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In-hospital medication self-management: the impact on medication adherence in patients with polypharmacy after hospital discharge

Submission date
06/12/2023

Recruitment status
No longer recruiting

Registration date
11/12/2023

Overall study status
Ongoing

Last Edited
27/05/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Healthcare providers usually manage medication for patients during hospitalisation, although patients are expected to self-manage their medication once discharged home. A lack of self-management competencies is found to be associated with low adherence levels and medication errors harming patients' health. Currently, patients seldom receive support or education in medication self-management. When self-management is allowed during hospitalization, it rarely is provided using a structured, evidence-based format. Therefore, an in-hospital medication self-management intervention (i.e., SelfMED) was developed based on current evidence. To date, empirical data demonstrating the effect of SelfMED on medication adherence is lacking. The primary objective of this study is to evaluate the effect of the SelfMED intervention on medication adherence at 2 months after discharge in patients with polypharmacy, as compared to usual care. The secondary objectives are to evaluate the effect of in-hospital medication self-management on outcomes at the patient level (i.e., self-management, knowledge, satisfaction), at the healthcare provider level (i.e., staff satisfaction, workload) and the healthcare system level (i.e., healthcare services utilization).

Who can participate?
Dutch-speaking patients aged 18 years and over who are taking five or more chronic medications at the time of hospital admission (i.e., polypharmacy) of which at least three are administered orally, hospitalized for at least 3 days at one of the participating wards and planned discharge towards home, will be eligible for inclusion. A medication is classified as chronic when it is taken consistently for a minimum of 3 months. An additional criterion for patients being recruited consists of being eligible for medication self-management according to the SelfMED-assessment tool.

What does the study involve?
The study will start with a control phase investigating usual care (i.e., medication management entirely provided by healthcare providers), followed by an intervention period, investigating the effects of the SelfMED-intervention. SelfMED consists of multiple components: (1) a stepped assessment evaluating patients' eligibility for in-hospital medication self-management, (2) a

monitoring system allowing healthcare providers to follow-up medication management and detect problems, and (3) a supportive tool providing healthcare providers with a resource to act upon observed problems with medication self-management. Patients recruited during the control and intervention period will be monitored over 2 months after discharge. Medication adherence will be measured at 2 months after discharge, along with self-management, medication knowledge, patient and staff satisfaction, perceived workload and healthcare service utilization.

What are the possible benefits and risks of participation?
The SelfMED intervention offers the opportunity to enhance patients' medication self-management competencies during hospitalisation, under the supervision and with support from healthcare providers to promote safe medication use at home. Patients will have the opportunity to become acquainted with medication that is newly prescribed or altered, which will benefit medication knowledge, thereby increasing proper medication use. The team of healthcare professionals can identify and address issues in medication management during hospitalisation and hence prevent problems after discharge. In-hospital medication self-management will stimulate patient involvement, autonomy and independence regarding medication management which will contribute to patient satisfaction about pharmaceutical care services. There are no direct risks to the participants in this study.

Where is the study run from?
University of Antwerp (Belgium)

When is the study starting and how long is it expected to run for?
November 2021 to October 2025

Who is funding the study?
1. Research Foundation Flanders (Belgium)
2 University of Antwerp (Belgium)

Who is the main contact?
Laura Mortelmans, laura.mortelmans@uantwerpen.be (Belgium)

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
version 1.0 - 11/12/2023

Study information

Scientific Title
The effect of an in-hospital medication self-management intervention (SelfMED) on medication adherence in polypharmacy patients post-discharge: a pre-post intervention study

Acronym
SelfMADiP

Study objectives
Current study hypothesis as of 03/04/2024:
The primary hypothesis is that, compared to usual care, the SelfMED intervention improves medication adherence at two months post-discharge. The secondary hypotheses are that patients' medication self-management, medication knowledge and patient and staff satisfaction improves while workload and healthcare service utilization will decrease.

Previous study hypothesis:
The primary hypothesis is that, compared to usual care, the SelfMED intervention improves medication adherence by 15% at two months post-discharge. The secondary hypotheses are that

patients' medication self-management, medication knowledge and patient and staff satisfaction improves while workload and healthcare service utilization will decrease.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/11/2023, Ethics committee of Antwerp University Hospital (Drie Eikenstraat 655, Edegem, 2650, Belgium; +32 (0)3 821 38 97; ethisch.comite@uza.be), ref: B3002023000176

Study design
Multicentre prospective pre-post intervention study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home, Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Hospitalised patients with polypharmacy (i.e., taking five or more chronic medications)

Interventions
During the control period, care as usual will be offered which comprises medication management (storage, preparation and administration) entirely provided by healthcare providers during hospitalisation.

During the intervention period, self-management of medication during hospitalisation (i.e. SelfMED) will be offered with rigorous control of medication-taking behaviour and with education and support from nurses, physicians and hospital pharmacists to improve pharmaceutical self-care. SelfMED is an evidence-based intervention consisting of multiple components:
1. A validated stepped assessment tool evaluating patients' eligibility for medication self-management during hospitalisation (SelfMED assessment)
2. A monitoring system allowing healthcare providers to follow adherence and detect errors in patients' medication self-management (i.e., SelfMED monitor)
3. Measures for healthcare providers to support medication self-management in patients (i.e., SelfMED support)

Patients recruited during the control and intervention period will be monitored over a course of 2 months post-discharge.

Intervention Type
Other

Primary outcome measure
Medication adherence measured by pill counts, based on preserved medication packages, and determined at 2 months post-discharge. A threshold of 80% of medications taken will be used to differentiate between adherent and non-adherent patients.

Secondary outcome measures
1. Patient-reported medication adherence: A self-report questionnaire (i.e., Probabilistic Medication Adherence Scale) will be completed by patients upon admission and 2 months post-discharge. During 2 months, patients are requested to keep a diary in which medication-related problems are registered (on paper).
2. Self-management of medication will be defined as 'the patients' ability to manage their medication regimen'. Upon admission and 2 months post-discharge, problems with medication self-management experienced by patients will be evaluated through a self-developed self-report survey.
3. Medication knowledge: Upon admission and 2 months post-discharge, four types of medication will be randomly selected from the patient's medication list. Regarding these medications, knowledge will be assessed including medication name, indication, dose, administration route and administration time (correct yes/no). The sum scores (sum of all correct answers) of total knowledge of chronic medication will be calculated.
4. Patient satisfaction with pharmaceutical care: At discharge, patients will be questioned about their satisfaction with the received pharmaceutical care during hospitalisation through a visual analogue scale.
5. Healthcare providers' satisfaction with pharmaceutical care: At the end of the study, nurses, physicians and pharmacists will be questioned about their satisfaction with pharmaceutical care provided through a visual analogue scale, as well as the advantages and disadvantages of usual care and medication self-management using open-ended questions.
6. Healthcare providers' workload: At the end of the study, nurses, physicians and hospital pharmacists indicate the impact of pharmaceutical care on their workload using a 10-point rating scale.
7. Healthcare service utilization: 2 months post-discharge, patients will be questioned about medication-related advice-seeking behaviour and health services utilization through a self-reported questionnaire including number of hospital readmissions, nurse visits and consultations with general practitioners.

Overall study start date
01/11/2021

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Dutch-speaking
2. 18 years or older
3. Taking five or more chronic medications at the time of hospital admission (i.e., polypharmacy) of which at least 3 oral medications. Medications are considered chronic if used for at least 3

months.
4. Hospitalized for at least 3 days
5. Planned discharge towards home
6. Being eligible for medication self-management according to the SelfMED-assessment tool

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
450

Key exclusion criteria
1. Nursing home residents
2. Patients with a neuro-psychiatric diagnosis of dementia or Mini Mental State Examination <24 /30
3. Patients with a terminal illness (i.e., life expectancy less than 3 months)
4. Patients where preparation and administration of medication are usually performed under the supervision of an (in)formal caregiver
5. Patients unable to provide consent

Date of first enrolment
01/02/2024

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
Belgium

Study participating centre
Antwerp University Hospital
Belgium
2610

Study participating centre

Jessa Hospital
Belgium
3500

Sponsor information

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University/education

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ROR
https://ror.org/008x57b05

Funder(s)

Funder type
Government

Funder Name
Fonds Wetenschappelijk Onderzoek

Alternative Name(s)
Research Foundation Flanders, Flemish Research Foundation, FWO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location

Belgium

Funder Name
Universiteit Antwerpen

Alternative Name(s)
University of Antwerp, UAntwerp, Universiteit van Antwerpen, Uantwerpen

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Belgium

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
28/02/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Tinne Dilles (tinne.dilles@uantwerpen.be).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/05/2024	16/05/2024	Yes	No