Interprofessional medication assessment among home care patients: Any impact on functioning? Results from a randomised controlled trial

Kati Johanna Auvinen (kati.nuopponen@gmail.com)
The East Savo Hospital District https://orcid.org/0000-0003-4832-8497
Ari Voutilainen
Ita-Suomen yliopisto Kuopion kampus
Johanna Jyrkkä
Ita-Suomen yliopisto Kuopion kampus
Eija Lönnroos
Ita-Suomen yliopisto Kuopion kampus
Pekka Mäntyselkä
Ita-Suomen yliopisto Kuopion kampus

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Abstract

Background

Multimorbidity and polypharmacy are related to the use of potentially inappropriate medicines and negative clinical outcomes including drug-related adverse events and functional decline. Home care clients are a vulnerable patient group often exposed to these risks. The aim of this study was to examine whether interprofessional medication assessment has effects on the functioning of home care patients.

Methods

The FIMA study was a randomised controlled intervention study comparing general practitioner-led interprofessional medication assessment conducted at the baseline of the study with usual care in six-month follow-up. We used linear mixed models (LMM) with a random subject effect to detect differences in outcome measures Katz index of Activities of Daily Living (ADL), Lawton and Brody scale of Instrumental Activities of Daily Living, Timed up and go-test (TUG), Mini-Mental State Examination, Geriatric Depression Scale and The 3-level version of EQ-5D between the usual care and intervention groups.

Results

Home care patients (n= 512) had major disease burden and functional limitations. Regarding TUG times, the LMM showed a statistically significant interaction between time and treatment (p=0.017) favoring the intervention. Correspondingly, ADL showed to have an interaction between time and treatment (p=0.025). The ADL score decreased in both groups, but the decline was steeper in the intervention group.

Conclusions

Interprofessional medication assessment prevented worsening of mobility and balance performance in vulnerable older people.

Trial registration

The Interprofessional Medication Assessment for Older Patients**,** Clinical Trials.gov. NCT02398812. First registration, 26 March 2015. Retrospectively registered. https://www.clinicaltrials.gov/ct2/how/NCT02398812 .

Background

The number of home care patients is increasing rapidly with ageing of the populations. A key prerequisite for living at home in old age is maintaining physical and psychosocial functioning. Medication related problems and functional decline are closely associated among vulnerable older people [1, 2]. Potentially inappropriate prescribing and drug-related adverse events increase the risks of cognitive impairment, falls and hospital admissions [3, 4].

Several studies have reported on results of medication assessment to reduce complex medications and inappropriate prescribing [5-7], but less attention has been given to concrete health outcomes such as drug-related adverse events, functioning, general health and quality of life [8, 9]. The scarcity of studies concerning these health outcomes might partly be because designing a practical and feasible medication assessment model for older patients with multimorbidity and polypharmacy is very challenging.

An interprofessional team approach has been suggested as a solution to promote rational medicine use among older people [10]. The Finnish Interprofessional Medication Assessment (FIMA) is a general practitioner (GP) led, repeatable and practice-based model for medication optimization of older people [11]. The FIMA model was developed in home care settings. Baseline findings of the FIMA study showed that home care patients had significant disease burden. Most of patients (87%) had excessive polypharmacy (≥10 medicines), clinically relevant drug-drug-interactions (74%) and risk of drug-induced impairment

in renal function (85%). Functional limitations including mobility and balance problems were also common in this patient group. In the present study, we examined whether the FIMA intervention had effects on the home care patients' physical, cognitive, and psychosocial functioning, or health-related quality of life.

Methods

Study design and participants

The FIMA study was a randomized, controlled intervention study with comparison between GP-led interprofessional medication assessment and usual care in public home care settings. The study was conducted in public home care settings in five areas in Finland: Forssa, Haapajärvi, Lahti, Juva and Savonlinna. The complete study design of the FIMA study has been published previously [11]. The Research Ethics Committee of Northern Savo Hospital District and Kuopio University Hospital approved the FIMA study protocol on February 3, 2015. The FIMA study was registered with Clinical Trials.gov on March 20, 2015 (identifier: NCT02398812). Reporting follows the CONSORT 2010 statement.

We screened and recruited patients receiving regular home care services in the study areas. The inclusion criteria were age ≥ 65 years and registration to public home care services, and at least one of the following: ≥ 6 medicines in use, dizziness, orthostatic hypotension or a recent fall. We excluded patients whose medication was not managed by the home care and patients with active cancer therapy.

In total, 512 patients were recruited by home care nurses from February to December 2015 (Figure 1). Characteristics of the participants have been described previously [11]. Written informed consent was obtained from all individual patients included in the study or their closest proxy if the patient had cognitive impairment. After baseline measurements, patients were randomized to receive intervention or care-as-usual using block randomization with blocks of ten. The study assistant implemented the random allocation sequences. Intervention and usual care groups were treated similarly except for the interprofessional medication assessment.

Data collection

Medication use was verified by a home care nurse who printed patient's current medication list from the electronic medical record before the baseline measurements. At patient's home, the nurse checked prescription and over-the-counter medicines and updated the medication list accordingly. Performance in daily activities, patient's physical and cognitive performance, depressive symptoms and quality of life were assessed. Sociodemographic variables were also collected.

The physician of home care team documented patients' diagnoses from the existing medical records. In this study, we used a modified Charlson Comorbidity Index (CCI) [12] to describe home care patients' disease burden. The index was calculated using the following diseases with corresponding scores: metastatic or terminal cancer (score of 6); non-metastatic cancer or moderate or severe renal insufficiency (score of 2); heart failure, coronary artery disease, type 1 or 2 diabetes, chronic asthma or chronic obstructive pulmonary disease, rheumatoid arthritis or other forms of inflammatory arthritis, peripheral vascular disease, cerebrovascular disease, dementia of any type or history of gastrointestinal bleeding (score of 1).

Intervention

The structured medication assessment included review of medication, gathering the clinical information, and an interprofessional team meeting. An interprofessional team consisting of a pharmacist, physician and registered nurse working regularly in home care conducted the medication assessment within two weeks after the baseline measurements. Patients' updated and verified medication lists, baseline measurements, and electric medical records including patients' medical history were available during the assessment.

Before the team meeting, the pharmacist reviewed the patients' medication lists using four databases: SFINX® (currently INXBASE®) for drug-drug-interactions, PHARAO® (currently RISKBASE®) that complements SFINX® with regard to 11 clinically

relevant adverse effects, RENBASE® for renal risks [13] and the Database of Medication for the Elderly (Meds75+) [14]. The physician gathered information from patients' medical records and on current clinical status.

In the interprofessional team meeting, the professionals discussed on the patient's current health status and functioning, and reviewed patient's medications accordingly. The physician made clinical decisions and wrote recommendations into the patient's medical records at the end of the team meeting. The nurse updated patient's medication regimen and informed the patient about the changes, or if necessary, the patient participated in the interprofessional team meeting. The average time for the interprofessional team meeting was 20 minutes, and 27 minutes for the structured review done by the pharmacist.

All pharmacists had a qualification in comprehensive medication review or current continuing professional development in clinical pharmacy. All interprofessional team members received a one-day training or a personal introduction concerning the FIMA protocol.

Usual care

Patients randomised to usual care did not receive interprofessional medication assessment. Information on their medication use were collected in a similar manner as in the intervention group but their baseline medication lists were reviewed by pharmacist only after the six-month measurements were conducted.

Outcome measures

Katz index of Activities of Daily Living (ADL) [15] and the Lawton and Brody scale of Instrumental Activities of Daily Living (IADL) scale [16] were used to assess patients' performance. Maximum score in ADL is six and in IADL eight, with lower scores indicating increased requirement for assistance in daily activities. The Timed Up and Go (TUG) test was used to assess mobility, lower extremity strength and balance. The time taken to complete the TUG test correlates with level of functional mobility [17]. The Mini-Mental State Examination (MMSE) was used for screening cognitive function. The MMSE scores $\leq$24 indicate impaired cognitive function [18]. Geriatric Depression Scale (GDS-15) was used for assessing depressive symptoms. Sum scores $\geq$6 are suggestive of depression [19]. The preference-based, five-dimension instrument provided by EuroQol (EQ-5D-3L)(1) [20] was used for measuring health-related quality of life. These measurements were carried out at baseline and repeated at six-month follow-up.

Statistical methods

Data were analysed according to randomisation group irrespective of whether the patients received the intervention as planned (the intention to treat principle). Baseline characteristics of the sample were summarized using proportions, percentages, and means with standard deviation (SD).

We used linear mixed models (LMM) with a random subject effect to detect differences in ADL, IADL, TUG, MMSE, GDS-15, and EQ-5D-3L between the usual care and intervention groups. Treatment (FIMA vs. usual care), time (baseline vs. 6-month follow-up), and gender served as factors, and age and CCI (excluding dementia) at baseline served as covariates. The models also included a treatment-time interaction. IBM® SPSS® Statistics Version 25 served as the statistical platform.

Results

Participant characteristics

The mean age of men was 83.1 (SD 6.9) and that of women was 85.2 (SD 6.2) years. Most participants, 64.1% of men and 81.2% of women, were living alone. The mean number of all medicines was 15 in both genders, ranging from 2 to 36 in women and from 4 to 35 in men. The corresponding numbers for regularly taken medicines were 9.5 (range: 1–20) in women and 9.6 (3–17) in men. At baseline there were no statistically significant differences between intervention and usual care groups either among women or among men (Table 1).

Impact on functioning and health-related quality of life

Regarding TUG times there was a statistically significant interaction between time and treatment (Table 2). In the usual care group, the performance in the TUG test worsened (i.e. the time increased) between baseline and follow-up measurements whereas, in the FIMA group, the performance improved (Table 3). Correspondingly, regarding ADL, the LMM showed a statistically significant interaction between time and treatment (Table 2). The ADL score decreased in both groups, but the decline was steeper in the FIMA group (Table 3).

Discussion

We investigated the impact of interprofessional medication assessment on home care patients' functioning in a randomised, controlled study design, and found that interprofessional medication assessment improved balance and mobility performance or at least prevented worsening of it in older home care patients. During the six-month follow-up, ADL functioning declined. Instrumental activities, cognitive functioning, mood and quality of life did not show significant changes during the follow-up. These findings are in line with results of a systematic review and meta-analysis of randomised, controlled trials with medication review as isolated short-term intervention [22].

In our study, changes in TUG times were different in intervention and usual care groups favoring the intervention. In general, TUG performance is better among men than women [23]. Results of our LMM analysis were concordant with this fact. We conducted TUG analysis separately for men and women also using ANCOVA which showed that the intervention was beneficial specifically for women (data shown as request). In previous studies, longer TUG-times have been associated with lower executive function performance, risk of falls, functional decline and frailty [24–26]. A Canadian study [24] examining older, community-dwelling people, found that the longer it took to complete the TUG test, the greater was the person's risk for decline in activities of daily living. The three-month risk for decline in daily functioning increased from 5 to 9-fold when TUG times raised from 20–29 s to ≥ 30 s. In addition, TUG times ≥ 30 s represented nearly 4-fold risk for frailty compared with TUG times ≤ 10 s. Enhancing mobilty and balance perfomance may decrese these risks.

Medication assessments have been examined in several studies in varying settings among older people. A systematic review and meta-analysis of randomised, controlled trials concerning effectiveness of medication reviews [22] found minimal effect on clinical outcomes and no effect on quality of life. However, the meta-analysis suggested that medication review may decrease the number of falls, which supports our findings on mobility and balance performance. A Cochrane review concerning pharmacist services for non-hospitalised patients [27] concluded that pharmacist services may slightly improve physical functioning, but physical functioning measured by SPF-36 questionnaire seemed to enhance only in diagnose-specific trials among approximately 48–66 years old patients. Two randomised, controlled medication review trials among older patients with multiple conditions [28, 29] found no change in physical functioning. Regarding our and former findings, improving physical functioning by an isolated intervention is difficult in older people with high disease burden.

Among home care clients, the general trend in ADL and IADL functioning is descending. Our intervention could not prevent the decline in ADLs. ADL scores declined in all sub-groups, and contrary to expected, even more in the intervention than in the control group. With regard to clinical relevance, the changes in the mean ADL scores were small. At baseline, the scores were around 5 indicating dependency in one daily activity. The maximum decline measured at six-month follow-up was less than 0.5 points whereas the minimum of clinically relevant change is considered to be 0.5 or 1.0 point [30]. It could be possible that updated medication may impact specifically on mobility and balance but not on the overall functioning.

Our study has several strengths. It was a randomised, controlled study in a real-life context. Furthermore, the study has a practice-based design with public home care team conducting a pragmatic intervention. In addition, medication assessments are particularly indicated among home care patients. We assume that our findings are generalizable to older home care patients with polypharmacy and increased risk of falls. We used well-known, validated outcome measures to examine different dimensions of functioning. The detection and assessment of medication related risks and interactions were based on four decision support systems that are available and commonly used in the Finnish health care.

The FIMA procedure is systematically described and transferable to different contexts. The procedure is produced by public health care professionals, which means that information on patient's clinical conditions is relevantly considered in the medication assessment. Furthermore, the physician can make changes to patient's medication at the interprofessional team meeting, when all the information is available. In the FIMA procedure, the home care nurse conducts the verification of current medication that patient uses at home, which enables medication assessments for large number of patients in routine care. In addition to the records in the patient files, the nurse receives instructions for patients' further follow-up directly in the interprofessional team meeting, which reduces the risks of information disconnections and misunderstandings.

This study has some limitations. Due to high age and multimorbidity, this sample was medically unstable which may diminish impact of any intervention, especially that of single-domain interventions. We assessed the impact of medication assessment performed only once, although regular and repeated assessments are preferable for vulnerable home care patients with chancing health and functioning. Furthermore, it is not recommended to make several changes in older peoples' medications concurrently. The follow-up time was six months, in which older people's clinical conditions could change affecting functioning. In addition, same home care units treated both intervention and usual care patients, which may have been caused observer effect. Although all the interprofessional teams had one-day training, we were not able to verify the implementation of the intervention procedure. Therefore, there may have been variation in working between the teams.

Conclusion

To conclude, it is challenging to improve functioning or prevent functional decline among vulnerable home care patients. Our findings indicate that an interprofessional medication assessment may improve or at least prevents worsening of mobility and balance performance in older people receiving home care services. Significant improvement in other dimensions of functioning were not found.

Abbreviations

FIMA: The Finnish Interprofessional Medication Assessment; GP: General Practitioner; ADL: Activities of Daily Living; IADL: Instrumental Activities of Daily Living; TUG: Timed Up & Go Test; MMSE: Mini-Mental State Examination; GDS-15: Geriatric Depression Scale; CCI: Charlson Comorbidity Index; EQ-5D-3L: EuroQol five-dimension instrument for health-related quality of life; SD: standard deviation

Declarations

Ethics approval and consent to participate

The Research Ethics Committee of Northern Savo Hospital District and Kuopio University Hospital approved the FIMA study protocol on February 3, 2015. The FIMA study was registered with Clinical Trials.gov on March 20, 2015 (identifier: NCT02398812). Written informed consent was obtained from all individual patients included in the study or their closest proxy if the patient had cognitive impairment.

Consent for publication

Not applicable

Availability of data and materials

Not applicable. The data will not be publicly available due to national regulations and agreements obtained to perform the study.

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

KA, AV, JJ, EL and PM conceived, designed and implemented the study. KA, AV and JJ collected and analyzed the data. KA, AV, JJ, EL and PM drafted the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1. Baseline characteristics of the study participants by sex and randomization status (intervention or usual care)

	Women		Men	
	Intervention	Usual Care	Intervention	Usual Care
	n=177	n=190	n=81	n=64
Age (years), *mean (SD)*	85.1(6.62)	85.1(5.75)	82.9(6.59)	83.4(7.18)
Living alone, *n (%)*	149(84)	149(78)	53(65)	40(63)
Chronic diseases, *n (%)*				
Cardiovascular diseases	164(93)	174(91)	72(89)	60(92)
Diseases of musculoskeletal system	115(65)	125(65)	43(53)	30(46)
Diabetes	63(36)	66(35)	28(35)	26(40)
Cerebrovascular diseases	48(27)	54(28)	35(43)	32(49)
Dementia	62(35)	62(33)	23(28)	14(22)
Asthma or chronic obstructive pulmonary disease	29(16)	41(16)	23(28)	12(19)
Psychiatric diseases				
Cancer	34(19)	32(17)	15(19)	7(11)
Gastrointestinal diseases	24(14)	21(11)	22(28)	12(19)
Neurological diseases	30(17)	28(15)	11(14)	8(12)
	23(13)	20(11)	13(16)	12(19)
Charlson Comorbidity Index, *mean (SD)*	3.05(2.48)	2.65(2.26)	3.81(3.09)	3.22(2.41)
All medicines[†], *mean (SD)*	15(5.4)	16(5.2)	15(4.8)	15(4.6)
Regularly taken	9(3.1)	10(3.0)	10(2.9)	10(3.1)
Taken as needed	3(2.7)	4(2.6)	4(2.9)	3(2.2)

[†] Including prescription and over-the-counter medicines

Table 2. P-values from linear mixed models regarding effects of age, comorbidity (CCI), gender, treatment (FIMA), follow-up time (FUT), and the interaction of treatment and time on functioning. Signs before statistically significant p-values (<0.05) indicate whether the effect was negative of positive.

Outcome	Age	CCI	Gender	FIMA	FUT	Interaction
ADL	0.102	(-) 0.038	0.784	0.474	(-) <0.001	0.025
IADL	(-) 0.001	0.981	0.125	0.593	(-) <0.001	0.063
TUG, s	0.441	(-) 0.002	(F-) 0.029	0.599	0.330	0.017
MMSE	(-) <0.001	(+) 0.003	0.727	0.315	(-) 0.025	0.561
GDS-15	(-) 0.034	0.374	0.108	0.209	0.818	0.338
EQ-5D-3L	0.316	0.102	0.747	0.905	0.083	0.846

Notes. CCI: a modified Charlson Comorbidity Index excluding dementia. FIMA: The Finnish Interprofessional Medication Assessment. ADL: Katz index of Activities of Daily Living. IADL: Lawton and Brody scale of Instrumental Activities of Daily Living. TUG: Timed up and go - test. MMSE: Mini-Mental State Examination. GDS-15: Geriatric depression scale. EQ-5D-3L: Health-related quality of life. F: Female.

Table 3. Functioning at baseline (0 months) and six-month follow-up (6 months) together with predicted values (LMM) in intervention and usual care groups. 0 month and 6 months values indicate crude mean ± SD, predicted values indicate mean, 95% CI. The Finnish Interprofessional Medication Assessment (FIMA) served as an intervention and usual care served as a control treatment.

	n	0 month	LMM	*n*	6 months	LMM
FIMA						
ADL	258	4.98±1.30	5.02, 4.84-5.19	229	4.71±1.49	4.72, 4.54-4.89
IADL	258	4.05±2.01	4.00, 3.74-4.27	229	3.73±2.11	3.66, 3.39-3.93
TUG, s	236	28.6±28.2	27.5, 24.6-30.4	198	26.6±22.3	26.5, 23.5-29.5
MMSE	257	22.4±4.59	22.4, 21.8-23.0	226	22.2±4.84	22.0, 21.4-22.6
GDS-15	258	5.43±3.20	5.51, 5.11-5.91	226	5.27±3.18	5.43, 5.01-5.84
EQ-5D-3L	257	0.58±0.25	0.58, 0.55-0.62	227	0.57±0.29	0.57, 0.53-0.60
Usual Care						
ADL	254	4.82±1.27	4.83, 4.65-5.01	220	4.78±1.37	4.74, 4.56-4.93
IADL	254	4.05±2.06	3.98, 3.71-4.25	220	4.00±2.14	3.86, 3.59-4.14
TUG, s	230	25.5±15.9	24.8, 21.8-27.8	196	26.6±17.7	27.1, 24.0-30.2
MMSE	252	22.7±4.68	22.7, 22.1-23.3	217	22.5±4.64	22.5, 21.9-23.1
GDS-15	252	4.95±3.10	5.07, 4.66-5.49	216	5.00±3.03	5.21, 4.78-5.64
EQ-5D-3L	251	0.59±0.25	0.58, 0.55-0.62	218	0.56±0.27	0.56, 0.52-0.60

ADL: Katz index of Activities of Daily Living IADL: Lawton and Brody scale of Instrumental Activities of Daily Living. TUG: Timed up and go - test. MMSE: Mini-Mental State Examination. GDS-15: Geriatric depression scale. EQ-5D-3L: Health-related quality of life.

Figures

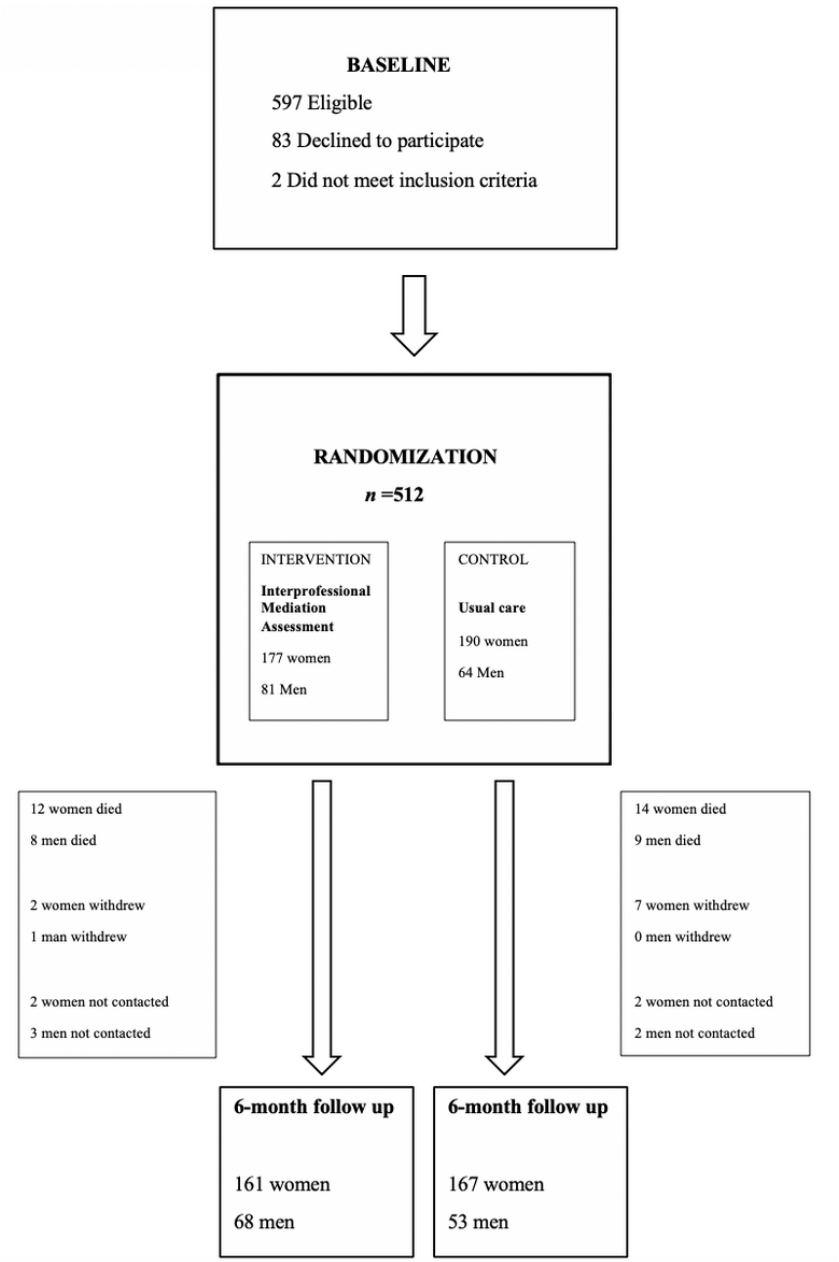

Figure 1

Flow chart of the study

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