List of Abbreviations

***A*-SCHFI**	The Arabic version of the Self-care of Heart Failure Index
ABS	Australian Bureau of Statistics
BMI	Body mass index
CINAHL	Cumulative Index for Nursing and Allied Health Literature
CFA	Confirmatory factor analysis
CONSORT	Consolidated standards of reporting trials
ED	Emergency department
EFA	Exploratory factor analysis
FAMILY	Family focused Approach to iMprove heart failure care In Lebanon
HF	Heart failure
HFPEF	Heart failure preserved ejection fraction
HFREF	Heart failure reduced ejection fraction
HRQoL	Health related quality of life
LDLR	Low density lipoprotien receptor
NYHA class	New York Heart Association class
QOL	Quality of life
RCT	Randomised controlled trial
SHARE Index	Survey of Health, Ageing and Retirement in Europe index
SPSS	Statistical package for social sciences
STTI	Sigma Theta Tau International
UTS HREC	University of Technology Sydney Human Research Ethics Committee
WHO	World Health Organisation

8 Glossary of Terms

Arghile or narghile: Tobacco smoking through a water pipe instrument designed to humidify the tobacco.

Collectivism: A societal context involving a group of individuals seeing themselves as part of the group (society) embracing norms, duties and beliefs outlining their behaviour.

Confirmatory factor analysis (CFA): This is a theory driven statistical analysis used to confirm the explicitly stated hypothesis. This is done by drawing the model and linking constructs and items of constructs based on findings of the EFA and theory.

Consolidated standards of reporting trials (CONSORT): It is the gold standard in evaluating health care interventions. It provides the guidelines for reporting and evaluating randomised controlled trials.

Exploratory factor analysis (EFA): This is a method of data reduction by seeking unobserved variables that are reflected in the observed variables. Variables measuring the same construct are then grouped together to identify this construct.

Framingham criteria: A set of major and minor symptoms which are common in patients with heart failure. This criteria is used to confirm diagnosis of heart failure where either two major or one major with two minor symptoms confirm the diagnosis.

Frailty: It is the outcome of decline in physical, social and psychological wellbeing together and is linked to ageing.

Heart failure preserved ejection fraction: A chronic condition characterised structural and functional changes consistent with cardiac remodelling and abnormalities in diastolic function.

Heart failure reduced ejection fraction: A chronic condition characterised structural and functional changes consistent with cardiac remodelling and abnormalities in systolic function.

Health care utilisation: it is the pattern of seeking medical advice. It differs based on the health condition, its severity and chronicity in addition to the culture of the sick person.

Quality of life: It is the individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.

Randomised controlled trial: This is a type of scientific experiment where groups of people are randomly assigned to different groups to test whether a cause-effect relation exists between the treatment and outcomes under study. It is the gold standard of testing a new intervention.

Self-care: A naturalistic decision making process involving the choice of behaviours that maintain physiologic stability (maintenance) and the response to symptoms when they occur (management).

9 Abstract

Background: Heart failure is a growing burden globally and Lebanon is no exception. Achieving optimal health outcomes requires adherence to many life-style changes and adaptation of self-management strategies. To date, many theoretical models of self-care have focused on the individual with less intentional focus on caregivers and the socio-cultural factors that impact self-care behaviours, particularly within collectivist cultures.

Objectives: To develop a theoretically-informed, culturally-adapted intervention to improve heart failure outcomes tested in a randomised controlled trial (RCT).

Methods and design:

A series of sequential, interdependent studies contributed to the intervention development tested in a prospective, randomized controlled trial.

Phase 1: An integrative review defining the burden of cardiovascular diseases in Lebanon as a guide to the development of a culturally-appropriate intervention.

Phase 2: A Systematic review of family involvement in self-care of patients with chronic conditions.

Phase 3: Developing a culturally-appropriate, family-centred, nurse-led intervention aimed to improve heart failure outcomes in Lebanon.

Phase 4: Translation and validation of the Arabic version of the Self-care of Heart Failure Index (*A*-SCHFI).

Phase 5: Evaluation of the intervention through a multi-site RCT assessing all-cause readmission, self-care, quality of life, emergency department presentation, major vascular events, and health care utilization. The intervention group, patients and their primary family caregivers, received a comprehensive educational session on self-care and symptom management and a branded bag with self-care resources, while the control group received the self-care resources only.

Results:

Phase 1: A total of 28 peer-reviewed articles and 15 reports were identified in this search. Cardiovascular diseases were found to be the leading causes of morbidity and mortality in Lebanon. A range of social, political, economic and cultural factors explain the burden of these diseases including the unique traits of the Lebanese culture such as the narghile smoking and the high rates of familial hypercholesterolemia (*Collegian*, doi:10.1016/j.colegn.2014.04.004).

Phase 2: A total of ten articles addressing family involvement in self-care of patients with chronic conditions were identified. Family-centred approaches were found to be more appropriate in Non-western, collectivist cultures. Outcomes varied based on the type of support provided to different patient populations and on the type and frequency of the interventions.

Phase 3: The FAMILY Intervention Heart Failure Model was developed using linguistically and culturally appropriate methods while considering the Lebanese health care sector and the available resources. This model concepts included partnership, collaboration, behaviour change, family unit, empowerment and information sharing (*Journal of Advanced Nursing*. doi: 10.1111/jan.12768).

Phase 4: The *A*-SCHFI was shown to have enough face and content validity as evaluated by the panel of experts. The three constructs explained 37.5% of the variance with the maintenance construct having the least appropriate loading. The modified A-SCHFI was evaluated to be a valid and reliable measure of self-care in the Lebanese population.

Phase 5: The mean age of the 256 patients was 67 (SD=8) years and 55% were male; most caregivers were the patients' spouse (43%). Readmission was significantly lower in the intervention group compared to the control group (n=10, 33% vs. n=20, 67%, $p<0.05$ respectively) at one month follow up. Self-care scores, lower at baseline, improved at 30 days with significant improvement in the intervention group over the control group in both the maintenance and confidence scales (67 (SD=14) vs. 58 (SD=19), ($p=0.0001$) and 64 (SD=20) vs. 55 (SD=22), ($p=0.002$) respectively). No changes were noted in quality of life scores or emergency department presentations between the groups. Significantly more participants in the control group needed health care facilities than in the intervention group (n=24 (23%) vs. n=12 (11%) respectively, $p<0.05$) at follow up. Three cases of major vascular events were noted in the control group but none in the intervention group.

Conclusion: As the burden of chronic diseases increases globally, particularly in emerging economies, developing models of intervention that are appropriate to the socio-cultural context are necessary. In addition, implementation of valid and reliable outcome measures is warranted. Future research on family involvement through multi-session educational conferences and longer follow-up periods are warranted.

11. Chapter One

11.1 Introduction and Overview

This chapter provides an overview to the presentation of the thesis, **F**amily focused **A**pproach to i**M**prove Heart Failure care **I**n **L**ebanon Qualit**Y** (FAMILY) Intervention: A Randomized Controlled Trial. The thesis is presented in six manuscripts following this introductory chapter. This chapter provides a summary of epidemiological and conceptual issues explicated in the presented manuscripts. It is noted that this may provide some duplication but consider this chapter provides scene setting for included manuscripts.

11.1.1 Definition of heart failure

Chronic heart failure is a complex clinical syndrome. This condition is characterized by pulmonary or systemic fluid retention and/ or fatigue and end-organ damage (Yancy et al. 2013). Chronic heart failure is a disabling and progressive condition and is the final pathway of most heart diseases, namely coronary artery disease and hypertension. The National Heart Foundation/Cardiac Society of Australia and New Zealand defines CHF (Krum et al. 2011) as a:

" ..complex clinical syndrome with typical symptoms (e.g. dyspnoea, fatigue) that can occur at rest or on effort, and is characterised by objective evidence of an underlying structural abnormality or cardiac dysfunction that impairs the ability of the ventricle to fill with or eject blood (particularly during physical activity). A diagnosis of CHF may be further supported by improvement in symptoms in response to treatment."

The symptom burden of breathlessness, fatigue and oedema has led to adverse health outcomes and distress for patients living with HF (Malik, Gysels & Higginson 2013). HF is associated with depression, and this association is linked with a worse prognosis (Fan et al. 2014). Furthermore, heart failure is associated with increased burden of comorbidities, more functional and cognitive impairment and a greater risk of death (Murad et al. 2015).

11.1.2 Prevalence of heart failure

It is estimated that 2.4% and up to 2% of the general population in the United States and Australia respectively have heart failure (Heidenreich et al. 2013; Krum et al. 2011). The prevalence increases with age to become 10% among the Australian older adults and more than 50% among those aged more than 85 years (Krum et al. 2006). To date there is limited data on heart failure in Lebanon (Deek et al. 2014). In Europe, a continent accommodating 900 million individuals, 10 million people are thought to have heart failure while another 10 million have systolic dysfunction with no heart failure symptoms (Becker, Gates & Newsom 2004). The prevalence of heart failure among the European older adults is thought to be between 10% and 20% in those aged between 70 and 80 years and is equally divided between the two sexes in this age group. Furthermore, it is reported that the average age of patients with heart failure in developed countries is 75 years (Driscoll, Worrall-Carter & Stewart 2006). Heart failure is more prevalent among men in younger age groups and that is because the leading cause of this condition, which is ischemic heart disease, is more prevalent among men. The prevalence equals between the two sexes after the age of 65 (McMurray, Adamopoulos, Anker, Auricchio, Böhm, Dickstein, Falk, Filippatos, Fonseca & Gomez-Sanchez 2012).

Heart failure is classified into heart failure reduced ejection fraction (HFREF) and heart failure preserved ejection fraction (HFPEF), where both are characterised by structural and functional changes consistent with remodelling and abnormalities in either systolic (HFREF) or diastolic function (HFPEF) (Yancy et al. 2013). Although the treatment is similar in both groups, better outcomes are seen with systolic dysfunction (Atreya et al. 2015)

11.1.3 Prognosis of heart failure

Some clinicians consider heart failure to be a 'malignant' condition (Yancy et al. 2013) since the outcomes of this disease can be poor and its associated mortality is high. Although some patients can survive with this chronic condition for many years, around 50% pass away within four years of their diagnosis and 40% of those admitted either die during their hospitalisation or are readmitted within the same year following discharge (Driscoll et al. 2009). Readmission within 6 months occurs in 50% of those previously admitted for heart failure (Jessup et al. 2009). It was reported that in the year 2000, an estimate of 22,000 patients with heart failure were admitted for heart failure management in Australia and 42% of those were below the age of 75 (Chriss et al. 2004). Men with heart failure have an estimated 20% higher mortality rate than women do and mortality rates increase as more time passes after diagnosis (Rho et al. 2012).

11.1.4 Estimated Burden of heart failure in Lebanon

Limited data is available on the prevalence of heart failure in Lebanon and little is known about the prevalence of its risk factors. More reports than peer-reviewed research articles are available about these risk factors, which are summarised as such: while heart failure is a condition of the elderly (Davidson, Inglis & Newton 2013), 9.2% of the Lebanese population is aged more than 65 years and this percentage is expected to increase (The World Factbook 2011). Heart diseases are predicted to be the leading causes of death for it was reported that 45% of deaths accounting for non-communicable diseases in Lebanon are due to heart diseases (Riedner 2014). Furthermore, 31% of the Lebanese population are thought to be hypertensive, 32% hyperlipidemic and 21% diabetic (Sibai et al. 2008). Familial hypercholesterolemia was found to be high in prevalence due to the high rates of consanguinity and the heterozygosity of the LDL receptor (LDLR) gene (Fahed et al. 2011). Physical activity was reported to be low in 46% of a random representative sample of 1,982 individuals aged between 25 and 64 years, where sedentary lifestyles were reported in more men than women (52% vs. 40% respectively). Overweight was another reported risk factor where 65% of the same sample had a mean body mass index (BMI) of 27.5kg/m2 (Sibai & Hwalla 2009). Finally reported, cigarette and narghile (or water-pipe) smoking is very common among the Lebanese youth and is a practice that continues throughout life. It is estimated that 40% of the Lebanese population are current cigarette smokers with more men than women (47% vs. 32% respectively). Cigarette smoking causes endothelial damage and consequently vascular dysfunction (Messner & Bernhard 2014). The nicotine and carbon monoxide (CO) boosts reduce nitric oxide availability and increase platelet and macrophages adherence to the epithelial walls. This provokes an inflammatory and procoagulant environment leading to cardiovascular diseases and lung cancer (Jacob et al. 2013; Messner & Bernhard 2014). The estimated prevalence of narghile smoking is 22% of the whole population, which is equally divided between the sexes (Sibai & Hwalla 2009). Although less prevalent than cigarette smoking, active and passive exposure to narghile smoking is a common risk factor among all the Lebanese population for it being a culturally acceptable practice (Tamim et al. 2007). In addition to the cardiovascular risks associated with arghile smoking, it is thought to weaken the autonomic function of the cardiovascular system (Cobb et al. 2012) and expose the individuals to great risk of leukaemia related to high benzene exposure (Jacob et al. 2013).

11.2 Literature Review

This chapter provides a contextual background on the outcomes of interest in this study: hospital readmission, self-care, quality of life, emergency department presentation, major vascular events and health care utilization. While frailty is not one of the outcomes under study, we have defined it and included it as a baseline assessment of our study sample to test its effect on the outcomes. Frailty has gained recent attention in the literature and is closely studied with older adult population which fits with our patient population (Jha et al. 2015). We have also defined the concept of family under social support and presented how it may affect patient outcomes in collectivist societies where the family unity is vital. At the end of this chapter, after defining all the concepts, we have presented some of the recent literature on self-care interventions and their positive effects on some of the outcomes of interest namely readmission, self-care, and quality of life.

11.2.1 Hospital admission and readmission

Hospitalization is a regular event with heart failure accounting for 1.1 million admissions annually in the United States of America (Ambrosy et al. 2013). It is one of the dreaded outcomes associated with this health condition and the most feared by the patients (Shah, Rahim & Boxer 2013). In 2003, an estimated 40,000 newly diagnosed patients were hospitalized for heart failure in Australia (Driscoll et al. 2009).

Patients may have a certain tolerance level of their symptoms with which they can live until these symptoms become life threatening. Some symptoms of heart failure are acute and require urgent hospitalization; these are usually due to fluid overload (Collins et al. 2013). Factors thought to be associated with readmission as reported by cardiologists, patients, caregivers and nurses are: worsening of the condition, other co morbid diseases, and arrhythmias. Excessive salt intake was found to be the main cause of hospital readmission in patients with HF, accounting for 59% of the admissions (Annema, Luttik & Jaarsma 2009). Although this finding is controversial (O'Donnell et al. 2013). Other reported reasons were excessive fluid intake (Parrinello et al. 2015), angina (Chun et al. 2012), poor compliance with medication administration (Granger et al. 2015) and high levels of anxiety, where the latter was shown to increase the risk of readmission three times as compared to patients with low anxiety level (Volz et al. 2011).

Reducing heart failure readmissions can be challenging, and interventions implemented to reduce those numbers are tailored to educating the patients and/or their caregivers (Feltner et al. 2014). Interventions determined to be effective include: adhering to evidence based recommendations (Yancy et al. 2013), partnering with community services or other local hospitals, arranging follow-up visits, connecting with the primary physicians and providing them with the patients' hospital records and having staff to follow-up on abnormal test results. These interventions were found to significantly reduce readmission, which was further reduced when a combination of these strategies were implemented (Bradley et al. 2013).

11.2.2 Self-care in heart failure

Self-care is an essential requirement in the management of chronic diseases, the lack of which is likely to cause poor outcomes (Riegel & Dickson 2015). Despite the existence of this concept long before the 1980s, limited scholarly debate and discussion occurred prior to that time (Riegel & Dickson 2008), whereas Riegel & Dickson (2008) reported that over 25,000 articles are currently available investigating self-care. Self-care is defined differently across the disciplines. In nursing, the definition of self-care is based on outlining the treatment goals and assessing the patient's capability of carrying out certain activities to reach these goals (Gantz 1990).

The word self-management emerged to mean involving the patient in their own treatment and their ability to manage their health condition, symptoms and lifestyle changes (Coster & Norman 2009) but nowadays, self-management and self-care are used interchangeably in the literature (Moser & Watkins 2008; Riegel & Dickson 2008). These authors (Riegel & Dickson 2008) determined self-care to be based on two major concepts, maintenance and management. Self-care maintenance is where one decides to adopt behaviours to maintain wellbeing; whereas, self-care management is to act as a response to physiologic instability to restore wellbeing. The application of self-care on patients with heart failure has shown positive outcomes including lower readmission rates (Carr et al. 2014), mortality rates (Laxy et al. 2014), better quality of life (DeWalt et al. 2012) and reduced cost of management (Mejía et al. 2014).

11.2.2.1 Factors affecting self-care

The diagnosis of heart failure can have significant impact on the patients as they are notified of a chronic condition and the urgent need to change their life style substantially (Murad et al. 2015). These changes in eating habits, fluid intake, routine check-ups, and symptom monitoring can be worrisome and tedious for newly diagnosed patients with heart failure (Riegel & Dickson 2015). Some refer to this period of transition as a crisis, where patients are faced with an unexpected but inevitable condition threatening their wellbeing (Yancy et al. 2013). Symptom management involves three equally important components, which are symptom acknowledgment, knowledge and the effect of value (Riegel & Dickson 2008). Well informed patients about their health condition are significantly more likely to recognise and treat their symptoms and more likely to evaluate their progress. In addition to that, choosing to live to see one's children grow and "to be there", has a positive effect on heart failure outcomes.

It is still unknown why some people can manage their disease condition and care for their health better than others despite receiving education about their condition and the steps to manage it. In psychology, it is believed that moving from one phase to another in a self-regulatory goal process requires motivation and will arising from within (Schwarzer 1999). Yet some believe that once these caring skills are acquired, the patient becomes an "expert" in self-care due to the lived experience of heart failure, rather than knowing it theoretically like most caregivers (Goodman et al. 2012). In fact, patients reported that the best resource for heart failure education was provided through another person's experience of the same condition. One patient reported finding it useful to go to the supermarket with a friend who helped him choose healthy food and read labels (Dickson & Riegel 2009).

Besides experience and motivation, socio-demographic variables, such as age and living conditions, were found to have an effect on the self-care skills. Older adults were significantly more likely to keep their appointments with their health care providers, report their symptoms, take their prescribed medications and get their flu vaccines when compared to their younger counterparts (Chriss et al. 2004). Men were found to be significantly more keen about getting their flu vaccines than women (Pressler et al. 2009), while women had more confidence in their management and actions upon encountering a symptom (Chriss et al. 2004). Non-married individuals were significantly more likely to adhere to self-care instructions such as fluid restriction and rest when manifesting dyspnoea, compared to married individuals. However, it was found that patients with heart failure, living with a significant other, were significantly more likely to ask for help and call their doctors when they manifested shortness of breath or ankle swelling when compared to those who lived alone. They were also found to be more physically active and reported more happiness (Alla et al. 2002).

Personal characteristics and knowledge were also contributors to better self-care. Patients who perceived their disease control to be good, had better knowledge and more confidence in their knowledge, practiced better self-care than those who did not, regardless of their gender (Heo et al. 2008). Dickson & Riegel (2009) found that half the patients did not weigh themselves daily for the wrong notion that weight gain is only due to adipose tissue accumulation rather than fluid retention. They also stated that patients with multiple co morbidities were facing more confusion than patients with only heart failure. Physical activity was also an issue for those who had always adopted sedentary lifestyles where advices on physical activity were found delusional (Dickson & Riegel 2009). Other factors affecting self-care were confidence in ones' ability, cultural attitudes towards specific symptoms, ability to integrate self-care into daily routine, cognitive status, depression, access to care and social support (Riegel, Jaarsma & Strömberg 2012). Davidson, Inglis & Newton (2013) have identified factors to be considered in improving self-care in heart failure. These factors which are based on the WHO model of adherence elements are outlined in **Error! Reference source not found.**.1.

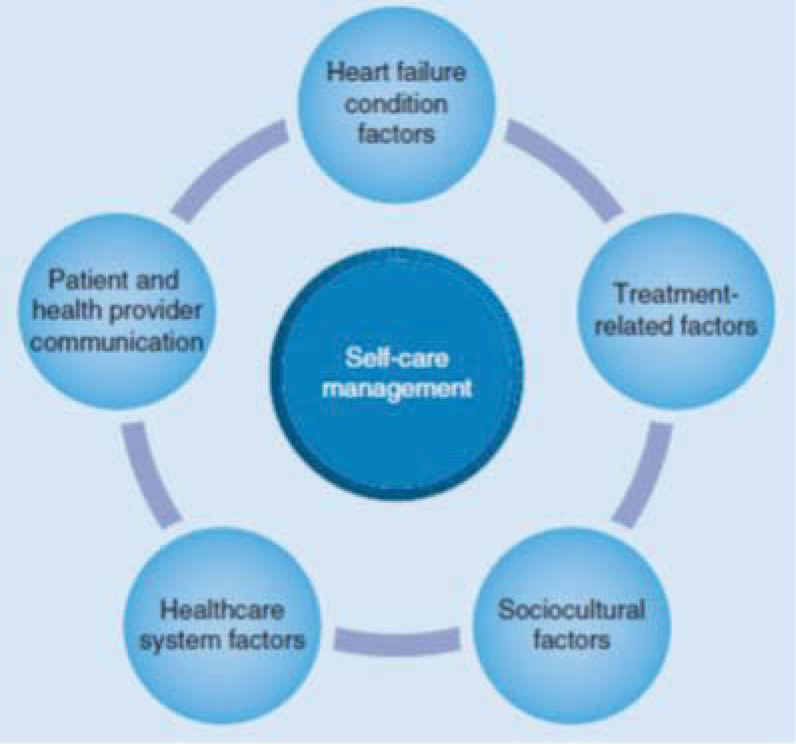

Figure 1. 1 Factors to be considered in self-care management in chronic heart failure based on WHO model of adherence elements (Davidson, Inglis & Newton 2013)

11.2.3 Quality of life of patients with heart failure

Quality of life is defined by the World Health Organization as: “the individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (World Health Organization 2002). It is an important outcome to evaluate when the patients general wellbeing is of interest. Health-related quality of life (HRQoL) is a multi-dimensional concept that includes domains related to physical, mental, emotional and social functioning (Fayers & Machin 2013). This is a patient reported outcome that goes beyond direct measures of population health, life expectancy and causes of death, and focuses on what impact the patient’s health status has on his/her quality of life. A related concept of HRQoL is well-being, which assesses the positive aspects of a person’s life, such as positive emotions and life satisfaction (Herrman, Saxena & Moodie 2005). The key dimensions embedded in these constructs are: physical abilities, emotional wellbeing, social life, intimate interactions, satisfaction in life, one’s own view of health, output (Volz et al. 2011), mental health and physical pain (Åstedt-Kurki et al. 2004). Some investigators reported that frequent readmissions (Piamjariyakul et al. 2012) and changes in social support (Heo, Lennie, et al. 2014) reflect quality of life in patients with heart failure.

When diagnosed with heart failure, patients hold positive beliefs about the possibility of cure and the provided treatments, however, these beliefs significantly weaken with time when they become aware of the chronicity of the condition. Patients' quality of life begins poor due to the burdening symptoms manifested at the primary presentation and remains as such throughout their life course (Mulligan et al. 2012). Poor QOL can be assessed by its predictors, which are the higher levels of depression, anxiety and lower functional capacity (Moser et al. 2013). QOL is influenced by other comorbidities such as chronic obstructive pulmonary disease, hypertension (Mulligan et al. 2012) and diabetes (Fujita et al. 2012), which are common with heart failure. Furthermore, correcting anaemia and improving physical symptoms was associated with improved functional status and consequently QOL in patients with heart failure (Heo, Moser, et al. 2014; Singh et al. 2013). This effect was also seen with patients having sinus rhythm, rather than atrial fibrillation (Suman-Horduna et al. 2013) and those having lower heart rates (Ekman et al. 2011).

Literacy levels and social support were also associated with QOL, where higher literacy levels and adequate social support significantly improved QOL especially in older adults (Årestedt et al. 2013; Macabasco-O'Connell et al. 2011). When looking at the aged population, which is typical in heart failure, scores of emotional QOL were significantly higher when compared to their younger counterparts'. This is due to the loss of activities and roles associated with heart failure which is not easily accepted by the younger cohort (Moser et al. 2013). In addition to those factors, severity of heart failure, increased age, multiple pills, and lower educational levels were significant negative correlates of quality of life (Demir & Unsar 2011).

11.2.4 Emergency department presentation

Emergency department (ED) presentations are common events in patients having heart failure accounting for approximately 658,000 encounters annually in the US (Weintraub et al. 2010). These presentations are approximately similar in patients with heart failure preserved ejection fraction (HFPEF) and heart failure reduced ejection fraction (HFREF) (Atreya et al. 2015). It has been reported that almost 80% of those presenting to the emergency department for heart failure symptoms end up hospitalized, while 50% of those admitted could be safely discharged home after proper managemet in the ED (Collins et al. 2013). On the other hand, those newly diagnosed with heart failure, managed and discharged home from the ED have the highest rates of ED revisits and hospitalization (Ezekowitz et al. 2011).

The main reasons contributing to ED presentations are frailty (McNallan et al. 2013) and poor self-care (Riegel & Dickson 2015) leading to fluid overload and manifestations of burdening symptoms. Decreasing the burden of ED presentations, hospitalizations and their accompanied risks can be prevented by community intervention (Weintraub et al. 2010), and while this type of care is currently being launched in Lebanon (Hijazi, Weissbecker & Chammay 2011), there are no reported studies on emergency department visits for HF exacerbation.

11.2.5 Major vascular events

Atrial fibrillation is the most common arrhythmia manifested among patients with heart failure, and its prevalence increases among older adults (McManus, Rienstra & Benjamin 2012). Atrial fibrillation and uncontrolled blood pressure trace the prognosis of patients with heart failure (Arima et al. 2011). Major vascular events, such as ischemic strokes, heart attacks and peripheral vascular events, are caused by those abnormalities among others. Therefore, it has been shown that control of these events with proper medication has produced improved outcomes (McManus, Rienstra & Benjamin 2012).

11.2.6 Health care utilization

Patients with heart failure are susceptible to frequent episodes of clinical decompensation and their life illness trajectory can be perceived as a rollercoaster, their New York Heart Association class changes back and forth very frequently (Jaarsma et al. 2009). Therefore, seeking medical advice is a common scenario after diagnosis. The trend of seeking this advice varies across countries and between different cultures, the most frequently adopted are emergency department presentations, pharmacy consultations, outpatient department (clinic) visits/family doctor or a health care specialist approaches (McNallan et al. 2013). Seeking medical advice from a nearby pharmacy in Lebanon is usual practice especially for symptoms relating to upper respiratory tract infection of or changes in blood pressure (Kheir et al. 2008).

11.2.7 Frailty assessment

Frailty is the outcome of decline in physical, social and psychological wellbeing together (Rockwood 2005). It is a condition highly linked to ageing and is expected in patients having heart failure for the latter being a disease of the older adults (Davidson, Inglis & Newton 2013). Frailty impacts on patient’s quality of life (Romero-Ortuno et al. 2010) and this fact is especially true in patients with heart failure. Frailty, involving both physical and psychological dysfunction can impact adversely on self-care outcomes (Jha et al. 2015).

11.2.8 Family and social support

To date discussion, debate and interventions have focussed on the individual with a lesser focus on the broader socio-cultural context of the individual and in particular the role of the family unit in moderating health outcomes. Considerations of family approaches to improving health care management have focussed on family and social support in patients with chronic conditions (Hartmann et al. 2010). Social support can be provided in different forms; emotional, informational and instrumental (Kalichman, Sikkema & Somlai 1996), which are all necessary for patients with heart failure (Clark et al. 2014). Emotional support is the provision of comfort and empathy to the chronically ill patient and understanding his/her fears. Informational support is the delivery of the appropriate knowledge specific to the patient's current condition, while instrumental support is aiding the patient with activities of daily living when needed (Cohen 1998; Linn et al. 1993; Meyerowitz 1980). This support can be provided from family members, partners, friends, health care professionals and others (Pressler et al. 2013). Having social support is highly associated with positive patients' physical and psychological outcomes such as less depression in patients with heart failure (Heo, Lennie, et al. 2014). Psychological symptoms were significantly more frequent when the source of social support was other than the spouse (Maunder et al. 2015). Similarly, having the support of the spouse was found to be significantly associated with better self-care in terms of medication adherence and dietary restrictions (Gallagher, Luttik & Jaarsma 2011). However, the significance was lost when confidence was studied which only improved when the source of support was a friend (Sayers et al. 2008). This finding could be explained by the fact that living with spouse divided the responsibility between the patient and their caregiver and thus making them more dependent on their spouse. However, there has been a limited investigation of these discrete constructs in a collectivist culture (Davidson et al. 2007).

11.2.8.1 Family Support

Family-focused care was introduced almost 60 years ago and has its underpinnings in the care of sick children (Coyne et al. 2011). This concept has been addressed extensively in the literature and analysed through two approaches; either seeing the family as an equal partner of care or having the family supervised by health care professionals (Hutchfield 1999). This type of informal care recently evolved to include the adult population when the focus of care shifted from curative to palliative (Pressler et al. 2013). In addition to the costly treatment and the nursing shortage, the burden of chronic conditions pushed the family to become partners of care in the community settings (Kaakinen et al. 2014). This is especially true in low and middle income countries (Tolle 2009).

Family-centred care has been advocated in the literature to improve patient outcome. Some reported strategies include being involved in a wider range of self-care while also fostering patient independence, provision of informational support and helping the patient integrate self-care into daily practices (Clark et al. 2014). Benefits of a family-centred approach include better patient and caregiver satisfaction (Riegel & Dickson 2008), improved follow-up (Myer et al. 2014), better patients' understanding of the disease (Foster, Whitehead & Maybee 2010) and therefore better coping with their condition and higher adherence to self-care instructions (Driscoll et al. 2009). Moreover, as patients with chronic conditions have to modify their life styles to avoid complications of the disease, involving family members was found to divide the burden amongst the family members and having patients adopt the new lifestyle with far less difficulty, more durability and less stress (Buck et al. 2014). In addition to that, married patients with heart failure had significantly longer event free survival than their non-married counterparts for up to 18 months after follow up (Chung et al. 2009). This finding was extended to a four year follow up when the quality of marriage was rated as high (Coyne et al. 2001). Furthermore, the spouses' confidence was found to have a significant positive effect on the patients' self-efficacy in their management (Rohrbaugh et al. 2004).

In non-western societies, family involvement is the tenet of care in patients with chronic conditions (Beitin & Aprahamian 2014). Members of collectivist societies see themselves as part of a family unit embracing similar norms and beliefs, rather than being individualists (Ayyash-Abdo 2001). Everyday behaviours are shared and practiced collectively including those related to health and sickness despite them being unstructured.

It is vital to target the culture, rather than an individual, in a culturally driven society when aiming to change behaviour (Davidson et al. 2007; Nastasi 1998). Culturally specific interventions had been initiated in African-American cultures, where the effect of tobacco smoking on health had been evaluated. While the efficacy of culturally-specific intervention has been controversial (Varjas et al. 2005; Webb 2008), perception of its success has been linked to the type of participants receiving it, where those having high traditional values voiced better appreciation and more willingness towards the interventions than the "acculturated" individuals (Webb 2008). Furthermore, it is predicted that involving the family caregiver could strengthen the patients' confidence which is thought to be a key to success in improving patients' self-care skills (Davidson, Inglis & Newton 2013).

11.2.9 Self-care interventions in heart failure

Heart failure is a health condition with a progressively declining health trajectory and poor clinical outcomes (Fang et al. 2015). Self-care in heart failure is a growing science and is the key to improving patient outcomes (Riegel & Dickson 2015). Heart failure management programs are structured multicomponent interventions where patient education is provided on diet, medication adherence and self-monitoring (McMurray, Adamopoulos, Anker, Auricchio, Böhm, Dickstein, Falk, Filippatos, Fonseca & Gomez-Sanchez 2012). These programs aim to address patients' physical and psycho-social aspects to reach wellbeing through encouraging them to assume responsibility of their health (Smeulders et al. 2009).

In a systematic review of 29 studies summarizing interventions of heart failure management, it was found that such programs can reduce heart failure related and all cause readmission rates by 27% and 73% respectively. A cost reduction in heart failure treatments was also noted in 83% of these trials when these programs were implemented (McAlister et al. 2004). Heart failure management programs have produced varying levels of success (Barnason, Zimmerman & Young 2012; Feltner et al. 2014), with significant improvement in patients' knowledge in many instances. Knowledge levels, however, barely reflected on patients' self-care skills or their clinical outcomes (Davis et al. 2012). On the other hand, interventions targeted to heart failure symptoms showed better outcomes than brief and general educational interventions (Baker et al. 2011). Targeted interventions include education on weight monitoring and diuretic dose management based on the patients' daily weight, symptom assessment, and proper follow-up. The effect of targeted interventions was demonstrated in a study on 570 patients with varying literacy levels. Significant improvement in knowledge, self-care and quality of life was noted one month after implementing the educational sessions. During this period, patients in the targeted intervention received 5 to 8 phone calls to emphasise the provided education (Baker et al. 2011). Patients less likely to be enrolled in these programs were those with lower literacy levels, lower education, lower income and worse HF symptoms (Baker et al. 2011). Moreover, among those enrolled, better outcomes were demonstrated with patients having higher education levels, even after one year of implementing the educational interventions. Such outcomes include significant improvement in self-care behaviour (González et al. 2014).

Although costly, home transitional care interventions, including home visits and telephone support, have shown to be the most efficacious in reducing all-cause readmission rates at 30 days. Significant improvements in readmission and mortality rates were also noted after 6 months of follow up when a multi-disciplinary approach was implemented (Feltner et al. 2014). HF related readmission was also significantly reduced with phone support and tele-monitoring for up to six months after the intervention as reported in a systematic review (Inglis 2010).

In another systematic review evaluating the effect of educational programs on the outcomes of heart failure, it was concluded that QOL scores of patients receiving discharge education significantly improved when compared to scores of the control groups (Wakefield et al. 2013). The same significant effect was seen when educational booklets were provided to patients admitted for heart failure symptoms. This intervention was followed by four-weekly telephone follow ups to emphasise education and refer as necessary. QOL scores improvement was noted for up to three months after discharge. This study was conducted in a non-western country where extensive discharge education is not provided and limited community resources are available (Yu et al. 2015).

However, some argue as to how education can affect QOL and if this association is direct. This is explained by the fact that education can improve the physical, emotional and social dimensions which are all predictors of QOL (Boyde et al. 2011).

When the effect of educational programs was established with patients having heart failure, randomized trials were implemented to test the difference between single sessions and multi-sessions of these programs. DeWalt et al. (2012), found that patients with low literacy levels improved their outcomes for up to 6 months when provided with a multi-session educational program. Starting with a 40 min educational session and followed with 5 to 8 phone calls after discharge, significant improvement was noted in all-cause readmission and mortality. This improvement, however, was lacking with the high literacy group. Both low and high literacy groups showed improvement in their quality of life (QOL) scores after 6 months with multisession programs (DeWalt et al. 2012).

This chapter has introduced the key issues framing this study. We defined each of the concepts of interest including self-care and the factors affecting self-care. Those included knowledge, motivation, age, living conditions, personal characteristics and social support, in addition to those identified by the WHO model of adherence elements. Furthermore, we highlighted some self-care interventions that were deemed effective in reducing readmissions and mortality, improving self-care, QOL, knowledge and cost. Some of the reported effective interventions were targeted interventions, transitional care interventions, including phone support and periodic follow ups and finally interventions targeting health literacy (Baker et al. 2011; Inglis 2010; Molloy, Johnston & Witham 2005). Finally, although there has been discussion and debate on the robustness of studies in these evaluations (Clark, Savard & Thompson 2009), the importance of implementing evidence based recommendations cannot be denied.

11.3 Problem Statement/ Research Aim

The effectiveness of heart failure disease interventions for people with heart failure has been demonstrated in several previous studies. To date, no heart failure disease management intervention has been developed and tested within the socio-cultural context of Lebanon. The aim of this research is to evaluate a theoretically derived intervention, tailored and targeted to the Lebanese context and specifically assessing the impact of family involvement in an educational intervention to improve self-care of patients with heart failure.

11.4 Research objectives

To achieve this aim, this thesis will address four objectives as described below:

1. Document the burden of heart diseases in Lebanon
2. Review the literature on the involvement of family caregivers in self-care of patients with chronic diseases
3. Develop The FAMILY Intervention Heart Failure Model
4. Evaluate the effect of the FAMILY intervention on heart failure outcomes through a randomised controlled trial.

11.5 Research questions

1- Can a culturally derived family model of a heart failure educational intervention:
   a. Reduce all-cause readmission and mortality;
   b. Improve self-care and quality of life;
   c. Reduce emergency department presentations and major vascular events of patients with heart failure?

2- What are the socio-demographic variables and clinical characteristics of patients admitted to the study hospitals for exacerbation of heart failure and patterns of health care utilisation?

11.6 Methodology

11.6.1 Study phases

11.6.1.1 Phase 1 Identification of the cardiovascular burden in Lebanon (Presented in Chapter Two)

In order to develop a family-focussed intervention to improving outcomes of patients with chronic diseases a number of approaches were employed including literature reviews and expert consultation. Using the method of integrative review (Whittemore & Knafl 2005) and in consultation with a health librarian, databases were accessed using key words such as: "Lebanon", "cardiovascular disease", "research", "health", "arghile", "narghile", and "water pipe smoke". The mesh terms used for some databases were: "health knowledge, attitudes, and practice" and "health care sectors". Databases accessed were Academic Search Complete, Cumulative Index for Nursing and Allied Health Literature (CINAHL), Google scholar and MedLine. More data were extracted from The World Health Organization and Central Intelligence Agency websites.

11.6.1.2 Phase 2 Identification of the effective elements of self-care interventions in chronic conditions (Presented in Chapter Three)

To identify elements of effective family-centred interventions likely to improve patient outcomes of patients with chronic conditions, a systematic review was undertaken. Experimental studies targeting patient outcomes through family-centred interventions were retrieved using systematic methods in the following databases: MedLine, CINAHL, Academic Search Complete, PsychInfo, and Embase. Search terms used were: "family", "spouse", "carer", "caregiver", "chronic", "chronic disease", "self-care", self-management", and "self-efficacy". Reference lists of related articles were further reviewed for studies. Data were synthesised qualitatively using a structured narrative approach.

11.6.1.3 Phase 3 Development of the Family Intervention Heart Failure Model (Presented in Chapter Four)

The family intervention heart failure model used five linked methods: (1) Appraisal of theoretical models; (2) synthesis of findings of systematic reviews on educational interventions promoting self-management in chronic conditions; (3) socio-cultural context identification from selected papers; (4) expert consultation using consensus methods; and (5) model development.

11.6.1.4 Phase 4 Evaluation of the psychometric properties of the *A*-SCHFI (Presented in Chapter Six)

In order to assess self-care, a valid, reliable and culturally acceptable instrument is required. The Self-care of Heart failure Index was translated to Arabic (*A*-SCHFI) using best practice translation recommendations (Duffy 2006). The baseline scores of the *A*-SCHFI administered to 223 Lebanese patients with heart failure was used to validate this instrument. Face and content validity were assessed by a panel of experts and construct validity was assessed using factor analysis. Reliability evaluation was performed using the composite reliability coefficient which was found appropriate for multi-dimensional scales (Barbaranelli et al. 2014).

11.6.1.5 Phase 5 Evaluation of the Family Intervention Heart Failure Model (Presented in Chapter Seven)

To evaluate the Family Intervention Heart Failure Model, a block randomized controlled trial was conducted to evaluate the following outcomes: All-causes readmission, self-care, quality of life, emergency presentation, major vascular events, and health care utilization.

11.6.1.5.1 Methodology justification of phase 5

A block randomised controlled trial was considered to be the most efficacious method to test the family focussed intervention in order to control for confounding factors. Data was collected and monitored using the CONSORT guidelines (Schulz, Altman & Moher 2010).

11.6.2 Sampling

Patients with heart failure were identified by the cardiologist, echocardiography technician and by manual screening of the medical records for patients meeting the eligibility criteria in the cardiac care unit, emergency department or other medical units for heart failure management. Patients were included if admitted through the emergency department or electively as referred by a cardiologist.

Participants for this study were identified based on the typical heart failure findings identified by the Framingham criteria (McKee et al. 1971). These criteria are outlined in Figure 1.2. For confirmation of HF diagnosis either two major or one major and two minor criteria need to be present. Newly diagnosed patients underwent the assessment recommended by the American heart Association to confirm their new heart failure diagnosis (Jessup et al. 2009). Patients with any of HFPEF and HFREF with symptoms associated with the condition were included in the study.

Major Criteria

- ☐ Paroxysmal Nocturnal dyspnea
- ☐ Neck vein distention
- ☐ Rales
- ☐ Radiographic cardiomegaly
- ☐ Acute pulmonary edema
- ☐ S3 gallop
- ☐ Increased central venous pressure (>16 cm H2O at right atrium
- ☐ hepatojugulat refluc
- ☐ weight loss > 4.5kg in 5 days in response to treatment

Minor Criteria

- ☐ Bilateral ankle edema
- ☐ Nocturnal cough
- ☐ Dyspnea on ordinary exertion
- ☐ hepatomegaly
- ☐ pleural effusion
- ☐ Decrease in vital capacity by one third from maximum recorded
- ☐ tachycarid (>120BPM)

Figure 1. 2 Framingham Criteria; major & minor

11.6.3 Setting

This study was conducted in three large tertiary medical centres in Lebanon; Rafic Hariri University Hospital, Makassed General Hospital and Mount Lebanon Hospital. These hospitals are located in the capital city of Beirut and in Mount Lebanon. Their locations amid crowded living regions make them accessible to people in need of urgent clinical management. These hospitals have beds covered by all the different parties providing financial health coverage in Lebanon, in varying proportions. The cardiac care units in these hospitals are well equipped and well-staffed to manage critical conditions arising from cardiac events. Their units' capacities range between 9 and 20 beds.

11.6.4 Selection Criteria

11.6.4.1 Inclusion criteria

All those admitted to one of the three study hospitals for acute decompensated HF regardless of the aetiology, aged $\geq$18 years and willing to participate were invited to this study. The family caregiver had to be nominated by the patient and willing to care for the patient and participate in the study.

11.6.4.2 Exclusion criteria

Patients having limited life expectancy of less than 30 days, severe cognitive impairment limiting their judgement and activity, awaiting cardiac bypass or valve replacement surgery with limited functionality, and aged less than 18 years were excluded.

11.6.5 Intervention

Investigators believe that a unique intervention tailored to meet a patient's knowledge demands would produce better outcomes. Although such interventions have not been well addressed in previous studies, a family-centred approach was implemented in the current study to test its efficacy on the Lebanese population. Concepts were derived from the literature and fitted into a model of interventions aimed at improving heart failure outcomes. The model was put together using liked methods: (1) appraisal of theoretical models; (2) systematic reviews on educational interventions in chronic conditions; (3) identification of sociocultural context; (4) expert consultation; and (5) model development. The Family Intervention Heart Failure Model is outlined in **Error! Reference source not found.**. The concepts of this model are introduced and defined below:

- Linkage: also known as coordination, is associated to care of patients with HIV where access to care is encouraged (Knight et al. 2015). It is associated with less complications and cost (Rothman et al. 2012).
- Partnership: where the family members become partners in the care and play the role of the community nurse (Clark & Dunbar 2003).
- Collaboration: is the provision of adequate information to the family caregivers on symptoms management and when to take initiatives (Callahan et al. 2006).
- Information sharing: is a two way concept where investigators learn about patients' habits and self-care skills then educate these patients on self-care (Riegel & Dickson 2015).
- Behaviour change: is one of the aims of most intervention studies as the most improvements in healthcare outcomes are shown when patients are convinced to change their behaviours (Michie, van Stralen & West 2011).
- Support: family support in heart failure self-care is essential in collectivist societies (Riegel, Jaarsma & Strömberg 2012).
- Empowerment: also known as autonomy support. It is when patients are encouraged to make their own health decisions (Dunbar et al. 2005).

- Family unit: This is when people acknowledge being part of a group sharing similar norms and beliefs (Ayyash-Abdo 2001). The family ties are strengthened when one member's health is compromised (Orem, Renpenning & Taylor 2001).
- Self-regulation: It is when a person is motivated to change behaviour. It might be led by perceived risk of a desired goal (Schwarzer 1999)

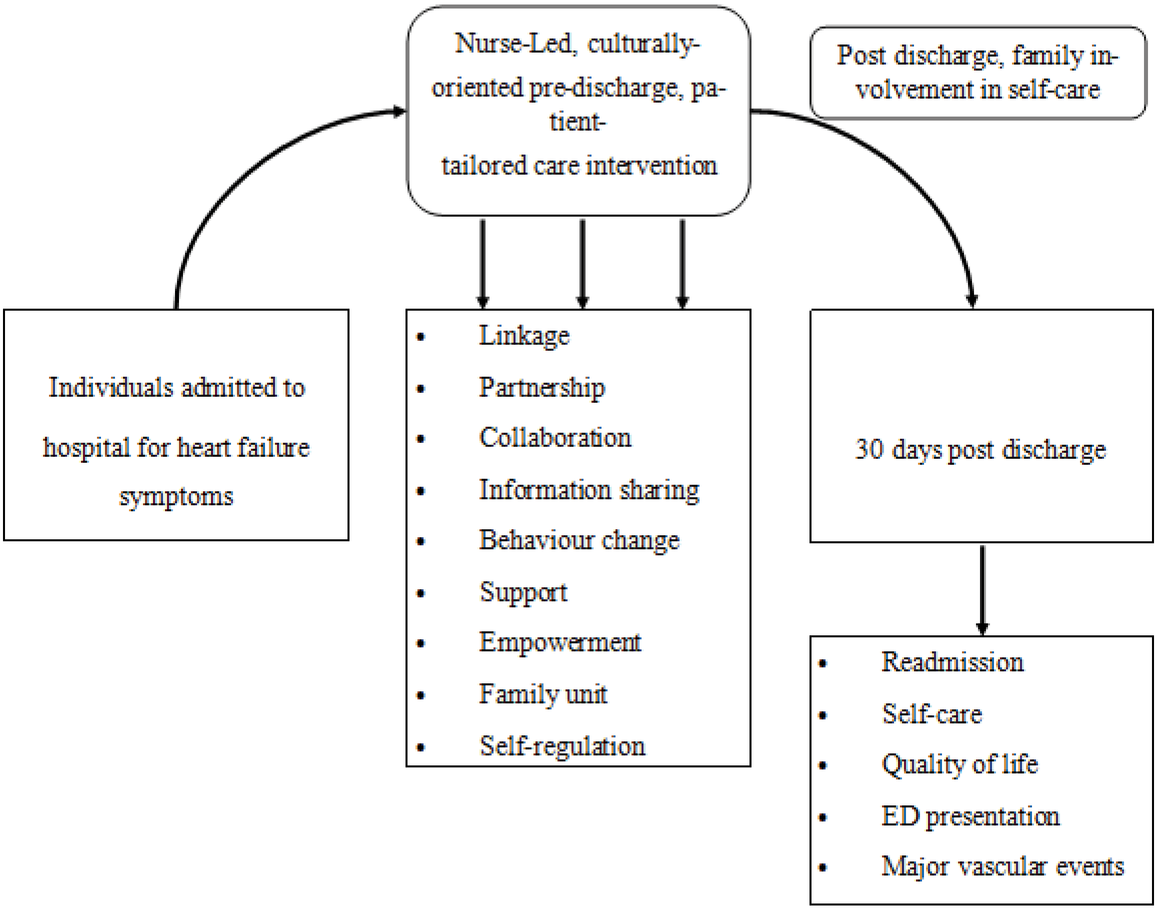

Figure 1. 3 Family Intervention Heart Failure Model

When testing a culturally specific intervention in a Lebanese context, examples on cultural behaviours were used to guide the educational session. These examples included the effects of active and passive smoking of the narghile, smoking cessation, and the unique allele in the Lebanese culture reflecting high prevalence of familial hypercholesterolemia, the rates of cardiovascular diseases in Lebanon and their high rates of related mortality, hypertension, uncontrolled diabetes mellitus, and overweight. Although data reflecting the unique influence of each item on morbidity and mortality in Lebanon are lacking in most cases, international data were used for this purpose to convince participants of better health practices. Moreover, oral and documented educational material was provided in the patients' and caregivers' native language, Arabic, to enhance better comprehension of the material. Data collection was also done in Arabic to assure accuracy.

11.6.6 Screening visit and enrolment

Patients and their primary family caregivers (for example spouse, partner, child, or grandchild) were approached by the primary investigator when the patients were stabilized and planned for discharge. During this encounter, the purpose of the study was introduced, the consent form (Appendix 1) was signed, baseline data were collected, and the participants were randomized.

11.6.7 Randomization

Block randomization of four participants was performed using SPSS random number generator to allocate each case number with either the intervention or the control group. This was done separately in an investigator's office prior to meeting the potential participants. After consenting, patients were assigned with case numbers and the investigator was contacted and asked for group assignment related to the case number.

11.6.8 Baseline visit

This visit defined the difference between the control and the intervention group. Both groups were visited to avoid the risk of contamination arising from an extra visit to the intervention group. During this encounter both groups were provided with the self-care resources which are: a digital weighing scale, a calibrated bottle, a medication box and a diary (Appendix 2). This encounter differed between the two groups in the following manner:

A. The control group was provided with a branded bag with the FAMILY logo which included the aforementioned self-care resources and no verbal explanation was provided
B. The intervention group, including the patient and his/her identified family caregiver, was offered one family conference extending for approximately 40 minutes depending on necessity. This conference was tailored to the patients' condition, unique symptoms (if present) and subjective demands. It was structured to include information about heart failure causes, symptoms and management. The latter comprised a big portion of the educational session focusing on self-management and roles of the family caregiver. Education included topics about salt and fluid restriction, physical activity, symptom recognition, smoking cessation, and adherence to the prescribed medications in addition to the aforementioned culture specific practices. Items in the bag were explained separately emphasising the need to have the medication box filled with the daily pills according to the prescribed dosages, by the

family carer, monitor fluid intake as recommended by their cardiologist with the help of the calibrated bottle used to store the daily fluid allowance, weighing daily after waking up in the morning with light clothes, and documenting the weight in the provided diary. In consultation with their treating cardiologist, a flexible diuretic plan was implemented. Participants were instructed to take an extra pill of their diuretic if their weight increased by 1kg over 24 hours or 2kg over 5 days. They were also advised to contact their cardiologist if their weight continued to increase despite the proposed plan.

Both groups were provided with contact details of their cardiologist and the specialist nurse to refer to in case of an emergency.

11.6.9 The FAMILY Study Diary

The diary included the educational material that was presented to the intervention group, expressive pictures of the unique symptoms usually manifested by heart failure patients presenting to the emergency departments, medication list prescribed on that admission, designated spaces for documentation of their daily weight, and contact details of their cardiologist in case of an emergency.

11.6.10 Study endpoints

The primary endpoint was all-cause readmissions and the secondary endpoints were self-care, quality of life, emergency department presentations, major vascular events and health care utilization.

11.6.11 Sample size calculation

Assuming a readmission rate of 30% (Aranda, Johnson & Conti 2009), in order to demonstrate a 15% reduction in readmission at 30 days and achieve a significant difference between the groups, a sample size of 130 participants in each of the study arms was found necessary to achieve 80% power at an alpha level of 0.05 (2-tailed) while allowing for an attrition rate of 10%.

11.6.12 Data collection

Baseline data were collected before randomization. At this stage, the baseline datasheet (Appendix 3) including the SHARE index, the A-SCHFI and the Arabic SF-12v2 were collected.

Follow up data was collected 30 days post discharge by a phone call. Follow-up data were collected using the follow-up data sheet which included questions on hospitalisation, seeking medical advice, occurrence of major vascular event and health care utilization (Appendix 4). The *A*-SCHFI (Appendix 5) and the SF-12v2 (Appendix 6) were also collected during the phone call. The trained researcher conducting the phone calls was blinded to the participants' treatment allocations to avoid detection bias and this call lasted for 7 minutes only. The time frame and data collection plan is outlined in **Error! Reference source not found.**.1.

Table 1. 1 Timeframe and data collection plan

	TIME FRAME		**DATA COLLECTOR**	
INSTRUMENT/ DATA COLLECTED	Baseline	30 days	Primary investigator	Student researcher
INITIAL DATA SET	X		X	
***A*-SCHFI**	X	X	X	X
SF 12V2	X	X	X	X

11.6.13 Measurements

a. Baseline data sheet: this sheet included questions about the patients' past medical and surgical history, socio-demographic status, NYHA class, medication profile, cause of heart failure, and results of diagnostic findings (Appendix 5).
b. Hand grip is one of the items identified in Fried's model in assessing frailty (Fried et al. 2001). Patients in both groups were assessed for hand grip strength before randomization. Using a dynamometer, hand grip strength was done on both arms twice and the highest score was recorded.
c. The Arabic translated version of Riegel's Heart failure Self-care Index (*A*-SCHFI) was collected. This instrument outlines heart failure patients' basic knowledge about their disease condition and their self-care practices. The second section of this instrument helps to assess patients' ability to recognise their abnormal symptoms and act accordingly to alleviate those symptoms then evaluate their performance. The third section of this tool is to assess patient's confidence in performing self-care measures. The validity of this tool had been tested against the European Heart Failure Self-Care Behavioural Scale (Jaarsma et al. 2003) and was found to be moderately correlated in the maintenance items only since the management and the confidence are not measured in the European Heart Failure Self-Care Behavioural Scale.
d. Quality of life was evaluated using the Short Form-12v2. This tool addresses the physical functioning of the patients, role limitations, social and emotional status (Ware Jr, Kosinski & Keller 1996). The health survey SF-36 had previously been translated and validated then tested on a Lebanese sample (Sabbah et al. 2003). The SF-12 has not been tested on a Lebanese sample yet, however it had been used with patients having diabetes mellitus in

Saudi Arabia. It was first translated and content validated by a panel of experts then adjusted and reworded after piloting to be better comprehended and easily administered (Al-Shehri et al. 2008). The larger translated form of this questionnaire was shown to be easily administered over the phone (Montazeri et al. 2005); similarly this short form did not produce a burden when administered for this study.

11.6.14 Ethics approvals

Ethics approval was granted from the University of Technology Sydney Health Research Ethics Committee (Appendix 7) and the IRB of RHUH (Appendix 8). Two additional sites were added after approving the study; Makassed General Hospital (Appendix 9) and Mount Lebanon Hospital (Appendix 10). Amendment was then requested to add these two sites to the study and approval was granted from the UTS HREC on this amendment (Appendix 11).

11.6.15 Funding of the FAMILY Study

Funding was generously provided by the Sigma Theta Tau International Honour Society of Nurses for conducting this research. The application (Appendix 12), referral letters (Appendix 13 &Appendix 14), abstract (Appendix 15), grant offer (Appendix 16), reviewers comments (Appendix 17), and guidelines for preparing the Grant final report (Appendix 18) enclosed.

11.7 Significance and Scope of the Thesis

Heart failure is a burdensome condition globally. This problem has received scant attention in Lebanon and the lack of data has outlined the need for focused attention on the heart failure management and outcomes. Although the family unit has always been integral to the Lebanese culture, following recent conflict which has left enduring physical, emotional and social disturbances on the Lebanese population, this is more critical. Moreover, the involvement of the family as a unit in a crisis concerning one of its members is crucial in the Lebanese setting and is hypothesised to produce positive outcomes.

11.8 Overview of the Thesis

This thesis is presented in eight chapters. All chapters, but the first and last are accepted publications or under consideration for publication in peer-reviewed journals. Chapters two through seven begin with an introduction to the chapter linking it to the thesis, aim of each chapter and a brief summary of the results. Some repetition was unavoidable to assure the flow of the presented work. A brief overview of each chapter is presented here.

Chapter one is the introduction chapter of this thesis. This chapter has outlined the background, rationale and outcomes for this study along with the significance and research questions under study.

Chapter two: The first paper was published in Collegian journal, an integrative review was done that included both peer-reviewed and grey literature for better introduction of the Lebanese context. Deek, H., Newton, P., Inglis, S., Kabbani, S., Noureddine, S., Macdonald, P. S., & Davidson, P. M. (2014). Heart health in Lebanon and considerations for addressing the burden of cardiovascular disease. *Collegian*. doi: 10.1016/j.colegn.2014.04.004.

Chapter three: The revised version of the second paper was submitted to the Journal of Advanced Nursing. It is a focussed review paper on experimental studies involving the family/carers in self-care of patients with chronic conditions. Deek, H., Hamilton, S., Brown, N., Inglis, S. C., Digiacomo, M., Newton, P., Noureddine, S., Macdonald, P. S., & Davidson, P. M. (2015). Family-centred approaches to health care interventions in chronic diseases: A quantitative systematic review. *Revised version submitted to Journal of Advanced Nursing, September, 2015*.

Chapter four is the paper presenting the theoretical underpinning of the FAMILY Intervention Heart Failure model with the five steps leading to the formation of this model. This paper was accepted for publication in the Journal of Advanced Nursing. Deek, H., Noureddine, S., Newton, P. J., Inglis, S. C., Macdonald, P. S., & Davidson, P. M. (2015). A family focused intervention for heart failure self-care: Conceptual underpinnings of a culturally appropriate intervention. *Journal of advanced nursing*. doi: 10.1111/jan.12768.

Chapter five presents the protocol used for the randomised trial. This trial was registered in the Iranian registry and the paper was accepted for publication in Nurse Researcher. Deek, H., Noureddine, S., Newton, P. J., Inglis, S. C., Al Arab, G., Kabbani, S., Chalak, W., Timany, N., MacDonald, P. S., & Davidson, P. M. (2015). Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: protocol for block randomized controlled trial. *Nurse Researcher. Accepted June 9th, 2015*.

Chapter six presents the translation and validation of the Arabic version of the Self-care of Heart Failure Index (*A*-SCHFI). The brief report was submitted to the Journal of Cardiovascular Nursing. Deek, H., Chang, S., Noureddine, S., Newton, P., Inglis, S., MacDonald, P. S., Al Arab, G., & Davidson, P. M. (2015). *Translation and Validation of the Arabic version of the Self-care of Heart failure Index (A-SCHFI)*. Under review /Journal of Cardiovascular Nursing.

Chapter seven presents the main findings of the trial including the primary and secondary outcomes under study. The paper was submitted for publication to the European Journal of Heart Failure. Deek, H., Chan, S., Newton, P. J., Noureddine, S., Inglis, S. C., Arab, G., Kabbani, S., Chalak, W., Timany, N., Macdonald, P. S., & Davidson, P. M. (2015). *Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: A randomized controlled trial. Under review/*European Journal of Heart Failure.

Chapter eight is the conclusion chapter where we wrap up this thesis by presenting some of the findings, conclusions and set a platform for future research while we outline some of the limitations which were not addressed in the previous chapter

11.9 List of Appendices

11.10 References

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12. Chapter Two: Heart health in Lebanon and considerations for addressing the burden of cardiovascular disease

12.1 Introduction of Chapter Two

Chapter two presents a review of cardiovascular health in Lebanon (Deek et al. 2014). This paper sought to summarise available data on cardiovascular epidemiology and identify aspects of culture and health service delivery relevant to developing a tailored and targeted health intervention. The paper was published in Collegian in 2014 as per the following citation and permission for including the manuscript in this thesis was gained as per Appendix 19.

Deek, H., Newton, P., Inglis, S., Kabbani, S., Noureddine, S., Macdonald, P. S., & Davidson, P. M. (2014). Heart health in Lebanon and considerations for addressing the burden of cardiovascular disease. *Collegian*. doi: 10.1016/j.colegn.2014.04.004.

A comprehensive literature search for papers and reports on the burden of cardiovascular diseases, its causes and risk factors relating to the Lebanese population was undertaken in order to firstly provide a context for the study and secondly identify sociocultural aspects relevant for developing an intervention for heart failure. The search was performed in several databases and websites with no set year limit.

12.2 Published article

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Heart health in Lebanon and considerations for addressing the burden of cardiovascular disease

Hiba Deek, RN, PhD Research student[a,*],
Phillip Newton, RN, PhD[a,1],
Sally Inglis, PhD, RN, BN, BHSc(Hons), NFESC[a,2],
Samer Kabbani, MD,FACC, FSCAI[b,3],
Samar Noureddine, RN, PhD, FAHA[c,d,4],
Peter S. Macdonald, MD[e], Patricia M. Davidson, RN, PhD[f,5]

[a] *Centre for Cardiovascular and Chronic Care, Faculty of Health, UTS: University of Technology, Sydney, Level 7, Building 10, City Campus, PO Box 123, Broadway, NSW 2007, Australia*
[b] *Clinical Research Unit, Rafik Hariri University Hospital, Lebanon*
[c] *Hariri School of Nursing, American University of Beirut, Beirut 1107 2020, Lebanon*
[d] *Johns Hopkins University School of Nursing, United States*
[e] *Victor Chang Cardiac Research Institute, St Vincent's Hospital, University of NSW, Australia*
[f] *Faculty of Health, University of Technology, Sydney St Vincent's Hospital, Sydney, Level 7, Building 10, City Campus, PO Box 123, Broadway, NSW 2007, Australia*

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KEYWORDS
Lebanon;
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Summary

Introduction: Lebanon is a small country located at the western boundary of the Middle East. Approximately 40% of health care in Lebanon is financed by the public sector. Cardiovascular diseases in Lebanon are scarcely addressed in the literature raising the need for baseline data on these health condition to be better treated.

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[*] Corresponding author. Tel.: +61 413422585.
E-mail addresses: Hiba.a.deek@student.uts.edu.au, hiba.deek@gmail.com (H. Deek), Phillip.newton@uts.edu.au (P. Newton), Sally.inglis@uts.edu.au (S. Inglis), kabbanisamer@hotmail.com (S. Kabbani), sn00@aub.edu.lb (S. Noureddine), pmacdonald@stvincents.com.au (P.S. Macdonald), patriciamary.davidson@uts.edu.au (P.M. Davidson).
[1] Tel.: +61 2 9514 2858; fax: +61 2 9514 4474; mobile: +61 0411 057 056.
[2] Tel.: +61 2 9514 4819; fax: +61 2 9514 4474.
[3] Tel.: +961 01 744773/2; mobile: +961 03 080603.
[4] Tel.: +961 1350000x5966; fax: +961 1744476.
[5] Tel.: +61 2 9514 4822; fax +61 2 9514 4474.

http://dx.doi.org/10.1016/j.colegn.2014.04.004

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Research;
Health;
Arghile;
Narghile;
Water pipe smoke

Aim: To (1) aggregate and define the burden of cardiovascular disease in Lebanon and (2) describe implications for policy, practice and research to improve health outcomes in Lebanon.
Method: An integrative review was conducted of both peer-reviewed papers and unpublished reports. CINAHL, Medline, Google Scholar and Academic Search Complete were searched along with the websites of The World Health Organization, Ministry of Public Health Lebanon and Central Intelligence Agency of Lebanon. No year limit was applied to our search.
Results: The search yielded 28 peer-reviewed articles and 15 reports. Cardiovascular diseases are the leading cause of morbidity and mortality in Lebanon and is also the primary cause of hospital admission. A range of social, political, economic and cultural factors explain the burden of cardiovascular diseases, some of these risks are culture specific such as the arghile smoking and the high rates of familial hypercholesterolemia. Workforce shortage produced by high rates of migrating nurses also has an implication on the patients' outcomes.
Conclusion: Much of the presented data are sourced from the gray literature; more research, using systematic and prospective data collection methods, are needed to inform health services planning, delivery and evaluation. Primary care needs to be enhanced to produce better outcomes for a population with high profile of cardiovascular risk factors.

Introduction

Cardiovascular diseases are major causes of morbidity globally and Lebanon is no exception (Dumit, 2008; Noureddine, Froelicher, Sibai, & Dakik, 2010). Lebanon is a small country located at the western boundaries of the Middle East bordered by the Mediterranean Sea on one side and by Syria and Israel on the other. The capital city of Lebanon is Beirut and the estimated country area is 10,452 m^2 with an approximate population of 4.2 million (The World Factbook, 2011) and a male to female ratio of 0.96 (Lebanon Sex Ratio, 2013). Lebanon has been subjected to social and political upheavals, which have influenced the epidemiological and population profile, and accordingly health service delivery and planning (Abyad, 2001).

There are many reasons behind the deterioration in the Lebanese health context, the main three are the civil war (1975—1990), migration patterns and regional issues. Prior to the civil war, Lebanon, ''the Pearl of the Middle East'', was celebrated annually for the peace and beauty it held. The civil war destroyed much of its beauty and the accompanying peace for which it was known (Abyad, 2001). The war has also destroyed the country's economic health after it was considered ''the banking centre of The Middle East'' (Kronfol, 2006). The long years of war have caused an increase in the migration patterns from and inside Lebanon where the latter has caused crowded living conditions in the capital city Beirut and the surrounding regions. Further, it is now reported that the number of Lebanese outside Lebanon are equal to those residing inside (Abyad, 2001).

Political unrest damaged services and planning across the public and private sectors, including the health care system. Over the last two decades social, political and economic changes have taken place in Lebanon, increasing the need for understanding of the burden of cardiovascular diseases and specifically data to inform health services delivery and planning (Kronfol, 2006). Regional issues affecting the health sector are addressed below.

Health care in Lebanon

Health coverage in Lebanon is divided between the Ministry of Public Health (MOPH), National Social Security Fund (NSSF), the Army, private insurance companies and self-payers. MOPH covers those who are not insured by any other party regardless of their income and health status. This group accounts for almost 42% of the Lebanese population (Ammar, Wakim, & Hajj, 2007). The rest are covered by other parties as follows: (NSSF) National Social Security Fund (30%), private insurance (12%), Army (11%), and civil servants (5%) (Kronfol, 2006). These groups have no emergency department funding unless it is followed by hospitalization (Bayram, 2007). However, these numbers are not accurate when political matters are concerned, evidence suggests that health care availability is significantly linked to the dominant political group at the time of health care need (Chen & Cammett, 2012). These unique findings in Lebanon propose difficulties in seeking health care when needed, knowing that conflicts within its people and surrounding regions are common and require medical and nursing attention regularly.

There are 150 hospitals across Lebanon of which 29 are publicly funded (Abou Mrad, 2012). Furthermore, only 10% of the hospital beds in private hospitals accommodate those funded by the MOH, making bed availability extremely difficult for those not able to pay (Ammar et al., 2000). It was reported that there were 2.88 hospital beds for every 1000 population in the year 2000 (Kronfol, 2006) and this increased to 3.45 beds per 1000 population in 2011 (Harb, 2011) making it the highest ratio among countries in the Middle East and North Africa (MENA) region (Kronfol, 2006). This ratio, however, differs across the Lebanese governorates, where hospital beds are less available in the rural regions. Moreover, more than 65% of these beds are located in small hospitals of less than 70 beds in the North and South regions of Lebanon (Ammar et al., 2000; Harb, 2011) where the latter is a place of constant social and political unrest raising concern regarding the quality of care that can be delivered.

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The physician to population ratio was estimated to be 1:412 in 2006 whereas the nurses to population ratio is 1:1150, which are thought to be among the highest ratios worldwide (Kronfol, 2006). The majority of health care professionals work in tertiary care settings due to the lack of benefits provided in primary settings. Primary health care accounts for less than 5% of the funding spent on health; the bulk of health financing is spent on hospitalization, accounting for 62% of the total funding (Ammar et al., 2000).

Population profile and burden of cardiovascular disease in Lebanon

Mortality related to non-communicable diseases (NCDs) in Lebanon is 404.4 deaths per 100,000 individuals, with an estimate of 45% due to cardiovascular diseases (Lebanon, 2013), making "cardiovascular diseases" the leading cause of death as in many other countries (Noureddine et al., 2010). The hospital admissions reported to be of circulatory nature was the highest in 2011 accounting for 37,277 admissions, out of which 30,940 admissions were due to heart diseases, with the highest peak of hospitalization due to this condition in those aged between 60 and 65 years (Harb, 2011). All things considered, The INTERHEART Study (Yusuf et al., 2004) underscores the similarities in risk factors across regions globally. Health promotion and management of both communicable and NCDs have been priorities in health care projects aimed at diverting the focus from individual interventions to national or regional wellbeing. As a result, death rates have declined and the overall population is increasing, which in turn has shifted the focus of concern of disease consequences from death to disability (Health Promotion, 2013). In Lebanon, 9.2% of the population is aged 65 years and older (The World Factbook, 2011), and this proportion is expected to reach 10.2% by the year 2025 due to the decrease in fertility and mortality rates (Sibai, Sen, Baydoun, & Saxena, 2004). Moreover, 1.25% of the population is aged 80 years and older (Abyad, 2001), while life expectancy is 75.23 years at birth (The World Factbook, 2011).

In line with the purposes of the integrative review, this article seeks to: (1) aggregate and define the burden of cardiovascular disease in Lebanon and (2) describe implications for policy, practice and research to improve health outcomes in Lebanon.

Method

Using the method of integrative review (Whittemore & Knafl, 2005) and in consultation with a health librarian, databases were searched using the key words: "Lebanon", "cardiovascular disease", "research", "health", "arghile", "narghile", and "water pipe smoke". The latter three terms provide the same meaning but were used in the search to capture all articles addressing this habit. The mesh terms used for some databases were: "health knowledge, attitudes, and practice" and "health care sectors". Academic Search Complete, Cumulative Index for Nursing and Allied Health Literature (CINAHL), Google scholar and Medline were searched. The websites of the World Health Organization, Ministry of Public Health Lebanon and Central Intelligence Agency of Lebanon were also searched for this review and all included papers and reports were hand searched for relevant papers. Papers and reports providing data on the burden of cardiovascular diseases, its causes and risk factors relating to the Lebanese population were included and no year limit was applied to our search. Papers were excluded if they presented global data not linked to Lebanon or were not relevant to the purpose of this paper. Considering that all resources were internet based, all unpublished resources such as abstracts were also excluded. The results of this search strategy are shown in Fig. 1.

Results

Twenty eight peer-reviewed articles and fifteen reports were a result of this search.

Burden of cardiovascular diseases in Lebanon

As in many countries where populations are aging, heart failure (HF) is of concern. A major cause of HF is ischemic heart disease (IHD) (Dickstein et al., 2008). IHD was reported to be the primary cause of death globally in 2002 and is expected to remain as such until 2030 in high and low income countries and as the second highest cause in middle income countries (Murray & Lopez, 1997). Hypertensive heart disease was found to be number 13 in the top 15 causes of mortality in countries of similar circumstances (Ammar et al., 2007). In the MENA (Middle East and North Africa) region, IHD and hypertensive diseases were responsible for 155,000 and 61,000 deaths respectively in 2001 (Harb, 2013). In Lebanon, IHD is the first cause of admissions subsidized by the MOH (Statistical bulletin 2011).

Risk factors for cardiovascular disease

While there are limited data on the burden of cardiovascular disease and risk factor profile in Lebanon, some studies provide documentation of the current profile.

Familial hypercholesterolemia is an inherited disorder characterized by abnormally elevated low density lipoprotein (LDL) cholesterol levels and premature cardiovascular disease. It is caused by mutation of the LDL gene. Individuals who have one abnormal gene typically develop premature cardiovascular disease at the age of 30—40, while individuals with two abnormal genes often present with severe cardiovascular disease in childhood (Fletcher et al., 2005). The prevalence of familial hypercholesterolemia is 1 in 500 in most countries, whereas, this condition is much higher among the Lebanese population (Fahed et al., 2011). This increase is due to increased rates of consanguinity. The production of this abnormal allele and its high prevalence among the Lebanese population led to its naming as "the Lebanese allele" (Lehrman et al., 1987). Furthermore, it was reported that 91.5% of those having familial hypercholesterolemia in Lebanon are carrying this mutated gene (Abifadel et al., 2009).

Hypertension is prevalent and the prevalence increases dramatically from 13% and 11% in males and females

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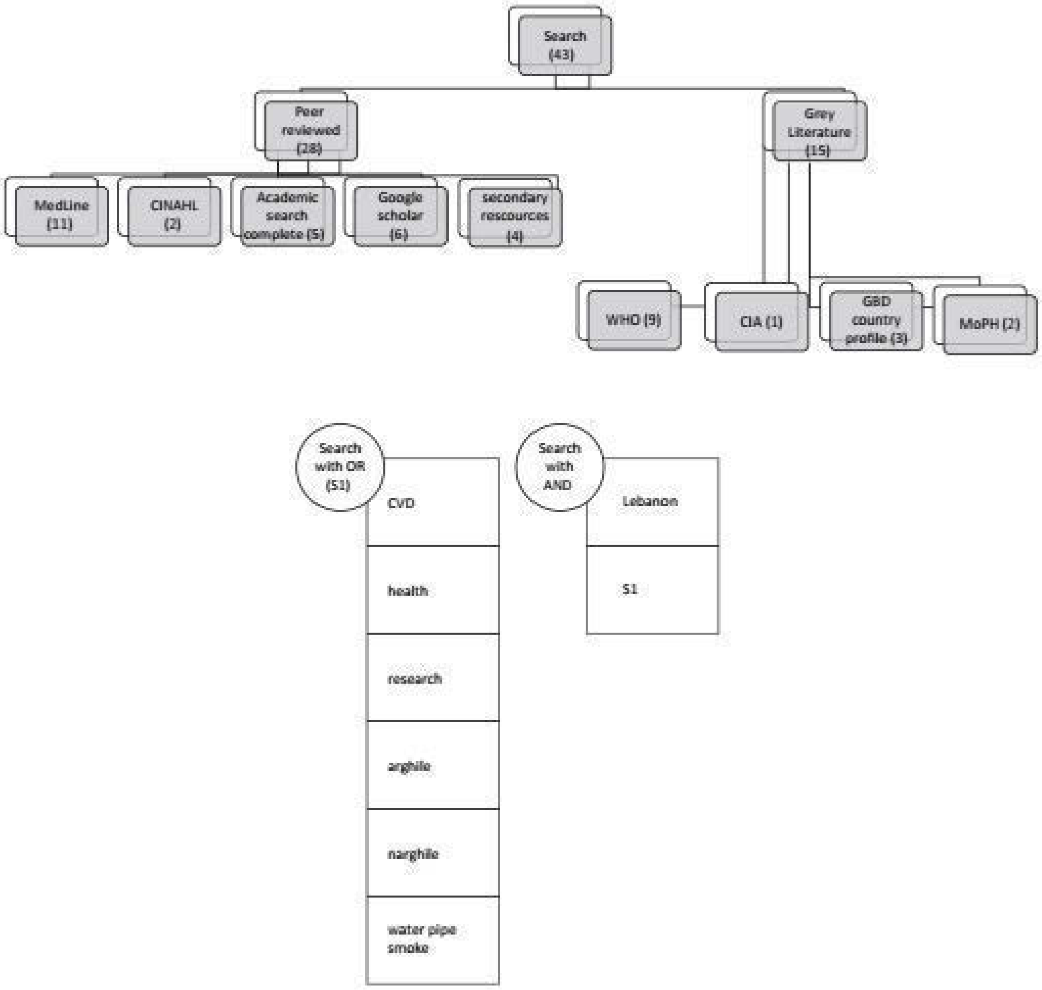

Figure 1 Search strategy and key terms.

respectively below the age of 25, to 33.9% and 26.1% for those aged 25 years and above (Lebanon: Health profile, 2012). On the other hand, a study reported the prevalence of hypertension in a sample of 2125 to be 23.1% while another 4.2% of this sample did not know if they were hypertensive or not (Tohme, Jurjus, & Estephan, 2005). Further, 20.5% of those diagnosed to be hypertensive do not take their prescribed medications (Sibai & Hwalla, 2009) while reasons reported to be behind this practice are cost of treatment, forgetfulness and busy lifestyles (Tohme et al., 2005).

Diabetes was assessed in a sample of 2518 participants from 3 regions of Lebanon in 1997 (Salti et al., 1997). It was found that 3.1% of participants had non-insulin dependent diabetes mellitus and 6% had impaired glucose tolerance. These conditions were very rare in those below the age of 40 years. Furthermore, it was found that those who were diabetic or had impaired insulin tolerance were significantly more obese than their counterparts and had higher cholesterol levels than those who were not diabetic. The latter findings did not reach statistical significance (Salti et al., 1997). A recent report states that 5.9% of the Lebanese population are diabetic while an estimate of 29.6% have never been tested for high blood sugar levels (Sibai & Hwalla, 2009).

Obesity is highly prevalent in Lebanon. 61.8% of the population were found to have a BMI over 25 while obesity accounts for 27.4% of the population ranging between 36.4% in the male population and 29.7% in the female population (NCD Country Profile, 2011). An earlier study showed a slightly higher prevalence of overweight and a lower prevalence of obesity of 64% and 25.1% respectively (Sibai et al., 2008). Heavy weights are due to unhealthy eating habits and sedentary lifestyle, with the former is currently thought to be the leading risk factor for NCD in Lebanon (GBD Profile: Lebanon, 2010). Moreover, 45.8% of the Lebanese population are reported to be physically inactive (Sibai & Hwalla, 2009).

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Among the other cardiovascular disease risk factors is smoking which is a habit adopted by approximately 38% of the Lebanese population (Lebanon, 2013; Sibai & Hwalla, 2009). In addition to the regular cigarette, Lebanese people smoke tobacco through a pipe like instrument, connected to a water base designed to humidify the tobacco. Narghile smoking is a Lebanese cultural habit that begins at an early age and continues to be a daily habit all through life. Tamim et al. (2003), in a sample of 2443 school students between the ages of 11 and 17, reported that the average age of the first smoked narghile was 12 years, with 25.6% of his sample continuing to smoke narghile after the first trial. It is currently reported that 22.4% of the Lebanese population are current narghile smokers (Sibai & Hwalla, 2009). Another study showed that 21.1% of university students smoked narghile while this practice was significantly higher in alcohol smoking male students (Tamim et al., 2007). It was reported that reasons for taking up narghile smoking were nicotine dependence, as an approach to improve morale, a substitute for eating when trying to lose weight and social influence where the majority of smokers are those who have nicotine dependence and social influence (Salameh, Waked, & Aoun, 2008). In a study comparing the amounts of different metals present in both the narghile and the regular cigarette, Shihadeh (2003) reported the following comparisons: arsenic weighed 164 ng and 120 ng in narghile and cigarettes respectively, chromium weighed 1340 ng and up to 70 ng with narghile and cigarette respectively, beryllium weighed 65 and 300 ng with narghile and cigarette respectively, while lead weighed 6870 ng and 34–85 ng in narghile and cigarette respectively, noting that those metals are human carcinogens (Shihadeh, 2003).

Depression has been shown to be a major risk factor for causing cardiovascular diseases in healthy individuals and a cause of major adverse health events in patients already diagnosed with these diseases (Whooley, 2006). Lebanese people have faced multiple safety threats that could lead to major depressive symptoms. A cross-sectional study assessing the lifetime prevalence of depression across four Lebanese regions showed it to be 27.8% among this entire population with the highest rates in the regions where the war lasted longest (Karam et al., 1998). A more recent study addressed the effect of war on the depression level of a Lebanese sample living in the villages mostly exposed to instability, they found in a regression model that with every 10 unit increase in the war exposure score, there was a 56% increase in the odds of having post-traumatic stress disorder (PTSD) which showed a significant correlation ($p < 0.001$) (Farhood & Dimassi, 2012).

The percentage of people in Lebanon with a history of heart disease was reported at 52.2% in a survey of 401 individuals not previously diagnosed with heart disease (Noureddine, Massouh, & Froelicher, 2013). Reporting of some of the aforementioned risks from estimates suggests the need for further studies. Also a professional's focus should extend beyond "chemical" treatments to a behavioral risk management program that includes education of patients not only on taking their medication but also on major life-style modifications including smoking cessation, increasing physical activity and healthy eating. Unfortunately, while patients consider their physicians as their role models, some of these physicians are smokers themselves (Jazra, 2004).

Resources and infrastructure for both primary and secondary prevention is limited. The average delay in seeking medical attention after a coronary event was 4.5 h in a Lebanese sample of 212 patients recently experienced a myocardial infarction (Noureddine et al., 2006). Most of this delay can be attributed to lack of knowledge of ischemic heart problems despite having experienced such events previously (Noureddine, 2009). These findings indicate that there is an urgent need to develop both primary and secondary prevention strategies for the Lebanese (Jazra, 2004).

Description of nursing in Lebanon and Implications for advance practice nursing roles

Nursing in Lebanon, as in most countries of the world suffers from a vast shortage of working nurses in hospitals. The unique context behind this shortage is the years of war which the country was subjected to in the past as well as the current unrest. The war has caused tremendous numbers of nurses to migrate from Lebanon (El-Jardali, Dumit, Jamal, & Mouro, 2008). Other reasons behind this shortage include the dissatisfaction of nurses with their roles, work environment, salaries, and managers among other reasons. This dissatisfaction caused 1 in 5 nurses to migrate 2 years after graduation (El-Jardali et al., 2011), not to mention the vital political activities which affect the country greatly from time to time (Lorenzo, Galvez Tan, Icamina, & Javier, 2007). The aggravation due to nursing shortages and professional dissatisfaction leads to negative impacts on patient outcomes (Baernholdt & Mark, 2009).

In light of the negative impact on patient outcomes, plans for improvements of hospital settings and community services are impending. Such services include those done by Nasser and Doumit (2011) for the care of elderly in specialized outpatient settings where basics of care such as food, toileting, treatments as well as financing and staffing were discussed to provide the necessary outpatient care for the elderly with chronic diseases. Others (Huijer, Dimassi, & Abboud, 2008) emphasize the importance of establishing palliative care programs for those with chronic diseases in Lebanon. Huijer (2006) reported the importance of the nursing profession in the provision of health in the Lebanese community and the promotion of health for those with chronic diseases such as heart failure. This type of community based care can lead to reduced hospital readmission rates as well as reduced length of hospital stay when hospitalization becomes inevitable. Improvements to the nursing profession are still in their infancy but progress is being made especially after the establishment of the Order of Nurses in 2002 despite of all the political unrest (Huijer, Noureddine, & Dumit, 2005). Recognition of the advanced roles of nurses should be implemented and will guarantee improvements in chronic care management.

Implications for policy, practice and research to improve health outcomes in Lebanon

Although these factors are salient in many countries, some elements are of a particular concern in Lebanon. Social and

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Tamim, H., Al-Sahab, B., Akkary, G., Ghanem, M., Tamim, N., Roueiheb, Z. E., et al. (2007). Cigarette and nargileh smoking practices among school students in Beirut, Lebanon. *American Journal of Health Behavior*, *31*(1), 56–63.

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12.3 Summary

The search yielded 28 peer-reviewed articles and 15 reports which have identified that cardiovascular diseases are the leading cause of morbidity and mortality in Lebanon and is also the primary cause of hospital admission. A range of social, political, economic and cultural factors explain the burden of cardiovascular diseases, some of these risks are culture specific such as the narghile smoking and the high rates of familial hypercholesterolemia. Workforce shortage produced by high rates of migrating nurses also has an implication on the patients' outcomes.

Much of the presented data are sourced from the grey literature; more research, using systematic and prospective data collection methods, are needed to inform health services planning, delivery and evaluation. Based upon this literature review it was identified that the hospital was the optimal setting for this study given the limited activity in primary care. In addition, as the burden of cardiovascular disease increases positioning nurses to deliver and coordinate chronic care is optimal.

The following chapter presents a literature review on experimental studies evaluating the effect of family involvement on outcomes of patients with chronic conditions.

12. Chapter Three: Family-centred approaches to health care interventions on chronic diseases: A focussed literature review

12.1 Introduction of Chapter Three

This chapter presents a review paper on family involvement in the self-care of patients with heart failure. The paper aimed to identify elements of effective family-centred self-care interventions likely to improve outcomes of patients. The revised version of this paper was submitted to the Journal of Advanced Nursing as per appendix 20.

Deek, H., Hamilton, S., Brown, N., Inglis, S.C., Digiacomo, M., Newton, P., Noureddine, S., Macdonald, P.S. & Davidson, P.M. 2015, 'Family-centred approaches to health care interventions in chronic diseases: A quantitative systematic review', *Revised version submitted to Journal of Advanced Nursing, September, 2015*.

Family involvement in self-care of patients with heart failure is often implicit in disease management models but not often systematically and prospectively applied. Literature on a family-focused approach in patients with heart failure is lacking. In order to establish an evidence base for the intervention, described in Chapter four, a literature review on experimental studies evaluating the effect of family involvement on outcomes of patients with chronic conditions was undertaken. A search strategy to capture for family, self-care and family-centred interventions, was developed in collaboration with by a health librarian. Several data bases were searched and the year limit was set to the past 14 years (2000-2014). Although a family approach was hypothesised to be appropriate in collectivist societies, the search included studies from international literature to better understand the needs of patients in general.

12.2 Submitted Article

Family-Centred Approaches to Health Care Interventions in Chronic Diseases: A Quantitative Systematic Review.

Abstract

Background: Increasingly there is a focus on self-care strategies for both malignant and non-malignant conditions. Models of self-care interventions have traditionally focussed on the individual and less on the broader context of family and society. In many societies, decision-making and as a consequence health seeking behaviours, involve family members.

Objective: To identify elements of effective family-centred self-care interventions that are likely to improve outcomes of individuals living with chronic conditions.

Design: Review paper.

Data Sources: MEDLINE (Ovid), CINAHL, Academic Search Complete, PsychInfo, and Scopus between 2000 and 2014.

Review Methods: Quantitative studies targeting patient outcomes through family-centred interventions were retrieved using systematic methods in January, 2015. Search terms used were: "family", "spouse", "carer", "caregiver", "chronic", "chronic disease", "self-care", self-management", and "self-efficacy". Reference lists of related articles were further reviewed for studies.

Study appraisal: Risk of bias assessment was performed using the Cochrane Collaboration's tool.

Synthesis methods: Data were reported using a narrative summary approach.

Results: Ten studies using quantitative approaches were identified. Improvements were noted in readmission rates, emergency department presentations, and anxiety levels using family-centred interventions compared to controls**.** Elements of effective interventions used were a family-centred approach, active learning strategy and transitional care with appropriate follow-up.

Conclusions: Involving the family in self-care has shown some positive results for patients with chronic conditions. The benefits of family-centred care may be more likely in specific socio-cultural contexts.

Limitations: The review has year limits and further research needs to identify support for both the patients and family caregivers.

Keywords: Literature review, nursing, caregiver, chronic disease, family, self-care and self-management**,** spouse**.**

Impact statements:
• Patient outcomes can be improved when the types of support; informational, instrumental and emotional are tailored to the patients' needs and health conditions.
• Family-centred approaches maybe more suited to Non-Western, collectivist cultures while patient-centred approaches may be more suited in Western cultures.
• The duration of the response may be more related to the type of outcomes targeted through the intervention rather than the dose of the intervention.
• No pooled evidence is available in the literature. There is a need for further intervention studies addressing the effectiveness of family-centred care in managing patients with chronic conditions.

Introduction

Chronic conditions are a major source of burden to individuals and society (Beaglehole et al. 2008), they account for 60% of global mortality and are expected to increase to 80% by 2020 (World Health Organization 2002). The increasing prevalence of these conditions is due to a range of factors including urbanisation, ageing population and changes in dietary and lifestyle patterns (Yach et al. 2004).

Most chronic conditions involve changes in lifestyle (including diet, activity, and medication adherence) and so management occurs mainly in the community setting (Jaarsma et al. 2003). An increasing focus on chronic and complex conditions has magnified the focus on self-care which is defined as an individual's decision to maintain wellbeing and an approach enacted to do so (Riegel & Dickson 2008). Self-care can be more broadly envisioned through a theoretical lens that represents the patient, with complex health conditions, as an agent needing care by another (Denyes, Orem & Bekel 2001) but this approach has been challenged by the need for self-agency. The burden imposed by chronic conditions, the severity and complexity of their regimens has necessitated novel approaches to providing care for chronic lifelong health conditions, such as thoughtfully and intentionally involving the family in health care (Chesla 2010). Filling medication prescriptions and assisting with administration, shopping for healthier food and encouraging the sick family member to do physical activity are approaches a family caregiver can be involved in to improve outcomes (Rosland & Piette 2010). Often this involvement is implicit but less explicitly defined. These are among the health, family, individual and environmental resources identified by Grey, Knafl & McCorkle (2006) to be factors affecting the delivery of self-care and self-management. Grey and colleagues proposed the Self and Family Management Framework highlighting the risk and protective factors affecting patient outcomes. These factors can be targeted though either individual or family approaches to improve patient outcomes. This framework was proposed due to the shift of care from tertiary to primary with the increasing burden of chronic conditions (Grey, Knafl & McCorkle 2006). This approach has also gained traction across the world with many health care systems placing an increased emphasis on care in the community (Islam et al. 2015).

As hospitalisation, quality of life, self-care and medication adherence are frequently used by policy makers as markers of both patient outcomes and organisational efficiency this review focussed on these constructs. This paper is timely as many governmental and funding agencies are interested in the role of family in health care (Davidson & DiGiacomo 2015).

Background

Definition and background of self-care

Self-care is essential in the management of chronic conditions and failing to engage in self-care practices is likely to contribute to adverse health outcomes (Riegel & Dickson 2015). The increasing burden of chronic conditions has fuelled scholarly debate and discussion on self-care approaches and its application in different settings and cultures (Davidson et al. 2013). Self-care is defined differently across disciplines. In nursing, which is our focus, self-care is based on outlining the treatment goals and assessing the patient's capability of carrying out activities to reach these goals (Gantz 1990). Riegel & Dickson (2008) defined self-care based on two major concepts, maintenance and management, where one decides to act as a response to physiologic instability to maintain wellbeing. The word self-management emerged to mean the ability to manage one's health condition, symptoms, and lifestyle changes and maintain physical and psychosocial wellbeing (Coster & Norman 2009). These terms; self-care and self-management, are sometimes used to reflect the same meaning and so are used interchangeably (Moser & Watkins 2008; Riegel & Dickson 2008).

How are social support & self-care addressed in the literature?

To date, discussion and debate on health care interventions have focussed on the individual with a lesser focus on the broader socio-cultural context of that person and this is attributable to the dominance of Western perspectives. This is true despite that a change in one family member's health condition can negatively affect the whole family (Ryan & Sawin 2009). Social support can be provided from family members, partners, friends, healthcare professionals and others (Pressler et al. 2013). It can be provided in different forms that are all necessary for optimal patient outcomes. These forms are emotional, informational and instrumental support (Kalichman, Sikkema & Somlai 1996). Emotional support is the provision of comfort, empathy, and understanding to the chronically ill patient. Informational support is the delivery of appropriate knowledge specific to the patient's current condition. Instrumental support is aiding the patient with activities of daily living when needed (Cohen 1998; Linn et al. 1993; Meyerowitz 1980).

Types of care provided from different support groups

The impact of social relationships on health has long been established in the literature; those who are socially isolated have more risk factors, poorer health outcomes and are less flexible to lifestyle changes (Hawton et al. 2011). Conceptually, there are potential links between qualities of relationships and improved tangible assistance in self-care behaviours (Salyer, Schubert & Chiaranai 2012). Different support people (i.e. spouse vs. son/daughter vs. other (friend or relative)), are thought to provide varying levels of care. For example, patients having a friend's support were found to have more self-care confidence which was lacking with those having spouse support (Sayers et al. 2008). This could be explained by the patients' dependence on the spouse. However, with the spouses' support, patients with heart failure had better lifestyle adaptation and medication adherence (Martire et al. 2010; Molloy, Johnston & Witham 2005). Moreover, married patients had significantly longer event-free survival than non-married patients, and those with a “high quality marriage” had significantly better survival after four years of follow-up than their counterparts (Rohrbaugh et al. 2004).

The concept of family involvement in care

Family-focussed care has its foundation in caring for children. This form of care is the tenet of nursing care for sick children globally (Coyne et al. 2011). The concept was introduced almost 60 years ago and has received considerable attention in the literature focussing on the theoretical basis and underpinning nursing constructs (Shelton 1987). Family-centred care has been analysed through two approaches, either parents viewed as equal partners of care for their children or being supervised by the nurse in a hospital setting (Hutchfield 1999). Family involvement evolved to include the adult population when treatment goals shifted from curative to palliative with chronic conditions (Pressler et al. 2013). This increasing burden of hospitalisation and increasing fiscal constraints have pushed the family to become partners of care in the community (Kaakinen et al. 2014). This is especially true in low and middle income countries where families play an important role in health care (Tolle 2009). This along with the natural family connectedness especially in non-western cultures (Beitin & Aprahamian 2014), make family involvement vital in the care of patients. Although starting as a resolution for shortage of resources and cost, family-centred approaches have been shown to be associated with improved caregiver satisfaction and quality of care in hospital settings (Tandberg et al. 2014). This was also highlighted in a number of studies using qualitative approaches where patients with stroke and aphasia emphasised the importance of family connectedness and support on their outcomes (Brown et al. 2012). Furthermore, an established positive relationship between healthcare workers and the family can lead to better understanding of the disease condition, coping and adherence to self-care instructions (Driscoll et al. 2009; Foster, Whitehead & Maybee 2010).

Application of self- care in chronic conditions has improved outcomes such as readmission rates (Carr et al. 2014), mortality rates (Laxy et al. 2014), and quality of life (DeWalt et al. 2012) and reduced healthcare cost (Mejía et al. 2014). However, interventions aimed at improving outcomes were described in the literature mainly without identifying the elements that led to their success.

Aim

As presented, the type and source of support needed by patients with chronic diseases differ according to their health conditions; so what elements of family-centred self-care interventions, that are likely to improve outcome of patients with chronic conditions, can be identified from quantitative studies?

Design

This review focussed on quantitative studies on family-centred interventions in chronically-ill adult patients. Studies included randomised and non-randomised experimental designs (level II, III-1 and III-2 studies according to NHMRC level of evidence scheme (Coleman et al. 2009) addressing the involvement of family members in the management of patients with any chronic condition. This design also conforms to the EPOC (Effective Practice and Organisation of Care) review guidelines which states the pertinence of including a wider range of quantitative studies in the absence of enough randomised trials to address questions on health care delivery and implementation strategies (EPOC Resources for review authors 2013). The EPOC guidelines were followed without deviations although an integrative approach, including both experimental and non-experimental studies, was considered to provide a greater understanding of the role of family caregivers.

Search methods

Databases searched were MEDLINE (Ovid), CINAHL, Academic Search Complete, PsychInfo, and Scopus (Elsevier). References of relevant articles were also searched for articles meeting the inclusion criteria. Search terms used were combinations of “family”, “spouse”, “carer”, “caregiver”, “chronic”, “chronic disease*”, “self-efficacy”, “self-care”, and “self-management”. These terms were searched for in titles, abstracts and keywords. Since self-care and self-management maybe used interchangeably in the literature, both terms were used in our search; but for this review we were interested in self-care defined as outlining treatment goals and adopting strategies to reach these goals. A family was defined as two or more persons, one of whom is at least 15 years of age, who are related by blood, marriage (registered or de facto), adoption, step or fostering, and who are usually resident in the same household (Australian Bureau of Statistics 2012). Family-centred interventions were defined as educational interventions on self-care that included sessions, handouts or prescheduled visits provided to the patient and the family caregivers. These sessions were about the health condition which had caused a hospitalisation or health decline. The search was limited to include only intervention studies on adult human beings of papers published in English, in peer-reviewed journals between 2000 and 2014. The search was last done in January, 2015.

Search outcomes

The primary outcomes of interest were readmission rates, self-care, quality of life and medication adherence. Secondary outcomes were cost, mortality, and satisfaction with no limit to the follow-up period under study. Studies were excluded if they were not intervention studies, caregiver-focused outcome interventions, had no family involvement, centred on paediatric and adolescent populations, review papers, pilot studies, protocols, or concerned non-chronic conditions. Papers having more than one exclusion criteria were categorized as irrelevant. Table 3.1 presents the search strategy used in the three databases; MEDLINE, Cumulative Index of Nursing and Allied Health Literature (CINAHL) and Academic Search Complete and the online. Table 3.5 presents the full online version of the search strategy.

Quality appraisal

The quality of the studies reviewed was appraised by two independent reviewers (HD & NB). Risk of bias assessment is presented in Table 3.2 (online version) using the Cochrane Collaboration's tool for assessing the risk of bias (Higgins et al. 2011). Risk of bias assessment was summarised for the review as a whole (EPOC Resources for review authors 2013).

Data abstraction

After removing the duplicates, screening for relevance and abstraction (title ad abstract) was performed by two people (HD and PJN) using pre-set search criteria that were devised with the assistance of a health librarian. Any disagreements were resolved by the involvement of the principal author of this paper (PMD) and there was no need to contact any of the paper authors for additional data.

Synthesis

Data were reported using a narrative summary approach due to heterogeneity across the studies of the outcomes reported.

Results

The primary search of the databases yielded 1265 articles. Articles extracted from the databases were as follows: MEDLINE (69), CINAHL (153), Academic Search Complete (546), PsychInfo (317), Scopus (Elsevier) (180). Additional articles were retrieved through hand searching of the reference lists of the relevant articles to yield an additional 7 articles. Duplicates were removed leaving 677 records to be screened. After screening the titles, 656 records were excluded leaving the remaining 23 papers for a full-text eligibility assessment. Ten articles met the search criteria. Figure 3.1 outlines the search strategy based on the PRISMA flowchart. Characteristics of the selected studies are presented in Table 3.3. Number of excluded articles and reasons for exclusions are presented in Table 3.4.

Following analysis of the retrieved studies, the following themes emerged: caregiver identification; identified studies and study types; interventions used across the studies, operationalization of the interventions, and outcomes achieved in the studies. These themes are addressed below:

Caregiver Identification

There was no consensus on a definition for a family caregiver across the studies. A caregiver was defined as the person helping with daily living activities and advocating on the patient's behalf (Kalra et al. 2004), a person living with the patient (Smith, Forster & Young 2004), or a family member/significant other/spouse or partner classified by the patient as their primary source of physical and emotional support (Northouse et al. 2005) or the spouse who provided emotional or physical care (Northouse et al. 2013; Northouse et al. 2007). Couples were recruited if they identified themselves as in a committed relationship which they perceived as viable for at least another year (Remien et al. 2005). Smith, Forster & Young (2004) and Ågren et al. (2012) identified the carer as someone living in the same household as the patient while Shahriari et al. (2013) added an age and a literacy factor where caregivers had to be aged more than 18 years and literate. No definition was provided by Coleman et al. (2004).

Identified studies and study types

We have used the American Heart Association disease management taxonomy that standardises and facilitates reporting and comparison of health care interventions (Krumholz et al. 2002). This taxonomy was used here to provide a summarised description of each individual study presented in Table 3.3. A total of 1,823 patients along with their family caregivers, which were all dyads, were recruited to test the impact of educational sessions on their chronic diseases. The identified chronic conditions were heart failure (Ågren et al. 2012; Shahriari et al. 2013), chronic obstructive pulmonary disease, coronary artery disease, diabetes, stroke, medical or surgical back conditions, hip fracture, peripheral vascular diseases, arrhythmias (Coleman et al. 2004), stroke (Kalra et al. 2004; Smith, Forster & Young 2004), persistent knee pain (Keefe et al. 2004), recurrent breast cancer (Northouse et al. 2005), prostatic cancer (Northouse et al. 2007), advanced cancer (Northouse et al. 2013), and HIV (Remien et al. 2005). All studies but one (Coleman et al. 2004) randomized their participants to intervention or control groups. All studies had either a control or an intervention group except for Keefe et al. (2004) who divided his participants into 3 intervention groups vs. usual care group and Northouse et al. (2013) who divided his participants into a brief intervention, extensive intervention or the control groups. The usual care group or the control group was not defined in some studies (Coleman et al. 2004; Keefe et al. 2004; Northouse et al. 2005), while others defined usual care as conventional care (Ågren et al. 2012; Northouse et al. 2013; Northouse et al. 2007; Shahriari et al. 2013), counselling provided to the patients and/or their caregivers on medication adherence (Remien et al. 2005), community services, encouragement to attend nursing activities and involvement in discharge planning (Kalra et al. 2004), or having a reader manual about the patient's health status available for the patient when needed (Smith, Forster & Young 2004). Participants were stratified by couple type (Remien et al. 2005), treatment type (Northouse et al. 2005), study site, phase of illness (Northouse et al. 2013; Northouse et al. 2007) and cancer type (Northouse et al. 2013) or Barthel Index scores (activities of daily living) and aphasia in stroke patients (Smith, Forster & Young 2004).

Interventions used across the studies

All studies involved face to face educational sessions with the patients and their caregivers. However, the type of sessions and the follow-up varied across the studies. These details are presented in Table 3.3 and briefly summarized below. Three categories of interventions were identified: self-care strategies, coping skills and education and support.

Improving patient self-care and carer support (Ågren et al. 2012; Coleman et al. 2004; Keefe et al. 2004; Remien et al. 2005; Shahriari et al. 2013)

Coleman et al. (2004) assigned a transition coach to the patients and their caregivers and arranged for a home visit within 72 hours of discharge from the hospital (Coleman et al. 2004). The coach's role was to encourage communication between the patients, their caregivers, and the healthcare professionals. The coach emphasised medication adherence, identified warning signs, provided more education about the condition and its treatment, and provided support to the caregivers in having an active role in their patients' treatment. This educational visit was followed by a series of telephone calls to the patient to enhance the provided education. The coach was involved in any hospital or clinic visit of the patient for 24 days after discharge (Coleman et al. 2004). Similarly, Ågren et al. (2012) administered psychosocial support intervention to both the patients and their caregivers to strengthen their physical and mental function and improve their perceived control over their health condition and consequently their self-care. Other interventions included 12 weekly, 2-hour sessions on spouse-assisted pain coping skills training (SA-CST), 60 min 3 times weekly exercise training (ET) or both to the caregivers comparing them to a control group (Keefe et al. 2004). HIV patients and their partners were invited to four discussion sessions over 5 weeks. These 45 to 60 min sessions included education on viral resistance, medication adherence and partner support (Remien et al. 2005) and caregivers of patients with heart failure were invited to 3 weekly educational sessions on the related health condition and self-care skills (Shahriari et al. 2013).

Increasing patient and carer coping skills (Northouse et al. 2005; Northouse et al. 2013; Northouse et al. 2007)

Northouse et al. (2005, 2007 & 2013) divided the FOCUS intervention into 2 phases: phase one comprised 2-4 monthly educational home visits involving both the patients and their caregivers and phase two was one or two 30 min phone calls identified as the booster phase. The latter phase included emphasis on the provided information and assessment of the patients' wellbeing. The FOCUS intervention involved education on Family involvement, Optimistic attitude, Coping effectiveness, Uncertainty reduction, and Symptom management (Northouse et al. 2005; Northouse et al. 2013; Northouse et al. 2007).

Patient and carer education and support (Kalra et al. 2004; Smith, Forster & Young 2004)

A multidisciplinary approach was adopted by Smith, Forster & Young (2004) where stroke patients and their caregivers were invited to fortnightly, 20 minute educational meetings in the stroke wards (Smith, Forster & Young 2004). On the other hand, Kalra et al. (2004) provided three to five educational sessions to caregivers of stroke patients. These sessions provided education on management of incontinence, nutrition, prevention of ulcers and positioning. These sessions also included hands on training on transferring, positioning and assisting their patients in their daily living activities (Kalra et al. 2004).

Operationalization of the interventions

Most educational sessions were conducted by trained post-baccalaureate clinicians with clinical experience. Clinicians included a PhD prepared psychologist (Keefe et al. 2004), a Masters prepared geriatric nurse practitioner certified in chronic disease self-management (Coleman et al. 2004), a Masters prepared nurse (Northouse et al. 2005; Northouse et al. 2013; Northouse et al. 2007), and a nurse practitioner (Remien et al. 2005). The multidisciplinary approach (Smith, Forster & Young 2004) included a rehabilitation team of doctors, nurses, physiotherapists and occupational therapists. There was no mention of who provided the educational sessions and the training in the studies conducted by Kalra et al. (2004) and Shahriari et al. (2013) while Ågren et al. (2012) mentioned that his interventions were nurse-led without identifying their qualifications.

Coleman et al. (2004) used a quasi-experimental approach to evaluate the effect of transitional care on readmission. Therefore outcomes such as level of confidence in care were only reported in the intervention group. The implementation of a randomized trial allows for control of confounding variables in both arms of the study. This was interpreted by Northouse et al. (2005) who found baseline difference between the control and the intervention group with less negative appraisal of illness and hopelessness in the former group. These differences were controlled for statistically when analysing the difference in outcomes between groups. Similarly, Remien et al. (2005) found a significantly different baseline variable between the groups where the control group had higher income than the intervention group. These baseline differences may have had an impact on the findings of these studies in producing less favourable results of the intervention. Other studies (Kalra et al. 2004; Keefe et al. 2004; Shahriari et al. 2013; Smith, Forster & Young 2004) found no significant differences between the groups at baseline.

Outcomes achieved in the studies

The main outcomes that were sought in this review were readmission rates, quality of life, self-care and medication adherence. Significant reductions in the readmission rates at 30, 90 and 180 days: adjusted odds ratios 0.52 at 30 days (95% CI, 0.28, 0.96, p = 0.04), 0.43 at 90 days (95% CI, 0.25, 0.72, p = 0.002), 0.57 at 180 days (95% CI 0.36, 0.92, p = 0.02) and a significant prolongation in time to rehospitalisation (Intervention 225.5 days, control 217.0 days. HR=0.59 (95% C.I.0.41, 0.83, p = 0.003) were noted after Coleman's intervention (Coleman et al. 2004). Patients' quality of life showed varied improvement across the studies at 3, 6 and 12 months (Ågren et al. 2012; Kalra et al. 2004; Northouse et al. 2005; Northouse et al. 2013; Northouse et al. 2007). Medication adherence with the HIV patients significantly improved (change score b = - 22.38; p < .001) when involving the caregiver (Remien et al. 2005). Also, self-care behaviours were significantly improved after the intervention (28 vs. 47 in the control group and the intervention group respectively, p<0.001) in patients with heart failure (Shahriari et al. 2013).

The lack of consistency across the studies limits providing a clear set of elements that could improve patients' outcomes. However, identifying specific patient needs and identifying specific caregiver roles were shown to be vital in improving these outcomes. Some elements of interventions pinpointed in these studies included hands on training to caregivers of patients with stroke. This specific training on prevention of bedsore, optimal nutrition, and positioning reduced the cost of hospitalisation and treatment of complications. Other elements of interventions that improved outcomes in terms of readmission were the provision of long term educational sessions on self-care with active learning strategies, identification of the warning signs, family-centred approaches, self-care tools such as diaries, transitional care and proper follow-up. These elements provided empowerment to the patients and their caregivers while caring for the identified chronic health condition.

Risk of bias assessment

Risk of bias was assessed using the Cochrane Collaboration's tool (Higgins et al. 2011) based on its seven criteria. For each criteria, each study was classified as low, unclear or high risk of bias. Sources of bias were identified with the absence of random number generator and blinding of participants and outcomes assessment leading to possible overestimation of the study findings.

Selection bias was carefully avoided in four studies only (Kalra et al. 2004; Remien et al. 2005; Shahriari et al. 2013; Smith, Forster & Young 2004). The remaining studies either did not randomise (Coleman et al. 2004) or did not mention the randomisation process (Table 3.2). Concealment of allocation or blinding of participants was not appropriate in any of the studies but one (Smith et al. 2004) when measuring medication adherence. Detection bias was violated in all studies but one (Northouse et al. 2007) with either no mention of blinding the outcome assessors or the absence of randomisation (Coleman et al. 2004). Furthermore, GRADE was used for grading the certainty of evidence of the outcomes of interest, readmission, self-care, quality of life and medication adherence. The grading was based on the design, risk of bias, inconsistency, indirectness, and imprecision. The scores (-1 or +1) are then summed to yield an overall score (4=high, 3=moderate, 2=low and 1=very low)(EPOC Resources for review authors 2013). The certainty of evidence was rated moderate for these outcomes. In brief, in addition to the moderate rating of the evidence, most information came from studies at low or unclear risk of bias. Therefore, despite effective intervention, results should be interpreted with caution.

Discussion

The importance of family involvement in the care of patients with chronic conditions has been outlined in the literature using experimental and qualitative approaches (Knafl et al. 2013; Shilling et al. 2013). In spite of this importance, only ten studies examining family/partner interventions were identified. The aim of the review was to present elements of family caregiver interventions likely to improve outcomes of patients with chronic conditions. The limited number of studies conducted, heterogeneous populations (i.e. patients with different chronic conditions) and the different clinical outcomes interventions studied, make it difficult to identify the elements that make family-centred interventions effective. However, outcomes varied depending on the type of support provided for each patient and how the roles of their caregivers were defined by the authors. When activities of daily living were the primary caregiver’s role i.e. instrumental support, quality of life improved significantly after the intervention (Kalra et al. 2004). This finding was supported by a study undertaken with patients with COPD where instrumental support was identified as one of the relevant domains affecting patients’ quality of life (Paap et al. 2014). Conversely, quality of life did not improve (Northouse et al. 2005; Northouse et al. 2013; Northouse et al. 2007) when the carer was a source of emotional support.

Similarly, readmission was not reduced when solely assistance in activities of daily living was provided (Kalra et al. 2004) while it improved significantly up to 180 days with empowering educational interventions to the dyads (Coleman et al. 2004). The latter finding was greatly supported by more recent literature (Peter et al. 2015; Wahba, Hughes & Baroni 2015). These findings suggest that outcomes can be better targeted for improvement when specific and subjective patient needs are met.

While there were significant differences between the intervention and control groups in outcomes at the short term follow up, these differences waned with longer follow-up periods (Ågren et al. 2012; Northouse et al. 2005; Northouse et al. 2013; Northouse et al. 2007; Remien et al. 2005). This trend was a consistent finding with intervention studies targeting health outcomes (Karinkanta et al. 2015), although the dosage of the intervention or the characteristics of the participants (Sheffet et al. 2015) may explain it. On the other hand, interventions targeting coping produced sustained improvements (Northouse et al. 2013) suggesting that the duration of the response may be more related to the type of outcome targeted through the intervention rather than the dose of the intervention (Northouse et al. 2013).

Multidisciplinary approaches

Pooled data have shown the significant effect of multidisciplinary approaches in improving outcomes of patients with severe chronic conditions, such as heart failure (McAlister et al. 2004). Systematic reviews demonstrate the effect of such approaches in reducing mortality, condition specific readmission and all-cause readmission (McAlister et al. 2004). The key to this success is the follow-up of these patients with a multidisciplinary team or in a multidisciplinary clinic. It was recommended in the review that caregivers be partners in care. They need to be provided information about the health condition, lifestyle management and medication adherence, be involved in the management plan and accompany their patients to follow-up appointments. In the current review, Smith, Forster & Young (2004) reported the effect of a multidisciplinary approach in reducing anxiety levels in stroke patients, but no readmission rates were reported. Within these complex interventions there is a need to carefully describe unique components and to date there has been a limited focus on family caregivers.

Informal caregiving in western vs. non-western societies

The importance of family unity is often more pronounced in non-western countries (Tseng & Verklan 2008). Family ties and the perception of society as a group of related individuals rather than individuals, a concept known as collectivism, is reflected in many minority groups, such as the African American (Kreuter et al. 2003). However, only one study from non-Western countries was identified in our search (Shahriari et al. 2013). In fact, all other nine studies were conducted in Sweden, the United Kingdom and the United States of America.

This review has some limitations. First, limiting the years of the search to the last 14 years and to the English language only may have excluded some important studies conducted within non-western cultures and before that time frame. However, we wanted to identify the most recent literature and the exhaustive database search was likely to cover the available studies. The other limitation was the exclusion of qualitative studies and the grey literature which could have enriched our findings and understanding of the concept of family-focused care. This exclusion however, was based on the aim of the study to identify the elements of effective interventions in chronic conditions and self-care. Furthermore, addition of search terms such as “parents” and naming the chronic condition such as diabetes and heart failure could have provided a richer input on other possible pathways of family models. Yet the paucity of studies using search terms and a strategy supported by a health librarian signal that there has been a limited focus of specifically involving the caregiver in interventions, although their involvement is often implicit (Davidson et al. 2013). It is worth noting that seven of the ten studies identified were between 2004 and 2007, one in 2012 and two in 2013. Finally, although a systematic search strategy was followed for this review, a meta-analysis was not suitable due to heterogeneity across the included studies in outcomes and interventions.

Conclusion

Involving the family in self-care has shown improved outcomes in patients with chronic conditions. Coping with a chronic illness may be facilitated when a family caregiver is involved. The distilled elements presented above need to be further studied across different settings with varying patient population. The benefit of family-centred care may be more likely in certain cultures that are collectivists like Asians, whereas, individual person-centred approaches may be more suited to Western cultures whereby individualism is prevalent. Support methods for these patients should be targeted to the needs of these patients based on the demands of the health condition. Caregiver needs should also be addressed in future research.

Relevance to clinical practice

Although nurses implicitly engage family members in interventions, tailored, focussed and structured processes are warranted that focus on the needs of both the individual patient and the family unit. Family caregivers should be aware of patients’ needs and appropriate education and support should be provided by health care professionals. Increasing the focus on family involvement in interventions, both conceptually and in the evaluation of interventions, is critical to address the global burden of chronic illness.

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Table 3. 1 Search strategy of the three databases

	CINAHL	**ASC**	**MEDLINE (Ovid)**
Date of search	January, 2015	January, 2015	January, 2015
Key words & combination	(“Family” OR “carer*” OR “caregiver*”) AND (“chronic” OR “ chronic disease*”) AND (“self-care” OR “self-efficacy” OR “self manag*)	(“Family” OR “carer*” OR “caregiver*”) AND (“chronic” OR “ chronic disease*”) AND (“self-care” OR “self-efficacy” OR “self manag*)	(“Family” OR “carer*” OR “caregiver*”) AND (“chronic” OR “ chronic disease*”) AND (“self-care” OR “self-efficacy” OR “self manag*)
Search limits	Academic journal, All adult, English, 2000-2014	English, Peer reviewed, Academic journals, 2000-2014	English, Adult, Humans, Clinical trials, 2000-2014
Number of hits	153	546	69
Number of relevant hits	1	3	2

Table 3. 2 Risk of Bias assessment based on The Cochrane's Collaboration Tool (Online version)

Studies										
	Agren et al (2012)	Coleman et al (2004)	Kalra et al (2004)	Keefe et al (2004)	Northouse et al (2005)	Northouse et al (2007)	Northouse et al (2013)	Remien et al (2005)	Shahriari et al (2013)	Smith et al (2004)
Generation of allocation sequence (selection bias)	Randomized done after baseline assessment but no mention of randomization method/ Unclear risk	None randomized /high risk	Block randomisation procedures; each block included 10 subjects. Used computer generated random numbers to prepare	Patients were randomly assigned to one of the two groups, no mention of the randomization process /Unclear risk	Dyads were randomized to the control or the experimental group, no mention of the randomization process /Unclear risk	Patients and spouses were randomized into control or experimental treatment arms, no mention of randomization process /Unclear risk	A stratified randomization process was used /Unclear risk	A randomization table was constructed from a random numbers list and stratified by couple type /low risk	Patients were initially selected by convenient sampling then randomly assigned to experimental and control groups equally /Low risk	Patients were randomly allocated to the education program or usual care using random length restricted permuted blocks and stratified

			the allocation schedule in advance /low risk							by Barthel Index / Low risk
Concealment of the allocation sequence (selection bias)	Concealment not applicable /high risk	None randomized/ high risk	Researchers undertook baseline assessments before randomization. Concealment not applicable /high risk	Concealment not applicable /high risk	Concealment not applicable /high risk	Concealment not applicable /high risk	Concealment not applicable /high risk	Concealment not applicable /high risk	Concealment not applicable /high risk	Concealed randomization was achieved using sealed, numbered, opaque envelopes kept in a locked separate location by an independe

										nt research assistant / low risk
Blinding of participants and personnel (performance bias) **Blinding of outcome assessment (detection bias)**	Not applicable /high risk	None randomized/ high risk (performance) Not applicable /high risk (detection bias)	Not applicable /high risk	Not applicable /high risk	Not applicable /high risk	Not applicable /high risk Data collection nurses were blinded to group assignment / low risk	Not applicable /high risk	Not applicable /high risk	Not applicable /high risk	Not applicable /high risk
Attrition and exclusions	Participants drop out at 3	Not reported/ unclear	Mortality and lost to follow up	No mention of dropouts	Mortality and lost to follow up	Percentages of study participants	Percentages of study participants	Dropouts were reported in	Mortality and dropouts	Mortality and lost to follow up

	and 12 months/ high risk		were reported and presented in a figure /Low risk	or attrition /Unclear Bias	were reported and justified / low risk	and times of completion reported /low risk	and times of completion reported /low risk	numbers /low risk	were reported in numbers /low risk	were reported and presented in a figure /Low risk
Selective reporting (reporting bias)	All pre-specified outcomes were reported /low risk	All pre-specified outcomes were reported /low risk	All pre-specified outcomes were reported /low risk	All pre-specified outcomes were reported /low risk	All pre-specified outcomes were reported /low risk	All pre-specified outcomes were reported /low risk	All pre-specified outcomes were reported /low risk	All pre-specified outcomes were reported /low risk	All pre-specified outcomes were reported /low risk	All pre-specified outcomes were reported /low risk
Other generic source of bias	None	None	None	None	None	None	None	None	None	None

Table 3. 3 Characteristics of included studies

Citation**	**Patient population**/ Study size****	**Intervention on recipient**	**Intervention* ****	**Methods/quality**	**Outcomes****
Agren et al. (2012) Sweden .	155 patient-caregiver dyads with chronic heart failure (IG=84, UCG=71) admitted to the emergency department or cardiology clinic or visited the nurse-led HF clinic. (Median Age: 71 yrs; 75% male)	patient-caregiver dyads	*Content:* psychosocial support *Delivery personnel: nurses* *Method of communication:* nurse-led face-to-face counselling, a computer-based CD-ROM program and other written teaching material. *Intensity/complexity:* three 60-minutes session 2, 6 and 12 weeks after discharge. *Environment* home or in the heart failure clinic.	RCT randomized using a random-number table, theory-based intervention, 2 site-studies. Reliability and validity of used instruments evaluated. Power calculation not performed.	**Perceived control:** low at baseline and significantly improved in the IG over UCG at 3 month (-2.2 ± 4.5 vs. -0.4 ± 4.8, P=0.03 respectively) but not at 12 months (-3.2 ± 5.4 vs. -2.9 ± 4.8, P=0.79 respectively). **Quality of Life and depression:** no significant difference between the groups at 3 and 12 months (SF-36; and Beck Depression Inventory-BDI-II) **Self-care:** no significant difference between the groups at 3 and 12 months (European Heart Failure Self-Care Behaviour Scale).

Coleman et al. (2004) USA	158 adults aged 65 years + with a condition likely to require community nursing or home help after discharge (conditions included CHF, COPD, CAD, diabetes, stroke, medical & surgical back conditions, hip fracture, PVD, arrhythmia) (mean age: 77 yrs; 45.4% male)	Patient and informal caregiver (if available).	*Content:* Personal Health Record + coaching, including active problem list, medication, red flag education and transition checklist. *Delivery personnel*: Transition coach *Method of communication*: Face to face and telephone. *Intensity/complexity*: Establishes contact during admission, home visit & min. three phone calls. *Environment*: Hospital and home	Quasi RCT. Single centre study. No power calculation. Randomisation using random number generator.	**Readmission to hospital at 30, 90 & 180 days:** Adjusted OR for intervention subjects 0.52 at 30 days (95% CI, 0.28, 0.96, p = 0.04), 0.43 at 90 days (95% CI, 0.25, 0.72, p = 0.002), 0.57 at 180 days (95% CI 0.36, 0.92, p = 0.02)
Kalra et al. (2004) UK.	300 stroke patients (IG: 151, CG: 149) admitted to stroke rehab. (mean age: 76 yrs; 53% male)	Patient and caregiver.	*Content*: conventional care + caregiver training for IG *Delivery personnel*: not stated.	Block RCT. Computer generated randomisation. Single centre study. Power calculation performed. Sensitivity	**Costs of care for one year:** Significantly lower for IG (£10 133 v £13 794, \$18 087 v \$24 619; €15 204 v €20 697); P = 0.001).

			Method of communication: face to face. *Intensity/complexity:* 3-5 sessions of 30-45 minutes each + follow up home session. *Environment*: hospital and home.	statistical analysis undertaken to assess effect of missing data.	**Patient psychological state:** Less anxiety (3 v 4.5; $P < 0.0001$), less depression (3 v 4; $P < 0.0001$) and better quality of life (65 v 60; $P = 0.009$) in IG after 1 year.
Keefe et al. (2004) USA	72 patients with knee pain and their spouse. (mean age: 59 yrs; 46% male)	Patient and spouse.	*Content:* Spouse assisted training pain coping skills training (SA-SCT) alone; SA-CST +exercise training (ET); ET alone or Standard Care (SC). *Delivery personnel*: SA-SCT: trained psychologists. ET: Trained exercise physiologists. *Method of communication:* Face to face *Intensity/complexity*: SA-SCT: 12 x 2 hour group sessions. ET: 3 x	Four arm RCT. Recruited from clinical and print media. Randomisation not described. Patients in the SA-CST alone and SA-CST plus ET had higher pre-treatment levels of pain than other participants. Pain pre-treatment	**Pain coping:** SA-CST+ET and SA-CST alone groups had significant improvements compared to ET alone (or SC). Spouses in SA-CST+ET (score rated their partners as showing significant improvements in coping attempts compared to ET alone or SC (Coping Strategies Questionnaire-CSQ). **Self-efficacy:** Significant improvements in self-efficacy and their spouses rated them as showing significant improvements in self-efficacy compared to ET alone or SC. Patients receiving SA-CST+ET who showed increased self-efficacy were more likely to

			60 minute group sessions per week for 12 weeks. Total hours: SA-SCT alone: 24 hours, ET alone: 26 hours, SA-CST + ET: 50 hours. *Environment*: not clear.	scores treated as additional covariate in analysis. Attendance rate for group sessions 85-92%.	have improvements in psychological disability (Arthritis self-efficacy questionnaire).
Northouse et al (2005) USA.	134 patents with breast cancer (IG: 69, CG: 65) and their family caregivers. (mean age: 54 yrs)	Patient & family caregiver/significant other (primary source of support).	*Content:* FOCUS program *Delivery personnel*: Nurse. *Method of communication* Face to face. *Intensity/complexity*: Initial phase: monthly home visits x 3 (approx. 1.5 hours each time). Booster phase: 2 x 30 minute phone calls. *Environment*: home	RCT stratified by current treatment (chemotherapy, combination, hormonal or BMT). Four centre study.	**Proximal: Appraisal:** Significant decrease in negative appraisal in IG at 3 months only ($F(1, 131) = 4.40$, $p = 0.04$). **Distal: Quality of life (FACT scales and SF-36):** No significant differences between group at 3 or 6 months.

Northouse et al (2007) USA	253 patients with prostatic cancer facing a new challenge (diagnosis, recurrence or metastasis) and their spouse (IG:112, CG: 123). (mean age: 63 yrs)	Dyads	*Content: FOCUS program* *Delivery personnel: Masters-prepared nurses* *Method of communication: Face to face* *Intensity/complexity:* Initial phase: monthly home visits x 3 (approx. 1.5 hours each time). Booster phase: 2 x 30 minute phone calls. *Environment: home*	RCT stratified by research site, phase of illness and treatment. Three centre study	**Quality of life:** no difference **Appraisal of illness:** no difference **Uncertainty:** significantly less in the IG compared to the control group (mean scores, 56.9 vs. 60, $p<0.05$) at 4 months.
Northouse et al (2013) USA	302 patients with advanced cancer. (mean age: 60.5 yrs; 38.6% male)	Patients and family caregivers	*Content: Brief FOCUS (3.5 hours) and extensive FOCUS (7 hours) program* *Delivery personnel: Masters-prepared nurses*	RCT (blocks of 3) stratified by baseline risk of distress, cancer type and research site.	**Dyads' coping (Brief Cope):** Significant group X time effect, $F=2.15$, $p=0.013$. Brief ($p=0.033$) and extensive ($p=0.001$) groups significantly decreased use of avoidant coping at 3 months, and 6 months for the brief group only ($p=0.045$). **Self-efficacy (Lewis Cancer Self-efficacy Scale):** extensive dyads self-efficacy

			Method of communication: Face to face and phone sessions *Intensity/complexity: brief intervention 2, 1.5 hour home visit and 30 minute phone session (3-session), extensive intervention 4, 1.5 hour home visit and 2, 30 minute phone sessions (6-session)* *Environment: home*		significantly increased at 3 months (p=0.041) not at 6 months. **Social Quality of life (FACT-G):** significant group X time effect, F=4.28, p=0.002 (decrease in social QOL in the control group at 3 months only).
Remien et al (2005) USA.	215 heterosexual and homosexual HIV-serodiscordant couples (IG: 106, CG: 109. Sample predominately lower income and ethnic minority groups. (mean age: 42 yrs; 54% male).	Couples	*Content*: adherence, patterns of non-adherence, developing communication and problem solving strategies, optimising partner support & building confidence. *Delivery personnel:* Nurse practitioner	RCT randomised by random number table, stratified by couple type. Intervention delivered at one centre, but participants recruited across city. Power calculation performed.	**Medication adherence at week 8 (MEMS cap):** Significant change in proportion of prescribed doses taken (change score *b* = -10.84; *P* = 0.021) and proportion of doses taken within specified time frame (change score *b* = - 22.38; *p* < .001) at 2 weeks and waned significance at 3 and 6 months.

			*Method of communication***:** structured face to face discussions. *Intensity/complexity*: four 45-60 min sessions over 5 weeks. *Environment*: Hospital clinic		
Shahriari et al. (2013) Iran.	64 patients with heart failure (IG=32, CG=32) referring to the hospitals for treatment. (54.6% male)	Caregivers	*Content:* definition, aetiology and treatment of heart failure, importance of self-care, importance of the role of family in disease control, communication factors and self-care strategies were explained and case scenarios given. *Delivery personnel:* no mention *Method of communication: face to face educational sessions*	RCT, convenient sample randomised to CG and IG. Randomisation not described. Sample size calculation not described. Three centre study. Questionnaire designed for this study, face and content validity and reliability confirmed by panel.	**Self-care:** Significant improvement in self-care scores at 30 days between the two groups.

			Intensity/complexity:3 weekly educational sessions, 1.5 hours each *Environment:* appropriate classroom in the medical educational centre		
Smith et al (2004) UK	170 patients (86 CG and 84 IG) admitted to stroke rehab and their carers (97). (mean age: 85 yrs; 58% male)	Patient and carer (where applicable)	*Content:* Specifically designed stroke information manual + fortnightly education meetings with multidisciplinary team. *Delivery personnel:* Multidisciplinary team *Method of communication:* Written materials and face to face group *Intensity/complexity:* 20 minutes every fortnight. *Environment:* ward dayroom	RCT (block, stratified by Barthel Index scores, presence of aphasia and presence of carer). Single centre study. Power calculation was performed, but not based on primary outcome measure. Knowledge questionnaire developed for this study. Other measures	**Knowledge of stroke and stroke services:** No significant difference between groups. **Mood (Hospital Anxiety and Depression Scale):** Significant reduction in anxiety score in IG at 3 months (IG – 1.5 vs CG 0, *p* = 0.034) & 6 months (IG – 3 vs. CG – 1, *p* = 0.021). No difference in depression scores. **Disability (London Handicap Scale), physical function (Barthel Index), social function (Frenchay Activities Index), satisfaction (Pound Scale):** No significant differences between groups.

				were validated in prior studies.	

Table 3. 4 Number and reasons for exclusion

Reasons for Exclusion	Number
No family involvement	153
Children/Adolescent population	101
Non-intervention study	73
Review paper	52
Non-chronic conditions (suicide)	31
Caregiver-focused outcomes	29
Pilot study	19
Guidelines	11
Protocol	7
Other languages	6
Irrelevant (e.g. peaceful death)	172
Total	**654**

Table 3. 5 Online version of the full search strategy of the three databases

	CINAHL	ASC	MEDLINE (Ovid)
Date of search	January, 2015	January, 2015	January, 2015
Key words	"family", "spouse", "carer", "caregiver", "chronic", "chronic disease*", "self-efficacy", "self-care" and "self-management"	"family", "spouse", "carer", "caregiver", "chronic", "chronic disease*", "self-efficacy", "self-care" and "self-management"	"family", "spouse", "carer", "caregiver", "chronic", "chronic disease*", "self-efficacy", "self-care" and "self-management"
Key word combination	("Family" OR "carer*" OR "caregiver*") AND ("chronic" OR " chronic disease*") AND ("self-care" OR "self-efficacy" OR "self manag*)	("Family" OR "carer*" OR "caregiver*") AND ("chronic" OR " chronic disease*") AND ("self-care" OR "self-efficacy" OR "self manag*)	("Family" OR "carer*" OR "caregiver*") AND ("chronic" OR " chronic disease*") AND ("self-care" OR "self-efficacy" OR "self manag*)
Search limits	Academic journal, All adult, English 2000-2014	English, Peer reviewed, Academic journals, 2000-2014	English, Adult, Humans, Clinical trials 2000-2014
Subheadings	Subject Major: Diabetes Mellitus, kidney failure, arthritis, stroke, multiple sclerosis, family, spouse, heart failure, chronic disease, chronic obstructive pulmonary	Subject thesaurus: Randomized controlled trials, diabetes, disease management, health self-care	

	disease, asthma, depression		
Number of hits	153	546	69
Number of relevant hits	1	3	2

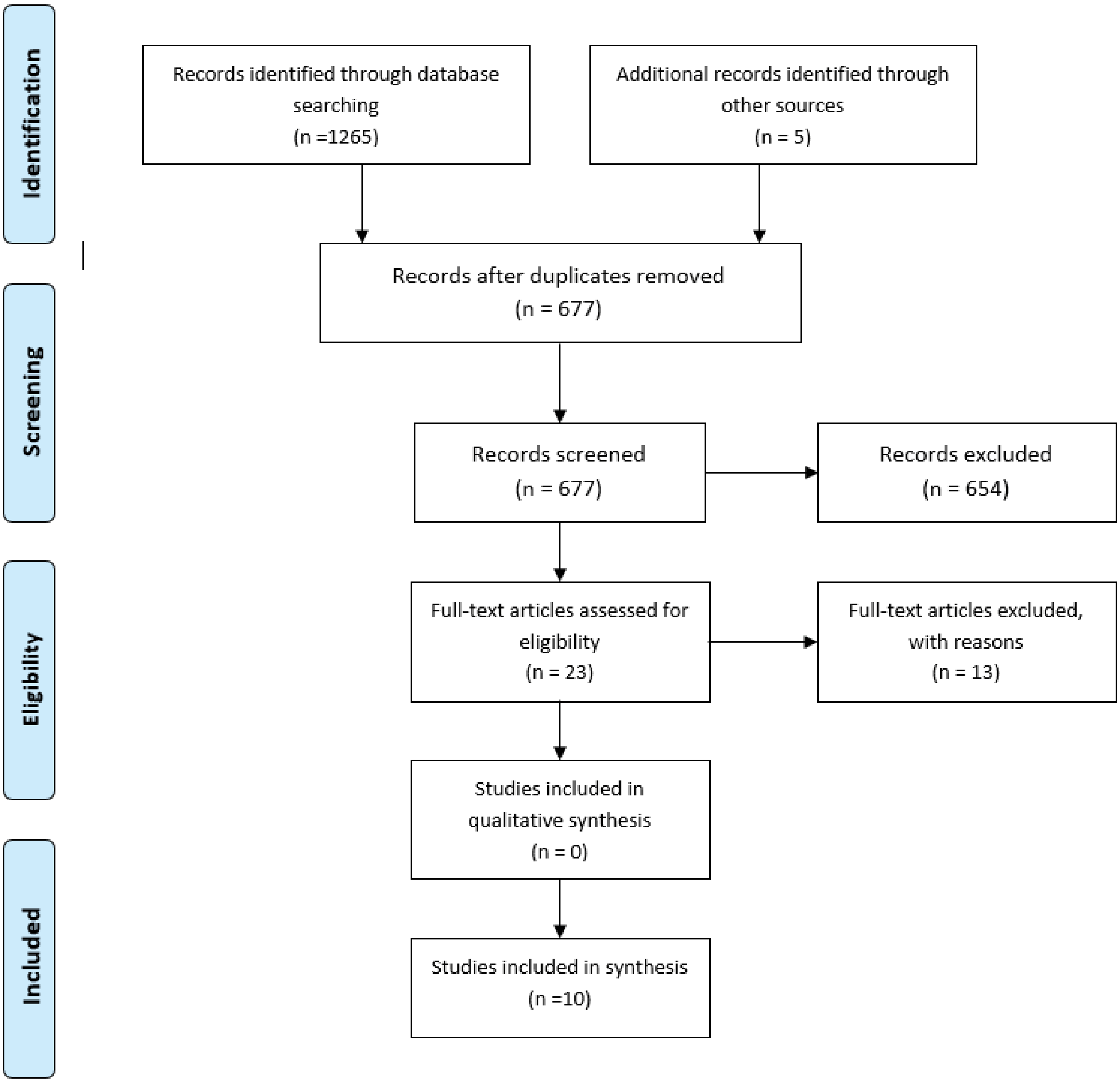

Figure 3. 1 Search strategy (based on PRISMA flowchart)

12.3 Summary

This chapter presented a review on family involvement in self-care of patients with chronic conditions. The search yielded ten papers addressing the involvement of a family member in the care of patients with chronic conditions. Interventions varied across the studies but all included face to face education session to the study dyads. Other interventions included the involvement of a transitional coach, written material, home visits and hands on training of positioning and sore care. Caregivers were defined differently across the studies and these definitions identified the type of care they provided. Based on caregiver definition and the patients' needs, outcomes varied i.e. when instrumental support was provided to the patients, their quality of life significantly improved. Similarly, with educational interventions (informational support), readmission rates and clinical outcomes improved.

The lack of consistency in the interventions, the studied patient outcomes and the different study populations made it difficult to identify a clear set of elements that would be judged as effective in intervention studies. However, some elements were common in different studies and were found effective, these included: active learning strategies, identification of the warning signs, family-centred approaches, and self-care tools such as diaries, transitional care and proper follow up.

The following chapter presents theoretical underpinning of the Family Intervention Heart Failure Model.

14. Chapter Four: A family focussed intervention for heart failure self-care: Conceptual underpinnings of a culturally appropriate intervention

14.1 Introduction of Chapter Four

Chapter four presents the discussion paper on the development of the Family Intervention Heart Failure Model (Deek et al. 2015). The published paper presents the conceptual elements of an intervention tailored to the needs of Lebanese families. It was published in the Journal of Advanced Nursing in 2015 and permission for reusing this manuscript was granted from JAN as per Appendix 20.

Deek, H., Noureddine, S., Newton, P. J., Inglis, S. C., Macdonald, P. S., & Davidson, P. M. (2015). A family focused intervention for heart failure self-care: Conceptual underpinnings of a culturally appropriate intervention. *Journal of Advanced Nursing*. Accepted August 4th, 2015. doi: 10.1111/jan.12768.

We devised a model of intervention that was appropriate for patients presenting to the hospitals due to the exacerbation of their symptoms, using the following linked methods:

(1) Appraisal of available theoretical models; (2) review of systematic reviews on educational interventions promoting self-management in chronic conditions in four databases with no year limit; (3) critical review of selected papers for unique elements of the socio-cultural context; (4) expert consultation using consensus methods; and (5) model development.

14.2 Published article

JAN
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RESEARCH METHODOLOGY: DISCUSSION PAPER – METHODOLOGY

A family-focused intervention for heart failure self-care: conceptual underpinnings of a culturally appropriate intervention

Hiba Deek, Samar Noureddine, Phillip J. Newton, Sally C. Inglis, Peter S. MacDonald & Patricia M. Davidson

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Correspondence to H. Deek:
e-mail: hiba.a.deek@student.uts.edu.au

Hiba Deek MSN RN
PhD Candidate
Centre for Cardiovascular and Chronic Care, Faculty of Health, University of Technology Sydney, Australia
@DeekHiba

Samar Noureddine PhD RN FAHA
Professor/MSN Adult Care Track Coordinator/Assistant Director for Academic Affairs
Rafic Hariri School of Nursing, American University of Beirut, Lebanon

Phillip J. Newton PhD RN FAHA
Chancellor's Post-Doctoral Research Fellow
Centre for Cardiovascular and Chronic Care, Faculty of Health, University of Technology Sydney, Australia

Sally C. Inglis BN BHSc(Hons) PhD RN NFESC FAHA
Senior Research Fellow
Centre for Cardiovascular and Chronic Care, Faculty of Health, University of Technology Sydney, Australia

Peter S. MacDonald MD
Medical Director/Head/Professor of Medicine
Transplantation Research Laboratory at the Victor Chang Institute, St Vincent Hospital, Darlinghurst, Australia

Patricia M. Davidson MEd PhD RN FAAN
Dean and Professor
Johns Hopkins School of Nursing, Baltimore, Maryland, USA

DEEK H., NOUREDDINE S., NEWTON P.J., INGLIS S.C., MACDONALD P.S. & DAVIDSON P.M. (2015) A family-focused intervention for heart failure self-care: conceptual underpinnings of a culturally appropriate intervention. *Journal of Advanced Nursing* 00(0), 000–000. doi: 10.1111/jan.12768

Abstract

Aim. A discussion of the conceptual elements of an intervention tailored to the needs of Lebanese families.

Background. The role of informal caregiving is strongly recommended for individuals with chronic conditions including heart failure. Although this importance is recognized, conceptual and theoretical underpinnings are not well elucidated nor are methods of intervention implementation.

Design. Discussion paper on the conceptual underpinning of the FAMILY model.

Methods and data sources. This intervention was undertaken using linked methods: (1) Appraisal of theoretical model; (2) review of systematic reviews on educational interventions promoting self-management in chronic conditions in four databases with no year limit; (3) socio-cultural context identification from selected papers; (4) expert consultation using consensus methods; and (5) model development.

Results. Theories on self-care and behavioural change, eighteen systematic reviews on educational interventions and selected papers identifying sociocultural elements along with expert opinion were used to guide the development of The FAMILY Intervention Heart Failure Model. Theory and practice driven concepts identified include: behavioural change, linkage, partnership and self-regulation.

Implications for nursing. Heart failure is a common condition often requiring in-hospital and home-based care. Educational interventions targeting the socio-cultural influences of the patients and their family caregivers through a structured and well-designed program can improve outcomes.

Conclusion. As the burden of chronic diseases increases globally, particularly in emerging economies, developing models of intervention that are appropriate to both the individual and the socio-cultural context are necessary.

Keywords: conceptual model, heart failure, intervention, nursing, nursing theory

Why is the research needed?

- Heart failure is a serious and complex condition that has raised interest, debate and research but its clinical outcomes remain poor.
- There are limited studies on involving the family in self-care using a theory-derived intervention.
- Theory-based interventions are generally easier to replicate and evaluate and heart failure interventions are no exception.

What are the key findings?

- Addressing self-care in heart failure is challenging but can be achieved if targeted through a family member in collectivist cultures.
- Educational interventions are most successful when they are multifaceted, theory-based, feasible and tailored to address behaviour change.

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

- Integrating targeted education into discharge planning is key to improve self-care practices and consequently heart failure outcomes.
- Recognizing family caregivers as vital partners in self-care interventions is very important in promoting the benefits of social norms and family dynamics.

Introduction

Heart failure (HF) is a major health crisis (Allen *et al.* 2012) with a high prevalence globally (Lloyd-Jones *et al.* 2010). Living with heart failure requires lifestyle adjustment, self-care strategies and monitoring (Riegel *et al.* 2009, Spring *et al.* 2013). In addition to the burden on the individual, HF is responsible for high societal costs, particularly in the form of healthcare utilization. In Lebanon, as in many countries, cardiovascular diseases, especially heart failure, constitute a growing problem where the prevalence of HF is estimated to be 72,000 patients and the cost is a great burden on the healthcare system accounting for over 100 million US dollars annually. This cost accounts for tertiary care since primary care is lacking (Tatari *et al.* 2015).

Background

Many complications of HF can be avoided with self-care strategies (Clark *et al.* 2010, Riegel *et al.* 2012). Self-care is the choice an individual makes to maintain well-being through behavioural changes and healthcare practices (Riegel *et al.* 2004), which is better approached when involving others (Heisler *et al.* 2013, Pressler *et al.* 2013). Challenges in cardiovascular risk factor behaviour persist in the Lebanese context. This is reflected with high smoking rates among patients with heart failure and the high rates of overweight and obesity. Readmission rates have been reported to be 15% within 30 days in a single Lebanese setting (Deek *et al.* 2014b) while no culturally specific interventions have been reported to deal with these lifestyles and readmission rates.

Many intervention studies have aimed at improving outcomes for the patients and their caregivers through discharge education (Sörensen *et al.* 2002, Piamjariyakul *et al.* 2013). Several reviews of HF self-care have underscored the importance of extending the focus from the individual to a broader sociocultural and health system context (Clark *et al.* 2010, 2014, Davidson *et al.* 2013), which is important in ensuring access to health care interventions and reducing healthcare disparities (Löfvenmark *et al.* 2011). There has also been several well-structured studies on theory-based interventions evaluating the effect of patient and family education and family partnership in self-care (Dunbar *et al.* 2013, 2014, Stamp *et al.* 2015). They have shown improved patient outcomes in terms of salt restriction, improved confidence, motivation, depression, family functioning and self-care (Dunbar *et al.* 2005, 2014, Stamp *et al.* 2015). These patient reported outcomes, however, lack quality and clinical outcomes such as readmission and mortality. Moreover, these interventions were evaluated using small sample sizes (Dunbar *et al.* 2005, 2014). Family interventions are hypothesized to improve patient outcomes in collectivist cultures such as Lebanon. This was demonstrated after the Lebanese war in 1990 where the family unity was an important factor in overcoming the physical and psychological damages (Farhood 1999).

Therefore developing linguistically and culturally appropriate interventions geared towards promoting self-care and deriving support from informal and formal systems is a high priority in addressing this burden (Riegel *et al.* 2009, Dickson *et al.* 2013). We identified factors of an effective family intervention to improve outcome of patients with heart failure after hospital admission, the design of this model was influenced by the Framework for the Study of Self and Family Management (Grey *et al.* 2006). This framework was guided by the shift of care presented in the US from tertiary to primary care while presenting the individual, family, environmental and health factors that can lead to change in patient outcomes. As presented, patient outcomes can be influenced by the followed approach; individual vs. family approach where the latter showed promising results in different studies of patients with chronic conditions. With the limited primary healthcare system in Lebanon and in the absence of such studies, the focus of this intervention was to highlight the significance of a family approach that would improve quality and clinical outcomes of patients with heart failure such as readmission and emergency department presentation. This model of intervention was developed while considering the Lebanese healthcare sector and the available resources.

To achieve desired outcomes, interventions need to focus on the target population and desired constructs (Davidson *et al.* 2013). Penchansky & Thomas (1981) consider five dimensions of access are important; availability, affordability, accessibility, accommodation and acceptability (Penchansky & Thomas 1981):

1. Availability: the volume of health resources fit with the volume and type of user need; there are limited numbers of transitional interventions from tertiary care to the community in Lebanon; however, these can be incorporated into care when they become accepted after proving their efficacy in improving outcomes.
2. Affordability: the costs of services fit with users' income and ability to pay; hospitalization in Lebanon is mainly covered by the ministry of public health, followed by other sectors (Kronfol 2006). However, there is no adequate coverage for out of hospital or home care.
3. Accessibility: the location of supply fit with the location of clients; tertiary healthcare availability in Lebanon is not a concern for hospitals are well distributed around the country (Ministry of Public Health 2010).
4. Accommodation: the organization of health care fit the clients' demands; most hospitals in Lebanon have bed availability for all types of health cases and financial coverage (Harb 2012).
5. Acceptability: the characteristics of the health service fit with the users' attitudes and characteristics; the issue remains for such interventions to become usual practice and be accepted by hospital and health stakeholders to adopt them in discharge planning and primacy health care.

There have been limited studies involving the family in self-care through well-structured theory-based interventions targeting the needs of the adult and older adult population. The aim of this paper is to discuss the theoretical underpinning of the intervention that was used in the FAMILY study (Deek *et al.* 2015).

Data sources

The Family Intervention HF Model was devised using five steps:

Theoretical model critique

Interventions most likely to achieve desired outcomes are those that not only appreciate the context of the problem but also use behaviour change strategies aligned with the clinical condition, specific needs and the norms of the target population (Glanz & Bishop 2010). Empirical appraisal of theoretical model critique on HF self-care was adopted and elements for self-care, behaviour change strategies and cultural appropriateness were identified (Moser & Watkins 2008, Riegel *et al.* 2012). In addition, models for behaviour change identified key conceptual elements (Michie *et al.* 2011).

Review of evidence and evidence-based guidelines

Evidence-based recommendations for HF self-care (Lainscak *et al.* 2011) and models involving family caregivers were reviewed. A systematic search was undertaken to find resources for best practices in self-management. This search was initially performed in July, 2013 and updated in January, 2015. Databases searched were: CINAHL, Proquest, Medline and PubMed using the following search terms: Self-care, self-management, self-efficacy, education, chronic disease, intervention and systematic review. Sub-headings used in some databases were: patient education, health education, intervention studies, intervention trials and adults. The search was limited to English language only. Inclusion criteria were systematic reviews of educational interventions targeting outcomes of chronic conditions. In addition, web sites of recognized organizations, such as the American Heart Association (Jessup *et al.* 2009, Riegel *et al.* 2009), the Cardiac society of Australia and New Zealand (Heart Foundation 2011) and the European Society of HF (McDonagh *et al.* 2011), were consulted. Considering our interest in identifying self-management interventions and their possible benefits in chronic diseases, selected items of the Joanna Briggs Institute Reviewers Manual on systematic review and synthesis of text and opinion data (Joanna Briggs Institute 2014) were sought from the retrieved systematic reviews. These items were the title, inclusion criteria and types of interventions.

Socio-cultural context

Selected papers were critically reviewed by two authors (HD and SN) to identify elements that are relevant to the

Lebanese context. The main concepts of interest were lifestyle, eating habits, social connection and collectivism. These were used to guide the design of the intervention to best fit the study context. These authors are cardiovascular nurse experts, who are bilingual and bicultural and have worked in Lebanon, Australia and the USA.

Expert consultation

After identifying cultural elements from the literature and outlining the intervention, it was proposed to a panel of experts for feedback; four cardiologists, two nursing professors, two PhD prepared nurses and two master prepared cardiology nurses. Following consensus methods (Nair *et al.* 2011), changes were made based on individual suggestions from the panel and the final intervention was approved by the panel. In addition, the views of patients and their families were elicited. After revision, their feedback was provided and a comparison was made of these points with the literature. Then they were weighed against the cultural norms and the current political happenings and conflicts.

Model development

Following the above steps, the model of the intervention was developed such that it is acceptable in the study setting.

Results

Theoretical model critique

As engaging in effective self-care requires both knowledge and strategies for behaviour change (Spring *et al.* 2013), a range of theoretical models (Webb & Sheeran 2006, Michie *et al.* 2011) and critiques (Noar *et al.* 2007) were reviewed. In addition, the seminal works of Riegel and Jaarsma were reviewed (Riegel *et al.* 2012, Riegel & Dickson 2015). The theoretical underpinnings of Dorothea Orem strongly influenced discourse and debate (Orem *et al.* 2001), but we extended these approaches by specifically tailoring and targeting self-care interventions to a vulnerable population through adopting a family care model. Moreover, these theories influenced our approach to shift the traditionally paternalistic focus of healthcare messaging in Lebanon to focus on an adult health model through an intervention that is theoretically, demographically and behaviourally tailored to each patient (Noar *et al.* 2007). Table 1 provides a brief description of each theory/model.

Review of evidence and evidence-based guidelines

The search for systematic reviews on educational interventions and chronic diseases yielded 98 articles from the following databases: Medline (11), Cinahl (11), PubMed (67) and Proquest (9). After screening the titles and abstracts for relevance, the final search yielded 18 articles. Extracted recommendations that were incorporated in the development of the current intervention include: caregiver involvement, behavioural support, focus on one health problem, use of interactive communication loop and align interventions with guidelines. Recommended interventions are: complex/multifaceted, tailored, feasible, educational and self-monitoring. The characteristics of the yielded studies and their recommendations are summarized in Table 2 (Norris *et al.* 2001, Monninkhof *et al.* 2003, Savelkoul *et al.* 2003, McGillion *et al.* 2004, Warsi *et al.* 2004, Williams *et al.* 2008, Du & Yuan 2010, Dennis *et al.* 2012, Lee *et al.* 2012, Radhakrishnan 2012, Viswanathan *et al.* 2012, Bryant *et al.* 2013, Franek 2013, McDermott & While 2013, Nolte & Osborne 2013, Stoilkova *et al.* 2013, Van Camp *et al.* 2013, Dickens *et al.* 2014).

Sociocultural context

The Lebanese context has similar cultural patterns to that of most of the surrounding Asian and Middle Eastern countries. However, there are some unique norms to this culture that are vital to take into account when designing a culturally tailored intervention. Gaining access to the participants' health life could be a challenge unless a social introduction preceded recruitment. Establishing rapport could be easy when starting a conversation with questions about their general well-being, answering questions about the researchers' well-being and accepting whatever they offer of sweets or coffee. Furthermore, direct questions about private matters could be offensive and should be avoided or carefully phrased. Such matters include questions on financial support and religious affiliation (Abdulrahim *et al.* 2012).

Social connections are vital in a Lebanese context; however, a strong family connection is the most important social structure (Zeeni *et al.* 2013). This was highlighted in the literature as to its effects in overcoming the effects of the war in Lebanon (Farhood 1999). This defines collectivism, which is a societal context involving a group of individuals seeing themselves as part of the group (society) embracing norms, duties and beliefs outlining their behaviour. In the Lebanese context, it was found that 67% of the population were collectivists and the majority of this

Table 1 Description of theories/models.

Author	Theory/conceptual model	Brief description/details
Spring *et al.* (2013)	Behaviour change in adults	Counselling steps, 5As: Assess, advise, agree, assist and arrange. Build patients self-efficacy to change behaviour, teach to self-monitor, use rewards and motivate, encourage social and family support, and organize regular follow up. Collaboration between healthcare teams and the patient to help the latter embrace a healthy lifestyle.
Michie *et al.* (2011)	Behaviour change wheel	A set of factors influence behaviour; these factors are interactive and can reduce or amplify the effect of an intervention. The COM–B system comprises these factors: Capability, Motivation and Opportunity. Intervention functions that influence these factors are: - Restrictions - Education - Persuasion - Incentivisation - Coercion - Training - Enablement - Modelling - Environmental restructuring
Webb and Sheeran (2006)	Does Changing Behavioural Intentions Engender Behaviour Change?	From a systematic review search for interventions evaluated through randomised trials, they calculated the effect size of intention on behaviour and concluded that: "Successful intention-change interventions lead to a small-to-medium change in behaviour, on average".
Noar *et al.* (2007)	Tailored Print Health Behaviour Change Interventions	A meta-analysis of theory-based, tailored health message interventions was performed to highlight key demographic, theoretical and behavioural factors that were found successful in changing behaviour: - More factors involved in the tailored intervention the higher the effect size produced. - Studies tailoring on any of attitudes, social support and process of change had larger effect sizes than their counterparts.
Riegel *et al.* (2012)	A middle-range theory of self-care of chronic illness	Provider-patient interaction; partnership to promote self-care and well-being. Concepts are: self-care maintenance, self-care monitoring and self-care management. Self-care activities can be executed by the patient, healthcare professionals or the family. Decision-making and reflection are key concepts in self-care; these are best practiced with adequate knowledge (education).
Orem *et al.* (2001)	Orem's self-care theory	Self-care can be universal, health-deviated or developmental. Imbalance between self-care demands and abilities leads to self-care deficit thus a need for a self-care agent (others: Nursing and/or family). Self-care is influenced by life experience, sociocultural factors, patterns of living, family system and available resources; these are known as self-care agency. Orem identifies the family as the origin of self-awareness; that people ascertain themselves as part of a group and their actions, beliefs and roles re-influenced by those of other family members. Therefore, when a deficit or a need for an individual is identified, it is the nursing responsibility to outline this deficit and strengthen family unity to compensate, support and assist in overcoming those deficits.
Riegel & Dickson (2015)	The situation-specific theory of heart failure self-care	Self-care involves a decision to maintain well-being, facilitate perception of symptoms and manage them based on education and experience among other factors. This involves the patients and their surrounding; autonomous and consultative elements.

group were female (75%). The latter finding reflects the traditional roles of men being more independent and women seeing their self as an extension of others (Ayyash-Abdo 2001).

Poor eating habits in Lebanon have lead to high rates of overweight and obesity reaching 64% and 26% respectively (Deek *et al.* 2014a). These habits, along with water pipe (arghile) smoking and sedentary lifestyles are thought to be the leading causes of chronic health conditions in Lebanon. Healthier eating habits, on the other hand, are influenced by the social body image perception and the media rather than healthy living (Zeeni *et al.* 2013). These factors were outlined as important considerations to guide practice in the Lebanese context (Davidson *et al.* 2007).

Table 2 Characteristics of the systematic reviews and their recommendations.

Author (year) Country	Title (inclusion bold)	Methods (search database, main search terms/inclusion criteria, year limit)	Total sample	Results (number of studies, *type of intervention*, main findings)	Conclusion/recommendations
Bryant *et al.* (2013) Australia	Improving medication adherence in chronic obstructive pulmonary disease: a systematic review	Data base search in Medline and Cochrane library for terms relating to *COPD* and *medication adherence/compliance* (no year limit)	$N = 1183$ participants	Seven studies identified. Counselling, monitoring and feedback and *multi-component interventions* significantly improved adherence.	*Caregiver involvement* improves medication adherence (recommended, not addressed in this paper)
Dennis *et al.* (2012) Australia	Which providers can bridge the health literacy gap in lifestyle risk factor modification education: a systematic review and narrative synthesis	Multiple data base search over 24 years (1985–2009) for studies conducted in primary health care on *health literacy* and *lifestyle changes (SNAPW)*	Not reported	52 studies identified. Multidisciplinary approaches with *moderate to high intensity interventions* with frequent sessions on motivational counselling or group education programs improved health literacy but not SNAPW.	Referral to intensive educational programs on SNAPW risk factors.
Dickens *et al.* (2014) United Kingdom	Complex interventions that reduce urgent care use in COPD: A systematic review with meta-regression	Electronic search in 6 databases for complex interventions using randomised trials for *COPD management* using *complex interventions* and a *measure of health care utilization at outcome* [*Lee et al.* 2012 #509][McDermott, 2013 #459](no year limit)	$N = 3941$ participants	Thirty two studies identified. Urgent health care significantly reduced by *complex interventions* including *education*, exercise and relaxation therapy.	Recommendation for *psychosocial* interventions
Du and Yuan (2010) China	Evaluation of patient self-management outcomes in health care: a systematic review	Electronic search of 6 databases over an 11 year period (1998–2009) for RCT evaluating *self-management education* in *chronic conditions*	$N = 7275$ participants	Nineteen studies identified in Western and Asian countries on *self-management interventions*. Self-management was evaluated by QOL, health status, health care utilization and psychological indicators and found crucial for success of interventions	Focus *to one health condition* may provide better insight on self-management
Franek (2013) Canada	Self-management support interventions for persons with chronic disease: an evidence-based analysis	Electronic search of 6 databases over a 12 (2000–2012) year limit for RCT evaluating *self-management support intervention* on *chronic conditions*	$N = 5995$ participants randomized. $N = 4996$ participants completed.	Ten studies identified, nine using the CDSMP in RCTs (*self-management support interventions*). Varying levels of improvements noted in QOL, self-efficacy, healthy behaviours and healthcare utilization outcomes	Evaluation of self-management programs on *clinical outcomes*.
Lee *et al.* (2012) South Korea	Effective Intervention Strategies to Improve Health Outcomes for Cardiovascular Disease Patients with Low Health Literacy Skills: A Systematic Review	Several local (Korea) and international databases searched over 18 years (1990–2008) for studies conducted on *CVD patients* with low *health literacy*.	$N = 2661$ participants.	Nine studies identified. *Self-monitoring and tailored intervention* improved weight evaluation. Periodic reminders improved medication adherence. Tailored counselling improved confidence. Interactive communication loop (Teaching back method) improved self-efficacy and medication adherence.	Tailored health literacy interventions for specific health conditions and patient needs.

Table 2 (*Continued*).

Author (year) Country	Title (inclusion bold)	Methods (search database, main search terms/inclusion criteria, year limit)	Total sample	Results (number of studies, *type of intervention*, main findings)	Conclusion/recommendations
McDermott and While (2013) United Kingdom	Maximizing the healthcare environment: a systematic review exploring the potential of computer technology to promote self-management of chronic illness in healthcare settings	Several databases searched for RCTs evaluating *PSMP* for chronic conditions through *computer-based interventions* (no year limit)	N = 1506 participants.	Eleven studies identified. Computer-based interventions showed significant improvement on behavioural and clinical outcomes. *Complex BCTs* show improved outcomes over basic techniques.	Computer- based interventions less effective with older adults.
McGillion *et al.* (2004) Canada	A systematic review of psychoeducational intervention trials for the management of chronic stable angina	Several databases were searched over a 12 year period (1990–2002) for RCTs testing *psycho-educational interventions* on *angina symptom severity, frequency, intensity and duration*; angina-related distress and physical functioning.	N = 610 participants.	Four studies identified. *Psycho-educational interventions* decreased distress and depression, showed improved scores on frequencies and severity of angina.	Future studies with robust methods should be implemented for appropriate recommendations.
Monninkhof *et al.* (2003) The Netherlands	Self-management education for patients with chronic obstructive pulmonary disease: a systematic review	Several databases were searched over a 16 year period (1985–2001) for RCTs on *self-management education* in patients with COPD.	N = 1295 participants.	Twelve studies identified. *Self-management education interventions* reduced use of rescue medication but no significant improvement in COPD symptoms. Varied results in QOL and other outcomes	Poor quality of trials, varied outcomes and small sample sizes limit conclusive findings. Future studies directed at COPD specific outcomes and self-treatment plans.
Nolte and Osborne (2013) Germany	A systematic review of outcomes of chronic disease self-management interventions	Four databases were searched over a 24 year period (1982–2006) for *self-management educational interventions* on patients with *chronic conditions*	N= 5635 participants.	Nineteen studies identified on *chronic disease self-management interventions*. Most studied effect of education on arthritis outcomes. Minor improvements were noted in pain, disability, depression and self-efficacy between the groups.	Measuring outcomes should be done through reliable measures rather than through patient reported outcomes.
Norris *et al.* (2001) USA	Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials	Three databases were searched over a 19 year period (1980–1999) for RCTs evaluating *self-management educational programs* on *type 2 diabetes outcomes*.	N = 3609 participants.	Seventy two studies identified. *Self-management educational programs* were associated with increased knowledge, frequency of SMBG and improved self-care.	Use behavioural therapies explicitly in design of educational programs that are practical and feasible.

Table 2 (*Continued*).

Author (year) Country	Title (inclusion bold)	Methods (search database, main search terms/inclusion criteria, year limit)	Total sample	Results (number of studies, *type of intervention*, main findings)	Conclusion/recommendations
Radhakrishnan (2012) USA	The efficacy of tailored interventions for self-management outcomes of type 2 diabetes, hypertension or heart disease: a systematic review	Several databases were searched over a 9 year period (2001–2010) for RCTs evaluating *educational interventions* on outcomes of *heart diseases, hypertension and type 2 diabetes.*	N = 3631 participants.	Ten studies identified. Minimal improvement noted with *tailored interventions* on fat intake, physical and screening while no improvement was noticed on medication adherence, smoking cessation and exercise.	Tailored interventions are better implemented when health related outcomes are targeted rather than cost and healthcare utilization. High quality trials are needed to assess effect of tailored interventions on long term health conditions.
Savelkoul *et al.* (2003) The Netherlands	Stimulating active coping in patients with rheumatic diseases: a systematic review of controlled group intervention studies	Several databases were searched for RCTs evaluating *active coping and self-management* in *chronic conditions* (no year or language limit)	Not reported	Fourteen studies identified on *controlled group intervention.* Varied improvement was noticed in quality of life and marginal improvement in coping.	Future research should aim at improving coping among patients with osteoarthritis.
Stoilkova *et al.* (2013) The Netherlands	Educational programmes in COPD management interventions: A systematic review	Several databases were reached over a 46 year period (1966–2012) for studies evaluating *COPD educational programs* on outcomes.	N = 8206 participants.	Eighty one articles addressing 67 studies on *COPD management interventions* were identified. Improved QOL, lung function, patient satisfaction and medication adherence with varied significance.	Tailored education is recommended in current practice
Van Camp *et al.* (2013) Belgium	Nurse-led interventions to enhance adherence to chronic medication: systematic review and meta-analysis of randomised controlled trials	Two databases were searched over a 5 year period (2006–2011) for RCTs evaluating *nurse-led interventions* on *medication adherence* in *chronic conditions*	N = 2587 Participants	Ten studies identified seven of which addressing adherence with HIV positive patients through *nurse-led interventions.* Individual Long term counselling and electronic monitoring were associated with better medication adherence.	Multi-faceted, nurse-led, tailored and long term intervention with continuous follow ups maybe the best approach to tackle medication non-adherence.
Viswanathan *et al.* (2012) USA	Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review	Two databases were searched for papers addressing RCTs evaluating *interventions* aimed at improving *medication adherence* (No year limit)	Not reported	Sixty seven studies identified in 73 articles addressing *medication adherence interventions.* Medication adherence leads to better health outcomes in some chronic health conditions including heart failure.	Patient education with behavioural support and continued follow up improved medication adherence in long term conditions. Identification of multicomponent intervention elements to improve medication adherence and health outcomes.

Table 2 (*Continued*).

Author (year) Country	Title (inclusion bold)	Methods (search database, main search terms/inclusion criteria, year limit)	Total sample	Results (number of studies, *type of intervention*, main findings)	Conclusion/recommendations
Warsi *et al.* (2004) USA	Self-management education programs in chronic disease: a systematic review and methodological critique of the literature	Two databases were searched over a 35 year period (1964–1999) for trials (with a control group) on *self-management education* and *clinical outcomes*.	N = 14618 participants	Seventy one studies identified. Self-management educational interventions improved intermediate outcomes such as glycosylated haemoglobin levels in patients with diabetes and systolic blood pressure in patients with hypertension.	Evaluation of programs should be conducted by investigators other than the program developers.
Williams *et al.* (2008) Australia	Interventions to improve medication adherence in people with multiple chronic conditions: a systematic review	Several multidisciplinary databases searched over a period of 10 years (1997–2007) for RCTs evaluating *medication adherence* interventions in multiple *chronic conditions*	N = 4000 participants	Eight studies identified on *medication adherence interventions*. Qualitative reporting of individual studies; marginal improvement in medication adherence noted. QOL varied between studies and had no impact on adherence.	Develop and test psychosocial intervention to improve medication adherence

Stanford CDSMP, Stanford chronic disease self-management program; SNAPW, smoking, nutrition, alcohol, physical activity and weight; CVD, cardiovascular disease; PSPM, patient self-management programs; COPD, chronic obstructive pulmonary disease; QOL, quality of life; SMBG, self-monitoring Blood glucose.

Expert consultation

Consultation with experts identified several factors that must be considered in the intervention. These included building rapport and credibility with patients, methods for identifying primary caregiver (the individual responsible and preference for partnership); simplifying information to consider issues of health literacy; tailoring information to local dietary and cultural norms, including scales to allow daily weighing and behavioural prompts in self-care kits, e.g. branded bag with the FAMILY logo and a diary. In addition to considerations germane to HF care, it was also considered important to reflect on factors that are common living in a conflict zone, such as higher rates of depression and increased fatalism (Khamis 2012, El Asmar *et al.* 2014).

Model development

Following the above steps, the FAMILY intervention HF Model was developed (Figure 1). Patients with HF have a continuous cycle of readmissions (Jaarsma *et al.* 2009). The presented model breaks this vicious cycle by intervening at a critical point in time; where patients believe that they are stabilized and healthy. This study adopts the phenomenon of a transitional coach who helps patients shift between two settings without changing their health practice (Stamp *et al.* 2014). Involving the family in the care of the sick in a collectivist society is predicted to be the key to maintaining well-being. The educational intervention is hypothesized to improve the patient outcomes at 30 days by integrating the following concepts in the model:

Linkage (coordination): This term is mostly associated with patients with HIV where the linkage to care forms a basis of support, encouraging access to care and facilitating an understanding to the therapy and its benefits (Turan *et al.* 2014, Knight *et al.* 2015). It was also associated with decreases complications, cost and possibly transmission of the virus (Rothman *et al.* 2012). In this study, patients were encouraged to follow up with their cardiologist in their clinics early after discharge and to communicate their unwelcome symptoms early with their caregivers and their healthcare providers to avoid deterioration (Fortenberry *et al.* 2012, Spring *et al.* 2013).

Partnership: This approach was emphasized by Clark and Dunbar (2003), where the family member is encouraged to participate in the self-care of the patient in a lifelong condition and be treated as a community nurse with unique knowledge. In this study, family caregivers were introduced to cooking tips, how to fill medication boxes and monitor fluid intake.

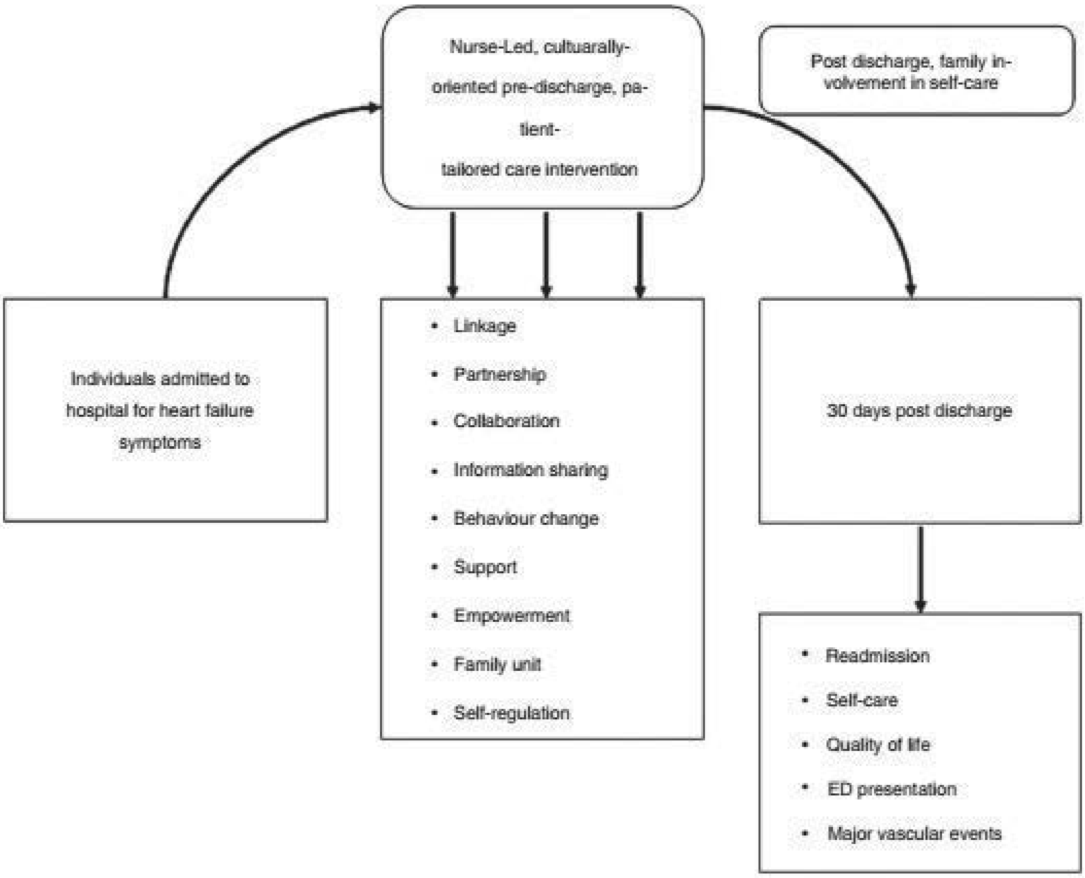

Figure 1 The family intervention heart failure model.

Collaboration: A collaborative care model has been tested previously to show an improved effect on the quality of care (Callahan *et al.* 2006). This approach involves the family caregiver in the care by providing adequate information on symptom monitoring and management, when to take initiatives and when to contact the healthcare team.

Information sharing: Educating patients is the main goal of most intervention studies and is the basis for adequate self-care (Riegel & Dickson 2015). This, however, is a two-way concept where researchers gain insights into the patients' lives and try to probe habits that may influence self-care.

Behaviour change: Michie *et al.* (2011) introduced a framework for understanding behaviour known as The COM-B system; capability, opportunity and motivation. These concepts interrelate to influence one another and to produce change in behaviour. The educational intervention was introduced to the participants as a new strategy to improve outcomes through empowering their caregiver and enhancing their will to avoid complications of their condition (Michie *et al.* 2011).

Support: Riegel *et al.* (2012) acknowledge that self-care usually refers to the individual but that it is mostly accomplished with the help and support from others. In a collectivist culture, support is usually gained from family members living in the same household as the patient. As observed, in Lebanon the wife is usually the source of support for the husband and the daughter for her mother.

Empowerment: Also known as autonomy support and defined as the practice where patients are encouraged to make their own decisions based on the provided health choices and their consequences to manage behaviour change (Dunbar *et al.* 2005). This includes the decision to take an extra urine pill or reduce fluid intake to manage their fluid overload as evaluated by their weight change.

Family unit: Family is identified as the basis of self-awareness where people's actions, beliefs and roles are influenced by the fact that they are part of a group. These come into consideration when one's health is affected and it is the role of the healthcare providers to strengthen the ties of the family and provide support (Orem *et al.* 2001).

Self-regulation: Is a process where a person decides to adopt new health practices and is guided by the primary motivator to change behaviour. One might be led by the perceived risk of specific behaviour; defensive optimism or the desired goal; functional optimism. The latter being a pre-requisite for behaviour change (Schwarzer 1999).

The family conference involved the patients and their primary family caregivers after successful HF treatment. It was provided in simple language, at a slow pace, in a quiet, comfortable and well-lit environment. The session lasted 30-45 minutes for each participant and caregiver and was provided by a nurse with rich experience in cardiovascular nursing. The participants were informed of the educator's experience and knowledge in the field to gain their confidence and establish rapport (John 1988). A diary developed using the recommendations of Hayes (2005) was included. It contained simplified educational material using a 5th grade level, 14-point Arabic language readable font and clear and precise instructions

Table 3 Intervention checklist (dialogue used).

Self-care items	Description	Rationale
Identify caregiver		Individual responsible and preference for partnership
Assess knowledge	- Heart failure cause - Unique symptoms - Role of medication - Role of caregiver	Adults are problem-centred and learn best when referring to their own knowledge and experience (Hayes 2005)
Explain causes of heart failure	Tailored to each individual	Subjective and tailored educational session (Radhakrishnan 2012, Lee *et al.* 2012)
Pathophysiology of heart failure and socio-environmental risk factors	There are many changes that happen to the body when the heart muscle is weak, among which are the obvious changes to the lungs, kidneys and the heart itself such as the shortness of breath, oliguria and fatigue. Other not so obvious changes are what happens to the liver and the spleen which become apparent when the condition progresses.	Self-directed learning and subjective problem-solving while linking their health condition with their environment (Lee *et al.* 2012)
Symptoms of heart failure (Unique symptoms if present)	There are many symptoms to this condition; some are very typical such as SOB and ankle swelling. Why did you come to the hospital this time? Is it the only symptom? Has it happened suddenly? Can you identify your unique symptom?	Tailored education for health related outcomes (Radhakrishnan 2012)
Symptom recognition	- Swelling starts at the ankles and travels upwards, you can notice that when you palpate your legs and compare them - Ascites and hard abdomen - SOB with the same number of pillows	Self-management educational interventions tailored to each individual (Warsi *et al.* 2004, McDermott & While 2013)
Self-care	- weight monitoring - salt restriction - low fat diet - smoking cessation - physical activity - medication adherence - fluid restriction - flu immunization	Self-monitoring interventions improve weight evaluation, self-efficacy and medication adherence (Lee *et al.* 2012). Medication adherence in heart failure improves health outcomes (Viswanathan *et al.* 2012).
Cooking tips	- replace fried with baked - avoid butter and animal fat - lean meat rather than greasy meat	Tailored information based on dietary and cultural norms (expert opinions)
Interactions and questions	Teaching back method	Improved researcher-patient interaction, assures understanding of the material, improve confidence and self-efficacy (Lee *et al.* 2012)

Table 4 Detailed self-care practices.

Self-care practices	Detailed description	Check
Weight monitoring	Weight monitoring is a vital practice in self-care; - Identify and avoid threshold by daily measurement, - Weigh daily in the morning - Daily record in the diary and evaluate. - Take an extra urine pill with an increase in weight by 1 kg in 24 hours or 2 kg in 5 days, - Contact health care provider, if weight increase persisted, - Keep the scales within reach and sight in the bathrooms.	
Salt restriction	Salt retains fluid inside the body, limit salt intake: - Avoid the salt shaker, processed and canned food; - buy fresh meat and vegetables; - ask for low salt diet when eating out; - Read food labels to check for amount of salt. - Avoid pickles, olives, salted nuts, tomato sauce, vegetable juice, soya sauce and salad dressing. - Choose low salted labneh (a traditional type of food made form yogurt) and cheese. - Replace salt with vinegar, lemon juice, spices, ginger, garlic and herbs	
Low-fat diet	Heart failure is mostly caused by blocked heart vessels with fat accumulation; familial hypercholesterolemia is common in high rates in Lebanon - Adopt a low-fat diet (fried food, etc…)	
Smoking cessation	Smoking weakens the heart muscle and forces it to put extra effort to pump blood out; tightens the heart arteries and puts strain on the lungs. - Avoid active and passive cigarrete and arghile smoking in open and closed environments	
Physical activity	Physical activity helps strengthen the heart muscle and maintain resistance to shocks. - Small, slow walks with small steps and progress gradually to longer walks - Take periods of rest - Enjoy the scenery. - Divide activity throughout the day - Family caregivers advised to accompany patients in their walks	
Medication adherence	Medication intake daily and as scheduled is vital and is prescribed based on individual conditions; tablets complement one another and hel the heart and kidneys better function. - Schedule the medication at the same time every day - Use reminders such as meals, medications boxes or alarms to avoid missing any. - Taking the urine pills in the morning and at noon is necessary to avoid disturbing night sleep. - Plan trips assure access to the bathrooms - If you forget a dose, take it as soon as you remember it - Never double the dose - Never stop any medication on your own - Consult with health care provider for new or worsening undesirable effects - Avoid over-the-counter drugs/consult with your doctor - Caregivers advised to fill the medication boxes daily	
Fluid restriction	Fluid allowance is based on subjective fluid balance (fluid intake and urine output) which was measured during hospitalization. - Measure fluid intake with the provided calibrated bottle - Fluids include soup, jello, coffee, ice cubes, tea, alcohol, soft drinks, milk, pudding, yogurt, ice cream, sauce, fruits like oranges and watermelon, vegetables like cucumber, tomatoes and lettuce, etc. - Thirst is augmented by salty diet	
Flu immunization	Flu immunizations can prevent hard colds and avoidable strains on the heart. - Take flu vaccines yearly - Avoid/contact with sick people	

presented in bulletins to avoid confusion (Hayes 2005). In addition, pictures and coloured headings were used throughout for a user-friendly template (Glanville 2000). Key elements of the intervention are summarized in Table 3 and the detailed self-care practices are presented in Table 4.

Discussion

The aim of this paper was to discuss the theoretical underpinning of the intervention used in the FAMILY study. Theory-based interventions, although difficult to achieve, provide a good base for evidence synthesis, allow replication and are easier to group for comparison and evaluation (Gardner *et al.* 2010). Similarly, theory-inspired interventions may be more generalizable than interventions lacking theoretical basis (Francis *et al.* 2007).This gives strength to the first randomised trial conducted on patients with heart failure in the Lebanese setting. This, along with other sources of power to this trial provides a strong basis for future research in a resource lacking context. Hesitance and lack of confidence towards the new intervention might be handled with showing the credibility of the message source which is one important feature of the theories of persuasion and is likely to lead to change in behaviour (Francis *et al.* 2007).

Although the role of the caregiver has been recognized in HF, few studies have engaged them in the execution of the intervention (Ferguson *et al.* 2014). Formalizing this involvement is critical as informal caregivers become more important in providing care in community-based settings. Moreover, to ensure transferability of results, interventions need to be carefully described to allow intervention fidelity (Hoffmann *et al.* 2014). Although it is not necessary to replicate studies for HF self-care across all study populations, identifying unique socio-cultural aspects is crucial.

One limitation of this paper is the use of selected items from the Joanna Briggs Institute quality checklist to assess the quality of the systematic reviews (step 2) where the other items could have provided deeper insights of their quality. However, based on the aim of this study, we were interested in the types of interventions and their outcomes. Another limitation is the search for all systematic reviews involving interventions without specifying the theory-based interventions that could have guided the development of the Family Intervention Heart Failure Model more critically. Although this model of intervention has been developed for individuals with HF in Lebanon, this intervention will likely have high utility across other Middle Eastern diasporas globally. Currently the efficacy of this intervention is being tested in a multisite randomized controlled trial in Lebanon where the education is provided to the intervention group and the outcomes measured at 30 days (Deek *et al.* 2015).

Implications for nursing

Heart failure is a serious condition requiring in-hospital and home care. Theory-based educational interventions targeting the socio-cultural influences of the patients and their family caregivers through a structured and well-designed program can improve outcomes. Addressing the cultural and the subjective needs of patients and providing the proper support along with adequate and well-structured patient follow up is lacking and needs to be integrated in discharge planning.

Conclusion

As the burden of chronic diseases increases globally, particularly in emerging economies, developing models of intervention that are appropriate to both the individual and the socio-cultural context are necessary. Furthermore, recognizing family caregivers as vital partners in self-care interventions is very important in promoting the benefits of social norms and family dynamics.

Author contributions

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/recommendations/)]:

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

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14.3 Summary

Theories on self-care and behavioral change, eighteen systematic reviews on educational interventions and selected papers identifying sociocultural elements along with expert opinion were used to guide the development of The FAMILY Intervention Heart Failure Model. Theory and practice driven concepts identified included: behavioural change, linkage, partnership and self-regulation. Unique sociocultural traits identified in the Lebanese context included establishing rapport, carefully phrasing questions on financial support and religious affiliations, in addition to acknowledging the family connectedness in this collectivist culture. Expert consultation also identified a number of factors to consider in the intervention. These include simplifying information to consider health literacy, tailored information to the local dietary and cultural norms, and provision of a branded bag with the FAMILY logo as a behaviour prompt. The self-care intervention was tailored to a vulnerable, elderly population through adopting a family care model.

Having used these interrelated methods, the importance of the conceptual issues with the evidence based recommendations were integrated into the FAMILY study intervention.

The following chapter presents the published protocol of the randomised controlled trial conducted to evaluate family involvement in self-care of patients with heart failure.

15. Chapter Five: Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: protocol for block randomized controlled trial for implementing an education family session

15.1 Introduction of Chapter Five

Chapter five reports the methodological design of the randomised controlled trial (Deek et al. 2015). The trial was conducted to evaluate the nurse-led, theory-inspired, culturally tailored intervention previously described. This paper was accepted for publication in Nurse Researcher in 2015 as per the following citation and permission was granted from Nurse Researcher to include it in this thesis.

Deek, H., Noureddine, S., Newton, P. J., Inglis, S. C., Al Arab, G., Kabbani, S., Chalak, W., Timany, N., MacDonald, P. S., & Davidson, P. M. (2015). Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: protocol for block randomized controlled trial. *Nurse Researcher. Accepted June 9th, 2015*.

The design and reporting of the trial was undertaken using the CONSORT guidelines (Schulz et al., 2010). The study design was planned based on the needs of this collectivist culture and the current country condition with mobile and transient population. Bias was carefully avoided throughout the implementation of the study and during the follow up phase.

15.2 Published article

Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: protocol for block randomized controlled trial for implementing an education family session

Abstract

Background: Self-care strategies are critical to improving health outcomes in heart failure. The family unity is crucial in collectivist cultures, however, little is known about involving the family is self-care of critically ill patients with heart failure. The purpose of this paper is to describe the methodological design of a randomised controlled trial conducted to evaluate a culturally tailored nurse-led educational intervention.

Methods/Design: The FAMILY project was a multi-site, block randomised controlled trial conducted in Lebanon over a 12-month period. Inclusion criteria were adult patients presenting to one of the three study hospitals for heart failure symptoms. Participants were excluded if they had a debilitating condition. Patients allocated to the intervention group along with their primary family caregivers were provided with a comprehensive, culturally appropriate, educational session on self-care maintenance and symptom management along with self-care resources. The usual care group received the self-care resources only. The primary endpoint was 30 day readmission, and the secondary endpoints were emergency department presentation, quality of life, self-care, health care utilization and major cardiovascular events.

Discussion: Involving the family in self-care of heart failure is a novel approach. To our knowledge no one has evaluated this approach through a randomized controlled trial.

Key words: Heart failure; family; education; trial; readmission; nursing, protocol.

Trial registration: Iranian Registry of Clinical Trials IRCT2014101919593N1

Funding source: Funding was kindly provided by STTI nursing honour society after completion of data collection. The money will be used for dissemination of the study findings.

Word count of manuscript: 2,764 words

Conflict of interest: None

Disclosure: None

Background

Heart failure is a global health issue requiring complex and coordinated primary (Cleland et al., 2002), secondary (National Collaborating Centre for Chronic Conditions, 2003) and tertiary (Tandon et al., 2004) health care. Self-care is defined as “a naturalistic decision-making process involving the choice of behaviours that maintain physiologic stability and the response to symptoms when they occur”(Riegel and Dickson, 2008). It is the cornerstone in the management of heart failure (Davidson et al., 2013); and an important factor in reducing health events and poor outcomes (Jaarsma et al., 1999). While the cardiovascular (CV) risk factor burden in Lebanon is known to be high, little is known on heart failure prevalence, treatment and follow up (Deek et al., 2013). Lebanon is a collectivist culture with tightly knit family structures where families of patients with cardiac illness get involved significantly in their health seeking behaviour (Noureddine et al., 2014)**.** Moreover, the importance of the family unity was reported in overcoming the detrimental effects of war and maintaining physiologic and psychological wellbeing (Farhood, 1999). Thus involving the family in self-care is a novel culturally tailored approach aimed at educating the family caregiver on health maintenance and symptom management. Culturally tailored interventions address the socio-cultural aspects of the participants’ lives and are hypothesized to improve outcomes through behavioural change(Rosal et al., 2011).

This culturally derived nurse-led family model of a heart failure educational intervention is hypothesized to:

1) Reduce all-cause readmission;
2) Improve self-care and quality of life;
3) Reduce emergency department presentations and major vascular events of patients with heart failure.

The aim of this paper is to describe the methodological design of the randomised controlled trial used to evaluate the FAMILY study.

Methods

Study design

The FAMILY study is a multicentre, non-blinded, parallel arm (1:1); block randomized controlled trial involving 256 patients with heart failure (HF) admitted to one of the three study hospitals in Lebanon. Data were collected and monitored using the CONSORT guidelines (Schulz et al., 2010). Study sampling, randomisation, intervention and follow up are summarised in the flow diagram (figure 5.1).

Sampling

Heart failure in-patients were identified by the cardiologists, cardiology fellows or cardiac care unit (CCU) staff as to those admitted for heart failure management. Patients were included if they were admitted through the emergency department or electively referred to by a cardiologist. Participants were identified based on the typical heart failure findings identified by the Framingham criteria (McKee et al., 1971) outlined in figure 5.2. For confirmation of the diagnosis, either two major or one major and two minor criteria needed to be present. Newly diagnosed patients underwent the assessment recommended by the American Heart Association to confirm their new heart failure diagnosis (Jessup et al., 2009). Patients with both preserved and reduced ejection fraction heart failure who had symptoms associated with the condition were included in the study.

Eligibility Criteria

Recruitment took place between November, 2013 and November, 2014. All patients admitted to one of the three study hospitals for acute decompensated HF regardless of the aetiology, aged 18 years or more and willing, along with their primary family caregivers, to participate were invited to this study. Patients who were illiterate were included if their family caregivers were literate and able to make health related decisions for the patient. Illiterate patients, those with no reading and writing skills, were asked to finger print the consent form after a thorough explanation was provided about the intervention and adequate support provided by their caregivers. Patients were excluded if they were living alone or in a nursing home, aged less than 18 years, or had a debilitating health conditions that hindered their participation as judged by their physician or family caregiver. Such conditions included a life expectancy of less than 30 days, severe cognitive impairment limiting their judgement and activity or were awaiting cardiac bypass or valve replacement surgery with limited functionality. Also conditions that would hinder the progress of the intervention such as impaired cognition or blindness of the caregiver excluded the possibility of participation.

Randomization

Block randomization (blocks of four) were performed using the Statistical Package for Social Sciences (SPSS) random number generator. Using blocks divides the recruited participants equally into the two groups within the blocks of four thus avoids straining the single researcher who was both recruiting patients and giving the intervention. Block randomization was done by an independent co-investigator who was not involved in the data collection. Therefore, when a candidate was identified, they were consented, baseline data was collected and then randomization was done.

Sample size

Since local Lebanese data is lacking, we assumed a baseline readmission rate of 30% (Aranda et al., 2009) based on the international literature. In order to demonstrate a 15% reduction in readmission at 30 days and allowing for an attrition rate of 10%, a sample size of at least 130 participants in each of the study arms was considered necessary to achieve 80% power at a 2-tailed significant alpha level of 0.05 (Citea, 2014).

Screening visit and enrolment during hospitalization

Patients and their primary family caregiver (spouse, partner, child, or grandchild) were approached by the primary investigator. During this encounter, the purpose of the study, along with the intervention, was introduced, the consent form was signed, baseline data were collected, and the randomization took place.

Second visit during hospitalization:

Both groups were contacted to avoid the risk of contamination arising from an extra visit to the intervention group. During this encounter, both groups were provided with the self-care resources; a scale, a calibrated bottle, a medication box and a diary.

The diary contained the educational material that was presented to the intervention group, expressive pictures of the unique symptoms usually manifested by heart failure patients, the medication list prescribed on that admission, designated spaces for documentation of their daily weight measurements, and contact details of their cardiologist in case of an emergency.

The second visit differed between the two groups in the following manner:

a- The usual care group: patients were provided with a bag of the aforementioned items with no verbal explanation provided.

b- The intervention group: patients and their family caregiver were provided with a single educational session lasting 30-60 minutes based on their individual needs. This meeting was tailored to the patients' condition, unique symptoms (if present) and subjective demands.

Intervention

Although nurse coordinated interventions for heart failure have been well addressed in previous studies (Clark et al., 2007, McAlister et al., 2004), a family centred approach was implemented in the current study to test its efficacy on the Lebanese population. We developed the Family Intervention Heart Failure Model using the following steps: 1) critique of theoretical models on behaviour change and self-care (Michie et al., 2011, Orem et al., 2001, Riegel et al., 2012, Noar et al., 2007); 2) review of the evidence and evidence-based practice (Jessup et al., 2009, Heart Foundation, 2011, Heart Failure Society of America, 2010); 3) identification of sociocultural elements (Deek et al., 2013); 4) expert consultation; and 5) refining a model of intervention that is acceptable and appropriate to a resource poor setting (Patterson, 1988). The Family Intervention Heart Failure Model is outlined in figure 5.3 and is described in greater depth elsewhere (Deek et al., 2015).

The intervention included a single educational session. This session was structured to include information about heart failure causes, symptoms and management. HF management comprised a big portion of the educational session focusing on self-management and roles of the family caregiver. Education included points about salt and fluid restriction, physical activity, symptom recognition, smoking cessation, and adherence to prescribed medication, in addition to culture specific risk factors. These factors include active and passive water-pipe smoking (arghile), high prevalence of familial hypercholesterolemia reflecting the unique allele in the Lebanese culture, cardiovascular disease and its high rates of related mortality, hypertension, uncontrolled diabetes mellitus, and overweightness. Where literature on the unique influence of cardiovascular risk factors' morbidity and mortality in Lebanon was lacking, international data was used to convince participants of better health practices.

Self-care resources provided in the bag were explained separately. Emphasis was made on the need to have the medication box filled daily with the prescribed pills by the family caregiver; limited fluid intake based on the daily allowance recommended by the cardiologist with the help of the calibrated bottle; weight taken daily and documented in the diary after waking up in the morning with light clothes. In consultation with their treating cardiologist, a flexible diuretic plan was adopted for each participant. Participants were instructed to take an extra pill of their diuretic if their weight increased by 1 kg over 24 hours or 2 kg over 5 days. They were also advised to contact their cardiologist if their weight continued to increase despite the proposed plan. Both groups were provided with the contact details of their cardiologist to refer to in case of an emergency. Verbal education and written material were provided in the patients' native language, Arabic, to enhance better comprehension of the material. Baseline and follow up data collection, including the self-care index and the quality of life questionnaire, was also done in Arabic to assure accuracy.

To standardize the implementation of the FAMILY intervention, a checklist was made of the items that were addressed in the educational conference and were ticked off as they were explained.

The intervention also adapted a flexible approach where all questions raised by the patient and family caregiver were answered, subjective concerns met and adequate referrals were made. Further, the same investigator implemented the intervention for all participants in the intervention group to ensure fidelity of implementation.

Data collection

Baseline data were collected before randomization, and then the same data except for demographic and admission clinical variables were collected at 30 days post discharge. Follow-up data were collected by phone calls to ask participants about their wellbeing and if they had been hospitalized or visited the emergency department (ED) during the 30 day period. The Arabic version of the self-care of heart failure index (A-SCHFI) and the SF-12 questions were relayed during the phone call which lasted for less than 10 minutes. The trained researcher conducting the phone calls was blinded to the treatment allocations. The time frame and data collection plan are outlined in **Error! Reference source not found.**.

Primary & secondary endpoints

The primary endpoint was readmission at 30 days of hospital discharge. Secondary endpoints were emergency department presentation, self-care, quality of life, health care utilization and major cardiovascular events. This time frame was chosen based on the quality indicators implemented by financial bodies such as the Medicare where early readmission within 30 days may be a reflection of poor quality of care and discharge planning (Kociol et al., 2013, Vaduganathan et al., 2013).

Measurements

a- Baseline tool: this sheet included questions about the patients' past medical and surgical history, socio-demographic status, New York Heart Association (NYHA) class, medication profile, cause of heart failure, and results of diagnostic findings. These data were collected from the medical records when necessary to avoid burdening the participants with many questions; all other data were collected through an interview with the patients and their caregivers.

b- The Arabic translated version of Riegel's Heart failure Self-care Index (A-SCHFI) (Riegel et al., 2009) was collected. This index was translated to Arabic and then back translated to English twice by 2 researchers independently. Face, content and construct validity were evaluated. The detailed presentation of the translation and validation of the instrument is reported elsewhere (Unpublished work).

c- Quality of life was measured using the Short Form-12. This tool addresses the physical functioning of the patients, role limitations, social and emotional status (Ware Jr et al., 1996). The health survey SF-36 had previously been translated and validated then tested on a Lebanese sample (Sabbah et al., 2003). The SF-12 had not been tested on a Lebanese sample before this study; however, it had been used with patients having diabetes mellitus in Saudi Arabia. It was first translated and content validated by a panel of experts then adjusted and reworded after piloting to be better comprehended and easily administered (Al-Shehri et al., 2008). The larger translated form of this questionnaire was shown to be easily administered over the phone (Montazeri et al., 2005), similarly, this short form did not produce burden when administered for this study.

d- Frailty was measured using the frailty instrument (SHARE-FI) from the Survey of Health, Ageing and Retirement in Europe (SHARE) trial (Romero-Ortuno et al., 2010). This simple to use instrument, requires only a single physical measure (hand grip strength); the other domains of frailty (exhaustion, weight loss, slowness and low activity) are measured using one question per domain. The domains of frailty are in keeping with the Fried Frailty index. Hand grip is one of the items identified in Fried’s model in assessing frailty (Fried et al., 2001). Patients in both groups were assessed for hand grip strength before randomization. Using a dynamometer, hand grip strength was measured in both arms twice and the highest score was recorded.

Data analysis

Data analysis was done using the latest version of SPSS (version 21). Analysis was conducted according to the intention-to-treat principle, with readmission at 30 days as the primary outcome measure. All-cause readmissions were recorded to capture any admissions related to iatrogenesis and errors in classification (HF vs. non-HF readmission). Baseline differences were compared between the study arms using Student's t-test (two-tailed) for normally distributed continuous variables, the Chi-square test for discrete variables, and the Wilcoxon rank-sum test for categorical variables and continuous variables not normally distributed. The Cox proportional-hazards regression was used to identify predictors of readmission within 30 days of enrolment. Kaplan-Meier survival curves were used to measure the probability of survival without readmission during the follow-up period.

Ethical concerns

The study was implemented based on the principles of the declaration of Helsinki (World Medical Association, 2001) and the CONSORT guidelines for reporting clinical trials (Zwarenstein et al., 2008). Ethical approval was secured from the University of Technology Sydney health ethics committee (UTS HREC) [UTS approval number: 2013000485] and from the Institutional review board (IRB) of the corresponding sites. All patients and their family caregivers were consented ahead of data collection and after introducing the study. The consent stated clearly that their refusal to consent to this study will not affect the care they receive and that they are free to withdraw at any time shall they wish to. Patients who were illiterate were excluded from the study unless their family caregiver consented and provided good explanation and enough support to the patient. Finger print replaced the signature for those who are illiterate; this act is accepted in the Lebanese context. The privacy of the participants is protected where all documentations are coded and thus having no participant identifying data. A separate sheet with the patients' details and unique code is stored alone under lock and key in the principal investigator's office. The trial is registered with the Iranian Registry of Clinical Trials as IRCT2014101919593N1.

Discussion

Involving the family in self-care of heart failure is a novel approach. To our knowledge, there is only one study reporting the rates of heart failure readmission in Lebanon (Deek et al., 2014) using a retrospective design. However, this trial provides a valid comparison of outcomes between the usual care group and the intervention group. The chosen study design, randomized control trial, sheds light on the advantages of educational programs and proper follow up. Furthermore, this design is considered to be the most efficacious method to control for confounding factors (Schulz et al., 2010). Although this method can have serious implications in terms of time and cost. This cost however, can be refundable when outcomes are improved and hospital fees are reduced(Johnston et al., 2006). Bias was carefully avoided throughout the trial. Selection bias was avoided by randomizing the participants after collecting baseline data, and this was done by a researcher independent of the ongoing data collection process. Detection bias was avoided by having the follow up data collected by a researcher that was not involved in the randomization and baseline data collection.

In conclusion, prospectively involving the family in self-care of heart failure using a theoretically derived and protocol driven approach is a novel approach. Furthermore, this is the first trial conducted in Lebanon on patients with heart failure, which is appropriate in a collectivist culture where the family is involved in many aspects of patients' lives.

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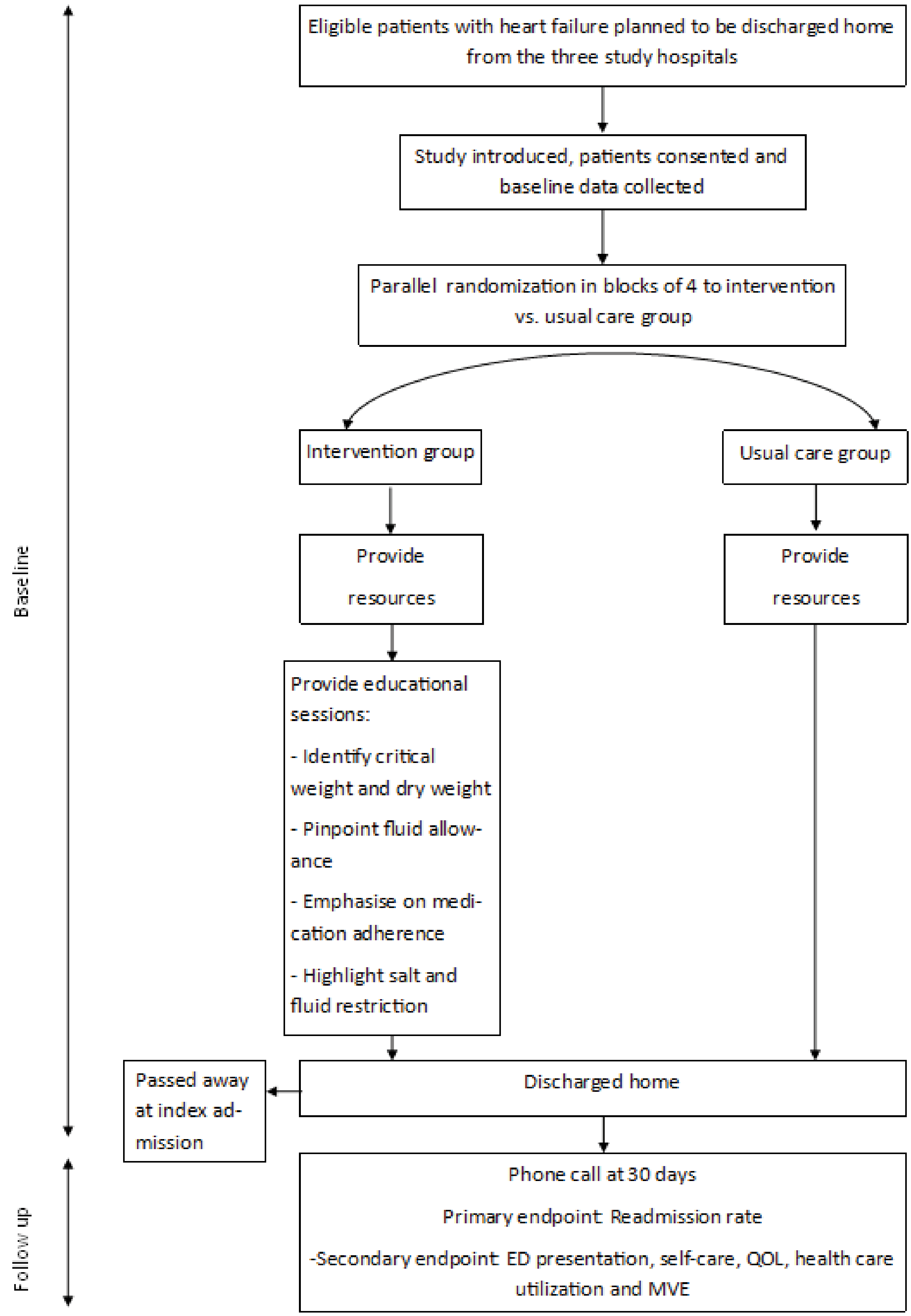

Figure 5. 1 Representation of the study sampling, randomization, intervention and follow up according to the CONSORT guidelines

Major Criteria

- ☐ Paroxysmal Nocturnal dyspnea
- ☐ Neck vein distention
- ☐ Rales
- ☐ Radiographic cardiomegaly
- ☐ Acute pulmonary edema
- ☐ S3 gallop
- ☐ Increased central venous pressure (>16 cm H2O at right atrium
- ☐ hepatojugular reflux
- ☐ weight loss > 4.5kg in 5 days in response to treatment

Minor Criteria

- ☐ Bilateral ankle edema
- ☐ Nocturnal cough
- ☐ Dyspnea on ordinary exertion
- ☐ hepatomegaly
- ☐ pleural effusion
- ☐ Decrease in vital capacity by one third from maximum recorded
- ☐ tachycaria (>120BPM)

Figure 5. 2 The Framingham Criteria

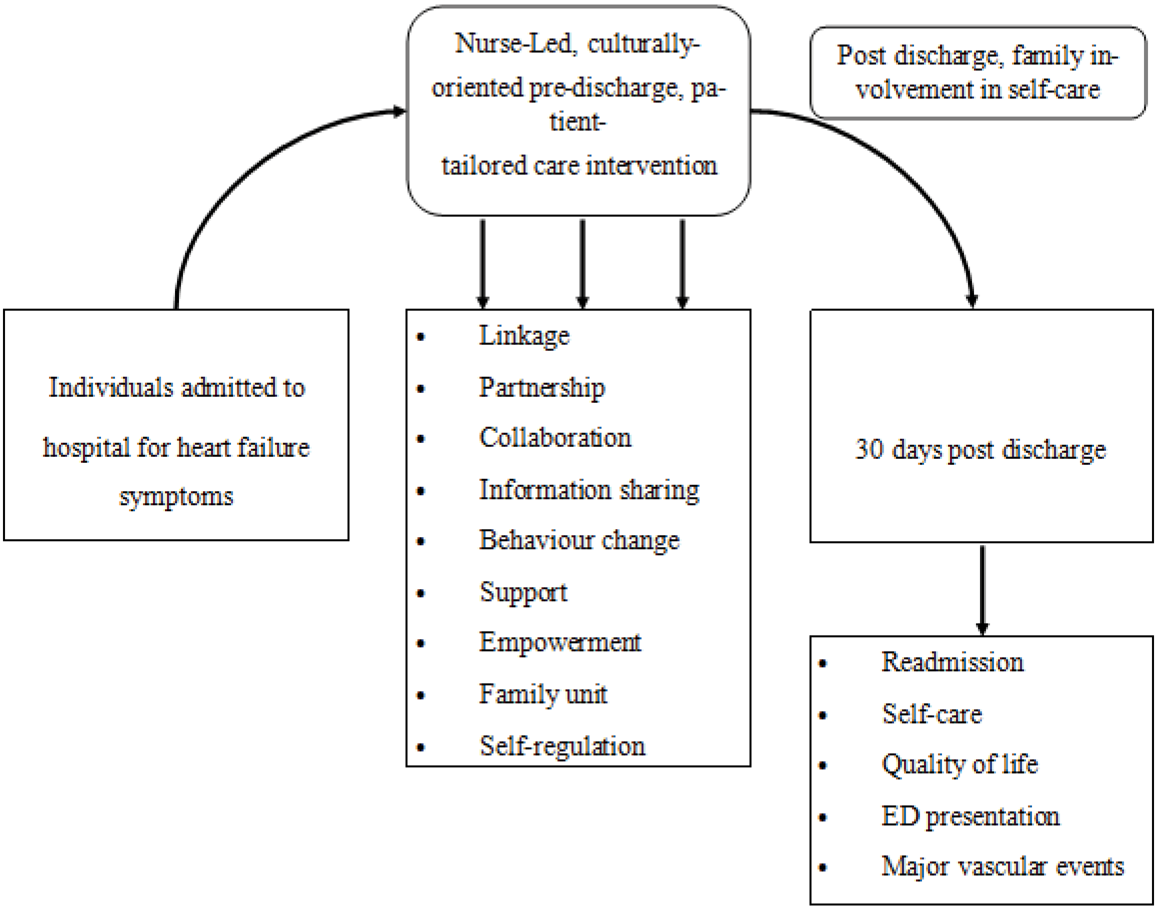

Figure 5. 3 The Family Intervention Heart Failure Model

Table 5. 1 Timeframe and data collection

	Time frame	
Instrument/data collected	**Baseline**	**30 days**
Baseline tool	X	
SCHFI	X	X
SF-12	X	X
Follow up tool		X

Table 5. 2 Data collectors

	Data collector	
Instrument/data collected	**Primary investigator**	**Nurse Researcher**
Baseline tool	X	
SCHFI	X	X
SF-12	X	X
Follow up tool		X

15.3 Summary

This chapter presented the methodological design of the randomised controlled trial conducted to evaluate a culturally tailored nurse-led intervention. The FAMILY project was a multi-site, block randomised controlled trial conducted in Lebanon over a 12-month period. Inclusion criteria were adult patients presenting to one of the three study hospitals for heart failure symptoms. Participants were excluded if they had a debilitating condition. Patients allocated to the intervention group along with their primary family caregivers were provided with a comprehensive, culturally appropriate, educational session on self-care maintenance and symptom management along with self-care resources. The usual care group received the self-care resources only. The primary endpoint was 30 day readmission, and the secondary endpoints were emergency department presentation, quality of life, self-care, health care utilization and major cardiovascular events.

To my knowledge, this is the first prospective trial conducted in the Lebanese setting. The chosen study design, randomized control trial, sheds light on the advantages of educational programs through proper follow-up. Furthermore, this design is considered to be the most efficacious method to control for confounding factors. Nevertheless, this method can have serious implications in terms of time and cost. This cost however, can be refundable when outcomes are improved and hospital fees are reduced.

The following chapter presents the brief report presenting the psychometric evaluation of the Arabic version of the Self-care of Heart Failure Index (*A*-SCHFI) using the baseline scores of this instrument in the FAMILY Study.

16. Chapter 6: Translation and Validation of the Arabic version of the Self-care of Heart failure Index (*A*-SCHFI)

16.1 Introduction of Chapter Six

Chapter six presents the psychometric evaluation of the Arabic version of the Self-care of Heart Failure Index (*A*-SCHFI). Anecdotal evidence suggests that self-care among the heart failure population is poorly practiced in Lebanon, therefore, we translated the SCHFI to Arabic and administered it to the Lebanese sample of the FAMILY study population. This was undertaken in consultation with Dr. Barbara Riegel, developer of the SCHFI. The paper reporting the validity and reliability evaluation of the A-SCHFI is submitted to the Journal of Cardiovascular Nursing. Demonstration of submission is provided in Appendix 23.

Deek, H., Chang, S., Noureddine, S., Newton, P., Inglis, S., MacDonald, P. S., Al Arab, G., & Davidson, P. M. (2015). *Translation and Validation of the Arabic version of the Self-care of Heart failure Index (A-SCHFI)*. Under review/Journal of Cardiovascular Nursing.

Face and content validity were confirmed by a panel of experts and construct validity was established using both exploratory and confirmatory factor analyses. Reliability was evaluated using composite reliability coefficient which was thought appropriate for multidimensional scales.

16.2 Submitted article

Translation and Validation of the Arabic version of the Self-care of Heart failure Index (A-SCHFI)

Abstract

Background: Heart failure is a complex clinical syndrome globally with high demands for self-care. The Self-care of Heart Failure Index (SCHFI) was developed to measure self-care and has demonstrated robust psychometric properties across populations.

Objective: To assess the psychometric properties of the Arabic version of the SCHFI (*A*-SCHFI)

Methods and results: The scores of the *A*-SCHFI administered to 223 Lebanese patients with heart failure was used to validate this instrument. Face and content validity, assessed by a panel of experts, were found sufficient. The three constructs of the *A*-SCHFI explained 37.5% of the variance. Adequate fit indices were achieved using the modification procedure of controlling error terms. Reliability coefficient was poor in the maintenance and adequate in the management and confidence scales.

Conclusion: Following modification, the *A*-SCHFI was shown to be a valid and reliable measure of self-care among the Lebanese population.

Key words: Heart failure, Self-care, SCHFI, Arabic, psychometrics

Funding source: Funding was generously provided by the Sigma Theta Tau International Honor Society for Nursing.

Word count: 1,838 words

Background

Heart failure is a complex clinical syndrome with high morbidity and mortality [1]. Cardiovascular diseases are the leading causes of morbidity and mortality in Lebanon with high prevalence reaching 20% [2]. While we know little on the prevalence and burden of HF in Lebanon, prevalence of its risk factors, including hypertension, hyperlipidemia and diabetes are higher reaching 23%, 20.7% and 13.8% respectively [2]. Furthermore, smoking among the HF population is higher in Lebanon than Saudi Arabia (42% vs. 18% respectively) and the average body mass index (BMI) among this population was 29.33 $\underline{+}$5.95 kg/m^2, reflecting overweight [3]. These findings suggest how poorly self-care is practiced among the HF population.

Self-care in heart failure

Riegel, Lee, Dickson, Carlson [4] have defined self-care as: "A naturalistic decision making process involving the choice of behaviors that maintain physiologic stability (maintenance) and the response to symptoms when they occur (management)". In HF, dietary and proper follow-up with health professionals are fundamental to improving patient outcomes including readmission, mortality and quality of life [5].

Self-care assessment

There are a number of instruments used for measuring self-care in heart failure. The European Heart Failure Self-Care Behavioral Scale (EHFScBS) and the Self-Care of Heart Failure Index (SCHFI)[4,6] have been widely studied and validated in a number of settings and cultures [7-9].

Self-care of Heart Failure Index

Riegel, Carlson, Moser, Sebern, Hicks, Roland [10] developed and updated [4] an index of three scales that measure the level of involvement in self-care amongst patients with HF. The first is the maintenance scale, a 10-item scale, measuring patients' knowledge on their disease condition and their self-care practices. The second, a 6-item scale, assesses the patients' ability to recognize their abnormal symptoms and self-manage them; the management scale. And the confidence scale, a 6-item scale, assesses the patient's confidence in performing self-care. The first two scales directly measure self-care while the confidence scale is a moderator of self-care and outcomes [4].

This tool uses a four-point Likert scales rating, except for item 16 of the management scale which uses 5 points. A summative mean score of the three scales is calculated [4] and a total score of 70 or more is a reflection of adequate self-care.

Aim

The aim of this study was to examine the validity and reliability of the Arabic version of the self-care of HF index (*A*-SCHFI) in Lebanese older adults with HF in Lebanon.

Methods

Translation

Following the instrument translation recommendations [11], one researcher translated the updated version [4] into Arabic which was then back translated to English by two independent researchers unfamiliar with the study. Minor wording conflicts across the final two English translated versions were discussed and resolved. All translations were conducted using clear, direct and simple phrases and questions addressed to mostly older adults with low literacy levels. All three translators were bilingual and fluent in both English and Arabic languages with rich clinical experience in nursing cardiology. The final Arabic version was then revised by a fluent speaker of both languages.

Data were used from the baseline scores of *A*-SCHFI collected from a randomized controlled trial aimed at testing a family-centered educational intervention on the outcomes of patients with HF. The details of the trial are discussed elsewhere [12] and are briefly presented here. Arabic speaking patients admitted for HF exacerbation to one of the three study sites were recruited for this study. Baseline data were collected Including the *A*-SCHFI. A single educational session, on self-care skills and symptoms management, was provided to the intervention group. Follow up was conducted through a phone call at 30 days. Baseline scores of the *A*-SCHFI collected from the Lebanese participants only were used for its validation.

Statistical analysis

Descriptive analysis of 22 items in the *A*-SCHFI was undertaken. Construct validity was examined through both exploratory factor analysis and confirmatory factor analysis. Exploratory factor analysis (EFA) was performed using the Statistical Package for the Social Sciences (SPSS 22) program. Confirmatory factor analysis was carried out was carried out using Analysis of Moment Structure (AMOS 22) program. Composite reliability calculation was done using numbers derived from AMOS program.

Tool Validity

Face and content validity: The final version of the *A*-SCHFI was discussed by a panel of ten, including cardiologists and PhD and masters prepared cardiology nurses for face and content validation. Minor wording differences were resolved through panel discussions.

Construct validity: Ten cases/ items are needed to perform factor analysis [13], therefore, a sample of 223 participants is adequate for an index of 22 items. The factorability of the data was assessed using Bartlett's test of sphericity (significant at <0.05) [14], and the Kaiser-Meyer-Oklin (KMO) measure of sampling adequacy (>0.6) [15,16]. Following the format of the original version (three scales)[4], three distinct but somewhat correlated constructs were enforced into the measurement model. As such, EFA was conducted using principal component analysis with direct oblimin rotation [17]. All variables were retained if they illustrated significant loading in the original version of the SCHFI.

Confirmatory factor analysis (CFA) was performed to test factorial validity of the three constructs solution. CFA uses structural equation modelling to test a hypothesized model for goodness of fit to the actual data.

Tool Reliability

The multidimensionality of the scale has been demonstrated previously [18], which deems Cronbach's alpha inappropriate for reliability evaluation. Composite reliability coefficient (CR) was performed on each scale separately as suggested by Riegel, Lee, Dickson, Carlson [4], using the following formula:

CR = (sum of standardized loading)^2 / (sum of standardized loading)^2 + sum of indicator measurement error) [19].

These numbers were extracted from the CFA output.

Results

This analysis was done on the 223 Lebanese patients of this study. Descriptive characteristics for this sample with the *A*-SCHFI scores are presented in Table 6.1. The mean age of the sample was 67 (13) years and the majority were male (55%). The scores were generally low with large SD. Item 16 had a small value of 0.27 and items 3, 4, 6, 10 and 15 had large standard deviations exceeding 1.2 on a 4 point Likert scale while only items 5 and 8 had values above 3.40. Scores of the management scale ranged between 1.10 and 2.65 except for item 11 scoring 0.79 and item 16 scoring 0.27. Items of the confidence scale ranged between 1.94 and 2.6.

Tool Validity

Minor wording differences were resolved through discussions among the expert panel members. These differences were in expressing HF or weakness in the heart and in keeping the word "nurse" in the items 5 and 15. The word 'HF' was kept and 'nurse' was deleted since seeking medical advice from a nurse is not general practice in Lebanon. Therefore, the *A*-SCHFI was evaluated by the panel to have sufficient validity to assess self-care in the Lebanese context.

Exploratory factor analysis was performed on the self-care index. Kaiser-Meyer-Olkin measure of sampling adequacy was performed to yield 0.669 indicating that the sample size was adequate for factor analysis. Bartlett test of sphericity was significant (x^2=1596.408, *df*= 231, p=0.000) indicating that the correlation matrix had significant correlations amongst variables. The three constructs explained 37.5% of the variance. Items of the maintenance scale scattered between the three constructs with items 1, 6, 8 and 9 loading in their theoretical structure, while items 2, 3 and 10 loaded in the management construct and items 4, 5 and 7 in the confidence construct. Out of the six items in the management construct, five loaded in their theoretical structure while item 15 loaded in the maintenance construct. Similarly, four items of the confidence scale loaded in their theoretical structure while items 21 and 22 loaded in the management construct.

To achieve the best fit with the CFA model, covariance between the three constructs were included. Error terms were controlled for the following items: items 12 & 13 and items 17 & 18. Also, after further analysis on the findings of the EFA and the primary evaluation of the descriptive statistics, items 15, 21 and 22 were removed from the model. These changes produced adequate fit indices: Chi-square= 339.800, GFI= 0.868, TLI= 0.827, CFI= 0.851, NFI=0.768 and RMSEA= 0.072. The path diagram is presented in Figure 6.1.

Instrument Reliability

Following the formula, CR was calculated in the maintenance scale to be 0.51, in the management scale 0.84 and the confidence scale 0.87.

Discussion

The aim of this study was to evaluate the validity and reliability of the *A*-SCHFI in the Lebanese context. As presented, most of the items of the maintenance scale had low mean scores showing poor daily self-care practices among the Lebanese sample of HF patients. The only exceptions were in items 5 and 8 where the latter is a reversed item that could have caused confusion among the older adults. Item 5 measures the practice of keeping their doctor's visits which shows the dependability of these patients on the health care professionals and inadequate self-care. This finding is further confirmed by the low mean scores of items 11 and 16 in the management scale which assess patients' ability to recognize symptoms and evaluate the treatment.

Based on the original index, three different scores are used to measure self-care; therefore, performing construct validity was used to validate summated scales. In the EFA, only items measuring salt intake, medication adherence and daily weight loaded correctly in the maintenance scale with moderate loading value, while all the other items loaded in other constructs. This poor loading might also be related to limited self-care knowledge and health education. In the management scale, only one item loaded in the incorrect construct; item 15 measures the remedies used to relief trouble breathing or ankle swelling: contact your doctor. The incorrect loading of item 15 could be due to poor self-management knowledge and low rates of providing education on diagnosis and hospitalization. Alternatively, patients may have the knowledge/confidence but that does not necessarily translate into practice. Limited self-management was reported through a study conducted on cardiovascular patients in the Lebanese context. Results of this study suggested that patients delay seeking medical attention despite having passed through cardiovascular events previously and knowing their severity [20]. As presented earlier in the mean scores, patients with HF demonstrated limited knowledge on symptom recognition and treatment evaluation. This was further confirmed in the EFA where items assessing these measures (items 21 and 22) loaded incorrectly in the management construct rather than in their theoretical structure; the confidence construct. The incorrect loading of these items should be further evaluated in future studies.

Reliability evaluation of the *A*-SCHFI demonstrated to be adequate on the confidence and management scales when items of low scoring were removed based on the output of the CFA. However, CR was below acceptable in the maintenance scale. The latter finding can be explained by the multidimensionality of this scale; measuring multiple behaviors of self-care maintenance[18].

Conclusion

The study findings suggest that following adaption to the socio-cultural context, the *A*-SCHFI can be used as a valid and reliable instrument in the Lebanese HF population. Ongoing psychometric validation of this instrument in the Arabic population is warranted.

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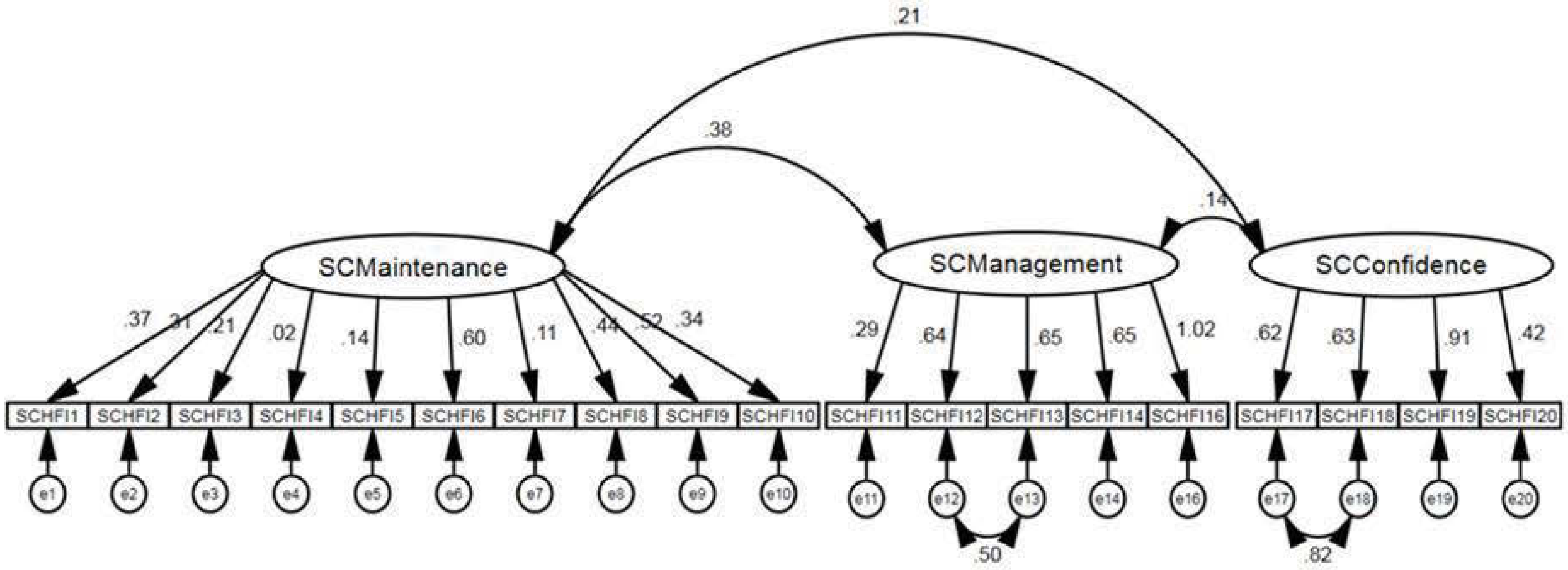
Table 6. 1 Descriptive characteristics for the study sample

Variables	Total (%)
Socio-demographic profile	
Age	67 (13)
Male**	122 (55)
At least high school education**	52 (23)
Spouse as primary caregiver**	94 (42)
Risk factors**	
DM	100 (45)
HTN	159 (71)
COPD	41 (18)
CAD	148 (66)
CHF profile**	
History of HF	157 (70)
Ischaemic aetiology	126 (57)
EF	36 (11)
NYHA class II &III	213 (95)
A*-SCHFI Scores	
Self-maintenance	33 (23-43)
Self-management	15 (0-20)
Self-confidence	39 (33-50)

Legend: Data presented in mean and standard deviation; *values not normally distributed presented in median (25th-75th percentile); **categorical data presented in frequency and percentage; DM: diabetes mellitus; HTN: hypertension; COPD: chronic obstructive pulmonary disease; CAD: coronary artery disease; HF; heart failure; EF: ejection fraction; NYHA class: New York Heart Association classification; *A*-SCHFI: Arabic version of the Self-care of H13eart Failure Index.



Chi-square=339.80, GFI= 0.87, TLI=0.84, CFI=0.86, NFI=0.77, RMSEA=0.07

Figure 6. 1 Path diagram of the confirmatory factor analysis results with the standardized estimates for the factors and items of the A-SCHFI

Self-care maintenance; SCManagement: self-care management; SCConfidence: self-care confidence.

16.3 Summary

The validation analysis was performed on 223 Lebanese participants with a mean age of 67 years (13) and the majority being male participants (55%). Descriptive analysis revealed that a number of scores were low with large standard deviations; this was especially true with the scores of the maintenance scale, which reflects how poorly self-care is practiced. Face and content validity, assessed by a panel of experts, were found sufficient. The three constructs of the *A*-SCHFI explained 37.5% of the variance. Adequate fit indices were achieved using the modification procedure of controlling error terms. Reliability coefficient was poor in the maintenance and adequate in the management and confidence scales.

The following chapter presents the findings of the randomised controlled trial undertaken to evaluate the FAMILY study. The study outcomes: readmission; self-care; quality of life; emergency department presentation; major vascular events and health care utilisation are reported.

17. Chapter Seven: Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: A randomized controlled trial

17.1 Introduction of Chapter Seven

This chapter presents the findings of the FAMILY study which was evaluated through a randomized controlled trial. The aim of this study was to evaluate family involvement in self-care of patients with heart failure. The paper presenting the findings of this trial has been submitted to the International Journal of Cardiology. Evidence of submission is provided in Appendix 24.

Deek, H., Noureddine, S., Newton, P. J., Inglis, S. C., Al Arab, G., Kabbani, S., Chalak, W., Timany, N., MacDonald, P. S., & Davidson, P. M. (2015). Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: A randomized controlled trial. *Submitted to The* European Journal of Heart Failure.

As presented, heart failure burden is of concern in Lebanon and globally. Disease management programs in Lebanon are limited and are necessary due to the high burden of the unique risk factors, readmission rates and the poorly practiced self-care. The FAMILY Study was the first RCT to be conducted in the Lebanese setting. Having three study sites from Beirut and Mount Lebanon that admit patients with diverse backgrounds from all over the country allow for generalising our study findings to the Lebanese population. In addition, the inclusion of a governmental hospital that admits patients from all financial coverage is also an advantage for generalizability.

17.2 Submitted Article

Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: A randomized controlled trial

Abstract

Background: Heart failure is a growing problem in Lebanon but to date there has been no systematic evaluation of a disease management intervention. The aim of this study was to evaluate the effect of a family-based intervention on the self-care of patients with heart failure to decrease readmission to the hospital.

Methods and results: A multi-site randomised controlled trial of a tailored heart failure management intervention was conducted on 256 patients hospitalized with heart failure. The mean age was 67 ± 8 years, 55% were male, and the majority of caregivers were the patient's spouse (43%). The intervention comprised of a single family-focussed educational conference focussed on self-care and symptom management. Follow-up phone calls were conducted 30 days following discharge. Readmission at 30 days was significantly lower in the intervention group compared to the control group (n=10, 33% vs. n=20, 67%, $p<0.05$ respectively). Self-care scores improved in both groups at 30 days with significantly larger improvement in the intervention group over the control group in the maintenance and confidence scales. No differences were seen in quality of life scores or emergency department presentations between the groups. Significantly more participants in the control group needed health care facilities than in the intervention group (23% vs. 11%).

Conclusions: This model of intervention, tailored to a collectivist culture, was successful in decreasing readmission to the hospital and improving self-care for individuals discharged with a confirmed diagnosis of heart failure.

Trial registration: Iranian Registry of Clinical Trials IRCT2014101919593N1

Source of Funding: Funding was generously provided by the Sigma Theta Tau International Honour Society for Nurses.

Conflicts of interest: None

Word count: 3,410 words

Keywords: Heart failure; clinical trial; nursing; education; disease management; family

Introduction

Heart failure (HF) is a clinical syndrome with complex treatment regimen, progressively declining disease trajectory and unpredicted health events (1). This ‘malignant’ condition (2) is the terminal stage of most cardiovascular diseases and is usually associated with multiple co-morbidities and poor outcomes (1). Readmission rates, mortality and hospital stays are some of the measures used to evaluate the quality of care provided to patients with HF. In Lebanon, there is an estimated prevalence of 1.8% (72,000 patients) of HF (3).

In 2012, the Medicare in the United States started penalizing hospitals with 30-day readmission and mortality rates higher than their set benchmarks (4). The impact of these penalties, along with the increased visibility of adverse clinical outcomes, has intensified the focus on disease management programs (5). In Lebanon, HF exerts significant burden on the patients, families and the healthcare system. The average cost for a single hospitalization is almost $4000 and the total cost for HF care has exceeded one million US dollars annually (3) and is rising with limited interventions to control this cost. Care is mainly provided through tertiary settings, with limited awareness campaigns and disease management programs.

Disease management programs are structured multicomponent interventions that include educational elements on diet, self-monitoring and treatment adherence (6). These programs have produced varying levels of success on HF outcomes (7). An American Heart Association writing group identified eight domains for describing the components of these programs. These include identifying the patient population, intervention recipients (patients and their caregivers), the environment where the intervention takes place and the clinical outcomes (8). However, the real benefit of these programs is not only attributable to their complexity or dosing, it is greatly influenced by the patients’ willingness to adhere to self-care practices (9). Self-care can be influenced by the patients’ socio-economic status, knowledge, literacy level, skills and acceptability of personal and familial values (10). Readmissions, quality of life (QOL) and emergency department (ED) presentations are some of the clinical outcomes than can be improved by adopting self-care practices (10, 11).

Although the role of family caregivers is implicit and reflected in studies of patients with coronary artery disease in Lebanon (12), there has been no evaluation of the systematic involvement of the family in HF self-care. Spousal support has been found to be useful in promoting patient satisfaction and medication adherence (13). Moreover, satisfaction with the quality of marriage was associated with longer event-free periods in patients with HF (14). Despite these findings, it was recently acknowledged (15) that the benefits of this approach might be more integral than supplemental in non-western, collectivist cultures where the family unity is pivotal to societal function. In Lebanon, family involvement was proven to be a strong moderator in overcoming the detrimental effects of war on the physical and psychological wellbeing (16).

Conflicts in the Middle East, particularly the influx of refugees from Syria, require models of interventions that consider issues of access and acceptability (17). Not only do interventions need to be tailored to specific cultural needs, they need to be appropriate to societal needs, particularly a mobile and transient population. This paper presents the findings of the Family focused Approach to iMprove Heart Failure care In Lebanon QualitY intervention (FAMILY) study; a tailored HF disease management intervention, conducted in Lebanon on Lebanese and non-Lebanese patients from the surrounding countries.

Methods

Trial Design

The FAMILY study, described in depth elsewhere (18), was a multi-site block randomised controlled trial with blinded endpoint evaluation, conducted in three hospitals in Lebanon. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's human research committee (UTS HREC) and the ethical committees of the study hospitals. The trial was registered at the Iranian registry (IRCT2014101919593N1). All participants and their primary family caregivers signed a written informed consent when recruited.

Study population and eligibility criteria

Between November 2013 and November 2014, patients admitted to one of the three study tertiary medical centres in Lebanon, who fitted the inclusion criteria were invited to participate in the FAMILY study. Patients had to be adults (≥ 18 years) with a confirmed HF diagnosis. Patients living alone or in a nursing home and those in an active dying phase, awaiting cardiac surgery with limited functionality, or having a life expectancy of less than the follow-up period as judged by their treating physician were excluded. Caregivers had to be literate and free of hindering conditions such as blindness or impaired cognitive status. Both the patients and their caregivers had to be willing to sign a consent form. Patient recruitment took place when patients were stabilised, and the family-centred educational session was provided on the day of discharge. The study sites, with ED and cardiac units of 9 to 20 beds/site, are prepared to accommodate patients presenting with signs of HF exacerbation. Patients are cared for by cardiologists and experienced cardiology nurses where brief education is provided as usual care upon discharge.

Primary and secondary outcomes

The primary outcome was all-cause readmission within the 30-day follow-up period. The secondary outcomes were ED presentation, self-care, QOL, health care utilization and major vascular events during the same period. The outcome data were collected through phone calls conducted by a researcher unaware of the study allocation of each participant.

Sample size calculation

Sample size calculation was based on the primary outcome, 30-day readmission. To reduce readmission from 30% (19) in the control group to 15% in the intervention group, sample size was calculated to be 130 participants in each arm for a 2-tailed significant level of 0.05, power of 80% and an attrition rate of 10%.

Randomization procedure

Following baseline data collection, participants were randomised to one of the study arms. Randomisation was carried out using the Statistical Package for Social Sciences (SPSS) for generating a random list with blocks of four. Participant allocation schedules were kept with a researcher independent of the data collection process. Group allocation took place after baseline data were collected to avoid selection bias.

Intervention group versus control group

Self-care resources were provided to all participants equally. These included a digital weighing scale, medication box, calibrated bottle and a diary packed in a branded bag with a dedicated FAMILY logo as a behaviour prompt. Patients and their caregivers randomised to the intervention group also received one family-centred educational session on self-care and symptoms management. The identified family caregivers were educated on providing and filling the medication boxes, taking their patients' daily weight and managing their condition. Education was also provided on limiting salt intake, restricting fluid intake as directed subjectively while using the calibrated bottle, smoking cessation and physical activity. Details of the intervention and its theoretical underpinning are described elsewhere (15).

Data collection

Study instruments were administrated using interviews with clear phrases in spoken Arabic language. The baseline data sheet designed for this study included socio-demographic data, clinical data and the frailty index as presented below:

a- Socio-demographic data: including age, gender, marital status, education level, occupation, the identified family caregiver and his/her level of education. Social history included smoking history, alcohol consumption and yearly flu vaccination.
b- Clinical data: including medical history (retrieved from the medical chart), hospitalization history, New York Heart Association (NYHA) class, ejection fraction, medication profile, cause of HF and physical assessment.
c- SHARE index: this frailty measure is composed of six questions around activity and appetite and a hand grip measure assessing the strength in both arms (20).

Self-care was evaluated using the Arabic version of the self-care of HF index (*A*-SCHFI) that measures self-care through three scores; self-maintenance, self-management and self-confidence (21). The index was translated into Arabic following the translation recommendations (22). Details of the translation and validation of *A*-SCHFI are reported elsewhere (23).

Quality of life data, collected using the Medical Outcome Study Short Form SF-12v2 (4 week recall), assess two scales; physical component summary (PCS) and mental component summary (MCS). This measure had previously been translated and validated into the Arabic population (24). In this study, SF-12v2 scores for the PCS and the MCS applied a norm-based scoring algorithm derived from the data of a general population survey which assumes a mean of 50 and a standard deviation of 10 (25).

Due to issues in returning to the hospital for follow-up, a comprehensive in-hospital intervention with telephone follow-up was designed. Follow-up data collected 30 days after patient discharge were the *A*-SCHFI, the SF-12v2 and questions on whether they had been hospitalised, including the hospital location and the length of stay, had a major vascular event, sought medical advice and its source, or visited the ED during the follow-up period. Participants were also asked about their weight on the day of follow-up to compare that with their weight at discharge.

Statistical analysis

Data were analysed using version 22 of the Statistical Package for Social Sciences (SPSS). Analysis was carried out based on the intention-to-treat principle. Normality testing was done using the Kolmogorov-Sminov (KS) test. Group characteristics were compared using Student's t-test (two-tailed) for normally distributed interval and ratio level variables. Discrete variables and continuous variables not normally distributed were analysed using the Chi-square test and the Mann-Whitney U test respectively. To assess the independent effect of the intervention, ANCOVA was used for continuous post-intervention scores controlling for significant baseline characteristics. Likewise multiple logistic regression was used to assess association between groups and the rates of readmission adjusting for significant baseline characteristics. Finally, an analysis of length of time to readmission or death was performed using Cox's regression adjusting for covariates. Considering the small number of deaths and readmissions in this sample, cumulative event rates for time-to event analysis in each group were estimated using Kaplan-Meier curves.

Results

Participants: Patient recruitment, randomization and follow-up are presented in the flow chart in Figure 7.1. After randomization, 130 participants were allocated to the CG and 126 to the IG. Table 7.1 presents the baseline characteristics of the study sample based on their group allocation. The mean age of the study participants was 67±8 years with more men than women (55%). The majority were married (n=162, 63%) and most came from the capital city, Beirut (n=139, 54%). The level of education was low with 40% being illiterate.

