るとしている．ただし，周径の測定には誤差が生じやすいという問題がある．汎用性も考えた測定方法を慎重に検討していくべきである．

2）要介護高齢者に対するトレーニング

要介護高齢者は施設サービスを利用することが多いが，そのサービス利用中に機能訓練（運動プログラム）を取り入れることが必要とされている．筆者らが，その実施状況を通所介護サービスを利用する 18,460 名の対象者で調査したところ，個別プログラムを計画し指導員の配置を整え実施している対象者は，全体の 75.7％であった．介護度の高い要介護 3～5 の対象者でも 76.2％の実施ができており，要介護高齢者でも環境によっては高い割合で運動の実施ができることが明らかとなった．

高齢者の筋力トレーニングの効果は，Liu ら[12]のシステマティックレビューからも明らかとなっている．ただし，施設に入所する（long-term care）高齢者に対する，Forster ら[13]のメタアナリシスの結果では，有意な効果は確認されていない．これは，要介護高齢者のように筋力低下が進行している高齢者が効果を上げることの難しさを意味しており，今後，効果的な介入方法について検討していかなければならない．

3．障害を有する高齢者のサルコペニアにおける今後の方向性

要介護高齢者は，サルコペニアに加え廃用性の筋委縮を呈し，地域在住高齢者とは異なる筋の病態を呈しているといえる．ただし，現状ではこの病態を象徴するような筋量や筋力のデータは存在しない．要介護高齢者であっても測定や運動の実行可能性があることは明らかであるので，今後は有効な方法を早急に検討していかなければならない．

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The effects of multidimensional exercise on functional decline, urinary incontinence, and fear of falling in community-dwelling elderly women with multiple symptoms of geriatric syndrome: A randomized controlled and 6-month follow-up trial

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ABSTRACT

This study assessed the effects of multidimensional exercises on functional decline, urinary incontinence, and fear of falling in community-dwelling Japanese elderly women with multiple symptoms of geriatric syndrome (MSGS). Sixty-one participants were randomly assigned either to an intervention ($n = 31$) or to a control group ($n = 30$). For 3-month period, the intervention group received multidimensional exercise, twice a week, aiming to increase the muscle strength, walking ability, and pelvic floor muscle (PFM). Outcome variables were measured at baseline, and after intervention and follow-up. The functional decline of the intervention group decreased from 50.0% at baseline to 16.7% after intervention and follow-up ($Q = 16.67$, $p < 0.001$). For urinary incontinence, the intervention group decreased from 66.7% at baseline to 23.3% after intervention and 40.0% at follow-up ($Q = 13.56$, $p = 0.001$), whereas the control group showed no improvement. Intervention group showed greater and significant decrease in the score of MSGS compared to control group ($F = 12.66$, $p = 0.001$). Within the subjects that showed improvement to normal status of MSGS, a significantly higher proportion demonstrated increased maximum walking speed at follow-up ($Q = 6.50$, $p = 0.039$). These results suggest that multidimensional exercise is an effective strategy for reducing geriatric syndromes in elderly population. An increase in walking ability may contribute to the improvement of MSGS.

1. Introduction

The geriatric syndrome such as functional decline, urinary incontinence, and fear of falling are used to capture those clinical conditions that do not fit into discrete disease categories, and are serious problems among the elderly population (Inouye et al., 2007). Many studies have demonstrated that a decline in walking speed, muscle strength and balance ability of the elderly is strongly associated with the development of geriatric syndrome (Vellas et al., 1997; Ishizaki et al., 2000; Maggi et al., 2001).

It is well documented that as age advances, the proportion of people with more than one symptom of geriatric syndrome increases. In addition, people with MSGS have an increased prevalence of functional disability and mortality compared to people with only one or no symptoms present. Several studies have put emphasis on the fact that multidimensional exercises focusing on strength, balance, and mobility improvement, even into advanced age, was helpful in reducing functional decline, urinary incontinence and fear of falling (Nelson et al., 2004; Gitlin et al., 2006; Kim et al., 2007). These previous studies validated the effectiveness of the multidimensional exercises focusing on the improvement of a single geriatric syndrome such as functional decline or urinary incontinence, but did not provide any information on whether the subjects possessed symptoms other than functional decline or urinary incontinence. One study demonstrated (Tinetti et al., 1995) that falls and urinary incontinence were associated with the occurrence of functional decline, and that the identification of shared risk factors associated with falls and urinary incontinence is the key in establishing effective and efficient interventional strategies. However, few multidimensional exercises studies have been performed in community-dwelling elderly persons with MSGS.

In the present study, we hypothesize that deteriorations in muscle strength, walking and balance ability are common risk factors associated with functional decline, urinary incontinence and fear of falling. We conducted a randomized and controlled trial to evaluate the effects of the multidimensional exercises targeted at reducing the symptoms of functional decline, urinary inconti-

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nence, and fear of falling in community-dwelling Japanese elderly women with MSGS.

2. Methods

2.1. Study sample and procedures

Overall health surveys were conducted at the Tokyo Metropolitan Institute of Gerontology (TMIG), aiming at early screening of geriatric syndromes in elderly persons and at developing intervention strategies, which would reduce those geriatric syndromes. As subjects, 1016 women were chosen randomly from the Basic Resident Register as persons aged 70 or older residing in Itabashi ward of Metropolitan Tokyo.

A letter outlining the study and describing its objective, and the way that the personal data would be used was mailed to the elderly women selected, inviting them to participate in the study. The baseline survey was conducted in November 2004, and 669 women aged 70 years and older participated.

The participants were screened based on three geriatric syndromes: functional decline, urinary incontinence, and fear of falling. A person who was reported as having two or more geriatric syndromes present was defined as having MSGS. Out of the 669 women participated, 102 were classified as having MSGS (Fig. 1). A pamphlet containing information on the "Exercise Classes for the Treatment of Geriatric Syndromes" was mailed to the 102 potential participants. A response was obtained from 74 of them, of whom 61 were willing to participate. There were no statistically significant differences in physical fitness, age, and geriatric syndromes between the 61 willing participants and the 41 unwilling ones including those who did not submit any response. The research protocol was approved by the institutional review board, and informed consent was obtained from each participant.

2.2. Randomization

After baseline assessment, subjects were divided into two groups with an allocation ratio of 1:1 according to computer-generated random numbers. There was no attempt to equalize the sizes of the groups based on characteristics or to recruit subjects with specific characteristics. Thereafter, one group was allocated to the intervention ($n = 31$) and the other group to the control ($n = 30$) (Fig. 1).

2.3. Data collection

Data collected by interview and a physical fitness test at baseline, after 3-month exercise, and were reassessed at 6-month follow-up.

2.3.1. Interview survey

A face-to-face interview was conducted to assess the following variables: The functional decline was measured using the TMIG index of competence (Koyano et al., 1991). For each of the 13 items, "yes" was scored as 1 and "no" as 0 (maximum score: 13). A person with a TMIG index score less than 10 was defined as having functional decline. Urinary incontinence was assessed through the question "Have you ever experienced urine leakage during the last 1 year?" If a subject responded with a "yes", we would then ask concerning the frequency of urinary incontinence. The frequency of urinary incontinence was assessed based on a five-point scale through interview (1: several times per year; 2: once or more per month: 3: once or twice per week; 4: once every 2 days; 5: everyday). A person whose response ranged 2–5 was defined as having urinary incontinence (Burgio et al., 1991). The fear of falling was assessed by asking "At this moment, are you afraid of falling?" and classified as "1. not at all", "2. somewhat", "3. very much", and "4. activity restriction due to fear of falling". Subjects who responded within 2 and 4 were assigned to the fear group (Maki et al., 1991).

The effect of the multidimensional exercises on the geriatric syndromes was assessed based on shifts of the responses from the interview, which was conducted at a baseline, completion of the 3-month exercise, and at the 6-month follow-up. The scores of geriatric syndromes were calculated as follows: functional decline, 0 for TMIG index score more than 11, 1 for 10, 2 for 9, and 3 for less than 8; urinary incontinence, 0 for no urine leakage or several times per year, 1 for once or more per month, 2 for once or twice per week, and 3 for once every 2 days or everyday; fear of falling, 0 for not at all, 1 for somewhat, 2 for very much, and 3 for activity restriction due to afraid of falling. The score of MSGS was calculated as add up three geriatric syndrome score (functional decline, urinary incontinence, and fear of falling). And, a participant with a MSGS score less than 1 was defined as improvement of MSGS.

