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Patient activation for drug reviewing by telemedicine

Submission date
18/03/2019

Recruitment status
Stopped

Registration date
29/03/2019

Overall study status
Stopped

Last Edited
11/07/2022

Condition category
Other

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Due to the ageing of the population, the simultaneous existence of multiple chronic diseases (mulitmorbidity) and the associated use of multiple drugs (polypharmacy) is a growing problem in western countries. A recent European study showed that a third of the European adults aged 65 or more years take five or more medications per day. Polypharmacy has been related to an increased risk for adverse drug reactions, contributing to morbidity and mortality, especially concerning older patients. It is also associated with hospitalisations, nursing home placements and increased costs. A way to reduce inappropriate polypharmacy seems to be deprescribing (stopping previously prescribed drugs). Studies on the effectiveness of deprescribing are promising; however, more research is needed to confirm that they really affect patients in a way that they e.g. reduce hospital admissions. Studies using the principle of shared decision making (informing the patient on a specific topic and discussing it in an open way) seems to be most effective in stopping pre-existing prescribing. Telemedicine, which includes the use of electronic information and communications technologies to provide and support healthcare when distance separates the participants, could be used to involve patients in the process of deprescribing. Telephone interventions are part of this and have been used a lot, for example with regard to triage, coaching of chronic patients or patients during rehabilitation, monitoring patients discharged from hospitals, or for lifestyle change of patients. Telephone interventions have also been successful for the recruitment of patients for participation in cancer screening, preventive medicines or research trials. General practitioner (GP) endorsement and more personalized reminders were found to be especially effective. As far as we know, telemedicine has never been used for activating and involving patients in deprescribing. The aim of this study is to find out whether patient activation by telephone call or letter sent out by an insurance company is effective in encouraging patients to discuss their medication use with their GP.

Who can participate?
Patients age 60 or older, insured at SWICA, who are German-speaking and using at least five different drugs

What does the study involve?
There are two active (were an intervention takes place) groups and the intervention consists of two steps. Step 1: Patients from both intervention groups receive a postal letter encouraging

them to talk to their GP about their medication. In addition, they receive information about an algorithm that their GP could use to reduce the number of drugs. Patients participating in intervention group 1 additionally receive a phone call (within two weeks after sending the letter) from a trained santé24 physician or pharmacist who follows a structured script to motivate the patient to plan a consultation with their GP to review their medication use and explain the algorithm. If patients do not have a GP, the santé24 physician or pharmacist suggests to the patient to contact the physician prescribing most of his/her drugs for a deprescribing consultation. If the patient rejects this suggestion, the santé24 provider offers a telephone consultation with a santé24 physician for this purpose within one week. Step 2: After four months, patients of both intervention groups receive a reminder to speak to their GP about their medication use. In addition, they receive a questionnaire asking whether an encounter with the GP has taken place and if they discussed the medication list. If this was the case, they are asked if the algorithm has been used or - when the algorithm was not used - which barriers exist for using the algorithm. There is also a control group who receive usual care.

What are the possible benefits and risks of participating?
By participating in this study, participants may help to find a better approach towards activating patients' self-empowerment. It is possible that participants may benefit from a individual adjustment or deprescribing of their medication. Participating supports a meaningful and practical study and contributes towards better patient health and lower health costs. In case of success the results of this study will be widely distributed. The researchers consider the risk to all study participants to be minimal. The intervention consists of activating patients to discuss their medication use with their GP. The GP will only decide to deprescribe if he/she thinks there are no substantial risks involved, thus providing usual medical care for the patient. There is no extra risk due to the study intervention which would exceed the risks of usual care while prescribing or deprescribing drugs. As the intervention is encouraging patients to see their GPs in order to do the drug review in consensus with the patient, the researchers do not see a risk that patients would stop any drugs without contact with their GPs.

Where is the study run from?
University Hospital Zurich (Switzerland)

When is the study starting and how long is it expected to run for?
May 2019 to May 2021

Who is funding the study?
1. University of Zurich (Switzerland)
2. SWICA insurance

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2018-02385

Study information

Scientific Title
Impact of telemedicine activation of older patients with polypharmacy: a randomised acceptance and feasibility study in Switzerland

Study objectives
Patients that are activated by telephone call or letter to discuss their medication use with their GP will more often have a medication review with their GP than patients who are not activated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/02/2019 by the Cantonal Ethics Committee Zurich (Kantonale Ethikkommission Zürich), Stampfenbachstrasse 121, (Eingang Georgengasse 6 benützen!), 8090 Zürich, Tel: +41 (0) 43 259 79 70, Email: info.KEK@kek.zh.ch, BASEC-Nr.: 2018-02385

Study design
Randomised controlled study with two intervention arms and one control arm

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patient activation

Interventions
There are two intervention arms and the intervention consists of two steps.

