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Original Study

Interprofessional Medication Assessment has Effects on the Quality of Medication Among Home Care Patients: Randomized Controlled Intervention Study

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A B S T R A C T

Objective: Multimorbidity and complex medications increase the risk of medication-related problems, especially in vulnerable home care patients. The objective of this study was to examine whether interprofessional medication assessment has an effect on medication quality among home care patients.
Design: The FIMA (Finnish Interprofessional Medication Assessment) study was a randomized, controlled study comparing physician-led interprofessional medication assessment and usual care.
Setting and Participants: The FIMA study was conducted in home care settings in Finland. The participants were ≥65-year-old home care patients with ≥6 drugs daily, dizziness, orthostatic hypotension, or a recent fall.
Methods: Primary outcome measures over the 6-month follow-up were number of drugs, drug-drug-interactions, medication-related risk loads, and use of potentially inappropriate medications (PIMs) examined by SFINX, RENBASE, PHARAO, and Meds75+ databases. The databases classified information as follows: A (no known pharmacologic or clinical basis for an increased risk), B (evidence not available/uncertain), C (moderately increased risk which may have clinical relevance), and D (high risk, best to avoid). Logistic regression adjusted for age, sex, and the baseline level of the outcome measure served as statistical methods.
Results: The mean number of all drugs for home care patients (n = 512) was 15. The odds of drug-induced impairment of renal function (RENBASE D, $P = .020$) and medication-related risk loads for bleeding (PHARAO D, $P = .001$), anticholinergic effects (PHARAO D, $P = .009$), and constipation (PHARAO D, $P = .003$) decreased significantly in the intervention group compared with usual care. The intervention also reduced the odds of using PIMs (Meds75+ D, $P = .005$). There were no significant changes in drug-drug-interactions or number of drugs.
Conclusions and Implications: FIMA intervention improved the medication quality of home care patients. Risks for renal failure, anticholinergic effects, bleeding, constipation, and the use of PIMs were reduced significantly.

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Home care clients are a growing and vulnerable patient group with multimorbidity and complex medications. They are often exposed to drug-related adverse events, which may increase risks of negative clinical outcomes such as functional and cognitive decline, frailty, falls, hospital admissions, and even mortality.[1,2] Therefore, improving medication quality may support older persons' functioning and living at home.

High medication quality can be defined as appropriate medication with clear and relevant care targets and carefully considered patient

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safety with minimized risks. In addition, the medication should enhance the functioning of an older patient. Recent research suggests that medication quality is associated with cognitive and physical functioning among older patients.[3]

Older people with multimorbidity and polypharmacy are often exposed to medication-related problems (MRPs), including potentially inappropriate medications (PIMs), drug-drug interactions (DDIs) and drug-related adverse events.[4] However, polypharmacy is often clinically indicated in patients with multimorbidity.[5] On the other hand, inappropriate medication endangers older people to MRPs, and increases healthcare and medication costs.[1,4,6,7]

Older people with polypharmacy in particular need regular medication reviews and prescribing optimization.[8] Accordingly, numerous interventions to improve the appropriateness of medication among older people have been described.[9] However, medication assessments in older people with multimorbidity can be complicated and time-consuming.[10] An interprofessional team approach is suggested to be advantageous when assessing patients with multimorbidity and complex medications,[10,11] nevertheless the effectiveness of these interventions remains uncertain because of the relatively small number of randomized controlled trial (RCTs).[12] In addition, the effects of medication assessments on medication quality are unclear.[9]

The Finnish Interprofessional Medication Assessment (FIMA) is a physician-led, practice-based model for medication optimization for older people.[13,14] In the present RCT, we examined whether the FIMA intervention had effects on the number of drugs, DDIs, risks of drug-induced impairment of renal function, medication-related risk loads, and PIM use among home care patients.

Methods

Study Design and Participants

The FIMA study was a randomized, controlled intervention study with a comparison between physician-led interprofessional medication assessment and usual care in public home care settings in Finland. The complete study design of the FIMA study has been published previously.[13] The reporting follows the CONSORT statement.[15]

In Finland, municipalities are responsible for arranging the social and health services, including home care and nursing services, that older people require. Finnish home care services include support and assistance in activities of daily living (ADLs), home nursing and physician services, rehabilitation, home hospital services in acute situations, and the end- of-life care. In 2016, 91% of Finnish older people (≥75 years of age) lived at home, and 11% of them received regular home care services.[16] Patients who are regular clients of home care services must have substantial functional limitations in basic and instrumental ADLs.

In the FIMA study, the inclusion criteria were age ≥65 years and registered for public home care services, and at least 1 of the following: taking ≥6 drugs daily, having dizziness, orthostatic hypotension, or a recent fall. Recruited patients had regular and long-lasting need for home care and nursing services. We excluded patients whose medication was not managed by home care and patients with active cancer therapy.

Potentially eligible patients were screened and after they had given their consent to participate, the baseline examinations were carried out within 2 weeks (Figure 1). The patients were randomized into intervention or usual care in blocks of 10. The enrollment and baseline examinations were conducted from February to December 2015.

Data Collection

All patient medication use was verified by home care nurses according to a structured protocol. The nurse printed the patient's current medication list from the electronic medical record before a home visit. At the patient's home, the nurse checked prescription and over-the-counter (OTC) drugs as well as vitamins and natural remedies and asked the patient about the actual use of drugs and updated the medication list accordingly. Vitamins and natural supplements without official CE-marking *(Conformité Européenne)*[17] were not regarded as drugs or included in the patient's medication list. The nurse assessed the patient's performance in daily activities and physical functioning and collected data on demographic variables and patient characteristics.

The physician of the home care team documented patients' diagnoses from the existing medical records. A modified Charlson comorbidity index was used to describe the home care patients' disease burden.[13] The glomerular filtration rate (GFR) was calculated with the Chronic Kidney Disease − Epidemiology collaboration formula.[18]

Intervention

An interprofessional team consisting of a pharmacist, physician, and registered nurse working regularly in home care conducted the structured medication assessment within 2 weeks of the baseline measurements. Patients' updated and verified medication lists, current health measurements, and electronic medical records including patients' medical history were available during the assessment.

Before the team meeting, the pharmacist reviewed the patients' medication lists using 4 databases which are available in Terveysportti.fi health portal. Databases were used to identify DDIs,[19] medication-induced renal risks,[20] risks of clinically relevant adverse effects[19] at a single drug level and as pharmacodynamic risk loads in the whole medication, and the appropriateness of drugs for older people.[21] The physician gathered information from patients' medical records and on current clinical status.

In the interprofessional team meeting, the professionals discussed the patients' current clinical condition and reviewed patients' medications, considering the current health status, and clinically significant aspects. In addition, the pharmacist focused his/her medication review recommendations on clinically relevant issues that came up in the team discussion. The physician made clinical decisions and wrote recommendations into the patients' medical records. After the team meeting, the nurse updated the patient's medication regimen. If the patient did not participate the team meeting, the nurse informed the patient about the changes and the changes were implemented if the patient accepted them.

All pharmacists had a qualification in comprehensive medication review (CMR) or current continuing professional development in clinical pharmacy. All interprofessional team members received a 1-day training or a personal introduction on the FIMA protocol.[13]

Outcome Measurements

The following 4 databases were used to detect drug-drug interactions, risks of drug-induced impairment of renal function, medication-related risk loads, and PIMs.

SFINX[19] is a drug-drug interaction database containing short and concise evidence-based information on the consequences of and recommendations for about 18,000 drug interactions. The interactions are classified according to clinical significance: A (minor interaction of no clinical relevance), B (clinical outcome of the interaction is uncertain and/or may vary), C (clinically relevant interaction that can be managed by dose adjustments), and D (clinically relevant interaction that is best avoided).[20]

RENBASE[21] categorizes the patient's renal function, based on estimated GFR, into 5 categories: normal (GFR >80 mL/min), mild renal failure (GFR 80-50 mL/min), moderate renal failure (GFR 49-30 mL/min), severe renal failure (GFR 29-10 mL/min), and end-stage

renal failure (GFR <10 mL/min). In addition to the characteristics of a particular drug, the safety and dosage recommendations are defined on the basis of the patient's GFR category. Four categories are used: A (no need for dosage modification), B (the information is not available or the recommendation is estimated based on the pharmacokinetic characteristics of the substance), C (modification of the dose or dosage interval is needed), and D (use should be avoided).[22] Our study refers to RENBASE classes C and D.

PHARAO[19] is a database presenting a risk profile of a patient's medication based on the pharmacodynamic properties of drugs. PHARAO contains over 12,000 evaluations of the risk profile of approximately 1400 drugs with regard to 9 clinically relevant adverse effects (anticholinergic effect, constipation, sedation, orthostatism, risk of bleeding, serotonergic effect, risk of seizures, QT-prolongation, and renal toxicity). Each adverse effect is defined by an algorithm and classified according to clinical significance: A (no known pharmacologic or clinical basis for an increased risk), B (somewhat increased risk), C (moderately increased risk), and D (high risk). We used the term "medication-related risk load" to define PHARAO results.

The Meds75+ database of medication for older persons[23] supports clinical decision-making in the pharmacotherapy of patients ≥75 years of age. Drugs are classified into categories indicating how suitable the drug is for persons ≥75 years of age: A (suitable for older persons), B (little research evidence, practical experience or efficacy in older persons), C (suitable for older persons, with specific cautions), and D (avoid use in older persons). We used Meds75+ class D to define the use of PIMs among home care patients.

Control

The patients who were randomized into the control group continued receiving usual home care. Their updated and verified baseline medication lists were reviewed after the 6-month measurements were conducted. In the review, the pharmacists used the same databases as with the intervention group.

Follow-up

Six months after the baseline measurements, the home care nurse checked the patients' medication use according to the study protocol and also repeated the other measurements that were conducted at the baseline. This occurred between September 2015 and May 2016.

Statistical Analyses

Analysis was conducted on both prescription and OTC drugs taken regularly or as needed. Data were analyzed according to the randomization group irrespective of whether the patients received the intervention as planned (the intention to treat principle). The baseline characteristics of the sample were summarized using proportions, percentages, and means with standard deviation (SD). Statistical comparisons between study groups were carried out using the χ^2-test or independent samples t-test. The significance of the results is presented as P values, and values of less than 0.05 are considered statistically significant.

We performed separate logistic regressions for each risk group. The dependent variable 0 denoted no risk at 6 months, and 1 denoted risk at 6 months. We controlled the logistic regressions for sex, age, and the risk in question at baseline. The variable regarding the baseline risk was dichotomous: 0 denoted no risk, and 1 denoted risk. First, we carried out logistic regressions for the combined risks of classes C that signify moderate risk and D that signify high risk. Second, we performed additional logistic regressions for the class D risks solely.

We performed a logistic regression for Meds75+ category D drugs, in which the use of drugs at 6 months, yes or no, served as a dependent variable. The use of drugs at baseline, sex, and age served as covariates. We did not perform logistic regressions for Meds75+ categories A–C, as preliminary cross tabulations indicated no statistical differences in these categories between intervention and control groups.

Research Ethics

We obtained written informed consent from all patients or from their closest proxy if the patient had diagnosed dementia or suspected cognitive impairment. The Research Ethics Committee of Northern Savo Hospital District approved the study protocol on February 3, 2015. The study was registered with Clinical Trials.gov, on March 26, 2015 identifier: NCT02398812.

Results

Participant Characteristics

There were no statistically significant differences in the baseline characteristics between intervention and usual care groups. The mean age of all the 512 home care patients was 84 (SD 6.4) years; the majority were women (72%) and lived alone (76%). The mean Charlson comorbidity index of participants was 2.5 (SD 1.6). Almost all patients (92%) had a cardiovascular disease and two-thirds (61%) had a disease of the musculoskeletal system. Approximately one-third of the patients had diabetes (36%), cerebrovascular disease (33%), or dementia (31%). The average GFR was 62 (SD 19) mmol/L, and furthermore, 81% of the patients had at least mild renal insufficiency (GFR ≤ 80 mmol/min).

At baseline, the mean number of all prescription and OTC drugs taken regularly or as needed was 15 in both study groups; range: 4–36 in the intervention and 2–32 in the usual care group (Table 1). The proportion of patients using 9 or more drugs was 92% in the intervention and 94% in the usual care group. The mean number of regularly taken drugs was 9.2 (range: 2–20) in the intervention and 9.5 (range: 1–20) in the usual care group. The number and range of drugs taken as needed was 3.5 (0–20) and 3.8 (0–13) in the intervention and usual care groups, respectively.

Effects of Intervention on Medication

Compared with the usual care group, there were no statistically significant changes in the number of drugs in the intervention group over the 6-month follow-up (Table 1).

SFINX class C and D DDIs decreased in both study groups (Figure 2). High risk interactions (class D) decreased by 6% in the intervention group while there was no change in the usual care group, but the difference between the groups was not statistically significant.

Changes in RENBASE alerts, indicative of clinically relevant risks of drug-induced impairment of renal function, favored intervention statistically significantly when considering class C and D risks together ($P = .023$, adjusted for age, sex, and corresponding database risk alerts at baseline) or high risk class D alerts alone (adjusted $P = .020$).

The medication-related class D risk load for bleeding decreased statistically significantly in the intervention group when compared to the change in the usual care group, adjusted $P = .001$. The changes in the risk loads for constipation favored intervention. Combined class C and D risk loads for constipation also decreased significantly, adjusted $P = .003$. Furthermore, the number of medication-related risk loads for anticholinergic effects decreased in the intervention group but increased in the usual care group. The change between the groups was significant for the combined class C and D anticholinergic risk loads (adjusted $P = .009$) and also for class D risk load alone (adjusted $P = .003$). The medication assessment intervention did not have a

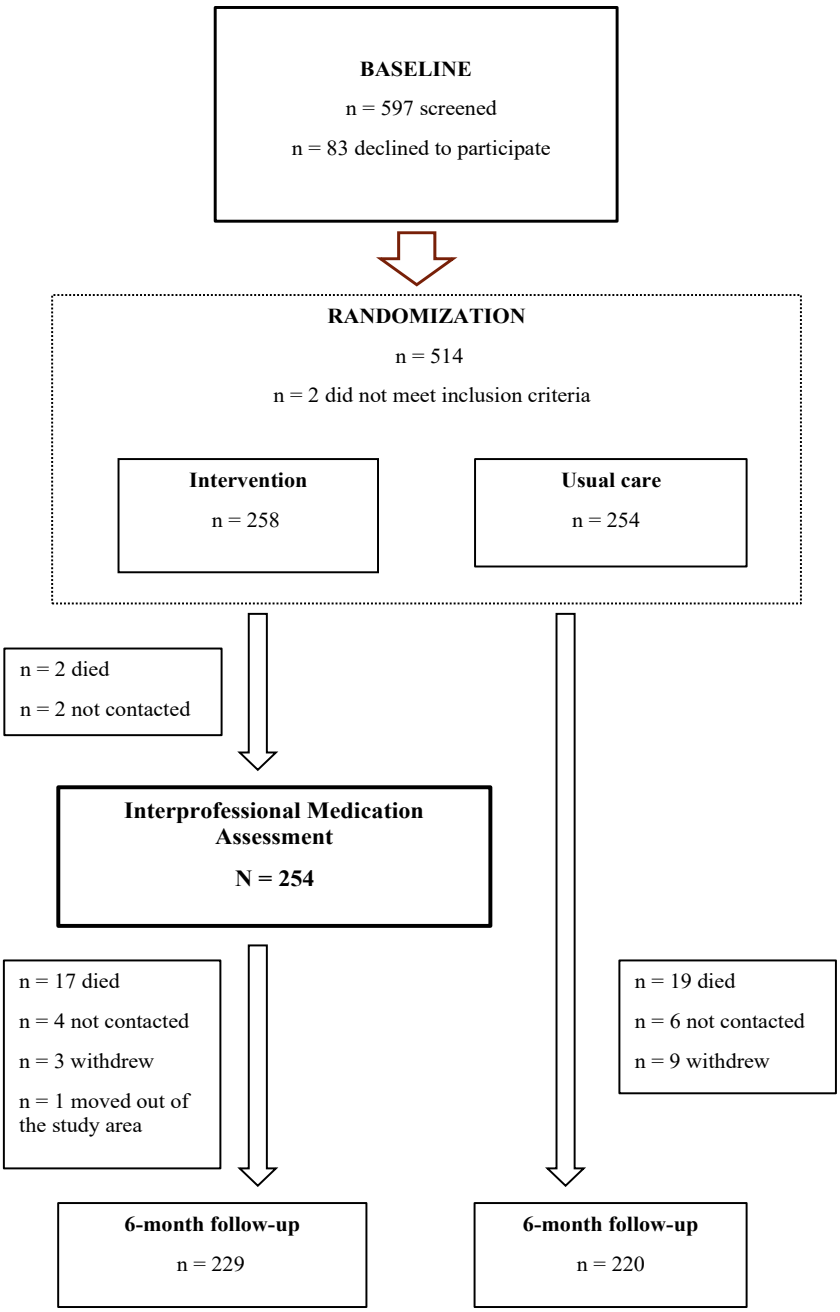

Fig 1. Flow chart of the FIMA study.

statistically significant effect on the risk loads of orthostatic hypotension, sedation, QT-prolongation, and serotonergic effect compared with the usual care. The risks of seizures were too rare to perform statistical analyses.

At baseline, 42% of the intervention and 53% of the usual care group patients had at least one PIM (defined as Meds75+ class D drug) in use. At the 6-month follow-up, the proportions were 33% in the intervention group and 50% in the usual care group. The odds of using PIM at the 6-month follow-up was 2.1 times higher in the control group compared with the intervention group (adjusted $P = .005$). The intervention also reduced the number of Meds75+ class C drugs per patient and increased that of class A drugs (Table 2).

Discussion

Key Findings

We investigated the effect of interprofessional medication assessment on medication quality among home care patients in RCT design. We found that the FIMA intervention improved medication quality by reducing statistically significantly the risk of drug-induced impairment of renal function, medication-related risk loads for anticholinergic effects, bleeding and constipation, and the use of PIM over a 6-month period. The intervention had no effects on medication-related risk loads for orthostatic hypotension, sedation, serotonergic effects or QT-prolongation.

Table 1
Medication Use and Risks of Clinically Relevant Drug-Drug Interactions, Risks of Drug-Induced Impairment of Renal Function, and Medication-Related Risk Loads at Baseline and after 6 Months in Intervention and Usual Care Groups

	Intervention		Usual Care		*P* Value*
	Baseline	6 Mo	Baseline	6 Mo	
All drugs†, mean (SD)	14.7 (5.2)	13.8 (4.7)	15.3 (5.1)	14.7 (5.2)	.387
Regularly taken	9.2 (2.9)	9.2 (3.1)	9.5 (3.1)	9.5 (3.0)	.855
Taken as needed	3.5 (2.8)	3.0 (2.2)	3.8 (2.6)	3.5 (2.5)	.443
Drug-drug interactions (SFINX)‡, n (%)					
Class C and D	156 (69)	145 (64)	168 (79)	159 (74)	.336
Class D	31 (14)	18 (7.9)	15 (7.0)	15 (7.0)	.202
Risks of drug induced impairment of renal function (RENBASE)§, n (%)					
Class C and D	182 (81)	178 (79)	187 (88)	191 (90)	.023
Class D	14 (6.2)	7 (3.1)	12 (5.7)	15 (7.1)	.020
Medication-related risk loads (PHARAO)‖, n (%)					
Bleeding					
Class C and D	139 (61)	137 (60)	151 (71)	152 (71)	.275
Class D	65 (29)	51 (23)	72 (34)	77 (36)	.001
Constipation					
Class C and D	126 (56)	106 (47)	122 (57)	126 (59)	.003
Class D	89 (39)	75 (33)	83 (39)	85 (40)	.080
Orthostatic hypotension					
Class C and D	111 (49)	117 (52)	124 (58)	128 (60)	.755
Class D	64 (28)	64 (28)	63 (29)	58 (27)	.449
Anticholinergic effect					
Class C and D	64 (28)	54 (24)	67 (31)	73 (34)	.009
Class D	38 (17)	26 (12)	36 (17)	42 (20)	.003
Sedation					
Class C and D	40 (18)	48 (21)	50 (23)	60 (28)	.409
Class D	30 (13)	34 (15)	31 (15)	37 (17)	.606
QT-prolongation					
Class C and D	31 (14)	26 (12)	29 (14)	25 (12)	.813
Class D	19 (8.4)	10 (4.4)	7 (3.3)	7 (3.3)	.653
Serotonergic effect					
Class C and D	4 (1.8)	2 (0.9)	8 (3.7)	7 (3.3)	.235
Class D	0	0	5 (2.3)	4 (1.9)	n/a**
Seizures					
Class C and D	1 (0.4)	2 (0.9)	3 (1.4)	3 (1.4)	n/a**
Class D	1 (0.4)	2 (0.9)	3 (1.4)	3 (1.4)	n/a**

*All drugs: t-test for the change in the number of drugs between groups. Interactions, renal failure, and risks of adverse events: logistic regression (1: yes at 6 months, 0: no at 6 months) adjusted for gender, age, and baseline level of the outcome measure.

†Including prescription and over-the-counter drugs; n is 230 in the intervention group and 219 in the usual care group, except for all drugs in which n in the usual care group is 220.

‡SFINX database classes C (interactions can be handled) and D (should be avoided); n is 227 in the intervention group and 214 in the usual care group.

§RENBASE database classes C (dose modifications are needed) and D (drug should be avoided); n is 226 in the intervention group and 212 in the usual care group.

‖PHARAO database classes C (moderate risk of adverse events) and D (high risk); n is 227 in the intervention group and 214 in the usual care group, except for sedation in which *n* in the intervention group is 226.

**Too few cases to perform a logistic regression.

Comparison with Previous Studies

The impact of different medication management interventions has been examined widely among older patients in various settings. A systematic review and meta-analysis of medication assessment RCTs[24] reported that several MRPs decreased or increased less than in the reference groups. In contrast, a Cochrane Review[9] found no consistent effects on MRPs in interventions that attempted to improve the appropriateness of polypharmacy among older people.

An interprofessional team approach has been highlighted because older people usually do better when their medication is managed by a multidisciplinary team.[25] RCTs conducted in home care settings in Sweden[26] and the United States[27] reported that interprofessional medication assessment improved medication quality. The former study showed a reduction in the use of PIMs and the latter in the use of therapeutic duplication. The interprofessional teamwork was found to be feasible in home care settings, which is in line with our experience.

The number of drugs was high among our study participants. This may partly reflect the fact that the use of ≥6 drugs was one of our inclusion criteria. In our study, the numbers of all drugs decreased in both study groups, but the reduction was not significantly greater in the intervention group. Meta-analysis of RCTs investigating the effectiveness of medication assessment[24] reported a greater decrease or smaller increase in the number of drugs. However, only 2 RCTs included in the meta-analysis were conducted in community settings.[27,28]

Medication-related anticholinergic burden exposes vulnerable older patients to several types of adverse events and negative health outcomes, such as falls, cognitive decline, and confusion.[29] Our intervention decreased the rate of clinically relevant anticholinergic risk load from 17% to 12% in the intervention group, while it increased from 17% to 20% in the usual care group. Our results are in line with a medication assessment study[30] that showed a decrease in the anticholinergic load of drugs among older people.

The prevalence of class D risk load for bleeding was 29% at baseline measurements and 6% units lower at 6-month follow-up measurements. In a Finnish primary care study of older adults,[31] the prevalence rates for the risk of bleeding were 25% and 21% among older patients with and without diabetes, respectively. A study assessing effects of CMR[32] found no changes in self-reported bruises or bleeding.

Constipation is a common adverse effect of drugs with anticholinergic properties.[33] In our study, the class C and D risk loads for constipation reduced from 56% to 47% in the intervention group and increased from 57% to 59% in the usual care group. RCTs[32,34] evaluating

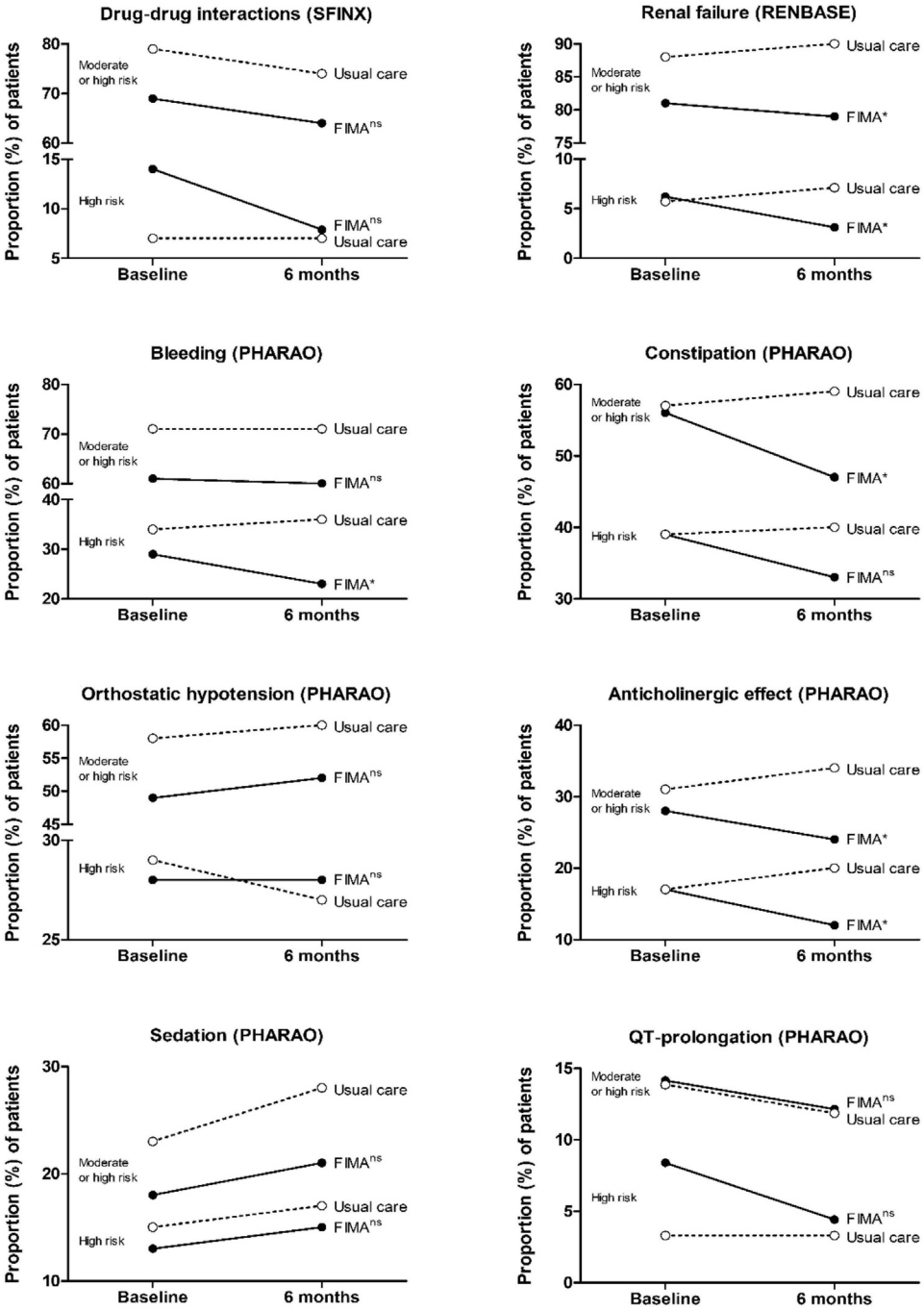

Fig. 2. Drug-related risks over 6 months among patients receiving usual care or interprofessional medication assessment (FIMA). The risks were evaluated according to 3 databases: SFINX, RENBASE, and PHARAO. An asterisk indicates a statistically significant ($P < .05$) unadjusted difference in change between the usual care and FIMA intervention, and ns indicates a statistically nonsignificant difference. Note the various scales of y-axes.

CMR among older people did not find an effect on drug-related constipation. However, comparisons to our findings are limited due to differences in outcome measures.

The prevalence of the use of PIMs was high at the baseline of our study. In a recent systematic review, the rate of PIM use varied from 20% to 48% depending on the criteria used.[35] In our study, the FIMA intervention reduced PIM use significantly. This is in line with findings of previous studies investigating the effects of multiprofessional medication assessment on PIM use in various settings.[36,37]

Strengths and Limitations

Our study has several strengths. It was a randomized study with the intervention based on experiences from clinical practice. The participants were clients of public home care without exclusion criteria regarding morbidity or functionality. Therefore, we assume that our findings are generalizable to the home care context. Information on the use of medication were checked to match the actual usage.

Table 2
Drug Use According to Meds75+ at Baseline and at 6 Months

	Intervention		Usual Care		*P* Value*
	Patients	Drugs	Patients	Drugs	
	n	Mean ± SD	n	Mean ± SD	
Meds75+ Class A†					
No. at baseline	258	6.36 ± 2.77	253	6.94 ± 2.74	.016
No. at 6 mo	230	6.48 ± 2.76	220	6.74 ± 2.66	.348
Change in no.	230	0.12 ± 1.67	219	−0.20 ± 1.71	.044
Meds75+ Class B‡					
No. at baseline	258	0.22 ± 0.46	253	0.25 ± 0.45	.321
No. at 6 mo	230	0.29 ± 0.49	220	0.32 ± 0.49	.562
Change in no.	230	0.07 ± 0.44	219	0.06 ± 0.41	.974
Meds75+ Class C§					
No. at baseline	258	4.87 ± 1.98	253	4.72 ± 1.88	.224
No. at 6 mo	230	4.54 ± 2.01	220	4.72 ± 2.08	.365
Change in no.	230	−0.32 ± 1.62	219	0.00 ± 1.39	.022
Meds75+ Class D‖					
No. at baseline	258	0.66 ± 1.00	253	0.80 ± 1.01	.116
No. at 6 mo	230	0.47 ± 0.81	220	0.73 ± 0.91	.002
Change in no.	230	−0.18 ± 0.74	219	−0.08 ± 0.61	.101

*t-test for the change in the number of drugs between groups.
†Suitable for the older persons.
‡There is little research evidence, practical experience or efficacy in older persons.
§Suitable for older persons, with specific cautions.
‖Avoid use in older persons.

The average time used in team meetings was 20 minutes per patient, and the pharmacist used approximately 27 minutes to conduct the medication review before team meeting.[14] The FIMA procedure does not cause extra work for home care nurses and physicians because updated information on patients' medication use, GFR, blood tests, blood pressure, orthostatic hypotension, cognitive function, depressive symptoms, and functioning in ADLs and instrumental ADLs are tasks of usual home care. The FIMA procedure is practical and easy to conduct in home care settings with minor investments, resulting from pharmacist recruitment mostly.

There were also some limitations. We were not able to analyze the risks based on drug doses or number of drugs affecting the risk loads. The PHARAO database does not consider doses but only the pharmacologic properties of drugs. Therefore, for example, the risk load for sedation may remain high although the doses of index drugs are reduced substantially. We were not able to verify the complete implementation of the FIMA procedure and totally exclude some variation between teams. Because of the substance of the intervention, blinding was not possible. In addition, the same professionals treated the intervention and usual care patients possibly resulting in observer effect. We assessed the impact of medication assessment performed only once although regular assessments are preferable for older people. Though our intervention improved medication quality and patient safety, this may not necessarily mean large scale functional improvements among home care patients with multimorbidity and functional limitations,[14] yet we believe that improved medication quality of itself is an important and clinically relevant achievement.

Conclusions and Implications

Interprofessional medication assessment improves home care patients' medication quality by reducing the risks of drug-induced impairment of renal function, medication-related risk loads for anticholinergic effects, bleeding and constipation, and the use of PIMs.

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