protein, 2% oligosaccharide, Nestle Japan Ltd. Tokyo, Japan) is provided in the Appendix.

*Resistance training*

Participants performed 90 minutes of group training sessions 3 times a week for the 3 months of the study. Each exercise class used a standardized format that included 10 minutes of warm-up exercises, 60 minutes of progressive strength training, 10 minutes of flexibility and balance exercises, and 10 minutes of cool-down activities. The warm-up exercise consisted of movement of legs, trunk, and arms to include all joints and major muscle groups in activities such as mild dancing. Strength training consisted of progressive resistive exercises using an elastic band and exercise machines.

Participants performed biceps curls, double-arm pull downs, seated row, leg press, leg curl, and leg extension exercises on the resistance training machines. Training loads were chosen using the 10-repetition maximum (10-RM, the maximal weight that can be lifted 10 times). Participants used the 10-RM for 3 sets of 10 repetitions for each machine exercise. Participants were required to adjust the training weight to ensure failure at the 10-RM.

A sequence of progressively more difficult exercises was also performed to improve static and dynamic balance. Although exercises could be performed in a sitting position, the importance of performing in a standing position to improve balance was encouraged. Physiotherapists evaluated each participant twice during the study period to ensure adherence to the exercise protocols during classes.

*Outcome measurements*

A physiotherapist blinded about the group allocation of each subject administered the test of interest at the baseline visit, and later at the completion of the 3-month intervention. All baseline measures were completed before group allocation. Before the study started, all staff members received training by one of the authors (MY) about the correct protocols to administer the measures included in this study.

*Skeletal muscle mass index (SMI)*

Bioelectrical impedance analysis (BIA; Physion MD; Physion Co. Ltd, Kyoto, Japan) was performed to determine body composition (26). This system applies a constant current of 800 mA at 50 kHz through the body. Participants were assessed in supine position with their arms and legs extended and relaxed. Using segmental body composition and muscle mass, a value for the appendicular skeletal muscle mass was determined and used for the present analysis. Muscle mass was converted to the skeletal muscle mass index (SMI) by dividing appendicular skeletal muscle mass by squared height (kg/m$^2$). This index has been used in several epidemiological studies (5, 27).

*Measurement of physical performances*

For all participants, the following 6 measurements were obtained: 10-m maximum walking time (28), the timed up and go (TUG) test (29), the functional reach (FR) test (30), the five chair stand (5CS) test (31), the hand grip strength (HGS) (32), and the knee-extension strength (KES) (33). If a walking aid was normally used at home, this aid was used during the TUG test and 10-m walking.

In the maximum walking, participants were asked to walk 15 m at a maximum pace. A stopwatch was used to record the time required to reach the 10 m point (marked in the course). The time recorded in 2 trials was averaged to obtain the parameter used in the present analyses.

In the TUG test, participants were asked to stand up from a 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 2 trials was averaged to obtain the parameter used in the present analyses.

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 placed on the wall at shoulder height. The distance that a participant could reach while extending forward from an initial upright position to the maximal anterior leaning position without moving or lifting the feet was visually measured in centimetres according to the position of the tip of the third finger against the placed meter stick. The distances measured in 2 trials were averaged to obtain the variable used in the present analyses.

In the 5CS, participants were asked to stand up and sit down five times as quickly as possible, and they were timed from the initial sitting position to the final standing position at the end of the fifth stand. The5CS score was defined as the better performance of two trials.

In the HGS, participants used a hand-held dynamometer with the arm by the side of the body. The participants squeeze the dynamometer with maximum isometric effort. No other body movement was allowed. The HGS score was defined as the better performance of their two trials.

The KES was measured with hand-held dynamometer (HHD; mTas F-1; ANIMA, Tokyo, Japan) during isometric contraction of the knee extensor. In a sitting position, the subject kept the hip and knee at 90° angle. The maximal isometric strength was measured after adequate pre-

measurement trials. The HHD was placed 25 cm distal to the knee joint. Torque was calculated by multiplying strength by the arm (25 cm) and expressed at the percentage of bodyweight (Nm/kg). The KES score was defined as the better performance of two trials.

*Assessment of sarcopenia*

For the present study we adopted the SSCWD criteria (2). The SSCWD recommended to define sarcopenia as the concurrent presence of slow walking speed (equal to or less than 1 m/sec) and low appendicular muscle mass. Japanese criteria for sarcopenia assessed by appendicular muscle mass/squared height were less than 6.87 kg/m$^2$ in men and less than 5.46 kg/m$^2$ in women (24).

*Statistical analysis*

Baseline characteristics of S/Ex and Ex groups were compared to examine the comparability of the 2 groups. Differences in the physical function variables between the 2 groups were analysed using the Student's t-test or chi-square test.

Analysis of covariance (ANCOVA) was used to determine the effect of the intervention program on each outcome measure, with baseline values as covariates. Post hoc Tukey tests were used to assess which group or time periods showed significant differences.

Data were entered and analysed using the SPSS (Windows version 18.0, SPSS, Inc., Chicago, IL). A P value <0.05 was

**Table 1**
Baseline characteristics of study participants according to the S/Ex and Ex groups

| Characteristics | | S/Ex group (n=35) Mean | SD | Ex group (n=35) Mean | SD | P-value |
|---|---|---|---|---|---|---|
| Age | Mean±SD | 74.4±7.3 | | 75.6±6 | | .411 |
| Height | cm, Mean±SD | 156.2±9.1 | | 157.2±8.7 | | .603 |
| Weight | kg, Mean±SD | 55.2±8.8 | | 55.9±10.4 | | .733 |
| BMI | kg/m$^2$, Mean±SD | 22.6±3.1 | | 22.5±3.3 | | .890 |
| Gender (female) | n (%) | 17 (48.5%) | | 19 (54.3%) | | .408[a] |
| Medication | number, Mean±SD | 5.2±2.9 | | 5.7±3.7 | | .499 |
| Walking aid user | n (%) | 24 (68.6%) | | 25 (71.4%) | | .500[a] |
| Fear of falling | n (%) | 26 (74.3%) | | 24 (68.6%) | | .398[a] |
| Falls in past year | n (%) | 12 (34.3%) | | 14 (40.0%) | | .402[a] |

a. chi-square test

**Table 2**
Functional fitness items in each group at pre- and post-intervention

| Items | | Baseline Mean | SD | Post Mean | SD | main effect (time) F-value | P-value | Group _ Time Interaction F-value | P-value |
|---|---|---|---|---|---|---|---|---|---|
| Maximum walking time, sec | S/Ex | 13.3 | 7.3 | 12.5 | 6.3 | 7.83 | .01 | 5.98 | .02 |
| | Ex | 12.5 | 5.2 | 12.5 | 5.3 | | | | |
| Timed up & go test, sec | S/Ex | 15.8 | 8.3 | 14.8 | 7.9 | .78 | .38 | 1.87 | .18 |
| | Ex | 14.2 | 5.0 | 14.5 | 6.7 | | | | |
| Functional reach, cm | S/Ex | 17.7 | 8.3 | 20.3 | 5.8 | 7.84 | .01 | .06 | .82 |
| | Ex | 20.4 | 6.8 | 23.5 | 6.9 | | | | |
| Five chair stand, sec | S/Ex | 13.0 | 6.1 | 12.3 | 6.0 | 3.35 | .07 | .21 | .65 |
| | Ex | 13.2 | 3.9 | 12.7 | 3.7 | | | | |
| Hand grip strength, kg | S/Ex | 24.4 | 8.4 | 26.1 | 8.3 | 2.26 | .14 | .36 | .55 |
| | Ex | 23.1 | 6.7 | 24.1 | 8.2 | | | | |
| Knee extension torque, Nm/kg | S/Ex | .55 | .25 | .63 | .30 | 4.38 | .04 | .15 | .70 |
| | Ex | .61 | .28 | .65 | .30 | | | | |
| Appendicular muscle mass, kg/m$^2$ | S/Ex | 4.62 | .87 | 4.87 | .99 | $ 17.78 | <.01 | 8.61 | <.01 |
| | Ex | 4.41 | .77 | 4.45 | .74 | | | | |

Notes: Columns indicating pre- and post-intervention values are expressed as mean (SD); $ Post hoc test: S/Ex vs Ex (P<0.05)

considered statistically significant for all analyses.

## Results

A total of 96 people were screened, and 77 (80.2%) meeting the inclusion criteria of the trial and agreeing to participate were enrolled (Figure 1). Twelve participants were excluded because they did not match the inclusion criteria or refused to participate, and 7 participants were also excluded because they did not match the criteria for low muscle mass.

Among the 77 individuals selected for the study, 70 (90.9%) completed the 3-month intervention: 35 in the S/Ex group (92.1%) and 35 in the Ex group (89.7%).

All the 24 scheduled intervention sessions were completed. The median relative adherence was 83% (25th–75th percentile, 73–88%) in the S/Ex group and 77% (73–88%) in the Ex 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 by adjustment of the intervention. Participants in the S/Ex and Ex groups were comparable and well matched with regard to their baseline characteristics (Table 1).

The significant time effects were found for maximum walking time, FR, KES and SMI ($P<0.05$) (Table 2). Participants in the S/Ex group had significantly greater improvements in maximum walking time and SMI ($P<0.05$) (Table 2). However, the other outcome measures were not significantly different between the 2 groups ($P > 0.05$).

At pre-intervention, the prevalence of sarcopenia was 65.7% and 68.6% in the S/Ex and the Ex groups, respectively, while at post-intervention, that was 42.9% and 68.6% in the S/Ex and the Ex groups, respectively. The relative risk was calculated as 1.60 (95% CI: 1.03-2.49).

## Discussion

In this 3-month pilot trial to address the role of combination of resistance training and nutritional supplementation intervention for frail older adults with low muscle mass, we have shown that SMI and walking speed were significantly improved only in the S/Ex group. These results suggested that combination of resistance training and nutritional supplementation program may be beneficial for frail older adults to prevent and treat sarcopenia. On the other hand, the reported time effects for improved walking speed, balance function, leg strength and SMI confirm that a resistance training intervention may be able to increase physical function in older persons.

Interestingly, no significant time effects were not found for TUG, 5CS or HGS, despite previous studies showed that the resistance training is effective for improving strength (8) and eliciting gains in muscle mass in older adults (9). However, a recent meta-analysis showed that the resistance training is effective for improving maximal strength, but does not consistently improve physical performance such as walking speed (34). Longer interventions might be effective for the improvement of physical performance. Our study showed that in the Ex group, a 3-month resistance training program was not effective to improve walking speed.

In the present trial, we tested a multinutrient intervention particularly rich in vitamin D and proteins. It has been shown that vitamin D supplementation may enhance muscle strength in frail older adults with vitamin D deficiency (35). Although the primary source of vitamin D is sunlight, it still can be obtained from diet. In serum, vitamin D3 is transported to the liver by binding to a vitamin D-binding protein. In the kidney, 25(OH) D3 is further metabolised into a biologically active form of vitamin D (36, 37). However, the vitamin D production capacity of the skin at the age of 70 is reduced to only 30% of that of 20-year-old persons (38, 39), and an increased dietary intake should be recommended in older adults.

Protein supplementation has been shown to augment the muscle strengthening effect of resistance exercise (14, 40). Older adults have a high risk of inadequate protein intake (41), and their synthetic response to protein intake may be blunted (42). Several studies found a positive association between protein intake and muscle mass (43, 44). In fact, aminoacids intake has a stimulatory effect on muscle protein synthesis (45).

Despite of a short period of supplementation (3 times a week for 3 months), the intervention was effective at increasing muscle mass in frail sarcopenic older adults. Moreover, the present results showed that the nutritional supplementation provided added benefits to those from the resistance training for increasing muscle mass and physical performance. Longer interventions might turn out to be more effective, even for the other outcomes (e.g. knee extension torque and falls) for which we did not reported significant findings. Further studies are required to address the effect of nutritional supplementation and exercise on sarcopenia and physical performance.

Several limitations of the present study need to be mentioned. First, single participants were not randomized. Therefore, the evidence level is not so strong as it would be obtained from a randomized controlled trial (RCT). Second, these findings should be considered as preliminary due to the relatively small sample size. This issue may introduce some error of inference, reduce the power of the analysis, and limit

generalization. Third, no follow-up after completion of the trial was conducted. Since there is a lack of evidence regarding the long-term effect of nutritional supplement on the treatment of sarcopenia, this issue also needs to be addressed in future specific studies. Forth, the intake of dietary food was not recorded. The nutritional supplement may have changed dietary intakes. Fifth, the measurement of SMI was estimated using the BIA which is far from the gold standard to accurately assess sarcopenia. Sixth, serum levels of 25 (OH) D were not measured. Therefore, the relationship between the nutritional supplement and 25 (OH) D cannot be determined. Finally, a control group not engaged in interventions was lacking. Participants in S/Ex group may have had higher motivation and interest in health issues than the general elderly population.

In conclusion, results of our study suggest that the combination of resistance training and nutritional supplementation program may be more effective at improving SMI and walking speed than resistance training only. These results imply the importance of these prevention programs to reduce sacropenia in older adults. A larger RCT is needed to confirm and extend the present results.

## Appendix

Micro- and macro-nutrients of the adopted nutritional supplementation

| | | 125 ml |
|---|---|---|
| Protein | g | 10.0 |
| Vitamin D | μg | 12.5 |
| Fat | g | 8.2 |
| Carbohydrate | g | 20.6 |
| Oligosaccharide | g | 2.0 |
| Natrium | mg | 100 |
| Fluid | g | 93.5 |
| Mineral | mg | 91.7 |
| Vitamin A | μgRE | 244 |
| Vitamin E | mg | 4.5 |
| Vitamin K | μg | 11 |
| Vitamin B1 | mg | 0.6 |
| Vitamin B2 | mg | 0.8 |
| Niacin | mg | 9.8 |
| Vitamin B6 | mg | 0.9 |
| Vitamin B12 | μg | 1.3 |
| Folate | μg | 125 |
| Pantothenic acid | mg | 4.4 |
| Vitamin C | mg | 56.0 |
| Biotin | μg | 9 |
| Unsaturated fatty acid | g | 0.35 |

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Original Study

# Community-Based Exercise Program is Cost-Effective by Preventing Care and Disability in Japanese Frail Older Adults

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*Keywords:*
Care prevention program
long term care insurance
older adults
Japanese

A B S T R A C T

*Background:* In Japan, older adults are assessed by frailty checklist for care prevention. However, the effect of care prevention programs in community-dwelling frail older adults is still unclear.
*Objectives:* The purpose of this study was to investigate whether the care prevention program would reduce care and disability and to measure its cost-effectiveness in frail older adults.
*Design:* This is a prospective study using propensity score matching.
*Setting and subjects:* A total of 610 community-dwelling older adults were recruited in 2 cities of Japan.
*Intervention:* Subjects in the exercise group (n = 305) attended physical exercise sessions once a week for 16 consecutive weeks. The exercise sessions were in a standardized format consisting of moderate-intensity aerobic exercise, progressive strength training, flexibility and balance exercises, and cool-down activities. The control group (n = 305) received only screening evaluation.
*Measurements:* Primary outcome was long term care insurance requirement certification during the 1-year follow-up period. Secondary outcome measurements were changes of frailty checklist, and care and medical cost.
*Results:* Twenty-five subjects (8.1%) in the exercise group and 55 (18%) in the control group were newly certified for long-term care insurance service requirement in 1 year after the intervention (RR = 2.16, 95% CI = 1.46–3.20). Consequently, the health care cost for the subjects in the exercise group was significantly lower than in the control group ($P < .001$). Moreover, subjects in the exercise group had significant improvements in total scores of the frailty checklist compared with the control group that worsened after 1 year (exercise group: from 7.41 ± 3.98 to 7.11 ± 4.00, control group: from 7.34 ± 4.27 to 8.02 ± 4.81, $F = 12.84$, $P < .001$).
*Conclusion:* These results suggested that physical exercise is effective in preventing the progression of frailty and further disability in older adults living in the community. We could save heath care costs by our care prevention program.



The aged population in Japan is increasing faster than in any other country. Frailty in older adults is a serious problem in aged countries, such as in Japan. In general, frailty can be defined as a vulnerable state that places older adults at high risk for adverse health outcomes, such as falls, hospitalization, and mortality.[1] Therefore, to prevent the adverse outcomes of frailty, multicomponent exercise programs have been implemented and provided a beneficial effect on activities of daily living (ADLs) and instrumental ADL disability for community-dwelling moderately frail older adults.[2]

Japan implemented a long term care insurance (LTCI) system in April 2000 to deal with the extremely rapid aging process of our population. Before 2000, long term care services were provided under a tax-based social welfare system targeting seniors with limited economic resources and family support.[3] After LTCI implementation, however, LTCI services have been provided to the elderly who are certified, as a support requirement or care requirement according to their care needs and certification assessment.[4] The selection process for classifying dependent older adults is first based on a questionnaire that evaluates a person's current mental and physical condition (74 items), and then the first decision is reached by computerized algorithm. The second decision is made by a long term care approval board based on the first computer decision, doctor's recommendation, and the home-visit report. Finally, people who are certified as dependent older adults are subdivided into 7 levels (requiring support levels 1 and 2 and care levels 1 to 5) depending on their conditions. They are provided home- and community-based or institutional services according to the care needs. Individuals who are not eligible for long term care or support care may use preventive care services.

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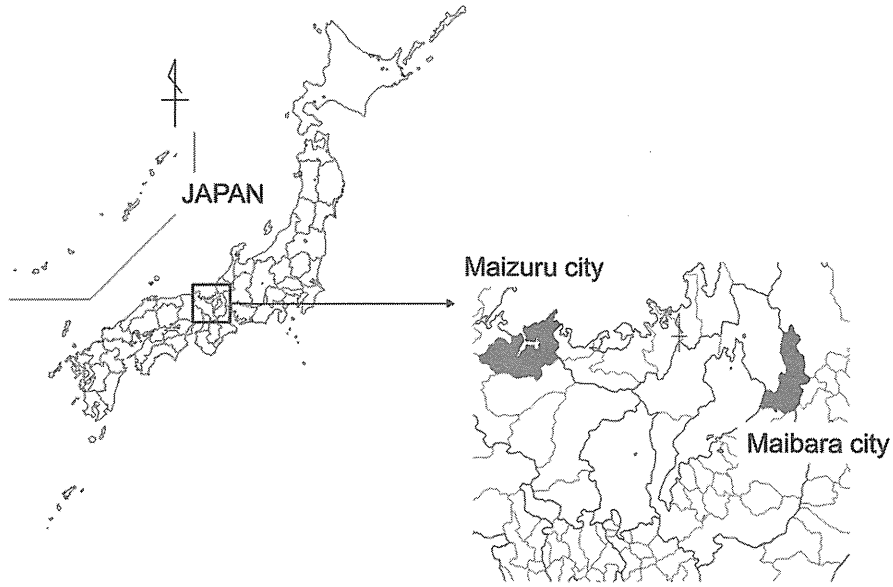


**Fig. 1.** Location of Maibara and Maizuru City in Japan.

In 2006, the LTCI system was revised and new preventive benefits were introduced. The aim of this system was to allocate the limited resources to impaired elderly by providing services intended to improve physical strength, nutritional status, oral function, and mental health.[5] The LTCI system also increased emphasis on preventive care services for those with lower needs and those at risk for needing care in the future, in which pre-frail and frail older adults can be selected by a frailty checklist. The local governments provide a frailty checklist to uncertified older adults, and all older adults are required to fill out a basic yes or no questionnaire consisting of assessments of their lifestyle, motor abilities, nutrition, oral function, seclusion, forgetfulness, and emotions. According to the results of impairment on a specific domain, the government provides several intervention programs to prevent care and disability of older adults; however, the effect of the care prevention program on frail older adults is still unclear.

The aim of the current study, therefore, was to evaluate the effect of an exercise intervention on care and disability classified by LTCI service requirement certification and health care cost in community-dwelling older adults. We hypothesized that subjects who attend the care prevention program have a lower chance of being certified for the LTCI service requirement than nonparticipants, and as a result, the intervention can save health care costs.

## Methods

### *Subjects*

We analyzed the cohort data from a prospective study: the Japan Multi-center Aging Cohort for Care prevention. In this study, in 2009, we recruited community-dwelling older adults who were

**Table 1**
Frailty Checklist of Japan

| Domain | Question | Items | Yes | No |
|---|---|---|---|---|
| Lifestyle | 1 | Do you ride the bus or train alone? | 0 | 1 |
| | 2 | Do you buy household goods for everyday use? | 0 | 1 |
| | 3 | Do you withdraw and deposit savings? | 0 | 1 |
| | 4 | Do you visit your friends' homes? | 0 | 1 |
| | 5 | Do you give advice to family and friends? | 0 | 1 |
| Motor abilities | 6 | Can you climb stairs without holding onto a handrail or the wall? | 0 | 1 |
| | 7 | Can you get up from a chair without grabbing something? | 0 | 1 |
| | 8 | Are you able to keep walking for about 15 minutes? | 0 | 1 |
| | 9 | Have you fallen in the past year? | 1 | 0 |
| | 10 | Are you very worried about falling? | 1 | 0 |
| Nutrition | 11 | Have you ever lost more than 2–3 kg of weight in a 6-month period? | 1 | 0 |
| | 12 | BMI is less than 18.5. | 1 | 0 |
| Oral function | 13 | I cannot eat hard foods as well as 6 months ago. | 1 | 0 |
| | 14 | Have you ever choked on tea or soups? | 1 | 0 |
| | 15 | Are you concerned with being thirsty? | 1 | 0 |
| Seclusion | 16 | Do you leave your home at least once a week? | 0 | 1 |
| | 17 | Compared to last year, has the number of times you go out decreased? | 1 | 0 |
| Forgetfulness | 18 | Are you told that you are forgetful or you always tell me the same thing? | 1 | 0 |
| | 19 | Do you look up phone numbers and make phone calls yourself? | 0 | 1 |
| | 20 | Do you sometimes forget the date and month? | 1 | 0 |
| Emotions | 21 | (In the past 2 weeks) I do not feel fulfillment in my daily life. | 1 | 0 |
| | 22 | (In the past 2 weeks) The activities I used to enjoy are no longer enjoyable. | 1 | 0 |
| | 23 | (In the past 2 weeks) The activities I used to carry out with ease have become troublesome. | 1 | 0 |
| | 24 | (In the past 2 weeks) I do not think I am a useful person. | 1 | 0 |
| | 25 | (In the past 2 weeks) I feel tired for no reason. | 1 | 0 |

BMI, body mass index.

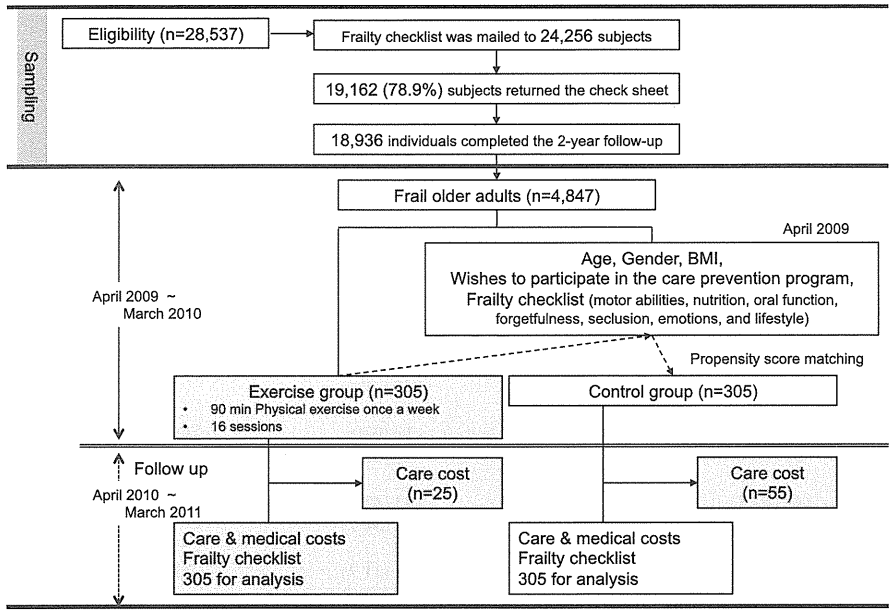


**Fig. 2.** A flow chart showing the distribution of subjects throughout the trial.

independent in ADLs in 2 cities (Maibara City in Shiga Prefecture and Maizuru City in Kyoto Prefecture) (Figure 1). The exclusion criteria were older adults who were already ADL-dependent and were eligible to receive benefits from LTCI services.

A total of 28,537 residents were eligible for this study in April 2009. The self-administered frailty checklist was mailed to 24,256 subjects, and the response rate was 78.9%. We further excluded individuals who died or moved from the cities in the 2-year follow-up, and analyzed 18,936 elderly. Subjects for the care prevention program were recruited using direct mail. We screened subjects in an initial interview and recruited frail older adults 65 years or older.

This study was conducted in accordance with the guidelines proposed by the Declaration of Helsinki, and the study protocol was reviewed and approved by the Ethics Committee of Kyoto University Graduate School of Medicine.

### *Frailty Checklist*

The frailty checklist includes simple yes/no questions concerning lifestyle (questions 1 to 5), motor abilities (questions 6 to 10), nutrition (questions 11 to 12), oral functions (questions 13 to 15), seclusion (questions 16 to 17), forgetfulness (questions 18 to 20), and emotions (questions 21 to 25) (Table 1). We calculated the scores in each of these 7 domains.

**Table 2**
Baseline Characteristics of the Study Subjects in Exercise and Control Groups

| | Exercise Group (n = 305) | | Control Group (n = 305) | | *P* Value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| Age, y | 79.7 | 6.3 | 80.3 | 6.6 | .275 |
| Gender, female | 231 (75.4%) | | 238 (78.0%) | | .560* |
| Height | 151.5 | 8.0 | 151.1 | 8.3 | .509 |
| Weight | 53.1 | 10.0 | 51.8 | 10.2 | .128 |
| BMI, kg/m$^2$ | 23.0 | 3.4 | 22.6 | 3.5 | .129 |
| Falls in past year | 107 (35.1%) | | 114 (37.4%) | | .670* |
| Total scores of frailty checklist | 7.41 | 3.98 | 7.34 | 4.27 | .814 |

BMI, body mass index.
*Chi-square test.

Impaired physical condition was defined as having 3 points or more in motor ability items according to the Japanese Ministry of Health, Labor, and Welfare. Malnutrition was defined as having 2 points in nutrition items, poor oral health as having 1 point or more in oral function items, seclusion as having 1 point or more in seclusion items, cognitive decline as having 1 point or more in forgetfulness items, and depressive mood as having 2 points or more in emotion items. Frailty was defined by scores of 10 or more points on questions 1 to 20.

### *Definition of Frail Older Adults in this Study*

In this study, we defined frail older adults as those who need to maintain or to improve daily functions. These individuals are not eligible for the LTCI service requirement as defined by the government, but have a high risk of becoming dependent based on the results of the frailty checklist.[5] Those older adults are defined as having impaired motor abilities, malnutrition, poor oral health, or impaired lifestyle as described in the previous paragraph.

### *Care Prevention Program*

The subjects received 90 minutes of group training sessions once a week for 16 consecutive weeks. The exercise class was supervised by a physiotherapist. The exercise sessions were conducted according

**Table 3**
Comparison of New LTCI Service Requirement Certification Between the 2 Groups

| | Exercise Group, n (%) | Control Group, n (%) | RR | 95% CI |
|---|---|---|---|---|
| LTCI requirement | 25 (8.1%) | 55 (18.0%) | 2.16 | 1.46–3.20 |
| Support level | | | | |
| 1 | 11 | 15 | | |
| 2 | 7 | 14 | | |
| Care level | | | | |
| 1 | 4 | 13 | | |
| 2 | 3 | 7 | | |
| 3 | 0 | 3 | | |
| 4 | 0 | 3 | | |
| 5 | 0 | 0 | | |

CI, confidence interval; LTCI, long term care insurance; RR, relative risk.

**Table 4**
Frailty Checklist Scores in Each Group at Baseline and After Intervention

| | Baseline | | After Intervention | | Group × Time Interaction | |
|---|---|---|---|---|---|---|
| | n (%) | *P* Value | n (%) | *P* Value | F Value | *P* Value |
| Motor ability domain score | | | | | | |
| Exercise (n = 305) | 181 (59.5) | .414 | 177 (58.0) | .087 | | |
| Control (n = 305) | 185 (60.7) | | 158 (51.7) | | | |
| Nutrition domain score | | | | | | |
| Exercise (n = 305) | 10 (3.4) | .348 | 11 (3.5) | .364 | | |
| Control (n = 305) | 13 (4.3) | | 8 (2.6) | | | |
| Oral function domain score | | | | | | |
| Exercise (n = 305) | 114 (37.5) | .210 | 113 (37.0) | .073 | | |
| Control (n = 305) | 104 (34.0) | | 94 (30.7) | | | |
| Forgetfulness domain score | | | | | | |
| Exercise (n = 305) | 139 (45.6) | .430 | 120 (39.3) | .037 | | |
| Control (n = 305) | 142 (46.7) | | 145 (47.6) | | | |
| Seclusion domain score | | | | | | |
| Exercise (n = 305) | 66 (21.6) | .349 | 19 (6.2) | <.001 | | |
| Control (n = 305) | 61 (20.0) | | 50 (16.5) | | | |
| Emotions domain score | | | | | | |
| Exercise (n = 305) | 144 (47.3) | .407 | 133 (43.6) | .008 | | |
| Control (n = 305) | 140 (46.0) | | 167 (54.7) | | | |
| Lifestyle domain score | | | | | | |
| Exercise (n = 305) | 47 (15.5) | .517 | 36 (11.7) | .003 | | |
| Control (n = 305) | 46 (15.1) | | 64 (21.0) | | | |
| Total score | | | | | | |
| Exercise (n = 305) | 7.41 ± 3.98 | | 7.11 ± 4.00 | | 12.84 | <.001* |
| Control (n = 305) | 7.34 ± 4.27 | | 8.02 ± 4.81 | | | |

*Two-way analysis of variance adjusted for age and gender.

to a standardized format consisting of 20 minutes of moderate-intensity aerobic exercise, 30 minutes of progressive strength training, 20 minutes of flexibility and balance exercises, and 20 minutes of cool-down activities. The aerobic exercise was composed of global movement of the legs, trunk, and arms involving all joints and major muscle groups in activities such as dance. Strength training consisted of progressive resistive exercises using an elastic band. A sequence of progressively difficult exercises was also performed to improve static and dynamic balance. The control group received screening evaluation only.

### *Propensity Score Matching*

We used propensity score matching to assemble a cohort of the exercise group, then the 2 groups would be well matched on all measured baseline characteristics, such as age, gender, body mass index, wishes to participate in the care prevention program, motor abilities, nutrition, oral function, forgetfulness, seclusion, and emotions. We estimated the scores of the exercise group for each subject using a multivariable logistic regression model. We were able to match 305 pairs of exercise and control subjects who had similar propensity scores.

### *Outcome Measures*

Primary outcome was the new LTCI service requirement certification at 1 year after the conclusion of the intervention. Secondary outcomes were changes of frailty checklist, LTCI cost, and medical cost. The LTCI cost indicates use of home care services, nursing care, or day care services and nursing home. The utilization records of LTCI benefit services during 1 year were collected from the local governmental office. The medical cost covers almost all medical treatment, including diagnostic tests, medications, surgery, supplies and materials, physicians, and other personal cost.

### *Statistical Analysis*

Baseline characteristics of the intervention and control groups were examined for comparability of the 2 groups. Differences in the demographic variables between the 2 groups were analyzed using the Student *t* test or chi-square test. Relative risk was then calculated, and the chi-square test was used to evaluate the effect of the care prevention program on the new LTCI service requirement and the influence on each domain of frailty checklist. Analysis of covariance was used to determine the effect of the care prevention program on total points of frailty checklist, using age as covariates. Post hoc Tukey tests were used to assess whether group or time periods showed significant differences. Multiple logistic regressions using a stepwise method was performed to investigate which of age, gender, or the decline in frailty checklist for each category was independently associated with the change of frailty checklist (improvement, maintenance, or deterioration). Finally, differences in the care and medical cost between the 2 groups were analyzed using the Student *t* test. Data were entered and analyzed using the Predictive Analytics Software (Windows version 18.0, SPSS, Inc., Chicago, IL). A *P* value less than .05 was considered statistically significant for all analyses.

**Table 5**
Change of Each Domain in Frailty Checklist After Exercise Intervention

| Dependent Variables | Adjusted Odds Ratio (95% Confidence Interval) | | | | | | |
|---|---|---|---|---|---|---|---|
| | Motor Abilities | Nutrition | Oral Functions | Forgetfulness | Seclusion | Emotions | Lifestyle |
| Change in checklist | 2.29 (1.58–3.31) | 5.32 (1.52–18.62) | — | 1.77 (1.22–2.57) | — | — | — |

1 = improvement, 0 = maintenance or deterioration.

**Table 6**
Comparison of Long Term Care Insurance and Medical Costs Between the 2 Groups

| | Exercise Group, n = 305 | Control Group, n = 305 | *P* Value |
|---|---|---|---|
| | Mean ± SD | Mean ± SD | |
| Care costs* dollars | 1126.8 ± 1797.9 | 4430.7 ± 6324.7 | <.001 |
| Medical costs dollars | 2458.7 ± 1968.7 | 3458.0 ± 5847.1 | <.001 |

One dollar = 88 yen.
*Exercise group: n = 25, control group: n = 55.

## Results

Of the 610 individuals, all subjects completed the 1-year follow-up: 305 in the exercise group, and the others in the control group (Figure 2). All 16 scheduled intervention sessions were completed. The median relative adherence was 100% (25th–75th percentile, 88%–100%) in the exercise group. No fall incidents or health problems, such as cardiovascular or musculoskeletal complications, occurred during training sessions or testing. Minor problems were muscle ache and fatigue. All problems were managed easily using adjustment of the intervention, and they improved during the intervention. Subjects in the exercise and control groups were comparable and well matched with regard to their baseline characteristics (Table 2).

During 1 year after the intervention, 25 subjects (8.1%) in the exercise group and 55 (18.0%) in the control group were newly certified for the LTCI service requirement. Therefore, the relative risk for new LTCI service requirement in the control group compared with the exercise group was 2.16 (95% confidence interval [CI] = 1.46–3.20) (Table 3).

At baseline, all domains of the frailty checklist were not significantly different between the 2 groups (Table 3). Subjects in the exercise group had significant improvements in total scores of the frailty checklist compared with the control group that worsened after 1 year (exercise group: from 7.41 ± 3.98 to 7.11 ± 4.00, control group: from 7.34 ± 4.27 to 8.02 ± 4.81, F = 12.84, $P < .001$) (Table 4) as well as in forgetfulness, seclusion, emotion, and daily life domains ($P < .05$); however, the other domains were not significantly different between them ($P > 0.05$).

Stepwise logistic regression analysis revealed that motor ability domain (OR = 2.29, 95% CI 1.58–3.31), nutrition domain (OR = 5.32, 95% CI 1.52–18.62), and forgetfulness domain (OR = 1.77, 95% CI 1.22–2.57) were significant and independent determinants of the change in frailty checklist ($P < .001$) (Table 5).

Finally, we calculated the cost-effectiveness of this intervention, and found that subjects in the exercise group spent significantly lower care cost than the control group (exercise group: $1126.8 ± 1797.9, control group: $4430.7 ± 6324.7, $P < .001$) (Table 5), whereas subjects in the exercise group spent significantly less on medical costs than the control group (exercise group: $2458.7 ± 1968.7, control group: $3458.0 ± 5847.1, $P < .001$) (Table 6).

## Discussion

In this study, we addressed the role of the physical exercise program for frail older adults, and have shown that the subjects who received physical exercise sessions demonstrated a lower incidence of new LTCI service requirement, improved frailty checklist, and reduced care and medical costs.

The current results indicated that the care prevention program had a beneficial effect on frailty in older adults. Specifically, the physical exercise program showed more beneficial effects on older adults with impaired motor ability, malnutrition, and forgetfulness. Previous studies also confirmed the benefits of physical exercise training on frail older adults.[6,7] In addition, a systematic review by Daniels and colleagues[2] suggested that multicomponent exercise programs have a positive effect on ADL and instrumental ADL disability for community-living moderate physically frail older adults. These reports and our findings suggested that the physical exercise program is effective in preventing frailty.

Moreover, our results indicated that the care prevention program could reduce health care costs. Owing to the positive effect on cognition, seclusion, depression, and instrumental ADLs, the program might also be associated with fewer medical costs. In addition, intervention by the prevention program showed a lower incidence of new LTCI service requirement certification, resulting in lower care costs. On the other hand, Frick and colleagues[8] reported that the physical exercise program was not cost-effective by evaluating the cost-effectiveness of fall-prevention programs for fall-related hip fractures in older adults. These results suggest that all the physical exercise programs are not always cost-effective. Further study is required to determine how to perform cost-effective interventions in frail older adults.

There were several limitations of this study that warrant mention. First, we did not measure physical performance, and used only the frailty checklist to define frailty. There is a possibility that the frailty checklist may not be the best instrument to define frailty, such as the Short Physical Performance Battery that evaluates balance, gait, strength, and endurance by examining an individual's ability.[9] Second, our study design was not a randomized controlled trial. Therefore, these findings should be interpreted with caution.

This is the first study to demonstrate that the care prevention program is effective to improve the scores of the frailty checklist. In addition, subjects who received the care prevention program demonstrated a lower incidence of new certification of LTCI service requirement with a lower cost during the follow-up period. These results implicated the importance of care prevention programs to reduce care and disabilities in older adults. A larger study is needed to confirm the present results and to evaluate the most effective exercises for the prevention of disability in older adults.

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# PEDOMETER-BASED BEHAVIORAL CHANGE PROGRAM CAN IMPROVE DEPENDENCY IN SEDENTARY OLDER ADULTS: A RANDOMIZED CONTROLLED TRIAL

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**Abstract:** *Background:* Recent studies suggested that pedometer-based walking programs are applicable to older adults. *Objectives:* The purpose of this study was to evaluate the use of pedometer in sedentary older adults to improve physical activity, fear of falling, physical performance, and leg muscle mass. *Design:* This was a pilot randomized controlled trial (RCT). *Setting and participants:* Eighty-seven community dwelling sedentary older adults living in Japan. *Intervention:* The intervention group (n=43) received a pedometer-based behavioural change program for 6 months, while the control group (n=44) did not. The participants in the intervention group were instructed to increase their mean daily steps by 10% each month. Thus, at the end of 6 months, participants in the intervention group were expected to have 77 % more daily steps than their baseline step counts. Written activity logs were monthly averaged to determine whether the participants were achieving their goal. *Measurements:* Outcome measures were physical activity, fear of falling, physical performances, and leg muscle mass. *Results:* In this 6-month trial 40 older adults (93%) completed the pedometer protocol with good adherence. In the intervention group, average daily steps were increased by 83.4% (from 20311323 to 3726 1607) during the study period, but not in the control group (from 20471698 to 22671837). The pedometer-based behavioral change program was more effective to improve their physical activity, fear of falling, locomotive function, and leg muscle mass than control ($P<0.05$). *Conclusion:* These results suggested that the pedometer-based behavioral change program can effectively improve the physical activity, fear of falling, physical performance, and leg muscle mass in sedentary older adults.

**Key words:** Pedometer-based behavioral change program, physical activity, sedentary older adults, RCT.

## Introduction

Physical activities show positive associations with various components of physical functions such as walking speed, lower-limb strength, and balance, and negative associations with the incidence of coronary artery disease, obesity, osteoporosis, and other causes of morbidity and mortality in the elderly (1-5). On the other hand, increased physical activity is associated with improvement in numerous health conditions, such as quality of life and physical and psychological functions, and can facilitate independent living and reduce the risk of dementia in older adults (6-9).

Behavioral change intervention should be based on scientific theory, and interventions should use evidence-based behavioral change techniques such as goal setting, planning, and self-monitoring (10-12). Pedometers are attracting interests as potential means to enhance the effectiveness of interventions and to promote physical activities, yet surprisingly few trials have been conducted using pedometers (13, 14). Most pedometer-based studies have been focused on middle-aged adults and have measured health outcomes such as body mass index and blood pressure (13).

Only a few reports have evaluated the use of pedometers in older adults. A 12-week trial of a pedometer-based walking program in older adults (mean age, 73 years) showed a 21% to 34% increase in physical activity over baseline (15). In a 4-week trial of pedometer-based walking program in older adults (mean age, 82 years), a significant improvement was observer in average number of daily steps (2992 to 3670) and physical function (16). These data suggested that pedometer-based walking programs are applicable to older adults.

The purpose of this randomized controlled trial (RCT) was to evaluate the use of pedometer in sedentary older adults to improve their physical activity, fear of falling, physical performance, and leg muscle mass. We hypothesized that our pedometer-based behavioral change program could lead to a 10% monthly increase in average daily steps in each month during the 6-month intervention, and was effective in fear of falling, physical performance, and leg muscle mass.

## Methods

### *Participants*

Participants were recruited using an advertisement in the local press. The following criteria were used to screen

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participants: age 65 years or over, participants who walked less than 5,000 steps/day by pedometer, 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) (17), could walk independently (or with a cane), willingness to participate in group exercise classes for at least 6 months, had access to transportation, had no significant hearing and vision impairments, and had no regular exercise in the last 12 months. We used the cutoff of 5,000 steps/day because the average daily steps were 5,0812,633 step/day in sarcopenic older Japanese (18).

The interview was also used to exclude participants based on the following exclusion criteria: severe cardiac, pulmonary, or musculoskeletal disorders; co-morbidities 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 2 groups. Opaque envelopes bearing group names were numbered and the 87 participants were then randomly assigned to either a pedometer-based behaviour change program (intervention) group (n=43) or a control group (n=44).

***Intervention***

Participants randomized to the intervention group received pedometer-based behavioural change programs for 6 months. A valid, accurate, and reliable pedometer, Yamax Powerwalker EX-510 was used to measure free-living step counts (19). The physical activity of older adults is susceptible to weather change (temperature and precipitation). Therefore, this intervention was conducted between November 2010 and April 2011, because in Japan, we have almost the same temperature and precipitation in October and May and tried to avoid the rainy season (June and July). We expected that the outcome measures were not affected by a remarkable difference in temperature before and after the intervention.

We instructed the participants to increase the number of daily steps by 10% each month. Thus, at the end of 6 months, participants were expected to walk 77 % above their baseline step counts. Written activity logs were averaged monthly to determine whether the participants were achieving their step goal.

The intervention consisted of motivation for walking followed by goal setting, self-monitoring, and feedback. Participants were asked to record the date on the calendar, steps taken at the end of each day. A sheet for brief feedback and setting the number of daily steps was mailed to all participants to evaluate the recorded calendar monthly. We checked the adherence by the recorded calendar.

***Measurement of physical performance***

For all participants, the following 4 measures were obtained: 10-m walking time (20), the timed up and go (TUG) test (21), the functional reach (FR) test (22), and the five chair stand (5CS) test (23). A physiotherapist blinded to group allocation was responsible for these measures at baseline, and after the 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 10-m walking test and TUG test.

In 10-m walking, each participant was requested to walk comfortably without assistance for 15-m and the time was measured for the intermediate 10-m to allow for acceleration and deceleration. The average time calculated from two trials was used for the present analyses.

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 2 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 2 trials were averaged to obtain the FR score.

In 5CS, participants were asked to stand up and sit down five times as quickly as possible, and were timed from the initial sitting position to the final standing position at the end of the fifth stand.The5CS score was defined as the better performance of their two trials.

***Bioelectrical impedance analysis (BIA) measurement***

A bioelectrical impedance data acquisition system (Physion MD; Physion Co. Ltd, Kyoto, Japan) was used to determine the bioelectrical impedance of the right upper and lower limbs [24]. This system applies a constant current of 800 mA at 50 kHz

through the body. Participants lay supine with their arms and legs extended and relaxed during bioelectrical impedance measurement. Leg muscle mass adjusted by their whole-body weight (LLM) was used for analysis (25).

### *Fall experience and fear of falling*

We assessed fear of falling by asking a single yes or no question "Are you afraid of falling?",which has a high test-retest reliability (26). This question was asked at the pre- and post-intervention. The test-retest reliability using the Kappa coefficient was 0.960.

### *Measurement of physical activities*

Measurement of step counts was conducted between October 2010 and May 2011. Participants were instructed to wear the pedometer in their pocket of dominant leg for 14 consecutive days except bathing, sleeping, and performing water-based activities. This pedometer has a 30-day data storage capacity. We calculated the averages of their daily step counts for 2 weeks.

### *Required sample size*

Previous pedometer-based walking program showed a significant improvement in average daily steps from 7,220 to 10,410 (effect size = 0.77) (27). We designed the effect size of the current study to be 0.7. With a significance level of 0.05, a power of 80%, and a moderate effect size (0.7), a minimum of 34 participants were needed in both intervention and control groups. Accounting for a potential 20% attrition rate, a total of 82 participants were recruited for this study, which was deemed large enough to detect statistically significant differences.

### *Statistical analysis*

Baseline characteristics of intervention and control groups were compared to examine the comparability of the 2 groups. Differences in the demographic variables between the 2 groups were analysed using the Student's t-test or chi-square test.

Relative risk was then calculated, and the chi-square test was used to evaluate the effect of interventions on fear of falling. The effect of exercise on outcome measures was analyzed using a mixed 2 × 2 (group (intervention and control groups) × time (pre-intervention, post-intervention)) analysis of variance. Post hoc Tukey tests were used to assess whether group or time periods showed significant differences.

In the intervention group, the relationship between the percent change of daily steps and percent change of other measures was investigated with the Spearmann correlation coefficient.

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

## Results

Overall, 103 people were screened, and 87elderly (84.5%) who met the inclusion criteria for the trial and agreed to participate were enrolled (Fig. 1). Among the individuals who did not meet the inclusion criteria (n = 16), most were excluded because they had exercised regularly in the 6 months before screening. Four people who were eligible for the study withdrew their consent after telephone screening. Of 87 individuals selected for the study, 82 (94.3%) completed the 12-month follow-up: 40 in the intervention group (93.0%) and 42 in the control group (95.5%).

All 24 scheduled intervention sessions were completed. The median relative adherence was 100% (25th–75th percentile, 95.6–100%) in the intervention group. No health problems, including cardiovascular or musculoskeletal complications, occurred during daily walking or testing. Minor problems such

**Figure 1**
Flow chart showing the distribution of participants throughout the trial

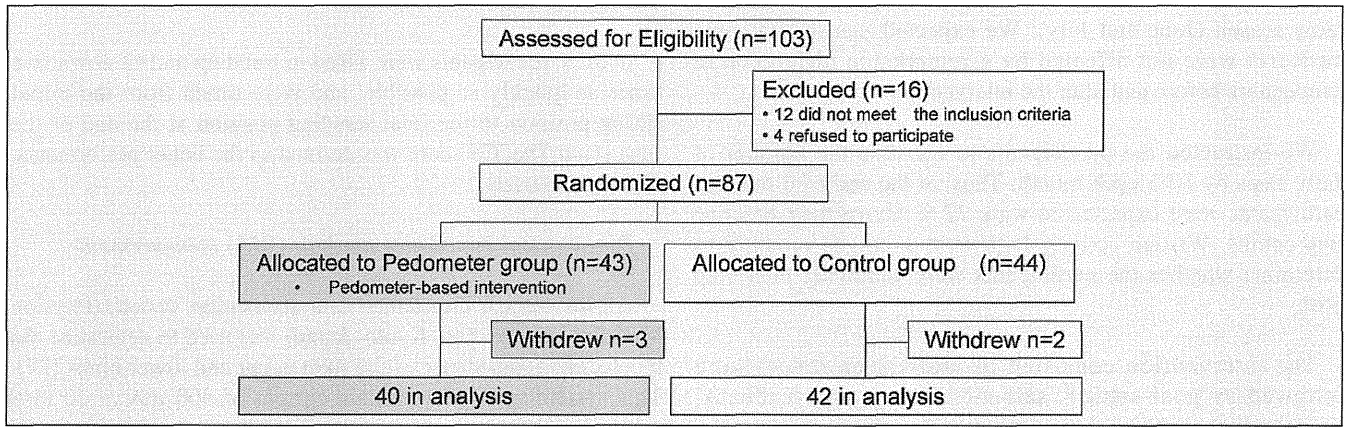

**Tableau 1**
Comparison of demographic characteristics and measurements in intervention and control groups

| | Mean | SD | Mean | SD | P-value |
|---|---|---|---|---|---|
| Age (year) | 75.5 | 5.9 | 75.8 | 7.6 | 0.83 |
| Gender, female | 20 (50.0%) | | 20 (47.6%) | | 0.50 |
| Height (cm) | 159 | 10.7 | 157.2 | 8.9 | 0.28 |
| Weight (kg) | 57.6 | 9.1 | 59.1 | 10.9 | 0.42 |
| BMI (kg/m$^2$) | 22.7 | 2.5 | 24.1 | 5.1 | 0.10 |
| Number of Medications | 4.6 | 1.9 | 5.0 | 1.9 | 0.29 |
| RDST | 8.3 | 1.9 | 8.0 | 2.2 | 0.61 |
| Walking aids | 6 (15.0%) | | 5 (11.9%) | | 0.47 |
| Falls in the last 1 year | 10 (25.0%) | | 14 (33.3%) | | 0.28 |

BMI: body mass index; RDST: rapid dementia screening test

**Table 2**
Functional fitness in each group at pre- and post-intervention

| | | | Baseline | | Post-intervention | | | Time X group effect | |
|---|---|---|---|---|---|---|---|---|---|
| measures | | group | Mean | SD | Mean | SD | | F-value | P-value |
| Lean leg mass | (kg/weight) | I | 0.154 | 0.016 | 0.168 | 0.027 * | # | 5.01 | 0.03 |
| | | C | 0.158 | 0.018 | 0.159 | 0.020 | | | |
| Walking time | (sec) | I | 11.7 | 3.2 | 10.8 | 2.7 ** | # | 5.90 | 0.02 |
| | | C | 11.7 | 2.9 | 11.7 | 3.3 | | | |
| Timed up & go test | (sec) | I | 12.0 | 4.1 | 11.4 | 3.1 * | # | 6.10 | 0.02 |
| | | C | 12.3 | 3.3 | 12.6 | 4.2 | | | |
| Functional reach | (cm) | I | 20.2 | 8.8 | 23.7 | 7.2 | | 3.00 | 0.09 |
| | | C | 20.3 | 6.1 | 20.7 | 6.7 | | | |
| Five chair stand | (sec) | I | 12.0 | 5.0 | 12.2 | 6.0 | | 0.06 | 0.81 |
| | | C | 13.3 | 4.1 | 13.3 | 4.9 | | | |
| Physical activity | (steps) | I | 2031 | 1323 | 3726 | 1607 | ## | 51.66 | <0.01 |

I: Intervention group; C: Control group; * P<0.05, ** P<0.01: As calculated by comparing pre-intervention value; # P<0.05, ## P<0.01: As calculated by group comparison

as muscle pain after the first training sessions and fatigue were observed in the intervention group. All problems were managed easily using adjustment of the intervention, and they improved during the intervention.

Participants in intervention and control groups were comparable and well matched with regard to their baseline characteristics (Table1). There were no significant differences in age, body weight, height, gender, RDST scores, number of medications, users of walking aids, or experiences of falls in the previous year.

In the intervention group, average daily steps were increased by 83.4% (from 20311323 to 3726 1607) during the study period, but not in the control group (from 20471698 to 22671837). Participants in the intervention group had significantly greater improvements in secondary outcome measures such as LLM, walking time, TUG, and physical activity ($P < 0.05$). However, other secondary outcome measures were not significantly different between the 2 groups ($P > 0.05$) (Table2).

In the pre-intervention period, fear of falling was 55.0% and 47.6% in the intervention and control groups, respectively. The relative risk was calculated as 0.865 (95% CI: 0.566 - 1.322) for fear of falling for participants in the control group compared with those in the intervention group ($p = 0.327$). After the intervention, fear of falling was decreased to 30.0% in the intervention group, while that was not changed in the control group (52.4%). Relative risk was calculated as 1.746 (95% CI: 1.003 – 3.039) for fear of falling for participants in the controlgroup compared with those in the intervention group ($p = 0.033$).

To determine the association of percent change in daily steps withthatin other outcome measures, we analysed Spearmann's

correlation coefficients in the intervention group. The percent change of daily steps was correlated with that of leg muscle mass (r=0.476, P=0.014), walking time (r=-0.789, P<0.01), TUG (r=-0.441, P=0.009), and functional reach (r=0.450, P=0.006). The percent change of daily steps was not significantly correlated with that of 5CS (r=-0.234, P=0.295).

## Discussion

In this 6-month pilot RCT to address the role of pedometer-based intervention for older adults, we have shown that the average daily steps were successfully increased by 83.4%in the intervention group, and that the pedometer-based behavior change program was very effective for the improvement of physical activity, fear of falling, locomotive function, and leg muscle mass. These results suggested that pedometer-based behavioral change programs can be applied to sedentary older adults to prevent the progression of frailty and disability.

We showed that the pedometer-based behavioral change program was very effective for the improvement of average daily steps. Goal setting and self-monitoring of behavior are crucial for behavioral change. In this study pedometers were primarily used as a motivational tool and our behavioral support seemed to have mainly affected the behavioral change toward increasing physical activity.

We found that there was moderate correlation between percent change of daily steps and that of other physical functions. These results suggest that the promotion of physical activity is potentially beneficial for a wide spectrum of health-related outcomes in older adults. Due to such benefits, physical activity should be indicated to prevent sarcopenia, frailty and disability. Recent study suggested that the physical activity is correlated with leg muscle mass (18) and the lower extremity function such as walking speed and knee extension torque (28) in the elderly aged 75 years and above. As an underlying mechanism, Tissandier et al. reported that regular physical activity could maintain higher levels of insulin-like growth factor-1 (29). Further, improvement of inflammation, oxidative damage, and insulin resistance may be related to higher physical activity and could mediate the improvement of the health status and protection from negative health-related events. However, in spite of its simple and inexpensive applicability, few studies have addressed the relationship between physical activity and physical function by pedometer-based intervention in older adults. In 12-week pedometer-based trial of older with knee osteoarthritis, Talbot et al showed increased daily steps, walking speed, and knee extension strength (30). A 4-week trial of a pedometer-based walking program in older adults shows an improvement in number of daily steps, lower limb endurance, and locomotive function (16). These reports and ours indicated that increased physical activity (daily steps) is associated with improvements in numerous physical functions.

The pedometer-based behavioral change program was effective in improving leg muscle mass and fear of falling. These results suggest that the pedometer-based behavioral change program is effective for the prevention of sarcopenia and reducing falls in community-dwelling older adults. A pedometer is very small and relatively inexpensive, and may be useful as a large population approach for the prevention of dependency. However, not only increased physical activity, but also better nutrition such as sufficient protein intake is important for the prevention of sarcopenia (31).

There are several limitations to this study. First, these findings should be considered as preliminary because of the relatively small sample size (n=82). Second, statistical analyses were performed for each of the four outcome measures separately, including the physical performance tests, which increased the possibility of false-positive findings (type 1 error). Finally, as indicated by their willingness to participate in this study, participants in both groups may have had higher motivation and interest in health issues than the general elderly population.

This is the first study to demonstrate that the pedometer-based behavior change program is useful in improving physical activity, fear of falling, physical performance, and leg muscle mass in sedentary older adults. A larger study is needed to confirm the present results and to evaluate the most effective exercises for the prevention of dependency.

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*Conflict of Interest:* None

*Sponsor's Role:* None

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ORIGINAL ARTICLE: EPIDEMIOLOGY, CLINICAL PRACTICE AND HEALTH

# Faster decline of physical performance in older adults with higher levels of baseline locomotive function

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**Aim:** The purpose of this longitudinal study was to determine whether the rate of decline in community-dwelling older adults varies according to baseline locomotive function levels.

**Methods:** This longitudinal study was conducted in community-dwelling older adults in Kyoto, Japan. In addition to information about falls, physical performance was assessed using a series of tests, including 10-m walking time, timed up and go (TUG) test, functional reach, one-leg stand test, and five chair stand test. The outcomes for each patient were measured once in 2009 and then followed up 1 year later. The change in physical performance was then determined. We divided the participants into tertiles (T1, T2, and T3) according to timed up and go test results, and the differences among the three groups were compared.

**Results:** Of the 252 individuals who were enrolled in the study, 231 (91.6%) completed the 12-month follow-up: 77 in the T1 group; 78 in the T2 group; and 76 in the T3 group. The T1 group showed a significantly larger decrease than the T2 and T3 groups in the 10-m walking time and TUG tests ($P < 0.05$). However, there were no significant differences in functional reach, one-leg standing test, or five chair stand test among the three groups. In the T1 group, the number of falls and elderly who had developed fear of falling increased during the study period.

**Conclusions:** This study demonstrated that elderly with the highest baseline performances were more likely to show a greater decline in locomotive performance than the other groups. Further study is required to elucidate the mechanism of faster physical functional decline in robust elderly. **Geriatr Gerontol Int 2012; 12: 238–246.**

**Keywords:** level of frailty, locomotive function, longitudinal study, robust elderly.

## Introduction

Maintenance of physical performance in later life is an important component of healthy aging.[1] Walking speed has been identified as one of the most influential physical performances associated with deterioration in activity of daily living among older adults.[2] The timed up and go test (TUG) is a simple tool developed to screen basal mobility performance, which has been shown to be significantly associated with activity of daily living in frail older adults.[3] Thus, evaluating walking speed and TUG is important for predicting the risk of functional decline.

Several cross-sectional studies have shown that a gradual decline in physical performance is significantly

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associated with age.[4,5] Several longitudinal studies have also found a time-dependent decline in the physical performance of community-dwelling older adults.[6,7] However, few studies have addressed the factors involved in longitudinal change in physical performance. Therefore, we conducted several studies to demonstrate that the differential factors are related to daily activities and depend on community-dwelling older adults' level of frailty.[8] Our data suggests that a resistance training program is effective for improving physical performance in frail elderly, but not in non-frail elderly,[9] indicating a difference in the effect of physical training on elderly persons with varying levels of physical fitness. Therefore, it is important to examine longitudinal changes in the physical performance of elderly persons with varying levels of physical fitness.

The purpose of this longitudinal study was to determine whether the rate of decline in older adults differs according to baseline locomotive function levels.

## Methods

### *Participants*

Study participants were recruited through ads in the local press requesting healthy community-dwelling volunteers. A total of 252 Japanese participants, 65 years and older living in Kyoto city, were included in the baseline survey in October 2009. One year later in October 2010, the second survey was conducted. We screened 332 people, and 252 who agreed to participate were enrolled. Of the 252 individuals, 231 (91.7%) completed the 12-month follow-up (Fig. 1).

The screening process was used to exclude participants based on the following criteria: severe cardiac, pulmonary, or musculoskeletal disorders; comorbidities associated with an increased risk of falling such as Parkinson's 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 Helsinki, 1996.

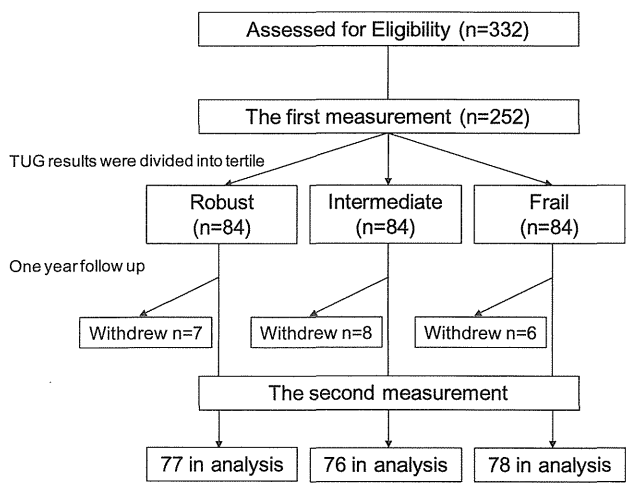


**Figure 1** A flow chart showing the distribution of participants.

### *Outcome measures*

All participants underwent five tests for measurements: 10-m walking time,[10] TUG test,[3] functional reach (FR),[11] one-leg standing (OLS) test,[12] and five chair stand (5CS) test.[13] Outcome measures were conducted in October 2009 and October 2010. No exercise program was prescribed to participants during the interim period. Before the study started, all researchers were trained by one of the authors (MY) on correct protocols for administering the assessment measures. If a participant normally used a walking aid, this aid was used during the 10-m walking time and TUG tests.

In the 10-m walking time test, participants walked 15 m at a comfortable pace, as determined by the individual. A stopwatch was used to record the time required to reach the 10-m point that was marked in the middle of the path. The test-retest reliability using the intertrial correlation coefficient (ICC; 1.1) was 0.943. The better performance of the two trials was used as the walking time score in the analysis. 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 test-retest reliability using the ICC (1.1) was 0.929. The TUG score was defined as the better performance of the two trials. In the FR test, each participant was positioned next to a wall with one arm raised at 90° and fingers extended. A meterstick 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 measured in centimeters according to the position of the tip of the third finger against the mounted meterstick. The distances measured in the two trials were averaged to obtain the FR score. The test-retest reliability using the ICC (1.1) was 0.915. In the OLS test, participants were instructed to start from a standing position with a comfortable base as support with their 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. The test-retest reliability using the ICC (1.1) was 0.905. The participants stopped the OLS if the time exceeded 60 s. In 5CS, participants were asked to stand up and sit down five times as quickly as possible. They were timed from the initial sitting position to the final standing position

at the end of the fifth stand. The test-retest reliability using the ICC (1.1) was 0.954. The 5CS score was defined as the better performance of the two trials. The percent change for physical performance was calculated as follows:

Percent change (%) = 100 × (2010 measurement – 2009 measurement)/2009 measurement

### *Falls and the fear of falling*

Participants were interviewed about falling during the past year and their fear of falling in 2009 and 2010. Falls were defined as all situations in which a participant suddenly and involuntarily came to rest upon the ground or a surface lower than their original station.[14] Falls resulting from extraordinary environmental factors (e.g. traffic accidents or falls while riding a bicycle) were excluded.

We assessed participants' fear of falling by asking a single yes-or-no question with a high test-retest reliability, "Are you afraid of falling?"[15] This question was asked during the interviews in 2009 and 2010. The test-retest reliability using the kappa coefficient was 0.960.

### *Statistical analysis*

We divided the participants into tertiles (T1, T2, and T3) according to TUG test results. TUG was chosen for several reasons. First, it is a simple measure of physical function that involves lower extremity strength, dynamic balance, gait, and agility. Second, TUG has been shown to identify physical function limitations in geriatric patients in a clinical setting.[16,17]

We analyzed the outcome measurements using a two-way ANOVA. Tukey tests were used for post-hoc analysis. Differences in the physical variables between elderly who had or had not fallen and between those with or without a fear of falling were analyzed by two-way ANOVA. Data were analyzed using SPSS v. 18.0 for Windows (Chicago, IL, USA). A *P*-value of <0.05 was considered statistically significant for all analyses.

## Results

Of the 252 individuals, 231 (91.7%) completed the 12-month follow-up: 77 in T1 group (91.7%), 78 in T2 group (92.9%) and 76 in T3 group (90.5%) (Fig. 1). There were no significant differences in all performance measurements and age between men and women.

### *Baseline characteristics*

There were significant differences in age (T1, 73.9 ± 6.6; T2, 79.1 ± 7.0; T3, 82.0 ± 6.9; F = 25.2, $P < 0.001$), walking time (T1, 7.4 ± 1.4 sec; T2, 9.7 ± 2.8 sec; T3, 12.7 ± 2.6 sec; $P < 0.05$), TUG (T1, 6.9 ± 0.9 sec; T2, 9.2 ± 0.9 sec; T3, 12.7 ± 1.3 sec; $P < 0.05$), FR (T1, 29.0 ± 7.0 cm; T2, 26.5 ± 6.7 cm; T3 21.3 ± 7.1 cm; $P < 0.05$), OLS (T1, 19.5 ± 13.6 sec; T2, 10.0 ± 10.7 sec; T3, 5.4 ± 5.5 sec; $P < 0.05$), and 5CS (T1, 8.5 ± 2.4 sec; T2, 10.4 ± 2.1 sec; T3, 13.5 ± 3.8 sec; F = 28.0, $P < 0.001$). There were no significant differences in height or weight (Table 1).

### *Follow-up measures*

There were significant differences in walking time (T1, 8.0 ± 1.9 sec; T2, 9.3 ± 2.0 sec; T3, 12.3 ± 2.7 sec; $P < 0.001$), TUG (T1, 7.5 ± 1.5 sec; T2, 9.3 ± 1.8 sec; T3, 13.0 ± 3.2 sec; $P < 0.001$), FR (T1, 30.2 ± 8.8 cm; T2, 27.6 ± 8.4 cm; T3, 21.0 ± 6.5 cm; $P < 0.001$), OLS (T1, 19.0 ± 12.8 sec; T2, 8.7 ± 9.4 sec; T3, 4.3 ± 3.8 sec; $P < 0.001$), and 5CS (T1, 7.4 ± 2.0 sec; T2, 9.5 ± 3.2 sec; T3, 13.6 ± 5.5 sec; $P < 0.001$) (Table 1, Fig. 2).

Group-time interactions are summarized in Table 1. A statistically significant group-time interaction was observed for walking time and TUG ($P < 0.05$).

### *Falls and fear of falling*

In the T1 group, the number of falls and elderly who had developed a fear of falling increased between baseline and follow-up (falls, 19.5% to 27.2%; fear of falling, 13.0% to 26.0%). There were no significant differences in FR, OLS, or 5CS. In T2 and T3 groups, the number of falls and elderly who had developed fear of falling did not change between baseline and follow-up (Table 1).

### *Characteristics of elderly with or without falls*

Group-time interactions are summarized in Tables 2, 3, and 4. In T1 group, a statistically significant group-time interaction was observed for TUG and 5CS ($P < 0.05$). However, we did not find any significant differences in T2 and T3 groups (Tables 2, 3 and 4).

### *Characteristics of elderly with or without fear of falling*

Group-time interactions are summarized in Tables 2, 3, and 4. In T1 group, a statistically significant group-time interaction was observed for TUG ($P < 0.05$) (Table 2). In T2 group, a statistically significant group- time interaction was observed for TUG and 5CS ($P < 0.05$) (Table 3). In T3 group, there were no significant differences (Table 4).

## Discussion

In the current study, we have shown that elderly with the highest baseline performances are more likely to show a decline in locomotive performance than the

**Table 1** Comparison of outcome measurements among the three groups

| | T1 (≤8.2) ($n$ = 77) | T2 (8.3–10.9) ($n$ = 76) | T3 (≥11.0) ($n$ = 78) | F-value | *P*-value | *Post-hoc* |
|---|---|---|---|---|---|---|
| Age | 73.9 ± 6.6 | 79.1 ± 7.0 | 82.0 ± 6.9 | 25.2 | <0.001 | †‡§ |
| Height (cm) | 157.1 ± 9.0 | 155.0 ± 8.1 | 155.8 ± 10.9 | 0.5 | 0.620 | – |
| Weight (kg) | 57.7 ± 9.8 | 56.5 ± 8.3 | 54.5 ± 10.1 | 0.7 | 0.492 | – |
| Gender, female | 57 (74.0) | 60 (78.9) | 60 (76.9) | | | – |
| Falls, $n$ (%) | | | | | | |
| 2009 | 15 (19.5) | 20 (26.3) | 26 (33.3) | | | |
| 2010 | 21 (27.2) | 22 (28.9) | 28 (35.9) | | | |
| Fear of falling, $n$ (%) | | | | | | |
| 2009 | 10 (13.0) | 29 (38.2) | 36 (46.2) | | | |
| 2010 | 20 (26.0) | 30 (39.5) | 37 (47.4) | | | |
| Walking time (sec) | | | | | | |
| 2009 | 7.4 ± 1.4 | 9.7 ± 2.8 | 12.7 ± 2.6 | 9.227 | <0.001 | †‡§ |
| 2010 | 8.0 ± 1.9 | 9.3 ± 2.0 | 12.3 ± 2.7 | | | †‡§ |
| Change (%) | 5.3 ± 17.6 | –5.1 ± 25.2 | –3.4 ± 20.1 | | | †‡ |
| Timed up and go (sec) | | | | | | |
| 2009 | 6.9 ± 0.9 | 9.2 ± 0.9 | 12.7 ± 1.3 | 3.361 | 0.037 | †‡§ |
| 2010 | 7.5 ± 1.5 | 9.3 ± 1.8 | 13.0 ± 3.2 | | | †‡§ |
| Change (%) | 5.8 ± 14.1 | 2.4 ± 16.2 | 2.6 ± 22.6 | | | †‡ |
| Functional reach (cm) | | | | | | |
| 2009 | 29.0 ± 7.0 | 26.5 ± 6.7 | 21.3 ± 7.1 | 1.254 | 0.291 | |
| 2010 | 30.2 ± 8.8 | 27.6 ± 8.4 | 21.0 ± 6.5 | | | |
| Change (%) | 5.5 ± 28.0 | 5.8 ± 28.1 | –3.3 ± 37.9 | | | |
| One-leg standing (sec) | | | | | | |
| 2009 | 19.5 ± 13.6 | 10.0 ± 10.7 | 5.4 ± 5.5 | 0.906 | 0.439 | |
| 2010 | 19.0 ± 12.8 | 8.7 ± 9.4 | 4.3 ± 3.8 | | | |
| Change (%) | –5.3 ± 41.4 | –2.9 ± 31.2 | –6.7 ± 32.8 | | | |
| Five chair stand (sec) | | | | | | |
| 2009 | 8.5 ± 2.4 | 10.4 ± 2.1 | 13.5 ± 3.8 | 0.217 | 0.885 | |
| 2010 | 7.4 ± 2.0 | 9.5 ± 3.2 | 13.6 ± 5.5 | | | |
| Change (%) | –10.0 ± 24.5 | –6.4 ± 33.3 | 1.0 ± 31.7 | | | |

†T1 *versus* T2. ‡T1 *versus* T3. §T2 *versus* T3.