Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention

Protocol summary

Summary

Background: Chronic heart failure is a chronic and complex condition. Achieving optimal health outcomes requires adherence to a range of evidence-based strategies. This requires life-style changes and incorporation of self-management strategies. To date, many theoretical models of self-care have focused on the individual and have not addressed the unique socio-cultural factors impacting on health seeking behaviours. Aim: The program of research for this PhD study seeks to derive a theoretically derived, culturally appropriate intervention to improve heart failure outcomes in Lebanon. Method: This study involves a block randomised control trial where 260 patients will be recruited from three tertiary medical centres in Lebanon. Inclusion criteria are adult patients admitted for heart failure exacerbation to one of the study hospitals. Outcomes to be measured are: all causes readmission, heart failure related readmission, self-care ability, quality of life, emergency presentation, major acute vascular events, and health care utilization. Potential outcomes: As in most of the world, chronic heart failure is a major health issue. A range of social, political and economic factors have meant that there has been a limited focus on implementing disease management interventions in Lebanon. This study seeks to implement a culturally appropriate intervention to facilitate transitional care for heart failure and support self-care strategies using a family-focussed approach. The efficacy of the intervention will be assessed on the basis of all cause rehospitalisation, heart failure readmissions, self-care ability, quality of life, emergency presentation, major acute vascular events, and health care utilization at 30 days.

General information

Acronym

FAMILY

IRCT registration information

IRCT registration number: **IRCT2014101919593N1**
Registration date: **2014-10-25, 1393/08/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-10-25, 1393/08/03

Registrant information

Name

Hiba Deek

Name of organization / entity

University of Technology Sydney

Country

Australia

Phone

+61402315084

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hiba.a.deek@student.uts.edu.au

Recruitment status

Recruitment complete

Funding source

None

Expected recruitment start date

2013-10-31, 1392/08/09

Expected recruitment end date

2014-08-31, 1393/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention

Public title
Family focused Approach to iMprove Heart Failure care In Lebanon QualitY (FAMILY) Intervention
Purpose
Supportive
Inclusion/Exclusion criteria
Selection Criteria Inclusion criteria: All those admitted to the site hospital for acute decompensated HF regardless of the aetiology, aged >18 years and willing to participate will be included in this study. The family member nominated by the patient should be willing to care for the patient and participate in the study. Patients with illiteracy will be included if their family caregiver is literate and can reach a proper decision in favour of their patient. Patients will be asked to finger print the consent form after a thorough explanation is provided about the intervention and adequate support is provided by the caregiver. Exclusion criteria Patients having limited life expectancy of less than 30 days, severe cognitive impairment limiting their judgement and activity, pending cardiac bypass or valve replacement surgery with limited functionality, living alone or in nursing home, and aged less than 18 years will be excluded. Also conditions that hinder the progress of the intervention such as impaired cognition or blindness of the caregiver exclude the possible participants.
Age
From **18 years** old to **139 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **260**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
WHO
Secondary trial Id
UTN: U1111-1163-1944
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
University of Technology HREC
Street address
University of Technology, Sydney, Broadway, Johns strees
City
Sydney
Postal code
2007
Approval date
2013-09-10, 1392/06/19
Ethics committee reference number
2013000485

Health conditions studied

1

Description of health condition studied
Heart Failure
ICD-10 code
I50.0
ICD-10 code description
Congestive heart failure

Primary outcomes

1

Description
readmission rates
Timepoint
30 days
Method of measurement
phone calls

Secondary outcomes

1

Description
self-care, QOL, ED presentations, health care utilization and major vascular events
Timepoint
30 days
Method of measurement
phone calls

Intervention groups

1

Description
Both groups will be approached at baseline. The study will be introduced and the participants along with their family caregivers will be consented to participate.

Baseline data collection will be done to included: socio-demographic data, social and medical history, physical assessment, laboratory values, discharge medication and frailty scale. Also the translated version of the quality of life questionnaire and that of the self-care of heart failure index will be collected. Patients will then randomized into the control group and the intervention group based on a unique allocated code to each participant. The second encounter will define the difference between the control and the intervention group. During this encounter both groups will be provided with a scale, a calibrated bottle, a medication box and a diary. This encounter will differ between the two groups in the following manner: a- The control group, when approached, will be provided with a packed bag of the aforementioned items. No verbal explanation will be provided to the group rather they will be provided with a paper containing the instructions of how to use those items.

Category

N/A

2

Description

Both groups will be approached at baseline. The study will be introduced and the participants along with their family caregivers will be consented to participate. Baseline data collection will be done to included: socio-demographic data, social and medical history, physical assessment, laboratory values, discharge medication and frailty scale. Also the translated version of the quality of life questionnaire and that of the self-care of heart failure index will be collected. Patients will then randomized into the control group and the intervention group based on a unique allocated code to each participant. The second encounter will define the difference between the control and the intervention group. During this encounter both groups will be provided with a scale, a calibrated bottle, a medication box and a diary. This encounter will differ between the two groups in the following manner: b- The intervention group: a family conference will take place with the patient and their family carer extending for 60-90 min depending on necessity. This conference will be tailored to their condition, unique symptoms (if present) and subjective demands. The educational session will be structured to include information about heart failure causes, symptoms and management. The latter will comprise a big portion of the educational session focusing on self-management and roles of the family caregiver. Education will include points about salt and fluid restriction, physical activity, symptom recognition, smoking cessation, and adherence to prescribed medication in addition to the aforementioned culture specific practices. Items in the bag will be explained separately emphasising the need to have the medication box filled, with the daily pills according to the prescribed dosages, by the family carer, monitor fluid intake as recommended by their cardiologist with the help of the calibrated bottle used to store the daily fluid allowance, weigh daily after waking up in the morning with light clothes, and documenting the weight in the provided diary. In consultation with their treating cardiologist, a flexible diuretic plan will be implemented. Participants will be instructed to take an extra pill of their diuretic if their weight increases by 1kg over 24 hours or 2kg over 5 days. They will also be advised to contact their cardiologist if weight continues to increase despite the proposed plan. Both groups will be provided with contact details of their cardiologist and the specialist nurse to refer to in case of an emergency.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rafic Hariri University Hospital/ Makassed General Hospital/ Mount Lebanon Hospital

Full name of responsible person

Dr Samer Kabbani (RHUH), Dr Nadim Timany (MGH), Dr Wael Chalak (MLH)

Street address

Jnah/ Beirut/ Mount Lebanon

City

Beirut

2

Recruitment center

Name of recruitment center

Added at 2016-09-07: Mount Lebanon Hospital

Full name of responsible person

Added at 2016-09-07: Dr Marie Merheb

Street address

Added at 2016-09-07: P.O.Box: 470

City

Added at 2016-09-07: Hazmieh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

No sponsor

Full name of responsible person

No sponsor

Street address

No Sponsor

City

No Sponsor

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

No sponsor

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
University of Technology Sydney
Full name of responsible person
Hiba Deek
Position
PhD candidate
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty