The Care Homes Independent Prescribing Pharmacist Study (CHIPPS): A cluster randomised controlled trial to evaluate safety and effectiveness

Objectives: Pharmaceutical care in care homes requires significant enhancement. The ability of 'pharmacist independent prescribers' (PIPs) to assume responsibility for its provision in care homes provides a new model for improving residents' outcomes. We aimed to estimate care home PIP effectiveness, cost-effectiveness (to be reported elsewhere) and safety.

Design: Cluster randomised controlled trial: with clusters based on triads of a pharmacist independent prescriber, a general practice, and one to three associated care homes.

Setting: Care homes across England, Scotland and Northern Ireland, their associated general practices, and Pharmacy Independent prescribers (PIPs) formed triads.

Participants: 49 triads and 882 residents were randomised. Participants were care home residents, ≥65 years, on ≥1 medication, recruited to 20 residents/triad.

Intervention: Each PIP provided pharmaceutical care to approximately 20 residents across 1-3 care homes with weekly visits over six months. PIPs developed a pharmaceutical care plan for each resident, undertook medicines review/reconciliation, staff training, support with medicines-related procedures, deprescribing and prescription authorisation. Those in the control group received usual care.

Outcomes: Primary outcome was fall rate/person at 6 months analysed by intention to treat, adjusted for prognostic variables. Secondary outcomes included: quality of life (EQ-5D by proxy), Barthel score, drug burden index, hospital admissions and mortality. Assuming a 21% reduction in falls, 880 residents were required, allowing for 20% attrition.

Results: The average participant age at study entry was 85 years; 70% were female. At 6 months the fall rate risk ratio was not significantly different between groups (RR: 0.91, 95% CI 0.66-1.26, p=0.58), nor were other secondary outcomes with exception of drug burden index, which significantly favoured the intervention. 32.7% of PIP interventions involved medicines associated with falls. No adverse events or safety concerns were identified.

Conclusions: Change in primary outcome of falls was not significant. Limiting follow up to six months combined with a small proportion of interventions predicted to affect falls may explain this. A significant reduction in Drug Burden was realised and would be predicted to yield future clinical benefits for patients. This large trial of an intensive weekly pharmacist intervention with care home residents was also found to be safe and well received.

Trial registration: ISRCTN 17847169

What this paper adds box

What is already known on this topic:

- Medicine management for care home residents is in need of significant improvement with observational studies indicating >50% residents experience medication errors daily
- Interventions to improve medicines management in care homes have shown limited effectiveness
- UK pharmacists can prescribe independently, yet to date no study has assessed the effectiveness of Pharmacist Independent Prescribers (PIPs) in care homes

What this study adds:

- An intervention introducing PIPs to visit care homes weekly for approximately four hours was safe and welcomed by care home staff and GPs, and was most valued where PIPs already had an established relationship with the GP practice
- Introducing PIPs to care homes did not reduce falls in care home residents over a six month follow-up period
- PIPs did reduce the Drug Burden Index, suggesting that they can successfully improve residents' medication which may yield health benefits to residents beyond six months but needs further testing

Background

The need to improve prescribing and processes surrounding medicines in care homes (long-term care facilities) is internationally recognised.[1 2] A large-scale United Kingdom (UK)-based observational study in 2009 identified that 70% of care home residents experienced medication errors daily.[2] The authors identified the need for one individual to assume central responsibility for care home medicines management.[2] In response, the UK government called for suitable interventions to address the problem.[3] However, interventions to improve medicines management within care homes, usually involving either pharmacists or doctors providing medication reviews, demonstrate limited evidence for clinical effectiveness.[4]

Reasons postulated for the lack of evidence include variability in trial design, lack of intervention development and poor selection of outcome measures.[4] Hence there have been calls for 'high-quality cluster-randomised controlled trials testing multidisciplinary interventions that measure well-defined, important resident-related outcomes'.[4] A 2019 systematic review reported falls as the only patient centred outcome to be improved as a result of pharmacist interventions in care homes.[5] Equally, the usual model of care, which is based on pharmacists making recommendations for medication changes, creates extra work for doctors and, as frequently not enacted, represent a waste of pharmacist time.[6]

UK legislative changes in 2006 enabled accredited pharmacists to independently prescribe,[7] and they can operate autonomously when assuming a central medicines optimisation role e.g. within care homes. Pharmacist independent prescribers (PIPs) are able to identify pharmaceutical needs and initiate, change or monitor medicines without secondary authorisation. Several studies have demonstrated PIP effectiveness in non-care home contexts,[8-10] but no evaluation has been undertaken in care homes. Implementation of pharmacist prescribing generally in the UK has been variable with relatively little evaluation of clinical effectiveness.[11 12] However, with the expansion of clinical pharmacy in English general practice and the requirement now for newly qualified pharmacists to be trained as prescribers,[13] pharmacist prescribing is currently being implemented nationally and includes prescribing for care home residents.[12]

In 2015 the UK National Institute for Health and Care Research (NIHR), funded a programme of research [the Care Homes Independent Pharmacist Prescriber Study (CHIPPS)] to evaluate this model of care. The programme followed Medical Research Council guidance on development and evaluation of complex interventions,[14] with extensive stakeholder engagement,[15] selection of outcome measures,[16] development of a training programme to enhance fidelity,[6 17] and a feasibility study in four UK locations which demonstrated acceptability of the service and confirmed feasibility of recruitment.[18]

These culminated in this cluster randomised controlled trial (cRCT) with an internal pilot,[19 20] which was designed to assess the clinical and cost effectiveness (to be reported elsewhere) of Pharmacist Independent Prescribers (PIPs) providing pharmaceutical care[21] within care homes against usual care.

Method

Study design

This cluster-RCT was conducted in Aberdeen (Scotland), Belfast (Northern Ireland), Leeds (Northern England), and Norwich (East of England), with ethical approval obtained from NHS East of England Central Cambridge Research Ethics Committee (for England and N. Ireland) - Ref: 17/EE/0360; and by

Scotland A REC – Ref: 17/SS/0118. The trial protocol,[19] summarised below, commenced with an internal pilot. Recruitment and intervention delivery ran from March 2018 to March 2020.

Participants

Recruited triads (clusters) of a General Practice (GP), Pharmacist Independent Prescriber (PIP) and care home(s) providing approximately 20 residents each.

Inclusion/exclusion criteria

All our Pharmacist Independent Prescribers (PIPs) needed to be a UK accredited prescriber, and were excluded if they already provided a similar service to the recruited care home, or had a conflict of interest through employment with the supplying community pharmacy. General practices were included if they managed sufficient care home residents to support recruitment of 20 eligible participants. Care homes were included if they provided care primarily to adults aged over 65 years, and were associated with a participating general practice. They were excluded if their residents already received regular, medication-focused review services (defined as monthly or more frequently), or if they were under formal investigation by a regulator. Residents were included if under the care of a participating practice, over 65 years, permanently resident in a participating care home, taking at least one regular medicine and able to provide (directly or via an appropriate representative) informed consent/assent. Residents were excluded if they were receiving end-of-life care or participating in another study.

Triad & resident identification and recruitment

Invitation packs, containing invitation letters, information sheets, and consent forms, were used to recruit PIPs & GPs, identified using local networks. Consenting GPs then approached up to three care home(s) to enable recruitment of approximately 20 residents. Care home managers distributed invitation packs, signed by the GP, to potential residents or appropriate third parties e.g. next of kin, for those residents lacking capacity to consent.

Randomisation and blinding

Randomisation was undertaken (1:1 ratio: intervention to control) at triad level, stratified by the four geographical areas, using a web-based electronic system integrated into the centrally maintained REDCap[22] database. Researchers responsible for recruitment of residents, care homes and medical practices were blinded to allocation during the recruitment phase only. PIPs allocated to the intervention arm were trained for role post-randomisation and broke blinding for care homes and medical practices once they started their formal interactions. Incidents of blinding being broken for research associates were recorded.

Intervention (see supplementary file: CHIPPS protocol, [19] and the service specification [Appendix 2])

We developed the PIP service specification with stakeholders and identified potential barriers to implementation with a clearly defined PIP role and effective communication deemed key to success[15]. PIPs received study-specific training for their role over a six week period post-randomisation[17] and provided with materials required for their role at this stage e.g. PowerPoint slides from training, STOPP/START criteria for medication review.[23] This training programme was developed based on a systematic review[6] along with stakeholder engagement, expert panel consensus and feasibility testing.[17] The training programme involved face-to-face training on managing medicines for complex older people, a personal development framework and mentorship. Subsequent to training PIPs were assessed by a GP and a pharmacist mentor, and their competencies signed-off.[24] To allow for completion of training and sign-off, time zero was standardized at six weeks post-randomisation.

The PIPs, all of whom, by definition, were independent prescribers, visited the care homes to perform medication review, optimise therapy for all residents, and created pharmaceutical care plans (PCPs) to record their activity and provide a plan for future activity. PCPs also allowed their actions/plans to be recorded for the care home and resident's GP. The PIPs provided support for: improving processes for medicines ordering (to minimise opportunity for missed doses); medicines administration (to reduce administration errors); medicines reconciliation when residents transferred between settings (to minimise opportunity for transcription errors); and staff training (to optimise requests for new medicines e.g. anti-psychotics, laxatives, pain control). The nature and extent of delivery of each element of the intervention was individualised for the care home by the PIP, who were allocated four hours/week to manage 20 residents over six months.

PIPs were responsible for updating resident records within care homes and medical practices and for communicating changes to the supplying pharmacist. They decided on the most appropriate methods for communicating changes to medical practices and care homes i.e. orally, written, in person or not, depending on the activity. The intervention was tailored to context e.g. training to Care Home staff; and was delivered dependent on need.

Control: usual GP-led care which could range from GP visits purely in response to individual requests to regular GP weekly sessions to provide more proactive care. Pharmacist provision could be of medicine provision only (by a community pharmacist); to three, six or twelve monthly visits by primary care based pharmacists undertaking medication reviews. Few, if any of the latter reviews would have involved pharmacists actively prescribing, as opposed simply to providing advice to the GP. PIPs recruited and trained within the trial had no interaction with control homes.

Outcomes

A Core Outcome Set was developed for effectiveness trials of prescribing in care homes to inform selection of outcomes for this trial[16] combined with data from our feasibility study.[18] From that work, we selected a primary outcome of fall rate/person over six months, as recorded in care homes' falls records, which are required by regulators. Secondary outcomes (at six months unless stated otherwise) selected were: resident (by proxy) quality of life (EQ-5D-5L)[25] at three and six months with responses converted into a utility score where 0 is death and 1 is full health;[26] proxy modified physical functioning score (Barthel) where zero is most dependent to 20, least dependent;[27] Drug Burden Index (DBI), a measure of anticholinergic and sedative drug exposure, collected via GP recorded medication data, where higher scores indicate greater anticholinergic potential and increased risk of drug-related morbidity;[28] hospital admissions over six months follow-up, collected from GP records supplemented by care home records; mortality; and health service utilisation and associated costs. Our CHIPPS logic model informed outcome selection (Supplementary materials). Data collection commenced in September 2018 and concluded in July 2020.

Safety

SAEs (Serious Adverse Events) were defined as unexpected inpatient hospitalisation and/or death related to the study intervention. Suspected SAEs were reported prospectively by GPs and identified retrospectively by the trial manager through proactive monthly care home contact. SAEs were assessed by the resident's GP for causality and association with the PIP intervention. In addition, a dedicated email address was provided to all care home staff to report concerns. Finally, a 20% random sample of PCPs (weighted towards earlier trial stages), was assessed by a study geriatrician for clinical appropriateness and safety.

Sample size calculation

Based upon the fall rate observed in the CAREMED study (to assess effectiveness of multi-disciplinary medication review in care homes),[29] 880 participants (440/arm) was aimed for. This number was sufficient to provide 80% statistical power to detect a 21% difference in fall rate from 1.50/resident over six months to 1.18, using a two-sided 5% significance level, and included an assumed attrition of 20%. It was assumed that the study would consist of 44 clusters, with a mean of 20 participants in each, and an assumed intra-class correlation coefficient (ICC) of ≤0.05. The estimate of a reduction in falls was half that suggested by another UK care home pharmacist intervention.[30]

Statistical analysis

A frequentist approach was used, with a two-sided 5% statistical significance level for hypothesis testing, providing estimates of between group differences and corresponding 95% confidence intervals. The primary analysis was on an intention-to-treat basis (i.e. participants analysed within their allocated group, rather than by actual treatment received), with a per protocol analysis also completed for participants deemed to have received the PIP intervention as intended. We anticipated that the primary outcome would follow a Poisson distribution, but the data proved to best-fit a Negative Binomial model, which was used instead. Parameters were estimated using a Generalised Estimating Equation (GEE) approach, to account for the clustered design, with an offset included for length of follow-up. Length of follow-up varied from participant to participant due to death or drop-out.

The final primary outcome model included baseline fall rate, key prognostic variables (defined as baseline values of DBI,[28] Barthel score,[27] Charlson Comorbidity Index,[23] and home status [nursing/residential]), with group as a fixed factor. An offset of logarithm of follow-up time was also included to allow inclusion of information from participants lost to follow-up prior to six months. Secondary and sensitivity analyses were conducted using an analogous GEE model, with an appropriate change to the link and error term, depending upon the nature of the outcome of interest.

Mortality analyses were carried out using a Cox Proportional Hazards regression model (time from consent to death, or otherwise censored), where robust sandwich estimates of standard errors were used to adjust for clustering within care homes. Analyses were conducted in SAS v.9.4.

The trial was overseen by a Data Monitoring Committee and an over-arching Trial Steering Committee.

Process evaluation

Following MRC guidance,[9] a mixed methods process evaluation, including quantitative and qualitative data collection at the end of each six-month implementation period, was conducted and is reported elsewhere.[31]

Patient and Public Involvement (PPI)

We worked with our local Public and Patient in Research (PPIRES) group from the outset with feedback received on the original project idea from PPIRES members and subsequent involvement in the grant application as it developed. With support from our care home expert (HH) we visited a home to undertake a focus group with residents, listening to their views regarding the project and what was needed from a resident perspective. Residents had no concerns regarding a pharmacist prescriber looking after their medicines but they wanted involvement in all decisions. Training regarding this was incorporated into the final intervention.

To enhance research effectiveness we recruited four patient and public involvement (PPI) members with an interest in care homes through PPIRES: two onto the management group and two for the independent steering committee. PPI members were family carers of people with complex conditions requiring polypharmacy. One had previous experience of working in care homes. The views of those involved in the management group were sought at all points during the study and one wrote an article about this.[32] They reviewed participant information leaflets, consent forms, training materials and qualitative data, so as to include their different perspectives on our findings. PPI members also reviewed abstracts and papers prior to publication. In addition, we engaged with the Patients' Association to support dissemination of findings and help organise our final dissemination event. PPI collaborators were involved in dissemination through a public facing conference for GPs, Pharmacists and care home staff.

Results

Forty nine triads (49 general practices, 49 PIPs and 72 care homes) were recruited (see Figure 1 - Consort diagram). In total, 25 triads, including 449 residents, were randomly allocated to the intervention and 24 triads, including 427 residents, to control; between 15/2/2018 and 10/9/2019. Almost all losses to follow-up at six months (137/168, 82%) were resident deaths. Excluding those, primary outcome data were available for 96% of participants. One care home closed during the study (11 residents), whilst three out of 25 intervention PIPs did not deliver the full service; one of which did not deliver the intervention at all. Five cases of unblinding of researchers to care home allocation were reported.

Baseline comparison between groups is provided in Table 1. Whilst most variables were similar between groups, the control group had rather more male residents (33% vs. 28%), and a greater proportion in nursing home care (59% vs 42%). In contrast, the intervention group had higher Barthel scores (8.34 vs. 7.07 i.e. greater independence), and a greater rate of falls, with mean falls in the previous 90 days of 0.78 vs. 0.57 in controls.

Outcome data are provided in Table 2. The median follow-up time was 198 days in the intervention arm and 197 days in the control. There were 697 recorded falls in the intervention group (1.55 per resident) and 538 falls in the control (1.26 per resident) at 6 months. Adjusting for all model covariates, there was no significant difference between groups, with a rate ratio of 0.91, (95% CI: 0.66-1.26). Per-protocol analysis of the primary outcome did not change the outcome. The intra-class correlation (ICC) was 0.051 when including all model covariates; very close to our assumed ICC of 0.05.

In total, 66 deaths (14.7%) were reported in the intervention group compared to 71 (16.6%) in control, with a mean time to death of 109 vs. 103 days, respectively. Cox's Proportional Hazards model found no evidence of an intervention effect (adjusted hazard ratio = 0.93; 95% CI 0.64-1.35, p=0.68, Supplementary file 1).

Table 3 shows secondary outcome results including DBI, hospitalisations and Barthel scores. DBI results showed an effect in the intervention group with an improvement from 0.72 to 0.66, whilst the control group values worsened from 0.70 to 0.73, with the ratio of DBI scores at six months between intervention and control of 0.83 (95% CI: 0.74-0.92, p<0.001). No other secondary outcome showed a statistically significant difference.

Table 4 shows EQ-5D results. Across both arms the level of missing EQ-5D data at baseline, 3 and 6 months was 10.1% (see Table 1), 14.2% and 11.4% (see Table 4). EQ-5D scores were very similar at baseline between groups and changed little through follow-up, with small, statistically non-significant differences at three and six months.

No safety concerns were identified from review of PCPs or independent assessment of SAEs, of which none recorded were related to the intervention.

Discussion

Introducing PIPs to care homes did not reduce falls in care home residents over a six month follow-up period. However, the anticholinergic/sedative 'burden' of medication taken by care home residents was reduced by almost a fifth compared to usual care, suggesting effective deprescribing occurred. All other secondary outcomes, after adjustment for baseline differences, demonstrated no significant difference.

In terms of validity, this was a large trial, involving 72 care homes, 49 PIPs and GP surgeries and 876 residents. We recruited to target, so had sufficient power to test our hypothesis of a 21% decrease in falls. As a cluster trial we removed the potential for contamination affecting performance of different care homes managed by the same general practice. Follow-up of residents was thorough and complete with primary outcome data available for 96% of residents at six months when deaths were excluded.

This trial was the culmination of a five-year programme grant where the team, assiduously following MRC guidance,[14] developed the intervention and PIP training[17] in careful consultation with a wide array of key stakeholders to ensure PIPs were maximally effective. We also conducted a feasibility study[18] to ensure PIPs were appropriately prepared; residents, care homes and GPs could be recruited; and outcome data collected efficiently.

In hindsight, benefits from medication interventions, particularly deprescribing, take time to be realised, so a six month intervention and follow-up period may have been insufficient. The intervention development phase also highlighted a need for PIPs to be part of the general practice team; but during recruitment, there were insufficient General Practice-based pharmacists to recruit solely from that pool. It was also unfortunate that three PIPs (12%) failed to deliver the full intervention; but as a pragmatic study, this is consistent with what would happen in everyday practice. It was also not possible to blind homes to their group status, and researchers may have been aware of that status when collecting follow-up data.

We developed a Core Outcome Set[16] to support selection of the most valid outcome measures for this group, which were tested in the feasibility study.[18] Falls was identified as the most suitable primary outcome as it is readily obtainable and objective, has low potential for missing data, is resident-centred, is relevant to a wide range of morbidities, and a direct and indirect consequence of medication effects. However, many other factors contribute to a resident's fall(s), such as their condition, their environment and their general care.[33] Furthermore, whilst criteria are available for defining and recording a fall in a care home,[34] in practice these are not universally adopted, nor is there a standardised template for recording a fall. Although these differences should average out across as large a study as this one; this 'random misclassification' had the potential to reduce evidence of effectiveness.

Our process evaluation[31] identified that just over a quarter of residents experienced an intervention which had the potential to reduce the likelihood of falls, but in a small proportion interventions had the potential to increase that likelihood. Both reduction and increases in risk of falls are rarely immediate consequences of drug changes, rather it is the likelihood of falling over time which is modified. Thus, a 12 or even 24-month follow-up may have been more desirable.

Our result contrasts with the evidence for pharmacist independent prescriber effectiveness in other contexts.[8-10] These studies were however, based in younger populations and focused in one disease area. Care home residents are, by definition, complex and frequently on a steep downward trajectory with respect to quality of life. Consequently, results are not comparable.

Anticholinergic/sedative burden is associated with increased mortality,[35] falls,[36] hip fractures,[37] frailty[38] and reduced quality of life.[38] Thus, the significant reduction in DBI observed should predict improved resident outcomes. However, data on DBI and risk have been based on a minimum 12 months of observation.[36-39] Again, this study's six month follow-up may have been unlikely to fully realise clinical improvements.

The broad resident inclusion criteria mean our findings are highly generalisable and relevant across the UK care home sector, and also internationally; though few other countries have pharmacists with full prescribing rights yet.[40 41]

In conclusion, this large, rigorously conducted, cluster-RCT, testing a pharmacist independent prescriber regularly visiting care homes to manage residents' pharmaceutical care, demonstrated this was a safe, well received intervention,[31] which decreased anticholinergic/sedative prescribing. Whilst the latter would be expected to realise future clinical benefits, the intervention demonstrated no improvement in our primary outcome of falls. Integration of PIPs into care homes and medical practices was identified as necessary to enhance intervention effectiveness. Equally, care home triallists have yet to identify a fully appropriate patient-centred outcome, able to measure clinically relevant changes across a wide range of residents.

Dissemination plans

We actively involved our patient and public involvement collaborators in our final dissemination event which included representatives from all stakeholder groups. The final NIHR report will be available to patients and public.

Words: 3,527

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Competing interests

DW received speaker fees from Desitin Pharma and speaker fees and unrestricted education grants from Rosemont Pharmaceuticals. Bond reports personal fees as the Editor in Chief of the International Journal of Pharmacy Practice, during the conduct of the study. All other authors have no competing/conflict of interest.

Contributorship statement+ guarantor (see http://resources.bmj.com/bmj/authors/article-submission/authorship-contributorship)

All authors have reviewed the paper prior to submission. David Wright led the whole project jointly with Richard Holland. Richard Holland and Christine Bond led the main trial, on which this paper is based. Richard Holland: Conceptualisation, funding acquisition, methodology, project administration, writing – original draft, writing – review & editing. Christine Bond: Conceptualisation, funding acquisition, methodology, project administration, writing – review & editing. David Phillip Alldred: Conceptualisation, funding acquisition, methodology, project administration, writing – review & editing. Carmel Hughes: Conceptualisation, funding acquisition, data curation, methodology, project administration, writing – review & editing. Garry Barton: Conceptualisation, funding acquisition, methodology, project administration, writing – review & editing. Fiona Poland: Conceptualisation, funding acquisition, methodology, project administration, writing – review & editing. Lee Shepstone: Conceptualisation, Formal analysis, funding acquisition, methodology, project administration, writing – review & editing. Antony Arthur: Conceptualisation, funding acquisition, methodology, project administration, writing – review & editing. Linda Birt: Data curation, methodology, project administration, writing – review & editing. Jeanette Blacklock: Data curation, writing – review & editing. Annie Blyth: Data curation, project administration, resources, writing – review & editing. Stamatina Cheilari: Data curation, writing – review & editing. Amrit Daffu-O'Reilly: Data curation, project administration, writing – review & editing. Lindsay Dalgarno: Data curation, project administration, writing – review & editing. James Desborough: Conceptualisation, funding acquisition, methodology, writing – review & editing. Joanna Ford: Project administration, writing – review & editing. Kelly Grant: Formal analysis, writing – review & editing. Bronwen Harry: Data curation, project administration, writing – review & editing resources. Helen Hill; Conceptualisation, funding acquisition, methodology, project administration, writing – review & editing. Jacqueline Inch: Data curation, project administration, writing – review & editing. Phyo Kyaw Myint: Funding acquisition, project administration, writing – review & editing. Nigel Norris: Conceptualisation, funding acquisition, data curation, methodology, project administration, writing – review & editing. Maureen Spargo: Data curation, project administration, writing – review & editing. Vivienne Maskrey: Data curation, project administration, writing – review & editing. David Turner: Formal analysis, project administration, writing – review & editing. Laura Watts: Data curation, project administration, resources, writing – review & editing. Arnold Zermansky: Conceptualisation, funding acquisition, methodology, writing – review & editing. David Wright: Conceptualisation, funding acquisition, data curation, methodology, resources, original draft writing - review & editing

The lead authors David Wright and Richard Holland* accept full responsibility for the finished work and the conduct of the study, had access to the data, and controlled the decision to publish.

*The manuscript's guarantors.

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The lead authors David Wright and Richard Holland* affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Data sharing statement (see http://www.bmj.com/about-bmj/resources-authors/article-types/research)

Data will be available upon reasonable request:
Deidentified participant data, including primary, secondary and patient reported outcome data, interview transcripts and prescription data, protocol and Statistical Analysis Plan are available from available upon request from Professor David Wright (d.j.wright@leicester.ac.uk; 0000 0003 3690 9593) Professor Lee Shepstone (l.shepstone@uea.ac.uk; ORCID number 0000-0001-5524-7818) and Norfolk and Waveney Integrated Care research office (NWICB; nwicb.RandDoffice@nhs.net). Reuse of the CHIPPS dataset will be made available to reasonable requests for the purpose of improving patient care in health and social care and will be subject to completion of a data sharing agreement between NWICB, University of East Anglia and the third party organisation.

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Patient and public involvement statement

The following is included at the end of the method section:

"We worked with our local Public and Patient in Research (PPIRES) group from the outset with feedback received on the original project idea from PPIRES members and subsequent involvement in the grant application as it developed. With support from our care home expert (HH) we visited a home to undertake a focus group with residents, listening to their views regarding the project and what was needed from a resident perspective. Residents had no concerns regarding a pharmacist prescriber looking after their medicines but they wanted involvement in all decisions. Training regarding this was incorporated into the final intervention.

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Table 1: Trial groups at baseline

	Intervention N =449 residents	**Control N=427 residents**	**Overall N=876 residents**
Age at consent in years: mean (SD)	85.1 (7.7)	85.4 (7.6)	85.3 (7.7)
Gender: n (%)			
Male	125 (27.8%)	141 (33.0%)	266 (30.4%)
Female	324 (72.2%)	286 (67.0%)	610 (69.6%)
Consent: n (%)			
Participant	59 (13.1%)	51 (11.9%)	110 (12.6%)
Consultee	390 (86.9%)	376 (88.1%)	766 (87.4%)
Resident care home status: n (%)			
With nursing	188 (42.3%)	250 (59.0%)	438 (50.5%)
Residential only	256 (57.7%)	174 (41.0%)	430 (49.5%)
Missing	5	3	8
Number of Medications:			
Median ($q_{0.25}$,$q_{0.75}$)	6 (4, 9)	6 (4, 9)	6 (4, 9)
Min, Max	1, 19	1, 19	1, 19
Missing[1]	2	4	6
Falls in previous 90 days:			
Median ($q_{0.25}$,$q_{0.75}$)	0 (0, 1)	0 (0, 1)	0 (0, 1)
Min, Max	0, 30	0, 18	0, 30
Mean (SD)	0.78 (2.30)	0.57 (1.43)	0.68 (1.93)
Hospital admissions in previous 90 days:			
Median ($q_{0.25}$,$q_{0.75}$)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Min, Max	0, 2	0, 3	0, 3
Mean (SD)	0.07 (0.26)	0.08 (0.30)	0.09 (0.33)
Barthel Score : mean (SD)	8.34 (5.78)	7.07 (5.77)	7.74 (5.81)
Missing	10	35	45
Drug Burden Index: mean (SD)	0.72 (0.75)	0.70 (0.69)	0.71 (0.72)
Missing	5	2	7
Charlson Co-Morbidity Index: mean (SD)	5.94 (1.84)	5.98 (1.52)	5.96 (1.69)
Missing	5	6	11
EQ-5D self-utility score: mean (SD) *	0.49 (0.37)	0.33 (0.36)	0.41 (0.37)
Missing	396	377	773
EQ-5D proxy utility score: mean (SD)*	0.31 (0.35)	0.29 (0.37)	0.30 (0.36)
Missing	34	55	89

* EQ-5D utility scores set to zero for participants that died

Table 2: Falls at 6 months – Summary

	Intervention N=449	Control N=427	Rate ratio[1] (model 1)	Rate ratio[2] (model 2)
Total Falls	697	538		
Follow-Up (Person-Days)	79 803	76 904		
Crude Fall Rate/yr and RR	3.19	2.56	1.00	0.91
Confidence interval			0.73-1.36	0.66-1.26
p-value			0.992	0.580
Minimum, Maximum	0, 59	0, 27		
Q_{25}, Q_{75}	0,2	0,1		
Median	0	0		

[1]Model 1 – adjusted for falls at baseline (in 90 days prior to enrolment), all 876 participants included, however only 844 had non-zero follow-up time.

[2]Model 2 – adjusted for falls at baseline, Barthel, DBI, Charlson index, Home status (nursing/residential); 812 participants included.

Table 3: Secondary Outcomes at 6 months

	Intervention N=449	Control N=427	Comparison[1]	Fully adjusted comparison[2]
Hospitalisations per person:				
median ($q_{0.25}$,$q_{0.75}$)				
min, max	0 (0, 0)	0 (0, 0)		
mean (SD) or RR	0, 4	0, 3		
95% CI	0.19 (0.50)	0.18 (0.47)	0.98	0.90
p-value			0.66 to 1.46	0.61 to 1.32
			0.932	0.573
Barthel Score:				
mean (SD) or RR	8.12 (5.84)	6.46 (5.66)	1.19	1.20
95% CI			0.96 to 1.49	0.96 to 1.49
p-value			0.116	0.107
Missing	113	110		
Drug Burden Index:				
mean (SD) or RR	0.66 (0.74)	0.73 (0.69)	0.83	0.83
95% CI			0.74 to 0.92	0.74 to 0.92
p-value			<0.001	<0.001
Missing	10	9		

[1]Comparison adjusted for baseline values of main variable only
[2]Comparison adjusted for baseline value of main variable, and Barthel, Charlson, Home status and DBI

Table 4: EQ-5D Proxy outcomes at 3 and 6 months

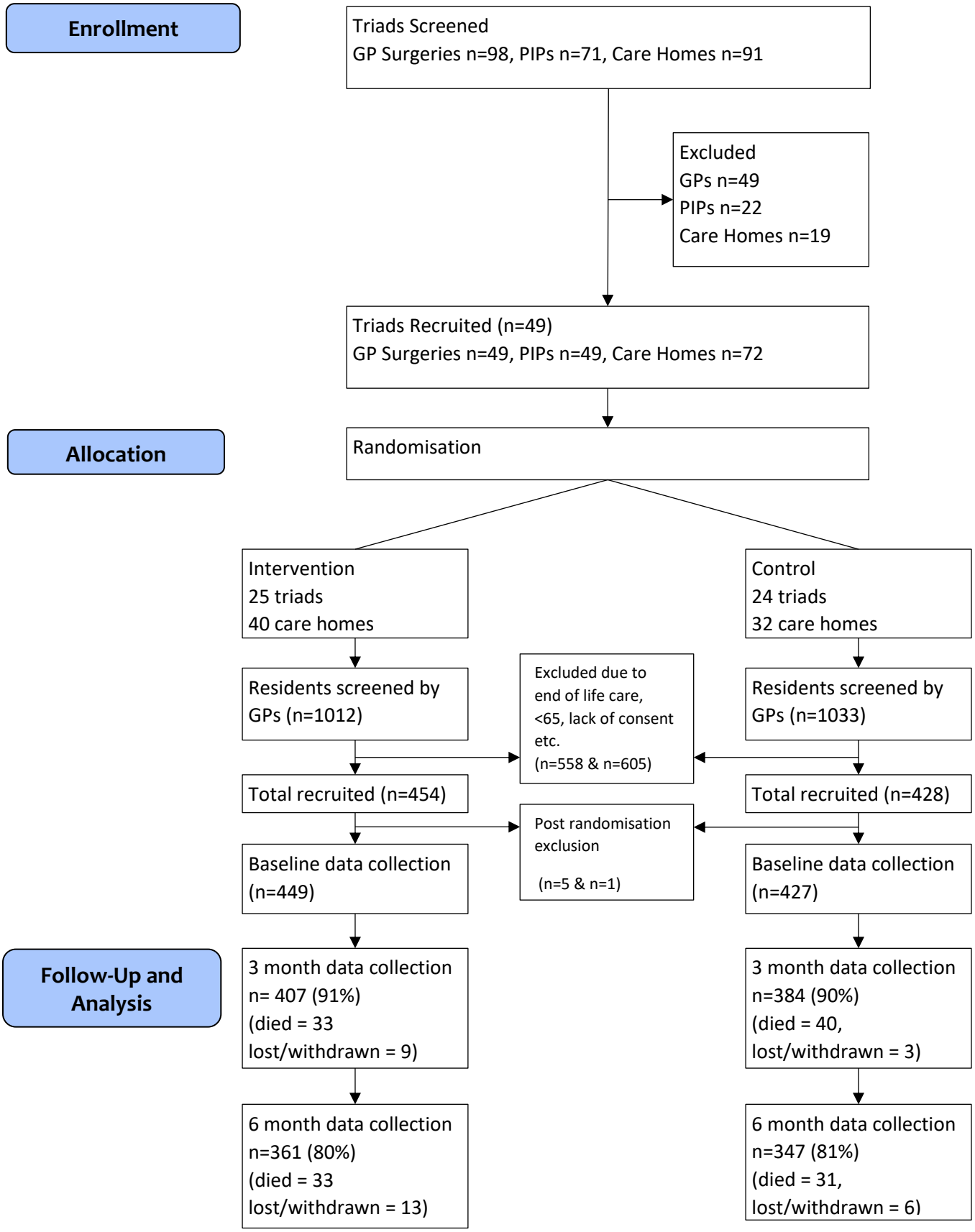
	Intervention N=449	Control N=427	Absolute difference Intervention to control[1]	Absolute difference Fully adjusted comparison[2]
Three Months:				
EQ-5D proxy utility score: mean (SD) * Missing	0.28 (0.35) 77	0.28 (0.35) 47	-0.017 (-0.073 to 0.039) p=0.556	-0.043 (-0.092 to 0.006) p=0.082
Six months:				
EQ-5D proxy utility score: mean (SD)* Missing	0.26 (0.35) 53	0.21 (0.33) 47	0.030 (-0.021 to 0.080) p=0.249	0.042 (-0.043 to 0.052) p=0.862

[1]Comparison adjusted for baseline values of EQ-5D only
[2]Comparison adjusted for baseline value of EQ-5D, and Barthel, Charlson, home status and DBI.
Self-report data are available from the authors, but were only collected from 6.5% of resident participants
* EQ-5D utility scores set to zero for participants that died

Table 5: Number and type of PIP interventions per patient

Category		
Interventions per resident (average)		1.8
Technical interventions (n (%))		69 (11.2%)
Educational intervention (n (%))		3 (0.4%)
Clinical interventions (n (%))		570 (85%)
Type of clinical intervention	Medicine discontinuation/dose reduction*(n (%))	386 (68%)
	Start new medication (n (%))	87 (15.2%)
	Change medication (n (%))	47 (8.2%)
	Dose increase (n (%))	26 (4.5%)
	Monitoring (n (%))	24 (4.2%)

Figure 1: Consort diagram for cluster randomised controlled trial



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