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OptImizing prescribing for older people in primary care

Submission date
21/03/2012

Recruitment status
No longer recruiting

Registration date
05/04/2012

Overall study status
Completed

Last Edited
23/02/2018

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Older people are one of the biggest consumers of healthcare, particularly medicines. One in five Irish adults aged 50 and over takes five or more medications. This increases to almost half for those aged 75 years and over. Older people tend to have multiple medical conditions requiring multiple medications. They also experience age-related changes in how the body breaks down medications. Prescribing for older populations is therefore a complex and challenging task, with the potential for adverse outcomes. Prescriptions can be considered potentially inappropriate where a more effective or lower risk treatment is available to use. The potential for harm from prescribing certain medications in older people can be assessed by different quality markers such as potentially inappropriate prescribing (PIP). Tools used to measure PIP usually consist of lists of drugs to be avoided in older people or in certain medical conditions, and drugs that should not be prescribed together. One such measure is the Screening Tool of Older Peoples Prescriptions (STOPP). Using this measure, the prevalence of PIP in older people (aged 70 and over) in Ireland is estimated at 36%. The total expenditure on PIPs by the state is estimated at just over 45 million (or 9% of the overall expenditure on medicines in that age group). PIP is associated with increased morbidity (illness), adverse drug reactions and increased healthcare utilisation such as being hospitalised. Improving the quality and safety of prescribing in older people is a challenge. A number of different interventions have been used to improve PIP such as computerised decision support (CDSS). While CDSS has shown a lot of promise, no one interventional strategy has proven to be the most effective for reducing PIP. The aim of this research is to test if a multi-faceted intervention that combines a pharmaceutical treatment algorithm and quality improvement strategy delivered using decision support materials and academic detailing is effective at reducing PIP in older people in Irish primary care.

Who can participate?
GP practices can participate if they have 80 or more older patients (aged 70 or over) on their patient panel. Patients can participate if they are aged 70 or over and are being prescribed one or more selected PIP drugs on a repeat basis.

What does the study involve?
Participating GP practices will be randomly allocated to either the intervention group or the control group. In both groups GPs will identify a random sample of patients aged 70 or over and

invite them to take part in the study. The intervention group GPs will conduct a medication review with their patients using the intervention materials at the next medicines review appointment. The control group GPs will continue to provide usual care for patients and allow the research team to feed back summary information with regards to medicines prescribed to participating patients. Patients in both groups will fill in a questionnaire, either by post or over the telephone, about them (e.g. age, marital status), their general health and well-being, and beliefs about medication.

What are the possible benefits and risks of participating?
The potential for risks from taking part in this study are minimal. Any changes to medication regimes that arise from this study will be made in consultation between the patient and the GP. All patients will have their medicines reviewed and the GP alerted should any concerns arise due to medications that may need to be looked at. For the GPs, we will be seeking permission to grant CME points for participation in this study and any materials developed for this study will be available to all participating GPs at the end of the study, free of charge.

Where is the study run from?
This study is organized by a team of researchers from the HRB Centre for Primary Care Research based in the Royal College of Surgeons in Ireland (RCSI)

When is the study starting and how long is it expected to run for?
April 2012 to October 2013

Who is funding the study?
This study is funded by the HRB as part of the PhD Scholarship in Health Services Research and The HRB Centre for Primary Care Research (Ireland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
OPTImizing preSCRIbing for older People in primary care: a cluster randomized controlled Trial

Acronym
OPTI-SCRIPT

Study objectives
A multi-faceted intervention that combines a pharmaceutical treatment algorithm and quality improvement strategy delivered using decision support materials and academic detailing, with alternative recommendations for GPs, has an effect in reducing PIP in older people in Irish primary in intervention practices as compared to controls

Ethics approval required
Old ethics approval format

Ethics approval(s)
Irish College of General Practitioners (ICGP), 13/03/2012

Study design
Pragmatic two-arm cluster randomised controlled trial with qualitative analysis

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Instances of potentially inappropriate prescribing (PIP) in older people in primary care

Interventions
Practices will be assigned to intervention or control using minimization to ensure balance between the groups in terms of practice size (number of whole-time-equivalent GPs) and practice location (urban/rural, an urban area is defined as a relatively small centre of population, with 5000 or more residents).

In the intervention arm of the trial, the intervention comprises of:
1. GP Training
General practitioners (GPs) will be trained about PIP and in how to use the intervention decision support material via academic detailing style visits to practices by a GP research team member

2. Medicines Review
GPs will be asked to conduct a medicines review with participant patients using the intervention material at the next appointment.

3. Decision Support
The decision support materials will be available in both paper and web-based versions available for use during the medication review. The materials are divided into the following sections:
Section A: The individual PIP with reason for concern
Section B: Alternative pharmacological and non-pharmacological treatment options
Section C: Background information (where relevant)

4. Patient information leaflets about the recommended treatment options will also be provided in pdf format for printing.

In the control arm of the trial, practices will continue to provide usual care but will also be provided with simple feedback. Data for patients in the control group will be reviewed during recruitment and a personalised patient list, summarising the potentially inappropriate prescriptions, will be fed back to the GP. Participants will not be prompted to carry out a medicines review with the individual patients and will not receive decision support with alternative therapy options.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Proportion of patients with a PIP (composite measure i.e. any number of the study PIPs)
2. Mean number of PIPs per patient

Secondary outcome measures
1. Drug-specific outcomes:
1.1. The absolute number of PIPs per patient of the top five occurring PIP drugs:
1.1.1. Proton pump inhibitor (PPI) for peptic ulcer disease at full therapeutic dosage for >8 weeks
1.1.2. Long-term use of non-steroidal anti-inflammatory drug (NSAID) (>3 months) for relief of mild joint pain in osteoarthritis

1.1.3. Long-term (i.e. >1 month), long-acting benzodiazepines e.g. chlordiazepoxide, fluazepam, nitrazepam, chlorazepate and benzodiazepines with long-acting metabolites e.g. diazepam
1.1.4. Any regular duplicate drug class prescription
1.1.5. Tricyclic antidepressants (TCAs) with an opiate or calcium channel blocker
1.2. Mean number of PIPs per patient of the top five PIP drugs (as above)

2. Process evaluation measures:
2.1. Number of times alternatives were prescribed
2.2. Decisions made per PIP
2.3. Reported primary reason for decision made e.g. risks outweigh benefits, patient preference, hospital/consultant initiated

3. Patient-reported outcomes:
3.1. Quality of Life (as measured using EQ-5D)
3.2. Patients medication beliefs (as measured using the Beliefs About Medicines Questionnaire, BMQ)
3.3. Well-being (as measured by the Well-Being Questionnaire, WBQ-12)

4. Process of care measures:
4.1. Number of GP visits
4.2. Number of hospital admissions

Overall study start date
01/04/2012

Completion date
01/10/2013

Eligibility

Key inclusion criteria
GP practices:
1. Have approximately 80 or more older patients (aged ≥ 70 years) on their patient panel

Patients:
1. Aged 70 years or above
2. They are being prescribed one or more selected potentially inappropriate prescribing (PIP) drugs on a repeat basis (only patients with existing PIP will be included as the intervention is specifically targeting PIP management).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Recruitment of 22 GP practices and 220 patients (10 per practice)

Key exclusion criteria
GP practices:
1. Involved in the development and piloting of the intervention or other concurrent medication quality related studies

Patients:
1. Have significant mental or physical illness which is likely to impair their ability to participate in the study or their ability to give informed consent
2. They are unable to attend the GP surgery for consultation (e.g., nursing home resident)
3. They are participating in another medication quality related study

Date of first enrolment
01/04/2012

Date of final enrolment
01/10/2013

Locations

Countries of recruitment
Ireland

Study participating centre
The Health Research Board
Dublin
Ireland
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Sponsor information

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

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Sponsor type
Government

Website
http://www.hrbcentreprimarycare.ie/

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Research organisation

Funder Name
Health Research Board - PhD Scholars Programme in Health Services Research (Ireland), ref: PHD /2007/16

Funder Name
The Health Research Board Centre for Primary Care Research (Ireland), ref: 1139

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/03/2013		Yes	No
Other publications	development and pilot study	14/08/2013		Yes	No
Results article	results	01/11/2015		Yes	No
Results article	results	02/06/2016		Yes	No

Other publications	process evaluation	03/08/2016	Yes	No