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

Trial registration ISRCTN11899506.

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.

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 admission[4] 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 MEdication 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 selected[10] and co-designed[11] 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 trials[12] 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 protocol[13] (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

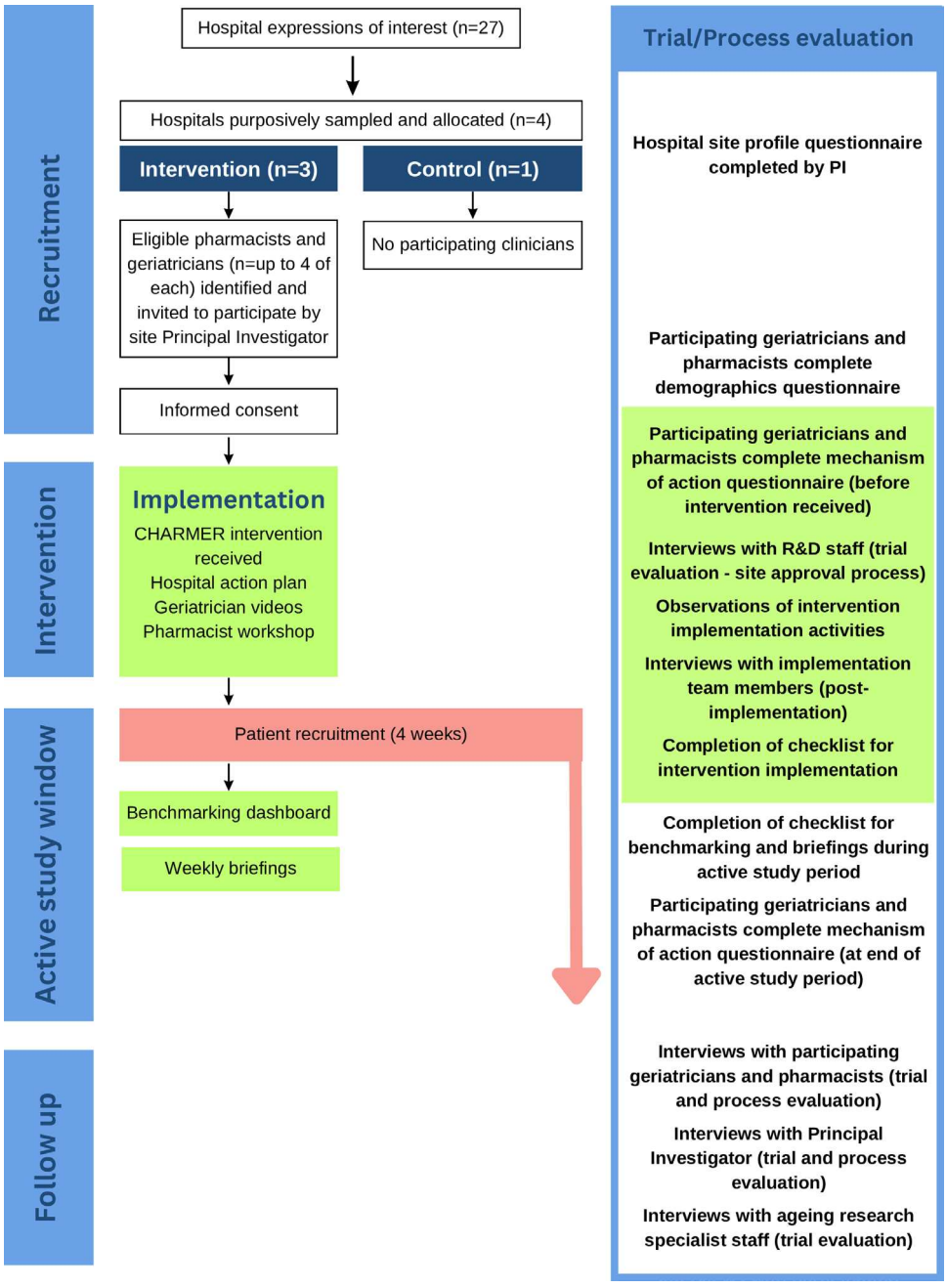

Figure 1 Overview of study design and process evaluation.

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;
- eing 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 interventions[9] 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)

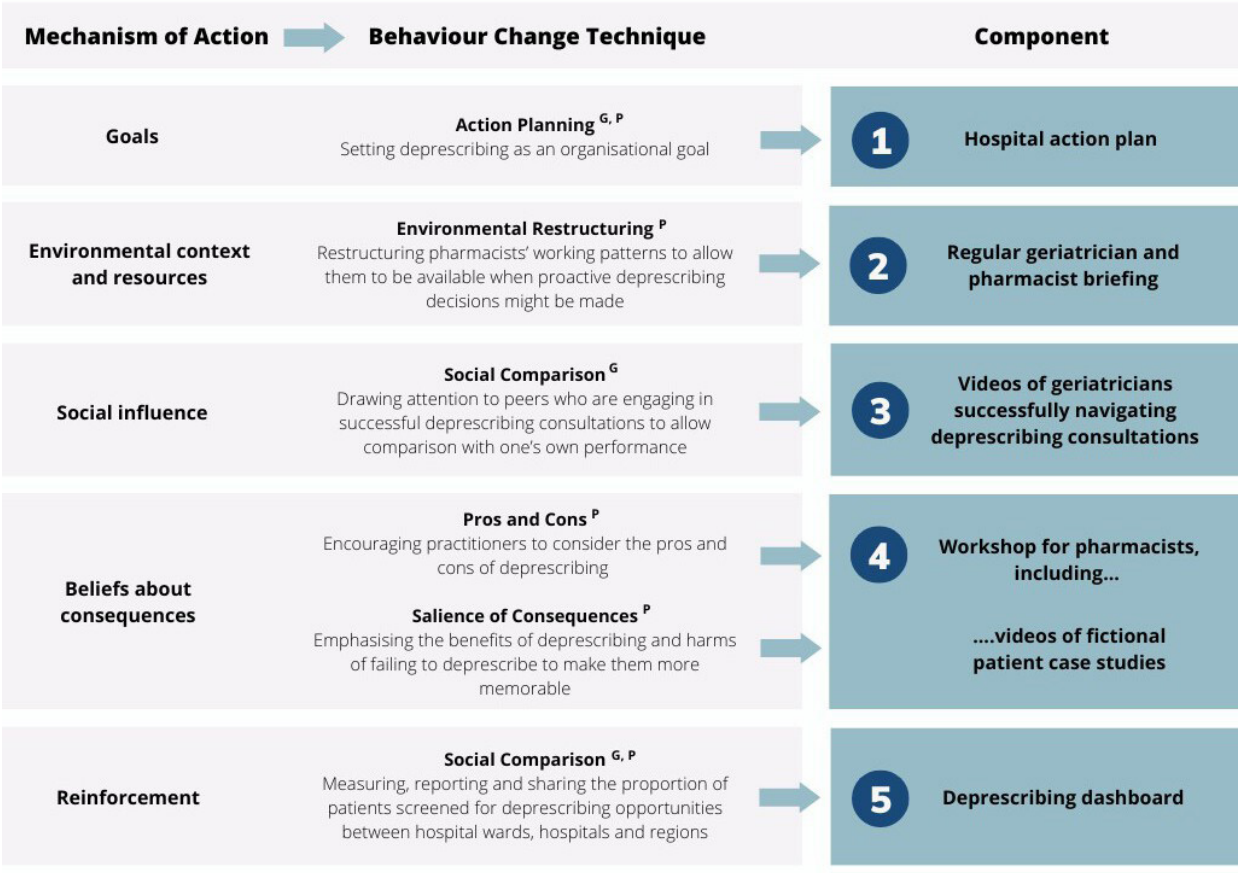

Figure 2 Overview of the five-component CHARMER intervention.

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

The validated EQ-5D-5L[14] 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 SF36[15] 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 review[17] and cross-sectional survey[18], 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.[14 15 16 17 18]

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:

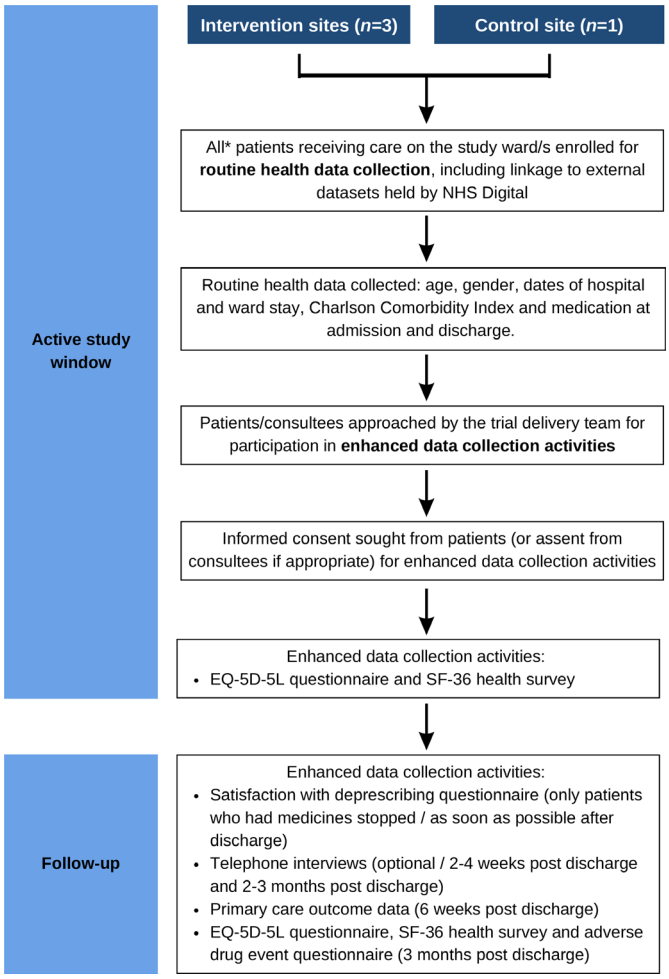

Figure 3 Overview of patient participant involvement. *Unless patient record indicates they have opted out of all research. EQ-5D-5L, EuroQol 5-Dimension Questionnaire; SF36, Short Form 36 Health Survey.

- 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 fidelity[21] 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

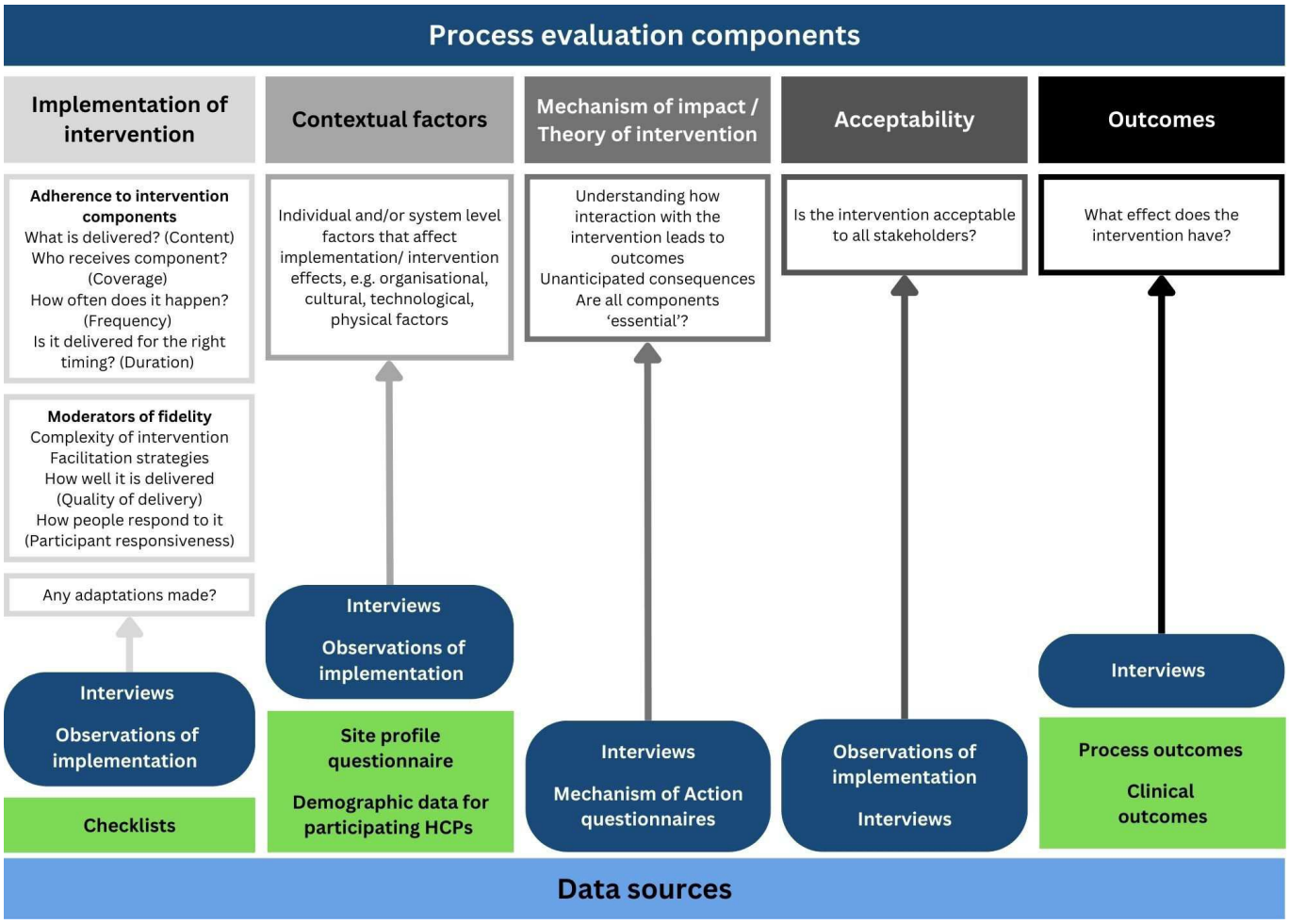

Figure 4 Overview of process evaluation. HCPs, healthcare professionals.

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 analysis[26] 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 analysis[27] 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 TDF[28] and NPT[29] 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.

Triangulation[30] 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 approved 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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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1 manuscript
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Abstract manuscript
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	1 protocol V.4
Funding	4	Sources and types of financial, material, and other support	Declarations manuscript
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Author statement manuscript
	5b	Name and contact information for the trial sponsor	1 protocol V.4
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	1-6 protocol V.4
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	14 protocol V.4

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-7 manuscript
	6b	Explanation for choice of comparators	5-7 manuscript
Objectives	7	Specific objectives or hypotheses	6-7 manuscript
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7 manuscript

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7-24 manuscript
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-24 manuscript
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-24 manuscript
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	7-24 manuscript
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7-24 manuscript
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7-24 manuscript
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	17-19 manuscript
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9, 15 manuscript

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7-24 manuscript
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7-24 manuscript
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_____
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7-24 manuscript
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	7-24 manuscript

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	7-24 manuscript
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	7-24 manuscript
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	62-66 protocol V.4
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	62-66 protocol V.4
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	62-66 protocol V.4
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	62-66 protocol V.4
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	25-26 manuscript
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	25-26 manuscript

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7-24 manuscript
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	7-24 manuscript
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	69 protocol v.4
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	58-62 protocol V.4
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	67-69 protocol V.4 and 25-26 manuscript
	31b	Authorship eligibility guidelines and any intended use of professional writers	69 protocol V.4
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary file 3, 4 manuscript
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Supplementary file 2: Detailed 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) The death of a patient for any reason	Death certificate data from the ONS*	Once at 90 days post discharge	Routine hospital data
Number of hospital stays (secondary outcome measure) The number of planned and unplanned admissions and re-admissions to hospital for treatment or monitoring health	HES* Admitted Patient Care dataset from NHS Digital and Site Medical Record	Once at 90 days post discharge	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 one month prior to assessment	Once at 90 days post discharge	Patient/consultee reported (telephone)

Quality of life (secondary outcome measure) The standard of health, comfort and happiness experienced by an individual, including quality of life relating to medication use	EuroQol 5-dimension questionnaire (EQ-5D-5L), Short Form 36 Health Survey (SF36)	Twice – at discharge and at 90 days post discharge	Patient/consultee reported (telephone)
Economic outcomes			
All patients on study ward during active study window			
Number of hospital stays The number of planned and unplanned admissions and re-admissions to hospital for treatment or monitoring health	HES Admitted Patient Care dataset from NHS Digital	Once, at 90 days post discharge	Routine hospital data
Length of hospital stay for index admission The number of days	Site Medical Record	Once, at discharge from hospital	
Patients providing consent/consultee assent for enhanced data collection activities			
Number of primary care consultations The number of consultations with General Practitioners or Practice Nurse for treatment or monitoring health	GP records	Once, at 6 weeks post discharge	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

The number of medicines that a patient has been prescribed for regular use when discharged from hospital			
Number of prescribed medicines for when required use at discharge The number of medicines that a patient has been prescribed for when required use when discharged from hospital	Site Medical Record	Once, at the point of discharge	Routine hospital data
Number of prescribed medicines that are stopped The number of medicines that have been discontinued during study window AND while patient is on study ward	Site Medical Record	Once, at the point of discharge	Routine hospital data
Number of prescribed medicines with dosage reduced The number of medicines which have had the dosage reduced during study window AND while patient is on study ward	Site Medical Record	Once, at the point of discharge	Routine hospital data
Number of stopped medicines that are re-started The number of medicines that were discontinued during study window AND while patient is on study ward that are subsequently restarted during follow-up	Community pharmacy dispensed medicines submitted to NHS Business Services Authority, dataset from NHS Digital	Once at 90 days post discharge	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).

Document 29

CHARMER
COMPREHENSIVE GERIATRICIAN-LED MEDICATION REVIEW

NHS Trust Header

CHARMER Work Package 3 TOPIC GUIDES

Research and Development Team members (Site set up) [30 min]

Implementation team [45 minutes]

Ageing Specialty Research Staff including PIs [60 minutes]

Recruited practitioners – geriatricians and pharmacists (Intervention sites only) [60 minutes]

Patients [45 minutes]

Consultees [45 minutes]

Primary care members with prescribing role [45 minutes]

Scott S, *et al. BMJ Open* 2023; 13:e075795. doi: 10.1136/bmjopen-2023-075795

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Research and Development Team members (Site set up) [30 min]

Introduction:

I am a researcher working on the CHARMER study. The CHARMER study is a programme of research to develop and test an intervention to support geriatricians and pharmacists to proactively deprescribe unnecessary or harmful medicines for older people in hospital.

I am keen to hear your thoughts on how the study went from your perspective – both positive and negative aspects. There are no right or wrong answers. The information you provide will help us to understand what worked/went well and what could be improved. Today, I will be recording our discussion but only myself, the researchers working on the study and the person who transcribes the interview will hear what we say. When the interview is transcribed, we remove any identifiable information such as your name so that we have an anonymised record of what we talked about. After the interview is transcribed, we will securely destroy the recording of the interview.

If we use any quotes from you in our reports, you will not be able to be identified in any way. You can also stop the interview at any time and without giving a reason.

Do you have any questions for me before we start?

Firstly, can you tell me about your role?

Can you tell me about how the site approval process for the CHARMER study happened, from your perspective?

Prompts:

Time required; documentation review; discussions

What worked well?

What didn't work so well and how could we improve this?

Prompts:

Was there anything that you think particularly had an impact on approval of the study at your site?

Were there particular documents that helped with the process?

What was your experience of the communication between yourself, the PI and the CHARMER research team during approvals and set up?

Is there anything else we could do to support sites with set up for the CHARMER study?

Is there anything else that you would like to discuss that we have not covered?

Scott S, *et al. BMJ Open* 2023; 13:e075795. doi: 10.1136/bmjopen-2023-075795

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Implementation team [45 minutes]

Introduction: I am a researcher working on the CHARMER study. The CHARMER study is a programme of research to develop and test an intervention to support geriatricians and pharmacists to proactively deprescribe unnecessary or harmful medicines for older people in hospital.

Today I'd like to ask you about your experience of being involved in the implementation/delivery of the CHARMER study. I am keen to hear your thoughts on how the study went from your perspective – both positive and negative aspects. There are no right or wrong answers. The information you provide will help us to understand what worked well and what could be improved.

Today I will be recording our discussion but only myself, the researchers working on the study and the person who transcribes the interview will hear what we say. When the interview is transcribed, we remove any identifiable information such as your name so that we have an anonymised record of what we talked about. After the interview is transcribed, we will securely destroy the recording of the interview.
If we use any quotes from you in our reports, you will not be able to be identified.
You can also stop the interview at any time and without giving a reason.
Do you have any questions for me before we start?

Can you tell me a bit about yourself and your role?

What was your role in the CHARMER study?

Can you tell me about your experience of being involved in the CHARMER study?
Prompts:
What went well? What could be improved?

What do you think of the CHARMER intervention?
Prompts:
What did you think about the different components of the intervention?
Do you think all components are useful?
For each intervention component (as appropriate): how did you find this? Was it useful?
Could it be improved, and if so how?

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Can you tell me about the implementation/delivery of the CHARMER intervention?
Prompts:
How were the implementation events structured?
How many healthcare professionals were invited and how many attended the implementation days? If not everyone attended, what were the reasons?
How do you feel the participating geriatricians and pharmacists interacted during the implementation sessions?
Can you tell me why you think this happened?
Did they interact/engage more with certain components of the intervention?

Can you tell me about the information you received before you began the implementation/delivery of the CHARMER intervention?
Prompts:
How many days did you spend preparing for the implementation days? How did you prepare for the implementation?

What aspects did you find useful?
What aspects do you think could be improved? How did you find the implementation manual?

What impact do you think the CHARMER intervention has had?
Prompts:
What have you noticed?
How do you think this has happened?

Do you feel there were any factors at your site that either helped or hindered the CHARMER intervention?
Prompts:
These could be related to for example, people, technology, structures etc.
Was the intervention adapted or changed in any way during the implementation days?
How did that happen and what was the effect of doing this?

Is there anything else that you would like to discuss that we have not covered?

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Ageing Specialty Research Staff including PIs [60 minutes]

Introduction:
I am a researcher working on the CHARMER study. The CHARMER study is a programme of research to develop and test an intervention to support geriatricians and pharmacists to proactively deprescribe unnecessary or harmful medicines for older people in hospital.
Today I'd like to ask you about your experience of being involved in the CHARMER study. I am keen to hear your thoughts on how the study went from your perspective – both positive and negative aspects. There are no right or wrong answers. The information you provide will help us to understand what worked well and what could be improved.
Today I will be recording our discussion but only myself, the researchers working on the study and the person who transcribes the interview will hear what we say. When the interview is transcribed, we remove any identifiable information such as your name so that we have an anonymised record of what we talked about. After the interview is transcribed we will securely destroy the recording of the interview.
If we use any quotes from you in our reports, you will not be able to be identified.
You can also stop the interview at any time and without giving a reason.

Do you have any questions for me before we start?

Can you tell me about your role in the CHARMER study?

Can you tell me about your experience of being involved in the CHARMER study?
Prompts:
Why did you decide to be involved in the study?
How did you find the study?
What worked well? What worked less well and what improvements are needed?

(PIs only) **Can you tell me how you found the set up process for CHARMER at your site?**
Prompts:
How long did approvals and set up take?
Can you tell me about your experience of meetings with the CHARMER research team before and during set up?
Can you tell me about the documentation you received? Can we provide additional information or present information in a different way?

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What do you think of the CHARMER intervention?
Prompts:
What did you think about the different components of the intervention?
For each intervention component (as appropriate): How did you find this? Was it useful? Could it be improved, and if so how?

(PIs only) **Can you tell me about your experience of being involved in the implementation/delivery of the CHARMER intervention?**
Prompts:
How were the implementation events structured?
How many healthcare professionals were invited and how many attended the implementation days? If not everyone attended, what were the reasons?
How do you feel the participating geriatricians and pharmacists interacted during the implementation sessions? Can you tell me what you noticed? Can you tell me why you think this happened?
Can you tell me more about how you felt people interacted/engaged with the different components of the intervention?
Do you think any improvements are needed to the intervention or its delivery?

What impact do you think the CHARMER intervention has had?
Prompts:
What have you noticed?
Why do you think this has happened?

Do you feel there were any factors at your site that either helped or hindered the CHARMER intervention?
Prompts:
These could be related to for example, people, technology, structures etc.
Was the intervention adapted or changed in any way during the implementation days?
How did that happen and what was the effect of doing this?

If time:
How did you find the process of recruiting people into the study?
Prompts:
What worked well? Are any changes needed?
Did they have particular questions about the study?
What types of questions, if any, did potential participants have about the study?

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Can you tell me about your experiences of collecting data within the CHARMER study?

Prompts:

Were there data that were easier to collect?

Were any data items burdensome to collect?

Could we make any changes to data collection processes, if so what?

How was your experience of the collection of data from patients and consultees?

Some of the data collection was by phone, how did this go?

Is there anything else that you would like to discuss that we have not covered?

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COMPREHENSIVE GERIATRICIAN-LED MEDICATION REVIEW

NHS Trust Header

Recruited practitioners – geriatricians and pharmacists (Intervention sites only) [60 minutes]

Introduction:
I am a researcher working on the CHARMER study. The CHARMER study is a programme of research to develop and test an intervention to support geriatricians and pharmacists to proactively deprescribe unnecessary or harmful medicines for older people in hospital.

Today I'd like to ask you about your experience of being involved in the CHARMER study. I am keen to hear your thoughts on how the study went from your perspective – both positive and negative aspects. There are no right or wrong answers. The information you provide will help us to understand what worked well and what could be improved.
Today I will be recording our discussion but only myself, the researchers working on the study and the person who transcribes the interview will hear what we say. When the interview is transcribed, we remove any identifiable information such as your name so that we have an anonymised record of what we talked about. After the interview is transcribed, we will securely destroy the recording of the interview.

If we use any quotes from you in our reports, you will not be able to be identified.
You can also stop the interview at any time and without providing a reason.

Do you have any questions for me before we start?
Can you tell be a bit about yourself?
Can you tell me about your role in the CHARMER study?

Can you tell me about your experiences in the study?
Prompts:
Why did you decide to take part? What worked well? What didn't work so well? How could we improve this?

What do you think of the CHARMER intervention?
Prompts:
Did you access and use all components or only some? (as relevant e.g. pharmacist accessed all pharmacist components etc)
What did you think about the different components of the intervention? For each intervention component (as appropriate): how did you find this? Was it useful? Could it be improved, and if so how?

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What impact do you think the CHARMER intervention has had?
Prompts:
What have you noticed?
How do you feel the intervention impacted on discussions you have with patients?
Can you tell me about how your experience of having discussions with patients and/or their carers about their medicines? How did these conversations happen? Were they easy or difficult?
Were there any barriers to having these conversations or anything that could be changed to make these discussions easier?
How confident did you feel about undertaking proactive deprescribing? Do you feel you need any other training or skills to undertake this?
Did you notice other colleagues doing proactive deprescribing?
Do you feel the intervention had impacts on any other aspects? If yes, can you tell me more about these impacts and how they happened?
What are your thoughts on proactive deprescribing? Important part of your role? How have your proactive deprescribing activities changed? Can you see benefits of proactive deprescribing?

Do you feel there were any factors at your site that either helped or hindered the intervention?
Prompts:
These could be related to for example, people, technology, structures etc.
Are/were there any events or initiatives happening at your site that you think may have had an impact on the intervention?
Do you think any changes needed to the intervention itself/mode of delivery for it to be delivered smoothly at your site?

If time:
Can you tell me about your experience of being recruited into the CHARMER study?
Prompts:
What made you decide to take part?
Did you have enough information when approached or were there things you wanted to know?
Do you think any changes need to be made to the process of recruitment? (If yes): can you tell me what these would be?

