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Heidelbergian Integrated Case Management for Chronic Heart Failure in general practice

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

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 Phycicians 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-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

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?
Protocol article	protocol	23/08/2007		Yes	No
Results article	results	17/05/2010		Yes	No