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Evaluating the practicality of the 'My Medicines Journey' intervention for older people living with frailty and other long-term conditions

Submission date 15/01/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 21/01/2025	**Overall study status** Ongoing	
Last Edited 04/04/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The research is about a toolkit called ''My Medicines Journey'', designed to help older people living with frailty and other long-term conditions manage their medicines after leaving the hospital.

Who can participate?
This study targets men and women aged 75 and older who have been clinically assessed as living with frailty or other long-term conditions. Participants must be taking five or more regular medicines, have undergone at least one change to their medicines, have been medically optimised for discharge, and be returning home after hospitalisation.

What does the study involve?
The study will employ questionnaires to assess how the toolkit enhances post-discharge medicine experiences. It aims to foster collaboration between hospitals and community pharmacies to improve patient care. The pharmacy team will deliver the intervention, streamlining current processes without adding extra work for staff. Patients will receive information and a checklist to facilitate discussions with pharmacists. At the same time, the pharmacy team will assess patients' needs, develop plans in partnership with them, and share relevant information with community pharmacies. The research team will observe the process, ask staff questions, and conduct interviews to see how well the intervention fits into regular work and whether it is ready for a larger trial. Additionally, there will be a non-intervention component to gather data from a 'control group', aiding in planning a future trial.

What are the possible benefits and risks of participating?
The results of this study will improve the toolkit and implementation plan, ultimately leading to a proposal for a large-scale trial at multiple sites. This research can potentially assist individuals living with long-term conditions and their families in managing their medicines more effectively. It will also help healthcare professionals understand patients' medication management experiences. However, participants may face some burdens, such as fatigue from answering questionnaires or interview questions.

Where is the study run from?
The study is being conducted in England and will be managed by the Bradford Teaching Hospitals NHS Trust. It will take place across eight NHS sites throughout the country. The plan is to recruit 28 patients at each site over the course of four months, which averages to about two participants per week.

When is the study starting and how long is it expected to run for?
March 2024 to February 2026

Who is funding the study?
This study is funded by the National Institute for Health Research (NIHR).

Who is the main contact?
The study contact is Dr Justine Tomlinson, Assistant Professor in Medical Education at the University of Bradford; email j.e.c.tomlinson@bradford.ac.uk.

Contact information

Type(s)
Public

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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
345079

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 65550, NIHR205391

Study information

Scientific Title
Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: a multi-methods evaluation

Study objectives
This multi-method study aims to assess the feasibility of implementing our intervention within the current NHS provision and explore how contextual factors influence its uptake. The findings will inform the development of a subsequent multi-site randomised controlled trial (RCT) to test the intervention’s effectiveness and cost-effectiveness.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/02/2025, South West - Frenchay Research Ethics Committee (Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 2071048075; frenchay.rec@hra.nhs.uk), ref: 24/SW/0152

Study design
Non-randomized; Both; Design type: Process of Care, Education or Self-Management, Complex Intervention, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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
Ageing

Interventions
This is a mixed-method feasibility study of a co-designed intervention called the 'My Medicines Journey' toolkit. The aim is to support older people in better managing their medicines after hospital discharge. The intervention will be initiated in the hospital and continued after discharge with the patient's community pharmacy.

The intervention will be led by the pharmacy team and is designed to optimise existing processes rather than add more tasks for the team. However, both patients and pharmacy teams will play crucial roles in implementing the intervention.

-For the patient: They will be provided with information resources to prepare them to discuss their medicines with the pharmacist. They will also receive a checklist of what they need to know before discharge. A non-intervention arm (n=84) will be recruited to explore whether the outcome measures can be collected from a 'control' group to inform the future trial and boost our questionnaire sample size to enable PREM validation. This arm will receive usual care for that hospital ward but will additionally be asked to complete outcome measure questionnaires (e.g., baseline data, PREM, EQ-5D-5L, healthcare utilisation).

PREM 1 will be administered to the intervention two weeks after discharge, while PREM 2 will be administered three months after discharge. In addition, we shall invite up to 20 older people /carers who have used the intervention to take part in semi-structured interviews. These interviews will be conducted face-to-face or online (via Microsoft Teams or Zoom), depending on the participant's convenience, and will be facilitated by the research team. The control group (n=84) will be asked to complete patient surveys at the same time points, including PREMs, EQ5D5L, baseline data, healthcare utilisation, adherence, self-efficacy, and Medicines related problems (MRPs).

-For the pharmacy team: They will be expected to ask the patient about their medicines management/support needs at home, complete a short action plan with the patient for managing their new medications at home, and, if possible, allow the patient to self-administer one or two doses before going home so they can practice, and transfer information to the community pharmacy to initiate DMS. We shall also conduct staff observations at various times over eight (8) weeks at each site. In addition, we shall ask up to 30 hospital staff to complete a survey questionnaire. Furthermore, we shall ask up to twelve (12) hospital staff members to take part in semi-structured face-to-face or online (via Microsoft Teams or Zoom) interviews. For those who opt for face-to-face interviews, the research team will conduct them within the hospital setting.

We will ask four NHS sites, to each use a purposive sampling technique to recruit twenty-one (21) patients over a span of four (4) months, which averages out to about two (2) patients per

week (and accounts for attrition) following the eligibility criteria.
In summary, this mixed-method feasibility study is designed to test whether the pharmacy team can incorporate the intervention into their regular work, assess its positive and negative impacts, and determine whether progression criteria are met, indicating a move to full trial.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Rate of recruitment measured using Median Recruitment Rate (MRR) at months 1, 2, 3, 4, 5, and 6 of the overall recruitment period
2. Loss of follow-up at 2 months measured using the Percentage Method at 2 months post-discharge
3. Intervention delivery measured using observations and interviews at months 19, 20, 21, 22, 23 and 24 of the overall study period
4. Participation engagement with the intervention measured using routine data, observations, questionnaires and interviews at months 19, 20, 21, 22, 23 and 24 of the overall study period
5. Evidence of feasibility of collecting outcome measures measured using PREM questionnaires, EQ5D questionnaire, healthcare utilisation questionnaire, MARS_5 scale, SEAMS scale and MRP questionnaire at 2 weeks post-discharge and 3 months post-discharge

Secondary outcome measures
1. [PREM] measured using a questionnaire [2 weeks post-discharge and 3 months post-discharge].
2. [Quality of Life] measured using the EQ5D questionnaire [2 weeks post-discharge and 3 months post-discharge]
3. [Healthcare utilisation] measured using a healthcare utilisation questionnaire [2 weeks post-discharge and 3 months post-discharge]
4. [Adherence] measured using a MARS_5 scale [2 weeks post-discharge and 3 months post-discharge]
5. [Self-efficacy] measured using the SEAMS scale [2 weeks post-discharge and 3 months post-discharge]
6. [Medicines-related problems (MRPs)] measured using an MRP questionnaire [2 weeks post-discharge and 3 months post-discharge]

Overall study start date
01/03/2024

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. Aged 75 years plus
2. Living with frailty (based on clinical judgement)
3. Living with one or more long-term condition(s)
4. Using five or more regular medicines

5. Returning to a domiciliary setting
6. At least one medicine change during inpatient stay
7. Manage medicines without a formal social care package, i.e., the patient does not rely on formal paid carers for the administration of medicines

Participant type(s)
Patient

Age group
Senior

Lower age limit
75 Years

Sex
Both

Target number of participants
Planned Sample Size: 168; UK Sample Size: 168

Key exclusion criteria
1. Are on the End-of-Life pathway
2. Are discharged to a temporary care setting
3. Reside in a care home
4. Medicines are administered by formal paid care providers
5. Lack capacity (assessed by the care team and/or research nurse)

Date of first enrolment
10/04/2025

Date of final enrolment
10/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
To follow
United Kingdom
-

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

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Bradford Royal Infirmary
Duckworth Lane
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United Kingdom
BD9 6RJ
+44 1274 272575
jane.dennison@bthft.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.bradfordhospitals.nhs.uk/

ROR
https://ror.org/05gekvn04

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

We plan to publish the anonymised study results in high-impact, peer-reviewed scientific journals, internal reports, conference presentations, and on our website. The publication of results is planned for approximately one year after the overall study end date. The research team will also email a copy of the approved study results to all the participating sites. In addition, the study participants will be notified that they can request a copy of the study report or publications from the research team/CI. The research report or publications will be emailed to the interested participants after the Final Study Report has been compiled or after the results have been published.

Intention to publish date

01/03/2027

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be stored in a publicly accessible repository (ConnectedBradford/https://bradfordresearch.nhs.uk/connectedbradford/). Our objective is to ensure that our research data is easily discoverable and openly available to other researchers within our discipline and related fields, thereby fostering opportunities for reuse. Upon completion of the study, and following the analysis and dissemination of results, we will deposit the study data into the Connected Bradford repository. Both quantitative and qualitative anonymised datasets will be stored in this repository, facilitating secondary analysis by other researchers in accordance with the access criteria established by Connected Bradford. There will be an embargo period of up to two years on any publications, after which the data will become accessible to the broader research community via Connected Bradford. We will obtain informed consent from study participants to share anonymised data with other researchers, thus ensuring ethical compliance. The data will be securely maintained in accordance with Connected Bradford's policies. Following the conclusion of the project and the expiration of the two-year embargo, interested researchers will be required to follow Connected Bradford's access procedures to obtain the data.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.2	07/01/2025	16/01/2025	No	No