Efficacy, feasibility and acceptability of the OptiMEDs tool for multidisciplinary medication review in nursing homes

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Running title:

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Key words

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Key points

The OptiMEDs intervention can support a multidisciplinary medication review, and it was feasible and to the satisfaction of the health care professionals.

These medication reviews, supported the OptiMEDs tool, resulted in a decrease of at least one medication in 36% and least one Possible Inappropriate Medication in 26% of residents.

Declarations

There were no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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1 Abstract

Aim(s): Exploring efficacy, feasibility and acceptability of a complex multifaced intervention (OptiMEDs) supporting multidisciplinary medication reviews in Belgian nursing homes (NHs).

Methods: A pilot study in 2 intervention, 1 control NH was held, involving dementia and non-dementia NH residents (>65 years). OptiMEDs provided automated assessment of possible inappropriate medications (PIMs) and patient-specific nurse observation lists of potential side-effects. Medication changes were evaluated one month after the medication review. Feasibility and acceptability was collected via surveys among the health-care professionals. Trial registration NCT04142645, 31/10/2019.

Results: Participants (n=148, n=100 in the intervention NHs) had a mean age of 87.2 years, with 75.0% females and 49.3% non-dementia patients. Prevalence of PIM use was 84.7% and of potential medication side-effects 84.5%, (range 1-19 per resident).

One month after the intervention, the medication use decreased in 35.8% and PIM use in 25.9% of surviving intervention NHresidents (n=88). GPs changed more medications when side-effects were observed (42% when side-effects present versus 12% when no side-effects, p=0.019).

Median workload for nurses was 45 minutes, 20 for pharmacists, and 8 for GPs. User satisfaction for the OptiMEDs tool was high (n=33, median score of 8, IQR 6 -8), with GPs (n=19) showing the highest appreciation. Nurses (n=9) reported a median score on the System Usability Scale of 70 (IQR 55 – 72), with lower scores for learnability aspects.

Conclusion: The OptiMEDs intervention was feasible and user-friendly, showing decreases in the medication and PIM use; without affecting patient safety. A cluster-randomized trial is needed to explore impact on patient-related outcomes.

2 Introduction

The older adults residing in a nursing home are a vulnerable, multi-morbid population, often with severe physical and cognitive dysfunction [1–3]. They often use a considerable number of systemic medication chronically, while they are more sensitive to the effects and side-effects of medications due to pharmacokinetic and pharmaco-dynamic changes [4,5].

Advanced age, a high level of multimorbidity and a high medication intake may affect functional and cognitive capabilities, social life, and quality of life (3). Predominantly psychotropic agents, antiplatelet agents, hypoglycemic medications and hypno-sedatives are related to Drug Related Problems (DRPs) [6,7]. DRPs can lead to unwanted symptoms (such as dry mouth, orthostatic hypotension, dizziness, sedation, confusion, hallucinations, bleeding) that will affect quality of life, but also lead to unwanted outcomes such as cognitive impairment, falls, hospitalization and even premature death [7–13].

Single interventions to optimize prescribing in old age resulted in a significant improvement in a cohort of hospitalized older adults [14], and reduced health care usage (hospitalizations, mortality) and health-related costs [15].

Prescribers face a complex medication choice process in older poly-morbid and poly-medicated residents. Changing treatment goals and limited life-expectancy may alter the traditional and documented balance of benefit and harm in this frail population. Single interventions to reduce PIM use, such as computerized decision-support systems, educational interventions, and pharmacists-led interventions have produced inconsistent effects [15,16]. Multifaceted complex interventions involving all actors in the medication management process (NH resident, nurse, pharmacist, GP) may be more likely to improve prescribing than single interventions [17–20].

Although physicians are invited to perform medication reviews, this is not implemented comprehensively nor performed regularly. Little state-of-the art ICT support is available. Moreover, not one of these initiatives is automated, electronically available, tailored to the NH setting, and designed to appraise the total medication intake of older adults.

To support general practitioners in optimizing the prescribing quality of nursing home residents, we have designed the OptiMEDs intervention; an electronic assessment tool for the automated recognition of possible inappropriate medications and for the generation of patient-specific lists of side effects for observations by nurses. This tool is intended to structure and support a medication review with input of nurses, pharmacists and general practitioners GPs). The overall final objective is to provide an evidence-based, feasible, and ICT-enabled method of regular multidisciplinary medication review to obtain a more appropriate, safer, and more cost-effective pharmacotherapy in nursing home residents. In a pilot study, we explored the feasibility and acceptability aspects of the tool involving three nursing homes, and explored changes in the prevalence of possible inappropriate medication.

3 Methods

A pilot study was performed in three Belgian nursing homes, between October 2019 and March 2020. Two nursing homes were assigned to the intervention arm, and one NH to the control arm to reflect usual care.

Originally, the study period was set to last until June 2020. Due to the COVID-19 pandemic and the national lockdown in Belgium, the data collection in the NH was suspended in March 2020. The last data collected was the 1-month follow up of discontinuation problems and the capture of the medication data at that moment. The planned evaluation of changes in the medication chart and patient-related outcomes after 4 months could no longer be done/performed in the confined nursing homes, as Belgium went into general lock down, and complete isolation of nursing homes, from April 2020 on, for two months.

3.1 Setting

A pilot study was performed in three nursing homes in Eastern-Flanders, one of the 10 provinces of Belgium. Nursing Homes in Belgium are long-term care institutions for older adults with a care-dependent profile. Nursing Homes can be private, public or part of a bigger group, yet the quality of care and nurses per residents is comparable.

In Belgium, NH residents can freely choose their own GP, yet most keep their general practitioner. A typical NH in Belgium has around 100 residents and is visited by a median of 30 general practitioners [21]. The GPs are coordinated by a peer GP who has a responsibility for training and quality of care initiatives in the NH.

There is one pharmacist responsible for delivering mediations to the NH. Communication with the pharmacists who supply the medicines to the nursing homes is limited. Pharmaceutical care activities of pharmacists in support of the appropriateness of prescribing are only emerging [22].

Medication reviews are recommended by the Belgian government, but not mandatory. There are no structured guidelines on how to perform a systematic review. As a result, multidisciplinary medication reviews do generally not take place in the Nursing Homes setting.

3.2 Participants

Nursing homes were eligible to participate if they had a capacity over 100 beds and had a mixed population (dementia, non-dementia).

Nursing home residents were eligible if they were at least 65 years of age, were not residing in short-stay beds or revalidation beds and provided written informed consent. NH residents were excluded if their GP refused to participate, or if they had a life-expectancy of less than 3 months.

Recruitment ran between October - December 2019. Recruitment was halted in each NH when 50 residents provided informed consent.

3.3 Intervention

The OptiMEDs intervention is a multifaceted intervention with the aim of holding a multidisciplinary medication review, with input of nurses, pharmacists and GP, supported by the OptiMEDs tool. The OptiMEDs tool was conceptualized by a consortium between Ghent University, University of Antwerp and RAMIT (a spin-off of Ghent University, www.ramit.be) and programmed by the latter. The tool was accessible for the users throughout a secured weblink, with a personalized log-in.

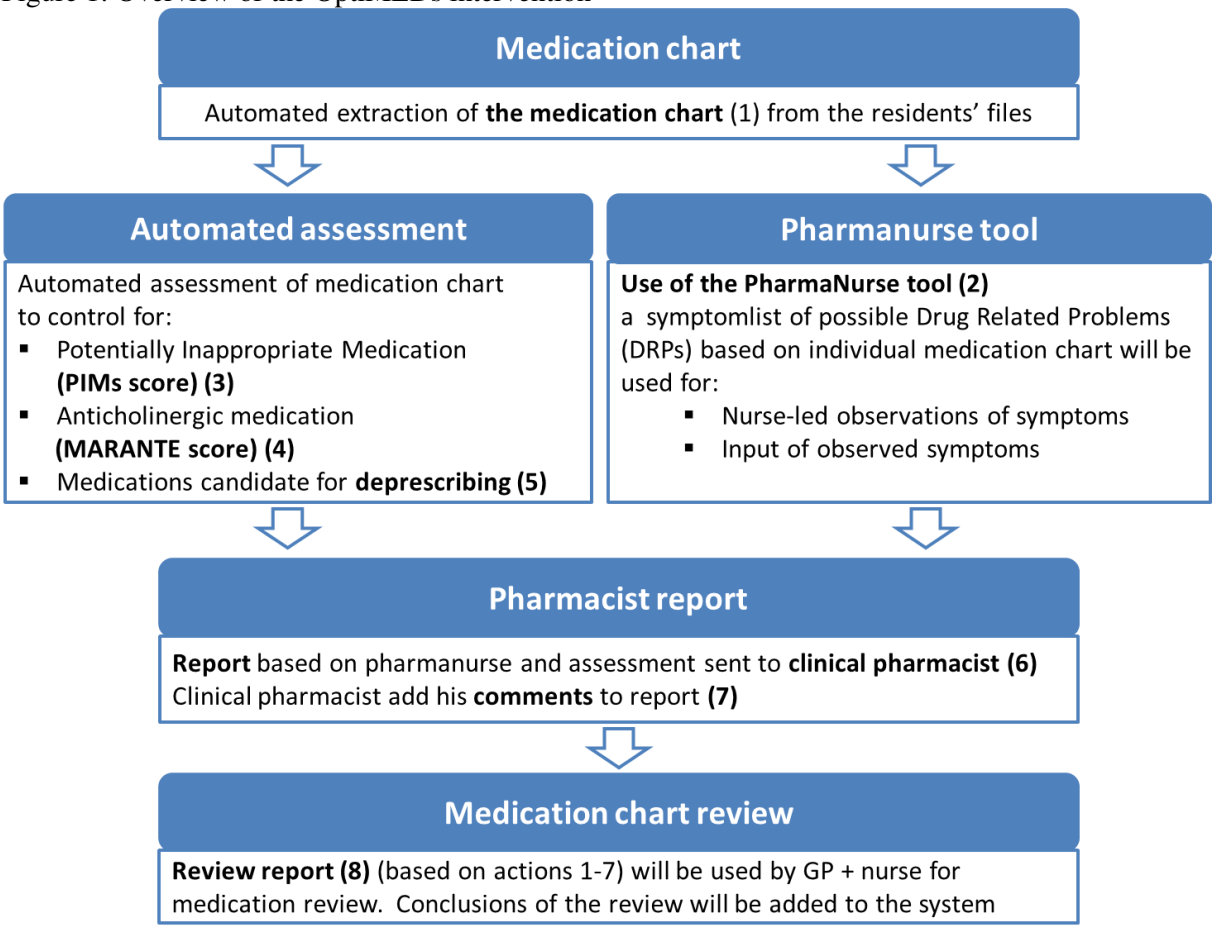
The OptiMEDs intervention consisted of the following steps:

1. The nurse enters the national number and name of the NH resident in the tool and uploads **the medication administration chart (1)** of NH resident to the OptiMEDs platform.
   After encrypting of identifiable data, the medication data is recoded with the WHO ATC Classification (WHO ATC/DDD index, version 2013) to perform the next (2 – 5) processes.
2. Using the **Pharmanurse tool (2),** a list of possible medication-related symptoms is automatically generated based on the medication list of each individual NH resident. Nurses then use this patient-specific list as checklist to perform focused observations per NH resident for actual medication-related side-effects, the level of pain and level of alertness. After the observations, the nurses record their findings in the tool
3. In parallel step 2, the extracted medication data is analyzed by an **automated assessment tool** that will **flag potentially inappropriate medications (3)** using explicit criteria from the PIM-repository; a combination of the most current version of EU(7)-PIM, START/STOPP-2 and the Beers' list.
4. The extracted data are then analyzed for the **presence, potency and dosage of anticholinergic medications (4)** using the MARANTE scoring system [23]**.**

5. A list of medications for **deprescribing (5) based on deprescribing.org** is used to flag all medications that can be considered for deprescribing in view of the old age and a limited life expectancy.
6. The input of nurses (step 2) and the automated assessments (3,4,5) are then summarized in a **standardized electronic report (6).** The pharmacist receives notice (through email) when nurses have performed their observations for one patient.The pharmacist analyzes this report and amend it (7) to return his comments, additional suggestions, and proposals for alternative treatments.
7. **A review report (8)** including all previous actions (1 to 7) is made available for general practitioners and nurses as a support and guidance for the medication chart review by the GP and the responsible nurse. The nurse invites the GP to the NH by mail to perform the medication review together. Afterwards, the nurse puts the conclusions of the review (the possible adaptations and instructions) into the **final medication review report**. The nurse implements all changes to the medication list in the computerized prescription ordering entry system of the nursing home.

The moment a medication review was performed, and the proposed changes were implemented, the follow-up period for a NH resident commenced.

Figure 1: Overview of the OptiMEDs intervention



3.4 Baseline Data collection

All data was collected by the nurses in the NH, either from administrative files, or by observation of NH residents.

The general data collection included personal data (age, gender, …), administrative data (date of NH admission, …), health care usage (number of GP visits, hospitalization, falls…) and functional data. (quality of life as measured by the EQ-5D-5L; cognitive function as measured by the Mini-Mental State Examination; care dependency by Katz Activities of Daily Living scale and Katz disorientation scale). An overview of the standardized test can be found in box 1.

Box 1: Overview of standardised tests and questionnaires used for data collection.

Type of data	Scale / test	Subtopic	Range	Lowest score: meaning (cut-off, meaning)
Cognitive status	Mini-Mental State Examination (MMSE)	Orientation in time, space, memory, comprehension and constructive praxis	0 – 30	0: severe cognitive impairment
	KATZ disorientation	Disorientation in time and place	1 – 8	1: no disorientation (>5, disorientation)
Care dependency	KATZ ADL – activities of daily living	Continence, nutrition, feeding, personal hygiene, toileting and mobility.	6 – 24	6: care independence
Alertness	VAS	Alertness	1 – 6	1: being unalert (<3, unalert)
Pain	VAS (non-dementia patients)	Pain	1- 10	1: No pain
	PAIN-AD (dementia patients)	Breathing, negative vocalization, facial expression, body language, consolability	1 – 10	1: No pain
Quality of life	EQ-5D-5L	Mobility, self-care, usual activities, pain/discomfort and anxiety/depression Vas scale for perceived quality of living today	1 - 100	0: worst quality of life

* MMSE, Katz disorientation scale and Katz ADL scale was collected from the nursing home records. The responsible nurses performed data collection on their ward.

4 Outcome data collection

For this pilot study, three sets of process indicators were used; medication related outcomes, acceptability outcomes and feasibility outcomes. The medication related outcomes were investigated in the intervention nursing homes, the acceptability and feasibility outcomes in the participating health-care professionals of the intervention arm.

Due to the COVID-19 pandemic, the outcome data collection was not possible in the control nursing home. The automated medication data collection for the control nursing home that was programmed for June (six months after the date of consent) was suspended.

4.1.1 Measuring the effect on changes in the medication chart of the OptiMEDs intervention

The primary outcome in this study was set as the percentage of residents with a decrease of at least one PIM (Potentially Inappropriate Medication, an anticholinergic or a candidate for deprescribing).

Differences were calculated between the baseline medication list and the medication list obtained 1 month after the medication review for those residents still alive in the intervention home.

4.1.2 Assessing safety events

In the month after the medication review, there was a follow-up for discontinuation problems or any harms when ceasing medications in the intervention homes. Nurses had to document the nature of the event, date of onset and end date, severity, their assessment of and assess possible relatedness with ceasing medication, the consultation process with the GP, and actions taken by the GP.

4.1.3 Measuring feasibility aspects of the OptiMEDs intervention

Workload of the nurses and pharmacists in the intervention homes when using the OptiMEDs tool was collected on paper.

The duration and practical problems encountered in the organization of medication reviews were registered by the nurses on paper. Nurses had to fill in for each resident the number of attempts to contact the GP for organizing the medication review, the timing of the medication review and how long (in minutes) the medication review took

4.1.4 Measuring the acceptability aspects of the OptiMEDs intervention

To measure the acceptability, the user experience with regard to using the OptiMEDs tool was captured. An online survey was sent out to all nurses, pharmacists and GPs that used the OptiMEDs tool. In the survey, there were questions on how users appreciated the use of the tool, the content of the tool, the cooperation with the other health-care professionals. For nurses, there were additional questions on the subjective usability and learnability aspect of the tool, as measured by validated 10-item questionnaire System Usability Scale (SUS).

The SUS is technology agnostic, meaning it can be used to evaluate a wide range of hardware and software systems [24]. It provides an easy-to-understand overall score from 0 (lowest feasibility) to 100 (highest feasibility). The SUS can be divided into two separate factors, specifically representing the ease of use (usability: 8 items) and ease of learning (learnability: 2 items) of the evaluated tool [25]. Although no explicit cut-off for feasibility is determined, it is generally accepted that SUS-scores >50 are sufficient to consider the tool feasible in current practice [26].

4.2 Data handling

4.2.1 Medication data

This data were collected from the medication administration chart of NH residents. Only medications labelled as chronic were transferred to the OptiMEDs platform. The medications (brand/generic name) were translated to the Anatomical Chemical Therapeutic (ATC) classification index of the WHO, to permit a standardized application of the PIM criteria and assessments.

4.2.2 Medication related symptoms

The medication related symptoms were collected and handled through the Pharmanurse module. Based on an individual medication list, this module generated an individual list of potential medication-related symptoms for the nurses to observe [27].

4.2.3 Possible inappropriate medications

Possible inappropriate medications were counted as the presence of Potentially Inappropriate Medications (PIMs), anticholinergics and Candidates for Deprescribing. PIMs were selected from the international repository of PIMs (including Beers 2015 list, STOPP/START 2 and EU(7)-PIMs list) by Ivanova et al. [28]. For this study, only those PIM criteria that can be assessed without clinical data were used (64% of the total criteria in the repository). Anticholinergic medications were medications from the Duràn list, for which medication an anticholinergic load was calculated by the multiplication of the dosage and potency values of an individual medication [23,29]. The exposure is the sum of different anticholinergic loads of medications. The candidates for deprescribing were derived from the Deprescribing guidelines (found at: wwwv.deprescribing.org) and from STOPPFrail and the Morin's list [30,31].

4.3 Statistics

Analysis of data collected to investigate the feasibility and acceptability of the intervention mainly consist of descriptive statistics. Continuous variables (most semi-quantitative score variables or skewed numbers) will be presented with median and range and will be compared using non-parametric statistics

(Mann-Whitney-U-test). Categorical variables will be presented with percentage and will be compared using chi-square test

4.4 Ethical Considerations

An approval was granted by the Biomedical Ethics Committee of Gent University Hospital (Belgian Registration number B670201940251). The Federal Agency for Medicines and Health Products (FAMHP) authorized the use of OptiMEDs as a class I medical device in a clinical trial. The funder reviewed the privacy and security measures for data handling in this study. The study was registered at clinicaltrials.gov under number NCT04142645 on 29 October 2019.

Permission for this study was given by the board of directors and supervising physician of each participating nursing home. All participants (nursing home residents or their proxy, nurses, GPs, pharmacists) gave written informed consent before participating in the study, NH residents could only be asked for consent after written consent for participation from their treating GPs.

5 Results

5.1 Characteristics and medication use of the Nursing Home Population

A total of 7 nursing homes were contacted to participate in the pilot study. In order for a NH to participate, the nursing home board, the coordinating GP and the pharmacists had to consent to participate. One agreed but had to refuse due to a decision from the umbrella organization, NH refused due to a high anticipated workload and two were not eligible (use of other software for handling their medications).

An overview of the participating NHs can be found in table 1. All were located around and in the proximity of Ghent, Belgium. The two intervention NHs used a different software system.

Table 1: Overview of the participating nursing homes in the OptiMEDs pilot

	Intervention NH 1	**Intervention NH 2**	**Control NH**
Organizational sector	Private (non-profit)	Private (non-profit)	Public
When is medication delivered?	Daily	Daily	Daily
Use of tablets on wards?	No	Yes	No
Number of beds	155	115	122
Number of wards	7	3	3
Number of wards for persons with dementia	1	1	1
Number of visiting GPs	30 – 40	50 – 60	35 - 40

The participants (n=148) mean age was 87,2 years (range 67 – 101) with 75.0% females. There was a mean chronic medication use of 6.6 (±3.2) medications at baseline. The mean medication use varied between a mean of 5.6 (intervention NH 2) and 7.6 (control NH). There were three NH residents without chronic medication intake in the intervention group.

Alimentary medications were most used (83.3%), followed by cardiovascular (77.1%) and nervous system medications (75.7%). The psychotropic medication use was high, with 33.3% taking an antidepressants and 25.7 taking a benzodiazepine.

Table 2: Baseline characteristics of the OptiMEDs population (n=148)

	Total	Intervention	Control

	N = 148	N = 100	N = 48
Mean age in years (range)	87.2 (67 – 101)	87.7 (67 – 100)	86.5 (82 – 101)
Females (%)	75.0	78.0	68.8
Cognitive status			
Capable to answer questions (%)	49.3	48.0	52.1
Median MMSE score (range)	20 (13 - 25)	19.50 (12 – 24)	21 (14 – 26)
Median KATZ disorientation (range)	4 (2 – 6)	4 (2 – 6)	6 (2 -6)
Care dependency			
Median ADL level (range)	17.5 (14 – 21)	18 (14 – 21)	17 (13 – 21)
Median level of Alertness (IQR)	1 (1 – 2)	1 (1 -2)	2 (1 – 3)
Median level of pain (IQR)	2 (1 – 5)	2 (1 – 5)	2 (1 – 5.75)
Quality of life			
Median quality of life (IQR)	60 (50 – 75)	65 (50 – 75)	60 (50 – 70)

5.2 Baseline observations in the OptiMEDs tool

The automated assessment of the medication chart at baseline of all residents (n=145) showed that 94.5% of the population had at least one possible inappropriate medication in their medication list. Medications that are considered a candidate for deprescribing were most prevalent (85.5%, predominantly proton pump inhibitors) followed by PIMs (84.1%, predominantly proton pump inhibitors). Anticholinergics were taken by 50.3% of the population (predominantly escitalopram, trazodone and ipratropium). For 33.1% of the population, the anticholinergic exposure was considered high (MARANTE score of 2 or more).

Following the nurse observations for potential medication-related symptoms (n=97 in the intervention arm), 82.5% of residents in the intervention arm had at least one symptom potentially related to their medication use. The most observed symptoms included fatigue (22.6%), disorientation (22.6%) drowsiness (20.6%), skin problems (19.6%) and dry mouth (18.6%).

5.3 Initial results of the OptiMEDs intervention

In the intervention arm, a total of 88 medication reviews were performed. Three nursing home residents had no chronic medication intake, two GPs didn't perform the medication review and 7 NH residents died before the medication review could take place.

5.3.1 Process and Result of the medication review

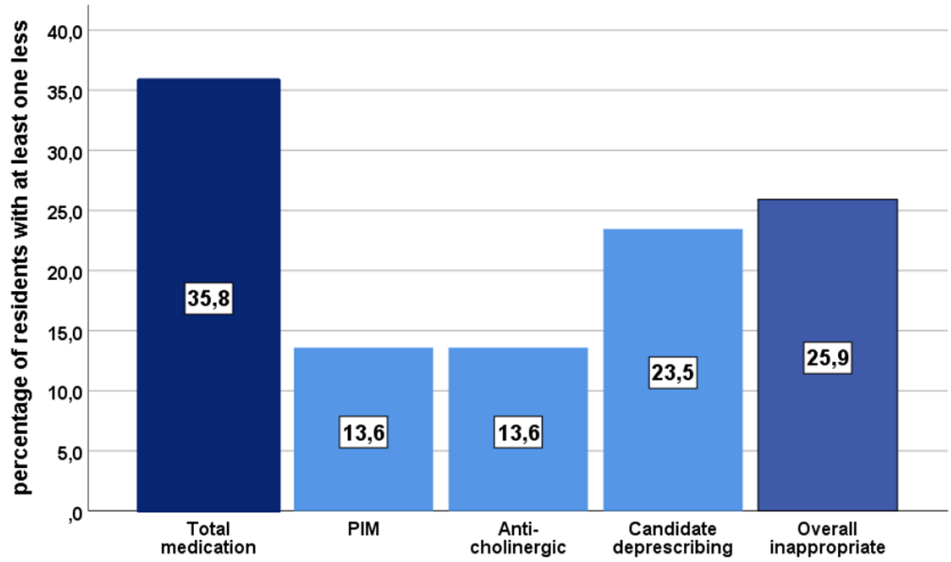
The pharmacists (one for each NH) assessed 617 medication lines across the intervention group (n=88) and gave up to 4 advices in 45.7% of the residents. Predominant advice given was by formulating questions directed to the GP via the comment option (n=39 times). From the pre-set options, the pharmacists predominantly chose to decrease the dose (n=10 times) or suggest an alternative (n=9 times). Pharmacists most frequently commented when the automated assessment identified a medication as an anticholinergic medication. Additionally, they proposed (non-pharmacological) alternatives for chronic use of sleeping pills or they suggested several times the use of a pain reliever in case of an increased pain scale.

The next step was the assessment by GP and nurse. In 35.9% of the residents, the GP and nurse changed at least one prescription (range 1 – 6). Predominant changes included the immediate stop of a medication (n=34 times), followed by stopping with tapering (n=7 times) and a decrease of the dose (n=6).

The primary outcome was focused on changes in the medication use one month after the medication review. Overall, there was a decrease in total number of medications in 35.8% of patients. There was a decrease of at least one possible inappropriate medication in 25.9% of the residents. The GPs mainly

targeted medications that were listed as candidates for deprescribing (decrease in 23.5% of residents). In 13.6% of residents, there was a decrease in the prevalence of PIMs and prevalence of anticholinergics.

Figure 1: Overview of changes to the prevalence of chronic medication use and categories of possible inappropriate medication intake one month after the medication review (n=88).



5.3.2 Factors contributing to changes in the medication use

All components in the intervention showed univariate associations with the decision to change a medication that a GP had taken during the medication review. GPs performed at least one change to the medication list if the resident took a PIM.

The GP changed the medication list in 42.3% of those residents with symptoms, as compared to 11.8% of those without symptoms (p = 0.019). For every potential medication-related symptom a NH resident showed, the GP was 17% more likely to change the medication list. Similarly, the GP changed more medication lists in those where the pharmacist gave advices (45.0% compared to 29.2% where the pharmacist did not give advice). For every advice (up to 4), the GP was 2.2 times more likely to change something to the medication list.

	GP changed at least 1 prescription		
	YES (n)	NO (n)	Odds Ratio (95% CI)
Automated assessment			
PIMs	43.2 (n=74)	0 (n=0)	/
Anticholinergic	50.0 (n=38)	26.0 (n=50)	2.85 (1.16 – 6.98)
Deprescribing	38.7 (n=75)	23.1 (n=13)	2.10 (0.53 – 8.28)
Nurses symptom observations			
Mean number of symptoms (continuous)	6.9 (n=71)	4.7 (n=17)	1.17 (1.03 – 1.32)
Pharmacist review			
Mean number of pharmacist advices (continuous)	1.0 (n=40)	0.4 (n=48)	2.21 (1.21 – 4.02)

5.3.3 Safety concerns

The deprescribing of medications after the medication review resulted in two discontinuation problems, of which the predominant involved the occurrence of heartburn after the discontinuation of a proton-pump inhibitor, which was resolved after re-initiating the PPI.

In the intervention arm, there were six mortality cases after the medication review. The occurrence of these deaths was not related to the intervention, according to the treating GPs of the patients who died. All deaths were related to either sudden, unexpected death or due to general deterioration. In the control group, there were 4 mortality cases.

5.4 Feasibility aspects of the OptiMEDs intervention

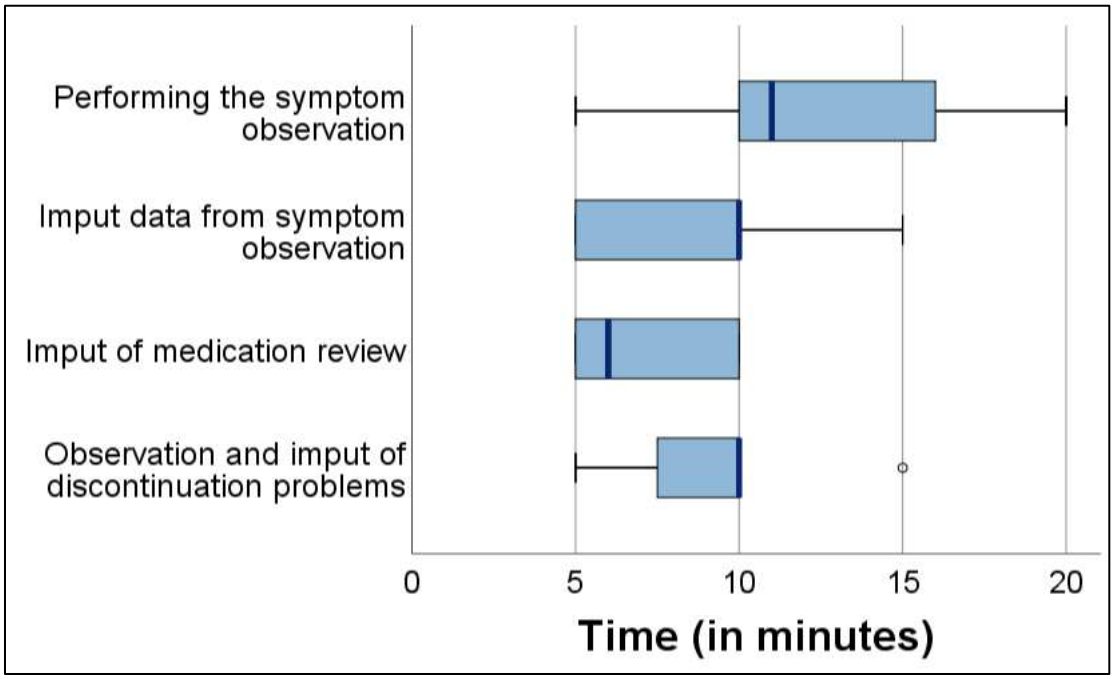
There were no functionality problems that hampered the use of the tool during the study period.

The workload questionnaires were filled in by the 9 nurses who used the OptiMEDs tool intensively. The mean total time investment to perform all tasks (from symptom observation to the observation and reporting of potential discontinuation problem) was around 45 minutes per NH resident. The most time-intensive task was performing the symptom observation, which required talking to the NH resident.

Performing the pharmacist review took around 20 minutes per NH resident. The two pharmacists evaluated the medication use at the same time with other software to detect potential interactions.

Regarding the medication review, data was collected for n=52 NH residents. The nurses had to contact the GP a mean number of 1.3 (range 1-3) times before a medication review could be planned. The medication review took a median of 8 minutes (IQR 7 – 10).

Figure 2: Overview of time needed for the different tasks in the OptiMEDs intervention by the nurses (n=9).

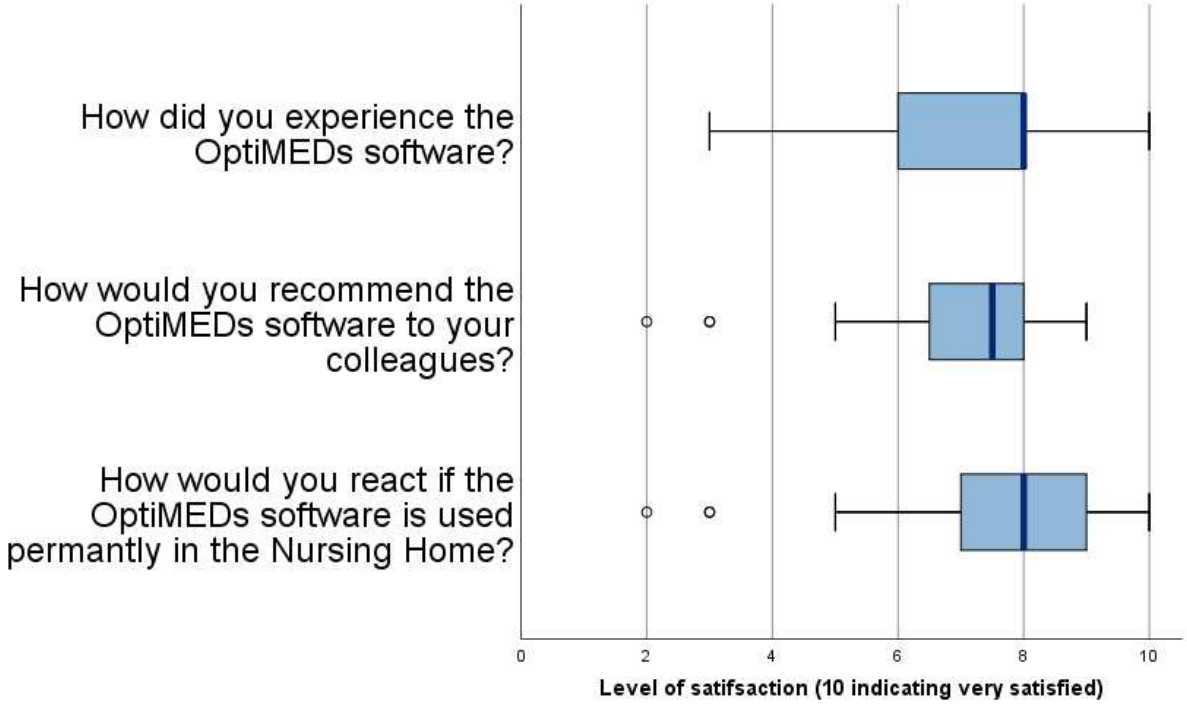


5.5 Acceptability of the OptiMEDs intervention

A total of 33 respondents of which n=12 nurses (92% of all nurses), n=2 pharmacists (100% of pharmacists) and n=19 GPs (31% of all GPs) responded to the survey, out of a potential 76. The median age of the respondents was 49.5 years (range 26 – 69), and the majority was male (56.2%).

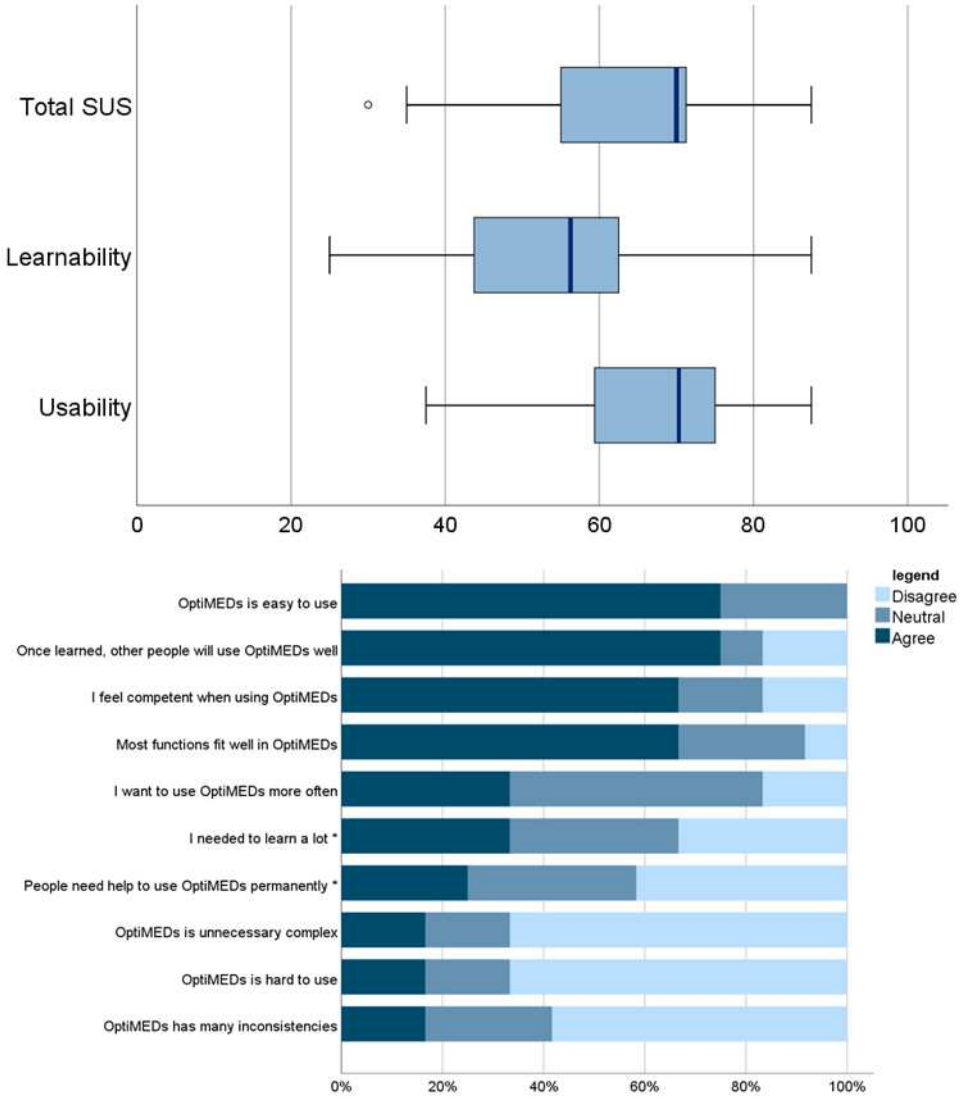
The users experienced the use as quite satisfactory scoring a median 8 (IQR 6 – 8), they were positive towards using the tool in the future (median 8, IQR 7 – 9) and would recommend it to their colleagues (median 8, IQR 6.5 – 8.5). Pharmacists were most satisfied (median 9.5), followed by GPs (median 7.2) and then nurses (median 6.9). GPs particularly appreciated the cooperation with the nurse during the medication review (median 8, IQR 7.5 – 9).

Figure 3: Overview of the general satisfaction of the users of the OptiMEDs tool (n=33)



The subjective usability and learnability of the OptiMEDs tool, as measured by the System Usability Scale (scale range 0 – 100, 100 indicating highest usability) was measured using feedback from the nurses (n=12). The median SUS-score was 70 (IQR 55 – 72), with a median learnability score of 57 (IQR 43 – 62) and a median usability score of 71 (IQR 59 - 76) .

Figure 4: Overview of the results from the System Usability Scale. At the top, boxplots are shown for the results on the SUS as judged by the nurses (n=11). At the bottom, a breakdown per question in the SUS is given.



6 Discussion

6.1 Main findings

Our main finding is that the OptiMEDs intervention is that a multidisciplinary medication review supported by an automated electronic tool was feasible and to the satisfaction of the health care professionals. The main strengths of the tool is the facilitation of communication between nurse, GP and pharmacist, through the platform in a structured and guided process. These medication reviews, supported the OptiMEDs tool, resulted in a decrease of at least one medication in 36% and least one Possible Inappropriate Medication in 26% of residents. The different components (either nurse observations, PIMs, anticholinergics, candidates for deprescribing) contributed to changes in the medication list.

Our second finding is that the OptiMEDs intervention, supported by the OptiMEDs tool is feasible, acceptable and is of low-risk for the patient. The workload required for performing the OptiMEDs intervention could be clearly documented for nurses (median 45'), pharmacists (15-20') and GPs (7-10'). fAt the level of acceptability, nurses as well as GPs and pharmacists appreciated the OptiMEDs

intervention. At the level of safety, very few discontinuation problems and no mortality events related to medication withdrawal were observed.

6.2 Strengths and limitations

This pilot study had several strengths, and the complex, yet multifaceted aspect of the OptiMEDs intervention involving the essential health-care professionals in a nursing home. Another strength was the pragmatic approach for the trial. Most of the data collection included routinely collected data but that was handled in an automated manner through the tool to guide the process towards holding a medication review. The nurse was the central person in the initiation of the intervention and for realizing the medication reviews. Feedback from pharmacists could be structured through our tool, omitting the necessity of meeting in person. Another strength of our tool was the broad scope of the structured feedback, addressing aspects of potential underuse, overuse, potential medication side-effects, deprescribing etc.) yet individualized for each resident.

A limitation is that the explicit criteria used in the tool (from the STOPP-START-2, Beers 2015 and EU(7)-PIM list) were medication-only criteria. These criteria do not allow to take individual aspects into consideration, although attempts were made to alert GPs for clinical oriented explicit criteria (i.e."this drug is potentially inappropriate, especially if the NH resident has renal impairment").

Another limitation is the presence of a potential selection bias at the level of the nursing home, the participating GPs, and the NH residents.

Due to the national lockdown in Belgium during our pilot study, we had to suspend any further data collection with the nursing home residents. . The last data collection was the systematic observation for potential discontinuation problems one month after the medication review for all NH residents. We were therefore unable to compare the intervention with usual care, nor was a pre-post comparison after 4 months possible (of for instance medication-related symptoms, prevalence of possible inappropriate medications, quality of life…) due to the national lockdown following the covid-19 pandemic

6.3 In relation to other work

More and more studies are emerging involving different often complex interventions to help reduce the prevalence of inappropriate prescribing in older adults (PRIMA-Eds, Strip, DIM NIHR). In the OptiMEDs intervention, the strength of the intervention lies between the synergy of including the observation of patient-relevant medication-related symptoms and on shared decision making between health-care professionals supported by an electronic tool [15].

Due to the pilot study design, the small sample and the short follow-up, no conclusions can be drawn in the efficacy of the OptiMEDs intervention. Improving pharmacotherapy in older adults is a longitudinal process with several steps, as GPs will not drastically alter the medication list immediately. Despite the short follow-up period of 1 month, potential clinically significant effects were seen. To fully grasp the effect of our intervention, a full pragmatic cluster-randomized controlled trial is needed, with a decent follow-up time. Further investigation may give insights in what component of the OptiMEDs intervention drives the choice to deprescribe or alter medications.

The clinical relevance and persistence of OptiMEDs must also be evaluated after repeated use.

Ultimately, decreasing the number of medications shouldn't be the ultimate goal in the care for older adults, and especially in those with dementia who cannot vocalize their concerns about their pharmacotherapy [1,21,32]. Therefore, a next endeavor should be a full pragmatic study involving multiple nursing homes, with a longer follow-up period and with a focus on patient-relevant outcomes (mobility, quality of life, pain, level of alertness, …). In this pilot study, a more patient-centered approach was not a point of focus, and needs to be further considered in the development of the OptiMEDs intervention. Nurses were more involved, appreciated the engagement with the patient, and

the direct communication with to the GPs on their observations of symptoms that burdened the NH residents in their daily life [33,34].

Similar studies could not demonstrate the benefit of complex interventions on clinical effects, neither in the DIM-NHR nor Opti-Script trial [35]. The direct comparison of these interventions still remains difficult, as interventions are embedded within national health care systems [36,37] or on different levels in health care (at hospital discharge [38]). The Dutch DIM-NHR intervention involved external pharmacists, while our study was more nurse-driven. We believe that nurses (as well as all allied-health care personnel within a nursing home) who are directly involved in the care and lives of residents, may be crucial for the success of interventions [34].

When designing a tool for the automated assessment of potentially inappropriate medications, the guidelines the tool is based on should be as unambiguous and extensive as possible [39], and possibly adapted for the specific long-term care setting [40,41]. In the COME-ON study, the authors noticed that deprescribing a PIM in some cases led to the prescribing of another PIM [42]. Given the high prevalence of PIMs in this study, we encourage designers of lists of explicit criteria to collaborate to make lists as explicit and universally applicable as possible. Attention should be given to potential safer alternatives of PIMs, in order to avoid the false sense of safety with GPs when discontinuing a PIM and replacing but starting another PIM.

The overall usability of the OptiMEDs tool was acceptable, but more focus is needed on the learnability aspect (need to learn, need for assistance). During the pilot study, nurses asked for help during their first tries with the tool, but once familiar with the tool, no further assistance on site was needed. Learnability issues can be addressed with more training, in-person or in-app tutorials, or clear functionality or instructions for use [43]. For future reference, the study team will add dummy patients and an on-computer initiation of the tool.

Implementing a complex intervention involving multiple healthcare professionals in an overburdened care setting is difficult, and a pragmatic approach in the design of the study may be crucial for the success of a study. For feasibility aspects, this study was designed to support a medication review where the most important actors in a medication review could rely on their core competences. We found it encouraging that GPs valued the input of nurses above the tool. GPs are to some degree aware of problems of NH residents, yet the feedback of nurses that it affects the daily life of NH residents on a regular interval may have influenced the GP in changing the medication. It also could have been that GPs disregarded the alerts from the tool (due to alert fatigue), or deemed the feedback was useful but difficult to scale as demonstrated in earlier attempts for computerized pharmacotherapeutic decision support systems [44,45].

7 Conclusion

The OptiMEDs intervention added evidence that a multidisciplinary medication review supported by an automated electronic tool was feasible and to the satisfaction of the health care professionals. One month after the intervention, the total number of medications and number of possible inappropriate medications decreased, without affecting patient safety. For demonstrating the impact on patient-related outcomes of the OptiMEDs intervention, a full cluster-randomized trial is needed.

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