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Hospital discharge study

Submission date 03/01/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/01/2018	**Overall study status** Completed	
Last Edited 01/09/2022	**Condition category** Other	

Plain English summary of protocol

Background and study aims:
Elderly patients suffering from multiple diseases often have to take a large variety of different drugs. Unfortunately and even though every individual drug might have its justification and benefits, long and complicated medication lists bring along a considerable risk of unwanted drug effects. These might be due to unforeseen interactions of the many preparations or due to the increasing probability of prescription or intake errors. During a hospital stay, the number of prescribed medicines often rises once more. On the other hand, follow-up general practitioners or the patients themselves show a tendency not to maintain the changes introduced in the hospital after discharge, but to switch back to the usual drug regimens that they are already familiar with. The purpose of the present study is to examine whether a systematic discharge procedure coupled with better communication among hospital physicians, the patients and their general practitioners can help to improve the patients' medication at discharge. We expect that the successful study will promote shortening of overly long medication lists by "deprescribing" inappropriate drugs. Ultimately, this study will help to extend the time until the next hospital admission and thus lead to a higher quality of life after discharge.

Who can participate?
Senior hospital physicians of participating hospitals in the German-speaking part of Switzerland with their subordinate assistant physicians and their in-hospital patients of at least 60 years of age and with 5 or more drugs prescribed.

What does the study involve?
The senior hospital physicians are assigned by chance to either the intervention or the control arm of the study. The senior hospital physicians are then be instructed by the study center about their respective discharge and communication strategy and in turn teach their assistant physicians how to apply it to the patients to be discharged. Over a period of up to 4 months, the hospital physicians apply the assigned discharge strategy to about 50 suitable patients per senior hospital physician. In particular, the medication lists and quality of life scores of these patients are recorded at the time of leaving the hospital. Subsequently, after 1, 3 and 6 months, more data is collected from the patients on their number of drugs, quality of life and doctor contacts, hospital readmissions or deaths. In case of incomplete responses from the patients themselves, the study team tries to collect the missing data from relatives, general practitioners or health insurance companies.

What are the possible benefits and risks of participating?
Study participants may benefit directly from the favorable effects of an optimized medication list and an improved information flow at discharge. However, changing their medication lists might also lead to undesirable consequences. Therefore, the general practitioners will be informed about their patients' participation in the study and will be asked to pay particular attention to possible side effects. Moreover, should previously well-controlled symptoms of illnesses appear more frequently or in higher intensity after a change of drugs, then that same change can be reversed immediately at any time.

Where is the study conducted?
Institute of Primary Care of the University of Zurich, Switzerland

When is the study starting and how long is it expected to run for?
January 2017 to September 2021 (updated 10/07/2020, previously: December 2020)

Who is funding the study?
1. National Research Programme "Smarter Health Care" (NRP 74), Swiss National Science Foundation (Switzerland)
2. Institute of Primary Care, UniversityHospital Zurich (Switzerland)

Who is the main contact?
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Improving inappropriate medication and information transfer at hospital discharge: A cluster-RCT

Acronym
HDS

Study objectives
A simple medication review tool in combination with a defined communication strategy at hospital discharge leads to longer hospital readmission times compared to usual care at discharge, and has the potential to improve the patients' health outcomes and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/02/2019, Ethikkommission Zürich (Ethics Committee Zurich, Stampfenbachstrasse 121, CH-8090 Zurich, Switzerland; +41 (0)43 259 79 70; info.kek@kek.zh.ch), ref: BASEC-Nr. 2018-00215

Study design
Double-center double-blind cluster-randomized parallel-controlled clinical trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Discharge of multimorbid elderly hospital patients

Interventions
Randomisation on the level of senior hospital physicians (= clusters) is done using a software random number generator. A minimization approach is used to restrict potential imbalance between the two study arms in terms of cluster covariates.

In the intervention group, the senior hospital physicians takes part in a teaching session of two hours duration about how to integrate a structured medication review and specific elements of communication into the daily discharge routine. The senior physicians are responsible for instructing their assistant physicians in patient recruitment and carrying out the correct discharge procedure.

The assistant physicians critically review their patients' medication lists, discuss the results of these reviews and their suggestions with the patients and compile revised medication lists which they then communicate to the patients' general practitioners with an invitation for discussion.

The senior hospital physicians in the control group undergo a two hour instructiont addressing multimorbidity, patient in- and exclusion and the handling of the different data collection forms. Their assistant physicians will follow the "usual" discharge routine of their clinics.

Intervention Type
Behavioural

Primary outcome(s)
1. Time (in days) without readmission to hospital is collected using Patient records (patient questionnaires and/or calls, general practitioner records, hospital records, health insurance company records) and consecutive calculation, within 6 months after discharge

Key secondary outcome(s))
1. Readmission rates are collected using patient records (patient questionnaires and/or calls, general practitioner records, hospital records, health insurance company records) within 1, 3 and 6 months after discharge
2. Numbers of emergency department visits or general practitioner encounters are measured using patient records (questionnaires and/or calls, general practitioner records, hospital

/emergency department records, health insurance company records) within 1, 3 and 6 months after discharge
3. Deaths during follow-up of 6 months are measured using patient records (general practitioner records, hospital records, health insurance company records)
4. Reasons for hospital readmission (when applicable), emergency department visits, general practitioner encounters or death are measured using patient records (questionnaires and/or calls, general practitioner records, hospital/emergency department records, health insurance company records)
5. Numbers of drugs at discharge and at 1, 3 and 6 months after discharge are measured using hospital records at discharge and patient records and/or calls (general practitioner records, health insurance company records)
6. Anatomical therapeutic chemical classes (ATC-codes) of the drugs prescribed/de-prescribed at discharge and at 1, 3, and 6 months after discharge are measured using hospital records at discharge and patient records and/or calls (general practitioner records, health insurance company records) and consecutive classification at study center
7. Proportions of potentially inappropriate medications (PIMs) at discharge and at 1, 3 and 6 months after discharge are measured using hospital records at discharge and patient records and /or calls (general practitioner records, health insurance company records) and consecutive classification at study center based on updated Beers criteria (2012) and PRISCUS list
8. Patients' quality of life at discharge and at 1, 3 and 6 months after discharge is measured using patient questionnaire (EQ-5D-3L-scale)

Descriptors of clusters (hospital types, type and size (number of beds) of clinics) and of individual participants (sex, age) will be collected and treated as covariates. Additionally, the following indicators of process quality will be collected: Hospital physician-general practitioner contacts with regard to the impending discharge, frequency of general practitioners' utilization of communication offer by hospital physicians, ratings of feasibility/acceptance among hospital physicians, barriers and enablers of deprescribing, dropout rates of hospital physicians, general practitioners and patients.

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. In-hospital patient at the time of inclusion
2. Male or female of 60 years or older with 5 or more drugs prescribed
3. Signed informed consent or – in case of a patient incapable of judgement – written consent of a representative according to the Swiss law (fulfillment of the criteria laid down in HFG Art. 24, 1a.-c. with a legal representative according to ZGB Art. 378)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
687

Key exclusion criteria
1. End-stage disease with a life expectancy below 3 months
2. Cognitive inability to follow study procedures neither independently nor with assistance
3. Hospitals who took part in the Swiss national pilot project “progress! Sichere Medikation an Schnittstellen” will not be considered for participation in the trial (but may be involved in the pilot phase of the study).

Date of first enrolment
01/05/2018

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Zurich
Institute of Primary Care
Pestalozzistrasse 24
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CH-8091

Study participating centre
University Hospital Bern
Institute of Primary Health Care
Gesellschaftsstrasse 49
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Sponsor information

Organisation

University Hospital of Zurich

ROR
https://ror.org/01462r250

Funder(s)

Funder type
University/education

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung, National Research Programme “Smarter Health Care” (NRP 74)

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

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

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available in anonymised form upon reasonable request for result verification or other scientific purposes related to the present study from the primary contact under the condition that all data will be deleted at the latest 10 years after termination of the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/08/2022	01/09/2022	Yes	No
Protocol article	protocol	27/12/2018		Yes	No
Other publications	process evaluation	27/05/2021	01/06/2021	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