ISRCTN41009897 https://doi.org/10.1186/ISRCTN41009897

# Pilot testing of a new approach to improving the prescribing of many drugs for older people who live in their own home and are cared for by general practitioners

**Submission date**
18/11/2019

**Recruitment status**
No longer recruiting

**Registration date**
19/11/2019

**Overall study status**
Completed

**Last Edited**
12/09/2022

**Condition category**
Other

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

## Plain English summary of protocol

Current plain English summary as of 09/12/2020:

Background and study aims
In the past, prescribing many medicines (polypharmacy) was seen in a negative light. However, because people are living longer and have a number of medical conditions at the same time, views on polypharmacy have changed. The challenge is to have the correct balance between enough medicines and too many medicines. Members of the research team have developed a new approach to achieving this balance. This approach has been tested in two general practices in Northern Ireland (NI). The approach (intervention package) currently consists of two parts: (1) a video showing how general practitioners (GPs) can prescribe appropriate polypharmacy for older patients, and (2) an appointment system for patients to visit a GP to have their medicines reviewed. As the intervention package was developed and tested in NI, further testing needs to be carried out in NI and the six border counties of the Republic of Ireland (ROI; Cavan, Donegal, Leitrim, Louth, Monaghan, and Sligo). This will be done in three stages or phases. In phase 1, which is now complete, 13 GPs were interviewed across 12 practices in the six border counties in the ROI; shown the video, asked about this new approach and asked if any changes are needed before doing more testing. In the next two phases (Phase 2 & 3) a small study will be carried out involving 12 practices: six practices in NI and six practices in the six border counties in the ROI and approximately 10 patients per practice. GP practices will either receive the intervention package and conduct medication reviews with recruited patients (intervention group) or continue to treat recruited patients as usual (control group). Interviews with up to 10 GPs and six members of practice staff (i.e. those involved in implementing the intervention within each practice) respectively in the six intervention group practices will also be conducted at the end of the intervention. Patients from the six intervention group practices will be asked to complete a feedback questionnaire at the end of the intervention. The aim of the study is to test and compare the delivery of the intervention across NI and the ROI and to decide whether to progress to a full-scale randomised trial at a later date.

Who can participate?
GP practices in Northern Ireland and the border counties of the Republic of Ireland, willing to take part in the study, the GPs who work there and adult patients over the age of 70 who take at least four different medications.

What does the study involve?
GPs who work at participating practices that consent to take part in the study will be assigned at random, that is, by a method of chance, into one of two groups to the intervention group or control group (usual care) (6 GP practices per group). GPs allocated to the intervention will be given access to the online video and asked to perform medication reviews with approximately 10 patients on two occasions. GPs allocated to the control group will continue with usual care. The video will be available to GPs on the internet and they can view it as often as they wish over a period of one year. Patients who are eligible to take part from the intervention group practices will be invited to attend an appointment with their GP at the start of the study and at six months into the study, during which their medication will be reviewed by their GP and discussed with them. Data will be collected from recruited GPs, recruited patients and practice records. Recruited patients will be asked to complete a number of questionnaires relating to their general well-being and use of the health service (e.g. hospital admissions) at baseline, six months and nine months post-initial medication review in the intervention arm and the equivalent time points in the control arm. Patient data (including medical history, clinical conditions, biochemical data (i.e. test results) and prescribed medications) will also be collected from GP records at baseline, six months and nine months post-initial medication review in the intervention arm and the equivalent time points in the control arm by a Research Nurse from the Northern Ireland
Clinical Research Network (NICRN Primary Care) or Trinity College Dublin (TCD).

At the end of the intervention, interviews will be conducted with up to 10 GPs and six members of practice staff (i.e. those involved in implementing the intervention within each practice) respectively in the six intervention arm practices. GPs will be asked about their views on the support provided by the research team; the intervention package (and supporting materials); study procedures (e.g. screening, recruitment etc.), while practice staff will be asked about their views on the study procedures (e.g. screening, recruitment etc.) and acceptability of the intervention. Patients from the six intervention group practices will be asked to complete a feedback questionnaire after the delivery of the intervention (i.e. after completion of their final follow-up questionnaires). Patients will be asked about their views on the study procedures (e.g. completing questionnaires, recruitment etc.) and acceptability of the intervention.

What are the possible benefits and risks of participating?
There is little risk to participants (GPs and patients) taking part in the study and participants can withdraw at any time. However, during the medication reviews that will be conducted, patients may become upset or distressed by prompting thoughts related to their health and the medicines that they take. Risk will be minimised by providing patients with a study information sheet and by having medication reviews performed by GPs who work in the patients' local general practice.
There is a risk that poor practice may be identified during the current study. We anticipate that this will be extremely rare, but we recognise that we need to be prepared for this. In the unlikely event that this occurs, any cases will be reported to the Chief Investigator (Hughes) who will, in the first instance, refer it to the health professionals concerned and if appropriate, to the appropriate regulatory authority. This procedure will have been outlined to participants in the information sheet for participation in the study and this has been standard practice in our previous studies.

Where is the study run from?
The study is run from Queen's University Belfast and Trinity College Dublin and will take place in 12 recruited GP practices in Northern Ireland and the border counties of the Republic of Ireland.

When is the study starting and how long is it expected to run for?
September 2019 to January 2022

Who is funding the study?
HSC R&D Division Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN), UK and Ireland

Who is the main contact?
Prof. Carmel Hughes
c.hughes@qub.ac.uk

———

Previous plain English summary:

Background and study aims
In the past, prescribing many medicines (polypharmacy) was seen in a negative light. However, because people are living longer and have a number of medical conditions at the same time, views on polypharmacy have changed. The challenge is to have the correct balance between enough medicines and too many medicines. Members of the research team have developed a new approach to achieving this balance. This approach has been tested in two general practices in Northern Ireland (NI). The approach (intervention package) currently consists of two parts: (1) a video showing how general practitioners (GPs) can prescribe appropriate polypharmacy for older patients, and (2) an appointment system for patients to visit a GP to have their medicines reviewed. As the intervention package was developed and tested in NI, further testing needs to be carried out in NI and the six border counties of the Republic of Ireland (ROI; Cavan, Donegal, Leitrim, Louth, Monaghan, and Sligo). This will be done in three stages or phases. In phase 1, which is now complete, 13 GPs were interviewed across 12 practices in the six border counties in the ROI; shown the video, asked about this new approach and asked if any changes are needed before doing more testing. In the next two phases (Phase 2 & 3) a small study will be carried out involving 12 practices: six practices in NI and six practices in the six border counties in the ROI and approximately 10 patients per practice. GP practices will either receive the intervention package and conduct medication reviews with recruited patients (intervention group) or continue to treat recruited patients as usual (control group). Interviews with up to 10 GPs and patients respectively in the six intervention group practices will also be conducted at the end of the intervention. The aim of the study is to test and compare the delivery of the intervention across NI and the ROI and to decide whether to progress to a full-scale randomised trial at a later date.

Who can participate?
GP practices in Northern Ireland and the border counties of the Republic of Ireland, willing to take part in the study, the GPs who work there and adult patients over the age of 70 who take at least four different medications.

What does the study involve?
GPs who work at participating practices that consent to take part in the study will be assigned at random, that is, by a method of chance, into one of two groups to the intervention group or control group (usual care) (6 GP practices per group). GPs allocated to the intervention will be

given access to the online video and asked two perform medication reviews with approximately 10 patients on two occasions. GPs allocated to the control group will continue with usual care. The video will be available to GPs on the internet and they can view it as often as they wish over a period of one year. Patients who are eligible to take part from the intervention group practices will be invited to attend an appointment with their GP at the start of the study and at six months into the study, during which their medication will be reviewed by their GP and discussed with them. Data will be collected from recruited GPs, recruited patients and practice records. Recruited patients will be asked to complete a number of questionnaires relating to their general well-being and use of the health service (e.g. hospital admissions) at baseline, six months and 12 months. Patient data (including medical history, clinical conditions, biochemical data (i.e. test results) and prescribed medications) will also be collected from GP records at baseline, six months and 12 months by a Research Nurse from the Northern Ireland Clinical Research Network (NICRN Primary Care) or Trinity College Dublin (TCD).

At the end of the intervention, interviews will be conducted with up to 10 GPs and patients respectively in the six intervention arm practices. GPs will be asked about their views on the support provided by the research team; the intervention package (and supporting materials); study procedures (e.g. screening, recruitment etc.), while patients will be asked about their views on the study procedures (e.g. screening, recruitment etc.) and acceptability of the intervention.

What are the possible benefits and risks of participating?
There is little risk to participants (GPs and patients) taking part in the study and participants can withdraw at any time. However, during the medication reviews that will be conducted, patients may become upset or distressed by prompting thoughts related to their health and the medicines that they take. Risk will be minimised by providing patients with a study information sheet and by having medication reviews performed by GPs who work in the patients' local general practice.
There is a risk that poor practice may be identified during the current study. We anticipate that this will be extremely rare, but we recognise that we need to be prepared for this. In the unlikely event that this occurs, any cases will be reported to the Chief Investigator (Hughes) who will, in the first instance, refer it to the health professionals concerned and if appropriate, to the appropriate regulatory authority. This procedure will have been outlined to participants in the information sheet for participation in the study and this has been standard practice in our previous studies.

Where is the study run from?
The study is run from Queen’s University Belfast and Trinity College Dublin and will take place in 12 recruited GP practices in Northern Ireland and the border counties of the Republic of Ireland.

When is the study starting and how long is it expected to run for?
September 2019 to September 2021

Who is funding the study?
HSC R&D Division Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN), UK and Ireland

Who is the main contact?
Prof. Carmel Hughes
c.hughes@qub.ac.uk

# Contact information

### Type(s)
Scientific


### Contact name
Prof Carmel Hughes

### ORCID ID
https://orcid.org/0000-0002-4656-6021

### Contact details
School of Pharmacy
97 Lisburn Road
Belfast
United Kingdom
BT9 7BL
+44 (0)2890 972147
c.hughes@qub.ac.uk


# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
NCT04181879

### Protocol serial number
B19/20

# Study information

### Scientific Title
A pilot cluster randomised controlled trial of a theory-based intervention to improve appropriate polypharmacy in older people in primary care

### Acronym
PolyPrime

### Study objectives
The overall aim of the study is to undertake a pilot cluster randomised controlled trial (cRCT) of a theory-based intervention targeting prescribing of appropriate polypharmacy in primary care (PolyPrime) to assess the feasibility of a definitive cRCT of the PolyPrime intervention

### Ethics approval required
Old ethics approval format

### Ethics approval(s)

1. Approved 05/06/2019, North of Scotland Research Ethics Committee 1 (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE; +44 (0)1224 558458; nosres@nhs.net), ref: 19/NS/0100
2. Approved 23/07/2019, Irish College of General Practitioners (ICGP) Research Ethics Committee (4/5 Lincoln Place, Dublin 2, Ireland; +353 (0)1 6763705; info@icgp.ie), ref: n/a

## Study design
Pilot cluster randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Multiple medications (polypharmacy) in older adults

## Interventions
Current interventions as of 09/12/2020:

Twelve GP practices will be recruited from Northern Ireland (NI) and the border counties of the Republic of Ireland (ROI; Cavan, Donegal, Leitrim, Louth, Monaghan and Sligo). The GP practices will be randomly assigned (6 GP practices per arm) to the intervention group or control group (usual care). Eligible GP practices will be allocated to intervention or control group by a Northern Ireland Clinical Trials Unit (NICTU) statistician using an automated randomisation system. Practices will be randomised on a 1:1 allocation ratio stratified by country (i.e. NI or ROI). GPs allocated to the intervention will be given access to the online video and asked to perform medication reviews with approximately 10 patients on two occasions. GPs allocated to the control arm will continue with usual care. A total of 120 patients (60 per study arm, 10 patients, randomly selected, per GP practice) will be enrolled into the study.

The existing intervention package consists of two components: (a) an online video demonstrating how GPs can improve appropriate polypharmacy during typical consultations with older patients; (b) a patient recall process (appointment with the GP for a medication review). Rather than introducing new tasks for GPs to perform, the video component seeks to enable GPs to use available time more efficiently by demonstrating how appropriate polypharmacy can be prescribed during routine consultations with older patients ('Modelling or demonstrating of behaviour') and emphasising the potentially positive consequences of performing this behaviour ('Salience of consequences'). The intervention seeks to introduce small, but potentially sustainable changes in GPs' current clinical practice aimed at improving prescribing for older people.

For those practices allocated to the intervention arm, the Research Fellow/Assistant will arrange a meeting at the practice to instruct GP participants on how to implement the intervention package. The video will be uploaded onto a secure web server and GPs in intervention sites will be asked to watch the video, which they will be able to access with site-specific usernames and passwords. GPs will have access to this video throughout the intervention delivery phase. The Research Fellow/Assistant will be fully contactable during the study to answer any questions or queries that participating GPs may have about accessing the video. As part of the patient recall process, GPs will make explicit plans of when and how they will ensure that eligible patients are prescribed appropriate polypharmacy, and will be prompted by reception staff to perform a

medication review when patients arrive for their appointments. This will involve designated practice staff screening practice records for patients meeting inclusion criteria, and issuing written invitations to patients to ask if they would be interested in taking part in the study. GPs in the intervention arm will be asked to schedule appointments with consenting patients (telephone or online consultations where a face-to-face consultation is not possible), while those in the control arm will continue with usual care. During these appointments, GPs will undertake medication reviews ('a structured, critical examination of a person's medicines with the objective of reaching an agreement with the person about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste') and arrange a six-month follow-up appointment with patients to conduct a second medication review.

Recruited patients (n=120) will be asked to complete questionnaires relating to their quality of life and health and social care use at baseline, six months' and nine months' post-initial medication review in the intervention arm and the equivalent time points in the control arm. The follow up time points for the control arm will be based on the average length of time from the completion of baseline data collection to six and nine months post initial medication review in the intervention arm. Data will also be extracted from recruited patients' medical records at baseline, six months' and nine months' post-initial medication review in the intervention arm and the equivalent time points in the control arm. The extracted data will include details of patient demographics (i.e. age, gender), medical history, clinical conditions, biochemical data (i.e. test results) and prescribed medications, both acute list items and repeat list items.

Analysis in relation to the outcome measures in this study (medication appropriateness, health-related quality of life, health and social care service use) will be largely descriptive as the trialists are not seeking to assess effectiveness of the intervention at this pilot phase of testing.
A process evaluation will be embedded in the study to (a) assess if the intervention was delivered by GPs and received by patients as intended (i.e. intervention fidelity), (b) assess the acceptability of the intervention to GPs, practice staff and patients and (c) to identify the intervention's likely mechanism of action. This will involve face-to-face qualitative interviews conducted with up to 10 GPs and six members of practice staff (i.e. those involved in implementing the intervention within each practice) respectively in the six intervention arm practices at the end of the intervention. Patients from the six intervention group practices will be asked to complete a feedback questionnaire after the delivery of the intervention (i.e. after completion of their final follow-up questionnaires). Furthermore, audio-recording of a medication review with one patient in each of the recruited GP practices (allocated to the intervention arm).

_____

Previous interventions:

Twelve GP practices will be recruited from Northern Ireland (NI) and the border counties of the Republic of Ireland (ROI; Cavan, Donegal, Leitrim, Louth, Monaghan and Sligo). The GP practices will be randomly assigned (6 GP practices per arm) to the intervention group or control group (usual care). Eligible GP practices will be allocated to intervention or control group by a Northern Ireland Clinical Trials Unit (NICTU) statistician using an automated randomisation system. Practices will be randomised on a 1:1 allocation ratio stratified by country (i.e. NI or ROI). GPs allocated to the intervention will be given access to the online video and asked to perform medication reviews with approximately 10 patients on two occasions. GPs allocated to the control arm will continue with usual care. A total of 120 patients (60 per study arm, 10 patients, randomly selected, per GP practice) will be enrolled into the study.

The existing intervention package consists of two components: (a) an online video demonstrating how GPs can improve appropriate polypharmacy during typical consultations with older patients; (b) a patient recall process (appointment with the GP for a medication review). Rather than introducing new tasks for GPs to perform, the video component seeks to enable GPs to use available time more efficiently by demonstrating how appropriate polypharmacy can be prescribed during routine consultations with older patients ('Modelling or demonstrating of behaviour') and emphasising the potentially positive consequences of performing this behaviour ('Salience of consequences'). The intervention seeks to introduce small, but potentially sustainable changes in GPs' current clinical practice aimed at improving prescribing for older people.

For those practices allocated to the intervention arm, the Research Fellow/Assistant will arrange a meeting at the practice to instruct GP participants on how to implement the intervention package. The video will be uploaded onto a secure web server and GPs in intervention sites will be asked to watch the video, which they will be able to access with site-specific usernames and passwords. GPs will have access to this video throughout the intervention delivery phase. The Research Fellow/Assistant will be fully contactable during the study to answer any questions or queries that participating GPs may have about accessing the video. As part of the patient recall process, GPs will make explicit plans of when and how they will ensure that eligible patients are prescribed appropriate polypharmacy, and will be prompted by reception staff to perform a medication review when patients arrive for their appointments. This will involve designated practice staff screening practice records for patients meeting inclusion criteria, and issuing written invitations to patients to ask if they would be interested in taking part in the study. GPs in the intervention arm will be asked to schedule appointments with consenting patients, while those in the control arm will continue with usual care. During these appointments, GPs will undertake medication reviews ('a structured, critical examination of a person's medicines with the objective of reaching an agreement with the person about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste') and arrange a six-month follow-up appointment with patients to conduct a second medication review.

Recruited patients (n=120) will be asked to complete questionnaires relating to their quality of life and health and social care use at baseline, six months' and 12 months' post-baseline. Data will also be extracted from recruited patients' medical records at baseline, six months' and 12 months' post-baseline. The extracted data will include details of patient demographics (i.e. age, gender), medical history, clinical conditions, biochemical data (i.e. test results) and prescribed medications, both acute list items and repeat list items.

Analysis in relation to the outcome measures in this study (medication appropriateness, health-related quality of life, health and social care service use) will be largely descriptive as the trialists are not seeking to assess effectiveness of the intervention at this pilot phase of testing. A process evaluation will be embedded in the study to (a) assess if the intervention was delivered by GPs and received by patients as intended (i.e. intervention fidelity) and b) to identify the intervention's likely mechanism of action. This will involve face-to-face qualitative interviews conducted with up to 10 GPs and patients respectively in the six intervention arm practices at the end of the intervention. Furthermore, audio-recording of a medication review with one patient in each of the recruited GP practices (allocated to the intervention arm).

## Intervention Type
Behavioural

## Primary outcome(s)

Current primary outcome measure as of 09/12/2020:

1. Recruitment: The number of patients and GP practices contacted and recruited. The retention rate of patients and GP practices at the end of the study
2. Health outcomes: Medication appropriateness assessed using STOPP/START criteria at baseline, six months' and nine months' post-initial medication review in the intervention arm and the equivalent time points in the control arm

---

Previous primary outcome measure:

1. Recruitment: The number of patients and GP practices contacted and recruited. The retention rate of patients and GP practices at the end of the study
2. Health outcomes: Medication appropriateness assessed using STOPP/START criteria at baseline, six months' and 12 months' post-baseline

## Key secondary outcome(s))

Current secondary outcome measures as of 09/12/2020:

1. Fidelity and mechanism of action (assessed at end of study):
1.1. The number of video view counts per GP participant for the online video
1.2. The numbers of appointments scheduled
1.3. The number of medication review appointments attended (first and second reviews)
1.4. The length of the medication reviews (based on audio-recordings of a selection of reviews with relevant consent)
1.5. The number of scheduled weekly meetings within each practice at which explicit plans were made to recall patients for medication reviews and the number of prompts made by reception staff (based on study-specific data collection forms)
2. Health economics (assessed at end of study):
2.1. The resource use and associated costs of the intervention
2.2. Participant health and social care service use over the study period as reported in GP notes and compared with self-reported health service use
3. Health-related quality of life measured using the EQ-5D-5L at baseline, six and nine months' post-initial medication review in the intervention arm and the equivalent time points in the control arm
4. Validation of the MRB-QoL tool: Medication-Related Burden Quality of Life measured using the MRB-QoL at baseline, six and nine months' post-initial medication review in the intervention arm and the equivalent time points in the control arm
5. Data to inform sample size calculation: Estimates of effect size between groups, cluster size and intraclass correlation coefficients (ICCs)

---

Previous secondary outcome measures:

1. Fidelity and mechanism of action (assessed at end of study):
1.1. The number of video view counts per GP participant for the online video
1.2. The numbers of appointments scheduled
1.3. The number of medication review appointments attended (first and second reviews)
1.4. The length of the medication reviews (based on audio-recordings of a selection of reviews

with relevant consent)
1.5. The number of scheduled weekly meetings within each practice at which explicit plans were made to recall patients for medication reviews and the number of prompts made by reception staff (based on patient electronic records)
2. Health economics (assessed at end of study):
2.1. The resource use and associated costs of the intervention
2.2. Participant health and social care service use over 12 months as reported in GP notes and compared with self-reported health service use
3. Health-related quality of life measured using the EQ-5D-5L at baseline, six and 12 months' post-baseline
4. Validation of the MRB-QoL tool: Medication-Related Burden Quality of Life measured using the MRB-QoL at baseline, six and 12 months' post-baseline
5. Data to inform sample size calculation: Estimates of effect size between groups, cluster size and intraclass correlation coefficients (ICCs)

### Completion date
31/01/2022

## Eligibility

### Key inclusion criteria
GP practices:
1. Provide written informed consent and Research Governance sign-off
2. Stable internet service in order to access the video

Patients:
1. ≥70 years of age
2. Receiving four or more regular medicines
3. Resident in the community
4. In receipt of a valid general medical services (GMS) card in the Republic of Ireland, or in the case of Northern Ireland patients, registered for NHS primary care services
5. Registered with and/or regularly attending the practice for a minimum of 12 months

### Participant type(s)
Mixed

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
All

### Total final enrolment
68

### Key exclusion criteria

GP practices:
1. Participating in other studies related to medicines management in older people

Patients:
1. Care home residents
2. Cognitively impaired
3. Terminal illness
4. Involved in other Investigational Medicinal Product (IMP) or medicines management studies

### Date of first enrolment
01/08/2019

### Date of final enrolment
28/02/2021

## Locations

### Countries of recruitment
United Kingdom

Northern Ireland

Ireland

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

### Study participating centre
**Trinity College Dublin**
School of Pharmacy and Pharmaceutical Sciences
Panoz Institute
Dublin
Ireland
D02PN40

## Sponsor information

### Organisation
Queen's University Belfast

**ROR**
https://ror.org/00hswnk62

# Funder(s)

**Funder type**
Government

**Funder Name**
HSC R&D Division Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN) Award (CHI/5431/2018)

# Results and Publications

**Individual participant data (IPD) sharing plan**
The current data sharing plans for this study are unknown and will be available at a later date

**IPD sharing plan summary**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 10/09/2022 | 12/09/2022 | Yes | No |
| Protocol article | Process evaluation | 14/07/2021 | 16/07/2021 | Yes | No |
| Protocol article | | 19/03/2021 | 05/08/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |