


Self-assessed medication risk factors as part of comprehensive health screening in home-dwelling older adults

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Abstract

Background: Poor medication management may negatively impact the health and functional capacity of older adults. This cross-sectional study aimed to identify medication-related risk factors in home-dwelling residents using a validated self-assessment as part of comprehensive health screening.

Methods: The data were derived from comprehensive health screening (PORI75) for older adults of 75 years living in Western Finland in 2020 and 2021. One of 30 validated measures in health screening focused on identifying medication-related risk factors (LOTTA Checklist). The Checklist items were divided into (1) systemic risk factors (10 items) and (2) potentially drug-induced symptoms (10 items). Polypharmacy was categorized according to the number of used drugs: (1) no polypharmacy (<5 drugs), (2) polypharmacy (≥5 and <10), and (3) excessive polypharmacy (≥10). The linearity across these three polypharmacy groups was evaluated using the Cochran–Armitage test.

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Results: Altogether, 1024 out of 1094 residents who participated in the health screening consented to this study ($n = 569$ in 2020 and $n = 459$ in 2021). The mean number of all drugs in use was 7.0 (range 0–26; SD 4.1), with 71% of the residents using >5 drugs, that is, having polypharmacy. Of the systemic risk factors most common was that the resident had more than one physician responsible for the treatment (48% of the residents), followed by missing drug list (43%), missing regular monitoring (35%), and unclear durations of the medication (35%). The most experienced potentially drug-induced symptoms were self-reported constipation (21%), urinating problems (20%), and unusual tiredness (17%). An increasing number of drugs in use, particularly excessive polypharmacy, was associated with various medication-related risk factors.

Conclusion: As a part of comprehensive health screening the LOTTA Checklist provides useful information to prevent medication-related risk factors in home-dwelling older adults. The Checklist could be used to guide planning and implementing health services in the future.

KEYWORDS

health screening, home-dwelling, medication-related risks, older adults

1 | INTRODUCTION

Older adults worldwide live longer than before,¹ which puts pressures on national and local aging policies to improve preventive support services for home-dwelling older adults.^{2–4} Medication risk management is a strategy that aims to prevent or decrease risks associated with the use of medicines.⁵ Poor medication risk management may lead to preventable adverse drug events, which can impair health and quality of life and increase mortality, morbidity, hospitalization, and the economic burden to society.⁶ Over the last several decades, numerous studies have described risk situations and adverse events caused by medicines in hospitals and outpatient care.^{7,8} The risks cumulate for those with multiple diseases and multiple medications. These people are often older adults.⁹ Because most of the medications are used at home,^{6,7,10,11} it is important to prospectively observe how medications of older people are managed in this setting.

A potential strategy to monitor medication-related risk factors in home-dwelling older adults is to include medication risk assessment in the comprehensive health screening. This approach is justified because inappropriately planned, implemented, and self-managed medications may negatively impact their health and functional ability.^{12,13} Despite this situation, factors contributing to medication-related risks are not routinely included in the comprehensive health screenings even though age-specific medication risk assessment tools exist that can be self-administered by older adults.¹⁴ This cross-sectional study aimed to identify the preventive medication-related risk factors in home-dwelling older adults aged 75 years using a new Delphi-validated self-assessment screening tool^{15,16} (LOTTA Checklist) as part of a comprehensive health screening.

2 | METHODS

2.1 | Context of the study

Finland has a publicly funded social and healthcare system, complemented by occupational healthcare and private services.^{17,18} Life expectancy at birth is one of the highest in the world; so is the proportion of aging people of the entire population. These statistics have been among the main reasons leading to ongoing major social and healthcare reform.^{17,19} The reform aims to combine social and healthcare services and improve the coordination and integration of care to ensure equal geographic and socioeconomic access to care. Access to care is also enhanced by strengthening primary healthcare and increasing digital services.²⁰ Administratively, the reform will restructure current hospital districts to well-being service counties that will cover primary and secondary care and social services in the region.¹⁹ Electronic patient records are under development regionally and nationally to ensure seamless care and care pathway formation. The goal is that the patient data are recorded and structured in a format that enables secondary use as data lakes that can guide planning and implementation of health and social services.²¹ These principles are outlined in the new Act on the Secondary Use of Health and Social Data which was enacted in Finland in 2019. The Act states that patient data can be used by service providers to plan preventive services, conduct clinical research, lead knowledge, and optimize cost-effectiveness.²²

This study was conducted in the Social Security Center of Pori providing primary care services to the residents of Pori, Ulvila, and Merikarvia municipalities. The Center was located in the Satakunta Hospital District in the Western Finland which was transferred to the Wellbeing Service County of Satakunta in the beginning of 2023 (1 of the

22 regional providers of social and health services in Finland).¹⁹ This study included 10 public healthcare centers within these 3 municipalities, with 99,485 residents. Twelve percent of them were ≥ 75 years old in 2020.²³

2.2 | Preventive health screening procedure for older residents (PORI75)

The Social Security Center of Pori started to develop a preventive health screening procedure for 75-year-old residents in 2019 to enhance secondary use of patient data. The procedure (PORI75) consists of 30 validated measures divided into three categories: (1) self-assessment screenings (9 measures), (2) nurse-conducted screenings (14 measures), and (3) laboratory tests (7 measures).²⁴ A detailed description of the development of the procedure has been published elsewhere.²⁴ The study was conducted in cooperation among Satakunta University of Applied Sciences (SAMK), Social Security Center of Pori and the University of Helsinki, Finland.

2.3 | The self-assessment tool for medication-related risk factors (LOTTA Checklist)

One of the validated measures (LOTTA Checklist) included in the PORI75 health screening procedure focuses on identifying medication-related risk factors, targeted to ≥ 65 years old medicine users.¹⁶ The use of validated LOTTA Checklist has been recommended by the Finnish Medicines Agency Fimea.²⁵ Furthermore, the Checklist is designed to be self-administered by older adults. It helps older people take more responsibility for their medication at home. Particularly, it encourages them to establish and maintain an up-to-date medication list and to self-monitor effects of their medication.¹⁵

The Checklist is based on the validated risk assessment tool for drug-related problems (DRPs) to be used by practical nurses (PN) (DRP-RAT),²⁶ for example, during home visits. The DRP-RAT tool was further validated in a three-round Delphi survey to make it a usable self-assessment tool for older medicine users. In addition, national and international literature was used to develop the Checklist. After the Delphi rounds involving 19 geriatric care and pharmacotherapy experts, the resulting checklist was tested for comprehensibility in a two-round user test involving 90 older medicine users.¹⁵ The Checklist includes eight items which are divided into the following two categories in this study: (1) systemic risk factors in medication management (7 items; 10 risk factors); and (2) symptoms that are potentially drug-induced (1 item; 10 risk factors). All Checklist items are structured so that the answer options are "None," "Yes," and "I cannot say." Options "Yes" and "I cannot say" refer to existing or potential medication-related risk factors.¹⁶

2.4 | Data collection

All residents ($n = 1245$, 2020; $n = 1402$, 2021) who turned 75 years old in 2020 and 2021 and lived at home with or without the support

of home care were sent an invitation letter to participate in the PORI75 health screening between January 2020 and December 2021. The residents who participated in the health screening were given oral and written information about the study protocol prior consenting. Voluntary residents personally or with help of their caregiver/closest proxy signed the written informed consent during the health screening appointment with the PN if they were willing to participate in the study. Before the PN appointment, residents were asked to visit the laboratory for the health tests included in the PORI75 procedure.²⁴ They were also asked to fill in the self-assessments at home and return them at the PN appointment. Along with the self-assessments, they were asked to list all medicines they were taking, including prescription and over-the-counter medicines, food supplements, and herbal medicinal products in a structured template. They were asked to provide the following information on the medicines and other products they used: the name of the compound, strength, dose, purpose of use, and whether it was used "regularly" or "when needed." In the PN appointment, the PN performed nurse-conducted screenings, interviewed the residents to ensure the correctness of the self-reported medication list and reconciled the list with the electronic medication records. In addition, the PN recorded the results of the health screenings in the electronic health records. After the PN appointment, all the patient data gathered by self-assessments, nurse-conducted screenings, and laboratory tests were transferred from patient records to a pseudonymized secondary research database.

The medications the residents reported taking were also entered to the pseudonymized database after they were categorized according to the ATC Classification System.²⁶ The following aspects were considered in the categorization: If the compound contained two or more active ingredients, they were documented separately, if possible. Food supplements were excluded from this study. The following five criteria for potentially harmful medications were used to identify possible risks in the medications: (1) potentially inappropriate medication use in older adults was identified using Beers Criteria²⁷ by The American Geriatrics Society. (2) Renbase^{®28} and (3) Heparbase^{®29} databases from the National Health portal³⁰ were used to identify nephrotoxic and hepatotoxic drugs per drug users. (4) Sedative load of used drugs was assessed using Sedative Load Model.³¹ The sedation sum scores were totaled per drug user. (5) The prevalence and burden of drugs with anticholinergic properties (DAPs) were identified according to Duran's list.³² Polypharmacy³³ was categorized according to the number of drugs in use: (1) no polypharmacy (< 5 drugs), (2) polypharmacy (≥ 5 ³³ and < 10 drugs), (3) excessive polypharmacy (≥ 10 drugs).³⁴ The distribution of systemic and drug-induced symptoms risk factors-items were presented, and "Yes" answers were put into three polypharmacy categories.

The following background variables were used: demographic factors, smoking "current smoker or non-smoker (having never smoked or having stopped smoking,)" health-related quality of life (15D),³⁵ nutritional status (MNA-SF),³⁶ alcohol consumption (AUDIT-C),³⁷ mood and depressive symptoms (GDS15),³⁸ cognition (memory

and reasoning) (MMSE),³⁹ orthostatism (decrease in systolic blood pressure at least 20 mmHg and/or in diastolic blood pressure 10 mmHg on assuming an upright position),⁴⁰ and falls risk (FROP-Com; the first item).⁴¹ In addition, the following laboratory tests were calculated: glomerular filtration rate (GFR), plasma potassium and sodium, average sugar levels, and hemoglobin from basic blood count.

2.5 | Statistical analysis

Data are presented as frequencies, percentages, ranges, and means with standard deviations. The linearity across the three polypharmacy groups was evaluated using the Cochran–Armitage test (χ^2 test for trend); Monte Carlo *p*-values were used when the number of observations was small. Stata 17.0, StataCorp LP statistical package was used for statistical analyses.

3 | RESULTS

Of invited 75-year-old residents, 596 in 2020 and 498 in 2021 participated in the comprehensive health screening (PORI75), yielding 48% and 33% participation rates, respectively. Of the participating residents, 569 in 2020 and 455 in 2021 gave written consent to be included in the study (i.e., 96% and 91%, respectively).

Residents' characteristics (*n* = 953) are summarized in Table 1. The health-related quality-of-life of the study participants was good. The pt-GFR level was ≤ 60 (mL/min) for 12% of the residents. The other reviewed laboratory tests aligned with clinically accepted normal ranges.⁴² The participants did not have identified risk of depression or cognitive impairment. Orthostatism was self-reported by 15% of the residents, and 25% reported falling at least once in 12 months before the assessment.

The drug therapy characteristics of the residents are shown in Table 2. The mean number of all drugs used was 7.0 (range 0–26; SD 4.1). Drugs in regular use were 5.3 (range 0–20; SD 3.4). The prevalence of nephrotoxic drugs in use (mean 0.73; SD 0.83) was the highest of the harmful medication categories, followed by PIMs (mean 0.66; SD 0.90), hepatotoxic drugs (mean 0.62; SD 0.74), and drugs with sedative load (mean 0.41; SD 1.01). More than two-thirds (71%) of the participants had polypharmacy: 47% had 5–9 drugs in use, and 24% had 10 drugs or more. The most used drug categories were “Vitamin A and D, including combinations of the two” (A11C) (84% of the residents), followed by “Lipid modifying agents” (C10A) (64%) and “Antithrombotic agents” (C10) (63%).

According to the LOTTA Checklist, the following four factors were the most common self-assessed systemic risk factors (Figure 1): treated by more than one physician (48% of the residents), a paper or electronic list of all medications was missing (43%), the duration of medication care was unclear (35%), and regular monitoring of medication care was missing (35%). The other six systemic risk factors were identified by 5% of residents or less.

TABLE 1 Characteristics and health status of the 75-year-old residents who participated in the comprehensive health screening (*n* = 953).

Variable	Measures
Demographic characteristics	
Gender	
Female, <i>n</i> (%)	569 (60)
Male, <i>n</i> (%)	384 (40)
Clinical characteristics	
HRQoL (15D), mean (SD)	0.902 (0.087)
Mini nutritional assessment MNA-SF, mean (SD)	13.4 (1.1)
Alcohol (AUDIT-C), mean (SD)	1.9 (1.8)
Smoker, <i>n</i> (%)	44 (5)
Glomerular filtration rate (Pt-GFR), mean (SD) [436]	74.9 (12.5)
≤ 60 (mL/min), <i>n</i> (%)	54 (12)
K ⁺ , mean (SD) (mmol/L) [436]	3.9 (0.3)
Na ⁺ , mean (SD) (mmol/L) [436]	140 (3)
B-hemoglobin, mean (SD) (g/L) [436]	
Women	137 (11)
Men	147 (14)
B-HbA1c, mean (SD) (mmol/mol)	38.5 (6.7)
Functioning	
GDS15	5.6 (1.3)
MMSE	27.8 (2.3)
Orthostatism, <i>n</i> (%)	141 (15)
Falls in the previous 12 months, <i>n</i> (%)	
None	701 (75)
1	161 (17)
2	50 (5)
3+	28 (3)

Abbreviations: AUDIT-C, alcohol use disorders identification test consumption; FROP-Com, falls risk for older people in the community assessment; GDS15, geriatric depression scale; GFR, glomerular filtration rate; HbA1c, average blood glucose; HRQoL, heart-related quality of life; K⁺, serum potassium; MMSE, mini-mental state exam; MNA-SF, mini nutritional assessment; Na⁺, serum sodium.

The most common of the potentially drug-induced symptoms that had repeatedly disrupted residents' normal life in the past 4 weeks before the self-assessment were constipation or other abdominal symptoms (21% of the residents), difficulty urinating (20%), and unusual tiredness or sleepiness during the day (17%) (Figure 2). The most seldomly self-reported symptoms were confusion (1%), falls (3%), and nausea (4%).

The distribution of systemic and drug-induced symptoms risk factors or items categorized into three polypharmacy groups are

TABLE 2 The drug therapy characteristics and prevalence of potentially harmful medication use for the 75-year-old residents ($n = 953$).

Drug therapy characteristics	Measures
Drugs in use ^a	
All drugs in use, mean (SD) [range]	7.0 (4.1) [0–26]
Drugs in regular use, mean (SD) [range]	5.3 (3.4) [0–20]
PIMs in use (Beers Criteria ²⁷), mean (SD)	0.66 (0.90)
Nephrotoxic drugs in use (Renbase ^{®28}), mean (SD)	0.73 (0.83)
Hepatotoxic drugs in use (Heparbase ^{®29}), mean (SD)	0.62 (0.74)
Drugs with sedative load ³¹ in use, mean (SD)	0.41 (1.01)
Anticholinergic drugs (Duran's list) in use, mean (SD)	0.04 (0.20)
Polypharmacy ^b	
<5 drugs in use, n (%)	279 (29)
≥5 and <10, n (%)	445 (47)
≥10, n (%)	229 (24)
10 most used drug categories ^b	
Vitamin A and D, incl combinations of the two (A11C), n (%)	797 (84)
Lipid modifying agents, plain (C10A), n (%)	606 (64)
Antithrombotic agents (B01A), n (%)	600 (63)
Other analgesics and antipyretics (N02B), n (%)	570 (60)
Anti-inflammatory and antirheumatic products, non-steroids (M01A), n (%)	537 (56)
Agents acting on the renin-angiotensin system (C09C), n (%)	462 (48)
Beta blocking agents (C07A), n (%)	382 (40)
Vitamin B12 and folic acid (B03B), n (%)	354 (37)
Drugs for peptic ulcer and gastro-esophageal reflux disease (A02B), n (%)	352 (37)
Calcium (A12A), n (%)	322 (34)

Abbreviation: PIM, potentially Inappropriate medicine.

^aDrugs per resident.

^bNumber of residents.

shown in Table 3. The higher number of drugs in use (i.e., residents belonging to polypharmacy and excessive polypharmacy groups) was associated with the following systemic risk factors: treated by more than one physician ($p \leq 0.001$), a paper or electronic list of all medications was missing ($p = 0.023$), the duration of medication care was unclear ($p = 0.031$), and necessary medications were compromised because of financial situations ($p = 0.027$). Correspondingly, polypharmacy and excessive polypharmacy were associated with all other potentially drug-induced symptoms ($n = 8$) except falls ($p = 0.350$) and confusion ($p = 0.490$). Of the residents with excessive

polypharmacy (≥ 10 drugs in use), about one-third self-reported constipation or other abdominal problems (33%), urinating problems (30%), and dry mouth (30%).

4 | DISCUSSION

This study identified the most common medication-related risk factors in a regional cohort of Finnish home-dwelling 75-year-old adults. We used a new Delfoi-validated self-assessment screening tool, the LOTTA Checklist¹⁵ as part of a comprehensive health screening. The main finding was that an increasing number of used drugs, particularly excessive polypharmacy was associated with various systemic risk factors in medication management and drug-induced symptoms as risk factors.

In the excessive polypharmacy group, the proportion of older adults self-reporting potentially drug-induced symptoms was as high as 25%–33% for the following symptoms: constipation or other symptoms of abdominal problems, difficulty urinating, dry mouth, and unusual tiredness or sleepiness during the day. These common, potentially drug-induced symptoms need closer examination as they may significantly impair health and functional ability, and thus, ability to live at home. These findings call for better organized medication monitoring, at least for older residents having excessive polypharmacy but also for other home-dwelling older residents using medicines. Our results indicate that regular systematic monitoring may be currently lacking as the proportion of residents reporting missing regular monitoring was almost the same in all three polypharmacy groups regardless of the number of medicines in use. Similar results of the missing medication monitoring have been previously reported from Finland and elsewhere.^{43–45}

The special emphasis of ongoing social and healthcare reform is on heavy users of social and health services: they need to be identified so that the services they need can be better planned and coordinated.⁴⁶ Our results showed that special emphasis should be focused on older adults with excessive polypharmacy in this respect. Polypharmacy was connected to all other drug-induced symptoms except falls and confusion, which are traditionally stated in geriatric syndromes in older adults.⁴⁷

Falls and medications that increase fall risk in older adults have been paid a lot of attention in social and healthcare.^{48,49} As a consequence, preventive actions to decrease fall risk have been developed nationally and internationally.^{48,50} Surprisingly, only 3% of our study residents reported at least one fall within 1 year period. A reason for the low fall rate may be that our study participants were in good health and functional ability. Furthermore, their use rate of medicines increasing fall risk was low (see Table 2). The proportion of those who had fallen at least once within a year would have been probably higher if the participation rate had been higher. As the participation rate was quite low, presumably residents with good health took part in the health screening. This may have influenced our results and skewed them to provide too a positive impression of the health status and functional ability of all home-dwelling older adults

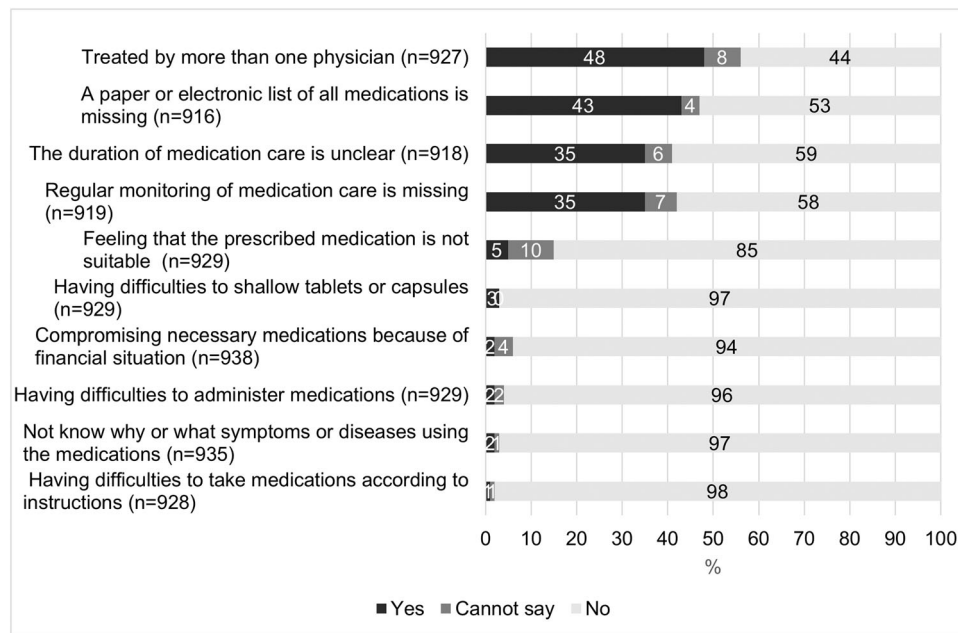


FIGURE 1 The self-assessed systemic medication-related risk factors in 75-year-old residents ($n = 953$) by using the LOTTA Checklist.

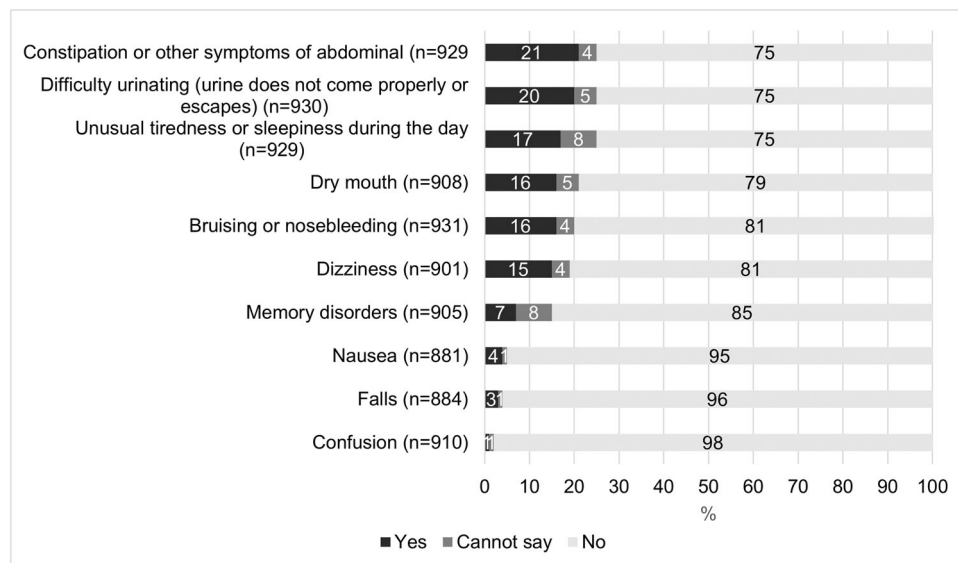


FIGURE 2 Self-reported potentially drug-induced symptoms that had repeatedly disrupted 75-year-old residents' normal life within the 4 weeks before self-assessment by using the LOTTA Checklist ($n = 953$).

living in the region. This possible bias should be remembered when the results are used to estimate the future need for social and health services in the region.

Our study's strength is that the residents consisted of a relatively large cohort of home-dwelling older adults ($n = 1024$), even though participation rates in comprehensive health screening were 48% ($n = 596$) in 2020 and 33% ($n = 498$) in 2021. A limitation of our study was that the participants (569 in 2020 and 455 in 2021, given written consent) might give too positive a picture of 75-year-old adults, as residents in good condition may be more interested in participating in

health screening. In addition, the COVID situation may have affected the participation rate. The results of laboratory tests were available from 436 residents. It is important to consider the pharmacies' role as a part of comprehensive health screening to increase the participation rate in health screenings in the future, especially in recognizing medication-related risk factors. In further studies, it would be interesting to examine what proportion of home-dwelling 75-year-old residents were guided to pharmacists by PNs and whether there are associated factors with other health measures, including comprehensive health screening. This study was conducted at the

TABLE 3 The distribution of "Yes" answers into three polypharmacy categories self-assessed by 75-year-old residents by using the LOTTA Checklist ($n = 953$).

Item ($n = \text{yes answers}$)	Polypharmacy, n (%)			p Value ^a
	<5 ($n = 279$)	≥5 and <10 ($n = 445$)	≥10 ($n = 229$)	
Systemic risk factors				
Treated by more than one physician ($n = 442$)	77 (28)	223 (51)	142 (65)	<0.001
A paper or electronic list of all medications is missing ($n = 389$)	119 (45)	194 (45)	76 (35)	0.023
The duration of medication care is unclear ($n = 325$)	80 (31)	154 (36)	91 (40)	0.031
Regular monitoring of medication care is missing ($n = 317$)	89 (34)	149 (35)	79 (35)	0.840
Feeling that the prescribed medication is not suitable ($n = 45$)	11 (4)	20 (5)	14 (6)	0.290
Having difficulties with shallow tablets or capsules ($n = 27$)	6 (2)	12 (3)	9 (4)	0.260
Compromising necessary medications because of the financial situation ($n = 18$)	2 (1)	8 (2)	8 (3)	0.027
Having difficulties administering medications ($n = 17$)	5 (2)	4 (1)	8 (4)	0.220
Not knowing why or what symptoms or diseases using the medications ($n = 21$)	5 (2)	9 (2)	7 (3)	0.390
Having difficulties taking medications according to instructions ($n = 9$)	3 (1)	2 (0)	4 (2)	0.520
Drug-induced symptom risk factors				
Constipation or other symptoms of abdominal ($n = 195$)	3 (12)	8 (20)	73 (33)	<0.001
Difficulty urinating (urine does not come properly or escapes) ($n = 187$)	3 (14)	8 (19)	68 (30)	<0.001
Unusual tiredness or sleepiness during the day ($n = 153$)	2 (10)	6 (16)	57 (25)	<0.001
Dry mouth ($n = 148$)	2 (9)	5 (13)	67 (30)	<0.001
Bruising or nose bleeding ($n = 145$)	2 (9)	6 (15)	53 (24)	<0.001
Dizziness ($n = 131$)	2 (9)	6 (14)	47 (22)	<0.001
Memory disorders ($n = 61$)	1 (4)	2 (7)	21 (10)	0.026
Nausea ($n = 31$)	(2)	1 (4)	12 (6)	0.014
Falls ($n = 22$)	(2)	8 (2)	8 (4)	0.350
Confusion ($n = 9$)	(0)	6 (1)	2 (1)	0.490

^a p for linearity.

Social Security Center of Pori. Future studies are needed to identify medication-related risk factors in home-dwelling older adults nationally.

AUTHOR CONTRIBUTIONS

Jonna-Carita Kanninen: Conceptualization; data curation; investigation; methodology; project administration; visualization; writing—original draft. **Juha Puustinen:** Conceptualization; funding acquisition; investigation; methodology; supervision; writing—review & editing. **Marja Airaksinen:** Conceptualization; data curation; investigation; methodology; supervision; writing—review & editing. **Hannu Kautiainen:** Data curation; formal analysis; investigation; methodology; writing—review & editing. **Anna-Liisa Koivisto:** Writing—review & editing. **Pauliina Hietasalo:** Writing—review & editing. **Anna-Maija Heikkilä:** Writing—review & editing. **Susanna Kunvik:** Writing—review & editing. **Terhi Toivo:** Writing—review & editing. **Maarit Dimitrow:** Writing—review & editing. **Jussi Bergman:** Writing—review & editing. **Anu Holm:** Conceptualization; data curation;

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approval of the manuscript; and decision to submit the manuscript for publication.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from Wellbeing Services County of Satakunta. Restrictions apply to the availability of these data, which were used under license for this study. Data are available from kirjaamo(at)sata.fi with the permission of Wellbeing Services County of Satakunta.

ETHICS STATEMENT

The study was approved by the Ethics Committee of the Hospital District of Southwest Finland (ETMK 58/2019). The research permit was approved by the Social Security Center of Pori to carry out the research at Health Center. Informed consent was obtained from each resident and/or their closest proxy before any study procedure was performed.

TRANSPARENCY STATEMENT

The lead author (Jonna-Carita Kanninen) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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