

Fig. 1. Flow chart of participants in randomized controlled trial of Ex and HSGS for knee pain.

among the Ex + HSGS, Ex, HSGS, and HE groups. There were no significant differences between the groups in all variables including age, body weight, body mass index, BMD, TUG, degree of knee pain, and chronic medical conditions.

The repeated measure ANOVA showed significant improvements in VAS ( $P = 0.006$ ) and total JKOM score ( $P = 0.034$ ) in the Ex + HSGS group compared with the HE group (Table 2). TUG was significantly faster in the Ex + HSGS and Ex only groups, than in the HSGS or HE groups. The Ex + HSGS group also showed significantly greater changes in all other measures of mobility; usual walking speed ( $P < 0.001$ ), and stride length ( $P < 0.001$ ); as well as grip strength ( $P = 0.001$ ). The GLM analysis showed no

significant differences from baseline to post-intervention in the JKOM subscales of pain and stiffness of the knees, condition in daily life, general activities or health conditions, or in one leg standing time between any of the groups.

Fig. 2 shows the changes in VAS from pre- to post-intervention. Significant improvements were found in the Ex + HSGS group (39.4%,  $P < 0.001$ ) and the HSGS group (26.9%,  $P = 0.032$ ). The improvements were significantly greater in the Ex + HSGS and HSGS groups compared with the HE group.

There was a significant improvement in the Ex + HSGS group (14.2%,  $P < 0.001$ ) for TUG from pre- to post-intervention (Fig. 3). Improvements in TUG were also observed in the Ex

Table 1  
Selected baseline variables of participants by study group.

Variables <sup>a</sup>	Category	M ± SD				F-Value <sup>b</sup>	P-Value
		Ex + HSGS group n = 38	Ex group n = 37	HSGS group n = 38	Education group n = 37		
Age (yr)		80.50 ± 2.41	80.86 ± 2.30	80.29 ± 2.96	80.54 ± 2.70	0.311	0.817
Height (cm)		149.42 ± 6.50	147.70 ± 4.90	149.17 ± 5.87	146.78 ± 4.78	1.888	0.134
Body weight (kg)		51.82 ± 7.89	51.73 ± 8.01	51.46 ± 7.31	50.72 ± 6.25	0.168	0.918
Body fat (%)		32.16 ± 3.69	32.86 ± 4.15	31.58 ± 4.68	32.47 ± 4.10	0.625	0.600
Body mass index (kg/m <sup>2</sup> )		23.16 ± 2.78	23.67 ± 3.20	23.12 ± 2.91	23.59 ± 3.09	0.341	0.796
BMD (g/cm <sup>2</sup> )		0.29 ± 0.06	0.30 ± 0.07	0.29 ± 0.06	0.30 ± 0.06	0.159	0.924
Calf girth (cm)		33.61 ± 2.72	33.66 ± 3.13	33.88 ± 2.93	33.73 ± 2.45	0.063	0.979
Grip strength (kg)		20.70 ± 4.43	19.75 ± 3.71	20.51 ± 4.74	19.81 ± 3.69	0.493	0.688
Usual walking speed (m/s)		1.11 ± 0.24	1.13 ± 0.23	1.11 ± 0.21	1.14 ± 0.27	0.192	0.902
Stride length (cm)		105.84 ± 15.53	103.92 ± 11.37	106.26 ± 16.39	98.64 ± 18.25	1.564	0.202
TUG (s)		8.67 ± 4.01	7.54 ± 1.91	7.80 ± 2.27	8.30 ± 3.63	1.012	0.389
One leg standing time (s)		26.55 ± 23.37	27.05 ± 22.66	31.76 ± 23.58	32.00 ± 24.47	0.586	0.625
Degree of knee pain	Light	55.3	59.5	50.0	48.6	2.066	0.914
	Medium	34.2	27.0	34.2	40.5		
	Severe	10.5	13.5	15.8	10.8		
Falls	Yes	23.7	24.3	21.1	10.8	2.734	0.435
Fear of falling	Yes	92.1	83.8	78.9	83.8	2.622	0.454
Urinary incontinence	Yes	47.4	35.1	39.5	43.2	1.267	0.737
Chronic medical conditions (%)	Stroke	5.3	10.8	7.9	5.4	1.118	0.773
	Heart disease	21.1	29.7	31.6	24.3	1.363	0.714
	Diabetes	15.8	5.4	15.8	8.1	3.179	0.365
	Osteoporosis	44.7	45.9	44.7	43.2	0.055	0.997

<sup>a</sup> Data are presented as M (mean) and SD (standard deviation) for continuous variables, and percentage for categorical variables.

<sup>b</sup> One-way ANOVA for continuous variables and chi-square test for categorical variables.

**Table 2**  
Comparison of physical function and JKOM between groups before and after the 3-month intervention.

Variables	Group	M ± SD		P value <sup>a</sup>	Post hoc analysis
		Baseline	After intervention		
JKOM					
VAS (mm)	Ex + HSGS	36.28 ± 20.89	19.64 ± 16.42	0.006 <sup>a</sup>	Ex + HSGS > HE
	Ex	39.60 ± 24.14	33.77 ± 21.91		
	HSGS	45.68 ± 19.99	34.06 ± 24.54		
	HE	32.76 ± 19.78	37.86 ± 22.58		
Total score (point)	Ex + HSGS	44.74 ± 9.74	41.29 ± 9.10	0.034 <sup>a</sup>	Ex + HSGS > HE
	Ex	45.38 ± 11.59	42.72 ± 11.55		
	HSGS	46.94 ± 13.68	44.29 ± 11.72		
	HE	45.82 ± 12.80	48.24 ± 13.80		
Subscale 1: pain and stiffness in the knees (point)	Ex + HSGS	16.74 ± 5.52	13.96 ± 4.24	0.121 <sup>b</sup>	
	Ex	15.40 ± 4.72	14.00 ± 3.89		
	HSGS	16.25 ± 5.09	15.41 ± 5.19		
	HE	16.94 ± 5.67	17.42 ± 5.93		
Subscale 2: condition in daily life (point)	Ex + HSGS	16.33 ± 4.50	15.11 ± 4.18	0.370 <sup>b</sup>	
	Ex	17.03 ± 4.90	15.93 ± 5.15		
	HSGS	17.34 ± 5.64	16.56 ± 5.08		
	HE	18.52 ± 6.83	18.94 ± 7.06		
Subscale 3: general activities (point)	Ex + HSGS	7.19 ± 1.52	7.59 ± 2.08	0.327 <sup>b</sup>	
	Ex	7.93 ± 2.32	7.93 ± 2.66		
	HSGS	8.44 ± 3.04	8.19 ± 2.66		
	HE	9.30 ± 4.25	8.94 ± 3.03		
Subscale 4: health conditions (point)	Ex + HSGS	4.11 ± 1.28	3.78 ± 1.22	0.603 <sup>b</sup>	
	Ex	4.07 ± 1.36	3.60 ± 1.25		
	HSGS	4.31 ± 1.65	4.09 ± 1.57		
	HE	4.30 ± 1.63	4.45 ± 1.52		
Physical function measures					
TUG (s)	Ex + HSGS	8.47 ± 4.19	7.00 ± 3.00	0.004 <sup>a</sup>	Ex + HSGS, Ex > HSGS, HE
	Ex	7.51 ± 1.96	6.21 ± 1.22		
	HSGS	7.51 ± 2.11	7.28 ± 2.06		
	HE	7.94 ± 2.96	7.65 ± 2.52		
Usual walking speed (m/s)	Ex + HSGS	1.14 ± 0.22	1.36 ± 0.21	<0.001 <sup>a</sup>	Ex + HSGS > HE
	Ex	1.17 ± 0.22	1.40 ± 0.20		
	HSGS	1.13 ± 0.20	1.23 ± 0.19		
	HE	1.14 ± 0.28	1.18 ± 0.27		
Stride length (cm)	Ex + HSGS	105.84 ± 15.53	114.76 ± 14.21	<0.001 <sup>a</sup>	Ex + HSGS > HE
	Ex	103.92 ± 11.37	114.42 ± 12.06		
	HSGS	106.26 ± 16.39	105.86 ± 16.50		
	HE	98.64 ± 18.25	102.53 ± 17.91		
Grip strength (kg)	Ex + HSGS	20.96 ± 4.49	22.15 ± 4.74	0.001 <sup>a</sup>	Ex + HSGS > HE
	Ex	20.47 ± 3.35	21.10 ± 3.09		
	HSGS	20.97 ± 4.87	20.00 ± 4.67		
	HE	19.74 ± 3.71	18.88 ± 3.83		
One leg standing time with eyes open (s)	Ex + HSGS	32.86 ± 24.06	33.46 ± 22.88	0.807 <sup>b</sup>	
	Ex	27.42 ± 23.67	27.74 ± 24.17		
	HSGS	33.21 ± 23.35	27.67 ± 22.29		
	HE	31.89 ± 24.88	28.09 ± 22.19		

<sup>a</sup> a = P value was calculated using ANOVA; b = P value calculated by generalized linear model.

<sup>†</sup> Scheffe post hoc method.

only group (13.2%,  $P = 0.001$ ); however no significant changes were observed in the HSGS (1.9%) and HE groups (2.8%). Significant improvements were observed in the Ex + HSGS group (7.1%,  $P = 0.032$ ) for total JKOM score from pre- to post-intervention (Fig. 3). The ANOVA results revealed that the Ex + HSGS group had significantly greater improvements compared with the HE group in total JKOM score (Fig. 3), although no superiority between the other intervention groups were observed.

The multiple logistics regression showed that significant effects on changes in VAS were observed in the HSGS group (OR = 7.06, 95% CI = 2.37–23.25) and the Ex + HSGS group (OR = 9.88, 95% CI = 3.09–36.88); whereas significance was seen in the Ex + HSGS (OR = 3.73, 95% CI = 1.16–11.99) group on changes in TUG. Only the Ex + HSGS intervention had a significant effect on changes in the

combination of VAS and TUG (OR = 8.60, 95% CI = 2.82–32.73), while the separate HSGS and Ex interventions did not have a significant effect (Table 3).

#### 4. Discussion

The data suggest that heat therapy combined with exercise showed beneficial effects on elderly Japanese women with chronic knee pain, as hypothesized. The combination group observed knee pain reductions of 39.6%, as well as increases in functional mobility as measured by TUG (14.2%). The participants in the Ex group did not show significant improvements in knee pain or JKOM, while the HSGS group showed significant alleviation of knee pain, but not JKOM or functional mobility.

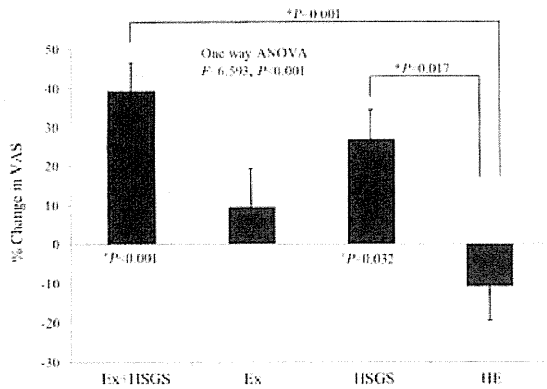


Fig. 2. Percent changes in VAS between study groups. <sup>†</sup>P-value for within-group analyses. \*P-value for between-group analyses.

One previous study reported that exercise treatment can have an 8–27% reduction in knee pain and a 10–39% improvement in function (Deyle et al., 2000). Exercise alone in the current study successfully improved functional mobility, but only reduced knee pain by 9.5%, as measured by VAS. However, exercise combined with the HSGS sheet produced a 39.4% reduction in knee pain and a 14.2% improvement in TUG, a measure of functional mobility, both which are comparable values to those found in previous studies. The improvements observed in the Ex + HSGS group are clinically relevant as several published works have suggested that changes ranging from 12% to 25% may be considered clinically important and could represent meaningful changes in patients with lower-extremity knee pain (Angst, Aeschlimann, & Stucki, 2001; Barr et al., 1994).

Several studies have presented positive results of exercise treatments on knee pain and physical function in elderly adults with knee OA (Deyle et al., 2000; Ettinger et al., 1997; Kovar et al., 1992; Roddy et al., 2005). There has been evidence that exercise can also decrease knee pain through various proposed mechanisms including improved knee cartilage glycosaminoglycan content with increased exercise (Fransen & McConnell, 2008; Roos & Dahlberg, 2005; Tse, Wan, & Ho, 2011); nevertheless, the Ex group only showed a slight, non-significant decrease in stiffness and pain as seen in Table 2. As for non-specific knee pain, the results of this study suggest that exercise alone may be insufficient in relieving pain in community-dwelling elderly people. Recently Woollard et al. (2011) reported that there were no changes in the pain and stiffness subscales of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) in the 17 participants who underwent physical therapy programs similar to the program provided in the current study. However, in comparing the results of the current study with the study by Woollard et al., it is important to note that their study population included those with radiographically diagnosed knee OA, not non-specific knee pain; they compared pain levels from baseline to 1-year follow up, and did

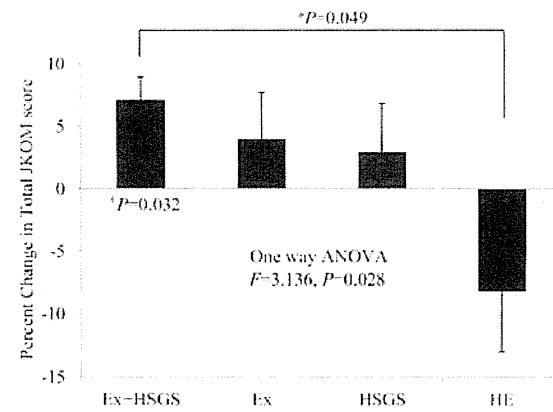
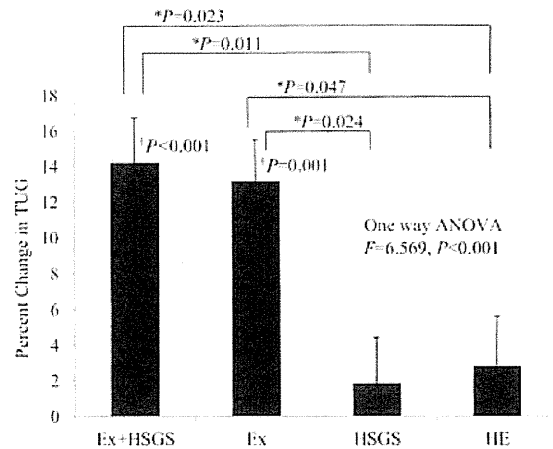


Fig. 3. Percent changes in TUG and JKOM total score. <sup>†</sup>P-value for within-group analyses. \*P-value for between-group analyses.

not report pain levels immediately after the 6-week physical therapy program; and had a very small sample size of 17 people. Nevertheless, both our study and the study by Woollard et al. showed little overall change in pain levels in elderly participants after similar exercise programs. Perhaps the inconsistent evidence of whether exercise can relieve knee pain is due to the differences in exercise dosage (frequency, intensity, and duration), as mentioned by (Fransen & McConnell, 2008). Further research investigating the effects of various exercise dosages on knee pain is required.

The use of HSGS seems to promote significantly greater pain reductions than exercise alone. Our data shows that significant reductions in pain, as measured by VAS, were observed in the Ex+HSGS and HSGS groups. The results support previous findings that have reported the pain-relieving effects of heat

Table 3  
Adjusted ORs with 95% CIs for changes in single and combined variables of VAS and TUG according to study group.

Dependent variable <sup>a</sup>	Adjusted ORs (95% CI)		
	HSGS	Ex	Ex + HSGS
Change in VAS	7.06 (2.37–23.25)	2.82 (0.98–8.50)	9.88 (3.09–36.88)
Change in TUG	0.79 (0.31–2.04)	2.57 (0.87–7.51)	3.73 (1.16–11.99)
Change in VAS and TUG	2.78 (0.92–8.37)	3.12 (0.95–10.26)	8.60 (2.82–32.73)

Reference: HE.

<sup>a</sup> 1 = improve, 0 = no change or decrease.

(Nadler et al., 2002; Seto et al., 2008). While our data could not confirm the mechanisms of HSGS use and exercise on knee pain, Seto et al. suggested that significant alleviation of pain of the knee can improve gait with the use of HSGS due to the increase in soft-tissue flexibility and decrease in pain from improved blood circulation (Seto et al., 2008). Consistent with such previous findings, even in the subjective JKOM subscales used in this study, the results did indeed show significant alleviation of knee pain and stiffness in the Ex + HSGS group. These results seem to suggest that perhaps the combination of exercise and thermal therapy have more beneficial effects on pain and stiffness of the knee than thermal therapy alone in this population.

The Ex + HSGS group improved significantly in measures of functional fitness compared with the HE group, especially in functional mobility measured by TUG. This test was originally developed to easily evaluate the risk of falls using balance and basic functional mobility (Podsiadlo & Richardson, 1991), and there have been recent studies that report the effectiveness of TUG for functional evaluation in knee OA patients (Adegoke, Babatunde, & Oyeyemi, 2012; Zeni, Axe, & Snyder-Mackler, 2010). One particular study (Kennedy, Stratford, Wessel, Gollish, & Penney, 2005), reported that the TUG test has excellent reliability for examining outcomes in persons with knee OA. The TUG test is a test measuring function, and previous studies have shown that knee extensor and flexor muscles training has beneficial effects on functional mobility including standing, walking, lifting, transferring loads and rising from a chair in individuals with rheumatoid arthritis (McMeeken, Stillman, Story, Kent, & Smith, 1999).

Comparably, in the present study, exercise focusing on strengthening the muscles surrounding the knee, combined with HSGS showed significant improvement in TUG in community-dwelling elderly people with non-specific knee pain. While the results of this study did not show that the combination of exercise and HSGS was more beneficial than exercise, our results along with previous studies confirm that exercise and the HSGS is effective in the treatment of not only knee pain, but functional mobility as part of a multifactorial treatment method.

The improvement in functional mobility seen with exercise and HSGS in participants with knee pain is an important finding. We believe the most effective treatment of knee pain involves improvement in not only pain itself, but in functional mobility as well. In our study, we found that the combination of exercise and HSGS had a significant effect on the combined improvements of pain (VAS) and TUG (OR = 8.60, 95% CI = 2.82–32.73; Table 3), suggesting that knee pain treatment using both exercise and heat therapy can have added beneficial effects on pain alleviation and functional mobility improvement compared with exercise or heat therapy alone.

This study has several limitations. First, the measures used to assess pain were based on subjective answers. However, the VAS and JKOM measures have been shown to be valid and reliable methods of assessing degree of knee pain (Akai et al., 2005; Carlsson, 1983). Hence, the validity of the results obtained in this study should not affect the interpretation of the results. Secondly, the data does not show the physiological mechanisms of how HSGS and exercise reduced knee pain. Third, this study did not investigate the long term effects of the exercise and HSGS. Whether or not the reductions in knee pain and improvements in walking ability affected daily physical activity levels in community-dwelling elderly women could not be determined. Fourth, some caution is needed in interpreting the results of this study as a non-thermal placebo group was not included, and the possibility that other non-thermal sensory stimuli may have affected the participants' perception of pain cannot be denied. Moreover, although the ideal study design to examine the pain-relieving effects of the interventions would have been to include a control

group taking established forms of pain relief methods such as non-steroidal anti-inflammatory drugs, this could not be done in the current study. Finally, there were 13 dropouts in this study who were not included in the post-intervention analyses. However, these dropouts have very little effect on the primary outcome of this study, as there were no significant differences in baseline values between the dropouts and the participants. Future research should focus on the physiological changes induced by the combination of exercise and HSGS, long term effects, as well as the comparison of the introduced interventions with other common non-invasive forms of pain alleviation.

## 5. Conclusion

The combined exercise and heat therapy intervention resulted in improvements of knee pain and functional mobility that can be considered clinically important. While both exercise and heat therapy have beneficial effects on physical function and pain, respectively, the combination of both treatments may be beneficial as a wider range of improvements were observed in physical function, pain and QOL.

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## Why not use your own body weight to prevent falls? A randomized, controlled trial of balance therapy to prevent falls and fractures for elderly people who can stand on one leg for $\leq 15$ s

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### Abstract

**Background** Maintaining or improving motor (balance) ability is essential to extending the healthy lifespan of elderly people, and developing effective and efficient strategies to prevent falls of elderly people is an urgent. The purpose of this study was to determine the effects of balance exercise on fall and fracture prevention for elderly people with poor balance.

**Methods** A 6-month, randomized controlled trial was conducted to verify whether one-leg standing with eyes open for a total of 1 min, three times a day (dynamic flamingo exercise) prevents falls and fractures. Setting and

participants were elderly people  $\geq 75$  years of age and one-leg standing time  $\leq 15.0$  s living in their own home. They were visiting orthopaedic clinics for orthopaedic handicaps. Subjects with poor balance were allowed to hold on to something. If a subject's lifted leg touched the ground during the exercise, they were allowed to lift it again and continue so that they stood on one leg for a total of 60 s.

**Results** The dynamic flamingo exercise group (410 people; 86 men, 324 women) and the no exercise group (455 people; 78 men, 377 women) were compared. After dynamic flamingo exercise for 6 months, significant differences were seen in the increase in one-leg standing time with eyes open (men right/left, women right/left), in the improvement in independence in daily living (women), number of people who fell during the 6 months (women),

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and adverse events (women). The number of fractures was not significantly different for men or women.

**Conclusions** Dynamic flamingo exercise prevents falls but no significant difference was demonstrated in fracture prevention in elderly women with poor balance.

## Introduction

As the aging of society accelerates, a very important question is how to maintain daily living functions in elderly people so that they can spend their remaining life comfortably. Elderly people with underlying osteoporosis are susceptible to fractures of the proximal femur, and their mortality 1 year after a fracture is high (10–27 %) [1–3]. Prevention of proximal femur fractures is believed to be beneficial for extending the healthy life span of elderly people. One-third of elderly people  $\geq 65$  years of age are said to fall once a year [4], and more than half of these need to be hospitalized for trauma accompanying the fall [5]. Strategic development and implementation of effective and cost-efficient means of preventing falls of elderly people is a pressing global health challenge. Sherrington et al. [6], conducted a systematic review and meta-analysis of the most effective methods for fall prevention, and concluded that effective methods are training for  $\geq 50$  h during trials, training in standing on both legs with narrow bases of support, or center of gravity balance control training standing on one leg. Walking training was not included among the most effective methods. Selection of methods with superior cost performance must also be considered in exercise training [7].

Haeney [8] listed three elements related to the growth and deterioration of bone: genetics, endocrine activity, and mechanical stress. As seen from this, mechanical stress is a crucial element for bone metabolism. Bone density of the proximal femur of astronauts returning to earth after a space flight of 6 months, during which time there is little mechanical stress, requires a long period of approximately 900 days to return to its original level [9]. Various kinds of exercise therapy are recommended, but this exercise therapy must combine three basic rules:

1. dynamic loading;
2. short duration; and
3. customary mechanical loading environment [10].

To prevent fractures of the proximal femur caused by minor trauma when osteoporosis is a background factor, it is necessary not only to prevent falls but also to apply loads to the proximal femur to increase its density and to improve bone quality and strengthen the bone.

Standing on one leg with the eyes open for 1 min 3 times a day (dynamic flamingo (DF) therapy [11]), uses the fact that one-leg standing places a load on the femoral head that is 2.75 times greater than the load on one leg when standing on two legs. This exercise theory is based on the finding, for the elderly, that the total load on the femoral head when standing on one leg with eyes open for 1 min is equivalent to the total load placed on the femoral head on one side from walking for 53.3 min (160/3 min) [12]. DF therapy has points in common with Tai Chi exercise, which is reported to be effective in preventing falls [13, 14]. It is also reported to be effective in increasing bone density in the proximal femur [15, 16]. DF therapy is exercise that uses the body's own weight as mechanical stress, and it requires no special equipment. It is also a very simple exercise therapy that does not require special exercise instruction. A randomized trial was conducted for 6 months to determine whether this DF therapy is, in general, effective in preventing falls and fractures for elderly people with an orthopedic handicap who live at home. If this therapy were to be effective in fall prevention, it may be beneficial in preventing femoral neck fractures by increasing bone density in the femoral neck and preventing falls.

## Subjects

The subjects were men and women  $\geq 75$  years of age who lived at home and visited an orthopedic clinic or hospital for an orthopedic handicap and who could stand on one leg, both right and left, with the eyes open for  $\leq 15$  s (the Ministry of Health, Labor, and Welfare of Japan designates men and women  $\geq 75$  years of age who can stand on one leg with eyes open for  $\leq 15$  s as having musculoskeletal ambulation disability symptom complex). The time of one-leg standing with eyes open for the left and right legs is measured with the subject standing on one leg with both hands placed at the hips until the subject takes a hand off his or her hip or the other leg hits the floor. The subject is first allowed one attempt as practice, and the second attempt is measured using a stopwatch to the first decimal place. The time of one-leg standing with eyes open was measured for up to 20 s for each leg for elderly individuals

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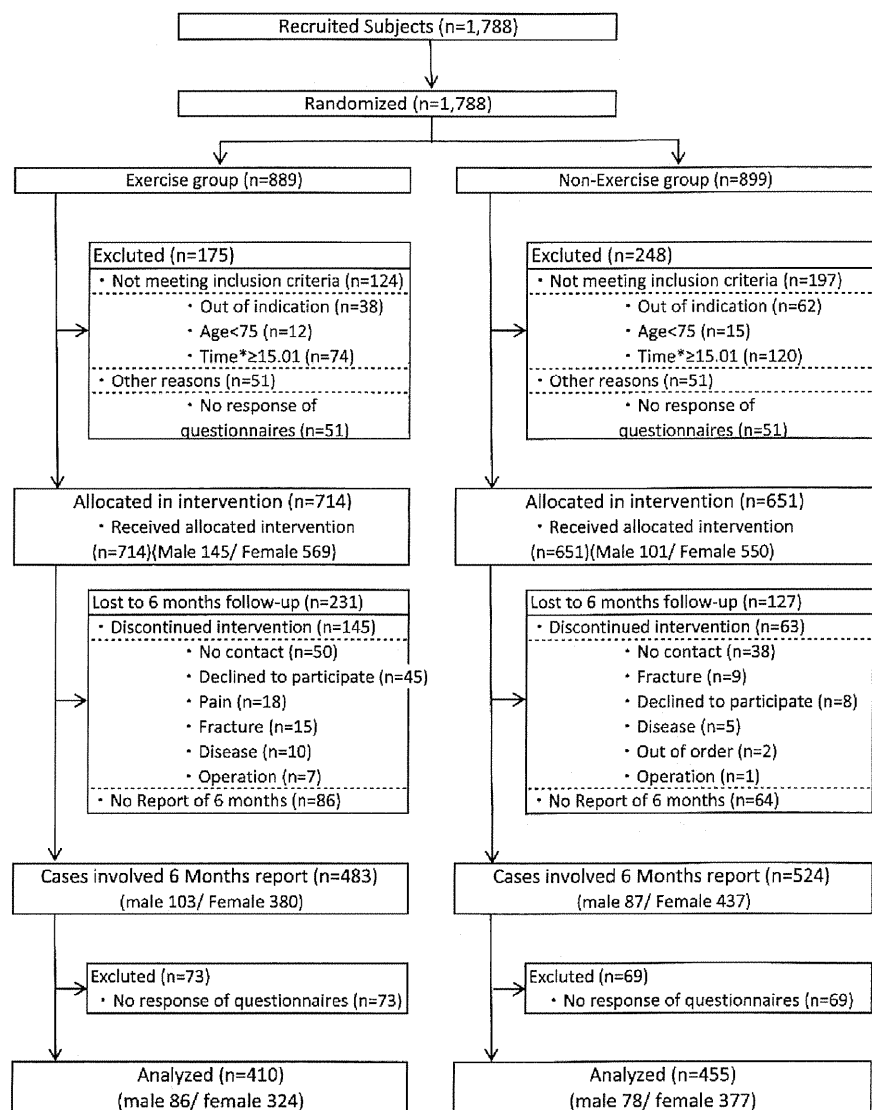
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aged  $\geq 75$  years, and those with a time  $\leq 15$  s for both legs were allocated to the Entry group. To ensure accuracy in judgments of the effect of one-leg standing exercise training, subjects were usually people with the ability to communicate and those who could continue training. It had been recommended to these people that they participate in exercise without DF therapy. After presenting a written explanation, consent was obtained from the subjects in writing for participation in the clinical study. People with Parkinson's disease or other conditions that made them susceptible to falls, people with artificial joints, and people

with cognitive disorders were excluded. From April 2007 until March 2010, 1,788 subjects were recruited (exercise group 889, non-exercise group 899; Fig. 1; flow diagram: trial profile [17]). Those who did not meet the stipulations were excluded, as were subjects with no responses for dominant leg, weight, height, and other items on a questionnaire. Next, those for whom there was no report at the end of the 6 months were excluded. Final reports were collected for 483 people in the exercise group and 524 in the no exercise group. Of these, those with items with no responses in the report were excluded. The comparative

**Fig. 1** Flow diagram trial profile



\*Time: Unipedal standing time



**Table 1** Diagnosis of subjects at baseline survey between exercise group and non-exercise group (the first diagnosis name described on report sheet)

Female				Male	
Exercise group		Non-exercise group		Exercise group	
Diagnosis	<i>N</i>	Diagnosis	<i>N</i>	Diagnosis	<i>N</i>
OA (knee)	97	OA (knee)	97	Spondylosis deformans	24
Osteoporosis	72	Osteoporosis	90	LCS	14
LSD	31	LCS	45	OA (knee)	13
LCS	30	LSD	40	Osteoporosis	6
Spondylosis deformans	18	Vertebral fracture	22	Cervical spondylosis	5
Painful shoulder	10	Cervical spondylosis	21	LDD	4
Cervical spondylosis	8	Non-vertebral fracture	12	Diabetes meritis	4
Hypertension	7	Rheumatic arthritis	10	Lumbar spondylosis	3
Vertebral fracture	6	Painful shoulder	8	Painful shoulder	3
MAD	5	LDD	7	Vertebral fracture	2
Low back pain	4	Heart disease	4	etc.	8
CTS	4	OA (shoulder)	3	Total	86
Non-vertebral fracture	4	MAD	2		
LDD	3	OA (hip)	2	Non-exercise group	
Lumbar disc hernia	3	Low back pain	2	Diagnosis	<i>N</i>
Cranial infarct	3	etc.	13	LCS	16
Rheumatic arthritis	2	Total	378	OA (knee)	15
CDD	2			Spondylosis deformans	13
Scoliosis	2			Osteoporosis	8
Rotator cuff injury	2			Cervical spondylosis	8
etc.	11			Painful shoulder	4
Total	324			Lumbar disc hernia	3
				Rheumatic arthritis	3
				Gout	2
				etc.	6
				Total	78

## Exercise group versus non-exercise group

OA osteo arthritis, LSD lumbar spondylosis deformans, LCS lumbar canal stenosis, MAD musculoskeletal ambulation disability symptom complex, CTS carpal tunnel syndrome, LDD lumbar disc degeneration, CDD cervical disc degeneration, *N* number

analysis was finally conducted with 410 people from the exercise group (86 men, 324 women) and 455 people from the no exercise group (78 men, 377 women).

The ailments diagnosed in each group are listed in Table 1. Among women in both groups, osteoarthritis of the knee was the most common ailment (97 subjects). Among men, spondylosis deformans was the most common in the exercise group (24 subjects), and lumbar canal stenosis was the most common in the no exercise group (16 subjects).

## Methods

Application for approval of this study was made to the Ethics Committee of the School of Showa University, and

the randomized, controlled trial (RCT) was conducted for 6 months after approval was obtained. To prevent feelings of unfairness among participants, random allocation to the intervention group (exercise group) or control group (non-exercise group) was conducted at the institution level, meaning that all participants attending the same institution belonged to the same group. The following randomization method was applied. The  $10 \times 5$  (= 50) random number tables with  $5 \times 5$  (25) numbers were prepared and 2 ten-faced dice (one green, one yellow) were thrown to decide which table to use. Two six-faced dice were then thrown to select the number within the chosen random number table to decide whether the institution would be designated an exercise or non-exercise institution. Dice were repeatedly thrown in this manner until the target number of facilities had been allocated to each group.

Subjects were recruited with the cooperation of the Japanese Orthopaedic Association and the Japanese Society for Musculo-skeletal Rehabilitation over 3 years from April 2007 to March 2010. They were patients undergoing outpatient orthopedic treatment or rehabilitation who could stand on one leg with eyes open for  $\leq 15$  s with both the left and right leg. They were divided into a group that did one-leg standing exercise with eyes open for 1 min 3 times a day and a group that did not do this exercise. The effectiveness of exercise training in preventing falls and fractures was then examined.

In the DF exercise, people with poor balance held on to a table, chair, bar, or other object while standing on one leg (when they became accustomed to this, they stood on one leg without holding on to anything). If their free leg touched the ground, they lifted it once more so the total one-leg standing time was 60 s. They stood on one leg for a total of 1 min in this way 3 times a day with each leg. The basic position for one-leg standing was to have one leg swung slightly forward with the knee bent, but the subjects were free to adopt any one-leg standing position. However, when standing on one leg, precautions such as a table, chair, or bar were in place to prevent falls, in case the person lost his or her balance. The exercise was done as a home exercise so that it could be continued daily. To confirm the exercises were done, every day subjects were asked to complete a "Flamingo Record" with a "●" when the exercises were done 3 times a day, a "Δ" on days of falls, and an "x" for fracture (fracture was confirmed and recorded by a doctor). Exercises were continued every day, but 2 days off a week were allowed, and the Flamingo Record was checked at the time of examination at a clinic once a month.

The initial survey items for the subjects were: 1. sex, 2. date of birth, 3. dominant leg, 4. age at the start of exercise, 5. weight, 6. height, 7. one-leg standing time with eyes open (right, left), 8. name of primary disease, 9. medical history, 10. history of fracture, 11. complications, 12. presence or absence of osteoporosis, 13. medications, 14. number of falls in past year, 15. exercise habit, 16. use of cane or walking aid, and 17. level of ADL independence\*. At the end of 6 months, items 5, 6, 7, 10 (fracture), 14 (falls or no falls, and number), 19 (ADL\*), and 20 (adverse events) were surveyed.

\*ADL: by Long-Term Care Insurance Act (The Ministry of Health, Labor and Welfare of Japan, December 17th 1997) (Table 2).

Statistical analysis was conducted by consulting statisticians (Hamano Statistical Analysis). The software used was SAS System 91.3 (SAS Institute), with the paired *t* test used for means and McNemar's test used for proportions.

**Table 2** Classification of the disability of elderly people

ADL independent (people have some disability but ADL are independent and they go out without help)
J1: Able to go out using public transport
J2: Able to go out to visit neighbors only
ADL dependent (requires assistance to leave home)
A. Lives independently indoors but requires assistance to go out
A1: Goes out with assistance, stays out of bed most of the day
A2: Seldom goes out, has several rests in bed during the day (Nearly bedridden)
B. Requires some assistance living indoors and spends most of the day in bed, although sitting up
B1: Uses a wheelchair to move about, but gets up for meals and to go to the toilet
B2: Moves about in a wheelchair with assistance (Completely bedridden)
C. Spends all day in bed requires assistance to urinate/defecate
C1: Can turn over in bed unassisted
C2: Cannot turn over in bed unassisted

By Long-Term Care Insurance Act (The Ministry of Health, Labor and Welfare of Japan, December 17th 1997)

## Results

A comparison of men and women in the DF exercise group and the no exercise group at the start of the RCT (Table 3) revealed that, in men, there were more users of canes and aids in the no exercise group. Other than that, there were no significant differences in items from dominant leg to level of ADL independence. In women, one-leg standing time was increased with both legs, number of falls in the past year was greater, level of independence in activities of daily living (ADL) was higher in the exercise group. No significant differences were seen in other items between the groups. No significant differences were seen between the groups other than in sex, height, weight, and history of fracture. In a comparison of the DF exercise group and the no exercise group at the completion of the 6-month RCT (Table 4), one-leg standing time on both the right and left legs was clearly and significantly increased in the exercise group. However, no significant difference was seen other than in one-leg standing time in men. In women, on the other hand, in the exercise group, one-leg standing time with both the right and left legs was increased, there were fewer people who fell, and the level of ADL independence was higher. However, no significant difference was seen between the groups in the mean number of falls. There were also significantly more adverse events in the exercise group.

Data for men at the time of baseline for the RCT and after 6 months were compared (Table 5). In the DF exercise group, body weight decreased after 6 months of exercise training, and one-leg standing time with both the right and left legs was increased approximately 3 times. In

**Table 3** Comparison of clinical data at baseline survey between exercise group and the non-exercise group

	Male			Female		
	Exercise group (%)	Non-exercise group (%)	Statistical <i>p</i> value	Exercise group (%)	Non-exercise group (%)	Statistical <i>p</i> value
Number	86	78		324	377	
Dominant leg: right	77 (89.5)	72 (92.3)	0.538 <sup>#</sup>	283 (87.3)	331 (87.8)	0.856 <sup>#</sup>
Age (years)	80.5 ± 4.1	80.7 ± 4.0	0.3548 <sup>§</sup>	80.1 ± 4.0	80.5 ± 4.1	0.199 <sup>§</sup>
Weight (kg)	58.8 ± 9.8	58.5 ± 10.6	0.849 <sup>§</sup>	49.8 ± 8.2	49.6 ± 8.9	0.755 <sup>§</sup>
Height (cm)	158.9 ± 6.1	159.7 ± 6.7	0.458 <sup>§</sup>	147.0 ± 5.9	146.4 ± 6.1	0.191 <sup>§</sup>
One leg time (right)	5.8 ± 4.2	5.6 ± 3.8	0.836 <sup>§</sup>	5.9 ± 4.1	5.1 ± 3.8	0.013 <sup>§</sup>
One leg time (left)	5.2 ± 3.7	5.4 ± 3.6	0.731 <sup>§</sup>	5.9 ± 4.0	5.2 ± 3.8	0.025 <sup>§</sup>
History of fracture	25 (29.1)	27 (34.6)	0.446 <sup>#</sup>	134 (41.4)	167 (44.3)	0.433 <sup>#</sup>
Complication	78 (90.7)	73 (93.6)	0.446 <sup>#</sup>	285 (88.0)	318 (84.4)	0.169 <sup>#</sup>
Osteoporosis	17 (19.8)	14 (17.9)	0.766 <sup>#</sup>	251 (77.5)	276 (73.2)	0.193 <sup>#</sup>
Falls yes/no	23 (26.7)	27 (34.6)	0.274 <sup>#</sup>	120 (37.0)	114 (30.2)	0.057 <sup>#</sup>
No. of falls	0.5 ± 1.3	1.3 ± 3.8	0.09 <sup>§</sup>	1.1 ± 2.2	0.6 ± 2.0	0.005 <sup>§</sup>
Exercise habit yes/no	41 (47.7)	39 (50.0)	0.766 <sup>#</sup>	127 (39.2)	186 (49.3)	0.007 <sup>#</sup>
Use of aids yes/no	16 (18.6)	31 (39.7)	0.003 <sup>#</sup>	114 (35.2)	159 (42.2)	0.059 <sup>#</sup>
ADL Independence	81 (94.2)	71 (91.0)	0.438 <sup>#</sup>	310 (95.7)	344 (91.2)	0.019 <sup>#</sup>

Dominant leg, leg to kick a ball, number of right leg (%); age, average (Av) years ± standard deviation (SD); weight, Av ± SD; height, Av ± SD; one leg time, one leg standing time (seconds) with eyes open, Av ± SD; history of fracture, number with fracture history (%); complication, number of people who had complications (%); osteoporosis, number of people who had osteoporosis (%); falls yes/no, number of people (yes) who had a fall in past year (%); No. of falls, number of falls in 1 year, Av ± SD; exercise habit yes/no, number of people (yes) who have exercise habit (%); use of aids, number of people (yes) who use of cane or walking aid (%); level of ADL, number of people who are independent in activities of daily living (J\*1 + J\*2)

J\*1, J\*2: criteria for independence in ADL by the Ministry of Health, Labour and Welfare of Japan

<sup>#</sup> The paired *t* test for means

<sup>§</sup> McNemar's test used for proportions

the no exercise group, on the other hand, one-leg standing time on the left side increased significantly, but there were no other significant differences.

In a comparison of the data at the time of RCT registration and after 6 months for women (Table 6), after 6 months, weight and height decreased and one-leg standing time with both the right and left leg increased significantly in the DF exercise group. Because the survey period differed for fractures (history), number of people who fell, and number of falls, tests of significance were not conducted. For the women in the no exercise group, on the other hand, one-leg standing time with both the right and left legs was significantly increased, but the increase in the number of seconds was small. It was supposed all participants had some physical treatment at their clinics or hospitals and their therapy was apparent as good effects on time dependence. For both men and women, the one-leg standing time with eyes open in the no exercise group increased significantly after 6 months compared with the time of entry, but the increase in the one-leg standing time with eyes open was much larger in the DF exercise group. The number of fractures, which is viewed as the most important outcome, was 10 in the no exercise group in women

(5 compression fractures of the spine, 3 rib fractures, 1 fracture of the scaphoid bone, and 1 fracture of the proximal femur) versus 3 in the DF exercise group (2 fractures of the distal radius and 1 fracture of the fifth metacarpal bone). The number was larger in the no exercise group, but there was no significant difference. Among men, there was one compression fracture of the spine in the DF exercise group and one fracture of the distal radius in the no exercise group. No significant difference was seen between the groups. There was one adverse event (knee pain) in men and four (knee pain 1, lower limb pain 1, palpitations 1, fall during training 1) in women in the DF exercise groups.

## Discussion

Methods to prevent proximal femur fractures include treatment for osteoporosis, which is a background factor that is a risk for proximal femur fractures, and fall prevention. Currently, many drugs, including bisphosphonates [18, 19], alfacalcidol [20, 21], and selective estrogen receptor modulators (SERM) [22, 23], are widely used for treatment of osteoporosis. Many reports on exercise

**Table 4** Comparison of clinical data at 6-month survey between exercise group and non-exercise group

	Male			Female		
	Exercise group (%)	Non-exercise group (%)	Statistical <i>p</i> value	Exercise group (%)	Non-exercise group (%)	Statistical <i>p</i> value
Number	86	78		324	377	
Weight (kg)	58.4 ± 9.8	58.8 ± 10.9	0.815 <sup>§</sup>	49.3 ± 7.9	49.6 ± 9.1	0.641 <sup>§</sup>
Height (cm)	158.2 ± 7.9	159.4 ± 6.8	0.290 <sup>§</sup>	146.6 ± 6.1	146.2 ± 6.1	0.401 <sup>§</sup>
One leg time (right)	17.7 ± 35.1	6.4 ± 5.0	0.004 <sup>§</sup>	16.2 ± 21.6	7.2 ± 7.9	<0.000 <sup>§</sup>
One leg time (left)	19.3 ± 44.4	6.7 ± 6.0	0.011 <sup>§</sup>	15.0 ± 21.2	6.1 ± 6.1	<0.000 <sup>§</sup>
Cases of fracture	1 (1.2)	1 (1.3)	0.945 <sup>#</sup>	3 (0.9)	10 (2.7)	0.091 <sup>#</sup>
Falls yes/no	10 (11.6)	14 (17.9)	0.253 <sup>#</sup>	46 (14.2)	78 (20.7)	0.025 <sup>#</sup>
No. of falls	0.2 ± 0.8	0.5 ± 1.7	0.183 <sup>§</sup>	0.3 ± 1.2	0.3 ± 0.7	0.687 <sup>§</sup>
ADL independence	82 (95.3)	72 (92.3)	0.416 <sup>#</sup>	313 (96.6)	345 (91.5)	0.005 <sup>#</sup>
Adverse event	1 (1.2)	0 (0.0)	0.339 <sup>#</sup>	4 (1.2)	0 (0.0)	0.031 <sup>#</sup>

Weight, average ± standard deviation (Av ± SD); height, Av ± SD; one leg time, one leg standing time (seconds) with eyes open, Av ± SD; cases of fracture, number of fracture cases (%); falls yes/no, number of people (yes) who had a fall in past 6 months (%); No. of falls, number of falls in 6 months, Av ± SD; ADL independence, number of people who are independent in activities of daily living (J\*1 + J\*2), (%); adverse event, number of adverse events, (%)

J\*1, J\*2: criteria for independence in ADL by the Ministry of Health, Labour and Welfare of Japan

<sup>#</sup> The paired *t* test for means

<sup>§</sup> McNemar's test used for proportions

therapy with the objective of preventing falls have also been published. However, they include reports that such therapy is both ineffective [24, 25] and effective [13, 26, 27]. A common point among reports that exercise therapy is effective in preventing falls is that the exercise is not short, vigorous exercise but slow, sustained mechanical load. Balance control by standing on both legs with a narrow base of support or standing on one leg is also recommended [6, 10].

Although DF exercise is a method of repeating one-leg standing exercise with eyes open for the short time of 1 min, 3 times a day, it is thought to satisfy the three basic rules stated by Turner [10]. DF exercise is a profoundly superior exercise in that it is a means of placing a mechanical load on the femoral head. It is also useful in balance training. In this RCT, the increase in one-leg standing time in the DF exercise groups in both men and women compared with the time of entry (men 3.1–3.7 times, women 2.5–2.7 times longer) was striking. In a study using Cybex II [28], the one-leg standing time with eyes open for elderly people ≥65 years of age reflected the strength of the quadriceps femoris muscle of that person. When knee extensor muscle strength dropped below 0.60 Nm/kg, one-leg standing for 30 s was impossible, and when it dropped below 0.40 Nm/kg, one-leg standing for 5 s was impossible. The increase in one-leg standing time with eyes open resulted in strengthening of that person's quadriceps femoris muscle. One-leg standing with eyes

open also reflects a person's ADL and mortality [29]. Elderly people who can stand on one leg for ≥30 s are judged to be active people. For elderly people ≥70 years old, those who can stand for a long time on one leg with eyes open are reported to have high bone density [30]. Increase in one-leg standing time with eyes open leads to a larger total mechanical stress load on the femoral head, and is advantageous for improving bone density of the proximal femur. There is a good correlation between one-leg standing time with eyes open and the timed up-and-go test, which is used to assess motor ability in elderly people. Measurements of one-leg standing time with eyes open can be used as a simple means of judging the vitality of elderly people.

Looking at the results of this RCT, it can be seen that, while the increase in one-leg standing time with eyes open was marked for both men and women in the DF exercise group, there was a male–female difference in the decrease in the number of people who fell. A significant difference was not seen among men, but a significant difference was seen among women. Comparison of the number of people who were independent in ADL, which is thought to best reflect improvement in the level of vitality from DF exercise, revealed no significant difference between the DF exercise group and the no exercise group in men, but showed that there were significantly more independent people in the exercise group in women. However, no significant difference was seen in either men or women in the mean number of falls.

**Table 5** Comparison of data between baseline and at 6 months (male)

	Male					
	Exercise group (%)			Non-exercise group (%)		
	Baseline	6 months	Statistical <i>p</i> value	Baseline	6 months	Statistical <i>p</i> value
Number	86	86		78	78	
Dominant leg: right	77 (89.5)	–	–	72 (92.3)	–	–
Age (years)	80.5 ± 4.1	–	–	80.7 ± 4.3	–	–
Weight (kg)	58.8 ± 9.8	58.4 ± 9.8	0.028 <sup>§</sup>	58.5 ± 10.6	58.8 ± 10.9	0.353 <sup>§</sup>
Height (cm)	158.9 ± 6.1	158.2 ± 7.9	0.246 <sup>§</sup>	159.7 ± 6.7	159.4 ± 6.8	0.313 <sup>§</sup>
One leg time (right)	5.8 ± 4.2	17.7 ± 35.1	0.002 <sup>§</sup>	5.6 ± 3.8	6.4 ± 5.0	0.089 <sup>§</sup>
One leg time (left)	5.2 ± 3.7	19.3 ± 44.4	0.004 <sup>§</sup>	5.4 ± 3.6	6.7 ± 6.0	0.019 <sup>§</sup>
History of fracture	25 (29.1)	1 (1.2)	– <sup>‡</sup>	27 (34.6)	1 (1.3)	– <sup>‡</sup>
Complication	78 (90.7)	–	–	73 (93.6)	–	–
Osteoporosis	17 (19.8)	–	–	14 (17.9)	–	–
Falls yes/no	23 (26.7)	10 (11.6)	– <sup>‡</sup>	27 (34.6)	14 (17.9)	– <sup>‡</sup>
No. of falls	0.5 ± 1.3	0.2 ± 0.8	– <sup>‡</sup>	1.3 ± 3.8	0.5 ± 1.7	– <sup>‡</sup>
Exercise habit yes/no	41 (47.7)	–	–	39 (50.0)	–	–
Use of aids yes/no	16 (18.6)	–	–	9.7	–	–
ADL Independence	81 (94.2)	82 (95.3)	0.564 <sup>#</sup>	71 (91.0)	72 (92.3)	0.564 <sup>#</sup>
Adverse event	–	1 (1.2)	–	–	0 (0.0)	–

Dominant leg, leg to kick a ball, number of right leg (%); age, average years ± standard deviation (SD); weight, average ± SD; height, average ± SD; one leg time, one leg standing time (seconds) with eyes open, average ± SD; history of fracture, number with fracture history (%); complication, number of people who had complications (%); osteoporosis, number of people who had osteoporosis (%); falls yes/no, number of people (yes) who had a fall in past year (%); no. of falls, number of fall times in 1 year, average ± SD; exercise habit yes/no, number of people (yes) who have exercise habit (%); use of aids, number of people (yes) who use of cane or walking aid (%); level of ADL, number of people who are independent in activities of daily living (J\*1 + J\*2); adverse event, number of people (%)

J\*1, J\*2: Criteria for independence in ADL by the Ministry of Health, Labour and Welfare of Japan

<sup>#</sup> The paired *t* test for means

<sup>§</sup> McNemar's test used for proportions

<sup>‡</sup> No statistical analysis because of different observation period

One-leg standing with eyes open for 1 min 3 times a day can be continued daily without undue effort or the use of special equipment. It is effective not only in the prevention of falls, but also in improving bone density in the femoral neck [30], and it is also expected to be effective in preventing fractures of the proximal femur. In this 6-month RCT, however, no significant difference was seen in prevention of proximal femur fractures (DF exercise group 0 fractures, no exercise group 1 fracture). From these results, it is thought that, although DF exercise is an effective exercise therapy for improving leg muscle strength in men and women who can stand on one leg with eyes open for ≤15 s, in intervention to reduce the number of people who fall, DF exercise results in too small an exercise load for men but is effective exercise therapy for preventing falls in women. In addition, one-leg standing with eyes open may tend to induce pain in the knees or legs because it increases the load on the standing side. It is necessary to prevent falls

during training, and adequate fall prevention instruction (to hold on to a bar or how to put the free leg down on the floor, to fall forward, etc.) is required before implementing the exercise training. For adverse events during DF training, it is thought that leg alignment can be corrected by providing wedge-shaped foot plates to prevent knee and leg pain.

In conclusion, DF exercise is effective exercise therapy for increasing one-leg standing time and improving leg muscle strength in men and women ≥75 years of age who can stand on one leg with eyes open for ≤15 s. DF exercise did not seem to prevent falls in elderly men, but a significant difference in falls was seen in women ≥75 years of age. However, no significant difference was demonstrated for fracture prevention. Even so, an increase in one-leg standing time with eyes open is thought to lead to prevention of fractures of the proximal femur for 75-year-old women with osteoporosis.

**Table 6** Comparison of data between baseline and 6 months (female)

	Female					
	Exercise group (%)			Non-exercise group (%)		
	Baseline	6 months	Statistic <i>p</i> value	Baseline	6 months	Statistic <i>p</i> value
Number	324	324		377	377	
Dominant leg: right	283 (87.3)	–	–	331 (87.8)	–	–
Age (years)	80.1 ± 4.0	–	–	80.5 ± 4.1	–	–
Weight (kg)	49.8 ± 8.2	49.3 ± 7.9	0.001 <sup>§</sup>	49.6 ± 8.9	49.6 ± 9.1	0.781 <sup>§</sup>
Height (cm)	147.0 ± 5.9	146.6 ± 6.1	0.001 <sup>§</sup>	146.4 ± 6.1	146.2 ± 6.1	0.011 <sup>§</sup>
One leg time (right)	5.9 ± 4.1	16.2 ± 21.6	<.000 <sup>§</sup>	5.1 ± 3.8	7.2 ± 7.9	<.000 <sup>§</sup>
One leg time (left)	5.9 ± 4.0	15.0 ± 21.2	<.000 <sup>§</sup>	5.2 ± 3.8	6.1 ± 6.1	0.002 <sup>§</sup>
History of fracture	134 (41.4)	3 (0.9)	– <sup>‡</sup>	167 (44.3)	10 (2.7)	– <sup>‡</sup>
Complication	285 (88.0)	–	–	318 (84.4)	–	–
Osteoporosis	251 (77.5)	–	–	276 (73.2)	–	–
Falls yes/no	120 (37.0)	46 (14.2)	– <sup>‡</sup>	114 (30.2)	78 (20.7)	– <sup>‡</sup>
No. of falls	1.1 ± 2.2	0.3 ± 1.2	– <sup>‡</sup>	0.6 ± 2.0	0.3 ± 0.7	– <sup>‡</sup>
Exercise habit yes/no	127 (39.2)	–	–	186 (49.3)	–	–
Use of aids yes/no	114 (35.2)	–	–	159 (42.2)	–	–
ADL Independence	310 (95.7)	313 (96.6)	0.366	344 (91.2)	345 (91.5)	0.796 <sup>#</sup>
Adverse event	–	4 (1.2)	–	–	0 (0.0)	–

Dominant leg, leg to kick a ball, number of right leg (%); age, average years ± standard deviation (SD); weight, average ± SD; height, average ± SD; one leg time, one leg standing time (seconds) with eyes open, average ± SD; history of fracture, number with fracture history (%); complication, number of people who had complications (%); osteoporosis, number of people who had osteoporosis (%); falls yes/no, number of people (yes) who had a fall in past year (%); <sup>‡</sup>no. of falls, number of falls in 1 year, average ± SD; exercise habit yes/no, number of people (yes) who have exercise habit (%); use of aids, number of people (yes) who use of cane or walking aid (%); level of ADL, number of people who are independent in activities of daily living (J\*1 + J\*2); adverse event, number of people (%)

J\*1, J\*2: Criteria for independence in ADL by the Ministry of Health, Labour and Welfare of Japan

<sup>#</sup> The paired *t* test for means

<sup>§</sup> McNemar's test used for proportions

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**Conflict of interest** The authors declare no conflict of interest related to this study.

#### Appendix: Principal Clinical sites

Furukawabashi Hospital, Kimuramorokado Hospital, Takatsu Chuoh Hospital, Kamiitabashi Dai2 Hospital, Nishikamata Clinic, Kyoudou Clinic, Kuchiishi Hospital, Kobayashi Clinic, Tsurumaki Orthopaedic Clinic, Sawatari Clinic, Kayama Orthopaedic Clinic, Musashiyamato

Orthopaedic Clinic, Suzuki Orthopaedic Clinic, Sekimizu Orthopaedic Clinic, Central Hospital, Sakura Orthopaedic & Rehabilitation Hospital, Fukuzawa Orthopaedic Clinic, Furuoka Orthopaedic Clinic, Maeda Hospital, Yoshimura Orthopaedic Clinic, Chouritu Ogano Central Hospital, Tomakomai Hospital, Toyooka-Central Hospital, Hirosaki City Hospital, Iwate Medical University, Tokyo Kyousai Hospital, Yonehara-Central Hospital, Tokyo Jikeikai Medical University, Toho University Oohashi Hospital, Tokyo Metropolitan Rehabilitation Hospital, Kugayama Hospital, Washiya Hospital, Dokyou Medical University, Rounenbyo-Kenkyusyo Hospital, Shirogane Orthopaedic Hospital, Kikkouman Clinic, Shinnkawabashi Hospital, Yamanashi Prefectural Hospital, Nirasaki City Hospital, Fukui University, Gifu University, Ohgaki Central Hospital, Kouritu Morinomachi Hospital, Mie University, Yamada Orthopaedic Hospital, Maizuru Red-Cross Hospital, PL Hospital, Saiseikai Suita Hospital, Kinki University Sakai Hospital, Kobe 100 Nen Kinen Hospital, Kouritu Toyo-oka Hospital, Hyougo Medical University, Mimuro Prefectural

Hospital, Nara Rehabilitation Centre, Misasa Onsen Hospital, Sanin Rosai Hospital, Kaike Onsen Hospital, Okayama University, Cyugoku Denryoku Hospital, Kosei Sogou Hospital, Kagawa Rosai Hospital, Tosa City Hospital, University of Occupational and Environmental Health, Sinal Cord Injury Centre, Kawashima Orthopaedic Hospital, Ohita Orthopaedic Hospital, Kumamoto University, Miyazaki University, Nichinan Hospital, Komaki Hospital, Iida Hospital, Showa University, Kouritsu Tan-Nan Hospital, Showa University Yokohama Hokubu Hospital, Hiraosaki Kinenn Hospital, Teikyuu University Chiba Medical Centre, Shiota Sogo Hospital, Sekigawara Hospital, Tsusima City Hospital, Minamikawa Orthopaedic Hospital, Isahaya Sogo Hospital, Tkachiho-Mmachi Hospital, Kusimaoto Hospital, Momotake Orthopaedic Hospital, Kumamoto Kino Hospital, Kitade Hospital, Uguisu-Yado Onsen Hospital, Hachiya Orthopaedic Hospital, Yonago Medical Centre, Seibu Shimane Medical Centre, Hiroshima Tetsudo Hospital, Moji Rosai Hospital, Kimachi Rehabilitation Hospital, Ohta Sogo Hospital, Sapporo Eikeigeka-Jyunkanki Hospital, Aomaori Prefectural Hamanasu Medical Centre, Edogawa Hospital, Gamagouri City Hospital, Suga Orthopaedic Hospital, Tamana Central Hospital, Kijima Orthopaedic Clinic, Seigo Clinic, Niigata Rehabilitation Hospital, Nakamura Orthopaedic Clinic, Murai Orthopaedic Hospital, Noto Orthopaedic Clinic, Nakayama Orthopaedic Clinic, Asai Orthopaedic Clinic, Yanagi Orthopaedic Clinic, Kojima Orthopaedic Clinic, Ishizaka Orthopaedic Clinic, YUKiyoshi Clinic, Takahashi Orthopaedic Clinic, Ohkawa Clinic, Motomachi Hospital, Iwate Medical University Hanamaki Onsen Hospital, Mizuhara-Go Hospital, Nissan Tamagawa Hospital, National Center for Geriatrics and Gerontology, Tomizawa Hospital, Sato Hospital, Ehime National Hospital, Ishikawa Prefectural Central Hospital, Chikuma Central Hospital, Ohta Hospital, Mazda Hospital, Ube Kyouritu Hospital, Yokohama City University, Kusunoki Orthopaedic Clinic, Nezu Orthopaedic Clinic, Kubota Orthopaedic Clinic, Saiseikai Otaru Hospital, National Hirosaki Hospital, Sanai Hoppital, Yamanaka Onsen Hospital, Sakasita Hospital, Yoshida Orthopaedic Clinic, Jinsen Onsen-Kaigo Rehabilitation, Suzuka Central Hospital, National Kochi Hospital, Ohita Jyunkanki Hospital, Honma Orthopaedic Clinic, Ishii Clinic, Niigata Prefectural Kamo Hospital, Kuwana Hospital, Nishi Niigata Central Hospital, Akishima Hospital, Namekawa Hospital, Kita Orthopaedic Clinic, Sanyudo Hospital, Yonago Higashi Hospital, Tama Hokubu Medical Centre, Ohdate City Hospital, Mirai Orthopaedic & Pain Clinic, Saku-Daira Orthopaedic Clinic, Minano Hospital, Hiramatu Orthopaedic Clinic, Kurata Hospital, Yourou Orthopaedic Clinic, Takeda Orthopaedic Clinic, Nakane Orthopaedic Clinic, Kanematsu Orthopaedic Clinic,

Ebihara Hospital, Tama Medical Rehabilitation Clinic, Nasu Orthopaedic Clinic, Kichikawa Orthopaedic Clinic, Nagata Clinic, Hirose Clinic, Honda Orthopaedic Clinic, Mikami Orthopaedic Clinic and Mori Orthopaedic Clinic.

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