

Prioritising and optimising multi-medication in multimorbidity

Submission date 21/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/08/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/09/2019	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.allgemeinmedizin.uni-frankfurt.de/forschung.html>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

NCT01171339

Secondary identifying numbers

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 $H_0: \mu_1 = \mu_2$ (the mean difference MAI T1 - T0 is equal in the two groups) against the alternative hypothesis $H_1: \mu_1 \neq \mu_2$ (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

Secondary study design

Cluster randomised trial

Study setting(s)

GP practice

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet (German only)

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 'Geriatric' of the guideline group of Hesse (part 1 and 2).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

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.

Secondary outcome measures

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)
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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.

Overall study start date

01/08/2010

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

Age group

Adult

Sex

Both

Target number of participants

No. GP: 70; No. patients: 490

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

Germany

D-60590

Sponsor information

Organisation

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Sponsor type

University/education

Website

<http://www.uni-frankfurt.de/english/index.html>

ROR

<https://ror.org/04cvxnb49>

Funder(s)

Funder type

Government

Funder Name

Bundesministerium für Bildung und Forschung

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

Planned publication in an open access peer reviewed journal.

Intention to publish date

01/06/2018

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