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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
18/05/2009		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
07/07/2009	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
17/12/2018	Other			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Christiane Muth

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers 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

## Secondary study design

Cluster randomised trial

# Study setting(s)

GP practice

# Study type(s)

Quality of life

## 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

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 procede 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 measure

- 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

## Secondary outcome measures

- 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

#### Overall study start date

13/05/2009

#### 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** 

#### Age group

Senior

#### Sex

Both

# Target number of participants

100

#### 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)

## Sponsor details

Hannoversche Strasse 28-30 Berlin Germany 10115

#### Sponsor type

Government

#### Website

http://www.bmbf.de

#### **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 Education and Research, BMBF

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

# **Location**Germany

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

# Intention to publish date

# 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