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The MultimorbiditY COllaborative Medication Review And DEcision Making (MyComrade) intervention: testing out a new programme to support general practitioners and practice-based pharmacists to review the medications prescribed to people with more than one long-term condition

Submission date
09/10/2019

Recruitment status
No longer recruiting

Registration date
04/11/2019

Overall study status
Completed

Last Edited
17/01/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims

It is common for people attending their GP to have many ongoing medical conditions. For example, a person attending their GP could have diabetes AND heart disease AND high blood pressure AND high cholesterol. This is a situation that is called multimorbidity, which means that a person is living with more than one long-term condition. When doctors follow guidelines for each condition, people who are living with more than one long-term condition can end up taking a large number of different medications each day. Sometimes the medications that are prescribed to help one condition can make another condition worse. In addition, some medicines can affect how other medicines work. Also, when a large number of medications are taken, the chances of medication side effects are much higher. Internationally, people are looking for new approaches to managing medications in multimorbidity. The researchers have studied how GPs make decisions about managing medications in people with more than one long-term condition. They found that GPs in this situation often speak with their GP colleagues to help them make the best treatment plan. In this study, they want to understand what happens when two colleagues review the medication list of a person with more than one long-term condition. MyComrade+ takes place in the Republic of Ireland and in Northern Ireland. In recent years, special pharmacists called practice-based pharmacists have been added to all primary care teams in Northern Ireland. As a result, the researchers can compare what happens when two GP colleagues pair up to review their patients' medication in the Republic of Ireland, with medication reviews between a GP and a PBP in Northern Ireland. This project is a pilot study, meaning the researchers will try out the MyComrade+ programme to see if GPs, PBPs and people living with multiple long-term conditions like and use the programme, and to work out

any problems. They will use the information we gather during the pilot study to plan a larger version of the MyComrade+ study in future to see if it can effectively improve the way medications are managed in primary care for people with multiple conditions.

Who can participate?
Patients aged 18 or over who have been prescribed 10 or more medications

What does the study involve?
People who have been prescribed 10 or more medications may receive a letter from their GP describing the study and inviting them to take part. Once up to 20 people have been recruited from each practice taking part in the study, the practices are randomly placed in the intervention group or a control group. In practices in the intervention group, participant's medications are reviewed by a pair of GPs in ROI or a GP/PBP pair in NI. Any possible changes to medications are talked about with participants before making any changes. This happens at the participant's next appointment with their GP. Participants do not have to do anything differently. For participants in the control group, the care they receive from their GP and PBP continues as normal. Participants in the medication review group or the control group are asked to complete two questionnaires at three different times during the study. The first set of questionnaires is completed when the participant first joins the study. Participants are sent two more sets of questionnaires to complete by post in about four months, and again four months after that. Participants are offered help to complete the questionnaires by telephone if they like. Through the questionnaires and participants' GP medical records, the researchers collect some information, like age, gender, diagnoses and list of medications. Some participants are also contacted after the study is finished to complete an interview about their experience of the study, and of living with more than one long-term condition.

What are the possible benefits and risks of participating?
There are some benefits that might be linked with taking part in this study. Participants may feel good about having a talk with their GP about their medicines, and about knowing that their primary care team are thinking about them and their treatment. It is hoped that the results of this study will help other people living with more than one long-term condition and their GP and PBP, as they work together to figure out the best plans for their medicines. The researchers will share the information from this study with everyone who takes part and with the wider medical community by writing articles and newsletters, and speaking at meetings and conferences. This study does not involve serious risks. Having medicines reviewed might cause participants some worry or anxiety. However, reviewing medications is an important part of getting good quality medical care and GPs will talk participants through any changes they think might be a good idea. The researchers will do their best to keep the information participants share with them during the study safe. It is possible that information about could be shared by accident during the study, but the researchers will do everything they can so that does not happen. For example, they will keep questionnaires locked in a locked cabinet, in a locked office.

Where is the study run from?
1. Queen's University Belfast (UK)
2. NUI Galway (Ireland)

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

Who is funding the study?
INTERREG Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN)

Who is the main contact?
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2. Dr Collette Kirwan, collette.kirwan@nuigalway.ie
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Additional identifiers

Protocol serial number
1.3

Study information

Scientific Title
MyComrade+: a pilot cluster randomised controlled trial, for patients with multimorbidity, of the MultimorbiditY COllaborative Medication Review And DEcision Making (MyComrade) intervention, use of practice based pharmacists (PBP's) or PBP's plus and adaptation of MyComrade

Acronym
MyComrade+

Study objectives
The primary objective of this study is to conduct, on the island of Ireland, a pilot cluster randomised controlled trial (cRCT) of the MyComrade intervention, involving pairs of general practitioners in the Republic of Ireland (ROI) and a GP and practice-based pharmacist (PBP) in Northern Ireland (NI). This will determine a proposed trial's broader feasibility and acceptability with GPs, PBPs and people living with two or more long-term conditions, potential efficacy and potential cost-effectiveness. Secondary objectives include an exploration using a mixed-methods approach of inter-operability in conducting research and managing medications between the two systems in ROI and NI, and building primary care research capacity on the island.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Republic of Ireland: Approved 05/12/2018, Research Ethics Committee of the Irish College of General Practitioners (ICGP) (4/5 Lincoln Place, Dublin 2, Ireland; Tel: +353 (0)1 6763705; Email: info@icgp.ie)
Northern Ireland: Approved 08/07/2019, Office for Research Ethics Committees Northern Ireland (ORECNI) (Customer Care & Performance Directorate, Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn BT28 2RF; Tel: +44 (0)28 95361407; Email: reca@hscni.net), REC ref: 19/NI/0120

Primary study design
Interventional

Study design
Multi-site cross-border pilot cluster randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multimorbidity

Interventions
MyComrade+ is a multi-site, cross-border pilot cRCT where GP practices are the units of randomisation (the clusters), and individual patients with multimorbidity (two or more long-term conditions) and polypharmacy (prescribed 10 or more repeat medications) are the units of

analysis (the participants). The researchers will enroll a total of 16 primary care practices (eight in ROI; eight in NI) and randomise practices to the intervention or control arm. In ROI the intervention arm will involve medication review using the MyComrade programme by pairs of GPs. In NI, medication reviews using the MyComrade+ programme will be conducted by a GP and PBP colleague. From each practice, 20 people living with multimorbidity and prescribed 10 or more repeat medications will be recruited (a total of 320 patients). Practice randomisation will take place once participants have been recruited, and practices will be block randomised. Participants will not be informed about practice allocation to the intervention or control group. Providers will be aware of practice allocation. The study statistician will be blinded to practice allocation.

The MyComrade+ intervention aims to support active medication reviewing by primary care providers (GPs and PBPs) by overcoming identified barriers, such as lack of treatment guidelines for multimorbidity, and lack of time. The MyComrade intervention is a complex intervention, which includes five behaviour change techniques selected from the Behaviour Change Technique (BCT) Taxonomy v1 (Michie et al., 2013), selected for the intervention to increase active medication reviewing in primary care. The principal BCT is collaborative peer-supported medication review, with two colleagues (GP pair; GP & PBP) reviewing the medications prescribed to a patient living with mutlimorbidity (BCT = practical social support). The other four techniques are (BCT in parentheses):
1. Using a prescribing checklist to guide the collaborative reviews (prompts and cues)
2. Developing a practice action plan for the reviews (action planning)
3. Allocating protected time to conduct the reviews (restructuring of the social environment)
4. Recording the activity towards annual appraisal requirements for continuing professional development and audit in clinical practice (self-incentives)
The prescribing checklist has seven points addressing multiple aspects of the prescription, and was adapted from the “NO TEARS” tool for medication review (Lewis, 2004).

In intervention practices, the research team will deliver an education session on the topic of multimorbidity and polypharmacy, and explain the MyComrade intervention. The education sessions in all practices will be audio-recorded to allow qualitative process evaluation of content and time required. The audio recordings will also be analysed for fidelity, comparing intervention implementation across and between ROI and NI. GPs and PBPs will be provided with a list of (up to) 20 patients prescribed 10+ medications who have consented to participate in the study.

Participating GPs and PBPs will schedule a time to discuss these patients' medications in pairs, using the adapted NO TEARS checklist to guide the discussion and noting any potential changes to medications on a hard copy of the checklist, which they will scan into the patient’s notes. Providers will be encouraged to complete 2-3 reviews per week, and reviews should be complete before the 4-month follow-up. A member of the research team who is also a GP will follow up 3 and 6 weeks after the education sessions to check-in regarding completion of reviews and address questions or concerns. The previous feasibility study (Sinnott et al., 2017) suggests that reviews will take approximately 10 minutes each. GPs will be advised to highlight any potential options for medication changes in the patients’ notes and discuss these with the patient at their next consultation, prior to making any changes.

In control practices in ROI, providers will receive the list of up to 20 consented participants but usual care will continue otherwise. In NI, providers will be given the list of consented patients. The PBP will conduct medication reviews according to their usual practice.

Participants will respond to brief questionnaires at baseline, and 4- and 8-months after randomisation. Qualitative and quantitative data will be gathered from participants and providers to examine the implementation and outcomes of MyComrade+.

Intervention Type
Behavioural

Primary outcome(s)
Completion of medication reviews by GP pairs in ROI and GP/PBP pairs in NI, recorded in the intervention booklet and verified by patient record at 4-month follow-up

Key secondary outcome(s)
1. Changes to number of repeat medications (additions and de-prescribing) measured by review of patient records at baseline, 4- and 8-month follow-up
2. Potentially inappropriate prescribing (PIP) assessed using a list of 10 indicators of PIP developed by Avery et al. (2012), at baseline, 4- and 8-month follow-up
3. Participant quality of life measured using the EQ-5D-5L at baseline, 4- and 8-month follow-up
4. Treatment burden measured using the Multimorbidity Treatment Burden Questionnaire (MTBQ) at baseline, 4- and 8-month follow-up

Completion date
15/06/2021

Eligibility

Key inclusion criteria
1. Prescribed 10+ repeat medications
2. Aged 18 years or over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Sex
All

Total final enrolment
121

Key exclusion criteria

1. Undergoing terminal illness care
2. Too frail to enter into an 8-month study
3. Currently pregnant
4. Does not have the cognitive capacity to take part in the study, e.g. cannot provide informed consent
5. Does not have the emotional capacity to take part in the study, e.g. dealing with a family crisis

Date of first enrolment
28/08/2019

Date of final enrolment
25/03/2021

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Ireland

Study participating centre
Queen's University Belfast
Whitla Medical Building
97 Lisburn Road
Belfast
United Kingdom
BT9 7BL

Study participating centre
NUI Galway
General Practice
School of Medicine
Clinical Sciences Institute
Galway
Ireland
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Sponsor information

Organisation
National University of Ireland, Galway

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Government

Funder Name
INTERREG Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Andrew Murphy (andrew.murphy@nuigalway.ie).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/10/2022	06/10/2022	Yes	No
Protocol article		28/03/2022	17/01/2024	Yes	No
HRA research summary			26/07/2023	No	No