

Clinical medication review by a pharmacist of elderly people living in care homes—randomised controlled trial

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Abstract

Objective: to measure the impact of pharmacist-conducted clinical medication review with elderly care home residents.

Design: randomised controlled trial of clinical medication review by a pharmacist against usual care.

Setting: sixty-five care homes for the elderly in Leeds, UK.

Participants: a total of 661 residents aged 65+ years on one or more medicines.

Intervention: clinical medication review by a pharmacist with patient and clinical records. Recommendations to general practitioner for approval and implementation. Control patients received usual general practitioner care.

Main outcome measures: primary: number of changes in medication per participant. Secondary: number and cost of repeat medicines per participant; medication review rate; mortality, falls, hospital admissions, general practitioner consultations, Barthel index, Standardised Mini-Mental State Examination (SMMSE).

Results: the pharmacist reviewed 315/331 (95.2%) patients in 6 months. A total of 62/330 (18.8%) control patients were reviewed by their general practitioner. The mean number of drug changes per patient were 3.1 for intervention and 2.4 for control group ($P < 0.0001$). There were respectively 0.8 and 1.3 falls per patient ($P < 0.0001$). There was no significant difference for GP consultations per patient (means 2.9 and 2.8 in 6 months, $P = 0.5$), hospitalisations (means 0.2 and 0.3, $P = 0.11$), deaths (51/331 and 48/330, $P = 0.81$), Barthel score (9.8 and 9.3, $P = 0.06$), SMMSE score (13.9 and 13.8, $P = 0.62$), number and cost of drugs per patient (6.7 and 6.9, $P = 0.5$) (£42.24 and £42.94 per 28 days). A total of 75.6% (565/747) of pharmacist recommendations were accepted by the general practitioner; and 76.6% (433/565) of accepted recommendations were implemented.

Conclusions: general practitioners do not review most care home patients' medication. A clinical pharmacist can review them and make recommendations that are usually accepted. This leads to substantial change in patients' medication regimens without change in drug costs. There is a reduction in the number of falls. There is no significant change in consultations, hospitalisation, mortality, SMMSE or Barthel scores.

Keywords: clinical medication review, care home, clinical pharmacist, elderly, falls

Introduction

Elderly residents of care homes are often frail and have progressive degenerative health problems. They take multiple medicines with an increased risk of adverse drug events [1–4]. Their dependency and frequent cognitive impairment undermine their capacity to report symptoms. They there-

fore need regular review and adjustment of treatment. Previous studies have shown that only a minority of patients living at home have their medicines reviewed by their general practitioners (GPs) [5, 6]. The National Service Framework for Older People [7] proposed (without citing evidence of its value) regular review of care home residents and their treatment.

We previously reported pharmacist-conducted clinical medication reviews (CMRs) of elderly people living in the community. The pharmacist often recommended important changes to patients' medicines [8] that were acceptable to patients [9] and usually implemented by their doctors [10], reducing the number and cost of medicines without significant increase in the use of services or mortality [8]. We therefore hypothesised that a pharmacist, conducting CMRs of care home residents, might improve the quality and control of their treatment.

Objective

To measure the impact of pharmacist-conducted CMR with elderly residents of care homes.

Design

An open randomised controlled trial of CMR by a pharmacist of elderly care home residents against usual care.

Setting

Nursing, residential and mixed care homes for older people in Leeds, UK.

Participants

We approached all care homes in the Leeds area with six or more residents aged ≥ 65 , seeking to recruit all residents taking one or more repeat medicines.

We excluded those who were in another clinical trial, terminally ill (life expectancy under 1 month) or already receiving CMR by a pharmacist. We excluded individuals at the GP's request. After collection of baseline data, patients were randomised in randomly sized blocks of two to eight patients using an algorithm written in Visual Basic in Microsoft Access.

We obtained informed consent from those able to grant it and assent of the nearest relative from those with impaired capacity. We took the care home managers' views as to residents' ability to consent. If it became clear at the recruitment interview that the resident could not consent, assent was sought.

We included participants with dementia because they constitute a large proportion of care home residents and are more vulnerable than those who are able to articulate their concerns. We aimed to recruit 1,600 patients, which was calculated to have a 90% power at 5% significance level to detect differences of $1/6$ SD in measures of cognitive and physical functioning (see below). Patients were followed for 6 months from randomisation (± 3 weeks) (Figure 1).

We collected clinical data from GP records. The criterion for a medication review having occurred was if the term 'medication review' or 'drug review' or a similar phrase was recorded. (Although doctors could have reviewed patients' medicines without recording it, an unrecorded review is unsafe and not an acceptable practice in the context of recommendations of medical defence bodies, national service framework and prescribing guidelines [11–13].) A trained nurse (blind to randomisation) assessed cognitive and physical functioning using the Standardised Mini-Mental State

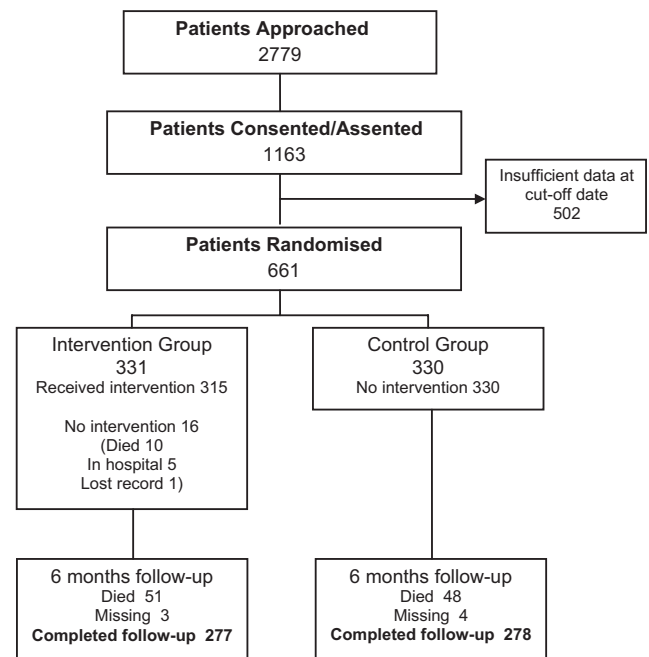


Figure 1. Consort diagram showing patient flow.

Examination (SMMSE) [14] and the Barthel Activities of Daily Living Index [15]. She obtained the number of falls from the homes' official accident book. The details of medication were from GP records. Drug costs were from the British National Formulary [16].

The study was approved by the Local Research Ethics Committees for Leeds (West Yorkshire, UK).

The study began on 16 April 2002.

Intervention

A CMR [17] was conducted by the study pharmacist within 28 days of randomisation. It comprised a review of the GP clinical record and a consultation with the patient and carer. The pharmacist formulated recommendations with the patient and carer and passed them on a written proforma to the GP for acceptance and implementation. GP acceptance was signified by ticking a box on the proforma. Control patients received usual GP care.

Outcome measures

The primary outcome measure was the number of changes in medication per participant. Secondary outcome measures were the following:

Medication outcomes

- number of repeat medicines per participant
- cost of 28 days of repeat medicines per participant at end date
- recorded medication reviews in the study period

Clinical outcomes in 6 months

- falls
- mortality
- hospital admissions

- number of GP consultations
- Barthel Index
- SMMSE

Statistical methods

Baseline values were described using frequency counts or means as appropriate. The primary analysis of the difference in the number of medication changes per participant was performed using a non-linear mixed model, with Poisson/normal error, and the effect of the nursing home accounted for as a random effect. Analogous analyses were undertaken for continuous and binomial outcomes. Difference in the mean cost was also described using a bootstrapped confidence interval.

Results

We obtained consent or assent from 1,163 patients, and baseline data for 661 patients in 65 homes (13 nursing, 38 residential and 14 mixed), who were randomised (Figure 1). Baseline data are summarised in Table 1. Randomisation was curtailed on 30 June 2003 when it became clear that the intended sample size was not achievable within the available timescale. Data were analysed on an intention-to-treat basis.

The pharmacist conducted CMRs on 315 of 331 intervention patients (95.2%). Only 62 of 330 control patients (18.8%) had a review by the GP in 6 months. The number of medication changes in the intervention group was significantly greater than that in the control group, although there was no significant difference in the number of medicines or cost per patient (Table 1).

There was a large and significant reduction in the number of falls (0.8 falls per patient in the intervention group, compared with 1.3 in the control group). The lower rate of hospitalisation in intervention patients did not reach statistical significance. There was no statistically significant difference in mortality, Barthel or SMMSE score between the two groups. In both cases, the 95% confidence intervals were narrow and appeared to exclude clinically important differences (Table 1).

There was no significant difference in GP consultation rate, although 38 patients (11.5%) were referred by the pharmacist to the GP.

The patient's GP accepted 75.6% (565/747) of the pharmacist recommendations. Of the accepted recommendations, 76.6% (433/565) were acted upon (Table 2). Other types of intervention by drug are also in Table 2. Interventions by patient are in Appendix 1 of supplementary data on the journal website (<http://www.ageing.oxfordjournals.org/>).

Table 1. Baseline and outcome data of trial

	Baseline data		Outcomes			
	CMR (n = 331)	Control (n = 330)	CMR	Control	Difference (relative risk 95% CI)	P-Value
Male, number (%)	75 (22.7)	79 (23.9)				
Assent, number (%)	172 (52.0)	177 (53.6)				
Age mean (interquartile range)	85.3 (81 to 90)	84.9 (80 to 90)				
Nursing home	86	82				
Residential home	164	160				
Mixed home	81	88				
Barthel [mean (SD)]	10.0 (6.3)	10.1 (6.1)	9.8 (6.1)	9.3 (6.2)	0.46 (-0.02 to 0.94) ^d	0.06
Change in mean			-0.3	-0.8		
SMMSE [mean (SD)]	13.8 (10.0)	13.1 (10.0)	13.9 (10.0)	13.8 (10.6)	-0.24 (-1.18 to 0.70) ^d	0.62
Change in mean			+0.1	+0.7		
Number of drug changes ^{a,b} , mean in 6 months (SD)			3.1 (2.7)	2.4 (2.6)	1.34 (1.21 to 1.48)	<0.0001
Repeat drugs ^b per patient (SD)	6.9 (3.3)	6.9 (3.5)	6.7 (3.3)	6.9 (3.6)	0.98 (0.92 to 1.04)	0.50
Drug cost/patient ^b —protocol defined (NIC 28 days), mean (SD)	£42.91 (38.93)	£41.67 (41.65)	£42.24 (38.33)	£42.95 (41.01)	-0.70 (-7.28 to 5.71) ^d	—
Post hoc ^c					-1.92 (-6.54 to 2.69)	0.41
GP consultations ^b , mean (SD)	3.2 (2.8)	3.2 (2.8)	2.9 (2.8)	2.8 (2.8)	1.03 (0.93 to 1.15)	0.50
Medication review	12 months	12 months	6 months	6 months		
By doctor ^b , number (%)	82 (24.8)	77 (23.3)	58 (17.4)	62 (18.8)	0.88 (0.56–1.37) ^c	
By pharmacist, number (%)	0	0	315 (95.2)	0		
Falls ^b mean per patient in 6 months (SD)	1.0 (1.7)	0.9 (1.7)	0.8 (1.7)	1.3 (3.1)	0.59 (0.49 to 0.70)	<0.0001
Patients falling ^b in 6 months (%)	145 (43.8)	128 (38.8)	84 (25.7)	106 (32.1)	0.73 (0.50 to 1.06) ^c	0.09
Hospitalisations ^b in 6 months/patient (SD)	0.23 (0.52)	0.23 (0.57)	0.20 (0.48)	0.26 (0.61)	0.75 (0.52 to 1.07)	0.11
Patients hospitalised ^b in 6 months, number (%)	61 (18.3)	62 (18.7)	47 (14.2)	52 (15.8)	0.89 (0.56 to 1.41) ^c	0.62
Deaths, number (%)			51 (15.3)	48 (14.5)	0.89 (0.56 to 1.41) ^c	0.81

CMR, clinical medication review; SMMSE, Standardised Mini-Mental State Examination.

^aPrimary outcome.

^bAdjusted for care home type random effect.

^cNIC, net ingredient cost—NHS drug price not including dispensing cost.

^dMean difference (95% CI).

^eDifference odds ratio (95% CI).

Table 2. Pharmacist recommendations and outcome by drug

Recommendation	Number	%
Technical	225	30.1
Test required	161	21.6
Stop medicine	100	13.4
Alter medicine	91	4.0
Switch	37	
Alter dose	40	
Alter formulation	12	
Alter timing	2	
Referred to GP to resolve	10	0.4
Rectify record mismatch	9	0.4
Start medicine	76	10.2
Non-medicine-related intervention	75	10.1
Total	747	100
Accepted by doctor ^a	565	75.6
Accepted and acted upon	433	
Accepted but other action	33	
Accepted but no action	99	
Rejected by doctor	52	7.0
No response to recommendation	113	15.1
Patient died before response	17	2.3
Total	747	100

^aIn writing on response form.

Discussion

The participants were very old (mean age 85) and generally frail and sick, demonstrated by their low SMMSE and Barthel scores, propensity to fall and high rates of hospital admission and mortality.

The intervention group has a much higher medication change rate than the control group. We conclude that this is the result of the medication review. There was no difference in the number of items per patient. This is because the pharmacist recommended nearly as many starts of new medicines as discontinuations.

Previous studies of pharmacist-conducted medication review have been criticised for not demonstrating an effect on health outcomes [18]. Our study shows a very significant reduction in the number of falls, which was 38% less in the reviewed population ($P \leq 0.0001$). This suggests that the intervention may have prevented 160 falls in 331 patients in 6 months—a clinically important outcome.

It is important to consider which interventions might have prevented falls. Stopping medication that causes confusion, sedation or hypotension is an obvious explanation. Adjusting or starting medication that improves mobility (such as anti-Parkinson's medication) is another. Almost one-third of medicines stopped were CNS drugs—a well-recognised cause of adverse drug effects, including falls [19]. Nearly 60% of medicines started were calcium and vitamin D preparations. Vitamin D supplementation in elderly people may reduce falls by over 20% [20], although others dissent from this view [21]. It is plausible to link the reduction in falls to the one-third lower hospital admissions in the intervention group, although this did not reach statistical significance ($P = 0.11$). This begs further study. Drug-related falls are an important cause of morbidity [22], and our data demon-

strate the benefit of careful review and adjustment of medication. (The HOMER study [23], in which hospital admissions increased after medication review, was of a population just discharged from hospital who were reviewed without the GP clinical records and cannot be extrapolated to a 'stable' care home population.)

The patients' ill health is reflected in the number of medicines, medication change consultation and hospitalisation rates, and mortality. This contrasts with our previous data for older people living in their own homes, who were younger, fitter and took fewer medicines [8]. Previous studies have reported that care home residents receive 5–5.8 medicines per patient [1, 24, 25]. We found an average of nearly 7 items per patient. This suggests that multiple medication in care homes is growing. Some express concern about the numbers of drugs prescribed [26, 27], but we believe this reflects the complex morbidity of this population and is justified if individual drugs are appropriate.

We previously expressed concern that many patients do not have an annual recorded medication review [6]. Our pre-baseline annual review rate was 24%, which is lower than in our previous study in older people living in their own homes (44%) [6]. Three-quarters of this vulnerable group are not having their medication reviewed. In 8 years since Zermansky's description of the low level of medication review in general practice [5], nothing seems to have changed. The fact that patients are seen six times a year by their GP does not reduce our concern. It highlights six missed opportunities.

There was no significant difference in the medication cost between intervention and control groups. Nor was there a significant change from baseline to endpoint. This does not mean that the pharmacist achieved no financial savings. More drugs were stopped in the intervention group, but such savings were eclipsed by the additional cost of new medicines added. The savings were therefore recycled to address new therapeutic issues, turning a cost-benefit into an opportunity-benefit with no increase in the overall cost.

Although there was no effect on GP consultation rate as measured, in practice, consultations would be saved. The National Service Framework requires that patients' medication be reviewed annually (or 6-monthly in patients on four medicines). The pharmacist's review saves the GP needing to do this in those who are not reviewed opportunistically (81.2% in 6 months in our control group) and thereby saves a consultation in over four-fifths of the patients. Because such consultations would have required a doctor visit, this is an important time saving.

The number of GP consultations per patient was lower in both groups (2.9 and 2.8 in 6 months in intervention and control groups, respectively) than in the Department of Health figures for patients over 75 generally, which quote 7 consultations per patient per annum [28]. This may reflect the lack of autonomy of care home residents, whose help-seeking may be modified by carers, institutionalisation or cognitive impairment, making them more accepting of symptoms. It might also reflect positively on the quality of care in homes, with better diet, safer environment and earlier health intervention.

The intervention produced no clinically significant change in the overall level of mental and physical functioning as measured by SMMSE and Barthel, respectively. The baseline functional level of residents (in both groups) was far lower than we expected, and it may have been unrealistic to expect significant improvement in these patients.

Mortality was high at 15.3% (intervention) and 14.5% (control) in 6 months, but there was no significant difference between the groups. Extrapolating from these figures, the annual casualty rate would be of the order of one-quarter of the care home population. Reducing mortality may not be feasible in this population.

The pharmacist recommended an intervention in 256 of 331 (77.4%) patients and in 657 of 2,280 (28.8%) existing medicines. Over 75% (565/747) of the latter were accepted by the patient's GP. The GP did not implement 23.4% (132/565) of the accepted recommendations, however. Over 7% (52/747) recommendations were rejected by the patient's doctor. The overall implementation rate of recommendations was therefore 58% (433/747). The low implementation rate might have been higher if the pharmacist had been allowed to implement agreed changes.

The most common intervention was 'technical change' (encompassing generic switching, altering quantities and dosage instructions, adding missing items and deleting discontinued medication). This is consistent with the previous work [10]. Although these might appear trivial, it is crucial from a risk-management perspective to maintain an accurate record. Stopping medicines accounted for 13.4% (100/747) of interventions. Almost one-third of these were CNS drugs, which are a recognised source of adverse drug events in older people.

Starting a medicine (76/747, 10.2% of interventions), including calcium and vitamin D, was recommended for under-treated or untreated conditions and drugs, such as aspirin, for ischaemic heart disease.

Of the intervention patients, 42% (139/331) required a test to monitor their condition and/or their medicines. For 24% (161/672) of medicine-related interventions, a test was recommended, 13.7% (23/161) of these resulting in a change in medication. The worrying finding that this population was sub-optimally monitored is consistent with a previous study [24].

Furniss *et al.* [1] (studying a comparable population) achieved a substantial reduction in prescribing costs, perhaps because they only recommended 14 new medicine starts but 96 stops in 158 patients. Of them, 28% were taking hypnotics or anxiolytics and 30% antipsychotics. Our study was conducted at least 4 years later, when the prevailing level of prescribing of these drugs was lower. They did not report hospital admissions. Like us, they found little effect on mental or physical functioning or mortality.

Limitations of the study

We were unable to randomise planned numbers because of the complexity of data collection in the context of the study resources—we simply ran out of time to collect full data sets on consented patients [29]. Collecting baseline data required the diary availability of study staff, patients, homes

and practices—the order in which full sets of data were obtained and patients randomised was therefore unselectable and unpredictable, although not strictly random.

The number of subjects recruited was less than the original target, reducing the available statistical power. However, analyses are described with confidence intervals that are universally narrow, giving quite precise estimates of the differences between the groups.

The short duration of the project with one medication review per patient and 6 months of follow-up limited the pharmacist's involvement with individual patients, care homes and doctors. A better service model would have a pharmacist in a continuing relationship with a smaller number of homes and practices and might provide a better quality of service and perhaps better outcomes. It would be prohibitively expensive to conduct a controlled clinical trial of this model.

Conclusions

We have demonstrated that a clinical pharmacist can review care home patients' medication and make recommendations to the GP that are usually accepted. This leads to a substantial change in patients' medication regimens without significant change in drug costs. These interventions seem to reduce the number of falls in this very frail group.

Medicine management of elderly care home residents is time-consuming and complex. It is not being done by GPs. A suitably trained clinical pharmacist with full access to the patient, carer, medical record and primary health care team can improve the quality of medicines' use in this population.

Key points

- Care home patients' medicines are reviewed infrequently by GPs.
 - Consultations with a clinical pharmacist are an effective method of reviewing the medicines of care home residents.
 - Clinical review by a pharmacist results in the following: (i) more drug changes and (ii) a reduction in falls, no adverse effect on GP consultations, hospitalisation or mortality.
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Trial registration details

NHS Trusts Clinical Trials Register Number: ISRCTN45416155.

Ethics approval

The study was approved by the Local Research Ethics Committees for Leeds (West Yorkshire, UK).

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Conflict of interest

None of the authors or contributors has any conflict of interest.

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