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Improving medicines use in people who take multiple medicines

Submission date
19/03/2019

Recruitment status
No longer recruiting

Registration date
28/03/2019

Overall study status
Completed

Last Edited
21/10/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Polypharmacy (prescribing multiple medicines to one individual) is widespread and growing in the UK. About 6% of adults take over ten regular medicines. Although often clinically appropriate, polypharmacy may be problematic and lead to a range of adverse outcomes. Despite recent national guidance, there is a lack of evidence for medication optimisation interventions that improve outcomes. The aim of this study is to develop and evaluate an intervention to optimise medication use for patients with polypharmacy in a general practice setting.

Who can participate?
Adults with polypharmacy registered at participating practices who are identified by the IMPPP case finding tool (developed in Phase 1 of the study)

What does the study involve?
Participants are asked to complete study questionnaires related to their health and wellbeing, how they cope with their medicines and what treatments and other health services they use. Some participants are asked to attend a short 20-minute appointment at their general practice to talk about the medicines they are taking and how they are getting on with them. Participants who attend this appointment are asked to complete a questionnaire afterwards and will be offered a follow-up appointment 6 months later.

What are the possible benefits and risks of participating?
Participants may or may not directly benefit from taking part. The data that participants provide however could help other people in the future. There should be no disadvantages from taking part as the study follows the same NHS guidelines for prescribing and medicines use as those currently used in routine practice.

Where is the study run from?
The research is being run by the Centre of Academic Primary Care at the University of Bristol, with the Universities of Dundee and Keele (UK)

When is the study starting and how long is it expected to run for?
February 2019 to October 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Protocol serial number
University of Bristol ref. 2018-2188; 41260

Study information

Scientific Title
Improving Medicines use in People with Polypharmacy in Primary Care (IMPPP)

Acronym
IMPPP

Study objectives
The aim of the IMPPP study is to develop, implement and evaluate an intervention to optimise medication use for patients with polypharmacy in a general practice setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Provisional approval 27/03/2019 from Wales REC 6 (Fourth Floor, Institute of Life Science 2, Swansea University, Singleton Park, Swansea, SA2 8PP; Tel: +44 (0)1792 606334; Email: penny.beresford@wales.nhs.uk), IRAS ID: 238586, REC ref: 19/WA/0090

Study design
Two phases; comprising a pilot feasibility study followed by a multicentre cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Details of the randomisation process
Randomisation will be generated using a computer algorithm. Practices will not be informed of whether or not they will be intervention practices before agreeing to participate. As soon as invitations to potential participants have been sent in a pair of practices, the practices will be randomised, one to intervention and one to control. Practices will be randomised in blocks, so the numbers of invitees in practices recruited later will be adjusted according to response /exclusion rates in earlier practices.

The IMPPP intervention will be based in general practice, and will involve GPs and practice pharmacists working together, drawing on the specific skills of each professional sensitive to the context of each practice. This is a complex intervention and will comprise two key elements:
1. A model for conducting a polypharmacy medication review (including pharmacist-GP collaboration and case finding)
2. Components seeking to enhance professional engagement (education, practice feedback, financial incentives)
An informatics tool integrated into GP clinical systems will help support the medication review element as well as the practice feedback component

The researchers will develop the IMPPP approach based upon what they have learnt from similar approaches their team has used in Scottish GP surgeries. Firstly, they will test the IMPPP approach in 5 Bristol-based GP surgeries. They will interview individuals in these surgeries to find out about any problems with IMPPP so they can improve it. They will then carry out a clinical trial in Bristol and the West Midlands comparing 27 surgeries using IMPPP to 27 surgeries using current, normal practice. They will check whether IMPPP results in improved medicines safety, less use of health services, and better quality of life and less burden of treatment for the patients. They will also check whether IMPPP is acceptable to patients, doctors and pharmacists and will find out the cost implications of IMPPP for the NHS. The research will provide valuable information about which people with polypharmacy might benefit most from having improvements made to their medicines, and indicate what approaches work best for improving the use of medicines in people with polypharmacy, including how GPs and pharmacists can work together most effectively to achieve this.

All participants (intervention and control) will be followed up for a period of 6 months.

Intervention Type
Other

Primary outcome(s)
Potentially inappropriate prescribing captured via patient notes pre-randomisation (T1), immediately pre-intervention delivery (T2), immediately post-intervention delivery (T3) and follow-up at 6 months (T4)

Key secondary outcome(s)
1. Patient experience:
1.1. Quality of life (EQ-5D, SF-12), medication adherence (patient-reported), burden of treatment (MTBQ) and medication literacy captured via questionnaire pre-randomisation (T1), immediately pre-intervention delivery (T2) and follow-up at 6 months (T4)
1.2. Medication adherence (prescription refills) captured via patient notes pre-randomisation (T1), immediately pre-intervention delivery (T2) and follow-up at 6 months (T4)
2. Health service utilisation: unplanned hospital admissions, primary care consultation rate, other hospital utilisation data (A&E) other service use (social care, private, etc) captured via patient notes and questionnaire pre-randomisation(T1), immediately pre-intervention delivery (T2) and follow-up at 6 months (T4)
3. Patient/medication safety: medication-related admissions, inappropriate polypharmacy score, all-cause mortality captured via patient notes pre-randomisation(T1), immediately pre-intervention delivery(T2) and follow-up at 6 months (T4)
4. Experience of medication review captured via questionnaire pre-randomisation(T1) and immediately post-intervention delivery (T3)

Completion date
03/10/2023

Eligibility

Key inclusion criteria
Persons experiencing potentially problematic polypharmacy in primary care and community settings. This will specifically include “hard to reach” groups, including nursing home residents, housebound individuals, and those who lack capacity to consent (e.g. dementia).
The exact patient population will be defined as part of the case finding approach to be determined by the development phase (Phase 1) of the project. It is anticipated the case finding tool will identify older people (≥60 years) who are receiving 10 or more medications regularly on prescription. This is because people in this group are more likely than younger people on fewer medications to trigger at least one of the prescribing quality indicators (being defined within Phase 1) which will underpin the case finding approach.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1983

Key exclusion criteria
1. Individuals receiving end-of-life care
2. Patients judged by their GP to have chaotic medication use (e.g. history of drug or alcohol misuse)
3. The GP deems contact to be inappropriate; for example, due to severe mental health problems, terminal illness, recent bereavement
4. Participant is unable to complete the study questionnaires or medication review appointment (either themselves or with the help of carers)
5. Individuals planning to move GP practice within the 6-month follow-up period

Date of first enrolment
01/06/2019

Date of final enrolment
26/09/2022

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
NIHR CRN: West of England
Bristol
United Kingdom
BS1 2NT

Study participating centre
NIHR CRN: West Midlands
United Kingdom
CV3 2TX

Study participating centre
NIHR CRN: South West Peninsula
United Kingdom
TA6 4RN

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
Health Services and Delivery Research Programme

Alternative Name(s)

Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Participant consent for sharing of anonymised research data will be sought as part of the consent process. Sharing of anonymised data is optional. Anonymous research data will be stored securely at the University of Bristol (the data.bris Research Data Repository, https://data.bris.ac.uk/data/) and kept for future open access. At the end of the study, members of the trial management group will develop a data sharing policy consistent with UoB policy. Requests for access to data must be via written confidentiality and data sharing agreements (DSA) with the CI (or his appointed nominee). A protocol describing the purpose and methods intended must be provided. Requests for data release outside of the planned analyses will be considered by the trial steering committee. As data will be anonymised and identifiers destroyed, future linkage will not be possible.
The DSA will cover limitations of use, transfer to 3rd parties, data storage and acknowledgements. The person applying for use of the data will be scrutinized for appropriate eligibility by members of the research team. All requests will require their own separate REC approval prior to data being released.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/10/2025	21/10/2025	Yes	No
Protocol article		08/11/2022	06/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative study results	01/07/2024	09/09/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes