INTERNATIONAL DEPRESCRIBING JOURNAL CLUB
Monday 19th June 16:00-17:00 CET

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Family Conferences to facilitate shared prioritisation and deprescribing in frail elderlies with polypharmacy cared for at home.

Results from of a pragmatic cluster randomized trial in primary care

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Gemeinsamer Bundesausschuss Innovationsausschuss

Förderkennzeichen
01VSF17053

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Institute of General Practice and Primary Care
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Frailty

Definition

is an „aging-related syndrome of physiological decline, characterized by marked vulnerability to adverse health outcomes“

Fried 2001

CSHA Clinical Frailty Scale

Rockwood 2005, 2007- 2009)

1 Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.

2 Well – People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.

3 Managing Well – People whose medical problems are well controlled, but are not regularly active beyond routine walking.

4 Vulnerable – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being "slowed up", and/or being tired during the day.

5 Mildly Frail – These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

6 Moderately Frail – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.

7 Severely Frail – Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).

8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

Polypharmacy

Definition

= Intake of five or more different drugs per day

- Polypharmacy can trigger or increase frailty

- Reduction of Polypharmacy is a promising intervention to improve safety of geriatric patients

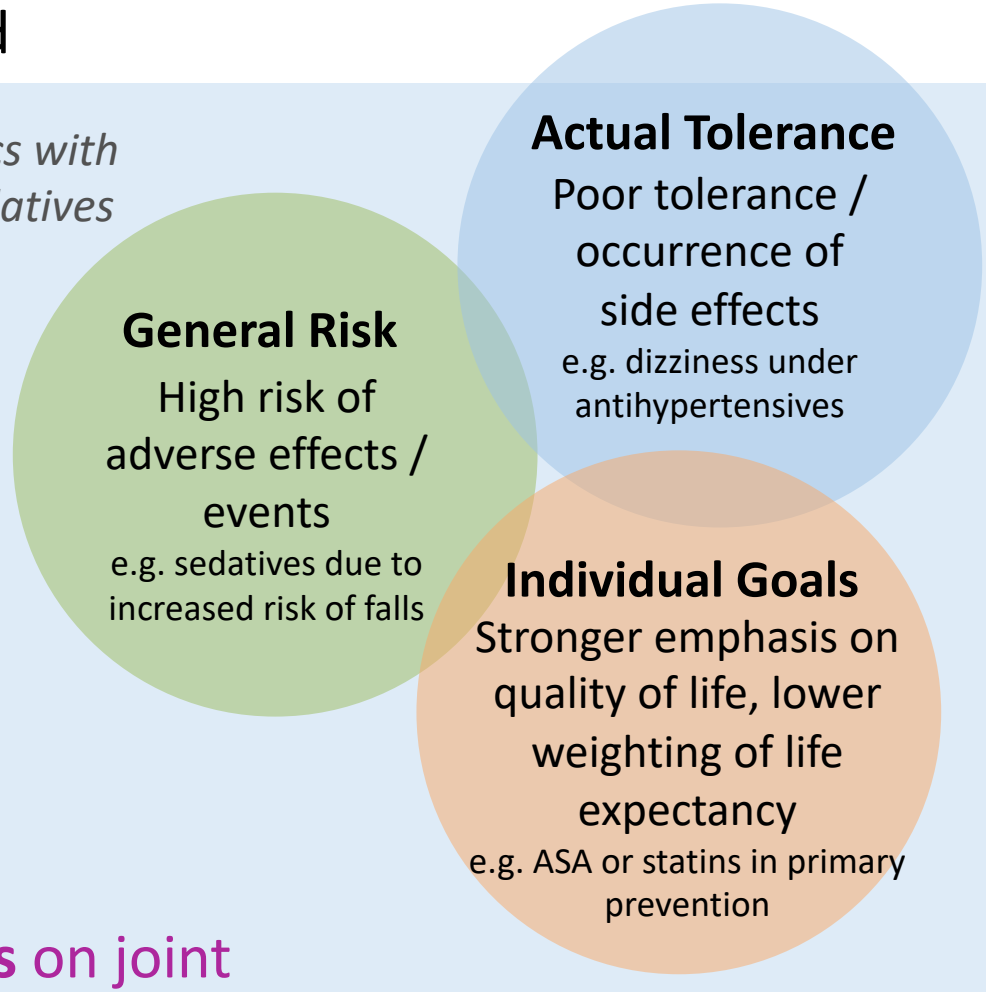
Deprescribing

Definition

… is the planned and supervised process of dose reduction or stopping of medication that might be causing harm, or no longer be of benefit

Deprescribing needs **good communication** between all actors involved

Discussion topics with patients and relatives



Research Question

to investigate the effects of **family conferences** on joint prioritisation and deprescribing for frail outpatients with polypharmacy

Methods

Study Design

Cluster randomised controlled trial

Assessments

- by GPs (from records) and by study nurses (interviews)
- **T0** Baseline, **T1** after 6 months, **T2** after 12 months

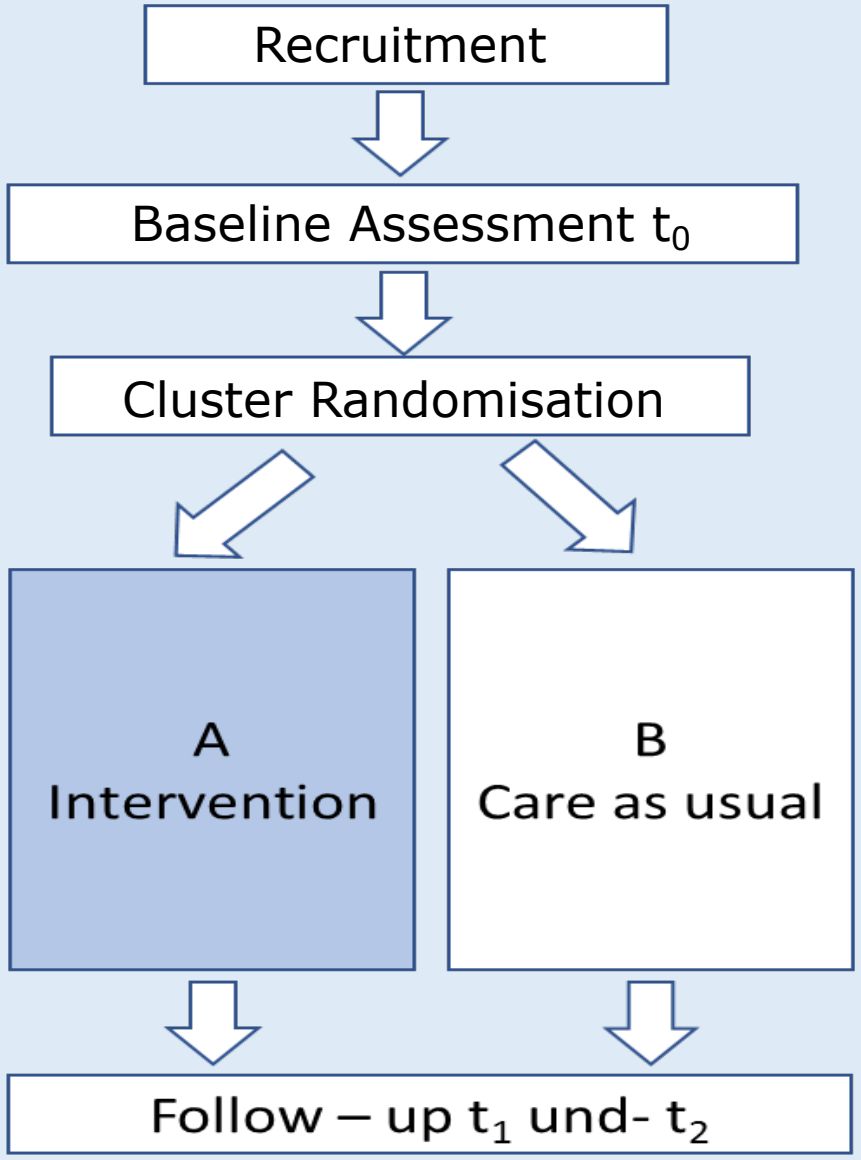
Outcomes

Primary Outcome:

- Mean number of hospitalisations

Secondary Outcomes:

- Mean number of drugs
- Potentially inappropriate medications (Eu7-PIMs)
- Geriatric assessment
- Health economic evaluation



Methods

Intervention

Training concept for GPs & developed tools

- **Conduction of three family conferences**
  - *Guideline Family Conference No. 1*

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Guideline Family Conference No.1

Preparation

- Making an **appointment** with the patient, the relative and if necessary, care service
- Update **medication plan**, print out twice and take it with you

(Place a copy in the COFRAIL project folder)

- **Using the deprescribing guide, decide which medication should be considered for discontinuation** (contact the pharmacology hotline if necessary)

Conduction of the 1st family conference

Start:

- Clarify the **setting** (e.g. sitting together at the same table)
- Explain the **agenda**: topic drugs, further topic(s)
- Determine needs (optional use of the patient preparation sheet)
- Agree **communication rules** (e.g. everyone should have a say)

Medical Message on Deprescribing: *„With increasing frailty, the tolerability and benefit of many drugs is no longer guaranteed. Stopping medication could stabilise your state of health (e.g. with regard to mobility/ ability to move) and could reduce the risk of emergency events!“*

Medication Check: Putting all drug **packages on the table** and discuss them one by one, **discuss** possible **options** for change for each drug:

Tolerance "How do you tolerate the drug?"

Therapeutic Goal "What is our goal with this drug?"

Risk "What are the potential risks associated with this drug?"

Final organisational steps:

- **Update the medication plan** by hand for the patient / care service
- Agree on further follow-up checks and follow-up appointment
- **Fill in the COFRAIL result sheet** and leave a copy with the patient

(take the original with you, submit to the study centre and place it to the COFRAIL project folder)

Follow-up

- **Update the medication plan**, print out twice, send it to the patient/ if necessary, also to the care service *(place a copy in the COFRAIL project folder)*
- **Follow-up checks/ follow-up appointment** (as agreed with the patient)

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of non-pharmacological actions

ysiotherapy, occupational therapy, medical
g service, preventive check-ups (e. g. cancer

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ent. Use the following questions[1] to identify
f applicable) are available to use. Note the
h the patient, taking into account existing
s requiring action.

t response/ a problem?	Agreed actions
.....	.....
.....	.....
es/ ☐ No	
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P) provided by Junius-Walker (not published), English

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Methods

Intervention

Training concept for GPs & developed tools

- **Conduction of three family conferences**
  - ➢ *Guideline Family Conference No. 1*
- **Consideration of non-pharmacological needs**
  - ➢ Non-pharmacological toolbox incl. *Checklist* and *Needs Analysis Manual*
- **Recommendations on deprescribing**
  - ➢ *Deprescribing Manual*

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Preparation

- Making an **appointment** with
- Update **medication plan**, prin

(Place a copy in the COFRAIL pro

- **Using the deprescribing guide discontinuation** (contact the

Conduction of the 1st family

Start:

- ➢ Clarify the **setting** (e.g. sittin
- ➢ Explain the **agenda**: topic dr
- ➢ Determine needs (optional
- ➢ Agree **communication rules**

Medical Message on De

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Medication Check: Puttir

by one, **discuss** possible **options**

Tolerance "How do

Therapeutic Goal

Risk "What are the po

Final organisational ste

- ➢ **Update the medication plar**
- ➢ Agree on further follow-up
- ➢ **Fill in the COFRAIL result sh**

(take the original with you, project folder)

Follow-up

- **Update the medication plan,** also to the care service *(place*
- **Follow-up checks/ follow-up**

Supplement 1

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CHECKLIST

for joint problem identification and determination of non-pharmacological actions

I) Make a note of any existing medical services: Remedies (e. g. physiotherapy, occupational therapy, medical foot care), aids (e. g. hearing aids, visual aids, walking aids), nursing service, preventive check-ups (e. g. cancer screening.

.....

.....

II) Discuss existing problems in everyday life together with the patient. Use the following questions[1] to identify problems. In addition, the *handbook* and the *preparation sheet* (if applicable) are available to use. Note the patient's responses and whether there is a problem. Discuss with the patient, taking into account existing medical services (see I), which actions should be agreed for problems requiring action.

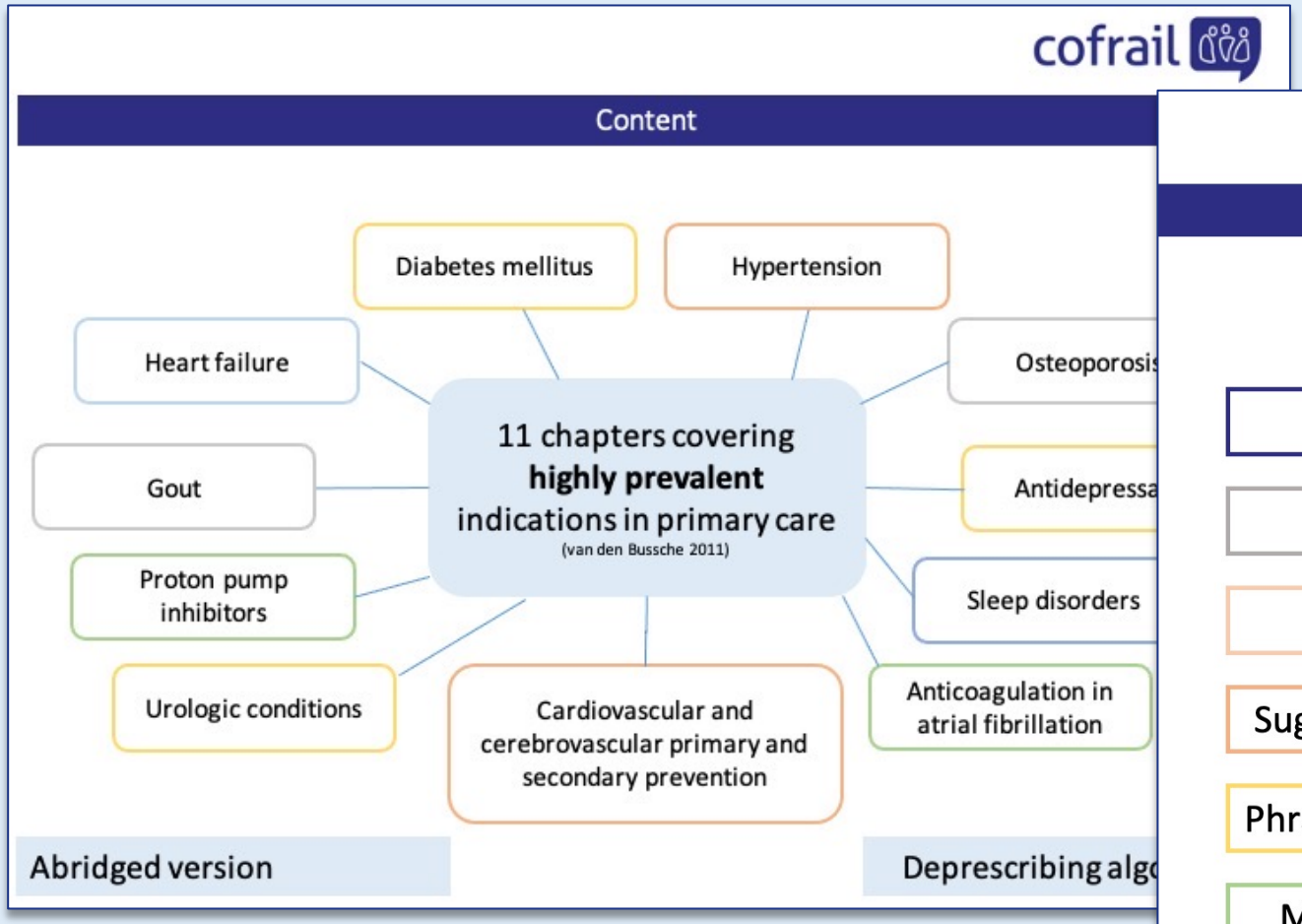
Identification of problems and problem areas	Patient response/ Is this a problem?	Agreed actions
1. Performance in everyday life *How much difficulty did you have doing usual activities or tasks, both inside and outside the house due to the state of health or mood?* [2]	☐ Yes/ ☐ No	
2. Social environment *Do you have someone who would be able to help you in case of illness or emergency, e. g. after a fall? Do you have anyone to trust or confide in?*[3]	☐ Yes/ ☐ No	
3. Mobility/agility *Are you physically active? If no, why not? You can no longer perform physical activities as usual (e.g., intensity, frequency)? If yes, why not?*[4]	☐ Yes/ ☐ No	
4. Falls *How many falls have you had over the last 6 months?*[5]	☐ Yes/ ☐ No	
5. Dizziness *Have you had dizziness in the last 6 months? Does the dizziness affect you in everyday life?*[6]	☐ Yes/ ☐ No	
6. Chronic pain *Are you currently in pain? If so, has it been going on for a long time?*[7] *How severe has your pain been in the last four weeks? To what extent has the pain hindered you in your everyday activities?*	☐ Yes/ ☐ No	
7. Vision impairments *Do you have difficulty seeing newspaper print even with glasses? Do you have difficulty recognizing people across the road even with glasses?*[8]	☐ Yes/ ☐ No	

