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Walking can be more effective than balance training in fall prevention among community-dwelling older adults

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Aim: To examine the effects of walking on falls among community-dwelling older adults while accounting for exposures.

Methods: A total of 90 older adults, ranging in age from 65 to 79 years, were allocated into either the walking (brisk walking, $n = 50$) or the balance (balance and strength training, $n = 40$) group to participate in a 3-month supervised and 13-month unsupervised fall-prevention program held from 2012 to 2014 in Japan. Falls and trips that occurred during the 16-month period were monitored with a monthly fall calendar. The risk of falls and trips was evaluated by person-year, physically active person-day and person-step.

Results: The walking group showed a significant reduction in the fall risk when evaluated by the falls per physically active person-day (rate ratio 0.38, 95% confidence interval 0.19–0.77) and falls per person-step (rate ratio 0.47, 95% confidence interval 0.26–0.85) compared with the balance group. In contrast, the number of trips significantly increased with walking, even when evaluated as trips per physically active person-day (rate ratio 1.50, 95% confidence interval 1.12–2.00).

Conclusion: The present findings suggest that walking among community-dwelling older adults can be more effective for fall prevention than balance training. However, because walking can induce more trips, walking should not be recommended for older adults who are susceptible to falling or frailty. **Geriatr Gerontol Int 2015; ••: ••–••.**

Keywords: accidental falls, aged, exercise, intervention studies, walking.

Introduction

Each year, one-third of community-dwelling older adults experience falls.[1] The consequences of the falls, including the fear of falling, restricted activity and fractures become more severe with advancing age.[2,3] The number of falls is expected to increase as the number of older adults increases worldwide.[4]

Walking exercise has the potential to be used as a population-wide fall prevention strategy, because it can be implemented regardless of time, location, previous sports experience or the presence of instructors, and is the most prevalent type of exercise.[5] However, a systematic review with a meta-analysis of 44 randomized controlled trials by Sherrington *et al.* reported that walking programs significantly increased fall outcomes.[6] The majority of the participants included in the meta-analysis were "high-risk" participants, such as frail nursing home residents, patients with Parkinson's disease, osteoporosis or stroke, or patients with a recent history of fractures.[7–11] A cross-sectional study by Okubo *et al.* showed that among high-risk older people, habitual walking was significantly related to a greater history of falls.[12] In contrast, among the general population who were not at high risk, habitual walking was significantly correlated with a lower history of falls.[12] Among the general population of community-dwelling older adults who were able to walk at a higher intensity than the high-risk population, a 3-month walking intervention resulted in significant improvements in physical and psychological functions, such as knee extension strength, gait velocity and fall self-efficacy.[13] Therefore, among the general population of community-dwelling

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older adults, we hypothesize that walking has a positive effect on fall prevention.

The problematic nature of a walking intervention aiming at fall prevention is that along with the improvements in physical and psychological functions, it is also accompanied by an increased exposure to environmental hazards (e.g. a greater chance of tripping while walking).[13] Wijlhuizen *et al.* developed the FAlls Risk by Exposure (FARE) by Exposure (FARE) measure, in which 1000 physically active person-days and the number of fallers over 10 months are computed to evaluate the risk of falling.[14] FARE was able to show the high relative risk of falls among participants with balance control difficulties, which could not be observed with a normal fall risk indicator by 1000 person-years. To the best of our knowledge, no previous intervention studies have evaluated the effects of walking on falls while also accounting for exposure (the numbers of physically active days and step counts). Therefore, the purpose of the present study was to examine the effects of walking on falls, and evaluate these effects by both time-period and exposure among community-dwelling older adults.

Methods

Design and ethics

The present study was an extension of the previously reported 3-month controlled trial with an additional 13-month follow-up survey (clinical trials registry: UMIN000012058).[13] The study protocol was developed in accordance with the Declaration of Helsinki, and was approved by the Research Ethics Committee of the University of Tsukuba, Japan (TAI23-42). Due to ethical reasons, the control group received common balance training as a fall prevention program, which was substantially different from walking.[15]

Settings and participants

The study was carried out in the University of Tsukuba, located in the Ibaraki prefecture of Japan. The study participants were recruited through advertisements in a community newspaper between 2012 and 2013 (Fig. 1). The eligibility criteria were as follows: aged 65–79 years, not care-dependent or support-dependent on a Japanese long-term care insurance system, not restricted from exercising by a doctor and without regular exercise habits. The participants were excluded if they had a high risk of falling (two or more of the following: using a walking aid, knee pain, using four or more medications and a history of recurrent falls/fractures during the previous year), were unable to participate in either of the two groups or had participated in another clinical trial during the previous year.[12] The remaining participants were then assigned to the walking or balance group using computer-generated random numbers. The numbers of participants were decided according to the capacity and safety of the program. Written informed consent was obtained from each participant.

Intervention

The previously described protocol[13] is summarized here. The intervention programs consisted of 12 2-h sessions held at the university once per week for 12 weeks. A session consisted of health lectures (20 min), a warm-up (10–15 min), recreational activity (0–10 min), primary exercise (30–50 min) and a cool-down (10–15 min).

Brisk walking on a pedestrian road was the primary exercise for the walking group. The participants were instructed to walk more quickly than their usual pace, but between "Light (11)" and "Somewhat hard (13)" according to the perceived exhaustion scale ("Rest" [6] to "Exhaustion" [20]).[16] The walking distance and pace of the groups were gradually increased by the instructors within both the aforementioned timeframe and the perceived exhaustion of the participants (1st week: 2.3 ± 0.2 km, 78.4 ± 3.6 m/min; 12th week: 4.5 ± 0.6 km, 96.2 ± 12.6 m/min). Based on the American College of Sports Medicine Guideline, walking for 30–50 min 3–5 days per week was also recommended for home exercise during the 3-month supervised and 13-month unsupervised follow-up periods.[17] The participants received pedometers (Lifecorder PLUS; Suzuken, Aichi, Japan) to wear every day, and they recorded their step counts and walking durations in their exercise diaries.

Balance training, muscle strengthening of the legs (15–20 min) and Tai Chi (30–40 min) were the primary exercises for the balance group. Beginner's Tai Chi (8 forms) and 24-form Tai Chi were taught by a professional Tai Chi instructor. The balance and strength training program was based on the Otago Exercise Program.[18] Balance training included a one-leg stance with the eyes opened/closed and decreasing support from the upper limbs.[6] Muscle strengthening targeted the ankle dorsiflexors and plantar flexors, knee extensors, knee flexors, and hip abductors. Squats and lunges were carried out at increasing levels of difficulty and repetitions (10–20 repetitions).[18] This group was instructed to carry out a set of the balance and muscle strengthening exercises at home 3–5 days per week. The participants recorded their home training in their exercise diaries.

Measurements

Characteristics

At baseline, information regarding sex, medication use, history of cataract/glaucoma, lumbar pain, knee pain,

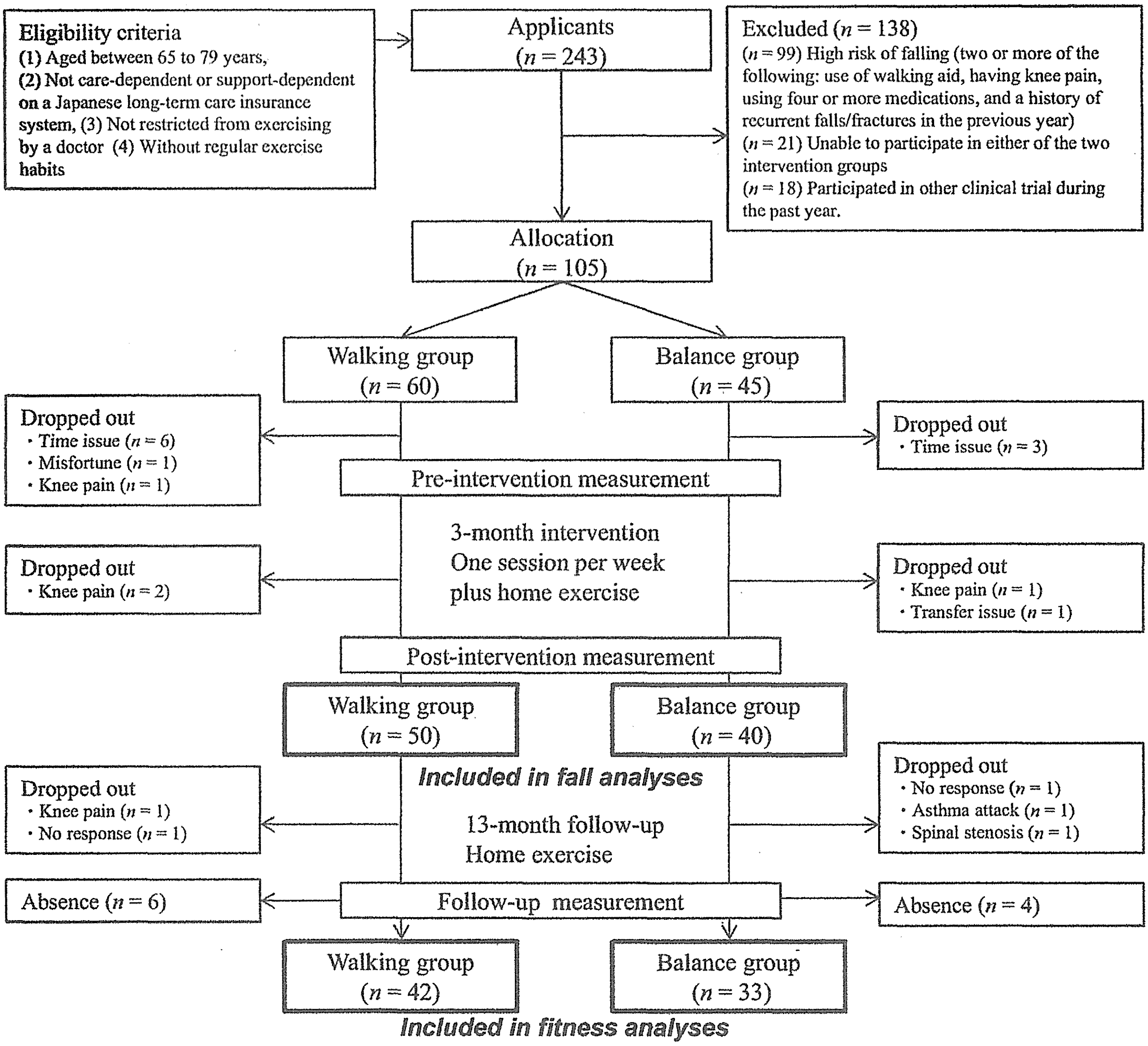

Figure 1 Flow chart of the study participants.

fear of falling and history of falling over the past year was collected. Bodyweights and heights were measured.

Main outcomes

Falls and trips

A fall was defined as "unintentionally coming to rest on the ground, floor or other lower level due to reasons other than sudden-onset paralysis, epileptic seizures, or overwhelming external forces."[19] To examine the effects of walking on falls, falls during bicycling were excluded. A trip was defined as "the act of stumbling over an object without landing on any part of the body."[20] The participants were asked to record the number of falls and trips daily in their fall calendars, and turn them in every month until the end of the 16th month.

Time and exposure variables

The number of months the participants were followed up was used in the analysis. At the end of the intervention, the number of physically active days was ascertained by the following question: "How many days in a month have you been physically active – walking for at least 30 min?"[14] Daily step counts were also measured with accelerometers (Life-coder PLUS, Suzuken, Japan), which were used by the participants for 1 week.

Table 1 Baseline characteristics of the study participants

Variables	Walking group (n = 50)	Balance group (n = 40)	P-value
Age (years)	70.3 ± 3.9	70.0 ± 3.7	0.686
Sex (female)	60.0	65.0	0.667
Height (cm)	157.6 ± 7.8	157.1 ± 7.5	0.750
Weight (kg)	56.1 ± 9.2	56.1 ± 10.6	0.983
Medication use (no)	1.1 ± 1.7	0.7 ± 1.1	0.505
Cataract/glaucoma (yes)	22.0	22.5	1.000
Lumbar pain (yes)	16.0	20.0	0.782
Knee pain (yes)	6.0	10.0	0.695
Fear of falling (yes)	32.0	15.0	0.085
Fall history in a past year (yes)	18.0	30.0	0.215

Mean ± standard deviation or prevalence (%); n = 90.

Secondary outcomes

As fall-related physical and psychological functions, we chose to assess gait, balance, fall-efficacy and physical activity at baseline, immediately after the 3-month intervention, and at the 1-year follow up.[21] Gait was assessed with an obstacle avoidance walk and a 6-min walk. Balance was assessed with a one-legged stance with the eyes closed. Fall self-efficacy was assessed with the fall self-efficacy scale for elderly Japanese.[22] Physical activity was assessed by the daily step counts.

Sample size calculation

To detect a significant (0.70) relative fall risk among the walking group with a 3.0 base incidence rate, 80% power and 5% alpha error, 100 participants were required.

Statistical analyses

The baseline characteristics of the walking and balance groups were compared with an unpaired t-test and χ^2-test. A Poisson regression analysis was used to calculate the adjusted rate ratio (RR) and 95% confidence intervals (CI) with the number of falls or trips as dependent variables, the sex and baseline fall history as covariates and the groups as independent variables. The offset variables included the time period (followed months), physically active days (followed months × physically active days / 10) or steps (followed months × daily steps / 100 000). Within-group changes and between-group interactions of the secondary outcome measurements between both groups at baseline, post-intervention and follow up were examined by a two-way analysis of variance (ANOVA) with the Bonferroni correction. These analyses were carried out using IBM SPSS Statistics software, version 21 (SPSS, Chicago, IL, USA), and the level of significance was set at 5%.

Results

Of the 90 participants who remained in the fall analyses (Fig. 1), the average age was 70.1 ± 3.8 years. No significant between-group differences were observed in the participant characteristics at baseline (Table 1). During the 16-month study period, an average of 1.4 ± 0.5 sets/day were carried out for 4.6 ± 2.0 days/week in the balance group, and an average of 45.2 ± 24.5 min/day of walking for 4.3 ± 1.7 days/week (231.4 ± 179.3 min/week) were carried out in the walking group.

During the follow-up period, which had an average ± standard deviation (SD) of 15.5 ± 2.2 months (range 5–16 months) (in a total of 116 person-years), 53 falls were observed in both groups (0.46 falls per person-year).

The adjusted RR (95% CI) of falls per physically active person-day (0.38, 0.19–0.77) and falls per person-step (0.47, 0.26–0.85) among the walking group were significantly lower than those of the balance group (Fig. 2). In contrast, the adjusted RR (95% CI) of trips per person-year (1.66, 1.34–2.05) and trips per physically active person-day (1.50, 1.12–2.00) of the walking group were significantly higher than those of the balance group. No other significant adjusted RR were observed.

Post-intervention, both groups showed significant improvements in the obstacle avoidance walk and 6-min walk (Fig. 3). At the follow up, both groups maintained the improvements in the 6-min walk. However, significant between-group interactions in the 6-min walk test, fall efficacy and daily step counts showed that the walking group exhibited greater improvements than the balance group (P for interaction <0.05). The obstacle-avoiding walk showed that the balance group improved more than the walking group, but this difference was not significant (P for interaction = 0.054). The one-leg stance with eyes closed significantly improved post-intervention, only in the balance group, but significantly

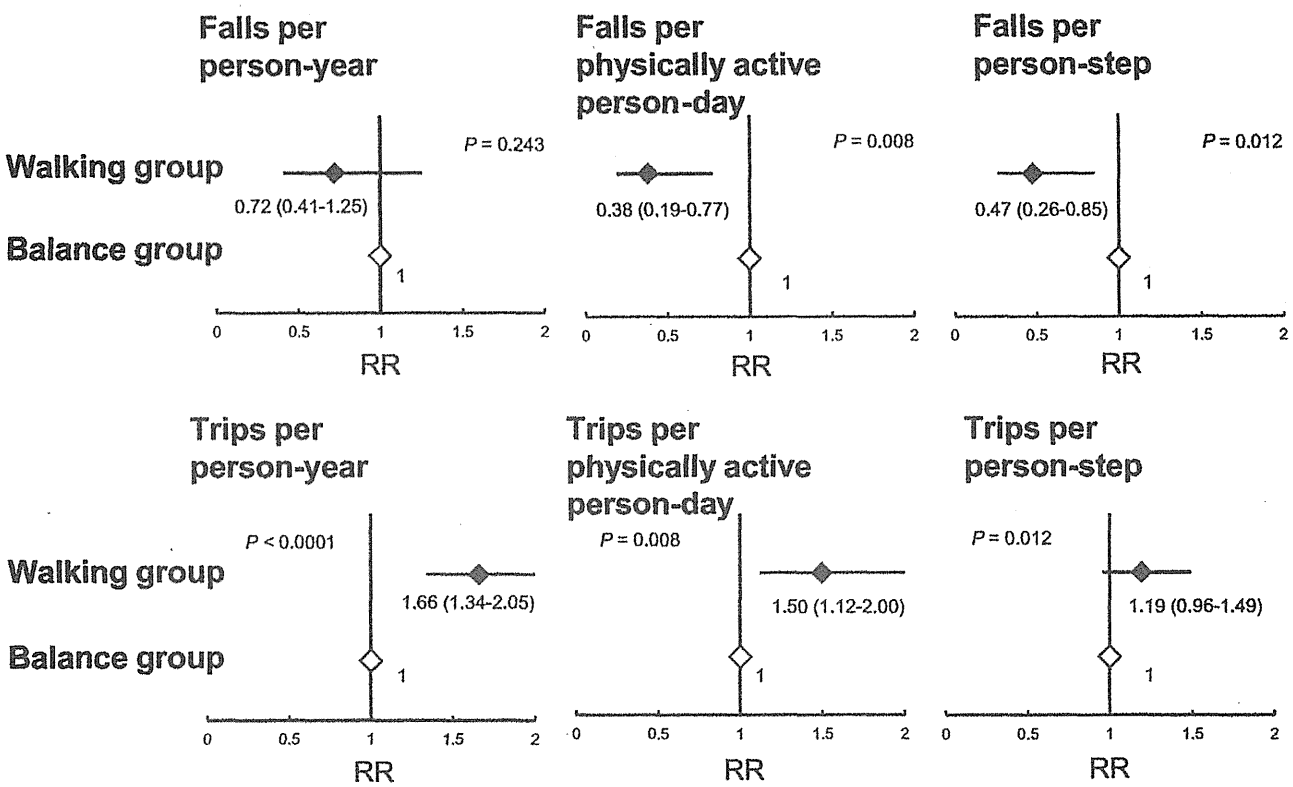

Figure 2 The rate ratio (RR) of falls and trips by period or exposures among the walking ($n = 50$) and balance ($n = 40$) groups. RR and 95% confidence intervals were adjusted for sex and baseline falls history.

decreased at the follow up. No significant between-group interaction was observed in the one-leg stance with eyes closed.

Discussion

To the best of our knowledge, this is the first study to show the beneficial effects of walking on fall prevention evaluated with exposure among community-dwelling older adults. Despite the increase of trips with walking, the significant fall reduction effect of walking was observed when the fall risk was evaluated as falls per person-physically active day and falls per person-step.

The discrepancy between the positive finding of the present study and the negative findings of the previous studies could be explained by a couple of reasons.[6] First, the systematic review with a meta-analysis showed that walking had adverse effects on the number of falls (RR 1.32, 95% CI 1.11–1.58).[6] However, the majority of the analyzed studies recruited high-risk participants, such as frail nursing home residents, patients with Parkinson's disease, osteoporosis or stroke, or those with a recent history of fractures.[7–11] Okubo *et al.* reported that the harmful association between walking and fall history was observed only among high-risk participants (adjusted odds ratio 4.61, 95% CI 1.32–16.09), and a beneficial relationship between walking and a lower fall history was observed among low-risk participants (adjusted odds ratio 0.44, 95% CI 0.20–0.97).[12] A similar modifying effect of frailty or having a high risk of falling on the association between walking and falls has been reported in longitudinal and intervention studies.[23,24] Second, the 165 community-dwelling women aged 66.4 ± 7.8 years with recent histories of upper limb fractures included in the randomized control trial by Ebrahim *et al.* were probably the closest to the present study participants in terms of age and living conditions.[11] Those participants were encouraged to gradually work up to walking for 40 min three times a week without supervision at a self-selected pace that was faster than their normal walking speed. In contrast, in the present study, the walking exercise carried out by the participants was supervised once a week for the first 3 months, and then the participants were encouraged to continue their walking for the 13-month follow up. Furthermore, the health lectures regarding fall-prone situations, walking patterns and the importance of paying proper attention might also have played a role. We warned the participants that although a fast walking speed and wide

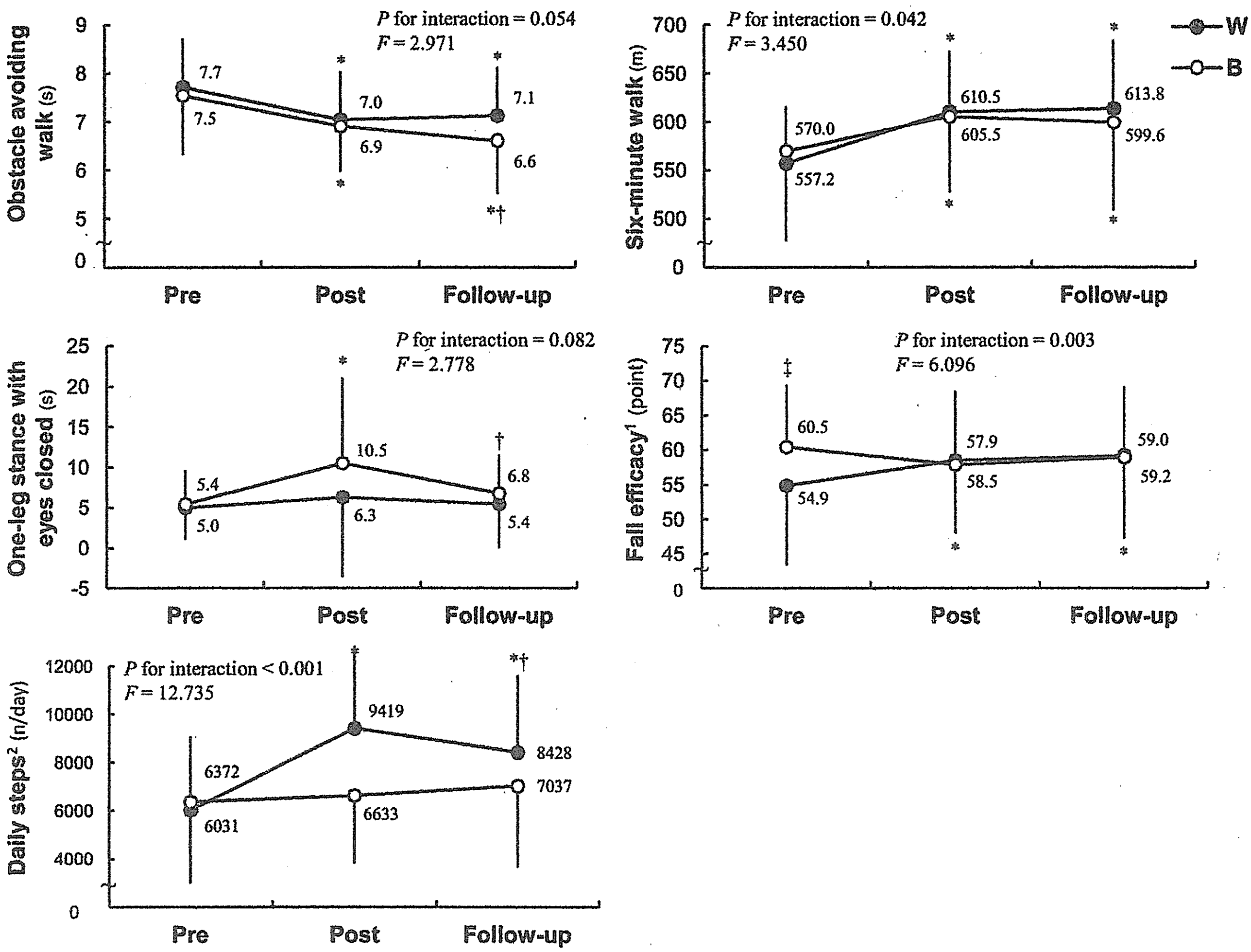

Figure 3 Changes of physical/psychological functions and physical activity at pre- and post-intervention, and follow-up among the walking (W; $n = 42$) and balance (B; $n = 33$) groups. Circle, mean; error bar, standard deviation. $^{*}P < 0.05$ versus pre-intervention; $^{\dagger}P < 0.05$ versus post-intervention, $^{\ddagger}P < 0.05$ versus the walking group at pre-intervention; [1]Balance ($n = 36$) and Walking ($n = 45$) groups; [2]Balance ($n = 35$) and Walking ($n = 47$) groups.

stride were important in improving their physical function, those walking patterns made them vulnerable to falling after trips and to slipping, respectively.[25,26]

In the current study, the significant fall prevention effect of walking would not have been detected if the data had not been analyzed according to exposures. The significant reduction of fall risk by exposure shows that the older adults were more physically active and walked more steps without falling. Wijlhuizen *et al.* reported that some older adults are afraid of falling, and prevented falls by reducing their physical activity.[27] However, a reduction in physical activity might lead to a faster functional decline and greater susceptibility to falling in the future. Additionally, Vetter *et al.* reported a non-significant increase in the number of falls by encouraging physical exercise, and a positive outlook about their better mobility, quality of life and even mortality.[28] A fall prevention program should allow older populations to safely and freely walk to maintain a good quality of life.

Although the mechanisms by which walking led to the reduction of fall risk compared with balance exercises are not fully understood, some possible explanations exist. First, the 6-min walk, which tests gait or endurance, of the walking group significantly improved to a greater extent than the balance group. Mertz *et al.*, studied 10 615 participants aged 20–87 years, and reported that low endurance levels were associated with a history of walking-related falls after adjusting for age.[29] The higher endurance capacity among the walking group could have contributed to preventing falls, because fatigue is detrimental to postural control, and a fall might occur when an individual is fatigued.[30] Second, the walking group in the present study experienced significantly more trips than the balance group did. Bhatt *et al.* reported an interesting laboratory experiment that showed an "inoculating effect" of a deliberate slipping experience against falling.[31] Bhatt *et al.* showed that community-dwelling older adults who were exposed to frequent slipping trials (a 3-month interval) were significantly better at controlling their stability in the slipping test than those who received less frequent exposure (a 6-month interval).[31] Pavol *et al.* reported that the quick initiation of a recovery step after a trip is important to avoid falling.[25] Rogers *et al.* reported that training with "involuntary stepping" induced by pulling the waist was more effective in improving step initiation timing than voluntary step training.[32] Grabiner *et al.* stressed the importance of task-specific training to avoid or to recover from tripping, and many studies have attempted to train older adults in situations similar to real-life tripping.[33–35] The increased trips experienced among the walking group could have served as the "involuntary" stepping and "real-life" recovery training to inoculate community-dwelling older adults against sudden and unpredictable chances of falling.

However, because walking did induce more trips, it should not be recommended for older adults who are frail or susceptible to falling. The participants in the current study were those who did not meet two or more of the following criteria: using a walking aid, knee pain, using four or more medications or a history of recurrent falls/fractures during the previous year.[12,23] These criteria, which are simple and can be quickly checked by the telephone, can be used to screen older adults who would benefit with regard to falls prevention by engaging in regular walking.

The results of the current study need to be interpreted with caution because of the following limitations. First, no blinding was applied. Second, there was a risk of overestimation, because an intention-to-treat analysis was not available. Third, we could not study a non-exercise group for ethical reasons. Fourth, the reliability of the trip data was not high. Fifth, because the exposure variables (physically active days and steps) were measured post-intervention, they did not reflect the change during the follow-up period. To be more precise, the exposure variables should be continuously measured throughout the follow-up period. A larger, high-quality randomized controlled trial is warranted to re-examine the results of the present study and explore the mechanisms.

Acknowledgments

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Disclosure statement

The authors declare no conflict of interest.

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Effects of walking on physical and psychological fall-related factors in community-dwelling older adults: Walking versus balance program

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Abstract This study aimed to examine the effects of walking, a common activity that has previously been reported *not* to be effective for fall prevention, on fall-related factors among a general population of community-dwelling older adults. A total of 90 men and women, ranging from 65-79 years of age, were randomly allocated into either the walking group (brisk walking) or the balance group (tai chi, balance and strength training) to participate in 12-week supervised and home-based exercise programs. Physical factors (11 items on gait, static/dynamic balance, and strength of the lower extremities), psychological factors (Japanese Falls Efficacy Scale or FES), and daily step counts were assessed. Falls and trips were recorded during the 12-week intervention period. In both groups, significant improvements ($P < 0.05$) over the 12-week intervention were observed in usual/maximum gait speed, timed up and go, 10-m walk over obstacles, 6-minute walk, functional reach, 30-s chair stand test, and isometric knee extension force. Only the walking group showed significant increases in fall self-efficacy (+3.1 ± 8.0 points) and daily step counts (+3366.4 ± 3212.5 steps/day) ($P < 0.05$). No significant differences between groups were observed in falls or trips. Our findings suggest that walking among general, community-dwelling older adults was specifically effective in improving fall-related psychological factors and physical activity levels, as well as in improving some fall-related physical factors such as gait, dynamic balance and dynamic strength of the lower extremities, which were also improved by the strength and balance program.
Keywords : accidental falls, aged, exercise, walking, intervention

Background

Approximately 30% of the community-dwelling elderly population experience falls each year[1]. Falls among the elderly are the leading cause of fractures[2], fear of falling[3], restricted activity[4], and consequent functional dependency[5]. In Japan's rapidly aging society, approximately one in four people are now 65 years old or older[6]. The number of falls is expected to increase in magnitude as the number of older adults increases worldwide[7]. Therefore, fall prevention programs that can be implemented on a population basis are urgently needed.

Walking, which can be implemented regardless of time, location, previous sports experience, or the presence of instructors, is the most prevalent type of exercise[8,9]. Although habitual walking can be effective in lowering physical fall-related factors such as poor lower extremity functional abilities, previous meta-analyses of randomized, controlled trials have reported that the inclusion of a walking program significantly increased fall outcomes[10,11]. One study that showed an increase in falls with a walking-related intervention reported that increased exposure to environmental hazards was likely the cause of the increased fall incidence[12]. A previous cross-sectional study showed that among high-risk, community-dwelling older people, habitual walking was significantly related to a history of a greater number of falls[13]. In general subjects, but not high-risk subjects, habitual walking was significantly correlated with a history of a lower number of falls[13].

Primary fall prevention strategies, for the general population of community-dwelling older adults who are not yet at high-risk, are potentially important because, among this population, approximately 20% experience falls each year[14]. This 20% of the older population is likely to transition to a high-risk category for future falls, because previous fall experience is consistently found to be one of the strongest predictors of future falls in various studies[15].

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Moreover, all older adults are subject to the possibility of developing a high-risk of falling in the future; we do not need to wait for that to happen to prevent or at least slow down the development of this risk.

Exercise interventions can be safer and more effective when older adults are physically fit and cognitively intact[16]. Although walking was reported to be less effective than strength and balance training among high-risk older adults[11], greater effects on physical function may be obtained among general older adults who can walk with a higher intensity and longer duration. The question remains whether regular walking is effective in improving lower-extremity muscle strength or balance[15] or in overcoming the fear of falling, and further, whether walking is comparable to strength and balance training. Therefore, the purpose of the study was to examine the effects of walking on physical and psychological fall-related factors compared to strength and balance training among general community-dwelling older adults.

Methods

Study design and ethical considerations. The study was a 2-armed intervention trial with an ongoing follow-up survey. The current research focused on examining the short-term effects of walking compared to a strength and balance program over a 12-week intervention. The protocol was registered with the UMIN Clinical Trials Registry (UMIN000012058). The study protocol was developed in accordance with the guidelines proposed in the Declaration of Helsinki and was approved by the Research Ethics Committee of the Faculty of Health and Sport Sciences of the University of Tsukuba, Japan (TAI23-42). The trial was conducted twice, from September to December 2012 and from April to July in 2013. In an attempt to accomplish both our research purposes and meet the ethical considerations of the study participants[17], the group to be compared in the trial underwent a normal fall prevention program[18] that was substantially different from walking.

Settings and participants. The study participants were recruited through advertisements in a community newspaper. The eligibility criteria were as follows: aged between 65 to 79 years, not care-dependent or support-dependent on a Japanese long-term care insurance system, not restricted from exercising by a doctor, and without regular exercise habits. Participants were excluded if they were at a high risk of falling (two or more of the following: using a walking aid, knee pain, using four or more medications, and a history of recurrent falls/fractures in the previous year)[13], were unable to participate in either of the two intervention groups, or had participated in another clinical trial during the previous year (Fig. 1). The remaining participants were then randomly assigned to one of the two

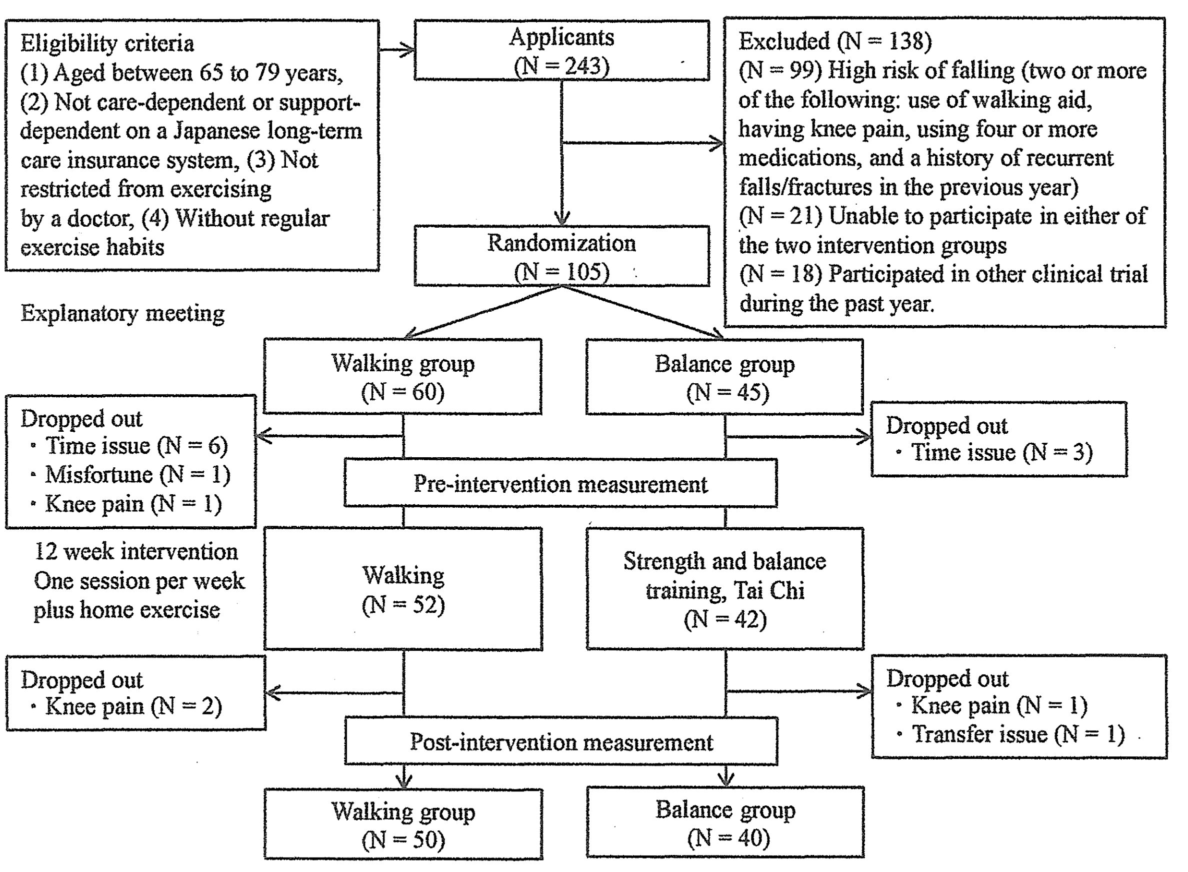

Fig. 1 Flow chart of the study participants.

study arms by the first author using computer-generated random numbers. The participants were ranked in order of the computer-generated random numbers; the top 20th (in 2012) or 25th (in 2013) ranks were assigned to the balance group and the remaining to the walking group. The numbers of participants were decided according to the capacity and safety of the program. Age and sex equality between the two groups was confirmed. If a participant was informed of his/her group allocation and was unable to participate in the allocated group, he/she was excluded from the study and considered as dropped out. We then held an explanatory meeting for study participants and obtained written informed consent. No blinding was applied.

Intervention

1. Common features of exercise classes

The intervention programs consisted of 12 2-h sessions held at the university once per week for 12 weeks. A session consisted of lectures (20 min), a warm-up (10-15 min), recreational activity (0-10 min), the main exercise (30-50 min), and a cool-down (10-15 min). The lectures included the following topics: fall prevention, the benefits of and tips for regular exercise, training mechanisms, etc. Heart rate (HR) was measured during the main exercise with a heart rate monitor (RS400, Polar Electro Japan, Tokyo, Japan). Percent HR max was calculated using the following formula: HR/age expected HR max (220 - age) × 100. All of the programs, except for the main and home exercise components, were the same in both groups.

2. Walking group

Brisk walking on a pedestrian road was the main exercise for the walking group. Proper walking technique and advice for purchasing suitable walking shoes were provided to the participants. The participants were instructed to walk more quickly than their usual pace, but between "Light (11)" and "Somewhat hard (13)" on the rating of Borg Rating of Perceived Exertion (RPE) scale[19]. According to the participant's walking ability and condition, they chose one of five groups of different walking paces, each led by a trained instructor. The duration (min), distance (km), and pace (m/min) in each group were recorded by a staff member. The duration of walking was extended from 30 min during the 1st week to 50 min by the 12th week. The walking distance and pace of the groups were gradually increased by the instructors within both the above timeframe and the perceived exhaustion of the participants (the 1st week: 2.3 ± 0.2 km, 78.4 ± 3.6 m/min, the 12th week: 4.5 ± 0.6 km, 96.2 ± 12.6 m/min). When walking outside was not feasible due to rain (twice in 2012, once in 2013), a walking-related exercise[20] was conducted indoors. Walking for 30 to 50 min, 3 to 5 days per week, was also recommended for home exercise[21]. The participants received pedometers (Lifecorder PLUS, Suzuken Inc., Aichi, Japan) to wear every day, and they recorded their step counts and walking durations in their exercise diaries for self-monitoring.

3. Balance group

Balance training, muscle strengthening of the legs (15-20 min), and tai chi (30-40 min) were the main exercises for the balance group. Beginner's tai chi (8 forms) and 24-form tai chi were taught by a professional tai chi instructor. The strength and balance program was based on the Otago Exercise Program, of which an individual could choose one of four levels of difficulty and intensity. All participants started from level 1 and were recommended to increase the level or perform multiple sets as they got used to the level[22]. Balance training included a one-leg stance with the eyes opened/closed, with decreasing support of the upper limbs[11]. Muscle strengthening consisted of ankle dorsiflexors and plantar flexors, knee extensors, knee flexors, hip abductors, squats, and lunges at increasing levels of difficulty and dose (10-20 repetitions)[22]. Balance and muscle strengthening training were also recommended for home exercise, to be done 3 to 5 days per week. The participants recorded the home training in their exercise diaries.

Main outcome measurements. Physical and psychological functional measurements that have been reported to be fall-related factors[15] and to be associated with functional dependence[23] were measured at baseline and after the 12-week intervention.

1. Gait

Usual and maximal gait speed[23] were measured along a 7-m course. Actual walking speed was measured over 5 m, starting with the first footfall past the 1-m mark and ending with the first footfall after the 6-m mark. For the 10-m walk over obstacles, the time to walk over 6 obstacles as quickly as possible along a 10-m course was measured. For the 6-minute walk, the farthest distance walked in 6 minutes along a 50-m course was recorded.

2. Balance

For the one-legged stance with eyes opened/closed, the time spent standing on one leg for a maximum of 60 s with eyes opened/closed in a standard position was measured. For the timed up and go test[24], the time taken to rise from a chair, walk forward 3 m as quickly as possible, turn 180 degrees, walk back to the chair, and sit was measured. For the functional reach test[25], the participants stood by the wall with their feet one shoulder width apart, raised their arms in front of them into a horizontal position (beginning position), and stretched their arms forward as far as possible (ending position). The distance from the beginning position to the ending position was measured.

Table 1. Baseline characteristics of the study participants (N = 90)

Variables	Total (N = 90)		Walking group (N = 50)		Balance group (N = 40)		*P* for difference
Age (year)	70.1	± 3.8	70.3	± 3.9	70.0	± 3.7	0.686
Gender (female)	62.2		60.0		65.0		0.667
Height (cm)	157.4	± 7.7	157.6	± 7.8	157.1	± 7.5	0.750
Weight (kg)	56.1	± 9.8	56.1	± 9.2	56.1	± 10.6	0.983
BMI (kg/m^2)	22.6	± 3.6	22.5	± 2.7	22.8	± 4.5	0.737
Body fat (%)	24.8	± 9.2	24.2	± 8.3	25.5	± 10.3	0.505
Medication use (n)	0.9	± 1.4	1.1	± 1.7	0.7	± 1.1	0.505
Hypertension: yes	15.6		20.0		10.0		0.248
Diabetes mellitus: yes	11.1		14.0		7.5		0.502
Heat disease: yes	1.1		0.0		2.5		0.444
Hyperlipidemia: yes	8.9		4.0		1.5		0.132
Cataract/glaucoma: yes	22.2		22.0		22.5		1.000
Lumbar pain: yes	17.8		16.0		20.0		0.782
Knee pain: yes	7.8		6.0		10.0		0.695
Fear of falling: yes	24.4		32.0		15.0		0.085
TMIG-IC Score	12.4	± 1.0	12.4	± 1.2	12.5	± 0.8	0.727

Mean ± standard deviation or %. TMIG-IC: Tokyo Metropolitan Institute of Gerontology Index of competence. *P* values were calculated using an unpaired *t* test for the continuous variables or a χ-square test for the categorical variables.

3. Strength

For the 30-second chair stand test[26], the number of repetitions of forming the initial sitting position from the final, fully erect position in 30 seconds was counted. Isometric knee extension force was measured using a dynamometer (Biodex system 3, Biodex Medical, New York, USA). Contractions were held with knees at 60° for 3 seconds, with a 5-second rest period between repetitions.

4. Fall self-efficacy

The Falls Efficacy Scale (FES) for elderly Japanese[27], which ascertains confidence in performing 15 activities of daily living that are common in Japan (*e.g.*, reaching up to a high shelf) without falling, was used. The sum of the items (15 to 75 points) was used in the analysis.

Secondary outcome measurements

1. Fall status

A fall was defined as "unintentionally coming to rest on the ground, floor, or other lower level due to reasons other than sudden-onset paralysis, epileptic seizures, or overwhelming external forces[28]". A trip was defined as "the act of stumbling over an object without landing on any part of the body[20]". The numbers of falls and trips were recorded separately at the beginning of each weekly session throughout the 12-week intervention period. Participants were also asked whether they suffered any injuries as a result of a fall, such as bruises, lacerations, or fractures.

2. Physical activity

Daily step counts were measured with a pedometer (Life-coder PLUS, Suzuken Inc., Japan), used by the participants for at least 12 hours per day for one week.

Statistical analysis. All the participants who remained in the study until the post-intervention measurement, regardless of attendance and exercise participation, were included in all the analyses. The participants with missing data (2 variables, 1 case each) were included with the last observation carried forward (LOCF) methods, assuming no change. The unpaired *t* test or χ-square test was used to examine the statistical significance of between-group differences at baseline. The paired-*t* test or Wilcoxon's signed-rank test was used to examine the statistical significance of improvements after the 12-week intervention. Two-way analysis of variance was used to examine the statistical significance of between-group interactions of the main effects (changes between pre- and post-intervention). In order to address imbalances between baseline values and sex, analysis of covariance was also used to examine the between-group difference in the changes of outcome measurements pre-and post-intervention, adjusted for baseline values and sex. Negative binomial regression analysis was used to examine the statistical significance of between-group differences in fall status. The data were analyzed using IBM SPSS Statistics software, version 21 (SPSS Inc., Chicago, IL, USA), with the level of statistical significance set at 5%.

Results

Of the 90 participants who remained in the final analysis (Fig. 1), the average age was 70.1 ± 3.8 years, and 62.2% were women. No significant between-group differences were observed in the participant characteristics (Table 1) and outcome measures at baseline, except for the fall self-efficacy scale (Table 3). The individual attendance rates were 95.0% for the walking group and 94.2% for the balance group. Adherence to home exercises (an average of 3 days/week or more) was 96.0% for the walking group and 95.0% for balance group. Ten participants in the walking group (16.6%) and 5 participants in the balance group (11.1%) dropped out of the study (Fig. 1). No significant differences in age and sex were observed between the participants who did or did not drop out.

The average speed and distance of walking in a session were 93.2 ± 7.9 m/s and 3.9 ± 0.3 km, respectively (Table 2). The %HR max values of the walking and balance groups (tai chi, strength and balance training) were 77.0 ± 9.6% and 55.1 ± 8.7% ($P < 0.01$), respectively.

Main outcomes. Significant improvements in both groups over the 12-week intervention were observed in usual/maximum gait speed, timed up and go, 10-m walk over obstacles, 6-minute walk, functional reach, 30-s chair stand test, and isometric knee extension force (Table 3). However, the knee extension force of the balance group (+4.9 ± 6.1 kg) showed significantly greater improvement than that of the walking group (+2.5 ± 4.7 kg) (P for interaction = 0.042). One-legged balance with eyes closed was significantly improved only in the balance group. The fall self-efficacy scale significantly improved in the walking group (+3.1 ± 8.0 points), but significantly worsened in the balance group (-2.6 ± 8.0 points) (P for interaction = 0.001). When adjusted for each baseline value and gender, the walking group showed significantly greater changes in the fall self-efficacy scale.

Fig. 2 represents between-group comparisons of the changes in outcomes over the 12-week intervention, adjusted for each baseline value and gender. A significant difference was observed in the fall self-efficacy scale ($P < 0.05$). No significant differences were observed in other outcome measures.

Secondary outcomes. The incidence rates (number of incidences per 100 person-months) of trips (Walking: 32.0, Balance: 25.8, P = 0.674), falls (Walking: 5.3, Balance: 9.2, P = 0.312), and injurious falls (Walking: 3.3, Balance: 3.3, P = 0.708) did not differ significantly between the two groups. Daily step counts were significantly improved only in the walking group (+3366.4 ± 3212.5 steps/day) (P for interaction < 0.001) (Table 3). A significant difference was also observed in daily step counts after adjusting for the baseline value and gender ($P < 0.05$).

Table 2. Exercise components during the 12-week intervention in walking and balance groups (N = 90)

Variables	Walking group (N = 50)	Balance group (N = 40)
Home exercise		
Frequency (days/week)	5.5 ± 1.2	5.8 ± 1.4
Walking		
Duration (min/day)	45.8 ± 22.8	NA
Amount (min/week)	262.8 ± 166.5	NA
Strength training (sets/day)	NA	1.7 ± 0.8
Supervised exercise		
RPE (6-20)	11.6 ± 0.9	12.3 ± 1.0**
HR (b/min)	115.2 ± 13.5	82.5 ± 12.8**
%HR max (%)	77.0 ± 9.6	55.0 ± 8.8**
Walking		
Distance (km)	3.9 ± 0.3	NA
Duration (min)	41.4 ± 2.1	NA
Speed (m/min)	93.2 ± 7.9	NA

Mean ± standard deviation. NA: not applicable, HR: heart rate, RPE: rating of perceived exertion. ** $P < 0.01$ vs the walking group.

Table 3. Fall-related physical and psychological functions and physical activity over the 12-week intervention among the walking (N = 50) and balance (N = 40) groups.

Variables	Group	Baseline		Post-intervention		*P* for difference	*P* for interaction
Usual gait speed (m/s)	W	1.37	±0.20	1.54	±0.18	<0.001	0.337
	B	1.40	±0.19	1.54	±0.20	<0.001	
Maximum gait speed (s)	W	2.05	±0.29	2.15	±0.28	0.005	0.803
	B	2.05	±0.26	2.17	±0.30	<0.001	
Timed up & go (s)	W	6.3	±0.9	5.7	±0.8	<0.001	0.548
	B	6.2	±0.7	5.7	±0.8	<0.001	
Obstacle avoiding walk (s)	W	7.8	±1.7	7.1	±1.2	<0.001	0.830
	B	7.6	±1.2	7.0	±1.0	<0.001	
Six-minute walk (m)	W	558.3	±57.9	609.7	±61.2	<0.001	0.069
	B	569.6	±88.1	603.8	±75.4	<0.001	
One-leg stance with eyes opened (s)	W	38.8	±21.3	40.1	±21.4	0.569	0.474
	B	38.9	±21.1	42.8	±18.5	0.207	
One-leg stance with eyes closed (s)	W	4.9	±3.8	6.3	±9.3	0.250	0.092
	B	5.7	±4.8	10.5	±10.4	0.004	
Functional reach (cm)	W	28.4	±5.0	31.0	±5.0	<0.001	0.674
	B	28.9	±5.1	31.2	±4.4	0.004	
Chair stand (n/30s)	W	21.2	±4.2	22.8	±4.5	0.003	0.240
	B	20.8	±4.7	23.3	±5.0	<0.001	
Knee extension force (Nm[1])	W	103.6	±36.1	111.1	±33.6	<0.001	0.042
	B	91.8	±31.4	105.9	±34.3	<0.001	
Fall self-efficacy (point)	W	54.5	±12.0*	57.6	±11.5	0.008	<0.001
	B	60.6	±9.0	58.0	±10.6	0.045	
Daily step counts (n/day[2])	W	6156.7	±3046.1	9448.6	± 3324.6	<0.001	0.001
	B	6121.9	±3284.3	6545.3	± 2798.3	0.167	

Mean ± standard deviation. * $P < 0.05$ vs the balance group at baseline. The last observation carried forward method was applied to [1] one missing datum in the balance group [2] and one missing datum in the walking group.

Discussion

Walking has previously been reported not to be effective for fall prevention[11]. However, this study suggested that walking, which is the most common exercise, was equally effective among general community-dwelling older adults in improving physical fall-related factors[15] - gait, dynamic balance, and strength of lower extremities - compared to the balance and strength program. Moreover, this was the first study that showed that walking was specifically effective in improving fall self-efficacy, a psychological fall-related factor.

Main outcomes: physical and psychological fall-related factors

1. Strength

Nemoto et al. reported that among middle-aged and older participants aged 63 ± 6 years, high-intensity interval walking (40% to 70% of peak aerobic capacity) for 4.5 days/week for 5 months significantly improved isometric knee extension force by 13%[29]. However, Kubo et al. reported that a self-selected, comfortable pace of walking for 40 min, 4 days/week for 6 months, did not improve the isometric knee extension force[30]. Nemoto et al. also reported that moderate-intensity walking, 4.5 days/week for 5 months, did not improve the isometric knee extension force[29]. In the current study, brisk walking, at an average pace of 93.2 m/s and %HR max of 77.0% for 12 weeks, significantly improved the isometric knee extension force by 7%. Morris et al. suggested that walking faster than a customary pace and regularly, in sufficient quantities, in the "training zone" of more than 70% of the maximal heart rate was required to develop and sustain physical fitness[8]. Rooks et al.[31] reported that among community-dwelling older adults aged 65-95, self-paced strength training done 3 days/week for 10 months resulted in a significant 65% increase in knee extension strength (1RM), but that self-paced walking for 45 min,

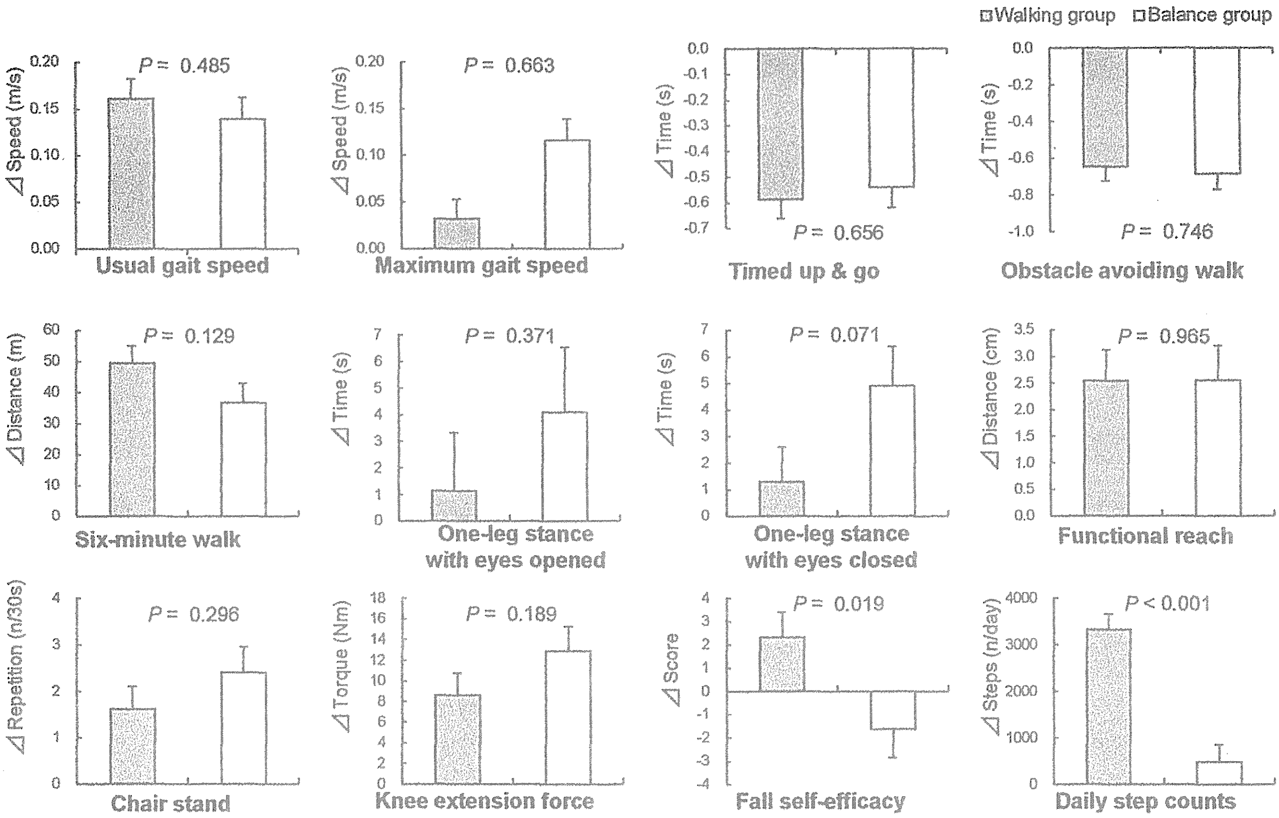

Fig. 2 Comparison of changes in fall-related physical and psychological functions and physical activity over the 12-week intervention between the walking (N = 50) and balance (N = 40) groups. *P*-values were calculated by ANCOVA and adjusted for gender and baseline values. Values are adjusted means ± standard errors.

3 days/week for 10 months, resulted in a non-significant decrease. In the current study, the effects of strength training (+16%) on the isometric knee extension force were greater than those from walking (+7%); however, this difference was not significant in the gender- and baseline-adjusted model. On the other hand, the effect of walking on dynamic strength of the lower extremities (30-s chair stand test) was similar to that of the balance and strength program. Dynamic strength, which is more closely related to movements in daily activities, is believed to be related to fall prevention because most falls occur during dynamic activities such as walking, turning, and reaching[32].

2. Balance

Walking was equally effective for improving dynamic balance (functional reach and timed up and go tests) as the strength and balance program, but not as effective for static balance (one-legged balance with eyes opened/closed). Paillard et al. also reported that brisk walking, done 5 days/week for 12 weeks, significantly improved dynamic balance (body sway on unstable platform), but not static balance (body sway on stable ground). Walking has been characterized as a "continuous process of recovery from a loss of balance[33]" and thus as a factor contributing to the maintenance of dynamic balance. Walking might be effective for static balance if continued for a longer period of time; Brown et al.[34] reported that endurance training consisting of brisk walking, cycling, and jogging for one year significantly improved one-leg balance at month 15, but not at month 3. With regard to the comparison with the strength and balance program, although the difference of the gender- and baseline-adjusted change in one leg stance with eyes closed was not significant ($P = 0.071$), a significant difference would likely be observed with a greater sample size. Rooks et al.[31] reported that self-paced walking significantly improved one-leg balance at month 10, but that a greater improvement was achieved by strength training. On the other hand, Rooks et al.[31] also reported that tandem walking, as an indicator of dynamic balance, was significantly improved in the walking group, but not in the strength training group. Future research should examine which of the static and dynamic balance improvements are more related to the prevention of falls.

3. Gait

As expected, 12 weeks of walking improved usual and maximum gait speeds by 12% and 4.9%, respectively. Fig. 2 indicates that the effects of walking on usual gait speed were equal to those of strength and balance training, but were slightly less with regard to maximum gait speed. Buchner et al. examined groups engaging in stationary cycling, walking, aerobic movement, or no exercise (controls), and only the walking group significantly improved in usual gait speed, by 5%[35]. Because slow walking speed was a strong risk factor for falling[15], we can argue that walking was effective in improving this fall-related physical function.

4. Fall self-efficacy

Fall self-efficacy, or the confidence of an individual in his ability to perform daily activities without falling[36], is important in maintaining an active lifestyle and physical function, as activity restriction due to loss of confidence or fear of falling can lead to future functional decline and a consequent increased risk of falling[37]. In the current study, fall self-efficacy was significantly increased only in the walking group and significantly decreased in the balance group. Yoo et al.[38] reported that among women of average age 70.9 ± 2.7 years old walking with ankle weights, 3 days/week for 12 weeks, resulted in a significantly decreased fear of falling. Okubo et al. also revealed that high-risk walkers aged 78.5 ± 2.7 years old had a significantly lower fear of falling (44.4%) than high-risk non-walkers (73.3%). Although the mechanism of how the fall self-efficacy is increased by walking remains uncertain, a possible explanation is that the walking group experienced a greater chance of falling, along with the 56% increased daily step counts, than the balance group, without actually falling at a greater rate. This experience of avoiding falling in an outside environment in the walking group might have increased the fall self-efficacy of the participants. While the walking group spent most of their exercise time outside, all of the strength and balance training was conducted inside of a building. While this way of improving fall self-efficacy requires increased caution for high-risk older adults due to increased environmental hazards, it is clearly desirable for general community-dwelling older adults to maintain a high level of physical activity.

Secondary outcomes: fall status and physical activity during the intervention period. The recent meta-analysis by Sherrington et al.[10] re-examined the effects of walking on falls, and suggested that walking can be included in fall prevention programs if the participants are not at high risk of falling. Our results partially supported this recommendation, because increased physical activity among general community-dwelling walkers did not result in a greater fall incidence over the 12-week intervention. Thees results were also consistent with the cross-sectional study by Okubo et al.[13], which showed that among general community-dwelling older adults, habitual walking for 48.1 ± 20.3 min, 5.3 ± 2.0 days/week for 7.6 ± 6.5 years, was significantly correlated with a history of fewer falls[13]. The participants in the current study improved obstacle avoidance, dynamic balance, and lower-extremity muscle strength, as well as succeeded in preventing falls and trips. The fall prevention lectures about fall-prone situations, walking patterns, and the importance of paying proper attention might have played a role in the improvements observed in the walking group, as these participants encountered greater exposure to environmental hazards. We clarified to the participants that although slow gait speed and a short stride were key characteristics of fall-prone elderly people[39], a fast walking speed and wide stride rendered participants vulnerable to falling after trips[40] and to slipping[41], respectively. In contrast to the walking group, almost no increase in physical activity was observed among the balance group. This may have contributed to the previous success of reducing falls by balance training without a walking component[10]. However, if the final goal of falls prevention is to allow elderly populations to safely and freely walk and maintain a good quality of life, an intervention that maintains or improves physical and psychological factors to the extent that older adults can sustain exposure to increased environmental hazards is required.

The high feasibility of this protocol as a health promotion program in communities is a strength of the current study; the dropout rate was low (14.3%) and the attendance rate was high (94%). In contrast, there were several limitations in the current study. First, the generalizability of the study may not be high because the participants were limited to an age range of 65 to 79 years. There may be populations older than 80 years of age that would benefit from regularly walking outside. Second, the sample size (n = 90) may have been insufficient to detect between-group differences for some outcome variables (effect size < 0.3). The between-group difference in changes for one-leg stance with eyes closed and knee extension force might be better detected with a bigger sample size (effect size: 0.15-2.0, α error: 0.05, β error: 0.8, sample size: 200-380). The non-significant differences in falls and trips between the groups might also have been due to an insufficient sample size and the short follow-up duration. Therefore, we are following up with our participants for 12 months to obtain data on their fall status, as well as contining the exercise and maintaining physical and psychological functions.

Conclusion

Our findings suggested that walking has specific effects on improving psychological fall-related factors, as well as similar effects as the balance and strength-training program on improving fall-related physical factors such as gait, dynamic balance, and the dynamic strength of the lower extremities, without an increase in falls over the 12-week intervention. Walking might be useful as a population-wide recommended approach for fall prevention among general community-dwelling older adults.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this article.

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Original Article

The Dose-Response Relationship Between Body Mass Index and the Risk of Incident Stage ≥3 Chronic Kidney Disease in a General Japanese Population: The Ibaraki Prefectural Health Study (IPHS)

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ABSTRACT

Purpose: To examine the relationship between body mass index (BMI) and the risk of stage ≥3 chronic kidney disease (CKD) in a general Japanese population.
Methods: A total of 105 611 participants aged 40–79 years who completed health checkups in Ibaraki Prefecture, Japan, and were free of CKD in 1993 were followed-up through 2006. Stage ≥3 CKD was defined by an estimated glomerular filtration rate <60 mL/min/1.73 m^2 reported during at least 2 successive annual surveys or as treatment for kidney disease. Hazard ratios (HRs) for the development of stage ≥3 CKD relative to the BMI categories were calculated using the Cox proportional hazards regression model, which was adjusted for possible confounders and mediators.
Results: During a mean follow-up of 5 years, 19 384 participants (18.4%) developed stage ≥3 CKD. Compared to a BMI of 21.0–22.9 kg/m^2, elevated multivariable-adjusted HRs were observed among men with a BMI ≥23.0 kg/m^2 and women with a BMI ≥27.0 kg/m^2. Significant dose-response relationships between BMI and the incidence of stage ≥3 CKD were observed in both sexes (P for trend <0.001).
Conclusions: Obesity was associated with the risk of developing stage ≥3 CKD among men and women.

Key words: chronic kidney disease; body mass index; obesity; dose-response relationship; epidemiology

INTRODUCTION

Chronic kidney disease (CKD) is a major public health problem. In Japan, CKD affects 13.3 million adults.[1] With the increasing incidence of hypertension and type 2 diabetes and the aging of the Japanese population, the number of individuals with CKD will likely continue to increase. CKD is recognized as an independent risk factor for myocardial infarction and cardiovascular mortality and can result in significant morbidity, mortality, and increased medical costs.[2]

Obesity is also a major public health issue, and its prevalence has been increasing worldwide. Obesity is associated with the development of many cardiovascular disease (CVD) risk factors, including type 2 diabetes mellitus,[3,4] hypertension,[5,6] dyslipidemia,[7] and CKD.[8] Prospective cohort studies have revealed the longitudinal relation between body mass index (BMI) and the risk of moderate CKD. A greater baseline BMI was associated with an increased risk of stage ≥3 CKD in the Physician's Health Study,[9] the Hypertension Detection and Follow-Up Program,[10] and the Framingham Heart Study.[11] Because treatment of long-term CKD is costly, the best approach is to reduce the incidence of stage ≥3 CKD or prevent it entirely. Examining the modifiable risk factors for stage ≥3 CKD,

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such as obesity, is important because of the public health implications.

A relationship between obesity and the risk of stage ≥3 CKD in Japanese participants has been reported.[12] However, not enough information was presented to examine the dose-response relationship between obesity and the risk of CKD (ie obesity was only considered as dichotomous data); consequently, the dose-response relationship in Japanese individuals remains unclear. An examination of the CKD risk using more-detailed BMI categories in a large cohort is warranted. Additionally, no studies have considered the age-specific relationship between BMI and the development of stage ≥3 CKD. Further research on this issue may help officials implement more effective public health and clinical efforts aimed at the primary prevention of CKD. The purpose of our study was to examine the dose-response relationship between BMI and the development of stage ≥3 CKD in a general Japanese population.

METHODS AND PROCEDURES

Study population

The study population consisted of 194 333 individuals (63 865 men and 130 468 women) aged 40–79 years who were living in Ibaraki Prefecture, Japan. These individuals had participated in community-based annual health checkups in 1993 (as part of the Ibaraki Prefectural Health Study), which were conducted by the local governments in accordance with the Law of Health and Medical Services for the Elderly. The Ibaraki prefectural government collected data from the local governments, and personal information was removed to ensure anonymity. We excluded 18 939 patients (2367 men and 16 572 women) because of incomplete data, 10 075 individuals (4101 men and 5974 women) because of a history of CVD, and 10 491 individuals (3615 men and 6876 women) because of the presence of stage ≥3 CKD and/or ongoing treatment for CKD. We further excluded 48 864 individuals (17 999 men and 30 865 women) who failed to participate in the 1994 survey, thereby ensuring that all of the participants were followed for at least one year.

Ultimately, the study included 105 611 participants (35 738 men and 69 873 women). These participants were followed by annual examinations until a diagnosis of stage ≥3 CKD, withdrawal from the repeated examinations, or the end of 2006, whichever occurred first. The Ibaraki Epidemiology Study Union Ethics Review Committee approved the protocol for this cohort study.

Measurements

Kidney function was assessed using the estimated glomerular filtration rate (eGFR). The eGFR was calculated using the new Japanese abbreviated prediction equation,[13] modified from the Modification of Diet in Renal Disease (MDRD) Study,[14] as recommended by the Japanese Society of Nephrology:

$$\text{eGFR (mL/[min}\cdot 1.73\,\text{m}^2]) = [194 \times (\text{serum creatinine [mg/dL]})]^{-1.094} \times (\text{age})^{-0.287} \times 0.739 \text{ (for women only)}$$

According to Levey et al, stage ≥3 CKD is defined as the presence of kidney damage or an eGFR <60 mL/min/1.73 m^2 reported at least twice in successive annual surveys.[15]

Serum creatinine level was measured using the Jaffe method with an automated analyzer (Hitachi 7350; Hitachi, Tokyo, Japan, or RX-30; Nihon Denshi, Tokyo, Japan) in 1993–2003; in 2004–2006, it was measured using the enzyme method with an automated analyzer (Hitachi 7770; Hitachi). The coefficient of validation for creatinine value was 0.61%. Serum creatinine measurements from 1993–2003 were converted to the value obtained in the enzyme method using the following equation:

$$\text{serum creatinine by enzyme method (mg/dL)} = 0.9915 \times \text{serum creatinine by the Jaffe method (mg/dL)} - 0.211$$

The serum creatinine values measured using the enzyme method and the serum creatinine values measured using the Jaffe method were then converted to the enzyme method from the same subjects at the same point in time, and the comparability between them was found to be excellent ($r = 0.99$, $P < 0.001$). Proteinuria was defined as a urinary protein excretion of 1+ or more by dipstick test (Ames Hemacombisticks; Bayer-Sankyo Ltd., Tokyo, Japan).

The patients' height in sock feet and weight in light clothing were measured at baseline. BMI was calculated as the weight in kilograms divided by the height in meters squared (kg/m^2).

We measured the following cardiovascular risk factors: serum total cholesterol, serum high-density-lipoprotein (HDL) cholesterol, serum triglyceride, plasma glucose, blood pressure, use of medications, cigarette smoking, and typical alcohol intake. Blood samples were drawn into two polyethylene terephthalate tubes from seated participants; one tube contained an accelerator, while the other contained sodium fluoride and ethylenediaminetetraacetic acid. Overnight fasting (≥8 h) was not mandatory. The serum total cholesterol and serum triglyceride levels were measured using the enzyme method with the RX-30 device in 1993–1995, the H7350 device in 1996–2003, and the H7700 device in 2004–2006. The HDL cholesterol levels were measured using the phosphotungstic acid magnesium method with an MTP-32 device (Corona Electric, Ibaraki, Japan) in 1993–1995, the selective inhibition method with the H7350 device in 1996–2003, and the H7700 device in 2004–2006. Dyslipidemia was defined as triglycerides ≥1.7 mmol/L, HDL cholesterol <1.036 mmol/L, or as the patient being prescribed medication for dyslipidemia treatment.

The blood glucose level was measured using the glucose oxidase electrode method with a GA1140 device (Kyoto Daiichi Kagaku, Kyoto, Japan) in 1993–1996, the enzyme method with a H7170 device (Hitachi) in 1997–2003, and