We are interested to find out about the data collection process within CHARMER. Can you tell me about your experiences of providing data during the CHARMER study?

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Prompts:
Time needed? Were there things that were easier to provide/complete? Were any data burdensome to complete? Could we make any changes to data collection, if so what changes do you think are needed?

Is there anything else that you would like to discuss that we have not covered?

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Patients [45 minutes]

Interview 1:

Introduction:

I am a researcher working on the CHARMER study. The CHARMER study is a programme of research to develop and test a method to support consultants and pharmacists to review and stop unnecessary or harmful medicines. I'm interviewing you because you were at one of the hospitals that took part in CHARMER and I'd like to hear your thoughts about your experience in hospital.

I am keen to hear your thoughts on how the study went from your perspective – both positive and negative aspects. There are no right or wrong answers. The information you provide will help us to understand what worked well and what could be improved.
Today I will be recording our discussion but only myself, the researchers working on the study and the person who transcribes the interview will hear what we say. When the interview is transcribed, we remove any identifiable information such as your name so that we have an anonymised record of what we talked about. After the interview is transcribed we will securely destroy the recording of the interview.
If you do disclose anything which might identify a risk to yourself or to others, I would have a duty to let someone know, such as your GP, but I would tell you if I thought this were the case.
If we use any quotes from you in our reports, you will not be able to be identified.
You can also stop the interview at any time and without giving a reason.
Do you have any questions for me before we start?

Can you tell me what led to you going into hospital and how long you stayed in hospital?

Can you tell me about what happened whilst you were in hospital?

Whilst you were in hospital, can you tell me if anything happened with any of your medicines?

(If yes) Prompts:
Who discussed this with you?
How did you feel about the discussion?
What were the decisions made about your medicines and how were you involved in these decisions?
How did you feel about these decisions?

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Do you remember being asked if you would like to be involved in the CHARMER study? A research nurse or doctor may have asked you.
Prompts:
Can you tell me about the conversation you had before deciding to take part?
Do you remember if you had any questions about the study?
Do you remember being given an information sheet about this study? If yes, what did you think of the study information sheet that you received?
Did it provide complete information about the study? If not, what more do you think should be included/made it clear?
Do you feel you received enough information about the study, or would you have liked to have received any other information?

Since you left hospital, what has happened?
Prompts:
Have you seen your GP or pharmacist? If yes, have you had any discussions about your medications with them?
[If medicines reviewed in hospital], have any of your medications changed since leaving hospital? [Explore medications that were stopped in hospital or dosage reduced and whether these were re-started or increased; and explore any medications started in hospital that have been stopped since discharge]

Part of being in the study has meant that you have phone calls with a nurse, and they ask you about your thoughts and feelings about how your current health impacts your daily life. How did/do you feel about answering these questions?
Prompts:
Could we do anything differently when asking you these questions?

Is there anything we haven't covered today that you would like to discuss?

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Interview 2:

Introduction:

I am a researcher working on the CHARMER study and we spoke X months ago. The CHARMER study is a programme of research to develop and test a method to support consultants and pharmacists to review and stop unnecessary or harmful medicines. I'm interviewing you because you were at one of the hospitals that took part in CHARMER and I am keen to hear your thoughts on what has happened since your last interview with me – both positive and negative aspects. There are no right or wrong answers. The information you provide will help us to understand what worked well and what could be improved.

Today I will be recording our discussion but only myself, the researchers working on the study and the person who transcribes the interview will hear what we say. When the interview is transcribed, we remove any identifiable information such as your name so that we have an anonymised record of what we talked about. After the interview is transcribed we will securely destroy the recording of the interview.

If you do disclose anything which might identify a risk to yourself or to others, I would have a duty to let someone know, such as your GP, but I would tell you if I thought this were the case.

If we use any quotes from you in our reports, you will not be able to be identified.

You can also stop the interview at any time and without giving a reason.

Do you have any questions for me before we start?

So today I am interested in hearing what has happened since we last met. Last time, you had left hospital X weeks before.

Since we met last for an interview, what has happened?

Prompt:

How has your health been?

(If appropriate) Last time you told me that some of your medicines changed in hospital.

Have your medicines stayed the same or have they changed since we last spoke?

Prompts:

Have you started any new medicines? Have you stopped any medicines? Do you know why these medicines changed?

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(If appropriate) How did you feel about the changes made to your medicines?
Prompts:
Did you agree with the changes?/How did you feel about the changes?
Did you understand why your medicines were changed?
Did you discuss the changes with anyone (e.g. family member)?

Have you seen your GP or pharmacist since we last spoke?
Prompts:
If yes, can you tell me about these visits? Have you had any discussions about your medications with them?

Part of being in the study has meant that you have phone calls with a nurse, and they ask you about your thoughts and feelings about how your current health impacts your daily life. How did/do you feel about answering these questions?

Is there anything we haven't covered today that you would like to discuss?

Scott S, *et al. BMJ Open* 2023; 13:e075795. doi: 10.1136/bmjopen-2023-075795

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Consultees [45 minutes]

Introduction:

I am a researcher working on the CHARMER study. The CHARMER study is a programme of research to develop and test a method to support consultants and pharmacists to review and stop unnecessary or harmful medicines. I'm interviewing you because you were at one of the hospitals that took part in CHARMER and I'd like to hear your thoughts about your relative's experience in hospital.

I am keen to hear your thoughts on how the study went from your perspective – both positive and negative aspects. There are no right or wrong answers. The information you provide will help us to understand what worked well and what could be improved.

Today I will be recording our discussion but only myself, the researchers working on the study and the person who transcribes the interview will hear what we say. When the interview is transcribed, we remove any identifiable information such as your name so that we have an anonymised record of what we talked about. After the interview is transcribed we will securely destroy the recording of the interview.

If you do disclose anything which might identify a risk to yourself or to others, I would have a duty to let someone know, such as your GP, but I would tell you if I thought this were the case.

If we use any quotes from you in our reports, you will not be able to be identified.

You can also stop the interview at any time and without giving a reason.

Do you have any questions for me before we start?

Can you tell me what led to your relative/friend going into hospital and how long they stayed in hospital?

Prompts:

When did they go to hospital? Was this an emergency or planned hospital stay?

Can you tell me about what happened when your relative/friend was in hospital?

Whilst they were in hospital, can you tell me if anything happened with any of their medicines?

Prompts:

Who discussed this with you?

How did you feel about the discussion?

What were the decisions made about their medications and how were you involved in these decisions?

How did you feel about these decisions?

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Do you remember being asked if you would like to be involved in the CHARMER study? A research nurse or doctor may have asked you.
Prompts:
Can you tell me about the conversation you had before deciding to take part?
Do you remember if you had any questions about the study?
Do you remember being given an information sheet about this study? If yes, what did you think of the study information sheet that you received?
Do you feel you received enough information about the study, or would you have liked to have received any other information?

Since your relative/friend left hospital, what has happened?
Prompts:
Have they seen their GP or pharmacist?
If yes, have you had any discussions about their medications with them?
[If medicines reviewed in hospital], have any of their medications changed since leaving hospital? [Explore medications that were stopped in hospital or dosage reduced and whether these were re-started or increased; and explore any medications started in hospital that have been stopped since discharge]

Part of being in the study has meant that you have phone calls with a nurse, and they ask you about your thoughts and feelings about how your relative/friend's current health impacts your daily life. How did/do you feel about answering these questions? Could we do anything differently when asking you these questions?

Is there anything we haven't covered today that you would like to discuss?

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Interview 2:

Introduction:

I am a researcher working on the CHARMER study and we spoke X months ago. The CHARMER study is a programme of research to develop and test a method to support consultants and pharmacists to review and stop unnecessary or harmful medicines. I'm interviewing you because you were at one of the hospitals that took part in CHARMER and I am keen to hear your thoughts on what has happened since your last interview with me – both positive and negative aspects. There are no right or wrong answers. The information you provide will help us to understand what worked well and what could be improved.

Today I will be recording our discussion but only myself, the researchers working on the study and the person who transcribes the interview will hear what we say. When the interview is transcribed, we remove any identifiable information such as your name so that we have an anonymised record of what we talked about. After the interview is transcribed we will securely destroy the recording of the interview.

If you do disclose anything which might identify a risk to yourself or to others, I would have a duty to let someone know, such as your GP, but I would tell you if I thought this were the case.

If we use any quotes from you in our reports, you will not be able to be identified.

You can also stop the interview at any time and without giving a reason.

Do you have any questions for me before we start?

So today I am interested in hearing what has happened since we last met. Last time, your relative/friend had left hospital X weeks before.

Since we met last for an interview, what has happened?

Prompts: How has your relative/friend's health been?

(If appropriate) Last time you told me that some of your relative/friend's medicines changed in hospital. **Have their medicines stayed the same or have they changed since we last spoke?**

Prompts:

Have they started any new medicines? Have they had any medicines stopped? Do you know why these medicines changed?

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(If appropriate) How did you feel about the changes to their medicines?
Did you agree with the changes?
Did you understand why their medicines were changed?
Did you discuss the changes with anyone?

Have you seen their GP or pharmacist since we last spoke?
If yes, have you had any discussions about their medications with them?

Is there anything we haven't covered today that you would like to discuss?

Scott S, *et al. BMJ Open* 2023; 13:e075795. doi: 10.1136/bmjopen-2023-075795

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Primary care members with prescribing role [45 minutes]

Introduction:

I am a researcher working on the CHARMER study. The CHARMER study is a programme of research to develop and test an intervention to support geriatricians and pharmacists to proactively deprescribe unnecessary or harmful medicines for older people in hospital.

I am keen to hear your thoughts on how the CHARMER intervention from your perspective in primary care– both positive and negative aspects. There are no right or wrong answers. The information you provide will help us to understand what worked well and what could be improved. Today I'd like to hear your thoughts and experiences relating to what happened to patients, who were involved in the CHARMER study, after they left hospital and accessed primary care. I'm particularly interested in hearing about how their medicines were managed.

Today I will be recording our discussion but only myself, the researchers working on the study and the person who transcribes the interview will hear what we say. When the interview is transcribed, we remove any identifiable information such as your name so that we have an anonymised record of what we talked about. After the interview is transcribed we will securely destroy the recording of the interview.

If we use any quotes from you in our reports, you will not be able to be identified.
You can also stop the interview at any time and without giving a reason.
Do you have any questions for me before we start?

Can you tell me a bit about yourself and your role?

How do you feel about proactive deprescribing being undertaken in hospital?

Can you tell me how many of your patients, that you are aware of, were involved in the CHARMER study?

Prompts:
How did you find out they were in the study?
Did they discuss the study or their hospital stay with you?

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What was your experience after the patient was discharged from hospital?
Prompts:
Can you tell me what happened after your patient(s) discharge from hospital?
Were any medications changed during their hospital stay?
Have they made an appointment to see you?
Have you had any discussions about their medications being deprescribed?
Which types of medicines? Can you tell me about how communication/coordination between the hospital and primary care happened?
Can you tell me about the quality of the discharge letters for these patients? What type of information was provided? Was there information that was helpful or information that was missing?

***(If applicable)* How do you feel about the decisions that were made in hospital for your patient(s) regarding their medication?**

How do you think the patient's experience was?
Prompts:
How do you think your patients and carers found their stay in hospital and decisions around their medicines?
Do you feel that patients understood what had happened during their hospital stay?
Did you have any discussions with your patients' carer after their discharge from hospital?
Can you tell me what questions they had or how they found the decisions about their relative's medication?

Were deprescribing decisions made in hospital maintained/implemented or changed?
Prompts:
Can you tell me about the communication between the hospital and primary care?
Were there any parts in the process that worked well?
Are any improvements that could be made to the CHARMER intervention/process?
How do you feel the CHARMER intervention has impacted you? (this could be positive or negative)

Is there anything we haven't covered today that you would like to discuss?

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Mechanism of Action (MoA) questionnaire

Participant ID:

Baseline/Follow-up (delete as appropriate)

1. I have the knowledge I need to enable me to make the right deprescribing decision/recommendations for my patients' medication.

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
☐	☐	☐	☐	☐

2. Proactive deprescribing has more advantages than disadvantages

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
☐	☐	☐	☐	☐

3. I feel confident that I could make the right deprescribing decision/recommendations for my patients' medication.

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
☐	☐	☐	☐	☐

4. Proactive deprescribing is a clinical practice that is accepted by patients and carers

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
☐	☐	☐	☐	☐

5. I have the skills I need to enable me to have effective consultations with patients and/or their carers about proactive deprescribing of their medication.

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
☐	☐	☐	☐	☐

6. If I did proactively deprescribe or recommend proactive deprescribing I would worry about it after.

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
☐	☐	☐	☐	☐

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7. Marking proactive deprescribing decisions and/or recommendations is consistent with what is expected of my role.

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
☐	☐	☐	☐	☐

8. I can actively support deprescribing within my regular workload

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
☐	☐	☐	☐	☐

9. My trust has a clear policy for deprescribing

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
☐	☐	☐	☐	☐

10. My department has a clear policy for deprescribing

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
☐	☐	☐	☐	☐

11. I feel that deprescribing efforts in my trust are noticed

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
☐	☐	☐	☐	☐

Document 6

CHARMER
COMPREHENSIVE GERIATRICIAN-LED MEDICATION REVIEW

NHS Trust Header

Practitioner - CONSENT FORM
(Version 1.0, 28/02/2022)

Title of Study: CHARMER WP3

Comprehensive Geriatrician led Medication Review

Chief Investigator:

Principal Investigator: <insert name and site>

Name of Participant:

Please initial box

1. I confirm that I have read and understand the information sheet version number 1, dated 28/02/2022 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. If I do withdraw, I understand that any data collected may continue to be used. ☐
3. I agree to receive CHARMER training and following this training to deliver the CHARMER intervention as described in the CHARMER Intervention Guide. ☐
4. I agree to facilitate CHARMER research processes within the hospital. ☐
5. I agree data collected in the study, may be looked at by authorised individuals from the research team, Sponsor, regulatory authorities, or from the NHS Trust. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
6. I agree to my contact details and a copy of this consent form being held securely and confidentially by CHARMER coordinating centre/Norwich Clinical Trials Unit. ☐
7. OPTIONAL: I am happy to be contacted about participating in a research interview which is part of this study. ☐
8. OPTIONAL: I understand that my research interview will be recorded. For interviews held via Zoom or Skype this recording will include audio as well as visual recording of my participation in the interview. ☐
9. I give permission for direct quotations to be used in the study report, research publications, conference proceedings and other academic outputs. I understand that quotes will be anonymised and I will not be identifiable in any way. ☐
10. I understand that a CHARMER research team member will observe some of the implementation events for the intervention and will make notes during these observations. I understand that my personal details will be kept confidential ☐

☐

Document 6

11. I agree that my research data may be used for future ethically approved research.

12. I would like to receive information about the study results ☐

13. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

3 copies:
1 for participant, 1 for location file (original) and 1 for Norwich CTU Trial Office

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CHARMER
COMPREHENSIVE GERIATRICIAN-LED MEDICATION REVIEW

NHS Trust Header

Patient - CONSENT FORM

Title of Study: CHARMER WP3

Comprehensive Geriatrician led Medication Review

Chief Investigator:

Principal Investigator: <insert name and site>

Name of Participant: _____

Please initial box

1. I confirm that I have read and understand the information sheet version number 1 dated 28/02/2022 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. If I do withdraw, I understand that any data collected may continue to be used. ☐
3. I agree that relevant sections of my medical records and data collected in the study may be looked at by authorised individuals from the research team, Sponsor, regulatory authorities, or from the NHS Trust where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I agree that my research data may be used for future ethically approved research. I understand that my personal details will be kept confidential, and I will not be identifiable in any public output, or data shared outside the immediate research team. ☐
5. I agree to my GP or other health and social care professionals being informed of my participation in this study. ☐
6. I agree to my contact details and a copy of this consent form being held securely and confidentially by CHARMER coordinating centre/Norwich Clinical Trials Unit. ☐
7. I agree to be contacted about participating in follow-up research questionnaires which are part of this study. ☐
8. OPTIONAL: I agree to be contacted about participating in research interviews to provide feedback on this study ☐
9. OPTIONAL: I understand that my research interview will be recorded. For interviews held via Zoom or Skype this recording will include audio as well as visual recording of my participation in the interview. ☐

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10. I give permission for direct quotations to be used in the study report, research publications, conference proceedings and other academic outputs. I understand that quotes will be anonymised and I will not be identifiable in any way. ☐

11. I would like to receive information about the study results ☐

12. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

4 copies:
1 for participant, 1 for location file (original), 1 GP practice and 1 for Norwich CTU Trial Office