PROCESS OPTIMIZATION OF THE MEDICINES' PATHWAY IN NURSING HOMES:

THE POOMAH STUDY

S68429

STUDY PROTOCOL

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1 SUMMARY

The **medicines' pathway** in nursing homes (NHs) 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.

The **Process Optimization Of the Medicines' pAthway in nursing Homes (POOMAH)** project will be set up to support Flemish NHs to improve the quality of their medicines' pathway. Objectives of POOMAH include to determine the quality of the medicines' pathway in NHs (i.e. baseline), to explore associations between organizational characteristics of NHs and the quality of the medicines' pathway, and to evaluate and compare the effectiveness of different formats and intensities of support (i.e. access to toolbox, intervision, external coaching or integration of a coordinating pharmacist) provided to NHs to improve the quality of the medicines' pathway.

Outcomes relate to the quality of the medicines' pathway in participating NHs, through the calculation of performance scores. Besides this, a thorough process evaluation will be performed.

In total, support will be provided for approximately 100 NHs in the overall three-year quality improvement project. The allocation of NHs to intervention arms (i.e. different formats and intensities of support) will be executed by means of stratified randomization.

Both quantitative and qualitative data will be collected and will be analyzed by appropriate statistical tests and content/thematic analysis, respectively.

2 SAMENVATTING

Het medicatieproces in woonzorgcentra is complex en uitdagend, wat leidt tot processen die foutgevoelig zijn en niet automatisch persoonsgericht. Er is daardoor nood aan kwaliteitsverbeterende initiatieven met een systeemsgerichte aanpak in plaats van afzonderliijke acties gericht op één specifiek aspect van het medicatieproces.

De POOMAH-studie, ofwel 'Optimalisatie van het medicatieproces in woonzorgcentra' wordt opgericht om Vlaamse woonzorgcentra te ondersteunen in het verbeteren van de kwaliteit van hun medicatieproces.

De doelstellingen van de POOMAH-studie omvatten het in kaart brengen van de huidige kwaliteit van medicatieprocessen in woonzorgcentra, bekijken welke verbanden er mogelijks zijn tussen de kwaliteit van het medicatieproces en organisatorische kenmerken van woonzorgcentra, en om te evalueren welke vorm en mate van ondersteuning het meest effectief is om woonzorgcentra kwaliteitsverbetering te laten realiseren inzake hun medicatieproces.

Uitkomsten die in kaart zullen gebracht worden, hebben betrekking op de kwaliteit van het medicatieproces. Meer bepaald zal er gebruik gemaakt worden van performantiescores. Daarnaast zal ook een grondige procesevaluatie worden uitgevoerd.

In totaal, in de loop van het 3-jaar-durende project, wordt ondersteuning voorzien voor ongeveer 100 woonzorgcentra. De vorm en mate van ondersteuning dat voorzien wordt, wordt bepaald door de interventie-arm waaraan het woonzorgcentrum wordt toegewezen. De toewijzing gebeurt aan de hand gestratifieerde randomisatie.

Zowel kwantitatieve als kwalitatieve data zullen verzameld en geanalyseerd worden, en dit door middel van, respectievelijk, gepaste statistische testen en een content/thematische analyse.

3 GENERAL INFORMATION

Supervisor:
Prof. Veerle Foulon
Clinical Pharmacology & Pharmacotherapy
Herestraat 49, O&N II, box 521
3000 Leuven
+32 16 32 34 64
Veerle.foulon@kuleuven.be

Postdoctoral researcher:
Amber Damiaens
Clinical Pharmacology & Pharmacotherapy
Herestraat 49, O&N II, box 521
3000 Leuven
+32 16 19 41 74
amber.damiaens@kuleuven.be

PhD researcher:
Astrid Frisson
Clinical Pharmacology & Pharmacotherapy
Herestraat 49, O&N II, box 521
3000 Leuven
+32 16 32 25 65
astrid.frisson@kuleuven.be

4 INTRODUCTION

The World Health Organization (WHO) defines **'quality of care**' as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes" (1). One of the many health services provided in nursing homes (NHs) is prescribing, administering and monitoring of medication – processes that belong to what is called '**the medicines' pathway**'.

Already some years ago, researchers in the UK observed at least one **medication error** in 69.5% of nursing home residents (NHRs) in either the prescribing, dispensing, administration or monitoring process of the medicines' pathway (2). A systematic review by Ferrah et al., on the other hand, indicated that 16 to 27% of NHRs were subject to medication errors in the same processes. Furthermore, they reported that 13-31% of NHRs were exposed to one or more medication errors after a transfer from the hospital to the NH (3). Recent studies in Spain and USA, as well, state that up to 40% of NHRs are exposed to medication errors at NH admission, either when arriving from home or from the hospital (4,5). In Belgium, a recent policy report (October 2022) on the quality of the medicines' pathway in Flemish NHs highlights gaps in the documentation of medication plans, as well as in the processes of medication storage and administration (6).

It is clear that the medicines' pathway in NHs is complex and challenging, resulting in processes that are prone to medication errors and not automatically person-centered. Hence, a need for quality improvement initiatives is present. As errors occur in all steps of the medicines' pathway, and challenges are present not only on resident but also on organizational level, the entirety of the medicines' pathway can be seen as an error-prone system (7). Hence, a **systems approach** to quality improvement, rather than single initiatives focusing on specific aspects, might be useful to reduce the prevalence of medication errors (i.e. to prevent them) and minimize their impact on NHRs (2,3).

As a means to support such systems approach, a framework has been developed by Strauven et al. that describes all medication-related activities in NHs. The framework defines a total of eight processes, going from (re-)admission of the resident over medication prescribing to medication administration and monitoring of medication (side-)effects, supporting the implementation of a safe and effective medicines' pathway. Processes are further divided into key activities (KAs) and best practices (BPs) (8). Following the RESPECT (RESident's Participation in the Evaluation and Customization of Therapy) project, the framework has been updated (2022) to not only support a safe and effective but also a person-centered medicines' pathway in NHs (9–12). The updated version of the framework contains eight processes, 29 KAs and 152 BPs (not yet published, see Appendix 1).

5 OBJECTIVES

The overall aim of the project is to improve the quality of the medicines' pathway in Flemish NHs. As defined by the WHO, quality health services should be **effective, safe, and person-centered** (13). Hence, quality improvement initiatives should focus on these attributes in order to achieve a qualitative medicines' pathway, one of the many health services provided in NHs. In this regard, the **Process Optimization Of the Medicines' pAthway in nursing Homes** (POOMAH) project will be set up to support Flemish NHs, guided by the aforementioned framework, to improve the quality of their medicines' pathway. Within POOMAH, four specific study objectives can be distinguished:

1) To determine the quality of the medicines' pathway in NHs (i.e. baseline)
2) To benchmark the quality of the medicines' pathway across NHs (i.e. baseline)
3) To explore the association between organizational characteristics of NHs and the quality of the medicines' pathway
4) To evaluate and compare the effectiveness of different formats and intensities of support (i.e. access to toolbox, intervision, external coaching or integration of a coordinating pharmacist) provided to NHs to improve the quality of the medicines' pathway (i.e. the primary objective)

6 OUTCOMES

6.1 Primary outcomes

The primary outcome consists of the quality of the medicines' pathway in participating NHs, represented by overall performance scores, measured at the end of the study (i.e. 1 year).

6.2 Secondary outcomes

The number of (psychoactive) medications used by NHRs will be considered as a key secondary outcome. Other secondary outcomes include the quality of processes and important key activities of the medicines' pathway, represented by process-specific and activity-specific performance scores, respectively, and the number of falls and hospitalizations of NHR.

6.3 Process evaluation

As proposed by the Medical Research Council (MRC), implementation of the intervention will be monitored through a process evaluation in order to clarify causal mechanisms and to identify contextual factors that might explain variation in outcomes (14).

Experiences of NH staff, NHRs and relatives (as considered relevant in each NH) with regard to their participation in the quality improvement project will be explored thoroughly, as well as the perspectives of external coaches and coordinating pharmacists on supporting NHs in their quality

improvement initiatives. Furthermore, a thick description will be made of quality improvement initiatives set up in NHs.

7 METHODOLOGY

7.1 Study design

The POOMAH study consists of a multi-arm pre-post cluster randomized controlled trial (RCT) in Flemish NHs. Nursing homes will perform a quality assessment of their medicines' pathway at baseline and will accordingly set up and monitor quality improvement initiatives. Hence, quality improvement initiatives can be expected to differ across participating NHs. A thorough process evaluation will be performed simultaneously.

Before progressing to the cluster RCT, a pilot study will be performed to assess the feasibility of executing the large-scale cluster RCT (e.g. participant recruitment, data collection, etc.).

7.2 Intervention arms

During the quality improvement project, support will be provided to NHs as a means to improve the quality of their medicines' pathway. Four different intervention arms (i.e. Tracks), providing different formats and intensities of support to NHs during one year, can be distinguished (see Figure 1).

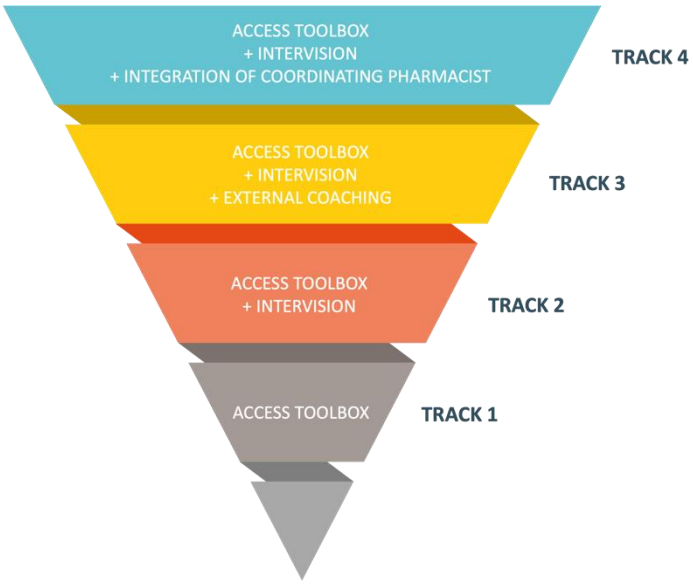

Figure 1: Four tracks of support in the quality improvement project

Nursing home staff will be made aware that the support provided in the context of the POOMAH study is of a temporary nature. Hence, the provided support (i.e. access to toolbox, intervision, external coaching, integration of a coordinating pharmacist) ends at conclusion of the study. Should NHs be willing to extend their access to the toolbox, the external coaching or the integration of a coordinating

pharmacist after conclusion of the study, NHs are expected to set up adequate agreements with KU Leuven (for the toolbox), or with external coaches or coordinating pharmacists on an individual basis, using their own financial resources if applicable.

7.2.1 Access to toolbox

All NHs will gain access to a (mainly digital) toolbox. This toolbox provides educational material and instruments that have been developed as part of earlier research projects (i.e. the Come-On study and the RESPECT-project). Tools include an e-learning on appropriate prescribing for NHRs, knowledge clips on goal-oriented care and medication decision-making, the RESPECT-tool to explore residents' personal health and life goals, the RESPECT-brochure to inform NHRs with regard to the medicines' pathway, etc. An overview of all educational materials and instruments that will be made available at the start of the project can be found in Appendix 2.

In addition to the digital part of the toolbox, a book will be made available for NHs. Each NH will receive four copies of the book. This book, authored by the research team, will offer detailed information about the medicines' pathway and how to improve the quality of the medicines' related processes.

Nursing homes will have access to the toolbox during their participation in the quality improvement project. If NHs want to keep using the toolbox after conclusion of the project, an appropriate agreement will be made up between the NH and the KU Leuven.

7.2.2 Intervision

Nursing homes assigned to Track 2, 3 and 4 will be invited to take part in intervision with fellow NHs. During these meetings, NHs will share experiences with regard to the evaluation and optimization of their medicines' pathway. Six intervision meetings will be organized during the POOMAH-study, for each intervention arm. Within each intervention arm, NHs will be grouped into smaller clusters of three to six NHs based on region. The intervision meetings will be organized in these smaller clusters in specific weeks, that will be communicated on beforehand (current planning: week 10/02; week 17/03; week 05/05; week 16/06; week 29/09; week 17/11).

Meetings will be conducted in real life at the participating NHs. Each NH will host at least one intervision meeting, with the hosting NHs responsible for organizing and moderating the meeting. The research team (VF, AD, AF) will provide all material needed for each intervision meeting, including a topic guide and supporting slides. .

To prepare the hosting NHs for their role, the research team will organize an online 'train the trainer' session one week before each intervision meeting. Per intervention arm, the project coordinators of the NHs that will host that specific intervision meeting, will be invited to the 'train the trainer' session.

During these sessions the NHs will receive comprehensive information on managing the intervision meeting and will go through the supportive material in detail.

Additionally, bi-monthly intervision meetings will be organized with external coaches (track 3) and with coordinating pharmacists (track 4). These intervision meetings will mainly be performed online, and will be moderated by the research team (AF, AD, VF).

7.2.3 External coaching

Nursing homes in Track 3 will receive six to eight visits (for a total of 12 guidance hours) from an external coach, e.g. someone who independently guides NH teams in their quality improvement efforts. External coaches are no members of the interprofessional team present in each NH, i.e. they remain independent. The NH itself is responsible for setting up and implementing initiatives to improve the quality of their medicines' pathway. During each visit, external coaches consult with the local project team and listen to their experiences with regard to setting up and implementing quality improvement initiatives. Accordingly, they can provide tips and tricks in order to help them with the development or implementation of their actions.

Between visits, NHs are allowed to consult the external coach for short questions, etc. However, the number of such 'extra' consultations should be limited to a minimum.

External coaches will have completed the lifelong learning course 'Coordinating pharmacist in nursing homes' (15), and will on their turn be supervised by the research team. Some of these pharmacists are already involved in supplying medication to NHs. If so, these pharmacists will be assigned to a NH they currently supply, provided it is geographically feasible. If no NH they supply is selected for the study in track 3, or if no match can be made, these pharmacists can be assigned a role as external coach to a NH that they do not deliver, based on geographical accessibility.

Pharmacists who are not involved in supplying NHs, will be assigned to NHs based on geographical accessibility. This approach ensures that both pharmacists who currently supply NHs and those who do not, are recruited, allowing for an exploration of both perspectives during the quality assessment of this study.

An agreement between KU Leuven and each external coach will be made up for the duration of the POOMAH study. This agreement includes a deontological clause which states that in carrying out the project, the deontological rules must be respected, and activities (actions) intended to promote or that could be interpreted as an attempt to promote their own pharmacy (or pharmacy group) must be avoided.

Furthermore, external coaches will be financially compensated for their contributions. Should NHs be willing to extend the services provided by the external coach beyond the support foreseen in the project, NHs are expected to set up an adequate agreement with the external coach themselves.

7.2.4 Integration of a coordinating pharmacist

A coordinating pharmacist will be integrated in the care team of each NH assigned to Track 4. The pharmacist will be present for 78 hours, spread over the whole intervention year. Coordinating pharmacists will become members of the interprofessional team present in each NH, i.e. they do **not** remain independent. The coordinating pharmacist leads the development and implementation of initiatives to improve the quality of the NH's medicines' pathway. He/she can therefor perform observations of the medicines-related processes in the NH, have in-dept discussions with HCPs active in the NH (including general practitioners),… Additionally, the coordinating pharmacist, as an active member of the care team, can talk with residents about medication, perform medication reviews, give training to nurses and care aids, participate in interprofessional discussions on a NHRs care plan,…

Coordinating pharmacists will have completed the lifelong learning course 'Coordinating pharmacist in nursing homes' (15), and will on their turn be supervised by the research team. Some of these pharmacists are already involved in supplying medication to NHs. If so, these pharmacists will be assigned to a NH they currently supply, provided it is geographically feasible. If no NH they supply is selected for the study in track 4, or if no match can be made, these pharmacists can be assigned a role as coordinating pharmacist to a NH that they do not deliver, based on geographical accessibility.

Pharmacists who are not involved in supplying NHs, will be assigned to NHs based on geographical accessibility. This approach ensures that both pharmacists who currently supply NHs and those who do not, are recruited, allowing for an exploration of both perspectives during the quality assessment of this study.

An agreement between KU Leuven and each coordinating pharmacist will be made up for the duration of the POOMAH study. This agreement includes a deontological clause which states that in carrying out the project, the deontological rules must be respected, and activities (actions) intended to promote or that could be interpreted as an attempt to promote their own pharmacy (or pharmacy group) must be avoided.

Furthermore, coordinating pharmacists will be financially compensated for their contributions. Should NHs be willing to extend the services provided by the coordinating pharmacist beyond the support foreseen in the project, NHs are expected to set up an adequate agreement with the coordinating pharmacist themselves.

7.3 Data collection

7.3.1 Quantitative data

Quality assessment

In each NH, a quality assessment of the medicines' pathway will occur at baseline (i.e. before) and at the end of the study (i.e. after). This assessment will be performed through the quick scan of the two-part quality assessment instrument that has been recently developed by our research group (see Appendix 3) (16). The quick scan is based on the KAs as defined in the framework of the medicines' pathway. For this quick scan, these KAs have been adjusted for readability during the pilot study. This way, the KAs are more understandable for each member of the interdisciplinary team in the NHs. The quick scan applies the importance-performance analysis (IPA) methodology, a method that has been successfully used in healthcare to identify quality aspects with the highest priority. In such assessment, respondents are asked to score both the importance and current performance of items under assessment (i.e. KAs) (17,18). The results of this analysis can be visualized on an IPA-graph that plots performance on the x-axis and importance on the y-axis. Four quadrants are formed in this process: "Concentrate Here" (high importance, low performance), "Keep up the Good Work" (high importance, high performance), "Low Priority" (low importance, low performance), and "Possible Overkill" (low importance, high performance) (19).

The only criterion applied with regard to respondents in the quick scan, is that they need to be involved in the medicines' pathway of the NH (e.g. coordinating physician, nurses, nurse aids, pharmacist, …). Respondents are asked to score the performance of each KA (i.e. To what degree is the KA performed as described?) using a 5-point Likert scale with response options 'Absolutely so', 'Rather so', 'A little', 'Rather not', 'Absolutely not'. Likewise, respondents are invited to score the importance of each KA (i.e. How important is it that the KA is performed as described?) by means of a 4-point Likert scale, including response options 'Very important', 'Rather important', 'Rather not important', and 'Not important'.

The quick scan is available in Limesurvey®, an online survey platform, and will be sent to the project coordinators of participating NHs. Project coordinators will be invited to complete the questionnaires themselves and to further distribute the quick scan to NH staff they consider relevant.

Next, the quality of the three processes 'storage', 'preparation' and 'administration' will be investigated using the detailed scan. This scan consists of 68 questions, to be answered on a five-point Likert Scale (see Appendix 17). This scan is also available in Limesurvey®. Only nurses and headnurses will be asked to complete this survey.

Other parts of the detailed scan can voluntarily be used by NHs to gain further insight in the quality of their medication process. The answers on these 'other parts' of the detailed scan are only for the NHs

to get more insight in these key activities, but will not be further used for data collection by the research team. In this way, these other parts of the detailed scan can be interpreted as just another tool of the toolbox.

Organizational characteristics

A survey has been developed, based on (inter)national literature and experiences from previous research projects, to map several organizational characteristics (see Appendix 4). The survey is divided into five categories, based on the System Engineering Initiative for Patient Safety (SEIPS) model: 1) persons, 2) tasks, 3) environment, 4) organization, and 5) technology and tools (20). The survey collects data on the number of residents and nurses employed at the NH (i.e. persons), on pharmacy services (i.e. tasks), on type pharmacy that delivers medication to the NH (i.e. environment), on the organization of medical pharmaceutical concertation (i.e. organization), on the types of patient files used (i.e. technology and tools), etc.

The survey on organizational characteristics will be made available in Limesurvey®. It will be sent to the project coordinator of each NH who will be asked to complete it.

Number of (psychoactive) drugs used by NHRs

The Flemish center of expertise in alcohol and other drugs (Vlaams expertisecentrum Alcohol en andere Drugs, VAD) provides a manual for NHs to develop a policy on the use of psychoactive medications by NHRs(21). The manual includes a monitoring tool for NHs to map the (psychotropic) medication use by NHRs, clinical outcomes (falls, hospitalizations), and the number of local interdisciplinary meetings. All data are collected on an institutional level; no data on individual residents are registered.

In POOMAH, this monitoring tool will be used to collect data on the number of (psychoactive) drugs used by NHRs, and the number of falls and hospitalizations. By comparing the number of (psychoactive) drugs used, falls and hospitalizations at the beginning and at the end of the intervention year, the impact of the project on prescribing (e.g. changes in number of chronic (psychoactive) medications used by NHRs) can be investigated.

The local project coordinator will be asked to complete the monitoring tool (Appendix 18) in collaboration with the supplying pharmacist, according to the instructions provided in the VAD manual, in the beginning (i.e. February) and at the end (i.e. December) of the intervention year .

Demographic data

Demographic data will be collected of each NH (see '*Organizational characteristics'*). Moreover, healthcare professionals participating in the NH's project team will be asked to complete a survey to collect their demographics (see Appendix 5). The same survey will be used to map demographic data

of healthcare professionals participating in interviews or focus groups (see '*6.3.2 Qualitative data*'). A tailored survey will collect demographics of nursing home residents and relatives participating in interviews or focus groups (see Appendix 6 and 7).

7.3.2 Qualitative data

Interviews and focus groups

Throughout the POOMAH study, semi-structured interviews and focus groups will be performed with members of local project teams (see '*7. Study population and recruitment*'), as well as with other NH staff, NHRs and relatives involved in quality assessment of the medicines' pathway or in setting up and monitoring of quality improvement initiatives. These interviews/focus groups will be organized during working hours, at the NH and at a time that fits participants' availabilities, and will last 30 minutes to one hour.

Intervision meetings with NHs will be considered as focus groups and will be included in the qualitative data analysis (see '*7.2.2 Intervision*'). Intervision meetings will be organized during working hours, and will last approximately one to two hours.

Likewise, the bimonthly intervision meetings with external coaches (i.e. Track 3) and coordinating pharmacists (i.e. Track 4), will be considered as focus groups.

All interviews and focus groups, including intervision meetings, will be performed by members of the research team: AF, AD, and/or VF. Preliminary topic guides for interviews and focus groups are shown in Appendix 8. Interviews and focus groups will be audio-recorded to facilitate data analysis.

Documentation

Nursing homes will be instructed to deliver all documentation related to the quality improvement project (i.e. performing the quality assessment, setting up and monitoring of quality improvement initiatives). The local project coordinator will collect all documents and will provide these to the research team via KU Leuven OneDrive in a pseudonymized manner (cfr. supra).

Tasks performed by external coaches and coordinating pharmacists

External coaches and coordinating pharmacists will be asked to register their activities throughout the study. The pharmacists will complete a shared registration form in Excel via KU Leuven OneDrive. In these forms, they will be asked to record the date of the visit, the duration of each visit and the activities performed during these visits.

7.4 Data analysis

7.4.1 Primary objective: effectiveness of different formats and intensities of support

The primary outcome measure consists of the overall performance score with regard to the medicines' pathway in participating NHs. This overall performance score will be calculated at baseline (i.e. before) and at the end of the study (i.e. after), and will be calculated on data collected with the quick scan, in particular the performance assessment. The importance assessment will thus not be used to determine the primary outcome.

For data analysis, responses collected through the performance assessment will be dichotomized. Responses 'Absolutely so' and 'Rather so' will be considered as 'key activity implemented (i.e. scored 1). The other response options ('A little', 'Rather not', 'Absolutely not') will be scored 0 and thus considered as 'not implemented'. For each respondent, a performance score will be calculated by determining the proportion of KAs considered as 'implemented'.

A before-after comparison of the overall performance scores will be executed by means of a linear, mixed model with random effects of NH and respondent (most respondents will be involved in before and after setting) and fixed effects of track, time (before/after), the interaction between track and time, type of respondent (coordinating physician, nurse, pharmacist, etc.), the NH's membership of a professional association and the number of beds available. Note that the focus of interest is the interaction between track and time. From the model, least-squares means (with 95% confidence intervals) and changes in means will be reported. If required, a transformation of the performance score will be considered to obtain a more symmetric distribution of the model residuals.

The changes of the activity-specific performance will be evaluated for each KA separately using a generalized linear mixed model (i.e. a logistic regression model with random effects of NH and respondent) with the same fixed effects as in the linear mixed model.

For the process-specific performance (which consists of a sum over a set of KAs), the same approach as for the overall performance score will be followed. However, since for some processes the number of KAs is small, an alternative approach will be considered, i.e. an analysis on KA level using the generalized linear mixed model modeling the binary outcome (Yes/No) on KA level with an additional random effect capturing the correlation between the multiple KAs per respondent at the same timepoint[1].

[1] Note that this alternative approach can also be considered for the overall performance score, i.e. modeling simultaneously the 29 binary KAs, instead of modeling the sum (using a logistic regression model with random effects of NH, respondent and respondent nested within a timepoint). The advantage is that no distributional assumption is required for the score obtained by summing the KAs. However, computational issues might arise, requiring a simplification of the random effects structure.

7.4.2 Secondary objectives

Number of (psychoactive) medications used by NHRs

The number of (psychoactive) medications used by NHRs will be considered as a key secondary outcome. These data will be collected at the beginning of the intervention and after the intervention and will be collected through the monitoring tool that has been developed by VAD.

A before-after comparison of the number of (psychoactive) medications will be executed by appropriate statistical methods.

Baseline quality of the medicines' pathway and Benchmark

Using the baseline data, descriptive statistics will be reported based on the proportion of respondents that indicated a KA is performed 'Rather so' and 'Absolutely so'. Descriptives will refer to overall performance score (sum over 29 KAs), process-specific performance (sum over set of KAs) and activity-specific performance (each KA separately). For benchmarking purposes, linear and generalized linear mixed models will be used on the baseline data yielding Empirical Bayes (EB) estimates for the NH-specific levels. These EB estimates "correct" for the difference between the number of respondents per center and for differences with respect to the fixed factors included in the model (type of respondent, membership of a professional association and the number of beds available). The linear model(s) will contain a random effect of NH and the generalized linear models (fitted on multiple KAs simultaneously) will additionally include a random effect of respondent (the latter to take into account the correlation between the KAs within the same respondent).

Associations between organizational characteristics and quality of the medicines' pathway

In a set of exploratory analyses, the aforementioned (generalized) linear mixed models planned for benchmarking will be extended to determine potential associations between organizational characteristics (see Appendix 9) and the quality of the medicines' pathway in NHs.

7.4.3 Process evaluation

As for the process evaluation, interview and focus groups will be transcribed ad verbatim. Subsequently, analysis of interview and focus group transcripts, as well as document analysis will be based on the principles of content and/or thematic analysis.

8 STUDY POPULATION AND RECRUITMENT

A pilot study will be performed first, in approximately five to ten NHs. The project call (see Appendix 10 and 11) for this phase is planned to be launched in February 2024 but will not occur before receiving

approval of the Ethics Committee. A call for the actual cluster RCT, which will include approximately 100 NHs, is scheduled to be launched in March 2024. As the sample size of 100 NHs has been determined and defined in the Decision of the Flemish Government, no sample size calculation has been performed.

Project calls for NHs will be distributed by Departement Zorg (Flemish Government) and umbrella organizations (i.e. VLOZO, VVSG and Zorgnet-Icuro). In addition to this, a dedicated call will be targeted at NHs that contacted the research team during the last year with regard to the lifelong learning course 'Coordinating pharmacist in nursing homes' or to request access to materials and tools developed during earlier research projects (e.g. Come-On study, RESPECT project).
Nursing homes who are interested to participate will be asked to register through an online application form that will be made available in Qualtrics (see Appendix 12). In this application form, NHs will be asked to formulate a motivation for participation, to indicate the willingness of the coordinating physician to participate, to make a proposal for the composition of their local project team, to suggest who will be the local project coordinator, etc.

Recruitment of NHs will occur in two stages. First, if more than 100 NHs apply, a set of 100 NHs will be drawn at random from the pool of NHs who have expressed their interest to participate in the study. This sampling, if performed, will take into account the NH's membership to a professional association, meaning that the selection of NHs will occur proportionally to the real-life distribution of NH memberships in Flanders (i.e. no membership, Zorgnet-Icuro, VVSG, and VLOZO).

The sample of 100 will be randomised into the different tracks (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 will be drawn at random.

In each NH, a local project team will be put together that consists of at least the NH's coordinating physician, quality coordinator and one head nurse. One of these will be appointed as local project coordinator. Other NH staff (e.g. nurses, care aids), as well as nursing home residents and relatives can be involved by local project teams, as considered relevant when setting up and monitoring quality improvement initiatives. 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).

Nursing homes assigned to track 3 and 4 will receive support of an external coach or a coordinating pharmacist (cfr. supra). External coaches and coordinating pharmacists will be recruited by the research team. The project call for pharmacists will be delivered via mail to all pharmacists who completed the lifelong learning course 'Coordinating pharmacist in nursing homes'. A tailored online application form will be made available for pharmacists (see Appendix 13).

9 ETHICAL AND LEGAL ASPECTS

9.1 Ethical commission

This protocol will be submitted to the ethical commission EC Research UZ/KU Leuven.

9.2 Confidentiality

The collected data will be treated in confidence. The researchers will ensure that the privacy is guarded and the identity of the participants will not be made public. The research data will only be used for scientific purposes and will be coded. Interview and focus group data will be coded by the member(s) of the research team performing the interview or focus group, and only they will be able to know the identity of participating healthcare professional, resident or relative. Documents related to the quality improvement project will be collected from the local project coordinator in a pseudonomyzed manner by replacing all identifiers (e.g. name, age, gender) by the person's function in the NH (e.g. [nurse]).
The collection, processing and disclosure of personal data, such as patient health and medical information is subject to compliance with applicable personal data protection and the processing of personal data (REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data), and repealing Directive 95/46/EC (General Data Protection Regulation).
Transcripts, survey data, registered data, etc. will be saved on a protected KU Leuven network drive (i.e. KU Leuven OneDrive). After transcribing interviews and focus groups, audiotapes will be deleted

9.3 Risks and liability

Nursing homes should be aware that KU Leuven will gain insight into the quality of their medicines' pathway. Hence, KU Leuven will potentially identify **major shortcomings** in the medicines' pathway of participating NHs and thus potential **risks to residents' safety**. Should this be the case, these shortcomings and risks will be brought to the attention of the NH's director and local project team. It is their responsibility to tackle these issues, using the support provided in the POOMAH study (cfr. intervention arm the NH is allocated to). KU Leuven is not responsible for the actions the NH does or does not set up in this regard.

In case a serious (medication-related) incident occurs during the NH's participation in the POOMAH study, the NH is expected to handle according to existing procedures with regard to the reporting of such incidents. Serious incidents should always be reported to Departement Zorg by the NH's director. More information and instructions in this regard can be found on: https://www.zorg-en-gezondheid.be/ernstige-gebeurtenis-melden-in-woonzorgvoorzieningen-en-verenigingen-voor-mantelzorgers-en#:~:text=Ernstige%20gebeurtenissen%20die%20de%20zorg,onmiddellijk%20aan%20het%20agentschap%20gemeld.

KU Leuven is and remains the owner of all data collected during the POOMAH study. Data of individual NHs will in no case be transferred to Departement Zorg or Zorginspectie. Only aggregated and processed data, in which NHs are not identifiable, will be reported to Departement Zorg, as sponsor of the study, and to other organisations that are part of the POOMAH steering committee (e.g. Zorginspectie).

9.4 Informed consent

Each study participant will receive written information concerning the nature, aims, possible risks and benefits of the research by means of a paper-based informed consent form. Informed consent forms (ICF) will be tailored to each participant's involvement in the study. All participants will be given sufficient time to consider participation. The participants will also be informed that they may withdraw from the study at any given time. Signed forms will be scanned and saved on KU Leuven OneDrive.

9.4.1 Signed study protocol and contracts

In each NH, the approved study protocol will be signed by the local project coordinator, the NH's coordinating physician and the NH's director. By signing the protocol, the project team acknowledges the NH's participation in the quality improvement study as well as their own responsibilities in this regard. Consent to process the survey on organizational characteristics and to provide pseudonymized documentation related to the quality improvement project will also be collected through this procedure. "The research team, in turn, commits to communicating all changes in advance and in writing via email to the relevant persons of the NH, and to always make the most recent version of the protocol, indicating the changes, available in the toolbox, behind a secure login on the POOMAH website."

Regarding external coaches and coordinating pharmacists, an appropriate contract will be made up for each participating pharmacist, who will be financially compensated for their contributions (in collaboration with KU Leuven LRD – Flemish and Federal Government Funding).

9.4.2 Informed consent for the quality assessment

Nursing home staff that completes the quality assessment by means of the quick scan will be requested to agree to the online information letter at the start of the assessment (see Appendix 15).

9.4.3 Informed consent for interviews and focus groups

Participants of interviews and focus groups in the context of process evaluation will be asked to sign a paper based ICF prior to the (first) interview or focus group they participate in (see Appendix 16).

10 REFERENCES

1. World Health Organization. Quality of care [Internet]. [cited 2023 Apr 6]. Available from: https://www.who.int/health-topics/quality-of-care#
2. Barber ND, Alldred DP, Raynor DK, Dickinson R, Garfield S, Jesson B, et al. Care homes' use of medicines study: Prevalence, causes and potential harm of medication errors in care homes for older people. Qual Saf Health Care. 2009;18(5):341–6.
3. Ferrah N, Lovell JJ, Ibrahim JE. Systematic Review of the Prevalence of Medication Errors Resulting in Hospitalization and Death of Nursing Home Residents. J Am Geriatr Soc. 2017;65(2):433–42.
4. Koprivnik S, Albiñana-Pérez MS, López-Sandomingo L, Taboada-López RJ, Rodríguez-Penín I. Improving patient safety through a pharmacist-led medication reconciliation programme in nursing homes for the elderly in Spain. Int J Clin Pharm. 2020;42(2):805–12.
5. Patterson ME, Bollinger S, Coleman C, Rhodes JAM. Medication discrepancy rates and sources upon nursing home intake: A prospective study. Research in Social and Administrative Pharmacy. 2022;18(5):2830–6.
6. Agentschap Zorg en Gezondheid. Medicatie in woonzorgcentra: Beleidsrapport. 2022.
7. Spinewine A, Evrard P, Hughes C. Interventions to optimize medication use in nursing homes: a narrative review. Eur Geriatr Med. 2021;12(3):551–67.
8. Strauven G, Vanhaecht K, Anrys P, De Lepeleire J, Spinewine A, Foulon V. Development of a process-oriented quality improvement strategy for the medicines pathway in nursing homes using the SEIPS model. Research in Social and Administrative Pharmacy. 2020;16(3):360–76.
9. Damiaens A, Van Hecke A, De Lepeleire J, Foulon V. Resident and informal caregiver involvement in medication-related decision-making and the medicines ' pathway in nursing homes : experiences and perceived opportunities of healthcare professionals. BMC Geriatr. 2022;22(81):1–12.
10. Damiaens A, Van Hecke A, Foulon V. Medication decision-making and the medicines' pathway in nursing homes: experiences and expectations of involvement of residents and informal caregivers. Int J Environ Res Public Health. 2023;20(11):1–13.
11. Damiaens A, Van Hecke A, Foulon V. The RESPECT-tool as a facilitator for person-centered medication reviews for nursing home residents: tool development and pilot study. Int J Clin Pharm. 2023;
12. Damiaens A, Van Hecke A, Foulon V. The RESPECT-brochure: Development of a tool to inform and empower residents and informal caregivers on the medicines' pathway in nursing homes. PEC Innovation. 2023;3(August).

13. World Health Organization. Improving the quality of health services: tools and resources [Internet]. 2018 [cited 2022 Dec 8]. p. 59. Available from: https://www.who.int/publications/i/item/9789241515085
14. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance. BMJ. 2021;374(2018):1–11.
15. KU Leuven. Getuigschrift coördinerend en adviserend apotheker in woonzorgcentra [Internet]. [cited 2023 Mar 16]. Available from: https://onderwijsaanbod.kuleuven.be/opleidingen/n/CQ_57044473.htm#activetab=diploma_omschrijving
16. Damiaens A, Strauven G, De Lepeleire J, Spinewine A, Foulon V. Stepwise development of a quality assessment instrument for the medicines' pathway in nursing homes. Research in Social and Administrative Pharmacy. 2023;19(11):1446–54.
17. Aeyels D, Seys D, Sinnaeve PR, Claeys MJ, Gevaert S, Schoors D, et al. Managing in-hospital quality improvement: An importance-performance analysis to set priorities for ST-elevation myocardial infarction care. European Journal of Cardiovascular Nursing. 2018;17(6):535–42.
18. Hoste P, Ferdinande P, Vogelaers D, Vanhaecht K, Hoste E, Rogiers X, et al. Adherence to guidelines for the management of donors after brain death. J Crit Care. 2019;49:56–63.
19. Martilla JA, James JC. Importance-Performance Analysis. J Mark. 1977;41(1):77–9.
20. Carayon P, Schoofs Hundt A, Karsh BT, Gurses AP, Alvarado CJ, Smith M, et al. Work system design for patient safety: The SEIPS model. Qual Saf Health Care. 2006;15(SUPPL. 1):50–8.
21. Popelier K, Peeters L. Psychofarmaca in woonzorgcentra [Internet]. 2018 [cited 2024 Dec 17]. Available from: https://vad.be/content/uploads/woocommerce_uploads/2018/11/VAD026_A4_Psychofarmaca_in_Woonzorgcentra-vd45xo.pdf

11 APPENDICES (SEE SEPARATE FOLDER)

1. Framework medicines' pathway in NHs
2. Overview of toolbox
3. Quick scan
4. Survey on organizational characteristics
5. Demographic data HCPs
6. Demographic data residents
7. Demographic data relatives
8. Preliminary topic guide for interviews and focus groups
9. Organizational variables
10. Project call NHs
11. Project call pharmacists
12. Application form NHs
13. Application form pharmacists (?)
14. Engagementsverklaring
15. ICF quality assessment
16. ICF interviews and focus groups
17. Detailed scan
18. Monitoring tool