

Primary care practice based care management for chronically ill patients

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

Study website
<http://www.pracman.org>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 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

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

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

Secondary outcome measures

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.

Overall study start date

01/10/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

2700

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)

Sponsor details

Im Neuenheimer Feld 672

Heidelberg

Germany

69120

Sponsor type

Hospital/treatment centre

Website

<http://www.klinikum.uni-heidelberg.de/>

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

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	29/06/2011		Yes	No
Results article	results	01/03/2016		Yes	No