

# Impact of multi-disciplinary treatment strategy on systolic heart failure outcome

<b>Submission date</b> 24/09/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/09/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/06/2020	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Patients with reduced ejection fraction have high rates of mortality and readmission after hospitalization for heart failure. In Taiwan, heart failure disease management programs (HFDMPs) have proven effective for reducing readmissions for decompensated heart failure or other cardiovascular causes by up to 30%. However, the benefits of HFDMP in different populations of heart failure patients is unknown.

### Who can participate?

Patients admitted for systolic heart failure with reduced EF radiographic evidence of pulmonary congestion or typical symptoms and signs of HF, aged over 18, and NYHA functional class II-IV

### What does the study involve?

This study compares mortality and readmission in heart failure patients who participated in heart failure disease management programs (HFDMP group) and heart failure patients who received standard care (non-HFDMP group) over a 1-year follow-up period after discharge. The HFDMPs include a patient education program delivered by the lead nurse of the HFDMP; a cardiac rehabilitation program provided by a physical therapist; consultation with a dietician, and consultation and assessment by a psychologist. The patients are followed up for at least 1 year after discharge or until death. Patient characteristics and clinical demographic data are compared between the two groups.

### What are the possible benefits and risks of participating?

Possible benefits include improved survival, reduced readmission, improved life quality and exercise capacity. There are no risks of participating.

### Where is the study run from?

Kaohsiung Chang Gung Memorial Hospital (Taiwan)

### When is the study starting and how long is it expected to run for?

January 2013 to December 2016

Who is funding the study?  
Chang Gung Medical Foundation (Taiwan)

Who is the main contact?  
Dr Shyh-Ming Chen  
syming99@cgmh.org.tw

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Shyh Ming Chen

**Contact details**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
Nil known

## Study information

**Scientific Title**  
Impact of multi-disciplinary treatment strategy on systolic heart failure outcome

**Study objectives**  
The multi-discipline disease management program is beneficial for heart failure patients.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Approved 02/09/2015, Chang Gung Medical Foundation Institutional Review Board (199, Tung Hwa North Rd. Taipei, Taiwan, ROC 10507; Tel: +886 (0)3 3196200; Email: violet1202@cgmh.org.tw), IRB no.: 104-5591B

**Study design**

Longitudinal case-control study

**Primary study design**

Observational

**Secondary study design**

Case-control study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Heart failure with reduced ejection fraction

**Interventions**

This observational cohort study compared mortality and readmission in heart failure patients who participated in a heart failure disease management programs (HFDMP group) and heart failure patients who received standard care (non-HFDMP group) over a 1-year follow-up period after discharge (December 2014 retrospectively registered). The components of the intervention program included a patient education program delivered by the lead nurse of the HFDMP; a cardiac rehabilitation program provided by a physical therapist; consultation with a dietician, and consultation and assessment by a psychologist. The patients were followed up for at least 1 year after discharge or until death. Patient characteristics and clinical demographic data were compared between the two groups. Cox proportional hazards regression analysis was performed to calculate hazard ratios (HRs) for death or recurrent events of hospitalization in the HFDMP group in comparison with the non-HFDMP group while controlling for covariates.

**Intervention Type**

Other

**Primary outcome measure**

Recurrent events of hospitalization assessed using medical records and telephone contact at one year

**Secondary outcome measures**

Total mortality assessed using medical records and telephone contact at one year

**Overall study start date**

01/01/2013

**Completion date**

31/12/2016

## Eligibility

**Key inclusion criteria**

1. HF patients admitted to hospital with reduced EF (EF<40%)
2. Radiographic evidence of pulmonary congestion or typical symptoms and signs of HF
3. Age > 18 years
4. NYHA functional class II-IV

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

159

**Key exclusion criteria**

1. Severe respiratory failure under ventilator support
2. Dementia
3. Expectation of short survival
4. Discharge to a geriatric clinic or home care
5. Current follow-up treatment at the nurse-led HF clinic

**Date of first enrolment**

01/07/2013

**Date of final enrolment**

31/12/2014

## Locations

**Countries of recruitment**

Taiwan

**Study participating centre**

**Kaohsiung Chang Gung Memorial Hospital**

123 Ta Pei Rd., Niao Sung Dist.

Kaohsiung City

Taiwan  
83301

## Sponsor information

### Organisation

Chang Gung Medical Foundation

### Sponsor details

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syming99@cgmh.org.tw

### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/02verss31>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Chang Gung Medical Foundation

### Alternative Name(s)

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

Taiwan

## Results and Publications

## Publication and dissemination plan

Planned publication in BMC Cardiovascular Disorders

## Intention to publish date

01/10/2019

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Shyh-Ming Chen ( syming99@gmail.com) and Yu-Tung Huang (anton.huang@gmail.com).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	15/10/2019	09/06/2020	Yes	No