Health history and current health profile: Most cases were chronic HF (68%) and the mean ejection fraction was 36% with the majority (95%) having a NYHA of II or III. The main causes of HF were ischemia and hypertension (56% and 46% respectively), among whom 21% classified both diseases to be a composite aetiologies of HF. The majority of the participants were discharged on angiotensin converting enzyme inhibitor/Angiotensin receptor blocker and beta blockers with the following rates 68% and 83% respectively. Readmissions and ED presentations in the past 12 months were frequent with rates of 56% and 12% respectively. The mean length of stay of the index admission was 9±7 days. There was no significant group differences at baseline except for higher percentage of emergency presentation in the intervention compared to the control group (18% vs. 6%, p=0.006)

Social history: Out of the current smokers (34%), 13% decided to stop smoking this admission, only a small number (6%) were alcohol consumers, 18% were overweight, 18% were obese and 5% were morbidly obese.

Baseline Frailty scores: The majority of patients were frail (71%), only 24% were pre-frail and 5% were non-frail with no significant difference between the two groups.

Caregivers: Patients were mostly cared for by their spouse or their children (43% and 41% respectively). Caregivers' education was higher than the patients' where only 11% were uneducated. Moreover, caregivers were significantly higher level of education in the control group (58% vs. 43%, p=0.039).

Study endpoints at 30 days

Out of the 260 enrolled patients, 256 patients remained in the study and four passed away before randomization. Out of the remaining sample, 5% (n=12) were lost to follow-up, 85% (n=218) were analysed, 10% (n=26) passed away with significantly more in the CG than in the IG (14% vs. 6%, p=0.037).

Primary endpoint

Readmission rates: The overall readmission rate at 30 days was 14%. Out of those readmitted (n=30), 15.4% (n=20) were in the control group and 8% (n=10) were in the intervention with a significant difference between the groups (p=0.020). Readmission was significantly associated with previous admission in the past 12 months (22 (27%) vs. 8 (73%), p=0.044) but not with ED presentation. Also NYHA class III and IV participants upon discharge were at significantly higher risk of readmission at 30 days than those with lower NYHA class (17 (57%) vs. 13 (43%), p=0.002).

Secondary endpoints

Self-care: At baseline, means of the maintenance, management and confidence scores of the whole sample were 35 (SD=15), 16 (SD=15) and 41(SD=15) respectively with no significant difference between the groups. At follow-up, scores across the three scales improved in both groups with higher scores in the intervention than in the control group.

This improvement was significant in the maintenance and confidence scale with mean scores of 67 (SD=14) vs. 58 (SD=19), (p=0.0001) and 64 (SD=20) vs. 55 (SD=22), (p=0.002) in the intervention and control group respectively. These findings are presented in figure 7.2 and Figure 7.3. Moreover, significantly more patients in the intervention took their weight at the day of follow-up as compared to patients in the control group (62% vs. 38%, p<0.0001). However, there was no significant difference between the groups in weight change over the 30 day period (n=41, mean rank=69.68 vs. n=85, mean rank=60.52, p>0.05 in the intervention and control group respectively, using non-parametric test.

Quality of life: All baseline and follow-up scores, except for the follow-up mental scale, reflected poor QOL with scores below 50. However, participants scored an average of 54 (SD=12) on the follow-up mental scale. QOL was shown to be poor on both mental and physical scales in the whole sample with no significant difference between the groups at baseline as shown in Table 7.1. After 30 days of their hospital discharge, only minimal improvement was noted in QOL scores across the whole sample on both the physical (35 (SD=7) vs. 37(SD=5)) and the mental scales (47 (SD=12) vs. 54 (SD=12)) with no difference between the groups.

Major vascular events: There were only 3 cases of major vascular events (heart attack, cerebral vascular accident and peripheral vascular event) within the 30 day period. All three cases were in the control group.

Health Care Utilization: Only 36 participants needed medical advice during the 30 days, with 25 presenting to the ED and 11 seeking help from a specialist through clinic visits. Out of the 36 participants, only five received treatment in the ED and were discharged home, 30 were readmitted and only one was provided advice in the physician's clinic. The health care utilization scheme is presented in Figure 7.4. Significantly more participants in the CG needed health care facilities than in the IG (24 (23%) vs. 12 (11%) respectively, p=0.017).

Multivariate Analysis

When controlling for caregiver education, the difference between the groups at the 30 day follow-up remained significant for self-care maintenance (df=217, f-statistics=16.005, p=0.000) and self-care confidence (df=217, f-statistics=9.027, p=0.003). The same results were seen in self-care maintenance (df=217, f-statistics=15.347, p=0.000) and self-care confidence (df=217, f-statistics=8.869, p=0.003) when controlling for ED presentations in the past 12 months (Table 7.2). When controlling for these two covariates in a logistic regression model, those in the control group were 2.492 times and 2.746 more likely for readmission (Table 7.3) and health care utilization (Table 7.4) than participants in the intervention group.

Survival analysis

Figure 7.5 compares the Kaplan-Meier curves of event-free survival for the study groups including 56 events with 18 (14%) versus 38 (29%) in the IG and CG respectively, p<0.001 (log-rank test). The hazard ratio for death or readmission event adjusting for covariates was 2.351, 95% CI= (1.341, 4.120) which is statistically different from 1 (p=0.003). Therefore, hazard ratio indicates that the probability of having an event in the CG is more than twice as that in the IG during the 30 day period.

Discussion

This study reports the findings of the first family-centred educational intervention evaluated in a randomised controlled trial in the Lebanese context. The main findings were a significant reduction in readmission, improvement in self-care maintenance and confidence, fewer major vascular events and health care utilization in the intervention group. Although this study was not powered to assess mortality, it was statistically significantly lower in the intervention group. The findings suggest the success of the family involvement in self-care of patients with HF. Interdependence and familial priorities are unique family values in non-western cultures where the wellbeing of the family outweighs that of the individual (26). Furthermore, the family commitments and responsibilities push these patients to adopt health practices and maintain wellbeing (27). These findings were supported by the views of patients on hemodialysis who identified the need for a supportive family environment to remind them of balanced diets, medication intake and maintaining wellbeing for the family's sake (26). Furthermore, the perceived support from family was found to be positively correlated with subjective wellbeing and satisfaction with life (27).

Educational interventions on family involvement in the care of patients with HF are few despite this recommended involvement in HF management guidelines (28). These interventions have shown improved self-care knowledge (29), confidence and motivation (30) as well as perceived control (31). However, we could find no educational intervention program involving the family in self-care in collectivist cultures.

In addition to the specific and intentional involvement of the family, a key aspect of this educational intervention was its timing to engage participants in the inpatient setting. This is important in settings with high numbers of refugees and population instability. Educational interventions at discharge, when the patient is stabilized after the acute phase and still having a fresh memory of the emergency experience, was reported in recent literature to be effective in avoiding readmission (32). The findings of this study (including the 8% readmission rate in the intervention group vs. 16% readmission rate in the control group) reflecting a 50% reduction between the groups, suggest the positive effect of a family conference at the point of hospital discharge.

The clinical progression of HF is sometimes ignored or unnoticed. Most patients with HF meet the Framingham criteria up to two years before presenting for symptoms, causing severe deterioration (33). This is largely due to the patient's self-management abilities and their need (or not) for periodic or intensive surveillance (11). Self-care was shown to be key to improved HF outcomes; despite that, more than half of the readmissions are due to non-adherence to self-care recommendations in addition to poor discharge planning and follow-up (11). In the current study, self-care scores at baseline were low with the lowest being the scores of the management scale. The low scores across the three scales suggest the high dependence on healthcare providers. Although a slight improvement was noticed after 30 days, the management scores were still below acceptable even in the intervention group reflecting lower ability for self-care. The lower scores across the three scales suggest the need for more intense and targeted interventions.

Seeking medical advice from a nearby pharmacy is a usual practice in Lebanon (34). We were interested to know if this applied to the HF population. The findings of this study demonstrated that participants sought advice from the ED or a specialist only, which is likely a favourable outcome of this intervention or the severity of illness. More research is warranted on health care utilization in this setting.

Limitations

Although the dosing of the intervention was tailored to the needs of the patients and their caregivers', a reinforcement session might have produced greater behaviour change and better self-care scores. Further, longer follow-up periods are necessary to evaluate the long term effect of the intervention especially on outcomes like readmission, mortality and quality of life. Also, providing self-care resources to the control group may have diluted the effect of the intervention and inflated the scores in that group. However, and despite this limitation significant differences were found between the groups in the study outcomes. Nonetheless, considering the small number of events, these findings should be interpreted with caution and validated in future research.

Another limitation is in the method used to collect the follow-up data. Despite using phone calls, we were able to follow-up with 85% of our sample at 30 days. Moreover, the patient-reported outcomes, such as self-care and QOL, may have been under- or over-reported. However, patients were asked about their weight at 30 days and these findings were compared with their weights at discharge to validate participants' self-care. In addition to that, both groups were provided with a patient held diary providing self-care instructions to isolate demonstration of the effect of the intervention. Future studies should examine these diaries for accurate self-care analysis.

Conclusion

This tailored and targeted, family-focussed disease management intervention was evaluated to be successful in decreasing readmission to the hospital. Further investigation of this model of intervention is warranted.

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Table 7. 1 Study participants' baseline characteristics based on group allocation (N=256)

Variables	**Total (100%)**	**Intervention group (N=126, 49%)**	**Control group (N=130, 51%)**	**p value**
Socio-demographic profile				
Age [Mean (SD)]	67 (8)	65 (14)	68 (14)	0.135
Male	141 (55)	67 (53)	74 (57)	0.615
Married	162 (63)	79 (63)	83 (64)	0.984
Paid employment	45 (18)	26 (21)	19 (15)	0.251
At least high school education	63 (25)	38 (30)	25 (19)	0.29
Spouse as primary caregiver	111 (43)	55 (44)	56 (43)	1.000
Caregiver at least high school education	127 (50)	72 (58)	55 (43)	0.039
Risk factors				
Smoking history	119 (78)	98 (77)	101 (77)	0.870
BMI	29 (8)	29 (8)	29 (7)	0.760
DM	118 (46)	58 (46)	60 (46)	1.000
HTN	185 (72)	90 (71)	95 (73)	0.782
COPD	46 (18)	22 (18)	24 (19)	0.872
CRF	76 (30)	39 (31)	37 (29)	0.683
A fib	82 (32)	35 (28)	47 (36)	0.180
CAD	165 (65)	83 (66)	82 (63)	0.696
Hospitalized in previous 12 months	142 (56)	69 (55)	73 (56)	0.900
Presented to ED in previous 12 month	30 (12)	22 (18)	8 (6)	0.006
CHF Profile				
History of HF	174 (68)	93 (74)	81 (62)	0.061
Ischaemic aetiology	144 (56)	68 (54)	76 (59)	0.529
EF*	36 (12)	37 (11)	36 (12)	0.250
NYHA Class II or III	243 (95)	117 (93)	126 (97)	0.163
Clinical Profile				
Systolic blood pressure *mm/Hg*	123 (19)	124 (19)	124 (19)	0.705
Diastolic blood pressure	68 (12)	70 (12	71 (13)	0.117

Sodium	138 (4)	138 (4)	138 (4)	0.756
Potassium	4 (1)	4 (1)	4 (1)	0.709
Creatinine*	1 [1,2]	1 [1,2]	1 [1,2]	0.701
Blood urea nitrogen values	34 (23)	33(23)	35 (24)	0.459
Haemoglobin	12 (2)	12 (2)	12 (2)	0.695
Frail	66 (71)	29 (63)	37 (79)	0.247
Medications				
ACE or ARB	173 (68)	85 (67)	88 (68)	1.000
Beta blocker	213 (83)	103 (82)	110 (85)	0.617
Diuretic	209 (82)	97 (77)	112 (86)	0.075
Quality of life measure				
PCS [Mean (SD)]	35 (7)	35 (7)	35 (7)	0.97
MCS [Mean (SD)]	47 (12)	46 (12)	48 (12)	0.46

LEGEND: BMI: body mass index; DM: diabetes mellitus; HTN: hypertension; COPD: chronic obstructive pulmonary disease; CRF: chronic renal failure; A fib: atrial fibrillation; CAD: coronary artery disease; ED: emergency department; HF: heart failure; EF: ejection fraction; NYHA: New York Heart Association class; ACEI: angiotensin-converting enzyme inhibitor; ARB: Angiotensin receptor blocker; PCS: physical component summary of the SF-12v2; MCS: mental component summary SF-12v2.

*: non-parametric testing used; continuous variables presented in mean and standard variation. Categorical variables presented in frequencies and percentages

Table 7. 2 Significant outcome difference when controlling for caregiver education and ED presentation using Covariate analysis

Covariate - Outcome	df	F statistics	p-value
Caregiver education			
- **Self-care maintenance**	- 217	- 16.005	- 0.000
- **Self-care confidence**	- 217	- 9.027	- 0.003
ED presentation			
- **Self-care maintenance**	- 217	- 15.347	- 0.000
- **Self-care confidence**	- 217	- 8.869	- 0.003

Table 7. 3 Adjusting for significant covariates using logistic regression for the outcome variable readmission

	B	S.E	Wald	df	Sig	Exp (B)	95% C.I for EXR (B)	
							Lower	Upper
Allocation (1)	0.913	0.422	4.683	1	0.030	2.492	1.090	5.699
ER 12 months (1)	-0.036	0.668	0.003	1	0.957	0.964	0.261	3.570
Caregiver education (1)	-0.114	0.661	0.030	1	0.864	0.893	0.244	3.260
Constant	-2.302	0.641	12.910	1	0.000	0.100		

Table 7. 4 Adjusting for significant covariates using logistic regression for the outcome variable health care utilization

	B	S.E	Wald	df	Sig	Exp (B)	95% C.I for EXR (B)	
							Lower	Upper
Allocation (1)	1.010	0.396	6.503	1	0.011	2.746	1.263	5.969
ER 12 months (1)	-0.527	0.561	0881	1	0.348	0.590	0.196	1.774
Caregiver education (1)	0.050	0.592	0.007	1	0.933	1.051	0.329	3.358
Constant	-1.727	0.526	10.796	1	0.001	0.178		

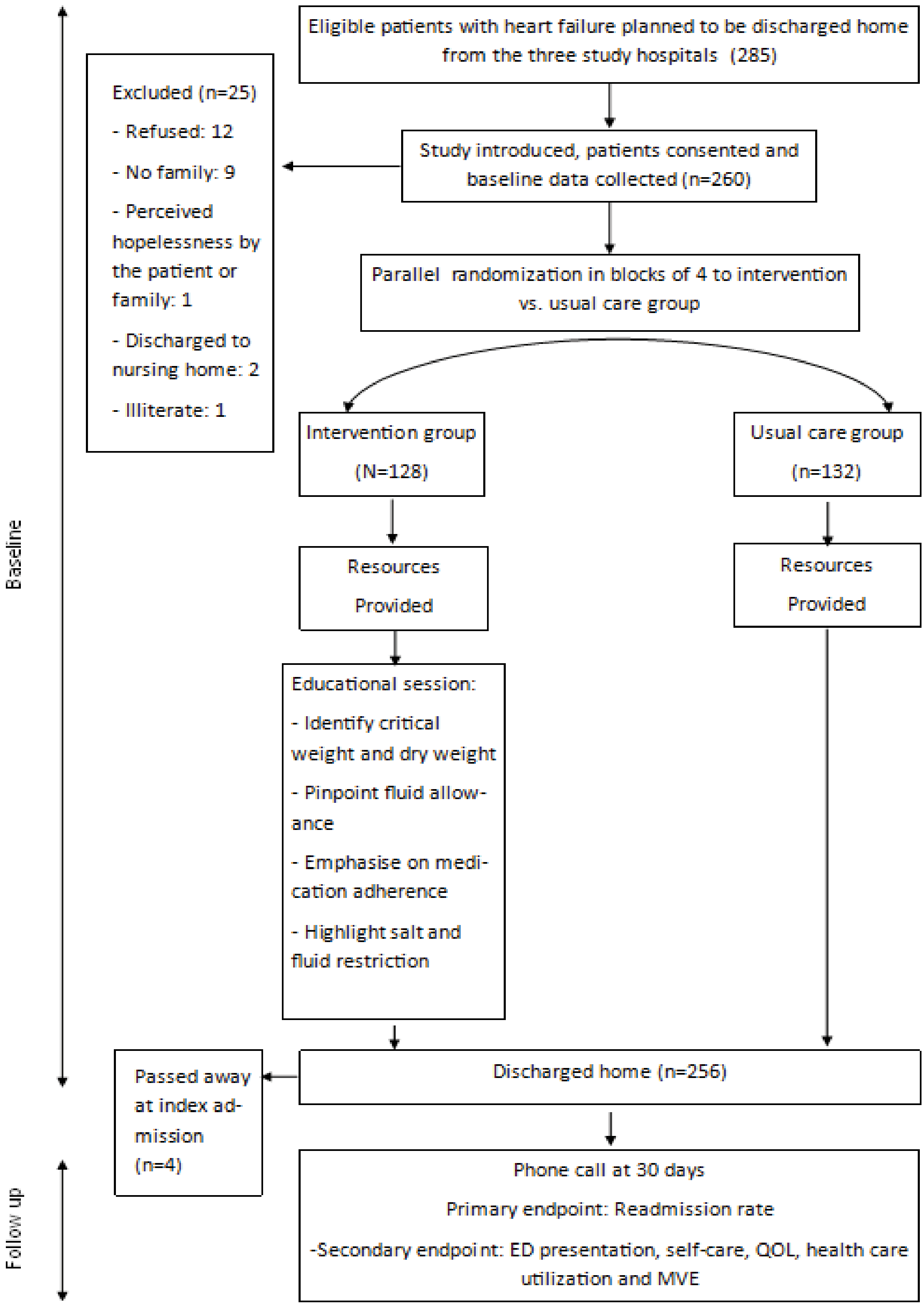

Figure 7. 1 Patient recruitment, randomisation and follow-up flow chart

LEGEND: ED: emergency department; QOL: quality of life; MVE: major vascular events

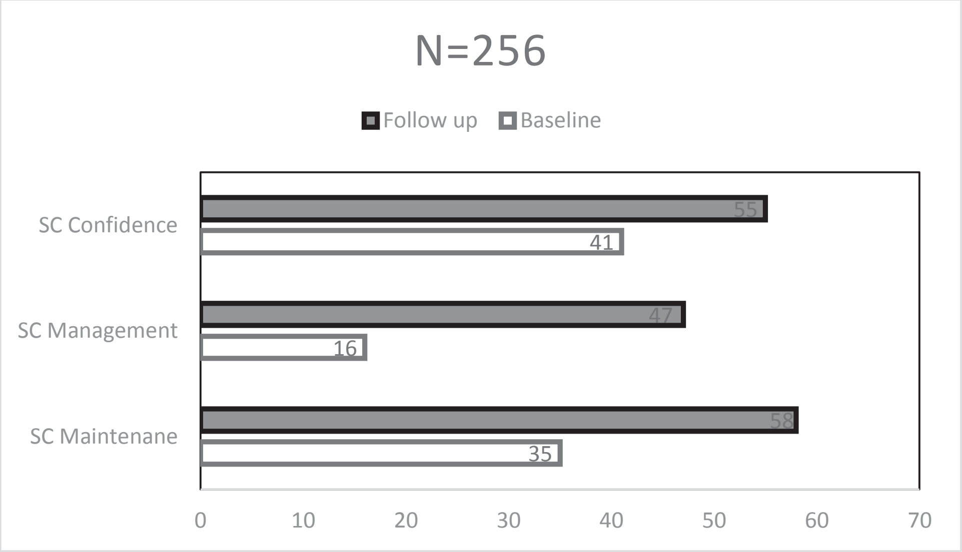

Figure 7. 2 A-SCHFI scores at baseline and follow-up for the whole sample (N=256)

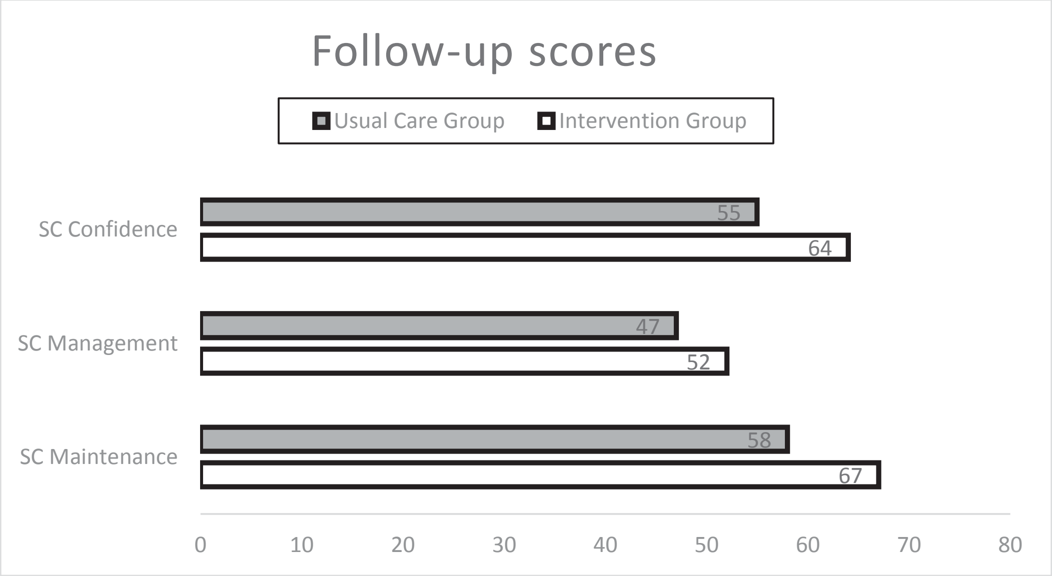

Figure 7. 3 Follow up scores for the intervention (n=126) and usual care group (n=130)

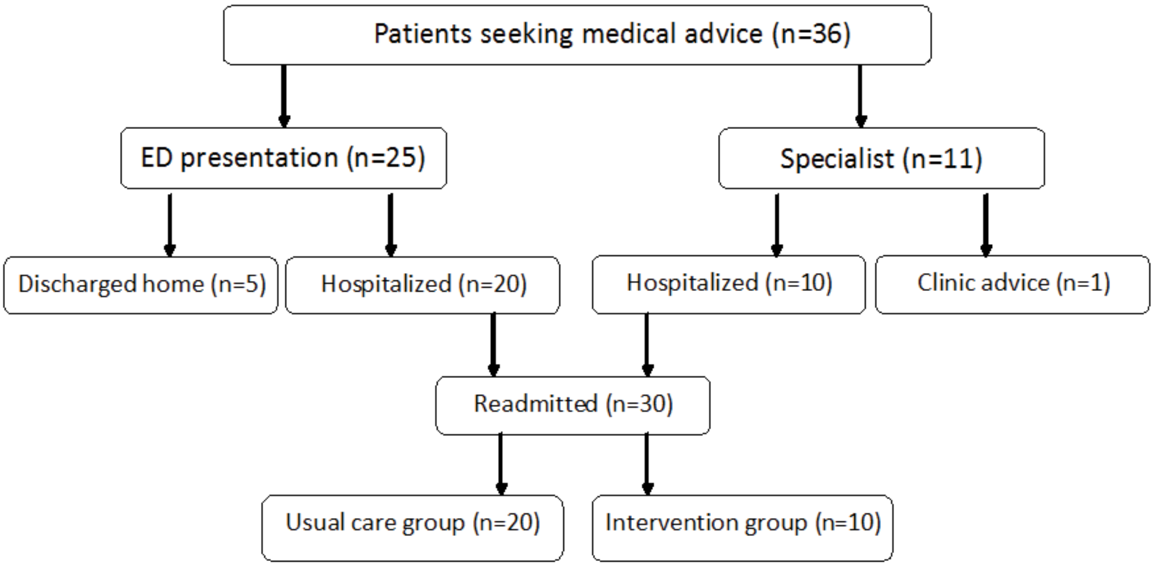

Figure 7. 4 Health care utilization scheme at 30 days (n=36)

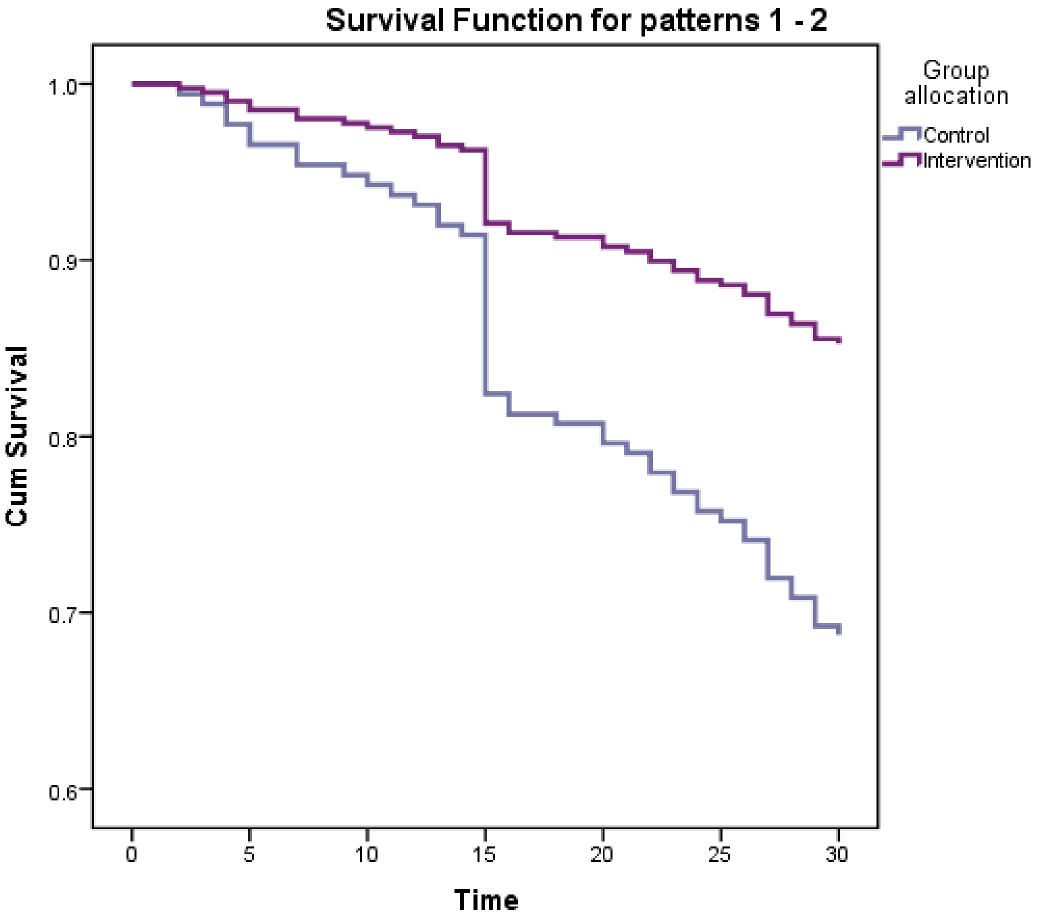

Figure 7. 5 Survival curves for the intervention and control groups

17.3 Summary

A multi-site randomised controlled trial of a tailored heart failure management intervention was conducted on 256 patients hospitalized with heart failure. The mean age was 67 ± 8 years, 55% were male, and the majority of caregivers were the patient's spouse (43%). The intervention comprised of a single family-focussed educational conference focussed on self-care and symptom management. Follow-up phone calls were conducted 30 days following discharge. Readmission at 30 days was significantly lower in the intervention group compared to the control group (n=10, 33% vs. n=20, 67%, $p<0.05$ respectively). Self-care scores improved in both groups at 30 days with significantly larger improvement in the intervention group over the control group in the maintenance and confidence scales. No differences were seen in quality of life scores or emergency department presentations between the groups. Significantly more participants in the control group needed health care facilities than in the intervention group (23% vs. 11%).

Based on the findings of this study, family involvement in self-care is vital to improving outcomes of patients with heart failure. This was demonstrated with the significant reduction in readmissions and the improvement in self-care scores. In addition to multiple educational sessions and longer follow up periods, future studies should address the needs of the family caregivers.

The following chapter presents a summary of the thesis, synthesis of the empirical findings based on the research objectives and finally presents the theoretical and policy implications of this study.

17. Chapter 8: Conclusion

17.1 Introduction

This thesis has followed a systematic approach in building a heart failure management intervention based on the unique findings of the Lebanese context. The specific aim of this PhD research was to evaluate the impact of family involvement in an intervention on self-care outcomes of patients with heart failure. This approach was considered to be culturally congruent in a collectivist society where family unity is vital and central to the physical and psychological wellbeing of the individuals. To achieve the research aim, two comprehensive literature reviews were undertaken. . The first was to identify and document the unique cardiovascular risk factors and the burden of these chronic health conditions in Lebanon. The second was to identify the elements of effective interventions aimed at improving outcomes of patients with chronic conditions such as heart failure. In order to develop an intervention suitable for the study culture, we reviewed the evidence from the literature, consulted experts and critically appraised already existing theories to finally devise The Family Intervention Heart failure Model. The intervention was then evaluated through a multi-site block randomised controlled trial.

17.2 Research aim

The aim of this research was to evaluate a theoretically derived intervention, tailored and targeted to the Lebanese context and specifically assessing the impact of family involvement in an educational intervention to improve self-care of patients with heart failure.

17.3 Research objectives

To achieve this aim, this thesis addressed the four objectives as described below:

5. Documented the burden of heart diseases in Lebanon;
6. Reviewed the literature on the involvement of family caregivers in self-care of patients with chronic diseases;
7. Developed The FAMILY Intervention Heart Failure Model; and
8. Evaluated the effect of the FAMILY intervention on heart failure outcomes through a randomised controlled trial.

17.4 Synthesis of empirical findings based on the research objectives

The main empirical findings of this research are presented in chapters two through seven. This section will synthesize the empirical findings to address the research objectives:

1. *Document the burden of heart disease in Lebanon*: In addition to the common cardiovascular risk factors across cultures including overweight/obesity, cigarette smoking and sedentary lifestyles, Lebanon has unique risks that identify its cardiovascular disease burden. These include the high rates of arghile smoking, higher rates of overweight and obesity compared to the some of the surrounding Arab countries and the overwhelmingly high rates of familial hypercholesterolemia attributed to the Lebanese gene. The socio-cultural context including ongoing stressors, such as the neighbouring Syrian crisis and political instability of the Middle East are critical factors in health care service planning.
2. *Review the literature on the involvement of family caregivers in self-care of patients with chronic diseases:* It is vital to tailor the provided support to the needs of patients with chronic diseases based on their health conditions, resource availability and the social, political and economic context. Although identifying specific elements for effective interventions was lacking due to the diversity of the study interventions and populations, some identified elements included family-centred approaches, active learning strategies, and provision of self-care tools.
3. *Develop the FAMILY Intervention Heart Failure Model:* Culture specific values to the Lebanese society were identified; these included carefully phrasing questions on sensitive topics such as religious affiliations and financial support. Factors identified by the expert panel included to consider health literacy, tailor information to the local dietary and cultural norms and provide branded bag with the FAMILY logo as a behaviour prompt. These traits and factors were considered when developing the model which was devised to include the following concepts: linkage, partnership, collaboration, information sharing, behaviour change, support, empowerment, family unity and self-regulation.
4. *Evaluate the FAMILY intervention on heart failure outcomes through a randomised controlled trial:* Readmissions were reduced by half when the intervention was administered to the patients and their primary family caregivers. Additionally, self-care scores although remaining below the average level, improved significantly in the self-care maintenance and confidence scales of the SCHFI after the intervention. The outcomes of this trial with all its gaps and limitations serve as a basis for bigger trials in the future.

17.3 Implications of the study findings

17.3.1 Theoretical implications:

The FAMILY Intervention Heart Failure Model was inspired by The Framework for the Study of Self and Family Management (Grey, Knafl & McCorkle 2006). The framework first identifies the individual, family and environmental factors that influence the patients' self-management. These factors can be protective or risk factors and can influence ones self-management positively or negatively. Interventions can target these factors to improve outcome. Alternatively, as stated by the framework, interventions can target the health outcomes by working with the individual or the family unit. In our study, the latter approach was followed in order to improve the outcomes of patients with heart failure. Educating both the individual and the family on self-care and symptoms management showed reduction in readmission rates and improved self-care scores on the SCHFI.

On the other hand, the former approach, targeting risk factors, is likely to produce added benefits in the Lebanese setting. However, the limited resources available in the study setting make this challenging to implement but lessons from other resource limited settings are likely to have salience and relevance to this setting.

17.3.2 Policy Implications:

There are limited transitional interventions from the tertiary settings to the community settings in Lebanon. Most of the readmissions in heart failure are attributable to poor adherence to recommendations on diet and medication. These readmissions could be avoided with clinical pathways involving transitional care, longer periods of follow up in heart failure clinics and linking patients to adequate resources in the community. Patient education is an important component in establishing a smooth transition from the hospital setting to the community. The effectiveness established in this intervention highlights the need for this cost saving and easily administered intervention in a resource limited country. However, with the growing burden on non-communicable diseases should be considered in the context of health care reform (Sibai et al. 2009). Advocacy and communication engagement will be important considerations for the future.

This study also has implications for nursing workforce development. With the high healthcare demands in the tertiary and acute settings, the nursing shortage and the needs for specialised nursing (Gallagher, Fry & Duffield 2010), adopting such a model is pivotal in keeping patients out of the hospital and free of or with the least complications. Having specialised nurses or advanced practice nurses has shown its effect in decreasing the demand on the acute settings, better patient satisfaction and better use of the emergency department in addition to providing safe, effective and quality care in the tertiary and community settings (Newhouse et al. 2011). In this study, comprehensive education upon discharge, provided by a Masters prepared nurse with heart failure specialisation, was able to significantly improve self-care practices and consequently clinical outcomes in patients with heart failure. This was evident with the reduction of readmission rates by half.

In addition to that, educating the healthcare providers on cultural sensitivity and awareness is vital in improving both patient and caregiver outcomes. The results of this education can improve healthcare utilisation without adding the health care expenditure (Guru et al. 2009; Majumdar et al. 2004).

17.4 Conclusions and Recommendations for future research

This thesis has provided a unique contribution to the literature and nursing science. Firstly, it has addressed the unique needs of the society in Lebanon that included Lebanese and non-Lebanese Arabs residing in Lebanon. Secondly, it has filled a gap in the health care system which lacks clinical pathways and discharge planning for patients with chronic conditions. The benefits of this trial should be considered within the discussion and debate of the potential effectiveness of these interventions when extended from the clinical trial phase (Clark et al. 2014).

Future studies should address the timing and intensity of the intervention. The chosen time for this intervention, before discharge, allowed time for the patients to improve from their distressing cause of hospital admission. This was appreciated by the patients who were free of the dooming thoughts of death accompanied with their symptoms. However, the drawback lies in the single intensive educational intervention provided upon discharge. This should be addressed in future studies where follow ups should be integrated through phone calls or heart failure clinics. Additionally, embracing a nurse-coordinated multidisciplinary approach in the intervention and during follow up is of added value to the practice and would produce further improved outcomes. This is especially true in the Lebanese culture, where the physician is extremely honoured and must be an active participant in any such intervention.

The sample size was powered to the primary endpoint, readmission. This covered the sample size needed to achieve a statistical difference between the groups in the self-care and quality of life scores. However, the lack of improvement in QOL scores may be due to the single education intervention and the short period of follow up. Therefore, the failure of the intervention to improve the quality of life is inconclusive and longer periods of follow up need to be integrated in future self-care models to allow time for a change in patient reported outcomes.

Being the first RCT to be conducted in the Lebanese context on heart failure care, it has outlined the gaps in management of this patient population and provided a clear and strong platform for future research. The limited knowledge in self-care reflected in the low scores of the maintenance and management scales of the *A*-SCHFI, highlight the urgent need for educational approaches in the primary health care settings as well, since heart failure is a chronic conditions where patients are treated in clinics unless when they develop exacerbations.

17.5 Limitations and strengths of the study

Limitations of individual studies comprising this thesis are provided in the preceding chapter. But there are several limitations to this research study to be considered. The first and foremost limitation is the single educational intervention provided without reinforcement. In spite of this limitation this could be considered a strength, particularly in a culture with a high transient population, particularly in the context of the ongoing Syrian crisis. Currently Lebanon is hosting 1.1 million Syrian refugees with significant pressures on the health, education and social systems (*Huffpost Impact* 2015).

Additional sessions would have produced better chances of retaining the provided educational material and higher chance in behavioural change. The application of multiple sessions, however, was not applicable knowing that the study was conducted by a single researcher rather than a team of researchers. Another limitation was the lack of follow up phone calls soon after patients were discharged home. These phone calls could aid the patients and their caregivers in the transition from a care-free environment in the hospital setting to the community where they have to take responsibility of their health condition and assume the role of their health care providers. Despite these limitations, significant differences were seen in readmission, mortality, self-care maintenance and confidence, health care utilization and major vascular events.

Both groups were provided with the self-care resources including a diary with the educational material. This diary was likely to dilute the effect of the intervention between the groups. However, the purpose of this was to isolate the effect of the intervention and correlate the outcomes of the study to the educational conference per se. In addition, it would not be ethical to deprive the control group of any intervention, considering that education through usual care is deficient.

This study underscores the importance of undertaking a contextual analysis and considering patient, provider and health care system factors in intervention development (Clark, Savard & Thompson 2009).

17.6 Conclusion

The implementation of a family-centred educational intervention focusing on promoting self-care behaviours showed improvement in heart failure outcomes in terms of readmission and self-care. The application of this model in a collectivist society such as Lebanon is advised for the benefits it has shown and its cultural congruency and competence. Furthermore, although its efficacy was established in the Lebanese context only, its application is appropriate to other Middle Eastern diasporas globally where collectivism, an enduring characteristic, is important.

Lebanon remains in a situation where political unrest is omnipresent and significant social changes and migration have influenced not just societal structure but also the health care workforce and available resources. Within this context and resource limitations it is easy for the focus on non-communicable diseases, such as heart failure to be diminished. But these are insidious conditions with a deleterious outcome not just on the individual and their family but on communities and society. This thesis has cast an important spotlight on a chronic, burdensome and lethal condition. Continuing this focus and future investigation is critical to improving health care outcomes in Lebanon.

17.7 References

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Appendix 1 Consent to participate in a research study

Development of the **F**amily focused **A**pproach to i**M**prove HF care **I**n **L**ebanon Qualit**Y** (FAMILY) Intervention

Investigators: Miss Hiba Deek
Phone: (01) 830000 ext:____

You are being asked to participate in a clinical research study conducted at Rafic Hariri University Hospital. Please take time to read the following information carefully before you decide whether you want to take part in this study or not. Feel free to ask the investigator if you need more information or clarification about what is stated in this form and the study as a whole. Also feel free to ask your doctor about participating if you think you need to.

1) Purpose of the study:

This study is aimed at testing the effect of education provision on outcomes of patients with heart failure. Quality of life, ability to care for oneself and readmissions are the primary endpoints. If you agree you will be randomly assigned to one of two groups. This assignment will be done by a third party not directly involved in the intervention, therefore, neither the participants nor the person giving the intervention have a say in the this assignment. Both groups will be provided with a bag of items, however the intervention group will be provided with an educational sessions with his family caregiver to test its effect on their outcomes. Once assigned, you will not be able to change groups. You will be contacted twice before discharge by a visiting heart failure nurse specialist, the first visit will last around 30 min and the second will last 5 min for the non-intervention group and around an hour for the intervention group. You will also be contacted after 30 days by phone where more data will be collected. This phone call is likely to last for 20 min. For this study around 260 participants will be enrolled and equally divided into the two groups.

2) Risks undertaken from participating in this study:

There will be no additional risks on your health as a result of participating in this study. This study is aimed at improving outcomes with people having your health condition. Emergency contacts will be provided in case needed. All your doctors are aware of this study and approve of it.

3) Benefit as a result of participating in this study:

There are no direct benefits from participating in this study. You will only get a packed bag of useful items in managing your health condition and have the opportunity to be involved in a study that might improve your health outcomes.

4) Alternative treatment

In case you were allocated to the non-intervention group, you will receive usual care provided by the hospital.

If you agree to participate in this research study, the information will be kept confidential. Unless required by law, only the study investigators and the trained researchers, the ethics committee and inspectors from governmental agencies will have direct access to your medical records.

This study is not likely to produce any harm to your health for it is designed to improve your health condition. However, should you need hospitalization during the study period there will be no compensation to cover such expenses in case it is not covered by a third party.

In case you have comments or queries about this study and wish to share your concerns with someone independent of the study, please contact the head of the IRB department at RHUH Dr Iyad Issa: Iyadissa71@gmail.com

If you wish to contact the person supervising this study, please feel free to contact Professor Patricia Davidson:
PatriciaMary.Davidson@uts.edu.au

NOTE:

This study has been approved by the University of Technology, Sydney Human Research Ethics Committee. If you have any complaints or reservations about any aspect of your participation in this research which you cannot resolve with the researcher, you may contact the Ethics Committee through the Research Ethics Officer (ph: +61 2 9514 9772 Research.Ethics@uts.edu.au). Any complaint you make will be treated in confidence and investigated fully and you will be informed of the outcome.

Investigator's statement:
I have reviewed, in detail, the informed consent document for this research study with ______________________ (name of patient/family member/legal representative) the purpose of the study and its risks and benefits. I have answered to all the patient's questions clearly. I will inform the participant in case of any changes to the research study.

_____________________ _______________
Name of Investigator or designee Signature

____
Date & Time

Patient's Participation:
I have read and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of this research study and I know that I can contact _Hiba Deek____ at _[redacted]___ or any of his/ her designee involved in the study in case of any questions, if I feel that my questions have not been answered, I can contact the Institutional Review Board for human rights at ________. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care or benefits. I know that I will receive a copy of this signed informed consent shall I request it.

_____________________ ________________
Name or patients or legal representative Signature

_____________________ ________________
Name of Family caregiver Signature

____
Date & Time

_____________________ _____________________
Witness's Name Witness's Signature

____
Date & Time

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دراسة الأسرة

Family focused **A**pproach to i**M**prove Heart Failure care **I**n **L**ebanon Qualit**Y** **(FAMILY)** Intervention

PATIENT DIARY

Patient name: *اسم المريض:*

General Details عامة
تفاصيل

Patient Name: المريض:
اسم

Family caregiver: مقدم الرعاية :
اسم

Cardiologist name: طبيب القلب :
اسم

Specific Details محددة للمريض
تفاصيل

Critical weight: الحرج :
الوزن

Daily fluid allowance: السوائل يوميا :
كمية

Date of phone call: المكالمة الهاتفية :
تاريخ

Contact Details الاتصال
تفاصيل

1. *Cardiologist* القلب
   1. طبيب
   - Name الاسم :
     -
   - Phone number: رقم الهاتف :
     -
2. *Fellow cardiologist* طبيب القلب
   2. زميل

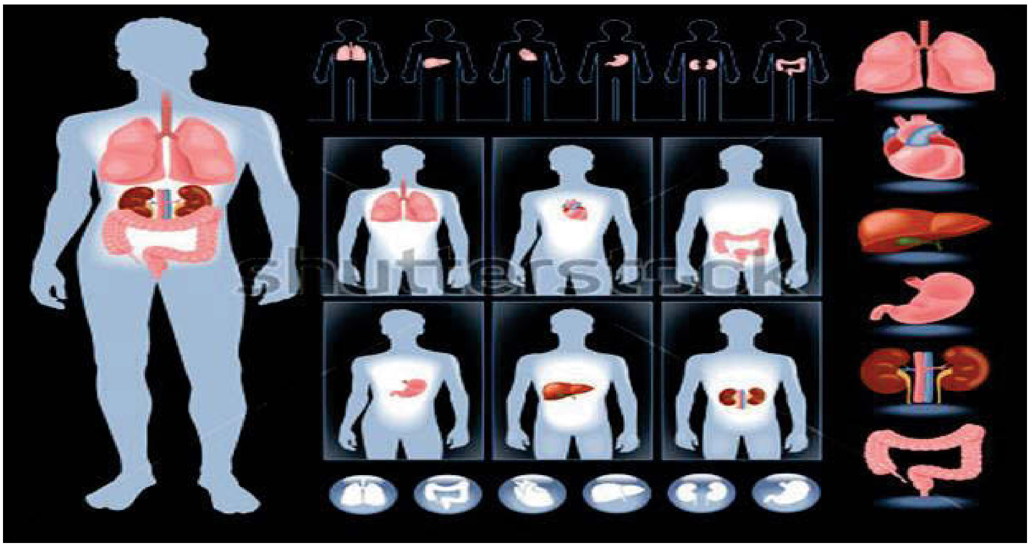
- Name: الاسم:
  -
- Phone number: - رقم الهاتف :

3. *Site investigator* الدراسة في الموقع
   3. محقق
- Name: الاسم:
  -
- Phone number: - رقم الهاتف :

4. Chief investigator فريق التحقيق
   4. رئيسة
- Name: Hiba Deek - الاسم:هبة الديك
- Phone number: 03 794184 - رقم الهاتف: 794184 03

ما هو قصور القلب؟ وما هي عوارضه؟

إن قصور عضلة القلب هو ضعف في العضلة التي تغذي اعضاء الجسم وهذا الضعف يتفاوت بالخطورة بحسب الاعراض التي يتعرض لها المريض. قصور العضلة لا يعني الذبحة القلبية بل هو تجمع سوائل في العضلة وحولها مما يرهقها وينتج عوارض المرض. من هذه العوارض ضيق في التنفس، تجمع المياه في الكعبين او حول البطن.



إن السيطرة على هذا المرض يتطلب تعاون من قبلك مع طبيبك والفريق المختص في حالتك ويتضمن تغيير في نمط حياتك.

هذا الكتيب يأتي لارشادك حول تحسين جودة ونمط حياتك.

ما هي العوارض الشائعة المتعلقة بقصور العضلة؟

- ضيق في النفس.
- الأستيقاظ خلال الليل بسبب ضيق التنفس.
- تعب اوإرهاق.
- تجمع سوائل في الكعبين.
- تجمع سوائل في البطن.

- سعال.
- دوار.
- تغيير في شهيتك على الاكل
- امساك

***العلاج :**

إن علاج هذا المرض يتضمن تغيير في نمط الحياة والتقيد بأخذ الأدوية التي وصفها لك طبيبك. إن إتباع التعليمات حرفياً يخولك ممارسة حياتك طبيعياً ويولد صحة جيدة ويقلل الاشتراكات والدخول الى المستشفى, من هذه الارشادات:

1- اخذ الأدوية التي وصفها الطبيب في مواعيدها المحددة.
2- أخذ الوزن يومياً فوراً بعد الاستيقاظ.
3- التقليل من كمية السوائل.
4- تخفيف الملح في الطعام.
5- توقف التدخين
6- ممارسة الرياضة وحركة الجسم.
7- الاتصال بطبيبك عند ملاحظة اي عارض من العوارض المذكورة اعلاه.

1) الادوية :

قبل خروجك من المستشفى سيزودك طبيبك بورقة أدوية حيث سيشرح لك أهمية الأدوية وكيفية تأثيرها على جسدك ودورها في السيطرة على تقدم المرض، لا ينبغي ان توقف اي دواء قبل استشارة طبيبك والتأكد من صحة ذلك.

ان كان لديك اي سؤال حول الأدوية اتصل فوراً بطبيبك أو الصيدلي المختص او الممرضة المختصة في حالتك.

2) أخذ الوزن :

ان الوزن هو معيار يعكس مدى تقدم حالة المرض او السيطرة عليه اذ عليك أخذ وزنك مرة واحدة يومياً عند الاستيقاظ باكراً ومقارنته باليوم الذي سبق وفي حال لاحظت زيادة في الوزن فهذا يعني ان كمية السوائل التي تدخل جسمك اكثر من السوائل الخارجة منه لذا اتصل بطبيبك عندما تلاحظ تزايد 1 كغ في الوزن خلال يوم او 2 كغ خلال 5 ايام.

3) التقليل من السوائل :

إن الضعف في عضلة القلب ينتج تجمع السوائل في العضلة وحولها مما يؤدي الى تدهور الصحة بشكل سريع لذا فعليك ان تحد من كمية السوائل الداخلة الى جسمك لذلك ينصح باستعمال ابريق مرقم لتكون عملية حساب السوائل دقيقة وصحيحة.

4) تخفيف الملح في الطعام

إن الملح بطبيعته يسحب المياه إليه فلهذا عليك تخفيف كمية الملح في الطعام لتجنب تجمع السوائل في جسدك. فعليك تجنب الأطعمة المعلبة والبزورات المملحة والمخللات.

5) **توقف التدخين** : عدم التدخين وعدم مجالسة المدخن.

6) ممارسة الرياضة بحركة الجسم :

الحركة الصحيحة للجسم تساعدك على تحسين جودة حياتك وأعضاء جسدك. ومن المهم ان توازن بين الحركة والراحة فلا ترهق نفسك ولا تبالغ في الراحة بل حرك جسدك بما هو مفيد له. ابدأ بالمشي لمدة خمس دقائق يومياً وتصاعد في عدد الدقائق وفي حال واجهت احدى العوارض المذكورة اعلاه استلق واتصل بطبيبك او الممرضة المختصة فوراً.

7) اتصل بطبيبك عند ملاحظة اي من العوارض المذكورة اعلاه :

اذا لاحظت زيادة في وزنك في يومين متتاليين او ضيق في نفسك عند الحركة او خلال الراحة او زيادة في حجم الكعبين او البطن او اي تدهور في حالتك الصحية اتصل بطبيبك او الممرضة المختصة في حالتك فوراً وان كان لديك اسئلة عن العلاج المطروح عليك او عن الادوية الموصوفة من قبل طبيبك نرجو منك مناقشة الأسئلة مع احد افراد الفريق المختص.

Medication list الأدوية
قائمة

Medication Name اسم الدواء	Strength جرعة	How do I take it كيف أخذ الدواء	When do I take it متى يمكنني أخذ الدواء	Comments تعليقات

Medication list
قائمة

الأدوية

Medication Name اسم الدواء	Strength جرعة	How do I take it كيف أخذ الدواء	When do I take it متى يمكنني أخذ الدواء	Comments تعليقات

Weight tracking *الوزن*
تتبع

Days	Week 1 الأسبوع الأول	Week 2 الأسبوع الثاني	Week 3 الأسبوع الثالث	Week 4 الأسبوع الرابع	Week 5 الأسبوع الخامس
Monday الاثنين					
Tuesday الثلاثاء					
Wednesday الأربعاء					
Thursday الخميس					
Friday الجمعة					
Saturday السبت					
Sunday الأحد					

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Appendix 3 Baseline data collection sheet

Hospital: *RHUH*

Subject initial: Hospital ID:

Date of collection: Date of discharge:

Duration of intervention:

Allocation:

0- Control
1- Intervention

Section A: socio-demographic data

1) Patient age: ____ years
2) Patient gender:
   0- Female
   1- Male
3) Place of residence:
   0- Home
   1- nursing facility
   2- other
4) Marital status:
   0- Single
   1- Married
   2- Divorced
   3- Widowed
5) Living conditions:
   0- Living alone
   1- Living with family
   2- Other: ___________
6) Occupation:
   0- Paid employment
   1- Home duties
   2- Retired
   3- Other
7) Level of education:
   0- No school certification or equivalent
   1- Primary school certification
   2- High school or equivalent
   3- Finished year 12
   4- University degree – Bachelor
   5- University degree – Masters
   6- University degree – Beyond
8) Area of residence:
   0- Beirut
   1- Mount Lebanon

2- North

3- South

4- Bekaa

9) Primary caregiver:

0- Spouse

1- Daughter/son

2- Sister/brother

3- Other, please specify ______

10) Family caregiver education:

0- No school certification or equivalent

1- Primary school certification

2- High school or equivalent

3- Finished year 12

4- University degree – Bachelor

5- University degree – Masters

6- University degree – Beyond

11) Smoking status:

0- Never

1- Ex-smoker , years since stopped: _____

2- Current smoker

0- No

1- yes

Amount if present: _____ cigarettes/day

Number of years of smoking: _____Years

Type if present:

0- Narghile

1- Cigarette

2- both

3- NA

12) Alcohol consumption:

0- No

1- Yes

Amount if yes: _____ Average glass/day, Average number of sittings per week _

Type of alcohol: ___________________

13) Did you get your flu/ pneumococcus vaccines before this fall?

0- No

1- Yes

Section B: History

1) Medical history:

- Diabetes Mellitus

0- No

1- yes

- Hypertension

0- No

1- yes
- ○ COPD
    0- No
    1- Yes
- ○ Renal failure/insufficiency
    0- No
    1- Yes
- ○ Hyperlipidemia
    0- No
    1- Yes
- ○ peripheral arterial disease
    0- No
    1- yes
- ○ Atrial Fibrillation
    0- No
    1- yes
- ○ CAD
    0- No
    1- yes
- ○ Myocardial infarction
    0- No
    1- yes
- ○ Sleep apnea
    0- No
    1- yes
- ○ CVA
    0- No
    1- yes
- ○ Other _____

2) ICD inserted:
    0- No
    1- Yes

3) Pacemaker inserted:
    0- No
    1- Yes
    2- CRT/ Biventricuar

4) Cause of heart failure:
- ○ Ischemic cardiomyopathy
    0- No
    1- yes
- ○ HTN
    0- No
    1- yes
- ○ Other Cardiomyopathy
    0- No

        1- yes
    - Valve disease
        0- No
        1- yes
    - Rheumatic heart disease
        0- No
        1- yes
    - idiopathic
        0- No
        1- yes
    - other : ____

5) New vs. chronic diagnosis:
    0- New case
    1- Chronic case
6) Have you been hospitalized in the previous 12?
    0- No
    1- Yes

if yes how many time? ____

if yes, cause: ______

7) Have you had emergency department only visits for HF exacerbation in the previous 12 months?
    0- No
    1- Yes

if yes how many times? ____

if yes, cause: ______

Section C: Physical Assessment

1) Date of admission: __/__/____
2) Date of discharge: __/__/____
3) Length of hospital stay: ____ days
4) NYHA class on discharge:
    1. I- Cardiac disease, no symptoms
    2. II- Mild symptoms
    3. III- Marked symptoms
    4. IV- Severe symptoms
5) Vital signs *on admission*:
    a. HR ____
    b. RR ____
    c. BP ____
    d. Temp ____ ºC
6) Vital Signs *on discharge*:

   a. HR _____
   b. RR _____
   c. BP _____
   d. Temp _____ °C

7) JVD:
   0- No
   1- Yes
8) Ankle edema on discharge:
   0- None
   1- Ankle level
   2- Shin level
   3- Knee level
   4- Thigh level
9) Ascites:
   0- No
   1- Yes
10) Height: _____, Weight: _____ (on admission)
11) Weight on discharge: _____
12) Arterial blood gases results on admission or the last available:
   - pH _____
   - PCO_2 ______
   - PO_2 ____
13) Laboratory values during the index hospitalization at discharge or the last available:
   a) CBCD:
      - Hgb _____
      - Platelets _____
   b) Electrolytes:
      - Na _____
      - K _____
      - Cl _____
      - CO_2 _____
   c) Creatinine _____
   d) Blood urea nitrogen _____
   e) eGFR _____
   f) Lipid profile:
      - Total cholesterol _____
      - LDL _____
      - HDL _____
      - Triglyceride _____
   g) Liver function tests:
      - SGPT _____
      - SGOT _____
      - ɤ GT _____
   h) Thyroid stimulating hormone:____
   i) Fasting blood sugar: _____

j) Troponin: ____
k) BNP: ____

14) Chest X ray results at index hospitalization (admission):
- ○ Congestion
  - 0- No
  - 1- yes
- ○ Pleural effusion
  - 0- No
  - 1- yes
- ○ Pulmonary edema
  - 0- No
  - 1- yes
- ○ Other: ____

15) Rhythm:
- 0- Sinus
- 1- Paced
- 2- Atrial fibrillation
- 3- Atrial flutter
- 4- Other: _____

16) Ejection fraction (last available): ____

17) Previous cardiac catheterization?
- 0- No
- 1- Yes

18) If yes to Q15. Catheterization results:
- 0- Normal
- 1- Single vessel
- 2- Multi vessel occlusion
- 3- N/A

19) Medications prescribed at discharge and dosages:
- ○ Loop Diuretics:
  - 0- No
  - 1- Yes, Dose ___, unit ____, frequency ___, Route____
- ○ Other diuretic:
  - 0- No
  - 1- Yes, Dose ____, unit ____, frequency ___, Route____
- ○ ACE I
  - 0- No
  - 1- Yes, Dose ____, unit ____, frequency ___, Route____
- ○ ARB
  - 0- No
  - 1- Yes, Dose ____, unit ____, frequency ___, Route____
- ○ Antiarrhythmic
  - 0- No
  - 1- Yes, Dose ___, unit ____, frequency ___, Route____

- ○ β Blocker
  - 0- No
  - 1- Yes, Dose ____, unit ____, frequency___, Route____
- ○ Calcium Antagonist
  - 0- No
  - 1- Yes, Dose ____, unit ____, frequency___, Route____
- ○ Statin
  - 0- No
  - 1- Yes, Dose ____, unit ____, frequency ___, Route____
- ○ Other lipid lowering agents
  - 0- No
  - 1- Yes, Dose ____, unit ____, frequency ___, Route____
- ○ Aldosterone antagonist
  - 0- No
  - 1- Yes, Dose ____, unit ____, frequency ___, Route____
- ○ Digoxin
  - 0- No
  - 1- Yes, Dose ____, unit ____, frequency ___, Route____
- ○ Anticoagulant
  - 0- No
  - 1- Yes, Dose ____, unit ____, frequency ___, Route____
- ○ Antiplatelet
  - 0- No
  - 1- Yes, Dose ____, unit ____, frequency ___, Route____
- ○ Nitrate
  - 0- No
  - 1- Yes, Dose ____, unit ____, frequency ___, Route____

Section D: Frailty

1) Exhaustion: In the last month, have you had too little energy to do things you wanted to do?
   - 0- No
   - 1- Yes
2) Loss of appetite: What has your appetite been like?
   - 0- Diminution in desire for food and/or eating less than usual
   - 1- No change in desire for food and/or eating the same as usual
   - 2- Increase in desire for food and/or eating more than usual
3) If non-specific to Q2: Have you been eating more or less than usual?
   - 0- Less
   - 1- More
   - 2- Neither more or less
4) Because of a physical health problem, do you have any difficulty walking 100 meters:
   - 0- No
   - 1- Yes
5) Because of a physical health problem, do you have any difficulty climbing one flight of stairs without resting:

   0- No
   1- yes

6) How often do you engage in activities that require a low or moderate level of energy such as gardening, cleaning the care or doing a walk?
   0- More than once a week
   1- Once a week
   2- One to three times a month
   3- Hardly ever or never
7) Maximum grip strength in kilograms:

- Right hand attempt 1:
- Right hand attempt 2:
- Left hand attempt 1:
- Left hand attempt 2:

Appendix 4 Follow up data collection sheet

Good morning Mr/ Mrs ____ (patient). My name is ____ from the FAMILY study which you had been enrolled in a month ago at RHUH. As previously notified, this call comes to check upon your wellbeing during the last 30 days. After your approval I will proceed with my questions. This call is not expected to exceed 20 min.

1) Has a need arisen for medical advice?
   - 0- No
   - 1- Yes
     - if yes, where did you get it?
       - 0- No need
       - 1- Emergency department
       - 2- Outpatient department/ general practitioner
       - 3- Nearby pharmacy
       - 4- Specialist

2) Have you been hospitalised during the past 30 days?
   - 0- No
   - 1- Yes
     - If yes, when was that? ___________
     - What was the cause? ___________
     - How long was you hospital stay (in days)? ___________
     - Which hospital were you admitted to? ___________

3) Have you visited an emergency department in the last 30 days?
   - 0- No
   - 1- Yes
     - If yes, what was the cause? ____________

4) Have you manifested any of the following events in the last 30 days:
   - 0- None
   - 1- Heart attack
   - 2- CVA
   - 3- Peripheral vascular event
5) What is your weight today?
6) Riegel's Self-Care Heart failure Index – Arabic version

7) SF-12

Please return the diary you were provided with at the onset of the study for it will be useful in evaluating your overall health condition. Do not write anything further in it, we are happy to receive it even with empty spaces.

Thank you for agreeing to participate in this study, we hope the outcomes will be of good use for heart failure patients. If you wish to be notified of the results, we will have it available at AUBMC upon completion.

Appendix 5 The Arabic version of the Self-care of Heart Failure Index (A-SCHFI)

مؤشر الرعاية الذاتية لقصور القلب

جميع الإجابات المطروحه أدناه ستكون سرية:
- خلال اجابتك عن هذه الأسئلة حاول ان تتذكر حالتك الصحية أو كيف كنت تشعر في الشهر الماضي / أو منذ تكلمنا أخر مرة

قسم أ:

ما مدى تكرار ممارستك لهذه التعليمات	أبداً أو نادراً	أحياناً	تكراراً	دائماً أو يومياً
١- أخذ الوزن	١	٢	٢	٤
٢- التحقق من ورم كاحلك	١	٢	٢	٤
٣-تجنب المرض (لقاح/طعم الإنفلونزا، تجنب أشخاص مصابة بمرض)	١	٢	٢	٤
٤- القيام ببعض النشاط الجسدي	١	٢	٢	٤
٥- الحضور عند موعدك المحدد مع الطبيب	١	٢	٢	٤
٦- أكل طعام قليل الملح	١	٢	٢	٤
٧- التمرين ل ٣٠ دقيقة	١	٢	٢	٤
٨- نسيان أخذ واحد من أدويتك	١	٢	٢	٤
٩- طلب طعام قليل الملح عند الأكل خارج المنزل أو عند زيارة الأخرين	١	٢	٢	٤
١٠- استعمال نظام (علبة أدوية/ منبه) ليساعدك على تذكر أخذ أدويتك	١	٢	٢	٤

المذكورة أدناه هي تعليمات عامة تتوفر عادةً لأشخاص عندهم ضعف في عضلة القلب.

قسم ب:

الكثير من الأشخاص يعانون من عوارض بسبب ضعف في عضلة القلب. الصعوبة بالتنفس وتورم الكاحلين هي عوارض شائعة عند الإصابة بالضعف في عضلة القلب.

خلال الشهر الفائت: هل عانيت من صعوبة بالتنفس أو تورم في الكاحلين؟ ضع دائرة حول إجابة وحدة:

(٠) كلا

(١) نعم

١١- في حال أصبت بصعوبة في التنفس أو تورم في الكاحلين خلال الشهر الفائت ... (ضع دائرة على إحدى الأرقام التالية). ما هي سرعة تعرفك على العارض على أنه بسبب ضعف في عضلة القلب؟

لم أصَب بهذا	لم أتعرف عليه	ليس بسرعة	سرعة نسبية	بسرعة	سرعة فائقة
-	٠	١	٢	٣	٤

المذكورة أدناه هي طرق علاج يستعملها بعض الأشخاص المصابين بضعف عضلة القلب. اذا أُصبت بصعوبة في التنفس أو تورم بالكاحلين, ما نسبة لجوئك الى تجربة واحدة من هذه العلاجات؟ (ضع دائرة على واحدة من هذه الاجابات)

	غير مرجح	مرجح نسبياً	مرجح	مرجح جداً
١٢ ـتخفيف كمية الملح في طعامك	١	٢	٣	٤
١٣ ـتخفيف كمية السوائل	١	٢	٣	٤
١٤ ـأخذ حبة إضافية من مدر البول	١	٢	٣	٤
١٥ ـالاتصال بطبيبك لارشادك	١	٢	٣	٤

١٦ـفكر في علاج قد لجأت إليه آخر مرة تعرضت لصعوبة في التنفس أو تورم في الكاحلين (ضع دائرة على إحدى الأرقام)

ما مدى ثقتك بنجاح هذا العلاج؟

لم اختبر شيئاً	لست واثقاً	واثق نسبياً	واثق	واثق جداً
٠	١	٢	٣	٤

<u>قسم ج:</u>

بشكل عام، ما مدى ثقتك بقدرتك على:

	غير واثق	واثق إلى حد ما	واثق جدا	واثق للغاية
١٧ ـتجنب عوارض ضعف عضلة القلب	١	٢	٣	٤

١٨- إتباع النصائح في العلاج المعطاة لك	١	٢	٣	٤
١٩- تقييم أهمية عوارضك	١	٢	٣	٤
٢٠ - التعرف على تغيير في حالتك الصحية فور حدوثها	١	٢	٣	٤
٢١-التصرف لمعالجه عوارضك	١	٢	٣	٤
٢٢- تقييم مدى فعالية العلاج	١	٢	٣	٤

UNIVERSITY OF
TECHNOLOGY SYDNEY

Appendix 6: The Arabic version of the Short Form 12 v2 (SF-12v2)

صحتك ورفاهيتك

يسأل هذا الاستبيان عن وجهة نظرك حول صحتك. ستساعد هذه المعلومات في تتبع شعورك وكيف كنت قادرا على القيام بنشاطاتك الاعتيادية بشكل جيد. *شكرا لإكمالك هذا الاستبيان!*

في كل واحد من الأسئلة التالية، الرجاء وضع إشارة ☒ في المربع الذي يصف بأفضل شكل إجابتك.

1. بشكل عام، تود أن تقول أن صحتك:

ممتازة	جيّدة جدا	جيّدة	معتدلة	ضعيفة
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. الأسئلة التالية تدور حول نشاطات من الممكن أن تقوم بها خلال يوم عادي. هل تقيّدك صحتك الآن في النشاطات التالية؟ إذا كانت كذلك، فإلى أي مدى؟

	نعم، تقيّدني كثيرا	نعم، تقيّدني قليلا	لا، لا تقيّدني على الإطلاق
	▼	▼	▼
ا. النشاطات معتدلة الشدة، مثل تحريك طاولة، دفع مكنسة كهربائية، السباحة أو ركوب الدراجة	☐ 1	☐ 2	☐ 3
ب. صعود الدرجات عدة طوابق	☐ 1	☐ 2	☐ 3

3. خلال الأسابيع الأربعة الماضية، كم من الوقت واجهت أيا من المشاكل التالية في عملك أو نشاطاتك اليومية الاعتيادية الأخرى نتيجة لصحتك الجسدية؟

	كلّ الوقت	معظم الوقت	بعض الوقت	قليل من الوقت	ولا في أي وقت
	▼	▼	▼	▼	▼
ا. أنجزت أقل مما كنت ترغب	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
ب. كنت مقيّدا/ة في نوع العمل أو النشاطات الأخرى	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. خلال الأسابيع الأربعة الماضية، كم من الوقت واجهت أيا من المشاكل التالية في عملك أو نشاطاتك اليومية الاعتيادية الأخرى نتيجة لأي مشاكل عاطفية (مثل الشعور بالاكتئاب أو القلق)؟

	كلّ الوقت	معظم الوقت	بعض الوقت	قليل من الوقت	ولا في أي وقت
	▼	▼	▼	▼	▼
ا. أنجزت أقل مما كنت ترغب	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
ب. قمت بعمل أو نشاطات أخرى بحذر أقل من المعتاد	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. خلال الأسابيع الأربعة الماضية، إلى أي مدى تدخل الألم بعملك الاعتيادي (بما فيه العمل خارج البيت أو العمل البيتي)؟

لا على الإطلاق	قليلا	بشكل معتدل	كثيرا	بشدة
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. هذه الأسئلة تستفسر عن شعورك وكيف سارت الأمور معك خلال الأسابيع الأربعة الماضية. لكل سؤال، الرجاء إعطاء الجواب الأقرب إلى الطريقة التي شعرت بها. كم من الوقت خلال الأسابيع الأربعة الماضية...

	كلّ الوقت	معظم الوقت	بعض الوقت	قليل من الوقت	ولا في أي وقت
ا. شعرت بالهدوء والطمأنينة؟	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
ب. كانت لديك طاقة كبيرة؟	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
ج. شعرت بأنك محزون/ة و مكتئب/ة؟	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. خلال الأسابيع الأربعة الماضية، كم من الوقت تدخلت صحّتك الجسديّة أو مشاكلك العاطفية في نشاطاتك الاجتماعية (مثل القيام بزيارات للأصدقاء، الأقارب، الخ.)؟

كلّ الوقت	معظم الوقت	بعض الوقت	قليل من الوقت	ولا في أي وقت
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

شكرا لإكمالك هذه الأسئلة!

Version: 1 dated July 16th, 2013

Appendix 7 University of Technology Sydney Human Research Ethics committee approval on one site

Dear Applicant

Thank you for your response to the Committee's comments for your project titled, "Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention". Your response satisfactorily addresses the concerns and questions raised by the Committee who agreed that the application now meets the requirements of the NHMRC National Statement on Ethical Conduct in Human Research (2007). I am pleased to inform you that ethics approval is now granted.

Your approval number is UTS HREC REF NO. 2013000485

Your approval is valid five years from the date of this email.

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

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

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

To access this application, please follow the URLs below:
* if accessing within the UTS network: http://rmprod.itd.uts.edu.au/RMENet/HOM001N.aspx
* if accessing outside of UTS network: https://remote.uts.edu.au , and click on "RMENet - ResearchMaster Enterprise" after logging in.

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

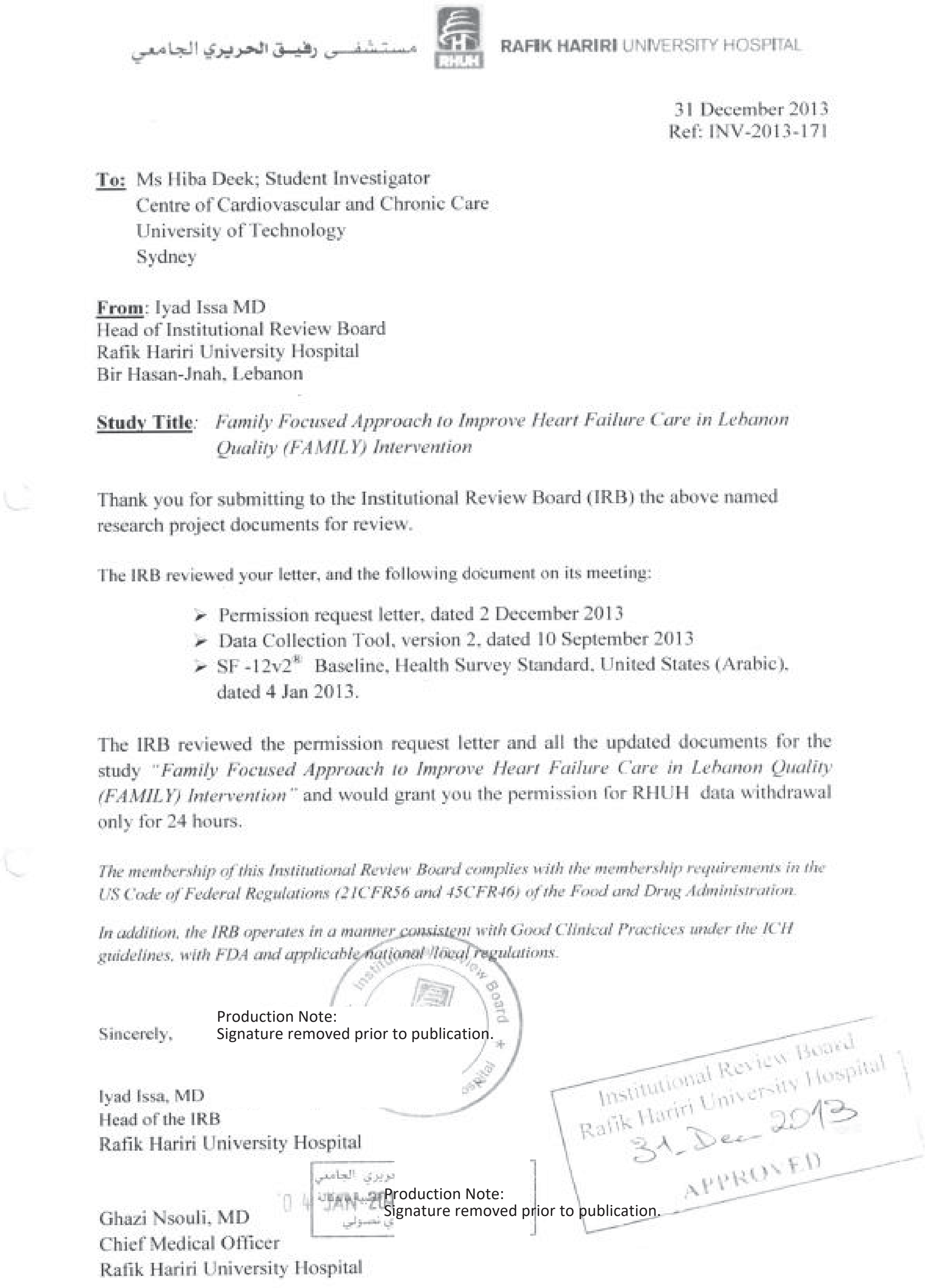
If you have any queries about your ethics approval, or require any amendments to your research in the future, please do not hesitate to contact Research.Ethics@uts.edu.au.

Yours sincerely,

Professor Marion Haas
Chairperson
UTS Human Research Ethics Committee
C/- Research & Innovation Office
University of Technology, Sydney
T: (02) 9514 9645
F: (02) 9514 1244
E: Research.Ethics@uts.edu.au
I: http://www.research.uts.edu.au/policies/restricted/ethics.html
P: PO Box 123, BROADWAY NSW 2007

[Level 14, Building 1, Broadway Campus]
CB01.14.08.04

Appendix 8 Rafic Hariri University Hospital Human Research Ethics Committee Approval



مستشفى رفيق الحريري الجامعي RAFIK HARIRI UNIVERSITY HOSPITAL

31 December 2013
Ref: INV-2013-171

To: Ms Hiba Deek; Student Investigator
Centre of Cardiovascular and Chronic Care
University of Technology
Sydney

From: Iyad Issa MD
Head of Institutional Review Board
Rafik Hariri University Hospital
Bir Hasan-Jnah, Lebanon

Study Title: *Family Focused Approach to Improve Heart Failure Care in Lebanon Quality (FAMILY) Intervention*

Thank you for submitting to the Institutional Review Board (IRB) the above named research project documents for review.

The IRB reviewed your letter, and the following document on its meeting:

- Permission request letter, dated 2 December 2013
- Data Collection Tool, version 2, dated 10 September 2013
- SF -12v2® Baseline, Health Survey Standard, United States (Arabic), dated 4 Jan 2013.

The IRB reviewed the permission request letter and all the updated documents for the study *"Family Focused Approach to Improve Heart Failure Care in Lebanon Quality (FAMILY) Intervention"* and would grant you the permission for RHUH data withdrawal only for 24 hours.

The membership of this Institutional Review Board complies with the membership requirements in the US Code of Federal Regulations (21CFR56 and 45CFR46) of the Food and Drug Administration.

In addition, the IRB operates in a manner consistent with Good Clinical Practices under the ICH guidelines, with FDA and applicable national /local regulations.

Sincerely,

Production Note:
Signature removed prior to publication.

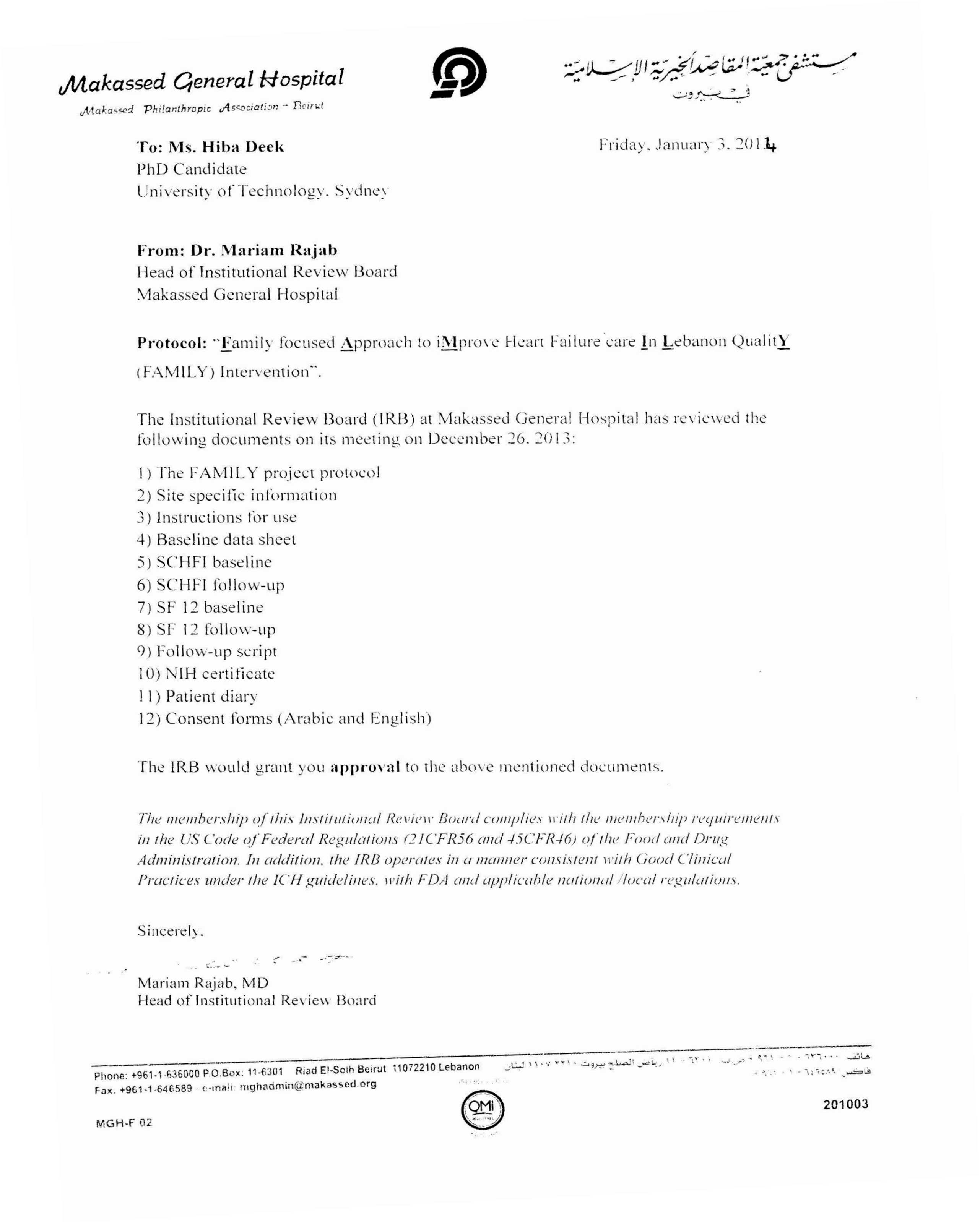
Iyad Issa, MD
Head of the IRB
Rafik Hariri University Hospital

Institutional Review Board
Rafik Hariri University Hospital
31_Dec_2013
APPROVED

Ghazi Nsouli, MD
Chief Medical Officer
Rafik Hariri University Hospital

Production Note:
Signature removed prior to publication.

Appendix 9 Makassed General Hospital Human Research Ethics Committee Approval



Makassed General Hospital
Makassed Philanthropic Association - Beirut

مستشفى جمعية المقاصد الخيرية الإسلامية
في بيروت

To: Ms. Hiba Deek
PhD Candidate
University of Technology, Sydney

Friday, January 3, 2014

From: Dr. Mariam Rajab
Head of Institutional Review Board
Makassed General Hospital

Protocol: "Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention".

The Institutional Review Board (IRB) at Makassed General Hospital has reviewed the following documents on its meeting on December 26, 2013:

1) The FAMILY project protocol
2) Site specific information
3) Instructions for use
4) Baseline data sheet
5) SCHFI baseline
6) SCHFI follow-up
7) SF 12 baseline
8) SF 12 follow-up
9) Follow-up script
10) NIH certificate
11) Patient diary
12) Consent forms (Arabic and English)

The IRB would grant you **approval** to the above mentioned documents.

The membership of this Institutional Review Board complies with the membership requirements in the US Code of Federal Regulations (21CFR56 and 45CFR46) of the Food and Drug Administration. In addition, the IRB operates in a manner consistent with Good Clinical Practices under the ICH guidelines, with FDA and applicable national /local regulations.

Sincerely,

Mariam Rajab, MD
Head of Institutional Review Board

Phone: +961-1-636000 P.O.Box: 11-6301 Riad El-Solh Beirut 11072210 Lebanon
Fax: +961-1-646589 - e-mail: mghadmin@makassed.org

هاتف ٦٣٦٠٠٠ - ١ - ٩٦١ + ص.ب ٦٣٠١ - ١١ رياض الصلح بيروت ٢٢١٠ ١١٠٧ لبنان
فاكس ٦٤٦٥٨٩ - ١ - ٩٦١ +

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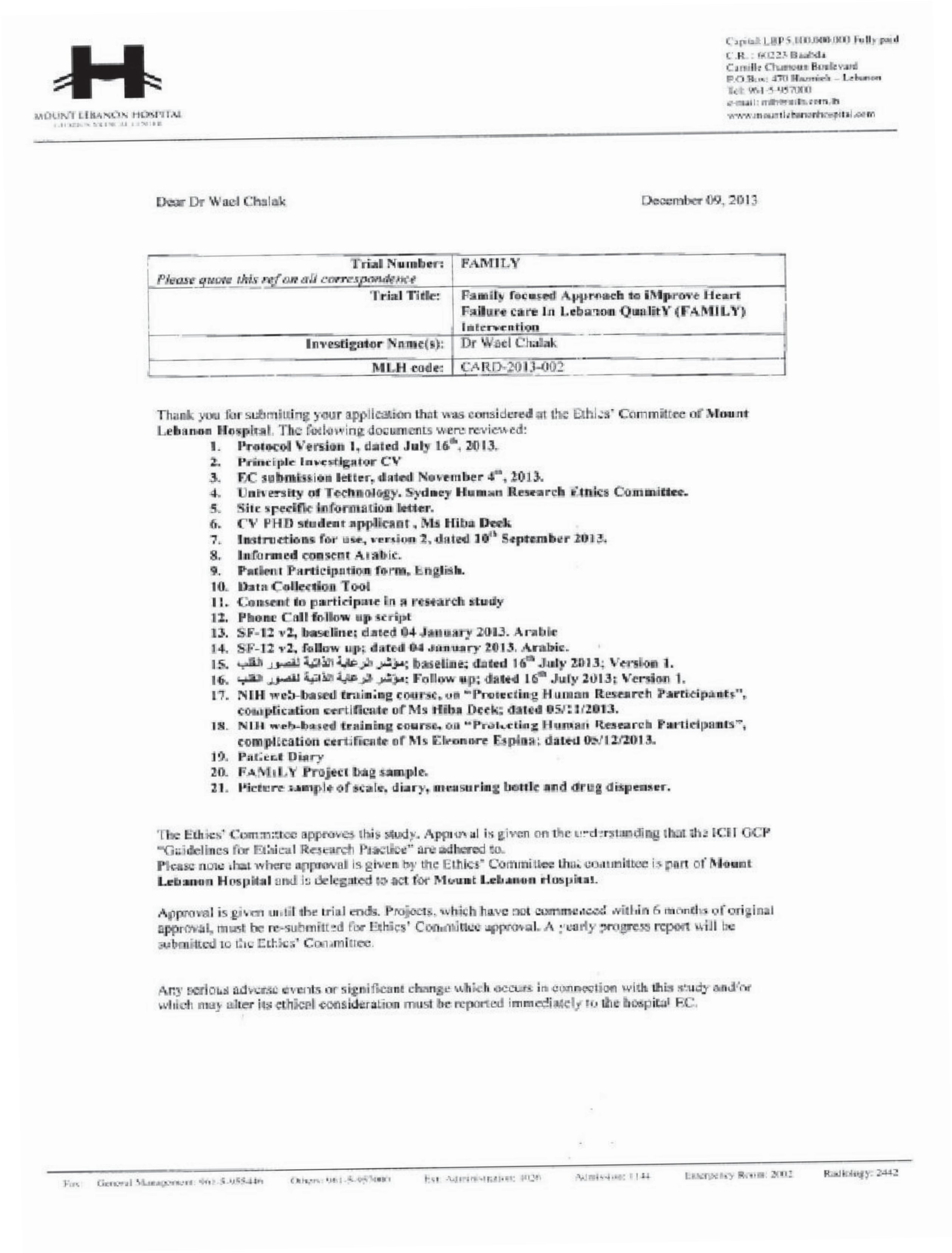
Appendix 10 Mount Lebanon Human Research Ethics Committee Approval



MOUNT LEBANON HOSPITAL

Capital: LBP 5,100,000,000 Fully paid
C.R.: 60223 Baabda
Camille Chamoun Boulevard
P.O.Box: 470 Hazmieh – Lebanon
Tel: 961-5-957000
e-mail: mlh@mlh.com.lb
www.mountlebanonhospital.com

Dear Dr Wael Chalak

December 09, 2013

Trial Number: *Please quote this ref on all correspondence*	FAMILY
Trial Title:	**Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention**
Investigator Name(s):	Dr Wael Chalak
MLH code:	CARD-2013-002

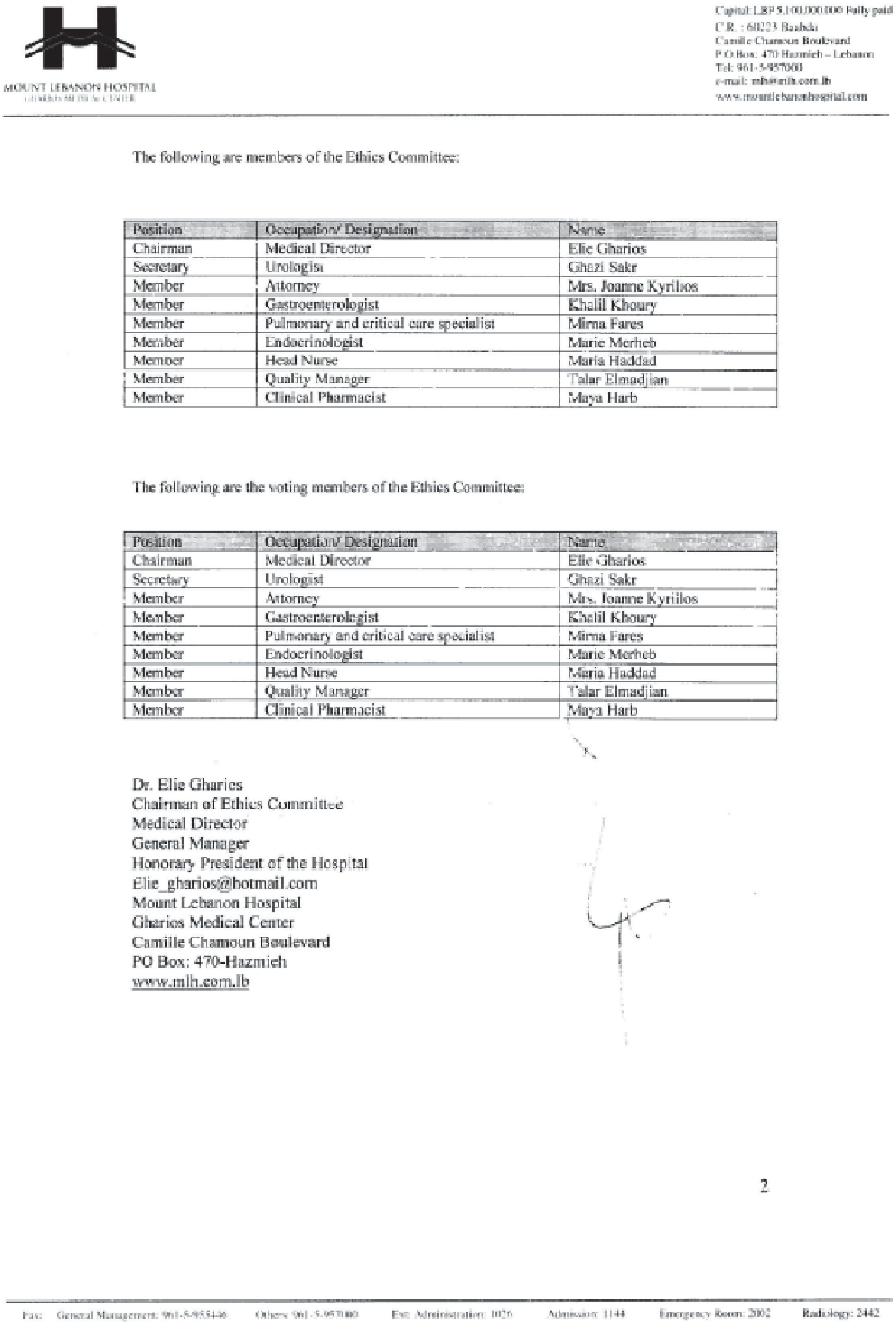
Thank you for submitting your application that was considered at the Ethics' Committee of **Mount Lebanon Hospital**. The following documents were reviewed:

1. **Protocol Version 1, dated July 16th, 2013.**
2. **Principle Investigator CV**
3. **EC submission letter, dated November 4th, 2013.**
4. **University of Technology. Sydney Human Research Etnics Committee.**
5. **Site specific information letter.**
6. **CV PHD student applicant , Ms Hiba Deek**
7. **Instructions for use, version 2, dated 10th September 2013.**
8. **Informed consent Arabic.**
9. **Patient Participation form, English.**
10. **Data Collection Tool**
11. **Consent to participate in a research study**
12. **Phone Call follow up script**
13. **SF-12 v2, baseline; dated 04 January 2013. Arabic**
14. **SF-12 v2, follow up; dated 04 January 2013. Arabic.**
15. **مؤشر الرعاية الذاتية لقصور القلب; baseline; dated 16th July 2013; Version 1.**
16. **مؤشر الرعاية الذاتية لقصور القلب; Follow up; dated 16th July 2013; Version 1.**
17. **NIH web-based training course, on "Protecting Human Research Participants", complication certificate of Ms Hiba Deek; dated 05/11/2013.**
18. **NIH web-based training course, on "Protecting Human Research Participants", complication certificate of Ms Eleonore Espina; dated 05/12/2013.**
19. **Patient Diary**
20. **FAMILY Project bag sample.**
21. **Picture sample of scale, diary, measuring bottle and drug dispenser.**

The Ethics' Committee approves this study. Approval is given on the understanding that the ICH GCP "Guidelines for Ethical Research Practice" are adhered to.
Please note that where approval is given by the Ethics' Committee that committee is part of **Mount Lebanon Hospital** and is delegated to act for **Mount Lebanon Hospital**.

Approval is given until the trial ends. Projects, which have not commenced within 6 months of original approval, must be re-submitted for Ethics' Committee approval. A yearly progress report will be submitted to the Ethics' Committee.

Any serious adverse events or significant change which occurs in connection with this study and/or which may alter its ethical consideration must be reported immediately to the hospital EC.



MOUNT LEBANON HOSPITAL
GHARIOS MEDICAL CENTER

Capital: LBP 5.100.000.000 Fully paid
C.R.: 60223 Baabda
Camille Chamoun Boulevard
P.O Box: 470 Hazmieh – Lebanon
Tel: 961-5-957000
e-mail: mlh@mlh.com.lb
www.mountlebanonhospital.com

The following are members of the Ethics Committee:

Position	Occupation/ Designation	Name
Chairman	Medical Director	Elie Gharios
Secretary	Urologist	Ghazi Sakr
Member	Attorney	Mrs. Joanne Kyrilos
Member	Gastroenterologist	Khalil Khoury
Member	Pulmonary and critical care specialist	Mirna Fares
Member	Endocrinologist	Marie Merheb
Member	Head Nurse	Maria Haddad
Member	Quality Manager	Talar Elmadjian
Member	Clinical Pharmacist	Maya Harb

The following are the voting members of the Ethics Committee:

Position	Occupation/ Designation	Name
Chairman	Medical Director	Elie Gharios
Secretary	Urologist	Ghazi Sakr
Member	Attorney	Mrs. Joanne Kyrilos
Member	Gastroenterologist	Khalil Khoury
Member	Pulmonary and critical care specialist	Mirna Fares
Member	Endocrinologist	Marie Merheb
Member	Head Nurse	Maria Haddad
Member	Quality Manager	Talar Elmadjian
Member	Clinical Pharmacist	Maya Harb

Dr. Elie Gharios
Chairman of Ethics Committee
Medical Director
General Manager
Honorary President of the Hospital
Elie_gharios@hotmail.com
Mount Lebanon Hospital
Gharios Medical Center
Camille Chamoun Boulevard
PO Box: 470-Hazmieh
www.mlh.com.lb

Appendix 11 University of Technology Sydney Human Research Ethics approval on three sites (amendment)

From: Valeria Passo Valeria.Passo@uts.edu.au on behalf of Research Ethics research.ethics@uts.edu.au

Sent: Monday, February 10, 2014 11:13 AM

To: Research Ethics; Hiba Deek; Patricia Davidson

Subject: RE: UTS HREC Approval

Dear Applicant

UTS HREC REF NO. 2014000008

The UTS Human Research Ethics Expedited Review Committee reviewed your amendment application for your project titled, "Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention", to amend the protocol by the addition of two sites to the protocol: Mount Lebanon Hospital and the Makassed General Hospital.

The committee agreed that the amendments meet the requirements of the NHMRC National Statement on Ethical Conduct In Human Research (2007). I am pleased to inform you that the Committee has approved the amendment listed above.

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

To access this application, please follow the URLs below:

* if accessing within the UTS network: http://rmprod.itd.uts.edu.au/RMENet/HOM001N.aspx

* if accessing outside of UTS network: https://remote.uts.edu.au, and click on "RMENet - ResearchMaster Enterprise" after logging in.

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

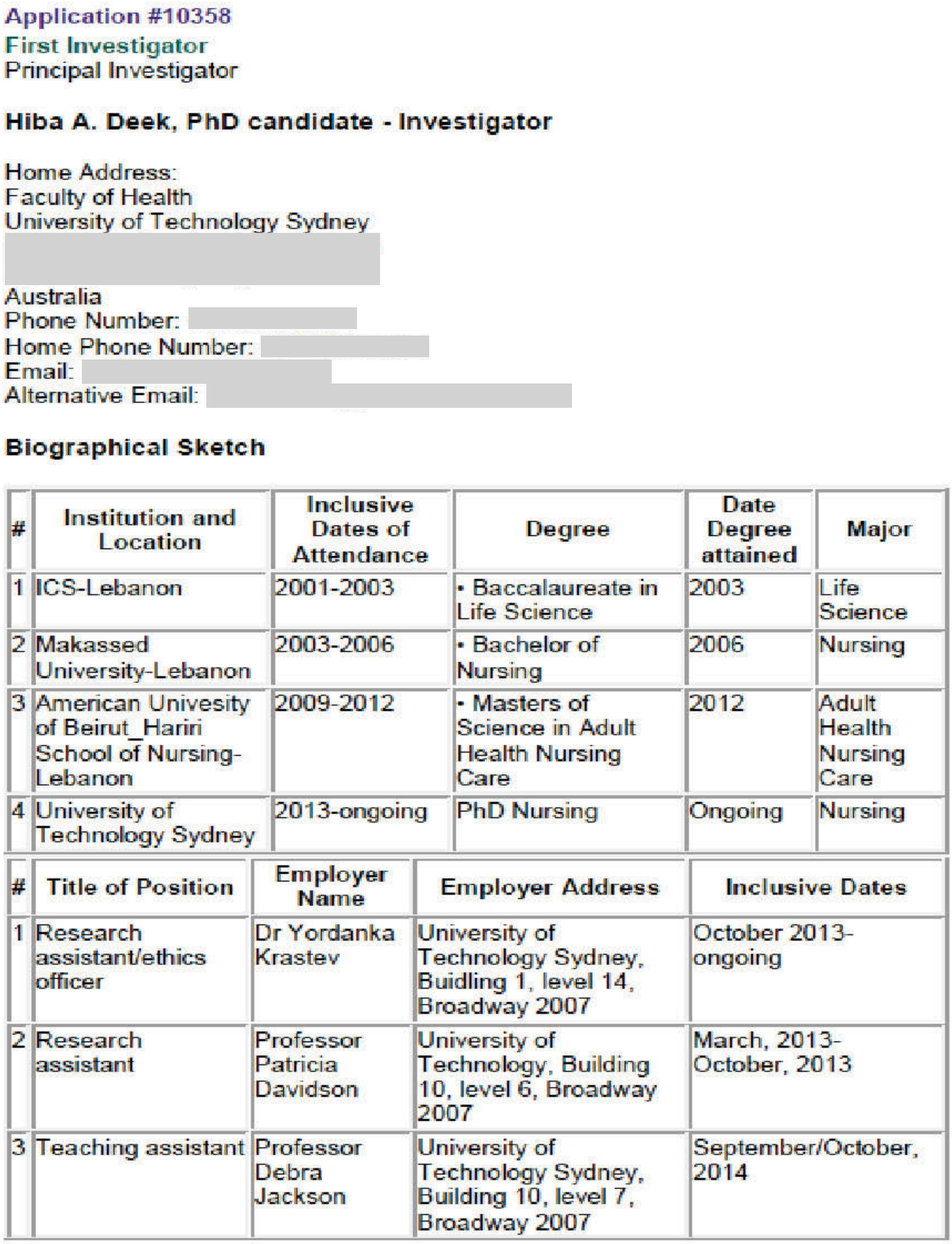
If you wish to make any further changes to your research, please contact the Research Ethics Officer in the Research and Innovation Office, Ms Racheal Laugery on 02 9514 9772.

In the meantime I take this opportunity to wish you well with the remainder of your research.

Yours sincerely,

Professor Marion Haas
Chairperson
UTS Human Research Ethics Committee
C/- Research & Innovation Office
University of Technology, Sydney
T: (02) 9514 9645
F: (02) 9514 1244
E: Research.Ethics@uts.edu.au
I: http://www.research.uts.edu.au/policies/restricted/ethics.html
P: PO Box 123, BROADWAY NSW 2007
[Level 14, Building 1, Broadway Campus]
CB01.14.08.04

Appendix 12 Sigma Theta Tau International (STTI) Honour Society of Nursing grant application



Application #10358

First Investigator

Principal Investigator

Hiba A. Deek, PhD candidate - Investigator

Home Address:
Faculty of Health
University of Technology Sydney
[redacted]
Australia
Phone Number: [redacted]
Home Phone Number: [redacted]
Email: [redacted]
Alternative Email: [redacted]

Biographical Sketch

#	Institution and Location	Inclusive Dates of Attendance	Degree	Date Degree attained	Major
1	ICS-Lebanon	2001-2003	• Baccalaureate in Life Science	2003	Life Science
2	Makassed University-Lebanon	2003-2006	• Bachelor of Nursing	2006	Nursing
3	American Univesity of Beirut_Hariri School of Nursing-Lebanon	2009-2012	• Masters of Science in Adult Health Nursing Care	2012	Adult Health Nursing Care
4	University of Technology Sydney	2013-ongoing	PhD Nursing	Ongoing	Nursing

#	Title of Position	Employer Name	Employer Address	Inclusive Dates
1	Research assistant/ethics officer	Dr Yordanka Krastev	University of Technology Sydney, Buidling 1, level 14, Broadway 2007	October 2013-ongoing
2	Research assistant	Professor Patricia Davidson	University of Technology, Building 10, level 6, Broadway 2007	March, 2013-October, 2013
3	Teaching assistant	Professor Debra Jackson	University of Technology Sydney, Building 10, level 7, Broadway 2007	September/October, 2014

4	Registered Nurse	Mr Mahmoud Takkoush	Beirut Jnah	October, 2006-January, 2013

Are you a Sigma Theta Tau International Member?: Yes
Chapter Number and Name: (511) Chi Iota Chapter 1255802
Title of Project:
Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: Rrandomized controlled trial for implementing an education family session

Research Specialties:
Adult Health: Older Adults
Clinical Practice: Evidence-Based Practice, Healthcare Delivery
Family Health
Health Related Behaviors: Exercise/Activity, Nutrition/Eating
Models and Mechanisms: Socio-Cultural
Research Methods: Quantitative
Symptom Management: Chronic Disease and Injury, Intervention Studies, Self Management
Abstract Text:

Subject Population

Patients with heart failure admitted to one of the three study hospitals for any signs of heart failure exacerbation and planned for discharge after stability.

Research Design

Multi-site, block randomized controlled trial

Instrument

1) Baseline data will be collected through a baseline data set including: socio-demographic data, health history, physical assessment, NYHA class, and medications prescribed.

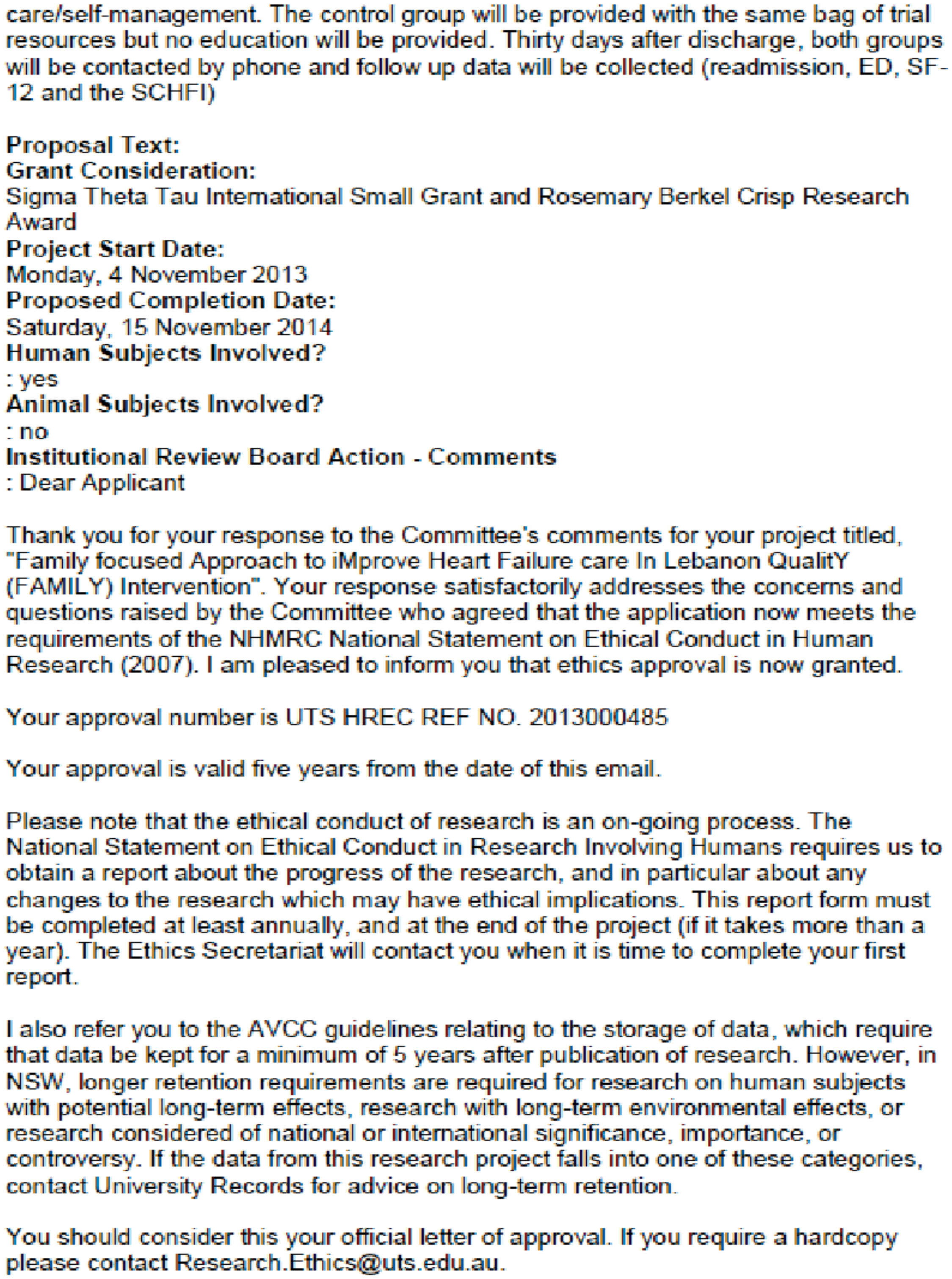
2) SHARE index: measuring frailty

3) Arabic version of the Self-care of heart failure index (A-SCHFI)

4) Arabic version of the SF-12

Procedure

Patients admitted to one of the three study hospitals will be recruited for this study. After introducing the study and consenting the patients and their family caregivers, baseline data will be collected (1-4). Patients will then be randomised into the control and the intervention groups. The former group with their family caregivers will be provided with the trial resources and a comprehensive educational session on self-



care/self-management. The control group will be provided with the same bag of trial resources but no education will be provided. Thirty days after discharge, both groups will be contacted by phone and follow up data will be collected (readmission, ED, SF-12 and the SCHFI)

Proposal Text:
Grant Consideration:
Sigma Theta Tau International Small Grant and Rosemary Berkel Crisp Research Award
Project Start Date:
Monday, 4 November 2013
Proposed Completion Date:
Saturday, 15 November 2014
Human Subjects Involved?
: yes
Animal Subjects Involved?
: no
Institutional Review Board Action - Comments
: Dear Applicant

Thank you for your response to the Committee's comments for your project titled, "Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention". Your response satisfactorily addresses the concerns and questions raised by the Committee who agreed that the application now meets the requirements of the NHMRC National Statement on Ethical Conduct in Human Research (2007). I am pleased to inform you that ethics approval is now granted.

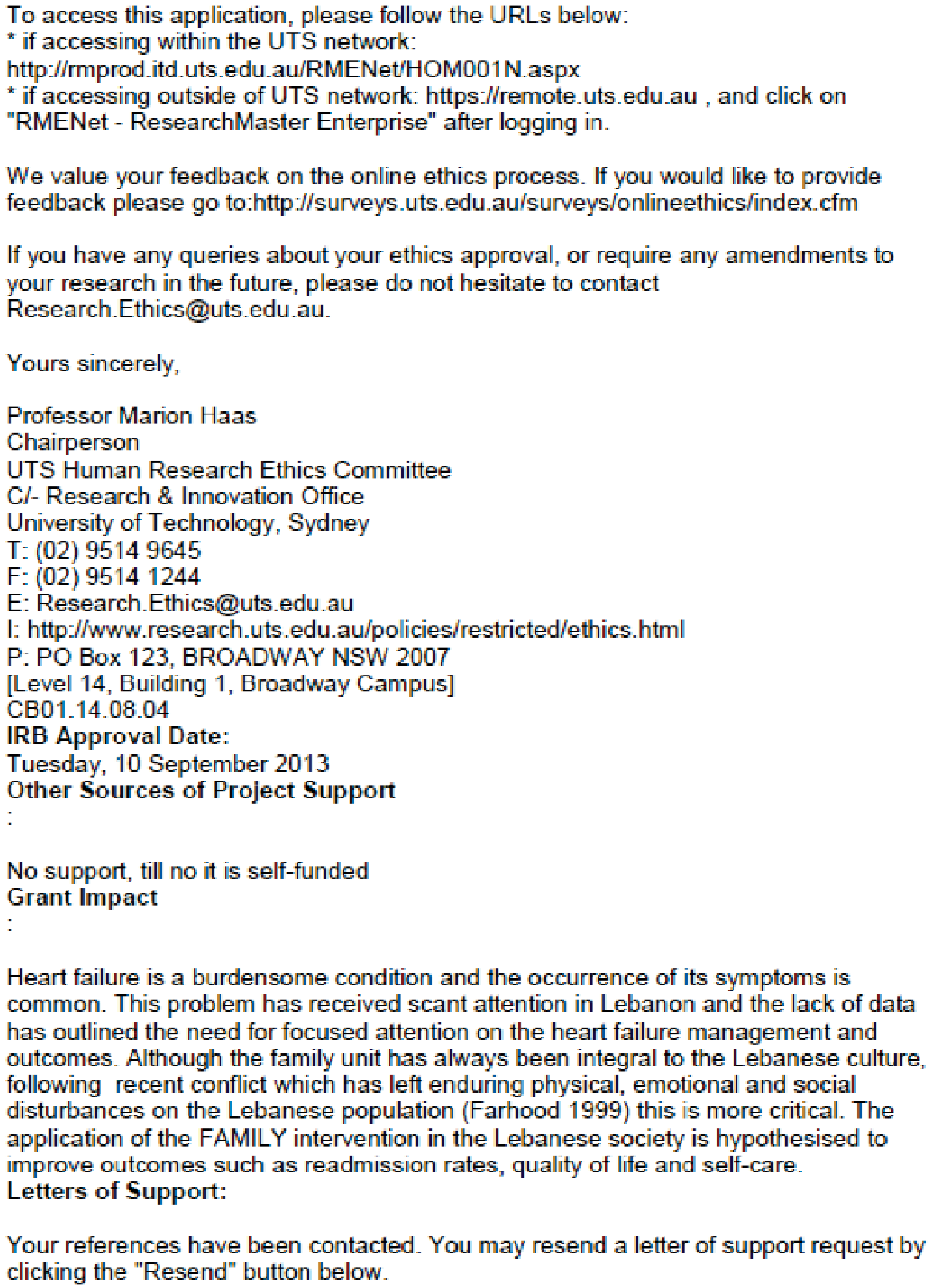
Your approval number is UTS HREC REF NO. 2013000485

Your approval is valid five years from the date of this email.

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

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

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



To access this application, please follow the URLs below:
* if accessing within the UTS network:
http://rmprod.itd.uts.edu.au/RMENet/HOM001N.aspx
* if accessing outside of UTS network: https://remote.uts.edu.au , and click on "RMENet - ResearchMaster Enterprise" after logging in.

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

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

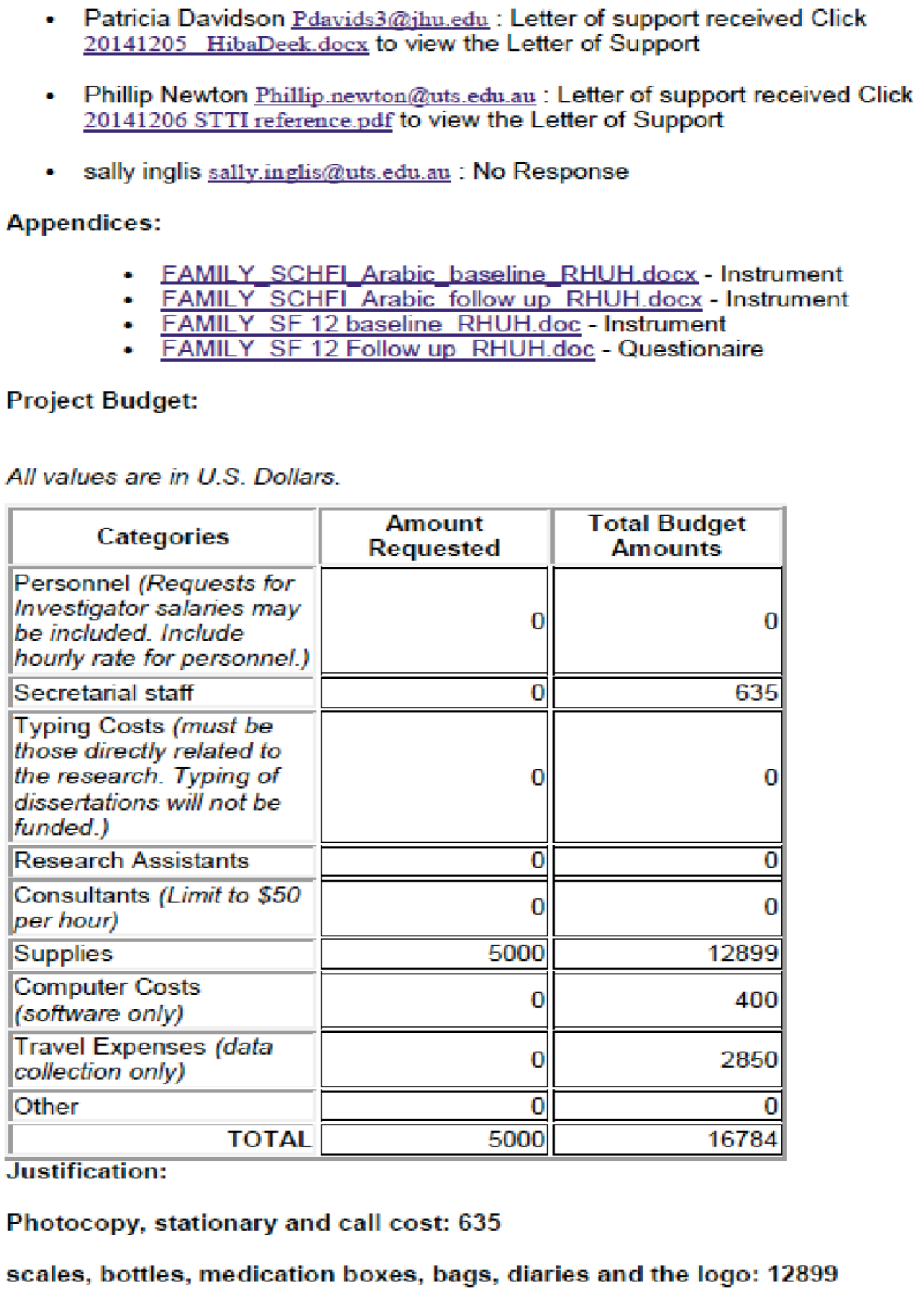
Yours sincerely,

Professor Marion Haas
Chairperson
UTS Human Research Ethics Committee
C/- Research & Innovation Office
University of Technology, Sydney
T: (02) 9514 9645
F: (02) 9514 1244
E: Research.Ethics@uts.edu.au
I: http://www.research.uts.edu.au/policies/restricted/ethics.html
P: PO Box 123, BROADWAY NSW 2007
[Level 14, Building 1, Broadway Campus]
CB01.14.08.04
IRB Approval Date:
Tuesday, 10 September 2013
Other Sources of Project Support
:

No support, till no it is self-funded
Grant Impact
:

Heart failure is a burdensome condition and the occurrence of its symptoms is common. This problem has received scant attention in Lebanon and the lack of data has outlined the need for focused attention on the heart failure management and outcomes. Although the family unit has always been integral to the Lebanese culture, following recent conflict which has left enduring physical, emotional and social disturbances on the Lebanese population (Farhood 1999) this is more critical. The application of the FAMILY intervention in the Lebanese society is hypothesised to improve outcomes such as readmission rates, quality of life and self-care.
Letters of Support:

Your references have been contacted. You may resend a letter of support request by clicking the "Resend" button below.



- Patricia Davidson Pdavids3@jhu.edu : Letter of support received Click 20141205 HibaDeek.docx to view the Letter of Support
- Phillip Newton Phillip.newton@uts.edu.au : Letter of support received Click 20141206 STTI reference.pdf to view the Letter of Support
- sally inglis sally.inglis@uts.edu.au : No Response

Appendices:

- FAMILY_SCHFI_Arabic_baseline_RHUH.docx - Instrument
- FAMILY_SCHFI_Arabic_follow up_RHUH.docx - Instrument
- FAMILY_SF 12 baseline_RHUH.doc - Instrument
- FAMILY_SF 12 Follow up_RHUH.doc - Questionaire

Project Budget:

All values are in U.S. Dollars.

Categories	Amount Requested	Total Budget Amounts
Personnel *(Requests for Investigator salaries may be included. Include hourly rate for personnel.)*	0	0
Secretarial staff	0	635
Typing Costs *(must be those directly related to the research. Typing of dissertations will not be funded.)*	0	0
Research Assistants	0	0
Consultants *(Limit to $50 per hour)*	0	0
Supplies	5000	12899
Computer Costs *(software only)*	0	400
Travel Expenses *(data collection only)*	0	2850
Other	0	0
TOTAL	5000	16784

Justification:

Photocopy, stationary and call cost: 635

scales, bottles, medication boxes, bags, diaries and the logo: 12899

ink, paper A 4: 400

travel expenses: flight ticket, transport between the hospitals and parking: 450

If you have applied for other sources of support, how will the conduct of this study be affected, if the other funding is not obtained?:

study is till now funded by the PhD student

Appendix 13 Referral Letter by Professor Davidson

Patricia M. Davidson, PhD, MEd, RN, FAAN

Dean & Professor

Johns Hopkins School of Nursing

525 N. Wolfe Street, Baltimore, MD 21205

P. 410-955-7544 | **F.** 410-955-4890 | **E.** pdavidson@jhu.edu

nursing.jhu.edu/dean | LinkedIn | Follow me @nursingdean

December 5th, 2014

Selection Committee

Sigma Theta Tau

Small Grants Review Panel

Dear Selection Committee,

I am the Dean and a Professor in the Johns Hopkins School of Nursing and have known Hiba Deek for three years and currently I am mentoring her PhD thesis project. I consider her to be a highly worthy recipient of this award.

Hiba is an enthusiastic cardiovascular nurse who is committed to developing a program of research in cardiovascular nursing. Relative to opportunity, her research output is impressive. She already has three publications and has two under review.

Hiba's proposed project, Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: Rrandomized controlled trial for implementing an education family session is addressing an issue of critically importance in Lebanon using a methodologically rigorous and conceptually congruent intervention.

Hiba is poised to be a leader in nursing research in Lebanon and her research trajectory shows an accelerated trajectory. The funds applied for will facilitate data collection and management.

I am confident Hiba will be an excellent ambassador for Sigma Theta Tau International.

Please do not hesitate to contact me should you require further information.

Yours sincerely,

Dr Patricia Davidson BA MEd PhD FAAN FAHA

Dean & Professor

Appendix 14 Referral Letter by Dr Newton

Centre for Cardiovascular & Chronic Care

UNIVERSITY OF TECHNOLOGY SYDNEY

Centre for Cardiovascular & Chronic Care
University of Technology Sydney
PO Box 123
BROADWAY NSW 2007

Telephone: +61 2 9514 2858
Facsimile: +61 2 9514 4474

6th December 2014

Selection Committee
Sigma Theta Tau
Small Grants Review Panel

Dear Selection Committee

It is my pleasure to write this letter of endorsement for Hiba Deek's application for the Sigma Theta Tau International Research Grant. I have known Hiba for the past three years as a member of her PhD supervision panel.

Hiba's project has focused on delivering a simple but innovative family focused intervention to people in Lebanon with heart failure. Whilst disease management programs are standard practice for people with heart failure in many western countries, they do not exist in Lebanon. Hiba conceived, developed and implemented her FAMILY intervention across three hospitals in Lebanon and has tested the intervention using a randomised control trial of 260 patients. This is a massive undertaking for a doctoral student and demonstrates she is a talented and tenacious researcher.

During her doctoral candidature Hiba has worked as a Research Assistant in addition to her full-time study load and despite being overseas collecting her data for many months she has been highly productive publishing three publications and submitting two others. Hiba has also served as the student representative on the Faculty of Health's Research Committee. This was a competitive selection process and her selection on the committee was in recognition of her leadership abilities and abilities as a developer researcher.

I believe Hiba would be a worthy recipient of this award.

Please contact me should you require any additional information.

Yours sincerely,

Dr Phillip Newton *RN PhD FAHA*
Director of Research Studies
University of Technology Sydney

Appendix 15 Abstract submitted to the STTI grant application

Subject Population

Patients with heart failure admitted to one of the three study hospitals for any signs of heart failure exacerbation and planned for discharge after stability.

Research Design

Multi-site, block randomized controlled trial

Instrument

1) Baseline data collected through a baseline data set including: socio-demographic data, health history, physical assessment, NYHA class, and medications prescribed.

2) SHARE index: measuring frailty

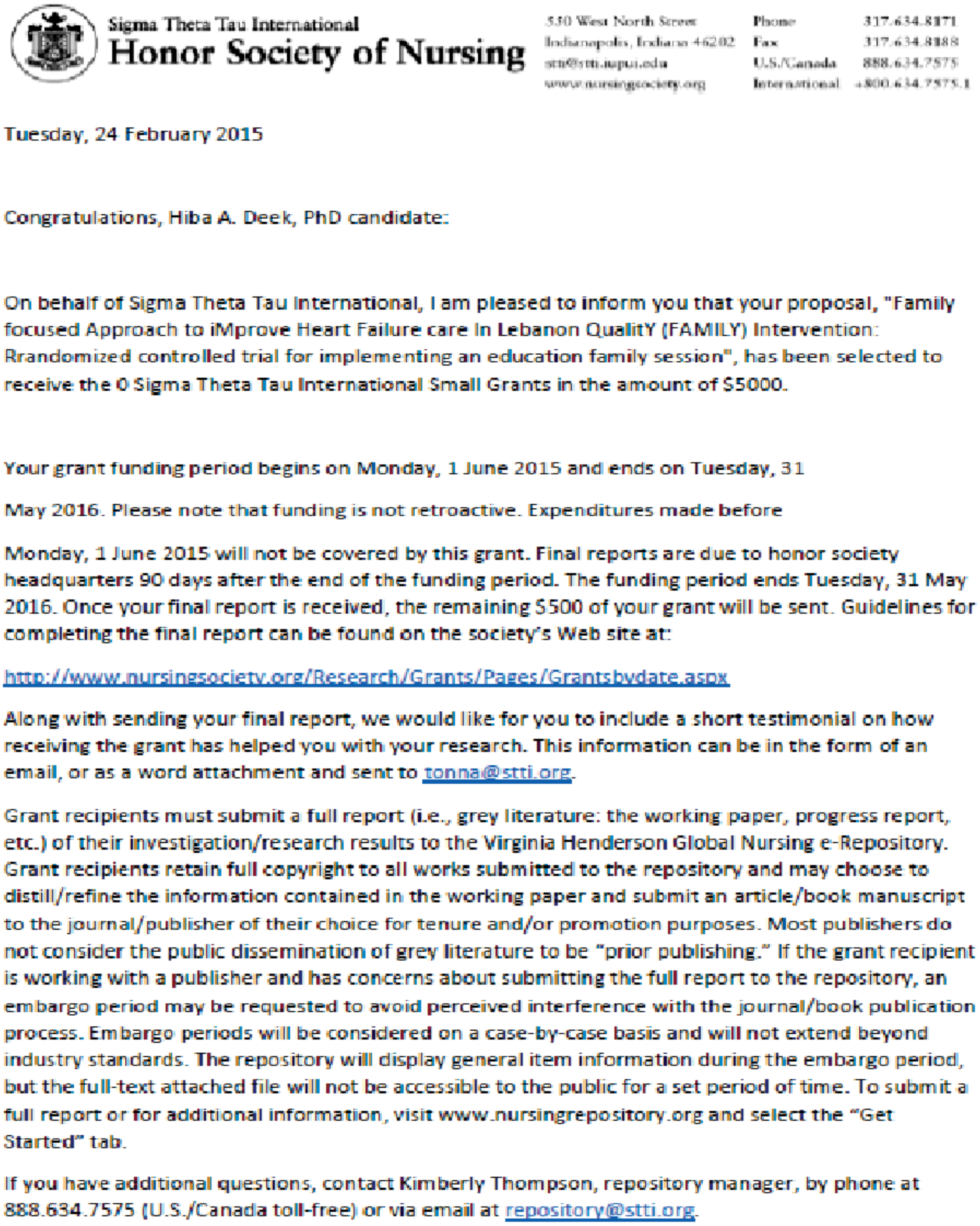
3) Arabic version of the Self-care of heart failure index (*A*-SCHFI)

4) Arabic version of the SF-12

Procedure

After introducing the study and gaining consent from the patients and their family caregivers, baseline data was_collected (1-4). Randomization took into the usual care or the intervention groups took place. The latter group with their family caregivers were provided with a bag of trial resources and a comprehensive educational session on self-care/self-management. The usual care group was provided with the same bag without any education. Thirty days after discharge, both groups were contacted by phone and follow up data was collected (readmission, ED, SF-12 and the SCHFI). Intervention planning was guided by behavioural models. The major limitation is the single educational session. Data analysis currently ongoing and dissemination of results will follow in peer-reviewed journals and international conferences.

Appendix 16 STTI Honour Society of Nursing grant offer



Sigma Theta Tau International
Honor Society of Nursing

550 West North Street
Indianapolis, Indiana 46202
stti@stti.iupui.edu
www.nursingsociety.org

Phone 317.634.8171
Fax 317.634.8188
U.S./Canada 888.634.7575
International +800.634.7575.1

Tuesday, 24 February 2015

Congratulations, Hiba A. Deek, PhD candidate:

On behalf of Sigma Theta Tau International, I am pleased to inform you that your proposal, "Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention: Rrandomized controlled trial for implementing an education family session", has been selected to receive the 0 Sigma Theta Tau International Small Grants in the amount of $5000.

Your grant funding period begins on Monday, 1 June 2015 and ends on Tuesday, 31

May 2016. Please note that funding is not retroactive. Expenditures made before

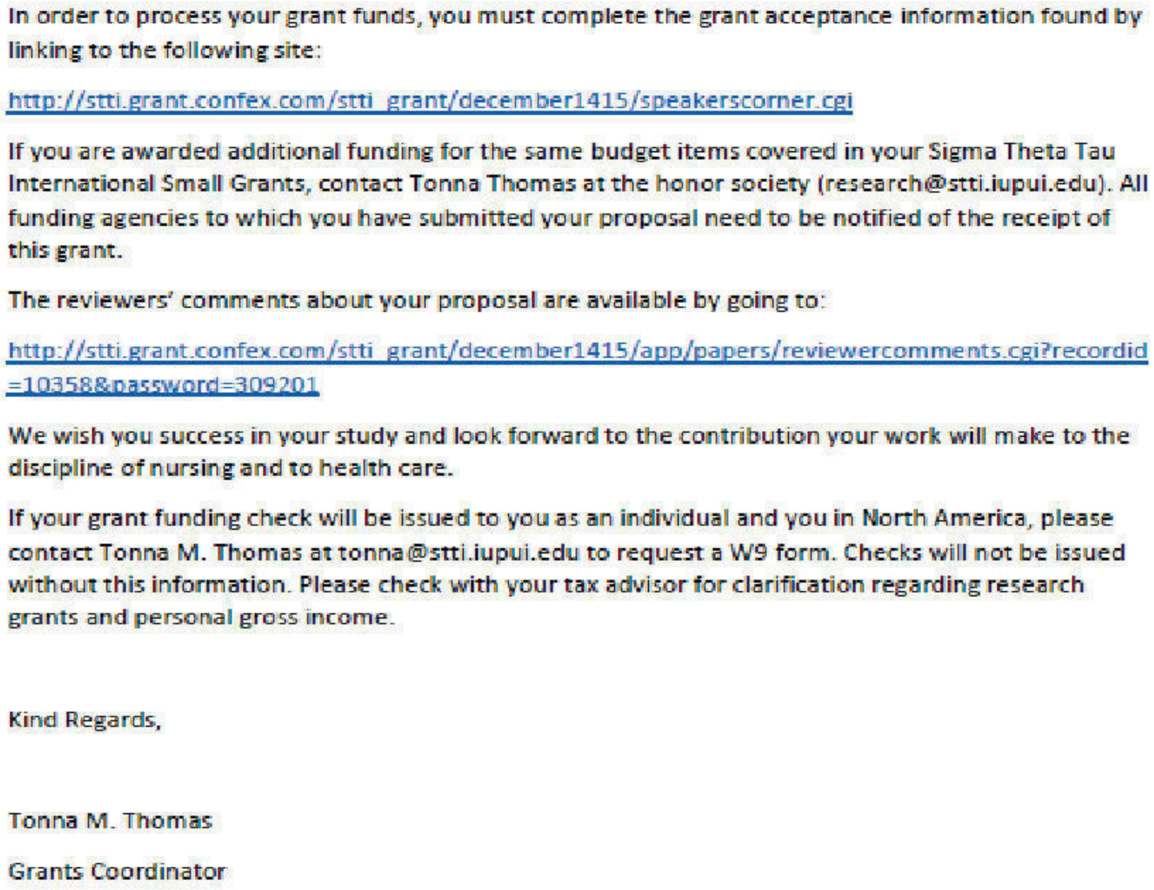
Monday, 1 June 2015 will not be covered by this grant. Final reports are due to honor society headquarters 90 days after the end of the funding period. The funding period ends Tuesday, 31 May 2016. Once your final report is received, the remaining $500 of your grant will be sent. Guidelines for completing the final report can be found on the society's Web site at:

http://www.nursingsociety.org/Research/Grants/Pages/Grantsbydate.aspx

Along with sending your final report, we would like for you to include a short testimonial on how receiving the grant has helped you with your research. This information can be in the form of an email, or as a word attachment and sent to tonna@stti.org.

Grant recipients must submit a full report (i.e., grey literature: the working paper, progress report, etc.) of their investigation/research results to the Virginia Henderson Global Nursing e-Repository. Grant recipients retain full copyright to all works submitted to the repository and may choose to distill/refine the information contained in the working paper and submit an article/book manuscript to the journal/publisher of their choice for tenure and/or promotion purposes. Most publishers do not consider the public dissemination of grey literature to be "prior publishing." If the grant recipient is working with a publisher and has concerns about submitting the full report to the repository, an embargo period may be requested to avoid perceived interference with the journal/book publication process. Embargo periods will be considered on a case-by-case basis and will not extend beyond industry standards. The repository will display general item information during the embargo period, but the full-text attached file will not be accessible to the public for a set period of time. To submit a full report or for additional information, visit www.nursingrepository.org and select the "Get Started" tab.

If you have additional questions, contact Kimberly Thompson, repository manager, by phone at 888.634.7575 (U.S./Canada toll-free) or via email at repository@stti.org.



In order to process your grant funds, you must complete the grant acceptance information found by linking to the following site:

http://stti.grant.confex.com/stti_grant/december1415/speakerscorner.cgi

If you are awarded additional funding for the same budget items covered in your Sigma Theta Tau International Small Grants, contact Tonna Thomas at the honor society (research@stti.iupui.edu). All funding agencies to which you have submitted your proposal need to be notified of the receipt of this grant.

The reviewers' comments about your proposal are available by going to:

http://stti.grant.confex.com/stti_grant/december1415/app/papers/reviewercomments.cgi?recordid=10358&password=309201

We wish you success in your study and look forward to the contribution your work will make to the discipline of nursing and to health care.

If your grant funding check will be issued to you as an individual and you in North America, please contact Tonna M. Thomas at tonna@stti.iupui.edu to request a W9 form. Checks will not be issued without this information. Please check with your tax advisor for clarification regarding research grants and personal gross income.

Kind Regards,

Tonna M. Thomas

Grants Coordinator

Appendix 17 STTI Honour Society of Nursing reviewer's comments

Submission 10358

Reviewers' summary of the major strengths and the major limitations of the proposal.

Review 1:
Strengths: Clearly written plan for RCT.Randomization procedure well documented. Strong support from faculty mentor and data colleciton sites.Good procedure for tranalation and back-translation of study instruments. Excellent choices for statistical analyses.

Review 2:
Thank you for submitting this grant proposal. This study has strengths in its simple design and the potential to learn more about a previously unstudied population of patients with heart failure. This proposal unfortunately does not present a clear theoretical framework, though a framework can be inferred generally from the text. In addition, the timeline of the grant and study period is unclear. Based on IRB dates and the project description, it appears that this study has already been completed. This is not reflected, however, in the proposed study period.

Review 3:
This study has the potential to contribute to the data base in the subject area. The limitations are not clear however.

Appendix 18 Guidelines for preparing the grant final report for the STTI

Guidelines for Preparing the Grant Final Report for The Honor Society of Nursing Sigma Theta Tau International*

1. The final report must be submitted within 90 days of the end of the funding period. Once the final report is received, up to remaining US $500 will be sent, if owed. The report may be submitted as an executive summary or abstract, a manuscript, a research abstract, a publication or journal article related to the funded project. Dissertations are not accepted as final reports. The final report should include the following:
    1. Summary of project aims
    2. Theoretical/conceptual framework
    3. Methods, procedures and sampling
    4. Summary of findings
    5. Recommendations
    6. Financial summary
    7. Check for any unused funds
    8. A 3-5 sentence testimonial on how receiving the grant assisted you in completing your research.
2. In addition, you must submit your abstract to the www.nursingrepository.org.
    - Grant recipients **must submit a full report (i.e., grey literature: the working paper, progress report, etc.) of their investigation/research results to the Virginia Henderson Global Nursing e-Repository. Grant recipients retain full copyright** to all works submitted to the repository **and may choose to distill/refine the information contained in the working paper and submit an article/book manuscript to the journal/publisher of their choice for tenure and/or promotion purposes.** Most publishers do not consider the public dissemination of grey literature to be "prior publishing." If the grant recipient is working with a publisher and has concerns about submitting the full report to the repository, an embargo period may be requested to avoid perceived interference with the journal/book publication process. Embargo periods will be considered on a case-by-case basis and will not extend beyond industry standards. The repository will display general item information during the embargo period, but the full-text attached file will not be accessible to the public for a set period of time. To submit a full report or for additional information, visit www.nursingrepository.org and select the "Get Started" tab. If you have additional questions, contact Kimberly Thompson, repository manager, by phone at 888.634.7575 (U.S./Canada toll-free) or via email at repository@stti.org.

3. Please recognize funding from the Sigma Theta Tau International Foundation upon publication and/or presentation.

The report can also should be e-mailed to research@stti.iupui.edu or faxed to +1.317.634.8188.
If you have questions, please contact research@stti.iupui.edu.

*Please note: This information is only for the grants submitted to the honor society. For grants submitted to the society's joint grant partners, please visit their Web site for specific guidelines.

Appendix 19 Elsevier permission to reuse publication: Heart Health in Lebanon and considerations for addressing the burden of cardiovascular disease

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Aug 24, 2015

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Appendix 20 Evidence of submission of the manuscript: Family-Centred Approaches to Health Care Interventions in Chronic Diseases: A Quantitative Systematic Review, *Journal of Advanced Nursing*.

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Sent: Wednesday, July 15, 2015 8:06 PM

To: Hiba Deek; [redacted]; sandy.hamilton@uwa.edu.au; Nicole.brown@uts.uts.edu; sally.inglis@uts.edu.au; michelle.digiacomo@uts.edu.au; Phillip.newton@uts.edu.au; sn00@aub.edu.lb; peter.macdonald@svha.org.au; pdavidson@jhu.edu

Subject: Revised submission to Journal of Advanced Nursing - Manuscript ID JAN-2015-0088.R1

15-Jul-2015

JAN-2015-0088.R1: FAMILY-CENTRED APPROACHES TO HEALTH CARE INTERVENTIONS IN CHRONIC DISEASES: A FOCUSSED LITERATURE REVIEW.

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Best wishes,

Gareth Watkins

Journal of Advanced Nursing

Appendix 21 Journal of Advanced Nursing (JAN) permission to reuse publication: A family focused intervention for heart failure Self-care: conceptual underpinnings of a culturally appropriate intervention

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Sent: Wednesday, August 26, 2015 1:34 AM
To: Hiba Deek
Subject: RE: JAN-2015-0088

Dear Hiba,

Thank you for your message. Congratulations on the acceptance of your article. You are welcome to include the manuscript in your thesis appropriately referenced.

Best wishes,
Gareth

Gareth Watkins
Associate Managing Editor
Journal of Advanced Nursing

From: Hiba Deek [mailto:[redacted]]
Sent: 24 August 2015 11:03
To: JAN
Subject: JAN-2015-0088

Dear editor

Thank you for accepting the manuscript titled: "A family focused intervention for heart failure Self-care: conceptual underpinnings of a culturally appropriate intervention" for publication at Journal of Advanced Nursing. This paper described the intervention used in the FAMILY study which evaluates the involvement of family members in self-care of patients with heart failure. We are seeking your agreement to include the manuscript in the PhD thesis describing and evaluating the FAMILY study.

The manuscript numbers is: JAN-2015-0088

Thank you for your support.

Warm regards
Hiba

Hiba Deek, RN, MSN, PhD Candidate

Centre for Cardiovascular and Chronic Care (CCCC) | Faculty of Health
University of Technology Sydney
Email: [redacted] [redacted]

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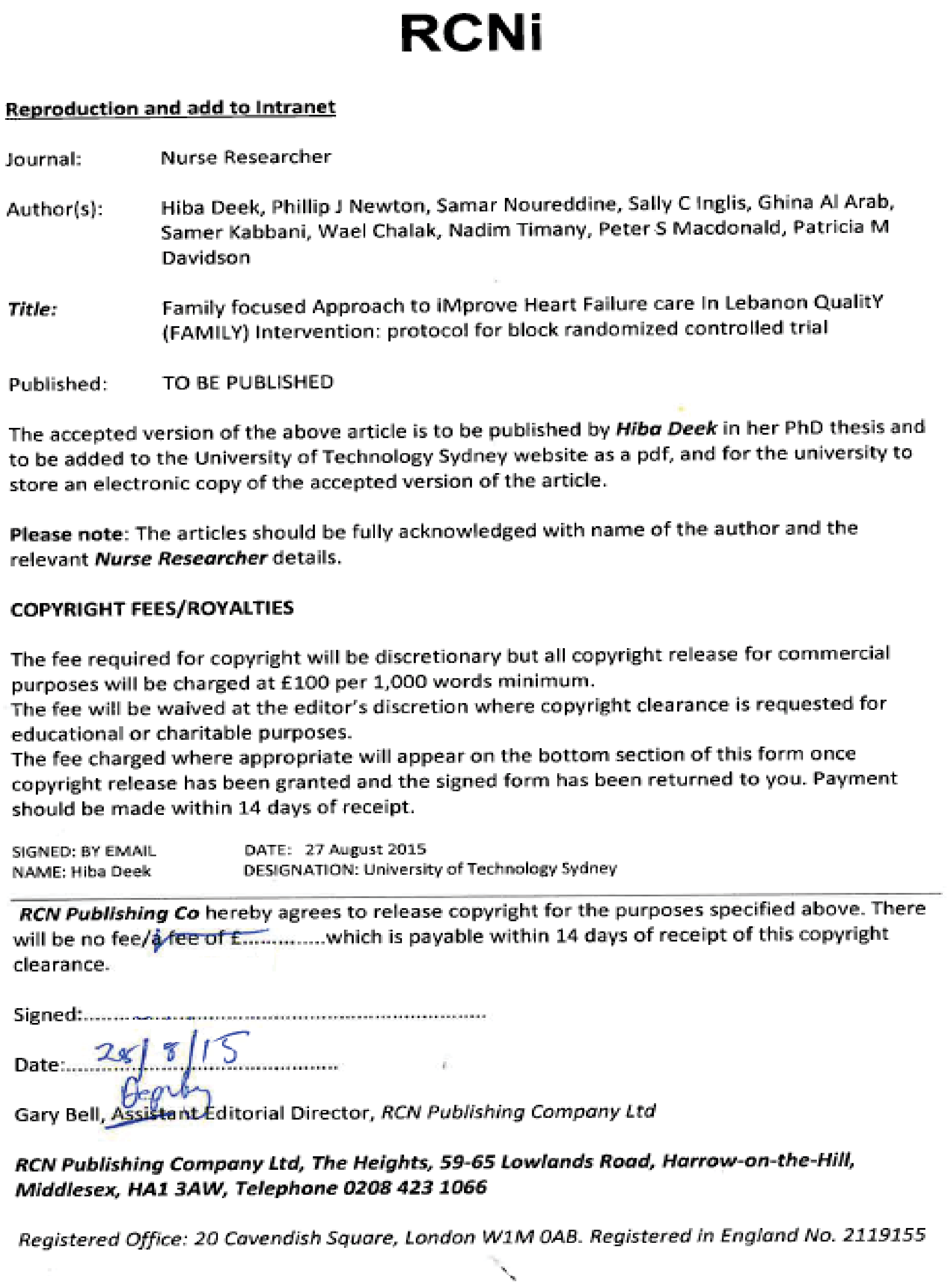

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Author(s): Hiba Deek, Phillip J Newton, Samar Noureddine, Sally C Inglis, Ghina Al Arab, Samer Kabbani, Wael Chalak, Nadim Timany, Peter S Macdonald, Patricia M Davidson

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Appendix 24 Evidence of submission of the manuscript: Family focused Approach to iMprove Heart Failure in Lebanon QualitY (FAMILY) Intervention: randomized controlled trial, International Journal of Cardiology.

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