

Heidelbergian Integrated Case Management for Chronic Heart Failure in general practice

Submission date 23/11/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 28/11/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/06/2010	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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

Primary study design

Interventional

Study design

Randomised controlled trial

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-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

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

Government

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