ISRCTN34664024 https://doi.org/10.1186/ISRCTN34664024

Implementing recommendations for Polypharmacotherapy of multimorbid Patients (PomP)

Submission date
22/07/2013

Recruitment status
No longer recruiting

Registration date
14/08/2013

Overall study status
Completed

Last Edited
08/03/2017

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

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 measure
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.

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

Overall study start date
01/11/2013

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

Age group
Senior

Sex
Both

Target number of participants
40 primary care practices, 1000 patients

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)

Sponsor details
represented by the European Commission
Stichting Katholieke Universiteit
Comeniuslaan 4
Nijmegen
Netherlands
6525 HP
-
cornelia.jaeger@med.uni-heidelberg.de

Sponsor type

Government

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

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	05/12/2013		Yes	No
Results article	results	13/01/2017		Yes	No
Other publications	process evaluation	06/03/2017		Yes	No