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Supporting medicines management in older adults with multiple medical conditions

Submission date
26/08/2016

Recruitment status
No longer recruiting

Registration date
20/10/2016

Overall study status
Completed

Last Edited
02/09/2024

Condition category
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Older people often take a number of medications and have multiple long-term medical conditions (multimorbidity). One in twenty Irish people aged over 65 years are prescribed 15 or more medications. Prescribing for older people with multiple medical conditions can be a challenging task for doctors as there is an increased chance of patients suffering from side effects, drug interactions (when one medication affects another) and potentially inappropriate prescribing (PIP). PIP is a term used to describe a number of substandard prescribing practices including overprescribing, misprescribing (prescribing the wrong drugs) and underprescribing of drugs. The study group has previously developed an program to target PIP in adults over 70 years called OPTI-SCRIPT. This involved providing education for GPs and a GP led medication review that was supported by a website which provided alternative treatment options for PIPs. The study showed that the program led to a lower chance PIP. There are now plans to build on this to incorporate the recommendations of the NICE Multimorbidity Guideline. This guideline recommends targeting people on 15 or more regular medicines and offering them a medication review. The guideline also focuses on reducing treatment burden for patients as well as stopping ineffective or inappropriate medication. Therefore, the aim of this current study is to determine the effectiveness and acceptability of an program designed to support GPs to improve medicines management and reduce treatment burden in patients with complex multimorbidity patients with multiple conditions involving three or more body systems) who are taking 15 or more regular medications.

Who can participate?
GP practices with 300 or more patients older than 65 years on their patient panel. Patients can participate if they are 65 years or older and are prescribed 15 or more regular medications.

What does the study involve?
Participating GP practices are given a patient finder tool to allow them to develop a list of patients aged 65 years or older and who are also being prescribed 15 or more regular medications. These patients are then invited to join the study. Questionnaires are sent out to all participating patients. Participating practices are then randomly allocated to one of two groups. The GPs in the first group conduct a medication review with their patients using a website to support them. They are also able to log in online to an educational presentation. GPs in the

second group continue to provide usual care for their patients. Six months later, the medical records of patients in both groups are reviewed to see if there are any changes in their medication use. Those in the second group are then given the opportunity to take part in the program.

What are the possible benefits and risks of participating?
Participants who are treated by GPs taking part in the program may benefit from the medication review by being able to reduce PIP and are able to discuss any concerns they have about their medications. There are very few risks for the patients participating in this study. Any decision on whether to change prescribed medication will be at the discretion of the prescribing GP in consultation with the patient.

Where is the study run from?
The study is run by the Royal College of Surgeons in Ireland and takes place in 30 GP practices throughout Ireland (Ireland)

When is the study starting and how long is it expected to run for?
August 2016 to January 2021

Who is funding the study?
The Heath Research Board Primary Care Clinical Trials Network (Ireland)

Who is the main contact?
Professor Susan Smith
susansmith@rcsi.ie

Contact information

Type(s)
Scientific

Contact name
Prof Susan Smith

Contact details
The Health Research Board
Centre for Primary Care Research
Royal College of Surgeons in Ireland (RCSI)
Lower Ground Floor
Beaux Lane House
Mercer Street Lower
Dublin
Ireland
Dublin 2
+353 (0)1 402 2473
susansmith@rcsi.ie

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
SuPporting medicines management in multimorbidity in Primary caRE: a cluster randomised controlled trial

Acronym
SPPiRE

Study objectives
A multi-faceted intervention that combines computer generated patient identification, with academic detailing for GPs and a structured medication review for patients, has an effect in reducing polypharmacy and PIP in older people in Irish primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Irish College of General Practitioners, 22/07/2016

Study design
Pragmatic two-arm cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See additional files

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

Interventions

Practices will be recruited throughout Ireland, and will then be supported in recruiting eligible patients. Once all patients are recruited baseline data will be collected through medical record review. Practices will then be randomised using minimisation to either intervention or control groups. This will be done by an independent third party using egminimpy software.

Intervention arm: GPs will receive log in details to access online academic detailing and will be asked to arrange a medication review with their recruited patients. This will be supported by a website which will provide a basic structure for the review and a patient outcome form which will collect information about any changes made to the medication regime and reasons for process evaluation. Follow up data will be collected 6 months after the medication review is completed.

Control arm: Usual care will be delivered for the duration of the study. Once follow up is complete for both groups the control arm will be invited to take part in the intervention.

Patient medical records are reviewed in both groups at baseline and 6 months to find out if prescribing practices have changed.

Intervention Type
Behavioural

Primary outcome measure
1. Number of repeat medications are measured through medical record review at baseline and 6 months post-intervention
2. Proportion of patients with any potentially inappropriate prescription (PIP) (defined by explicit criteria, used for OPTI-SCRIPT which were based on more prevalent STOPP-START PIP indicators) are measured through medical record review at baseline and 6 months post-intervention

Secondary outcome measures
Current secondary outcome measures as of 17/07/2017:
Measured through medical record review at baseline and 6 months post-intervention:
1. Reduction in proportion of patients with 15 or more medicines (100% at baseline)
2. Medication changes
2.1 Number of medications stopped
2.2 Numbers of medications started
2.3 Reduction in the number of PIP (per patient and absolute numbers in the intervention versus control
2.4 Proportion of patients with any reduction in PIP
3. Multimorbidity treatment burden questionnaire
4. Health related Quality of life (EQ5D)
5. Revised patient's attitudes to deprescribing
6. Patient-reported adverse drug withdrawal events (defined as either recurrence of the condition for which the drug was prescribed or a physiologic reaction to drug withdrawal)
7. Health service utilisation (based on chart data and provided by practice admin staff)
7.1 Number of GP/nurse visits
7.2 Number of out of hours visits
7.3 Number of Accident & Emergency (A&E) visits
7.4 Number of hospital admissions
7.5 Number of in-patient days
7.6 Number of out-patient visits

Previous secondary outcome measures:
Measured through medical record review at baseline and 6 months post-intervention:
1. Reduction in proportion of patients with 15 or more medicines (100% at baseline)
2. Medication changes
2.1 Number of medications stopped
2.2 Numbers of medications started
2.3 Numbers of high risk medications
2.4 Adverse drug withdrawal events (Naranjo adverse drug reaction probability scale)
3. Treatment burden (Translated Treatment Burden Questionnaire)
4. Health related Quality of life (EQ5D)
5. Shared decision making (DCS)
6. Moriskey Medicacation Adherence Measure
7. Patients' attitudes towards deprescribing (PATD)
8. Health service utilisation (based on chart data and provided by practice admin staff)
8.1 Number of GP/nurse visits
8.2 Number of out of hours visits
8.3 Number of Accident & Emergency (A&E) visits
8.4 Number of hospital admissions
8.5 Number of in-patient days
8.6 Number of out-patient visits

Overall study start date
04/04/2016

Completion date
30/01/2021

Eligibility

Key inclusion criteria
Practice inclusion criteria:
1. Have 300 or more older patients (aged ≥65 years) on their patient panel (based on the need to identify at least 15 patients per practice who are receiving 15 or more medicines and allowing for refusals)
2. Use Socrates or Health One as a practice management system

Patient inclusion crtieria:
1. Aged 65 years and over
2. Being prescribed at least 15 regular medications

Participant type(s)
Mixed

Age group
Senior

Sex
Both

Target number of participants

440 patients from 55 general practices, based on average cluster size of 8 (previously 15), and incorporating a potential loss to follow up of 10%.

Total final enrolment
404

Key exclusion criteria
Practice exclusion criteria:
Involved in the development and piloting of the intervention or other concurrent medication quality related studies

Patient exclusion criteria:
1. Significant mental or physical illness that would impair their ability to consent and take part in the study
2. Unable to attend the surgery for medication review (e.g. nursing home residents)
3. Those involved in another medication study

Date of first enrolment
19/04/2017

Date of final enrolment
19/12/2019

Locations

Countries of recruitment
Ireland

Study participating centre
Department of General Practice Royal College of Surgeons in Ireland
Department of General Practice
Royal College of Surgeons in Ireland
Beaux Lane House
Lower Mercer Street
Dublin
Ireland
Dublin 2

Sponsor information

Organisation
The Health Research Board - Centre for Primary Care Research (Ireland)

Sponsor details

c/o Ms Linda O'Connor
Royal College of Surgeons in Ireland (RCSI)
Lower Ground Floor
Beaux Lane House
Mercer Street Lower
Dublin
Ireland
Dublin 2
+353 (0)1 402 2473
lindapoconnor@rcsi.ie

Sponsor type
University/education

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Research organisation

Funder Name
The Health Research Board Primary Care Clinical Trials Network

Results and Publications

Publication and dissemination plan
1. Planned publication of the trial protocol (2016/2017)
2. Planned publication of RCT and process evaluation in a high impact journal (2018/2019)

Updated 23/07/2019:
1. Planned publication of RCT and process evaluation in a high impact journal (2020/2021)
2. Process evaluation protocol submitted for publication in HRB Open, currently under review

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository upon completion and publication of the trial results. Details of how and when this repository can be accessed will be made available upon completion of the study.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		01/09/2016	20/10/2016	No	Yes
Protocol article	protocol	01/08/2017		Yes	No
Protocol article	process evaluation protocol	23/08/2019	28/02/2020	Yes	No
Results article		05/01/2022	06/01/2022	Yes	No
Results article	Process evaluation	17/10/2022	18/10/2022	Yes	No
Results article	secondary analysis	16/11/2022	18/11/2022	Yes	No
Results article	Recruiting general practitioners and older patients with multimorbidity to randomized trials	04/04/2023	05/04/2023	Yes	No
Results article	Cost effectiveness	27/08/2024	02/09/2024	Yes	No