

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

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| Submission date 19/05/2014 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 17/06/2014 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 21/04/2015 | Condition category Other | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 Thuringia 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
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Study website

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

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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 referral
4. Share of hospital procedures with potential of substitution by outpatient procedure
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 prescribed
22. Costs of therapeutic aids
23. Number of therapeutic aids prescribed
24. Costs of rehabilitation (in- and outpatient)
25. Number of rehabilitation prescribed (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