

Primary care practice based care management for chronically ill patients

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|--|---|---|
| Submission date 20/10/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 24/11/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 04/02/2016 | Condition category Other | <input type="checkbox"/> 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
190/09

Study information

Scientific Title
Primary care practice based care management for chronically ill patients: An open multicentre cluster randomised controlled trial

Acronym

Study objectives

Primary care practice based care management reduces the number of all-cause hospitalisations in a population of chronically ill patients at high risk for future hospitalisation. The intervention will improve patients' quality of life, self-management and clinical status.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. The Ethical Committee of the University Hospital Heidelberg, 30/07/2010, ref: S-232/2010
2. The Ethical Committee of the Federal Medical Association Baden-Wuerttemberg, 31/08/2010, ref: B-F-2010-043

Study design

Open multicentre cluster randomised controlled clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic disease management; Type 2 diabetes mellitus; Chronic obstructive pulmonary disease; Chronic heart failure and comorbid conditions

Interventions

Care management delivered by teams of primary care physicians and trained health care assistants compared to usual care. Care management consists of comprehensive assessment of medical and non-medical needs, individualised care planning and goal setting, self-management support and care coordination and regular telephone monitoring of symptoms and self-management. The intervention period is 12 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Number of all-cause hospitalisations within 12 months of intervention/control

Key secondary outcome(s)

1. Health related quality of life (SF-12, EQ5D)
2. Medication adherence
3. Self-management
4. Patient reported delivery of chronic care elements (PACIC)
5. Health care costs
6. Contacts with specialists/generalists and supportive services

7. Mortality
8. Clinical status
9. Depression
All outcomes will be assessed at 12 and 24 months.

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Adults (18 years+) with any of the following index conditions and a high predicted likelihood of hospitalisation based on insurance claims data analysis:
 - 1.1. Type 2 diabetes
 - 1.2. Chronic obstructive pulmonary disease
 - 1.3. Chronic heart failure
2. Beneficiaries of a GP-centred care contract of the General Regional Health Fund (AOK)
3. Listed in one of the participating practices

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Active cancer disease (under ongoing radio- or chemotherapy)
2. Undergoing dialysis
3. Moderate to severe dementia
4. Concurrent participation in other clinical trials
5. Living in nursing homes
6. Physical, mental or other conditions that hinder active participation in the trial

Date of first enrolment

01/10/2010

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

Germany

Study participating centre

University Hospital Heidelberg

Heidelberg

Germany

69115

Sponsor information

Organisation

University Hospital Heidelberg (Germany)

ROR

<https://ror.org/013czdx64>

Funder(s)

Funder type

Government

Funder Name

General Local Health Insurance (Allgemeine Ortskrankenkasse [AOK]) Baden-Wuerttemberg (Germany)

Funder Name

General Local Health Insurance (Allgemeine Ortskrankenkasse [AOK]) Bundesverband (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 | 01/03/2016 | | Yes | No |
| Protocol article | protocol | 29/06/2011 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |