

Figure 2 Percent change in the walking time and timed up and go tests among the three groups. The means \pm SEM in T1, T2, and T3 groups are shown. * $P < 0.05$.

others. These results are quite unexpected. However, Koster *et al.* compared the leg strength of octogenarians and septuagenarians, and found more rapid decline in leg strength in septuagenarians.¹⁸ Moreover, it has been reported that active community-dwelling elderly men and women respectively lose 0.8% and 0.7% of lean leg mass per year on average.¹⁸ These characteristics of the aging process might account for why the T1 group showed a greater decrease in locomotive functions. Yet, it is possible that a floor effect may account for this longitudinal maintenance of physical performance in the T2 and T3 groups. Previous cross-sectional studies have shown an age-dependent gradual decline in locomotive function,^{4,5} while longitudinal studies have shown a time-dependent decline in locomotive function in community-dwelling older adults.^{6,7} The subjects of these studies were community-dwelling older adults with a relatively high level of performance, presumably equivalent to our study's T1 or T2 groups. However, participants in our study had a wider range of physical performance levels. For example, the reference values for TUG were 8.1 s for persons aged 60 to 69 years old, 9.2 s for persons aged 70 to 79 years, and 11.3 s for persons aged 80 to 99 years.¹⁹ The reference values for the T1 group was 6.9 s, 9.2 s for the T2 group, and 12.7 s for the T3

group. Thus, the level of physical performance may have affected our results.

The T1 group showed a significantly larger decrease in 10-m walking time and TUG than the other groups. An earlier longitudinal study indicated that the age-related decline was accelerated in lower extremity performance.⁷ Walking speed, in particular, is a good predictor for the onset of functional dependence in a Japanese community population.² In the same manner, TUG has been shown to be significantly associated with activities of daily living function in frail older adults.³ Thus, physical training, such as resistance training, maintains level of activity of daily living in healthy elderly is very important.

The T1 group showed an increase in falls (19.5% to 27.2%) and fear of falling (13.0% to 26.0%) in 2010. In general, at least one-third of people aged 65 and older fall at least once annually.^{20,21} In addition, the major risk factor for fear of falling is shown to be history of at least one fall.²² In the T1 group, elderly with a fear of falling were more likely to show a decline in locomotive performance than elderly without a fear of falling. Several studies have indicated that people who are afraid of falling appear to enter a debilitating spiral of loss of confidence, restricted physical activities, physical frailty, lack of social participation, falls, and loss of independence.^{23–28} Therefore, it is possible that the increased fear of falling is associated with decreased locomotive function in T1 group.

There were several limitations of this study that warrant mention. First, although we used TUG to define frailty, TUG may not be sufficient to define frailty. The Edmonton Frail Scale adopts eight other domains such as cognition, general health status, functional independence, social support, medication use, nutrition, mood, and continence other than TUG.²⁹ Further study is required to test the levels of these domains in this cohort. Second, the standard deviations for the percent change values are quite large, which shows major individual differences. These factors may have affected the current results. Third, the results of men and women were combined in this research because of the relatively small sample size. A larger sample size is required to analyze in each gender. Finally, participants were probably more motivated and showed greater interest in health than the general population of older adults.

This was a longitudinal study to demonstrate that the participants with the highest baseline levels of performance were more likely to show a greater decline in locomotive performance than the other groups. Further study is needed to explore the mechanism of a faster decline in physical performance in the robust elderly. Future work should also be done to determine whether the effects of a training program on physical performance differ according to the level of physical well-being.

Table 2 Characteristics of elderly who have or have not fallen and with or without a fear of falling in T1 group

	Falls (2010)		F-value	P-value	Fear of falling (2010)		F-value	P-value
	Falls (2010) (n = 21)	No falls (n = 56)			Fear (n = 20)	No fear (n = 57)		
Age	76.0 ± 6.6	73.1 ± 6.5		0.08 [†]	74.1 ± 7.5	73.9 ± 6.3		0.90 [†]
Height (cm)	155.5 ± 9.7	157.6 ± 8.8		0.49 [†]	158.7 ± 9.7	156.1 ± 8.5		0.34 [†]
Weight (kg)	61.0 ± 14.1	56.2 ± 7.2		0.26 [†]	62.0 ± 10.5	55.0 ± 8.6		0.08 [†]
Gender, female	15 (71.4%)	42 (75.0%)		0.48 [‡]	13 (65.0%)	44 (77.2%)		0.22 [‡]
Walking time (sec)								
2009	7.3 ± 1.5	7.4 ± 7.5	0.03	0.88	7.6 ± 1.6	7.4 ± 1.6	0.11	0.74
2010	8.4 ± 2.5	7.8 ± 1.2			8.9 ± 1.9	7.6 ± 1.8		
Change (%)	8.9 ± 18.6	3.8 ± 15.9			12.3 ± 17.5	2.4 ± 15.4		
Timed up and go (sec)								
2009	7.0 ± 0.9	6.8 ± 0.7	4.34	0.04	7.0 ± 1.1	6.9 ± 0.8	23.22	0.00
2010	7.9 ± 1.6	7.3 ± 1.2 [§]			8.2 ± 1.1	7.1 ± 0.9 [§]		
Change (%)	8.8 ± 15.1	4.6 ± 13.2			12.4 ± 16.9	3.5 ± 11.8		
Functional reach (cm)								
2009	27.7 ± 6.9	29.5 ± 7.0	0.80	0.37	27.9 ± 6.1	29.4 ± 7.3	0.65	0.42
2010	26.7 ± 7.6	30.5 ± 8.9			28.0 ± 7.4	31.0 ± 9.2		
Change (%)	-1.2 ± 24.5	8.2 ± 29.1			4.7 ± 32.8	5.8 ± 26.2		
One-leg standing (sec)								
2009	23.6 ± 32.4	20.5 ± 14.0	0.21	0.65	23.8 ± 14.1	20.7 ± 24.4	0.35	0.56
2010	15.0 ± 11.7	21.0 ± 12.9			22.7 ± 14.9	17.8 ± 11.7		
Change (%)	-11.2 ± -47.2	2.8 ± 39.3			-14.3 ± 27.9	-1.4 ± 46.1		
Five chair stand (sec)								
2009	8.2 ± 2.5	8.6 ± 2.3	6.33	0.02	8.6 ± 2.2	8.5 ± 2.5	0.44	0.51
2010	8.0 ± 2.4	7.1 ± 1.8 [§]			7.5 ± 2.2	7.3 ± 1.9		
Change (%)	-6.1 ± -25.4	14.1 ± 16.4			-10.6 ± 22.1	-13.1 ± 17.2		

[†]Student's *t*-test. [‡] χ^2 test. [§]As calculated by group comparison.

Table 3 Characteristics of elderly who have or have not fallen and with or without fear of falling in T2 group

	Falls (2010)		F-value	P-value	Fear of falling (2010)		F-value	P-value
	Falls (2010) (n = 22)	No falls (n = 54)			Fear (n = 30)	No fear (n = 46)		
Age	79.9 ± 6.6	78.8 ± 7.2		0.57 [†]	79.5 ± 7.9	78.9 ± 6.5		0.72 [†]
Height (cm)	155.0 ± 8.9	155.0 ± 8.0		0.99 [†]	154.6 ± 7.1	155.2 ± 8.9		0.83 [†]
Weight (kg)	58.0 ± 8.5	56.0 ± 8.4		0.62 [†]	57.9 ± 6.8	55.7 ± 9.2		0.54 [†]
Gender, female	17 (77.3%)	43 (79.6%)		0.52 [#]	22 (73.3%)	38 (82.6%)		0.25 [#]
Walking time (sec)								
2009	10.3 ± 1.8	9.5 ± 3.0	0.09	0.76	10.1 ± 2.0	9.6 ± 3.1	0.10	0.75
2010	9.8 ± 1.7	9.2 ± 1.9			10.0 ± 2.0	9.0 ± 1.6		
Change (%)	-6.4 ± 0.1	-4.5 ± 0.3			-1.8 ± 15.0	-7.2 ± 30.0		
Timed up and go (sec)								
2009	9.4 ± 0.7	9.3 ± 0.7	2.70	0.11	9.5 ± 0.7	9.3 ± 0.7	4.31	0.05
2010	9.9 ± 1.5	9.2 ± 1.9			10.1 ± 1.9	8.9 ± 1.6 [§]		
Change (%)	3.1 ± 0.1	-4.8 ± 0.2			4.3 ± 14.2	-7.3 ± 16.7		
Functional reach (cm)								
2009	25.4 ± 6.4	26.9 ± 6.8	0.43	0.52	24.2 ± 5.7	28.0 ± 6.9	0.36	0.56
2010	24.2 ± 6.2	27.9 ± 8.9			24.7 ± 6.9	29.4 ± 8.9		
Change (%)	-4.9 ± 0.3	6.3 ± 0.3			6.3 ± 29.9	5.5 ± 27.1		
One-leg standing (sec)								
2009	7.7 ± 9.1	11.1 ± 14.4	0.00	0.99	11.1 ± 17.4	9.5 ± 9.7	0.01	0.93
2010	6.3 ± 4.9	10.1 ± 11.1			5.8 ± 5.3	11.0 ± 11.4		
Change (%)	-1.4 ± 0.4	-0.1 ± 0.3			-13.8 ± 30.8	7.7 ± 35.1		
Five chair stand (sec)								
2009	10.6 ± 3.1	10.3 ± 1.5	0.01	0.93	10.7 ± 1.5	10.2 ± 2.4	5.84	0.02
2010	10.4 ± 4.2	9.2 ± 2.8			11.3 ± 3.0	8.2 ± 2.7 [§]		
Change (%)	-8.9 ± 0.1	-12.4 ± 0.2			2.6 ± 17.7	-22.0 ± 16.8		

[†]Student's *t*-test. [#] χ^2 test. [§]As calculated by group comparison.

Table 4 Characteristics of elderly who have or have not fallen and with or without fear of falling in T3 group

	Falls (2010)		F-value	P-value	Fear of falling (2010)		F-value	P-value
	Falls (2010) (n = 28)	No falls (n = 50)			Fear (n = 37)	No fear (n = 41)		
Age	82.0 ± 6.4	82.0 ± 7.3		0.99 [†]	83.9 ± 7.6	80.1 ± 6.8		0.02 [†]
Height (cm)	155.6 ± 9.8	155.9 ± 11.5		0.94 [†]	153.2 ± 10.8	161.5 ± 8.0		0.07 [†]
Weight (kg)	49.2 ± 5.4	56.3 ± 10.8		0.14 [†]	52.0 ± 11.6	59.5 ± 8.4		0.09 [†]
Gender, female	20 (71.4%)	40 (80.0%)		0.17 [#]	28 (75.7%)	32 (78.0%)		0.35 [#]
Walking time (sec)								
2009	11.87 ± 2.01	12.99 ± 2.94	3.53	0.07	12.6 ± 2.7	12.6 ± 2.7	0.14	0.71
2010	12.47 ± 2.89	12.27 ± 2.54			12.3 ± 2.2	12.4 ± 3.1		
Change (%)	2.91 ± 14.69	-7.09 ± 21.47			-3.6 ± 22.4	-3.4 ± 17.2		
Timed up and go (sec)								
2009	12.92 ± 1.08	12.73 ± 1.21	0.52	0.47	12.9 ± 1.2	12.7 ± 1.1	0.36	0.55
2010	12.91 ± 2.58	13.28 ± 4.03			13.3 ± 3.5	13.0 ± 3.7		
Change (%)	-3.17 ± 17.78	2.40 ± 26.53			2.0 ± 23.7	3.4 ± 23.8		
Functional reach (cm)								
2009	22.42 ± 7.11	20.69 ± 7.06	0.37	0.55	22.4 ± 7.5	20.3 ± 6.6	0.01	0.92
2010	22.92 ± 5.56	20.11 ± 6.72			21.6 ± 5.9	20.3 ± 7.0		
Change (%)	5.68 ± 25.46	-2.01 ± 43.44			-5.1 ± 37.1	1.4 ± 39.3		
One-leg standing, sec								
2009	4.47 ± 3.28	5.29 ± 5.80	0.16	0.69	4.7 ± 4.0	5.3 ± 6.0	0.49	0.49
2010	3.67 ± 2.92	4.29 ± 4.08			3.6 ± 3.2	4.6 ± 4.2		
Change (%)	-8.63 ± 38.58	-0.62 ± 45.06			-2.7 ± 41.0	-1.4 ± 45.9		
Five chair stand (sec)								
2009	14.89 ± 3.39	12.90 ± 3.94	0.41	0.53	13.1 ± 3.4	14.3 ± 4.6	1.79	0.19
2010	15.72 ± 6.70	12.57 ± 4.67			14.1 ± 6.3	12.7 ± 3.8		
Change (%)	3.44 ± 24.64	-4.73 ± 30.54			1.6 ± 30.8	-8.0 ± 24.5		

[†]Student's *t*-test. [#]χ² test.

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ORIGINAL ARTICLE: EPIDEMIOLOGY,
CLINICAL PRACTICE AND HEALTH

Complex obstacle negotiation exercise can prevent falls in community-dwelling elderly Japanese aged 75 years and older

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Objectives: The aim of the present study was to evaluate whether a complex course obstacle negotiation exercise (CC), a 24-week exercise program, can reduce falls and fractures in older adults, as compared with a simple course obstacle negotiation exercise (SC).

Methods: This trial was carried out on older adults, aged 75 years and above in Japan. In total, 157 participants were randomized into the CC group ($n = 78$) and the SC group ($n = 79$). Participants were enrolled in the exercise class using the CC program or the SC program for 24 weeks. The outcome measure was the number of falls and fracture rates in CC and SC groups for 12 months after the completion of the 24-week exercise class.

Results: Two participants (2.8%) in the CC group and 19 (26.0%) in the SC group experienced falls during 12 months. During the 12-month follow-up period after the intervention, the incidence rate ratio (IRR) of falls in the SC group against the CC group was 9.37 (95% CI = 2.26–38.77). One participant (1.4%) in the CC group and eight (10.9%) in the SC group had experienced fractures during 12 months after the exercise class. The IRR of fractures in the SC group compared with the CC group was 7.89 (95% CI = 1.01–61.49).

Conclusions: The results of the present trial show that the participants who received individualized obstacle avoidance training under complex tasks combined with a traditional intervention had a lower incidence rate of falls and fractures during the 12 months after the intervention. *Geriatr Gerontol Int* 2012; 12: 461–467.

Keywords: fall prevention, obstacle negotiation exercise, older adults, randomized controlled trial.

Introduction

Falls are relatively common events in older people. One-third of community-dwelling people, aged 65 years and older, and up to 50% of those aged 80 years and older

experience a fall each year.^{1,2} A previous study also reported that in community-dwelling elderly individuals, over 50% of the falls are a result of trips and slips that usually occur during walking.³ In many of these cases, there is an external factor, such as an obstacle, that provokes and contributes to the fall.⁴ In addition, the incidence of osteoporotic fractures is reported to increase with age,⁵ and more than 50% of all fragility fractures in the community arise in women aged 75 years and older.⁶ A recent systematic review of fall prevention programs has convincingly shown that exercise interventions are effective for reducing the risk of

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falls and fall injuries.^{7,8} However, the kind of exercise intervention most effective for fall prevention is not fully addressed.

Concurrent cognitive or motor tasks, such as talking or carrying objects, are crucial for mobility in daily life. Because of the increasingly recognized role of cognition in postural control and gait, many researchers have used complex task paradigms incorporating a concurrent cognitive task to improve their studies investigating fall risk.⁹ Changes in performance during multitasking are significantly associated with an increased risk for falls in older adults.⁹ The ability to modulate attention might also play an important role in the acquisition of complex task coordination skills. Therefore, we developed a trail walking exercise (TWE), in which a person walks from numbered flags in either an ascending or descending order, to evaluate cognitive and motor function simultaneously.¹⁰ Our previous randomized controlled trial (RCT) showed that TWE has the benefit of decreasing the incidence of falls in community-dwelling elderly adults.

In everyday life, when walking in a challenging and distracting environment, older people might have to avoid ground level obstacles when their attention is divided. In this instance, obstacle-avoidance performance is likely to be further impaired, as shown by most multitask research among older adults.^{11–13} In addition, Jasmine *et al.* reported that when their attention is divided, older people negotiate obstacles more slowly and contact more obstacles.¹⁴ Therefore, in the present study, we added obstacles to the area of TWE (complex course obstacle negotiation) to mimic a “real world” walking environment with a high fall risk.

The present RCT examined the effect of fall and fall-related fracture prevention programs on attention demands of obstacles during walking under complex task conditions in community-dwelling elderly Japanese adults aged 75 years and older. The aim of the present study was to evaluate whether the complex course obstacle negotiation exercise (CC), a new 24-week exercise program, would be effective in reducing falls and fall-related fractures in community-dwelling older adults. We hypothesized that complex task walking is improved to a greater extent with the CC program than with the simple course obstacle negotiation exercise (SC). From these results, we can assume that the CC program is more effective in preventing falls and fall-related fractures than is the SC program.

Methods

Participants

Participants were recruited using an advertisement in the local press. The following criteria were used to screen participants in an initial interview: age 75 years

and older, community-dwelling, had visited a primary care physician within the past 3 years, had no severe cognitive impairment (Rapid Dementia Screening Test [RDST] score of 4 or less),¹⁵ can walk independently (or with a cane), willingness to participate in group exercise classes for at least 6 months, has access to transportation, has no significant hearing and vision impairments, and had no regular exercise in the past 12 months.

The interview was also used to exclude participants based on the following exclusion criteria: severe cardiac, pulmonary or musculoskeletal disorders; comorbidities associated with greater risk of falls, such as Parkinson disease and stroke; and use of psychotropic drugs. Written informed consent was obtained from each participant for the trial in accordance with the guidelines approved by the Kyoto University Graduate School of Medicine and the Declaration of Human Rights, Helsinki, 1975.

Study design and randomization

Participants were randomized into two groups. Opaque envelopes bearing group names were numbered and the 157 participants were then randomly assigned to either the CC ($n = 78$) or SC ($n = 79$) group.

Intervention

All participants received 45 min of group training sessions once a week for 24 weeks. Participants were randomly assigned to one of the two training groups: standardized training with CC and standardized training with SC.

The exercise class was individualized for each group and supervised by a physiotherapist. Each exercise class used a standardized format that included 10 min of moderate-intensity aerobic exercise, 15 min of progressive strength training, 10 min of flexibility and balance exercises, and 10 min of cool-down activities. The aerobic exercise consisted of movement of the legs, trunk and arms to involve all joints and major muscle groups in activities, such as dancing. Strength training consisted of progressive resistive exercises using an elastic band. A sequence of progressively more difficult exercises was also carried out to improve static and dynamic balance. Although exercises could be carried out in a sitting position, the importance of carrying the exercises out in a standing position to improve balance was stressed. Physiotherapists evaluated the participants twice during the study period to ensure adherence with exercise protocols during classes.

Complex course with obstacle negotiation exercise

In the CC training field, the flags and obstacles were positioned as shown in Figure 1.¹⁰ Flags were randomly

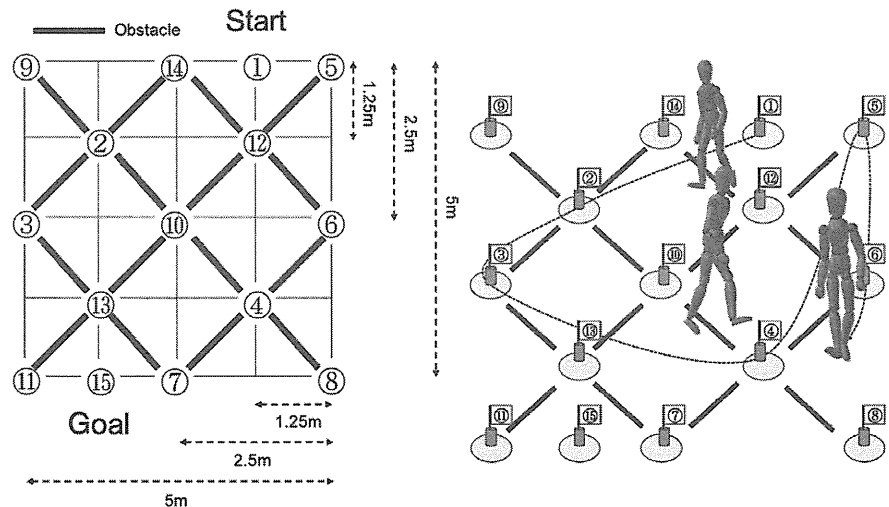


Figure 1 Schematic representation of the complex course obstacle negotiation exercise. Participants were asked to pass sequentially from numbers 1 to 15 as quickly and as correctly as possible during obstacle avoidance.

moved for each trial: Participants in the CC group were asked to sequentially pass from number 1 to 15 while avoiding the obstacles (Fig. 1). A 30-cm diameter circle was drawn on the ground around each flag, and the participants were required to step in the circle to pass the flag. The height of the flag was 30 cm. The tester gave the following instructions to participants, "Please move to flag number 15 as quickly and correctly as possible while avoiding obstacles". Throughout the weeks, the obstacles were made increasingly more difficult for participants to notice. The obstacles consisted of 16 wooden white (contrasting the floor colour) blocks (3, 100 and 1 cm in height, length and width, respectively) in weeks 1–6, wooden black blocks (2, 100 and 1 cm in height, width and depth, respectively) in weeks 7–12, wooden dark brown blocks (1, 100 and 1 cm in height, length and width, respectively) in weeks 13–18 and wooden brown (matching the floor colour) blocks (0.5, 100 and 1 cm in height, length and width, respectively) in weeks 19–24. Flag and obstacle positions were changed on each day of training. Participants carried out two sets of the CC program per training session.

Simple course with obstacle negotiation exercise

Participants were asked to walk along a walkway at a self-selected speed and to avoid contact with the obstacles. These sessions were designed as controls for the additional physical activity in the CC session. Participants walked along a level walkway, 15 m in length. The obstacles used in the simple course were as follows: six wooden white (contrasting the floor colour) blocks (3, 100 and 1 cm in height, length and width, respectively) in weeks 1–6, wooden black blocks (2, 100 and 1 cm in height, length and width, respectively) in weeks 7–12, wooden dark brown blocks (1, 100 and 1 cm in height, width and depth, respectively) in weeks 13–18,

wooden brown (matching the floor colour) blocks (0.5, 100 and 1 cm in height, length and width, respectively) in weeks 19–24. These obstacles were placed across the walkway at intervals randomly ranging from 30 to 150 cm for each day of training. Each participant carried out six walking trials.

Falls and fall-related fractures

The primary outcome of this trial was the occurrence of falls and fall-related fractures during the follow-up period of 12 months after the intervention was completed. Falls were defined as all situations in which a participant suddenly and involuntarily came to rest on the ground or at a surface lower than their original station.¹⁶ Falls resulting from extraordinary environmental factors (e.g. traffic accidents or falls while riding a bicycle) were excluded. The participants were asked to record any falls in fall diaries mailed every month by research assistants. If participants failed to send the fall diaries, research assistants collected data on falls over the telephone. All participants who had fallen were interviewed during these calls using a structured questionnaire about a fall event and its consequences. The diagnosis of fractures was based on radiological evidence of fracture.

Secondary outcome measures

For all participants, the following six measurements were obtained: 10-m walking time,¹⁷ the timed up and go (TUG) test,¹⁸ the functional reach (FR) test,¹⁹ the one-leg stand (OLS) test,²⁰ the SC test, and the CC test. A physiotherapist blinded to group allocation administered these measures at baseline, on completion of the 24-week intervention. All baseline measures were completed before randomization. Before the study started,

all staff members received training on correct protocols for administering all assessment measures included in the study from one of the authors (MY). If a walking aid was normally used at home, this aid was used during the TUG test, 10-m walking, SC test and CC test.

In the 10-m walking, participants walked 15 m at a speed at which they felt comfortable. A stopwatch was used to record the time required to reach the 10 m point that was marked in the middle of this walk. The time recorded in two trials was averaged as the walking score.

In the TUG test, participants were asked to stand up from a standard chair with a seat height of 40 cm, walk a distance of 3 m at a maximum pace, turn, walk back to the chair, and sit down. The time recorded from two trials was averaged to obtain the TUG score.

In the FR test, each participant was positioned next to a wall with one arm raised at 90° and fingers extended. A meter stick was mounted on the wall at shoulder height. The distance that a participant could reach while extending forward from an initial upright posture to the maximal anterior leaning posture without moving or lifting the feet was visually measured in centimetres according to the position of the tip of the third finger against the mounted meter stick. The distances measured in two trials were averaged to obtain the FR score.

In the OLS test, participants were instructed to start from a standing position with a comfortable base as support with eyes open and arms at their sides. They were then instructed to stand unassisted on either leg. OLS was measured in seconds from the time one foot was lifted from the floor to when it touched the ground or the standing leg.

In the SC test, participants were asked to walk along the walkway at a self-selected speed and to avoid contact with the obstacles. Participants walked along a level walkway, 10 m in length. The simple course consisted of six wooden white (contrasting the floor colour) blocks (3, 100 and 1 cm in height, length and width, respectively). These obstacles were placed across the walkway at intervals of 2 m. Time to complete each walking trial was recorded using a stopwatch. The number of obstacles contacted was recorded. The SC test was carried out only once for each participant at each time-point.

In the CC test, the field test was the same as that used for the CC exercise (Fig. 1). The complex course consisted of 16 wooden white (contrasting the floor colour) blocks (3, 100 and 1 cm in height, length and width, respectively). The test-retest reliability using the intra-class correlation coefficient was 0.935. The positions in which the flags and obstacles were placed are shown in Figure 1. The tester gave the following instruction to the participants: "Please move to number 15 as quickly and as correctly as possible while avoiding obstacles". Time to complete each walking trial was recorded using

a stopwatch. The number of obstacles contacted was recorded. The CC test was carried out only once for each participant at each time-point.

Required sample size

A previous study showed that approximately 30% of the Japanese community-dwelling adults, 65 years of age or older, fall at least once a year. This result was consistent with a previous report.² We designed the current study to detect a 30% difference in fall rate between the groups (CC group = 10% and SC group = 30%), for which a sample size of 72 per group ($\alpha = 0.05$ and power = 80%) was necessary. With an estimated dropout rate of 5%, a final sample size of 76 per group was required.

Statistical analysis

Baseline characteristics of CC and SC groups were compared to examine the comparability of the two groups. Differences in the physical function variables between the two groups were analyzed using the Student's *t*-test or χ^2 -test.

The number of falls and fall-related fractures was calculated from the beginning of the study to the participant's death, withdrawal from the trial or the end of the 12-month follow-up period. Confidence intervals (CI) for the falls and fall-related fracture rates were calculated assuming that the number of falls and fall-related fractures followed a negative binomial distribution. Incidences of falls and fall-related fractures with 95% CI were calculated for participants in the CC and SC groups, and compared using negative binomial regression analysis. Results were presented using incident rate ratios (IRR) with their 95% CI. The effect of exercise on outcome measurements was analyzed using a mixed 2×2 (group [CC and SC groups] \times time [pre-training, post-training]) analysis of variance. Post-hoc Tukey tests were used to assess which group or time periods showed significant differences.

Data were entered and analyzed using the SPSS (Windows version 18.0, SPSS, Chicago, IL, USA). A *P*-value of <0.05 was considered statistically significant for all analyses.

Results

Overall, 207 people were screened, and 157 (75.8%) who met the inclusion criteria for the trial and agreed to participate were enrolled (Fig. 2). Of the individuals not meeting the inclusion criteria ($n = 50$), most were excluded because they had exercised regularly in the 6 months before screening. Seven people who were eligible for the study withdrew their participation after a

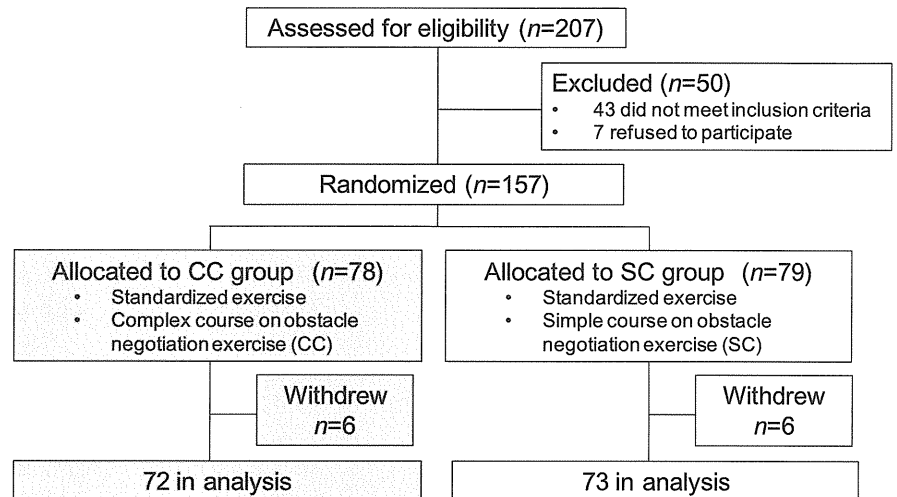


Figure 2 A flow chart showing the distribution of participants throughout the trial.

Table 1 Baseline characteristics of the study participants in complex course obstacle negotiation exercise and simple course obstacle negotiation exercise groups

Characteristic	CC group <i>n</i> = 72	SC group <i>n</i> = 73	<i>P</i>
Age (years)	85.8 ± 5.9	85.3 ± 5.7	0.71
Bodyweight, (kg)	44.9 ± 9.8	47.8 ± 9.4	0.36
Height (cm)	145.1 ± 9.0	147.8 ± 9.2	0.22
Female, <i>n</i> (%)	63 (88.7%)	64 (86.5%)	0.59
RDST (points)	7.5 ± 2.2	7.6 ± 2.5	0.80
Medication (<i>n</i>)	3.7 ± 2.9	3.8 ± 3.3	0.89
Walking aids, <i>n</i> (%)	34 (47.2%)	30 (41.1%)	0.28
Falls in the last year, <i>n</i> (%)	28 (38.9%)	29 (39.7%)	0.59

CC, complex course obstacle negotiation exercise; RDST, Rapid Dementia Screening Test; SC, simple course obstacle negotiation exercise.

telephone screening. Of the 157 individuals selected for the study, 145 (92.3%) completed the 12-month follow up: 72 in the CC group (92.3%) and 73 in the SC group (92.4%).

All 24 scheduled intervention sessions were completed. The median relative adherence was 96% (25th to 75th percentile, 88–100%) in the CC group and 96% (88–100%) in the SC group. No fall incidents occurred during training sessions or testing. No health problems, including cardiovascular or musculoskeletal complications, occurred during training sessions or testing. Minor problems observed in both groups were muscle ache after the first training sessions and fatigue. All problems were managed easily using adjustment of the intervention, and they improved during the intervention. Participants in the CC and SC groups were comparable and well matched with regard to their baseline characteristics (Table 1).

Two participants (2.8%) in the CC group and 19 (26.0%) in the SC group had experienced falls during the 12 months after the exercise program. During the 12-month follow-up period, the IRR of falls in the SC group against the CC group was 9.37 (95% CI 2.26–38.77). One participant (1.4%, distal radius *n* = 1) in the CC group and 8 (10.9%, distal radius *n* = 2; proximal humerus *n* = 3; hip *n* = 3) in the SC group experienced fall-related fractures during the 12-month follow-up period. The IRR of fall-related fractures in the SC group against the CC group was 7.89 (95% CI 1.01–61.49).

Participants in the CC group had significantly greater improvements in secondary outcome measures including the performance time and the number of obstacles contacted under the CC condition (*P* < 0.05) (Table 2). However, other secondary outcome measures were not significantly different between the two groups (*P* > 0.05).

Table 2 Functional fitness items in each group at pre- and postintervention

Item	Pre-intervention	Postintervention	Group \times Time Interaction <i>F</i> -value	Interaction <i>P</i> -value
10-m walking time (s)				
CC group	16.2 \pm 7.4	14.1 \pm 4.4	0.01	0.91
SC group	18.6 \pm 10.0	15.1 \pm 6.2		
10-m walking step (<i>n</i>)				
CC group	27.5 \pm 8.1	26.6 \pm 7.2	1.08	0.30
SC group	31.6 \pm 14.3	27.3 \pm 9.9		
TUG (s)				
CC group	13.6 \pm 5.2	13.7 \pm 5.3	0.18	0.67
SC group	18.3 \pm 9.4	14.8 \pm 7.1		
Functional reach (cm)				
CC group	15.9 \pm 9.3	16.1 \pm 8.2	3.21	0.08
SC group	13.8 \pm 7.5	14.0 \pm 6.8		
One leg standing (s)				
CC group	6.0 \pm 7.4	5.1 \pm 5.7	2.56	0.12
SC group	3.2 \pm 3.6	4.9 \pm 6.1		
Performing time under simple course (s)				
CC group	15.9 \pm 8.8	14.5 \pm 4.0	0.28	0.60
SC group	17.2 \pm 7.9	15.5 \pm 5.9		
Performance time under complex course (s)				
CC group	132.6 \pm 36.9	105.7 \pm 18.7	5.63	0.02
SC group	152.0 \pm 54.1	140.9 \pm 53.8		
No. obstacles contacted under simple course (times)				
CC group	1.0 \pm 1.1	0.3 \pm 1.1 [†]	0.60	0.44
SC group	1.2 \pm 1.4	0.2 \pm 0.6 [†]		
No. obstacles contacted under complex course (times)				
CC group	1.9 \pm 2.1	0.1 \pm 0.4 [†]	5.62	0.02
SC group	1.7 \pm 2.0	1.8 \pm 2.8 [†]		

[†]As calculated by group comparison $P < 0.05$. Columns indicating pre- and postintervention values are expressed as mean (SD). CC, complex course obstacle negotiation exercise; SC, simple course obstacle negotiation exercise; TUG, timed up and go test.

Discussion

The SC exercise is an obstacle-avoidance program under simple task conditions. The CC exercise is an obstacle-avoidance program under complex task conditions, and is designed to address multiple domains, such as attention, short-term memory and balance, which when impaired have been shown to increase fall risk.²¹ The present results show that the CC program can improve the performance time of the CC test. This result is consistent with our previous study.¹⁰

In the CC program, the obstacles were organized to gradually increase the level of difficulty. Therefore, it is possible that the CC program improves the participants' performance by decreasing the number of obstacles contacted under the CC conditions. This result suggested that the obstacle-avoidance program, which increases attention demands for obstacles during

walking under complex task conditions, is useful for the improvement of obstacle-avoidance capability. Previous studies have shown that the obstacle-avoidance success rate was decreased by the presence of a secondary task.^{22,23} Furthermore, elderly individuals with a high risk for falls chose an early transfer of gaze strategy when challenged with an obstacle under dual-task conditions.¹³ The present study showed that our CC program could improve divided attention under complex task conditions.

The differences in fall and fall-related fracture rates between CC and SC groups were significant during the 12 months after the intervention. The improvement in the number of obstacles contacted and the performance time of the CC test became apparent in increased capacity in a real-life environment.

There were several limitations of the present study that warrant mention. First, the participants were

probably more motivated and showed greater interest in health and fall risk than the general population of older adults. Second, the information about the medications for osteoporosis was not included in the analysis. It is possible that such medications have an effect on the fracture incidence.

The results of this RCT suggest that the CC program is more effective in improving the number of obstacles contacted and the performance time of the CC test than the SC program. In addition, participants who received individualized obstacle-avoidance training under complex tasks combined with a traditional intervention showed a lower incidence rate of falls and fall-related fractures during the 12-month follow-up period. These results implicated the importance of population-based prevention programs to reduce falls and fall-related fractures in older adults (75 years and older). This is the first study to show that the obstacle-avoidance program, focusing on attention demands of obstacles during walking under complex task conditions, is useful in preventing falls and fall-related fractures in older adults. A larger study is needed to confirm the present results and to evaluate the most effective exercises for the prevention of falls and fall-related fractures.

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Disclosure statement

The authors declare no conflict of interest.

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