Protocol for the process evaluation of a cluster randomised controlled trial to determine the effectiveness and cost-effectiveness of independent pharmacist prescribing in care home: the CHIPPS study

CURRENT STATUS: ACCEPTED

Christine Bond
University of Aberdeen Institute of Applied Health Sciences

c.m.bond@abdn.ac.uk Corresponding Author
ORCiD: https://orcid.org/0000-0003-0429-5208

Richard Holland
University of Leicester Medical School

David Alldred
Leeds School of healthcare

Antony Arthur
University of East Anglia School of Health Sciences

Garry Baton
University of East Anglia

Linda Birt
University of East Anglia School of Health Sciences

Annie Blyth
University of East Anglia

James Desborough
University of East Anglia

Joanna Ford
Addenbrookes Hospital

Christine Handford
Norfolk and Suffolk Primary and Community Care Research office
Helen Hill
Athena Care Homes

Camel Hughes
Queens University Belfast

Vivienne Maskrey
University of East Anglia

Phyo Myint
University of Aberdeen Institute of Applied Health Sciences

Nigel Norris
University of East Anglia

Fiona Poland
University of East Anglia

Lee Shepstone
University of East Anglia

Arnold Zermansky
University of Leeds

David Wright
University of East Anglia

DOI:
10.21203/rs.2.16304/v2

SUBJECT AREAS
Internal Medicine   Integrative & Complementary Medicine

KEYWORDS
Older people, pharmacist prescribing, care homes, polypharmacy, process evaluation of randomised controlled trial
Abstract

**Background:** Prescribing, monitoring and administration of medicines in care homes could be improved. A cluster RCT is ongoing to evaluate the effectiveness of an independent prescribing pharmacist assuming responsibility for medicines management in care homes compared to usual care.

**Aims and Objectives:** To conduct a mixed methods process evaluation of the RCT, in line with MRC process evaluation guidance, to inform interpretation of main trial findings and if the service is found to be effective and efficient, to inform subsequent implementation.

**Objectives:**

1. To describe the intervention as delivered in terms of quality, quantity, adaptations and variations across triads and time.
2. To explore the effects of individual intervention components on the primary outcomes.
3. To investigate the mechanisms of action.
4. To describe the perceived effectiveness of relevant intervention components (including PIP training and care home staff training) from participant (GP, care home, PIP and resident/relative) perspectives.
5. To describe the characteristics of GP, care home, PIP and resident participants to assess reach.
6. To estimate the extent to which intervention delivery is normalised among the intervention healthcare professionals and related practice staff.

**Methods:** A mix of quantitative (surveys, record reviews) and qualitative (interviews) approaches will be used to collect data on the extent of the delivery of detailed tasks required to implement the new service, to collect data to confirm the mechanism of action as hypothesised in the logic model, to collect explanatory process and final outcome data, and data on contextual factors which could have facilitated or hindered effective and efficient delivery of the service.

**Discussion:** Recruitment is ongoing and the trial should complete in early 2020. The systematic and comprehensive approach that is being adopted will ensure data is captured on all aspects of the study, and allow a full understanding of the implementation of the service and the RCT findings. With
so many interrelated factors involved it is important that a process evaluation is undertaken to enable us to identify which elements of the service were deemed to be effective, explain any differences seen, and identify enablers, barriers and future adaptations.

**Trial Registration** ISRCTN 17847169

Date registered: 15/12/2017

Link: [http://www.isrctn.com/ISRCTN17847169](http://www.isrctn.com/ISRCTN17847169)

**Introduction**

Medication management in care homes is sub optimal\(^1\). Despite various policy recommendations\(^2-7\) the majority of care home residents continue to receive inappropriate medication, and a significant number of administration errors occur\(^8\). Many residents are on multiple medications, and there is overuse of psychotropic medicines, as well as more general concern such as lack of biochemical monitoring of high-risk drugs including methotrexate, azathioprine, amiodarone, warfarin etc. and lack of regular medication review\(^9\). Further there is often poor communication between GPs, care home staff, community pharmacists, residents and their relatives, and a need for training of care home staff, many of whom may not have a theoretical understanding of the requirements for supply, storage, recording and administration of medicines. High staff turnover and the frailty of the resident population are further factors. It has been suggested that errors would be reduced if a single person took on overall responsibility for the medicines management in care homes. Our team proposed this should be an independent prescribing pharmacist (PIP) linked to the care home, and are undertaking a programme of work which has identified logistical and professional barriers to a PIP care home service, and devised solutions to address them\(^10\), devised a training programme for the PIPs to ensure they have the requisite competencies to deliver the service, and identified provisional measures of outcome\(^11\) in preparation for a definitive cluster randomised controlled trial (RCT) to compare the outcomes from the PIP service with usual care. A mixed methods non-randomised feasibility study\(^12\) confirmed the acceptability and feasibility of the processes for participant identification, recruitment and informed consent. The PIP service was found to be acceptable to all
stakeholders and benefits were reported by GPs and care home staff. Appropriate outcome measures and tools were confirmed and minor refinements were made to the service specification and RCT protocol. The definitive cluster RCT is ongoing and will complete in May 2020. An internal pilot within the definitive trial has confirmed: (i) the feasibility of recruiting and randomising sufficient GP practices, PIPs, care homes and residents; (ii) the availability of data for primary outcome at 3 months; (iii) confirmation that there are no intervention related safety concerns and (iv) researcher blinding and unblinding. The definitive RCT was approved by Ethics Committees in England and Scotland, and registered with the ISRCTN registry (Registration number ISRCTN 17847169). A protocol paper (Protocol version 5 1.7.18) for the main trial, following SPIRIT guidance, has been submitted to BMC Trials. This current paper describes the protocol for the process evaluation protocol that accompanies the definitive RCT; it follows the 2014 guidance on process evaluations and details are in Process Evaluation protocol version 4 11.12.18 available from the authors on request. Causal Assumptions The definitive RCT is evaluating the efficacy and efficiency of implementing and delivering a PIP service and comparing outcomes for care home residents who receive the PIP service with outcomes for residents who continue to receive usual care. In total 44 GP/PIP/care home groups (subsequently referred to as triads) and 880 patients will be included in four geographical areas of East Anglia, Leeds, North East Scotland and Northern Ireland. As noted above the problem is that medicines management in care homes is sub-optimal and complex, because the frailty and comorbidities of residents means many are on multiple medications. A logic model was developed (Appendix 1) to demonstrate how the proposed PIP service could address the various issues. The PIP intervention is described below.

The Intervention

At intervention care home(s), PIPs working in collaboration with the relevant GP(s), will assume responsibility for the medicines management of a mean of 20 care home residents living in one or
more care homes associated with the GP practice. To ensure competency in professional role and study procedures the recruited PIPs are qualified independent prescribers, and have attended a two day face-to-face training programme, which included an overview of the trial design, project delivery, and preparation for the role; the service specification and completion of the Pharmaceutical Care Plans (PCPs). This was followed by time to develop relationships with medical practices (for those unfamiliar with the practice), care homes and community pharmacists, including performing medication reviews with GPs and observing medication administration by care staff, before final sign off by clinically qualified professionals independent of the research team.

A service specification for the PIPs has been developed iteratively in the earlier stages of the project, and is attached (see Appendix 2). In summary it includes:
reviewing a participating resident’s medication and developing and implementing a Pharmaceutical Care Plan
assuming prescribing responsibilities
supporting systematic ordering, prescribing and administration processes within each care home, GP practice and supplying pharmacy where needed
providing training to staff in care home and GP practice
communicating with GP practice, care home, supplying community pharmacy and study team

*The Control arm*

At each control care home, medicine management is according to usual practice, in which the GP(s) has responsibility for the medicines management of care home residents living in one or more care homes associated with the GP practice. Pharmacy provision is also according to usual practice in that area.

*The CHIPPS RCT process evaluation*

The aims of the process evaluation, described in this paper are informed by the logic model and the stages of the MRC process evaluation framework 14,15. These are listed below.

1. To describe the intervention as delivered in terms of quality, quantity, adaptations and variations across triads and time (see Table 1).

2. To explore the effects of individual intervention components on the primary outcomes (see Tables 2 and 3).
3. To investigate the mechanisms of action (see Table 2).

4. To describe the perceived effectiveness of relevant intervention components (including PIP training and care home staff training) from participant (GP, care home, PIP and resident/relative) perspectives (see Tables 2, 3 and 4).

5. To describe the characteristics of GP, care home, PIP and resident participants to assess reach (see Table 4).

6. To estimate the extent to which intervention delivery is normalised among the intervention healthcare professionals and related practice staff (see Table 4).

7. If the service is found to be effective and efficient, to inform subsequent implementation.

Methods

Design

In line with the MRC guidance on process evaluation\textsuperscript{14,15} this mixed methods process evaluation using qualitative and quantitative approaches will collect data on implementation of the intervention, mechanisms of impact, outcomes and contextual factors. The tasks, aims, data and data source for each of these are summarised in Tables 1-4. All data is collected, from intervention arm participants only, after the 6 month study period is completed for an individual participant.

Implementation

Data will be collected on the effectiveness of the training, and the services delivered by the PIPs (see Table 1 below) to provide an understanding of whether the PIPS were adequately prepared for the role and the fidelity with which it was delivered.

Mechanism of impact

Data will be collected to confirm the mechanism of impact of the intervention in achieving the desired aim of improved patient quality of care (see Table 2 below). This section draws particularly on the logic model and hypotheses for addressing the highlighted issues. Data will only be collected from the intervention group because we want to see if any observed differences in outcomes between the
groups can be explained by different components of the PIP service. None of these happen in the control (usual care) group.

Outcomes

The outcomes that are collected and which will be used in the process evaluation are described in Table 3. The selected outcomes are those where there is a clear link to the intervention proposed and where they inform the process.

Contextual factors

Any contextual factors identified which might have affected the delivery and impact of the intervention are described in Table 4 below. This information may include factors related to individual personnel and organisations as well as macro-level issues such as CQC requirements or head office requirements.

Data collection methods

The following text refers to the data sources identified in Tables 1-4 above

Quantitative

Data sources related to training and pharmacist competency

Training feedback: At each PIP training event, PIPs are asked to complete a feedback form at the end of the two-day face-to-face session

Pre intervention competency: Following the training PIPs submit their competency framework to one of the study competency assessors who discuss these with the PIP and signs them off as ‘fit to practise’ as a CHIPPS PIP, prescribes further training or that they are not competent to deliver the study

Review of Pharmaceutical Care Plans (PCPs): Following an agreed process (see Appendices 4 and 5) a random 20% of PCPs are reviewed for appropriateness by study team members who are specialists in care of the elderly medicine. Whilst this process is primarily about safety, the assessment templates also capture data on missed opportunities.

Data sources related to activity

PIP activity log: Intervention PIPs are asked to keep an activity log of their daily activity detailing the time spent on tasks as listed in the service specification (see Appendix 2)

PIP survey: Following each phase, intervention PIPs will be asked to complete a short questionnaire asking about their experiences and the extent to which they delivered aspects of the intervention focussing especially on non-medication review aspects of the service specification (see also NoMAD\textsuperscript{16} survey below).

Data sources related to prescribing

Most of the prescribing associated data is collected as part of the main trial processes to assess
effectiveness and efficiency of the intervention (GP records, health care utilisation, falls records, hospitalisations and deaths) and processes are detailed in the main trial protocol (version 5 1.7.18).

The following lists additional data collected as part of the process evaluation

**Adverse Events**: Adverse events which are not deemed serious are reported using a standard template emailed to the Clinical Trials Unit. All study participants with a professional role (PIP GP, GP staff and CH staff) are made aware of this template and are asked to use this facility if they suspect any adverse event, whether or not there is a perceived causal relationship with the intervention

**Pharmaceutical Care plans**: these are completed by the PIP as a clinical record of their actions including the rationale for these. Data extraction from these will inform the details of medication changes that underpin the global measures such as total number of medicines, BNF categories most involved in changes, and overall DBI. They will also include information on homely remedies and medications available from pharmacies (P medicines) and other retail outlets (GSL medicines) which could result in therapeutic duplication

Data sources related to variability

Variability may be due to inherent non-modifiable differences across participating organisations, sites and individuals, or to the way the CHIPPS service has been delivered or normalised. The former will be explored using sub group analyses and the latter by General Estimating Equations and applying normalisation process theory (NPT) via a NoMAD survey to all participating GPs, PIPS and care home staff at the end of each phase. These are described below.

**Sub group analyses**: The following sub group analyses will be conducted.

1. Comparison of intervention effect by care home types, i.e. nursing versus residential.

2. Comparison of intervention effect by the employment status of the PIPs ie those PIPs that were previously employed, and therefore had an established working relationship, with the study GP practice, and those who were not).

For both of the above an interaction term (between treatment and subgrouping factor) will be added to the primary model and formally tested for a non-zero value.

**General Estimating Equations (GEE)**: Any effect of the PIP intervention is likely to be mediated through a decrease in the DBI. This will be tested using a GEE, adjusting for group membership (this is in order to remove any effect of the PIP intervention on falls mediated via a different causal route).

**NoMAD survey**: The NoMAD survey is an implementation measure based on the Normalisation Process Theory (NPT). The survey form includes preliminary demography and general questions about experiences and satisfaction followed by four sections each relating to one of the NPT domains of coherence, cognitive participation, collective action and reflexive monitoring.

Qualitative
Feedback from all stakeholders on their experiences and views of the intervention is a core part of this process evaluation. This will help contextualise the intervention and increase understanding of the process of implementation and any variation between sites and stakeholders. 

*Interviews:* At the end of each phase of the intervention a purposive sample of up to three of each of GPs, care home managers, staff, residents and relatives (if available) in each of the four geographical areas will be invited to take part in a semi-structured interview. Sampling will be based on a maximum variation sample to reflect differences in site and PIP characteristics e.g. PIP employment status, previous PIP experience, demographic profile of care home residents, rural or urban location. All PIPS will be invited to take part in an interview.

Interviews will be guided by a topic guide (see Appendix 5, developed from the qualitative outputs from the earlier non-randomised feasibility study). Topics will include participants’ views of the PIP service implementation and delivery, communication between staff, perceived effectiveness of the intervention and the identification of any unintentional consequences. All aspects of the service will be probed and there will be specific probes for unforeseen effects to understand whether anything else about the service impacted positively or negatively on patient care or cost-effectiveness. In addition to the above topics the PIP interview will explore their perception of the training programme and its utility.

*Conduct and analysis:* All participants invited to interview will be given an information sheet and consent form prior to participation. Ideally, interviews will be held face to face at a location of the interviewee’s choice but virtual modes will be considered for logistical reasons. All proceedings will be audio recorded and transcribed verbatim. Thematic analysis will draw on the NPT framework but an inductive approach will enable recognition of unexpected emergent themes. Data will be managed in NVIVO.

*Documentary evidence:* Minutes of meetings will provide researcher-reported information on barriers, facilitators and other confounding factors that may have affected delivery of the trial eg (recruitment challenges, reach)

*Data integration/synthesis*
Once all process and main trial outcomes are reported, all the data sets (qualitative and quantitative) will be integrated\cite{19} using a triangulation approach to consider agreement, partial agreement, silence and dissonance across the findings. This will identify relevant actions, and clarify and relate causal pathways to experiences, providing an enriched means to explain unexpected outcomes, and identify optimal intervention contexts. Should the main RCT findings suggest the CHIPPS service is effective and efficient the process evaluation will inform recommendations for implementation into routine services. The process evaluation will also be interrogated to understand reasons why the intervention has not been successful, including variable success rates in different sites.

