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The Prevention of Polypharmacy in Primary Care Patients Trial (4P-RCT)

Submission date
23/10/2014

Recruitment status
No longer recruiting

Registration date
31/10/2014

Overall study status
Completed

Last Edited
09/07/2019

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The taking of multiple drugs (polypharmacy), overuse of drugs and misuse of drugs are increasing problems in the care of people with a number of health conditions (polymorbid) and the elderly. It leads to an increase in poor health (morbidity) , hospital admissions (hospitality rates), health related costs and number of deaths (mortality). Up to now, only few clinical tools to guide the withdrawal (deprescribing) of medicaments (drugs) are available. A recently published study using a newly developed algorithm for a systematic reduction of medication (Good Palliative Geriatric Practice, GPGP) showed that deprescribing resulted in a significant positive effects in the health in elderly people. Here, we slightly adapted the GPGP algorithm and carried out a study to how practical and acceptable it would be to use it in a primary care setting. The algorithm enforces a systematic drug reviewing considering patients perspective and preferences. As family doctors take care of a majority of polymorbid patients, our tool has a potentially high impact on polypharmacy in primary care settings. Up to now, studies carried out that test ways (interventions) to reduce polypharmacy in primary care settings are lacking. This study intends to bridge this gap.

Who can participate?
Primary care physicians in the Northern part of Switzerland and their polymorbid patients (60 years and older).

What does the study involve?
The practices are randomly allocated to either the intervention or the control group. The practices assigned to the intervention group will undergo a physician's training with instruction how to use the algorithm. The control group is given a lecture on polymorbidity and instructions for collecting data in a usual care activity. For the patients in the intervention group the practice nurse will create a list of what medication they currently take. Then the GP decides on the four major clinical problems and, together with the patient, the four most important complaints from the patients' perspective. Physicians now decide for every medicament listed whether its use is correct, whether there are side effects, whether an alternative treatment that should be tried or a change in the dose. After discussion, the patient and doctor decide together whether to stop a

drug, to change the dose of a drug or to switch to an alternative drug, with the option to restart if symptoms should increase or the disease deteriorate. Patients of the control group receive care as usual.

What are the possible benefits and risks to participating?
The patients of the intervention group have the benefit of receiving a systematic drug review considering patients' perspective and preferences. Physicians will receive a financial incentive. Our study focuses on prescribing the appropriate medication, this includes the possibility to restart the stopped medication if it is necessary. Therefore, an additional risk is not expected.

Where is the study conducted?
University of Zurich (Switzerland)

When is the study starting and how long is it expected to run for?
January 2015 to September 2017 (updated 09/07/2019, previously: July 2017)

Who is funding the study?
1. Institute of Primary Care - University of Zurich (Institut für Hausarztmedizin der Universität Zürich) (Switzerland)
2. Gottfried und Julia Bangerter-Rhyner-Stiftung, Basel (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Systematic Deprescribing of medicaments in polymorbid primary care patients: a randomized-controlled study in Swiss General Practices

Acronym
4P-Study

Study objectives
The implementation of an algorithm adapted to the Good Palliative Geriatric Practice (GPGP) algorithm to systematically deprescribe medicaments leads to a long-term reduction of polypharmacy among Swiss family doctors and their polymorbid patients (60 years and older). Furthermore, this implementation improves patients' quality of life and the course of the disease for which the drug was originally prescribed for (safety issues of the intervention).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Single-centre two-arm double-blind cluster-randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Polypharmacy

Interventions
1. Practices in the control group: The control group is given a lecture on multimorbidity and instructions for collecting data in a usual care activity
2. Practices in the intervention group: Doctors in the intervention group undergo a physicians' training with instruction how to use the algorithm including a communication skills training. After obtaining informed consent from the patient, a practice nurse creates a list of patient's present medication. Then the GP defines the four major clinical problems and, together with the patient, the four most important complaints in patients' perspective. Physicians in the intervention group now decide for every medicament listed whether the indication is correct, whether there are side effects, whether an alternative treatment is making sense or whether a change in the dosage is indicated (key questions of the algorithm). After discussion with the patient doctor and patient decide together whether to stop a drug, to change the dosage of a drug or to switch to an alternative drug, with the option to restart if symptoms should increase or the disease deteriorate.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Change in the number of drugs (deprescribing rate) 12 months after applying the deprescribing tool.

Key secondary outcome(s)
1. Change in the number of drugs immediately after the encounter and six months later
2. Reason for a change, categorized in the four options of the algorithm, number of drugs in each category
3. Discrepancy in the decision to quit, change or continue the drug between doctor and patient
4. Number of drugs the patient is taking not known to the doctor
5. Time consumption of the intervention
6. Disease-specific variables to evaluate the course of the disease(s) which the patient is treated for, including hospitalization and unexpected adverse event rates. Measurement will be performed by biometric analysis (e.g. blood pressure monitoring, serum glucose) and validated disease specific scores (e.g. pain, depression)
7. Number of drugs readopted due to an unfavorable course of the disease(s) (readoption rate)
8. Change in quality of life after 12 months, measured by a standardized short form questionnaire (EQ-5D) and a single Likert-scale item
9. Barriers perceived by patients against the approach / algorithm

After the baseline assessment (including socioeconomic variables) systematic follow-up measurements will take place after six and 12 months.

Completion date
30/09/2017

Eligibility

Key inclusion criteria
1. Aged at least 60 years and capable of judgement
2. Taking five or more medicaments in the long term (six months or longer)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
334

Key exclusion criteria
Life expectancy less than 12 months

Date of first enrolment

01/01/2015

Date of final enrolment
30/07/2016

Locations

Countries of recruitment
Switzerland

Study participating centre
Institut für Hausarztmedizin der Universität Zürich
Zürich
Switzerland
8091

Sponsor information

Organisation
Institute of Primary Care - University of Zurich (Institut für Hausarztmedizin der Universität Zürich) (Switzerland)

ROR
https://ror.org/02crff812

Funder(s)

Funder type
Other

Funder Name
Institute of Primary Care - University of Zurich (Institut für Hausarztmedizin der Universität Zürich) (Switzerland)

Funder Name
Gottfried und Julia Bangerter-Rhyner-Stiftung, Basel (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

The majority of data will be included in the planned submissions. Other datasets generated during and/or analysed during the current study are planned to be available upon personal request from the Institute of Primary care, University of Zurich, Zurich, Switzerland. Contact stefan.zechmann@usz.ch .

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/08/2017	09/07/2019	Yes	No
Results article	results	14/05/2019	09/07/2019	Yes	No
Protocol article	protocol	26/08/2015		Yes	No
Basic results		14/09/2018	14/09/2018	No	No