

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

<b>Submission date</b> 23/11/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/11/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/06/2010	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

**Study website**  
<http://www.klinikum.uni-heidelberg.de/HICMAN-gestartet-7-2006.102718.0.html>

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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 Physicians of Baden-Württemberg on the 31st October 2006 (ref: B-244-06-f).

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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

#### **Secondary outcome measures**

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

#### **Overall study start date**

01/12/2006

#### **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-ventricular) ejection fraction of 45% or less (affirmation with echocardiography, no older than 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

## Age group

Other

## Sex

Not Specified

## Target number of participants

200

## 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)

## Sponsor details

Hannoversche Strasse 28-30  
Berlin  
Germany  
10115

## Sponsor type

Not defined

## Website

<http://www.bmbf.de/en/index.php>

## ROR

<https://ror.org/04pz7b180>

# Funder(s)

## Funder type

Government

## Funder Name

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

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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?
<a href="#">Protocol article</a>	protocol	23/08/2007		Yes	No
<a href="#">Results article</a>	results	17/05/2010		Yes	No