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Katharina Tabea Jungo on behalf of the OPERAM study team

Optimizing Therapy to Prevent Avoidable Hospital Admissions in Multimorbid Older Adults (OPERAM): a cluster randomised controlled trial

OPERAM

HORIZON 2020

Optimizing Therapy to Prevent Avoidable Hospital Admissions in Multimorbid Older Adults (OPERAM): cluster randomised controlled trial

Blum MR; Sallevelt BTGM; Spinewine A; O'Mahony D; Moutzouri E; Feller M; Baumgartner C; Roumet M; Jungo KT; Schwab N; Bretagne L; Beglinger S; Aubert CE; Wilting I; Thevelin S; Murphy K; Huibers CJA; Drenth-van Maanen AC; Boland B; Crowley E; Eichenberger A; Meulendijk M; Jennings E; Adam L; Roos MJ; Gleeson L; Shen Z; Marien S; Meinders AJ; Baretella O; Netzer S; de Montmollin M; Fournier A; Mouzon A; O'Mahony C; Aujesky D; Mavridis D; Byrne S; Jansen PAF; Schwenkglenks M; Spruit M; Knol W; Dalleur O; Trelle S; Rodondi N

thebmj

Blum et al. BMJ. 2022.

CONFLICT OF INTEREST DISCLOSURE

I have no potential conflict of interest to report.

FUNDING OF THE OPERAM TRIAL

- EU Horizon 2020
- Swiss State Secretariat for Education, Research and Innovation (SERI)
- Swiss National Science Foundation (SNSF)

In the context of the increasing prevalence of older adults with multiple chronic conditions …

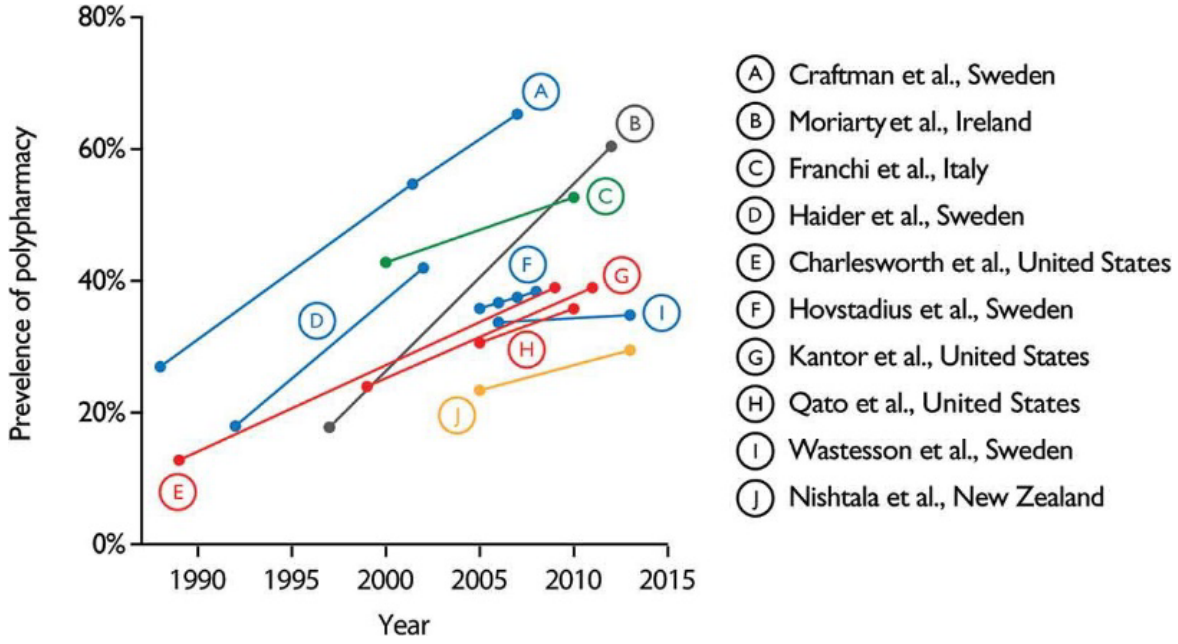


Figure 1. International polypharmacy trends (2)

… there is an increasing number of older adults with polypharmacy

Sources: Laires et al. Eur J Ageing. 2019. | Wastesson et al. Expert Opinion on Drug Safety. 2018

Polypharmacy is associated with an increased risk of inappropriate prescribing, which in turn leads to different negative outcomes:

- Adverse drug events
- Cognitive impairment
- Falls
- Functional decline
- Hospital (re-)admissions

→ Despite this there is limited evidence on interventions to improve medication appropriateness and lower the risk of adverse clinical outcomes

Sources: Davies et al. Journal of the American Medical Directors Association. 2020. | Liew et al. Annals of Family Medicine. 2019. | Mekonnen et al. Br J Clin Pharmacol. 2021. | Rochon et al. The Lancet. Health Longevity. 2021. | Xing et al. Ann Pharmacotherapy. 2019.

OPERAM trial

- Large **multinational randomized clinical trial** led by the Department of General Internal Medicine and Institute of Primary Health Care of the University of Bern

- Other clinical study centres:
  - Utrecht, Netherlands
  - Brussels, Belgium
  - Cork, Ireland

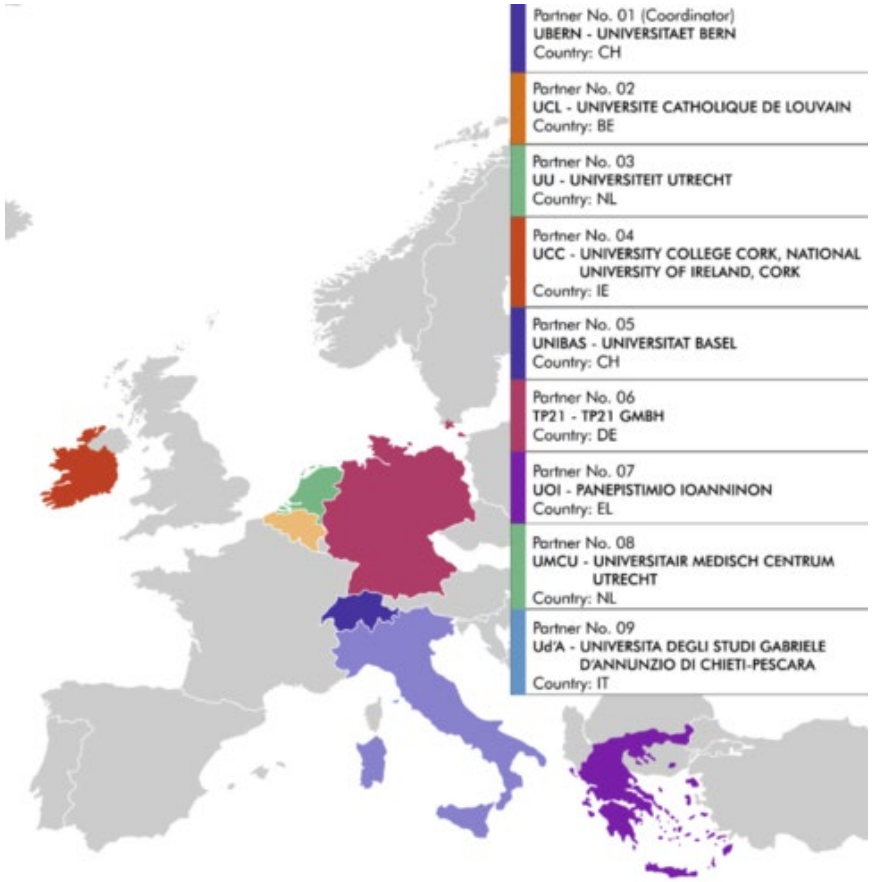


Figure 2. Countries participating in the OPERAM trial

Source: https://www.operam-2020.eu/index.php?id=1502, accessed 26.08.2022

OPERAM study participants

- Adults aged **≥ 70 years**
- Admitted to a participating hospital ward
- **Multimorbidity** (≥ 3 chronic conditions)
- **Polypharmacy** (≥ 5 daily drugs)

- Few exclusion criteria to maximize generalizability

OPERAM Intervention

- Cluster-randomisation at the level of attending hospital physicians
- 1:1 randomisation to the intervention or control arm
- Intervention performed by team of a doctor and a pharmacist
- Structured assessment of preadmission medication list

OPERAM Intervention *(continued)*

- Web-based evidence-based structured medication review using STRIP assistant
  - Based on the STOPP/START criteria (1)

    STOPP = Screening Tool of Older Person's Prescriptions
    START = Screening Tool to Alert to the Right Treatment

- Generation of patient specific prescribing recommendations: Stop, start, adapt dosage, etc.

- Final report sent to general practitioners with all prescribing recommendations

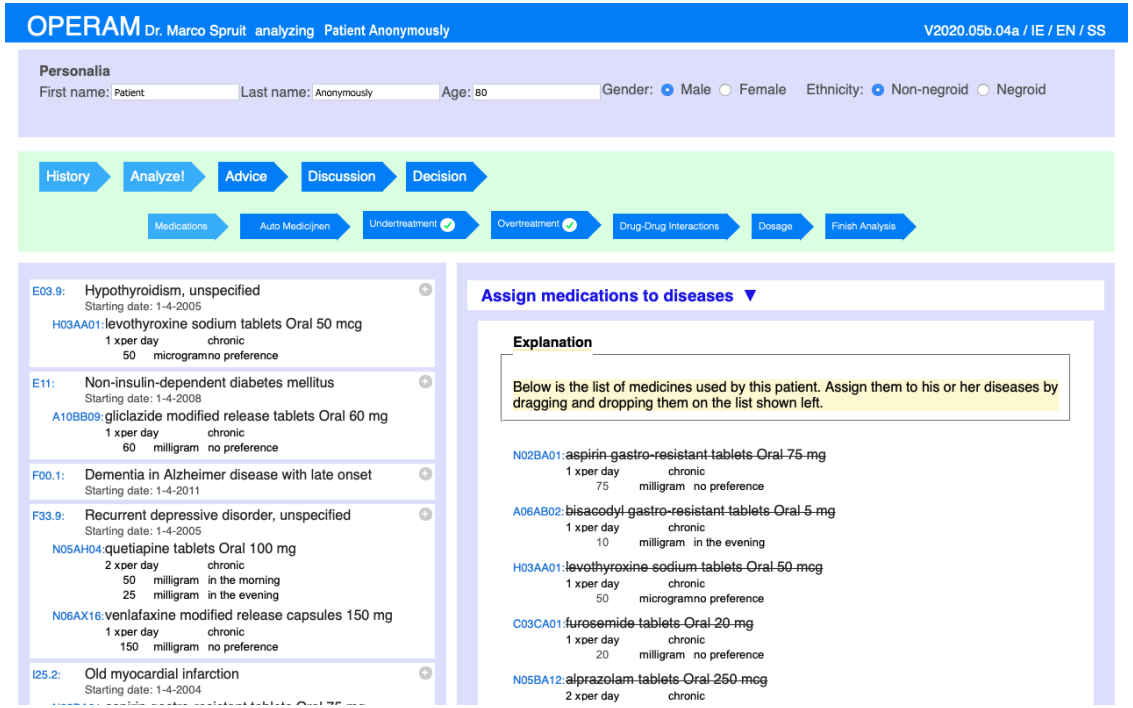


Figure 3. Excerpt from the 'Systematic Tool to Reduce Inappropriate Prescribing' (STRIP) assistant

Sources: (1) O'Mahony et al. Age Ageing. 2015. | Drenth-van Maanen et al. J Eval Clin Pract. 2018. | Crowley et al. BMC Health Serv Res. 2020. | Adam et al. BMJ Open. 2019

Study Outcomes

Primary outcome

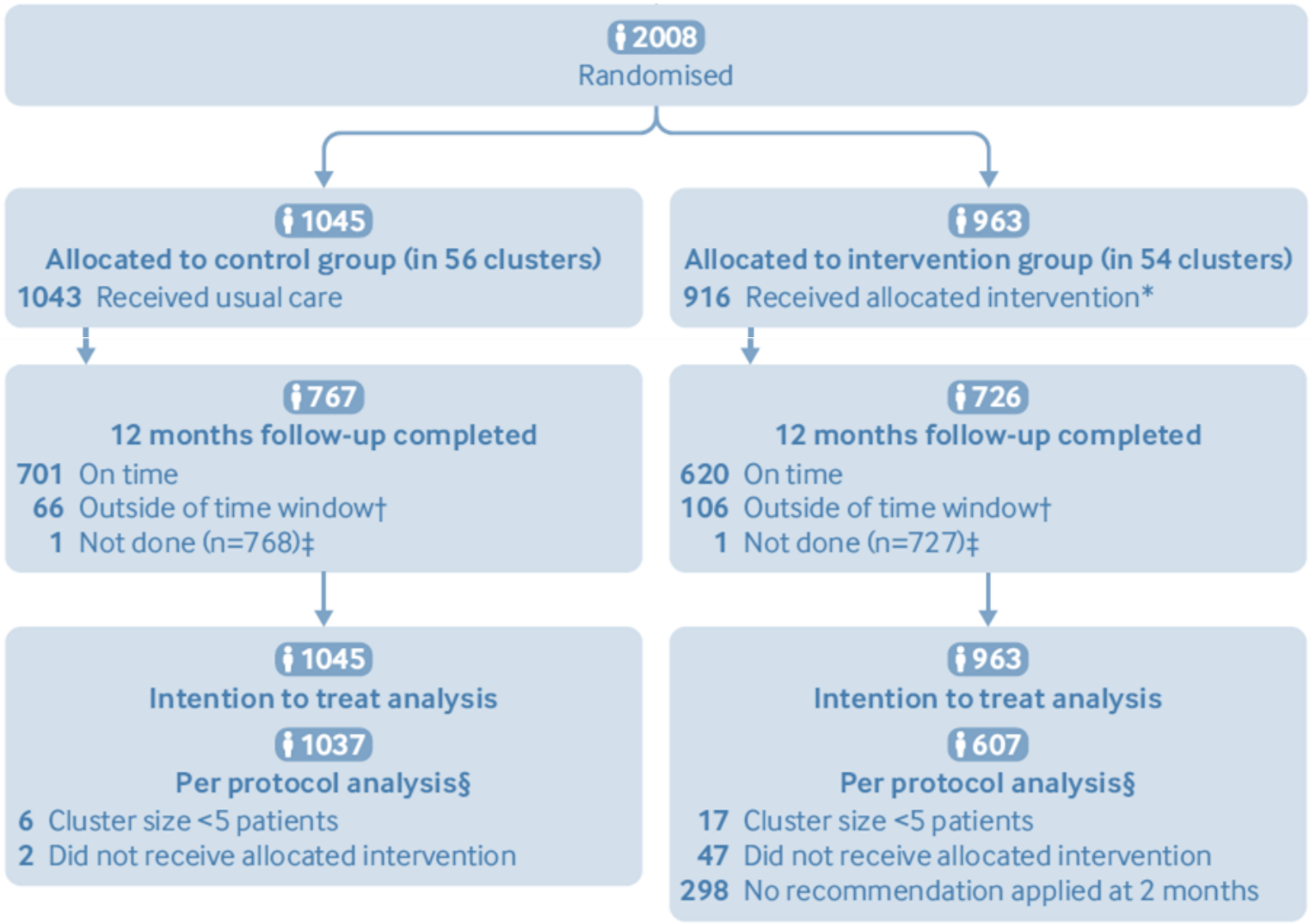
Drug-related hospital admissions after hospital discharge, within 12 months

- Adjudicated by a blinded adjudication committee

Secondary outcomes

- All-cause death
- Falls
- Patient reported outcomes
  - Quality of life (QoL)
  - Pain, discomfort
  - Activities of daily living
- Drug-related
  - Clinically significant drug-drug interactions
  - Number of long-term medications

Study Flow Chart



- Total recruitment:
  - **54 clusters**
  - **2’008 patients**

Source: Blum et al. BMJ. 202

Drug prescribing recommendations

	Mean (SD)	Range
Recommendations		
Recommendations per patient	2.8 (2.2)	0 - 19
789 (86.1%) participants with ≥ 1 recommendation		
STOPP recommendations per participant	1.8 (1.9)	0 - 18
START recommendations per participant	1.0 (1.2)	0 - 7
Recommendations implemented (at 2-month follow-up)		
Implemented recommendations per participant	1.2 (1.5)	0 - 12
491 (62.2%) participants with ≥ 1 implemented recommendation		
Implemented STOPP recommendations per participant	0.9 (1.4)	0 - 12
Implemented START recommendations per participant	0.2 (0.5)	0 - 4

Most common START recommendations

	Description	Implemented, N (%)
START E3	Vitamin D supplement in patients with known osteoporosis and previous fragility fracture(s) and/or Bone Mineral Density T-scores more than -2.0 in multiple sites	22 (22.9)
START H2	Laxatives in patients receiving opioids regularly	12 (14.6)
START A6	Angiotensin Converting Enzyme (ACE) inhibitor with systolic heart failure and/or documented coronary artery disease	19 (23.8)
START E5	Vitamin D supplement in older people who are housebound or experiencing falls or with osteopenia	31 (38.8)
START E2	Bisphosphonates and vitamin D and calcium in patients taking long-term systemic corticosteroid therapy	21 (28.4)

Most common STOPP recommendations

	Description	Implemented, N (%)
STOPP A1	Any drug prescribed without an evidence-based clinical indication*	428 (51.7)
STOPP A3	Any duplicate drug class prescription	95 (64.6)
STOPP D5	Benzodiazepines for ≥ 4 weeks	45 (39.1)

** 10 most common identified drug classes with no evidence-based indication, in descending order of frequency: antacids, mineral supplements, psychoanaleptics, lipid modifying agents, psychotropics, antithrombotics, vitamin, analgesics (including opioids), laxatives, and drugs for obstructive airway diseases.*

Clinical Outcomes

	Events (%)		Hazard ratio (95% confidence interval)
	Control	Intervention	
First drug related hospital admission	**234 (22.4)**	**211 (21.9)**	**0.95 (0.77 to 1.17)**
Death	203 (19.4)	172 (17.9)	0.90 (0.71 to 1.13)
First fall	263 (25.2)	237 (24.6)	0.96 (0.79 to 1.15)
First preventable DRA	100 (9.6)	84 (8.7)	0.89 (0.63 to 1.25)
First DRA in patients with ≥1 STOPP recommendation implemented at 2-month follow-up	156/875 (17.8)	64/398 (16.1)	0.88 (0.65 to 1.19)

DRA = drug-related hospital admission

Strengths

- Enrolment of patients with multimorbidity with minimal exclusion criteria
- Few patients lost to follow-up
- Addressing limitations of previous trials through
  - Cluster randomisation
  - Maximized blinding
  - Adjudication of hospital readmissions

Limitations

- Some medication changes in the control group could have been similar to the intervention

  → might have led to a bias towards the null

- Cluster randomisation at the doctor level (not hospital), potential for contamination in control clusters not completely ruled out

- Single timepoint intervention

Conclusions

- Inappropriate prescribing is highly prevalent in older people with multimorbidity and polypharmacy
- Structured pharmacotherapy optimization intervention reduced inappropriate prescribing

- The intervention did not
  - significantly reduce drug related hospital admissions
  - but it also did not cause any detriment to patient outcomes

- Future pharmacotherapy optimization trials should further explore
  - the successful implementation of prescribing recommendations

Thank you very much for your attention

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Bastiaan Sallevelt on behalf of the OPERAM study team

Evaluation of the in-hospital medication review process

CONFLICT OF INTEREST DISCLOSURE

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FUNDING OF THE OPERAM TRIAL

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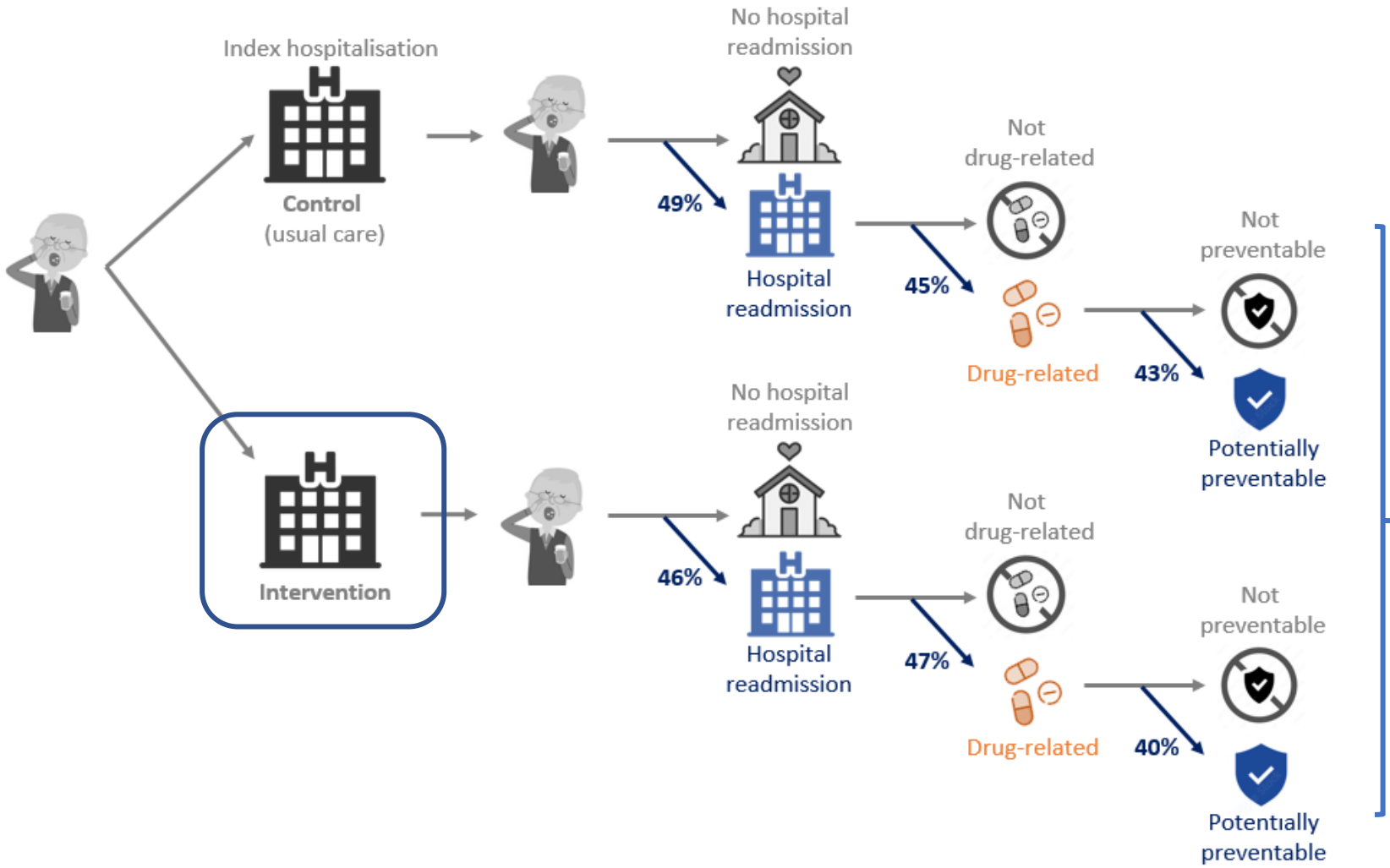
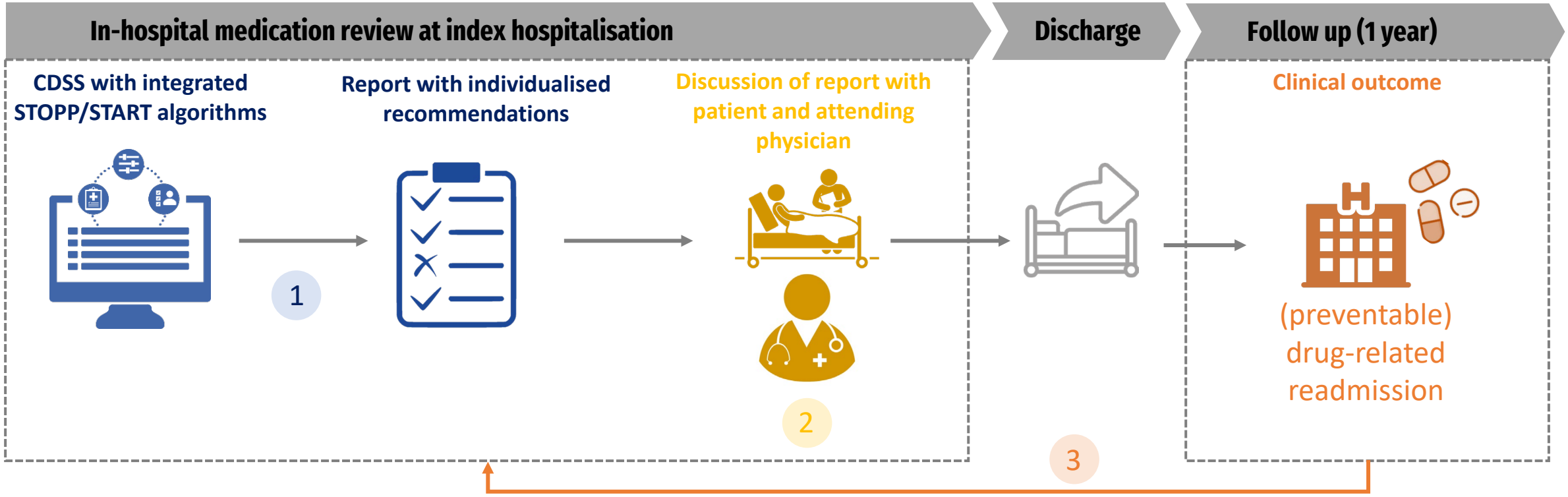
Summary of OPERAM trial - primary outcome



The intervention did not significantly reduce drug related hospital admissions (compared to usual care)

Blum et al. *BMJ.* 2022

OPERAM intervention: three substudies



1 What is the frequency and acceptance of CDSS-generated STOPP/START signals in a hospital setting?

2 What is the patient's and attending physician's agreement with proposed medication optimisation recommendations?

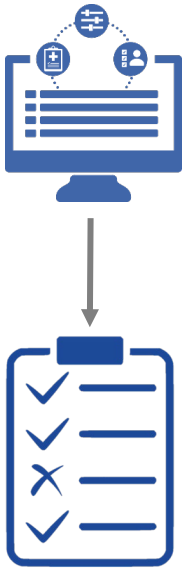
3 Why were medication errors identified at hospital readmission not addressed by a prior in-hospital medication review?

1 Frequency and acceptance of CDSS-generated STOPP/START signals

Study population

- OPERAM intervention patients (*n* = 963) for whom data on CDSS-assisted signals was available (missing data *n* = 137)
- Total eligible patients: *n* = 826

Results



- In 819/826 (99%) of the patients, at least one STOPP/START signal was generated (median 6; IQR 4–8)
- Overall, 39% of the 5080 generated signals were accepted by the pharmacotherapy team and resulted in a recommendation to change medication
- The acceptance ranged from 2.5 to 75.8% for the top ten most frequently generated STOPP and START signals
- No difference in mean acceptance of STOPP versus START signals was found
- Multivariate regression showed that patient-related potential determinants were poor predictors of acceptance.

Sallevelt et al. *Drugs Aging.* 2022

1 Frequency and acceptance of CDSS-generated STOPP/START signals

Conclusion

An expert team's involvement in translating population-based CDSS signals to individual patients is essential, as more than half of the signals for potential overuse, underuse and misuse were not deemed clinically appropriate in a hospital setting.

