

# 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.

<b>Submission date</b> 21/02/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/05/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/10/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 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 September 2025

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

**Contact name**

Prof Debi Bhattacharya

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

312494

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

IRAS 312494, 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

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

Hospital

**Study type(s)**

Other

## 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

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.

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## 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 measure

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.

### **Secondary outcome measures**

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

### **Overall study start date**

21/02/2022

### **Completion date**

30/09/2025

## **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)**

Patient, Health professional, Mixed

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

4 sites, 3 intervention sites recruiting up to 6 staff members each. 3 intervention and 1 control site recruiting up to 100 patients each. Total participants circa 400

### **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**

England

United Kingdom

### **Study participating centre**

#### **Northwick Park Hospital**

Northwick Park and St Marks NHS Trust

Watford Road

Harrow

United Kingdom

HA1 3UJ

### **Study participating centre**

#### **Norfolk and Norwich University Hospital**

Colney Lane

Colney

Norwich

United Kingdom

NR4 7UY

### **Study participating centre**

#### **Salford Royal Hospital**

Stott Lane

Eccles

Salford

United Kingdom

M6 8HD

### **Study participating centre**

#### **Royal Albert Edward Infirmary**

Wigan Lane

Wigan

United Kingdom

WN1 2NN

## **Sponsor information**

**Organisation**

University of Leicester

**Sponsor details**

University Road  
Leicester  
England  
United Kingdom  
LE1 7RH  
+44 1163736508  
rgosponsor@leicester.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 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

01/02/2026

## 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 Digital governance requirements

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol article</a>		04/08/2023	07/08/2023	Yes	No