CompreHensive geriAtRician-led MEdication Review (CHARMER)
A programme grant to develop and test a practitioner behaviour change intervention for deprescribing in the hospital setting

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Programme Management Group Meeting

Wednesday 10th January 2024

14:00 – 15:30

MINUTES

1. Attendees:

David Alldred (DA)	David Wright (DW)
Debi Bhattacharya (DB)	Martyn Patel (MP)
Allan Clark (AC1)	Victoria Keevil (VK)
Kelly Grant (KG)	Sion Scott (SS)
Amber Hammond (AH)	Michael Sheridan (MS)
Erika Sims (ES)	David Taylor (DT2)
Jack Webb (JW)	Ian Kellar (IK)
Cara Beswick (CB)	Ben Daley (BD)
Helen Jukes (HJ)	Janet Gray (JG1)
Erica Berardi (EB)	Charlotte Jones (CJ)
Sujata Walkerley (SW)	Jackie Martin-Kerry (JMK)
Lindsey Tashlin (LT)	Jakhura Yaseen (JY)
Katherine Murphy (KM)	Miles Witham (MW)
Jo Taylor (JT)	Antony Colles
David Turner (DT1)	

2. Apologies:

Bethany Atkins (BA)	Jennie Griffiths (JG)

Action Points:	For	By
Provide effect size information from Canadian study to PSC	DB/JMK	January 2024
Circulate updated opinion piece to authorship team	JMK	Late January 2024
Report on WP3 manuscript completion and submission	SS	April PMG meeting
Report on finance meeting with DW and Helen Jukes	JMK	April PMG meeting
Progress primary care engagement strategy with Primary Care Advisory Group	JMK	May 2024
Develop page for Primary Care on CHARMER study website	JMK/BA	May 2024
BA to update benchmarking elements according to feedback	BA	Late January 2024
Share blog post for feedback and send final copy to ISCRTN	JMK	Mid-January 2024
Group to share thoughts on journal submissions, and upcoming conferences where CHARMER can be presented	ALL	April PMG meeting

3.	**Previous meeting minutes** ***Review of previous meeting actions:*** DB confirmed that summer meeting minutes (July 2023) had been circulated by JMK for accuracy and requested the group to confirm approval by email, prior to being uploaded to the website. The PSC wanted information about the effect size seen in the Canadian study – remains to be actioned. Further details on the Primary Care Advisory Group will be picked up later in the meeting, as additional group input is required. The feasibility main results paper will be covered later in the agenda. JMK has been in touch with MP regarding the paper exploring proactive deprescribing from geriatricians and pharmacists' perspectives. **Action: DB/JMK to provide effect size information from Canadian study to PSC** ***Review of previous minutes:*** DB noted no redactions were required. Minutes were approved.
4	**New Team Members**

	DB introduced the newest team members since the last PMG. LT joined the CHARMER team as a full-time Clinical Trial Assistant in November. LT relocated from Toronto about a year ago where she worked in health care and research. JY has joined us from the De Montfort University working on the Human Brain Project. JY is in a part-time role as the Work Package 4 (WP4) Dissemination Coordinator for CHARMER, including the website and social media. BD has extensive experience as a researcher and is now a clinical medic as a specialty doctor. BD will be part-time with the Dissemination team, supporting the Work Package 4 (WP4) Case Study which is guided by the Work Package 5 (WP5) framework. DB added that WP5 is a dissemination framework whereby a case study is being developed to operationalise the framework using WP4. This differs from JY's role which is dissemination more broadly applied across all CHARMER activities. CJ is a pharmacist with a background in community pharmacy, working in research over the last year. CJ will be assisting BA with the implementation process in WP4.
1.	**Work Package (WP) Progress Update** DB shared the PMG Newsletter which has been sent out. WP4 will be covered in detail later. WP1 & 2 are complete. JMK shared that the WP1 opinion piece regarding challenges with patient involvement with Core Outcome Sets (COS) is being revised, moving away from trials journals and will be submitted to Age and Aging journal. DB added that the focus is about making the methodology appropriate to support older people's inclusion in the COS development process. An update on WP3 papers was provided by SS. The feasibility study protocol paper was published in BMJ Open last year. SS is drafting the main results paper with a high-level summary of the process evaluation while JMK has also begun work on a separate comprehensive process evaluation paper that will use Normalisation Process Theory (NPT) and Theoretical Domains Framework (TDF) in the analysis. SS asked the group to make a decision regarding missing data results from WP3 which have yet to be shared from NHS England (NHSE). These data link the hospital stay information

	(including mortality) with the information reported in primary care regarding the restarting of medicines. SS suggested one of two options, use the data that is available from NHSE noting this as a limitation, or wait until the complete dataset is available. The amount of time for NHSE to deliver the data is unknown. MW suggested looking at the purpose of the paper – is it showing the results of the feasibility study or processing methodology? The former necessitating waiting for the data. MW added that part of the learning of the study was the difficulty in obtaining the data and this is a potential strength. AC pointed out that the key learnings have been done as the study has progressed to the main trial, the paper is to report the findings regardless of the data which does not change those findings nor the progression of the trial. MW also pointed out that a feasibility study should not be rigid and an evolving protocol is permitted in progressing to the definitive study. DA agreed with these points adding that the wait time to receive the data has gone well beyond the anticipated timeline. SS will continue with the manuscript without the NHSE data. **ACTION: JMK to circulate revised opinion piece to authorship team** **ACTION: SS to report on WP3 manuscript completion and submission**
2.	**Budget Update** DB noted no changes from previous meeting. JMK commented that DW, JMK and Helen Jukes (Research Administrator, University of Leicester) will be meeting with finance officer next week to review the budget and obtain accurate numbers. **ACTION: JMK to report on finance meeting with DW and Helen Dukes.**

3.	**WP4** **Capability & Capacity, and Randomisation** DA provided an update. A key change in terms of the definitive trial was a move of the start date to 1st February 2024. This required multiple meetings and discussions for approval given that sites were struggling to provide Capability and Capacity confirmation in time for 1st December 2023 as previously reported in the newsletter. This will have an impact on the Gantt Chart which will be discussed later. DA continued that the study needed 20 sites to open simultaneously in the step wedge design, with an intervention at different points throughout the trial. In addition, there will be four reserve sites in case a site has to drop out, bringing the total to 24. To date 18 sites have provided Capability and Capacity, 16 sites have been randomised, two sites are ready to be randomised and 10 sites are actively engaging with the team for the final six spots. The expectation is to have all five sites per step and the four reserve sites established before the end of January in order to provide the necessary printed documents and training for data collection. There is a good geographic representation of the participating sites covering the north, south, south coast and midlands. DA shared via slide the 10 sites, what items were outstanding in order to be in the trial and the date the team were last in communication, all within one or two days. DA noted the effort the CHARMER Clinical Trial Unit group has put in to secure the sites and despite the delayed start, the outlook, overall, is positive. **Primary Care Engagement (PCE) Strategy** JMK spoke to the PCE strategy having circulated the corresponding documents prior to the meeting. This strategy resulted from an awareness that during the feasibility study no discussion occurred with primary care staff who had a patient involved in CHARMER. It arose that understanding what occurred once the patient was back under primary care could address any confusion about the medications that changed, were medications restarted, or did the patient have multiple questions about what occurred. In meetings with the Primary Care Advisory Group (PCAG) concerns around the discharge summary were raised due to variability, and possible lack of clarity in these documents. PCAG was made aware that CHARMER is its own intervention without control over the discharge summaries. As a result, a primary care engagement strategy was developed to hear from primary care colleagues and perhaps also support

	transition from secondary care to primary care. JMK continued that work with PCAG helped identify different stakeholders that may want to know about CHARMER and send these groups a flyer or similar. However, there has been some concern from members of the team that this process might contaminate the trial and may change behaviours. JMK noted that recruitment numbers were low in the feasibility study which may have impacted hearing back from primary care. In addition, the primary care flyer has been updated for clarity. JMK invited comment from the group on this strategy. MW commented that a light touch in PCE would not likely impact nor would it accomplish anything concrete. Something more in depth may start to have the dimension of an intervention. MW continued that the feedback that had been given focused on the discharge summary which is out of the remit of the trial and concluded that unless it was something truly impactful there was unlikely to be a substantial difference. Discussion continued around the process of engaging with primary care and/or practice managers through one or two letters as patients in the enhanced data collection will be asked to identify their GP practice; determining the goal of PCE strategy; concern around changing behaviours of hospital staff, GPs and Primary care staff. DT2 noted that the PPI group are drafting separate CHARMER pages for the website, targeting the different audiences: patients, public, researchers and hospital staff. DT2 posited that a page for primary care was also required, noting that no real risk of contamination existed by passively providing information. DA added the importance of raising awareness with the GPs and directing them for answers to questions was acceptable as long as it was done lightly and was not in danger of becoming part of the intervention. DB further shared that the Programme Steering Committee were keen to have the experiences of the primary care group as a part of CHARMER, as not having their input was seen as a weakness. This has led to the work around the PCE strategy to have additional engagement from the primary care group. DB asked for comment regarding encouraging responses to the requests for interviews. Feedback consensus was for the CHARMER group to conduct phone follow-ups to the identified GP practice to raise response rates, and this is already in the protocol and planned processes.

	JMK shared a draft of a flyer that potentially could be sent out, a generic one for wider distribution, as well as a targeted one for hospitals participating in the trial. Discussion ensued around generating interest, timing of sending the flyer, who will be targeted. DB concluded that we will progress with the proposal from the PCAG, the letters from the feasibility study have been enhanced for contacting primary care and receiving feedback from GPs and primary prescribers within the primary care setting. A flyer will be sent after the enhanced data collection, during the implementation phase. **ACTION: JMK to progress strategy with PCAG** **ACTION: JMK/BA to develop page for Primary Care on CHARMER study website** **Changes to trial design and intervention based on feasibility study** JMK presented using a series of slides put together with AH, DB and BA. Implementation learning for the definitive trial: ▪ Gantt chart provided by CHARMER would assist the sites to plan for their implementation phase; CHARMER has also created a checklist and manual which will be uploaded to REDCap and provide prompts to do the required elements. ▪ The handbook was re-written for clarity and now provides in depth detail about who is responsible for which tasks. ▪ A Project Manager was allocated for the implementation phase to ensure it runs smoothly. Feasibility study learning ▪ The PIs were unclear on the meaning of 'Action Plan', nor the 'Launch an Action Plan' ▪ It was planned that the PI would develop a hospital-wide action plan for proactive deprescribing, but it was determined that would be difficult to do in a short timeframe ▪ Most participating geriatricians and pharmacists were unaware of an action plan at their site Changes for definitive trial

	▪ Action plan is now the plan for implementing the other four components of the intervention ▪ A template has been provided to depict what the action plan can look like ▪ Additional guidance has been given on how to launch the action plan e.g., screen savers, departmental meetings The template will be located on Redcap where the sites can then download, adapt, complete the required information and upload it back to Redcap. It captures what happens when, as previously the requested checklist was not returned by the sites making it unclear if they had done the action plan, workshop or other. **Benchmarking reports** Feasibility study learnings ▪ Unclear with definition of 'medicines stopped', nor that the medicines to capture were only the pre-admission medicines. ▪ Confusion around terminology interchange between 'dashboard' and 'benchmarking reports'. ▪ Benchmarking reports were sent as a link in and email but either did not read the email or did not have time to follow through on the link ▪ Data collection and extraction process were not clear, with sites struggling to know what they were meant to be doing. Changes for definitive trial ▪ Clearer definitions and terminology; only using the term benchmarking going forward. ▪ Only pharmacists will be responsible for showing reports, with sites choosing how they want to do this e.g., print and post, bring to briefings. ▪ Additional data will be collected - now including the number of prescribed medicines across all patients on the ward, followed by standardising to account for ward size and number of patients on the ward; this is because in WP3 sites struggled with sharing the number of discussions they had. It was determined sites may only manage to record the number of medicines stopped and standardising the data will allow them to compare themselves to other trusts regardless of whether their conversations are recorded. ▪ More guidance built in on how sites will plan for and monitor benchmarking

Weekly benchmarking reports will capture three elements

1. **Number of preadmission medicines**
   Across all patients on the study ward(s), combined number of medicines each patient was taking before coming to the hospital
2. **Number of preadmission medicines stopped**
   Across all patients on the study ward(s), combined number of preadmission medicines that were stopped.
3. **Number of deprescribing discussions between a healthcare professional and patient**
   Across all patients on the study ward(s), combined number of discussions between a healthcare professional and patient or their representative about potentially stopping a preadmission medicine (as defined above)

Feedback resulted in a request to more explicitly capture the number of patients, the number of discussions should more clearly state that it is per patient as opposed to per medicine, making sure this includes as needed medicines (prn), ensuring sites are creating a proactive system for capturing the number discussions.

Action: BA to update benchmarking elements according to feedback

Briefings

Feasibility study learnings

- It was suggested that sites have planned time for briefings, but one site preferred to have ad-hoc conversations between pharmacists and geriatricians.
- Feedback from one site indicated that benchmark reports could be viewed during briefings.

Changes for definitive trial

- Encourage sites to decide during the implementation period how geriatricians and pharmacists would prefer to meet – set meetings, ad hoc or other.
- Suggest that benchmarking reports are reviewed during the briefings.

	DB shared that tagging the benchmarking reports to the briefings would encourage engagement with them. **Trial Learnings** AH highlighted the key learnings through a slide presentation. Feasibility study learnings ▪ Difficult to approach patients/consultees for consent due to COVID/lack of access. ▪ Data definitions were difficult to understand when inputting data e.g., acute medicines, pre-admission medicines, ward-based or hospital-based medicines. ▪ Consent rates for patients were very low for the feasibility study, possibly due to nurses not being able to assess patients 'capacity beforehand. ▪ Confusion surrounding professional consultees, uncertain who was considered a professional consultee. ▪ CPMS upload issues (CPMS is the database the patient numbers are uploaded to and which record the sites accruals for the recruitment). ▪ SF-36 questionnaire was inappropriate for the patients on the ward, too lengthy and caused confusion with patients. ▪ PI and CRN nurses were sometimes unclear about their role and requirements. Changes for definitive trial ▪ Have added remote consent as an option to face-to-face consent. The protocol now includes the option of phoning for consent, emailing a link to consent, or having it completed on paper and uploading to REDCap. ▪ Capturing pre-admission medications and comparing to medications they are on at discharge, as well as adding additional information to REDCap to reduce confusion. ▪ A tool for assessing capacity has been built into REDCap for nurses to use prior to taking consent, eliminating the need to wait and ask a consultant if the patient can be approached to consent. This should increase the consent rates and allows nurses to assess and consent in one fluid interaction. ▪ Consultees have been limited to carers only, unless a patient is a resident of a care home in which case they can use a staff member from the home as a professional consultee if a personal consultee is not available.

	▪ CPMS upload will be conducted by the CHARMER team each month; the sites will send in their logs and the figures will be directly uploaded in a consistent and timely manner. ▪ Only the EQ-5D will be used in the trial, which is shorter, more straight-forward and more appropriate for use in the study than the SF-36. ▪ CRN nursing teams will have step-by-step guides to explain how to collect the required data and how to use REDCap, as well as a handbook for PIs outlining the activities and when to action them.
6.	**Planned manuscripts** WP1 – Core Outcome Set was published. Opinion piece about involving older people in COS studies will be submitted soon. A second opinion piece is being developed with JMK and MP are working on a paper focused on the challenges with recruiting older people, with recommendations for future studies. WP2 Intervention development paper has been published. WP3 has included a narrative review about developing and evaluating complex interventions by DB, SS and JMK. The main protocol paper was published in August 2023. WP3 feasibility study results (including rapid analysis findings) with SS has tentatively been proposed to send to Research in Social and Administrative Pharmacy but noted this is also where WP2 the intervention paper was sent. SS has asked for the group to read the manuscript when it is circulated and propose a different journal for the feasibility study if appropriate. **Action: SS to share WP3 feasibility study paper and ask for feedback on journal options** WP3 feasibility study looking at the process evaluation results. This is a planned analysis using NPT/TDF to take a deeper look at what occurred during the study. JMK has suggested Implementation Science as the journal to approach for submission but is open to alternative suggestions. WP3 feasibility study data highlighted the different approaches of pharmacists and geriatricians to deprescribing depending on context and the patient needs. JMK

	developed this idea from the data and listening to discussions around deprescribing. The suggested journal is Age and Ageing. WP4 has five planned papers: main protocol; process evaluation detailed protocol; main trial results; health economics; process evaluation results; with no identified journals to submit to as yet. WP5 Dissemination framework paper is being finalised by BA with SS, DB. It is to be finalised and submitted later this month to the journal Research in Social and Administrative Pharmacy. DT2 and JMK have put together a blog potentially to be submitted to ISRCTN where the CHARMER trial has been registered. It will be submitted soon with the aimed timing to coincide with the trial start. JMK will share the draft for feedback and finalise in the next week. **Action: JMK to share blog post for feedback and send final copy to ISRCTN** JMK asked the group to share any ideas around upcoming conferences or opportunities where CHARMER can be presented. **Action: Group to share thoughts on journal submissions, upcoming conferences where CHARMER can be presented**.
7.	**Planned Dissemination & Media Engagement** KM shared that the group had the dissemination framework case study and now are beginning to work on and operationalise. Upcoming tasks included writing to the CEO of NHS England, the Patient Safety Commissioner for England, the British Geriatric Society, the Royal Pharmaceutical Society and the Royal College of Physicians. KM noted two reasons for reaching out to these groups: raising awareness of the CHARMER trial starting on 1st February and the hospitals and trusts involved, and more importantly who within their organization should the dissemination team be working with to ensure the success of the CHARMER project. KM further noted that the group will be reaching out to the communications departments of all the hospitals for permission to name them and use their logo in press releases and other communications over the duration of the trial, as well as requesting a paragraph of support around their decision to be a part of the CHARMER trial. KM shared that a statement from Care Quality Commission had already been provided following the work DB and KM had done over several months. KM finished with noting the additional

	intention of writing to National Healthwatch England and the local Healthwatch groups associated with Trusts involved in the trial.
8.	**Gantt chart** ES updated the group sharing that AH and team are finishing the trial setup and the expectation is the trial will open on 1st February and run for 21 months. This means that the trial will extend past the current contracted trial period to June 2025, month 58. A team met yesterday to discuss the impact and aim of the group. ES noted the funder is aware the trial is behind, owing in part to the six-month delay of the delivery of WP3, in turn hindered by issues associated with delivery of WP1 and WP2 associated with COVID, as well as additional challenges. The funder has advised against applying for a costed extension until the trial is in the final year of the grant, the middle of 2024. The three main trial groups at University of Leicester, University of Leeds and University of East Anglia have been setting aside funds, where they are able, to assist in underpinning the extension period. ES continued that the end of the trial will be October 2025, with sites in Step 4 having additional data collection to come through in an allowable additional one month. With the primary outcome data coming from NHS England an estimation of receipt of this data is February 2026 followed by an additional 6-months for analysis. This takes the trial to 72 months and effectively a 14-month extension (less the six the funder is aware of, the extension request would be for 8 months). ES continued that conversations with the respective research offices have begun to assess the budgets, underspend and likely request for the costed extension. The expectation is that a full 14-month amount will not be required. ES finished with a comment that they plan to provide the finances at the Trial Steering Committee in early March to provide an estimate of what may be required for the extension. A formal report would be submitted in August 2024, followed by the issuance of the formal extension request form.
9.	**Risk register/horizon scanning** In the interest of time this item was deferred to the next meeting. Action: Add Risk register/horizon scanning to next meeting
4.	**AOB**

	No other business raised.
5.	Next meeting – 16th April 2024