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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
25/11/2024

Recruitment status
Recruiting

Registration date
11/12/2024

Overall study status
Ongoing

Last Edited
21/05/2025

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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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Type(s)
Public, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2023

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

Age group
Adult

Sex
Both

Target number of participants
170

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
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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)

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Sponsor type
Government

Website
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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, ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
1. The effectiveness of the intervention will be published in a primary care/general medicine journal
2. The factibility, feasibility and fidelity will be published in a primary care journal

Intention to publish date
31/12/2026

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