**Discussion**

This detailed mixed method process evaluation will provide an in-depth understanding of the interactions, barriers and facilitators which underpin the main study quantitative findings. For example, it will provide evidence of the effectiveness of the training in preparing the PIPS to deliver their role, show to what extent the mechanism of impact – improved medication management – has been implemented and the barriers and facilitators that have been encountered. Learning from these will enable decisions to be made about future roll out of the PIP service. Further, if the main trial does not demonstrate that there has been an improvement in patient outcomes it will allow an informed judgement to be made as to whether the service is wrong in principle or whether its implementation has been sub-optimal. Our findings will be especially pertinent and timely as PIPs are already being introduced into care homes for roles such as we are evaluating. The systematic and comprehensive approach that is being adopted is in line with the MRC guidance on process evaluations\cite{14,15}. It will ensure data is captured on all aspects of the study, and allow an understanding of the implementation of the service, confirm its mechanism of action, explore secondary, possibly explanatory, outcomes and any contextual factors. In summary, with so many interrelated factors involved it is important that a process evaluation is undertaken to enable us to identify which elements of the service were deemed to be effective and explain any differences seen whilst also identifying adaptions, enablers and barriers.

**Trial status**
Resident recruitment for the RCT began in February 2018 and will continue until October 2019. Recruitment for the process evaluation started Spring 2019 and will continue until June 2020.

**Declarations**

**Ethics approval and consent to participate**

The study has been approved by both the East of England Research Ethics Committee (REC) and the Scottish REC. Approval in both countries was required because of differences in national laws for involving subjects lacking capacity to consent. R and D approvals have also been secured as necessary for all NHS organisational units involved. All subsequent amendments are submitted as necessary to the relevant committee and not enacted until approval awarded. All participants were formally invited and consented in line with the processes described in the paper.

**Consent for publication**

No individual person’s data in any form is included in this paper. In the reporting of the findings from the process evaluation anonymised quotes may be used. Consent for this has been confirmed.

**Access to data**

Requests for access to the data will be considered, and approved in writing where appropriate, after formal application to the Trial Management Committee/Programme Steering Committee\(^\text{13}\). Considerations for approving access are documented in the Project Management Group/Programme Steering Committee Terms of Reference\(^\text{13}\).

**Declaration of interests**

None of the investigators, grant holders or any of the research team members have any financial or competing interests.

**Funding**

This study is funded by the National Institute for Health Research (NIHR) [Programme Grants for Applied Research (Grant Reference Number RP-PG-0613-20007)]. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care. Other than receiving routine monitoring reports, the funders have had no further involvement in the design and conduct of the trial nor any input to this paper. A copy of the paper has been sent to them for
information.

**Dissemination policy**

Trial results will be communicated to participants, other healthcare professionals, the public, and other relevant groups via local dissemination events, briefing papers, publications in academic and professional journals, conference presentations and other invited speaker events. These results will include the relevant findings from the process evaluation. The PPI representatives will be especially involved in advising on dissemination to the residents, relatives and care home stakeholders, and the wider public. The main trial results will be reported on the study website (https://www.uea.ac.uk/chipps) and via Social media, eg the study Twitter account (@CHIPPS_Study) but these may not include all the process evaluation unless directly relevant.

**Authorship eligibility**

CB led the writing of the manuscript. All authors confirm their eligibility as authors due to their involvement in developing the grant application (AA, DA, AB, CB, GB, LB, JD, JF, CH, CMH, HH, RH KM, VM, PKM, NN, FP, LS, DW AZ) and/or subsequent to funding being awarded, their involvement in the detailed development of the protocol, and its supporting documentation. All authors (other than KM (deceased)) have commented on successive drafts of this paper and approved the final version.

**Acknowledgements**

We also thank the members of the research team who have or are contributing daily to deliver the process evaluation (University of East Anglia: Laura Watts, Joanna Williams, Bronwen Harry, Jeanette Blacklock, Caroline Hill, Frances Johnston; University of Aberdeen: Jacqueline Inch, Frances Notman, Lindsey Dalgarno; University of Leeds Amrit Daffu O’Reilly; Queens University Belfast: Mairead McGrattan); PPIRes (Public and Patient Involvement in Research) for being formal collaborators on the grant and for advice on ongoing conduct of the study as represented by Kate Massey (sadly deceased) and Christine Handford. We thank Ian Small lead primary care medicines management pharmacist in Norwich (now retired) and a co-applicant on the NIHR programme grant. On behalf of the CHIPPS Team, we would also like to acknowledge NHS South Norfolk Clinical Commissioning Group (CCG) as the study sponsor and host of PPIRes, and especially Clare Symms, Norfolk & Suffolk Primary
and Community Care Research Office for her contribution towards management of the study budget.

References

1. Alldred D, Raynor D, Hughes C, Barber N, Chen T, Spoor P. Interventions to optimise prescribing for older people in care homes. Cochrane Database of Systematic Reviews 2013(2).

2. Department of Health: The use of medicines in care homes for older people DH ALERT (2010) 001. 2010.

3. NHS England Clinical Pharmacists in general

Practitioner. https://www.england.nhs.uk/gp/gpfv/workforce/building-the-general-practice-workforce/cp-gp/ Accessed July 10th 2019

4. Scottish Government Primary Care Fund – Pharmacists in GP

Practitioner. https://www.gov.scot/Topics/Health/NHS-Workforce/Pharmacists/Pharmacy Accessed July 10th 2019

5. NHS Wales Clinical pharmacists in GP practices http://www.wales.nhs.uk/news/40188 Accessed July 10th 2019

6. Health and Social Care Board Practice Based Pharmacists http://www.hscboard.hscni.net/our-work/integrated-care/gps/investment-in-gp-practices/ Accessed July 10th 2019

7. Wickware, C., Government announces extra role for pharmacists in care homes as part of £3.5bn funding package The Pharmaceutical Journal, December 2018, Vol 301, No 7920, online DOI: 10.1211/PJ.2018.20205790

8. Fadya Al –Hamadani Medicines Management in Care homes. PhD thesis Cardiff University http://orca.cf.ac.uk/123409/1/2019fadyaphd.pdf

9. Barber N, Alldred D, Raynor D, al. The Care Homes Use of Medicines Study: Prevalence, causes and potential harm of medication errors in care homes for older people. Quality and Safety in Healthcare. 2009;18:341-6

10. Bond, C.M., Lane, K., Poland, F., Maskrey, V., Blyth, A., Desborough, J.A., Barton, G., Alldred, D.P., Hughes, C.M., Myint, P., Massey, K., Holland, R. and Wright, D., 2016. Care homes independent pharmacist prescribing study (CHIPPS): GP views on the potential role for pharmacist independent
prescribers within care homes. *International Journal of Pharmacy Practice, 24*(s2), pp. 6

11. Millar A, Daffu-O’Reilly A, Hughes CM, Alldred DP, Barton G, Bond CM, et al. Development of a core outcome set for effectiveness trials aimed at optimising prescribing in older adults in care homes. Trials. 2017;18(175.):doi:10.1186/s13063-017-1915-6.

12. Jacqueline Inch; Frances Notman; **Christine Bond**; David Alldred,; Antony Arthur; Annie Blyth; Amrit Daffu-O’Reilly; Joanna Ford; Carmel Hughes; Vivienne Maskrey; Anna Millar; Phyo Myint; Fiona Poland; Lee Shepstone; Arnold Zermansky; Richard Holland; David Wright The Care Home Independent Prescribing Pharmacist Study (CHIPPS)-A non-randomised feasibility study of independent pharmacist prescribing in care homes Pilot Feasibility Studies *(2019)* 5:

89. https://doi.org/10.1186/s40814-019-0465-y#citeas Accessed August 29th 2019

13. Christine Bond; Richard Holland; David Alldred,; Antony Arthur; Garry Barton; Annie Blyth; James Desborough; Joanna Ford; Christine Handford; Helen Hill; Carmel Hughes; Vivienne Maskrey; Kate Massey; Phyo Myint; Nigel Norris; Fiona Poland; Lee Shepstone; David Turner; Arnold Zermansky; David Wright Protocol for a cluster randomised controlled trial to determine the effectiveness and cost-effectiveness of independent pharmacist prescribing in care home: the CHIPPS study Invited resubmission/minor revision  BMC September 2019

14. Moore G, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O’Cathain A, Tinati T, Wight D, Baird J. Process evaluation of complex interventions: Medical Research Council guidance. MRC Population Health Science Research Network, London, 2014

15. Moore G, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O’Cathain A, Tinati T, Wight D, Baird J. Process evaluation of complex interventions: Medical Research Council guidance. BMJ 2015; 350:h1258 doi:10.1136/bmj.h1258

16. NoMaD survey http://www.normalizationprocess.org/npt-toolkit/ Accessed August 29th 2019

17. May C, Finch T, Mair F, Ballini L, Dowrick C, Eccles M, Gask L, MacFarlane A, Murray E, Rapley T, et al. Understanding the implementation of complex interventions in health care: the normalization process model. BMC Health Serv Res. 2007;7:148.

18. May C, Mair FS, Finch T, MacFarlane A, Dowrick C, Treweek S, Rapley T, Ballini L, Ong BN, Rogers
A, et al. Development of a theory of implementation and integration: Normalization Process Theory.
Implement Sci. 2009;4:29.

19. O’Cathain Alicia, Murphy Elizabeth, Nicholl Jon. Three techniques for integrating data in mixed methods studies BMJ 2010; 341 :c4587 https://doi.org/10.1136/bmj.c4587 Accessed August 29th 2019

Tables
Table 1: Implementation tasks and data collected as part of process evaluation

| Task                     | Aim (what is being assessed)          | Data collected               | Data source                                                                 |
|--------------------------|---------------------------------------|------------------------------|----------------------------------------------------------------------------|
| Provide training for PIPs| Effectiveness of training              | PIP views on training        | Post training feedback for day training session                              |
|                          |                                       |                              | PIP Interview PIP questionnaire                                             |
|                          |                                       | Competency                   | Competency assessment independent assessors                                  |
|                          |                                       |                              | Appropriateness of PCPs sample:appendices 3,4                                |
|                          |                                       |                              | Views of stakeholders (in)                                                  |
| PIP delivery of the intervention | Fidelity to intervention      | Services provided and frequency with which provided | PIP activity logs Number of pharmacuetic.                                   |
|                          |                                       |                              | PIP questionnaire                                                            |
|                          |                                       | Quality of medication review  | Review of 20% of pharmacuetic.                                               |

Table 2: Mechanism of impact and data collected as part of process evaluation
| Impact | Mechanism of impact | Data collected | Data source |
|-------|---------------------|----------------|-------------|
| Medication changes identified | PIP medication review | Recommendations for change and rationale | Pharmaceutical care, PIP interview, PIP questionnaire |
| Medication changes made | PIP prescribing | Total no. medications per patient at baseline and 6 months | Pharmaceutical care |
| | | No. medications stopped per patient at 6 months | GP records |
| | | No. medications started per patient at 6 months | GP records |
| | | No. medications amended e.g. dose change, formulation change | GP records |
| | | No. antipsychotics/psychotropics prescribed at baseline and 6 months | Pharmaceutical care, GP records |
| Biochemical monitoring | PIP medication review | Recommendations made for biochemical monitoring | Pharmaceutical care |
| Medication errors | PIP medication review | Number of prescribing, dispensing and administration errors | Pharmaceutical care, GP records |
| Non-patient facing activities improved eg medication storage advice | PIP support for care home | Services provided and frequency | PIP activity log |
| | | Views on usefulness of services | Care home staff interviews, PIP interview, PIP questionnaire |
| Better/tailored training for staff | PIP training for care home staff | Training provided and frequency | PIP activity log |
| | | Views on usefulness of training | Care home staff interviews, PIP interview, PIP questionnaire |
| Quality of communication between care home, GP and community pharmacy improved | PIP input into improved communication | Views of care home staff | Care home staff interviews, GP interview, PIP interview, PIP questionnaire |
| | | Views of GPs | |
| | | Views of PIPs | |

**Table 3: Outcomes and data collected as part of process evaluation**

| Aim | Outcome | Data collected | Data source |
|-----|---------|----------------|-------------|
| To improve quality of care for those over 65 years old resident in care homes | Falls | Fall rate per person at 3 months | Care home falls record |
| To assess intervention safety | Mortality | Information on numbers dying and time to death. | Monthly call to care home |
|-------------------------------|-----------|------------------------------------------------|--------------------------|
| Hospitalisations             |           | Information on numbers hospitalised             | Monthly call to care home |
| (NB not always a negative marker of safety) |           |                                                 |                          |
| *Global view                 | Perceptions of GPs | GP interview                                    |                          |
|                              | Perceptions of care home staff | Care home staff interview |                          |
|                              | Perception of residents/consultee/WPOA | Resident/consultee/WPOA |                          |
|                              | Perceptions of PIPs | PIP interview |                          |
| *Adverse events              | New drug related symptoms | Stakeholder feedback using standard template |                          |
| *Serious adverse events     | See hospitalisations/deaths | Monthly call to care home |                          |
| *Sudden unexpected serious adverse events | See hospitalisations/deaths | Feedback from GPs/independent medical assessor on causal link with PIP intervention |                          |

*Other than those asterisked these are also primary and secondary outcomes for main trial and will be compared across groups.

Table 4: Contextual factors collected as part of process evaluation
| Contextual factor | Data collected | Data source |
|-------------------|---------------|-------------|
| Barriers to delivering the intervention | Feedback from stakeholders | Care home staff interview, GP interview, PIP interview, NoMAD\(^{16}\) survey to GPs, home staff, Other anecdotal feedback |
| Facilitators to delivering the intervention | Feedback from stakeholders | Care home staff interview, GP interview, PIP interview, NoMAD\(^{16}\) survey to GPs, home staff, Other anecdotal feedback |
| Site and participant factors | Inter PIP variation, Competency | Variation in outcomes, Review of PCPs for both opportunity, Employment status, Baseline PIP questionnaires, Qualifications, Baseline PIP questionnaires, Inter site variation, Care home factors, Baseline CH survey, Qualifications, Baseline PIP questionnaires, Inter location variation, Views of researchers, Baseline resident data, Meeting minutes |
| Normalisation of intervention into routine practice | Actions taken by participants to ensure the intervention works, Coherence (Making sense of the service) | NoMAD survey\(^{16}\) to PIPs, GP Interview, CH staff Interviews, PIP interview, Cognitive participation (Engaging with the service), NoMAD\(^{16}\) survey to PIP, Interviews (GP and CH's), PIP interview, Collective action (delivering the service/responding to the service), NoMAD\(^{16}\) survey to PIP, GP interview, CH staff interviews, PIP interview, Reflexive monitoring (appraising and reviewing the service), NoMAD\(^{16}\) survey to PIP, GP interview, CH staff interviews, PIP interview |

**Supplementary Files**

This is a list of supplementary files associated with this preprint. Click to download.

GRAMMS checklist.doc.pdf
SPIRIT_Fillable-checklist.pdf