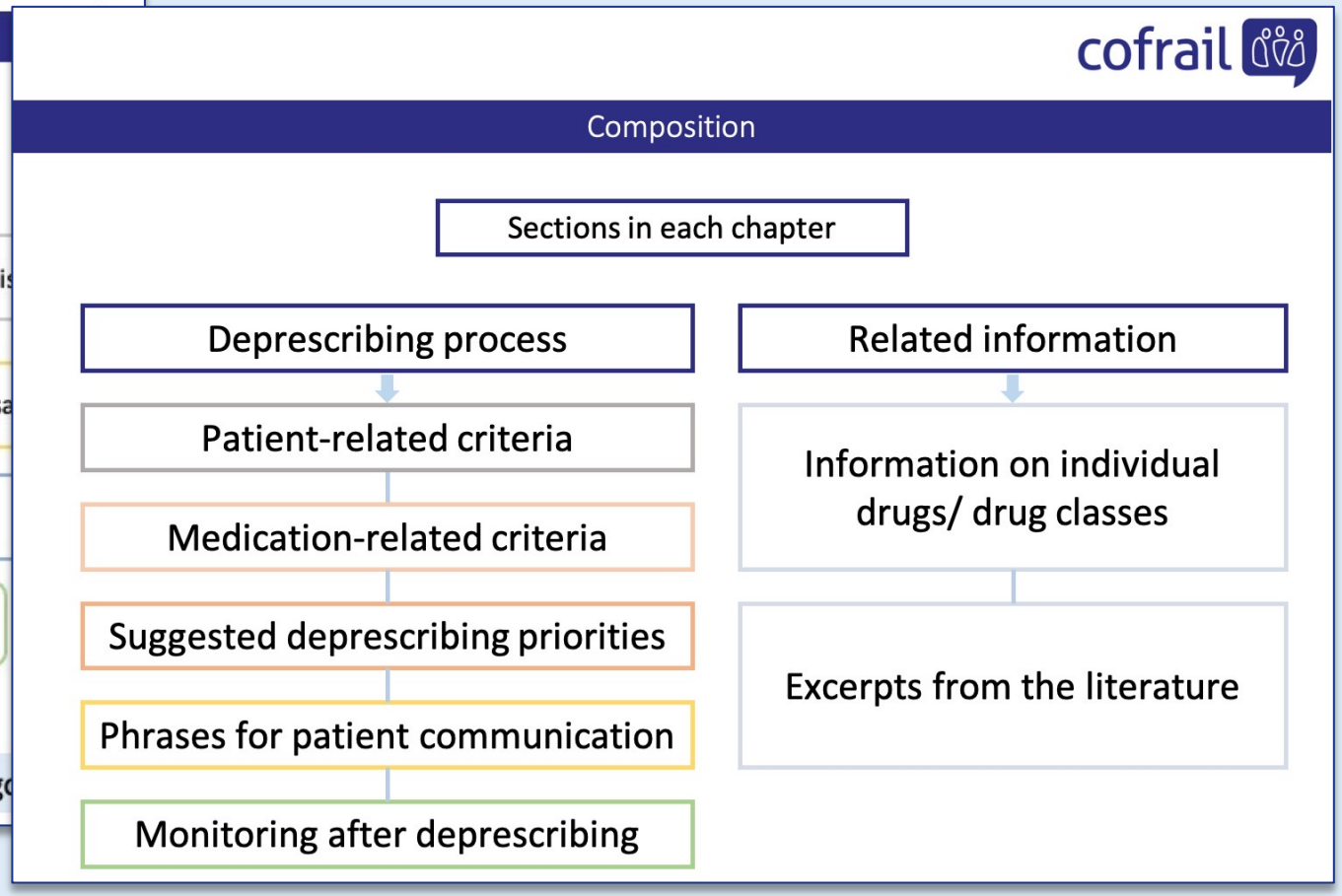
[1] English version of questions taken from the MAGIC-Assessment (short version of STEP) provided by Junius-Walker (not published), English version of additionally derived or adopted questions by the COFRAIL study group
[2] MAGIC question 1, Version 2013
[3] MAGIC question 7, Version 2016
[4] COFRAIL question, Version 2019 (derived from the DEGAM Guideline)
[5] MAGIC question 4, Version 2016
[6] COFRAIL question, Version 2019 (derived from the DEGAM Guideline)
[7] COFRAIL question, Version 2019 (adopted from DEGAM Guideline)
[8] MAGIC question 2, Version 2016

1

Intervention

Deprescribing Manual: Content and Composition





Mann NK, Schmiedl S, Mortsiefer A et al. Development of a deprescribing manual for frail older people for use in the COFRAIL study and in primary care. Ther Adv Drug Saf. 2022 Sep 6; 13:20420986221122684. doi: 10.1177/20420986221122684

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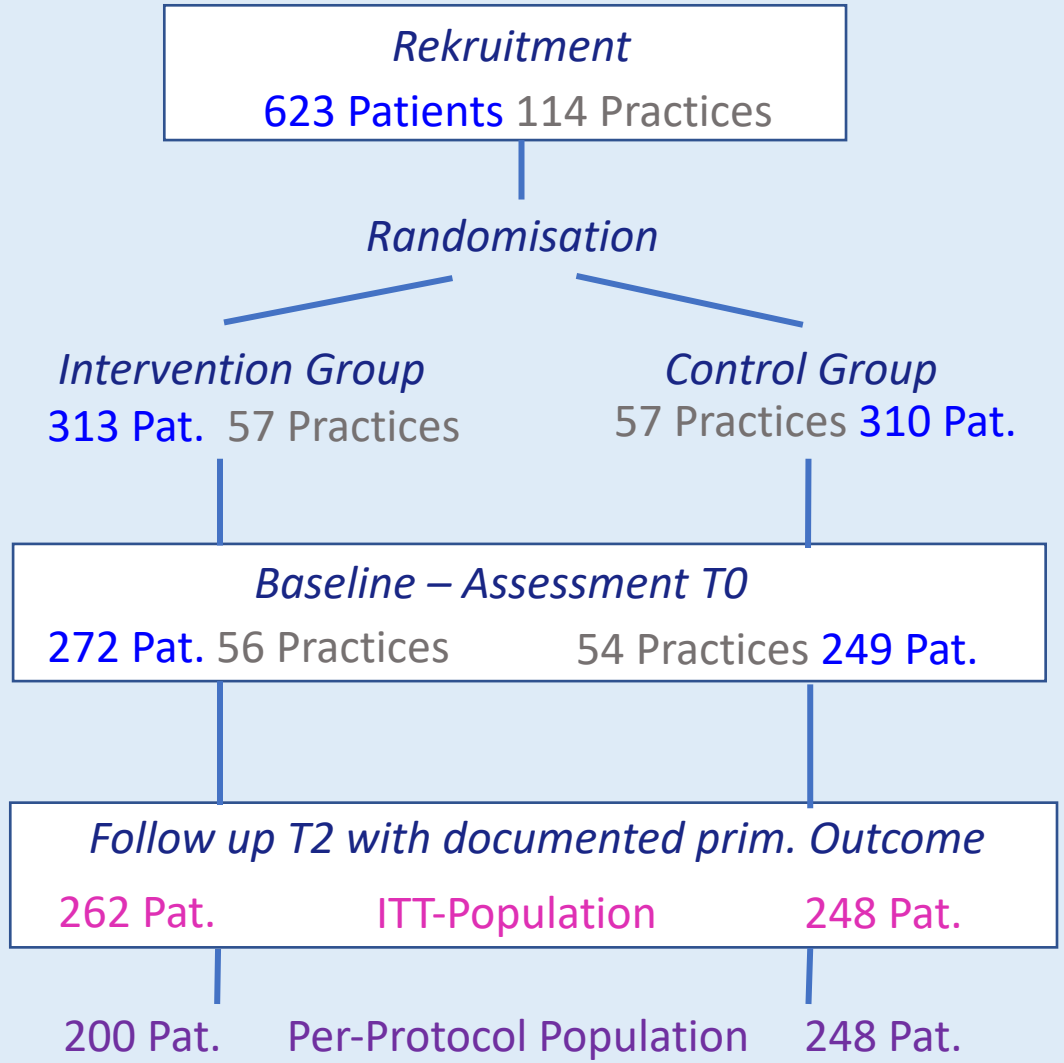
Study Population



Baseline Charakteristics	*Intervention*	*Control*
No.	272	249
Female, %	66.5	70.3
Age *Mean value (±SD)*	83.69 (6.08)	83.29 (6.29)
Clinical Frailty Scale (CFS)		
5=mild, %	51.1	51.5
6=moderate, %	38.1	37.7
7=severe, %	10.8	10.9
No. Diagnoses Mean value *(±SD)*	11.77 (4.11	12.11 (4.12)
Medications Mean value (± SD)	9.28 (3.78)	9.37 (3.40)

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Primary Outcome

Does the intervention lead to an increase in patient safety with a **reduction in hospitalisation admissions**?

Study participants	Mean number of hospitalisations * (± SD)		Mixed model ** IRR [95% CI]
	Intervention group	Control group	
ITT (n=510)	**0.98** (±1.72)	**0.99** (± 1.53)	1.08 [0.84; 1.39] (p=0.533)

Mixed-effect Model Poisson Regression, practices were taken into account as random effect

*adjusted for an oberservation period of 12 months
** Adjusted variables: Observation period, age, sex, number chronic diseases, retrospective hospitalisation rate at baseline

IRR = Incidence Rate Ratio; ITT = Intention-to-treat Analyse; SD = Standard Deviation; 95% CI = 95% Confidence Interval

No difference in hospital admissions between intervention and control group

Secondary Outcomes I

Number of medications

Study participants	Mean number of drugs (± SD)		Mixed model * IRR [95% CI]
	Intervention group	Control group	
T0 at baseline	**8.98** (± 3.56) (N=198)	**9.24** (± 3.44) (N=184)	-
T1 after 6 months	**8.11** (± 3.21) (N=193)	**9.32** (± 3.59) (N=181)	0.88 [0.82; 0.95] (**p < 0.001**)
T2 after 12 months	**8.49** (± 3.63) (N=197)	**9.16** (± 3.42) (N=184)	0,94 [0.88; 1.01] (p=0.073)

* Mixed-effect poisson regression model adjusted for the number of medications at Baseline. Practices were taken into account as random effect.
IRR = Incidence Rate Ratio; SD = Standard Deviation; 95% CI = 95% Confidence Interval

Significant **difference of the number of drugs after 6 months**
no significant difference after 12 months

Secondary Outcomes I — Number of potentially inappropriate medications (PIM)

	Mean number of EU(7) PIMs (± SD)		**Mixed model *** IRR [95% CI]
	Intervention group	Control group	
T0 at baseline	**1.57**(±1.15) (N=176)	**1.80** (± 1.16) (N=171)	-
T1 after 6 months	**1.30** (± 1.05) (N=176)	**1.71** (± 1.25) (N=171)	**0.84** [0.70;0.99] **(p =0.043)**
T2 after 12 months	**1.45** (± 1.21) (N=176)	**1.64** (± 1.15) (N=171)	**0.97**[0.82;1.15] (p=0.720)

*Mixed-effect Poisson regression model adjusted for the number of EU(7) PIMs at baseline. Practices were taken into account as a random effect.

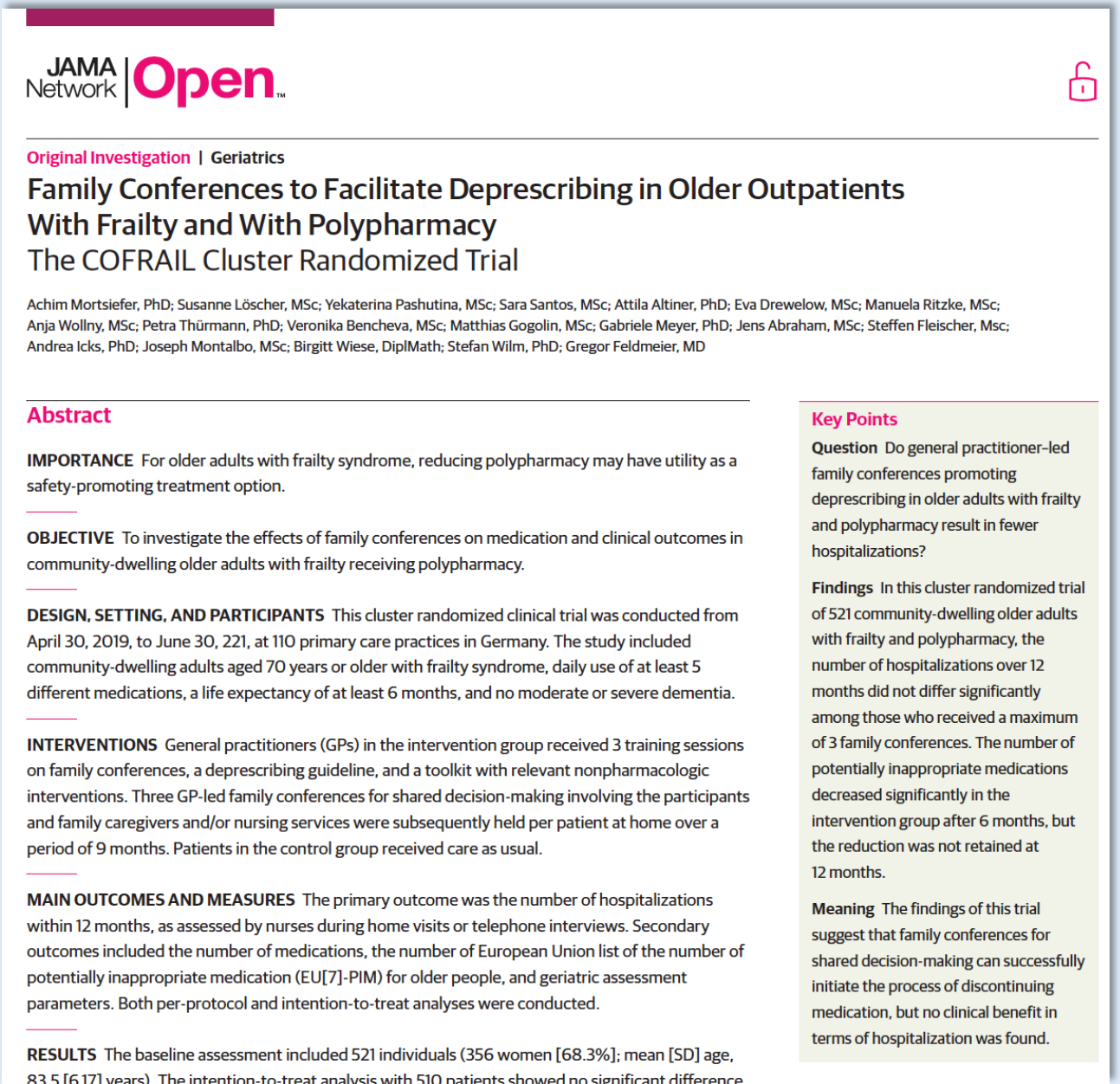
IRR = Incidence Rate Ratio; SD = Standard Deviation; 95% CI = 95% Confidence Interval

→ Significant **difference after 6 months**, no significant difference after 12 months

Secondary Outcomes II — **Functional status of patients** in geriatric assessment

no differences between intervention and control group

Publications



JAMA Network | Open

Original Investigation | Geriatrics

Family Conferences to Facilitate Deprescribing in Older Outpatients With Frailty and With Polypharmacy
The COFRAIL Cluster Randomized Trial

Achim Mortsiefer, PhD; Susanne Löscher, MSc; Yekaterina Pashutina, MSc; Sara Santos, MSc; Attila Altiner, PhD; Eva Drewelow, MSc; Manuela Ritzke, MSc; Anja Wollny, MSc; Petra Thürmann, PhD; Veronika Bencheva, MSc; Matthias Gogolin, MSc; Gabriele Meyer, PhD; Jens Abraham, MSc; Steffen Fleischer, Msc; Andrea Icks, PhD; Joseph Montalbo, MSc; Birgitt Wiese, DiplMath; Stefan Wilm, PhD; Gregor Feldmeier, MD

Abstract

IMPORTANCE For older adults with frailty syndrome, reducing polypharmacy may have utility as a safety-promoting treatment option.

OBJECTIVE To investigate the effects of family conferences on medication and clinical outcomes in community-dwelling older adults with frailty receiving polypharmacy.

DESIGN, SETTING, AND PARTICIPANTS This cluster randomized clinical trial was conducted from April 30, 2019, to June 30, 221, at 110 primary care practices in Germany. The study included community-dwelling adults aged 70 years or older with frailty syndrome, daily use of at least 5 different medications, a life expectancy of at least 6 months, and no moderate or severe dementia.

INTERVENTIONS General practitioners (GPs) in the intervention group received 3 training sessions on family conferences, a deprescribing guideline, and a toolkit with relevant nonpharmacologic interventions. Three GP-led family conferences for shared decision-making involving the participants and family caregivers and/or nursing services were subsequently held per patient at home over a period of 9 months. Patients in the control group received care as usual.

MAIN OUTCOMES AND MEASURES The primary outcome was the number of hospitalizations within 12 months, as assessed by nurses during home visits or telephone interviews. Secondary outcomes included the number of medications, the number of European Union list of the number of potentially inappropriate medication (EU[7]-PIM) for older people, and geriatric assessment parameters. Both per-protocol and intention-to-treat analyses were conducted.

RESULTS The baseline assessment included 521 individuals (356 women [68.3%]; mean [SD] age, 83.5 [6.17] years). The intention-to-treat analysis with 510 patients showed no significant difference

Key Points

Question Do general practitioner–led family conferences promoting deprescribing in older adults with frailty and polypharmacy result in fewer hospitalizations?

Findings In this cluster randomized trial of 521 community-dwelling older adults with frailty and polypharmacy, the number of hospitalizations over 12 months did not differ significantly among those who received a maximum of 3 family conferences. The number of potentially inappropriate medications decreased significantly in the intervention group after 6 months, but the reduction was not retained at 12 months.

Meaning The findings of this trial suggest that family conferences for shared decision-making can successfully initiate the process of discontinuing medication, but no clinical benefit in terms of hospitalization was found.

Mortsiefer A, Löscher S, Pashutina Y, et. al. Family Conferences to Facilitate Deprescribing in Older Outpatients With Frailty and With Polypharmacy: The COFRAIL Cluster Randomized Trial. JAMA Netw Open. 2023 Mar 1;6(3):e234723. doi: 10.1001/jamanetworkopen.2023.4723

Publications

Contents lists available at ScienceDirect

PEC Innovation

journal homepage: www.elsevier.com/locate/pecinn

Development of a shared decision-making intervention to improve drug safety and to reduce polypharmacy in frail elderly patients living at home

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ARTICLE INFO

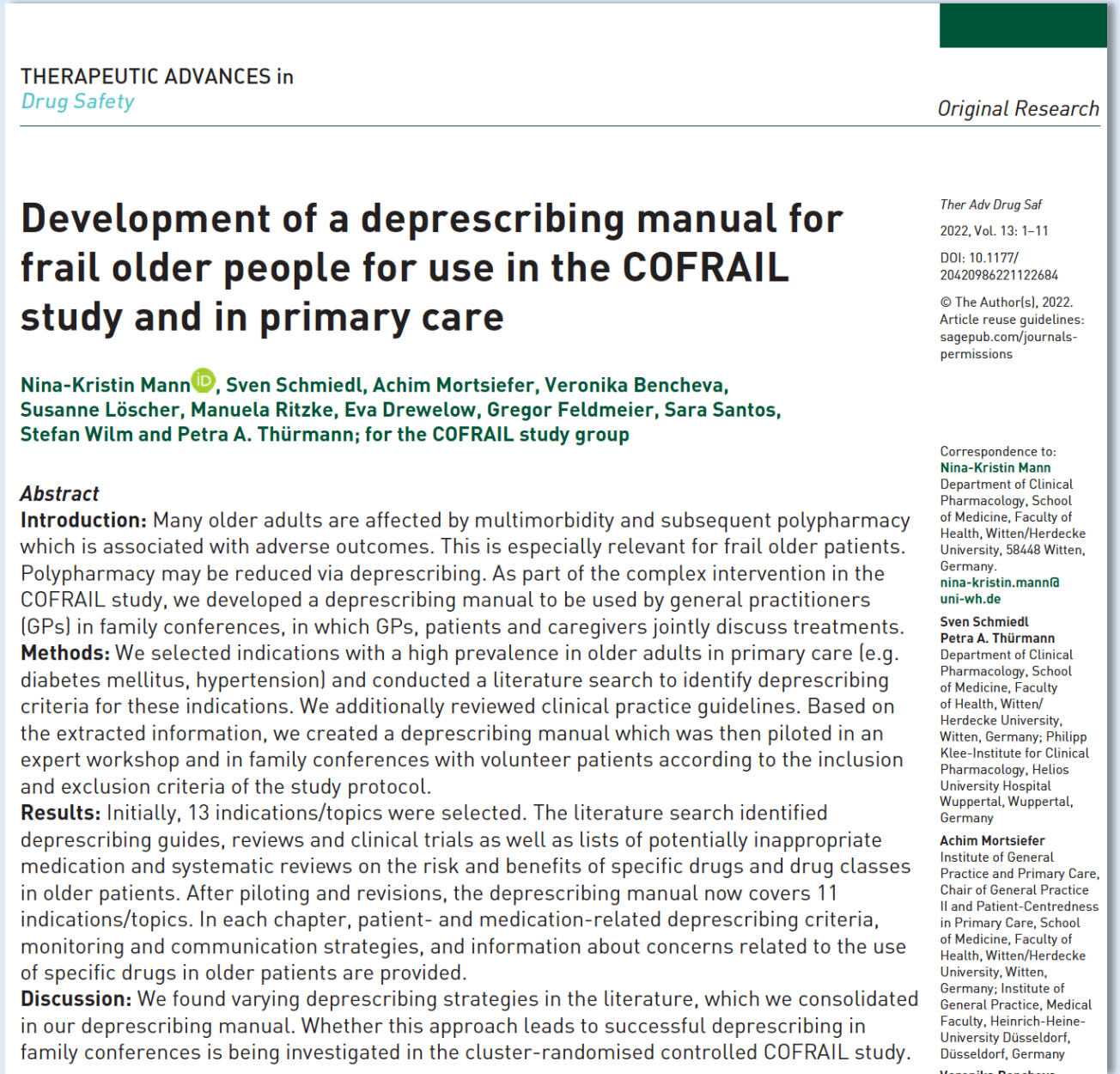
Keywords:
Frailty
Polypharmacy
Deprescribing
Family Conference
Primary Care

ABSTRACT

Objectives: For patients with geriatric frailty, reducing inappropriate medication is an important goal to improve patient safety in primary care. GP-side barriers include knowledge gaps, legal concerns, and lack of communication between the actors involved. The aim was to develop a multi-faceted intervention to facilitate deprescribing and shared prioritisation among frail elderlies with polypharmacy living at home.
Methods: Mixed methods study including: 1) scoping review on family conferences, expert panels; 2) group discussions with GPs, mapping of needs and challenges in Primary Care; 3) workshops and expert interviews with GPs, patient advocates, researchers as a basis for a theoretical intervention model; 4) piloting.
Results: A major challenge for GPs is to conduct a productive discussion with patients and family cares on deprescribing and drug safety. A guideline for a structured family conference with a medication check and geriatric assessment was developed and proved to be feasible in the pilot study.
Conclusion: The intervention developed to facilitate deprescribing and shared prioritisation of drug therapy based on family conferences seems suitable to be tested in a subsequent cRCT.
Innovation: Adapting family conferences to primary care for frail patients with polypharmacy.

Drewelow E, Ritzke M, Altiner A, et al. Development of a shared decision-making intervention to improve drug safety and to reduce polypharmacy in frail elderly patients living at home.
PEC Innov. 2022 Mar 24;1:100032.
doi: 10.1016/j.pecinn.2022.100032

Publications



THERAPEUTIC ADVANCES in
Drug Safety

Original Research

Development of a deprescribing manual for frail older people for use in the COFRAIL study and in primary care

Nina-Kristin Mann, Sven Schmiedl, Achim Mortsiefer, Veronika Bencheva, Susanne Löscher, Manuela Ritzke, Eva Drewelow, Gregor Feldmeier, Sara Santos, Stefan Wilm and Petra A. Thürmann; for the COFRAIL study group

Ther Adv Drug Saf
2022, Vol. 13: 1–11
DOI: 10.1177/20420986221122684

Abstract

Introduction: Many older adults are affected by multimorbidity and subsequent polypharmacy which is associated with adverse outcomes. This is especially relevant for frail older patients. Polypharmacy may be reduced via deprescribing. As part of the complex intervention in the COFRAIL study, we developed a deprescribing manual to be used by general practitioners (GPs) in family conferences, in which GPs, patients and caregivers jointly discuss treatments.

Methods: We selected indications with a high prevalence in older adults in primary care (e.g. diabetes mellitus, hypertension) and conducted a literature search to identify deprescribing criteria for these indications. We additionally reviewed clinical practice guidelines. Based on the extracted information, we created a deprescribing manual which was then piloted in an expert workshop and in family conferences with volunteer patients according to the inclusion and exclusion criteria of the study protocol.

Results: Initially, 13 indications/topics were selected. The literature search identified deprescribing guides, reviews and clinical trials as well as lists of potentially inappropriate medication and systematic reviews on the risk and benefits of specific drugs and drug classes in older patients. After piloting and revisions, the deprescribing manual now covers 11 indications/topics. In each chapter, patient- and medication-related deprescribing criteria, monitoring and communication strategies, and information about concerns related to the use of specific drugs in older patients are provided.

Discussion: We found varying deprescribing strategies in the literature, which we consolidated in our deprescribing manual. Whether this approach leads to successful deprescribing in family conferences is being investigated in the cluster-randomised controlled COFRAIL study.

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Mann NK, Schmiedl S, Mortsiefer A, et al. Development of a deprescribing manual for frail older people for use in the COFRAIL study and in primary care.
Ther Adv Drug Saf. 2022 Sep 6;13:20420986221122684.
doi: 10.1177/20420986221122684

Conclusions

- The COFRAIL – Intervention had no influence on hospitalisations *(Prim. Outcome)*
- The number of medications per patient decreased by 0.87 in the intervention group after six months
- Family conferences for shared decision-making can successfully initiate the process of deprescribing

Point for discussion

- Would you generally recommend a non-inferiority approach to deprescribing studies?

95th EGPRN Meeting Oct. 2022 - Antwerp, Belgium

Family Conferences to facilitate shared prioritisation and deprescribing in frail elderlies with polypharmacy cared for at home.

Results from of a pragmatic cluster randomized trial in primary care

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