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Polypharmacy reduction in patients treated for chronic diseases

Submission date 07/01/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/01/2014	**Overall study status** Completed	
Last Edited 24/01/2017	**Condition category** Other	

Plain English summary of protocol

Background and study aims
More and more people are now suffering from long-term diseases and multimorbidity (multiple medical conditions in one person), and are treated with an increasing number of long-term drugs. However, polypharmacy (use of multiple medications by a patient) involves severe risks for patient safety. Also, patients are often unable to monitor their frequency of dosage. Reducing inappropriate polypharmacy will contribute to lower levels of adverse drug events and drug-related side effects and will increase patient safety and quality of life. This study will test the effectiveness of an intervention (use of pharmacist-based narrative medication review) within hospitals and aims at reducing the number of long-term prescribed drugs among multimorbid and chronically ill patients.

Who can participate?
Patients aged 60 years and older, taking five or more prescribed long-term drugs, and likely to spend at least one week in the hospital.

What does the study involve?
The hospital wards are randomly allocated to either the intervention or the control group. Patients in the intervention wards receive a pharmacist-based narrative medication review in hospital. Patients in the control group wards receive care as usual. The number of prescribed long-term medications are compared between both groups at 12 months after discharge as well as health-related quality of life.

What are the possible benefits and risks of participating?
The findings of this study may result in a major impact on reducing polypharmacy by enhancing both patient-centeredness and patient autonomy. No risks to participants are expected.

Where is the study run from?
Two hospitals in Mecklenburg-Western Pomerania (Germany)

When is the study starting and how long is it expected to run for?
November 2013 to August 2017

Who is funding the study?
German Federal Ministry of Education and Research (BMBF) (Germany)

Who is the main contact?
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Additional identifiers

Protocol serial number
Ref. No. 01GY1332

Study information

Scientific Title
Polypharmacy reduction in patients treated for chronic diseases a patient-centered approach utilizing the interface between secondary and primary care

Acronym
POLITE-RCT

Study objectives
Whether a patient-centered medication review performed by pharmacists and consented with the patients General Practitioners will be effective to sustainably reduce polypharmacy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at the Rostock University Medical Center, June 2014, ref: A 2014-0101

Study design
Cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with chronic diseases and polypharmacy (≥ 5 prescribed long-term drugs)

Interventions
During in-patient treatment of chronically ill patients affected by polypharmacy, a pharmacist specially trained in communication skills performs a narrative-based medication review. Apart from detecting potentially inadequate medication, a major aim is to identify patient preferences and to include them - whenever possible - into a list of evidence-based medication recommendations. Patients will be motivated to narrate the drugs they currently take and describe their experiences and expectations related to these drugs. Based on this information the pharmacist prepares a list of possible drugs to be stopped, which will then be discussed with the hospital physician in charge and will be submitted for consent to the patients General Practitioner. The active involvement of patients allows for transparency of the decision-making process and will increase the chance for a sustainable medication optimization.

Patients of the control group receive care as usual.

The intervention in the intervention group will take place once, shortly after the admission to hospital. The duration of the entire trial will be 36 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The two independent main outcomes are:
1. Health-related quality of life, measured using the EQ-5D
2. The difference in the number of prescribed long-term pharmaceutical agents between intervention and control group at T3. Primary outcome is defined as pharmaceutical agents rather than number of drugs because combination drugs are commonly used in Germany.

During the baseline and intervention periods, primary outcomes for each patient will be measured at four points in time: at admission to the hospital (T0) and discharge from hospital (T1), as well as 6 (T2) and 12 months (T3) after discharge from the hospital.

Key secondary outcome(s))
1. Appropriateness of prescribed medication
2. Patient satisfaction
3. Patient empowerment
4. Patient autonomy
5. For all patients insured with the largest public German health insurance provider AOK, cost effectiveness and further aspects of quality of care will be analyzed

Measured at T0, T2 and T3

Completion date
31/08/2017

Eligibility

Key inclusion criteria
Two local hospitals will recruit patients with chronic diseases and polypharmacy meeting the following inclusion criteria:
1. Aged 60+ years
2. Taking ≥ 5 prescribed long-term drugs
3. Likely to spend at least one week in the hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Inability to take their medication by themselves
2. Inability to give informed consent (e.g. due to dementia)
3. Severe language difficulties
4. Diseases that usually make poly-pharmacotherapy unavoidable (e.g. active malignoma,

acquired immunodeficiencies [HIV], hemodialysis)
5. Presumed life expectancy of less than 12 months

Added 20/01/2017:
6. Patients being diagnosed with any type of cancer after recruitment will be excluded from the study

Date of first enrolment
01/08/2014

Date of final enrolment
31/10/2016

Locations

Countries of recruitment
Germany

Study participating centre
Rostock University Medical Center
Rostock
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Sponsor information

Organisation
German Federal Ministry of Education and Research (BMBF) (Germany)

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung (Ref. No. 01GY1332)

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 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	06/10/2014		Yes	No
Protocol article	protocol	06/10/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes