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A case management intervention for older patients with myocardial infarction

Submission date 10/02/2009	**Recruitment status** No longer recruiting	✓ Retrospectively registered ✓ Protocol added ? SAP not yet added ✓ Results added ? Raw data not yet added ✓ Study completed
Registration date 27/03/2009	**Overall study status** Completed	
Last Edited 19/06/2018	**Condition category** Circulatory System	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
BMBF ref: 01ET0713

Study information

Scientific Title
A case management intervention for older patients with myocardial infarction: a randomised parallel-group single-centre trial

Acronym
KORINNA

Study hypothesis
The primary objective is to assess whether a case management intervention by trained nurses can reduce readmission in older patients with myocardial infarction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Bavarian Chamber of Physicians, 28/07/2008, ref: 08064

Study design
Randomised parallel-group single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Condition
Coronary heart disease (CHD), myocardial infarction (MI)

Interventions
Experimental intervention: Case management by trained nurse on the basis of telephone contacts and home visits

The study intervention will consist of an initial information session as well as physical examination (approximate duration 2 hours) which will take place one or two days before hospital discharge. In this session, carried out by the study physician together with the study

nurse, the specific problems of the patient will be identified and documented. In addition, the patient will be provided with information material about the disease (and comorbidities), about medication and with behavioural recommendations (nutrition, physical activity, smoking etc.).

Furthermore, an individual plan for each patient will be set up. The activities will be planned in agreement with the patient, as this will improve compliance. A first home visit will be arranged (within one to two weeks after discharge or after completion of the rehabilitation), if accepted by the patient, otherwise an appointment for a telephone call will be made. If possible, close relatives of the patient will also be informed in detail and may participate in the discharge session.

The GP of the patient will be informed about the study participation at discharge. The medication at discharge will not be influenced by the intervention. In case of problems with medication, the study nurse will contact the GP of the patient after the first contact with the patient.

Telephone calls (at least every 3 months) and home visits (1 to 4) will be carried out according to patient need. The patients will primarily be responsible themselves to carry out the planned activities, and the study nurse will only support the patients. If the patient needs further assistance or advices, the study nurses will be achievable for the patient in the daytime by telephone on weekdays.

The most important elements of the home visits will be: to detect problems or risks, to give advice and to refer to the general practitioner, if necessary. Risk assessment will be done according to four prespecified risk categories. The higher the group level the more contacts (telephone and home visits) will be arranged by the study nurse. The risk level will be determined by the compliance, the social network, and the comorbidity. The duration of the visit should be between 60 and 90 minutes. At the first home visit patients will be instructed how the prescribed drugs have to be taken and what would happen in the case of non-compliance with medication. Furthermore, to patients with diabetes advice will be given regarding nutrition and physical activity, and to patients with congestive heart failure (CHF) information to encourage regular weight control. During the visits, measurements of blood glucose, blood pressure, and weight will be performed.

Control intervention: Usual care. Patients can use or apply for all available services in the area. In both groups, patients may be subscribed to a disease management program (DMP) if their general practitioner participates in a DMP of their statutory health insurance company. In addition, they may use out-patient nursing services during the follow-up period. However, patients who already receive out-patient nursing services at time of recruitment will be excluded from the study.

Duration of intervention and follow-up per patient: One year

Patients will receive a baseline assessment and will be contacted by phone after 3, 6, and 9 months. Final investigation: after one year

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Time from randomisation to first (unplanned) hospital readmission

Secondary outcome measures
1. Activities of daily living: Barthel Index and Health Assessment Questionnaire Disability Index (HAQ-DI) (baseline and 1-year follow-up)
2. Instrumental activities of daily living (IADL) scale developed by Lawton/Brody (baseline and 1-year follow-up)
3. Mobility: Timed up and go (baseline and 1-year follow-up)
4. Hand grip strength measurement (baseline and 1-year follow-up)
5. Cognition: Mini Mental State Test (baseline and 1-year follow-up)
6. Nutrition: Seniors in the Community: Risk evaluation for eating and nutrition, Version II (SCREEN II) (baseline and 1-year follow-up)
7. Quality of life: EQ-5D (baseline and 3-/6-/9-/12-months follow-up) and World Health Organization (WHO) Five Well-being Index (baseline and 1-year follow-up)
8. Social network: Social Support Questionnaire (Fragebogen zur Sozialen Unterstützung [F-SozU]) (baseline and 1-year follow-up)
9. Depression: Geriatric depression Scale (baseline and 1-year follow-up)
10. Items on vision, hearing, chewing and swallowing from Geriatric Assessment (Lachs) (baseline and 1-year follow-up)
11. Baseline questionnaire including items on multimorbidity and physical examination (baseline and 1-year follow-up)
12. Health care utilisation (baseline and 3-/6-/9-/12-months follow-up)

Overall study start date
01/09/2008

Overall study end date
31/12/2010

Eligibility

Participant inclusion criteria
All patients of the age group 70 years and older with a first or recurrent myocardial infarction during the recruitment period (September 2008 to December 2009) who are treated in the Augsburg Hospital.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
304

Participant exclusion criteria

1. Patients who already live in institutionalised care or who are already receiving regular support by ambulatory care services. In addition, patients who already plan to move into institutional care or outside the study region within the next months.
2. Patients with severe comorbidity (e.g., terminal cancer) which makes rehospitalisation within the next months necessary or is associated with a life expectancy of less than one year
3. Patients who are not able to communicate in German language
4. Patients who are unable or unwilling to give written informed consent (e.g., patients with dementia)

All consecutive patients screened for eligibility will be documented in a patient log with anonymous data on age, gender, comorbidity, and reasons for ineligibility.

Recruitment start date
01/09/2008

Recruitment end date
31/12/2009

Locations

Countries of recruitment
Germany

Study participating centre
Augsburg Hospital
Augsburg
Germany
86156

Sponsor information

Organisation
Federal Ministry of Education and Research (BMBF) (Germany)

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Sponsor type
Government

Website
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ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Federal Ministry of Education and Research (BMBF) (Germany)

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
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	27/05/2010		Yes	No
Results article	results	29/10/2013		Yes	No
Results article	results	19/03/2014		Yes	No
Results article	results	26/03/2015		Yes	No

Results article	results	01/04/2015	Yes	No
Results article	results	01/06/2016	Yes	No
Results article	results	07/06/2018	Yes	No