Faculty of Health

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

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2. Certificate of Original Authorship

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

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7 List of Abbreviations

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

8 Glossary of Terms

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

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

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

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

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

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

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

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

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

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

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

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

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

9 Abstract

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

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

Methods and design:

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

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

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

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

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

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

Results:

Phase 1: A total of 28 peer-reviewed articles and 15 reports were identified in this search. Cardiovascular diseases were found to be the leading causes of morbidity and mortality in Lebanon. A range of social, political, economic and cultural factors explain the burden of these diseases including

the unique traits of the Lebanese culture such as the narghile smoking and the high rates of familial hypercholesterolemia (*Collegian*, doi:10.1016/j.colegn.2014.04.004).

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

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

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

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

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