

BMJ Open Study protocol for a hybrid I randomised clinical trial to evaluate an audit and feedback and a pharmacist-led intervention to reduce potentially inappropriate medications in older adults: the AIM study

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ABSTRACT

Introduction Potentially inappropriate prescriptions (PIPs) in older adults, such as long-term use of benzodiazepines, proton pump inhibitors without indication or antipsychotics in dementia, are associated with adverse events and increased healthcare utilisation. Despite clinical guidelines discouraging their use, PIPs remain frequent in primary care. An audit and feedback (A&F) intervention of PIPs to general practitioners (GPs), led by pharmacists, may reduce the prescription of PIPs in primary care.

Methods and analysis A two-arm, pragmatic, controlled trial will be conducted to evaluate the effectiveness of an A&F-based intervention and a pharmacist-led intervention to reduce the proportion of patients aged ≥65 years receiving inappropriate prescriptions. A total of 170 participating GPs, 85 per group, are required. GPs will be randomised into intervention or control groups (1:1). The intervention includes feedback reports, pharmacist-led academic detailing and access to online training modules. The primary outcome is the proportion of older adults receiving at least one PIP at 12 months as well as the total number of PIPs. A random effects Tobit regression model, censored at 0 and 100, will be used to estimate between-group differences adjusted for baseline prescribing. Subgroup analyses will explore heterogeneity of effect by baseline prescribing level and healthcare region. Implementation outcomes, including reach, fidelity, engagement and maintenance, will be evaluated using the Reach, Effectiveness, Adoption, Implementation and Maintenance framework, combining quantitative and qualitative data.

Ethics and dissemination Ethical approval was obtained by the Balearic Island Committee Ethics (IB5219/23PI). Study findings, including primary and secondary outcomes and qualitative implementation results, will be disseminated through peer-reviewed publications and stakeholder reports.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is a large, multicentre randomised trial conducted across diverse healthcare regions in Spain.
- ⇒ The intervention is theory-informed, evidence-based and embedded in routine clinical practice.
- ⇒ The use of electronic health records ensures objective, standardised and high-quality prescribing data. However, potential adverse outcomes related to de-prescribing cannot be assessed, as prescribing patterns are captured only at the prescribing level and are not linked to patient-level clinical consequences.
- ⇒ Generalisability may be limited to healthcare systems with similar primary care infrastructure and digital tools.

Trial registration number [ISRCTN14449434](https://www.isrctn.com/ISRCTN14449434).

INTRODUCTION

Adverse drug events are a major contributor to potentially avoidable morbidity and mortality, particularly among older adults.¹ In response to the growing burden of medication-related harm, the WHO launched the Global Patient Safety Challenge: *Medication Without Harm* in 2017, identifying it as a critical public health priority.² Potentially inappropriate medications (PIMs) are defined as those for which the risks of adverse effects outweigh the anticipated clinical benefits, especially when safer or more effective alternatives are available. Internationally developed explicit lists provide guidance for the identification and reduction of PIMs use.

At least 24 tools and four guidelines have been developed to detect PIMs in adults aged 65 years and older. Some of the most widely recognised explicit PIMs lists include the American Geriatrics Society 2023 updated Beers Criteria,³ the French consensus panel list,⁴ the German PRISCUS list,⁵ the Austrian consensus panel list,⁶ the STOPP/START criteria⁷ and the EU (7)-PIM developed by seven European Union countries.⁸ Half of patients aged 65 and older in primary care settings are prescribed at least one PIM.^{9 10}

Almost two-thirds of all PIM prescriptions were accounted for by five drug classes: analgesics and non-steroidal anti-inflammatory drugs (NSAIDs), proton pump inhibitors (PPIs), benzodiazepines and benzodiazepine-like agents, antidepressants and neuroleptics.¹⁰

In Spain, PPIs and benzodiazepines use are particularly prevalent. Benzodiazepines alone account for about 11% of all PIM prescriptions, and both benzodiazepines and PPIs exhibit higher usage rates in Spain compared with other regions.¹¹

Prolonged benzodiazepine use is associated with increased risks of falls and fractures, memory and cognitive impairment and dependence. Guidelines recommend limiting their use to a maximum of 4 weeks for insomnia and twelve weeks for anxiety, however they are often prescribed for longer periods.

Accordingly, deprescription of benzodiazepine receptor agonists should be offered to elderly adults (aged ≥ 65 years).¹²

Similarly, PPIs are widely prescribed for the management of gastrointestinal conditions and to prevent gastrointestinal bleeding in patient on antiplatelet treatment or NSAIDs in patients with risk factors for gastrointestinal bleeding. However, long-term use has been associated with adverse outcomes, including hypochlorhydria, an increased risk of pneumonia and enteric infection, bone fracture and reduced absorption of vitamins and minerals, nutrients and a heightened risk of osteoporotic fractures.¹³ Long-term use should be avoided, except in individuals with Barrett's oesophagus, severe oesophagitis (grade C or D), or a documented history of gastrointestinal bleeding and deprescribing is recommended in adults who have completed at least 4 weeks of treatment for heartburn, mild to moderate gastro-oesophageal reflux disease or oesophagitis, if symptoms have resolved.¹³

There is growing concern about overprescription in patients with dementia. The use of antipsychotics in this population is linked to sedation, cognitive decline and increased mortality, particularly in individuals with Lewy body dementia. Regular evaluation of treatment is advised to assess the need for ongoing antipsychotic therapy. It is strongly recommended deprescribing antipsychotics for adults with behavioural and psychological symptoms of dementia if they have been treated for at least 3 months without symptom improvement or if the symptoms have stabilised.¹⁴

Appropriate medication use involves both appropriate initial prescription and a structured, supervised process of

deprescribing, aimed at discontinuing medications that may cause harm or provide no benefit to the patient.¹⁵

Pharmacist-led interventions, educational outreach and A&F initiatives have been identified as effective strategies to optimise prescribing practices.¹⁶⁻¹⁸

This study aims to evaluate the effectiveness of a 12-month intervention targeting primary care physicians to reduce potentially inappropriate prescriptions (PIPs) of benzodiazepines, PPIs and antipsychotics in patients aged 65 and older.

Primary objective

The primary objective of this study is to evaluate the effectiveness of a multifaceted intervention in reducing the prescriptions of benzodiazepines, PPIs and antipsychotics in patients aged 65 years and older in primary care.

Secondary objectives

Secondary objectives include to assess the proportion of patients aged 65 years and older with a prescription for benzodiazepines; to assess the proportion of patients aged 65 years and older with a prescription for PPIs; to assess the proportion of patients aged 65 years and older with a prescription for antipsychotics; to evaluate the reach, engagement, adoption, fidelity and maintenance of the intervention using the RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) implementation framework.

METHODS AND ANALYSIS

Trial design

This study is a hybrid 1, two-arm, parallel-group, randomised controlled trial designed to evaluate the effectiveness and implementation of an A&F intervention aimed at reducing PIPs in adults aged 65 years and older. The study will be conducted between 2023 and 2027. An overview of the time points for data collection is provided in [table 1](#).

Three regional health systems in Spain will be recruited: IB-SALUT (Mallorca), Catalan Institute of Health (Tarragona-Reus) and the Department of Universal Health (Paterna Health District), and all general practitioners (GPs) from healthcare centres from the three districts will be randomised individually in a 1:1 ratio into intervention or control groups.

The study was approved by the Balearic Island, Valencia and IDIAP Jordi Gol ethical committee. This protocol has been developed by the Standard Protocol Items: Recommendations for Interventional Trials guidelines (REF) and final results will be reported in accordance with the Consolidated Standards of Reporting Trials^{19 20} and the TIDieR checklist for complex interventions.²¹

Eligibility criteria

All GPs actively assigned to patient panels within the participating primary care centres will be eligible for inclusion. To ensure continuity throughout the study

Table 1 Overview of time points for interventions, data collection across effectiveness and implementation outcomes

Time point	Enrolment and allocation		Intervention period			Postintervention
	-30 d		0 d	6 m	12m	18m
Randomisation						
Group allocation						
Intervention						
A&F						
Pharmacist consultations						
Clinical messages						
Online training						
Patient information sheet						
Assessments						
Demographics						
Percentage of benzodiazepines, PPI and antipsychotics			x	x	X	X
Implementation						
Reach			X	X	X	
Engagement			X	X	X	
Adoption		X	X			
Fidelity			X	X	X	
Maintenance					X	X

1. Time point: d=day; m=month; 2. A&F: general practitioners (GPs) receive monthly email reports throughout the intervention period; 3. Pharmacist consultation: provide only to GPs identified as having the highest potential for improvement; 4. Clinical messages: send brief, evidence-based prescribing reminders monthly alongside the feedback reports; 5. Online training: accessible throughout the entire intervention period, GPs can complete it at their own pace; 6. Patient information sheet: provide for use during consultations, at the GPs' discretion based on clinical judgement.
A&F, audit and feedback; d, days; m, months; PPI, proton pump inhibitors.

period, only GPs with a stable employment status (eg, permanent or long-term contracts) will be included. Temporary or short-term contracted professionals will be excluded. All GPs who meet the eligibility criteria will be automatically included in the study.

Randomisation

All GPs will be individually randomised at the beginning of the study in a 1:1 ratio to either the intervention or control group. The randomisation process will be conducted centrally using a computer-generated allocation sequence to ensure allocation concealment.

GPs will be followed for 12 months post-randomisation. Inclusion in the per-protocol analysis will require continuous clinical activity with a stable patient list. GPs who experience significant changes in their assigned patient population or who transfer to a different post or healthcare centre during the study period will be excluded from the per-protocol analysis, although they will be retained in the intention-to-treat (ITT) analysis.

Blinding

While participating GPs will not be blinded to allocation, both data extractors and data analysts will remain blinded.

Treatment arms Intervention

GPs randomised to the intervention group will receive a multi-component intervention aimed at reducing PIPs of benzodiazepines, PPIs and antipsychotics in older patients with dementia. The strategy includes a personalised A&F intervention, pharmacist-led consultations, educational clinical messages, online training and patient-directed educational materials. Components were selected based on current evidence for de-prescribing and medication optimisation in older adults.

Audit and feedback strategies

Each month, GPs will receive a personalised prescribing report via email, generated using Power BI (Microsoft). Reports will visualise the proportion of patients aged ≥ 65 receiving PIMs: (1) Benzodiazepines prescribed >3 months, (2) PPIs prescribed >8 weeks without a valid

indication and (3) Antipsychotics prescribed >3 months in patients with dementia.

These reports will include individual performance data, peer benchmarking (eg, Prescribing performance will be displayed as an individual percentile reflected in a bar, enabling comparison with peers) and guidance based on national and international recommendations. Graphical breakdowns will display prescribing patterns by drug class and diagnosis, helping GPs identify areas for improvement and supporting reflection on clinical practices.

Pharmacist-led consultations

Primary care pharmacists will identify high-prescribing GPs (eg, top 25th percentile based on baseline data) and invite them to participate in face-to-face sessions (25–35 mins). These sessions will include a review of prescribing indicators, discussion of clinical cases, clarification of guidelines and co-development of personalised improvement goals.

Throughout the intervention period, GPs in the intervention group will have the opportunity to request consultations to address specific clinical or prescribing questions.

Clinical messages

Brief monthly messages will accompany the feedback reports, providing targeted, evidence-based information on de-prescribing strategies and appropriate prescribing in older adults. These messages will include de-prescribing algorithms and practical guidance, adapted from trusted clinical sources (eg, deprescribing.org), to help reinforce behavioural change.

Online training

A self-paced, online training module will be made available to all GPs in the intervention group. The course will be hosted on an online platform (Moodle) and include content on safe prescribing practices, national de-prescribing recommendations and case-based examples focusing on benzodiazepines, PPIs and antipsychotics in the elderly.

The training, developed by clinical leaders and pharmacists, is designed to strengthen clinical decision-making and encourage sustained changes in prescribing behaviour.

Control

The control group will receive an active control intervention consisting of a structured A&F approach aimed at optimising antibiotic prescribing in primary care. This includes detailed reports comparing the volume, type and indications of antibiotics prescribed with peer benchmarks guided by the National Plan on Antibiotic Resistance.

Patient information sheet

GPs will receive a short, easy-to-use leaflet to support communication with patients and caregivers regarding medication risks. The leaflet will explain why some

medications may no longer be necessary or appropriate and provide alternatives to improve understanding and reduce resistance to de-prescribing efforts.

Outcomes (primary and secondary)

The primary outcome measure is the PIM prescription (benzodiazepines, PPIs 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. The secondary outcome measures are the proportion of patients over 65 years old using benzodiazepines, PPIs and antipsychotics in patients diagnosed with dementia in patients over 65 years old.

Prescription data will be extracted from regional electronic prescribing systems (RELE (Mallorca), ECAP (Tarragona-Reus), Receta Electrónica (Paterna)) and clinical information will be gathered from electronic medical records.

Additional data will be collected to characterise prescribing patterns, including drug class (ATC classification), dose, duration and diagnostic indication associated with each prescription.

Implementation outcomes

To evaluate the implementation process, the study will apply the RE-AIM framework and assess GP engagement in the intervention²² and fidelity by the Implementation Outcomes Framework.²³ The following dimensions will be explored: reach, engagement, adoption, fidelity and maintenance of the intervention. Reach defined as the percentage of participating GPs relative to the total number of eligible GPs. Adoption is defined as the absolute number, proportion and representativeness of settings and intervention agents who are willing to initiate a programme. Implementation refers to the extent to which the intervention is delivered as intended in the real-world setting, including consistency, cost and adaptations made during delivery. Maintenance examines the extent to which a programme becomes institutionalised or part of routine organisational practices and policies over the long term, both at the individual and setting levels. Fidelity will be evaluated by auditing adherence to the planned components of the intervention, including timely and consistent delivery of personalised feedback, execution of pharmacist-led sessions and access to the online training course.

Data management

Prescription and clinical data will be obtained from the electronic health records and prescribing systems of each participating health district, including RELE (IB-SALUT, Balearic Islands), ECAP (Catalan Institute of Health, Tarragona-Reus), Receta Electrónica (Paterna Health District) and e-rezeta (Osakidetza). Data will be extracted at baseline and at 12-month follow-up using standardised protocols to ensure consistency across regions.

Patient-level data will be extracted by authorised data managers within each health district. These data include anonymised prescribing and diagnostic information for patients aged ≥ 65 years. All personal identifiers (eg, name, ID number, address) will be removed at source before any data are transferred. Each patient record will be assigned a unique, non-identifiable code that allows longitudinal tracking of prescriptions without revealing personal information.

All data will be anonymised at source and coded prior to analysis. A unique identifier will be assigned to each participating GP, allowing linkage of prescribing data over time without disclosing personal or patient-level information. Data will be stored securely on encrypted institutional servers, accessible only to authorised members of the research team.

To ensure data integrity, predefined quality control procedures will be applied, including verification of data completeness, logical consistency checks and random cross-validation against original source records. Any discrepancies or outliers will be reviewed and resolved collaboratively with local data managers.

The study will comply with national and European data protection regulations (eg, General Data Protection Regulation (GDPR)) and has received ethical approval from relevant regional committees. No individual GPs or patient consent is required, as data will be handled in aggregated, anonymised form and the intervention is part of routine quality improvement strategies.

Sample size

The sample size assumes a baseline prevalence of 28% of PIPs, defined as the proportion of patients aged ≥ 65 years listed with each GP who have at least one PIP (benzodiazepines, PPIs or antipsychotics in patients with dementia) at baseline. Based on an expected 4-percentage-point reduction in the intervention group, with $\alpha=0.05$, 80% power, a SD of 8.8 and accounting for 10% attrition, the required total sample size is 170 GPs (85 per group).

Statistical analysis

All statistical analyses will follow the ITT principle, maintaining GPs in their originally assigned groups regardless of adherence to the intervention or loss to follow-up. A per-protocol analysis will also be conducted for comparison, including only those GPs who completed the study as planned and received the full intervention package. Quantitative data on prescribing outcomes and implementation indicators will be aggregated at the GP level, using anonymised identifiers. No individual-level patient data will be accessed.

Descriptive analyses will be performed to summarise baseline characteristics of GPs and outcome variables. Distribution patterns, missing data and potential outliers will be examined using appropriate graphical and statistical tools. Baseline comparisons between intervention and control groups will be conducted to assess balance and identify potential covariates for adjusted models.

Outcome analysis

The primary effectiveness outcome will be the PIM prescription (benzodiazepines, PPIs and antipsychotics in patients with dementia) in patients aged ≥ 65 years, measured using proportion of PIPs and the number of prescriptions extracted from the e-prescription databases of each health district at 12-month follow-up. Generalised mixed models will be used adjusting for baseline prescriptions and other GP characteristics.

Secondary outcomes include the proportion of each specific inappropriate prescription type (eg, long-term benzodiazepine use, prolonged PPI therapy). Given the bounded nature of the outcome (proportion values ranging between 0 and 1 or 0% and 100%), a random-effects Tobit regression model will be used, with censoring at 0 and 100. This model allows for appropriate handling of left- and right-censored values and accounts for the non-normal distribution of proportions. The model will estimate the effect of the intervention on the postintervention prescribing proportion, adjusting for baseline prescribing levels and other GP characteristics where imbalances are detected.

In addition, binary definitions of clinically meaningful improvement (eg, $\geq 10\%$ reduction in inappropriate prescribing rate) will be used to calculate absolute risk reduction, relative risk reduction, number needed to treat. These estimates will provide clinically interpretable metrics of effectiveness.

Subgroup and interaction analyses

Subgroup analyses will be conducted to explore whether intervention effects differ by: baseline prescribing level (quartiles), primary care teaching centres, healthcare region, age group (young-old < 75 years vs old-old ≥ 75 years), number of medications at baseline, duration of therapy with each PIM. Interaction terms will be included in regression models to test for effect modification across these subgroups.

Missing data

Missing outcome data due to loss to follow-up will be addressed using multiple imputation with chained equations. Fifty imputed datasets will be generated, incorporating baseline prescribing values and relevant GP-level variables. Estimates from imputed datasets will be pooled using Rubin's rules.

All analyses will be performed using Stata V.18.0 and SPSS for Windows V.21.0. Statistical significance will be set at $p < 0.05$, and effect sizes will be reported with 95% CIs.

Implementation outcomes

Implementation data (eg, reach, fidelity, adoption, engagement) will be analysed descriptively and, where appropriate, compared across time points and between sites. Quantitative survey data will be summarised using means, medians and proportions.

Qualitative data from semi-structured interviews will be transcribed and analysed thematically using a hybrid inductive–deductive approach, informed by the RE-AIM framework and Proctor's implementation outcomes taxonomy. Coding will be performed using software such as Atlas.ti, ensuring methodological rigour through triangulation, team-based coding and saturation verification.

Patient and public involvement

Patients and the public will not be involved in the design, conduct, reporting or dissemination plans of this research.

DISCUSSION

This study protocol outlines a pragmatic, hybrid effectiveness-implementation trial designed to reduce PIPs of benzodiazepines, PPIs and antipsychotics in older adults within Spanish primary care. The intervention combines personalised A&F, pharmacist-led consultations, targeted clinical messaging, online training and patient-facing materials, components grounded in current evidence on deprescribing and behavioural change strategies in healthcare settings.

Systematic reviews and meta-analyses have demonstrated that A&F can lead to moderate but meaningful improvements in prescribing quality, especially when feedback is repeated, tailored and delivered by trusted sources.²⁴

Pharmacists play an important role in supporting rational prescribing practices. In primary care, pharmacist-led interventions have been associated with reductions in inappropriate medication use and improvements in therapeutic appropriateness.^{25 26} Structured consultations that combine clinical review with individual feedback may enhance prescriber engagement and facilitate the application of deprescribing principles in routine care.

Despite encouraging findings from previous research, implementation remains variable and the overall quality of evidence is mixed. Questions persist about the optimal design, duration and intensity of A&F interventions to achieve sustained behavioural change. This study addresses these gaps by evaluating not only clinical outcomes but also key implementation indicators, such as reach, fidelity and maintenance, using the RE-AIM framework. Findings will provide insights into how multifaceted interventions can be effectively integrated into routine primary care and how professional prescribing practices can be improved at scale.

The results of this trial will contribute to the broader evidence base on deprescribing in older adults, a population particularly vulnerable to medication-related harm.

ETHICS AND DISSEMINATION

Ethical approval was obtained from the Balearic Islands Research Ethics Committee (IB5219/23PI). The

committee approved a waiver of consent for GPs, given that their prescribing data are individually analysed. No waiver was required for patients, since patient-level data are only used in aggregated and anonymised form and no patients are directly recruited. Study findings, including primary and secondary outcomes and qualitative implementation results, will be disseminated through peer-reviewed publications and stakeholder reports.

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Competing interests None declared.

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