

# Improving medication prescription through a pharmacist-led educational intervention and audit & feedback approach in primary care for patients over 65 years of age

<b>Submission date</b> 25/11/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/12/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/05/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Polypharmacy (when people are taking a number of medicines) is a global issue, particularly concerning in adults over 65 years of age due to its association with increased risks of falls, cognitive decline, hospitalizations, and death rates. In Spain, it is estimated that 31.6% of adults over 65 years old are affected by polypharmacy. The situation is similar across Europe, where the prevalence of polypharmacy is about 30-40%. In this context, studies on the deprescription of potentially inappropriate medications are crucial.

This study aims to evaluate the efficacy of a pharmacist-led educational intervention and an adaptive Audit & Feedback (A&F) intervention of 12-month follow-up, aimed at primary care general practitioners (GPs), to reduce the prescription of benzodiazepines, proton pump inhibitors and antipsychotics in patients diagnosed with dementia, in patients over 65 years old.

### Who can participate?

GPs with assigned patients in their primary health care center in three Spanish Health Care Districts: Mallorca (Balearic Islands), Paterna (Valencia) and Tarragona-Reus (Catalonia)

### What does the study involve?

All GPs will receive individualized graphs and tailored messages containing information about their prescriptions. GPs who request it, as well as those in the highest prescribing quartile, will receive an individualized intervention from the study pharmacist. This face-to-face intervention will involve setting specific objectives and creating an action plan, in addition to providing support for discussing specific cases. Participants will also receive an online educational intervention and access to a formative and accredited online course.

### What are the possible benefits and risks of participating?

The benefits include reducing the prescription of potentially inappropriate medications. No risks are anticipated.

Where is the study run from?  
Primary Care Management of Mallorca (Spain)

When is the study starting and how long is it expected to run for?  
January 2023 to December 2026

Who is funding the study?  
Carlos III Institute of Health (PI22/01669) (Spain)

Who is the main contact?  
1. Dr Alfonso Leiva, aleiva@ibsalut.es  
2. Dr Caterina Vicens, catalina.vicenscaldentey@ibsalut.es

## Contact information

**Type(s)**  
Public, Principal investigator

**Contact name**  
Dr Alfonso Leiva

**ORCID ID**  
<https://orcid.org/0000-0001-5306-8533>

**Contact details**  
c/Escola Graduada, 3  
Palma  
Spain  
07002  
+34 (0)971 17 58 97  
aleiva@ibsalut.es

**Type(s)**  
Scientific

**Contact name**  
Dr Caterina Vicens

**ORCID ID**  
<https://orcid.org/0000-0002-9387-625X>

**Contact details**  
c/Escola Graduada, 3  
Palma  
Spain  
07002  
+34 (0)971 17 58 97  
catalina.vicenscaldentey@ibsalut.es

## Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Protocol serial number

Nil known

# Study information

## Scientific Title

A pharmacist-led educational intervention and audit and feedback approach to reduce inappropriate medication prescriptions in primary care for patients over 65 years of age

## Acronym

AIM

## Study objectives

An Audit and Feedback intervention targeting primary care general practitioners (GPs), which includes individualized graphical information on potentially inappropriate prescriptions of benzodiazepines, proton pump inhibitors, and antipsychotics, recommendations for correct prescribing, and guidance on how to withdraw the medication, with an individualized intervention by a primary care pharmacist for GPs who request it or those with significant potential for improvement in their prescribing (above 75th percentile), along with an online educational component achieves at least a 4% absolute reduction in the proportion of patients over 65 years of age with inappropriate prescriptions from these therapeutic groups at 12 months.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 14/07/2023, Balearic Islands Ethics Committee (c/Calçat, 2A, 2n, Palma, 07011, Spain; +34 (0)971177378; ceic\_ib@caib.es), ref: IB 5219/23 PI

## Study design

Multicenter parallel randomized clinical trial

## Primary study design

Interventional

## Study type(s)

Efficacy

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

Inappropriate prescription (benzodiazepines, proton pump inhibitors and antipsychotics for patients with dementia) in patients over 65 years old

## Interventions

The method of randomization is simple random sampling. The unit of randomization will be the General Practitioner (GP). They will be randomly assigned to either the control or intervention group in a centralized manner.

General practitioners (GPs) in the intervention arm will receive monthly information about their prescription, combined with an individualized, face-to-face intervention by a primary care pharmacist for GPs with significant potential for improvement in their prescribing practices (above the 75th percentile), along with an online educational component. GPs in the control group will receive an intervention to reduce antibiotic prescriptions.

The 12-month intervention will consist of a pharmacist-led educational intervention and an adaptive Audit & Feedback (A&F) approach. All participating GPs will receive individualized graphs and tailored messages with information regarding their prescriptions in patients over 65 years old of benzodiazepines, proton pump inhibitors, and antipsychotics for patients with dementia. GPs who request it, as well as those in the highest prescribing 75th percentile (p75), will receive an individualized intervention from the study pharmacist. This face-to-face intervention will include setting specific objectives, creating an action plan, and providing support for discussing particular cases. Participants will also receive an online educational intervention and have access to an accredited formative online course. Additionally, GPs will have the option to receive lists of patients prescribed potentially inappropriate medications. All data will be analyzed according to the intention-to-treat principle, and a Tobit regression model will be used to handle censored data with two censoring points (0 and 100). Acceptability, suitability, feasibility, fidelity, coverage, sustainability, and implementation costs will also be evaluated.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Potentially inappropriate medication prescription (benzodiazepines, proton pump inhibitors, and antipsychotics in patients diagnosed with dementia) in patients over 65 years old, measured using the number of prescriptions extracted from the e-prescription databases of each health district at 12-month follow-up.

## **Key secondary outcome(s)**

1. The proportion of patients over 65 years old using benzodiazepines, measured using the number of prescriptions from the N05BA (diazepam, chlordiazepoxide, potassium clorazepate, lorazepam, bromazepam, clobazam, ketazolam, alprazolam, halazepam, pinazepam, clotiazepam, bentazepam), N05CD (flurazepam, flunitrazepam, triazolam, lormetazepam, midazolam, brotizolam, quazepam, lorprazolam) and N05CF (zopiclone, zolpidem, zaleplon) groups of the Anatomical Therapeutic Chemical (ATC) Classification System code, extracted from the e-prescription databases of each health district at 12-month follow-up.
2. The proportion of patients over 65 years old using proton pump inhibitors for more than 8 weeks with indications other than Barrett's esophagus, severe esophagitis C or D, peptic ulcer disease, history of bleeding peptic ulcer, or concomitant prescription of NSAIDs, antiplatelet agents, anticoagulants, or corticosteroids, measured using the number of prescriptions from the A02BC (proton pump inhibitors) group of the ATC Classification System code, extracted from the e-prescription databases of each health district at 12-month follow-up.
3. The proportion of patients over 65 years old with a diagnosis of dementia using antipsychotics, measured using the number of prescriptions from the N05A (antipsychotics) and N05AX (other antipsychotics) groups of the ATC Classification System code, extracted from the e-prescription databases of each health district at 12-month follow-up.

Added 08/05/2025:

4. The reach, engagement, adoption, fidelity and maintenance of the intervention. Reach will be

defined as the percentage of participating GPs relative to the total number of eligible GPs. Engagement will measure the degree of active involvement in the intervention, including use of the feedback reports, participation in pharmacist-led sessions, and integration of recommendations into clinical practice. Adoption will be measured at the organizational level as the percentage of healthcare management units that have agreed to implement the intervention. Fidelity to the intervention will be assessed through audits of adherence to the planned feedback delivery process. This includes consistency in the timing and content of reports, implementation of pharmacist consultations, and completion of online training modules. Maintenance of the intervention will be assessed at 6 and 12 months post-intervention, focusing on the degree to which the intervention becomes institutionalized within the healthcare system.

**Completion date**

12/12/2026

## Eligibility

**Key inclusion criteria**

All GPs with assigned patients in their primary health care center will be included

**Participant type(s)**

Health professional

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

10/05/2025

**Date of final enrolment**

31/12/2025

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

**Balearic Islands Health Service (IB-Salut)**

Carrer de l'Escola Graduada, 3  
Palma  
Spain  
07002

**Study participating centre**

**Paterna Health District (Conselleria de Salut Universal; Arnau de Vilanova-Llíria district)**

Paterna  
Spain  
46980

**Study participating centre**

**Tarragona-Reus Health district (Institut Català de la Salut; Tarragona-Reus district)**

Tarragona  
Spain  
43480

## Sponsor information

**Organisation**

Primary Care Management of Mallorca (Gerencia de Atención Primaria de Mallorca)

## Funder(s)

**Funder type**

Government

**Funder Name**

Instituto de Salud Carlos III

**Alternative Name(s)**

SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Spain

## **Results and Publications**

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

The datasets analyzed during the study will be made available in a public repository.

**IPD sharing plan summary**

Stored in publicly available repository