Protocol for a block randomised controlled trial of an intervention to improve heart failure care

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Abstract

Aim To describe the design of a randomised controlled trial conducted to evaluate a culturally tailored, nurse-led educational intervention.

Background Self-care strategies are critical to improving health outcomes in heart failure. The family unit is crucial in collectivist cultures, but little is known about involving the family in the self-care of patients with heart failure.

Discussion Involving the family in the self-care of heart failure is a novel approach. To the authors' knowledge, no one has evaluated it using a randomised controlled trial.

Conclusion A valid comparison of outcomes between the control group and the intervention group involved in the study was provided in this trial. The chosen design, randomised controlled trial, enabled the assessment of the intervention.

Implications for practice The application of a family self-care intervention in a collectivist culture was shown to improve clinical and quality outcomes of patients with heart failure. Considering the individual and the community needs is vital in improving these outcomes.

Keywords randomised controlled trial, heart failure, family, trial, readmission, nursing, protocol, culture

Introduction

HEART FAILURE (HF) is a global health issue requiring complex and coordinated primary (Van Riet *et al* 2014), secondary (Steventon *et al* 2012) and tertiary (Qian *et al* 2015) health care.

Self-care is 'a naturalistic decision-making process involving the choice of behaviours that maintain physiologic stability and the response to symptoms when they occur' (Riegel *et al* 2008). It is the cornerstone of HF management (Davidson *et al* 2013) and an important factor in reducing incidents (Moser *et al* 2012).

While the number of cardiovascular (CV) risk factors in Lebanon is high (Siba and Hwalia 2009), little is known about HF prevalence, treatment and follow-up (Deek *et al* 2015). Lebanon is a collectivist culture with tightly knit family structures. Family unity helps to overcome the detrimental effects of war and maintain physiologic and psychological stability (Farhood 1999).

Families of patients with cardiac illness involve themselves significantly in the patients' health-seeking behaviours (Noureddine *et al* 2015). People with HF are older and frailty is increasingly a marker of this condition (Jha *et al* 2015). They require assistance to adhere to treatment recommendations, further highlighting the role of the family in supporting self-care.

Thus educating the family caregiver about health maintenance and symptom management is a culturally-tailored approach. Culturally-tailored interventions, such as glycaemic control, self-efficacy and diabetes knowledge through behavioural change, have shown improvements in patient outcomes (Davidson *et al* 2007, Rosal *et al* 2011).

A culturally-derived, nurse-led, family model of HF intervention was tested in Lebanon using a randomised controlled trial, the gold standard in evaluating interventions (Schulz *et al* 2010).

The aim of this paper is to describe the design of this trial of the Family-focused Approach to iMprove heart failure care In Lebanon qualitY (FAMILY) study.

Methods

Study design The FAMILY study was a multicentre, non-blinded, parallel arm (1:1), block randomised controlled trial involving 256 patients with 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 Figure 1.

Sampling Hospitalised patients were identified as having HF by the cardiologists, cardiology fellows or cardiac care unit (CCU) staff. Patients were included in heart failure management if they had been admitted through the emergency department or electively referred by a cardiologist and met typical HF findings in the Framingham criteria (McKee *et al* 1971) outlined in Box 1.

For confirmation of the diagnosis once referred to the study 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 (Jessup *et al* 2009) to confirm the HF diagnosis.

Eligibility criteria Recruitment took place between November 2013 and November 2014. Patients aged 18 years old or more admitted to any of the three study hospitals with symptoms associated with preserved and reduced ejection fraction HF were invited to participate in the study, regardless of aetiology.

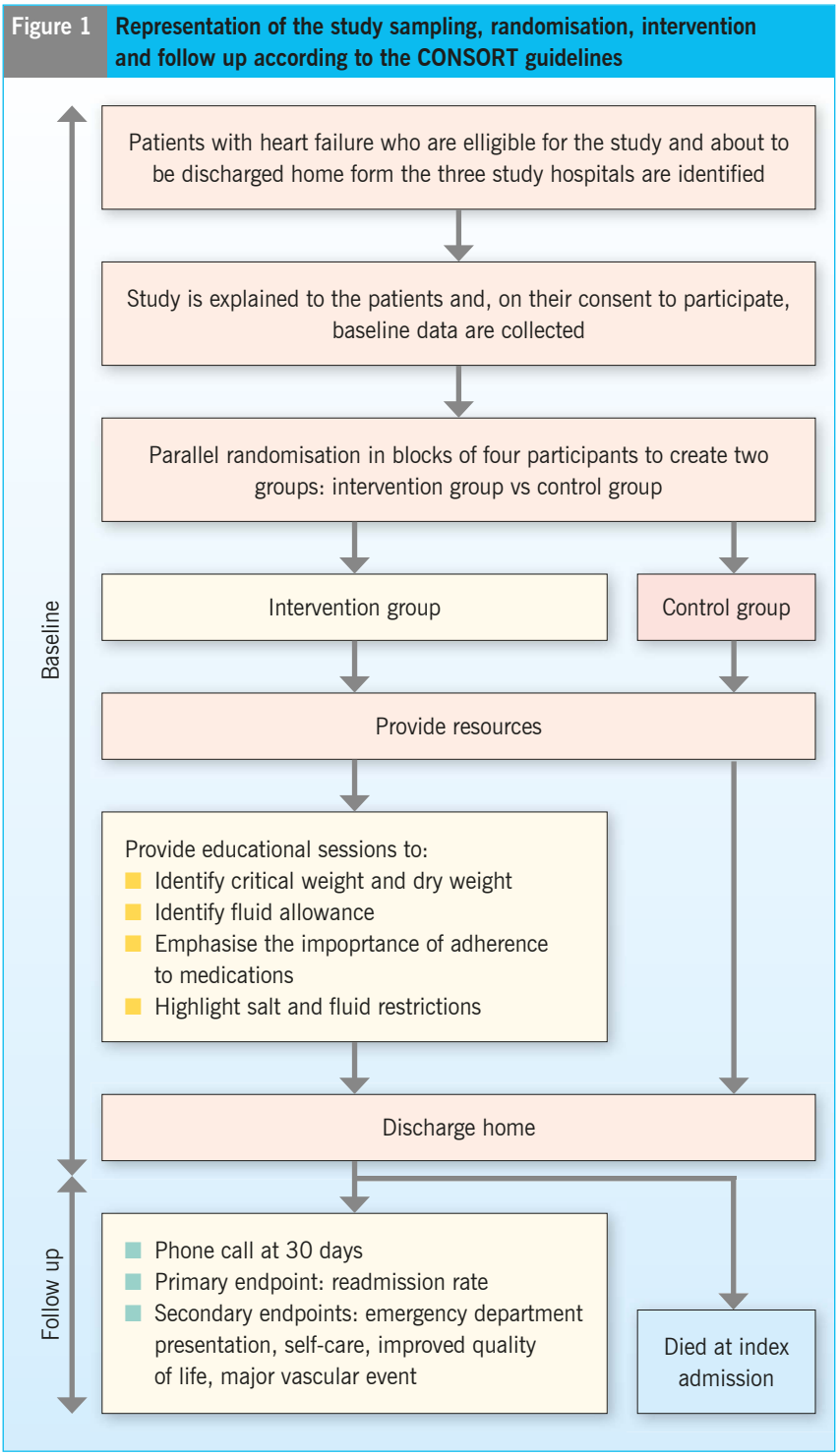
Illiterate patients were included in the study only if their family caregivers were literate and could make health-related decisions for them. They were provided with a thorough explanation of the intervention and, after they had been recruited, adequate support from their caregivers.

Patients were excluded if they were living alone or in nursing homes, were younger than 18 years old, or of they had a terminal condition or severe health condition that their physicians or family caregivers judged would hinder their participation.

Factors that would have resulted in exclusion include a life expectancy of less than 30 days; severe cognitive impairment limiting the patient's judgement and activity; a need for cardiac bypass or valve-replacement surgery; or anything that would hinder the progress of the intervention, such as impaired cognition or a blind caregiver.

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 and the institutional review boards of the sites involved.

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



Box 1 The Framingham criteria

Major criteria

- Paroxysmal nopcturnal dyspnea
- Neck vein distention
- Rales
- Radiographic cardiomegaly
- Acute pulmonary edema
- S3 gallop
- Increased central venous pressure >16cm H_2O at right atrium
- Hepatojugular reflux
- Weight loss > 4.5kg over five 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
- Tachycardia >120BPM

(McKee *et al* 1971)

Patients and their caregivers consented only after they had been introduced to the study. The consent form stated that refusal to consent to the study would not affect the care they received and they were free to withdraw from the study at any time.

Data were collected only after the patients' consent, and their privacy was protected by coding the documents and ensuring participants could not be identified. Patients who were illiterate were excluded from the study unless their family caregivers consented, and were willing to provide explanations and support. The patients' fingerprints were taken instead of their signatures; this is acceptable practice in Lebanon.

After patients and caregivers had signed the consent form, baseline data were then collected and randomisation undertaken The patients' details and unique codes were locked in the lead researcher (HD)'s office. The trial was registered with the Iranian Registry of Clinical Trials.

Randomisation Block randomisation was performed by an independent co-investigator, who was not involved in collecting data, using the SPSS software's random number generator. This divided the recruited participants into groups of four, and subdivided each of these groups into an intervention group of two and a control group of two. Thus the researcher (HB) who was recruiting and providing the intervention would not be overwhelmed.

Sample size Since the available readmission data for Lebanon was lacking, we assumed a baseline readmission rate of 30% (Aranda *et al* 2009), based on the international literature. Allowing for an attrition rate of 10%, a minimum sample size of 130 was considered necessary in each of the study arms to achieve 80% power at a two-tailed significant alpha level of 0.05, to demonstrate a 15% reduction in readmission at 30 days.

Second visits during hospitalisation Both groups were contacted to avoid the risk of bias arising from an extra visit only to the intervention group. All participants were provided with the self-care resources: a scale, a calibrated bottle, a medication box and a diary placed in a bag, branded with a specific logo as a behavioural prompt.

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

Members of the control group were given no verbal explanation while patients and caregivers in the intervention group were provided with an educational session lasting 30-60 minutes based on their individual needs. This session was tailored to the patient's condition, unique symptoms (if present) and subjective demands.

Intervention Although interventions for HF coordinated by nurses have been well addressed in previous studies (McAlister *et al* 2004, Clark *et al* 2007), a family-centred approach was implemented in the study to test its efficacy on the Lebanese population. To develop the model the researchers:

- Studied theoretical models of behaviour change and self-care (Noar *et al* 2007, Michie *et al* 2011, Riegel *et al* 2012).
- Undertook a review of the evidence and evidence-based practice (Jessup *et al* 2009, Heart Failure Society of America *et al* 2010, National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand 2011).
- Identified sociocultural elements (Deek *et al* 2015).
- Undertook expert consultation.
- Ensured the model of intervention would be acceptable and appropriate to a resource-poor setting (Patterson 1988).

The resulting family intervention heart failure model is outlined in Figure 2.

The intervention included a single educational session. This session was structured to include information about HF causes, symptoms and management. HF management comprised a big portion of this session, focusing on self-management and roles of the family caregiver. The education included tips about salt and fluid restriction, physical activity, symptom recognition, smoking cessation and adherence to prescribed medication. It also included culture-specific risk factors, such as active and passive water-pipe smoking, high prevalence of familial hypercholesterolemia reflecting the unique allele in the Lebanese culture, CV 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 were used.

Self-care resources provided in the bag were explained separately, emphasising the need for the family caregiver to fill the medicine box daily with the prescribed pills; fluid intake to be limited with the help of the calibrated bottle, based on the daily allowance recommended by the cardiologist; and weight in light clothes to be taken daily after waking up in the morning, and documented in the diary.

A flexible diuretic plan was created for each participant in consultation with his or her treating cardiologist. Participants were instructed to take an extra pill of their diuretic if their weight increased by 1kg over one day or 2kg over five days. They were also advised to contact their cardiologists if their weight continued to increase despite the proposed plans.

Both groups were provided with the contact details of their cardiologists in case of an emergency. Verbal education and written material were provided in the patients' native language, Arabic, so they would better understand it. Baseline and follow-up data collection were also done in Arabic to assure accuracy.

To standardise the implementation of the FAMILY intervention, a checklist was made of the items that were to be addressed in the educational sessions; these were ticked off as they were explained. The intervention also adapted a flexible approach in which all questions raised by patients and caregivers were answered, subjective concerns met and adequate referrals made. Furthermore, HB implemented the intervention for all participants in the intervention group to ensure fidelity of implementation.

Data collection Baseline data were collected before randomisation; the same data, except for demographic and admission clinical variables, were collected 30 days following discharge. Follow-up data were collected by phoning participants to ask about their wellbeing and if they had been hospitalised or visited the emergency department since discharge. Each call lasted for less than 10 minutes and the trained researcher (GA) conducting the phone calls was blinded to the treatment allocations.

Tool sheets

Various tools were used to collect these data:

Figure 2 The Family Intervention Heart Failure model

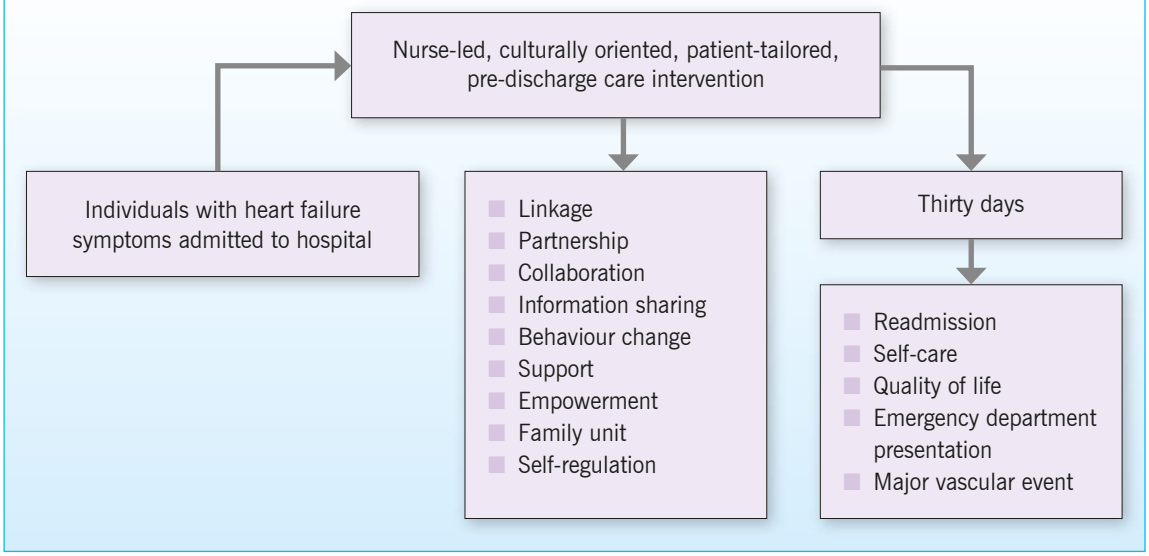


Table 1 Timeframe of data collection and data collectors

Instrument or data collected	Time when used		Data collector	
	Baseline	After 30 days	Primary investigator	Nurse researcher
Baseline tool	✓		✓	
A-SCHFI	✓	✓	✓	✓
SF-12	✓	✓	✓	✓
Follow-up tool		✓		✓

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

Arabic SCHFI (A-SCHFI) The self-care of heart failure index (SCHFI) (Riegel *et al* 2009) was used to measure the level of self-involvement of patients with heart failure in their self-care. For this study, it was translated into Arabic and then back to English twice by two researchers independently. Face, content and construct validity were evaluated, before the Arabic version was administered during the follow-up phone calls.

SF-12 Quality of life was measured using the Short Form-12 (SF-12) questions (Ware Jr *et al* 1996) which address the physical functioning of the patients, role limitations, and social and emotional status. Although the health survey, SF-36, had previously been translated, validated then tested on a Lebanese sample (Sabbah *et al* 2003), SF-12, a subset of SF-36, had not. However, it had been used with patients with diabetes mellitus in Saudi Arabia.

Before use in the study, SF-12 was translated into Arabic and validated by a panel of experts. It was then adjusted and reworded after piloting to be better understood and easily administered (Al-Shehri *et al* 2008). The larger translated form of SF-36 was shown to be easily administered over the phone (Montazeri *et al* 2005); similarly, this short form did not burden the participants in this study when administered during follow-up calls.

SHARE-FI Frailty was measured using the frailty instrument from the Survey of Health, Ageing and Retirement in Europe (SHARE) trial: SHARE-FI (Romero-Ortuno *et al* 2010). This is simple to use, requiring only a single physical measure (hand-grip strength) and one question for each of the other domains of frailty it measures: exhaustion, weight loss, slowness and low activity. These domains are in keeping with the Fried Frailty index for assessing frailty (Fried *et al* 2001), with hand-grip strength one of the items identified in the index.

Patients in both groups were assessed for hand-grip strength before randomisation using a dynamometer. Hand-grip strength was measured in both arms twice, with the highest score recorded for each arm.

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Primary and secondary endpoints The primary endpoint was readmission at 30 days of hospital discharge. Secondary endpoints were emergency department presentation, self-care, quality of life, healthcare use and major CV events. This time-frame was chosen based on the quality indicators implemented by financial bodies such as Medicare , which assures the money paid for healthcare is being used with credibility, 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). The time-frame and data collection plan are outlined in Table 1.

Data analysis The data were analysed using SPSS according to the intention-to-treat principle, with readmission at 30 days as the primary outcome measure. Readmissions were recorded for any cause, to capture any admissions related to iatrogenesis and errors in classification (HF versus non-HF readmission) (Chang *et al* 2014). Baseline differences between the study arms were compared 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 that are 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.

Discussion

There is increasing recognition of the need to make models of HF care more appropriate and accessible to a target population's different ages, genders and cultures. Involving the family in self-care of HF is a novel approach and highly appropriate to collectivist cultures (Davidson *et al* 2007). To our knowledge, there is only one study reporting the rates of HF readmission in Lebanon (Deek *et al* 2014) and this uses a retrospective design.

This trial provides a valid comparison of outcomes between the control group and the intervention group involved in the study. The chosen design, randomised controlled trial, enabled the assessment of the intervention and had previously been used to evaluate family educational interventions in other patient populations (Rosal *et al* 2011, Rothschild *et al* 2012). Furthermore, it is considered to be the most efficacious method to control for confounding factors (Schulz *et al* 2010) and although it may require more time and money than other methods, costs can be recouped when outcomes are improved and hospital fees reduced (Johnston *et al* 2006).

Bias was carefully avoided throughout the trial. Selection bias was avoided by having an independent researcher randomise the participants after the baseline data had been collected. Detection bias was avoided by having the follow-up data collected by a researcher who was not involved in randomisation or collection of the baseline data.

In conclusion, prospectively involving the family in HF management using a theoretically derived and protocol-driven approach is novel. Furthermore, this is the first trial conducted in Lebanon on patients with HF, which is appropriate in a collectivist culture where the family is integrally involved in all dimensions of the individuals' lives.

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Conflict of interest
None declared

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