

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

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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes