Home-based medication review in a high risk elderly population in primary care—the POLYMED randomised controlled trial

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Abstract

Objective: to assess whether home-based medication review by a pharmacist for at-risk older patients in a primary care setting can reduce hospital admissions.

Design: randomised controlled trial comparing home-based medication review with standard care.

Setting: home-based medication review of 136 patients registered with one general practice.

Method: study participants were over 80 years of age, living at home, taking four or more medicines, and had at least one additional medicines-related risk factor. The intervention comprised two home visits by a community pharmacist who educated the patient/carer about their medicines, noted any pharmaceutical care issues, assessed need for an adherence aid, and subsequently met with the lead GP to agree on actions.

Main outcome measure: total non-elective hospital admissions within 6 months. Secondary outcomes included number of deaths, care home admissions and quality of life (EQ-5d). Impact on number of medicines prescribed was also assessed.

Results: at 6 months, no difference in hospital admissions (21 intervention versus 20 control, $P = 0.80$), and no difference in care home admissions or deaths were detected between groups. There was a small (non-significant) decrease in quality of life in the intervention group. There was a statistically significant reduction in the mean number of medicines prescribed ($-0.87$ items in favour of the intervention group, $95\%$ confidence interval $-1.66$ to $-0.08$, $P = 0.03$).

Conclusions: no positive impact on clinical outcomes or quality of life was demonstrated, however, this intervention did appear to reduce prescribing. This is in line with other evidence and suggests that this form of intervention may not have a clear health gain, but may lead to modest savings in terms of reduced prescribing. Future research should focus on whether such a prescribing effect would make this type of intervention cost effective.

Keywords: aged, 80 years and over, community pharmacy service, drug utilisation review, polypharmacy, primary health care, elderly

Introduction

As people get older, their use of medicines tends to increase. In England, 21% of the population is over 60 years old [1], yet they receive 56% of prescriptions dispensed [2]. The National Service Framework (NSF) for older people recommends medication review to reduce medicine-related problems encountered by the elderly [3, 4]. The NHS Plan [5] and associated implementation programme for the pharmacy profession [6] proposed that pharmacists should play a key role in this. However, large randomised trials of pharmacist-led medication review in the United Kingdom [7–10] have not detected a positive impact on clinical outcomes such as hospital admissions. One of the largest of these [8] showed a significant increase in hospital admissions in the intervention group at 6 months. In that trial, communication from the review pharmacists to GPs was routinely done by letter, with occasional phone calls but no face-to-face contact. It is
possible that the remoteness of the review pharmacist/GP working relationship hindered the implementation of the pharmacists’ recommendations.

Trials of medication review [9, 10], where the pharmacist had direct access to medication records and closer liaison with GPs, have reported better resolution of pharmaceutical care issues and potential cost savings. However, one study identified that many participants declined to participate as they considered themselves too unwell to attend the surgery [11]. Conducting a review in the patients’ own home is likely to be the most convenient for the patient and provides the opportunity to understand their medicine-taking in the context of the home environment. The aim of the ‘Polymed’ trial was to study whether a home-based intervention in an at-risk elderly population, where the medication review pharmacist liaised closely with a GP and the practice team, could reduce hospital admissions.

Methods

Setting

Study participants were recruited from a dispensing general practice with 9 GPs, situated in rural north Norfolk. The practice had a population of approx 14,000 patients, of whom 9% were over 80 years old (twice the national average). Census data (2001) shows that 98.5% of the population in the local town of Holt are white compared to 90.9% for England [1]. Further data on the age distribution of the practice population are given in Appendix A in the supplementary data on the journal website http://www.ageing.oxfordjournals.org/.

Study pharmacist

One community pharmacist experienced in home-based medication reviews, with a post-graduate qualification in pharmacy practice, conducted all the interventions for this study.

Selection and recruitment

This study recruited patients over 80 years, living in their own homes, who were prescribed at least four oral daily medicines. At least one of the following criteria were also present: living alone; record of confused mental state, vision or hearing impairment; prescribed medicines associated with medication-related morbidity; or prescribed >7 regular oral medicines. Patients were excluded from the study if they were resident in a care home or if there was documented use of an adherence aid.

Eligible patients were sent a letter and information leaflet inviting them to take part and were phoned 4 days later. A carefully conducted telephone consent procedure was undertaken with those who agreed to participate. Randomisation was carried out by a third party, and was stratified by whether the patient lived alone.

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The intervention

Intervention participants were visited within 2 weeks of the initial phone call. The referral to the review pharmacist included a copy of the participant’s current medication and medical history. This was used to highlight areas to be addressed at the visit including possible drug interactions, adverse effects or storage issues. Wherever possible, the home visit was arranged for a time when the pharmacist could meet any carers who helped with the patient’s medicines. At the first visit, the pharmacist educated the patient, removed out-of-date drugs, and assessed the need for an adherence aid.

The review pharmacist and GP held regular meetings. Possible changes to the patient’s prescribed medication were discussed and agreed amendments were put into action by the GP, or delegated to the practice dispensing team.

A follow-up visit occurred 6 to 8 weeks later to reinforce the original advice, and assess whether there were any further pharmaceutical care issues to address with the GP.

The control group

The control group received standard care during the 6-month follow-up period. They were then contacted to be offered the medication review visits.

Outcomes and analysis

The primary outcome was the total number of non-elective hospital admissions at 6 months. Deaths, admission to care homes, number of drug items prescribed and self-assessed quality of life (EQ-5d [12]) were measured as secondary outcomes. Results were analysed according to the ‘intention to treat’ principle.

Data on hospital admissions were obtained from Hospital Episode Statistics (HES). All oral, topical, inhaled and injected medicines were counted at baseline and follow-up.

A medical history summary was printed for all registered patients at six months to provide details of any nursing or residential home admissions since baseline. Participants completed an EQ-5d questionnaire by telephone at recruitment and at 6 months. The EQ-5d provides a utility score of between −0.59 (worst health) to 1 (perfect health) and a visual analogue scale (VAS) for respondents to rate their health between 0 (worst imaginable health state) to 100 (best imaginable health state).

Poisson regression was used to compare the number of hospital admissions between groups. The proportion of participants who died was analysed using the chi-square test. Change in utility scores and VAS scores from the EQ-5d and the change in the medication item count were analysed using Student’s t-test.

Sample size calculation

A review of admission statistics for patients over 80 years of age in Norfolk, who had an emergency readmission to hospital, showed that the mean number of emergency
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readmissions was 0.8 per patient within 6 months of discharge. Data from a previous study [13] suggested that the level of hospital admissions could be reduced by as much as 25% over 6 months. It seemed reasonable to investigate whether a highly integrated service provided in primary care to a high-risk elderly population could achieve the same level of reduction in hospital admissions (from 0.8 to 0.6 admissions per patient per 6 months). A sample size calculation suggested that, at a 0.05 significance level and 80% power, approximately 164 subjects should be recruited in total.

Results

Participant recruitment and follow-up

Patients numbering 165 met the inclusion criteria, of which 136 participants were recruited to the study (82% eligible subjects). The randomised groups appeared similar. Please see baseline comparison data Appendix B in the supplementary data on the journal website http://www.ageing.oxfordjournals.org/.

Figure 1 shows the flow of participants through the trial. Two participants (1 intervention, 1 control) withdrew from the trial shortly after recruitment and were excluded from all outcome analyses. Primary outcome data were available for 134 (99%) participants.

Intervention visits

Of the 69 participants randomised to the intervention group, 65 patients received first visits. Of the four intervention patients who did not receive a visit, one withdrew from the trial shortly after recruitment, two declined the visit, and one was admitted to hospital before the scheduled visit.

Five participants did not receive a second visit. In two cases, the participant declined a second visit, one participant died before the second visit, and another two participants were too unwell.

Further detail about the intervention, including a summary of recommendations and comments the pharmacist made to the GP is given in Appendix C in the supplementary data on the journal website http://www.ageing.oxfordjournals.org/.

Adherence aids

The pharmacist noted that adherence aids were already in use by 4/65 (6%) patients who were visited. In all these cases, the aid was filled by the patient or their carer. In addition, the pharmacist recommended adherence aids in three cases, 5% of those who received a first visit. Two were filled by the patient or carer; one was filled by the local community pharmacy.

Primary outcome—number of non-elective hospital admissions

In total, there were 21 unplanned admissions in the control group, and 20 unplanned admissions in the intervention group. Analysis using the Poisson model demonstrated a non-significant reduction in admission of 8% (i.e. relative risk = 0.92, 95% confidence interval 0.50–1.70, P = 0.80).

Secondary outcomes

Mortality data were available for 134 (99%) participants. There were seven deaths in the intervention group and six in controls (1.3% difference in proportions, confidence interval −12.1 to 14.7%, P = 0.81 [Pearson chi-squared]). There were fewer care home admissions in the intervention group compared to the control group (1 versus 3), but again, this result was nonsignificant (−3.0% difference in proportions, confidence interval −11.0 to 5.0%, P = 0.30 [Pearson chi-square]).

Quality of life data

Change in utility scores was available for 56/69 (81%) intervention participants and 49/67 (73%) control participants. If deaths are excluded, the response rates were 90% and 80% for intervention and control groups respectively. In both groups, the EQ-5d utility score decreased over 6 months follow-up. There was a small difference in the change in utility scores over 6 months in favour of the control group, but this was not statistically significant (see Table 1). For those individuals who provided both baseline and 6 month VAS data, the intervention group fell by 1.98 units over 6 months, whereas the control group increased by 2.87 units. This difference of 4.85 units in favour of the control group was not statistically significant.

Number of medication items prescribed

The mean total number of items prescribed was available for 86% of intervention group and 82% control group participants (Table 2). The mean number of items prescribed to participants in the control group increased from 9.85 to 10.33 items over 6 months. In the intervention group, there was a reduction in the mean number of items from 9.01 to 8.68. The mean difference in the change in the number of items prescribed over 6 months was −0.87 items per patient per 6 months in favour of the intervention group, which was statistically significant (95% confidence interval −1.66 to −0.08, P = 0.03, Student’s t-test).

Discussion

This trial did not demonstrate any difference between the control and intervention groups on any of the main outcome measures with the exception of reduced prescribing. The number of events and proportion of deaths in each group were closely matched.

The recruitment rate was high, with 82% of those approached agreeing to participate. Follow-up of participants was good, with only two cases excluded from analysis of the primary outcome. Outcome data on acute hospital admissions were provided by hospital episode statistics (rather than self-report) and are therefore unlikely to be biased. Complete quality-of-life data were collected for 85%
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of eligible patients. These aspects of internal validity would therefore appear to be good. However, it is important to note that the research was carried out in one rural GP practice with a single experienced review pharmacist, which has a bearing on the generalisability of the results.

The 95% confidence intervals around the point estimates for the main outcomes were broad. The risk of admission in the intervention group could have been reduced by 50%, or could have been more than doubled. Recruitment was slightly under target (by 17%) and the hospital admission rate was lower than anticipated, both of which would have reduced the power of the trial. Nevertheless, the finding of no effect on hospital admission is not out of step with similar UK trials [7–10]. In contrast, a number of trials have been published since ‘Polymed’ was initiated, which provide evidence in support of interventions that are focused in specific disease areas such as heart failure [14] or gastritis [15].

The mean EQ-5d utility scores decreased in both groups, but they decreased more in the intervention group. There was an improvement in the visual analogue scores over six months in the control group, with a negative change in the intervention group over this time. None of these results reached statistical significance, but may have favoured the control group due to the fact that 10% fewer controls responded. In contrast, the losses in drug item data did not

![Figure 1. Flowchart describing progress of participants through ‘Polymed’ trial.](image)

**Table 1. Mean EQ-5D utility scores and visual analogue scale scores for groups at baseline and six-month follow-up**

<table>
<thead>
<tr>
<th></th>
<th>Control group (n = 67)</th>
<th>Intervention group (n = 69)</th>
<th>Difference in change in utility score over 6 months (intervention minus control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EQ-5d utility at baseline</td>
<td>0.57 66*</td>
<td>0.62 68*</td>
<td></td>
</tr>
<tr>
<td>EQ-5d utility at 6 months</td>
<td>0.56 49b</td>
<td>0.57 56b</td>
<td></td>
</tr>
<tr>
<td>EQ-5d utility: change over 6 months</td>
<td>−0.02 49</td>
<td>−0.1 56</td>
<td>0.09 (CI −0.19 to 0.02 p = 0.10 [Student’s t-test])</td>
</tr>
<tr>
<td>VAS at baseline</td>
<td>65.2 64</td>
<td>63.7 67</td>
<td></td>
</tr>
<tr>
<td>VAS at 6 months</td>
<td>68.3 48</td>
<td>63.8 44</td>
<td></td>
</tr>
<tr>
<td>VAS: change over 6 months</td>
<td>2.9 48</td>
<td>−2.0 44</td>
<td>4.8 (CI −12.5 to 2.8 p = 0.21 [Student’s t-test])</td>
</tr>
</tbody>
</table>

* One patient in each group completely withdrew consent shortly after randomisation.

b See Figure 1 for reasons for losses to follow-up in quality-of-life data at 6 months.
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Table 2. Mean number of total medication items prescribed at baseline and 6 month follow-up

<table>
<thead>
<tr>
<th></th>
<th>Control group (n = 67)</th>
<th>Intervention group (n = 69)</th>
<th>Difference in change in items prescribed over 6 months (intervention minus control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. participants</td>
<td>Score availableb</td>
<td>Score availableb</td>
<td></td>
</tr>
<tr>
<td>for whom data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total medication items at baseline</td>
<td>9.85</td>
<td>9.01</td>
<td>0.87 (CI -1.66 to -0.08 P = 0.03)</td>
</tr>
<tr>
<td>Total medication items at 6 months</td>
<td>10.33</td>
<td>8.68</td>
<td></td>
</tr>
<tr>
<td>Change in total medication items over 6 months</td>
<td>0.56</td>
<td>-0.31</td>
<td></td>
</tr>
</tbody>
</table>

1 Data available for 55/67 control group participants (82%). Reasons for missing data: death before follow-up (n = 6), participant withdrawal (n = 5), loss to follow-up (n = 1).
2 Data available for 59/69 intervention group participants (86%). Reasons for missing data: death before follow-up (n = 7), participant withdrawal (n = 3).

differ between groups, and the results showed a significant difference in the change in the number of items prescribed over the 6-month follow-up, in favour of the intervention group. Two other large studies of this type undertaken in a primary care setting [16, 17] did not show any decrease in the number of prescribed medicines. The lesser degree of change in Zermansky’s study [16] may be explained by the difference in age group (>65 in Zermansky’s study compared to >80 in ‘Polymed’), the lower threshold of eligibility regarding number of medicines (3 or more in Zermansky’s study compared to 4 or more in ‘Polymed’), and the mean number of medicines at baseline (4.1 in Zermansky’s study compared to 9.0 in ‘Polymed’).

At £112, the cost of the ‘Polymed’ intervention was greater than the pharmacist costs calculated in the Zermansky study [9] (£21 per hour, or £7 per patient reviewed). This partly reflects the relative intensity of the home-based intervention—two visits totalling approximately 2 h plus travel, and the time required for preparation, discussion of medication issues with the GP and administration. This model was felt to be appropriate as the intervention was targeted at a subset of elderly people who were likely to experience difficulties in getting to the GP surgery. As such, they may not have been able to access the service evaluated in Zermansky’s study, in which the study population was younger and more able to travel. A combined service model, with provision of home-based outreach when a patient cannot access a GP-based clinic may be the most effective, and should be evaluated in future research.

The results of the ‘Polymed’ study provide some indication that this model of medication review, where the review pharmacist and GP(s) work closely together, may help to rationalise prescribing. This need not be an unduly costly aspect of the intervention if, as in this study, a lead GP for medication reviews is identified, and the brief meetings or phone contact with the pharmacist deal with issues from several reviews together.

Conclusions

The intervention in this trial did not demonstrate a positive impact on nonelective hospital admissions, deaths or quality of life. This was a relatively small study using one pharmacist in a single general practice setting, therefore the generalisability of these findings on their own are limited. However, the results are supported by evidence from larger studies which, together, indicate that the general introduction of medication review services for all older people across primary care, as currently advocated by the National Service Framework for older people, appears unlikely to yield large health gains. A statistically significant reduction in the mean number of medicines prescribed was observed in the intervention group at 6 months. Any future trial should involve multiple practices and pharmacists and embed a full economic analysis in order to assess the true impact on drug costs, health care contacts and quality of life.

Key points

- Home-based medication review by pharmacists does not appear to reduce hospital admissions.
- Medication review services in primary care should focus on at-risk populations rather than older people in general.

Sources of research funding

The main author’s post was funded by NHS Executive Eastern Region research funding.

Possible conflict of interest

The medication review intervention was funded by Holt Medical Practice who hosted the research.

Informed consent

Informed consent was gained for all participants by telephone, as detailed in the research paper. The study was approved by the Norwich District Local Research Ethics Committee in March 2002 (Ref: LREC 2002/025).

References


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