Sallevelt et al. *Drugs Aging.* 2022

2 Patient's and attending physician's agreement with proposed recommendations

Study population

- Dutch OPERAM intervention patients with CDSS-assisted medication review (*n* = 201)
- Total eligible patients: n = 137
- Total recommendations: n = 371

Results

- The overall agreement was 62% for STOPP and 61% for START recommendations
- Overall, the main reason for disagreement (40%) was patients' reluctance to discontinue or initiate medication
- The reasons for disagreement differed per drug class;
  - Reason for disagreement to discontinue benzodiazepines or z-drugs was mostly (91%) due to patient reluctance
  - The most important reason (30%) for disagreement to discontinue cardiovascular drugs was 'physician does not agree or does not feel qualified to advise

Huibers et al. *Eur Geriatr Med.* 2022

2 Patient's and attending physician's agreement with proposed recommendations

Conclusion

Better patient and physician education regarding the benefit/risk balance of pharmacotherapy, in addition to more precise and up-to-date medical records to avoid irrelevant recommendations, will likely result in higher adherence to medication optimisation recommendations

Huibers et al. *Eur Geriatr Med.* 2022

3 Detectability of medication errors with a STOPP/START-based medication review

Study population

- OPERAM intervention patients with a potentially preventable drug-related readmission, within one year after the medication review (*n* = 84)
- Total eligible patients: *n* = 72
- Total medication errors (i.e. overuse, underuse, misuse): *n* = 77

Results

- In ~50% of medication errors, these errors occurred after the in-hospital medication review
- In ~25% of medication errors, no recommendation was provided by the pharmacotherapy team after clinical evaluation at the individual patient level
- In ~25% of medication errors, a recommendation was given by the pharmacotherapy team but these recommendations were not implemented

Sallevelt et al. *Drug Saf. In press*

3 Detectability of medication errors with a STOPP/START-based medication review

Conclusion

Medication errors identified at readmission were not addressed by a prior single in-hospital medication review because either they occurred after the medication review, or no recommendation was given, or the recommendation was not implemented

Sallevelt et al. *Drug Saf. In press*

What have we learned and how can we explain the OPERAM results?

1
2
3

Conclusion

The association between a patient-specific medication review in older people and the clinical outcome ‘drug-related hospital admission’ is difficult to establish with a randomised controlled trial, because the study population, the intervention and outcome are highly variable

Thank you very much for your attention

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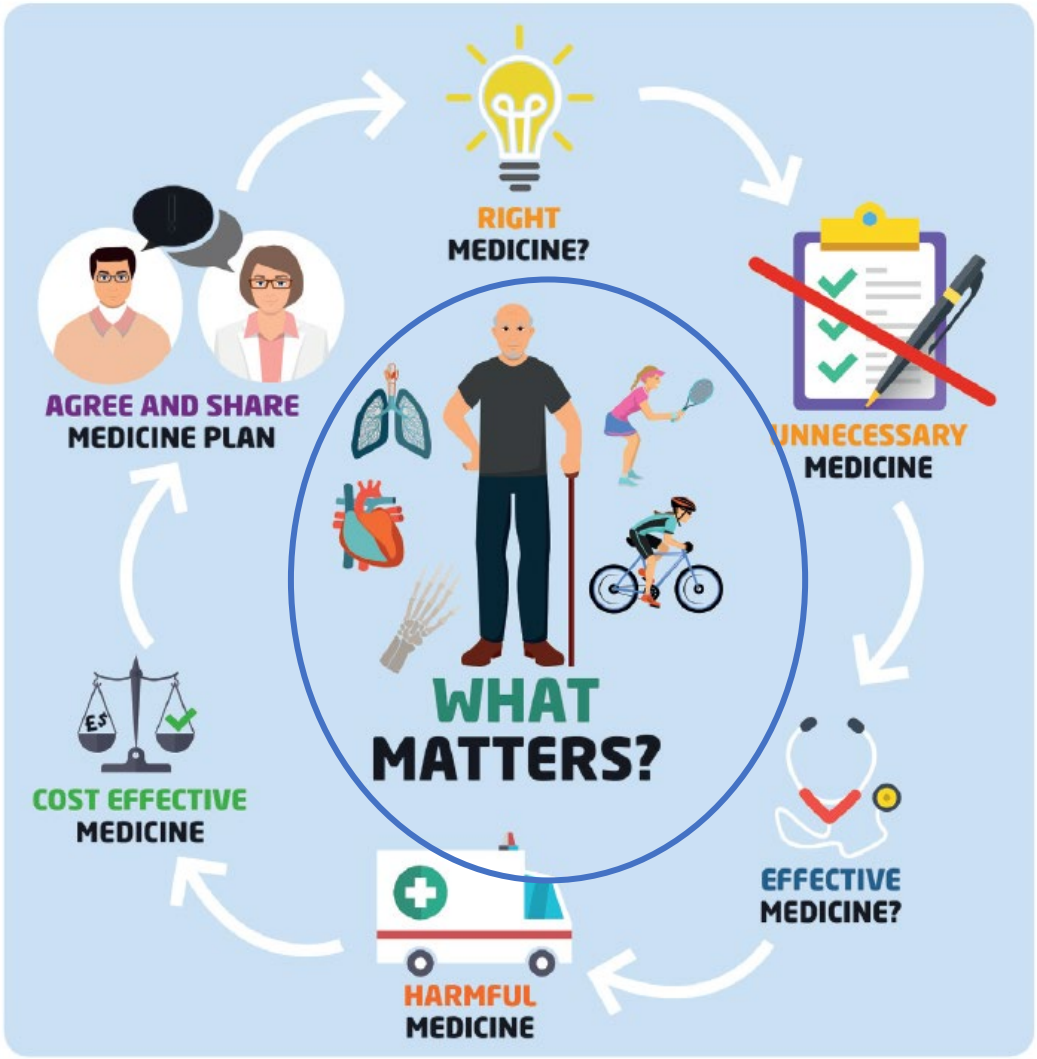
Stefanie Thevelin

Experience of hospital-initiated medication changes in older people with multimorbidity

CONFLICT OF INTEREST DISCLOSURE

I have no potential conflict of interest to report

A patient-centred approach is essential in medication review



Mair et al. The polypharmacy programma in Scotland: realistic prescribing, 2019.

ORIGINAL RESEARCH

OPEN ACCESS

Experience of hospital-initiated medication changes in older people with multimorbidity: a multicentre mixed-methods study embedded in the OPtimising thERapy to prevent Avoidable hospital admissions in Multimorbid older people (OPERAM) trial

Stefanie Thevelin ,[1] Catherine Pétein,[1] Beatrice Metry,[2] Luise Adam,[3] Anniek van Herksen,[4] Kevin Murphy ,[5] Wilma Knol ,[6] Denis O'Mahony,[7] Nicolas Rodondi,[2,3] Anne Spinewine,[1,8] Olivia Dalleur[1,9]

BMJ Qual Saf. 2022 Mar 29;bmjqs-2021-014372. doi: 10.1136/bmjqs-2021-014372

STUDY AIM & RATIONALE

Aim

To explore multi-morbid older people's experience of hospital-initiated medication changes

Why is it important?

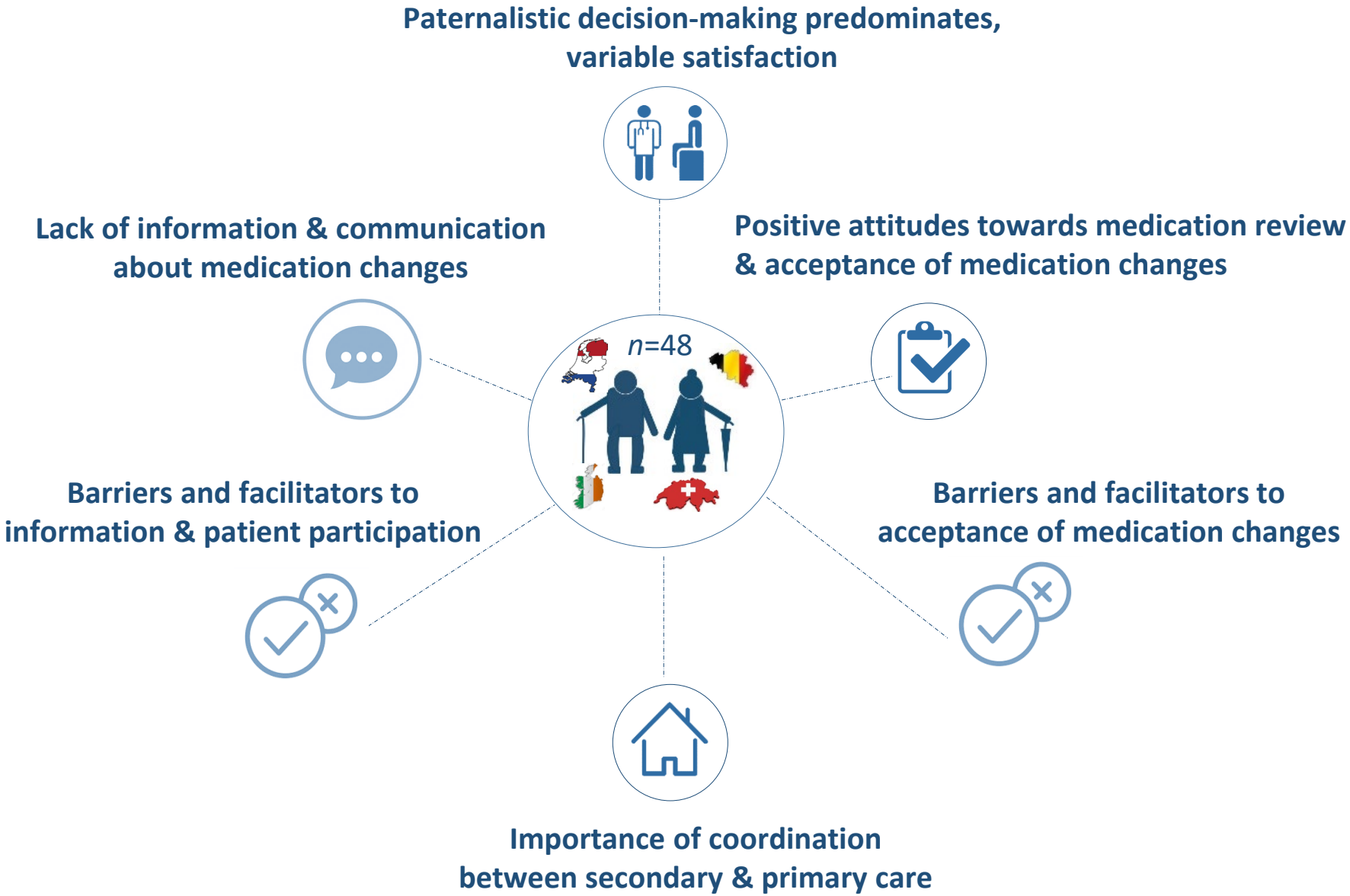
↑ understanding of the implementation of the OPERAM intervention, contextual factors and mechanisms affecting invention effectiveness

METHODS

Study design, setting	• Mixed methods study embedded in OPERAM combining qualitative and quantitative data • 4 OPERAM study sites: Bern, Brussels, Cork, Utrecht
Inclusion criteria	• ≥ 70 years + multi-morbidity + polypharmacy (=OPERAM inclusion criteria) • ≥ 1 change in chronic medication during hospitalisation (e.g. stop, start or modification of medication)
Participant selection	• Purposive sample – variation in study status (intervention/control), country, age, gender, ward, education
Data collection	• Semi-structured interviews based on NHS patient experience framework + BMQ + data on SDM (*n*=48) • Mean interview duration: 37 min (min 19 – max 80) • Quantitative data on clinician's perspective of patient participation (SDM-Q-DOC)
Data analysis	• Transcriptions in the local language • Thematic inductive analysis (Framework approach)

Patient characteristics (*n*=48)

Variable	Value
Age (years; median [P_{25}-P_{75}])	76 [72–81]
>70-≤80 years (*n*, [%])	34 [71]
>80-≤90 years (*n*, [%])	13 [27]
>90 years (*n*, [%])	1 [2]
Sex (*n*, [%])	
Female	23 [48]
No. of medications on admission (median [P_{25}-P_{75}])	10 [7-14]
Country (*n*, [%])	
Belgium 	15 [31]
Ireland 	7 [15]
Switzerland 	11 [23]
The Netherlands 	15 [31]
OPERAM study status (*n*, [%])	
Control group	21 [44]
Intervention group	27 [56]
Ward specialty (*n*, [%])	
Medical ward	36 [75]
Surgical ward	12 [25]
Educational level (*n*, [%])	
Less than high school completed	7 [15]
High school degree	23 [48]
Post-secondary degree	18 [37]
Place of residence (*n*, [%])	
Home	45 [94]
Nursing home	3 [6]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n=48
Barriers and facilitators to information & patient participation
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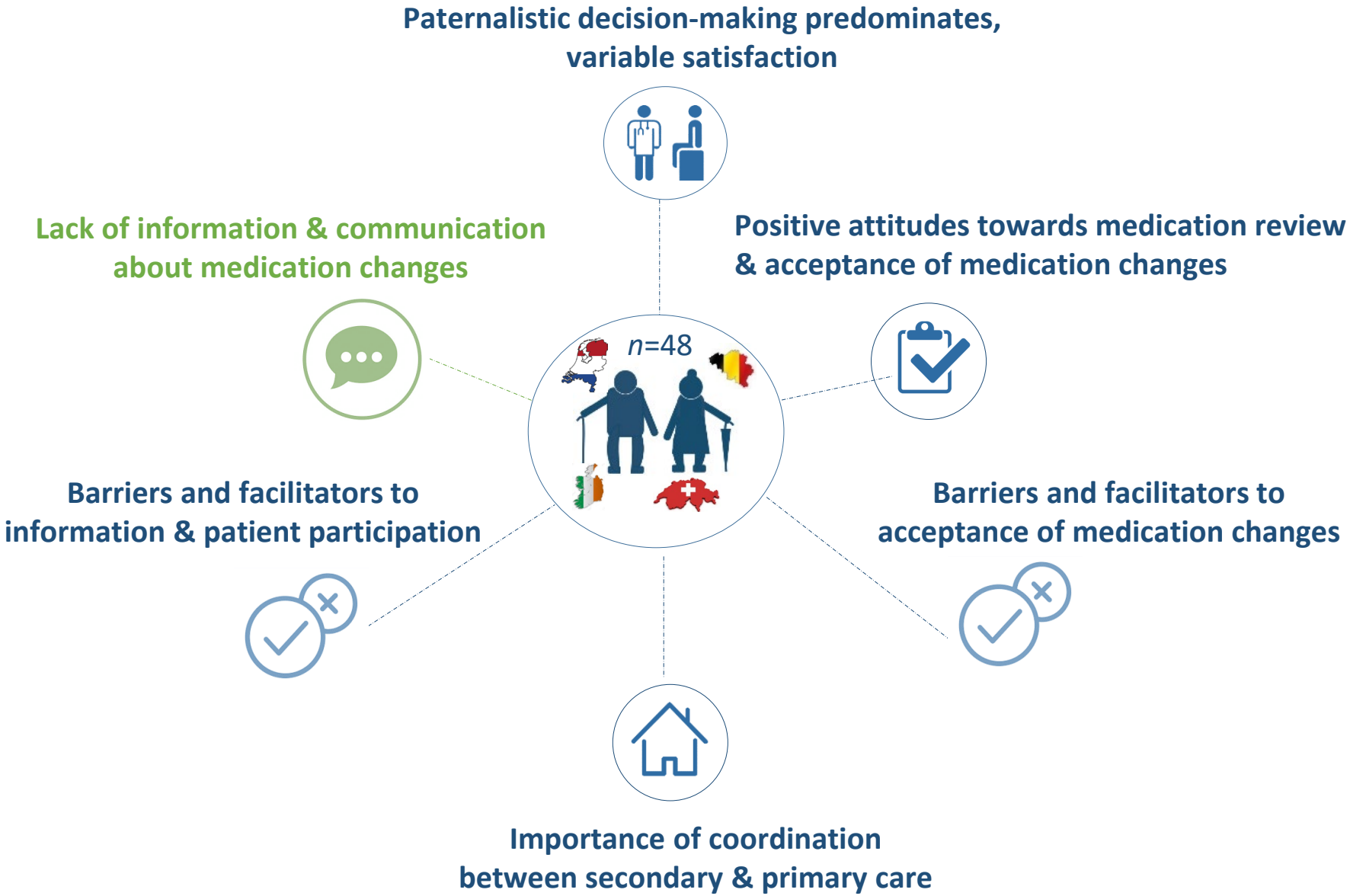
Importance of coordination between secondary & primary care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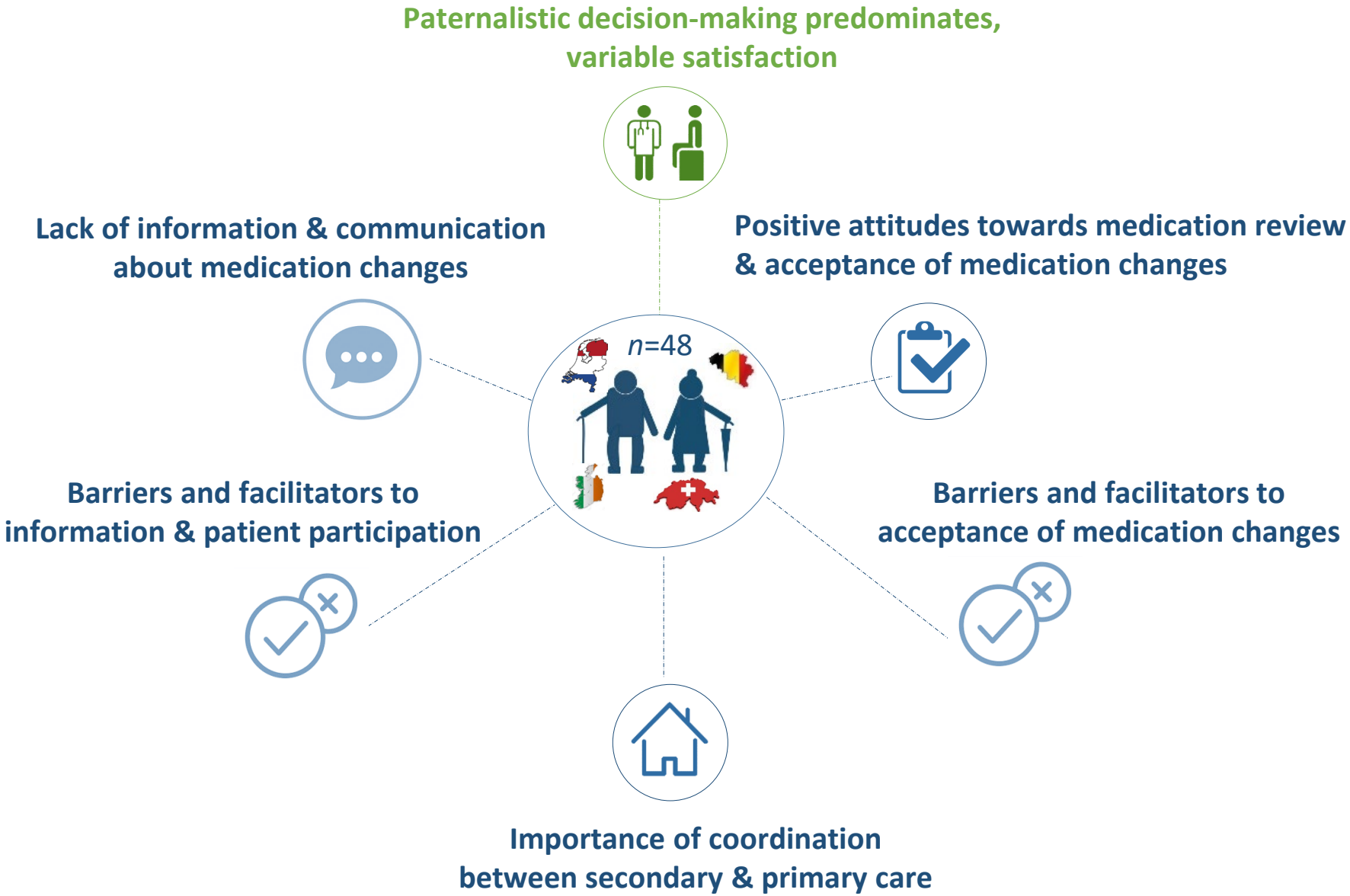
Lack of information and communication

- Lack of recall
- Limited opportunities for asking questions
- Use of jargon and language issues
- Mixed satisfaction with information received

« When I was discharged, they just told me, so you've got this and that, and this instead of that. As for the whys and wherefores, I've no idea. » [Patient, Belgium]

« It was clear. I felt that they granted me that I'd understand them. That I knew what they'd be talking about. » [Patient, Ireland]

« Yes, they all have their drug lingo. And that's what's difficult to grasp at times. » [Patient, Belgium]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Predominant paternalistic decision-making, variable satisfaction

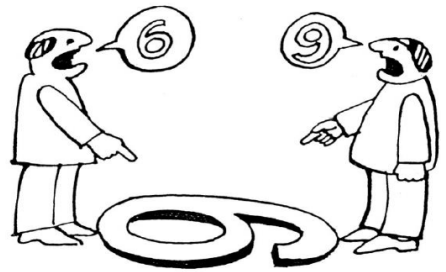
- Paternalistic decision-making
- Patient-centred decision-making
- Discussion of patient preferences
- Satisfaction with participation in decision making

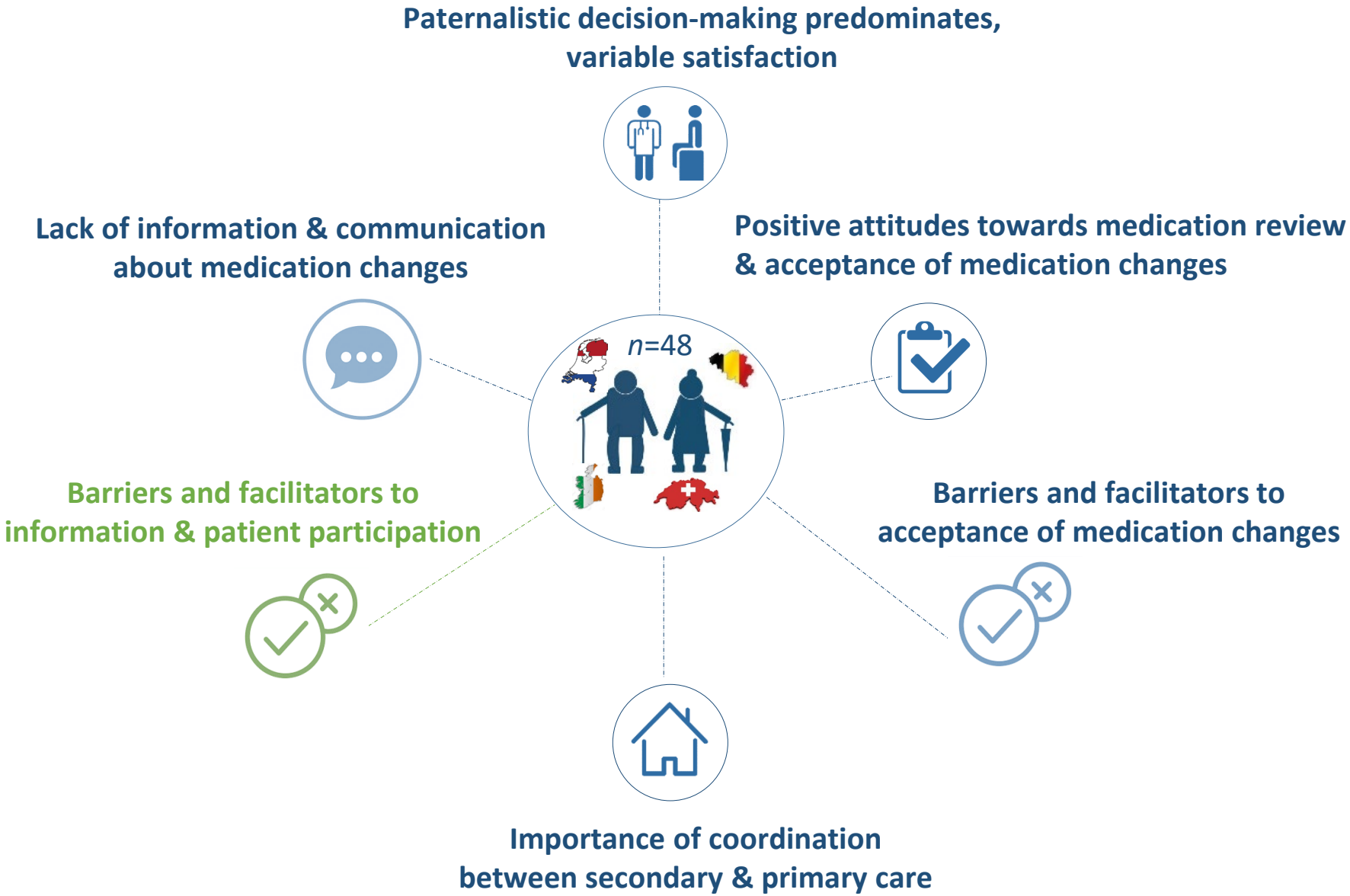
« But the fact that they consulted me and told me why they were changing, I was happy with that. I wouldn't know anything really about the medications and the fact that they recommended them was good enough for me really. » [Patient, The Netherlands]

« They completely ignored me…As if I wasn't there at all. I thought they should have discussed it with me because I was the person taking the medications. They were prescribing it to me. » [Patient, Ireland]

Perceptual differences between patients & clinicians about patient participation

Clinicians' perspective on patient participation in decision-making	
Implementation data on the SDM component of the OPERAM intervention for intervention patients (*n*=27)[a]	
n[%] of intervention patients for whom medication changes were discussed	23 [85]
n[%] of intervention patients for whom formal SDM was performed	19 [70]
SDM-Q-DOC score (median [P_{25}-P_{75}])[b]	
Total participating prescribing clinicians (*n*=17)	76 [69-82]
Prescribing clinicians' intervention group (*n*=10)	77 [74-81]
Prescribing clinicians' control group (*n*=7)	69 [53-81]
Patients' perspective on participation in decision-making	
n [%] of patients reporting participation in decision-making[c]	
All patients (*n*=48)	11 [23]
Intervention patients (*n*=27)	8 [30]
Control patients (*n*=21)	3 [14]

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Information & patient participation: barriers [B] & facilitators [F]

- Beliefs about the patient role **[B/F]**
- Bad timing of medication discussions **[B]**
- Health literacy and personal resources **[F]**
- Interpersonal characteristics of clinicians **[B/F]**
- Trust and patient-clinician relationship **[B/F]**
- Overwhelmed by multiple clinicians in care **[B]**

« I don’t ask for information. He (the doctor) is smarter than me. If you tell me to do something, I do it. It’s your job so…» [Patient, Belgium] **[B]**

« I made the decision freely. It can’t be any other way. I can’t imagine another situation where the healthcare provider takes on the role of instructor, telling you ‘you have to do this, you need to do that. » [Patient, Belgium] **[F]**

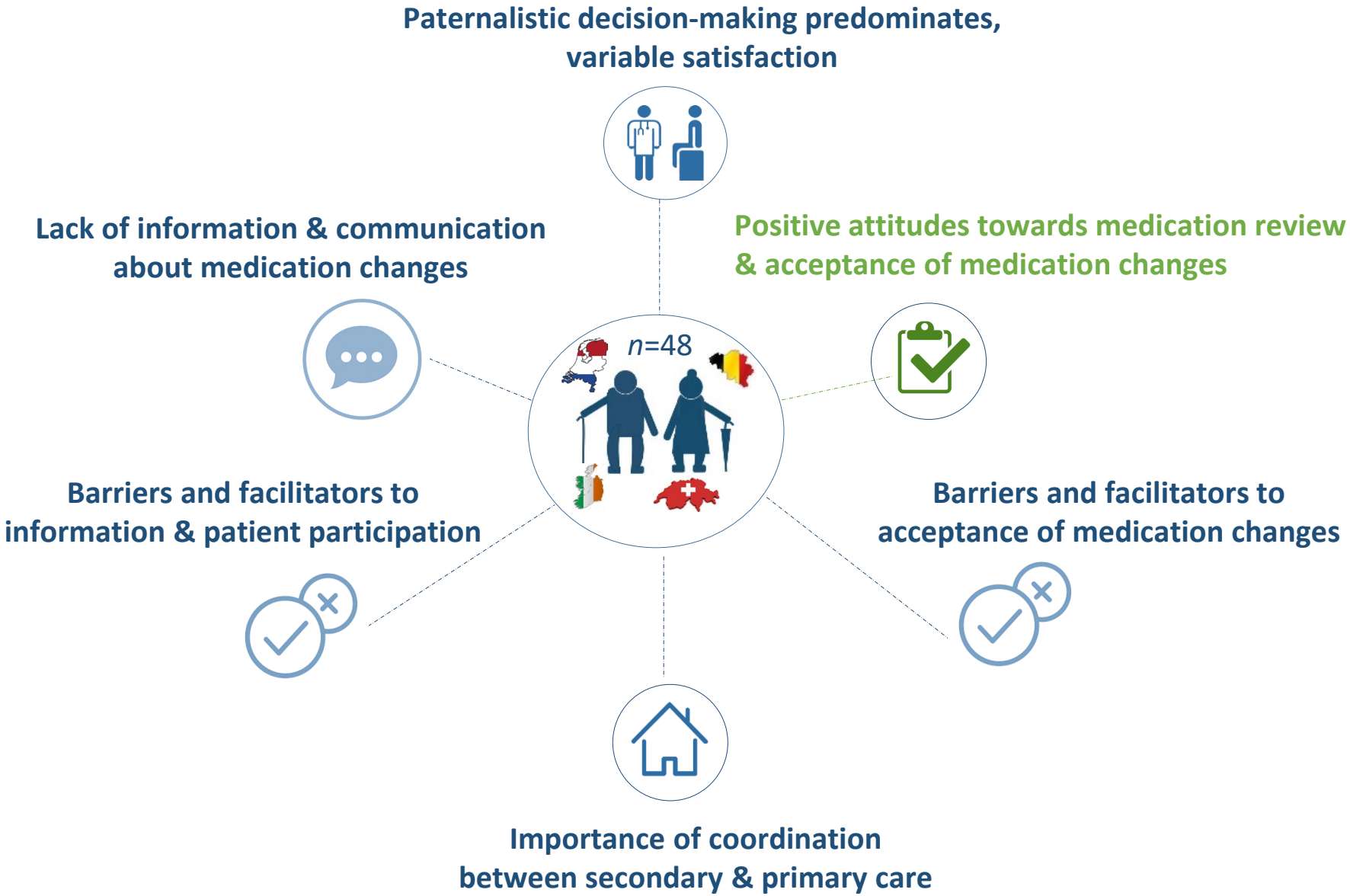
Information & patient participation: barriers [B] & facilitators [F]

- Beliefs about the patient role **[B/F]**
- Bad timing of medication discussions **[B]**
- Health literacy and personal resources **[F]**
- Interpersonal characteristics of clinicians **[B/F]**
- Trust and patient-clinician relationship **[B/F]**
- Overwhelmed by multiple clinicians in care **[B]**

« For three or four days after the operation, you're in a foggy sort of state [laughs], and as far as I was concerned, the medication problem wasn't important to me at all, not at all… It was just a detail. » **[B]**

« There's a lot of time spent on the patient's experience, their feelings. I think that's really nice because all to often in hospitals you feel a but like a number. » [Patient, Belgium] **[F]**

"I was on [loperamide], that transformed my life 30 years ago. But they seemed to dismiss that like you know… They just more ore less dismissed. I don't think they were listening at all." [Patient, Ireland] **[B]**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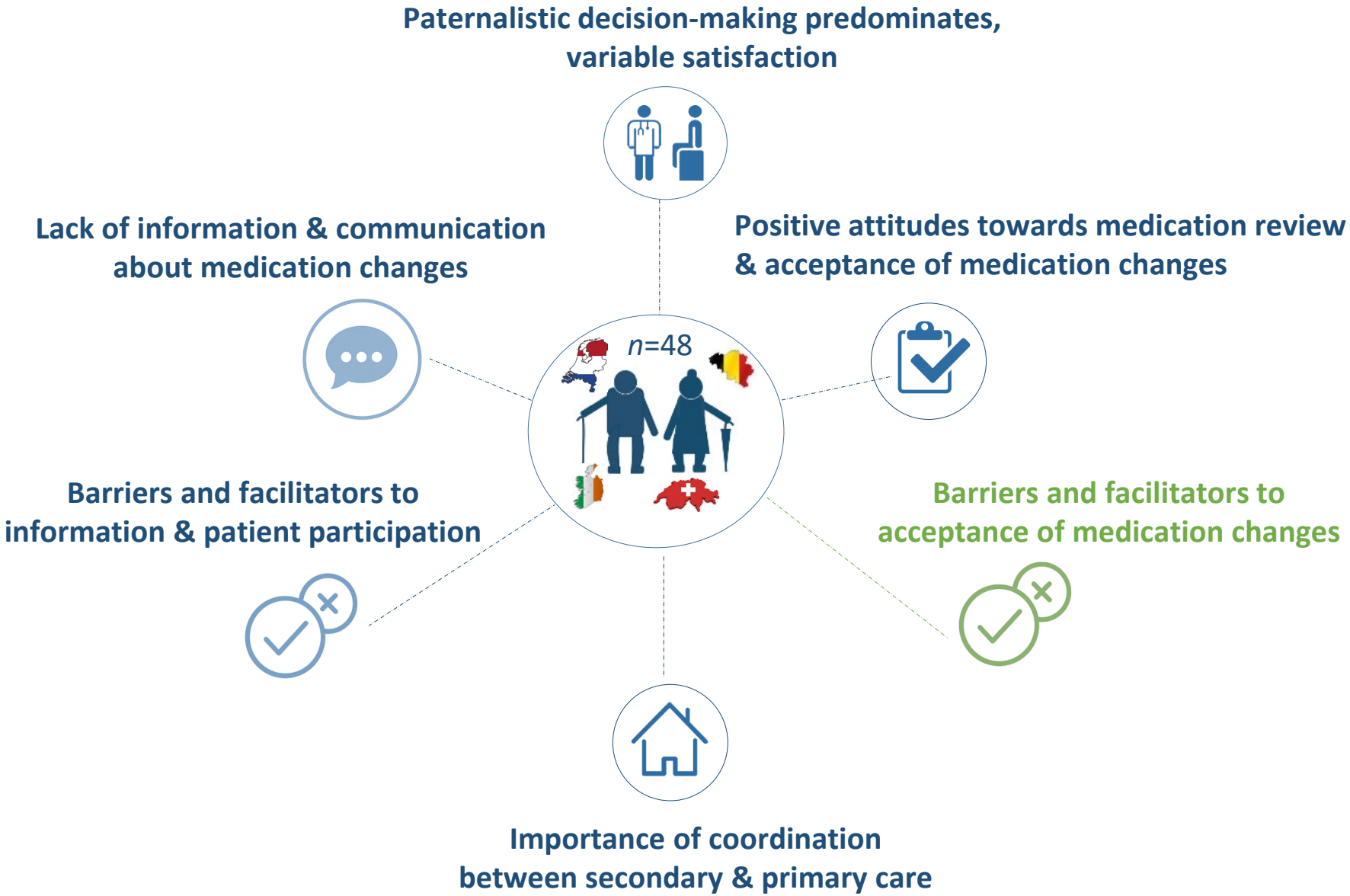
Positive attitudes towards medication review & acceptance of medication changes

- Medication review is ‘a good thing’, but the GP should be involved
- Acceptance of hospital-initiated medication changes

« Yes, I do think it’s a good idea to review things. What had built up, too, over a lifetime and over the whole time. Because the situations and illnesses change too. » [Patient, Switzerland]

« There should be another person there, the GP. It’s a good idea for them to be involved in the discussion. » [Patient, Belgium]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Acceptance of medication changes: barriers [B] & facilitators [F]

- Beliefs about medication changes **[B/F]**
- Trust and balancing advice between different providers **[B/F]**
- Medication changes perceived as minor **[F]**
- Experiencing a benefit or harm from a medication change **[B/F]**

« All these medicines are pretty essential for me, you know, it's very important. I now take Zyrtec and Immodium to help me make it through the day. I have to take them, otherwise I wouldn't be able to cope. » **[F]**

« I mean, they're using a sledgehammer to crack a nut. With a whole host of side effects, it's just not necessary. » [Patient, Belgium] **[B]**

Beliefs about medicines questionnaire (BMQ)

Table 6: Patients' beliefs about medicines (*n*=48)

BMQ subscale	Median score [P_{25}-P_{75}]	*n* [%] of patients above the scale midpoint
General-Overuse[a]	13 [10-15]	25 [52]
General-Harm[a]	11 [8-12]	10 [21]
Specific-Necessity[b]	21 [17-24]	40 [83]
Specific- Concerns[b]	12 [10-14]	11 [23]
Necessity-concern differential[c]	8 [4-12]	43 [90]

BMQ, Beliefs about Medicines Questionnaire

[a]Scale ranges from 4 to 20 where high scores indicate negative beliefs about medicines.

[b]Scale ranges from 5 to 25, higher scores indicate stronger necessity or concern beliefs.

[c]Scale ranges from -20 to 20, positive scores indicate that the patient perceives necessity outweighs concerns.

Acceptance of medication changes: barriers [B] & facilitators [F]

- Beliefs about medication changes **[B/F]**
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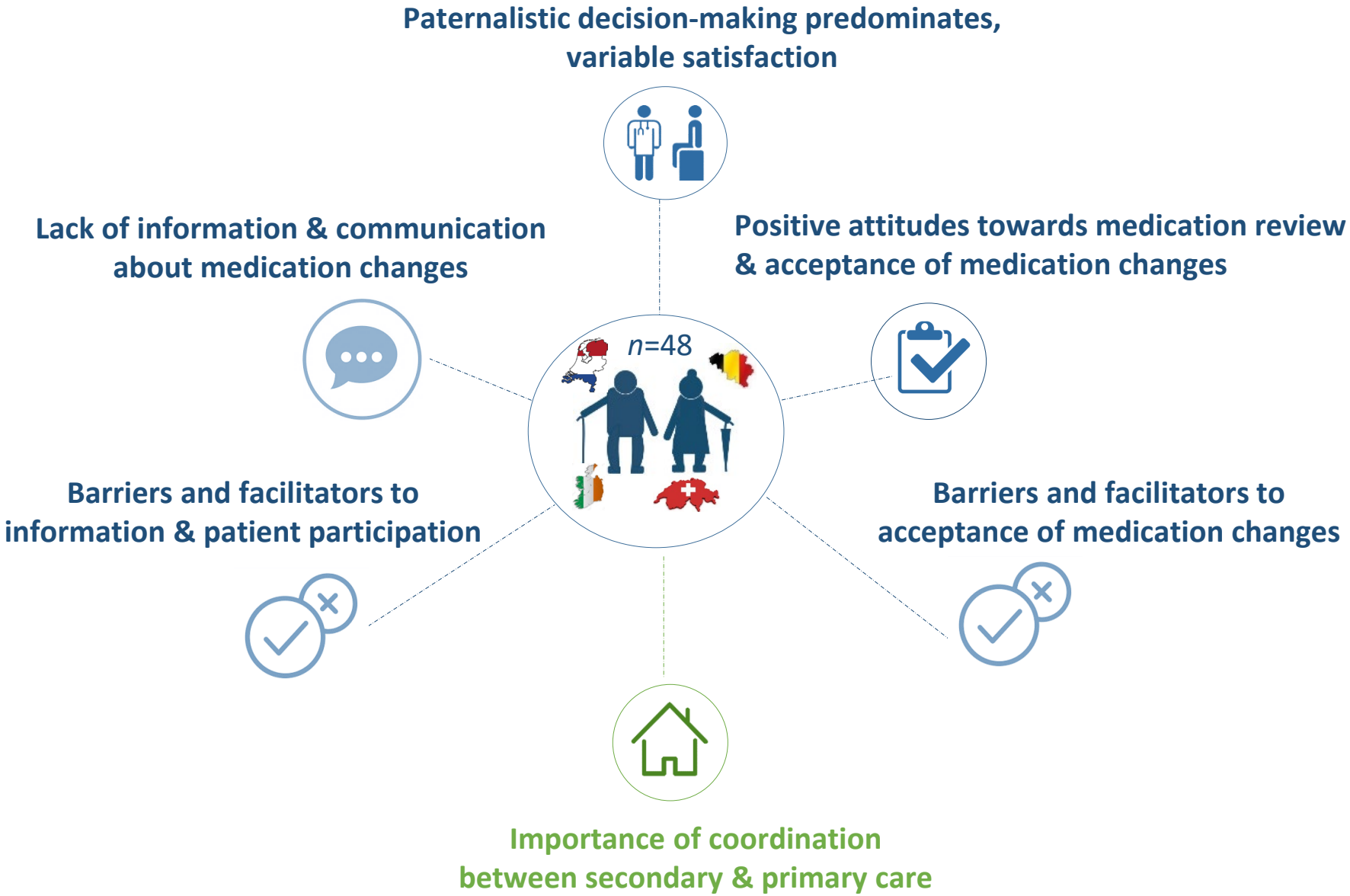
« Because anyway with all the changes they suggested, I went to see my GP – I have a lot of confidence in her, she's obviously known me for years… And for the statins (prescribed as part of the OPERAM intervention), I said that I wouldn't take them. Since she (the GP) was not at all in favour of using statins, i didn't pursue the matter. » [Patient, Belgium] **[B]**


Paternalistic decision-making predominates, variable satisfaction
Lack of information & communication about medication changes
Positive attitudes towards medication review & acceptance of medication changes
n=48
Barriers and facilitators to information & patient participation
Barriers and facilitators to acceptance of medication changes
Importance of coordination between secondary & primary care

Importance of coordination and continuity of care

- Better preparation for discharge
- Follow-up support
- Poor communication between secondary and primary care

« Afterwards, I asked her (the GP), 'Why don't I have to take those brown tablets anymore?' And she said it was because of my blood pressure. That had changed. So she explained me why. And then I was reassured. » [Patient, Switzerland]

« That's the problem: when they change something, they do it at the hospital and there's no follow-up outside. » [Patient, Belgium]


OPERAM
Effectiveness of medication review
Balancing advice between different healthcare providers
Beliefs about medicines
Paternalistic decision-making
Trust
Lack of information & communication
Health literacy
Beliefs about patient role
Experiencing a benefit or harm from medication changes
Clinicians' attitudes & interpersonal skills
Involvement of companions
Overwhelmed by multiple clinicians in care

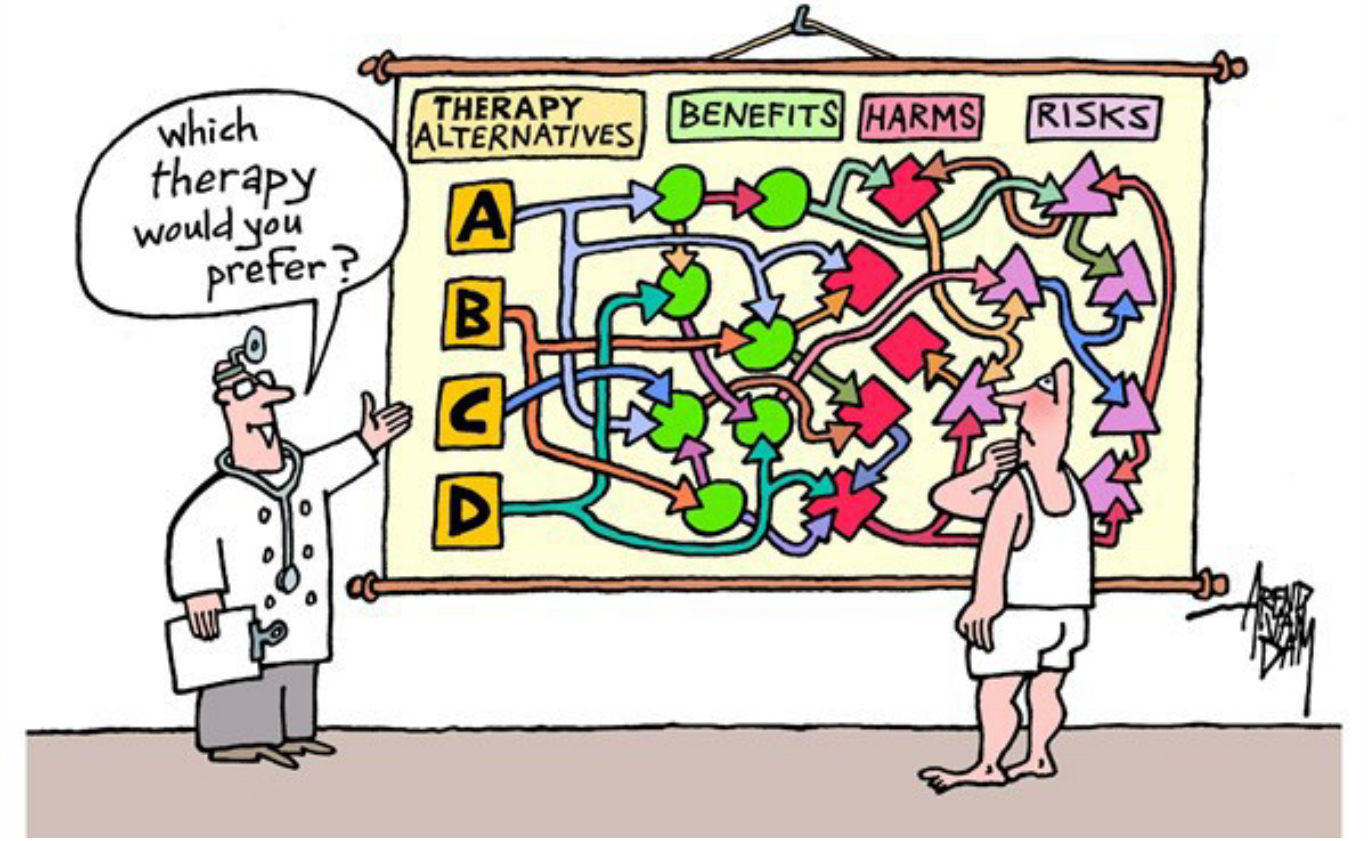
KEY POINTS

- ✓ Patients generally display positive attitudes towards medication review and hospital-iniated medication changes
- ✓ Yet an interplay of factors related to unmet information needs, patients' beliefs, clinicians' attitudes, trust and doctor-patient relationships highlight the **complexity** of medication review and SDM and may affect its effectiveness
- ✓ Patients may feel disempowered to participate in decision-making during hospitalisation
- ✓ Importance of involvement of a 'trusted ally' and (relational) continuity of care
- ✓ Future medicines optimisation interventions should better prepare patients and clinicians for SDM, enhance information exchange at discharge and post-discharge, enhance collaborative medication review across care settings

STRENGTHS & WEAKNESSES

- ✓ In-depth understanding of multi-morbid older patients' needs and preferences for medication review – first cross-country evaluation of patient experiences
- ✓ Transferability: Large purposive sample, variation of patient characterisitics but views of cognitive fit, educated older people, in their 70ies, living independently at home
- ✓ Credibility: Respondent validation, researcher triangulation
- ✓ 'Only' the patient perspective
- ✓ No objective measure of SDM

Thank you!


which therapy would you prefer?
THERAPY ALTERNATIVES
BENEFITS
HARMS
RISKS
A
B
C
D