ISRCTN18752158 https://doi.org/10.1186/ISRCTN18752158

The general practice-based pharmacist: supporting medicines management in older adults

Submission date 03/03/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 15/04/2020	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 27/02/2024	**Condition category** Other	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims

In an increasingly medicalised and ageing population patients are prescribed complex regimens of medications. Improving the quality and safety of prescribing is an important health measure as those patients who take a large number of medicines are at an increased risk of adverse drugs reactions (ADRs) and subsequent hospitalisations. General practitioners (GPs) have very demanding workloads and are typically the main point of contact for patients who may be seeing a number of different specialists. As such, GPs are managing very complex medication regimens for patients who are being looked after by separate hospital clinics. There have been a number of studies done to help ease the pressure on GPs and to improve medication management for patients. One such measure was the integration of pharmacists into the GP clinic. The NHS has recently formally introduced pharmacists into GP clinics and has provided funding for this role. Researchers previously conducted a small feasibility study examining GP-based pharmacists. The aim of this current study is to build on the general practice pharmacist (GPP) feasibility study, and to examine further the impact a pharmacist may have working in a GP clinic in the Irish setting to support prescribing and improve outcomes for patients.

Who can participate?

Adult patients who are 65 years of age or older, who are taking 10 or more regular monthly medications, live in the community and who are able to attend their GP practice to take part in the study are eligible to participate. This study will be conducted in general practice surgeries in Ireland. For the GP practice to be eligible to take part in this study, they must have at least 500 patients aged 65 years or older attending their practice.

What does the study involve?

The study involves testing the effectiveness of a pharmacist working with patients and GPs to improve medicines prescribing and the health needs of patients. Patients will be invited to meet with the pharmacist in the practice to discuss their medications and any issues they may be having with them. The pharmacist will work with patients and practice staff for a period of 4

months. During this time they will meet with patients who are participating in the trial and support the GPs in tasks in the practice as they are needed, for example, they may review medicines, give educational medication talks and help manage repeat prescriptions.

What are the possible benefits and risks of participating?
Patients' medicines will be reviewed by the pharmacist and appropriate recommendations will be made to their GP regarding treatment. Overall it is hoped that this will help GPs manage the demands on their time and ensure prescribing is safe and effective. Also, patients will have the opportunity to discuss their medications and alleviate any concerns they may have. The risks of taking part in this study are minimal. Any medication changes that may be recommended for patients taking part will be made in consultation between the individual patient and their GP.

Where is the study run from?
Royal College of Surgeons (Ireland)

When is the study starting and how long is it expected to run for?
November 2019 to June 2023

Who is funding the study?
Health Research Board (Ireland)

Who is the main contact?
Aisling Croke
aislingcroke@rcsi.ie

Contact information

Type(s)
Public

Contact name
Ms Aisling Croke

ORCID ID
https://orcid.org/0000-0002-2674-7474

Contact details
Department of General Practice
Royal College of Surgeons in Ireland
123 St Stephens Green
Dublin
Ireland
D02 YN77
+353 (0)14774016
aislingcroke@rcsi.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The general practice-based pharmacist medicines optimisation programme: a pilot cluster randomised controlled trial, process and economic evaluation

Study objectives
The aim of this study will be to conduct and evaluate a cluster randomised controlled trial of an intervention of pharmacists based in general practice, to optimise prescribing in patients with complex polypharmacy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/11/2019, Irish College of General Practitioners Research Ethics Committee (ICGP, 4-5 Lincoln Place, Dublin 2, Ireland; +353 (0)1-6763705; colleen.oneil@icgp.ie), ref: N/A

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Polypharmacy, multimorbidity

Interventions
The intervention will involve a pharmacist integrating into the GP practice where they will support prescribing-related activities. The first component of the intervention will be the medicines optimisation element delivered by targeted patient medication reviews and based on improving safety and addressing national medicines management priorities and guidelines. There will be a focus on high risk prescribing, potentially inappropriate prescribing (PIP) and deprescribing.

Practice staff will identify a list of potentially eligible patients on 10 or more regular medicines. Potential patients will be contacted by practice staff. The researchers will recruit a random selection of eligible patients from each practice. Those who consent will be asked to complete baseline data before they are randomised to the intervention group or waitlist control.

Practices will be randomly allocated to intervention or control arms by an independent researcher using a computer-generated random sequence, this researcher will be blinded to practice details to avoid potential practice level selection bias. Blocked randomisation will be used to achieve equal numbers of participants in both intervention and control arms.

Patients in the intervention arm will make an appointment with the pharmacist for a medication review. Pharmacists will work with both patients and prescribers to address any issues identified. The intervention will run for 4 months in each practice with follow-up data to be collected at completion. Control practices will continue to provide care as usual with no input from the pharmacists and follow-up PROMs data will be collected from control practices at matched time points. Previous 'current prescriptions' at trial initiation and all prescription data for that period will be reviewed to provide contemporaneous medication data for the pilot cRCT. On study completion, this medication review process will be carried out with control patients.

The second component of the intervention will evaluate the role and impact of a pharmacist on care provision within the general practice when integrated into the practice team. This will involve a pharmacist joining the practice team and engaging in activities to support GPs and other practice staff such as audit, medication review, educational sessions and a medicines information role.

Any individual prescribing issues identified will be discussed with the GP. The GP will exercise their own clinical judgement and expertise, and will have the final decision in any medication changes, in consultation with the patient. Data that will be recorded for the purposes of this study will be anonymised practice-level data on prescribing, a description of the activities that the pharmacist undertakes and the length of time undertaken to complete those activities.

Intervention Type
Other

Primary outcome(s)
Mean PIPs per patient, measured at baseline and 4 months

Key secondary outcome(s))
Measured at baseline and 4 months:
1. Medication-related outcomes, measured through medical review:
1.1 Number of repeat medications each patient is regularly taking as per patient medication record (PMR)
1.2 Proportion of patients with polypharmacy (≥ 10 regular medications) as determined from study data
1.3 Medication changes:
1.3.1. Deprescribing measured by reported study data
1.3.2. Medications started measured by reported study data
1.3.3. Number of medications prescribed generically measured by recorded information on PMR
1.3.4. ADRs leading to drug withdrawal measured by reported study data
2. Patient-reported outcome measures:
2.1 Health-related quality of life measured by the EQ5D-5L
2.2 Patients' beliefs and attitudes towards deprescribing measured by the Patients Attitudes Towards Deprescribing (PATD) questionnaire
2.3 Burden of treatment measured by Multimorbidity Burden of Treatment Questionnaire
2.4 Patients' beliefs about the necessity of medicines and concerns measured by the Patients' Beliefs about Medicines Questionnaire
3. Role and impact of pharmacist, measured throughout intervention by the means of a research pharmacist maintained 'Pharmacist Activity Log':
3.1. Activities undertaken
3.2. Condition-specific domains
3.3. Engagement with other healthcare professionals and practice staff

3.3.1. GPs
3.3.2. Community pharmacists
3.3.3. Hospital staff
3.3.4. Practice staff
3.3.5. Other healthcare professionals

Completion date
30/06/2023

Eligibility

Key inclusion criteria
GP practices:
1. Over 500 patients aged ≥65 years on patient panel

Patients:
1. ≥ 65 years of age
2. Complex polypharmacy (defined as ≥10 repeat medications)
3. Living in the community
4. Ability to attend GP practice for medication review with the pharmacist

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Sex
All

Key exclusion criteria
GP practices:
1. Practices will be excluded if they have <500 older patients

Patients:
1. Under the age of 65
2. Terminally ill leading to death or major disability during study follow-up period
3. Severe cognitive impairment psychiatric/psychological morbidity sufficient to impair informed consent provision
4. Resident in nursing home
5. Currently participating in a related study

Date of first enrolment
01/02/2021

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
Ireland

Study participating centre
Royal College of Surgeons in Ireland
Department of General Practice
123 St Stephens Green
Dublin 2
Ireland
D02 YN77

Sponsor information

Organisation
Royal College of Surgeons in Ireland

ROR
https://ror.org/01hxy9878

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Ireland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository. Data will be stored for 7 years in line with RCSI data management policy and shared at the time of publication where facilities permit and under ethical and data protection requirements. Once final data analysis has been undertaken and peer-reviewed publications secured, the data controller will be responsible for deleting the files containing the key to pseudonymised data, and ensuring any personal identifiable data has been deleted.

Anonymised data arising from this study may be accessed by contacting the PI and data may be placed on publicly accessible sites such as the Irish Social Science Data Archive (ISSDA). The ISSDA provides a number of professional curation and management services to depositors, including preservation of data (updating of data formats, and are planning to implement Digital Object Identifiers (DOIs) for datasets and documentation. The ISSDA requires metadata to adhere to the DDI standard, hence this standard will be used for reporting metadata associated with this study. Researchers who wish to access the data can submit a request to the ISSDA and can use the data for research or teaching purposes with appropriate attribution and citation.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/03/2021	24/03/2021	Yes	No
Other publications	Systematic review	06/02/2023	15/03/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes