

Implementing recommendations for Polypharmacotherapy of multimorbid Patients (PomP)

Submission date 22/07/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/08/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/03/2017	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Three evidence-based recommendations addressing polypharmacotherapy (use of multiple therapies to treat disease) in primary care are: structured medication counselling, use of medication lists, and medication reviews to avoid potentially inappropriate medication (PIM). Although promising to improve patient outcomes, these recommendations are not well implemented in German routine care. This study examines a tailored intervention to implement the recommendations addressing polypharmacotherapy into primary care practices.

Who can participate?

Primary care physicians (PCP) who are enrolled in a general practice centered care contract of a German health insurance (HZV AOK) and organised in quality circles with three-monthly meetings will be recruited as participants of the study. Each PCP will include 2025 patients aged > 64 years, being diagnosed with more than two chronic conditions and being repeatedly prescribed more than four drugs.

What does the study involve?

The practices are randomly allocated to either the intervention or the control group. From the practices assigned to the intervention group at least one physician and one health care assistant will participate in a workshop about polypharmacotherapy. The practice teams will create an individual concept which describes how they are planning to implement the recommendations into their practice. They will put their concept into practice and perform medication reviews and medication counselling for the included patients. Checklists, posters and flyers will be offered to them to facilitate implementation. Patients in the intervention group will complete an educational tool concerning medication-related topics on a tablet PC. Patients and physicians of the control group will perform care as usual and will not receive any special training or information material.

What are possible benefits and risks of participating?

The patients of the intervention group have the benefit of receiving intensified medication management. Physicians will receive a financial allowance. The intervention aims at changing

organisational processes in German primary care practices and does not include any specific treatment for patients. Therefore, an additional risk is not expected.

Where is the study run from?

Department of General Practice and Health Care Researches of the University of Heidelberg

When is the study starting and how long is it expected to run for?

November 2013 to June 2014

Who is funding the study?

European Union

Who is the main contact?

Dr Cornelia Jäger

Cornelia.jaeger@med.uni-heidelberg.de

Contact information

Type(s)

Scientific

Contact name

Prof Joachim Szecsenyi

Contact details

Department of General Practice and Health Services Research

Voßstraße 2, Geb. 37

Heidelberg

Germany

69115

-

joachim.szecsenyi@med.uni-heidelberg.de

Additional identifiers

Protocol serial number

European Union EU Framework 7 program, theme HEALTH.2013.3.1-1, grant agreement no 258837

Study information

Scientific Title

A tailored implementation intervention to implement recommendations addressing Polypharmacotherapy of multimorbid Patients (PomP): study protocol of a cluster-randomized controlled trial

Acronym

PomP

Study objectives

The hypothesis is that physicians participating in a tailored implementation program succeed more in implementing recommendations for the treatment of multimorbid patients receiving polypharmacotherapy than physicians not participating in this program.

The null hypothesis is that there is no difference between these two groups.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval pending from the Ethical Review Committee of the University of Heidelberg, Germany

Study design

6 months cluster randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Implementation of recommendations for polypharmacotherapy in multimorbid patients

Interventions

Practice teams (1 general practitioner, 1 health care assistant per practice) will participate in a workshop about polypharmacotherapy. The practice teams will create an individual concept which describes how they are planning to implement the recommendations into their practice. They will put their concept into practice and perform medication reviews and medication counselling for the included patients. Checklists, posters and flyers will be offered to them to facilitate implementation. Patients of the intervention group will complete an educational tool concerning medication-related topics on a tablet PC.

Patients and physicians of the control group will perform care as usual and will not receive any special training or information material.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The degree of implementation of the three recommendations measured at patient level. The degree of implementation will be expressed by the number of indicators fulfilled per patient included in the study.

Key secondary outcome(s)

A comprehensive process evaluation will be performed including questionnaires for intervention fidelity and measures to evaluate the tailoring strategy.

Completion date

01/06/2014

Eligibility

Key inclusion criteria

For general practitioners:

1. Enrolment in a general practice centred care contract (HZV AOK Baden-Wuerttemberg)
2. Continuous attendance in a specific quality circle every three months in the previous 12 months

For patients:

1. Aged over 64 years
2. Enrolment in general practice-centred care contract (HZV AOK Baden-Wuerttemberg)
3. Repeated prescriptions of more than four drugs in one quarter of the year
4. Being diagnosed with at least three chronic conditions
5. Especially in need for intensified medication management (according to the personal assessment of the general practitioner, e.g. non-adherence, hospitalisation due to medication related events).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. For physicians: Physicians having participated in another study focusing on multimorbidity or polypharmacotherapy in the last year are excluded
2. For patients: Lacking ability or need for intensified medication management according to the personal assessment of the general practitioner.

Date of first enrolment

01/11/2013

Date of final enrolment

01/06/2014

Locations

Countries of recruitment

Germany

Study participating centre
Department of General Practice and Health Services Research
Heidelberg
Germany
69115

Sponsor information

Organisation
European Union (Netherlands)

ROR
<https://ror.org/019w4f821>

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme, theme HEALTH.2013.3.1-1, grant agreement no 258837

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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	13/01/2017		Yes	No
Protocol article	protocol	05/12/2013		Yes	No
Other publications	process evaluation	06/03/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes