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A cluster randomised controlled trial to determine effectiveness and cost-effectiveness of a care home independent pharmacists prescribing service

Submission date
04/12/2017

Recruitment status
No longer recruiting

Registration date
15/12/2017

Overall study status
Completed

Last Edited
01/11/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The use of medicines in care homes could be improved and as a result the health of residents should be better. 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. This study tests 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 would sign and order monthly prescriptions whilst carefully monitoring how each resident respond. It is believed that such a change to the management of medicines in care homes is likely to be a good use of NHS money. However, to develop and test this idea in the best way possible we need to undertake six inter-linked work packages (WP). This application is for WP6 of this programme which is a randomised controlled study (with internal pilot) following WP5 which was a feasibility study which tested the delivery of the service to 40 participants.

Who can participate?
Pharmacists prescribers, GPs, and 20 care home residents.

What does the study involve?
Groups are randomly allocated to one of two groups. Those in the first group receive treatment as usual is where GPs have responsibility for the medicines management of care home residents associated with the GP practice. Those in the second group have the pharmacist prescriber assuming responsibility for managing their medicines, overseen by the GP. This includes the pharmacists prescriber reviewing medications, assuming prescribing responsibilities, supporting systematic ordering, prescribing and administration with in the care home, providing training within the care home and liaising with relevant staff involved in residents care. At baseline, three months and six months, the researchers collect data from the residents including falls rates, NHS

resource use, information on hospitalisations and deaths as well as quality of life measures. Data is compared between the residents in the intervention arm and those receiving treatment as usual.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. University of East Anglia (UK)
2. University of Aberdeen (UK)
3. Queens University Belfast (UK)

When is the study starting and how long is it expected to run for?
June 2017 to April 2020

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

Who is the main contact?
Ms Annie Blyth
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Study website
http://www.uea.ac.uk/chipps

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

35846

Study information

Scientific Title
Care Homes Independent Pharmacist Prescribing Service (CHIPPS): A cluster randomised controlled trial to determine both its effectiveness and cost-effectiveness Work Package 6: RCT with internal pilot: a definitive randomised controlled trial

Acronym
CHIPPS

Study objectives
Providing a pharmacist independent prescriber within care homes will show patient benefit (reduced resource use, reduced falls) compared with care homes with no pharmacist prescriber.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. English REC: East of England, Cambridge Central Research Ethics Committee, 28/11/2017, ref: 17/EE/0360
2. Scottish REC: Scotland A Research Ethics Committee, NHS Lothian, 08/11/17, ref: 17/SS/0118

Study design
Randomised; Interventional; Design type: Process of Care, Management of Care

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Care home, GP practice, Pharmacy

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
No specific disease

Interventions
This is a cluster randomised control trial, pharmacists prescribers and GPs are randomised to treatment as usual (no pharmacist independent prescriber) or to the intervention. The intervention is the provision of a pharmacist independent prescriber for 6 months. This

intervention was developed in an earlier feasibility study, and involves a pharmacist independent prescriber collaborating with a care home residents GP, assuming responsibility for managing their medicines. This includes reviewing medications, assuming prescribing responsibilities, supporting systematic ordering, prescribing and administration with in the care home, providing training within the care home and PG, and liaising with the local pharmacy, PG and care home staff as well as the research team.

The residents will have their data collected at baseline, 3 months and 6 months.

Intervention Type
Other

Primary outcome measure
Falls data, collected from care home falls register or resident notes, measured at baseline, 3 months and 6 months.

Secondary outcome measures
1. Quality of life is meaured using the proxy EQ-5D-5L at baseline, 3 months and 6 months
2. Face to face self-reported EQ-5D-5L (only applicable for participants with capacity), measured at baseline, 3 months and 6 months
3. Mortality and hospitalisations, collected from Primary Care (GP) records and from Care Home records, measured at baseline, 3 months and 6months.
4. Proxy Barthel Index (physical functioning measure), collected at baseline and 6 months
5. Health-service utilisation (and associated costs), collected from Primary Care (GP) records, collected at baseline and 6 months

Overall study start date
01/06/2017

Completion date
30/04/2020

Eligibility

Key inclusion criteria
Pharmacist inclusion criteria:
1. Registered as a pharmacist independent prescriber
2. Following training can demonstrate to their mentor and independent GP assessor competence to deliver service specification
3. Ability to work flexibly and commit a minimum of 16 hours a month to deliver the service for six months

GP inclusion criteria:
GP practice must manage sufficient care home residents to enable invitation of a minimum of 35 eligible care home residents in one or more care homes.

Care home resident inclusion criteria:
1.65 years and over
2. Under the care of the recruited GP practice
3.65 years or over
4. Currently prescribed at least one regular medication

5. Able to provide informed consent/assent, or have a consultee (England and Northern Ireland) or Welfare Power of Attorney (WPoA) (Scotland) able to provide informed consent
6. Permanently resident in care home (not registered for respite care/temporary resident)

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 880; UK Sample Size: 880

Total final enrolment
880

Key exclusion criteria
Independent Prescribing Pharmacist (PIP) exclusion criteria:
1. Substantive employment with the community pharmacy (branch/store) which supplies medicines to the care home with which the PIP would work, to protect against conflict of interest
2. Already providing an intensive service to the care home

GP exclusion criteria:
GP practice managing less than 35 care home residents across > 1 care home

Care Home exclusion criteria:
1. Care homes which receive regular (e.g. a monthly visit or more frequently, from a pharmacist) and provision of intensive medication focussed services
2. Care homes which are currently under formal investigation with Care Quality Commission (CQC) in England, Care Inspectorate in Scotland or Regulation or Quality Improvement in Northern Ireland
3. Care homes that are participating in any other study likely to affect the outcome of the CHIPPS trial (e.g. Falls intervention study, Rehydration study, e.t.c)

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 intervention research study

Date of first enrolment
18/12/2017

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

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

Study participating centre
University of Aberdeen
King's College
Aberdeen
United Kingdom
AB24 3FX

Study participating centre
Queens University Belfast
University Road
Belfast
United Kingdom
BT7 1NN

Sponsor information

Organisation
NHS South Norfolk CCG

Sponsor details
Lakeside
400 Old Chapel Way
Norfolk
Norwich

England
United Kingdom
NR7 0WG

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
The intention is to publish and disseminate trial results in a high-impact peer reviewed journal in 2021. The Study protocol will be available on the programme website: https://www.uea.ac.uk /chipps/summary

Intention to publish date
01/12/2021

Individual participant data (IPD) sharing plan
The 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?
Protocol article	protocol	21/01/2020	23/01/2020	Yes	No
Other publications	Process evaluation	02/10/2021	04/10/2021	Yes	No
Protocol article	Protocol for the process evaluation	29/05/2020	18/01/2023	Yes	No
Results article	Primary and secondary outcome results	14/02/2023	15/02/2023	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			26/07/2023	No	No
Other publications	secondary analysis of interview data collected as part of the process evaluation undertaken in CHIPPS	31/10/2023	01/11/2023	Yes	No