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Prioritising and optimising multi-medication in multimorbidity

Submission date	Recruitment status	[_] Prospectively registered
21/07/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/08/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/09/2019	Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01171339

Protocol serial number
01GK0702

Study information

Scientific Title
Prioritising and optimising multiple medications in elderly multi-morbid patients in general practice: a pragmatic cluster-randomised controlled trial

Acronym
PRIMUM

Study objectives
The primary objective of the study is to determine whether the complex intervention will improve the appropriateness of prescriptions compared to usual care. The primary efficacy endpoint is the change in the Medication Appropriateness Index (MAI) score from baseline (T0) to 6 months after baseline (T1), i.e. the difference MAI T1 - T0. The study objective will be statistically formulated as a test of the null hypothesis H0: $\mu 1 = \mu 2$ (the mean difference MAI T1 - T0 is equal in the two groups) against the alternative hypothesis H1: $\mu 1 \neq \mu 2$ (the mean MAI T1 - T0 are different in the two groups). The null hypothesis will be tested at the two-sided significance level of $\alpha=0.05$.

Because of the cluster randomisation, the primary efficacy analysis will use a multilevel regression approach with patients at level one and practices at level two. The primary analysis will be performed adhering to the intention-to-treat principle. An additional sensitivity analysis will be conducted on a per-protocol analysis set.

Please note that the pilot study to this trial was registered with an ISRCTN on 07/07/2009 (see https://www.isrctn.com/ISRCTN99691973 for details of this pilot project).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Medicine at Johann Wolfgang-Goethe University, 20/05/2010, ref: E 46/10

Study design
Pragmatic cluster-randomised controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Multi-morbidity

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

In the control arm patients are treated as usual in accordance with the recommended standard.

In the intervention arm patients are treated with a single application of the following complex intervention and as usual based on the recommended standard. The intervention consists of several components which have been shown to be feasible in the pilot study (ISRCTN99691973):

1. Medication reconciliation (brown-bag review)
2. Structured interview lead by health care assistant (HCA) on problems related to medications based on a checklist (Medication Monitoring List [MediMoL])
3. Use of a computerised decision support system on medications ('ArzneimittelinformationsDienst' [AiD+])
4. GP-patient consultation on medication-related problems

All of the components of the complex intervention will be applied one time to each of the patients in the intervention arm. The total duration of the complex intervention per patient is about one week. The total duration of the follow-up in both arms is nine months. The recommended standard in both arms is the clinical practice guideline 'Geriatrie' of the guideline group of Hesse (part 1 and 2).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Difference in Medication Appropriateness Index (MAI) score 6 months from baseline minus baseline (MAI T1 - T0).

There are three timepoints of data collection in both, the intervention and the control arm:
T0: baseline, before randomisation and before beginning of the intervention
T1: six months after baseline
T2: nine months after baseline
Data are collected via practice documentation (case report forms), patient questionnaire, and patient interview.

Key secondary outcome(s))
Current secondary outcome measures as of 02/11/2017:
MAI T2 - T0 and the difference in the following scores 6 and 9 months from baseline minus baseline (T1 - T0 and T2 - T0):
1. Complexity of medication: Medication Regimen Complexity Index (MRCI), no. of prescriptions / single doses
2. Observed adherence: drug score, dose score, regimen score
3. Reported adherence: adherence according to Morisky
4. Patient attitude toward medication: Beliefs about Medicines Questionnaire (BMQ)
5. Generic health related quality of life (EQ-5D)
6. Functional disability: Vulnerably Elderly Survey 13 items (VES-13)
7. Pain assessment: grade of severity of chronic pain
8. All cause hospitalisation: hospital days
9. Satisfaction with shared decision making: Man-Sin-Hong scale (MSH)
10. Patient's future expectation, expected/desired lifetime duration: Years of Desired Life (YDL)
11. Cognitive dysfunction: Verbal Fluency Test (VFT)
12. Depression: Geriatric Depression Scale (GDS)

There are three timepoints of data collection in both, the intervention and the control arm:
T0: baseline, before randomisation and before beginning of the intervention
T1: six months after baseline

T2: nine months after baseline
Data are collected via practice documentation (case report forms), patient questionnaire, and patient interview.

Previous secondary outcome measures:
MAI T2 - T0 and the difference in the following scores 6 and 9 months from baseline minus baseline (T1 - T0 and T2 - T0):
1. Complexity of medication: Medication Regimen Complexity Index (MRCI)
2. Observed adherence: drug score, dose score, regimen score
3. Reported adherence: adherence according to Morisky
4. Patient attitude toward medication: Beliefs about Medicines Questionnaire (BMQ)
5. Patient satisfaction regarding information about medication
6. Generic health related quality of life (EQ-5D)
7. Functional disability: Vulnerably Elderly Survey 13 items (VES-13)
8. Pain assessment: grade of severity of chronic pain
9. All cause hospitalisation: hospital days
10. Satisfaction with shared decision making: Man-Sin-Hong scale (MSH)
11. Patient's future expectation, expected/desired lifetime duration: Years of Desired Life (YDL)
12. Cognitive dysfunction: Verbal Fluency Test (VFT)
13. Depression: Geriatric Depression Scale (GDS)

There are three timepoints of data collection in both, the intervention and the control arm:
T0: baseline, before randomisation and before beginning of the intervention
T1: six months after baseline
T2: nine months after baseline
Data are collected via practice documentation (case report forms), patient questionnaire, and patient interview.

Completion date
29/02/2012

Eligibility

Key inclusion criteria
Patients:
1. At least 60 years old of both sexes
2. At least three chronic diseases affecting two or more organ systems, which require pharmaceutical treatment
3. At least five long-term prescriptions with systemic effects
4. Health care provided by GP (at least one contact in most recent quarter)
5. Patient is legally competent to sign any documents
6. Ability to understand and participate in trial of own free will, to fill out questionnaires and participate in telephone interviews
7. Written informed consent to participate in trial

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 doctor with no specialist field
4. Internet access

5. Investigator's agreement to fulfil the contractual obligations arising from the trial
6. Investigator's agreement to the training of a health care assistant (HCA) from the practice for the intervention, as required by the trial

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
502

Key exclusion criteria
Patients:
1. Diseases cause life expectancy of less than 12 months
2. Abuse of alcohol or illegal drugs and visible clinical signs or symptoms thereof
3. Cognitive impairment that prevents trial participation (mini-mental state examination [MMSE] less than 26)
4. Emotional stress that prevents trial participation
5. Participation in a clinical trial within the last 30 days

Practices:
1. Practice focuses on unconventional medical treatments
2. Practice focuses on special indications (e.g. human immunodeficiency virus [HIV])

Date of first enrolment
01/08/2010

Date of final enrolment
29/02/2012

Locations

Countries of recruitment
Germany

Study participating centre
Institute for General Practice
Frankfurt / Main
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Sponsor information

Organisation
Johann Wolfgang Goethe University (Germany)

ROR
https://ror.org/04cvxnb49

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

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	24/02/2018		Yes	No

Results article	results	28/07/2018		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes