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Reducing medication-related harm in older people

Submission date	**Recruitment status**	[X] Prospectively registered
01/05/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
20/05/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
29/08/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Hospital discharge is a high-risk situation for experiencing medication-related harm (MRH). This may be due to side effects, consequences of not taking the medication, or medication errors. Older people at the point of discharge are at higher risk of medication-related harm (MRH). This is due to underlying health conditions, being on multiple medications, and changes in the way the body handles medication with older age. 1 in 3 adults aged 65 and over experience medication-related harm (MRH) in the 8 weeks after discharge, with half of these episodes being potentially preventable. A research team has developed a Risk Prediction Tool (RPT) which is the first objective approach to predict the absolute risk of an older adult experiencing MRH in the 8 weeks after discharge. This absolute risk is presented as a numerical score (percentage). NHS England acknowledged that risk-prediction tools can help in targeting appropriate interventions to those at the greatest risk of harm, and these high-risk groups are the ones most likely to benefit from such interventions. This study aims to reduce medication-related harm in older people after a hospital stay by improving the medicines information that a patient or their carer receives on discharge.

Who can participate?
Patients over the age of 65 years, admitted to an acute Elderly Care or General Medical Ward and likely to be discharged within 48 hours

What does the study involve?
Participants will have an equal chance of being allocated to the intervention group (additional information about their own risk and medications plus exchange of information between hospital pharmacists and community pharmacists) or to the usual care group (exchange of information between hospital pharmacists and community pharmacists). All study participants will have their risk related to their medicines calculated using the RPT. The study period is 8 weeks and will take place across multiple hospital sites. At the end of the 8 weeks, participants or their carers will be interviewed over the phone by the study pharmacist to identify if they have experienced MRH. If study participants were re-admitted to hospital in the 8-weeks period after joining the study, they will be assessed to check if the subsequent admission was due to MRH.

What are the possible benefits and risks of participating?
There are no foreseen risks to taking part in this study. Both groups will receive additional support in handling their medications in the 8-week period after leaving hospital through the NHS discharge medicines service. One group will receive additional medication information, support and advice just before discharge. Participants will be contributing to understanding how we can help protect patients from preventable harm.

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

When is the study starting and how long is it expected to run for?
April 2022 to December 2023

Who is funding the study?
Applied Research Collaboration Kent, Surrey, and Sussex (ARC KSS) (UK)

Who is the main contact?
Dr Khalid Ali
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
305313

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 305313, CPMS 52514

Study information

Scientific Title
Implementation of a medicine management plan (MMP) to reduce medication-related harm (MRH) in older people post-hospital discharge: a randomised controlled trial

Acronym
PRIME-3

Study objectives
Current risk stratification in clinical practice for MRH in older adults is based on clinical judgement. Clinical judgement is not useful in predicting medication-related harm (MRH). MRH risk prediction tools are not routinely used in clinical practice, as existing tools have not been assessed for impact and implementation. The PRIME tool has been transparently developed and validated. To satisfy the next stage of risk-prediction model creation, the impact of the tool will be assessed on a new sample of individuals. Targeted interventions at high-risk individuals may be a clinically and cost-effective solution in reducing rates of MRH in older adults. The PRIME team in collaboration with AHSN-KSS will implement a risk-stratification approach linked with the NHS DMS. The study will recruit patients aged 65 and older discharged from four NHS trusts. The control arm will consist of NHS DMS care only. The intervention arm will consist of NHS DMS with a specific medicines management plan (MMP) develop by the team in consultation with patients and carers. The MMP will be made of:
1. A copy of the discharge summary
2. Specific education about possible medication-related harm from the discharge medications. Education will be delivered by the ward pharmacist and/or the ward doctor at the point of discharge.
3. Clear guidance on who to contact (their GP or their community pharmacist) if they experience any MRH.
4. The name and contact of the community pharmacist will be provided by the ward pharmacist.
5. A copy of the percentage/probability of harm from medication calculated using the PRIME study RPT, and presented as a visual analogue scale will be offered to patients and (if available) their carers. See Appendix for document.

Research Question:
Will a Medicines Management Plan linked to the NHS DMS be more effective than the NHS DMS alone in reducing rates of MRH?

Objectives:
1. To measure and compare the rates of MRH in the two groups.
2. To measure the costs of delivering the intervention and any associated MRH-related service use in the two groups across the 8-week study period. To perform modelling to provide national cost estimates.
3. To undertake a process evaluation.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 22/03/2022, North West Haydock Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048211, +44 (0)2071048375, +44 (0)2071048248; haydock.rec@hra.nhs.uk), ref: 22/NW/0075

Study design
Multicenter interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Reducing medication-related harm (MRH) in older adults within 8 weeks post-discharge from the hospital

Interventions
Participants will undergo simple randomization into the two arms: a control arm and an intervention arm.

Participants in the control arm will receive the existing NHS Discharge Medicines Service, where patients are given information based on the pharmacists' assessments of the discharge medications patients will be taking home.

The intervention arm will receive the MMP consisting of:
1. A copy of the discharge summary
2. Specific education about possible medication-related harm from the discharge medications. Education will be delivered by the ward pharmacist and/or the ward doctor at the point of discharge.
3. Clear guidance on who to contact (their GP or their community pharmacist) if they experience any MRH.
4. The name and contact of the community pharmacist will be provided by the ward pharmacist.
5. A copy of the percentage/probability of harm from medication calculated using the PRIME study RPT, and presented as a visual analogue scale will be offered to patients and (if available) their carers

Participants will be followed up for 8 weeks to find out how many had medication-related harm over the 8 weeks period post-discharge.

Intervention Type
Other

Primary outcome measure
The number of participants that had medication-related harm who had only the NHS-discharge medicines services (DMS) and the number of participants with medication-related harm who had both the NHS-DMS with the medicines management plan (MMP), measured using a phone interview at the end of the 8-week period

Secondary outcome measures
1. The acceptability of the control and intervention arm among clinicians, service providers, researchers and other health workers involved in discharge planning assessed through focus group interviews during the study period
2. The cost-effectiveness of the intervention will be measured using economic analysis estimating the resources involved in delivering the intervention and treatment of medication-related harm within 8 weeks post-discharge

Overall study start date
01/04/2022

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Patients must be over the age of 65 years at the time of recruitment, admitted to an acute Elderly Care or General Medical Ward
2. Patients to be identified when they are likely to be discharged within 48 hours
3. Patients need to be registered with a General Practitioner within the areas covered by the recruiting hospitals
4. Informed written consent must be provided from patients with capacity OR personal consultees acting on behalf of patients without capacity

Participant type(s)
Patient

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
684

Total final enrolment
682

Key exclusion criteria

1. Patients lacking capacity and have no consultee to advise
2. Patients that are transferred to other acute healthcare trusts (but excluding step down or intermediate care facilities)
3. Patients who have a short life expectancy, due to a terminal illness
4. Patients who are unable to read/speak/understand English

Date of first enrolment
17/06/2022

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Sussex County Hospital Laboratory
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Royal Devon & Exeter Foundation Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre

Eastbourne District General Hospital
Kings Drive
Eastbourne
United Kingdom
BN21 2UD

Study participating centre
Ormskirk & District General Hospital
Wigan Road
Ormskirk
United Kingdom
L39 2JW

Study participating centre
Princess Royal Hospital
Lewes Road
Haywards Heath
United Kingdom
RH16 4EX

Study participating centre
Royal Berkshire & Battle Hospital (berkshire West Site)
London Road
Reading
United Kingdom
RG1 5AN

Sponsor information

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University of Sussex

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Sponsor type

University/education

Website
http://www.sussex.ac.uk/

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Research organisation

Funder Name
Applied Research Collaboration Kent, Surrey, and Sussex (ARC KSS)

Results and Publications

Publication and dissemination plan
Both protocol and the study results paper will be submitted for publication to an open-access journal to maximise reaching a wide audience. The protocol will be published within 3 months of the study starting and the study results paper, as well as being presented at scientific conferences, will be published within 18 months of the study starting.

The academic community will be informed about the study through the research team links with the KSS-CRN, the National Ageing Research Network, and the BGS. The chief investigator (CI) is the ageing specialty lead in KSS-CRN and well placed to report study outputs to the national and international scientific community. Dissemination activities will be supported by University of Sussex Impact Acceleration team.

The study participants, the KSS academic community, the national aging speciality group and the care home community (via the Enabling Research in Care Homes (ENRICH) platform) will be notified of study updates with a newsletter every 4 months. During the study, if new information relevant to continued participation becomes available during the study period, then the study team will send this information to the participant through their preferred choice (email or post). We consider this an unlikely possibility; this study trials a one-off intervention rather than a continuous one, and there will be no interim analyses.

The findings will be disseminated in collaboration with several organisations: the Brighton and London Chapters for ''Ageing 2.0; the Ageing Well: Changing the conversation platform''; the KSS AHSN and national AHSN network; the National Medicine Optimisation Network; the KSS Chief Pharmacy network; the KSS Medicine Safety Network and the NHS Improvement Patients Safety Collaborative Medicine Safety Programme. Additionally, the study team have connections with Healthwatch Brighton & Hove and the U3A group.

The service evaluation of the proposed study will provide knowledge of the enablers and barriers to scale up the study regionally and nationally. The National Adoption committee will work with Policy@Sussex and the ARC-KSS to continue to build awareness about the study and its findings. To sustain the impact of the study beyond the life of the study itself, we will continue working with the study partners, their organisations and commissioning groups in Sussex and nationwide to lobby for wider national implementation of the study findings.

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
Data sharing will be anonymised data of participants and will be available on request to the corresponding author Dr Khalid Ali via (khalid.ali10@nhs.net). Data will be available to the public after the publication of the findings of the study. Data has been anonymized and consent for publication has been sought from all study participants during recruitment. There are no ethical or legal restrictions associated as per the ethical clearance received from the HRA - ethics committee review.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	16/03/2022	11/05/2022	No	Yes
Protocol file	version 10	16/01/2022	11/05/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol article		11/11/2022	29/08/2025	Yes	No
Statistical Analysis Plan	version 10	16/01/2022	29/08/2025	No	No