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Original Article

Low-frequency Exercise and Vitamin D Supplementation Reduce Falls Among Institutionalized Frail Elderly[☆]

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SUMMARY

Background: Falls are a serious problem among frail elderly and their prevention is an important health concern. We compared the frequency of falls among institutionalized frail elderly residents following different interventions: low-frequency exercise, vitamin D supplementation, and a combination of both.
Methods: Participants (N = 91) were residents in an institution for frail elderly (84.8 ± 8.8 years of age, 69 women). Participants were randomly assigned to one of four conditions: (1) the control group (n = 23) was provided three sessions per week of individualized exercise and usual care, (2) the low-exercise group (n = 22) was provided two sessions of individualized exercise per week, (3) the nutrition group (n = 23) was given oral vitamin D (900 IU/day), and (4) the combined group (n = 23) performed low-level exercise and received vitamin D supplementation.
Results: A two-way analysis of variance including interactions between experimental group and time indicated a clear benefit in the groups that received supplementation with vitamin D. A Cox proportional-hazard regression analysis, adjusted for sex and age, showed that compared to the control group, the combined group had a reduced risk of falls (hazard ratio: 0.28, 95% CI: 0.08–0.92, $P < 0.05$). The other groups did not significantly differ from controls.
Conclusion: The intervention combining low-frequency exercise and vitamin D supplementation was effective for the reduction of falls among institutionalized frail elderly individuals.

1. Introduction

Falls are a serious health issue among the elderly, and residents of care facilities suffer from falls two to three times more than community-dwelling elderly individuals[1,2]. Falls can result in contusions, breaks, and severe cranial injuries[3,4]. Furthermore, quality of life (QOL) has been shown to be decreased among individuals who have experienced a fall, in part as a fear of falling again restricts their range of activities of daily living (ADL)[5,6].

Previous research has indicated that risk factors for falling include a past history of falling, muscle weakness, and gait disorders[7]. Furthermore, recurrent falls risk was associated with depression among veterans home elderly[8]. Frail elderly individuals who use a wheelchair suffer from falls more often than those who can walk, and kyphosis and dementia are the strongest risk factors for falls among elderly who use a wheelchair[9,10]. However, the risk factors for falls may differ between institutionalized frail elderly individuals and community-dwelling elderly individuals.

Vitamin D supplementation is one of the most effective interventions to prevent falls among frail elderly. One study showed that by increasing the daily vitamin D intake of facility residents to ≥800 IU, the rate of falls decreased by 22%[11]. Flicer et al. reported that increased vitamin D levels in the blood can significantly decease rate of falls[12]. Because many elderly individuals living in care facilities have decreased intestinal functioning and limited daylight exposure, they often cannot maintain the recommended level of blood 25-hydroxyvitamin D (≥30 ng/mL) from normal dietary intake alone[13]. Therefore, it is necessary to supplement vitamin D in frail elderly for the prevention of falls.

Fall-prevention effects have been shown for several multi-factor intervention methods. For example, it has been reported that a multifactorial intervention involving fall-prevention training for staff, living-space adjustments, an exercise program, the use of auxiliary tools, medication adjustments, the use of a hip protector, and after-fall conferences was able to decrease the incidence rate of falls[14]. In addition, it has been shown that fall-prevention improves

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when multi-factor interventions include patient education[15]. Conversely, a study using only a three-factor intervention consisting of living-space adjustments, medication adjustments, and improved transportation methods did not improve the incidence rate of falls[16]. This suggests that particular interventions may have differing effects on fall prevention, and that multifactorial interventions that address many potential factors may be best to prevent falls.

With regards to exercise interventions, many studies have used techniques such as muscle training and balance training[17]. A Cochrane systematic review summarizing these studies has indicated that exercise interventions have no positive effect on preventing falls among elderly residents of care facilities[18]. In particular, many facility residents had dementia, making it difficult to gain the positive effects of exercise. Therefore, exercise appears to offer only limited effects in the prevention of falls in care facilities[19,20]. However, a meta-analysis by Silva et al.[21] showed that falls prevention could be enhanced by limited-exercise interventions over a period of less than three months at a frequency of two to three times per week. Thus, there is no consensus regarding the role of exercise in falls prevention, especially among elderly living in care facilities. Indeed, most studies have been conducted with different protocols and different combinations of interventions, and for many possible interventions the fall-prevention effects have not been sufficiently investigated.

We considered that a synergistic effect may emerge when combining multiple interventions. In particular, we thought that the beneficial effects of exercise may be particularly strong if a low-frequency exercise routine (twice per week for less than three months) was combined with other interventions such as staff training, living-space adjustments, the use of auxiliary tools, medication adjustments, falls conferences, and vitamin D supplementation. The purpose of this study was to verify the beneficial fall-prevention effects of combining low-frequency exercise and vitamin D supplementation among institutionalized frail elderly.

2. Materials and methods

2.1. Sample and recruitment

The study design was a randomized, non-blind, controlled clinical trial (CCT), performed in one institutional care facility in Japan. The study was conducted between September 2013 and June 2014. Participants were recruited by poster and verbal announcement. The following inclusion criteria were verified during an initial interview: Participants must have lived in the care facility and not received any regular supplementation of vitamin D during the previous 12 months. We excluded residents receiving terminal care, or with renal failure (chronic kidney disease [CDK] stage 3 or an estimated glomerular filtration rate [eGFR] of G2 or poorer), poor glycemic control, or a pacemaker. Written informed consent was obtained from each participant in accordance with guidelines approved by the Osaka prefecture University Graduate School of Comprehensive Rehabilitation and the Declaration of Human Rights, Helsinki, 1975. This study was approved by the ethics committee of the organization responsible for the conduct of the experimental protocols.

Participants were randomized into one of four groups: control, low-exercise, nutrition, and combined (low-exercise and nutrition). Opaque envelopes containing the group names were numbered and the 91 participants were randomly assigned to either program.

Previous studies of institutionalized frail elderly reported that vitamin D intake reduced the fall rate by 22%[11]. Low-frequency exercise reduced the fall rate by 25%[21]. Therefore, we designed the current study according to the effect size of 0.5. With a significance level of 0.05 and a power of 80%, a minimum of 25 participants were required for each group.

2.2. Measurements

The primary outcome variable was the reported number of falls over the study period. Falls were carefully recorded by the staff who found a resident falling down. Falls were analyzed according to individual, number of falls, latency until first fall, and overall rate of falls. Falls were defined according to the International Classification of Diseases.

Physical therapists (who were not blind to experimental group) evaluated participants at baseline and after the 3-month intervention. For all participants, the following five measures were assessed: skeletal muscle-mass index (SMI), grip strength, functional-independence measure (FIM), levels of 25-hydroxyvitamin D (25(OH)D), and cognitive functioning. SMI was calculated by bioelectrical-impedance analysis (BIA; InBodyS10, InBody Co. Ltd, Tokyo, Japan) to determine body composition. Participants were assessed via their arms and legs while sitting. Using segmental body composition and muscle mass, appendicular skeletal muscle mass was determined and used in analyses. Muscle mass was converted to SMI by diving appendicular skeletal muscle mass by squared height (kg/m^2). Grip strength was assessed using a hand dynamometer with the participant's arm by their side. Participants squeezed the dynamometer with maximum isometric effort. Grip strength was calculated as the average of two trials. FIM was scored by physical therapists based on activities of daily living. Levels of 25-hydroxyvitamin D were analyzed by blood sample (SLR, Inc., Tokyo, Japan). Cognitive functioning was assessed by Hasegawa's Dementia Scale Revised (HDS-R) which correlates with the Mini-Mental State Examination (MMSE)[22]. Baseline information on age, sex, weight, height, and body mass index (BMI) was collected using medical chart review.

2.3. Intervention

The control group ($n = 23$) was provided usual care. Usual care included advice on environmental adaptations, falls-prevention education, a conference with caregivers, a selection of walking aids, two sessions of individualized exercise for 20 minutes per week, and one session of group exercise for 30 minutes per week. Environmental hazards in each participant's living space were reduced. Falls-prevention education was offered to all staff as a 1-hour educational session. Sessions were conducted by a physical therapist, who highlighted risk factors for falls and possible intervention strategies. The caregivers' conference was held to assess the risk of falls among institutionalized elderly and to discuss some methods to reduce this risk. The walking aids were selected after assessment by a physical therapist. Individualized exercise was designed to improve gait, balance, muscle strength, and transfer skill, and could have included sit-to-stand exercise, balance exercise, and resistance exercise with an elastic band, depending on the participant's abilities. The group exercise included warm-up exercises, sit-to-stand exercise (20 trials $\times$ 1 set), sitting and standing balance exercise, upper and lower-limb resistance exercise with an elastic band, and cool-down activities.

The low-exercise group ($n = 22$) did not perform group exercise, but were provided two sessions of individualized exercise each week. All other services were the same as the control group. The nutrition group ($n = 23$) was given daily oral vitamin D (900 IU), via an Isocal jelly PCF (500 IU) and a supplement (400 IU) (Appendix). Jelly vitamins were eaten at lunchtime and supplements were taken after dinner. Nurses and care workers confirmed that jellies and supplements were taken. The combined group ($n = 23$)

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performed the same exercise as the low-exercise group and received the same vitamin D supplementation as the nutrition group.

2.4. Statistical analyses

Baseline characteristics of each of the four groups were compared using analysis of variance (ANOVA) for continuous variables and chi-square tests for categorical variables. The number of new falls was recorded over a 6-month period. A Kaplan–Meier survival analysis for the incidence of new falls was performed. Cox proportional-hazard regressions were used to model time until first fall for each group compared to controls. A two-way analysis of variance was used to compare pre- and post-intervention measurements to assess the effect of the intervention. All statistical analyses were performed with SPSS version 22 (IBM Corp., New York, NY). $P < 0.05$ was used to indicate statistical significance.

3. Results

A total 97 people were screened, and 91 (93.8%) were enrolled (Fig. 1). Six residents were excluded because they met exclusion criteria. Among the 91 individuals included in the study, 75 (82.4%) completed the 3-month intervention and 6-month follow up: 17 (73.9%) in the control group, 22 (100%) in the low-exercise group, 17 (73.9%) in the nutrition group, and 19 (82.6%) in the combined group. Participants in all four groups were comparable and well matched with respect to their baseline characteristics (Table 1).

During the follow-up period, falls occurred in nine participants (52.9%) in the control group, seven participants (31.8%) in the low-exercise group, six participants (35.3%) in the nutrition group, and four participants (21.1%) in the combined group. In the two-way analysis of variance, group-by-time interactions indicated a clear improvement in 25(OH)D due to vitamin D supplementation. The level of 25(OH)D improved in the nutrition group from (pre) 13.2 ± 5.0 ng/mL to (post) 37.8 ± 11.2 ng/mL, and in the combined group from (pre) 12.5 ± 4.0 ng/mL to (post) 36.3 ± 4.8 ng/mL. However, the other outcome measures were not significantly different among the four groups (Table 2).

Survival-analysis curves are shown in Fig. 2 with a log-rank test comparing the rate of falls among the four groups. In this analysis, control and combined groups were significantly different (log-rank $P < 0.05$). The Cox proportional-hazard regression analysis adjusted for sex and age indicated that the hazard ratios (HR; compared to controls) for the low-exercise group (HR: 0.48, 95% confidence interval [CI]: 0.17–1.30) and nutrition group (0.58, 0.20–1.68) were

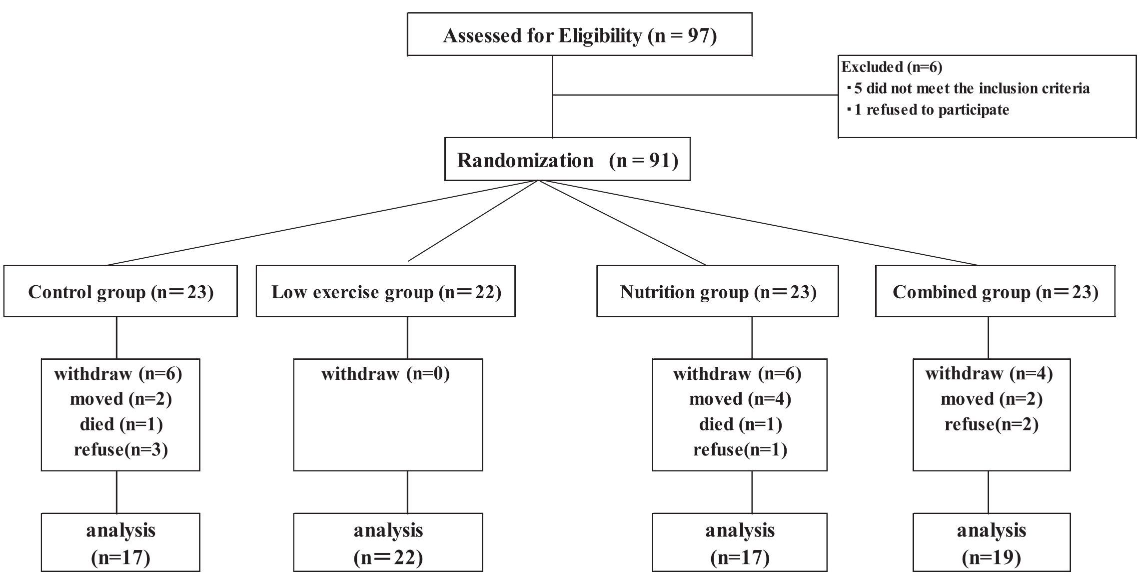

Fig. 1. Flow chart describing the study design.

Table 1
Baseline characteristics and assessment items of study participants according to each group.

	Control n = 23	Low exercise n = 22	Nutrition n = 23	Combined n = 23	P-value
Gender (female), n (%)	15 (65.2)	16 (72.7)	20 (86.9)	18 (78.3)	0.368[a]
Age, mean ± SD	82.5 ± 10.9	82.6 ± 9.1	84.6 ± 7.7	87.6 ± 6.5	0.175[b]
Height (cm), mean ± SD	150.3 ± 9.0	149.9 ± 10.5	147.9 ± 8.3	148.7 ± 9.3	0.814[b]
Weight (kg), mean ± SD	46.7 ± 9.1	46.2 ± 9.3	44.3 ± 7.6	45.0 ± 8.4	0.771[b]
BMI (kg/m^2), mean ± SD	20.6 ± 3.1	20.5 ± 3.2	20.4 ± 3.3	20.4 ± 3.7	0.987[b]
Hand grip strength (kg), mean ± SD	11.6 ± 7.9	11.3 ± 5.2	9.1 ± 5.2	11.2 ± 5.2	0.333[b]
25(OH)D (ng/mL), mean ± SD	11.3 ± 4.4	14.0 ± 6.1	14.1 ± 5.3	12.3 ± 3.8	0.170[b]
SMI (kg/m^2), mean ± SD	7.6 ± 1.2	7.2 ± 1.0	7.4 ± 1.0	7.4 ± 1.0	0.617[b]
HDS-R (score), mean ± SD	14.6 ± 7.9	12.4 ± 7.9	12.8 ± 8.6	12.7 ± 9.5	0.819[b]
FIM (score), mean ± SD	78.9 ± 22.0	84.6 ± 22.4	81.4 ± 27.4	84.5 ± 27.8	0.846[b]
Residents term (day), mean ± SD	315.9 ± 380.6	331.6 ± 222.5	325.6 ± 329.9	337.0 ± 387.4	0.997[b]

[a] Chi-square test.
[b] One-way analysis of variance.

Table 2
Items in four group at pre- and post-intervention.

Items		Baseline (n = 75)	Post (n = 75)	Main effect (time)		Group–time interaction	
		Mean ± SD	Mean ± SD	F-value	P-value	F-value	P-value
Hand grip strength (kg)	Control	10.4 ± 6.7	13.5 ± 7.6	0.422	0.114	2.061	0.114
	Low exercise	11.0 ± 5.3	11.9 ± 4.9				
	Nutrition	7.8 ± 4.4	10.2 ± 5.3				
	Combined	10.6 ± 4.3	11.6 ± 6.1				
25(OH)D (ng/mL)	Control	12.1 ± 4.6	13.0 ± 6.0	20.852	0.000	48.90	0.000
	Low exercise	14.0 ± 6.1	16.0 ± 11.5				
	Nutrition	13.2 ± 5.0	37.8 ± 11.2				
	Combined	12.5 ± 4.0	36.3 ± 4.8				
SMI (kg/m^2)	Control	7.8 ± 1.3	7.5 ± 1.2	0.985	0.405	1.064	0.370
	Low exercise	7.3 ± 1.0	7.1 ± 1.0				
	Nutrition	7.3 ± 1.0	7.2 ± 0.8				
	Combined	7.4 ± 1.0	7.4 ± 0.8				
HDS-R	Control	17.1 ± 7.2	17.0 ± 7.9	1.490	0,225	0.595	0.621
	Low exercise	12.4 ± 7.9	11.4 ± 7.7				
	Nutrition	12.0 ± 8.5	11.6 ± 8.6				
	Combined	13.2 ± 9.2	14.1 ± 8.9				
FIM	Control	83.9 ± 19.8	82.7 ± 20.1	0.856	0.468	0.335	0.468
	Low exercise	84.6 ± 22.4	84.6 ± 22.7				
	Nutrition	81.0 ± 27.7	82.2 ± 28.3				
	Combined	89.0 ± 22.4	87.0 ± 25.0				

Mean ± SD 25(OH)D: 25-hydroxyvitamin D; SMI: Skeletal Muscle Mass Index; HDS-R: Hasegawa's Dementia Scale for Revised; FIM: Functional Independence measure two-way ANOVA.

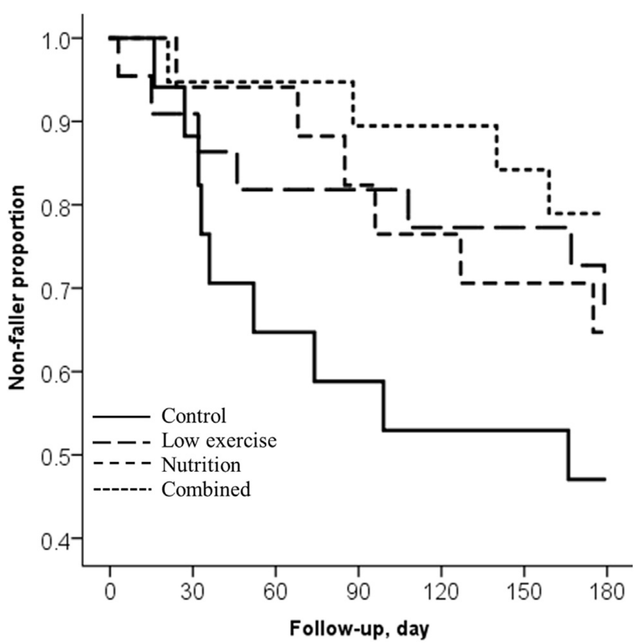

Fig. 2. Falls in follow-up. Kaplan–Meier estimates of the cumulative hazard for falls, for participants whose intervention compliance was 90% or greater. These curves show the differences in fall rate for the four groups. The combined group had a significantly lower fall rate than the control group. Compared with the control group: the low-exercise group (log-rank test, $\chi^2 = 1.9$, P = 0.17), the nutrition group (log-rank test, $\chi^2 = 1.5$, P = 0.22), the combined group (log-rank test, $\chi^2 = 4.4$, P = 0.04).

lower but not significantly different from controls. The combined group had an HR significantly lower than controls (0.28, 0.08–0.92; Table 3).

4. Discussion

Our multifactorial intervention combining low-frequency exercise and vitamin D supplementation was the most effective at preventing falls. This may be attributable to the combined effect of these two interventions wherein exercise and vitamin D both

Table 3
Result of Cox proportional-hazards (adjusted for sex, age).

	n	Hazard ratio	(95% CI)	P
Control	17	1		
Low exercise	22	0.475	0.173–1.301	0.147
Nutrition	17	0.575	0.197–1.678	0.311
Combined	19	0.276	0.083–0.924	0.037

CI: confidence interval.

potentiate the readiness of muscle function. Whereas falls decreased by 52.5% in the low-exercise group and by 42.5% in the nutrition group, the group receiving both of these interventions saw a significant 72.4% reduction in falls compared to controls. This suggests that strategies to prevent falls among institutional elderly residents should include a regulated program of low-frequency exercise and a liberal amount of vitamin D in the diet.

It is noteworthy that in our study, low-frequency exercise (the low-exercise group participated in less exercise than controls) promoted a greater reduction in falls than the 37% decrease due to vitamin D suggested in a Cochrane review[18]. Increasing the frequency of exercise beyond three times a week has been shown to have no effect on preventing falls in institutional residents[23,24]. Furthermore, these reports have pointed out that intensive exercise interventions are not feasible in people with impaired cognitive function, which may be a large proportion of elderly living at care facilities. Exercise interventions of just two or three sessions per week have been shown to effectively prevent falls[14,15,25], and indeed, two studies have shown the effectiveness of such interventions in less than three months[15,24]. Such findings suggest that exercise sessions conducted at a low frequency over as brief a period as three months may be optimal for elderly residents of care facilities. Although increasing the frequency of exercise may lead to greater activity, it does not appear to enhance physical function and may itself increase risk of falling. Thus, to prevent falls the frequency of exercise intervention should be kept relatively low at two sessions per week.

In the present study, vitamin D intake was supplemented for three months with over-the-counter jelly vitamins and supplement tablets that increased 25(OH)D levels to approximately three times their usual value. Elevating 25(OH)D to at least 30 ng/mL can improve stability enough to prevent falls[26] and is thought to possibly retard atrophy of type-II muscle fibers[27]. One study has noted that a daily dosage of 900 IU of vitamin D (through food and supplements) over three months can raise 25(OH)D levels to those recommended by the American Geriatrics Society[28]. Among community-dwelling elderly individuals, vitamin D deficiency is more rare, and vitamin D supplementation has been shown to be ineffective at preventing falls[29]. However, 91.2% of care-facility residents in the present study exhibited vitamin D deficiency, and addressing this deficiency likely had a strong effect on preventing falls.

The current study had several limitations. First, our desired sample size was not obtained, and thus a type-2 error (false negative) may have prevented us from seeing significant benefits of low-exercise or vitamin D supplementation alone. Second, physical therapists were not blind to experimental group. Third, since the study was carried out at a single institution, contact and information exchange between participants could have influenced the results. This may be especially likely since no participants had been recently admitted to the institution and all likely had well-established social circles. Fourth, members of the two groups receiving vitamin D took in 80 Kcal of food per day more than other residents. Fifth, it was not clear how much 25(OH)D levels, SMI values, and grip strength may have varied throughout the observation period as these were not measured.

In conclusion, high-dose vitamin D supplementation and low-frequency exercise may contribute to preventing falls in institutionalized frail elderly. Reducing falls will prolong the disability-free life expectancy of these individuals, which, in turn, will reduce the costs of medical and nursing care.

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Appendix

Table A1
Nutrition supplementation.

	Isocal jelly PCF	Nature made vitamin D
Total calories (kcal)	80	0.95
Protein (g)	4.0	0.1
Fat (g)	1.2	0.1
Carbohydrate (g)	13.3–13.7	0.232
Natrium (mg)	60.0	0–2.0
Water (g)	46.0	0
Kalium (mg)	7.0	0
Calcium (mg)	200.0	0
Magnesium (mg)	2.0	0
Phosphorus (mg)	200.0	0
Iron (mg)	7.0	0
Zinc (mg)	7.0	0
Copper (mg)	0.9	0
Selenium (ng)	25.0	0
Vitamin D (IU)	500.0	400.0
Niacin (mgNE)	1.2	0
Vitamin B_{12} (mg)	0.15–0.66	0

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