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A study evaluating an intervention for doctors and pharmacists working in older people's medicine wards in hospitals in England, to review and stop medicines no longer needed or where the risk of harm outweighs the benefit

Submission date	**Recruitment status**	[X] Prospectively registered
17/05/2023	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/07/2023	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/07/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

As we get older, our bodies are less able to handle some medicines. Medicines that were once effective and safe may not have as much benefit and may have an increased chance of causing harm. Research shows that almost half of older people in hospitals are prescribed a medication with a risk of harm, but these medicines are rarely stopped. In previous research, the study team asked older people and their carers about their thoughts on stopping these medicines. The team were told that they would like these medicines reviewed by doctors in the hospital during their stay and for those no longer needed or that could cause harm to be stopped. This is called 'proactive deprescribing' and is different to stopping a medicine after harm has occurred. To make this happen, changes to doctor and pharmacist behaviour are needed so that the idea of stopping medicines is more likely to be discussed with patients. The CHARMER (CompreHensive geriAtRician led MEdication Review) Programme has been funded by the NIHR and will develop and test a way to support geriatricians (doctors working on older people's medicine wards) and hospital pharmacists to proactively deprescribe for older people whilst they are in hospital. The study team have already explored the reasons why geriatricians and hospital pharmacists do not proactively deprescribe for older people, working with doctors, pharmacists and patients/carers. This work has been used to develop an intervention to support and encourage proactive deprescribing and this was tested in a feasibility study.

Who can participate?

Geriatricians or pharmacists working in older adult medicine wards in acute hospitals in England will take part.

Patients receiving care or participating study wards during the data collection phase will be eligible to take part.

What does the study involve?
Geriatricians and pharmacists at 20 hospitals will receive the intervention. Participating sites will take part in the study for 21 months.

What are the possible benefits and risks of participating?
Clinician participants - The intervention training includes time to work with geriatrician and pharmacist colleagues to optimise patients' medicines, which may be beneficial to patients being treated by participating clinicians. The intervention training may also contribute to personal and professional development. Patient participants - we do not anticipate that there are any benefits personally to patients by participating in the study. The CHARMER intervention has the potential to benefit patients in hospitals by supporting clinicians caring for them to stop medicines that may cause harm. Stopping medicines should also reduce the medicine administration burden and potentially improve medication adherence. Their assistance will help the research team to understand if the intervention may be helpful for patients in the future.

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

When is the study starting and how long is it expected to run for?
December 2022 to December 2026

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

Who is the main contact?
Prof. Debi Bhattacharya, d.bhattacharya@leicester.ac.uk

Study website
https://charmerstudy.org/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
323504

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
0920, CPMS 56862, IRAS 323504

Study information

Scientific Title
Stepped wedge design definitive study, with an internal pilot, of a hospital-based behaviour change deprescribing intervention to estimate effectiveness, cost-effectiveness, and safety

Acronym

CHARMER Definitive Trial

Study objectives
The CHARMER intervention reduces hospital readmission rate at 90 days post discharge

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/07/2023, Wales REC 2 (Health and Care Research Wales, Castlebridge 4, Cardiff, CF11 9AB, United Kingdom; +44 (0)2922 941119; Wales.REC2@wales.nhs.uk), ref: 23/WA/0184

Study design
A stepped wedge design definitive study

Primary study design
Interventional

Secondary study design
Stepped wedge

Study setting(s)
Hospital, Internet/virtual, Telephone

Study type(s)
Prevention, Quality of life, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patients who are over 65 and prescribed at least one potentially inappropriate medicine where the likely harms outweigh the benefits.

Interventions
Current interventions as of 03/07/2025:
This is a stepped wedge trial (with an internal pilot study) of a deprescribing behaviour change intervention targeting geriatricians and pharmacists caring for people admitted to older people's medicine wards.

The deprescribing intervention developed and refined in earlier CHARMER studies will be compared to usual care in older people's medicine wards at twenty hospital sites in England. Twenty-four hospitals will be recruited and collect data, to ensure that should hospital sites drop out during the study, the study will continue to have sufficient sample size to answer the principal research question. The aim of this definitive trial is to test the intervention on a large scale with the feasibility study refinements.
The study will include an evaluation of the trial design and a process evaluation.

Twenty-four sites will be selected from expressions of interest who meet the site criteria:
1. Hospitals providing acute Older People’s Medicine ward

2. Hospitals willing and able to implement the intervention into routine care
3. A named person willing and appropriate to take Principal Investigator responsibility
4. A minimum of one geriatrician and one pharmacist willing to be recruited to receive the intervention.
5. Suitably trained staff available to recruit patients and enter data
6. The hospital has an electronic prescribing system
7. The hospital has availability of a project manager at site

Patient data collection
All patients receiving care from clinicians on the study ward for the duration of the study will be enrolled. Routine data collection from site medical records will be collected for all patients by suitably trained site staff unless individual patients have chosen to opt-out. This will include admission and discharge dates, age, gender, and ethnicity. Identifiable data for each patient enrolled will be stored at the site for the purposes of accurate data linkage for study outcomes. Pseudonymised (no identifiers, with study ID only) data will be uploaded to the study database at Norwich Clinical Trials Unit.

To enable the collection of data for secondary study outcomes, during the control and intervention phases, there will be a 6-week period of enhanced data collection at 20 sites. This will include more detailed data from site records e.g. primary diagnosis, co-morbidities, medication on admission and at discharge and discharge destination.
During this period and prior to patient discharge from the hospital, a suitably trained member of site staff will approach patients for informed consent for patient-reported outcomes, GP records data, process evaluation interviews and data linkage of patient-reported outcomes and GP records data to national datasets (HES, mortality and prescription data) held by NHS England. The informed consent process with each patient will include a capacity assessment by trained site staff and where the participants are assessed as not having the capacity to consent site staff will seek advice from a consultee (personal consultee if possible or professional where the patient is a care home resident, and no personal consultee is available).

Following consent and prior to discharge from the hospital, patients or consultees where appropriate, will be asked to complete quality of life questionnaires (EQD-5L) with site staff at the bedside. At the same time, consenting patients who have experienced proactive deprescribing (a medicine being stopped) during the admission (or consultees where appropriate) will be asked to complete a questionnaire recording their satisfaction with the deprescribing process. This will be completed with a member of the research team or printed for them to complete on their own to reduce the burden and potential bias in reporting where patients may feel uncomfortable reporting dissatisfaction with the process to staff involved in their clinical care.

At 12 weeks post-discharge, consenting patients or consultees where appropriate, will re-complete quality of life questionnaires (EQ5D-5L) and an adverse drug events questionnaire to assess the presence or absence of common drug side effect symptoms over the preceding month. Patients will also be asked about their use of primary care services over the preceding month.
Once all site-collected data and follow-up data are entered into the study REDCAP database, sites will transfer patient identifiers for all patients receiving care on the study wards during the active study window to the lead NHS site - Norfolk and Norwich NHS Foundation Trust data haven via secure N3 connection.

Identifiers will not be available to the research team except where patients have provided informed consent and will be used for the purposes of arranging follow-up study activities or communicating important study information only.

The patient identifiers will be transferred to NHS England via a secure N3 connection by Norfolk and Norwich NHS Foundation Trust.
When national data is available for research use for 4 months after the active study window end, NHS England will perform the data linkage between the study dataset, HES admitted patient data (for readmissions), ONS data (mortality) and prescribing datasets (to assess medication changes in primary care post discharge i.e. whether deprescribing was sustained). Patient identifiers will be removed once data linkage is complete, and the data returned to Norwich Clinical Trials Unit for analysis.

Clinician data collection
During the implementation and intervention steps, a minimum of 20 and up to 24 sites will undertake the set-up and implementation of the intervention and clinician recruitment. A minimum of one geriatrician and one pharmacist will be approached by each site PI and consented at sites to receive the CHARMER intervention and complete clinician study activities.

Consenting clinicians will complete a demographics questionnaire providing details of age gender, job role, years in role, previous training in deprescribing and a Mechanism of Action questionnaire (which measures the extent to which they feel that known barriers and enablers to deprescribing affect them) prior to receiving the CHARMER intervention.

Once clinicians have received the intervention, they may begin to make use of the training received as part of their daily clinical practice. NB The intervention does not direct clinical decision-making regarding whether to proactively deprescribe. This will remain a clinical decision based on a partnership between the patient, prescriber, and (if appropriate) the consultee. The decision will be based on both the clinical picture and individual preference.

Evaluation of the intervention on clinical behaviour and patient outcomes will begin in a staggered process between month 7 and month 16 and the active study window at sites will last between 12 and 48 weeks depending on the group they are in within the stepped wedge design. Clinician participants will repeat the Mechanism of Action questionnaire during the active study window.

Process evaluation
A process evaluation is embedded in this study. The process evaluation will explore how the intervention components are delivered (what was delivered and received and by whom). Consenting patients or consultees where appropriate, participating clinicians, research and development staff at sites, project managers, and site Principal Investigators will be recruited to participate in the process evaluation. Staff with a prescribing role in primary care whose patient has been recruited to the study will also be approached for participation in the process evaluation. This will support the understanding of any impact of the intervention in primary care and enable the inclusion of primary care clinician perspectives

Activities will comprise:
Audio/visual recording of implementation sessions of the CHARMER intervention at sites
Interviews to explore the process and impact of the CHARMER intervention. Interviews will take place during the follow-up period and will take place face-to-face, by telephone or virtually. Observations and interviews will be conducted by the research team.

Previous interventions:
This is a stepped wedge trial (with an internal pilot study) of a deprescribing behaviour change intervention targeting geriatricians and pharmacists caring for people admitted to older people's medicine wards.

The deprescribing intervention developed and refined in earlier CHARMER studies will be compared to usual care in older people's medicine wards at twenty hospital sites in England. Twenty-four hospitals will be recruited and collect data, to ensure that should hospital sites drop out during the study, the study will continue to have sufficient sample size to answer the principal research question. The aim of this definitive trial is to test the intervention on a large scale with the feasibility study refinements.
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4. A minimum of one geriatrician and one pharmacist willing to be recruited to receive the intervention.
5. Suitably trained staff available to recruit patients and enter data
6. The hospital has an electronic prescribing system
7. The hospital has availability of a project manager from local QI or transition teams

Patient data collection
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To enable the collection of data for secondary study outcomes, during the control and intervention phases, there will be a 4-week period of enhanced data collection at 20 sites. This will include more detailed data from site records e.g. primary diagnosis, co-morbidities, medication on admission and at discharge and discharge destination.
During this period and prior to patient discharge from the hospital, a suitably trained member of site staff will approach patients for informed consent for patient-reported outcomes, GP records data, process evaluation interviews and data linkage of patient-reported outcomes and GP records data to national datasets (HES, mortality and prescription data) held by NHS England. The informed consent process with each patient will include a capacity assessment by trained site staff and where the participants are assessed as not having the capacity to consent site staff will seek advice from a consultee (personal consultee if possible or professional where the patient is a care home resident, and no personal consultee is available).

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intervention components are delivered (what was delivered and received and by whom). Consenting patients or consultees where appropriate, participating clinicians, research and development staff at sites, project managers, and site Principal Investigators will be recruited to participate in the process evaluation. Staff with a prescribing role in primary care whose patient has been recruited to the study will also be approached for participation in the process evaluation. This will support the understanding of any impact of the intervention in primary care and enable the inclusion of primary care clinician perspectives

Activities will comprise:
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Intervention Type
Behavioural

Primary outcome measure
Patient readmission to the hospital measured using Hospital Episode Statistics (HES) data 90 days post hospital discharge

Secondary outcome measures
Patient-oriented secondary outcomes measures:
1. Mortality is measured using the Office of National Statistics (ONS) records 90 days post-hospital discharge
2. The number of hospital stays post-discharge is measured using Hospital Episode Statistic (HES) data 90 days post-hospital discharge
3. Quality of life is measured using the EuroQol EQ-5D-5L validated questionnaire at discharge and 90 days post-hospital discharge
4. Satisfaction with deprescribing is measured using a 13-item bespoke questionnaire as soon as possible post-hospital discharge

Process secondary outcomes measures:
1. Number of regularly prescribed medicines at the point of leaving the ward is measured using site medical records at discharge
2. Number of prescribed medicines for 'when required use' at the point of leaving the ward is measured using hospital site medical records at discharge
3. Number of prescribed medicines that are stopped is measured using hospital-site medical records at discharge
4. Number of prescribed medicines with dosage reduced is measured using hospital site medical records at discharge
5. Number of stopped medicines that are restarted within three months of discharge is measured using community pharmacy dispensed medicines data 6. 90 days post-hospital discharge

Economic secondary outcomes measures:
1. Costs/resource use for the intervention is measured using the fidelity framework/expert-opinion/study records during active study periods
2. Length of hospital stay for index admission is measured using site medical records at hospital

discharge
3. Number of admissions in the follow-up period is measured using routine data at the end of the study

Overall study start date
01/12/2022

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/10/2024:
Practitioner inclusion criteria:
Consultant Geriatrician or Specialist Registrar and appropriately qualified Pharmacist working across Older People's Medicine wards

Patient inclusion criteria:
All patients receiving treatment in the study wards within the study window and under the care of a participating Geriatrician.

Previous inclusion criteria:
Practitioner inclusion criteria:
Consultant Geriatrician or Specialist Registrar and appropriately qualified Pharmacist working across Older People's Medicine wards

Patient inclusion criteria:
All patients receiving treatment in the study wards within the study window

Participant type(s)
Patient, Health professional, Carer

Age group
Adult

Sex
Both

Target number of participants
42,995

Key exclusion criteria
Current exclusion criteria as of 11/10/2024:
Practitioner exclusion criteria:
Less than0.3FTEof ward-based time

Patient exclusion criteria:
Not under the care of a participating Geriatrician

Previous exclusion criteria:
Practitioner exclusion criteria:
Less than0.3FTEof ward-based time

Date of first enrolment
01/02/2024

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Blackburn Hospital
Haslingden Road
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BB2 3HH

Study participating centre
University Hospitals Plymouth NHS Trust
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PL6 8DH

Study participating centre
East Surrey Hospital
Canada Avenue
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RH1 5RH

Study participating centre

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Minerva Road
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Anlaby Road
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HU3 2JZ

Study participating centre
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Lancaster Park Road
Harrogate
United Kingdom
HG2 7SX

Study participating centre
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Greetwell Road
Lincoln
United Kingdom
LN2 5QY

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
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Southampton
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Study participating centre
Royal Liverpool University Hospital NHS Trust
Royal Liverpool University Hospital
Prescot Street
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rgosponsor@le.ac.uk

Sponsor type
University/education

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

ROR
https://ror.org/04h699437

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
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/07/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to data sharing restrictions as part of section 251 approval and NHS England governance requirements.

IPD sharing plan summary

Not expected to be made available