

An evaluation of involving family caregivers in the self-care of heart failure patients on hospital readmission: Randomised controlled trial (the FAMILY study)



Hiba Deek^{a,*}, Sungwon Chang^a, Phillip J. Newton^a, Samar Nouredine^b, Sally C. Inglis^a, Ghina Al Arab^b, Samer Kabbani^c, Wael Chalak^d, Nadim Timani^e, Peter S. Macdonald^{f,g}, Patricia M. Davidson^{a,b,h}

^a Centre for Cardiovascular and Chronic Care, Faculty of Health, University of Technology Sydney, PO box 123, Broadway, Australia

^b Rafic Hariri School of Nursing, American University of Beirut, Lebanon

^c Rafic Hariri University Hospital Clinical Research Unit, Lebanon

^d Faculty of Medical Science, Lebanese University, Lebanon

^e Makassed General Hospital, Lebanon

^f Transplantation Research Laboratory at the Victor Chang Institute, St Vincent Hospital, Sydney, 390 Victoria Street, Darlinghurst NSW 2010 Australia

^g University of New South Wales, Australia

^h Johns Hopkins School of Nursing, 525 N. Wolfe Street, Baltimore, MD 21205 USA

ARTICLE INFO

Keywords:

Clinical trial
Disease management
Education
Family
Heart failure
Nursing
Self-care

ABSTRACT

Background: The prevalence of heart failure is increasing in Lebanon but to date there is no systematic evaluation of a disease management intervention.

Objective: The aim of this study was to evaluate the effect of involving family caregivers in the self-care of patients with heart failure on the risk of hospital readmission.

Design: A multi-site, block randomised controlled trial.

Settings: The study was conducted over a 13-month period in three tertiary medical centres in Beirut and Mount Lebanon, Lebanon.

Participants: Adult patients presenting for an exacerbation of heart failure to one of the study centres were included. Patients with limited life expectancy or physical functionality, planned cardiac bypass or valve replacement surgery, living alone or in nursing homes, or aged less than 18 years were excluded.

Methods: Patients allocated to the intervention group and their 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. Follow-up phone calls were conducted 30 days following discharge by a research assistant blinded to treatment assignment. The primary outcome was hospital readmission and the secondary outcomes were self-care, quality of life, major vascular events and healthcare utilization.

Results: The final sample included 256 patients hospitalized for heart failure randomised into control (130 patients) and intervention (126 patients) groups. The mean age was 67 (SD = 8) years, and the majority (55%) were male. Readmission at 30 days was significantly lower in the intervention group compared to the control group (n = 10, 9% vs. n = 20, 19% respectively, OR = 0.40, 95% CI = 0.02, 0.10, p = 0.02). Self-care scores improved in both groups at 30 days, with a significantly larger improvement in the intervention group than the control group in the maintenance and confidence sub-scales, but not in the self-care management sub-scale. No differences were seen in quality of life scores or emergency department presentations between the groups. More patients in the control group than in the intervention group visited health care facilities (n = 24, 23% vs. n = 12, 11% respectively, OR = 0.39, 95% CI = 0.18, 0.83, p = 0.01).

Conclusion: The trial results confirmed the potential of the family-centred self-care educational intervention under evaluation to reduce the risk of readmission in Lebanese patients suffering from exacerbated heart failure.

* Corresponding author at: Centre for Cardiovascular and Chronic Care, Faculty of Health, University of Technology Sydney, PO box 123, Broadway, 2007, Australia.
E-mail address: hiba.deek@gmail.com (H. Deek).

Further research is needed to validate these findings with longer periods of follow-up and to identify the intervention components and intensity required to induce sustained benefits on patients' self-care management and quality of life.

What is already known about the topic?

- Heart failure is of great burden to the patient, the family caregiver and the healthcare system at large.
- Heart failure disease management programs have shown promising results in improving patient outcomes in developed countries.
- There is an established need for implementation and evaluation of self-care education interventions for heart failure patients in resource-limited health care settings like in Lebanon.

What this paper adds

- The FAMILY study is the first randomised controlled trial which evaluated the implementation of a family-focused self-care promotion programme for heart failure patients in Lebanon.
- In terms of the primary outcome, this novel self-care promotion intervention resulted in a significant reduction in the 30-day readmission incidence among these seriously affected patients.
- This novel approach of family-focused self-care promotion evaluated through the FAMILY study emerged to be feasible in the Lebanese health care setting and has the potential to improve health outcomes in patients with heart failure.

1. Introduction

Heart failure is a clinical syndrome with complex treatment regimen, progressively declining disease trajectory and unpredicted health events (Gavazzi et al., 2015). This 'malignant' condition (Yancy et al., 2013) is the terminal stage of most cardiovascular diseases and is usually associated with multiple co-morbidities and poor outcomes (Gavazzi et al., 2015). It is estimated that up to 2% of the adults in developed countries have heart failure and this percentage increases in older adults to reach 10% (McMurray et al., 2012). In Lebanon, there is an estimated prevalence of 1.8% (72,000 patients) (Tatari et al., 2015). Like other progressing diseases, heart failure causes significant burden to affected patients and their families, but also to the society. The average cost for a single hospitalization is almost 4000 US dollars and the total cost for heart failure care has exceeded one million US dollars annually in Lebanon (Tatari et al., 2015) and is rising with limited interventions to control it.

Health care for patients with heart failure is predominately provided at tertiary medical centres when they present with exacerbating symptoms that require immediate treatment. Primary health services are lacking and disease management programs are often only implemented for research purposes in Lebanon (Deek et al., 2015). Heart failure hospitalization accounts for 36% of hospitalizations in Lebanon and frequent readmissions are typical (Deek et al., 2016d). The mean length of hospital stay is 11 days with an average cost of 4000 US dollars for each patient hospitalization. This cost of in-patient care is mainly provided by the public sector. Outpatient costs, averaged to 911 US dollars/year, are paid by the patients themselves since no money is allocated for this type of care by any paying party. Outpatient cost is divided between clinic visits, medication costs and diagnostic tests. Patients visit their treating physicians at an average of 2.6 times annually (Tatari et al., 2015). Heart failure treatment across the country is not consistent; physicians provide care based on the origin of their practicing schools thus adopting different guidelines (European vs. American). Nursing care, on the other hand, is moving towards consistency, with the Order of Nurses in Lebanon setting guidelines to be followed in nursing education and practice (Order of Nurses in

Lebanon, 2016).

Disease management programs are structured multicomponent interventions that include educational elements on diet, self-monitoring and treatment adherence (Pimouguet et al., 2011). These programs have produced varying levels of success on heart failure outcomes (Notte and Osborne, 2013). Many of the effective programs involve multidisciplinary teams with interventions delivered by nursing professionals. Nursing involvement was shown to have a positive impact on the outcomes of the interventions due to the longer contact hours with patients and their perceived easiness of approach for health information (Coster and Norman, 2009). Therefore, nursing involvement is an integral dimension of disease management programs for heart failure (Davidson et al., 2015), and is a vital component of this model of intervention. 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 (Krumholz et al., 2006). 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 (World Health Ranking, 2013). Self-care is the umbrella term that represents decisions and activities carried out by the individual to maintain health and prevent diseases. It is greatly influenced by the family and the surrounding community (World Health Organization, 2009). Self-care is also influenced by the patients' socio-economic status, knowledge, literacy level, skills and acceptability of personal and familial values (Riegel and Dickson, 2015). Self-care in heart failure is reflected by activities performed by patients to maintain wellbeing; such activities include salt and fluid restriction, physical activity, and smoking cessation (Riegel et al., 2009). Readmissions, quality of life and emergency department presentations are some of the clinical outcomes that can be improved by adopting self-care practices (Riegel and Dickson, 2015; Desai, 2012).

Although the role of family caregivers is implicit and reflected in studies of patients with coronary artery disease in Lebanon (Noureddine et al., 2014), there has been no evaluation of the systematic involvement of the family in heart failure self-care. Spousal support has been found to be associated with medication adherence (Molloy et al., 2005). In line with these findings, it was recently acknowledged (Deek et al., 2016a) that spousal support must be an integral part of, rather than just complementary to, self-care promotion programs in non-western, collectivist cultures where family unity is pivotal to societal function. Collectivism is when a group of individuals see themselves as part of a single society sharing similar norms and beliefs rather than being individualists (Ayyash-Abdo, 2001). This is true in Lebanon where family involvement was proven to be a strong moderator in overcoming the detrimental effects of war on the physical and psychological wellbeing (Farhood, 1999).

Conflicts in the Middle East, particularly the influx of refugees from Syria, require models of interventions that consider issues of access and acceptability (Penchansky and Thomas, 1981). 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. The purpose of the study was to evaluate the effectiveness of the Family focused Approach to improve Heart Failure care In Lebanon QualityY intervention (FAMILY) study on patient outcomes. The primary aim of this study was to evaluate the effectiveness of this tailored heart failure disease management intervention on hospital readmission. Secondary aims were to evaluate its effectiveness on self-care, quality of life, and health care utilization.

2. Methods

2.1. Trial design

The FAMILY study, described in depth elsewhere (Deek et al., 2016b), was a multi-site block randomised controlled trial with blinded outcome 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 study participants signed a written informed consent when recruited.

2.2. Study setting

The study sites were three large tertiary medical centres in Beirut and Mount Lebanon, Lebanon. All three sites have emergency departments and cardiac units of 9 to 20 beds/site, and are prepared to accommodate patients presenting with signs of heart failure exacerbation. Patients are cared for by cardiologists and experienced cardiology nurses. Moreover, brief patient instructions on the prescribed medications and salt restriction are provided shortly before discharge.

2.3. Study population and eligibility criteria

All patients admitted under the care of a cardiologist, to one of the three study sites between November 2013 and November 2014 were screened, and those who met the inclusion criteria were invited to participate in the FAMILY study. Eligible patients were included if admitted through the emergency department or electively through the admission office to cardiac or medical wards for management. Daily rounds were conducted on patients' charts in the cardiac and medical wards and patients were assessed for eligibility. Patients had to be adults (≥ 18 years) with a confirmed heart failure diagnosis validated by the Framingham Criteria (McKee et al., 1971), and admitted to one of the study sites for treating exacerbating symptoms of heart failure. Framingham criteria were assessed by the researcher and confirmed by the treating physician. Patients living alone or in a nursing home and those in an active dying phase, awaiting cardiac surgery with limited physical functionality, or having a life expectancy of less than the follow-up period as judged by their treating physicians were excluded. Caregivers had to be literate and free of hindering conditions such as blindness or inability to understand verbal commands and engage in a meaningful conversation with the researcher who carried out this assessment before recruiting. Both the patients and their caregivers had to be willing to sign a consent form.

2.4. Randomization procedure

Recruiting participants, obtaining their consent to participate and collecting their baseline data took place before group allocation. One researcher administered the baseline questionnaires and the intervention. Patients meeting the inclusion criteria, and their primary family caregivers, were approached during their index (first) admission and invited to participate in the study. Patients were approached once stabilized and ready to be discharged on the same day or the day after. The study was introduced, consent was obtained, baseline data were collected and patients were randomised to the groups. One researcher, independent from the data collection and interventions procedures, generated one random list for every study site, with blocks of four using the Statistical Product and Service Solutions (SPSS). This researcher was contacted for group allocation when a study participant was recruited and after the baseline data were collected by the first researcher at the study site. These lists were kept in a secure office at the American

University of Beirut and were accessible only to the researcher who generated them. Blinding of the participants to their group allocation was not possible since participants in the intervention group received the educational session whereas those in the control group did not.

2.5. Description of the intervention

The design of the intervention was guided by the Framework for the Study of Self and Family Management (Grey et al., 2006) and the following linked methods were used to define the intervention details: 1) appraisal of theoretical models, 2) review of systematic reviews on educational interventions promoting self-management in chronic conditions, 3) identification of the socio-cultural context from selected papers, 4) expert consultation and 5) model development (Deek et al., 2016c). Details of the intervention and its theoretical underpinning are described elsewhere (Deek et al., 2016c) and briefly summarised here. 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 behaviour prompt. Patients and their caregivers randomised to the intervention group also received one comprehensive family-centred educational session on self-care and symptoms management. Education was provided to the patients and their caregivers on limiting salt intake, restricting fluid intake, using the calibrated bottle, smoking cessation and physical activity. The identified family caregivers were educated on providing and filling the medication boxes, taking their patients' weight daily and managing their condition. The educational sessions were offered by a single research team member to all participants. To promote intervention fidelity at each educational session, this team member had to follow an intervention checklist including the main points to be addressed. Although the sessions were standardised in terms of content and mode of delivery, which was detailed explanation of the self-care activities, these sessions were tailored to the individual patient needs based on their fluid allowance, perceived understanding and the established need for further demonstration of the weighing and recording of weight. The educational sessions took place in the patient's room in the hospital or where he or she found comfortable.

2.6. Data collection of the primary and secondary outcomes

Follow-up data were collected 30 days after patient discharge about the primary outcome. Early readmission is considered as being an indicator of the poor quality of care provided in the in-hospital setting and the 30 day time frame has been studied critically with patients having chronic conditions such as heart failure. This is especially true with patients having no partners and those of Hispanic backgrounds (Damiani et al., 2015). The primary outcome was all-cause readmission and the secondary outcomes were self-care score, quality of life, health care utilization including emergency department presentation, and major vascular events (myocardial infarction, cerebrovascular accident or peripheral vascular event). Due to the inconvenience for patients to return to the hospital for follow-up data collection, given many were older adults and the unsafe conditions in the country at the time of the study, the intervention was provided during hospitalization, whereas the follow up data collection was done using phone calls conducted by a third researcher who was blinded to the study allocation of each participant. Study instruments were administered using interviews with clear phrases in spoken Arabic language. This method was chosen to provide speedier data collection with no missing data and more interaction between the researcher and the participants. The study participants were primarily sought for both the baseline and the follow-up data collection and caregivers were sought when it was difficult to communicate with the patient due to health issues such as shortness of breath.

Participants were asked questions on hospital readmission of more

than 24 hours during the follow-up period, including the hospital location and the length of stay, and major vascular events as in leg or chest pain or headache associated with health consequences. Hospital visits of less than 24 hours were considered under emergency department presentations. Seeking health information from a nearby pharmacy or a friend is usual practice (Kheir et al., 2008), so we were interested to know if this applied to patients having heart failure. To assess health care utilization, participants were asked if they had sought medical advice and if so the source of care (pharmacy, healthcare facility), or visited the emergency department during the follow-up period. To limit over or under estimation of the self-care reporting, we asked about the patient's weight at 30 days and compared it with their weight at discharge. These outcome data were collected using a survey designed for this study.

In addition, other secondary outcome data (self-care and quality of life) were collected at baseline and follow up using the Arabic version of well-established measurement instruments detailed below:

Self-care was evaluated using the Arabic version of the self-care of heart failure index (A-SCHF) that measures self-care through three scores; self-maintenance, self-management and self-confidence (Riegel et al., 2009). The index was translated into Arabic following the translation recommendations (Duffy, 2006). Face, content and construct validity were established along with the reliability evaluation appropriate for multidimensional scales (Barbaranelli et al., 2014). The modified version of the tool was found to be a valid and reliable tool. Modifications were based on the wording of items and application of modification indices with factor analysis. The three subscales (constructs) explained 37% of the variance. More details of the translation and validation of A-SCHF are reported elsewhere (Deek et al., 2016c).

Quality of life data were collected using the Medical Outcome Study Short Form SF-12v2 (4 week recall) which assesses two scales: physical component summary (PCS) and mental component summary (MCS). 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 (Ware et al., 2007). This tool addresses the physical functioning of the patients, role limitations, social and emotional status. The longer version SF-36 had previously been translated and validated in the Lebanese setting (Sabbah et al., 2003) and was shown to be easily administered via the phone (Montazeri et al., 2005). The SF-12 has not been tested on a Lebanese sample; however it had been used with patients having diabetes mellitus in Saudi Arabia. The instrument was first translated and validated by a panel of experts then adjusted and reworded after piloting to be better comprehended and easily administered (Al-Shehri et al., 2008). Based on these findings, we chose the shorter form SF-12 for the measurement of quality of life in the current study.

In addition to the outcome data, the following information was collected from the patients and family caregivers at baseline:

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, discharge medication prescription, cause of heart failure and physical assessment. Clinical data such as the NYHA class and the ejection fraction were assessed when patients were stabilized and able to perform the necessary tests.

c- SHARE (Survey of Health, Ageing and Retirement in Europe) index: This frailty measure is composed of six questions around activity and appetite and a hand grip measure. This measure determines the frailty of the patients based on their age and the expected range of pushing against the dynamometer in each hand. These norms, organized in a table, have been set up based on the findings from previous studies on healthy individuals. The comparisons are made based on

norms such as age, sex, mobility and weight loss (Fried et al., 2001; Bandeen-Roche et al., 2006). The validity of this index was tested in a large sample of over 30,000 individuals aged 50 years and above and was shown to have adequate construct and predictive validity (Romero-Ortuno et al., 2010). In this study, frailty was measured to evaluate its effect on the study outcomes.

2.7. Sample size calculation

Sample size calculation was based on the primary outcome, risk of one or more readmissions within 30 days. Considering that almost 50% of readmission could be prevented with adequate education and discharge planning (Van Walraven et al., 2012), we used this percentage as the estimated difference in readmission between the control and intervention group at follow up to estimate sample size. In a previous retrospective study in Lebanon (Deek et al., 2016d), a 15% readmission rate was documented in one large tertiary centre. Given the risk of under-reporting in retrospective analyses and variations between 13% and 50% in the readmission rates reported by other trial authors (Feltner et al., 2014), we assumed a 30-day readmission incidence of 30% as reference. Therefore, to demonstrate a reduction from 30% to 15% in our trial, the required sample size was calculated to be 130 patients in each group given a 2-tailed significance level of 0.05, a power of 80% and an attrition rate of 10% (Saver et al., 2015). Sample size calculation was done using the G power programme (Statistical Consulting Group, 2017).

2.8. Statistical analysis

Analysis was carried out based on the intention-to-treat principle. Data were analysed using version 22 of the Statistical Product and Service Solutions (SPSS). Normality testing was done using the Kolmogorov-Smirnov (KS) test and the level of statistical significance was determined to be less than 0.05.

Readmission was recorded as a dichotomous variable and analysed against the group allocation using Chi square. Analysis was based on the first readmission within 30 days. The readmission rate was calculated as the number of readmissions divided by the total number of patients that were recruited for the study. Sample descriptive analyses are presented as frequencies, percentages, means and standard deviations. For the bivariate analyses, the intervention and control groups were compared on readmission using the Chi-square test, and unadjusted odds ratio with confidence interval were calculated. The two groups were compared on self-care, quality of life and health care utilization using student's *t*-test (two-tailed) for normally distributed interval and ratio level variables, Chi Square or Mann-Whitney *U* test for categorical variables and continuous variables that were not normally distributed. In addition, since we found significant baseline group differences in caregiver education and previous emergency department (ED) presentations in the past 12 months, we opted to do a post hoc logistic regression analysis for the primary outcome to determine whether the treatment assignment was an independent predictor of readmission after adjusting for the baseline differences between the groups. Similarly, we did multiple linear regression analysis for the secondary outcomes. Multiple logistic and linear regression analyses were done to explore the modifier effect of baseline group differences on the study outcomes. All variables were entered simultaneously to this analysis. Finally, we estimated the event free survival from readmission using the Kaplan-Meier curve with mean and the corresponding 95% confidence intervals determined. The log-rank was done to compare the control and intervention groups with respect to the time till readmission.

3. Results

3.1. Participants

Patient recruitment, randomization and follow-up are presented in the flow chart in Fig. 1. Out of the 260 enrolled patients, 256 patients remained in the study. The remaining four patients, two in each group, were planned for discharge the following day but their condition suddenly deteriorated leading to their death before discharge. Out of the remaining sample (n = 256), we lost contact with 5% (n = 12; 4 in the intervention group and 8 in the control group), and 11% of the whole

sample (n = 28) passed away with more in the control (n = 19) group than in the intervention group (n = 9), so 84% (n = 216) remained in the analysis. There was no significant baseline differences between those who died before discharge and those included in the final analysis. Similarly, no significant difference was found between those who were lost to follow up or those who passed away during the follow up period and those included in the final analysis.

After randomization, 130 patients were allocated to the control group and 126 to the intervention group. Table 1 presents the baseline characteristics of the study sample based on their group allocation. The mean age of the patients was 67 (SD = 8) years and the majority were

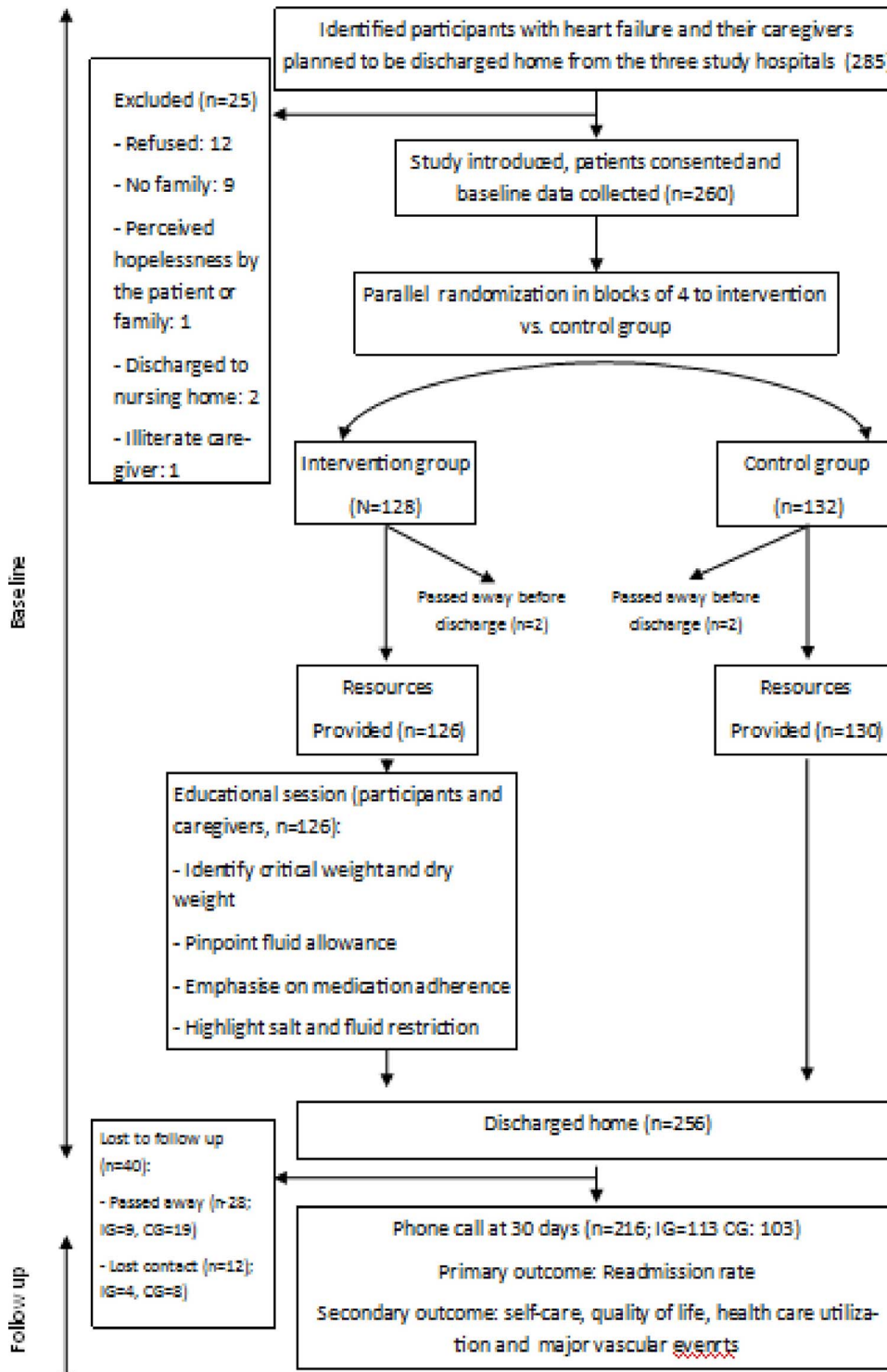


Fig. 1. Patient recruitment, randomization and follow-up flow chart.

LEGEND: IG: intervention group; CG: control group; ED: emergency department; QOL: quality of life; MVE: major vascular events.

Table 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)	0.13
Male	141 (55)	67 (53)	74 (57)	0.61
Married	162 (63)	79 (63)	83 (64)	0.98
Paid employment	45 (18)	26 (21)	19 (15)	0.25
At least high school education	63 (25)	38 (30)	25 (19)	0.29
Primary caregiver				
●Spouse as	111 (43)	55 (44)	56 (43)	0.06 ^b
●Daughter/son as primary caregiver	104 (41)	53 (42)	51 (39)	
●Brother/sister as primary caregiver	12 (5)	5 (4)	7 (6)	
●Other	29 (11)	13 (10)	16 (12)	
Caregiver at least high school education	127 (50)	72 (58)	55 (43)	0.04
Risk factors				
Smoking history	119 (78)	98 (77)	101 (77)	0.87
Body mass index	29 (8)	29 (8)	29 (7)	0.76
Diabetes mellitus	118 (46)	58 (46)	60 (46)	1.00
Hypertension	185 (72)	90 (71)	95 (73)	0.78
Chronic obstructive pulmonary disease	46 (18)	22 (18)	24 (19)	0.87
Chronic renal failure	76 (30)	39 (31)	37 (29)	0.68
Atrial fibrillation	82 (32)	35 (28)	47 (36)	0.18
Coronary artery disease	165 (65)	83 (66)	82 (63)	0.70
Hospitalized in previous 12 months	142 (56)	69 (55)	73 (56)	0.90
Presented to ED in previous 12 month	30 (12)	22 (18)	8 (6)	0.01
Weight [Mean (SD)]	78 (21)	79 (23)	78 (19)	0.75
CHF Profile				
Chronic heart failure	174 (68)	93 (74)	81 (62)	0.06
Ischaemic aetiology	144 (56)	68 (54)	76 (59)	0.53
Ejection fraction ^a [Mean (SD)]	36 (12)	37 (11)	36 (12)	0.25
NYHA Class II or III	243 (95)	117 (93)	126 (97)	0.16
Length of stay [Mean (SD)]	9 (7)	9 (6)	10 (8)	0.41
Clinical Profile				
Systolic blood pressure mm/Hg[Mean (SD)]	123 (19)	124 (19)	124 (19)	0.70
Diastolic blood pressure [Mean (SD)]	68 (12)	70 (12)	71 (13)	0.12
Sodium mEq/L [Mean (SD)]	138 (4)	138 (4)	138 (4)	0.76
Potassium mmol/L [Mean (SD)]	4 (1)	4 (1)	4 (1)	0.71
Creatinine ^a mg/dL [Mean (SD)]	1 [1,2]	1 [1,2]	1 [1,2]	0.70
Blood urea nitrogen values mg/dL [Mean (SD)]	34 (23)	33 (23)	35 (24)	0.46
Haemoglobin g/dL [Mean (SD)]	12 (2)	12 (2)	12 (2)	0.69
Frail ^c	66 (71)	29 (63)	37 (79)	0.25
Medications				
ACE or ARB	173 (68)	85 (68)	88 (68)	1.00
Beta blocker	213 (83)	103 (82)	110 (85)	0.62
Diuretic	209 (82)	97 (77)	112 (86)	0.07
Quality of life measure [Mean (SD)]^d				
Physical component summary	35 (7)	35 (7)	35 (7)	0.97
Mental component summary	47 (12)	46 (12)	48 (12)	0.46
Self-care Measure [Mean (SD)]^e				
Self-care maintenance	35 (15)	35 (15)	35 (14)	0.84
Self-care management	16 (15)	16 (15)	16 (15)	0.10
Self-care confidence	41 (15)	42 (15)	39 (15)	0.09

LEGEND: ED: emergency department; NYHA: New York Heart Association class; ACEI: angiotensin-converting enzyme inhibitor; ARB: Angiotensin receptor blocker.

^a : Non-parametric testing used; continuous variables presented in mean and standard variation. Categorical variables presented in frequencies and percentages.

^b : This p value is indicative of the group difference across all the categories of the primary caregivers.

^c : Frailty was evaluated with the SHARE index which includes 6 questions on appetite, physical activity and weight loss and a hand-grip dynamometer which measures the strength of the grip in both arms. Frailty is determined by the weight of the patient's grip against their age and sex in a predefined table.

^d : A mean score of 50 or above in each scale is considered adequate.

^e : A mean score of 70 or above in each of the subscales is considered adequate.

married, male and with less than high school education. The patients' primary caregivers were mostly the spouse or children. Over two thirds of the patients were diagnosed with chronic heart failure, and for the majority (56%) an ischemic aetiology was confirmed. Among likely risk factors, hypertension was recorded most frequently, affecting more than 70% of the sample. The mean length of hospital stay was 9 (SD = 7) days in this trial sample. The majority of the patients were discharged on angiotensin converting enzyme inhibitor/angiotensin receptor blocker and beta blockers. The majority of patients (71%) were frail.

The only significant baseline differences between the groups were the higher percentage of emergency presentations in the previous 12 months and a higher proportion of high school-educated caregivers in the intervention compared to the control group (18% vs. 6%, $p = 0.01$ and 58% vs. 43%, $p = 0.04$ respectively).

3.2. Implementation of the intervention

All patients allocated to the intervention group with their primary caregivers ($n = 126$) received the educational session. The intervention

was conducted as planned in terms of the content and duration. The mean length of individual educational session was 46 min (range 10–70 min, SD = 11). All participants were provided with the educational session on the day of their hospital discharge when medical clearance was provided and their stability was established. Based on anecdotal evidence, participants expressed gratitude for the attention and the resources they were provided with. Daily weight was a point of discussion especially with caregivers who found the concept of weight change over 24 h to be unusual. Participants allocated to the control group were provided with the self-care resources only without any education.

