





BMJ Open CompreHensive geriAtRician-led MEDication Review (CHARMER): protocol for a feasibility study of a hospital deprescribing behaviour change intervention

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To cite: Scott S, Atkins B, Martin-Kerry JM, *et al.* CompreHensive geriAtRician-led MEDication Review (CHARMER): protocol for a feasibility study of a hospital deprescribing behaviour change intervention. *BMJ Open* 2023;**13**:e075795. doi:10.1136/bmjopen-2023-075795

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2023-075795>).

Received 18 May 2023
Accepted 14 July 2023



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ABSTRACT

Introduction Over 50% of older adults are prescribed a medicine where the risk of harm outweighs the chances of benefit. During a hospital admission, older adults and carers expect medicines to be reviewed for appropriateness and any inappropriate medicines proactively deprescribed. While the principle of proactive deprescribing is an expectation of good prescribing practice, it is yet to become routine. The CompreHensive geriAtRician-led MEDication Review (CHARMER) study aims to develop and test a five-component behaviour change intervention to equip geriatricians and pharmacists to proactively deprescribe inappropriate medicines with older adults in hospital. This study aims to test the feasibility and acceptability of study processes and CHARMER implementation.

Methods and analysis A two-arm purposive allocation feasibility study is being undertaken at four acute hospitals in England, UK (three intervention and one control). The target sample is 400 patients across all hospitals. Primary outcome measures are: (1) participant recruitment rate and (2) participant attrition rate. Secondary outcome measures are: (1) hospital readmission rate; (2) mortality rate and (3) quality of life. Quantitative data will be checked for completeness and quality, and practitioner and patient demographics descriptively analysed. We will undertake a rapid qualitative analysis on observations, interviews and study meeting minutes data. A subsequent thematic analysis will be undertaken with codes mapped to the Theoretical Domains Framework and Normalisation Process Theory. Triangulation of qualitative and quantitative data will be undertaken.

Ethics and dissemination Ethics approval was obtained from Wales Research Ethics Committee 1 (IRAS ID 312494) and study approval from the Health Research Authority (22/WA/0087). Informed consent will be sought from all hospital staff involved in data collection activities and for patients involved in enhanced data collection activities. The findings

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study tests the feasibility of implementing a hospital deprescribing intervention that is underpinned by behaviour change theory and evidence about what factors help and hinder geriatricians and pharmacists to proactively deprescribe medicines.
- ⇒ This study tests the feasibility of using routinely collected data without patient consent to establish effectiveness.
- ⇒ The CHARMER intervention is being implemented at hospital level rather than individual healthcare professional level to avoid reactivity bias.
- ⇒ Patient and public involvement team members have worked with research team members to design the research processes including all patient facing materials.
- ⇒ Despite purposively sampling four hospitals with differing characteristics, other contextual factors may influence implementation of the CHARMER intervention or completion of study processes that are not represented in our sample and thus not prepared for prior to progressing to a future definitive trial.

of this study will be disseminated in peer-reviewed journals and conference presentations.

Trial registration ISRCTN11899506.

INTRODUCTION

Over 50% of older adults are prescribed a medicine where the risk of harm outweighs the chances of benefit.¹ This predisposes them to avoidable adverse outcomes including morbidity, (re)hospitalisation and mortality. The WHO's initiative Medication Without Harm has proposed proactive deprescribing as a potential solution to reducing medicine-related harm.²

Deprescribing is the process of stopping inappropriate medicines with the aim of managing polypharmacy and improving patient outcomes.³ Proactive deprescribing is the process of stopping a medicine before harm occurs.⁴ While the principle of deprescribing is an expectation of good prescribing practice, it is yet to become routine.^{5 6} Proactive deprescribing requires an accurate medication history and provision for adequate physiological monitoring to observe response to medication withdrawal.³ These two activities are routine during a hospital admission, thus affording an ideal opportunity to proactively deprescribe. Evidence also suggests that deprescribing is widely acceptable to older adults and carers; there is an expectation that prescribed medicines are reviewed for appropriateness and any inappropriate medicines stopped while in hospital.⁷ However, fewer than 1% of older adults have a medicine deprescribed during a hospital admission⁴ and in the vast majority of cases medicines are stopped after they have caused harm, that is, reactive deprescribing.

Proactive deprescribing is a complex and heterogeneous behaviour with multiple barriers and enablers (determinants) required to address in order for it to become routine.⁶ A behavioural science-underpinned scoping review reported that existing interventions largely target only one determinant of healthcare professionals' deprescribing behaviour,⁸ which may explain the limited efficacy of deprescribing interventions tested to date. The most commonly incorporated behaviour change technique (BCT) in existing interventions is adding objects to the environment—for example, deprescribing checklists and algorithms. While this BCT targets insufficient knowledge regarding how to deprescribe, it does not address the full breadth of determinants of deprescribing behaviour.

The CompreHensive geriAtRician-led MEducation Review (CHARMER) study is a UK National Institute for Health and Care Research (NIHR) programme of research to develop and test a behaviour change intervention to address the determinants of geriatricians' and pharmacists' proactive deprescribing behaviour. The CHARMER intervention was developed in accordance with the Medical Research Council (MRC) guidance for complex interventions.⁹ The development of the CHARMER intervention departs from existing interventions,⁸ by integrating evidence regarding the determinants that require addressing and utilising behaviour change theory to design components to address them. CHARMER intervention components were selected¹⁰ and co-designed¹¹ to address the prioritised barriers and enablers to geriatricians' and pharmacists' proactively deprescribing in a hospital context.

This protocol describes the methodology used to undertake the CHARMER Work Package 3 feasibility study. Previous work packages involved establishing a core outcome set (COS) for hospital deprescribing trials¹² and co-designing the CHARMER intervention.¹¹ Work Package three will test the feasibility and acceptability of

delivering and evaluating the intervention in hospitals in England. This will inform refinements to the intervention and trial processes for the definitive trial to evaluate the effectiveness and cost-effectiveness of CHARMER.

Aims and objectives

The study aims to determine the feasibility of undertaking a definitive trial to evaluate the CHARMER intervention and to describe the implementation and acceptability of the intervention.

Objectives are to:

- ▶ Describe the feasibility and acceptability of recruitment processes and determine attrition rates.
- ▶ Evaluate and refine data collection processes and determine the suitability of measures to assess effectiveness of the intervention in the definitive trial.
- ▶ Describe the feasibility and acceptability of intervention delivery/implementation.
- ▶ Estimate and understand fidelity of intervention delivery, receipt and enactment and identify enhancements.
- ▶ Evaluate the fidelity of the theory underpinning the intervention.
- ▶ Determine whether the intended determinants of proactive deprescribing behaviour are addressed by the intervention and identify whether any other determinants require addressing.
- ▶ Refine the CHARMER intervention logic model and design any necessary adaptations to the intervention.

METHODS AND ANALYSIS

The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 checklist supported creation of the protocol¹³ (online supplemental file 1).

Design

We will undertake a two-arm purposive allocation feasibility study at four NHS hospitals in England (three intervention and one control) over 3 months. A 4-week phase in which hospitals will implement the CHARMER intervention and deliver it to participating geriatricians and pharmacists (intervention hospitals only) will be followed by a 4-week active study window in which study data will be collected (intervention and control hospitals).

Participants have been recruited from June to November 2022. Data are being collected and is expected to be complete by September 2023.

Figure 1 provides an overview of the study design and embedded process evaluation procedures for participating healthcare professionals.

Recruitment

We secured expressions of interest from 27 eligible NHS hospitals in England through activities associated with CHARMER Work Packages 1 and 2. We will purposively sample four hospitals for Work Package 3 according to contextual factors likely to influence CHARMER implementation, including maturity of IT infrastructure, maturity of ward-based pharmacy service, strength of

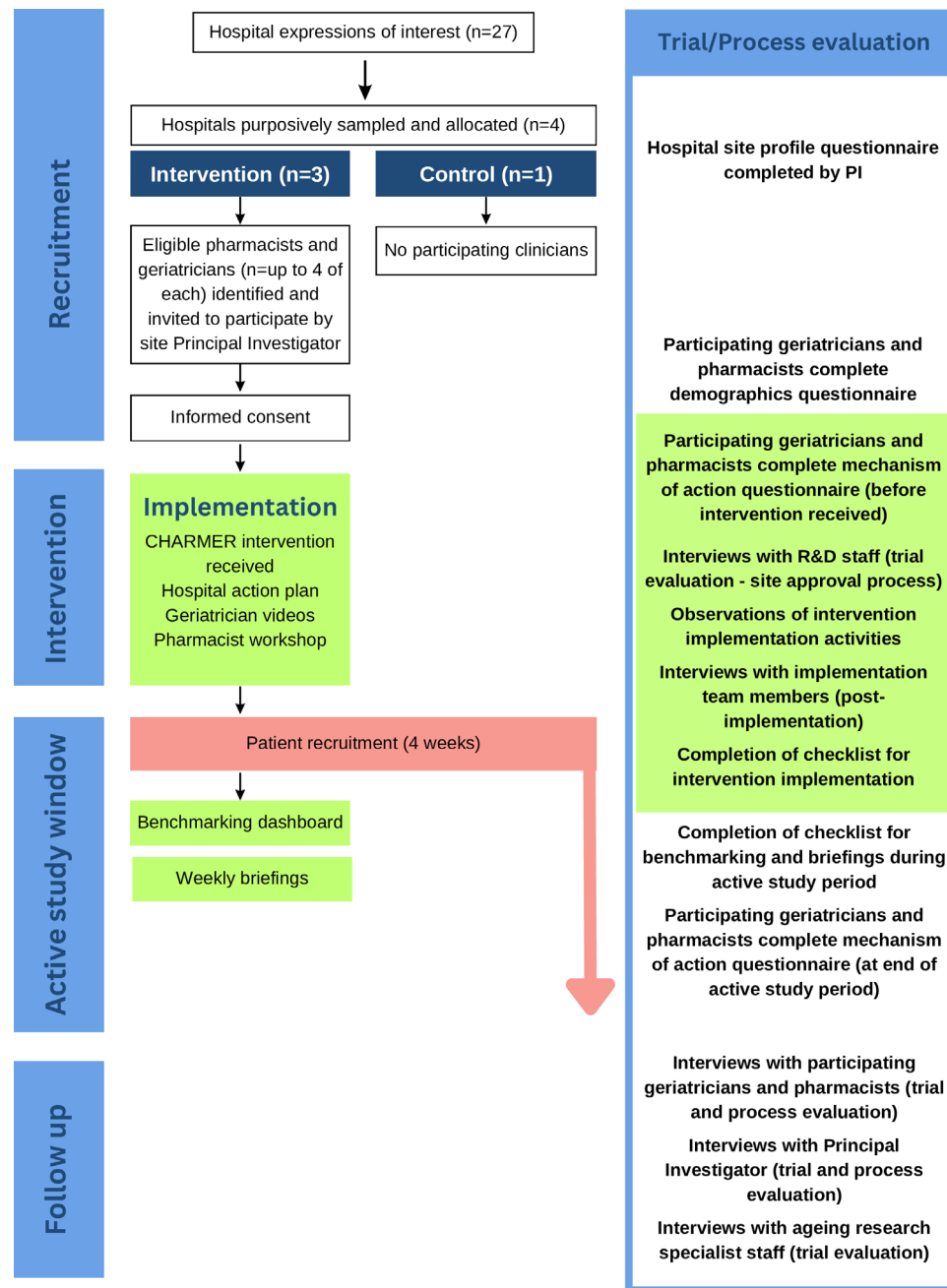


Figure 1 Overview of study design and process evaluation.

leadership for trust medicines management, number of older people's medicine (OPM) wards and diversity of the patient population served. The latter is to explore whether any geriatrician and pharmacist behaviour change as a result of the CHARMER intervention is acceptable to a diverse range of patient characteristics such as race, ethnicity and socioeconomic factors.

Eligibility criteria

Hospitals

All acute NHS hospitals in England with an OPM (geriatrics) service fulfilling the following criteria will be eligible:

- ▶ Willing and able to implement the CHARMER intervention into routine care.

- ▶ Suitable members of the organisation available to form the intervention implementation team (responsible for implementing the intervention) and study delivery team (responsible for consent and data collection).
- ▶ Up to four geriatricians and four pharmacists willing to receive the CHARMER intervention and consent to data collection.

Hospitals that are already taking part in studies evaluating deprescribing interventions will be ineligible.

Hospital staff participants

All geriatricians and pharmacists whose role includes at least 0.3 full-time equivalent (FTE) of OPM ward-based



clinical time will be eligible to receive the CHARMER intervention and provide study data. Any other hospital staff members involved in intervention implementation (implementation team, including Principal Investigators (PIs)) and staff involved in study set-up (research and development staff) and delivery (research nurses) will be eligible to provide study data.

Identification and enrolment

Hospital wards

The PI at each hospital will act as a gatekeeper and identify an OPM ward(s) to be a 'study ward'. Their selection will be informed by a range of factors, including the number of patient beds, average length of stay, pharmacy service provision and number of geriatricians.

Hospital staff participants

Geriatricians and pharmacists

The PI at intervention hospitals will identify and recruit up to four geriatricians and four pharmacists working on the study ward(s) to participate.

Implementation team and study delivery team

The PI at intervention hospitals will identify staff to form the intervention implementation team (staff responsible for implementing the intervention) and study delivery team (responsible for consent and data collection processes). The control hospital PI will identify staff to form the study delivery team.

Research and delivery staff

All PIs will ask research and delivery staff involved in approving the study at their hospital to participate in a short interview to share their views on research set-up and approval processes.

Consent

Hospital staff participants

The PI will invite all identified hospital staff to participate by sending an email and participant information Sheet (PIS) with a link to a consent form for the following:

- ▶ providing professional and demographic characteristics (practitioners receiving the intervention, intervention implementation team and study delivery team);
- ▶ participating in an interview to share their experiences of being involved in the study;
- ▶ being observed during intervention implementation events (implementation team and participating geriatricians and pharmacists).

The CHARMER intervention

CHARMER is a complex multi-component behaviour change intervention designed to address geriatricians' and pharmacists' determinants of proactive deprescribing in hospital.⁶ These determinants were identified in our previous research in which we used the Theoretical Domains Framework (TDF) to understand geriatricians' and pharmacists' barriers and enablers

to deprescribing and whether these differed between hospital contexts.⁶ The TDF is an integrative framework of behaviour change theories for developing interventions comprising 14 domains representing determinants of behaviour. The 14 TDF domains are linked to a taxonomy of BCTs. In our previous research, we prioritised five TDF domains for targeting in a deprescribing intervention and selected relevant BCTs linked to these domains using consensus methods. **Figure 2** provides a description of each CHARMER intervention component, its intended behavioural mechanisms of action (MoA) and the underpinning BCT. Three of the components (1, 3 and 4) are designed to facilitate initiation of proactive deprescribing behaviour, while the remaining two components (2 and 5) are designed to encourage maintenance of proactive deprescribing behaviour.

The intervention components were co-designed with hospital staff representing the intervention target audience and implementation team members in collaboration with older adult and carer stakeholders in line with MRC guidance for complex interventions⁹ using the hospital deprescribing implementation Framework.⁶

Intervention implementation

The implementation team will deliver the CHARMER intervention (**figure 2**) to participating geriatricians and pharmacists during the implementation phase. Components 2 (regular geriatrician and pharmacist briefings) and 5 (deprescribing dashboard) will be organised during the implementation phase and then enacted during the active study window (see **figure 1**).

Active study window

Outcome measures

Feasibility outcomes relate to the ability to set-up and deliver the intervention to inform the design of the definitive trial. The feasibility study will also explore whether outcome data can be collected and determine the quality of the data that will be used to measure the effectiveness of the intervention in the definitive trial. The outcomes include those within the COS for hospital deprescribing trials,¹² as well as other outcomes identified as important to collect in order to establish the effectiveness of CHARMER. **Table 1** provides an overview of all outcomes to be collected along with how and when they will be collected. See online supplemental file 2 for a detailed description of all outcome measures.

Primary outcome measures are (1) recruitment rate recorded as number of participants who consent to take part in the study by end of active study window, and (2) attrition rate recorded as number of participants who consent to participate that remain in the study until the end of follow-up. Secondary outcome measures are (1) hospital readmission rate measured using Hospital Episode Statistics admitted patient care data set at 3 months, (2) mortality rate measured using ONS death report data at 3 months and (3) quality of life measured using EuroQol 5-Dimension Questionnaire (EQ-5D-5L)

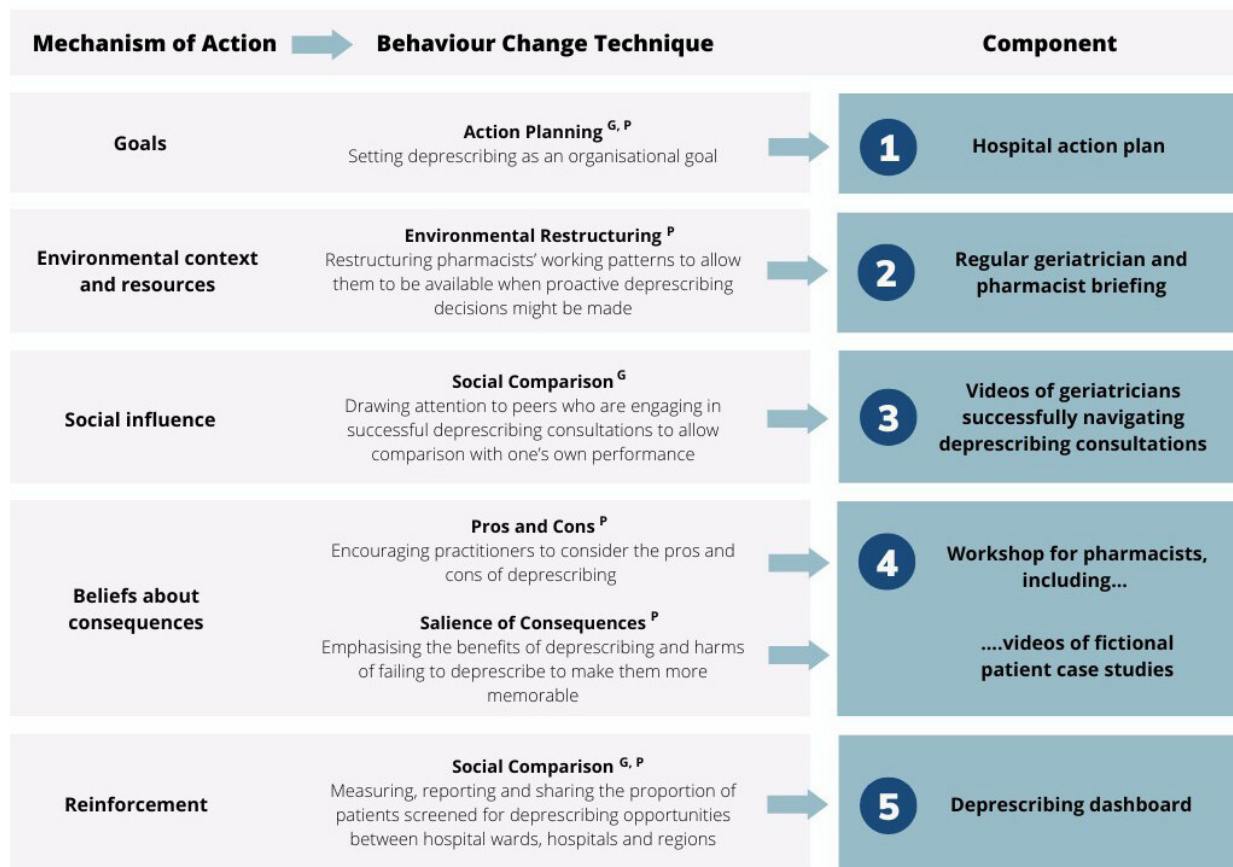


Figure 2 Overview of the five-component CHARMER intervention.

and Short Form 36 Health Survey (SF36) at baseline and at 3 months.

The validated EQ-5D-5L¹⁴ comprises five items scored from one (indicating no perceived problems with the health domain) to five (indicating extreme problem). It also includes a visual analogue scale from 1-100 indicating overall current health. The validated SF36¹⁵ comprises 36 items organised into eight scales, each scored from zero (best possible health) to 100 (best possible health). The medication related adverse events questionnaire comprises a list of 17 medication-related symptoms derived from an evaluation of medication-related patient reported common symptoms.¹⁶ A further item invites patients to report any symptoms that are not in the pre-specified list. The satisfaction with deprescribing questionnaire comprises 13 items. Eleven items capture the patient satisfaction with different aspects of the deprescribing process derived from a review¹⁷ and cross-sectional survey¹⁸, one item captures overall patient satisfaction on a 10-point scale (with one indicating very unsatisfied and 10 indicating very satisfied), and one item establishes who initiates the deprescribing discussion. Face and content validity were established through cognitive interviews with patients who had recently had a medicine deprescribed.

The CHARMER intervention targets the behaviours of pharmacists and geriatricians working on study wards(s). Consequently, all patients who are recipients

of their care during the 4-week active study window will be exposed to its potential effects. To determine whether the CHARMER intervention leads to improvements in patient outcomes, data for all patients who are exposed to its effects are required. All patients on the study ward(s) during the window will therefore be enrolled in the study cohort for routine health data collection unless their record indicates they have opted out of all research. **Figure 3** provides an overview of the study design for patients on the study ward during the active 4-week study window.

Two categories of patient data will be collected: routine health data that will be collected for all patients (n=estimate of 100 patients per hospital over 4-week active study window) and data that will be collected only from patients and where applicable consultees who provide consent (or assent) for patient/consultee-reported outcome data.

Informed consent will not be sought for collection of routine health data (see **table 1**) because it is deemed impractical to approach 100% of patients in hospital for consent.⁷

The study delivery team will approach patients and where applicable consultees for consent or assent to provide the following patient/consultee-reported outcome data (see **table 1**). They will also seek consent to be purposively sampled by the CHARMER research team to participate in a telephone interview about their

**Table 1** Overview of outcome measures

Outcome	Data source/measure	Frequency of collection	Method of collection
Patient-orientated outcomes			
All patients on study ward during active study window			
Mortality (secondary outcome measure)	Death certificate data from the ONS*	Once at 90 days postdischarge	Routine hospital data
Number of hospital stays (secondary outcome measure)	HES* admitted patient care dataset from NHS digital and site medical record	Once at 90 days postdischarge	Routine hospital data
Patients providing consent/consultee assent for enhanced data collection activities			
Satisfaction with deprescribing	A 13-item questionnaire capturing satisfaction with the procedures associated with any medicines that may have been stopped during the hospital stay	Once, as soon as possible after discharge	Patient/consultee reported (telephone)
Medication-related adverse events	A 18-item questionnaire to capture presence or absence of symptoms in the 1 month prior to assessment	Once at 90 days postdischarge	Patient/consultee reported (telephone)
Quality of life (secondary outcome measure)	EuroQol 5-Dimension Questionnaire (EQ-5D-5L), Short Form 36 Health Survey (SF36)	Twice—at discharge and at 90 days postdischarge	Patient/consultee reported (telephone)
Economic outcomes			
All patients on study ward during active study window			
Number of hospital stays	HES admitted patient care dataset from NHS digital	Once, at 90 days postdischarge	Routine hospital data
Length of hospital stay for index admission	Site Medical Record	Once, at discharge from hospital	
Patients providing consent/consultee assent for enhanced data collection activities			
Number of primary care consultations	GP records	Once, at 6 weeks postdischarge	Routine primary care data
Process outcomes			
All patients on study ward during active study window			
Number of regularly prescribed medicines at discharge	Site medical record	Once, at the point of discharge	Routine hospital data
Number of prescribed medicines for when required use at discharge	Site medical record	Once, at the point of discharge	Routine hospital data
Number of prescribed medicines that are stopped	Site medical record	Once, at the point of discharge	Routine hospital data
Number of prescribed medicines with dosage reduced	Site medical record	Once, at the point of discharge	Routine hospital data
Number of stopped medicines that are re-started	Community pharmacy dispensed medicines submitted to NHS Business Services Authority, dataset from NHS digital	Once at 90 days postdischarge	Routine primary care data
*Office for National Statistics (UK agency responsible for collecting and publishing related to the economy, population and society at national, regional and local levels) and Hospital Episode Statistics (a database containing details about admissions, A&E attendances and outpatient appointments at NHS hospitals).			

study experience. Any patients or consultees deemed inappropriate to be approached by the patients' usual healthcare team, such as those near end of life, will not be approached.

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Evaluation of outcome measures

This feasibility study is not powered to detect a difference in outcomes between intervention and control cohorts. The study will determine whether sufficient patient participants can be recruited for enhanced data

collection activities to meet the requirements of the definitive trial. Using the methods of Lewis *et al*¹⁹—a red zone progression criterion with an upper limit of 50% and a green zone lower limit of 70%—we estimate a sample size of 42 patient participants would be sufficient to address the feasibility aims. This is based on a one sample test comparing the 50% to the 70% at the one-sided 5% level of significance with 80% power. A sample size of 55 patient participants would be required at 90% power. These will pertain to the following feasibility criteria:

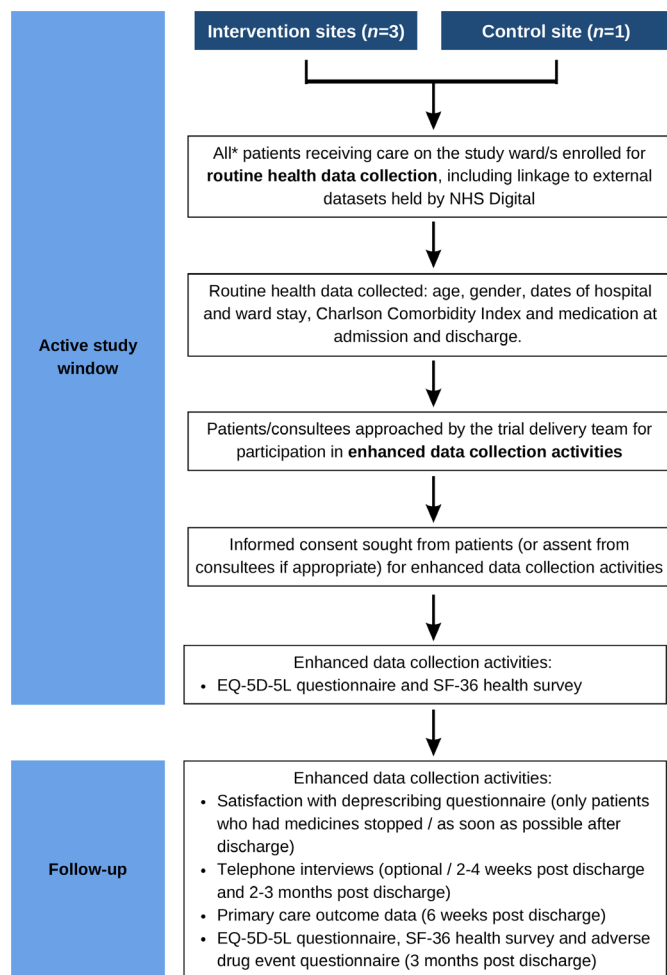


Figure 3 Overview of patient participant involvement.

*Unless patient record indicates they have opted out of all research. EQ-5D-5L, EuroQol 5-Dimension Questionnaire; SF36, Short Form 36 Health Survey.

- ▶ Recruitment rate of hospitals sufficient to achieve patient target.
- ▶ Consent rate for EQ-5D-5L or SF36 >70% of anticipated (green), ≥60% (amber), <50% (red).
- ▶ Attrition rate from follow-up EQ-5D-5L or SF36 <30% (green), 30–40% (amber), >40% (red).

If all criteria are green, we will proceed to internal pilot. If one or more criteria are amber, we will proceed to internal pilot if appropriate solutions are identified. If one or more criteria are red, we will work with our Programme Steering Committee to make a decision regarding whether to proceed. We will also explore ceiling and floor effects.

Process evaluation

The process evaluation will be underpinned by the TDF and Normalisation Process Theory (NPT). The TDF is an integrative framework of behaviour change theories. It underpins the development of the CHARMER intervention and is thus used in the process evaluation to evaluate the extent to which the intervention adheres to its underpinning MoA. NPT is a theory of intervention

implementation and is used in the process evaluation to identify barriers and enablers to hospitals implementing the CHARMER intervention.

We will follow MRC guidance for designing and conducting process evaluations of complex interventions^{9 20} to determine the feasibility and acceptability of implementing the CHARMER intervention and to identify refinements. A mixed-methods process evaluation will be undertaken comprising quantitative and qualitative data (focused ethnography, semi-structured interviews with key stakeholders for each site, documentary analysis of CHARMER team meeting minutes). Figure 4 provides an overview of the process evaluation components and data sources.

Fidelity framework

We have developed a fidelity framework and associated checklists based on the conceptual model for implementation fidelity²¹ to capture how each of the CHARMER intervention components are delivered, whether any adaptations are made and how each component is received by participating geriatricians and pharmacists. The fidelity framework and checklists will be tested and refined for the definitive trial.

Observations

We will undertake focused observations to evaluate the appropriateness of the fidelity framework and to explore barriers and enablers to intervention delivery for both the implementation team and the participating geriatricians and pharmacists. We will follow guidance on using focused ethnography within healthcare settings^{22 23} to understand how the CHARMER intervention is implemented in the context of the three intervention hospitals.

We will observe the implementation of the action plan launch (component 1), workshop for pharmacists (component 3) and video of geriatricians (component 4) to determine how recipients engage with these and how components are delivered, noting any adaptations. A member of the research team will attend implementation events or view recordings of the events at each hospital. Thick descriptions of site settings, activities, communication, body language, and barriers and facilitators will be noted to identify how similarities and contextual differences across hospitals influence the implementation and outcomes of the intervention.

Interviews

Qualitative semi-structured interviews will be undertaken with the PI (up to 60 min), study delivery staff members involved in patient recruitment (up to 30 min) and the research and development staff members (up to 30 min) at each hospital site. Staff participants involved in CHARMER implementation will be interviewed (up to 45 min) to understand how intervention components are delivered and received. We will also undertake semi-structured telephone interviews (up to 30 min) with

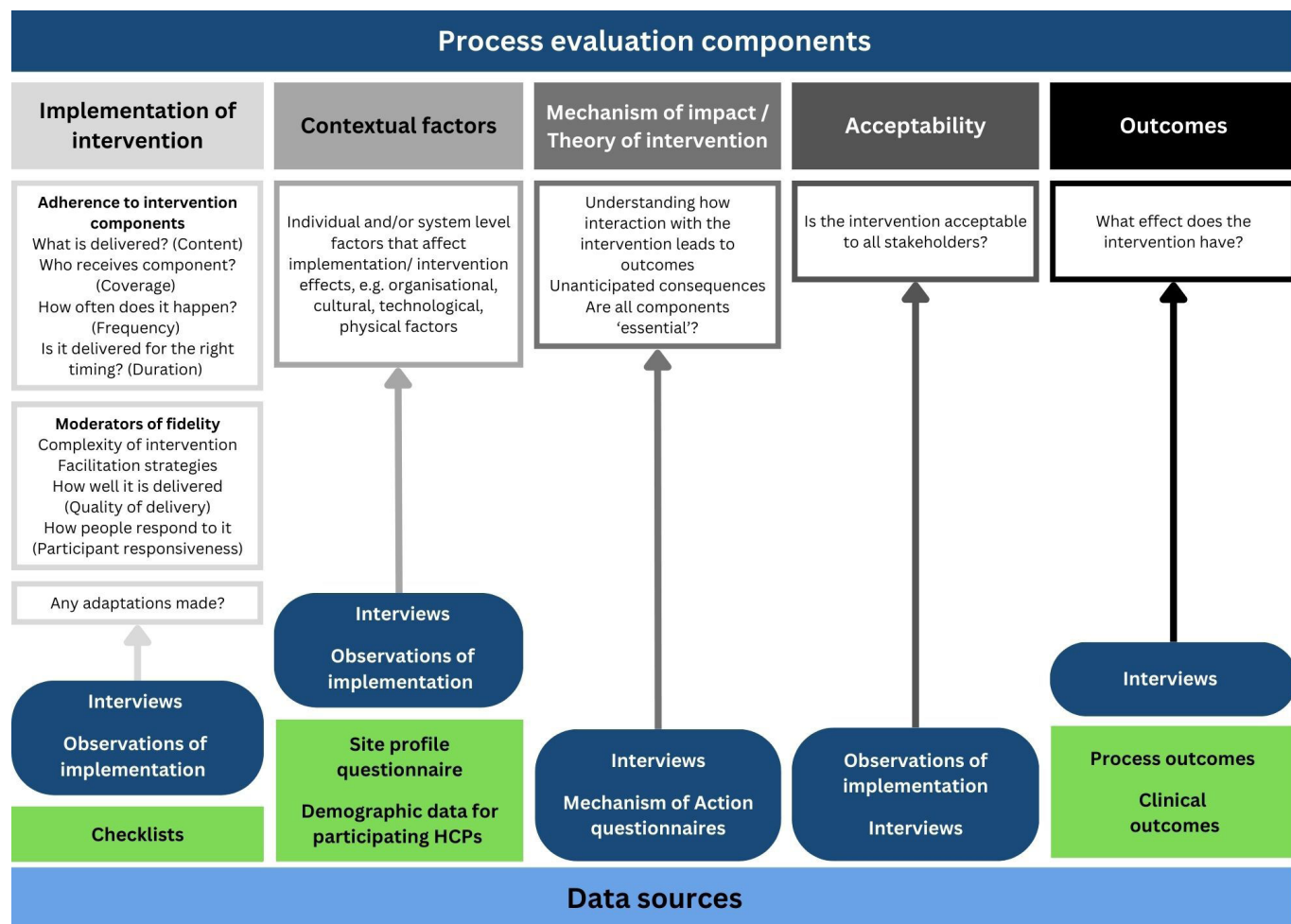


Figure 4 Overview of process evaluation. HCPs, healthcare professionals.

patients and consultees who consent to enhanced data collection activities (see figure 3). All interviews will use topic guides developed to support discussion (online supplemental file 3). We will use the observation descriptions (detailed above) to guide interviews to further explore aspects of observed intervention delivery. To complement interviews, we will develop an MoA questionnaire to evaluate fidelity of the theory underpinning the intervention.

MoA questionnaires

We have developed an MoA questionnaire (online supplemental file 4) to measure the extent to which the CHARMER intervention addresses the intended four barriers and one enabler to proactive deprescribing.⁶ Additionally, we incorporated items in the MoA questionnaire to measure other determinants of proactive deprescribing reported in the literature that are not intended to be addressed by the CHARMER intervention.⁵

MoA questionnaire items were derived from existing validated measures of behavioural determinants. These were developed by identifying relevant constructs of the Consolidated Framework for Implementation Research (CFIR)²⁴ and their mapped validated measures from

the Organisational Readiness to Change Assessment (ORCA).²⁵ Each item was contextualised to the specific intended barrier or enabler to deprescribing. For example, the ORCA item 'The {proposed practice changes or guideline implementation} are consistent with clinical practices that have been accepted by patients' was contextualised for the questionnaire as 'Proactive deprescribing is a clinical practice that is accepted by patients and carers'.

Construct validity of the MoA questionnaire is offered by selecting items from the previously validated measures from ORCA.²⁵ The items had therefore already been established to only measure the intended construct and to be stable over time. Face validity of the contextualised items for our intended audience of geriatricians and pharmacists was established through user testing and a workshop.

We will ask all participating geriatricians and pharmacists to complete the questionnaire before and after receiving the CHARMER intervention. For each individual intervention recipient, this will enable us to determine whether or not the intended determinants of proactive deprescribing behaviour were addressed and also whether any other determinants need addressing.

Meeting minutes

Regular research team meetings will be held in the planning stage ahead of the feasibility study and throughout the study period. These meetings will be used to discuss progress and delivery of the intervention, recruitment, data collection, issues arising during the study and opportunities for any modifications.

Primary care stakeholders

We will engage with primary care prescribers who have at least one patient in a CHARMER intervention hospital to explore the intervention's effect in primary care.

All patients consenting to enhanced data collection will have a letter sent from the hospital to their general practitioner (GP), indicating that the patient has participated in the study. The letter will include information for the GP (or other staff member with prescribing responsibilities) to express an interest in participating in an interview about their experiences of managing a patient post-hospital discharge. Consenting stakeholders will be invited to explore their experiences, whether any proactive deprescribing decisions are implemented by primary care and whether there are any unintended consequences of proactive deprescribing in hospital from their perspective.

Process evaluation data analysis

All interviews will be digitally recorded, transcribed verbatim by a member of the research team and anonymised. Transcripts will be checked for accuracy by JMM-K.

A researcher experienced in qualitative process evaluation (JMM-K) will undertake a rapid qualitative analysis²⁶ on data from observations, interviews and study meeting minutes to enable learnings to be identified during the feasibility study, including any necessary refinements for both intervention and study design features implemented. A subsequent inductive thematic analysis²⁷ will be undertaken by JMM-K. Codes will be reviewed at this stage through discussion with members of the research team with behaviour change expertise (DB, SS). This will be followed by deductive mapping of codes to the TDF²⁸ and NPT²⁹ by JMM-K and SS. This is to enable understanding of the barriers and enablers to site set-up and recruitment (of practitioners, patients and consultees) and to assist with identifying refinements in processes ahead of the definitive trial.

Quantitative data will be checked for completeness to establish whether the research team are able to collect data of sufficient quality and quantity for the definitive trial. Descriptive statistics will be used to report patient and practitioner data to characterise the study population, for example, according to patient demographics and medicines prescribed, and practitioner FTE and MoA questionnaire results. This will allow us to assess the feasibility and acceptability of recruitment processes and determine attrition rates.

Triangulation³⁰ will be undertaken examining data from each component of the study (observations, interviews,

MoA questionnaires, other quantitative data such as metrics of engagement with intervention content). We will visually present these data in tables and figures to allow us to identify where there is agreement or disagreement between findings from different data components and thus identify how the intervention and/or definitive trial and methods may need to be modified. While data will be analysed together, differences in perspectives between sites and stakeholder groups will be explored. After the process evaluation analysis, we will refine the logic model based on learnings about how the intervention is delivered, factors that influence this, and any contextual aspects at sites.

Patient and public involvement

A patient and public involvement (PPI) group consisting of older adults experiencing polypharmacy (n=3) and family members/carers (n=2) are core members of the CHARMER research team. Our members have contributed to the development and design of the feasibility study, including developing the study protocol, reviewing and editing PISs and consent forms to ensure readability and commenting on topic guide content. PPI members attend weekly feasibility study meetings and will support the research team in the analysis, write up and dissemination of the study findings. They will also help with refining the study procedures for the future definitive trial.

ETHICS AND DISSEMINATION

The study has received ethical approval from Wales Research Ethics Committee 1 (IRAS ID 312494) and study approval from the Health Research Authority (22/WA/0087). We also sought confirmation of capacity and capability prior to the study being initiated at participating hospital sites through the relevant research and development departments. Confirmation of capacity and capability took the form of a site agreement signed by both the Sponsor/Norwich Clinical Trials Unit and the relevant hospital site.

Informed consent will be sought from all hospital staff involved in data collection activities and for patients involved in enhanced data collection activities. A copy of the consent form (for hospital staff) can be found in online supplemental file 5 and a copy of the consent and assent forms (for patients/consultees) in online supplemental file 6. We will seek governance approval for the use of patient identifiable data for the purposes of accurate data linkage to external National Health Service datasets, where it is not possible to approach the patient for informed consent.

Hospitals are able to withdraw from the study at any time; if this happens, we will seek to understand the rationale to determine whether this has any implications for the study at remaining hospitals and the future definitive trial. Staff participants and patients taking part in enhanced data collection activities are free to withdraw from the study at any time, without providing a reason,

by informing a member of the research team. All patients retain the right to opt out of their data being used for research and any patients who have already opted out using the National Data Opt Out will be excluded from the data collection.

Study findings will be published in open-access journals and via national and international conference presentations. We will also disseminate the findings to older adults and family members via lay summaries published on the CHARMER website and via social media.

DISCUSSION

CHARMER Work Package three will be the first study to test the feasibility of implementing a deprescribing behaviour change intervention in the hospital setting. Following completion of the study, should progression criteria be met, we will use the learning and work with our PPI team members to develop and undertake the CHARMER definitive trial to test its effectiveness and cost-effectiveness.

Novel to the field of deprescribing, we will measure the extent to which components of the CHARMER intervention adhere to the hypothesised underpinning behavioural MoA using the behavioural science underpinned MoA questionnaire. The development and use of the MoA questionnaire will also enable identification of determinants of deprescribing not targeted by the CHARMER intervention that require addressing. In addition to measuring determinants of proactive deprescribing behaviour change, we will also identify and describe organisational determinants of implementing the CHARMER intervention using the implementation science NPT. The dual behavioural and implementation science underpinned process evaluation will permit a future definitive trial to delineate between factors of success or failure related to the intervention itself or the implementation process. An understanding of these factors may inform adaptation of the CHARMER intervention to settings beyond the hospital context in England for which it was originally designed.

Despite purposively sampling four hospitals with differing characteristics, other contextual factors may influence CHARMER implementation or completion of study processes that are not represented in our sample. The feasibility study will also not capture a full picture of seasonal variation; however, it will span the summer, autumn and winter periods and thus allow us to anticipate whether fluctuations in workload due to winter pressures will impact on feasibility.

This study tests feasibility of using routinely collected data without patient consent to establish effectiveness. If found to be feasible, this provides a novel approach to ensuring that 100% of the data is available to evaluate the effects of practitioner behaviour change interventions on patient outcomes. Another strength of our approach is that the intervention will be implemented at hospital level

to ensure that there is no reactivity bias from introducing CHARMER in one part of the hospital and not another.

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Acknowledgements We thank all participating NHS hospitals and principal investigators at these sites for identifying participants for the study, in particularly difficult times. We would also like to thank the NIHR Ageing Speciality Clinical Research Network for facilitating recruitment.

Contributors DB, DW, SS, DPA, ABC, KM, VK, IK, ES, JT, DT, MPatel and MW are study investigators. SS and DB are behavioural science researchers who identified the barriers and enabler to be addressed by the intervention. DB, SS, BA, IK, VK, JT and KM contributed to the design of the CHARMER intervention. BA, MPatel, MW, VK, DW, DA, DB and SS prepared intervention components. BA developed the implementation handbook for sites to use for implementation of the intervention with input from SS and JMM-K. JMM-K, SS, DB, JT and IK designed the embedded process evaluation. JMM-K developed the fidelity checklists and qualitative analysis plans, with input from the wider team and undertook interviews and observations at the study sites. KM led the PPI activities and coordinated and provided input into patient-facing documents and study procedures involving patients and consultees. MPritchard was responsible for the day-to-day study processes with oversight from ES and support from AH. ABC and DT reviewed the evaluation of outcome measures and provided input into analysis plans for quantitative data. AC led the development of data collection through REDCap. BA led drafting of the manuscript with input from JMM-K, MPritchard, SS and DB. All authors reviewed and revised the draft manuscript.

Funding This research is funded by the National Institute for Health and Social Care Research (NIHR) Programme Grants for Applied Research stream (award ID PGfAR 200874).

Disclaimer The views expressed in this publication are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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