

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

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| <b>Submission date</b><br>18/05/2009   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>07/07/2009 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>17/12/2018       | <b>Condition category</b><br>Other                | <input type="checkbox"/> 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

**Study design**

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

**Primary study design**

Interventional

**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

60590

**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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results                       | 25/07/2016   |            | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |