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Original article

Effects of unipedal standing balance exercise on the prevention of falls and hip fracture among clinically defined high-risk elderly individuals: a randomized controlled trial

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Abstract
Background. The aim of this study was to assess the effectiveness of the unipedal standing balance exercise for 1 min to prevent falls and hip fractures in high-risk elderly individuals with a randomized controlled trial. This control study was designed as a 6-month intervention trial.
Subjects. Subjects included 553 clinically defined high-risk adults who were living in residences or in the community. They were randomized to an exercise group and a control group.
Methods. Randomization to the subjects was performed by a table of random numbers. A unipedal standing balance exercise with open eyes was performed by standing on each leg for 1 min three times per day. As a rule, subjects of the exercise group stood on one leg without holding onto any support, but unstable subjects were permitted to hold onto a bar during the exercise time. Falls and hip fractures were reported by nurses, physical therapists, or facility staff with a survey sheet every month. This survey sheet was required every month for both groups.
Results. Registered subjects were 553 persons ranging in age from 37 to 102 years (average, 81.6 years of age). Twenty-six subjects dropped out. The number of falls and hip fractures for the 6-month period after the trial for 527 of the 553 subjects for whom related data were available were assessed. The exercise group comprised 315 subjects and the control group included 212 subjects. The cumulative number of falls of the exercise group, with 1 multiple faller omitted, was 118, and the control group recorded 121 falls. A significant intergroup difference was observed. However, the cumulative number of hip fractures was only 1 case in both groups. This difference was not statistically significant.
Conclusions. The unipedal standing balance exercise is effective to prevent falls but was not shown to be statistically significant in the prevention of hip fracture in this study.

Introduction

Injurious falls constitute an important health problem. Changes in the sensory, neurological, and musculoskeletal systems in older adults affect several motor tasks, including postural balance and gait. Various studies have examined the effects of specific exercises on balance in older people with conflicting results.[1,2] Postmenopausal or involutional osteoporosis in elderly people affects the fragility of the proximal femur and may ultimately lead to hip fractures. To prevent hip fracture, there are three methods: (1) prevention of falls,[3,4] (2) treatment of osteoporosis, and (3) hip protectors.[5,6] The unipedal standing exercise is useful for improvement of the proximal femoral bone density and postural balance.[7] To ascertain the effects of unipedal standing training on the prevention of falls and femoral neck

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fracture, the Japanese Orthopaedic Association Osteoporosis Committee conducted a randomized study on individuals clinically defined as high-risk adults, including residents of nursing homes and nursing care facilities and users of outpatient rehabilitation centers.

Subjects

Initially, orthopedic surgery departments at medical schools and universities across Japan were contacted to ask for their recommendations of special nursing homes for the aged and nursing care facilities at which motion exercise training might be accepted and carried out. Subsequently, a questionnaire was mailed to each recommended facility to ask for their participation in the present randomized study. Subjects defined as high-risk adults were residents of special nursing homes for the aged or nursing care facilities who could stand on their own while holding onto a bar, and users of outpatient rehabilitation centers. Dementia patients who had agreement from their family were also enrolled in this study, but severe dementia patients or patients without agreement provided by themselves or family were not enrolled.

Methods

Because the present study was a human trial, the study protocol was reviewed and approved by the Medical Ethics Review Board of Showa University School of Medicine in November 2002. Before participation in this study, all subjects were required to have an institutionally approved informed consent form signed by themselves, family, or the patient's guardians in accordance with the Helsinki Declaration. This form involved agreeing to be randomized to an exercise or a control group. Randomization of the subjects into an exercise group or a control group was performed by the Department of Information Science of our university.

In general, the unipedal standing balance exercise was carried out as follows. With their eyes open, subjects were instructed to stand on their right leg for 1 min and then their left leg for another minute, for a total of 2 min, three times in a day. If a subject was unable to stand on one leg continuously for 1 min and required several breaks, he or she was instructed to stand on either leg until the total duration of one-leg standing reached 1 min. A single set of this one-leg standing balance exercise consisted of standing on the right leg for 1 min and the left leg for 1 min. Each day, subjects performed three sets, one in the morning, one at noon, and one in the afternoon. A control group was observed without exercise in the follow-up period.

The unipedal standing balance exercise was carried out under the guidance of a physical therapist or a similarly qualified individual. The individuals who prescribed and monitored the unipedal standing exercise (or facility staff) were asked to complete a survey sheet every month and mail the survey to the study office (Department of Orthopaedic Surgery in Showa University School of Medicine).

Investigated items

The survey sheet was designed to collect information regarding clinical diagnosis, age, frequency of falls, and fracture site. In addition, the survey sheet also included items that assessed compliance with performance of the exercise as already described. Simultaneously, we ascertained the number of falls over the 6-month period immediately before the study (as indicated by patients' survey responses or ascertained from medical charts). A prospective, randomized, controlled clinical trial with the unipedal standing balance exercise was designed by the Department of Information Science of Show University.

Results

Participating institutions and participants

Before February 2005, survey sheets were received from a total of 32 institutions comprising 24 nursing care facilities, 3 special nursing homes for the aged, and 5 outpatient rehabilitation centers. A total of 553 (142 men and 411 women) subjects were enrolled in the present study. Of these subjects, 397 (94 men and 303 women) were residents of nursing care facilities, 38 (5 men and 33 women) were residents of special nursing homes for the aged, and 118 (43 men and 75 women) were users of outpatient rehabilitation centers.

Age of subjects

Subjects ranged in age from 37 to 102 years. The mean ages of male and female subjects were 77.2 and 83.1 years, respectively. For the exercise and control groups, the mean ages were 81.2 and 82.3 years, respectively. The overall mean age of the subjects was 81.6 ± 9.0 years (mean ± SD). Table 1 shows the age distribution of all subjects.

Medical conditions among subjects

Residents of nursing care facilities and special nursing homes for the aged, and the users of outpatient rehabilitation centers, had various underlying diseases and many patients had multiple diseases and ailments.

Table 2 summarizes the primary underlying diseases of the subjects in the present study.

Unipedal standing balance exercise and fall prevention

Even though grouping was carried out according to the randomized method (table of random numbers), the number of survey sheets received was lower for the control group and the number of falls before the study was higher for the exercise group. Table 3 shows the results at 3 months after the start of the investigation. Subjects (n = 553) included 337 individuals who underwent training to stand on one leg with eyes open (training group) and 216 individuals who did not undergo this training (control group). The number of falls over a 3-month period ranged from 0 (training group, n = 302; control group, n = 189) to 19 (training group, n = 1; control group, n = 0). Table 4 shows the distribution of the number of falls for the 6-month period after training of the 527 subjects for whom the related data were available. The exercise group comprised 315 subjects and the control group comprised 212 subjects.

Effects on the number of falls

A statistical comparison was conducted on the differences in the number of falls between the exercise and control groups. At 3 months, a total of 79 falls were observed for the training group, whereas 58 falls were recorded for the control group. A Fisher's probability test showed no significant difference between the training group (n = 337, 79 falls) and the control group (n = 216, 58 falls) (P = 0.4959). However, after excluding 1 subject in the training group who had multiple falls, the same test showed a significant difference (training group, n = 336, 60 falls; control group, n = 216, 58 falls) (P = 0.0500). At 6 months after training, 1 subject in the

Table 1. Age distribution

Age (years)	Men (n = 142)	Women (n = 411)	Total (n = 553)
37–39	2	0	2
40–44	0	0	0
45–49	3	0	3
50–54	1	2	3
55–59	6	1	7
60–64	3	9	12
65–69	13	9	22
70–74	11	29	40
75–79	35	66	101
80–84	29	104	133
85–89	22	107	129
90–94	16	74	90
95–99	1	8	9
100–	0	2	2

Table 2. Primary underlying disease of subjects

Underlying disease	Number of subjects
Cerebrovascular disorder	204
Dementia	91
Fracture	71
Spinal disease	66
Cardiovascular disease	38
Motor organ disease	32
Diabetes	16
Respiratory organ disease	7
Neuropsychiatric disorder	7
Others	21
Total	553

Table 3. Exercise training and number of falls at 3 months

			Exercise group		Control group			
Number of falls (a)	Number of subjects	Percent	Number (b)	Cumulative number of falls (a × b)	Number (b′)	Cumulative number of falls (a × b′)	Men	Women
0	488	88.2	300	0	188	0	126	362
1	40	7.2	25	25	15	15	9	31
2	12	2.2	7	14	5	10	2	10
3	5	0.9	1	3	4	12	1	4
4	3	0.5	1	4	2	8	0	3
5	1	0.2	0	0	1	5	0	1
6	1	0.2	1	6	0	0	1	0
8	2	0.4	1	8	1	8	2	0
11	0	0.0	0	0	0	0	0	0
12	0	0.0	0	0	0	0	0	0
13	0	0.0	0	0	0	0	0	0
19	1	0.2	1	19	0	0	0	1
Total	553	100	337	79	216	58	141	412

Table 4. Exercise training and number of falls at 6 months

Number of falls (a)	Subjects	Percent	Exercise group		Control group		Men	Women
			Number (b)	Cumulative number of falls (a × b)	Number (b′)	Cumulative number of falls (a × b′)		
0	408	77.4	247	0	161	0	108	300
1	68	12.9	42	42	26	26	13	55
2	20	3.8	14	28	6	12	5	15
3	20	3.8	8	24	12	36	5	15
4	4	0.8	0	0	4	16	0	4
5	1	0.2	1	5	0	0	0	1
6	0	0.0	0	0	0	0	0	0
7	2	0.4	1	7	1	7	1	1
11	1	0.2	0	0	1	11	0	1
12	1	0.2	1	12	0	0	1	0
13	1	0.2	0	0	1	13	1	0
29	1	0.2	1	29	0	0	0	1
Total	527	100	315	147	212	121	134	393

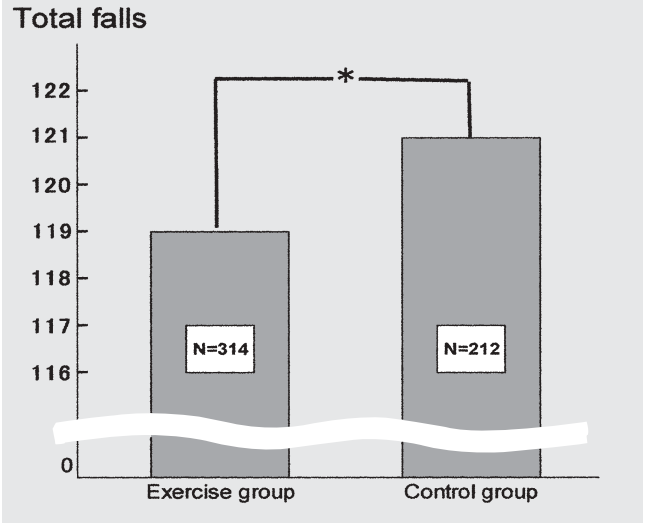

Fig. 1. Relationship of intervention to falls (*Fisher's exact probability test: *$P = 0.0067$; $P < 0.01$)

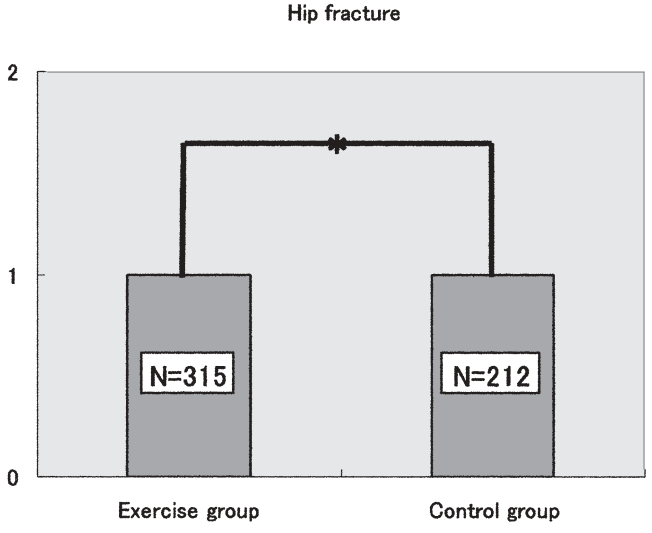

Fig. 2. Relationship of intervention to hip fractures (*Fisher's exact probability test: $P > 0.999$; *NS)

exercise group fell 60 times before the study and a total of 29 times after training; therefore, this subject was excluded from the statistical analysis. A Fisher's exact probability test was used to compare the cumulative number of falls between the exercise and control groups. A significant intergroup difference was observed ($P < 0.01$) (Fig. 1).

At 3 and 6 months after the start of the investigation, individuals who received a longer intervention tended to have lower P values, thus suggesting that the assessment of the effects of the intervention (training to stand on one leg with eyes open) was highly reliable.

Effects of unipedal standing balance exercise on hip fracture

At 1 month after the start of the study, a 61-year-old woman with Recklinghausen's disease in the control group had a femoral neck fracture. At 2 months after the start of the study, an 84-year-old woman with dementia in the exercise group had a femoral neck fracture. This fracture did not occur while the woman was exercising.

The incidence of hip fracture in the exercise group was 0.3% (1/315) whereas the incidence in the control group was 0.5% (1/212). However, this difference was not statistically significant (Fig. 2).

Discussion

The primary causes of hip fracture are osteoporosis of the femoral neck and falls.[8–11] According to an epidemiological study of hip fracture conducted by the Japanese Orthopaedic Association Osteoporosis Committee, a total of 110747 cases of femoral neck fracture were recorded from 1998 to 2000.[12] Of these, 74814 cases (74.0%) were caused by simple falls. Although the prevention of hip fracture using drugs is important,[13–16] these medications are very expensive.[17] From the point of view of cost-to-benefit ratio, a more effective way to prevent hip fracture would be to prevent falls.[3,4,18–20]

The following interventional exercise therapy programs have been demonstrated to be effective for preventing falls: muscle strengthening three times a week, balance training, and walking for 2 months[21]; 1 h muscle strengthening and endurance training three times a week for 6 months[21]; and a group Tai Chi class twice a week with two 15-min sessions of daily individual Tai Chi practice.[22] Although these exercise programs are effective for preventing falls, to remain effective they must be carried out continuously. However, it is difficult to administer an exercise program to elderly residents of nursing homes and nursing care facilities because of the difficulty faced by residents of these facilities in consistently carrying out the exercises. Therefore, it is necessary to design an exercise program that is more convenient for elderly individuals with various diseases who are at a higher risk for falls.

Several studies have reported that standing on one leg for 1 min with eyes open three times a day increases the bone mineral density of the femoral neck region.[23] Furthermore, it has been shown that unipedal standing for 1 min is equivalent to the amount of exercise gained through walking for approximately 53 min.[7]

In the present study, we investigated the effects of unipedal standing for 1 min with the eyes open on the prevention of falls and hip fracture in 553 residents of nursing homes and nursing care facilities. The cumulative number of falls over a 6-month period was 118 for the exercise group ($n = 314$) and 121 for the control group ($n = 212$). A Fisher's exact probability test showed a significant difference ($P = 0.0062$). Accordingly, with statistical significance established at the level of $P < 0.01$, the present exercise program was shown to prevent falls. However, as a single case of hip fracture was observed in each group, we could find no statistically significant intergroup difference for hip fracture incidence.

Conclusions

The results of the present study suggest that standing on one leg for 1 min with the eyes open is effective in preventing falls. Therefore, we believe that facilities should adopt this exercise program to prevent hip fracture among high-risk individuals.

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