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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
21/02/2022		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/05/2022	Ongoing	[X] Results		
Last Edited	Condition category	[] Individual participant data		
02/12/2025	Other			

# 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 hospital are prescribed a medication with a risk of harm, but these medicines are rarely stopped.

In our previous research we asked older people and their carers about their thoughts on stopping these medicines. They told us that they would like these medicines reviewed by doctors in 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 we need to change doctor and pharmacist behaviour 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.

We have already explored the reasons why geriatricians and hospital pharmacists do not proactively deprescribe for older people, working with doctors, pharmacists and patients/carers. We have used this work to develop an intervention to support and encourage proactive deprescribing and will test this in a feasibility study.

Who can participate?

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

What does the study involve?

Geriatricians and pharmacists at 3 hospitals will receive the intervention and those at the 4th will not, they will be the control hospital. We will test the intervention for 4 weeks in the hospitals. The findings from this will be used to design a larger, definitive study.

What are the possible benefits and risks of participating? None

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

When is the study starting and how long is it expected to run for? February 2022 to March 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

# Contact information

## Type(s)

Principal investigator

#### Contact name

Prof Debi Bhattacharya

#### Contact details

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# Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

312494

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

**CPMS 52420** 

# Study information

#### Scientific Title

Two arm, open, purposive allocation feasibility study of a deprescribing behaviour change intervention for use by physicians and pharmacists with acute patients admitted to secondary care geriatric wards

#### Acronym

**CHARMER** 

#### Study objectives

The aim of this feasibility study is to inform the development of the definitive trial protocol for CHARMER by testing on a small-scale, the feasibility and acceptability of delivering and evaluating the CHARMER intervention.

#### Ethics approval required

Ethics approval required

#### Ethics approval(s)

approved 07/04/2022, Wales REC 1 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0) 1792 606334; Wales.REC1@wales.nhs.uk), ref: 22/WA/0087

#### Study design

Two arm open purposive allocation feasibility study

### Primary study design

Interventional

#### Study type(s)

Other

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

Evaluation of a deprescribing intervention for geriatricians and pharmacists in older adult medicine setting in acute hospitals in England

#### **Interventions**

Current interventions as of 22/05/2023:

A theory and evidence-based intervention have been developed to address the barriers and enablers to geriatricians and pharmacists proactively deprescribing medicines in hospitals. The deprescribing intervention developed and refined in earlier CHARMER studies will be compared to usual care in older people's medicine wards at four hospital sites in England. The aim of this feasibility study is to inform the development of a definitive trial protocol to evaluate the intervention, by testing the feasibility and acceptability of delivering the intervention and trial.

During months 1 and 2, intervention sites will undertake the setup and implementation of the intervention and clinician recruitment. 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 month 3 and be monitored for 4 weeks. Three-month follow-up data from NHS Digital is expected in August/September 2023.

#### Previous interventions:

A theory and evidence-based intervention have been developed to address the barriers and enablers to geriatricians and pharmacists proactively deprescribing medicines in hospitals. The deprescribing intervention developed and refined in earlier CHARMER studies will be compared to usual care in older people's medicine wards at four hospital sites in England. The aim of this feasibility study is to inform the development of a definitive trial protocol to evaluate the intervention, by testing the feasibility and acceptability of delivering the intervention and trial. During months 1 and 2, intervention sites will undertake the setup and implementation of the intervention and clinician recruitment. 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 month 3 and the active study window at sites will last 4 weeks. Data collection at follow-up will last 3 months following the end of the active study window.

#### Intervention Type

Behavioural

#### Primary outcome(s)

Current primary outcome measures as of 22/05/2023:

- 1. Recruitment rate recorded as number of participants who consent to take part in the study by end of active study window.
- 2. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of follow up.

Previous primary outcome measures:

- 1. Recruitment rate recorded as number of participants who consent to take part in the study by end of active study window.
- 2. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of follow up at 3 months.

# Key secondary outcome(s))

- 1. Hospital readmission rate measured using HES Admitted patient care data set at 3 months
- 2. Mortality rate measured using ONS death report data at 3 months
- 3. Quality of Life measured using EQ5D-5L and SF36 at baseline and at 3 months

#### Completion date

# **Eligibility**

## Key inclusion criteria

Clinicians:

- 1. Geriatrician or pharmacists working in older adult medicine wards in hospitals in England Patients:
- 2. Patients receiving care from a participating clinician during the study window

#### Participant type(s)

Health professional, Mixed, Patient

## Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Total final enrolment

337

#### Key exclusion criteria

Clinicians:

1. Less than 0.3 FTE ward time

#### Date of first enrolment

29/06/2022

#### Date of final enrolment

11/11/2022

# **Locations**

#### Countries of recruitment

**United Kingdom** 

England

Study participating centre
Northwick Park Hospital
Northwick Park and St Marks NHS Trust
Watford Road

Harrow England HA1 3UJ

# Study participating centre Norfolk and Norwich University Hospital

Colney Lane Colney Norwich England NR4 7UY

# Study participating centre Salford Royal Hospital

Stott Lane Eccles Salford England M6 8HD

# Study participating centre Royal Albert Edward Infirmary

Wigan Lane Wigan England WN1 2NN

# Sponsor information

# Organisation

University of Leicester

#### **ROR**

https://ror.org/04h699437

# Funder(s)

# Funder type

Government

#### Funder Name

National Institute for Health 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**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not expected to be made available

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/11/2025	02/12/2025	Yes	No
<u>Protocol article</u>		04/08/2023	07/08/2023	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes