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

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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.

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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 unpredictable 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 (Nolte 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 than 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 Qualiti’ 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.

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.
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