Journal of Aging Research & Clinical Practice©
*Volume 1, Number 2, 2012*

# A DAIRY-BASED PROTEIN, CALCIUM AND VITAMIN D SUPPLEMENT REDUCES FALLS AND FEMORAL NECK BONE LOSS IN AGED CARE RESIDENTS: A CLUSTER RANDOMISED TRIAL

*S. Iuliano-Burns[1], J. Woods[3], K. King[2], A. Ghasem Zadeh[1], X.-F. Wang[1], Q. Wang[1], E. Seeman[1]*

**Abstract:** *Objectives:* To test if a dairy-based protein (9g/d), calcium (600mg/d) and vitamin D (960IU/d) supplement formulated to increase intakes to recommended levels would reduce falls and fracture risk in ambulatory low-level aged care residents. *Design:* Cluster-randomised, single-blind intervention. *Setting:* 16 low-level aged care facilities in Melbourne, Australia. *Participants:* 813 residents (mean age 86.1 ± 5.9 years, 76% female). *Intervention:* 12 months of observation in all facilities followed by 8 months of food-based supplementation (intervention) or usual intake (controls). *Measurments:* Number of fallers, and non-vertebral fractures, serum 25(OH)D, PTH, osteocalcin, bone mineral density (BMD), bone structure and volumetric BMD at the distal radius and tibia using high-resolution pQCT, balance (Lord's balance test) and functionality (timed up and go, walking velocity). Repeated measures ANOVA and logistic regression models were used to compare cases and controls. *Results:* Among the whole sample, supplementation reduced the number of fallers by 42% (OR = 0.58, 95% CI: 0.44 – 0.78, $p < 0.001$), Among the 58 participants with follow up data, supplementation prevented bone loss at the proximal femur, maintained serum 25(OH)D and reduced PTH by 16% ± 8%, $p < 0.03$. *Conclusion:* Fortifying foods with protein, calcium and vitamin D reduced falls in ambulatory aged care residents and is a widely accessible, and inexpensive approach to potentially reduce falls and slow the progression of bone fragility in the elderly.

**Key words:** Falls, fractures, aged-care, protein, calcium, vitamin D.

## Introduction

Falls and fractures are common in elderly persons living in aged-care facilities, in part because of the higher prevalence of co-morbidities, vitamin D deficiency and bone fragility (1). Falls are the leading cause of injury, disability and death in the elderly (2). About 30% of people >65 years of age fall one or more times each year (3). Over 30% of all hip fractures in the community arise from residents in aged care facilities (4). Fracture rates are higher in ambulatory low-level aged care residents than those in nursing home so this is a high-risk group in which targeting of therapies to reduce falls and fracture risk is most cost effective (5).

Deficiencies of protein, calcium and vitamin D are common in the elderly, and they increase fracture risk by producing reduced muscle strength, impaired balance, increased bone remodelling, bone loss and bone fragility (6-8). Therefore correcting nutrient deficiencies is a potentially useful approach to fracture prevention because such a method is accessible to all persons, low cost and free of adverse events.

Hip fracture patients are often malnourished, and protein supplementation improved serum IGF-1, shortened recovery time and reduced complications (9, 10). Calcium and vitamin D supplementation reduced fall frequency, bone remodelling and non-vertebral fractures in institutionalised elderly women (11, 12). Poor compliance with medications limits anti-fracture efficacy. However, food fortification is a potential vehicle to augment intakes, with a 12.3% decrease in PTH and a 16.9% increase in IGF-1 observed in elderly women after 1-month of supplementation using calcium and vitamin D fortified cheese (13).

We conducted a randomised, single-blind facility-based intervention in residents of low-level aged care facilities to determine if a dairy-based protein, calcium and vitamin D supplement that increases intakes of these nutrients to recommended levels will reduce falls and fracture risk in ambulatory aged-care residents.

1. University of Melbourne, Austin Health, West Heidelberg, Australia; 2. Austin Health, West Heidelberg, Australia; 3. Monash University, Clayton, Australia

*Corresponding Author:* Sandra Iuliano-Burns, PhD, Dept of Endocrinology, Level 2 Centaur Building, Heidelberg Repatriation Hospital, West Heidelberg, Australia, 3081, Email: sandraib@unimelb.edu.au, Phone: +61-3-9496-3216, Fax: +61-3-9496-3365

*Received November 17, 2011*
*Accepted for publication January 3, 2012*

## Methods

Twenty low-level (hostel) aged care facilities in Melbourne, Australia, housing 1370 residents were recruited, of which 16 facilities and 813 residents completed the trial. These facilities are equivalent to assisted care (USA) or residential care (UK) and were selected due to their higher falls rates compared to nursing home residents (14). All facilities are accredited therefore comply with Federal Government standards for care, provision of services, staffing requirements, residents' safety and facility layout. Only accredited facilities were recruited. Admission into aged-care is Government regulated so low-level residents have similar health needs. High-care (nursing home) facilities were not included in this study. No other fall prevention strategies were undertaken during the study. Facilities were stratified based on location (similar demographics) and randomised to supplementation or control. The study consisted of one-year of observation in all facilities to establish baseline falls and fracture rates, followed by a year of observation (controls), or 8 months of supplementation (intervention) to ensure the supplement was consumed prior to its "use-by" date.

Twenty five percent of residents consented to having their medical records reviewed that were maintained at facilities (Figure 1). 84 residents (10.3%) consented to undergo a full assessment (BMD, serum, strength and functional measures) at baseline and 58 residents were available at study completion. Loss to follow up was due to death (n=14) or transfer to high-care (n=12) (Figure 1). Residents without follow up were similar to those who completed the trial, however more were on vitamin D supplements, so more were vitamin D replete (Table 1). Those who failed to complete the trial tended to be males, and have higher dietary vitamin D intakes (p=0.1) (Table 1). Bone structure assessments (HR-pQCT) became available after initial recruitment, so only the 84 consented residents were allowed to be approached, of which 57 consented and were assessed at baseline. Bone structure data were available from 40 residents at trial completion. Loss to follow up was due to death (n=6), transfer to high-care (n=3), illness (n=2), unavailability (n=4), or refusal (n=2) (Figure 1). The human research ethics committees of Austin Health and Monash University approved the study.

## Supplementation

The dairy based supplement consisted of whey protein (Warrnambool Cheese and Butter Factory, Warrnambool, Australia), calcium derived from milk minerals and vitamin D3 (Murray Goulburn Co-op P/L, Brunswick, Australia). The prescribed dose of 2 tablespoons/day provided 9g protein, 600mg calcium and 960IU vitamin D3, to increase mean intakes to recommended levels. Food service staff were trained to incorporate the supplement powder into foods, and were provided with procedures manuals and on-site support. To aid administration, the supplement was also combined into 30 different foods items (La Croissant Bakery, Elsternwick, Australia) and provided to hostels weekly. Two food products/day provided the prescribed dose. Administration of the supplement was recorded using a standardised recording sheet of product usage (powder and fortified foods) and food delivery (pre-fortified foods) at each hostel. Individual compliance was monitored using 3-day weighed food records during and at intervention end (total=6 days).

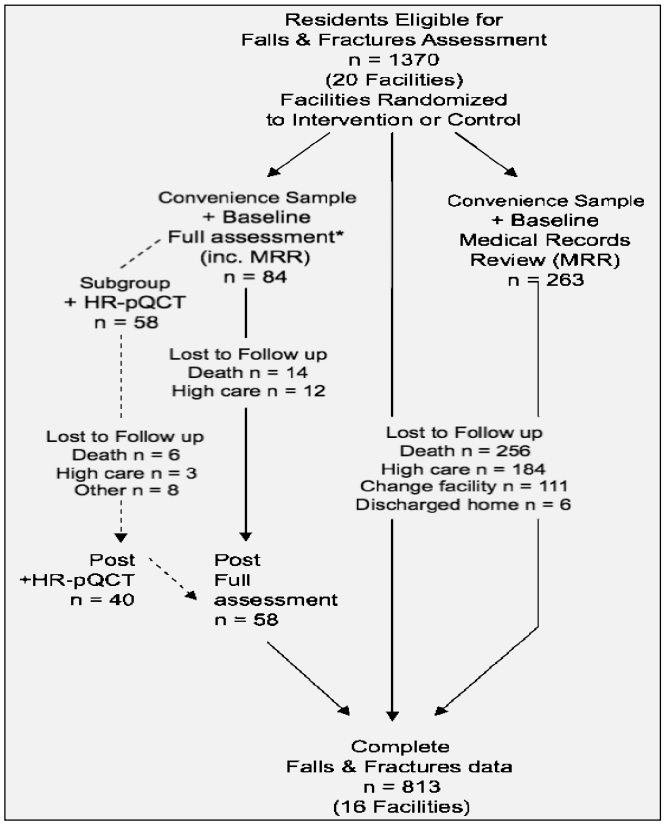


**Figure 1.** Flow Chart For Elderly Aged Care Residents From 20 Aged Care Facilities Participating in a Cluster Randomised Dairy Based Protein, Calcium and Vitamin D Intervention Trial. *BMD, serum, strength and functional measures

## Assessments

Falls, defined as an event which results in a person coming to rest inadvertently on the ground or other lower level, were monitored in all 813 residents using a standardised falls report sheet, that documented time, location and outcome of fall (i.e. injury type) (15). Data was validated from incident reports, as reporting of falls is mandatory in all facilities. Fractures were verified from hospital medical records.

**Table 1**
Baseline Characteristics of Elderly Low-Level Aged Care Residents Assigned to Intervention or Control Group, and a Comparison to Those Lost to Follow Up

| | Intervention n=45 | Control n=39 | P value | Lost to Follow Up n=26 |
|---|---|---|---|---|
| Age (yrs) | 86.5±6.3 | 85.2±7.3 | 0.43 | 86.7±6.0 |
| Males/Females (number) | 13/32 | 7/32 | 0.19 | 9/17 |
| Height (cm) | 156.2±8.1 | 154.8±7.9 | 0.43 | 1.58.2±8.6 |
| Weight (kg) | 64.8±11.0 | 65.0±11.7 | 0.94 | 66.0±10.1 |
| Lean (kg) | 39.4±7.5 | 37.5±5.5 | 0.20 | 39.5±6.5 |
| Fat (kg) | 22.2±8.4 | 24.2±8.5 | 0.17 | 22.9±8.2 |
| Medical conditions | 5.4±0.3 | 4.9±0.3 | 0.33 | 5.3±2.7 |
| Cardio-vascular (%) | 33 | 53 | 0.35 | 48 |
| Arthritis (%) | 56 | 47 | 0.42 | 46 |
| Depression (%) | 26 | 28 | 0.86 | 17 |
| Long term medications | 9.9±0.6 | 9.0±0.7 | 0.34 | 9.9±4.9 |
| Fracture history (%) | 35 | 31 | 0.69 | 36 |
| Vitamin D supplements (%) | 35 | 32 | 0.64 | 50^ |
| Calcium supplements (%) | 26 | 32 | 0.60 | 33 |
| Osteoporosis medication (%) | 26 | 22 | 0.61 | 27 |
| Serum 25(OH)D nmol/L | 49.8±31.2 | 49.5±32.5 | 0.96 | 56±32 |
| Vitamin D Status* (D/M/S) (%) | 21/40/39 | 16/48/36 | 0.90 | 21/24/55^ |
| Total Energy (kj/day) | 5932±1719 | 6209±1245 | 0.76 | 6177±1293 |
| Protein (g/day) | 52±13 | 55±12 | 0.54 | 53±12 |
| Calcium (mg/day) | 537±165 | 548±149 | 0.82 | 591±256 |
| Dietary Vitamin D (µg/day) | 2.58±0.24 | 2.17±0.49 | 0.90 | 3.23±0.84 |

D=severe/moderate deficiency (<25nmol/L), M=mildly deficiency (25-50nmol/L), S=sufficient (>50nmol/L) *based on Australian standards (40). Conversion of serum 25(OH)D to ng/ml = (nmol/L)/2.5
^p<0.01, different to those who remained in trial

Total body, lumbar spine and proximal femur bone mineral density (BMD), and body composition were measured using DXA (Prodigy, Version 7.51, GE Lunar, Madison, WI, CV=1%, inter-operator CV=2% determined on 5 adults scanned 5 times). Volumetric BMD and bone structure were assessed at the distal tibia and distal radius using 3-dimensional high-resolution peripheral quantitative computed tomography (HR-pQCT), (XtremeCT;Scanco Medical AG, Bassersdorf, Switzerland, CV<0.6–7.4%). Morning fasting blood samples were drawn before and at the end of supplementation and analysed for serum 25(OH)D; chemiluminescent immunoassay (CLIA) (Liason, DiaSorin, Stillwater, USA), calcium; indirect potentiometry (SYNCHRON LX, Beckman Coulter Inc. USA), parathyroid hormone (PTH); CLIA (DPC Immulite 2000, Los Angeles, USA), albumin; bichromatic digital endpoint (SYNCHRON DxC-800, Beckman Coulter Inc. USA), N-Mid Osteocalcin (OC); electrochemiluminescence immunoassay (Elecsys 1010 Analytics, Roche Diagnostics, Germany). The intra- and inter-assay CV's for serum measures were 7-13%.

Balance was assessed using the Lord's balance test measuring horizontal displacement at waist level over 30-seconds (16). Muscle strength at the knee (flexion/extension), ankle (dorsi/plantar flexion) and hip (abduction/adduction) of both legs was assessed using the Nicholas manual muscle tester (Lafayette Instruments, Lafayette, IN, USA), with the mean of three trials used (17). Mobility was determined using the timed 'up and go' (TUG) test and walking velocity over 6-meters (17, 18). The same researcher, blinded to group allocation, performed all assessments.

Nutrient intake was evaluated before and twice during supplementation (dietary + supplementary for intervention group) using 3-day weighed records of all foods, beverages, and food supplements served and consumed at meals and snack times. A recall of items consumed outside meal was taken. Foods were weighed to ±1g on digital scales (Soehnle Venezia, Switzerland). Mean daily nutrient intake was calculated using SERVE Nutrition Management System version 5.0.012, 2004 (Serve Nutrition Systems, St Ives, Australia). Vitamin D intake was calculated using FoodWorks Professional Edition, 2009 (XYRIS Software, Brisbane, Australia).

## *Statistics*

Independent t-tests were used to determine group differences at baseline. Repeated-measurement ANOVA was used for analysing the effect of the intervention on continuous variables or ANCOVA if group differences at baseline were detected. Differences were annualised [(post-pre)/time]. The effect of supplementation on number of fallers was determined using logistic regression models. Based on falls frequencies during the first year of observation, additional logistic regressions were performed with residents categorised as non- (no falls), infrequent- (1-2 falls) or frequent fallers (≥ 3 falls).

Based on a annual decline in muscle strength of 2.4%, prevention of this decline (0.0±3.6%) required 36 participants in each group, 28 were needed to detect a 3.0±4.0% difference in bone density and structure and 137 required to detect a 40% reduction in the number of fallers with 80% power at p<0.05 (19-21). Data were presented as mean±SD unless stated otherwise. P<0.05 is considered statistically significant, but values p<0.1 are reported.

## Results

Data were obtained from 7 intervention and 9 control facilities with loss to follow up due to facility closure (n=1) or sale (n=3). Falls data was available for 813 of 1370 residents (mean age 86.1±5.9 yrs, 75% females) with loss to follow up in 557 residents due to death (46%), transfer to high-care (33%), changed facilities (21%) or discharge home (1%) (Figure 1). A similar proportion from both the intervention and control group failed to complete the trial.

Intervention and control groups were similar at baseline (Table 1). Of those who provided follow up data, groups were similar in age, anthropometry and medical histories (data not shown), but differences were observed for total proximal femur BMD and TUG (Table 3).

Supplementation maintained serum 25(OH)D (which decreased in controls by 22±37%, p<0.01) and reduced

PTH (-16%±8%, p<0.03) (Table 3). No group differences in serum osteocalcin were observed (Table 3). Mean daily supplementation determined from weighed food intakes was 4.4±1.2g protein, 298±78mg calcium and 474±125IU vitaminD3. Total calcium (537±165 v 802±258mg/day, p<0.05) and vitamin D (2.58±0.24 v 13.62±3.73µg/day, p<0.01) intakes but not protein intake (52±13 v 55±17g/day) increased with supplementation. During the supplementation period, calcium (802±258 v 615±297mg/day, p<0.05) and vitamin D (13.62±3.73 v 2.23±0.89µg/day, p<0.01) intakes were higher in the intervention group compared to controls.

**Table 2**
Falls and Fracture Incidence in Ambulatory Aged Care Residents Before and After Supplementation With a Dairy Based Protein, Calcium and Vitamin D Supplement

| | Intervention n=301 | | Controls n=512 | |
|---|---|---|---|---|
| | Year 1 | Year 2 | Year 1 | Year 2 |
| No. fallers (%) | 158 (52.5) | 113 (37.5) | 233 (45.5) | 260 (50.8) |
| 1-2 falls | 96 | 58 | 160 | 144 |
| 3+ falls | 62 | 55 | 72 | 115 |
| Total falls | 594 | 478 | 749 | 1093 |
| Mean falls (range) | 2.0 (0-40) | 1.6 (0-18) | 1.4 (0-132) | 2.1 (0-149) |
| Non-vertebral fractures (%) | 4 (1.3) | 5 (1.6) | 9 (1.8) | 10 (2.0) |

The incidence of falls and fractures were similar in both groups during the observation year (Table 2). Supplementation was associated with a 42% reduction in the number of fallers relative to controls (OR=0.58, 95% CI:0.44–0.78, p<0.001). Among those who did not fall in the observation year, supplementation reduced the number of fallers by 65% relative to controls (OR=0.35 95% CI:0.22–0.57, p<0.001). For infrequent fallers (1-2 falls during the observation year), supplementation reduced the number of fallers by 46% (OR=0.54 95% CI:0.32–0.91, p<0.05). However, for frequent fallers (3+ falls during the prior year), supplementation did not reduce the number of fallers (OR=0.86, 95% CI:0.42–1.76, p=0.68) (Figure 2). For facilities that were supplemented (n=7), there was a trend for a dose effect of supplementation on falls reduction (r=-0.6, p=0.1) in that higher supplement consumption was associated with fewer fallers. Fracture incidence (1-2%) remained unchanged in both groups relative to the observation period (Table 2).

Total proximal femur BMD remained unchanged with supplementation but decreased by 2.5% in controls (p<0.09 unadjusted and p<0.05 after adjustment for baseline total proximal femur BMD). No group differences in spine BMD were observed (Table 3). At the distal tibia, trabecular bone volume fraction increased with supplementation (p<0.05) (Table 3). No group differences were detected for measures at the distal radius (data not shown). No group differences were observed for balance, walking velocity, mobility or lean mass (intervention 0.6±1.4kg v controls 0.2±1.0kg) (Table 3).

**Table 3**
Functional and Skeletal Changes Over Time in Supplemented and Non-Supplemented Elderly Aged Care Residents. Mean ± SD

| | Intervention (n=31) | | | Control (n=27) | | |
|---|---|---|---|---|---|---|
| | Pre | Post | Difference | Pre | Post | Difference |
| | | | *Strength (kg)* | | | |
| Knee (flexion/extension) | 9.9±3.4 | 7.1±1.8 [c] | -1.9±2.0 | 9.2±2.8 | 7.0±1.4 [c] | -2.1±2.1 |
| Hip (adduction / abduction) | 11.2±4.1 | 9.9±2.6 | -0.9±2.5 | 10.6±4.2 | 9.0±2.4 [d] | -1.5±3.0 |
| Ankle (dorsi / plantar flex.) | 13.0±3.2 | 9.5±2.4 [c] | -3.5±2.2 | 12.4±3.2 | 9.6±1.6 [c] | -2.9±2.2 |
| | | | *Function (sec)* | | | |
| Timed up & Go | 13.8±5.0 [e] | 16.2±10.2 | 1.6±4.5 | 17.0±7.7 | 14.2±5.0 | -2.7±5.0 |
| Velocity over 6m | 9.7±3.5 | 10.1±3.8 | 0.3±1.7 | 9.0±2.4 | 9.3±3.3 | 0.3±2.4 |
| | | | *Balance (mm of displacement)* | | | |
| Eyes open (EO) | 52±42 | 59±58 | 5±44 | 33±33 | 29±23 | -4±37 |
| Eyes closed (EC) | 59±79 | 46±54 | -6±64 | 34±37 | 30±28 | -4±37 |
| EO on foam | 31±18 | 42±75 | 8±37 | 26±25 | 23±13 | -3±27 |
| EC on foam | 21±13 | 37±44 | 11±30 | 15±10 | 19±18 | 4±19 |
| | | | *Densitometry-BMD (g/cm²)* | | | |
| Total prox. fem. region | 0.74±0.13 [f] | 0.74±0.13 | -0.01±0.03 [b*] | 0.67±0.07 | 0.63±0.12 | -0.03±0.06 |
| Lumbar spine (2-4) | 1.16±0.22 | 1.19±0.25 | 0.02±0.04 | 1.08±0.12 | 1.07±0.19 | - 0.01±0.05 |
| | | | *HR-pQCT* | | | |
| *Distal Tibia* | | | | | | |
| Trab. vBMD (mg HA/cm ³) | 161±44 | 164±44 | 3.1±2.4 [a] | 156±53 | 156±52 | 0.3±2.2 |
| - BV/TV fraction | 0.14±0.04 | 0.14±0.04 | -0.00±0.00 [b] | 0.13±0.04 | 0.13±0.04 | -0.00±0.00 |
| - Number (1/mm) | 2.2±0.5 | 2.2±0.5 | 0.1±0.2 | 2.0±0.7 | 2.0±0.7 | -0.1±0.2 |
| - Thickness (mm) | 0.06±0.01 | 0.06±0.01 | -0.00±0.01 | 0.07±0.03 | 0.07±0.03 | 0.00±0.01 |
| Cort. vBMD (mg HA/cm ³) | 657±139 | 651±128 | -6±24 | 755±90 | 757±94 | 2±12 |
| | | | *Serum markers* | | | |
| 25(OH)D nmol/L*^ | 37.6±23.0 | 51.4±38.7 | 13.7±40.4 [a] | 49.9±33.6 | 38.5±26.8 [c] | -11.4±16.3 |
| PTH (pmol/L)* | 9.6±6.8 | 7.8±5.4 | -1.8±3.6 [a] | 9.0±4.3 | 9.2±4.0 | 0.2±2.2 |
| Osteocalcin (ng/ml) | 26.8±13.0 | 24.9±10.7 | -1.2±6.7 | 35.3±27.6 | 34.7±28.3 | -0.7±14.2 |

a. p<0.05, b. p<0.09, different to control (repeated measures ANOVA), * p<0.05 after adjustment for baseline differences; c. p<0.01, d p<0.05, different to baseline. e. p<0.01, f p<0.05, group difference at baseline (unpaired t-test); Reference ranges: 25(0H)D; 75-250nmol/L, PTH 1.6-6.9pmol/L, osteocalcin 7.3–37.8 ng/ml (Post-menopausal Caucasian women); ^ ng/ml = (nmol/L divided by 2.5).

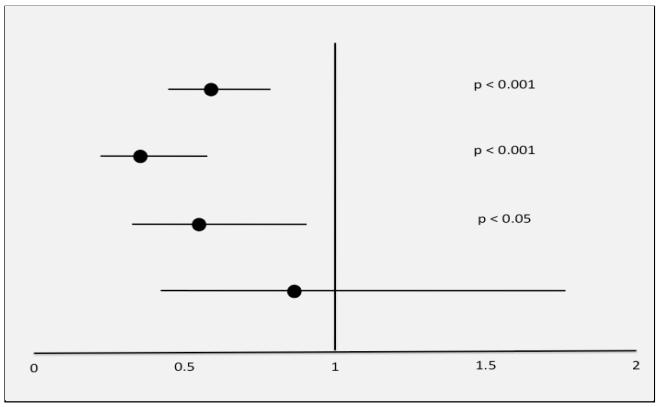


**Figure 2.** Odds ratio (95% CI) for risk of falls during year 2 (supplementation period) for residents receiving 8 months of supplementation using a dairy based supplement, relative to non-supplemented control residents. OR are for all residents (top, n = 813), and expressed according to falls history; non-fallers (second from top, n = 423), infrequent fallers (1-2 falls per year; third from top n = 253) and frequent fallers (3+ falls per year; bottom, n = 137, NS)

## Discussion

Among 813 residents in 16 aged-care facilities, supplementation with protein, calcium and vitamin D reduced the number of residents who fell by 42%. The benefit was confined to individuals with no or moderate (1-2/yr) histories of falls. Residents with a higher incidence of falls did not benefit from supplementation. Supplementation slowed bone loss at the proximal femur, maintained serum 25(OH)D and reduced PTH. No trials of falls reduction in the elderly have examined the effects of simultaneously supplementing with protein, calcium and vitamin D.

25(OH)D deficiency increases with age, therefore the maintenance of 25(OH)D with supplementation may have prevented detrimental changes in muscle and physical function and the increase in falls risk associated with vitamin D deficiency and ageing (22, 23). Given the low dietary vitamin D intakes in the residents, while the level achieved prevented some loss of hip strength, levels > 60 nmol/L may be required to improve physical function (24). This would require higher doses of vitamin D (25).

Secondary hyperparathyroidism is associated with increased bone remodelling and cortical bone loss (26). Supplementation reduced serum PTH and slowed bone loss at the proximal femur as reported using calcium plus vitamin D therapy (27). The combined dose of calcium and vitamin D, did improve total calcium and vitamin D intakes and likely contributed to the reduction in PTH.

400IU daily was effective in reducing wintertime lumbar spine bone loss in postmenopausal women with mean dietary vitamin D intakes of ~100IU/day (28). Therefore the vitamin D dose received with supplementation (474IU/day) likely contributed to the slowing of bone loss. This study was not powered to detect fracture risk reduction (27).

No benefits of supplementation were observed in balance or physical function, perhaps because most residents were mildly vitamin D deficient (25–50nmol/L). The efficacy of vitamin D supplementation on physical function in those with mild deficiency has not been proven as no studies have been limited to those with serum 25(OH)D levels between 25-50nmol/L (29). However, improvements in body sway have been observed after 8 weeks of vitamin D supplementation in vitamin D deficient women (30). The small number of residents with more severe vitamin D deficiency likely limited the power to detect benefits of supplementation on balance and physical function, and the dose received was likely insufficient. While the prescribed dose (960IU) for this study was in line with recommendations to reduce falls and improve physical function, the dose received was less than levels in prior trials where benefits to balance and physical function were observed (25).

Lean mass was preserved and hip strength did not significantly decline with supplementation. Protein deficiency is associated with reduced IGF-1 and lean muscle mass however, few residents were protein deficient (31). Supplementation of older women with 15g of essential amino acids increased IGF-1 expression, lean muscle mass and muscle protein synthesis, and muscle protein synthesis rates are enhanced by leucine from whey protein (32, 33). It has been suggested to maximise muscle protein synthesis and prevent sarcopenia, larger quantities (e.g. 25-30g) of high quality proteins are consumed per meal (34). The dose received in this trial was below 25-30g, and distributed throughout the day therefore may have only been sufficient to maintain but not improve lean mass and only partially prevent a decline in hip strength.

An increase in trabecular vBMD was observed at the distal tibia with supplemented group. However, the basis for this observation cannot be confirmed as current methods of assessing trabecular architecture using high-resolution pQCT are unable to distinguish between cortical bone that has become trabecularized, from trabecular bone of growth-plate origin (35).

This study had a number of limitations. The high staff turnover (>70%) contributed to the administered supplement dose being less than prescribed, because supplement delivery was reliant on food service staff. The powder required mixing prior to incorporation into foods (e.g. sauces, desserts) to ensure the prescribed dose was consumed. This task proved difficult for staff with limited expertise in food preparation, and high work demands. The provision of pre-fortified foods helped overcome these issues, as staff did not require specific skills or preparation time to administer supplemented foods. Staff favoured food-fortification as it had minimal impact on food service operations.

Food fortification has been used to successfully supplement aged care residents (13). Food fortification is practical as it does not require food intake to increase, and compliance is good as food waste is ~5% (36). The 95% consumption of the supplement in this trial was higher than trials using tablet forms during which 1/3 of residents consumed <75% of medications provided (37). Despite the moderate supplement dose, modest benefits were observed. Future trials of food fortification should be encouraged that incorporate higher doses of protein and vitamin D as a safe and cost effective means of addressing common nutritional deficiencies in institutionalized elderly.

Attrition in this elderly population was high and reduced the numbers available for follow-up resulting in diminished power to detect differences. Therefore to retain adequate power, sample sizes need to be larger to account for potential attrition rates >20%/year. Higher doses of protein and vitamin D would likely improve efficacy. Cluster randomisation (randomised by hostel not individual) was unlikely to have altered results as it accounts for ~0.4% of the variance of falls-related outcomes (38).

Falls and fractures increase morbidity and mortality and result in long-term nursing care and high costs to the community. Preventing falls and falls related injuries in hostel residents and maintaining residents at this level of care is cost effective as the cost of nursing home care is approximately three times that of low level hostel care (39). Food fortification is potentially a feasible, effective means of improving nutritional intake and reducing falls in ambulatory aged care residents.

*Funding:* This work was supported by Dairy Australia and the Gardiner Foundation.

*Acknowledgements:* All authors declare no conflicts of interest and have nothing to declare. We wish to thank the participating aged care facilities and residents, technician Alison Evans, research nurses Sheila Matthews and Judy Tan, Natalie El Haber and Berha Khodr from the NARI, and Mike Ferguson and staff from La Croissant Bakery.

## References

1. Sugarman JR, Connell FA, Hansen A, Helgerson SD, Jessup MC, Lee H. (2002) Hip fracture incidence in nursing home residents and community-dwelling older people, Washington State, 1993-1995. J Am Geriatr Soc. 50:1638-43.
2. Stevens JA, Olson S. (2000) Reducing falls and resulting hip fractures among older women. MMWR Recomm Rep. 49:3-12.
3. Tinetti ME, Speechley M, Ginter SF. (1988) Risk factors for falls among elderly persons living in the community. N Engl J Med. 319:1701-7.
4. Bischoff-Ferrari HA, Can U, Staehelin HB, et al. (2008) Severe vitamin D deficiency in Swiss hip fracture patients. Bone. 42:597-602.
5. Chen JS, Sambrook PN, Simpson JM, et al. (2009) Risk factors for hip fracture among institutionalised older people. Age Ageing. 38:429-34.
6. Flicker L, Mead K, MacInnis RJ, et al. (2003) Serum vitamin D and falls in older women in residential care in Australia. J Am Geriatr Soc. 51:1533-8.
7. Ribot C, Tremollieres F, Pouilles JM, et al. (1993) Risk factors for hip fracture. MEDOS study: results of the Toulouse Centre. Bone. 14 Suppl 1:S77-80.
8. Huang Z, Himes JH, McGovern PG. (1996) Nutrition and subsequent hip fracture risk among a national cohort of white women. Am J Epidemiol. 144:124-34.
9. Schurch MA, Rizzoli R, Slosman D, Vadas L, Vergnaud P, Bonjour JP. (1998) Protein supplements increase serum insulin-like growth factor-I levels and attenuate proximal femur bone loss in patients with recent hip fracture. A randomized, double-blind, placebo-controlled trial. Ann Intern Med. 128:801-9.
10. Delmi M, Rapin CH, Bengoa JM, Delmas PD, Vasey H, Bonjour JP. (1990) Dietary supplementation in elderly patients with fractured neck of the femur. Lancet. 335:1013-6.
11. Dawson-Hughes B, Dallal GE, Krall EA, Sadowski L, Sahyoun N, Tannenbaum S. (1990) A controlled trial of the effect of calcium supplementation on bone density in postmenopausal women. N Engl J Med. 323:878-83.
12. Recker RR, Hinders S, Davies KM, et al. (1996) Correcting calcium nutritional deficiency prevents spine fractures in elderly women. J Bone Miner Res. 11:1961-6.
13. Bonjour JP, Benoit V, Pourchaire O, Ferry M, Rousseau B, Souberbielle JC. (2009) Inhibition of markers of bone resorption by consumption of vitamin D and calcium-fortified soft plain cheese by institutionalised elderly women. Br J Nutr. 102:962-6.
14. Lord SR, March LM, Cameron ID, et al. (2003) Differing risk factors for falls in nursing home and intermediate-care residents who can and cannot stand unaided. J Am Geriatr Soc. 51:1645-50.
15. World Health Organization. (2007) WHO Global Report on Falls Prevention in Older Age. Geneva.
16. Lord SR, Ward JA. (1994) Age-associated differences in sensori-motor function and balance in community dwelling women. Age Ageing. 23:452-60.
17. Hill K, Schwarz J, Flicker L, Carroll S. (1999) Falls among healthy, community-dwelling, older women: a prospective study of frequency, circumstances, consequences and prediction accuracy. Aust N Z J Public Health. 23:41-8.
18. Podsiadlo D, Richardson S. (1991) The timed "Up & Go": a test of basic functional mobility for frail elderly persons. J Am Geriatr Soc. 39:142-8.
19. Forrest KY, Zmuda JM, Cauley JA. (2007) Patterns and correlates of muscle strength loss in older women. Gerontology. 53:140-7.
20. Iuliano-Burns S, King K, Woods J, Evans A, Ghasem Zadeh A, Seeman E. (2008) A dairy-based protein, calcium and vitamin D supplement preserves trabecular bone and reduces falls in aged care residents. Nutrition Society of Australia Annual Scientific Meeting; Glenelg, SA.
21. Boutroy S, Bouxsein ML, Munoz F, Delmas PD. (2005) In vivo assessment of trabecular bone microarchitecture by high-resolution peripheral quantitative computed tomography. J Clin Endocrinol Metab. 90:6508-15.
22. Snijder MB, van Schoor NM, Pluijm SM, van Dam RM, Visser M, Lips P. (2006) Vitamin D status in relation to one-year risk of recurrent falling in older men and women. J Clin Endocrinol Metab. 91:2980-5.
23. Dhesi JK, Bearne LM, Moniz C, et al. (2002) Neuromuscular and psychomotor function in elderly subjects who fall and the relationship with vitamin D status. J Bone Miner Res. 17:891-7.
24. Kuchuk NO, Pluijm SM, van Schoor NM, Looman CW, Smit JH, Lips P. (2009) Relationships of serum 25-hydroxyvitamin D to bone mineral density and serum parathyroid hormone and markers of bone turnover in older persons. J Clin Endocrinol Metab. 94:1244-50.
25. Bischoff-Ferrari HA, Dawson-Hughes B, Staehelin HB, et al. (2009) Fall prevention with supplemental and active forms of vitamin D: a meta-analysis of randomised controlled trials. BMJ. 339:b3692.
26. Parfitt AM, Rao DS, Stanciu J, Villanueva AR, Kleerekoper M, Frame B. (1985) Irreversible bone loss in osteomalacia. Comparison of radial photon absorptiometry with iliac bone histomorphometry during treatment. J Clin Invest. 76:2403-12.
27. Chapuy MC, Arlot ME, Duboeuf F, et al. (1992) Vitamin D3 and calcium to prevent hip fractures in the elderly women. N Engl J Med. 327:1637-42.
28. Dawson-Hughes B, Dallal GE, Krall EA, Harris S, Sokoll LJ, Falconer G. (1991) Effect of vitamin D supplementation on wintertime and overall bone loss in healthy postmenopausal women. Ann Intern Med. 115:505-12.
29. Latham NK, Anderson CS, Reid IR. (2003) Effects of vitamin D supplementation on strength, physical performance, and falls in older persons: a systematic review. J Am Geriatr Soc. 51:1219-26.
30. Pfeifer M, Begerow B, Minne HW, Abrams C, Nachtigall D, Hansen C. (2000) Effects of a short-term vitamin D and calcium supplementation on body sway and secondary hyperparathyroidism in elderly women. J Bone Miner Res. 15:1113-8.
31. Bonjour JP, Schurch MA, Chevalley T, Ammann P, Rizzoli R. (1997) Protein intake, IGF-1 and osteoporosis. Osteoporos Int. 7 Suppl 3:S36-42.
32. Dillon EL, Sheffield-Moore M, Paddon-Jones D, et al. (2009) Amino acid supplementation increases lean body mass, basal muscle protein synthesis, and insulin-like growth factor-I expression in older women. J Clin Endocrinol Metab. 94:1630-7.
33. Katsanos CS, Kobayashi H, Sheffield-Moore M, Aarsland A, Wolfe RR. (2006) A high proportion of leucine is required for optimal stimulation of the rate of muscle protein synthesis by essential amino acids in the elderly. Am J Physiol Endocrinol Metab. 291:E381-7.
34. Paddon-Jones D, Rasmussen BB. (2009) Dietary protein recommendations and the prevention of sarcopenia. Curr Opin Clin Nutr Metab Care. 12:86-90.
35. Zebaze RM, Ghasem A, Bohte A, et al. (2008) The neglected role of intracortical remodeling in age-related bone loss. J Bone Miner Res. 23:S29.
36. Woods J, Walker K, Iuliano-Burns S, Straus B. (2009) Malnutrition on the menu: nutritional status of institutionalised elderly Australians in low-level care. J Nutr Health Aging. 13:693-8.
37. Flicker L, MacInnis RJ, Stein MS, et al. (2005) Should older people in residential care receive vitamin D to prevent falls? Results of a randomized trial. J Am Geriatr Soc. 53:1881-8.
38. Rapp K, Lamb SE, Buchele G, Lall R, Lindemann U, Becker C. (2008) Prevention of falls in nursing homes: subgroup analyses of a randomized fall prevention trial. J Am Geriatr Soc. 56:1092-7.
39. Aged Care in Australia. www.health.gov.au. 2006 [viewed July 2009].
40. Working group from the ANZBMS. (2005) Vitamin D and adult bone health in Australia and New Zealand: a position statement. Med J Aust. 182:281-5.