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Educating nursing home staff on fracture prevention: a cluster randomised trial

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Abstract

Objective: to assess whether specialist osteoporosis nurses delivering training to care home staff can reduce fractures and improve the prescription of treatments to reduce fractures versus usual care.
Design: pragmatic cluster randomised controlled trial (RCT) with randomisation at the Primary Care Organisation (PCO) level.
Setting: care homes (residential, nursing and EMI) across England and Wales within PCOs.
Participants: all 300 PCOs in England and Wales were invited to take part. Of these, 58 agreed to participate and gained ethical approval in time to start the study: 29 clusters were randomised to the intervention group and 29 to the control.
Intervention: specialist osteoporosis nurses undertaking short training sessions with care home staff emphase the importance of fracture and fall prevention and train staff on how to identify those residents at high risk of fracture. Residents' risk of fracture and falls was reported to general practitioners (GPs) of patients along with treatment recommendations.
Outcome Measures: primary outcome measures were total fractures over the past 12 months and total hip fractures over past the 12 months. Secondary outcome measures were total home falls, number of residents sustaining a fall, number of residents prescribed bisphosphonates, number of residents prescribed calcium and vitamin D and number of residents wearing hip protectors. All outcomes were measured at the care home level.
Results: of the 230 care homes randomised data were collected from 209 of these containing 5,637 residents. There were no differences between the groups in the incidence rate ratios (IRRs) for total fractures (IRR = 0.94 [0.71, 1.26] $P = 0.70$) or total hip fractures (IRR = 0.86 [0.63, 1.18] $P = 0.36$). No differences were found between groups for home falls or hip protector use. A significant increase in bisphosphonate prescription was seen in the intervention group over the control group (IRR = 1.50 [1.00, 2.24] $P = 0.05$). Calcium and vitamin D prescription was significantly increased in the intervention group over the control group (IRR = 1.64 [1.23, 2.18] $P<0.01$).
Conclusion: the intervention significantly increased the prescription of bisphosphonates and calcium/vitamin D, but was not associated with a significant effect on the rate of falls or fractures.

Keywords: *Cluster RCT, fracture prevention, specialist training, elderly*

Introduction

It has been reported that residents of care homes are at increased risk, and have a greater incidence of fracture compared with a similar community dwelling population. One review identified that as many as 75% of nursing home residents fall annually, twice the rate of seniors living in the community [1]. This may partly be because nursing home residents are generally frailer, tend to be older and have more cognitive impairments [2]. They also tend to have more chronic illnesses, physically dependent and have a higher prevalence of walking problems [3]. However, it may also be due to lower exposure to sunlight and reduced calcium consumption. Some studies have provided evidence that calcium and vitamin D supplementation significantly decreases the incidence and risk of fracture and falls in residents of nursing and residential care homes. One trial of calcium and vitamin D3 supplementation in healthy elderly ambulant females in France has shown significant reductions in hip fractures [4]. Each day for 18 months, 1,634 women received tricalcium phosphate containing 1.2 g of elemental calcium and 20 μg (800 IU) of vitamin D3, and 1,636 women received a double placebo. The number of hip fractures was 43% lower and the total number of non-vertebral fractures was 32% lower among the women treated with vitamin D3 and calcium than among those who received the placebo.

More recently, a large multi-centre randomised controlled trial (RCT) in Australian care homes showed significant reductions in the incidence of falls in those taking 1,000 IU vitamin D2 (ergocalciferol) daily versus placebo for 2 years [5]. However, a cluster RCT of 2.5 mg ergocalciferol every 3 months (equivalent of 1100 IU daily) versus placebo reported no evidence that vitamin D prevents fractures or falls in elderly people in care home accommodation in the United Kingdom [6] although there was a large proportion of missing and unreturned data. Similarly, another recent trial of ergocalciferol in Wales among 3,440 people in residential homes who were individually randomised found no effect [7]. A recent systematic review has reported insufficient evidence for the effectiveness of interventions, both single and multi-faceted, aimed at reducing falls and fractures in care homes [8]. Given modest assumptions of effectiveness, however, calcium and vitamin D supplementation of women in residential care has been shown to be either cost saving or producing a significant reduction in hip fractures for a relatively low cost [9].

In addition to the use of calcium and vitamin D supplements, there are other measures that may be effective at preventing fractures. At the time when this study was being planned there was evidence that hip protectors, when used within a nursing home environment, were associated with a reduction in hip fractures [10], although more recent evidence has cast a doubt on their effectiveness [8, 11, 12]. There is also extensive evidence that treatment with bisphosphonates can reduce non-vertebral fracture incidence by anything from 20 to 60% in persons with adequate calcium and vitamin D status. This evidence has been summarised recently by the National Institute for Health and Clinical Excellence (NICE) [13].

Encouraging residents to use calcium and vitamin D supplements, bisphosphonates or hip protectors has been a problem. One reason for this is that within the same care home, there may be several different general practitioners (GPs) responsible for the care of the residents. However, the advent of primary care organisations (PCOs) (Primary Care Trusts and Local Health Boards) meant that medical care for nearly all patients in any one home became the responsibility of one PCO. This, in theory, should have led to a more cohesive approach to the planning and implementation of preventive strategies. Furthermore, the National Service Framework (NSF) for Older People identifies significant and persistent failings in services and drug prescription for falls and bone health, and encourages the use of strategies to reduce fall related fractures [14].

Other risk factors have been shown to predispose individuals to an even greater risk of fracture. These include low body weight (<58 kg), prior fracture, smoking habit, maternal history of hip fracture and inability to rise from a chair without using one's arms [15, 16]. These risk factors can readily identify residents who are at particularly high risk of fracture and, therefore may benefit from intervention.

The National Osteoporosis Society (NOS) undertook an initiative to use specialist osteoporosis nurses to undertake short training sessions with care home staff. This paper reports an evaluation of this initiative. Cluster randomisation was used for practicality and feasibility reasons because when evaluating healthcare professionals or organisational behaviour change, individual randomisation can be problematic as there is a risk of contamination resulting in an underestimate of the true effects [17, 18].

Participants and methods

Recruitment and randomisation

All 300 PCOs in England and Wales were invited to take part in 2003. Only those care homes were included in this evaluation for which the local ethics and research governance procedures were swift enough to enable them to be enrolled into the randomisation process (Figure 1).

Every care home within each participating PCO was sent a letter outlining the project and a demographic form to complete. Care homes were only considered for inclusion if this demographic information was provided. All PCO demographic data were forwarded to the Department of Health Science at the University of York for randomisation and allocation. Each PCO was randomised to receive the intervention at time 0 or commencing at 12 months. This, therefore, allowed a randomised comparison to take place by allocating PCOs to be offered training early or up to 12 months later, producing an intervention group and a control group. The randomisation procedure was undertaken as follows. The PCOs were stratified into two groups, larger PCOs and smaller PCOs based on the median number of care homes. Within each stratum, a single block of allocations was undertaken using a computer package to ensure equivalent numbers of PCOs in each group. The allocation was undertaken by an independent researcher.

Intervention and control groups

Half-a-day training sessions were organised by the PCO in a central location. Managers, qualified nurses and health care assistants attended the training and completed an evaluation at the end of the session, designed to assess the appropriateness of training. The training was given by specialist osteoporosis nurses employed by the NOS and included a background to the objectives of the project and sections on bone health and osteoporosis, falls and fall prevention, risk factors for falls and fractures, methods used for risk assessment and prevention of fractures in the workplace. The section on fall prevention included information on polypharmacy and the effectiveness of individual medications, such as benzodiazepines, and also detailed fall hazards in the home. Staff were trained on how to use the Black fracture risk assessment tool [15] and the STRATIFY fall risk assessment tool [19] and were encouraged to involve residents in the risk assessment process. Verbal training was supported by written literature.

The care home staff assessed each of their residents for risk of falling and fracture using the Black and STRATIFY tools.

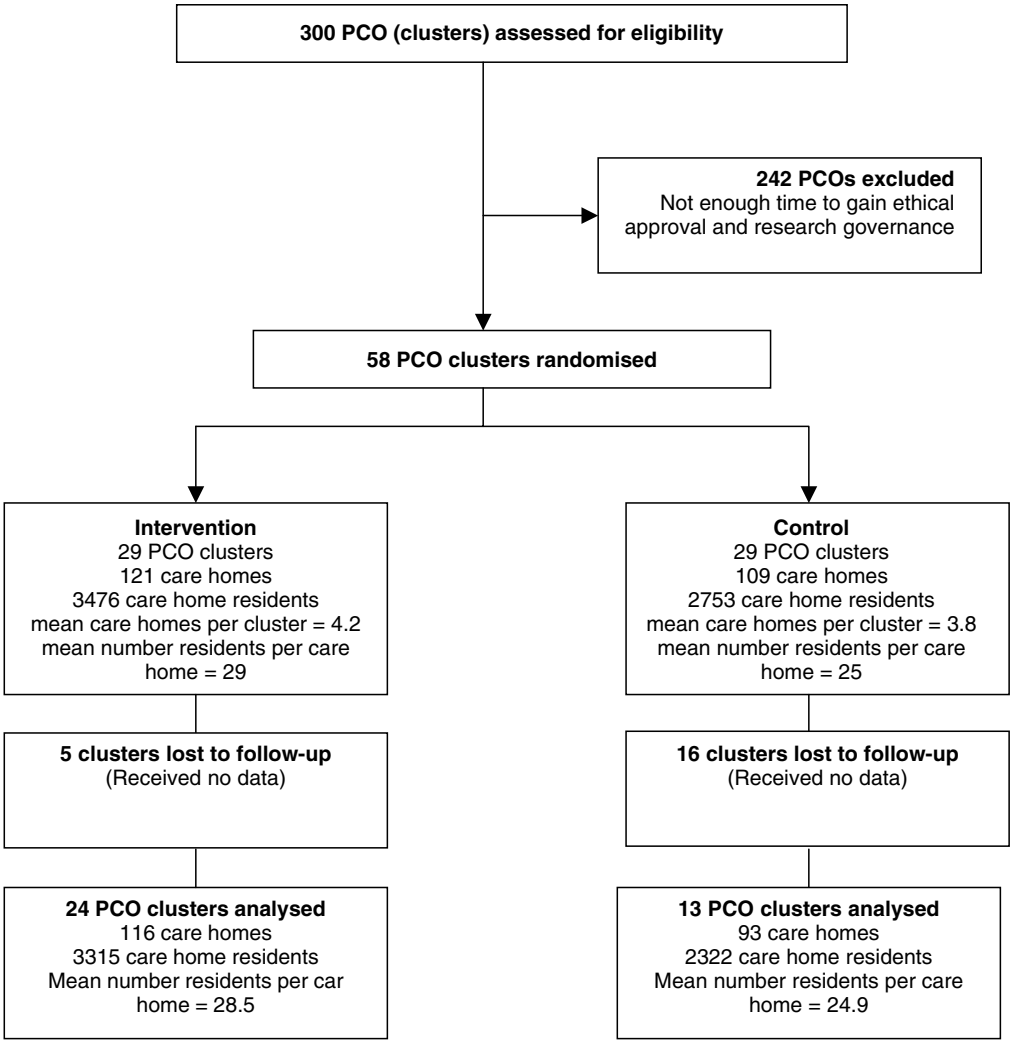

Figure 1. The flow of PCOs, care homes and participants through the trial.

The results of these assessments were sent to the specialist osteoporosis nurses who then calculated each patient's risk of fracture and falling. The nurses reported their results to the care home staff and also sent their assessment results to each individual's GP with treatment recommendations where appropriate. Recommendations were based on the Royal College of Physicians guidelines in 2000.

Outcomes

The primary outcome measures were total fractures over previous 12 months, and total hip fractures over previous 12 months expressed as incidence rate ratios (IRRs) aggregated up to the care home level. Secondary outcome measures included home falls in previous 12 months, number of residents prescribed bisphosphonates, number of residents prescribed calcium and vitamin D and number of residents wearing hip protectors, aggregated up to the care home level. All the outcome data were collected via questionnaire completed by each care home manager.

Sample size

We proposed to approach all 300 PCOs. On average, there were between 6 and 8 nursing/residential homes within each PCO with at least 30–40 residents. Working under the assumption that only 200 PCOs would be willing to take part, this would have approximated to 50,000 nursing/residential home residents in our study (i.e. 25,000 in each arm). As we used cluster randomisation (i.e. the PCO) and analysing at the level of the nursing home, we needed to take into account clustering effects on outcomes [20]. This sample size above was large enough to cope with a relatively large design effect on outcomes. The trial would allow us to observe a 20% decrease in hip fracture incidence from 3 to 2.4% between the groups with an 80% power at 5% significance, assuming a design effect of 2.0.

Statistics

This trial was randomised at cluster level for pragmatism and feasibility. However, such cluster randomisation may be confounded by clustering effects; therefore it is important

to take into account the clustering effect in the analyses, to avoid the inference of spurious findings which overestimate effect size in line with CONSORT statement on reporting of cluster trials [21]. A two-level analysis was used, with the care home nested within the PCO. The analysis was performed using the random effects poisson model in STATA with cluster as the random effect. The unit of analysis was care home; all other variables were used as fixed effects. This took account of the hierarchical nature of the data, including both the variability at the cluster level and at the care home level. Age was adjusted for in the final model as at baseline, there was a significantly higher proportion of residents in the over 85 group in wave one compared to wave two. The model was also adjusted for the total number of residents in each home as this varied between homes. Where the poisson model was not a good fit, then the negative binomial was used.

Results

A total of 29 PCOs were randomised to receive the early intervention and 29 to receive the late intervention control. No follow-up data were received from 5 of the clusters in the early intervention arm and 16 of the clusters in the late intervention control arm, giving return rates of 96 and 85% respectively. All of the clusters that were lost to follow-up contained one care home only.

Characteristics of sample

Table 1 shows descriptive data for the sample.

For Table 1 please see Appendix 1 in the supplementary data on the journal website http://www.ageing.oxfordjournals.org/

Fractures

Table 2 shows there was a greater number of total fractures in the late intervention control group than the early intervention group. The risk of fracture was reduced by 6% (IRR = 0.94, 95% CI 0.71–1.26) in the early intervention group compared to the late intervention control group, although this was not statistically significant.

There was a greater number of hip fractures in the late intervention control group than the early intervention group. The risk of fracture was reduced by 14% (IRR = 0.86, 95% CI 0.63–1.18) in the early intervention group compared to the late intervention control group, although this was also not statistically significant.

There was a greater number of falls in the early intervention group than the late intervention control group. The risk of falling was increased by 1.19 times than of the late intervention control group (IRR = 1.19 95% CI 0.93–1.53), although this was not statistically significant.

Prescription of bisphosphonates, calcium and vitamin D, and hip protectors

Bisphosphonates and calcium and vitamin D were prescribed significantly more in the early intervention group than in the late intervention control group. Bisphosphonates were 1.5 times more likely to be prescribed (IRR = 1.5 95% CI = 1.00–2.24) and calcium and vitamin D 1.64 times more (IRR = 1.64, 95% CI 1.23–2.18). There was no difference in the number of residents wearing hip protectors. Table 3 shows the percentage of the sample in each group that was prescribed bisphosphonates, calcium and vitamin D and hip protectors.

For Table 3 please see Appendix 1 in the supplementary data on the journal website http://www.ageing.oxfordjournals.org/

Discussion

People living in residential care have been found to be at greater risk of fracture than the general population. Risk factors for fracture are also highly prevalent among this population; therefore it is important that those at the highest risk are identified and offered preventive treatment. This pragmatic trial examined the effect of translating good practice into day-to-day 'real life' practice in a large number of care homes across the United Kingdom. The NOS specialist osteoporosis nurses delivered an educational programme and a written resource pack including information on standardised fracture risk screening tools and evidence-based good practice prompts for pharmacological treatment and other interventions. The principal aim was to evaluate the effect of such an approach on rates of fractures and also on the prescribing of evidence-based bone health treatments shown elsewhere to reduce the incidence of fractures. Although the majority of PCOs indicated that they would

Table 2. Incidence rate ratios for all outcomes by group

	IRR (incidence rate ratios) [control/intervention]	95% CI	*P*	ICC (intra-cluster correlation co-efficient)
Total fractures	0.94	(0.71,1.26)	0.70	0.20
Total hip fractures[a]	0.86	(0.63, 1.18)	0.36	0.21
Total home falls	1.19	(0.93, 1.53)	0.17	0.29
Biphosphonate prescription	1.50	(1.00, 2.24)	0.05	0.24
Calcium/vitamin D prescription	1.64	(1.23, 2.18)	<0.01	0.38
Hip protectors	0.93	(0.35, 2.39)	0.86	0.24

[a] Analysis used is a hierarchical negative binomial regression (or poisson). This takes into account the variation at the cluster level.

like to take part in the study, delays in obtaining multi-centre and local ethical approval followed by research governance meant that it was not possible to include all PCOs in this study. There was no significant difference in fracture rates between the groups, although the intervention did result in significant increases in the prescription of calcium and vitamin D and in bisphosphonate therapy. However, the level of prescribing was not as high as would be dictated by best practice guidelines. The difference in prescribing was probably a result of the GP letters detailing patient's fracture, fall risk and treatment recommendations. There was also a non-significant trend in the increased use of hip protectors, which at the time of the study's inception were still thought to be an evidence-based treatment.

This study has a number of limitations. Firstly, it is likely that data collection with regard to falls and fractures improved in the intervention arm due to training of care home staff by the specialist osteoporosis nurses in the importance of assessing the residents for risks of falls and fractures. This potential discrepancy in the accuracy of data collection may have underestimated the beneficial effect of the intervention. Secondly, there appears to be a difference in the response rates to the questionnaires between the two groups: 15% of the control arm compared to 4% of the treatment arm had no returns. This discrepancy may have been a source of bias which could have underestimated the effect of intervention, since those care homes with a large number of falls or fractures may not have returned their data because it might be deemed undesirable and a poor reflection on the care home. This could potentially reduce any effect by reducing the number of actual fractures and falls reported in the control group. Equally, those respondents in the intervention arm may have been more enthusiastic in reporting outcomes such as calcium, vitamin D and bisphosphonate prescription, which in turn could have increased the effect of the intervention on prescriptions. Thirdly, due to extremely long delays both in ethical approval and research governance, it was not possible to recruit sufficient PCOs to give the study statistical power to observe any effects on fracture incidents between the two groups. A further limitation is the method of data collection on falls. Data collection of retrospective and self-reported falls can underestimate fall incidence by up to 32% [22] compared to prospective data collection with the use of regular diaries.

Nevertheless these data suggest that a structured training intervention delivered by specialist osteoporosis nurses to care home staff can lead to increases in the prescription of treatments, that in the context of current evidence prevent fractures and reduce risk factors.

Key points

- Cluster RCT.
- Educational advice to nursing home staff.
- Fracture prevention.

Conflicts of interest

Dr Jean Hodson has received honoraria for educational talks from MSD in 2000 and sponsorship to attend educational meetings from Aventis in 2003. Dr Peter Selby is a trustee of the National Osteoporosis Society. He has received consultancy and/or speaker's fees from Alliance for Better Bone Health, Eli Lilly, MSD, Roche, Sevier and Shire. Anne Sutcliffe has received honoraria for lectures and fees from Shire. David Torgerson has received consultancy and research support from Shire.

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Supplementary data

Supplementary data for this article are available online at http://ageing.oxfordjournals.org.

References

1. Rubenstein LZ, Josephson KR, Robbins AS. Falls in the nursing home. Ann Intern Med 1994; 121: 442–51.
2. Bowman C, Whistler J, Ellerby M. A national census of care home residents. Age Aging 2004; 33: 561–6.
3. Bedsine RW, Rubenstein LZ, Snyder L. Medical Care of the Nursing Home Resident. Philadelphia, PA: American College of Physicians, 1996.
4. Chapuy MC, Arlot ME, Duoeuf F *et al*. Vitamin D3 and calcium to prevent hip fractures in elderly women. N Engl J Med 1992; 327: 1637–42.
5. Flicker L, MacInnis R, Stein M *et al*. Should older people in residential care receive vitamin D to prevent falls? Results of a randomised trial. J Am Geriatr Soc 2005; 53: 1881–8.
6. Law M, Withers H, Morris J *et al*. Vitamin D supplementation and the prevention of fractures and falls: results of a randomised controlled trial in elderly people in residential accommodation. Age Ageing 2006 35: 482–6.
7. Lyons RA, Johansen A, Brophy S *et al*. Preventing fractures among older people living in institutional care: a pragmatic randomised double blind placebo controlled trial of vitamin D supplementation. Osteoporos Int 2007; 18: 811–8.
8. Oliver D, Connelly JB, Victor CR *et al*. Strategies to prevent falls and fractures in hospitals and care homes and effect of cognitive impairment: systematic review and meta-analyses. BMJ 2007; 334: 82.
9. Torgerson DJ, Kanis JA. The cost-effectiveness of preventing hip fractures in elderly women using vitamin D and calcium. Q J Med 1995; 88: 135–9.
10. Kannus P, Parkkari J, Niemi S *et al*. Prevention of hip fracture in elderly people with use of a hip protector. N Engl J Med 2000; 343: 1506–13.

11. O'Halloran PD, Cran GW, Beringer TR *et al.* A cluster randomised controlled trial to evaluate a policy of making hip protectors available to residents of nursing homes. Age Ageing 2004; 33: 582–8.

12. Parker M, Gillespie W, Gillespie L. Effectiveness of hip protectors for preventing hip fractures in elderly people: systematic review. Br Med J 2006 332: 571–4.

13. National Institute of Clinical Excellence (NICE). Bisphosphonates (alendronate, etidronate, risedronate), selective oestrogen receptor modulators (raloxifene) and parathyroid hormone (teriparatide) for the secondary prevention of osteoporotic fragility fractures in postmenopausal women. Technology Appraisal Guidance 87, 2005.

14. DoH. A new ambition for old age. Next steps in implementing the national service framework for older people. April 2006.

15. Black DM, Steinbuch M, Palmero L *et al.* An assessment tool for predicting fracture risk in postmenopausal women. Osteoporos Int 2001; 12: 519–28.

16. Porthouse J, Birks YF, Torgerson DJ *et al.* Risk factors for fracture in a UK population: a prospective cohort study. QJM 2004; 97: 569–74.

17. Donner A, Klar N. Design and Analysis of Cluster Randomisation Trials in Health Research. London: Arnold, 2000.

18. Grimshaw JM, Campbell MK, Eccles MP *et al.* Experimental and quasi-experimental designs for evaluating guideline implementation strategies. Fam Pract 2000; 17: S11–8.

19. Oliver D, Britton M, Seed P *et al.* Development and evaluation of evidence based risk assessment tool (STRATIFY) to predict which elderly inpatients will fall: case-control and cohort studies. Br Med J 1997; 315: 1049–53.

20. Kerry SM, Bland JM. Statistics notes: Sample size in cluster randomisation. BMJ 1998; 316: 549.

21. Campbell MK, Elbourne D, Altman DG. CONSORT statement: extention to cluster randomised trials. BMJ 2004; 328: 702–8.

22. Cummings SR, Nevitt MC, Kidd S. Forgetting falls. The limited accuracy of recall in the elderly. J Am Geriatr Soc 1988; 36: 613–6.

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