Evaluation of GP-centred care in the German state of Thuringia

Submission date	Recruitment status	Prospectively registered
19/05/2014	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
17/06/2014	Completed	Results
Last Edited	Condition category	Individual participant data
21/04/2015	Other	Record updated in last year

Plain English summary of protocol

Background and study aims

Unlike other countries, such as the UK, general practitioners (GPs) in Germany have not typically acted as the gatekeepers to the countries' healthcare system. GP-centred health care (HzV), in which German GPs are the first point of contact to the rest of the healthcare system, is a medical care concept that allows GPs to act as coordinator, referring patients to other healthcare providers according to their medical needs. The benefits of this system have included an improvement in medical care and a decrease in the financial burden on the healthcare system. In the German state of Thuringia AOK PLUS beneficiaries can choose the GP-centered care contract since January 2011. It is designed as an add-on to regular care.

Who can participate?

Adult patients living in Thuringa and beneficiaries to the statutory health insurance fund AOK PLUS who entered the GP-centred health care programme between 1st Jan 2011 and 30th June 2011.

What does the study involve?

Participants are randomly allocated to one of two groups: one group receives GP-centered care for 18 months and the other receives usual care. The cost-effectiveness of the GP-centered care is assessed by comparing the costs to the healthcare system.

What are the possible benefits and risks of participating? Not provided at time of registration.

Where is the study run from?

The Department of General Practice and Family Medicine, Jena University Hospital, Germany.

When is the study starting and how long is it expected to run for? The study started in July 2012 and runs until December 2014.

Who is funding the study?

AOK PLUS (statutory health insurance fund for Saxony and Thuringia, Germany).

Who is the main contact? Prof Jochen Gensichen jochen.gensichen@med.uni-jena.de

Study website

http://www.allgemeinmedizin.uni-jena.de/content/research/hzv_evaluation/index_eng.html

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

GP-centered care evaluation in the state of Thuringia: a retrospective case-control intervention study

Study objectives

The health care costs of patients that are AOK PLUS beneficiaries receiving GP-centred care in Thuringia are lower than those of patients receiving conventional care after 18 months.

On 21/04/2015 the overall trial end date was changed from 31/12/2014 to 31/12/2015.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Ethics Committee of Jena University Hospital, 28/04/2014, ref. 4058-04/14

Study design

Retrospective case-control study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

GP-centered health care programme

Interventions

Group 1 = GP-centred programme: participants receive total coordinated health care over 18 months. The GP-centred health care programme includes morbidity lump sums, bonuses for rational pharmacotherapy, obligation for general practitioners to take part in quality circles, obligation of implementation of IT tools for supporting pharmacotherapy and extra payment for the utilisation of specialised health care assistants.

Group 2 = Conventional care.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Direct total health care costs to the sickness funds (in-patient hospital care, outpatient physician care, drugs, remedies, therapeutic aids, sick leave payment, home care, rehabilitation, post-acute care) - measured after 18 months

Secondary outcome measures

- 1. Share of patients with different GPs contacted
- 2. Share of patients with different specialists contacted
- 3. Share of specialist contacts without referal
- 4. Share of hospital procedures with potential of substitution by outpatient prodcedure
- 5. Number of hospital emergency cases
- 6. Number of home visits by GPs
- 7. Development of nursing care status
- 8. Number of prevention procedures by GPs
- 9. Number of different drugs (ATC Code)
- 10. Share of patients with polymedication (>5 drugs)
- 11. Share of patients older than 64 years with polymedication (>5 drugs)
- 12. Costs of hospital care cases
- 13. Number of in-patient cases
- 14. Costs of GP contacts
- 15. Number of GP contacts
- 16. Costs of specialist contacts
- 17. Number of specialist contacts
- 18. Costs of home care
- 19. Number of home care prescriptions
- 20. Costs of remedies
- 21. Number of remedies prescripted
- 22. Costs of therapeutic aids
- 23. Number of therapeutic aids prescripted
- 24. Costs of rehabilitation (in- and outpatient)
- 25. Number of rehabilitation prescripted (in- and outpatient)
- 26. Costs of subsequent nursing treatment
- 27. Number of subsequent nursing treatment prescriptions
- 28. Costs of sick leave payment
- 29. Number of cases of sick leave and days of sick leave
- 30. Costs of drug prescriptions
- 31. Number of drug prescriptions

All to be measured after 18 months

Overall study start date

01/07/2012

Completion date

31/12/2015

Eligibility

Key inclusion criteria

- 1. Patients living in Thuringia
- 2. Beneficiaries to the statutory health insurance fund AOK PLUS
- 3. Entry into GP-centered health care programme between 01/01/2011 and 30/06/2011

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

40,000

Key exclusion criteria

Patients aged < 18

Date of first enrolment

01/07/2012

Date of final enrolment

31/12/2014

Locations

Countries of recruitment

Germany

Study participating centre Jena University Hospital

Jena Germany 07743

Sponsor information

Organisation

AOK PLUS (Germany)

Sponsor details

Sternplatz 7 Dresden Germany 01067

Sponsor type

Industry

Website

https://www.aokplus-online.de

ROR

https://ror.org/004cmqw89

Funder(s)

Funder type

Industry

Funder Name

AOK PLUS, statutory health insurance fund for Saxony and Thuringia (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