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PRIMA-eDS: Polypharmacy in chronic diseases: Reduction of Inappropriate Medication and Adverse drug events in elderly populations by electronic Decision Support

Submission date
31/07/2014

Recruitment status
No longer recruiting

Registration date
31/07/2014

Overall study status
Completed

Last Edited
22/06/2020

Condition category
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic multimorbidity is rising in our aging population and leads to polypharmacy as a result of guideline adherent and also non-evidence based or inappropriate drug treatment of chronic diseases. Depending on definitions and setting between 25 and 50% of all patients aged over 75 are treated with five or more drugs. Inappropriate polypharmacy of older patients poses a serious threat to health and well-being. While there exists only limited evidence regarding the benefit of polypharmacy, the evidence regarding potential harm of inappropriate medication is increasing. An electronic tool, the PRIMA-electronic decision support (eDS) tool, will be developed to make current best evidence available to general practitioner (GP) in daily practice. The GP has to enter the patient's diagnoses, current medication including drugs that have not been prescribed by the GP, and general patient data like sex, age, height and weight. The GP will receive medication-related recommendations generated by the PRIMA-eDS tool on-screen. The medication can then be revised by the GP in a shared decision making process with the patient. It is thought that the reduction of polypharmacy and inappropriate prescribing according to current best evidence supported by the PRIMA-eDS tool will improve the clinical composite outcome of first hospitalization and death of older patients with multiple chronic diseases.

Who can participate?
Patients aged 75 and over, living in the community or in a nursing home, with >7 continuous drug prescriptions

What does the study involve?
Participating GP surgeries are randomly allocated to either the intervention group or the control group. The PRIMA-eDS tool is only available in the intervention group and not in the control group. The GPs in the intervention group use the PRIMA-eDS tool at the start of the study and at each follow up visit (study visits are scheduled after 8 months, 16 months, and 24 months) or any time in between visits. It is recorded which of the recommendations are followed by the GP. GPs in the control group are only asked to record general data and the medication of the

participating patients at the same time points as the intervention group with no advice given to continue or discontinue any of the drugs. GPs in the control group are advised to apply usual care according to current guidelines.

What are the possible benefits and risks of participating?
The study will provide new insights in the possible risks and benefits of polypharmacy in older multimorbid patients suffering from chronic diseases. A reduction in hospital admission and death rate by reducing polypharmacy as primary endpoint will be a clear indicator of improvement for patients with chronic diseases. Furthermore, it is expected that the intervention will result in a marked improvement of quality of life as well as physical and mental functioning of older people.

Where is the study run from?
The PRIMA-eDS study is coordinated by Witten/Herdecke University and carried out by five university-based centres recruiting GP-surgeries in their particular region/country:
1. University of Witten/Herdecke (Germany) – leading centre and coordinator
2. University of Manchester (UK)
3. University of Rostock (Germany)
4. Paracelsus Medical University (Austria)
5. South Tyrolean Academy for General Practice (Italy)
Each centre will enrol 67 GP practices (in total 335 practices).

When is the study starting and how long is it expected to run for?
December 2014 to November 2017 (as of 04/10/2018)

Who is funding the study?
Seventh EU Framework Programme

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Prof Andreas Sönnichsen

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Polypharmacy in chronic diseases - reduction of inappropriate medication and adverse drug events in elderly populations by electronic decision support: a multicenter cluster-randomized controlled trial

Acronym
PRIMA-eDS

Study objectives
Do multimorbid older patients in primary care taking eight drugs or more benefit from the implementation of the electronic decision support tool “PRIMA-eDS” which suggests a reduction of polypharmacy according to current best evidence, compared to patients with polypharmacy receiving usual care, regarding the combined endpoint of hospital admission and death?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethikkomission der Universität Witten/Herdecke, 03/12/2013, ref. 103/2013
2. NRES Committee North West - Greater Manchester East, 06/06/2014, ref. 14/NW/0197
3. Ethikkommission für das Bundesland Salzburg, 15/09/2013, ref. 08.04.2014 (415-E/1509/20-2014)
4. Ethikkommission der Universitätsmedizin Rostock, 03/02/2014, ref. A 2014-0020
5. Comitato etico di Belluno (Azienda ULSS), 26/06/2013, ref. 305388-2

Study design
Multicenter cluster-randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multimorbid older patients in primary care

Interventions
The PRIMA-eDS tool will only be available in the intervention group and not in the control group. The GP in the intervention group uses the PRIMA-eDS tool at each follow up visit (study visits are scheduled at baseline and after 8 months, 16 months, and 24 months). It will be recorded which of the recommendations were followed by the GP. GPs in the control group will only be asked to record general data and the medication of the participating patients at the same time points as

the intervention group with no advice given to continue or discontinue any of the drugs. GPs in the control group are advised to treat their patients applying usual care adherent to current guidelines.

Follow Up Length: 24 months; Study Entry: Single Randomisation only

Intervention Type
Other

Primary outcome(s)
Composite of first hospitalization and death measured at 24 months

Key secondary outcome(s))
Current secondary outcome measures as of 25/08/2015:
1. All cause mortality
2. Hospital admission (number of episodes and duration)
3. Falls
4. Fractures
5. Quality of life
6. The number and types of drugs discontinued
7. The number and types of drugs not discontinued despite the recommendation to discontinue
8. The number and types of drugs re-administered for symptom control
9. Medication costs
10. Adverse event rate
All measured at baseline, 8, 16, and 24 months.

Previous secondary outcome measures:
1. All cause mortality
2. Hospital admission (number of episodes and duration)
3. Falls
4. Fractures
5. Quality of life
6. The number and types of drugs discontinued
7. The number and types of drugs not discontinued despite the recommendation to discontinue
8. The number and types of drugs re-administered for symptom control
9. Medication and health care costs
All measured at baseline, 8, 16, and 24 months.

Completion date
30/11/2017

Eligibility

Key inclusion criteria
1. Age of 75 years and above living in the community or in a nursing home
2. At least 8 continuous drug prescriptions
3. Willing to participate
4. Able to sign informed consent according to the declaration of Helsinki

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
3904

Key exclusion criteria
1. Patients with a life expectancy assumed to be less than 1 year, e.g. patients with advanced cancer
2. Patients receiving chemotherapy and/or therapeutic radiation
3. Patients with dementia who are unable to provide informed consent

Date of first enrolment
01/12/2014

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
United Kingdom

England

Austria

Germany

Italy

Study participating centre
Witten/Herdecke University (Universität Witten/Herdecke) - leading centre and co-ordinator
Institute of General Practice and Family Medicine (Institut für Allgemeinmedizin und Familienmedizin)
Alfred-Herrhausen-Straße 50
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Study participating centre
The University of Manchester
5th Floor Williamson Building
Oxford Road
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Study participating centre
University of Rostock (Universität Rostock)
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18051

Study participating centre
Paracelsus Medical University (Die Paracelsus Medizinische Privatuniversität)
Strubergasse 21
Salzburg
Austria
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Study participating centre
South Tyrolean Academy for General Practice (Südtiroler Akademie für Allgemeinmedizin)
Wangergasse, 18
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I-39100

Sponsor information

Organisation
Witten/Herdecke University (Universität Witten/Herdecke)

ROR
https://ror.org/00yq55g44

Funder(s)

Funder type

Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/06/2020	22/06/2020	Yes	No
Protocol article	protocol	29/01/2016		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	baseline analysis	18/07/2018		Yes	No
Other publications	cross-sectional analysis of participant characteristics	18/07/2018	12/09/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes