Supplement

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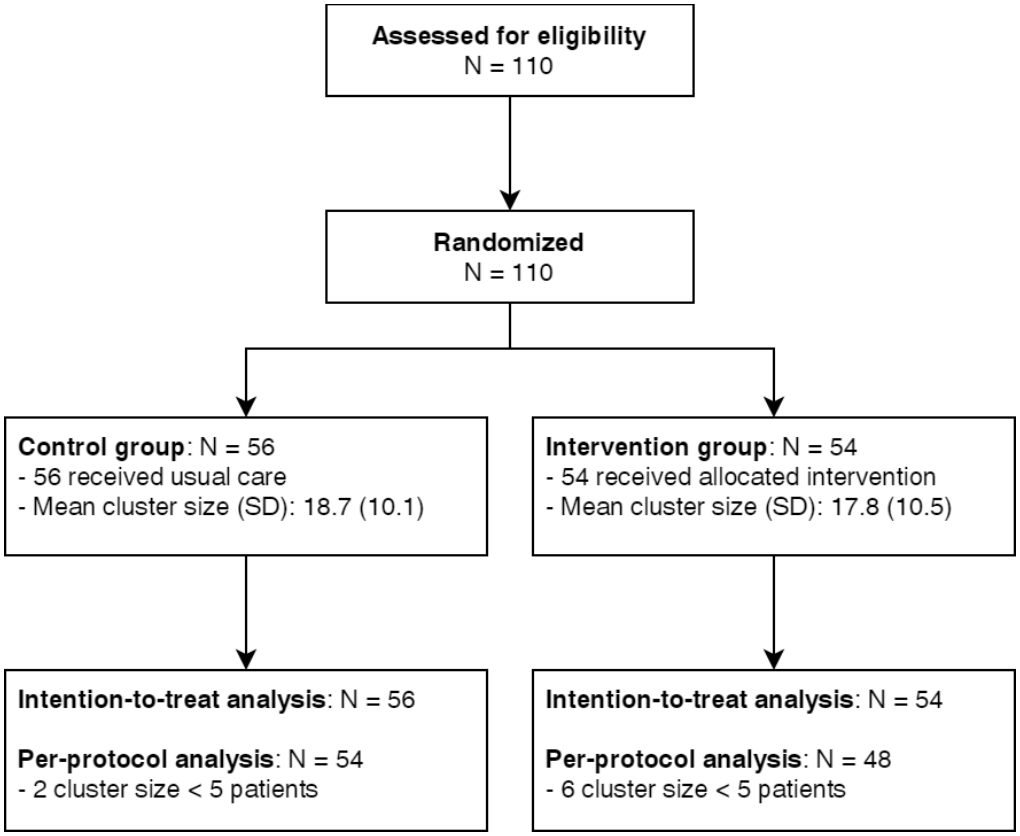
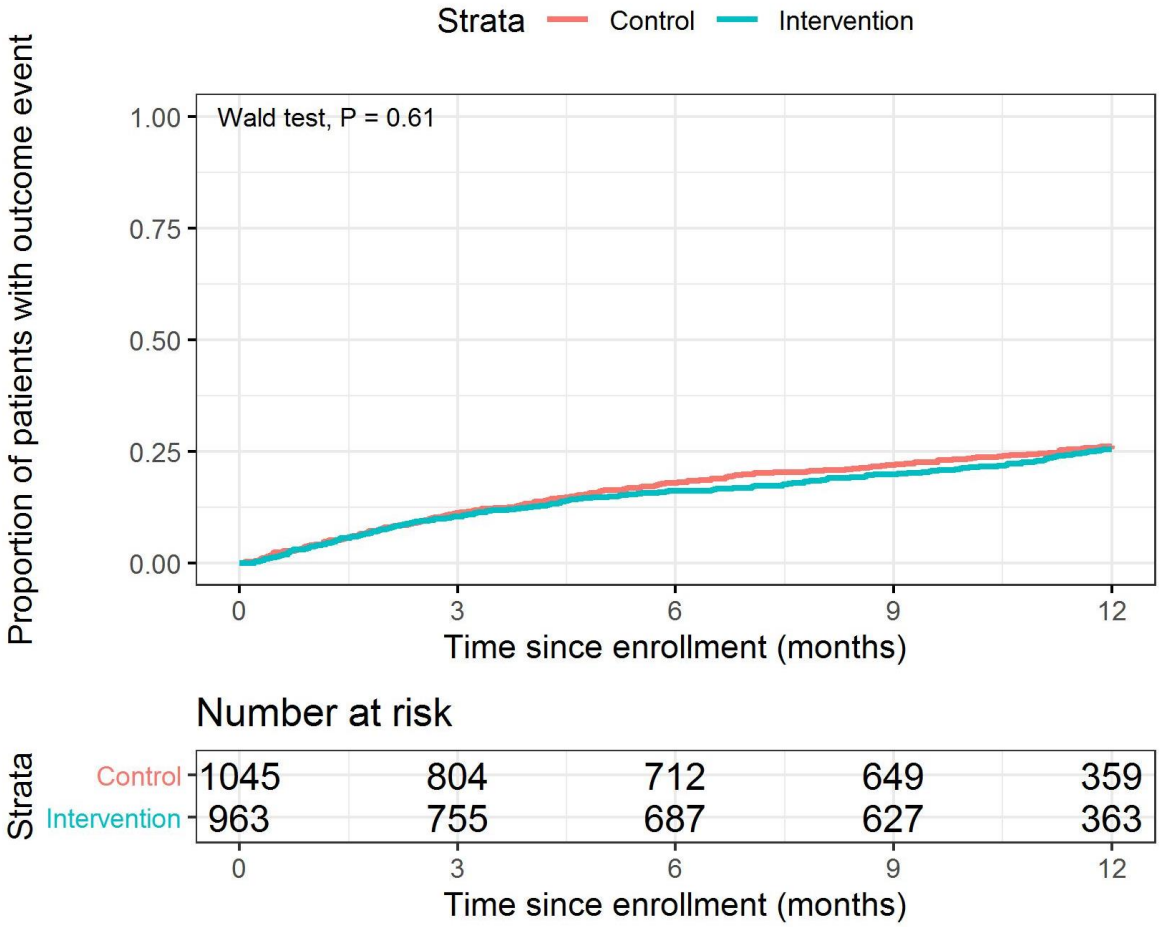
eFigure 1: Cluster flow chart



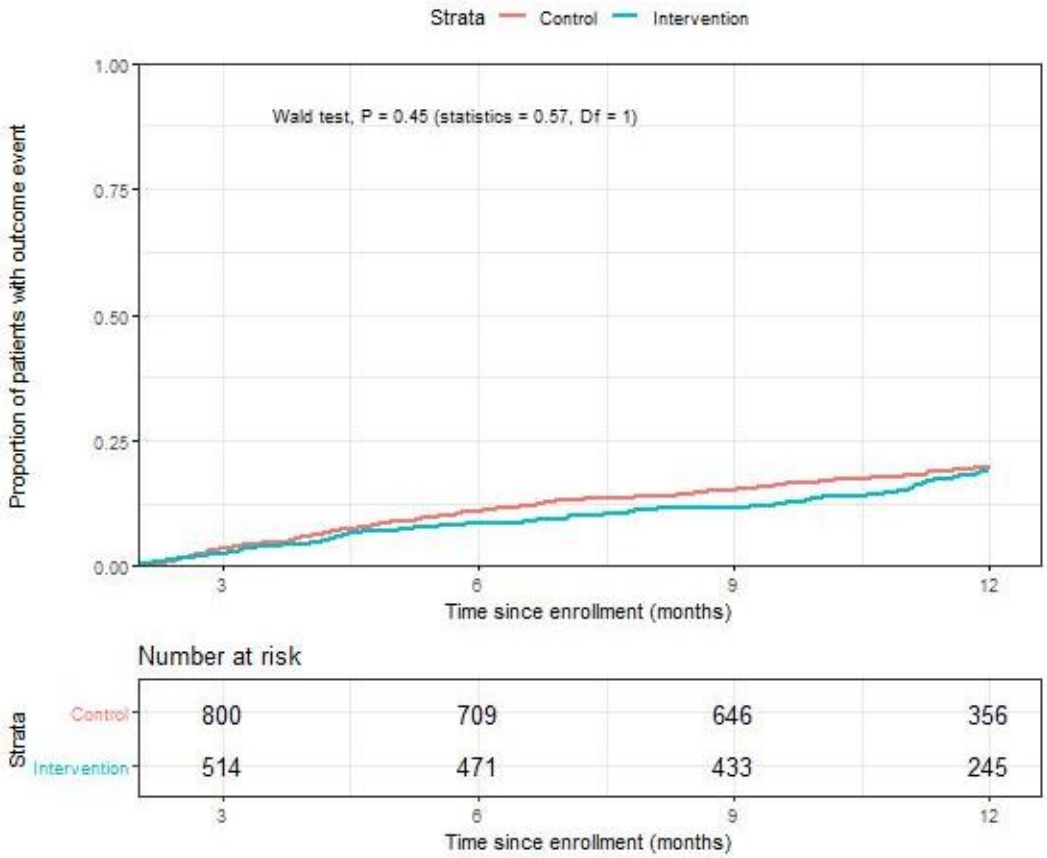
Abbreviations: N, number; SD, standard deviation

eFigure 2: Time to first drug-related hospital admission



Curve truncated at 365 days. Statistics = 0.26, Df = 1.

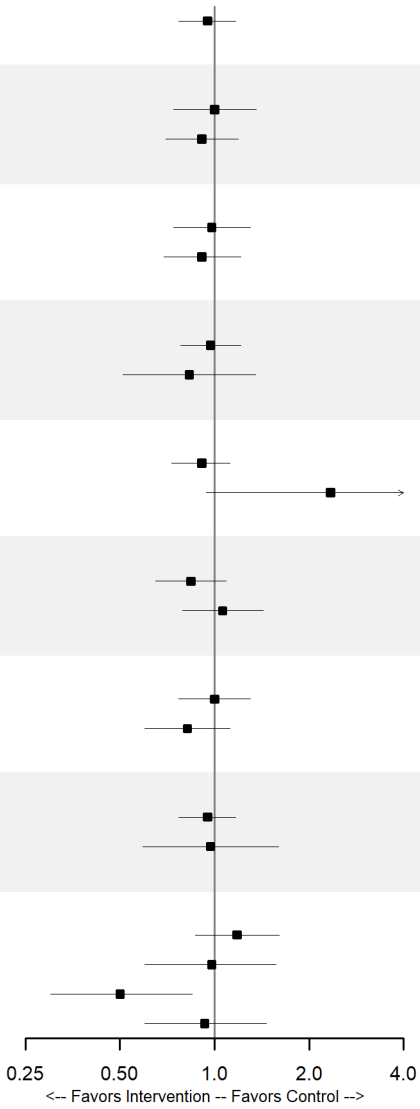
eFigure 3: Per-protocol analysis for time to first drug-related hospital admission



Curve truncated at 365 days. Statistics = 0.57, Df = 1.

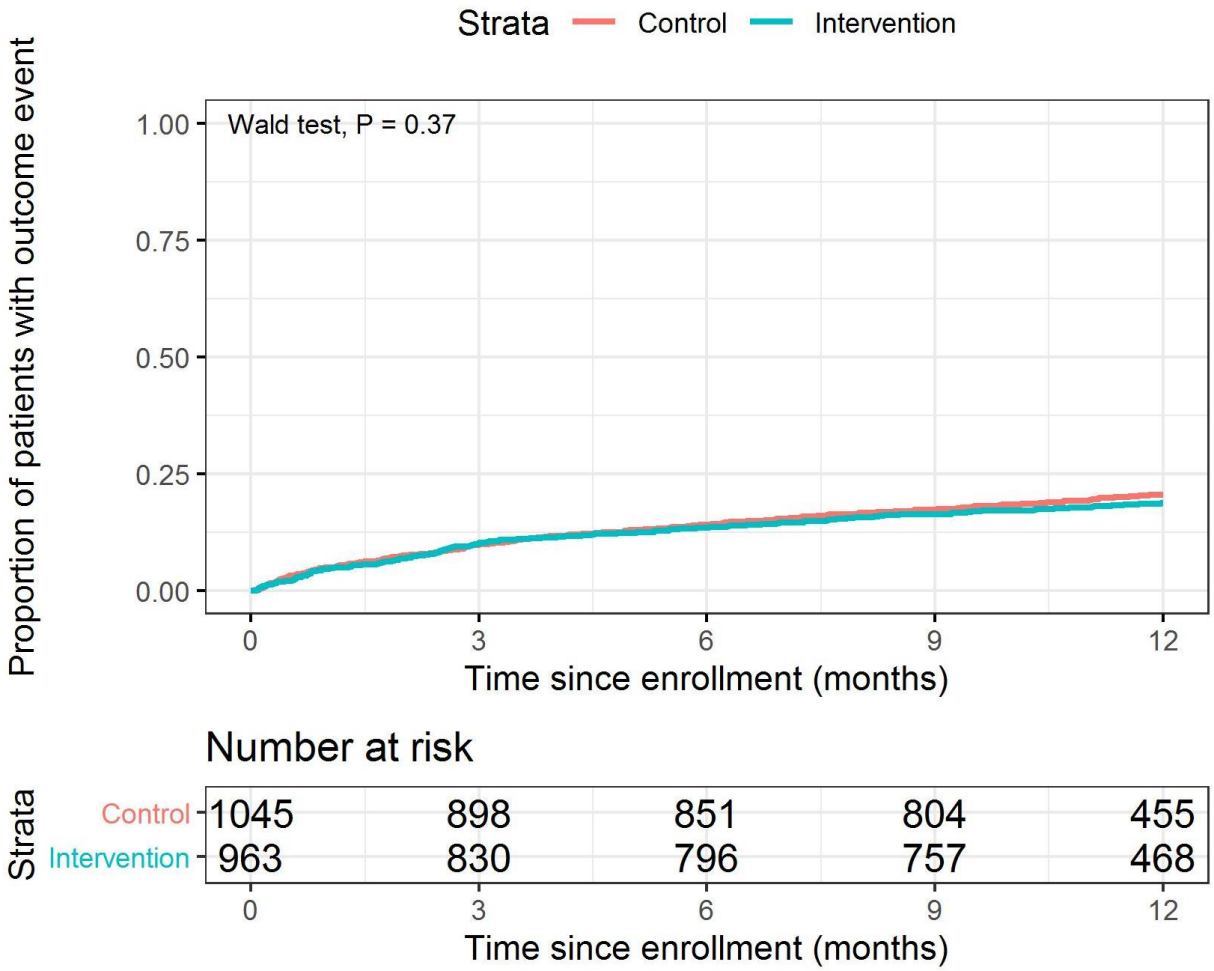
eFigure 4: Subgroup analysis for first drug-related hospital admission

Subgroup	HR (95%CI)	P for interaction (categorical)	P for interaction (continuous)
All (N=2,008)	0.95 (0.77 to 1.17)		
Sex		0.64	
Female (N=898)	1.00 (0.74 to 1.36)		
Male (N=1,110)	0.91 (0.70 to 1.19)		
Age		0.71	0.2
≥ 80 (N=930)	0.98 (0.74 to 1.30)		
< 80 (N=1,078)	0.91 (0.69 to 1.21)		
Living status		0.56	
Independent (N=1,612)	0.97 (0.78 to 1.21)		
Non-independent (N=384)	0.83 (0.51 to 1.35)		
Dementia		0.04	
No (N=1,905)	0.91 (0.73 to 1.12)		
Yes (N=100)	2.34 (0.94 to 5.81)		
Number of medications at baseline		0.23	0.33
≥ 10 (N=986)	0.84 (0.65 to 1.09)		
< 10 (N=1,019)	1.06 (0.79 to 1.43)		
Number of comorbidities at baseline		0.31	0.07
≥ Median (N=1,043)	1.00 (0.77 to 1.30)		
< Median (N=962)	0.82 (0.60 to 1.12)		
Departments of clusters		0.93	
Medical (N=1,589)	0.95 (0.77 to 1.17)		
Surgical (N=419)	0.97 (0.59 to 1.60)		
Site		0.05	
Bern (N=822)	1.18 (0.87 to 1.61)		
Cork (N=346)	0.98 (0.60 to 1.57)		
Louvain (N=388)	0.50 (0.30 to 0.85)		
Utrecht (N=452)	0.93 (0.60 to 1.46)		



Non-independently living was defined as living in a nursing home (at least 3 months in the 6 months before the index admission) or being housebound.
Abbreviations: CI, confidence interval; HR, hazard ratio; N, number; P, P value

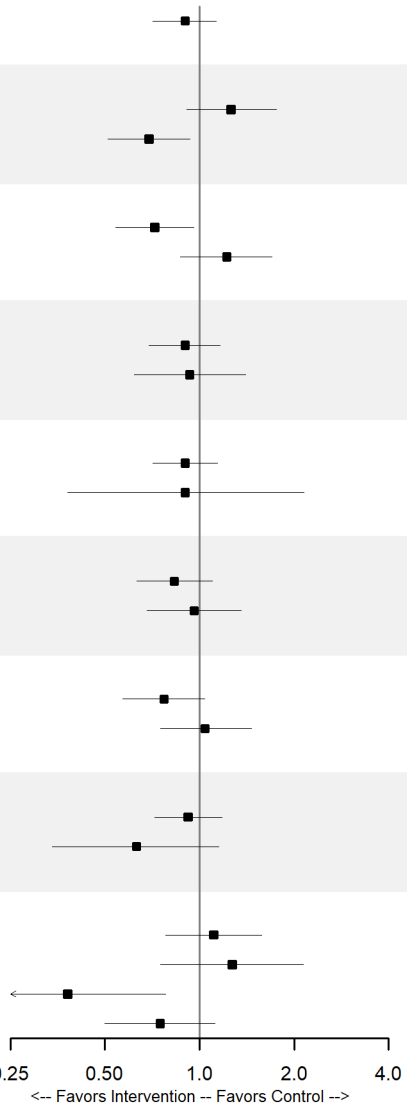
eFigure 5: Kaplan-Meier curve for all-cause death



Curve truncated at 365 days. Statistics = 0.79, Df = 1.

eFigure 6: Subgroup analysis for all-cause death

Subgroup	HR (95%CI)	P for interaction (categorical)	P for interaction (continuous)
All (N=2,008)	0.90 (0.71 to 1.13)		
Sex		0.004	
Female (N=898)	1.26 (0.91 to 1.76)		
Male (N=1,110)	0.69 (0.51 to 0.93)		
Age		0.01	0.35
≥ 80 (N=930)	0.72 (0.54 to 0.96)		
< 80 (N=1,078)	1.22 (0.87 to 1.70)		
Living status		0.87	
Independent (N=1,612)	0.90 (0.69 to 1.16)		
Non-independent (N=384)	0.93 (0.62 to 1.40)		
Dementia		1	
No (N=1,905)	0.90 (0.71 to 1.14)		
Yes (N=100)	0.90 (0.38 to 2.15)		
Number of medications at baseline		0.51	0.04
≥ 10 (N=986)	0.83 (0.63 to 1.10)		
< 10 (N=1,019)	0.96 (0.68 to 1.36)		
Number of comorbidities at baseline		0.17	0.46
≥ Median (N=1,043)	0.77 (0.57 to 1.04)		
< Median (N=962)	1.04 (0.75 to 1.46)		
Departments of clusters		0.25	
Medical (N=1,589)	0.92 (0.72 to 1.18)		
Surgical (N=419)	0.63 (0.34 to 1.15)		
Site		0.02	
Bern (N=822)	1.11 (0.78 to 1.58)		
Cork (N=346)	1.27 (0.75 to 2.14)		
Louvain (N=388)	0.38 (0.19 to 0.78)		
Utrecht (N=452)	0.75 (0.50 to 1.12)		



Non-independently living was defined as living in a nursing home (at least 3 months in the 6 months before the index admission) or being housebound.
Abbreviations: CI, confidence interval; HR, hazard ratio; N, number; P, P value

eTable 1: Baseline medications grouped by ATC drug class and study group

ATC code	ATC group name	Intervention group N (%)	Control group N (%)
B01	Antithrombotic agents	862 (8.6)	971 (9.3)
C03	Diuretics	644 (6.5)	685 (6.5)
A02	Drugs for acid related disorders	631 (6.3)	656 (6.3)
C10	Lipid modifying agents	570 (5.7)	651 (6.2)
R03	Adrenergics, inhalants	613 (6.1)	586 (5.6)
C09	Agents acting on the renin-angiotensin system	559 (5.6)	618 (5.9)
C07	Beta blocking agents	537 (5.4)	576 (5.5)
N02	Analgesics	547 (5.5)	526 (5.0)
A11	Vitamins	516 (5.2)	472 (4.5)
A10	Drugs used in diabetes	434 (4.4)	531 (5.1)
N05	Psychotropics	344 (3.5)	368 (3.5)
A12	Mineral supplements	344 (3.5)	339 (3.2)
N06	Psychoanaleptics	301 (3.0)	321 (3.1)
C08	Calcium channel blockers	276 (2.8)	287 (2.7)
G04	Urologicals	230 (2.3)	306 (2.9)
A06	Drugs for constipation	251 (2.5)	262 (2.5)
C01	Cardiac therapy	242 (2.4)	232 (2.2)
S01	Ophthalmologicals	202 (2.0)	179 (1.7)
B03	Antianemic preparations	170 (1.7)	205 (2.0)
N03	Antiepileptics	137 (1.4)	195 (1.9)
H03	Thyroid therapy	157 (1.6)	145 (1.4)
H02	Corticosteroids for systemic use	139 (1.4)	127 (1.2)
M04	Antigout preparations	110 (1.1)	156 (1.5)
Total		9,970	10,479

Note: Drug classes with <1% prevalence were omitted from this table for readability.

eTable 2: Involved or omitted medication classes in adjudicated drug-related hospital admissions

ATC group code	ATC group name	N (%)
C03	Diuretics	130 (14%)
B01	Antithrombotics	116 (13%)
C09	Agents acting on the renin-angiotensin system	87 (10%)
N02	Analgesics	69 (8%)
C07	Beta blocking agents	66 (7%)
N05	Psychotropics	60 (7%)
N06	Psychoanaleptics	54 (6%)
Lxx	Antineoplastic and immunomodulating agents	41 (5%)
H02	Corticosteroids for systemic use	39 (4%)
A02	Drugs for acid related disorders	33 (4%)
Jxx	Antiinfectives for systemic use	23 (3%)
C01	Cardiac therapy	21 (2%)
A10	Drugs used in diabetes	20 (2%)
N03	Antiepileptics	20 (2%)
C10	Lipid modifying agents	16 (2%)
G04	Urologicals	16 (2%)
C08	Calcium channel blockers	14 (2%)
R03	Drugs for obstructive airway diseases	14 (2%)
A06	Drugs for constipation	12 (1%)

Note: Medication groups with ≤10 counts were omitted from this table for readability.

eTable 3: Per protocol analysis for time to first event outcomes

Outcome	Events (%)		HR (95% CI) [1]	P value
	Control	Intervention		
Regression on cause-specific hazards				
First drug-related hospital admission	156/871 (17.9%)	93/556 (16.7%)	0.91 (0.69 to 1.19)	0.49
Death by cancer	37/943 (3.9%)	21/599 (3.5%)	0.87 (0.46 to 1.64)	0.66
First hospitalization	308/751 (41.0%)	182/491 (37.1%)	0.85 (0.70 to 1.04)	0.11
First fall	177/861 (20.6%)	115/548 (21.0%)	1.03 (0.81 to 1.31)	0.80
Death	125/943 (13.3%)	67/599 (11.2%)	0.85 (0.61 to 1.17)	0.32
First preventable drug-related hospital admission [2]	65/871 (7.5%)	38/556 (6.8%)	0.89 (0.58 to 1.37)	0.60
Regression on sub hazards (taking into account the competing risk of death)				
First drug-related hospital admission	156/871 (17.9%)	93/556 (16.7%)	0.91 (0.70 to 1.19)	0.51
Death by cancer	37/943 (3.9%)	21/599 (3.5%)	0.87 (0.46 to 1.65)	0.66
First hospitalization	308/751 (41.0%)	182/491 (37.1%)	0.85 (0.70 to 1.04)	0.11
First fall	177/861 (20.6%)	115/548 (21.0%)	1.03 (0.81 to 1.31)	0.79
First preventable drug-related hospital admission[2]	65/871 (7.5%)	38/556 (6.8%)	0.90 (0.59 to 1.37)	0.62

[1] HR<1 indicates fewer events in the intervention group; [2] Post hoc analysis.
drug-related hospital admission was considered preventable when deemed by the adjudication committee as potentially related to a drug overuse, underuse or misuse (i.e. drug with an indication, but error in prescribing, dispensing, administering or monitoring the medication).
Abbreviations: CI, confidence interval; HR, hazard ratio

eTable 4: Time-to-event analysis taking into account competing risks (regression on sub-hazards)

Outcome	Events (%)		HR (95% CI) [1]	P value
	Control (n=1045)	Intervention (n=963)		
First drug-related hospital admission	234 (22.4%)	211 (21.9%)	0.96 (0.79 to 1.18)	0.71
Death by cancer	55 (5.3%)	43 (4.5%)	0.76 (0.47 to 1.23)	0.27
First hospitalization	516 (49.4%)	447 (46.4%)	0.89 (0.77 to 1.03)	0.12
First fall	263 (25.2%)	237 (24.6%)	0.96 (0.81 to 1.16)	0.70
First preventable drug-related hospital admission [2]	100 (9.6%)	84 (8.7%)	0.91 (0.65 to 1.27)	0.58

[1] HR<1 indicates fewer events in the intervention group; [2] Post hoc analysis.
For the first drug-related hospital admission, first hospitalization and first fall, the analysis takes into account the competing risk of death. For death by cancer, the analysis takes into account the competing risk of other type of death. For first preventable drug-related hospital admission, the competing risk of other types of drug-related hospital admission were taken into account. Drug-related hospital admission was considered preventable when deemed by the adjudication committee as potentially related to a drug overuse, underuse or misuse (i.e. drug with an indication, but error in prescribing, dispensing, administering or monitoring the medication).
Abbreviations: CI, confidence interval; HR, hazard ratio

eTable 5: Analysis adjusted for baseline characteristics

Outcome	Control		Intervention		HR (95% CI) [1]	P value
	N	Events (%)	N	Events (%)		
First drug-related hospital admission	1,045	234 (22.4%)	963	211 (21.9%)	0.94 (0.76 to 1.16)	0.57
Death	1,045	203 (19.4%)	963	172 (17.9%)	0.89 (0.71 to 1.12)	0.33
	N [2]	Mean (SD)	N [2]	Mean (SD)	Adjusted difference (95% CI) [3]	
Number of long-term medications 2 months after enrolment [4]	893	11.0 (4.27)	833	11.2 (4.54)	-0.21 (-0.53 to 0.10)	0.18
Number of long-term medications 12 months after enrolment [4]	767	10.7 (4.57)	726	10.7 (4.54)	-0.39 (-0.73 to -0.04)	0.03

[1] HR<1 indicates fewer events in the intervention group; [2] Numbers of participants differ from those for clinical outcomes, as they were based on available data at months 2, 6, and 12 for medication-related outcomes, and non-available data at 12 months were mainly due to death (N of deaths until month 2, 6, 12: 167, 280, 385). [3] Adjusted difference: Adjusted for the baseline value of the outcome. Positive values indicate higher values in the intervention group. [3] Long-term medications are defined as use of a drug for >30 days.
Analysis further adjusted for baseline characteristics (i.e., site, departments of clusters, sex, non-independently living, age, number of medications at baseline, number of comorbidities at baseline, dementia).
Abbreviations: CI, confidence interval; HR, hazard ratio; N, number; SD, standard deviation

eTable 6: Variation of the intervention effect across time

Outcome		N	HR (95% CI) [1]	P value	P for interaction
First drug-related hospital admission	Before 2 months	2,008	0.98 (0.70 to 1.37)	0.91	0.80
	After 2 months	1,685	0.93 (0.73 to 1.19)	0.57	
Death by cancer	Before 2 months	2,008	0.71 (0.35 to 1.46)	0.35	0.82
	After 2 months	1,822	0.79 (0.47 to 1.33)	0.38	
First hospitalization	Before 2 months	2,008	0.91 (0.74 to 1.11)	0.34	0.76
	After 2 months	1,454	0.86 (0.71 to 1.03)	0.11	
First fall	Before 2 months	2,008	0.98 (0.72 to 1.33)	0.89	0.86
	After 2 months	1,660	0.94 (0.76 to 1.18)	0.61	
Death	Before 2 months	2,008	0.93 (0.64 to 1.35)	0.71	0.88
	After 2 months	1,822	0.88 (0.68 to 1.14)	0.33	

[1] HR<1 indicates less events in the intervention group
Abbreviations: CI, confidence interval; HR, hazard ratio; N, number

eTable 7: Patient-reported outcomes, considering only interviews within the pre-specified time window

Outcome	Follow-up (month) [1]	Control N	Control Mean (SD)	Intervention N	Intervention Mean (SD)	Adjusted difference (95% CI) [2]	P value
QoL/EQ-VAS [3]	2	625	64.6 (20.3)	614	65.7 (19.6)	0.56 (-1.50 to 2.63)	0.59
	6	657	65.6 (19.0)	631	67.0 (17.4)	0.98 (-1.06 to 3.02)	0.35
	12	648	64.8 (19.4)	568	67.0 (18.0)	2.26 (0.18 to 4.34)	0.03
Pain/discomfort score (EQ-5D) [4]	2	643	1.13 (1.19)	631	1.07 (1.11)	-0.05 (-0.17 to 0.07)	0.45
	6	670	1.19 (1.19)	644	1.05 (1.15)	-0.11 (-0.23 to 0.01)	0.08
	12	666	1.15 (1.21)	582	1.02 (1.11)	-0.12 (-0.25 to -0.00)	0.048
ADL [5]	2	631	86.9 (20.5)	627	88.6 (19.4)	0.94 (-1.29 to 3.17)	0.41
	6	660	88.0 (18.8)	638	89.4 (18.6)	0.73 (-1.49 to 2.96)	0.52
	12	658	87.0 (20.2)	575	88.6 (18.9)	1.60 (-0.64 to 3.83)	0.16
©MMAS-8 [6]	2	599	7.47 (0.924)	593	7.50 (0.861)	0.02 (-0.07 to 0.12)	0.65
	12	653	7.53 (0.886)	576	7.56 (0.823)	0.04 (-0.06 to 0.13)	0.43

[1] Time windows: ±14 days at the 2-month interview; ±30 days at the 6-month interview; ±30 days at the 12-month interview. [2] Adjusted difference: Adjusted for the baseline value of the outcome. Positive values indicate higher values in the intervention group. [3] QoL/EQ-VAS: Quality of life as measured by the visual analogue scale that is the second part of the 5-level version of the European Quality of Life-5 Dimensions questionnaire (EQ-VAS). Values ranged from 0 to 100. Higher values indicate higher quality of life. [4] Pain/discomfort score (EQ-5D): Pain/discomfort as measured in the 5-level version of the European Quality of Life-5 Dimensions questionnaire (EQ-VAS). Values ranged from 0 to 4. Higher values indicate higher level of pain or discomfort. [5] ADL: Basic Activities of Daily Living, as measured by the Barthel Index. Values ranged from 0 to 100. Higher values indicate higher functional independence. [6] ©MMAS-8: Drug compliance, measured by Medication Adherence Questionnaire (©MMAS-8) developed by Morisky (1–3). Values ranged from 0 to 8. Higher scores indicate higher levels of adherence.
Abbreviations: CI, confidence interval; N, number; OR, odds ratio; SD, standard deviation

eTable 8: Intracluster correlation for main outcomes

Outcome	ICC (95% CI)
First drug-related hospital admission	0.0103 (0 to 0.0763)
Death	0.0198 (0 to 0.1424)
First preventable drug-related hospital admission	0.0170 (0 to 0.1692)

The intracluster correlation calculations were made using the analysis of variance estimate of ICC and the associated CI calculated using modified Wald test (ICCbin package V1.1.1). Clusters with less than 2 patients were ignored.
Abbreviations: CI, confidence interval; ICC, intra-cluster correlation coefficient

Methods appendix

The multi-component intervention used in OPERAM was performed on the individual patient level, in several steps. The intervention protocol has been previously published.(4) The intervention was designed to identify the most relevant drug-related problems and optimize treatment during the index hospitalization and was based on the structured medication review using the systemic tool to reduce inappropriate prescribing (STRIP) method.(5)

The STRIP method was developed to support pharmacotherapy optimization in older patients. This method combines the STOPP/START criteria(6) to detect medication overuse and underuse with patient-centered implicit methods, such as the Structured History taking of Medication (SHiM, see form below), therapy adherence, adverse drug reactions and shared decision making on proposed medication changes and includes shared decision-making with the patient.(5,7)

Pharmacotherapeutic analysis is based on START/STOPP criteria, START/STOPP criteria version 2, with 114 criteria, reflect more complete and up-to-date sets of potentially inappropriate medications and potential prescribing omissions - explicit criteria - in comparison to version 1 in 2008. In addition, version 2 includes three implicit prescribing criteria (STOPP A1, A2, A3).

Newly admitted patients were screened, usually on the day of admission to the inpatient ward. Pre-admission medication was assessed using the SHiM questionnaire(7) with the patients or their proxies. In addition, at least one other information source was consulted (pharmacy, general practitioner) to improve the accuracy of the medication list.

Next, a trained research physician and pharmacist jointly performed the medication review using the STRIP method.(5) The pharmaceutical analysis was performed using the web-based STRIP Assistant (STRIPA), a decision-support system (see details below). Via the software, based on STRIP recommendations and their own complementary expertise, the physician and the pharmacist generated a first report with prescribing recommendations to discontinue, initiate or modify medications, accompanied by detailed evidence-based explanations.

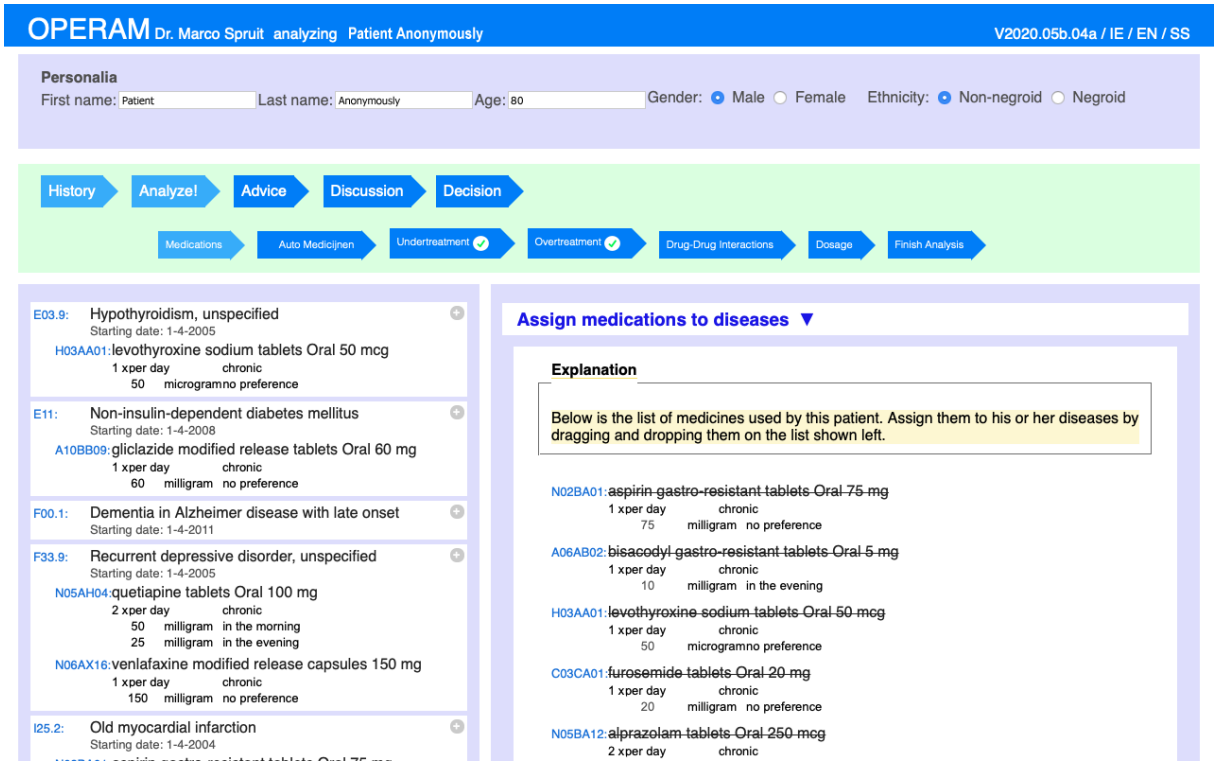
In the third step, this report was discussed with the attending hospital physician to reach a consensus about the recommendations. In addition, to promote patient engagement and to take patient preferences into account, a shared decision-making process with the patient or proxy took place. The researchers, treating hospital physicians and the patient agreed on the final medication changes. The research team was trained to each step of the intervention and standard operating procedures supported the process.

