The Care Home Independent Pharmacist Prescriber Study (CHIPPS): development and implementation of an RCT to estimate safety, effectiveness and cost-effectiveness

David Wright,[1*] Richard Holland,[2*] David Phillip Alldred,[3,4] Christine Bond,[5] Carmel Hughes,[6] Garry Barton,[7] Fiona Poland,[8] Lee Shepstone,[7] Antony Arthur,[8] Linda Birt,[8] Jeanette Blacklock,[1] Annie Blyth,[1] Stamatina Cheilari,[7] Amrit Daffu-O'Reilly,[9] Lindsay Dalgarno,[5] James Desborough,[1] Joanna Ford,[10] Kelly Grant,[5] Janet Gray,[11] Christine Handford,[11] Bronwen Harry,[12] Helen Hill,[13] Jacqueline Inch,[5] Phyo Kyaw Myint,[14] Nigel Norris,[15] Maureen Spargo,[6] Vivienne Maskrey,[16] David Turner,[7] Laura Watts[7] and Arnold Zermansky[17]

[1]School of Pharmacy, University of East Anglia, Norwich, UK
[2]Leicester Medical School, University of Leicester, Leicester, UK
[3]School of Healthcare, University of Leeds, Leeds, UK
[4]NIHR Yorkshire and Humber Patient Safety Translational Research Centre, Bradford, UK
[5]Academic Primary Care, Institute of Applied Health Sciences, University of Aberdeen, Aberdeen, UK
[6]School of Pharmacy, Queen's University Belfast, Belfast, UK
[7]Norwich Medical School, University of East Anglia, Norwich, UK
[8]School of Health Sciences, University of East Anglia, Norwich, UK
[9]School of Healthcare, University of Leeds, Leeds, UK
[10]Department of Geriatric Medicine, Cambridge University Hospital NHS Foundation Trust, Cambridge, UK
[11]PPIRes, NHS South Norfolk Clinical Commissioning Group, London, UK
[12]Norwich Clinical Trials Unit, Norwich, UK
[13]Care Management Services, Norwich, UK
[14]Ageing Clinical & Experimental Research (ACER) Team, Institute of Applied Health Sciences, University of Aberdeen, Aberdeen, UK
[15]School of Education & Lifelong Learning, University of East Anglia, Norwich, UK
[16]Retired
[17]Academic Unit of Pharmacy, Radiography and Healthcare Science, University of Leeds, Leeds, UK

[*]Corresponding authors d.j.wright@leicester.ac.uk and rch23@leicester.ac.uk

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/10.3310/JBPT2117.

Primary conflicts of interest: David Wright received speaker fees from Desitin Pharma and speaker fees and unrestricted education grants from Rosemont Pharmaceuticals during the conduct of the study. Christine Bond reports personal fees as the Editor-in-Chief of *International Journal of Pharmacy Practice* during the conduct of the study. Carmel Hughes reports membership of HS&DR Commissioned Panel member (2015–19). Garry Barton reports membership of a CTU funded by the NIHR (up to 2021). Lee Shepstone reports membership of EME Funding Committee member (2010–14). Antony Arthur reports membership of HS&DR Commissioned Board member (2014–16). Arnold Zermansky reports membership of HTA MPOH Panel (2011–18) Pharmaceuticals Panel.

Published December 2023
DOI: 10.3310/JBPT2117

Scientific summary

The Care Home Independent Pharmacist Prescriber Study (CHIPPS): development and implementation of an RCT to estimate safety, effectiveness and cost-effectiveness

Programme Grants for Applied Research 2023; Vol. 11: No. 10
DOI: 10.3310/JBPT2117

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

The predominant UK care home (CH) model for enhancing pharmaceutical care currently consists of a pharmacist visit at least yearly to conduct a medication review and support medication management processes. Evidence for improvements in clinical outcomes resulting from this is inconsistent and lacks consensus. Non-medical independent prescribing provided an opportunity for pharmacist independent prescribers (PIPs) to assume greater responsibility for improving pharmaceutical care for residents in CHs, whilst saving general practitioner (GP) time in prescribing activities.

Objectives

- Identify and describe the components stakeholders would specify in a feasible and acceptable PIP service.
- Identify the most appropriate outcomes to measure the impact of the Care Home Independent Pharmacist Prescriber Study (CHIPPS) intervention through the development of a core outcome set (COS).
- Identify and develop the components of a training package, which would prepare PIPs for the role.
- Test and refine the service specification and proposed study processes to inform a definitive trial.
- Estimate the effectiveness, cost-effectiveness and safety of a pharmacist independent prescribers assuming responsibility for providing pharmaceutical care to residents in CHs.

Methods

The study sites were located in Northern Ireland (one site), Scotland (one site) and England (two sites). Ethical approval was received for each work package (WP).

WP1 development of service specification

Views of residents, relatives, CH staff, CH managers, GPs, and pharmacists with experience of living or working in, or with, CHs regarding how to develop the PIP service were obtained by focus groups and through interviews.

Transcripts were iteratively analysed, using the Theoretical Domains Framework, to identify key components, initial codes and themes to inform our study design.

WP2 outcomes identification

We followed recognised methodology to develop a COS to identify and select potential outcomes for the CHIPPS trial.

Phase I: We generated a long list of outcomes through the literature review and stakeholder involvement (semi-structured interviews and focus groups) constituted for WP1, WP2 and WP4.

Phase II: We convened a consensus panel to rate the importance of the long list of outcomes and provide additional recommendations for new outcomes. The panel was then asked to re-rate those outcomes for which consensus was not achieved and any newly recommended outcomes. Consensus for inclusion was achieved when 70% of respondents rated an outcome as critical.

WP3 health economics

Costs were estimated in Great British pounds (£) at 2017/2018 financial year levels. PIPs maintained training and activity logs to enable their time to be costed. Details of healthcare use were obtained from GP/CH records. Unit costs were obtained from published resources.

Quality of life was measured using EuroQol Five Dimensions and Five Levels Rating Scale (EQ-5D-5L), which was completed by proxy. Mean quality-adjusted life-year (QALY) scores were estimated for the 6-month follow-up.

WP4 training package development

A training package was developed through six phases overseen by an expert advisory panel (EAP).

Systematic review and narrative synthesis

The review was registered with PROSPERO (20150907) and reported according to PRISMA guidelines. Published articles were selected by two independent reviewers if they provided primary empirical data describing a pharmacist intervention in the care home environment, including information regarding education and training. Systematic reviews and abstracts were excluded. Data were extracted to enable description of knowledge requirements for the role.

Initial stakeholder engagement

Within the interviews and focus groups outlined in WP1, participants were asked for views with respect to education and training requirements for PIPs.

Training-specific interviews and focus groups

Focus groups were convened with primary care pharmacists, GPs, community pharmacists and care home staff to obtain their views on the first draft of the training package derived by the EAP from Phases I and II.

Stakeholder engagement and consensus

Panels were held at each site to obtain consensus on the proposed training package.

Feasibility testing

A focus group was convened with PIPs to obtain feedback on the training package following feasibility testing.

Evaluation

All intervention PIPs received the training package during the definitive trial (WP6). Evaluation consisted of training day evaluation forms (PIP, *n* = 21), online survey (PIP *n* = 16) and semi-structured interviews (PIP, *n* = 14). The dataset was analysed separately and then triangulated.

WP5 feasibility study

Four triads (one in each location), consisting of a GP, PIP and care home (providing care to older persons) with 10 residents (65 years and older, prescribed at least one medicine), were recruited. PIPs were trained and provided the intervention for 3 months.

Data on recruitment and retention were collated. Outcome measures identified in WP2 were tested for suitability for inclusion within the main trial.

A safety assessment process was developed involving an independent review of PIP pharmaceutical care plans (PCPs) and adverse events, i.e. hospitalisations and deaths, plus enablement of independent reporting of concerns through a specific email address.

Post-intervention face-to-face semi-structured interviews were held with participants and a focus group was held with the PIPs. Proceedings were digitally recorded and transcribed verbatim.

WP6 definitive trial with internal pilot

This was a cluster randomised controlled trial (cRCT) involving the training of PIPs to collaborate with the care home residents' GP, care home staff and residents, to assume responsibility for medication management over 6 months.

Recruitment

General practices, CHs and PIPs were recruited in triads according to the following inclusion and exclusion criteria:

Inclusion criteria

- Pharmacists had to be an independent prescriber (PIP).
- General practices had to be caring for sufficient care home residents to enable recruitment of 20 eligible participants.
- Care homes had to be caring for adults aged ≥65 years and associated with a participating general practice.
- Care home residents had to be under the care of a participating general practice, ≥65 years old and prescribed at least one regular medicine.

Exclusion criteria

- Care homes in regular (monthly or more) receipt of a medication-focused review service or under formal investigation by a regulator.
- Care home residents receiving end-of-life care or participating in another study.

Identification

Pharmacist independent prescribers were identified using local networks. Care home(s) were approached by participating GPs.

General practices identified and screened residents against the inclusion and exclusion criteria. Eligible residents were provided with invitation packs by care home managers to obtain verbal permission for a researcher to approach for consent. For residents without capacity, consent packs were posted to the resident's next of kin.

Randomisation and blinding

Randomisation was at a general practice (triad) level and was stratified by the four geographical areas, using a web-based electronic system. Research associates were blinded to allocation during recruitment. PIPs, CHs and GPs were unblinded.

Training

Intervention PIPs undertook the training package, revised after WP5, over 6 weeks. Time-zero for the intervention was 6 weeks post-randomisation.

Intervention

The PIP intervention, 4 hours allocated per week per 20 residents, included

- developing and implementing PCPs
- assuming prescribing responsibilities
- supporting ordering, prescribing and administration processes
- medication management training of care home staff
- liaison between all parties to optimise medication-related activities.

Control
Pharmacist independent prescribers allocated to the control arm did not participate. Care homes and residents received usual care.

Sample size
Overall, 880 participants (440 in each arm) were required to detect a 21% decrease in fall rate from 1.50 per resident over 6 months with 80% power, at the 5% significance level and with an intra-class correlation coefficient of ≤0.05. We assumed a 20% loss to follow-up.

Primary outcome measure

- Fall rate per person from care home falls record over 6 months.

Secondary outcome measures

- Quality of life (EQ-5D-5L)
- Barthel Index
- Drug Burden Index (DBI)
- Hospital admissions
- GP visits
- Mortality

Statistical methods
Intention-to-treat analysis was performed with between-arm comparison of falls using a negative binomial model. Analyses were conducted using the generalised estimation equation approach adjusted for the clustered design. The final model included baseline fall rate, prognostic variables and arm as fixed factors.

Safety reporting of serious adverse events
Serious adverse events (SAEs), defined as hospitalisation or death, identified through routine monitoring, were assessed for association with PIP activity by residents' GPs.

An independent email address was created to enable concerns regarding the intervention to be confidentially reported.

A random 20% sample of PCPs and associated resident documents were assessed by study geriatricians during the intervention period for clinical appropriateness and safety.

Process evaluation
Quantitative (surveys of care home staff, GPs and PIPs, PIP activity logs, PCP review and trial outcomes) and qualitative (interviews with care home staff, residents, GPs and PIPs) data were collected.

Results

WP1 development of service specification
Twenty-seven pharmacists (care home and community), 24 GPs, 6 care home managers, 9 care home staff and 14 residents and relatives provided input.

The concept was broadly welcomed by all. Potential barriers were identified as pharmacists' knowledge of chronic disease management and older people's medication, the care home environment, requirement to provide clarity with respect to the role and the need to become integrated both socially and professionally within CHs and general practice teams.

Participants agreed that the PIP should assume responsibility and provide support for all elements of medication management within the home.

WP2 outcomes identification

Sixty-three outcomes were identified in Phase I (22 from the literature and 41 from stakeholders).

Twelve outcomes met consensus criteria for inclusion in round 1, with 17 achieving no consensus and the remainder achieving consensus for exclusion. Two outcomes were further included after round 2, yielding a final list of 14 potential outcomes.

WP3 health economics

The estimated mean per resident cost of the PIP intervention was £323 (including training). The mean (per resident) incremental cost of the PIP intervention, after considering other NHS costs and personal social services (PSS) and adjusting for any differences between arms, was £280. The mean incremental effect was estimated to be −0.004 QALYs. As the PIP intervention was estimated to be associated with higher costs and no improvement in quality of life, it was not estimated to be cost-effective.

WP4 training package development

Literature provided therapeutic and clinical knowledge requirements. Qualitative work added the importance of understanding local cultures and requirement to integrate into teams. Recognising that PIPs started from different baselines, the final training package consisted of

- face-to-face training for 2 days
- underpinning knowledge pack
- personal development framework
- personal development planning and implementation with mentor
- time to integrate into teams and understand local cultures
- oral competency assessment by a mentor and an independent medical assessor.

Pharmacist independent prescribers reported that all elements were useful and appropriate, enhancing their confidence for the role. Additional training on how to build effective relationships was recommended.

WP5 feasibility study

Four triads, each with 10 residents, were successfully recruited; 30% of the residents in CHs were found unsuitable following screening and 30% of those invited declined to participate or failed to reply.

Two outcome measures [Mini-Mental State Examination (MMSE) and QUALIDEM] were removed following testing. Differences in outcome measures pre- and post-intervention suggested that the intervention had the potential to enhance care.

No adverse events related to PIP activity occurred, and no major concerns were identified from reviewing PCPs.

Qualitative feedback confirmed acceptability of the intervention and identified potential for the intervention to improve patient care and safety and to save GP and care home staff time and effort.

WP6 definitive trial with internal pilot

Recruitment

Forty-nine triads (49 GPs and PIPs and 72 CHs) were randomly allocated to the intervention (n = 25) and control (n = 24) arms. Additionally, 454 residents were recruited to the intervention arm and 428 to the control arm.

Baseline characteristics

Baseline characteristics were largely similar between arms. The control arm had a greater proportion of CHs with nursing residents (59% vs. 42%) and lower performance with respect to activities in daily living. Residents in the intervention arm had a higher mean number of falls in the 3 months before service implementation (0.78 for intervention vs. 0.57 for control).

Primary outcome

A greater number of falls were recorded in the intervention arm in the 6-month follow-up. Once adjusted for differences at baseline, the result was non-significantly in favour of the intervention [rate ratio (RR): 0.91, 95% confidence interval (CI) 0.66 to 1.26; $p = 0.99$].

Secondary outcome measures

The intervention reduced residents' DBI by 25% compared with that by 15% in the control arm (RR 0.83, 95% CI 0.75 to 0.92; $p<0.001$). It had no effects on mortality, hospitalisation, activities of daily living or quality of life in the intervention and control arms.

Safety

No SAEs were related to PIP activity. Independent review of care plans revealed no safety concerns, and no concerns regarding PIP activity were received through email.

Process evaluation

Pharmacist independent prescribers largely adhered to service specification, varying provision according to need. Two-thirds of PIP time was spent on resident-related activities, of which approximately 24% was face-to-face. They spent 24% of their time on other general activities in the care home and 10% of their time travelling. Five PIPs stated that 4 hours per week was not enough, eight PIPs found it sufficient and three PIPs found it too much.

Overall, 668 interventions were recorded, of which 566 were clinical, including 379 for medication discontinuation or dose reduction, 86 for medication initiation or dose increase, 49 for medication change and 52 for monitoring. Among the 566 interventions, 189 (33.5%) involved medication for treating diseases of the central nervous system. Among the 189 interventions, 148 reduced the likelihood of falls, 37 increased it and 4 were unclassifiable. Moreover, 179 interventions reduced drug burden and 10 increased it.

The service was valued by most of the stakeholders. This was believed to be more effective where there was good communication, a readily accessible PIP, confidence on PIP competence, stable care home management and resonance between PIP activities and GP and care home needs.

Conclusions

Service specification, COS, training package and study design were delivered for use within a definitive trial designed to evaluate this model of care. The trial recruited and retained to target. Three PIPs (12%) failed to deliver any part of the intervention.

The intervention was well received and believed to enhance resident care and safety. Several medicines were discontinued or stopped, resulting in a significantly reduced drug burden. However, no difference in falls, the primary outcome measure, was identified. The PIP intervention was also not estimated to be cost-effective, as it was associated with an increase in costs and no improvement in QALYs.

Given the evidence of suboptimal prescribing in CHs, further work is recommended to develop interventions that improve resident clinical outcomes and are likely to be cost-effective.

Trial registration

This trial is registered as ISRCTN10663852, definitive trial: ISRCTN17847169.

Study registration

This study is registered as PROSPERO CRD20150907.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research programme (NIHR award ref: RP-PG-0613-20007) and is published in full in *Programme Grants for Applied Research*; Vol. 11, No. 10. See the NIHR Funding and Awards website for further award information.

Programme Grants for Applied Research

ISSN 2050-4322 (Print)

ISSN 2050-4330 (Online)

Programme Grants for Applied Research (PGfAR) was launched in 2013 and is indexed by Europe PMC, NCBI Bookshelf, DOAJ, Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and Scopus® (Elsevier, Amsterdam, Netherlands).

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full PGfAR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/pgfar.

Criteria for inclusion in the *Programme Grants for Applied Research* journal

Reports are published in *Programme Grants for Applied Research* (PGfAR) if (1) they have resulted from work for the PGfAR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Programme Grants for Applied Research programme

The Programme Grants for Applied Research (PGfAR) programme, part of the National Institute for Health and Care Research (NIHR), was established in 2006 to fund collaborative, multidisciplinary programmes of applied research to solve health and social care challenges. Findings are expected to provide evidence that lead to clear and identifiable patient benefits, in the relatively near future.

PGfAR is researcher led and does not specify topics for research; however, the research must be in an area of priority or need for the NHS and the social care sector of the Department of Health and Social Care, with particular emphasis on health and social care areas that cause significant burden, where other research funders may not be focused, or where insufficient funding is available.

The programme is managed by the NIHR Central Commissioning Facility (CCF) with strategic input from the Programme Director. For more information about the PGfAR programme please visit the website: https://www.nihr.ac.uk/explore-nihr/funding-programmes/programme-grants-for-applied-research.htm

This report

The research reported in this issue of the journal was funded by PGfAR as project number RP-PG-0613-20007. The contractual start date was in May 2015. The final report began editorial review in July 2021 and was accepted for publication in October 2022. As the funder, the PGfAR programme agreed the research questions and study designs in advance with the investigators. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, CCF, PGfAR or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the PGfAR programme or the Department of Health and Social Care.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).