Design and effectiveness of a collaborative general practitioner-pharmacist intervention to deprescribe potentially inappropriate proton-pump inhibitors in community-dwelling older adults

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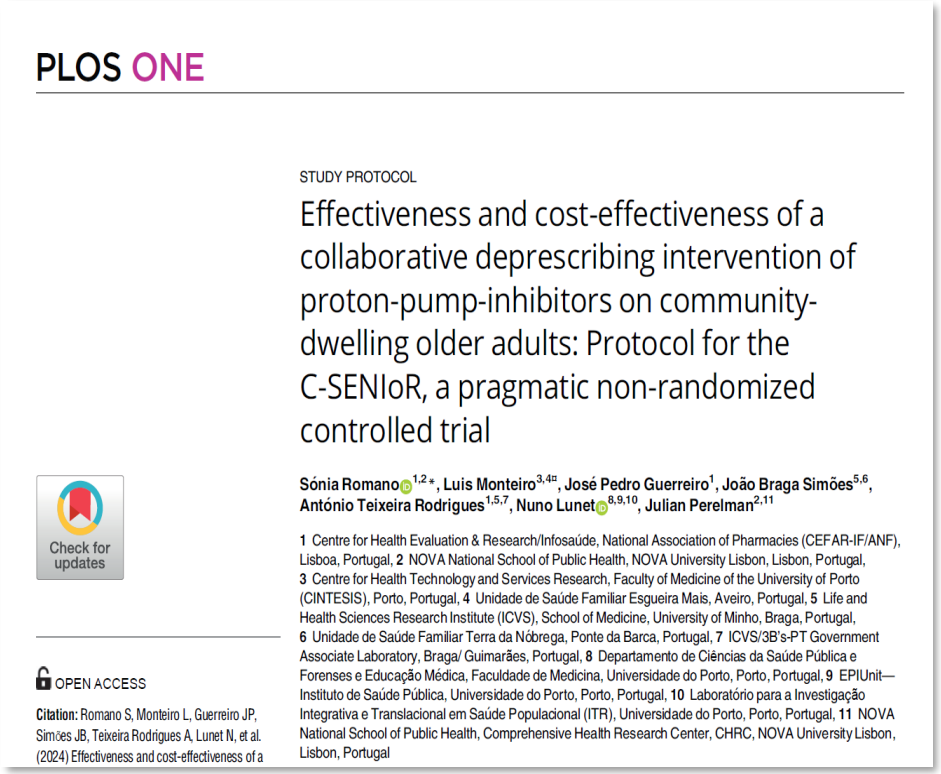

PLOS ONE

STUDY PROTOCOL

Effectiveness and cost-effectiveness of a collaborative deprescribing intervention of proton-pump-inhibitors on community-dwelling older adults: Protocol for the C-SENIoR, a pragmatic non-randomized controlled trial

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Effectiveness Study

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Antecedentes

- Proton-pump inhibitors (PPIs) are one of the most used classes of medications and are often prescribed inappropriately[1].
- While short-term use of PPIs appears relatively safe, long-term use is associated with an increased risk of several potentially severe adverse events[2].
- Deprescribing is a patient-centred intervention, supervised by a health professional, that aims to reduce or discontinue medications that may cause harm or no longer provide benefit[3].
- The goal is to reduce the medication burden while improving patient outcomes.
- Interest in deprescribing interventions is growing, particularly in aging populations, but the success of deprescribing interventions remains inconclusive, varying on factors such as intervention characteristics, class of medicines, and targeted population[4].
- Collaborative interventions involving pharmacists and medical doctors, combined with an educational component, have shown promising results.

1 Shanika LGT, Reynolds A, Pattison S, Braund R. Proton pump inhibitor use: systematic review of global trends and practices. Eur J Clin Pharmacol. 2023;79:1159–72;
2 Maideen NMP. Adverse effects associated with long-term use of proton pump inhibitors. Chonnam Med J. 2023;59:115
3 Reeve E, Gnjidic D, Long J, Hilmer S. A systematic review of the emerging definition of 'deprescribing' with network analysis: implications for future research and clinical practice. Br J Clin Pharmacol. 2015;80:1254–68;
4 Gnjidic D, Johansson M, Meng DM, Farrell B, Langford A, Reeve E. Achieving sustainable healthcare through deprescribing. Cochrane Database Syst Rev. 2022;10.

Objetivos

To assess the effectiveness of a collaborative intervention between community pharmacists and general practitioners in deprescribing inappropriate PPIs among community-dwelling older adults

Primary outcome

Successful discontinuation or dose reduction of any PPI at 3- and 6-months post-enrolment, assessed at the patient level.

Statistically significant absolute 20% reduction in medication use between the intervention and control groups

Secondary outcomes

Patient Reported Outcomes: adherence, health-related quality-of-life, beliefs about medicines, adverse drug events.
Drug-specific outcomes: number of medicines; drug-drug interactions
Patient Reported Experience: Satisfaction with the intervention (Intervention Group).

Métodos

Study design: 6-month, pragmatic, multicentre, 2-arm non-randomized controlled trial

INTERVENTION

STEP 1
COMMUNITY PHARMACIES
PATIENT EDUCATION

- Patient recruitment (≥65 years, PPI use >8 weeks, enrolled in FHUs of interest, with access to a telephone)
- Assessment of potential inappropriate PPI use (patient's self-report)
- Delivery of oral and written educational information (via booklet)
- Provision of patient medication list, including DDIs

Data shared with the general practitioner

STEP 2
FAMILY HEALTH UNITS
CLINICAL ASSESSMENT

- Clinical assessment of PPI indication
- Evaluation of listed medication and DDIs
- Contact with the patient (preferably by telephone)
- Discussion with patient / PPI appropriateness or deprescribing strategy

Data shared with the community pharmacist

STEP 3
COMMUNITY PHARMACIES
PATIENT FOLLOW-UP

- Patients' telephone follow-ups (2 and 4 weeks after GP appointment)
- Symptom relapse and patient concerns monitoring.
- GP referral if any severe symptoms were reported

Data shared with the general practitioner

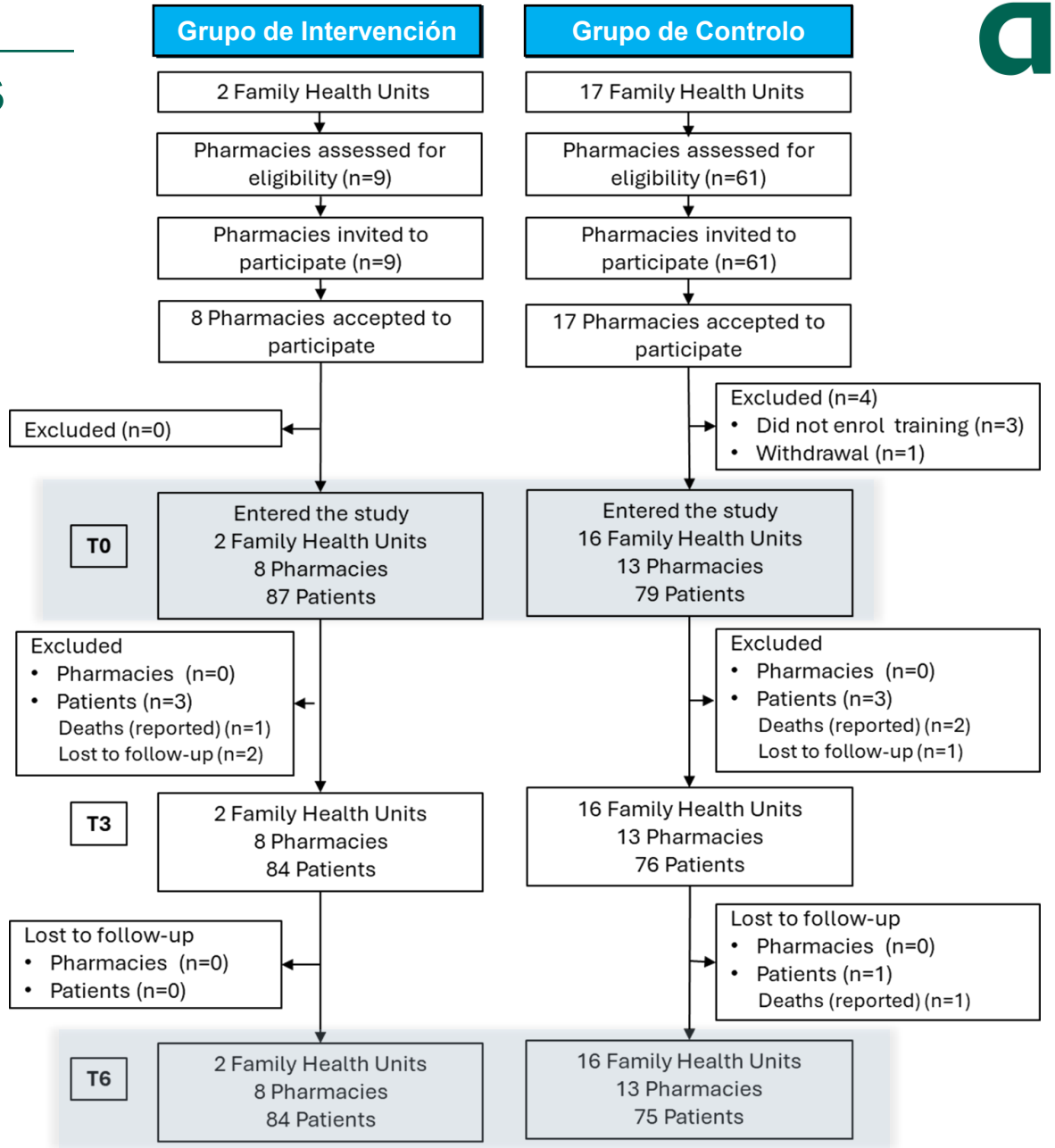
Comparator

Usual care.

Métodos

Resultados

Reclutamiento y seguimiento



166 patients*

* Recruited between Apr 27th and Nov 15th, 2023.

159 patients

Resultados

Sex
(% female, n)

Global = 59.0% (n=98)
IG = 58.6% (n=51)
CG = 59.5% (n=47)

Age, in years
(mean, SD)

Global = 74.2 (SD=6.0)
IG = 74.4 (6.1)
CG = 74.1 (5.9)

Duration
of PPI use (Y)
(median, Q1 and Q3)

Global = 10 (5 - 15)
IG = 10 (5 - 15)
CG = 10 (4 - 15)

Comorbidities
(median, Q1 and Q3)

Global = 5 (4 - 6)
IG = 5 (4 - 6)
CG = 5 (4 – 6.5)

No. chronic
medications
(mean, SD)

Global = 7.2 (3.0)
IG = 6.7 (2.7)
CG = 7.7 (3.2)

No significant differences ($p > 0.05$) between intervention group (IG) and control group (CG)

Resultados

Primary Outcomes

69.8% (n=61) IG patients with a medical recommendation to deprescribe

Intention-to-treat analysis of primary outcome*.

No. patients deprescribed/no. patients				
Follow-up	Intervention Group	Control Group	Adjusted absolute risk difference % (95% CI)	Adjusted relative risk (95% CI)
3-month	42/84 (50.0%)	4/76 (5.3%)	46.3 (32.8 – 59.9)	9.6 (3.6 – 25.6)
6-month	41/84 (48.8%)	4/75 (5.3%)	44.3 (30.8 – 57.8)	8.9 (3.3 – 23.6)

Adjusted for age class (65-74y, ≥75y); sex (F, M); Body mass index (<25, 25 - 30, ≥30 kg/m2); education level (≤4th grade, >4th grade) and self-rated health status (very poor to fair, good to excellent)

The intervention was found to be effective in reducing PPI use.

*Successful discontinuation or dose reduction of any PPI at 3- and 6-months post-enrolment, assessed at the patient level. Statistically significant absolute 20% reduction in medication use between the intervention and control groups

Statistical Analysis: GLM for binary outcome with an identity link function to estimate the absolute risk difference between the intervention and control groups, adjusted for age class, sex, body mass index, education level, and self-rated health status.

Resultados

Secondary Outcomes

Intention-to-treat analysis of secondary outcome.

	Intervention Group	Control Group	Difference-in-Difference (95% CI)	p-value
Patient Reported Outcomes				
Adherence (MTA score)[1]				
Mean (SD)				
Baseline (n=86 IG; n=75 CG)	5.7 (0.4)	5.8 (0.3)		
6-month follow-up (n=77 IG; n=66 CG)	5.8 (0.3)	5.8 (0.2)		
Change at 6 months (n=76 IG; n=63 CG)	0.09 (0.38)	0.05 (0.34)	0.04 (-0.08 to 0.17)	0.507
Health-related quality of life (HRQoL)[2]				
Mean (SD)				
Baseline (n=86 IG; n=76 CG)	0.81 (0.21)	0.84 (0.20)		
6-month follow-up (n=81 IG; n=66 CG)	0.82 (0.19)	0.84 (0.16)		
Change at 6 months (n=80 IG; n=64 CG)	0.01 (0.18)	-0.01 (0.18)	0.04 (-0.03 to 0.10)	0.238
Adverse Drug Events (ADEs)				
Patients with ADEs (n, %)				
Baseline (n=86 IG; n=73 CG)	9 (10.5)	4 (5.5)		
6-month follow-up (n=77 IG; n=67 CG)	7 (9.1)	9 (13.4)		
Change at 6 months (%, SD) (n=77 IG; n=62 CG)	0.00 (4.63)	6.45 (5.28)	-6.78 (-20.38 to 6.82)	0.329
Drug-specific outcomes				
Long-term medications per patient				
Mean (SD)				
Baseline (n=87 IG; n=77 CG)	6.8 (2.7)	7.6 (3.2)		
6-month follow-up (n=84 IG; n=73 CG)	6.3 (2.6)	7.4 (3.3)		
Change at 6 months (n=84 IG; n=73 CG)	-0.48 (1.11)	-0.19 (1.23)	-0.24 (-0.63 to 0.16)	0.238

Difference-in-difference analysis, adjusted for age class (65-74y, ≥75y); sex (F, M); Body mass index (<25, 25 - 30, ≥30 kg/m^2); education level (≤4th grade, >4th grade) and self-rated health status (very poor to fair, good to very good).
[1]MTA, 7-item Measure Treatment Adherence. Mean score ≥ 5 is considered adherent .
[2]HRQoL estimated based on the EQ-5D-5L questionnaire and national tariffs

No significant differences were observed between Groups in both PROs and drug-specific outcomes.

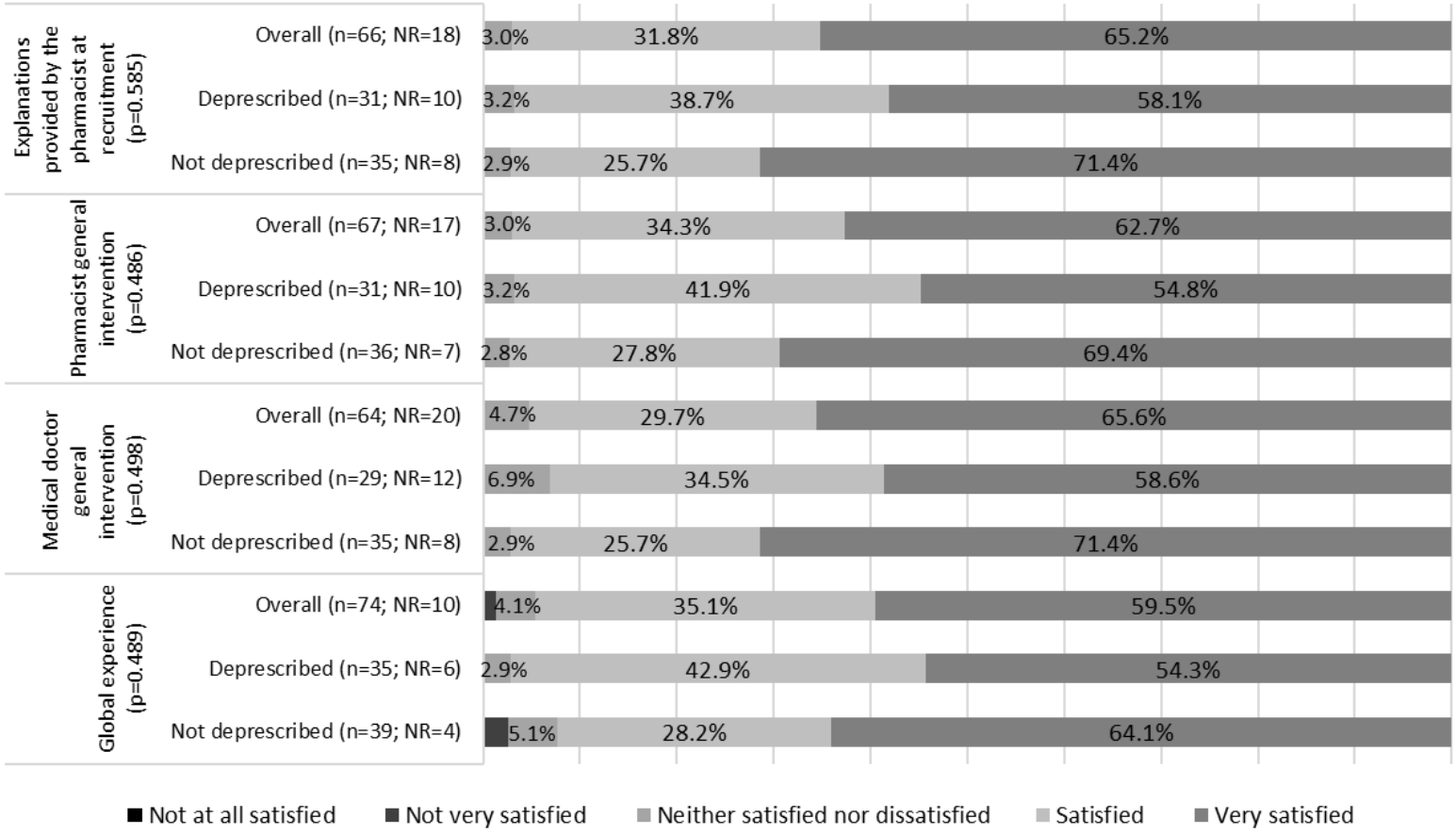
Statistical analysis: Secondary outcomes were computed using difference-in-differences estimators.

Resultados

Secondary Outcomes

Patient-Reported Experiences in the IG

> 90% Satisfied or very satisfied



Conclusiones

- A collaborative, patient-centred deprescribing approach proved **effective in reducing PPI use among older adults** and, if scaled nationally, could deliver significant clinical and economic benefits for patients and the healthcare system.
- **Interprofessional collaboration minimizes strain on healthcare systems**, ensures a patient-centred approach, and supports follow-up, highlighting its importance for sustainable interventions.
- Leveraging educational components can enhance the optimization of medication use.
- Successful large-scale implementation depends on having **supportive policies and a robust technological infrastructure that enables effective communication** among healthcare professionals.
- Further research will focus on evaluate whether the benefits justify the implementation costs.

Obrigada!
Gracias

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