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Primary care practice based care management for chronically ill patients

Submission date	Recruitment status	[_] Prospectively registered
20/10/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/11/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/02/2016	Other	

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

PraCMan

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 Commitee 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

Primary study design
Interventional

Study design
Open multicentre cluster randomised controlled clinical trial

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 participaton 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
Study website	Study website	11/11/2025	11/11/2025	No	Yes