3.3. Study outcomes at 30 days

The study outcomes were evaluated based on the group differences at 30 days as presented by Table 2.

3.4. Primary outcome

3.4.1. Readmission rates

The overall readmission rate at 30 days was 14%. Out of those readmitted, 20 (19%) were in the control group and 10 (9%) were in the intervention group with a significant difference between the groups (OR = 0.40, 95% CI = 0.18, 0.91, $p = 0.02$). Multiple logistic regression analysis revealed that the intervention was an independent predictor of readmission when controlling for the baseline differences ($df = 1$, Exp (B) = 2.49, CI = 1.09, 5.67; $p = 0.03$). The details of this analysis are presented in Table 3.

Fig. 2 compares the Kaplan-Meier curves of readmission-free survival for the study groups including the 30 readmissions with 10 (9%) versus 20 (19%) in the intervention group and control group respectively, with mean time to readmission 27 days (95% CI = 27, 29 in the control group) and 29 days (95% CI = 28, 29 in the intervention group); Chi-square = 4.80, $df = 1$, $p = 0.02$ (log-rank test).

3.5. Secondary outcomes

3.5.1. Self-care

Baseline scores of the three self-care subscales are presented in Table 1. At follow-up, scores in all three scales had improved in both groups with higher scores in the intervention than in the control group. The between-group differences at follow up were larger for the maintenance and confidence subscales than for the self-care management subscale. The descriptive finding was confirmed by the independent t -test which showed significant between-group differences in favour of the intervention group for the maintenance and confidence sub-scales

Table 2

Findings of the unadjusted bivariate outcome analyses.

Variable	Intervention Group (n = 113)	Control Group (n = 103)	OR	95% confidence interval		p value
	n (%)	n (%)		Lower bound	Upper bound	
Readmission	10 (9)	20 (19)	0.40	0.17	0.91	0.02
- Health Care Utilization ^a	–12 (11)	–24 (23)	0.39	0.18	0.83	0.01
- Specialist consultation	–4 (4)	–6 (6)				
- ED presentation	–7 (6)	–18 (17)				
Major vascular events	0 [0]	3 (3)	0.47	0.40	0.54	0.01
Patients reported weight at follow up	93 (74)	57 (44)	3.61	2.13	6.11	0.00
	Mean (SD)	Mean (SD)	Mean difference			
Self-care Maintenance	67.42 (14.30)	58.50 (18.90)	–8.93	–13.37	–4.49	0.00
Self-care management	51.60 (18.40)	47.11 (23.30)	–4.50	–14.84	5.84	0.39
Self-care confidence	64.20 (20.00)	55.22 (22.23)	–8.95	–14.60	–3.32	0.00
Quality of life- physical component scale	37.21 (4.70)	37.40 (4.70)	0.20	–1.06	1.43	0.77
Quality of life- mental component scale	53.99 (12.60)	54.61 (11.70)	–0.62	–3.87	2.62	0.25

LEGEND: OR: Odds ratio; ED: emergency department; SD: standard deviation.

^a For those utilizing health care services 30 were readmitted; 5 of those seeking a specialist consultation and the 25 patient presenting to the ED were readmitted.

but not for the management sub-scale.

When controlling for caregiver education and emergency department presentation in the last 12 months using multiple linear regression analysis, the difference between the groups at the 30 day follow-up remained significant for self-care maintenance ($F = 5.90$, $df = 3$, $R^2 = 0.63$) and self-care confidence ($F = 3.36$, $df = 3$, $R^2 = 0.03$) but not for self-care management as presented in Tables 4a, 4b and 4c. As noted in the regression coefficients in Tables 4a and 4b, patients in the intervention group had on average a score of 9.08 higher on self-care maintenance and a score of 8.67 higher on self-care confidence compared to the control group at 30-day follow up.

Significantly more patients in the intervention group took their weight at the day of follow-up as compared to patients in the control group ($n = 93$, 74% vs. $n = 57$, 44% respectively, OR = 3.61, 95% CI = 2.13, 6.11, $p = 0.00$). In the intervention group, weight measures reported by the participants at 30-day follow-up were similar to that recorded at baseline, while in the control group the mean weight at follow-up was slightly lower than at baseline.

3.5.2. Quality of life

All baseline and follow-up scores, except for the follow-up mental scale, reflected poor quality of life with scores below 50. Quality of life, at baseline, was shown to be poor in the whole sample as shown in Table 1. After 30 days of their hospital discharge, there was no difference between the intervention group and the control group in both the PCS (37 (SD = 5) vs. 37 (SD = 5), mean difference = 187, 95% CI = –1.06, 1.44, $p = 0.76$) and the MCS (55 (SD = 12) vs. 54 (SD = 13), mean difference = –6.25, 95% CI = –3.87, 2.61, $p = 0.70$) respectively.

3.5.3. Health care utilization

Only 36 patients needed medical advice during the 30 days, including ED presentation and specialist consultation; 30 patients of which were readmitted, 5 were discharged home after management and only 1 was referred to the physicians clinic for further advice, following his ED presentation. None of the study participants reported seeking medical advice from a pharmacy or a friend at follow up. Overall, significantly less patients in the intervention group needed support by health care facilities than in the control group (24 (23%) vs. 12 (11%), OR = 0.39, 95% CI = 0.18, 0.83, $p = 0.01$ respectively).

3.5.4. Major vascular events

There were only three 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.

Table 3
Multiple logistic regression analysis of the intervention effects on readmission.

Variables	B	Standard error	Wald	df	p value	Exp (B)	95% confidence interval for Exp (B)	
							Lower	Upper
Group allocation ^a	-0.91	0.42	4.68	1	0.03	0.40	0.17	0.92
ED presentation ^b	0.04	0.67	0.00	1	0.90	1.12	0.31	4.10
Caregiver education ^c	0.11	0.66	0.03	1	0.86	0.90	0.24	3.30
Constant	-1.54	0.64	5.80	1	0.01	0.21		

LEGEND: df = degree of freedom; ED: emergency department.

- ^a : Control as reference.
- ^b No presentation as reference.
- ^c No education as reference.

4. 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 include a significant reduction in readmission, improvement in self-care maintenance and confidence, fewer major vascular events and health care utilization in the intervention group. The findings suggest the success of the family involvement in self-care of patients with heart failure.

Educational interventions intentionally including family involvement in the care of patients with heart failure are few although such family involvement is explicitly recommended in existing heart failure management guidelines (McMurray et al., 2012). These interventions have shown improved self-care knowledge (Dunbar et al., 2014), confidence and motivation (Stamp et al., 2015) as well as perceived control (Agren et al., 2012). However, we could not find any educational

intervention programme involving the family in self-care in collectivist cultures.

In addition to the specific and intentional involvement of the family, a key aspect of the educational intervention evaluated in the FAMILY trial 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 (Baroni et al., 2015). The findings of the current study demonstrate a 50% reduction of the likelihood of readmission by the educational intervention relative to usual care, underscoring the positive effect of a family-targeted self-care education intervention at the point of hospital discharge.

The clinical progression of heart failure is sometimes ignored or unnoticed. Most patients with heart failure meet the Framingham

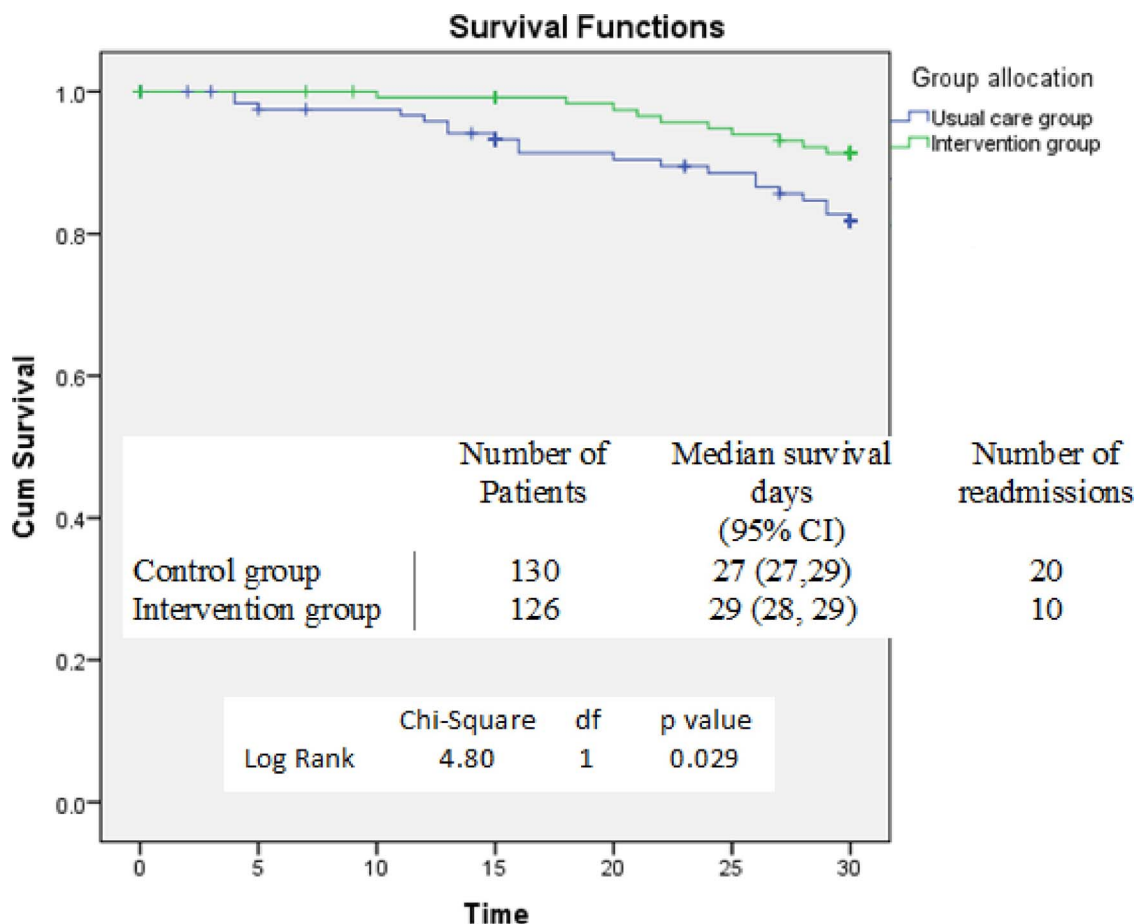


Fig. 2. Kaplan-Meier curves for the time to first readmission.

Table 4a
Multiple linear regression analysis of the intervention effects on self-care maintenance while controlling for baseline differences.

Variables	Unstandardized coefficient	Standard error	Standardized coefficient	t	p value	95% Confidence interval for B	
	B		Beta			Lower bound	Upper bound
Constant	63.08	3.63		17.36	0.00	55.92	70.23
Group allocation*	9.08	2.29	0.26	3.96	0.00	4.56	13.60
Caregiver education	−5.16	3.66	−0.09	−1.40	0.16	−12.39	2.07
ED presentation	−0.43	3.53	−0.00	−0.12	0.90	−7.40	6.53

Table 4b
Multiple linear regression analysis of the intervention effects on self-care confidence while controlling for baseline differences.

Variables	Unstandardized coefficient	Standard error	Standardized coefficient	t	p value	95% Confidence interval for B	
	B		Beta			Lower bound	Upper bound
Constant	54.15	4.62		11.70	0.00	45.03	63.27
Group allocation*	8.67	2.92	0.20	2.96	0.00	2.90	14.41
Caregiver education	1.06	4.67	0.01	0.22	0.82	−8.15	10.26
ED presentation	2.36	4.50	0.03	0.52	0.60	−6.51	11.23

Table 4c
Multiple linear regression analysis of the intervention effects on self-care management while controlling for baseline differences.

Variables	Unstandardized coefficient	Standard error	Standardized coefficient	t	p value	95% Confidence interval for B	
	B		Beta			Lower bound	Upper bound
Constant	34.75	8.10		3.90	0.00	16.83	52.70
Group allocation*	4.70	5.30	0.11	0.90	0.38	−5.90	15.30
Caregiver education	13.77	9.20	0.20	1.50	0.13	−4.52	32.07
ED presentation	−2.90	7.84	−0.04	−0.37	0.71	−18.60	12.75

LEGEND: ED: emergency department; *control as reference; **no presentation as reference; ***no education as reference.

criteria up to two years before presenting for symptoms, causing severe deterioration (V.Havakrishnan et al., 2012). Self-care was shown to be key to improved heart failure 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 (Desai, 2012). In the current study, self-care scores at baseline were low with the lowest being the scores of the management scale. Although a slight improvement was noticed after 30 days, the management scores were still below the acceptable cut-off point of 70 as suggested by the instrument developers (Riegel et al., 2009). This shows the dependability of this patient group on their health care providers and the need for intense education with targeted multi-session interventions.

The weight change in this sample is difficult to interpret considering its small size, the overweightness in both groups at baseline and the short follow up period. As noted, there was less weight change between baseline and follow up in the intervention group as compared to the control group. Although not significant, this change may reflect the better self-care practiced when education was provided to the intervention group by maintaining their discharge weight for the duration of follow up signifying no progression of edema. However, decrease in weight, although minor, could be interpreted as either lower prevalence of edema or increased risk of malnutrition. Significant weight maintenance in the intervention group might be seen with higher intensity interventions and longer periods of close follow-up. Additionally, future interventions of higher intensity may also have the potential to improve the quality of life of patients with heart failure. Thus, revision of the FAMILY intervention programme appears required to increase the intensity and sustainability of effects. Here, existing evidence on preferred components of heart failure care management programs reaching out to the outpatient setting (Wakefield et al., 2013) should be taken into account. For example, while the intervention programme in the current trial was tailored to the needs of the patients and their

caregivers, a reinforcement session may worth to be considered in future studies in order to achieve greater effects on behaviour change, self-care scores and consequently quality of life.

In future trials, 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 i.e. optimised usual care, may have diluted the effect of the intervention and inflated the scores in that group. Self-care resources had to be provided to the control group for ethical considerations. Still 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. In future studies, a complex trade-off between ethical requirements, risk of bias and statistical power needs to be made to identify the most favourable design of the control intervention, i.e. the usual care or optimised usual care.

5. Limitations

Despite using block randomization, the two groups differed in size by four participants; this is attributed to collection of data from three sites, which may have affected the efficiency of the implementation of the block randomization. Moreover, although the researcher collecting the follow-up data was blinded to the group allocation of the participants, participants were aware of their group allocation and this could have produced reporting bias due to social desirability. This could be true with reporting the occurrence of all the outcomes of the study except the self-care measure since social desirability was found to be irresponsible for the answers acquired when answering the SCHFI (Riegel et al., 2009).

Although we had no missing data from those collected by the researcher through phone call interviews, we were only able to follow-up

with 85% of our sample at 30 days. Out of the 15% loss, 10% was due to mortality which is unpredictable with patients having heart failure. Along the disease trajectory, sudden death is expected and the risk gets higher as the NYHA class increases (Jaarsma et al., 2003). This was expected in our study as many of those discharged were classified as either class III or IV per the NYHA classification. However, this should be accounted for when calculating the sample size and doing the analysis as we lost more than we assumed (15% vs. 10%), thus faced with an increased risk attrition bias and weakened statistical power. The statistical precision was also undermined by the readmission rates, which were much lower in the control group than assumed for sample size calculation. Thus, the actual size of the reduction of readmission rates observed in our trial is subject to some uncertainty and needs to be verified in future trials.

Moreover, the patient-reported outcomes, such as self-care and quality of life, may have been under- or over-reported. However, patients were asked about their weight at 30 days which 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.

In terms of the primary outcome, we were interested in the first readmission within the 30 day period, therefore no data on the number of readmissions per patient within this period of time was collected. However, this information should be included in future trials since it points to the severity of the conditions and is a good reflection of the quality of care provided during hospitalization (Hansen et al., 2011). As for the secondary outcomes, QOL evaluation for patients with heart failure could be more accurate with a disease specific QOL questionnaire. The generic QOL assessment tool SF-12v2 was chosen due to the lack of a reliable and valid heart failure specific QOL measure in Lebanon and the limited timeframe of the study. Psychometric evaluation of disease specific tools should proceed future studies evaluating quality of life.

Finally, our study findings have limited generalizability to other cultures since this context is known for its collectivism and strong familial connections; however, this intervention can be used with other collectivist societies in Western and Non-western countries.

6. Conclusion

The family-focused educational intervention evaluated in this trial to promote self-care in heart failure patients was demonstrated to have the potential to successfully reduce the risk of readmissions in this highly vulnerable population. The novel approach of family involvement was found to be appropriate in cultures that value and adhere to familial connections and traditions. This intervention can also be applied in Western and Non-western countries having collectivist societies. Further investigation of this model of intervention is warranted with more intensive, multicomponent interventions and longer periods of follow-up.

Trial registration

Iranian Registry of Clinical Trials IRCT2014101919593N1.

Funding

This work was supported by the Sigma Theta Tau International Honour Society for Nurses.

Conflict of interest

None.

Disclosure

None.

Acknowledgments

The authors would like to thank the funders of the FAMILY trial for their contribution; The Sigma Theta Tau International Honour Society of Nursing. Also we would like to acknowledge the administration of three participating hospitals in this study; RHHU, MLH and MGH. The medical team and the nursing staff at the three sites facilitated the flow of the data collection process and provided great support to the researchers. Special thanks to the cardiology department at Rafic Hariri University Hospital including Mrs Asia Nahhas at the Cardiology Diagnostic Unit for helping identify possible participants.

References

- Agren, S., Evangelista, L.S., Hjelm, C., Stromberg, A., 2012. Dyads affected by chronic heart failure: a randomized study evaluating effects of education and psychosocial support to patients with heart failure and their partners. *J. Card. Fail.* 18 (5), 359–366.
- Al-Shehri, A.H., Taha, A.Z., Bahnassy, A.A., Salah, M., 2008. Health-related quality of life in type 2 diabetic patients. *Ann. Saudi Med.* 28 (5), 352–360.
- Ayyash-Abdo, H., 2001. Individualism and collectivism. The case of Lebanon. *Soc. Beh. Personality: Int. J.* 29 (5), 503–518.
- Bandeem-Roche, K., Xue, Q.-L., Ferrucci, L., Walston, J., Guralnik, J.M., Chaves, P., et al., 2006. Phenotype of frailty: characterization in the women's health and aging studies. *J. Gerontol. Ser. A: Biol. Sci. Med. Sci.* 61 (3), 262–266.
- Barbaranelli, C., Lee, C.S., Vellone, E., Riegel, B., 2014. Dimensionality and reliability of the self-care of heart failure index scales: further evidence from confirmatory factor analysis. *Res. Nurs. Health* 37 (6), 524–537.
- Baroni, L.J., Hughes, B.H., Wahba, G.A., 2015. Effect of Continuous Education on Readmission Rates for CHF Patients. (Available from: http://digitalcommons.cedarville.edu/research_scholarship_symposium/2015/poster_presentations/38/).
- Coster, S., Norman, I., 2009. Cochrane reviews of educational and self-management interventions to guide nursing practice: a review. *Int. J. Nurs. Stud.* 46 (4), 508–528.
- Damiani, G., Salvatori, E., Silvestrini, G., Ivanova, I., Bojovic, L., Iodice, L., et al., 2015. Influence of socioeconomic factors on hospital readmissions for heart failure and acute myocardial infarction in patients 65 years and older: evidence from a systematic review. *Clin. Interv. Aging* 10, 237.
- Davidson, P.M., Newton, P.J., Tankumpuan, T., Paull, G., Dennison-Himmelfarb, C., 2015. Multidisciplinary management of chronic heart failure: principles and future trends. *Clin. Ther.* 37 (10), 2225–2233.
- Deek, H., Newton, P., Inglis, S., Kabbani, S., Noureddine, S., Macdonald, P.S., et al., 2015. Heart health in Lebanon and considerations for addressing the burden of cardiovascular disease. *Collegian* 22 (3), 333–339.
- Deek, H., Noureddine, S., Newton, P.J., Inglis, S.C., MacDonald, P.S., Davidson, P.M., 2016a. A family focused intervention for heart failure self-care: conceptual underpinnings of a culturally appropriate intervention. *J. Adv. Nurs.* 72 (2), 434–450.
- Deek, H., Newton, P.J., Noureddine, S., Inglis, S.C., Al Arab, G., Kabbani, S., Davidson, P.M., 2016b. Protocol for a block randomised controlled trial of an intervention to improve heart failure care. *Nurse Res.* 23 (4), 24–29.
- Deek, H., Noureddine, S., Newton, P.J., Inglis, S.C., MacDonald, P.S., Davidson, P.M., 2016c. A family-focused intervention for heart failure self-care: conceptual underpinnings of a culturally appropriate intervention. *J. Adv. Nurs.* 72 (2), 434–450.
- Deek, H., Skouri, H., Noureddine, S., 2016d. Readmission rates and related factors in heart failure patients: a study in Lebanon. *Collegian* 23 (1), 61–68.
- Desai, A., 2012. Does home monitoring heart failure care improve patient outcomes? Home monitoring heart failure care does not improve patient outcomes looking beyond telephone-based disease management. *Circulation* 125 (6), 828–836.
- Duffy, M.E., 2006. Translating instruments into other languages: basic considerations. *Clin. Nurse Spec.* 20 (5), 225–226.
- Dunbar, S.B., Butts, B., Reilly, C.M., Gary, R.A., Higgins, M.K., Ferranti, E.P., et al., 2014. A pilot test of an integrated self-care intervention for persons with heart failure and concomitant diabetes. *Nurs. Outlook* 62 (2), 97–111.
- Farhood, L.F., 1999. Testing a model of family stress and coping based on war and non-war stressors, family resources and coping among Lebanese families. *Arch. Psychiatr. Nurs.* 13 (4), 192–203.
- Feltner, C., Jones, C.D., Cené, C.W., Zheng, Z.-J., Sueta, C.A., Coker-Schwimmer, E.J., et al., 2014. Transitional care interventions to prevent readmissions for persons with heart failure: a systematic review and meta-analysis. *Ann. Intern. Med.* 160 (11), 774–784.
- Fried, L.P., Tangen, C.M., Walston, J., Newman, A.B., Hirsch, C., Gottdiener, J., et al., 2001. Frailty in older adults: evidence for a phenotype. *J. Gerontol. Ser. A: Biol. Sci. Med. Sci.* 56 (3), M146–M157.
- Gavazzi, A., De Maria, R., Manzoli, L., Bocconcelli, P., Di Leonardo, A., Frigerio, M., et al., 2015. Palliative needs for heart failure or chronic obstructive pulmonary disease: results of a multicenter observational registry. *Int. J. Cardiol.*
- Grey, M., Knaf, K., McCorkle, R., 2006. A framework for the study of self-and family

- management of chronic conditions. *Nurs. Outlook* 54 (5), 278–286.
- Hansen, L.O., Young, R.S., Hinami, K., Leung, A., Williams, M.V., 2011. Interventions to reduce 30-day rehospitalization: a systematic review. *Ann. Intern. Med.* 155 (8), 520–528.
- Jaarsma, T., Strömberg, A., Mårtensson, J., Dracup, K., 2003. Development and testing of the european heart failure self-Care behaviour scale. *Eur. J. Heart Fail.* 5 (3), 363–370.
- Kheir, N., Zaidan, M., Younes, H., El Hajj, M., Wilbur, K., Jewesson, P.J., 2008. Pharmacy education and practice in 13 Middle Eastern countries. *Am. J. Pharm. Educ.* 72 (6).
- Krumholz, H.M., Currie, P.M., Riegel, B., Phillips, C.O., Peterson, E.D., Smith, R., et al., 2006. A taxonomy for disease management a scientific statement from the american heart association disease management taxonomy writing group. *Circulation* 114 (13), 1432–1445.
- McKee, P.A., Castelli, W.P., McNamara, P.M., Kannel, W.B., 1971. The natural history of congestive heart failure: the Framingham study. *N. Engl. J. Med.* 285 (26), 1441.
- McMurray, J.J., Adamopoulos, S., Anker, S.D., Auricchio, A., Böhm, M., Dickstein, K., et al., 2012. ESC guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: the task force for the diagnosis and treatment of acute and chronic heart failure 2012 of the european society of cardiology. developed in collaboration with the heart failure association (HFA) of the ESC *eur heart J* (2012) 33 (14): 1787-1847 first published online may 19, 2012 10.1093/eurheartj/ehs104. *Eur. Heart J.* 1 (34), 9.
- Molloy, G.J., Johnston, D.W., Witham, M.D., 2005. Family caregiving and congestive heart failure: review and analysis. *Eur. J. Heart Fail.* 7 (4), 592–603.
- Montazeri, A., Goshtasebi, A., Vahdaninia, M., Gandek, B., 2005. The short form health survey (SF-36): translation and validation study of the iranian version. *Qual. Life Res.* 14 (3), 875–882.
- Nolte, S., Osborne, R.H., 2013. A systematic review of outcomes of chronic disease self-management interventions. *Qual. Life Res.* 22 (7), 1805–1816.
- Noureddine, S., Dumit, N.Y., Saab, M., 2015. Deciding to seek emergency care for acute myocardial infarction. *Clin. Nurs. Res.* 24 (5), 487–503. <http://dx.doi.org/10.1177/1054773814548508>. Epub 2014 Aug 26.
- Order of Nurses in Lebanon, 2016. Scientific Committee Order of Nurses in Lebanon. ([cited 2016 September 7]. Available from: <http://www.orderofnurses.org.lb/EnMenuLeft/CouncilCommittees/Comittees/ScientificComm/scientificCommittee.html>).
- Penchansky, R., Thomas, J.W., 1981. The concept of access: definition and relationship to consumer satisfaction. *Med. Care* 19 (2), 127–140.
- Pimouguet, C., Le Goff, M., Thiébaud, R., Dartigues, J.F., Helmer, C., 2011. Effectiveness of disease-management programs for improving diabetes care: a meta-analysis. *Can. Med. Assoc. J.* 183 (2), E115–E127.
- Riegel, B., Dickson, V.V., 2015. The situation-Specific theory of heart failure self-Care. *J. Cardiovasc. Nurs.*
- Riegel, B., Lee, C.S., Dickson, V.V., Carlson, B., 2009. An update on the self-care of heart failure index. *J. Cardiovasc. Nurs.* 24 (6), 485.
- Romero-Ortuno, R., Walsh, C., Lawlor, B., Kenny, R., 2010. A frailty instrument for primary care: findings from the Survey of Health, Ageing and Retirement in Europe (SHARE). *BMC Geriatr.* 10 (1), 57.
- Sabbah, I., Drouby, N., Sabbah, S., Retel-Rude, N., Mercier, M., 2003. Quality of life in rural and urban populations in Lebanon using SF-36 health survey. *Health Qual. Life Outcomes* 1 (1), 30.
- Saver, J.L., Goyal, M., Bonafe, A., Diener, H.C., Levy, E.I., Pereira, V.M., et al., 2015. Solitaire™ with the Intention for Thrombectomy as Primary Endovascular Treatment for Acute Ischemic Stroke (SWIFT PRIME) trial: protocol for a randomized, controlled, multicenter study comparing the Solitaire revascularization device with IV tPA with IV tPA alone in acute ischemic stroke. *Int. J. Stroke* 10 (3), 439–448.
- Stamp, K.D., Dunbar, S.B., Clark, P.C., Reilly, C.M., Gary, R.A., Higgins, M., et al., 2015. Family partner intervention influences self-care confidence and treatment self-regulation in patients with heart failure. *Eur. J. Cardiovasc. Nurs.* (1474515115572047).
- Statistical Consulting Group, 2017. Introduction to SAS UCLA: Statistical Consulting Group. ([cited 2017 March 30]. Available from: <http://stats.idre.ucla.edu/sas/modules/sas-learning-moduleintroduction-to-the-features-of-sas/>).
- Tatari, S., Soubra, L., Tamim, H., Akhras, K., Kabbani, S., 2015. The economic impact of patients with heart failure on the Lebanese healthcare system. *ESC Heart Fail.* 2 (3), 178–183.
- V.Havakrishnan, R., Steinhubl, S.R., Sun, J., Byrd, R.J., Daar, Z., Thompson, J., et al., 2012. Potential impact of predictive models for early detection of heart failure on the initiation of evidence-based therapies. *J. Am. Coll. Cardiol.* 59 (13s1), E949–E.
- Van Walraven, C., Jennings, A., Forster, A.J., 2012. A meta-analysis of hospital 30-day avoidable readmission rates. *J. Eval. Clin. Pract.* 18 (6), 1211–1218.
- Wakefield, B.J., Boren, S.A., Groves, P.S., Conn, V.S., 2013. Heart failure care management programs: a review of study interventions and meta-analysis of outcomes. *J. Cardiovasc. Nurs.* 28 (1), 8–19.
- Ware, J., Kosinski, M., Turner-Bowker, D.M., Gandek, B., 2007. User's Manual for the SF-12v2 Health Survey. QualityMetric Incorporated, Lincoln, RI.
- World Health Organization, 2009. Self-care in the Context of Primary Health Care. World Health Organization Regional Consultation, Bangkok, Thailand.
- World Health Ranking, 2013. World Life Expectancy. ([cited 2013 March 27]. Available from: <http://www.worldlifeexpectancy.com/lebanon-coronary-heart-disease>).
- Yancy, C.W., Jessup, M., Bozkurt, B., Butler, J., Casey, D.E., Drazner, M., et al., 2013. 2013 ACCF/AHA guideline for the management of heart failure: a report of the american college of cardiology Foundation/American heart association task force on practice guidelines. *Circulation* 128, 1–211.