

# Collaborative deprescribing intervention of Proton-Pump Inhibitors among community-dwelling older adults: The C-SENioR trial

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<b>Registration date</b> 14/06/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/03/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Increasing life expectancy is a positive achievement, but it also brings challenges. Older adults often have poor health and chronic conditions, which means they take medicines that can be harmful. Proton-pump inhibitors (PPI) are medications that can cause problems for older people, such as fractures, unnecessary emergency visits, and hospitalizations. Despite this, PPIs are still prescribed too often for older adults.

Preventing harm from medications is a global challenge for patient safety. Deprescribing is an approach that aims to reduce the number of medications and improve their use for patients. It involves healthcare professionals supervising the process of reducing or stopping medications that may be causing harm or no longer providing benefits. The goal is to optimize medication use and improve patient outcomes. While there is evidence supporting the withdrawal of PPIs, it can be challenging to stop using certain medications for various reasons. The value of deprescribing is still uncertain, which raises questions about its widespread implementation.

This study aims to evaluate how effective and cost-effective it is when community pharmacists and general practitioners work together to stop the inappropriate use of PPIs among older adults living in the community in Portugal.

### Who can participate?

People aged 65 years old or over with more than 8-weeks continuous PPI use, registered at the Family Health Units of interest, and with access to a telephone (fixed line or mobile phone) that agree to participate.

### What does the study involve?

This study is conducted in outpatient care and involves two groups (groups 1 and 2). In Group 1, pharmacies and their neighborhood Family Health Units (FHUs) are working together to deliver a collaborative intervention to identify and discontinue the long-term unnecessary and unsafe use of PPIs among their older patients. In group 2, pharmacies and the FHUs provide the usual care they normally offer to their patients.

Both participants in groups 1 and 2 are recruited in community pharmacies. In group 1, in addition to what the health professionals normally do when the patients ask for a PPI, patients are asked about the PPI clinical indication and receive an educational brochure from the pharmacist explaining the benefits and harms of the long-term use of these medicines. Then they are referred to the general practitioner (GP) in the engaged FHUs. GPs receive the pharmacist's first assessment/recommendations and book a patient's appointment for the PPIs' clinical assessment and possible discontinuation. The decision is discussed with the patient and a withdrawal strategy is defined. The pharmacist is informed by the GP about the clinical decision and the adopted strategy. Thus, the pharmacist does the patients' follow-up to monitor the deprescribing process and the management of any possible symptoms that arise from the withdrawal of the PPI.

What are the possible benefits and risks of participating?

Participating in the trial offers several potential benefits. For patients in the experimental group (group 1), who are using inappropriate PPIs, discontinuing their chronic use can have long-term advantages. This may reduce the risk of experiencing side effects associated with prolonged PPI use and also save money.

In the short term, there is a possibility that discontinuation PPIs could result in a relapse of stomach symptoms. However, we expect a low probability of relapses or complications since only non-evidence-based medications will be withdrawn and the best evidence-deprescribing guidelines will be followed to do that. Additionally, these patients will be closely monitored by both the pharmacist and the general practitioner to effectively manage any potential symptomatology that may arise.

Where is the study run from?

This study is taking place in primary care settings involving community pharmacies and Family Health Units in mainland Portugal.

When is the study starting and how long is it expected to run for?

March 2021 to June 2024

Who is funding the study?

No specific funding has been obtained to undertake this trial. The Portuguese National Association of Pharmacies (ANF) sponsored this trial.

Who is the main contact?

Ms Sónia Romano (principal researcher, Ph.D. student)  
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## Contact information

### Type(s)

Principal Investigator

### Contact name

Ms Sónia Romano

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

CSENIoR/1

## Study information

### Scientific Title

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

### Acronym

C-SENIoR

### Study objectives

The intervention will reduce at least 20% the use of inappropriate proton-pump inhibitors among intervention participants compared with their counterparts

### Ethics approval required

Ethics approval required

### Ethics approval(s)

1. Approved 24/03/2021, Ethics Research Committee of NMS|FCM-UNL (CEFCM) (Campo Mártires da Pátria, 130, Lisboa, 1160-059, Portugal; +351 218 803 039; cefcm@nms.unl.pt), ref: 16/2021/CEFCM

2. Approved 22/09/2022, Ethics Committee for Health from the Local Health Unit Alto Minho (Estrada de Santa Luzia, Viana do Castelo, 4901-858, Portugal; +351 258 802 108; comissao.etica@ulsam.min-saude.pt), ref: 50/2022/CES

### Study design

Pragmatic multicentre non-randomized 2-arm controlled trial with a trial-based economic evaluation

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Community, GP practice, Pharmacy

**Study type(s)**

Safety

**Participant information sheet**

See additional files

**Health condition(s) or problem(s) studied**

Overprescribing of proton-pump inhibitors

**Interventions**

The intervention is a collaborative care pathway, between community pharmacists and general practitioners aimed at deprescribing inappropriate PPI use and addressing other drug-related problems such as drug-drug interactions (DDIs). This patient-centered multifaceted intervention package consists of three main components:

1. Educational component provided by the pharmacist to the patient: The pharmacist assesses the appropriateness of PPI use based on the patient's self-reported clinical indication and the deprescription algorithm developed by the research team. The pharmacist then provides in-person oral and written educational information, including a booklet, regarding the rational use of medicines, indications and potential harms of chronic PPI use, benefits of deprescribing, potential withdrawal symptoms, and non-pharmacological strategies to alleviate symptoms. Additionally, a therapeutic profile of the patient's chronic medications, including relevant DDIs information, is compiled and shared with the general practitioner (GP).
2. Clinical assessment/deprescribing conducted by the GP: The GP contacts the patient, preferably by telephone, to discuss the appropriateness and strategy for PPI deprescribing, as well as to address any other medication-related issues. If the GP deems it necessary, a face-to-face appointment can be scheduled. Following the appointment, the clinical decisions are communicated to the pharmacist.
3. Patients' monitoring (symptoms and concerns): The community pharmacist conducts follow-up with the patients, assessing symptoms and addressing any questions. Telephone contact is made at 2 and 4 weeks after the GP appointment to evaluate potential symptom relapses and establish a symptom control strategy if needed. The 4-week telephone interview is conducted only for patients with indications for PPI dose reduction or withdrawal.

The comparator of the study is usual care.

**Intervention Type**

Mixed

**Primary outcome measure**

Successful discontinuation or dose decrease of any PPIs, defined as a statistically significant reduction in medication use between the intervention and control groups at 3- and 6-month

follow-up. Analysis of PPI use will be conducted using pharmacy medicine sales data linked to the patients' tax information number and confirmed through telephone interviews with the patients.

### **Secondary outcome measures**

1. Patients' beliefs about PPI, measured by the Beliefs about Medicines Questionnaire (BMQ-specific) at baseline and 3-month follow-up.
2. Time until withdrawal since recruitment.

Other measurements at baseline and 6-month follow-up:

3. Number of long-term medications and proportion of patients on polypharmacy (patients with 5 or more medicines).
4. Health-related quality of life, assessed using the five-level version of the European Quality of Life-5 Dimensions questionnaire (EQ-5D-5L instrument).
5. Self-reported adherence measured by the 7 items Measure Treatment Adherence questionnaire (MTA)
6. Number and degree of severity of DDIs identified by the dispensing software.
7. Adverse drug events, that is the absolute and relative counts of self-reported adverse drug events and type of events experienced by patients (e.g., needed professional support).
8. Healthcare resource utilization and costs (for the economic evaluation study)
9. For the intervention group - Satisfaction with the collaborative intervention (general and health professional related) is to be assessed only at the 6-month follow-up.

