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Process Optimization Of the Medicines' pAthway in nursing Homes

Submission date
25/03/2025

Recruitment status
No longer recruiting

Registration date
07/05/2025

Overall study status
Ongoing

Last Edited
07/05/2025

Condition category
Other

[_] 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
The medicines' pathway in nursing homes is complex and challenging, resulting in processes that are prone to medication errors and not automatically person-centered. A need for quality improvement initiatives is present for which a systems approach, rather than single initiatives focusing on specific aspects, might be useful. Hence, the POOMAH study has been set up, supporting nursing homes in the evaluation and improvement of their medicines' pathway. Objectives of POOMAH include to determine the baseline quality of the medicines' pathway in nursing homes, and to evaluate and compare the effectiveness of different support programs (i.e. access to toolbox, intervision, external coaching or integration of a coordinating pharmacist) provided to nursing homes to improve the quality of the medicines' pathway.

Who can participate?
All Flemish nursing homes were able to enroll.

What does the study involve?
Participating nursing homes are randomly allocated into one of four support programs. Nursing homes in Program 1 gain access to a toolbox that provides educational and supportive material with regard to the medicines' pathway and its processes (e.g. medication prescribing). Nursing homes in Program 2 gain access to that same toolbox and in addition are asked to take part in intervision with fellow nursing homes to share experiences. Nursing homes in Program 3 can access the toolbox, take part in intervision and are supported by an external coach, i.e. a pharmacist that acts as a process consultant. At last, nursing homes in Program 4 can access the toolbox, take part in intervision and are supported by a coordinating pharmacist who temporarily becomes an integral part of the multidisciplinary team of the nursing home (in contrast to the external coach who does not become a member of the multidisciplinary team).

What are the possible benefits and risks of participating?
The main benefit for participants in the study is the evaluation and improvement of the medicines' pathway in participating nursing homes. Insights of the study will help to shape a qualitative medication policy in participating and non-participating nursing homes and their residents. The study contains no risk for participating nursing homes or their residents.

Where is the study run from?
A total of 100 nursing homes has been recruited (i.e. 6 in the pilot study, 94 for the main part of the study). The study is organized by KU Leuven.

When is the study starting and how long is it expected to run for?
September 2023 to January 2026

Who is funding the study?
Department of Care (Flanders)

Who is the main contact?
Dr Amber Damiaens, amber.damiaens@kuleuven.be
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Study website
https://poomah.be/

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
S68429

Study information

Scientific Title
Evaluation and comparison of the effectiveness of four different support programs (from access to a toolbox to the integration of a coordinating pharmacist) on the quality of the medicines' pathway in nursing homes

Acronym
POOMAH

Study objectives

The study hypothesis states that the POOMAH intervention is effective in improving the quality of the medicines' pathway in nursing homes. In this regard, it can be hypothesized that Support Program 2 is more effective in improving the quality of the medicines' pathway in nursing homes than Program 1; Program 3 is more effective than 2; Program 4 is more effective than 3.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/03/2024, Ethics Committee Research UZ / KU Leuven (Herestraat 49, Leuven, 3000, Belgium; +32 16 34 86 00; ec@uzleuven.be), ref: S68429

Study design
Multi-arm pre-post cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Care home

Study type(s)
Other, Safety, Efficacy

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
Improvement of the quality of the medicines' pathway in nursing homes

Interventions
Nursing homes (NHs) are allocated to one of the four support programs, receiving different formats and intensities of support during one year (2025).

NHs in Program 1 gain access to a (mostly digital) toolbox. NHs in Program 2 gain access to that same toolbox, and take part in intervision with fellow NHs. NHs in Program 3 gain access to the toolbox, take part in intervision, and receive support from an external coach (i.e. a pharmacist by training, acting as a process consultant). At last, NHs in Program 4 gain access to the toolbox, take part in intervision, and receive support from a coordinating pharmacist (i.e. a pharmacist who temporarily becomes an integral part of the nursing home's multidisciplinary team).

The sample of 100 nursing homes is randomised into the different programs (cfr. supra), stratified on membership to a professional association, initial performance score and number of beds. Since these characteristics of all participating centres are known at the start of the study, a list can be created with all possible randomisations safeguarding the required balance in characteristics. From this list of acceptable randomisations, one is drawn at random.

Intervention Type
Other

Primary outcome measure
The primary outcome consists of the quality of the medicines' pathway in participating NHs. This quality is represented by overall performance scores which are calculated through performance questionnaires, measured both at baseline (end of 2024) at the end of the study (i.e. after 1 year, January 2026).

Secondary outcome measures
1. Number of (psychoactive) medications used by residents, reported in an Excel-file by each nursing home, both at baseline (end of 2024) at the end of the study (i.e. after 1 year, January 2026).
2. Quality of individual processes of the medicines' pathway, represented by process-specific performance scores that are calculated through performance questionnaires, measured both at baseline (end of 2024) at the end of the study (i.e. after 1 year, January 2026).
3. Quality of important key activities of the medicines' pathway, represented by activity-specific performance scores that are calculated through performance questionnaires, measured both at baseline (end of 2024) at the end of the study (i.e. after 1 year, January 2026).
4. Number of falls of residents, reported in an Excel-file by each nursing home, both at baseline (end of 2024) at the end of the study (i.e. after 1 year, January 2026).
5. Number of hospitalizations of residents, reported in an Excel-file by each nursing home, both at baseline (end of 2024) at the end of the study (i.e. after 1 year, January 2026).

Overall study start date
01/09/2023

Completion date
31/01/2026

Eligibility

Key inclusion criteria
1. Local project teams: at least the nursing home's coordinating physician, quality coordinator and one head nurse
2. Other nursing home staff: nurses, nurse aids, pharmacist, general practitioners, ... - if involved or targeted by the quality improvement initiatives set up by the nursing home
3. Nursing home residents and carers - if involved or targeted by the quality improvement initiatives set up by the nursing home

Participant type(s)
Health professional, Carer, Employee, Resident

Age group
Not Specified

Sex
Both

Target number of participants

100 nursing homes are included and allocated to one of the four support programs (i.e. 25 nursing homes in each arm).In each NH, we aim to recruit at least the members of the local project team (minimum 3), five other nursing home staff members involved or affected by the project, and five nursing home residents and relatives/informal caregivers involved or affected by the project (i.e. approximately 15 participants per NH).

Key exclusion criteria
1. Short stay, service flats, or revalidation
2. Refusal to participate

Date of first enrolment
11/03/2024

Date of final enrolment
15/05/2024

Locations

Countries of recruitment
Belgium

Study participating centre
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/05f950310

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Care (Flanders)

Results and Publications

Publication and dissemination plan
Planned publications in peer-reviewed journals.

Intention to publish date
31/01/2027

Individual participant data (IPD) sharing plan
Datasets generated during and/or analysed during the current study are not expected to be made available due to containing sensitive data.

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?
Protocol file	version 5	17/12/2024	01/04/2025	No	No