Lastly, after considering additional in-hospital clinical information (e.g. new diagnoses, adverse drug reactions), a final report was sent to the patient's GP to inform about in-hospital medication changes and all recommendations, including those that could not be implemented during the index hospitalization. All recommendations provided evidence-based reasons for changes.

STRIPA

The STRIP Assistant (STRIPA) version 2.0 is a stand-alone, web-based software tool that was used to perform a pharmaceutical analysis, an important step of the STRIP process. Data on diagnoses and current drug use (collected via SHiM and the actual medical record), recent measurements and laboratory values (e.g. renal function, blood pressure) and possible adverse drug reactions, as listed in the patient's medical record and according to patient information (SHiM) were entered in STRIPA. The assignment of drugs to diseases has been implemented through a drag and drop mechanism (see Methods appendix Figure). START A1 and START A2 were merged to one and STOPP A2 could not be converted into an algorithm, leaving a total of 79 STOPP and 33 START algorithms implemented into the clinical decision support system. Based on these data, pharmacotherapy optimization signals were generated by the clinical decision support software and evaluated for appropriateness on the individual patient level by the research physician and pharmacist.

Methods appendix Figure: Screenshot of STRIPA process during which medications are assigned to relevant medical conditions



Structured History Taking of Medication (SHIM)

Questions asked per drug on the medication list, provided by the community pharmacist

Drug no.: _____ Drug Name: _____

1. Are you using this drug as prescribed (dosage, dose frequency, dosage form)? Yes/No [Specify]
2. Are you experiencing any side effects? Yes [specify]/No
3. What is the reason for deviating (from the dosage, dose frequency, or dosage form) or not taking a drug at all? *(Please tick the box that applies)*

   Side effects ☐

Inconvenient	☐
Forgot	☐
Too expensive	☐
Difficult to swallow	☐
Unpleasant taste	☐
Other, …….	☐

4. Are you using any other prescription drugs that are not mentioned on this list? (view medication containers) Yes [specify]/No
5. Are you using nonprescription drugs? Yes [specify]/No
6. Are you using homeopathic drugs or herbal medicines (eg. St. Johns wort)? Yes [specify]/No
7. Are you using drugs that belong to family members or friends? Yes [specify]/ No
8. Are you using any "as needed" drugs? Yes [specify]/ No
9. Are you using drugs that are no longer prescribed? Yes [specify]/ No

Questions concerning the use of medicines

10. Are you taking your medication independently? Yes/No
11. Are you using a dosage system? Yes/No
12. Are you experiencing problems taking your medication? Yes [specify]/No
13. In case of inhalation therapy: What kind of inhalation system are you using? Are you experiencing any problems using this system?
14. In case of eye drops: Are you experiencing any difficulties using the eye drops?
15. Do you ever forget to take your medication? No/Yes. If so,

which medication	☐
why	☐
what do you do?	☐

16. Would you like to comment on or ask a question about your medication?
17. Do you have any drug allergies? Yes/No

b If yes, specify which drugs/drug classes

c If yes, specify the symptoms of the allergy

Rash	☐
Swelling/angio-oedema	☐
Collapse	☐
Hypotension	☐
Bronchospasm	☐
Other symptom,	☐

18 Do you have any drug intolerances? Yes/ No

b If yes, specify which drugs/drug classes

c If yes, specify the symptoms of the drug intolerance

For study team member to answer and enter in the eCRF:

Did the SHIM led to any change in the medication list? *(Please tick the correct box)*

Yes	☐
No	☐

If yes, specify which drug, dosage, dose frequency or dosage form.

Was medicine reconciliation done?

Yes	☐
No	☐

Definitions of underuse, overuse and misuse in Table 5

Underuse, overuse and misuse were based on START and STOPP criteria version 2, and using an algorithm run on the trial database. The START criteria were used to detect drug underuse (i.e., potential prescribing omissions); each STOPP criterion was categorized as either measuring overuse or measuring misuse (i.e., potentially inappropriate medication). In total, 30 of 34 START criteria and 65 or 80 STOPP criteria were included and measured, as some criteria required data that were not available (mainly (i) laboratory measurements that were not available at two months in this pragmatic RCT, and (ii) the implicit STOPP criteria A1, A2, and A3 that require evaluation at patient-level by a trained clinician. We developed and validated an algorithm for the measurement of the following outcomes: drug underuse, drug overuse, drug misuse. The algorithm was developed from previous experience and reports from our team related to the automated detection of STOPP and START criteria.(8,9) Research Team statisticians and programmers (Prof. Dimitris Mavridis and Mr Agapios Panos, University of Ioannina, Greece) developed an R package that provided automated evaluation for each criterion (https://github.com/agapiospanos/StartStopp). In summary, detection was performed by using a validated algorithm (that was applied to the research database), based on the STOPP and START criteria.

Drug-drug interactions were assessed using a validated consensus-based list of 66 drug-drug-interaction criteria that we have recently published.(10) Once again, research team statisticians and programmers developed an R package that evaluated patient data for drug-drug interactions based on these criteria, using ATC coded medication lists (https://github.com/agapiospanos/DDI). This algorithm identifies combinations of ATC codes and was pilot tested in several rounds to check for accuracy in the detection.

References

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