Process outcomes, such as the number of patients with a medical appointment and the number of pharmacist telephone follow-ups, will be collected ongoing to assess the fidelity and quality of the collaborative intervention

### **Overall study start date**

24/03/2021

### **Completion date**

15/06/2024

## **Eligibility**

### **Key inclusion criteria**

1. Community-dwelling older adults, aged 65 years old or over
2. Continuous use for more than 8 weeks of any PPI (ATC/WHO A02BC– esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole)
3. Registered at the selected Family Health Units
4. Access to a telephone

### **Participant type(s)**

Patient

### **Age group**

Senior

### **Lower age limit**

65 Years

**Sex**

Both

**Target number of participants**

222 participants (111 per group)

**Key exclusion criteria**

1. Live in nursing homes or assisted-living facilities
2. Unable to communicate or speak in Portuguese
3. Have any cognitive impairment or any other condition that does not allow them to understand the study objectives or the questionnaire completion as perceived by the pharmacist.

**Date of first enrolment**

28/04/2023

**Date of final enrolment**

15/11/2023

**Locations****Countries of recruitment**

Portugal

**Study participating centre****Community Pharmacies at Arcos de Valdevez Municipality**

Arcos de Valdevez

Portugal

4970

**Study participating centre****Community Pharmacies at Ponte da Barca Municipality**

Ponte da Barca

Portugal

4980

**Study participating centre****Family Health Unit Uarcos**

Rua Eng. Adelino Amaro da Costa

Arcos de Valdevez

Portugal

4970-458 Arcos de Valdevez

**Study participating centre**

**Family Health Unit Terra da Nóbrega**

Rua Dr. Francisco Sá Carneiro, nº 2  
Ponte da Barca  
Portugal  
4980-633 Ponte da Barca

**Study participating centre**

**Centre for Health Evaluation and Reserach (CEFAR), National Association of Pharmacies**

Rua Marechal saldanha 1  
Lisbon  
Portugal  
1249-069

## **Sponsor information**

**Organisation**

National Association of Pharmacies

**Sponsor details**

Rua Marechal Saldanha 1  
Lisboa  
Portugal  
1249-069  
+351 213400600  
anf@anf.pt

**Sponsor type**

Other

**Website**

<https://www.anf.pt/>

**Organisation**

Unidade Local de Saúde do Alto Minho

**Sponsor details**

Estrada de Santa Luzia  
Viana do Castelo  
Portugal  
4904-858 Viana do Castelo  
+351 258 802 100  
administracao@ulsam.min-saude.pt

**Sponsor type**

Government

**Website**

<https://www.ulsam.min-saude.pt/>

## Funder(s)

**Funder type**

Other

**Funder Name**

National Association of Pharmacies

## Results and Publications

**Publication and dissemination plan**

The Study Protocol will be submitted for publishing publication immediately after this trial registry. Furthermore, the research team has planned to prepare and submit two additional manuscripts to international peer-reviewed journals, with a preference for reputable open-access journals. The preliminary results will be presented at an international congress. Additionally, the project aims to disseminate the final results through various national and international congresses.

**Intention to publish date**

01/05/2024

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analyzed during the current study are/will be available upon request from the Centre for Health Evaluation & Research (CEFAR), Rua Marechal Saldanha 1, 1249-069 Lisboa, Portugal, [cefar@anf.pt](mailto:cefar@anf.pt)

Type of data: Patient-level data collected during the trial, after deidentification.

When will data be available (start and end dates): Beginning 12 months after the beginning of the study and 5 years following article publication

With whom: Researchers who provide a methodologically sound proposal

For what types of analyses: To achieve aims in the approved proposal and meta-analysis

By what mechanism will data be made available: Proposals should be directed to [cefar@anf.pt](mailto:cefar@anf.pt).

To gain access, data requestors will need to sign a data access agreement.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			13/06/2023	No	Yes

[Protocol article](#)

26/03/2024

27/03/2024

Yes

No