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Randomized controlled trial of exercise intervention for the prevention of falls in community-dwelling elderly Japanese women

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Abstract Falls are common in elderly people. Possible consequences include serious injuries and the post-fall syndrome, with functional decline and limitation of physical activity. The present randomized controlled study sought to clarify the benefits of a combined long-term and home-based fall prevention program for elderly Japanese women. The subjects were individuals aged over 73 years, living at home in a western suburb of Tokyo, who had attended a comprehensive geriatric health check. Persons with a marked decline in the basic activities of daily living (ADL), hemiplegia, or those missing baseline data were excluded. Fifty-two subjects who expressed a wish to participate in the trial were randomized, 28 to an exercise-intervention group and 24 to a control group. Baseline data for age, handgrip force, walking speed, total serum cholesterol, serum albumin, basic ADL, visual and auditory impairments, self-rated health, and experience of falls did not differ significantly between the two groups. Beginning from June 2000, the intervention group attended a 6-month program of fall-prevention exercise classes aimed at improving leg strength, balance, and walking ability; this was supplemented by a home-based exercise program that focused on leg strength. The control group received only a pamphlet and advice on fall prevention.

The average rate of attendance at exercise class was 75.3% (range, 64% to 86%). Participants showed significant improvements in tandem walk and functional reach after the intervention program, with enhanced self confidence. At the 8-month follow-up, the proportion of women with falls was 13.6% (3/22) in the intervention group and 40.9% (9/22) in the control group. At 20 months, the proportion remained unchanged, at 13.6% in the intervention group, but had increased to 54.5% (12/22) in the control group, which showed a statistically significant difference between the two groups (Fisher's exact test; $P = 0.0097$). The total number of falls during the 20-month follow-up period was 6 in the intervention group and 17 in the control group. We conclude that a moderate exercise intervention program plus a home-based program significantly decreases the incidence of falls in both the short and the long term, contributing to improved health and quality of life in the elderly.

Key words exercise intervention · geriatric exercise · home-based exercise · fractures

Introductions

A combination of osteoporosis and falls underlies most fractures in the elderly. In particular, falls account for 90% of the growing problem of femoral neck fractures [1]. Other forms of trauma such as bruises and sprains also have a high incidence, and a fear of falling (the "post-fall syndrome") leads to a marked decline in the activities of daily living (ADL) [2]. Falls are thus an important factor when considering quality of life (QOL) in the elderly. Predisposing risk factors include a gait deficit [3–12], visual impairment [13,14], the use of sedatives [4–15], and a history of falls [6–22]. In a long-term, longitudinal study of community-dwelling elderly people in Japan, "a history of a fall in the previous year" and "decreased free walking speed" were independent strong predictors of future falls [23]. Irrespective of age, maintaining muscle strength, balance, and walking ability seem to be important first steps in preventing falls.

An elderly person's gait is characterized by a decreased height of the swing phase and a decreased stride length [24], both changes probably increasing the individual's susceptibility to falls. Therefore, in addition to correcting visual acuity and eliminating adverse drug reactions, active correction of physical weakness, especially walking ability, should be a highly effective intervention both at individual and societal levels [25]. A recent review of 16 studies ranked the major risk factors for falls in the elderly, in descending order, as (1) muscle weakness, (2) a history of falls, (3) gait deficit, and (4)

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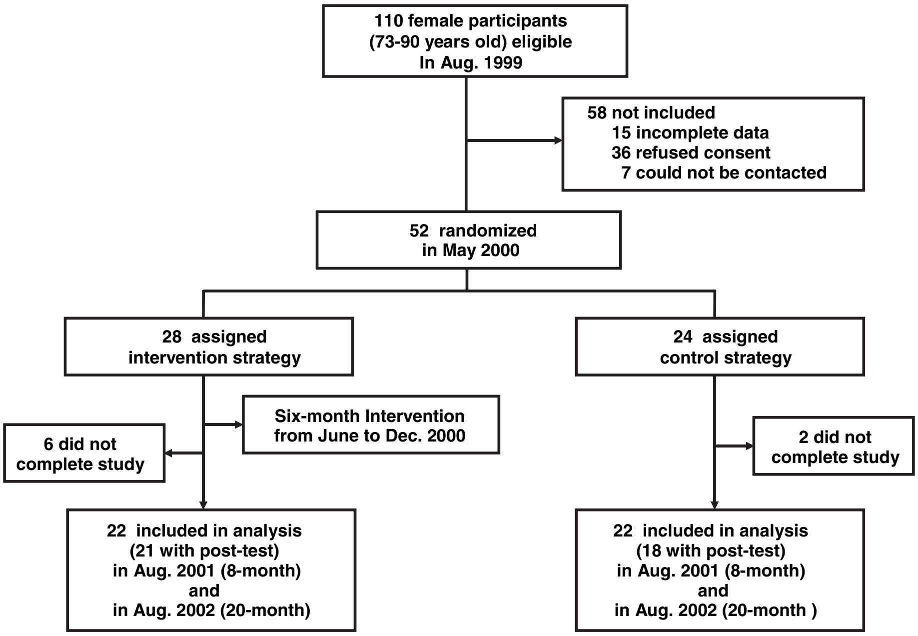

Fig. 1. Trial pofile

balance deficit [26]. The importance of addressing these risk factors as a practical preventive strategy has become widely recognized in Japan and elsewhere.

We therefore conducted a randomized controlled trial to examine the effectiveness of an intervention that aimed to improve overall physical function as a means of preventing falls. The two major goals of the intervention were (1) to improve muscle strength of the lower extremities and, thus, walking ability, and (2) to reduce the incidence of future falls through improvement of these physical attributes.

Subjects and methods

Subject sample

Subjects (Fig. 1) were selected from participants in the Tokyo Metropolitan Institute of Gerontology Longitudinal Interdisciplinary Study on Aging (TMIG-LISA), which was launched in 1991 [27,28]. In August 1999, 110 women, aged 73 to 90 years, living in Koganei City, a western suburb of Tokyo, attended a comprehensive geriatric health examination at the last survey in TMIG-LISA. Fifteen individuals were excluded for the following reasons: muscle strength could not be determined in 5 subjects, 5 had poor mobility due to hemiplegia, 2 had poorly controlled blood pressure, and 3 had communication difficulties due to impaired hearing.

In May 2000, a pamphlet containing information on "Fall Prevention Exercise Classes" was mailed to the remaining 95 subjects. Responses were obtained from 88 individuals; 52 agreed to join the exercise classes and 36 declined to participate. After obtaining informed consent, we allocated the 52 respondents randomly to an intervention group (n = 28) or a control group (n = 24). We expected the number of dropouts to be greater in the intervention group than that in the control group. Baseline data (August 1999) for age, handgrip force, walking speed, physical performance test scores, degree of dependence in basic ADL (moving, eating, personal toilet, dressing, bathing), and history of falls did not differ significantly between the two groups (Table 1).

The intervention group attended an exercise-centerd fall-prevention program, and also undertook a home-based exercise program aimed at enhancing muscle strength, balance, and walking ability. The control group received only a pamphlet and advice on the prevention of falls. Participants provided written informed consent to participate in this study, which the Institutional Review Board and Ethics Committee of the TMIG approved (Accepted, no. 12, June 8th, 1998).

Variables measured

Interview

An interview assessed the individual's history of fractures and falls over the previous year, basic ADL, instrumental ADL, and subjective changes in physical strength.

Measurements of physical function

Based on the items reported as effective in screening for falls in the elderly [3,29,30], and considering their

Table 1. Comparison of physical performance parameters (mean ± SD values) and questionnaire variables (%) at baseline survey in 1999 between control and intervention groups

Variables	Control group (n = 24)	Intervention group (n = 28)	P value*
Age[a]	78.45 ± 4.42	77.68 ± 3.41	0.477
NWS[b]	1.19 ± 0.24	1.19 ± 0.28	0.995
MWS[c]	1.73 ± 0.35	1.72 ± 0.34	0.869
GS[d]	21.38 ± 6.12	21.21 ± 4.36	0.913
STO[e]	23.83 ± 21.02	26.46 ± 22.00	0.663
STC[f]	4.33 ± 2.1	5.18 ± 4.47	0.378
TW[g]	8.79 ± 2.67	8.39 ± 3.51	0.651
FR[h]	27.81 ± 3.73	28.49 ± 4.49	0.562
KEP[i]	48.01 ± 13.49	49.90 ± 14.93	0.408
Fall[j]	16.7%	14.3%	0.556
ADL[k]	94.4%	100.0%	0.462

* Control group vs intervention group by *t*-test (a–i), and Fisher's exact test (j, k)
[a] Average age (years)
[b] Normal walking speed (m/s)
[c] Maximum walking speed (m/s)
[d] Grip strength (kg)
[e] Stork stand time with eyes open (s)
[f] Stork stand time with eyes closed (s)
[g] Tandem walking (steps)
[h] Functional reach (cm)
[i] Knee extension power (Nm)
[j] Fall experience within 1 year preceding baseline (%)
[k] Independence of basic ADL (%)

validity, reliability, and objectivity, the following items were selected to estimate muscle strength, balance, and walking ability.

Anthropometry
Height and body mass were measured, and the percentage of body fat was estimated by an impedance method (body fat analyzer, TBF-305; Tanita Tokyo, Japan).

Handgrip force
The peak handgrip force of each hand was determined to 5 kN, using a hand-held Smedley-type dynamometer.

Stork stand (eyes open)
While standing on a square (0.4 × 0.4 m), the subject either foot while watching a point set at eye level 1 m away, and tried to maintain this posture. A stopwatch measured the duration in seconds up to a maximum of 1 min, the longer of two attempts being recorded.

Stork stand (eyes closed)
The test was repeated, but with the eyes closed. The time was recorded up to a maximum of 30 s, the better of two attempts being noted.

Walking speed
A flat walking path of 11 m was marked with tapes at the 3-m and 8-m points. A stopwatch measured the time taken to walk 5 m, from the time when the foot touched the ground after the 3-m line to when the foot touched the ground after the 8-m line. The participants first took the test by walking at normal speed, and then by walking as fast as possible. Walking tests at both normal and maximum speeds were repeated and the faster speed was recorded in each walking test.

Tandem walking
A 2.5-m tape was affixed to a flat floor. The subject was instructed "to walk step-over-step" (walk with the tip of one foot touching the heel of the other foot). Note was taken of whether the subject could complete the 2.5-m walk; if successful, the number of steps and the time taken were also recorded.

Knee muscle power
The knee extension power (N) was measured in the dominant leg, using a hand-held dynamometer. The subject was asked to sit on a chair with the knee bent at a right angle. The dynamometer was placed at the ankle joint. The muscle strength was measured as the peak force during isometric extension when the subjects were asked to extend the knee by their maximum leg power. The test was carried out two times and the higher of two measurements made on the dominant leg was recorded.

Functional reach
The subject stood sideways against a wall in a natural position, and stretched both arms to the height of the shoulders. The positions of the fingertips were taken as the zero point. Then one arm was lowered. With the body tilted forward as far as possible, the subject continued to stretch the arm parallel to the ground. The greatest distance of forward reach was measured. Three measurements were made, and the mean value was recorded [31,32].

Intervention program

The intervention program comprised ten 1-h exercise sessions held at the community center once every 2 weeks for 6 months. Because this amount of exercise was insufficient to maintain and develop muscle strength, it was supplemented by an individual exercise program which subjects could practice at home. Participation was noted on a "Falls Prevention Exercise Record Card", which was brought to each of the formal exercise classes for confirmation. The following exercises were used.

Basic exercises
Before training, subjects participated in 10 to 15 min of warmup and stretching exercises, consisting of finger joining and pushing, bending the fingers backward, shoulder rotation, waist rotation, upward stretching, and lateral bending of the arms, forward bending, and other similar exercises.

Muscle strengthening of legs, waist, and abdomen
The muscle strengthening routine consisted of bending and flexing the ankles, raising the heels, bending the knees, raising one leg while lying on the back, raising both legs and bending backwards and forwards (while lying on the back), raising the upper part of the body while lying on the stomach, raising both knees (while lying on the stomach), and other similar items.

Balance and gait training
Gait training consisted of standing on one leg, shifting weight laterally from one foot to the other foot, and anterior-posterior weight shifting, performed in a position similar to a fencing position [33]. It also included side stepping on alternate legs and tandem walking. A wall or chair was used to provide a safe support when needed.

Resistance exercise
Moderate resistance training included two kinds of exercise, i.e., using a dumbbell (0.5-kg to 1.5-kg weights) and a rubber band (light-to-medium-resistance band). The dumbbell exercise was performed in a standing and/or chair-sitting position, with pushing up and down or pulling up and down at a resistance that permitted four to eight repetitions.

Exercises using the rubber band (Thera-Band, Sakai, Tokyo) included horizontal stretching of both arms with the band in front, up-and-down stretching with the band above the head, and sideways, striding exercise, and others.

Tai Chi exercise
In China, one of the most popular forms of Tai Chi is the Yang style. A 24-form simplified Tai Chi, based on Yang's system, was developed in 1965 by a group of Tai Chi experts. The subjects performed three to five basic forms, i.e., hand-holding and departing, one-hand pushing, empty step, backward-step, and clouding [34,35]. The duration of exercise was increased progressively to 30 min in the last three sessions.

Home exercise
Subjects were instructed to undertake home exercise with two to three sets of the 15 exercises which they had learned in the last session. They were also advised to do the home exercises at least three times a week for about 30 min per day. Subjects were asked to record the exercise times and number of sets performed on a "Fall Prevention Exercise Record Card".

Post-intervention measurements and follow-up

An interview and blinded physical function assessments were conducted at the end of the 6-month intervention. During the first 8 months of follow-up, the home-based exercise program was mailed monthly to each subject, and the "Fall Prevention Exercise Record Card" was returned by the participant. The number of falls was assessed by interviews conducted 8 and 20 months after the intervention.

Data analysis

As shown in Fig. 1, a total of 8 subjects dropped out (6 in the intervention group and 2 in the control group) during the entire follow-up period, and they could not be assessed at the end of the 6-month intervention or traced for falling events during the 20-month follow-up period. One of 22 subjects in the intervention group and 4 of 22 subjects in the control group failed to undergo physical function assessment at the end of the 6-month intervention (post-intervention measurements), but could be traced only for falling events during the 20-month follow-up period. Thus, among the 52 participants enrolled in this study, 44 (22 from the intervention group and 22 from the control group) responded twice to the outcome survey at 8 and 20 months after the

6-month intervention, and the information about falling events could be traced during the 20-month follow-up period.

Data were analyzed on an intention-to-treat basis. Means and SDs were calculated for each variable, and differences between the intervention and control groups were tested by *t*-tests. In samples with unequal variance, a *t*-test with Welch's correction was used. Repeated measures two-way analysis of variance (ANOVA) was performed on outcome variables. Significant interactions were examined (Scheffe's post-hoc analysis) to determine if effects were greater in the exercise or control group. A χ^2 test assessed the frequency of pre- and post-intervention events for the intervention and control groups. The proportions of women with falls during the follow-up period, for the intervention and the control groups, were also compared by χ^2 tests, except when cell sample sizes in the contingency table were small, in which case Fisher's exact test was used. All subjects who provided follow-up data at any time point were included in the analysis.

Results

Among 110 elderly female community living residents, 52 (47.3%) were recruited to participate in the study and were assigned to either an exercise group or a control group. As shown in Table 1, there were no sigsnificant differences between the two groups at baseline.

Of the 52 participants, 8 (6 in the intervention group and 2 in the control group) dropped out during the 6-month intervention period. Among the 6 dropouts (24.1%) in the intervention group, 4 complained of lumbago ($n = 2$) or knee pain ($n = 2$) and withdrew at an early stage of exercise intervention, and the remaining 2 dropped out later because of relocation or hospitalization due to worsening of hypertension. Table 2 compares the physical performance and baseline questionnaire data between the subjects in the intervention and control groups who completed the trial (without the dropouts in each group). There were no variables showing significant differences between the two groups, including fall experience within 1 year preceding the baseline survey, which had been confirmed to be a very strong predictor for future falls in our previous community-based cohort study [23].

Two persons (8.3%) in the control group dropped out because they did not wish to participate in the post-intervention measurements or to keep in contact during the follow-up period. It was impossible to trace all dropouts for the information about falling events. After the post-intervention measurements, there were no more

Table 2. Comparison of physical performance parameters (means ± SD) and questionnaire variables (%) at baseline survey in 1999 between subjects in the control and intervention groups who completed the trial

Variables	Control group ($n = 22$)	Intervention group ($n = 22$)	*P* value*
Age[a]	78.64 ± 4.39	77.31 ± 3.40	0.272
NWS[b]	1.18 ± 0.25	1.24 ± 0.23	0.365
MWS[c]	1.72 ± 0.35	1.80 ± 0.25	0.408
GS[d]	20.82 ± 5.65	21.82 ± 4.63	0.524
STO[e]	25.09 ± 21.33	29.59 ± 22.77	0.502
STC[f]	4.23 ± 2.07	5.73 ± 4.70	0.181
TW[g]	9.00 ± 2.62	9.23 ± 2.60	0.774
FR[h]	28.02 ± 3.80	29.04 ± 4.25	0.404
KEP[i]	47.11 ± 13.45	52.62 ± 15.42	0.214
Fall[j]	18.2	18.2	1.000
ADL[k]	95.5	100.0	1.000

* Subjects who completed trial *vs* dropouts in the intervention group, by *t*-test (a–i), and Fisher's exact test (j, k)
[a] Average age (years)
[b] Normal walking speed (m/s)
[c] Maximum walking speed (m/s)
[d] Grip strength (kg)
[e] Stork stand time with eyes open (s)
[f] Stork stand time with eyes closed (s)
[g] Tandem walking (steps)
[h] Functional reach (cm)
[i] Knee extension power (Nm)
[j] Fall experience within 1 year preceding baseline (%)
[k] Independence of basic ADL (%)

dropouts in either the intervention group or the control group. Thus, the two groups did not differ in the follow-up rate (Fisher's exact test; $P = 0.262$) or in reasons for dropout. Table 3 compares the physical performance and baseline questionnaire data between the subjects who completed the trial ($n = 22$) and dropouts ($n = 6$) in the intervention group. There were two variables (i.e. normal walking speed and knee extention power) showing significant difference between the two groups.

Attendance rate

Individual rates of attendance at the fall prevention exercise classes ranged from 64% to 86%, with a mean of 75.3%. Fifteen subjects (53.6%) attended all ten sessions. Six subjects who attended none to three times were regarded as failing to master the exercise program; the reasons were refusal to participate after randomization because of lumbago ($n = 2$), knee pain ($n = 2$), relocation ($n = 1$), and hospitalization ($n = 1$). Among the 22 subjects who completed the intervention, 21 subjects (95.5%) participated in more than seven sessions.

Interview survey

Change in physical fitness
When subjects were questioned about perceived changes in physical fitness, 28.6% of the intervention group (6 subjects) responded "improved", 57.1% (12 subjects) reported "no change", and 14.3% (3 subjects) responded "worsened". No subject in the control group responded "improved"; most (61.1%; 11 subjects) indicated "no change", but 38.9% (7 subjects) responded that their condition had "worsened".

Basic activities of daily living (BADL)
Before the intervention, 100% of the intervention group and 94.4% (17 subjects) of the control group were independent in BADL. After the intervention, 85.7% (18 subjects) in the intervention group were still independent, but 14.3% (3 subjects) were impaired, as compared to 88.9% (16 subjects) and 11.1% (2 subjects), respectively, in the control group.

Subjective changes in physical strength and confidence in fall prevention
Some 66.7% of exercise-class participants perceived that walking had stabilized, and 55.6% perceived that their leg muscles had become stronger during the program. Moreover, 61.1% were confident that they were able to prevent falling by themselves.

Physical function measurements

Comparison between intervention and control groups
Before the intervention, there were no statistically significant differences in muscle strength, balance, or walking ability between the intervention and control groups. After the intervention, there were significant differences in tandem walking (intervention group versus control group, 10.7 ± 0.86 versus 7.3 ± 3.46 steps) and functional reach (33.5 ± 4.7 versus 28.0 ± 4.6 cm). Knee extension power, though significantly increased after intervention in the intervention group, showed no significant difference in the comparison of the two groups.

Comparison of measurement changes between the intervention and control group
In comparison of measurements before and after the intervention, the intervention group developed significant gains in tandem walking (pre-intervention versus post-intervention: 9.24 ± 2.66 versus 10.67 ± 0.86 steps), functional reach (29.27 ± 4.22 versus 33.52 ± 4.70 cm), and knee extension power (52.12 ± 15.62 versus 56.81 ± 11.71 Nm; Fig. 2). The control group, in contrast, developed a significant decrease in handgrip force (pre-intervention versus post-intervention: 22.17 ± 5.57 versus 20.22 ± 4.21 kg), with no significant changes in any of the other variables.

Proportion of women with falls in each group, and numbers of falls during follow-up

Before the intervention, 16.7% (4 of 24 subjects) in the control group and 14.3% (4 of 28 subjects) in the intervention group had experienced falls (no significant difference). At the 8-month follow-up, the proportion of women with falls in the control group had increased to 40.9% (9 of 22 subjects), but had decreased to 13.6% (3 of 22 subjects) in the intervention group (Fisher's exact test, $P = 0.0883$). At the 20-month follow-up, the proportion of women with falls in the control group had increased to 54.5% (12 of 22 subjects), but remained unchanged, at 13.6% (3 of 22 subjects), in the intervention group (Fisher's exact test, $P = 0.0097$; Fig. 3). The number of falls sustained during the 20-month follow-up period was 6 in the intervention group and 17 in the control group. No subject in either group sustained a fracture.

Discussion

A Japanese national survey showed that the annual frequency of falls was greater than 20% in subjects aged over 65 years; approximately 10% of these falls resulted

Table 3. Comparison of physical performance parameters (means ± SD) and questionnaire variables (%) at baseline survey in 1999 between subjects who completed the trial and dropouts in the intervention group

Variables	Completed trial (n = 22)	Dropouts (n = 6)	P Value*
Age[a]	77.31 ± 3.40	79.00 ± 3.41	0.293
NWS[b]	1.24 ± 0.23	0.99 ± 0.36	0.047
MWS[c]	1.80 ± 0.25	1.41 ± 0.44	0.089
GS[d]	21.82 ± 4.63	19.00 ± 2.28	0.164
STO[e]	29.59 ± 22.77	15.00 ± 15.34	0.153
STC[f]	5.73 ± 4.70	3.17 ± 2.99	0.220
TW[g]	9.23 ± 2.60	5.33 ± 4.89	0.111
FR[h]	29.04 ± 4.25	26.04 ± 5.18	0.182
KEP[i]	52.62 ± 15.42	39.95 ± 7.33	0.011
Fall[j]	18.2	0.0	0.357
ADL[k]	100.0	100.0	—

*Subjects who completed the trial *vs* dropouts in the intervention group by *t*-test (a–i), and Fisher's exact test (j, k)
[a] Average age (years)s
[b] Normal walking speed (m/s)
[c] Maximum walking speed (m/s)
[d] Grip strength (kg)
[e] Stork stand time with eyes open (s)
[f] Stork stand time with eyes closed (s)
[g] Tandem walking (steps)
[h] Functional reach (cm)
[i] Knee extension power (Nm)
[j] Fall experience within 1 year preceding baseline (%)
[k] Independence of basic ADL (%)

in fractures [36]. Over 80% of femoral neck fractures in the elderly are caused by falls, and these usually require long-term hospitalization. Proposed methods of preventing fractures include increasing bone mineral density, preventing falls, and using appliances. Bone mineral density may be increased by either pharmacotherapy or exercise. However, most reports suggest that, in practice, it is difficult to use exercise for fracture prevention [37]. On the other hand, many studies agree that by strengthening the muscles and improving balance, exercise training can prevent falls that often cause fractures.

Walking ability is particularly important in preventing falls. Our recent 5-year follow-up study [23] showed that the incidence of falls was 26.3% in the group with a slow normal walking speed (0.96 m/s), compared with 11.4% in the group with a fast normal walking speed (1.28 m/s). Furthermore, a 1-m/s increase in walking speed lowered the risk ratio to 0.2 (95% confidence interval; 0.08 to 0.52) after adjusting for other variables. According to The Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT) study [38,39], muscle training and environmental modification were the most effective methods of preventing falls in the elderly. Gardner et al. [40] reviewed 11 randomized controlled trials based on a total of 4933 subjects aged over 60 years. Five of these trials found that exercise significantly reduced the incidence of falls or the risk of falling. Close et al. [41] conducted a randomized controlled trial on subjects aged over 55 years who were attending an emergency department because of falls, providing not only medical evaluation but also evaluation and interventions from the occupational therapy viewpoint. They achieved not only a reduced incidence of falls but also a reduction in the percentage of hospital admissions, indicating the effectiveness of practical approaches. Rubenstein et al. [42], in a randomized controlled trial, reported that, even for fall-prone elderly men with chronic impairments, a group exercise program (three times per week × 12 weeks) could significantly improve isokinetic strength, endurance, and gait, which resulted in a significant reduction of fall rates in the intervention group.

The types and intensities of exercise used in our study were chosen so that they could be implemented by the subjects themselves, at home. Home-based exercise is already known to be effective in preventing falls [43,44]. As a first outcome of our trial, we noted several perceived changes in functions. Over 50% of subjects in the intervention group perceived increased muscle power in their legs and approximately 70% also perceived greater stability when walking. Over 60% became

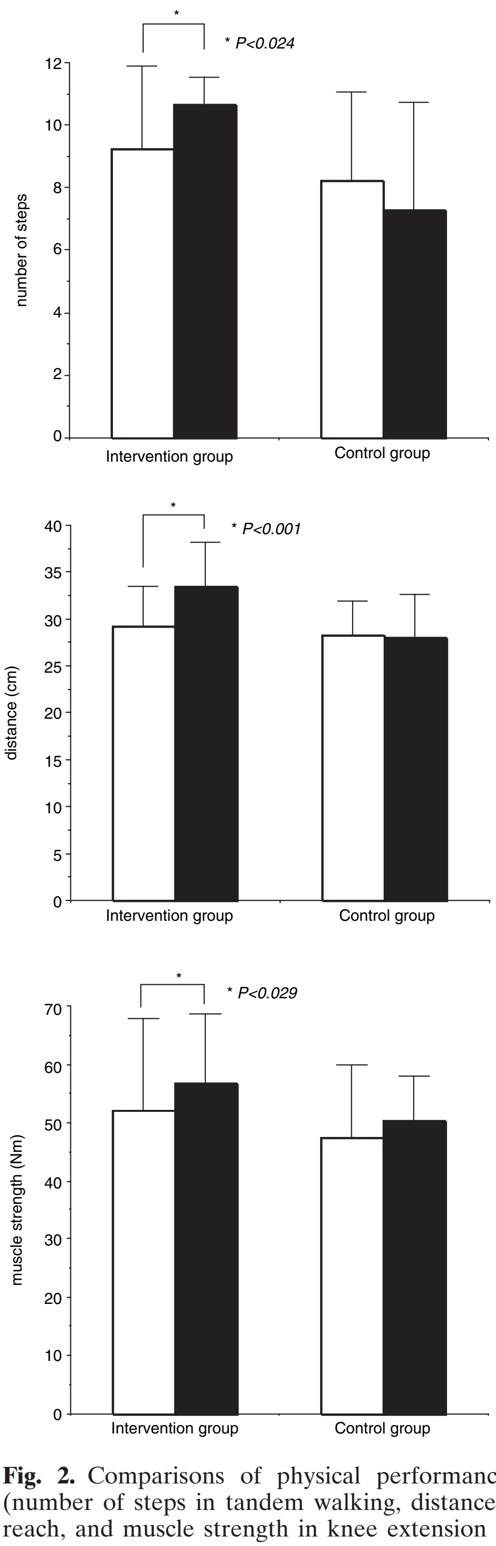

Fig. 2. Comparisons of physical performance parameters (number of steps in tandem walking, distance of functional reach, and muscle strength in knee extension power) in between intervention and control groups after 6-month intervention (paired *t*-test was used separately for both groups). *While bars*, pre-test; *black bars*, post-test

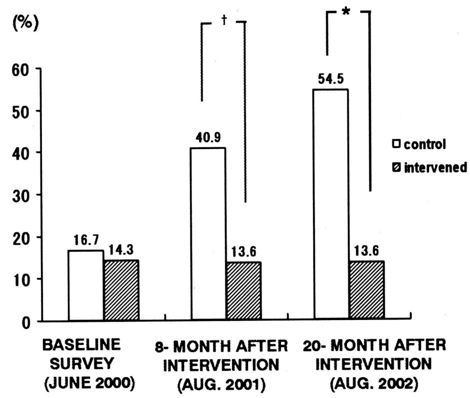

Fig. 3. Changes in proportions of women with falls (%), 8 and 20 months after intervention, in control (*white bars*) and intervention (*black bars*) groups. Fisher's exact test, $^{\dagger}P < 0.1$; $^{*}P < 0.05$

confident that they themselves could prevent falls, indicating an important psychological benefit from the program.

A second outcome was a significant improvement in dynamic balance and muscle strength in the lower extremities. Deficits in skeletal muscle strength, balance, and gait, being major causes of frailty and risk factors for falls, are equivalently and potentially reversible by exercise training. Binder et al. [45], in a randomized controlled trial, showed that intensive exercise training could improve those physical functions even in frail and impaired community elderly. In our study, it appears that an exercise class even once every 2 weeks is very effective in enhancing physical function in ambulatory individuals aged over 73 years, provided that it is supplemented by a home-based exercise program.

A third outcome was a significant reduction in the incidence of falls in the intervention group. This may translate into a smaller number of fractures, with resulting decreases in medical expenditure. In the control group, the cumulative incidence of falls was more than 50% over the 20-month follow-up period, a figure consistent with previous reports on the incidence of falls among elderly Japanese [13,36]. The beneficial effect of the intervention apparently continued not only over the short term (8-month follow-up) but also over the longer term (20-month follow-up).

In our study, there were some methodological weakness. First, the number of subjects was not sufficiently large, so that the incidence of falls during the follow-up period may have been influenced by chance. Second, the dropout rate of more than 20% in the intervention group may have produced a type-I error, as already reported by McMurdo et al. [46]. The high dropout rate in our randomized controlled trial may have reduced the statistical power to detect a significant effect of the interventions for fall prevention among the elderly. In spite of these limitations, this first randomized controlled intervention study for prevention of falls among the community elderly in Japan suggests beneficial effects of long-tem moderate exercise to improve physical activity and to reduce the incidence of falls. A large-scale study is needed to confirm the present results and to evaluate the most effective exercises for the prevention of falls.

The general conclusion to be drawn from this study is that the incorporation of exercises in daily life is important in maintaining an appropriate level of physical function in the elderly. Integrating exercises in daily life can strengthen muscles in the legs, waist and abdomen, improve balance, and increase the individual's self-confidence.

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