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

Submission date
18/05/2009

Recruitment status
No longer recruiting

Registration date
07/07/2009

Overall study status
Completed

Last Edited
17/12/2018

Condition category
Other

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

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