# A cluster randomised controlled trial to prevent injury due to falls in a residential aged care population

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## ABSTRACT

**Objective:** To test the effectiveness of using a full-time project nurse to assist residential aged care facilities in using evidence-based approaches to falls injury prevention.

**Design, setting and participants:** Cluster randomised controlled trial involving 5391 residents in 88 aged care facilities in the Hunter and Lower Mid North Coast areas of New South Wales. Residents were followed for 545 days or until death or discharge. Data were collected from July 2005 to June 2007.

**Intervention:** Employment of a project nurse to encourage best-practice falls injury prevention strategies during the 17-month intervention period.

**Main outcome measures:** Monthly data about falls, falls injury and falls injury prevention programs; audit of hospitalisation for fractured neck of femur.

**Results:** Despite significant increases in the provision of hip protectors and use of vitamin D supplementation in both intervention and control facilities, there was no difference in the number of falls or falls injuries between the intervention and control groups, nor a reduction in falls overall. There was also no difference between the 7-month pre-intervention period and the intervention period in the number of falls or falls injuries. Factors related to residents having an increased risk of falls with fractured neck of femur included being ambulant, having dementia, increasing age, and having a high falls risk assessment score.

**Conclusion:** It is difficult to change falls risk among high-risk populations, including people with dementia. The use of important strategies such as hip protectors and vitamin D and calcium supplementation increased during the study, probably with contamination of control facilities. Longer follow-up may be required to measure the impact on falls outcomes of the strategy of using a facilitating nurse.

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Around 30% of all hip fractures in the community occur in residential aged care, representing a substantial cost to the health care system. Evidence from overseas on calcium and vitamin D supplementation and hip protectors suggests these strategies could reduce hip fractures in aged care facilities by up to 50%.[1-3]

Falls injury prevention programs are difficult to sustain in aged care, given the many other demands on facility staff. Falls injury prevention programs often depend on one person, and prevention strategies struggle to survive if that person leaves. We proposed that employment of a full-time project nurse to assist residential aged care facilities to implement evidence-based falls injury prevention strategies would significantly reduce the number of hip fractures. A reduction of 10% of hip fractures would make the continued employment of the nurse cost-effective.

## METHODS

### Study design and participants

We undertook a cluster randomised controlled trial. All residential aged care facilities with at least 20 beds in the Hunter and Lower Mid North Coast areas of New South Wales were invited to participate in the study. Of the 92 eligible facilities, 88 took part. Consenting facilities were stratified according to mix of bed type (high-care, low-care and dementia-specific) and randomly allocated within strata into intervention or control groups by the statistician (REG) using the procedure "surveyselect" in SAS statistical software, version 9.1 (SAS Institute Inc, Cary, NC, USA). Forty-six facilities were allocated to the intervention group and 42 to the control group. Facility staff were not blinded as to whether they were in the intervention or control group. Data collection commenced in July 2005 and concluded in June 2007. Ethics approval was obtained from the Hunter New England Area Health Service Human Research Ethics Committee.

### Intervention

The intervention involved employment of a project nurse to encourage a range of best-practice strategies at the facilities during the 17-month intervention period. The strategies promoted were: falls risk assessment; mobility assessment; use of hip protectors; calcium and vitamin D supplementation; continence management; exercise programs; appropriate footwear; medication review; and post-fall management review.

The project nurse provided link people from each intervention facility with information and resources to assist with preventing falls and fractures. An initial training session was held in November 2005. A set of resources was developed to support the 2005 falls prevention guidelines (known as the "Big Green Box").[4] The implementation of these resources was further encouraged during 3-monthly network meetings, held from February 2006 to June 2007 (six meetings in total), convened by the project nurse and attended by the link people. Intervention facility staff were also invited to attend a workshop to learn how to plan and run exercise programs. Support for the intervention was obtained from Divisions of General Practice.

### Usual care

Staff from facilities allocated to the control (usual care) group attended a workshop where data collection procedures were explained, and they were prompted to submit monthly data.

### Outcomes and measures

The main outcomes of interest were change in use of vitamin D supplements and hip protectors, and change in the rate of fall events. Measurement and comparison of outcomes were undertaken at two levels.

The first level assessed whether the intervention resulted in an overall increase in use of vitamin D supplements and hip protec-

**1 Characteristics of 5391 residents in participating facilities at the time of the census, January–February 2006**

| | Control | Intervention |
|---|---|---|
| Median age in years (range) | 85 (27–107) | 86 (32–107) |
| Female | 1862 (72%) | 2049 (73%) |
| Ambulant* | 1757 (68%) | 1954 (71%) |
| Dementia-specific care | 578 (22%) | 553 (20%) |

* Defined as anyone who can stand and walk with or without assistance. ◆

tors and a reduction in falls in intervention facilities when compared with control facilities (facility-level data). For 7 months before the intervention and for each intervention month, facilities conducted a record audit and completed a standard form providing data on the aggregate number of falls, falls resulting in fracture and/or hospitalisation, and deaths within 3 months of fractured neck of femur resulting from a fall. Data were also collected on the number of medication audits carried out by a pharmacist, the number of residents taking vitamin D supplements or receiving and using hip protectors, and the number of falls risk assessments completed on admission. Failure to produce monthly data was followed up by the project nurse.

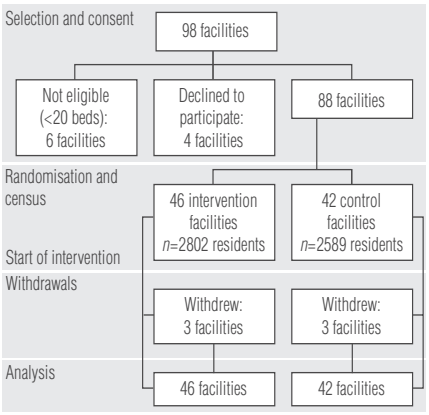
The second level involved assessment of the effectiveness of the intervention for reducing falls risk among the cohort of residents who were in the selected facilities at the start of the intervention period (individual-level data). All participating facilities completed a "census" during January–February 2006 that recorded current residents' date of birth, sex, resident classification scale (RCS) score, falls risk assessment score on admission, whether they were ambulant, and whether they were residing in a dementia-specific unit. Linkage to hospital separations data allowed ascertainment of fractured neck of femur and death.

### Statistical analysis

Facility-level data were investigated to determine change in the rate of events per 100 beds. A two-piece mixed (both fixed and random effects) model was fitted to the data for each outcome of interest, adjusting for bed type (low-care, high-care and mixed low- and high-care). The first piece of the model estimated the baseline rate (intercept) and change (slope) in the 7 months before the intervention commenced (pre-intervention period), and the second piece estimated change (second slope) for the duration of the intervention.

Differences in the number of falls resulting in fractured neck of femur between the intervention and control groups for individual-level data were estimated using single-level survival analysis before fitting a multilevel Cox proportional hazards model. Covariates within facility level included age, mobility, dementia status, RCS score and falls risk assessment score. The between-facility part of the model accounted for group (intervention or control), bed type and facility size. Differences in the number of deaths between intervention and control groups were estimated using survival analysis. All facilities were analysed according to random allocation (intention to treat) using SAS version 9.1 and Mplus version 5.1 (Muthén and Muthén, Los Angeles, Calif, USA). Sample size was fixed by the number of available facilities.

**2 Flow chart of selection, consent, randomisation and withdrawals***




* All withdrawals occurred after both the census and the start of the intervention. All facilities provided at least some data for analysis and none withdrew consent for use of these data. ◆

## RESULTS

### Study population and return of data

At the time of the census, there were 5391 permanent residents. Box 1 shows that randomisation produced reasonably similar characteristics for residents in the control and intervention groups.

Monthly falls data collection forms were returned by 76%–97% of facilities for each month from July 2005 to June 2007. There was no systematic bias in returns according to type of facility or phase of the study (pre-intervention or intervention). Overall, six facilities withdrew from the project during the intervention. All withdrawing facilities provided sufficient data to allow retention in analyses (Box 2).

### Outcomes

Mean use of vitamin D at baseline was 12.7 supplements per 100 beds (95% CI, 7.4 to 18.1) in the control group and was 6.7 per 100 beds (95% CI, 1.2 to 10.9) lower in the intervention group. Slope did not change during the pre-intervention period for either group ($P = 0.4$) but increased significantly during the intervention period, with mean slope of 2.0 supplements per 100 beds per month averaged over both groups ($P < 0.001$). A two-piece model with quadratic term, adjusted for bed type, showed that the intervention group had a significantly lower supplementation rate at baseline than the control group ($P = 0.015$). However, there were no differences in slopes, for either the first or second stage (pre-intervention and during intervention: $P = 0.161$ and $P = 0.092$, respectively), with respect to study group.

The baseline use of hip protectors was low, at only 5.1 per 100 beds (95% CI, 3.1 to 7.0). There was no difference between intervention and control groups, with both groups showing a small increase in use: first stage slope, 0.25 per 100 beds (95% CI, 0.06 to 0.43; $P = 0.008$); and second stage slope, 0.29 per 100 beds (95% CI, 0.17 to 0.41; $P < 0.001$).

There were no changes apparent for the use of risk assessments, medication reviews or calcium supplementation. Continence assessment was considered adequate at baseline in all but one facility. Similarly, only one facility did not have a regular exercise program, and nearly all facilities (87%) had regular footwear assessment programs in place.

Falls events recorded by facilities are shown in Box 3. For the entire cohort (intervention and control groups), there were 13.5 fractured neck of femur events per 1000 falls. Of these events, two occurred within the first 3 months of admission (15%). The risk of death within 3 months of a fall that resulted in a neck of femur fracture was 33%. Similar rates for all events were reported during the pre-intervention and intervention periods, after accounting for high variability of fall rates within facilities per month. The two-stage longitudinal regression model showed no evidence of

**3 Outcomes of falls in residential aged care**

| Period | No. bed-months | Mean no. (%) facilities reporting per month | Mean no. falls per month | Outcomes per 1000 falls per month | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Hospital admission | #NOF | Other fracture | #NOF within 3 months of admission | Death within 3 months of #NOF |
| Intervention facilities | | | | | | | | |
| Pre-intervention (7 months) | 2501 | 38 (83%) | 12 | 30 | 11 | 13 | 3 | 5 |
| Intervention (17 months) | 2709 | 41 (90%) | 13 | 51 | 17 | 16 | 2 | 4 |
| Control facilities | | | | | | | | |
| Pre-intervention (7 months) | 2236 | 35 (83%) | 10 | 65 | 16 | 18 | 1 | 4 |
| Intervention (17 months) | 2628 | 40 (95%) | 10 | 55 | 18 | 18 | 4 | 9* |

#NOF = fractured neck of femur. * One facility sustained a total of two falls in two consecutive months, each resulting in death. ◆

change in the rate of falls from 16.0 per 100 beds (95% CI, 14.2 to 17.9) for either the pre-intervention stage (0.14 falls per 100 beds per month; 95% CI, −0.17 to 0.45; $P = 0.37$) or after intervention commencement (−0.023 falls per 100 beds per month; 95% CI, −0.14 to 0.09; $P = 0.686$), when averaged over both groups. There were also no significant differences between intervention and control groups at commencement, with the intervention group being 2.40 falls per 100 beds (95% CI, −1.25 to 6.24; $P = 0.198$) higher than the control group (12.91 falls per 100 beds; 95% CI, 6.89 to 18.93), nor over the first slope representing the pre-intervention period (0.18 more falls per 100 beds per month; 95% CI, −0.39 to 0.76; $P = 0.532$) or over the second slope representing the intervention period (0.13 fewer falls per 100 beds per month; 95% CI, −0.36 to 0.10; $P = 0.259$).

Of the 5391 people in the cohort, 215 were identified as having fractured neck of femur during the intervention period (106 from the control group and 109 from the intervention group). Rates of femoral neck fractures were similar in both groups ($P = 0.8$) and over time. There was no difference in rates of fractured neck of femur between intervention and control groups during the 17 months of intervention, and no difference in fracture rates in the entire cohort between the first 6 months of the intervention and the last 6 months. Resident factors found to be related to an increased risk of fracture were being ambulant (hazard ratio [HR], 0.61; 95% CI, 0.03 to 1.19; $P = 0.04$), having dementia (HR, 0.63; 95% CI, 0.27 to 0.999; $P = 0.002$), increasing age (HR, 0.04; 95% CI, 0.02 to 0.05; $P < 0.001$) and having a high falls risk assessment score. When compared with a high falls risk assessment score, those with a low score had a negative HR (−0.56; 95% CI, −0.94 to −0.16; $P = 0.006$), as did those with a medium score (HR, −0.72; 95% CI, −1.08 to −0.37; $P < 0.001$).

A sensitivity analysis excluding facilities that withdrew indicated no change in results.

## DISCUSSION

Our trial tested the hypothesis that a full-time project nurse could assist a large number of aged care facilities to implement best-practice strategies to reduce hip fractures. However, there was no reduction in hip fractures in the intervention group compared with the control group, nor over time. A possible reason for this is that the addition of only one resource, the project nurse, was not sufficient to enable widespread uptake of best-practice strategies in the intervention facilities.

Alternatively, available best-practice strategies may not result in a reduction in hip fractures in this population. Few falls injury prevention programs in any setting — community, acute care or residential care — have produced a reduction in hip fracture rates.

Other trials of falls injury prevention in aged care facilities have produced varied results. One trial showed a reduction in falls by repeat fallers;[1] others failed to produce any reduction in falls or fractures;[2,3] and one showed reduction in hospital admissions.[1] The most significant results came from a French trial of vitamin D and calcium supplementation[5] and a Danish trial of hip protector use,[6] although the reductions in risk of hip fractures seen in these studies have not been replicated in subsequent studies. Two recent studies have used a wider range of strategies, with better results,[7,8] although the short period of intervention in one trial makes the results less convincing.

Another possibility is that the intervention period was too short. A German study seems to support this possibility.[8] Falls injury prevention programs may also not be effective if they involve a significant proportion of people with dementia. Subgroup analyses of an intervention trial in aged care facilities that showed an overall reduction in falls failed to show a reduction in residents with cognitive impairment.[7]

There was also a possibility of contamination between the intervention and control groups with regard to the introduction of the strategies. This almost certainly happened, because falls prevention was promoted widely by NSW Health to aged care facilities during this period. In addition, doctors responsible for prescription of calcium and vitamin D supplements visited both the intervention and control facilities.

Our study was further limited by use of self-reported data on the uptake of falls interventions and the occurrence of falls. However, our main outcome of interest, falls with fractured neck of femur, was ascertained from hospital records, limiting this potential reporting bias.

There is tremendous pressure on the staff of aged care facilities, leaving them little time to concentrate on programs such as falls injury prevention. There are also many barriers to using potentially effective strategies. There is currently no easily available calcium supplement that is palatable to older people, and neither of the two popular brands is listed on the Pharmaceutical Benefits Scheme (PBS), making cost an issue. The vitamin D supplement available on the PBS requires a daily dose, adding to cost and compliance issues. For this study, compounding pharmacists in the local area were able to market a 50 000 IU capsule to be taken monthly, which greatly reduced the price and compliance issues, but this was not available to all facilities.

There is also considerable confusion as to which of the five available brands of hip protector, all with different features and durability, should be recommended. Compliance with use of these protective garments remains an issue. Also, during the period of the trial, the system of medication reviews in aged care facilities changed, inducing some confusion in the minds of general practitioners.

In summary, there is still little evidence that hip fractures can be reduced in residential aged care facilities in Australia. A longer trial would be worthwhile if some obstacles can be resolved, but unless staffing of aged care facilities is improved, it remains difficult to implement effective prevention programs without dedicated funding. Potential savings to the health system from preventing hip fractures in residential aged care, however, are considerable.

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## COMPETING INTERESTS

Mandy Harden was employed as the project nurse for the research project.

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