ISRCTN10663852 https://doi.org/10.1186/ISRCTN10663852

CHIPPS Feasibility Study

Submission date
21/11/2016

Recruitment status
No longer recruiting

Registration date
24/11/2016

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
TThe use of medicines in care homes could be improved and as a result the health of residents would be better. Independent pharmacist prescribers (i.e. pharmacists specifically accredited to prescribe in a similar way to doctors), have already been shown to provide high quality care, which is safe and well received. We propose 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 independent pharmacist prescribers would share responsibility for managing the medicines of care home residents whilst carefully monitoring how each resident responds. The aim of this study is to test delivery of the new service in preparation for a large study looking at the effectiveness of the programme.

Who can participate?
Independent prescribing pharmacists (PIP), GPs who manage a minimum of 15 patients across 1-2 care homes and care homes with residents aged 65 years and over who are taking at least one prescribed medication.

What does the study involve?
A Pharmacist Independent Prescriber (PIP) and a GP are recruited to work together for the three months of the study. The PIP receives special training and then be put in place at a participating care home to implement the service to about 10 residents of the care home (participants). Participants in the study should be willing to have the PIP assume management of their medicines, during the three months duration of the study, in collaboration with their GP. A researcher visits participants at the care home, and asks them to complete a very simple memory assessment, fill out a consent form to take part in the project and ask the participant some simple questions about their health. The researcher then comes back and repeats some of these questions after 3 months. The researcher also asks the participant's permission to look at their records held in the care home and the GP practice, and record their medical history, the medicines that have been prescribed and the number of times they have seen the GP or other health care providers.

What are the possible benefits and risks of participating?
A possible benefit to participation could be that a PIP, who has been specially trained, and

working with the participant's GP, may help participants to get the best from their medicines. There are no notable risks or disadvantages involved with participating, however, if someone does not want to have a PIP prescribing their medicines, they will probably not want to take part.

Where is the study run from?
The study is run from University of East Anglia, University of Aberdeen, University of Leeds and Queen's University of Belfast and takes place in GP practices in Norfolk (England), Belfast (Northern Ireland), Yorkshire (England) and Grampian (Scotland) (UK)

When is the study starting and how long is it expected to run for?
May 2016 to May 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Annie Blyth
a.blyth@uea.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Annie Blyth

Contact details
University of East Anglia
Norwich Research Park
Norwich
United Kingdom
NR4 7TJ
+44 1603 593308
a.blyth@uea.ac.uk

Additional identifiers

Central Portfolio Management System (CPMS)
32660

Study information

Scientific Title
Care Homes Independent Pharmacist Prescribing Service (CHIPPS): Development and delivery of a cluster randomised controlled trial to determine both its effectiveness and cost-effectiveness. Work Package 5: Feasibility Study

Acronym
CHIPPS

Study objectives
The aim of this study is to test whether making 'specially trained pharmacist prescribers' part of the care home team, working alongside general practitioners, could improve the use of medicines and the care of residents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
REC East of England Essex, 13/09/2016, ref: 16/EE/0284

Primary study design
Interventional

Study design
Non-randomized; Interventional; Design type: Process of Care, Management of Care

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Health services and delivery research; UKCRC code/ Disease: Other/ General symptoms and signs

Interventions
In each of the four locations, one Pharmacist Independent Prescriber (PIP) and one GP, with whom the PIP will work for the three month duration of the study, will be recruited. The participating GP practice will identify a care home where they have resident patients, and we will invite this care home to participate in the study, following which 10 of the GP's patients as participants will be recruited.

The PIP will receive special training and then, will deliver the intervention, which involves the PIP, where appropriate:
1. Reviewing participant medication and developing and implementing a pharmaceutical care plan
2. Assuming prescribing responsibilities
3. Supporting systematic ordering, prescribing and administration processes with each care home, GP practice and supplying pharmacy where needed
4. Providing training in care home and GP practice
5. Communicating with GP practice, care home, supplying community pharmacy and study team

Participants (or, in the case of those without capacity, their consultee) will undergo informed consent and then baseline data will be collected by reviewing their care home and medical records. Quality of life will be measured by using the proxy EQ-5D, and in addition, those participants with capacity, will also complete the EQ-5D. All data collection will be repeated at 3 months.

Intervention Type
Other

Primary outcome(s)
1. Adverse drug events are measured by reviewing the patient notes at baseline and at 3 months
2. Health-service utilisation and associated costs are measured by reviewing the patient notes at baseline and three months
3. Medication appropriateness is measured using STOPP/START and Drug Burden Index at baseline and three months
4. Quality of life is measured using EQ=5D and QUALIDEM at baseline and three months
5. Mortality is measured by notification from the care home manager or PIP at any point during the three months of the study
6. Falls are measured by reviewing the patient notes at baseline and three months
7. Physical functioning is measured using the Barthel Index at baseline and three months
8. Cognitive functioning is measured using the Mini–Mental State Examination (MMSE) at baseline and three months
9. Care home staff job satisfaction is measured using qualitative interviews at three months

Key secondary outcome(s)
No secondary outcome measures

Completion date
31/05/2017

Eligibility

Key inclusion criteria
Independent Prescribing Pharmacist (PIP) inclusion criteria:
1. Registered with The General Pharmaceutical Council as a pharmacist independent prescriber
2. Following training can demonstrate competence to deliver the CHIPPS service Specification
3. Ability to work flexibly and commit a minimum of 16 hours a month to deliver the service for three months

GP inclusion criteria:
GP must manage a minimum of 15 patients across 1-2 care homes

Care Home inclusion criteria:
1. Care Quality Commission (CQC) registered specialism as caring for adults over 65
2. Primarily caring for residents over 65 years#

Resident Inclusion criteria
1. Residents currently prescribed at least one regular medication
2. Residents or their appropriate representative who are/is able to provide informed consent /assent
3. Permanent resident in care home (not registered for respite care/temporary resident)
4. Residents should be 65 years or over
5. Under the care of the participating GP practice

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
40

Key exclusion criteria
Independent Prescribing Pharmacist (PIP) exclusion criteria:
Substantive employment with the community pharmacy (branch/store) which supplies medicines to the care home with which the PIP would work.

GP exclusion criteria:
GPs managing patients across several (>2) care homes if they manage less than 15 patients in total across their two largest homes.

Care Home exclusion criteria:
1. Care homes which receive regular (i.e. a visit frequency ≥ monthly) additional medication focussed services
2. Care homes which do not have carers on site 24 hours a day
3. Care homes which are currently under formal investigation with the Care Quality Commission (CQC)

Resident exclusion criteria:
1. Residents who are currently receiving end of life care (equivalent to yellow (stage C) of the Gold Standards Framework prognostic indicator)
2. Resident with additional limitations on their residence (e.g. held securely)
3. Participating in another research study

Date of first enrolment
17/11/2016

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Study participating centre

University of East Anglia
Norwich Research Park
Norwich
United Kingdom
NR4 7TJ

Study participating centre
University of Aberdeen
Department of General Practice & Primary Care
Polwarth Building
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD

Study participating centre
University of Leeds
School of Pharmacy
The Baines Wing
Leeds
United Kingdom
LS2 9JT

Study participating centre
Queen's University of Belfast
School of Pharmacy
97 Lisburn Road
Belfast
United Kingdom
BT9 7BL

Sponsor information

Organisation
NHS South Norfolk CCG

Funder(s)

Funder type

Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/07/2019	29/11/2022	Yes	No
Results article		01/12/2023	21/01/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V5	21/07/2016	21/11/2016	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes