# Heidelbergian Integrated Case Management for Chronic Heart Failure in general practice

Submission date

Recruitment status

No longer recruiting

Registration date

Overall study status

28/11/2006 Completed

**Last Edited** 11/06/2010

23/11/2006

Condition category

Circulatory System

[X] Prospectively registered

[X] Protocol

[ ] Statistical analysis plan

[X] Results

Individual participant data

### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

### Type(s)

Scientific

### Contact name

Prof Wolfgang Herzog

#### Contact details

Im Neuenheimer Feld 410 Heidelberg Germany 69120

## Additional identifiers

Protocol serial number 01GI0205/21

# Study information

Scientific Title

### Acronym

HICMan-CHF

Study objectives

A randomised controlled trial will be performed to prove the effectiveness of Heidelbergian Integrated Case Management (HICMan).

The case management intervention group shows a significantly better outcome with respect to Quality of life (Qol) compared to the control group, at the one year follow-up (t0 to t1).

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethical consent was approved by the local committee of the University of Heidelberg on the 11th October 2006 (ref: 303/2006) and the committee of the State Chamber of Phycicians of Baden-Württemberg on the 31st October 2006 (ref: B-244-06-f).

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Chronic Heart Failure

#### **Interventions**

Introduction:

After enrolment the Case Manager (CM) will need approximately 30 minutes for an introduction of her function and to establish a relationship. Patients will get information about their diseases, realisation of symptoms and self-monitoring.

## Monitoring by telephone:

The CM carries out a telephone monitoring:

- 1. Low to medium risk (NYHA I/II) every six weeks, three personal home visits during the year substituting for the telephone monitoring.
- 2. High risk (NYHA III/IV) every three weeks, three personal home visits during the year substituting for the telephone monitoring.

#### Home visits:

Each home visit (three over the year) will evaluate the following in a structured, but varied way:

- 1. Physical, cardiac status
- 2. Self-management
- 3. Compliance/adherence
- 4. Depression and anxiety screening
- 5. Small geriatric assessment
- 6. Medication management

#### Patient education:

- 1. Physical activity
- 2. Smoking
- 3. Self management

### Recall-Reminder-Systems:

If necessary, active surveillance concerning prescription and doctor follow-up will be applied.

Participating doctors will get feedback about their guideline adherence for patients receiving the intervention (data from t0).

### Intervention Type

Other

### **Phase**

**Not Specified** 

### Primary outcome(s)

- 1. Health related quality of life (Short Form health survey (SF-36), scale physical function.
- 2. Change of Qol measured from t0 to t1).

### Key secondary outcome(s))

- 1. Other dimensions of Qol (SF-36)
- 2. The disease specific Qol (Kansas City Cardiomyopathy Questionnaire [KCCQ])
- 3. Patient perceived quality of care (Patient Assessment of Chronic Illness Care [PACIC])
- 4. Readmission to hospital or death due to heart failure (combined)
- 5. Improvement of heart failure according to N-Terminal prohormone Brain Natriuretic Peptide (NT-proBNP)
- 6. Cost-effectiveness

### Completion date

31/01/2008

# **Eligibility**

### Key inclusion criteria

- 1. Dyspnea New York Heart Association (NYHA) grade I, if hospitalisation due to heart failure within the previous 24 months, or Dyspnea NYHA grade II to IV
- 2. Objective Congestive Heart Failure (CHF) (left- or bi-ventriucular) ejection fraction of 45% or less (affirmation with echocardiography, no older then 24 months)
- 3. Age more than or equal to 40 years
- 4. Stability of the disease at the point of time of inclusion

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

#### Other

#### Sex

**Not Specified** 

### Key exclusion criteria

- 1. Primary valvular heart disease with relevant hemodynamic effects
- 2. Hypertrophic Obstructive CardioMyopathy/Restrictive CardioMyopathy (HOCM/RCM)
- 3. Organ transplantation
- 4. Acute left ventricular failure
- 5. Short life expectancy due to a serious concomitant illness
- 6. Impaired mental state that prevents accurate answers to questions
- 7. Addictive disorders with continuing drug abuse despite social, legal or professional conflicts

### Date of first enrolment

01/12/2006

### Date of final enrolment

31/01/2008

# Locations

### Countries of recruitment

Germany

### Study participating centre Im Neuenheimer Feld 410

Heidelberg Germany 69120

# Sponsor information

### Organisation

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany)

### **ROR**

https://ror.org/04pz7b180

# Funder(s)

# Funder type

### Funder Name

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (ref: 01GI0205/21) (Germany)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/05/2010		Yes	No
Protocol article	protocol	23/08/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes