Primary care

Does home based medication review keep older people out of hospital? The HOMER randomised controlled trial

Richard Holland, Elizabeth Lenaghan, Ian Harvey, Richard Smith, Lee Shepstone, Alistair Lipp, Maria Christou, David Evans, Christopher Hand

Abstract

Objective To determine whether home based medication review by pharmacists affects hospital readmission rates among older people.

Design Randomised controlled trial.

Setting Home based medication review after discharge from acute or community hospitals in Norfolk and Suffolk.

Participants 872 patients aged over 80 recruited during an emergency admission (any cause) if returning to own home or warden controlled accommodation and taking two or more drugs daily on discharge.

Intervention Two home visits by a pharmacist within two weeks and eight weeks of discharge to educate patients and carers about their drugs, remove out of date drugs, inform general practitioners of drug reactions or interactions, and inform the local pharmacist if a compliance aid is needed. Control arm received usual care.

Main outcome measure Total emergency readmissions to hospital at six months. Secondary outcomes included death and quality of life measured with the EQ-5D.

Results By six months 178 readmissions had occurred in the control group and 234 in the intervention group (rate ratio = 1.30, 95% confidence interval 1.07 to 1.58; P = 0.009, Poisson model). 49 deaths occurred in the intervention group compared with 63 in the control group (hazard ratio = 0.75, 0.52 to 1.10; P = 0.14). EQ-5D scores decreased (worsened) by a mean of 0.14 in the control group and 0.13 in the intervention group (difference = 0.01, − 0.05 to 0.06; P = 0.84, t test).

Conclusions The intervention was associated with a significantly higher rate of hospital admissions and did not significantly improve quality of life or reduce deaths. Further research is needed to explain this counterintuitive finding and to identify more effective methods of medication review.

Introduction

Twenty eight per cent of all prescribed drugs in the United Kingdom are consumed by the 7% of the population aged over 75[1 2]; 6.5% of hospital admissions have recently been shown to be related to adverse drug reactions, and these are significantly more likely to occur in older patients.[3] This may be due to a combination of factors, including polypharmacy and age related physiological changes. Older patients can also have considerable problems with adhering to their drug regimens—up to 50% of prescribed drugs are estimated to be not taken as prescribed.[4 5]

The national service framework for older people and the NHS plan recommend regular medication reviews for older patients to maximise therapeutic benefit and minimise potential harm.[6 7] Historically, UK studies of medication review have focused on prescribing outcomes rather than effects on hospital admissions.[8–10] An Australian study of a home based medication review-type intervention showed a 25% reduction in admissions and a reduction in deaths outside hospital.[11] We sought to investigate the effectiveness of home based medication review in terms of its impact on hospital admissions in the United Kingdom. We chose home visits to ensure that the intervention could reach all very elderly participants. We also considered that home visits would allow pharmacists to gain greater insight into patients' methods of managing their drugs. The trial involved a large number of pharmacists delivering the intervention to ensure its generalisability.

Methods

Recruitment and assignment

Researchers recruited patients from four general hospitals and six community hospitals if they were aged 80 or over, admitted as an emergency, intended to be discharged to their own home or warden controlled accommodation, and prescribed two or more drugs on discharge. Exclusion criteria were dialysis treatment and participation in an intensive discharge service on one site. We randomised patients to receive home based medication review or usual care. We used third party telephone randomisation based on a computer generated sequence in blocks of varying length. Randomisation was stratified by abbreviated mental test score (score ≥ 8 v < 8)[12] and whether the patient was living alone. We obtained written informed consent from all participants.

Pharmacists could participate if they held a postgraduate qualification in pharmacy practice or had recent continuing professional development in therapeutics. All pharmacists participated in a two day training course, including lectures on adverse drug reactions, prescribing in elderly people, improving concordance, and communication skills.

The intervention

Initial referral to a review pharmacist included a copy of the patient's discharge letter. Pharmacists arranged home visits at times when they could meet patients and carers. Pharmacists assessed patients' ability to self medicate and drug adherence, and they completed a standardised visit form. Where appropriate, they educated the patient and carer, removed out of date drugs, reported possible drug reactions or interactions to the general practitioner, and reported the need for a compliance aid to the local pharmacist. Where a compliance aid was recom-

mended, this was provided within the trial and a filling fee was paid to the local pharmacist. One follow up visit occurred at six to eight weeks after recruitment to reinforce the original advice.

Masking and the control group

Because of the nature of the intervention, no "placebo" could be provided. Participants were told after randomisation which group they were in. Those in the control group received "usual care." It is possible that a small number of patients in both groups may have had their medication reviewed during the follow up period by their general practitioner or community pharmacist.

Outcome data and analysis

The primary outcome was total number of emergency admissions to hospital over six months. Secondary outcomes included deaths, admissions to residential homes and nursing homes, and self assessed quality of life measured using the EQ-5D.[13–15] Utility scores, as measured by the EQ-5D, can vary from 1 (perfect health) to − 0.59 (worst imaginable health state). Patients also rated their health on a visual analogue scale from 100 (perfect health) to 0 (worst imaginable health).

We collected data on emergency admissions from hospital episode statistics. The Office for National Statistics provided mortality data. In addition, the project coordinator contacted all patients by telephone at three months and six months to collect data on admissions to nursing homes and residential homes and to maximise the response to mailed quality of life questionnaires. In addition, we collected data from practices containing more than 10 trial patients on home visits by general practitioners, attendance at general practices, and items prescribed over the six month follow up.

We used Poisson regression to compare the number of admissions between groups. We used survival analysis to compare mortality between the two groups by using the Cox proportional hazard ratio. In both analyses, we adjusted for the two stratification variables (living alone and confusion). We analysed the proportions admitted to nursing homes or residential homes by using the χ^2 test. We assumed that changes in quality of life followed a normal distribution and analysed them by using the two sample t test. We compared home visits by general practitioners and attendance at general practices by using Poisson regression, entering practices into the model as a random effect.

We analysed data according to randomisation group, irrespective of whether or not the patients received the intervention as planned (the intention to treat principle). We used Stata version 8.0 with statistical significance at the 5% level.

Sample size calculation

Local admission data showed a mean of 0.8 readmissions per patient within six months of discharge. A previous randomised controlled trial suggested that readmissions could be reduced by 25% in six months.[11] We aimed to show a more conservative reduction of 20%. Sample size calculations based on a normal approximation to the Poisson distribution indicated that we needed to recruit 850 patients to have 90% power to show this reduction at the 5% significance level.

Results

Participant flow and follow up

We invited 1399 patients to participate after screening them for eligibility between October 2000 and December 2002; 872 (62%) patients agreed and were randomised (fig 1). We excluded 17 recruited patients after randomisation. Reasons for exclusion were elective baseline admission (n = 5), discharge to nursing or
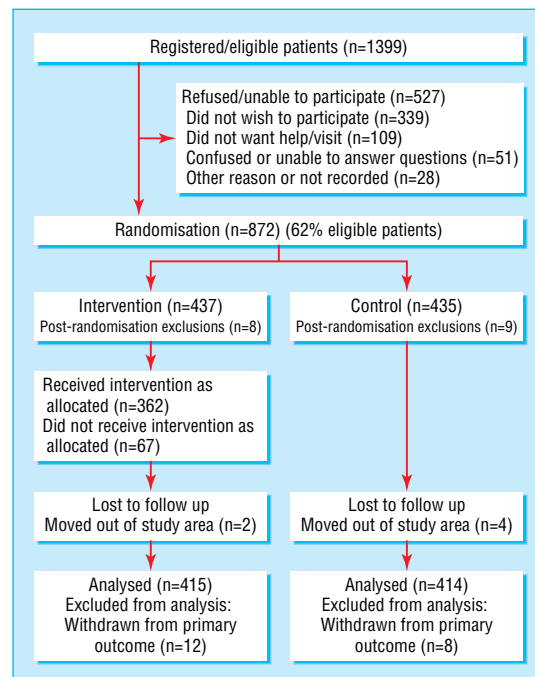

Fig 1 Flowchart showing progress of patients through the HOMER trial

residential home (5), death before discharge (4), previously recruited (2), and taking fewer than two drugs (1). Table 1 shows that the two groups were very similar at baseline. Twenty patients withdrew from the trial, and six moved from the study area. Primary outcome data were thus available for 829 (97%) patients.

Review pharmacists and intervention visits

We recruited 22 review pharmacists. Of 429 patients in the intervention group, 362 received first visits. Reasons for not visiting were visit not wanted (46 patients), pharmacist unavailable (11 patients), and patient unavailable due to death or early readmission (10 patients). Review pharmacists carried out a mean of 17 (range 1-37) first visits. More than 90% of first visits occurred within two weeks of recruitment (mean 7.2 days), and visits lasted a mean (SD) of 61 (23) minutes. Second visits were conducted for 297 patients and took a mean (SD) of 42 (19) minutes. Visits generated a total of 933 recommendations or comments to general practitioners (2.58/visited patient); 120 of these referred to possible drug reactions or interactions in 81 patients (22% of visited patients).

Compliance aids and pharmacists' view of intervention

Review pharmacists recommended compliance aids in 39 patients (11% of those receiving first visits). Pharmacists were asked after their second visit to record whether they believed the visits had been useful. For 216 (73%) patients, pharmacists felt the visits were definitely or probably useful; for 81 (27%) patients, pharmacists felt the visits were unlikely to be useful or not at all useful, generally when patients were found to be coping very well.

Number of hospital readmissions

A total of 178 emergency readmissions occurred in the control group and 234 in the intervention group (table 2). The Poisson model indicated a 30% greater rate of readmission in the intervention group (rate ratio = 1.30, 95% confidence interval 1.07 to 1.58; P = 0.009).

Table 1 Baseline comparison of intervention and control group patients. Values are numbers (percentages) unless stated otherwise

Characteristic	Intervention group (n=429)	Control group (n=426)
Female	262 (61.1)	272 (63.8)
Mean (SD) age (years)	85.4 (4.0)	85.5 (4.0)
Living alone	263 (61.3)	268 (62.9)
Mean (SD) abbreviated mental test	8.9 (1.6)	8.9 (1.5)
Mean (SD) daily drugs	6.0 (2.7)	5.8 (2.3)
Mean (SD) total drugs	6.4 (2.8)	6.3 (2.5)
Monitored dose system*	81 (19.8)	71 (17.4)
Social class (I, II, IIInm)†	170 (42.6)	163 (41.4)
Mean (SD) length of baseline admission (days)	13.6 (14.6)	13.4 (15.3)
Mean (SD) days from recruitment to discharge	1.7 (3.9)	1.8 (7.0)
Baseline diagnosis		
Cardiovascular (total):	134 (31.2)	144 (33.8)
Myocardial infarction/angina	57 (13.3)	65 (15.3)
Heart failure	38 (8.9)	34 (8.0)
Musculoskeletal (total):	61 (14.2)	65 (15.3)
Fracture	37 (8.6)	40 (9.4)
Gastrointestinal (total)	47 (11.0)	54 (12.7)
Respiratory (total):	48 (11.2)	49 (11.5)
COPD/asthma	15 (3.5)	13 (3.1)
Lower respiratory tract infection	16 (3.7)	22 (5.2)
Neurological:	40 (9.3)	25 (5.9)
Stroke/transient ischaemic attack	16 (3.7)	14 (3.3)
Senility/dementia	16 (3.7)	6 (1.4)
Genitourinary	17 (4.0)	16 (3.8)
Cancer (total)	15 (3.5)	7 (1.6)
Other or unclassified	67 (15.6)	66 (15.5)

COPD=chronic obstructive pulmonary disease.
*Monitored dose system data available for only 817 patients (409 intervention and 408 control).
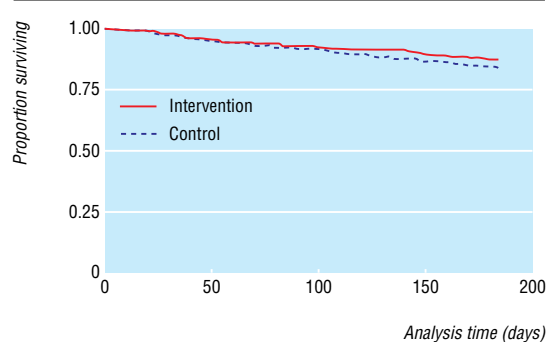†Employment details available for only 793 patients (399 intervention and 394 control).

Secondary outcomes

Mortality data were available for 829 (97%) patients. Fewer deaths occurred in the intervention group (49 v 63). Figure 2 shows the Kaplan-Meier survival graph. The hazard ratio for the intervention group compared with the control group was 0.75 (0.52 to 1.10; P=0.14). Data on residential or nursing home admissions were available on fewer patients, as these were collected by telephone (585, 68%). Table 3 shows that fewer control patients than intervention patients were admitted to residential or nursing homes, but again these differences were not statistically significant.

Quality of life data

Change in utility scores could be calculated for 308/380 (81%) surviving intervention patients and 284/362 (78%) surviving control patients. Both groups' scores decreased over the six month follow up period, but the changes were not significantly different between the groups (table 4). Scores on the visual analogue health scale also fell; the difference of 4.1 (95% confidence interval 0.15 to 8.09) units in favour of the control group was statistically significant (P=0.042).

Fig 2 Survival analysis over six month follow up period for patients in the HOMER trial

Primary care data

We included 165 patients from 12 practices in this analysis (84 intervention, 81 control). General practitioners carried out 204 home visits in the intervention group and 125 in the control group, a difference of 43% (rate ratio=1.43, 1.14 to 1.80; P=0.002). No statistically significant differences occurred between the groups in attendance at general practices or prescription items received.

Discussion

This trial shows that home based medication review by a pharmacist does not reduce emergency hospital admissions. Indeed, the intervention seemed to increase admissions by 30% and home visits by general practitioners by 43%. This finding was not balanced by improvements in quality of life. Although the overall EQ-5D utility score decreased in both groups, with no between group difference, scores on the visual analogue health scale decreased less in the control group than in the intervention group.

In terms of numbers of deaths, results were not statistically significant but favoured the intervention group, with a hazard ratio of 0.75. Although this result seems clinically important, it should be noted that the confidence interval was wide (0.52 to 1.10).

Validity of trial

This trial was large, involving more than 850 patients. The entry criteria ensured a broad sample of elderly people discharged from hospital, which, together with the relatively high participation rate and the large number of pharmacists involved, means that the generalisability of these results should be high. Follow up of the main outcome was good—only 3% of participants withdrew or were lost to follow up. Hospital admission data were provided by downloads from hospital episode statistics, which are unlikely to have introduced bias. Quality of life data were provided by almost 80% of patients. Slightly more intervention patients than controls provided these at six months (81% v 78%), which could have introduced a bias. At three months, however, when response was almost equal, no between group differences were apparent on either quality of life measure. Overall, the internal validity of this study seems high, although it should be

Table 2 Number of emergency hospital readmissions by group during six month trial follow up

Group	No of readmissions							Total admissions	Person years of follow up
	0	1	2	3	4	5	6		
Intervention	253	113	34	10	3	1	1	234	195.0
Control	281	99	26	5	3	0	0	178	191.6

Table 3 Number of admissions to residential or nursing homes by group during six month trial follow up

Admissions	No (%) of events		Difference‡ in proportions, with 95% CI and P value§
	Intervention group (n=429)*	Control group (n=426)†	
Total No admitted to residential home	21 (7.0)	17 (6.0)	1.0 (−3.1 to 5.2; P=0.61)
Total No admitted to nursing home	16 (5.3)	15 (5.3)	0.001 (−3.8 to 3.8; P=0.97)

*Data available for 300 intervention patients.
†Data available for 285 control patients.
‡Intervention minus control.
§χ^2 test.

noted that follow up was only for six months. Longer term benefits might have emerged had follow up been longer. However, we can envisage no theoretical grounds for a delayed benefit emerging long after the intervention had ceased.

These results seem counterintuitive. The reviews were intended to help patients to understand their drugs better, reduce adverse drug reactions,[3] and help patients to adhere to their drug regimens. We did not measure any of these intermediate outcomes directly. However, we hypothesised that the intervention would lead to a reduction in readmissions through these effects and seemed unlikely to cause harm. The pharmacists providing the interventions considered that in more than 70% of cases their interventions had probably or definitely been of value. Thus, we are left to explain how these interventions increased hospital admissions.

Possible explanations

Given the high internal validity of this study, its results are unlikely to be explained by bias or confounding. We cannot exclude the possibility of a type I error (chance). If, however, we consider the findings to be causally related, three possible explanations should be considered. The first is that pharmacists did help patients to understand their conditions better. This could have led patients to recognise warning signs earlier and promoted better help seeking behaviour, leading to more hospital admissions. This positive view is weakly supported by the non-significant decrease in deaths observed. Indeed, by preventing deaths of frailer patients our intervention may have increased admissions and general practitioner home visits—so-called "competing outcomes."

Two less favourable interpretations are possible, however. Previous studies have shown that interventions of this type by pharmacists tend to increase adherence to prescribed drugs.[16-19] Our patients were prescribed large numbers of daily drugs (mean = 5.9/day). By encouraging better adherence, our

pharmacists may have precipitated iatrogenic illness that previously had been avoided. Given the very elderly group studied, we did not collect data on adherence as we did not wish to burden patients with extra questionnaires beyond our quality of life assessment. This means that we cannot be sure that adherence improved. Indeed, another study using pharmacists to improve discharge from hospital found no effect on adherence.[20]

Finally, by visiting our patients at home and spending reasonably long periods of time there, we may simply have added to the complexity of their care. This may have increased anxiety and confusion or dependence on health services. The intervention group's scores on the visual analogue health scale fell more markedly than those of the control group. This suggests that they viewed their overall health as having worsened and may support a view that our intervention made patients focus more on their problems.

Evidence from other trials

Since this trial started, three large UK studies of community based medication review in elderly people have been published.[20-22] Two showed non-significant decreases in admissions,[20 21] whereas the other showed a non-significant increase in admissions.[22] These results, in combination with ours, indicate that it cannot be assumed that community based medication review necessarily reduces admissions, despite evidence from overseas.[11] Although our finding on mortality is potentially encouraging, UK results on this outcome are equivocal, with mixed, non-significant results.[20-22]

Evidence in the field of medication review is growing rapidly. More positive results seem to have resulted from interventions focused on diseases such as heart failure.[10] Alternative models to home visiting also exist, including reviews within a general practice surgery.[22] Such a review has the advantage of access to full patient records, potentially allowing a more thorough clinical medication review than was possible within this study. In addition, it allows pharmacists to build up a close working relationship with general practitioners, which is vital if the pharmacists' recommendations are to be followed.

Conclusions

Our trial suggests that home based medication review for older people recently discharged from hospital increased, rather than decreased, hospital admissions. It also seemed to worsen patients' quality of life compared with controls. The exact mechanism for this result is not apparent. Patients may have adhered better to their drugs, with a resultant increase in side effects or drug interactions. Alternatively, our intervention may have provoked better understanding and help seeking

Table 4 Mean EQ-5D scores and visual analogue health scale scores for groups at baseline, three months, and six months follow up

Measure	Intervention group (n=429)		Control group (n=426)		Difference* in change over six months, with 95% CI and P value†
	Score (SD)	No of respondents	Score (SD)	No of respondents	
EQ-5D					
Baseline	0.59 (0.29)	422	0.63 (0.28)	417	
Three months	0.47 (0.32)	320	0.48 (0.32)	325	
Six months	0.46 (0.33)	311	0.50 (0.31)	288	
Change over six months	−0.131 (0.33)	308	−0.137 (0.34)	284	0.006 (−0.048 to 0.059; P=0.84)
Visual analogue health scale					
Baseline	62.2 (18.3)	404	62.3 (18.5)	406	
Three months	54.3 (19.5)	322	55.6 (20.1)	315	
Six months	54.9 (19.8)	303	58.8 (19.4)	275	
Change over six months	−7.36 (24.4)	284	−3.24 (23.0)	266	−4.12 (−8.09 to −0.15; P=0.042)

*Intervention minus control.
†t test.

What is already known on this topic

Adverse drug reactions are an important cause of admission to hospital in elderly people

Patients have problems adhering to complex drug regimens

Medication review is recommended as a technique to reduce these problems

What this study adds

Home based medication review by pharmacists may increase hospital admissions

More effective forms of medication review need to be established, considering patients' quality of life and effects on both hospital and general practice, as well as prescribing outcomes

behaviour. Either way, a growing body of evidence suggests that further research is necessary to elucidate the most effective form and detailed effects of medication review. The recommendation in the national service framework for older people that this should be widely introduced in primary care seems to lack a clear evidence base.[7]

1 *ASTRO-PUs and chapter STAR-PUs: 2001 revision.* Leeds: Prescribing Support Unit, 2001.
2 Office for National Statistics. UK Census 2001. www.statistics.gov.uk/census2001/pop2001/united_kingdom.asp (accessed 9 July 2004).
3 Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. *BMJ* 2004;329:15-9.
4 Wright EC. Non-compliance—or how many aunts has Matilda? *Lancet* 1993;342:909-13.
5 Law R, Chalmers C. Medicines and elderly people: a general practice survey. *BMJ* 1976;i:565-8.
6 *Pharmacy in the future: implementing the NHS plan—a programme for pharmacy in the National Health Service.* London: Department of Health, 2000.
7 *National service framework for older people: implementing medicines related aspects of the NSF for older people.* London: Department of Health, 2001.
8 Raynor DK, Booth TG, Blenkinsopp A. Effects of computer generated reminder charts on patients' compliance with drug regimens. *BMJ* 1993;306:1158-61.
9 Begley S, Livingstone C, Hodges N, Williamson V. Impact of domiciliary pharmacy visits on medication management in an elderly population. *Int J Pharm Pract* 1997;5:111-21.
10 Goodyer LI, Miskelly F, Milligan P. Does encouraging good compliance improve patients' clinical condition in heart failure? *Br J Clin Pract* 1995;49:173-6.
11 Stewart S, Pearson S, Luke CG, Horowitz JD. Effects of home-based intervention on unplanned readmissions and out-of-hospital deaths. *J Am Geriatr Soc* 1998;46:174-80.
12 Jitapunkul S, Pillay I, Ebrahim S. The abbreviated mental test: its use and validity. *Age Ageing* 1991;20:332-6 .
13 Tidermark J, Bergstrom G, Svensson O, Tornkvist H, Ponzer S. Responsiveness of the EuroQol (EQ 5-D) and the SF-36 in elderly patients with displaced femoral neck fractures. *Qual Life Res* 2003;12:1069-79.
14 Holland R, Smith RD, Harvey I, Swift L, Lenaghan E. Assessing quality of life in the elderly: a direct comparison of the EQ-5D and AQoL. *Health Econ* 2004;13:793-805.
15 Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med* 2001;33:337-43.
16 Lowe CJ, Raynor DK, Purvis J, Farrin A, Hudson J. Effects of a medicine review and education programme for older people in general practice. *Br J Clin Pharmacol* 2000;50:172-5.
17 Varma S, McElnay JC, Hughes CM, Passmore AP, Varma M. Pharmaceutical care of patients with congestive heart failure: interventions and outcomes. *Pharmacotherapy* 1999;19:860-9.
18 Al-Eidan FA, McElnay JC, Scott MG, McConnell JB. Management of Helicobacter pylori eradication: the influence of structured counselling and follow-up. *Br J Clin Pharmacol* 2002;53:163-71.
19 Al-Rashed SA, Wright DJ, Roebuck N, Sunter W, Chrystyn H. The value of inpatient pharmaceutical counselling to elderly patients prior to discharge. *Br J Clin Pharmacol* 2002;54:657-64.
20 Nazareth I, Burton A, Shulman S, Smith P, Haines A, Timberal H. A pharmacy discharge plan for hospitalized elderly patients—a randomized controlled trial. *Age Ageing* 2001;30:33-40.
21 Krska J, Cromarty JA, Arris F, Jamieson D, Hansford D, Duffus PR, et al. Pharmacist-led medication review in patients over 65: a randomized, controlled trial in primary care. *Age Ageing* 2001;30:205-11.
22 Zermansky AG, Petty DR, Raynor DK, Freemantle N, Vail A, Lowe CJ. Randomised controlled trial of clinical medication review by a pharmacist of elderly patients receiving repeat prescriptions in general practice. *BMJ* 2001;323:1340-3.

School of Medicine, Health Policy and Practice, University of East Anglia, Norwich NR4 7TJ
Richard Holland *senior lecturer in public health medicine*
Elizabeth Lenaghan *senior research associate*
Ian Harvey *professor of epidemiology and public health*
Richard Smith *reader in health economics*
Lee Shepstone *reader in medical statistics*
Christopher Hand *honorary senior lecturer*

Great Yarmouth Teaching Primary Care Trust, Astley Cooper House, Estcourt Road, Great Yarmouth, Norfolk NR14 8AB
Alistair Lipp *director of public health*

Academic Pharmacy Practice Unit, University of East Anglia, Norwich NR4 7TJ
Maria Christou *education pharmacist*

Suffolk Public Health Network, Suffolk House, St Clement's, Foxhall Road, Ipswich IP3 8LS
David Evans *specialist adviser, pharmaceutical services*

Correspondence to: R Holland r.holland@uea.ac.uk

Amendment

This is Version 2 of the paper. In this version, the statistical power is given as 90% [rather than 80% as in the previous version] and the trial ISRCTN is included [omitted from the previous version].