ISRCTN18176245 https://doi.org/10.1186/ISRCTN18176245

Developing a way of improving the prescribing of many drugs for older people who live in their own home and are cared for by general practitioners

Submission date
18/01/2016

Recruitment status
No longer recruiting

Registration date
22/01/2016

Overall study status
Completed

Last Edited
16/02/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
In the last century, advances in medicine have led to people living much longer as previously fatal diseases are now treatable. Many people, particularly those over the age of 60, are living with two or more long-term medical conditions (multimorbidity). These patients often need to take a range of different medications to control their conditions (polypharmacy). In some cases, the prescribing of medications may not be appropriate and patients are given too much or too little of what they actually need. Many studies have tried to improve this and ensure that patients are prescribed all the medicines they actually need, however many have been unsuccessful. This may be because studies have not considered the views and opinions of patients or the way that health professionals make decisions about which medicines are needed. The aim of this study is to try to design a programme in order to improve polypharmacy prescribing practices of GP's for older people.

Who can participate?
GP practices in Northern Ireland willing to take part in the study, the GPs who work there and adult patients over the age of 65 who take at least 4 different medications.

What does the study involve?
GPs who work at participating practices that consent to take part in the study are given access to an online video which shows how to best prescribe multiple medications to older patients in a normal consultation. The video also contains feedback about why this approach works well. Appropriate patients are then invited to come in to see their GP for an appointment to review their medications. After each consultation, both the GPs and the patients complete anonymous feedback questionnaires to provide their opinions about the consultations. The results of these questionnaires are then reviewed to find out how acceptable the approach is. There are no specific follow-up appointments, but for the patients taking part, their medical records are reviewed 4 weeks later in order to see if there has been any change to their medication following the consultation.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to participants taking part in the study.

Where is the study run from?
The study is run from Queen’s University Belfast and takes place in two GP practices in Northern Ireland (UK)

When is the study starting and how long is it expected to run for?
April 2015 to September 2015

Who is funding the study?
Dunhill Medical Trust (UK)

Who is the main contact?
Prof. Carmel Hughes

Contact information

Type(s)
Scientific

Contact name
Prof Carmel Hughes

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2

Study information

Scientific Title
Development of an intervention to improve appropriate polypharmacy for older people in primary care

Study objectives

The overall aim of this project is to develop and feasibility test an intervention to improve the prescribing of appropriate polypharmacy for older people in primary care, focusing on healthcare professionals' (HCPs') encounters with patients in daily practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health and Social Care Research Ethics Committee A, 29/05/2015, ref: 15/NI/0104

Study design
Single-centre feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Polypharmacy in older people

Interventions
A feasibility study is conducted in order to assess the usability and acceptability of an intervention to improve the prescribing of appropriate polypharmacy for older patients in primary care. The intervention consists of a video demonstration of how general practitioners (GPs) can prescribe appropriate polypharmacy during a typical consultation with older patients and will be delivered as an online video. The video also includes feedback emphasising the positive outcomes of this type of approach.

During the recruitment phase of the study, a meeting is held between the researcher and GPs within each practice. During this meeting GPs are provided with an overview of the feasibility study protocol and intervention. Following the provision of written informed consent, GPs are provided with access to the online video, before information letters are issued by the practice to patients meeting inclusion criteria, inviting them to attend a scheduled consultation with their GP about their medicines.

Baseline assessments are conducted on the date that each practice chooses to invite patients for scheduled consultations with recruited GPs. These assessments involve the collection of data from three sources: GPs, patients and recruited patients' medical records. GPs complete a feedback questionnaire after they perform medication reviews during scheduled consultations

with recruited patients. Recruited patients are also asked to complete a feedback questionnaire after the scheduled consultations with their GPs. There is no direct follow-up with GP or patient participants after the scheduled consultations are completed. Data is also extracted from recruited patients' medical records at baseline and follow-up (one month after the scheduled consultation). The extracted data includes details of patient demographics (i.e. age, gender), clinical conditions and prescribed medications (both acute list items and repeat list items).

Intervention Type
Behavioural

Primary outcome measure
1. The usability and acceptability of the intervention for GPs is determined using a feedback questionnaire which recruited GPs complete at baseline (after medication reviews during scheduled consultations)
2. The usability and acceptability of the intervention for patients is determined using a feedback questionnaire which recruited patients complete at baseline (after medication reviews during scheduled consultations)

Secondary outcome measures
1. Feasibility of recruitment procedures is assessed by determining whether recruitment targets have been met at the end of the study
2. Feasibility of the data collection procedures is determined by applying validated assessments of prescribing appropriateness (i.e. STOPP/START criteria, Medication Appropriateness Index) and prescribing regimen complexity (i.e. Medication Regimen Complexity Index) to clinical data extracted from recruited patients' medical records at baseline and follow-up (four weeks after date of scheduled consultations)

Overall study start date
01/04/2015

Completion date
30/09/2015

Eligibility

Key inclusion criteria
General practice inclusion criteria:
1. Located in Northern Ireland
2. The practice was willing to implement the study
3. Individual general practitioners (GPs) willing to provide written informed consent.

Patient inclusion criteria:
1. Over the age of 65
2. Receiving four or more regular medicines
3. Not cognitively impaired
4. Resident in the community

Participant type(s)
Patient

Age group

Senior

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Not meeting the inclusion criteria
2. Not proving written informed consent

Date of first enrolment
01/06/2015

Date of final enrolment
31/08/2015

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Queen's University Belfast
School of Pharmacy
97 Lisburn Road
Belfast
United Kingdom
BT9 7BL

Sponsor information

Organisation
Queen's University Belfast

Sponsor details
Research and Enterprise Office
University Road
Belfast
Northern Ireland
United Kingdom
BT7 iNN

Sponsor type
University/education

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Dunhill Medical Trust

Alternative Name(s)
The Dunhill Medical Trust, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned submission of a feasibility study paper to a peer-reviewed journal.

Intention to publish date
30/09/2016

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/07/2017		Yes	No
Other publications	Development of intervention	16/11/2016	16/02/2023	Yes	No

HRA research summary	28/06/2023	No	No