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Evaluation of the effectiveness and acceptability of the Bristol Medication Review toolkit

Submission date	**Recruitment status**	[X] Prospectively registered
16/05/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/06/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/07/2024	Other	[X] Record updated in last year

Plain English Summary

Background and study aims
At a medication review a patient meets a GP or pharmacist to discuss the medicines they are using. Medication reviews are important to check that the medicines a patient is taking are the right ones for their conditions. Reviews also check that medicines are being used safely and effectively. Medication reviews are part of normal health care for people taking medicines long-term. However, research shows that medication reviews do not always improve care. Also, patients are not always included in decisions about their medicines. The National Institute for Health and Care Excellence (NICE) gives advice and guidance to the NHS. NICE has said better medication reviews are needed and many doctors and pharmacists agree.
To improve medication reviews, researchers at the University of Bristol have developed the Bristol Medication Review toolkit. Doctors, pharmacists, patients and researchers worked together to develop the toolkit. The toolkit gives doctors and pharmacists advice about how to do a medication review. It also gives patients advice about how to get the most from a review. This study aims to find out if giving GP practices the Bristol Medication Review toolkit improves medication reviews, and to find out if patients, doctors and pharmacists find the toolkit easy to use.

Who can participate?
Patients aged 18 years and over receiving a structured medication review at participating practices

What does the study involve?
The study has three parts:
1. The researchers will give the Bristol Medication Review toolkit to around 500 GP practices across the UK and give advice on how to use it. They will speak to patients, GPs and pharmacists to make sure the toolkit is as useful as possible, and that practices know how to use it properly.
2. Over 1 year, the researchers will compare medication use in the 500 GP practices that are using the Bristol toolkit with 500 GP practices that are not using it. They will collect information recorded by doctors and pharmacists in GP practice computer systems. They want to find out if medicines are being used safely, and other things like the number of medicines being given to

patients. They will also look for any other changes in the use of health services (for example, hospital admissions).
3. The researchers will interview patients, doctors and pharmacists about their views and experiences of medication reviews. They will ask some doctors and pharmacists about their experience of using the Bristol toolkit. A survey will be sent to some patients to find out about their experiences with their medication review. The researchers will also audio-record some medication reviews, survey GP practices, and collect information from their computer systems, to find out how practices do medicine reviews, with and without the toolkit.

What are the possible benefits and risks of participating?
The results will help to find the best way to carry out medication reviews in the future. This will help ensure medicines are used safely and effectively. It will also make sure patients are fully involved in discussions about their medicines. If the toolkit is found to be helpful and easy to use, it will be simple to make it available to all GP practices. The findings will be shared with doctors, pharmacists, NHS managers and policymakers (who decide what health services are provided), and with other researchers. Patients and members of the public have helped with the design of the research and with the toolkit we are testing. They will also help carry out the research and share our findings in ways that everyone can understand.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
October 2023 to March 2026

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

Who is the main contact?
Dr Deborah McCahon, deborah.mccahon@bristol.ac.uk

Study website
https://brismed.blogs.bristol.ac.uk/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327920

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2023-1503, IRAS 327920, CPMS 61141

Study information

Scientific Title
Pragmatic evaluation of effectiveness and acceptability of the Bristol Medication Review toolkit

Acronym
BRISMED

Study hypothesis
The aim of this project is to address the research question “how does the Bristol Medication Review (BMR) toolkit compare with standard general practice care, in terms of clinical effectiveness, and acceptability to patients and practitioners?”

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/03/2024, West of Scotland Research Ethics Service (WoSRES) (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)1174554310; wosrec1@ggc.scot.nhs.uk), ref: 24/WS/0031

Study design
Large pragmatic randomized controlled trial

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 contact details to request a participant information sheet

Condition
Medication optimisation

Interventions
This is a large, highly pragmatic, cluster randomised controlled trial with an embedded mixed-methods process evaluation. The trial will be conducted in around 1,000 general practices in England contributing data to the Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC), based in Oxford. The trial will compare the BRISMED toolkit to usual clinical care.

Practices will be recruited before randomisation. Randomisation will be generated using a computer algorithm. Randomistion will be by Primary Care Network (PCN) rather than individual practice to reduce inter-arm contamination risk as practice pharmacists generally work within PCNs. Practices will not be informed of whether they will be in the intervention arm before agreeing to participate. It is not possible to blind practices to randomisation status after randomisation, and although patients could discover which arm their practice has been randomised to, we will not draw attention to this. Analysis will be conducted in a blinded manner.

The BRISMED toolkit will be provided electronically to 500 randomly selected practices, with practices able to implement any or all of the resources as they see fit.

Medication reviews are recommended for any patient receiving long-term medication, so there are no constraints on which patients need to be reviewed. The BRISMED toolkit will be used at intervention practices over a 12-month period.

A mixed-method process evaluation will be conducted in a sub-set of 56 practices (e.g. 28 intervention and 28 control sites) to understand users' experience of the reviews that are being carried out, to explain the success or otherwise of the intervention, and to explore its acceptability to users. Implementation and adoption of the Bristol toolkit will be evaluated by conducting surveys in all practices, and extracting relevant data from electronic health records. Patient surveys will also be undertaken in the subset of 56 practices participating in the process evaluation to evaluate patient experience and quality of life. Interviews will be undertaken with 22 patients and 22 clinicians to further assess patient and clinician views, and observations of reviews will be used to assess intervention fidelity.

Intervention Type
Other

Primary outcome measure

Potentially inappropriate prescribing (PIP) at 12 months will be assessed using routine electronic health records.

Secondary outcome measures
1. Number of long-term medicines currently used at 12 months, captured via routine electronic health records
2. Medication Treatment Burden at 12 months, measured using Multimorbidity treatment burden questionnaire (MTBQ)
3. Medication Regimen Complexity Index at 12 months, captured via routine electronic health records
4. Medication adherence at 12 months, captured via routine electronic health records
5. Quality of life at 3 months post-review, measured using the EQ5D-5L
6. Rates of medication review at 12 months, assessed via routine electronic health records
7. Health service utilisation including GP consultations and unplanned hospitalisation over the past 12 months, captured via routine electronic health records and Hospital Episode Statistics (national administrative records)
8. All cause mortality at 12 months captured via routine electronic health records and Hospital Episode Statistics (national administrative records)
9. NHS costs (i.e. sum of GP prescribing, consultations, and hospital use) assessed using routine electronic health records and Hospital Episode Statistics (national administrative records) at 12 months

Overall study start date
01/10/2023

Overall study end date
31/03/2026

Eligibility

Participant inclusion criteria
1. General practices using EMIS or SystmOne clinical systems, and contributing to the secure data processing environment of the nationally representative Oxford-Royal College of GPs Clinical Informatics Digital Hub (ORCHID), will be eligible to participate in the trial. All patients aged ≥18 years who have not registered with their practice an opt-out of sharing data outside of the practice for purposes of research or planning, will be included in the main trial analysis.
2. Within the 56 practices participating in the process evaluation, all adult patients (aged ≥18 years) receiving a structured medication review during four 2-week blocks within the 12-month intervention period will be sent a patient-experience questionnaire, and all adult patients receiving a review within the 12-month intervention period will be sent a quality of life questionnaire. Additionally, a smaller number of patients will be approached and invited to provide consent to participate in an interview.

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
The population under study in the main trial analysis will include approximately 8 million patients registered with 1000 GP England practices contributing to the secure data processing environment of the nationally representative Oxford-Royal College of GPs Clinical Informatics Digital Hub (ORCHID).Patient consent to participate in the main trial will not be specifically sought since this is a practice-level intervention and practices already contribute anonymised routine data to the ORCHID network.

Participant exclusion criteria
1. Patients aged 17 years and under
2. Patients who have registered with their practice an opt-out of sharing data outside of the practice for purposes of research or planning

Recruitment start date
01/07/2024

Recruitment end date
31/07/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR CRN: West of England
Whitefriars
Lewins Mead
Avon
Bristol
Uganda
BS1 2NT

Sponsor information

Organisation
University of Bristol

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Sponsor type
University/education

Website
https://www.bristol.ac.uk/red/research-governance/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The study protocol is not currently available as ethical approval of the study is not yet in place. The researchers intend to make the protocol available as soon as study approvals have been confirmed.

The researchers will co-produce press releases with patient and public contributors and distribute via print media, websites and relevant patient organisations. They will work with the Royal College of General Practitioners (RCGP) and Royal Pharmaceutical Society (RPS) to promote the research findings. They will work with both to identify opportunities for workshops to disseminate findings and discuss implementation strategies. Papers will be submitted to high-impact medical journals and presented at academic conferences (e.g. SAPC, NAPCRG). A synopsis including introduction with rationale for the research, summary sections related to each component of the research (each tied to one or more published papers), an overall narrative discussion, and final conclusion will be avilable on the NIHR website and published in the NIHR journal series.

Intention to publish date
01/03/2026

Individual participant data (IPD) sharing plan
Anonymous research data from the process evaluation (but not the main trial analysis) will be stored securely at the University of Bristol 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 University of Bristol policy. Requests for access to data must be via written confidentiality and data sharing agreements (DSA) with the CI Deborah McCahon (deborah.mccahon@bristol.ac.uk) (or 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 third parties, data storage and acknowledgements. The person applying for the 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
Available on request