

Prioritising and optimising multiple medications in elderly multi-morbid patients in general practice

Submission date 18/05/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 07/07/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/12/2018	Condition category Other	☐ 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
01GK0702

Study information

Scientific Title
Prioritising and optimising multiple medications in elderly multi-morbid patients in general practice: a pilot open-label two-arm cluster-randomised controlled trial

Acronym

PRIMUM pilot

Study objectives

The aim of this pilot study is to test the feasibility of a complex intervention in the general practice on the appropriateness of medication in elderly multi-morbid patients and the feasibility of a cluster-randomised controlled trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Medicine, Johann Wolfgang-Goethe University, Frankfurt, 24/03/2009, ref: 54/09

Primary study design

Interventional

Study design

Pilot open-label two-arm cluster-randomised controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Multi-medication in elderly multi-morbid patients

Interventions

The trial has two arms: one intervention arm and one control arm.

The intervention consists of several components:

1. Medication reconciliation (brown-bag review)
2. Structured interview lead by practice nurse on problems related to medications based on a checklist (medication monitoring list, MediMoL)
3. Use of a computerised decision support system on medications (AiD+)
4. Counselling session with GP on medication-related problems

The total duration of the intervention is three weeks.

Practices in the control arm proceed as usual (i.e. there is no sham control).

The duration of the follow-up period (which starts after the second data collection) is six weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. To evaluate practicability: expenditure of time regarding intervention
2. To evaluate feasibility: number of patients who dropped out, reasons for why patients do not participate in study, time expenditure regarding data collection
3. Potential primary outcome for main study: appropriateness of medication (Medication Appropriateness Index [MAI])

There are three timepoints of data collection in both, the control and the intervention arm:

T0: before the beginning of the intervention

T1: six weeks after the beginning of the intervention

T2: twelve weeks after the beginning of the intervention

Key secondary outcome(s)

1. Complexity of medication (number of drugs, number of daily doses, Medication Regimen Complexity Index [MRCI])
2. Observed adherence (drug score, dose score, regimen score)
3. Reported adherence (Medication Adherence Report Scale [MARS] and adherence according to Morisky)
4. Patient attitude toward medication (Beliefs about Medicines Questionnaire [BMQ])
5. Patient satisfaction regarding information about medication
6. Health related quality of life (EQ-5D)
7. Functional disability (World Health Organization Disability Assessment Schedule II [WHO-DASII])
8. Pain (Verbal Rating Scale)
9. Hospital days
10. Number of medication side effects

There are three timepoints of data collection in both, the control and the intervention arm:

T0: before the beginning of the intervention

T1: six weeks after the beginning of the intervention

T2: twelve weeks after the beginning of the intervention

Completion date

03/11/2009

Eligibility

Key inclusion criteria

Patients:

1. At least 65 years old, either sex
2. At least three chronic diseases
3. At least five continuous prescriptions
4. At least one practice visit during the last quarter
5. Written informed consent
6. Ability to fill out a questionnaire and participate in a telephone interview

Practices:

1. Practice serves members of the German statutory health insurance system
2. GP practice
3. Physician is specialised in general practice or internal medicine, or without specialisation
4. Internet access
5. Availability of a practice nurse who can participate in the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

Patients:

1. Life expectancy of less than six months
2. Drug addiction problems
3. Cognitive impairment (Mini Mental State Examination [MMSE] score less than 26)
4. Emotional stress that would prevent participation in the study
5. Participation in a clinical trial within the last 30 days

Date of first enrolment

13/05/2009

Date of final enrolment

03/11/2009

Locations**Countries of recruitment**

Germany

Study participating centre

Johann Wolfgang Goethe University

Frankfurt

Germany

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Sponsor information**Organisation**

German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany)

ROR

<https://ror.org/04pz7b180>

Funder(s)

Funder type

Government

Funder Name

Bundesministerium für Bildung und Forschung (ref: 01GK0702)

Alternative Name(s)

Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/07/2016		Yes	No