Step 1: Patients from both intervention groups will receive a postal letter encouraging them to talk to their GP about their medication. Postal-mailed letters will be signed by SWICA and the Institute of Primary Care Zurich. In addition, they receive information about an algorithm that their GP could use to reduce the number of drugs. The algorithm is based on the Good Palliative Geriatric Algorithm for drug discontinuation and is tested in Swiss GP practices. For each drug, the following points are suggested to be discussed between patient and GP (or another physician):
- Is there still an indication for the patient's drug in the current situation?
- Is there a high potential of an adverse effect, or is even an adverse effect present?
- Is the actual dosing rate for the patient's situation correct?
- Is there a better alternative?

Patients participating in intervention group 1 will additionally receive a phone call (within 2 weeks after sending the letter) from a trained santé24 physician or pharmacist who follows a structured script to motivate the patient to plan a consultation with their GP to review their medication use and will explain the algorithm. If patients do not have a GP, the santé24 physician or pharmacist suggests the patient contact the physician prescribing most of his/her drugs for a deprescribing consultation. If the patient rejects this suggestion, the santé24 provider offers a telephone consultation from a santé24 physician for this purpose within one week. They will not give advice on patients' medication use during the activation call. They will only try to activate the patients to have a medication review with their GP (or other physician or santé24 physician). The santé24 physician making the telephone consultation will be trained by IHAMZ staff.

Step 2: After four months, patients of both intervention groups will receive a reminder to speak to their GP about their medication use. In addition, they will receive a questionnaire asking whether an encounter with the GP has taken place and if they discussed the medication list. If this was the case, they will be asked if the algorithm has been used or - when the algorithm was not used - which barriers exist for using the algorithm. The patients who do not return this questionnaire within three weeks will be contacted by telephone by a study nurse who will motivate the patient to fill in the questionnaire or answer the same questions by phone.

The control group will receive usual care.

Duration from start selection patients to last participation of patients will be around 6 months. Afterwards, follow up will last for 6 months, data collection will take 3 months longer.

Intervention Type

Behavioural

Primary outcome measure
Having a GP consultation with a medication review activity between the start of the study (when the patients of the intervention group receive the letter) and the moment of filling in the questionnaire, 4 months later. Information is asked for in the questionnaire collected at 4 months.

Secondary outcome measures
From claims data:
1. Number of drugs using ATC coding
2. Number of physicians prescribing drugs
3. Number of healthcare contacts (Emergency Department, hospital, specialist, GP)
4. Hospitalisation
5. Cost of drugs and healthcare services
Measurement takes place at the start of the study (when the letter has been sent to the patients of the intervention groups, T0), after 4 months (T1), after 7 months (T2), and after 10 months (T3). The study takes into account a delay of three months for the time it takes for patients to claim their used services and drugs and for the insurer to process this.

From questionnaires (if not reachable: by telephone interviews)
1. Barriers towards having a GP consultation, if the patient has not had a consultation
Only intervention groups:
1. Attitude towards receiving information from insurer to activate patients
2. Use of the algorithm during consultation with GP. If the algorithm is not used: what were barriers towards use of the algorithm
3. Readiness for alternative healthcare provider counseling, for example with pharmacist or physician santé24 or any other healthcare provider
4. Having a medication review with another physician
5. Having a medication review with telemedicine physician
All outcomes will be collected per patient

Overall study start date
30/05/2019

Completion date
31/05/2021

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Patients insured at SWICA
2. German-speaking
3. 60 years or older
4. Using at least five different drugs, at least three original packages over the last 12 months and at least one month distance in between. Exception of this 12 months rule and included in the data are androgens, vitamin B12, antineoplastic and immunemodulating agents and drugs for treating osteoporosis. Excluded drugs are topical (including dermatologicals, nasal-, throat-,

cough and cold preparations, transdermal opioids), intravenous and homeopathic drugs, vaccines, surgical dressings, contrast agents as well as products from these pharmaceutical companies (Ceres®, Similisan®, Omnida®, Spagyros® and Vogel®)
5. Signed Informed Consent after being informed

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
750

Total final enrolment
0

Key exclusion criteria
Patients insured at SWICA with a GP guided healthcare plan

Date of first enrolment
01/07/2019

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Zurich
Institute of Primary Care
Pestalozzistrasse 24
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Sponsor information

Organisation

University of Zurich

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Sponsor type
University/education

Website
https://www.hausarztmedizin.uzh.ch

ROR
https://ror.org/02crff812

Funder(s)

Funder type
University/education

Funder Name
Universität Zürich

Alternative Name(s)
University of Zurich, Switzerland, University of Zurich, UZH

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Funder Name
SWICA insurance

Results and Publications

Publication and dissemination plan
The study protocol will be submitted for publication in the BioMed Central journal “Implementation Science” before completion of patient recruitment. Full study results are intended to be published in an international scientific journal in 2021 and at medical conferences. The results of the study will also be communicated to the participated patients and their GPs. The researchers also plan to publish the protocol prior to the start of the study

Intention to publish date
31/05/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are currently unknown and will be made available at a later date. All study data will be archived at the study center (Institute of Primary Care, UniversityHospital Zurich) for a minimum of 10 years after completion or premature termination of the clinical trial.

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