SAGE Research Methods Cases
Medicine & Health
Submission for Consideration

Case Title

Lessons learned from CHIPPS (Care Homes Independent Pharmacist Prescribing Study): how feasibility studies informed ultimate randomised controlled trial design

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If you chose Medicine, Public Health, or Nursing as discipline, pick sub-discipline from the relevant list below. There are no sub-discipline options for Dentistry.

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Contributor Biographies

Christine Bond is Emeritus Professor at the University of Aberdeen **and** past Head of Centre of Academic Primary Care. She is Editor of the International Journal of Pharmacy Practice, and Chair of the Royal Pharmaceutical Society Science and Research Board. Her research interests are primarily around the expansion of the health care team, the contribution of pharmacy to the delivery of health care, and evidence based, safe and cost effective use of medicines. She has been awarded well over 100 research grants and has over 250 research publications.. She is a core member of the Pilot and feasibility studies group which published recent papers on conceptualizing pilot and feasibility studies and reporting pilot and feasibility trials, and co Chief Investigator for the CHIPPS non-randomized feasibility study and definitive controlled trial work packages, and principal investigator for the CHIPPS Study in Scotland.

David Alldred is Professor of Medicines Use and Safety at the School of Healthcare, University of Leeds and leads the Medicines Optimisation research theme. He is also the Lead for the Safe Use of Medicines theme for the NIHR Yorkshire and Humber Patient Safety Translational Centre. He has a background as a clinical pharmacist in primary and secondary care and has leading roles in the development, delivery and evaluation of complex interventions to improve the use of medicines through patient-randomised and cluster-randomised controlled trials. David is the principal investigator for the CHIPPS Study in Yorkshire and Humber and co-led the work package to determine the outcome measures to be used in the trial.

Carmel is Professor of Primary Care Pharmacy and Head of the School of Pharmacy at Queen's University Belfast. Her research interests centre on prescribing in older people, intervention development and evidence-based healthcare. She is an Editor for the Effective Practice and Organisation of Care (EPOC) Cochrane review group and an Associate Editor of Pilot and Feasibility Studies. She is a former Harkness Fellow and Primary Care Research Scientist. She has been appointed to Sub-Panel 3 as part of the Research Excellence Framework (REF) exercise which will take place in 2021. Carmel is the principal investigator for the CHIPPS Study in Northern Ireland and co-led the work package to determine the outcome measures to be used in the trial.

Richard is a Public Health doctor specialising in Health Services Research, and previous holder of an MRC Fellowship. His research interests focus on clinical trials in pharmacy practice and substance misuse. He has been awarded almost £4 million of research funding as a principal investigator and over £7 million as a co-applicant. he is co co-principle investigator on the Care Homes Independent Pharmacist Prescriber Study (CHIPPS) programme grant, and co Chief Investigator for the non-randomized feasibility study and definitive controlled trial work packages. Previously employed at the University of East Anglia Richard is currently head of

Leicester Medical School where he has led delivery of Leicester's new clinical curriculum, and achieved gains in student satisfaction and growth in size of the school, alongside his continuing research activity.

David Wright registered as a pharmacist in 1991 and practised for one year before embarking on a PhD to evaluate the role of the pharmacist in providing clinical pharmacy services within care homes. He became a lecturer in Pharmacy Practice in 1996. David was a practising pharmacist until 2015. David's research interest is in medicines optimisation in the older person with a special interest in medicines administration in people with dysphagia. David has developed expertise in trial design with a particular interest in the delivery of feasibility studies. He is the co-principle investigator on the Care Homes Independent Pharmacist Prescriber Study (CHIPPS), and principal investigator for the study in East Anglia. CHIPPS derived from research undertaken with Richard Holland to determine the value of multi-disciplinary medication review in care homes and with Christine Bond to test the concept of a pharmacist prescriber assuming responsibility for the management of chronic pain in primary care.

Published Articles

Millar AN, Daffu-O'Reilly A, Hughes CM, Alldred DP, Barton G, Bond CM, Desborough JA, Myint PK, Holland R, Poland FM, Wright D; CHIPPS Team, University of East Anglia. Development of a core outcome set for effectiveness trials aimed at optimising prescribing in older adults in care homes. Trials. 2017 Apr 12;18(1):175.

Wright DJ, Maskrey V, Blyth A, Norris N, Bond CM, Hughes CM, Holland R. Systematic review and narrative synthesis of pharmacist provided medicines optimisation services in care homes for older people to inform the development of a generic training or accreditation process IJPP 2019 In press

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

Christine Bond; Richard Holland; David Alldred,; Antony Arthur; Annie Blyth; James Desborough; Joanna Ford; Christine Handford, Helen Hill, Carmel Hughes; Vivienne Maskrey; Kate Massey, Phyo Myint; Nigel Norris, Fiona Poland; Lee Shepstone; 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 Trials 2019

Massey, Kate Not just a 'tick box exercise' - meaningful public involvement in research International Journal of Pharmacy Practice:2018 vol:26 iss:3 pg:197 -198

Abstract

The use of medicines in care homes could be improved and as a result, the health of residents would be better. Pharmacist prescribers (i.e. pharmacists specifically trained and qualified to prescribe), have been shown to provide safe, quality care in other patient groups. We proposed to test if making 'pharmacist prescribers' part of the care home team, working alongside general practitioners, could improve the use of medicines and the care of residents. These pharmacist prescribers authorised monthly prescriptions whilst carefully monitoring how each resident responded. We believe that such a change to the management of medicines in care homes is likely to be a good use of NHS money. This paper describes a series of developmental studies that were undertaken as part of a programme of work which followed the MRC Framework for developing and evaluating a complex intervention. The rationale for each study is described and for the final of these feasibility studies, when all components were tested together, we consider what went well, some of the challenges we encountered, and how they informed our decision to progress to a definitive randomised controlled trial.

Learning Outcomes

By the end of this case, students should be able to:

- Describe the steps required before a new intervention is tested via a definitive randomised controlled trial (RCT)
- Explain why preliminary feasibility work should be conducted before undertaking a full RCT
- Be able to create appropriate research questions for feasibility and pilot studies
- Report a feasibility study using the CONSORT 2010 statement: extension to randomised pilot and feasibility trials

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Case Study

[Insert your case study here. The main body of the text should be between 2,000 and 5,000

words.]

Note: Headings and sub-headings add structure to the body of your case, enhance online discoverability and make your case easier to read on screen.

Each main section with a top-level heading must be followed by a Section Summary. Each Section Summary should consist of 2-3 bullet points, written out as full sentences, succinctly encapsulating the preceding section.

Suggested headings:

Project Overview and Context
The Problem

Prescribing, monitoring and administration of medicines in care homes could be significantly improved, increasing residents' quality and quantity of life and improving use of NHS resources (1). Research has identified the need for one person to assume overall responsibility for the management of medicines within each care home (2).

The intervention
Pharmacist independent prescribers (PIPs) (i.e. pharmacists specifically trained to prescribe in a similar way to doctors), have been shown to provide high quality care in other patient groups, which is safe and well received. (3) We proposed to test if making 'pharmacist prescribers' part of the care home team, working in partnership with a patient's own general practitioner, could improve the use of medicines and the care of residents. These pharmacist prescribers could sign and order monthly prescriptions whilst monitoring how each resident responds.

Hypothesis
We believed that such a change to the management of medicines in care homes was likely to be a good use of NHS money.

Our ultimate aim was to test this hypothesis with a cluster-randomised controlled trial designed in accordance with SPIRIT(4) guidance. However, to ensure that we had the best chance of success (i.e. recruited to target, retained participants, collected data on at least 80% of residents) we undertook a number of smaller linked feasibility projects in line with national guidance for development and delivery of complex interventions (5).

Section summary

- *Prescribing of medicines in care homes is sub optimal*
- *Independent prescribing pharmacists could take responsibility for patients' medicines and improve outcomes of care*
- *Prior to conducting a definitive randomized controlled trial a programmer of feasibility work was undertaken…*

Research Design
We proposed a 5 year programme of research to develop, optimise and test the innovative pharmacist prescriber service model. We started by updating our knowledge of the research on how best to prescribe and use medicines in care homes, especially focussing on managing older frail patients who take multiple medications. We used the expertise of those working in

care homes to find out how best to introduce and deploy pharmacist prescribers as part of the care home team (Work package 1 (WP1). At the same time, we needed to find the best outcomes to use to measure the effect of the pharmacist intervention on residents, and staff in the care home and GP practice. To do that, we looked at how other researchers had measured the effect of pharmacists in care homes and ranked those methods for suitability (WP2).

Once we had identified how to introduce, run and test the new service, we had to design and test a training package to prepare pharmacists for this new prescribing role (WP4), before actually testing out the service and our recruitment and data collection in a small number of care homes for three months. We refer to this stage as the feasibility study (WP5). Following this, the main RCT began in four areas of the UK: East Anglia, Yorkshire, North-east Scotland and Northern Ireland (WP6). We adopted a cluster randomised design and randomised by prescribing pharmacist-GP-care home triad so that we had intervention triads and control triads (usual care by the GP) that were geographically distinct. This was to avoid the threat of contamination i.e. we wanted to ensure that the intervention did not spread to our control group (in this case residents not receiving the intervention). Had we randomised residents within a care home to receive, or not receive, our intervention, it is likely that any improved medicine 'systems' would have 'spread' beyond our intervention patients. As a result, we chose to randomise whole homes to either receive or not, our intervention. In this main RCT the intervention is being delivered for 6 months. There was an initial stage called an internal pilot trial to confirm that we could recruit enough doctors, care homes and residents. Once that was assured we continued to recruit our target of 880 care home residents in total from 49 homes spread across four different parts of the UK. Data from the internal pilot phase is retained within the study data set. After six months we will compare how residents, staff and care homes have done in the two different groups and determine the value of the service for residents and the NHS. At the time of writing this main trial is still ongoing.

Our programme aims and objectives are listed below, together with a reference to the Work Package (WP) which addresses the objective.

Aim

To determine the effectiveness and cost-effectiveness of pharmacist independent prescribing in care homes

Objectives

The objectives for the programme grant within the care home environment are to:

- Update evidence regarding the optimisation of medicines use (WP1: Phase 1)
- Obtain stakeholder views to inform the development of the service specification for a pharmacist independent prescriber who assumes responsibility for the management of prescribing (WP1: Phase 2)
- Prepare and refine a service model and initial service specification for pharmacist independent prescribing (WP1: Phase 3)
- Evaluate potential outcome measures to determine the effect of the service and identify the most suitable with respect to validity, reliability, utility and proximity to the intervention (WP2)
- Identify how data on costs and health economic outcomes (including utility) should be measured (WP3).
- Develop a training package to ensure that pharmacist independent prescribers are appropriately prepared to deliver the service (WP4)

- Test and refine service specification and proposed study processes including care home and resident recruitment and data collection (WP5)
- Conduct an internal pilot study to identify any likely difficulties with recruitment within the definitive trial (WP6)
- Perform a definitive study to determine the effectiveness of pharmacist independent prescribing in care homes (WP6)
- Estimate the cost-effectiveness of the intervention in the immediate and longer term (WP3)
- Outline how a model of care and associated training package for the integration of pharmacist independent prescribers into care homes can be introduced and delivered (WP4 & WP6)

In the rest of this paper, work packages 1-4 are summarised briefly before we describe in more detail our experiences of the feasibility study (WP5) (6) and the lessons we learned. The whole approach followed the MRC Framework (5) for the development and evaluation of a complex intervention (ie an interventions that contain several interacting components as in our proposed PIP led service). This approach emphasises the importance of undertaking preliminary work to identify the evidence base, model the process and outcomes and test procedures. All of these stages can be regarded as different aspects of feasibility work in which areas of uncertainty are explored. There is often also a stage referred to as a feasibility or pilot study (our WP5) in which most or all of the components are tested together (7).

Work packages

i) WP1: Service Specification Development

In this workpackage we updated an existing Cochrane review (8) of the literature regarding optimisation of medicines' use within care homes and undertook a further literature review to identify guidelines and research evidence supporting best practice in medicines administration and management within care homes. Based on these reviews, we developed an outline service specification to describe:

a) The roles and responsibilities of the PIP
- PIP visit frequency and availability
- Scope of service (prescribing, ordering, storage and administration)
- Use and role of PCPs (presentation and content)

b) The systems and procedures to be introduced:
- Access to medical and care records and prescribing budget
- Integration of the PIP into the established healthcare system
- Effective lines of communication between PIP, GP and home

We then undertook, focus groups and interviews with GPs, pharmacists, care home staff and care home residents to explore their views on the proposed service including logistical and professional barriers/solutions to implementation; and the most appropriate outcome to use in a future trial. All proceedings were audio-recorded, transcribed verbatim and thematically analysed. The findings reassured us that all stakeholders were very positive about the proposed service and confirmed it would meet a service need. The GPs emphasised that, if possible, they should already have good relationships with the pharmacists and it should not give then extra work (9).

On the basis of the stakeholder feedback details of the service specification were finalised and it was peer reviewed in each of the four participating regions at a one-day workshop, when any outstanding implementation issues were also addressed.

ii) WP 2: Identification of Outcome Measures

Many previously conducted trials of pharmacist interventions have either used a measure of process (eg number of changes made to a medication regime) or a condition-specific outcome eg blood pressure, or a generic measure such as quality of life or mortality. Using a process measure is limited because it does not demonstrate that the intervention has been of direct value to a patient, using a condition specific measure is not appropriate if the population includes individuals with different conditions and a generic measure such as quality of life can be insensitive to improvements resulting from interventions made to a medicine regime in old and frail populations such as those found in care homes.. Commonly-used outcome measures for similar interventions, such as falls and hospitalisations, also have limitations related to sensitivity and concerns regarding the quality of available data. We sought to identify valid and reliable outcomes for the care home population using a systematic literature review to identify potential outcome measures followed by a consensus process in which possible measures were assessed against predetermined criteria. The fall rate per person at 6 months was selected as the primary outcome measure. To address the concern about quality of available data, we used the falls recorded in the Care home falls book in which a fall is defined as an unintentional or unexpected loss of balance resulting in coming to rest on the floor, the ground, or an object below knee level (10). A paper: 'Development of a Core Outcome Set for effectiveness trials aimed at optimising prescribing in older adults in care homes' on this work was published soon after completion of the work package. As a general rule we feel it is important to disseminate findings as soon as possible so others can make use of them. (11).

iii) *WP 3: Health Economics*

The estimation of cost-effectiveness is an iterative process and consequently this work package was conducted alongside the feasibility study, and main study. As we were proposing a new service, it was anticipated that currently available resource use collection tools may need to be amended to ensure they captured relevant resource items. We planned to test our collection of cost data in the WP5 feasibility study using a combination of sources including care home records (length of residence; medication; visits from GP, practice/district nurse, and mental health practitioners); and medical records (inpatient services, outpatient services and A&E visits). As with any outcome data, it is important to know that the data is available, and can be collected reliably for all patients at all pre-specified time points. As well as understanding the costs involved and in line with previous research in care homes,(12) we anticipated using proxy EQ-5D completion as the main quality of life measure. With this method, the resident's key carer, or carer looking after them on the day of data collection, would be asked to complete the EQ-5D-5L proxy version 2 (see http://www.euroqol.org/eq-5dproducts/ eq-5d-5l/proxy-paper.html); those participants with capacity would also be asked to complete the EQ-5D-5L at both time points.

iv) WP4: Training

In contrast to a clinical trial of a drug when formulation, route of administration and dosage regimen are the main variables, a trial involving an intervention delivered by health care professional is more difficult to control in terms of consistency of the intervention. One way this can be at least partially addressed is to ensure those delivering the intervention have all been trained to a common minimal standard. In this study, a training package was designed based on a systematic review of the literature (13), and qualitative research. Following feedback from the feasibility study which is described below as work package 5, further small changes were made prior to the start of the main trial (Work package 6).

v) WP5: Feasibility study and service specification refinement

A full report of the feasibility study has been published (6) but key elements are summarised below followed by a reflection of what went well and what went less well and lessons learned.

The objectives of our non randomised feasibility study were to:

- Describe the appropriateness of and acceptability of both the service specification and proposed research design
- estimate the size of the eligible population and assess the feasibility of the recruitment processes
- describe the suitability of outcome measures for use in the main trial
- estimate willingness to participate and retention rates

Before delivering the intervention the PIPs received the training package developed previously, gave immediate written feedback and were also asked about the training in the post intervention focus group. They then provided the pre-defined service, to consenting residents for three months. Formal outcome data were collected at baseline and three months by researchers, local to each area. We recorded the:

- proportion of general practices, care homes, residents approached who consented to participate
- proportion of residents followed up at 3 months
- quality and completeness of data collected at baseline and follow-up

As part of this work package we undertook a process evaluation using interviews and focus groups with the PIPs and the other stakeholders across all sites to understand participants' experiences and inform changes to ensure the success of the subsequent main study. For example: was the new service acceptable, were changes to the service recommended, were the participant documents clear; did the arrangements for third party consent work smoothly; could patients be identified as proposed; and was the research burden acceptable.

The feasibility study was completed successfully, reported in accordance with recent guidance (14) and confirmed progression to main RCT. We confirmed that no major changes were needed and a protocol for the definitive trial with internal pilot was finalised (15) .

Section summary

- *...A non randomised feasibility study was undertaken to test all the components of the intervention together*
- *...Interviews and focus groups with participants explored the acceptability of the intervention and the research processes*

Research Practicalities

Having assembled all the building blocks it was essential to test these components together before embarking on a main study. At this stage it is important to consider whether this feasibility study should be randomised or not. If most of the uncertainty relates a central component other than the logistics of recruiting and randomisation it is probably best to undertake a non-randomised feasibility study, and to consider the challenges of randomisation and recruitment in an internal pilot at the next stage. This was the approach that was taken in this programme of work.

A feasibility study such as this needs to be large enough to be reasonably confident that the findings can reliably inform decisions about the next stage of the programme. Given the diverging nature of the NHS in the devolved countries it was agreed that the feasibility study needed to include all four regions. Secondly, although the professionals delivering the intervention are the pharmacist independent prescribers (PIPs), it is also necessary to recruit GPs, care homes and residents. The order in which this is done needs to be considered carefully. We decided that we would recruit one PIP working in each site (East Anglia, Yorkshire, North East Scotland and Northern Ireland) via local networks. We then used local research networks to identify all medical practices with links to care homes and explored their interest in taking part in either this feasibility study or the subsequent randomised trial.

We then had to match PIPs to GPs and in accordance with earlier findings, we prioritised selection of practices that had an established working relationship with a PIP where that was possible. Subsequently the GP/PIP team approached the care home(s) to explore their interest in participation before their permission was obtained. In practice we used different approaches in each of the four study locations to map onto local arrangements. Personal networks facilitated identification of key contacts.

Finally, we recruited 10 residents per home, 65 years old or older, on more than one regular medicine who gave their informed, written consent. For residents without capacity, this was done by proxy. The exact approach differed between Scotland, where the proxy person known as a Welfare Power of Attorney could consent on the resident's behalf, and the other three areas in which the proxy person known as a consultee was used in accordance with the Mental Capacity Act. Because of this difference in mental health regulations we also had to seek Ethical approval from research ethics committees in both England and Scotland. The Scottish

Section summary

- *Recruiting participants from four different inter-related populations is complex and ultimately needs to be adaptable to local contexts*
- *There are different approaches for recruiting research participants who lack capacity between Scotland and other devolved countries*

Method in Action

What went well

- The feasibility study recruited to target and was completed within the scheduled time frame
- The level of expressions of interest from eligible GPs confirmed sufficient participants for the main trial and the consent rate of residents informed the target number of care home patients required to be registered with the participating GP.
- The PIPs were very satisfied with the format and content of the training package
- The processes successfully identified and recruited trial participants (GPs, PIPs, care homes and residents) and retained them in the study for three months.
- No problems were identified with the approach to recruiting participants without capacity, including use of consultees and welfare power of attorney.
- A range of outcomes/outcome measures were tested and a subset verified as suitable for efficient collection with larger participant numbers. Some were removed because they were not completed well and some because they did not add anything
- The new service was welcomed by all stakeholders. There were individual instances where pharmacist interventions resulted in observable improvements in an individual and there were suggestions from the outcome data that residents benefited (but note, there was no formal control group to compare changes seen against).
- Small changes were suggested to the service specification these were not substantive
- The PIPs participating in this study included pharmacists employed by either primary care or the GP practice providing evidence that this service specification is adaptable to either model, although PIPs with a pre-existing relationship with the GP found it easier to arrange meetings.
- Reporting the study in line with recent guidance (15) ensured we remained focussed on feasibility objectives and did not pre and post statistical testing to assess efficacy

What challenged us

- There are differences in mental capacity regulations between Scotland and the rest of the UK. These affect the criteria for involving adults without capacity in studies, and also require Ethical Approval to be sought from a Research Ethics Committee in Scotland and England. Whilst the English Research Ethics Committee approved the study to include adults without capacity, the Scottish committee did not. Given that approximately three quarters of those in care homes do not have capacity we believed it was essential they should be allowed to take part in the study. We had several phone calls and written appeals to the Scottish REC justifying the inclusion of these residents and finally a favourable opinion was given.

- PIPs were asked to use a formal pharmaceutical care form as the basis for their decision making. The PIPs had contributed to the content of this form during the training but it was still quite complex and time-consuming to complete. Some of the PIPS used it more as an aide memoir for themselves and did not realise that it was also a source of research data. At the focus group, the work load associated with completing the form was highlighted. As a result, the form was simplified and at subsequent training events, the dual role of the form was emphasized and PIPs were requested to complete it as fully as possible. Nevertheless, whilst stream-lined

somewhat, the form has remained a ‘research burden’ and would be unlikely to translate in to a similar format outside our research environment.

- Data on medication were collected from both the care home and the GP record. This is a duplication of effort. Although the records did not match exactly, as has been noted before, it was agreed that in the subsequent trial, the definitive source of medication data would be the GP record.

- As a measure of safety all reported serious adverse event(s) (hospitalisations and deaths) were assessed for causality and potential association with the intervention by one of the medically qualified grant holders (RH). Given this can be a subjective judgement, this is open to bias and in the main study, independent GPs were employed to undertake this assessment following a standard protocol.

- Following accepted guidance, all hospitalisations are classified as serious adverse events; however, in a population of care home residents, they are relatively frequent and their reporting represented a heavy workload. In the main study a two-stage Serious Adverse Event (SAE) reporting procedure was incorporated into a Safety Management Plan, with only those events with a plausible link to the intervention, as judged by the triad GP, to be reported on for further detailed review.

- As a further safety measure, a random sample of eight forms (two per location) were selected and these were reviewed for appropriateness by one of two grant holders who were specialists in care of the elderly medicine. This process has been standardised to include grading of any concerns from no concern, through low, moderate and significant concern with appropriate feedback, further monitoring and ultimately PIP withdrawal if needed.

Section summary

- *Overall the feasibility study went well and confirmed progression to the randomised controlled trial*
- *The further qualitative work informed nuanced changes to some of the processes such as the training package and the record keeping …*
- *Measures of monitoring the safety of the intervention were developed…*

Practical Lessons Learned

The time invested in the early work packages was critical to the success of the feasibility study. Not only is it important to build on previous work, hence the systematic reviews, but it is also important to test the perceived need for the new service with stakeholders in the actual study context. Further, where possible, additional requests should be accommodated in the service specification. As one GP said to us in the early interviews, ‘there has to be something in it for me’.

We had nonacademic members as fellow grant holders (see acknowledgements below) representing service pharmacists, care home management, and lay representatives. They really helped us in working up the study details at grant application stage and post funding once we had secured the award. They gave helpful advice on the patient perspective at all stages of ongoing study conduct. Nonetheless their involvement needs to be well supported for it to be meaningful. In our case we always gave our patient representatives extra time and met with them separately to make sure they had protected time to discuss issues outwith more formal grant holder meetings[16].

It is important to check out any differences in regulations as soon as possible when undertaking a multisite study involving the devolved nations. Securing Ethical approval to involve adults without capacity became a very long drawn out process because of these differences. Despite all grant holders having worked with these type of participants before there were subtle changes to regulations which added complexity to the process

Despite the research team having considerable experience of undertaking this sort of study a feasibility study was essential. It is always important to remember that sitting at a desk and designing a study can never preempt the practicalities. Our early work suggested GPs would prefer to work with pharmacists they already knew and had worked with closely but in reality because of differences in implementation of both pharmacists prescribing and practice based pharmacists there was a smaller pool of eligible PIPS than expected. Further in some areas where there were eligible pharmacists in post in GP practices, their time was already committed to other priorities, so their line manager would not endorse their participation. Therefore recruitment approaches had to be modified to suit local need.

In order to reassure those reviewing the protocol for ethical and R and D we included labour intensive safety monitoring approaches. However given the life expectancy of the care home population hospitalizations and deaths are far more frequent than in the general population and so we adapted the standard definition of a serious adverse event to take this into account in the planning for the subsequent trial. All such changes were approved by submitting amendments to the relevant ethical committees.

Section summary

- *Local contexts, across different organizational units, may affect planned procedures and where possible should be understood before submitting applications for funding, ethics or R and D.*
- *Feasibility work is always important even when teams are experienced and have conducted recent work in similar settings …*
- *Public and patient involvement can improve planning and patient facing materials*

Conclusion

Having the luxury of a programme grant with a planned iterative set of work packages has allowed us to work up all aspects of the study prior to testing them together in the feasibility study reported above. The subsequent definitive trial is now in progress. We have worked efficiently by building on our own earlier work and that of others as well as undertaking new primary data collection where necessary to inform our own programme. This includes for example the preliminary interviews with stakeholders to assess their perception of the need for the programme. It also includes the learning needs assessment we undertook, including further systematic review, prior to developing the training package. It is important to be sure that where the active component of the intervention is a health care professional that they are all competent to provide the services as planned. We have also published the outputs from each stage to ensure our research findings have greater value by being made available to the wider research community. No randomized controlled trial should be conducted without such underpinning work which should be planned in accordance with the MRC Framework.

Section summary

- *Feasibility work is essential prior to undertaking a definitive trial …*
- *Previous research on a topic should always be taken into account in any new proposals …*

Classroom Discussion Questions

1. What are the benefits of looking at the literature in a systematic manner before embarking on a project of this nature?

2. What actions were taken by the team to increase the likelihood of the service being acceptable? Could these have been done differently

3. Why do you believe Falls was selected as the main outcome measure in this study? Consider issues with this outcome and why data on falls may not be considered ‘ideal’ or ‘perfect’.

4. Reflect on reasons why despite the good recruitment and retention of all stakeholders in this study, this might not be reproduced in a larger study with a longer intervention period. What could be done to mitigate these?

5. Discuss what uncertainties still remain that need to be explored in the internal pilot trial. What are they and how could they be tested. What happens if the internal pilot study identified major recruitment problems?

Multiple Choice Quiz Questions

1. The purpose of a feasibility study is to:

A. Address uncertainties in proposed trial design (CORRCET)

B. Confirm intervention acceptability

C Confirm intervention efficacy

2. When applying for Ethical approval you should:

A Always apply to each participating devolved nation

B. Apply to each participating devolved nation only for certain categories of participants (CORRECT)

C. Use the centralized UK service to apply to one ethics committee only

3. The primary outcome for a health care intervention should be;

A. A process measure

B. Any clinical measure

C. A validated clinical measure (CORRECT).

Declaration of conflicting interests

The Author(s) declare(s) that there is no conflict of interests.

Ethics approval and consent to participate in feasibility study

Ethical approval was received from East of England-Essex Research Ethics Committee (05/09/2016) (rec ref number 16/EE/0284) and Scotland A REC (08/09/2016) (rec ref number 206970) with subsequent approval from the Health Research Authority/NHS Research and Development.

Registration information

The trial was registered on the ISRCTN registry Registration number ISRCTN10663852. The study was overseen by a Programme Management Group (all grant holders, researchers, CTU representatives) and advised by an independent Trial Steering Committee. The protocol is available from the authors on request.

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expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health.

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Web Resources

Pilot and feasibility studies: giving your research the best chance of success https://pilotandfeasibilitystudies.qmul.ac.uk/ accessed 12.12.19

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