

# Primary care practice based care management for chronically ill patients

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

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

### **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

| <b>Output type</b>               | <b>Details</b> | <b>Date created</b> | <b>Date added</b> | <b>Peer reviewed?</b> | <b>Patient-facing?</b> |
|----------------------------------|----------------|---------------------|-------------------|-----------------------|------------------------|
| <a href="#">Results article</a>  | results        | 01/03/2016          |                   | Yes                   | No                     |
| <a href="#">Protocol article</a> | protocol       | 29/06/2011          |                   | Yes                   | No                     |
| <a href="#">Study website</a>    | Study website  | 11/11/2025          | 11/11/2025        | No                    | Yes                    |