2.3.2. Physical fitness test

Body mass index (BMI) was calculated from body weight (kg) divided by height (m) squared. Physical fitness tests were used for the assessment of muscle strength, walking speed, and balance ability. The following standardized tests were performed: grip strength (Suzuki et al., 2004); adductor muscle strength (Kim et al., 2007); usual and maximum walking speed (Suzuki et al., 2004); one leg standing time with eyes open (Suzuki et al., 2004); tandem walking (Speers et al., 1998); functional reach (Duncan et al., 1990). The staff members who performed the assessments did not know the subjects' group assignments.

2.4. Interventions

2.4.1. Exercise group

The exercise group participated in an intervention comprised of 60-min exercise sessions held at the TMIG Health Promotion Classes, twice per week for 3-month. Weight-bearing exercise: strength training of the thigh, abdominal, and back muscles was performed and included bending the knees, and other similar exercises.

PFM exercise: The exercise regimen was designed to strengthen the fast- and slow-twitch muscle fibers located at the pelvic floor. Participants were initially instructed to perform 10 fast contractions (3-s) with a 5-s relaxation period and 10 sustained contractions (6–8 s) with a 10-s relaxation period in between the contractions. The PFM exercise was performed in sitting, lying, and standing positions with legs apart, emphasizing training of the PFM and relaxation of the other muscles.

Chair exercises: Used in the early stage of the program. The exercises included seated toe and heel raises, seated lift foot and point/flex toes, and others.

Resistance band exercise: Focused on increasing the strength of the muscles of the upper extremities, abdomen, and lower extremities in frail elderly people (arm pull back, leg extension, and others).

Ball exercise: Exercises with a training ball were conducted using a small (diameter: 21 cm) and a large ball (diameter: 45–55 cm), aiming to increment the muscle strength and balance (sitting on the ball and extending legs, and others).

Walking ability training: Focused on maintenance of stability during walking and on the improvement of responses to postural changes during walking (walking with directional changes, gait pattern variations and enhancement, and others).

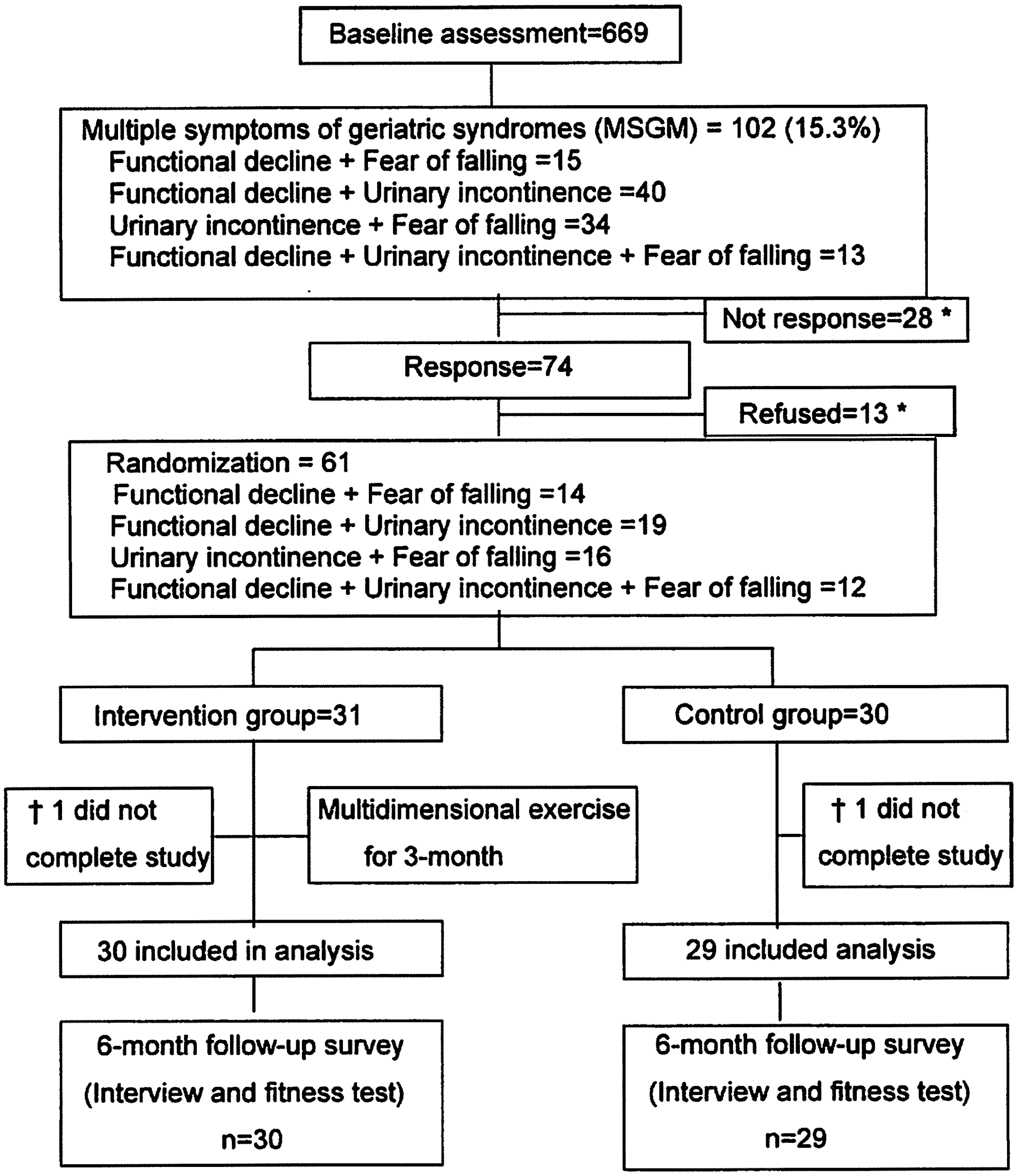

Fig. 1. Flow chart of participants through the randomized controlled trial of the exercise program and analysis. (*) Forty-one of MSGM ($n = 102$) were excluded due to the not response ($n = 28$) and refusal ($n = 13$). (†) Two subjects could not complete the study because of hospitalization ($n = 1$), and fracture ($n = 1$).

Balance training: Focused on the improvement of the static, dynamic, and lateral balancing ability (multidirectional weight shifts, tandem walking, and others).

2.4.2. Control group

The control group attended a general health education class (albumin, osteoporosis, and prevention of malnutrition) held at the TMIG once a month for a 3-month period.

2.5. Follow-up and compliance

During the 6-month follow-up period, subjects of the intervention group attended group exercise classes (60 min) once per month in addition to receiving a home-based exercise program. The home-based exercise program consisted of two to three sets of the 15 exercises and PFM exercise that they had learned during the group exercise session. They were also advised to do the home-based exercises at least three times or more per week for about 30-min per day. In order to accurately monitor the exercise times and the number of sets performed at home during the follow-up period, a pamphlet illustrating the PFM and strengthening exercises and a recording sheet were distributed to the participants, who were instructed to record the time and sets of exercises performed at home everyday. The record sheets were collected once a month at the group exercise class and analyzed in order to calculate the mean exercise frequency per week, and the mean exercise time per day.

2.6. Statistical analysis

Both the mean and standard deviation were calculated for each variable. The differences in the baseline data between the

Table 1
Selected variable characteristics of participants at baseline by study group, mean±S.D.

Variables	Intervention group	Control group	$p^{\dagger}$
Number	31	30	
Age (year)	79.0±3.9	78.1±4.4	0.424
Height (cm)	146.9±5.4	147.0±5.8	0.940
Body weight (kg)	47.4±6.4	50.7±9.1	0.108
BMI (kg/m^2)	22.0±2.6	23.4±3.6	0.084
One leg standing time (s)	29.2±23.5	34.6±22.8	0.367
Tandem walking (step)	7.2±4.7	7.8±4.7	0.631
Functional reach (cm)	31.0±7.1	33.2±4.9	0.167
Grip strength (kg)	16.5±4.3	17.9±4.7	0.239
Adductor muscle strength (kg)	17.3±4.0	18.0±5.1	0.740
Usual walking speed (m/s)	1.1±0.3	1.2±0.2	0.685
Maximal walking speed (m/s)	1.7±0.4	1.7±0.4	0.979
TMIG index score (point)	10.6±1.6	10.4±1.5	0.654
Urinary incontinence, yes (%)	64.5	50.0	0.252
Functional decline, yes (%)	51.6	43.3	0.517
Fear of falling, yes (%)	67.7	76.7	0.390
Chronic medical conditions, yes (%)			
Hypertension	58.1	60.0	0.902
Stroke	13.2	13.3	0.988
Diabetes	19.4	20.0	0.948

† Two group *t*-test for continuous variables and the χ^2-test for categorical variables.

exercise and control group were analyzed using *t*-test for the continuous variables and Chi-square test for the categorical variables. The changes in dependent variables pre-intervention, post-intervention and follow-up in the exercise and control group were analyzed using an analysis of variance (ANOVA) with repeated measures. Significant interactions were analyzed to determine whether or not the effects were greater in the intervention than the control group. Cochran's Q-test was used to evaluate within-group differences of the effect of the exercise on the categorical variables for pre-intervention, post-intervention, and follow-up data. In the case of items which were showing significant differences, a post hoc analysis was performed using McNumar's test. One-way ANOVA was performed to evaluate the within-subgroup effect of the intervention on multiple geriatric syndrome scores at baseline, after the 3-month exercise, and at 6-month follow-up. For the subgroup showing significant differences, a post hoc analysis was performed using Scheffe's method. The percentage improvement in physical fitness was calculated using the following formula: % improvement = {(after 3-month exercise or at 6-month follow-up values − baseline value)/baseline value × 100}. The percentage improvement was divided into tertiles. The power of the current study was calculated at 80% to demonstrate a difference in the outcome variable of at least 20% at a significance level of alpha = 0.05. All the analyses were performed using the SPSS software package for Windows version 15.0 (SPSS, Inc., Tokyo, Japan).

3. Results

There were no significant differences between the groups in any of the baseline characteristics such as age, BMI, walking speed, adductor muscle strength, functional decline, urinary incontinence, fear of falling, and chronic medical conditions (Table 1).

Attendance 15 (62.5%) or more than of the exercise sessions (24) was defined as trial completion. Two participants (3.3%) could not complete the trial after the randomization because of hospitalization (n = 1) and fracture (n = 1) (Fig. 1). The mean attendance rate was 77.4% (61.3–90.3%) during the intervention period and 74.2% during the follow-up. In the exercise group, 32.3% of the subjects attended the exercise sessions 24 times, 22.6% attended 20–23 times, 35.5% attended 16–19 times, 6.5% attended 15 times, and 3.3% attended 14 or less of the exercise sessions. During the follow-up, the mean frequency of performing the

Table 2
Comparison of physical fitness and geriatric syndrome variables between intervention = I (n = 30) and control = C (n = 29) groups after 3-month exercise and at 6-month follow-up, mean±S.D.

Variables	Gr	Baseline	3-Month exercise	6-Month follow-up	ANOVA F=	p=
Body weight (kg)	I	46.6±5.4	47.4±5.4	47.1±5.4	(1,57)=2.74	0.105
	C	51.0±9.5	51.0±9.4	50.6±9.1		
BMI (kg/m^2)	I	21.5±2.2	21.9±2.2	21.8±2.2	(1,57)=2.82	0.100
	C	23.4±3.9	23.4±3.8	23.3±3.6		
One leg standing time (s)	I	34.0±24.2	28.2±20.4	32.4±22.6	(1,57)=0.01	0.920
	C	33.4±23.4	28.8±23.5	32.4±24.6		
Tandem walking (step)	I	7.2±4.7	6.1±4.5	5.9±3.3	(1,57)=4.70	0.036
	C	7.8±4.7	5.2±3.8	3.5±2.0		
Functional reach (cm)	I	31.7±6.8	33.5±5.13	3.5±4.4	(1,56)=4.18	0.046
	C	33.7±4.7	32.7±5.3	31.6±8.8		
Grip strength (kg)	I	17.2±4.0	20.9±5.2	17.9±4.7	(1,57)=0.02	0.874
	C	18.0±4.6	21.5±5.1	18.6±4.8		
Adductor muscle strength (kg)	I	17.2±4.0	18.9±5.1	19.3±4.7	(1,57)=4.18	0.045
	C	17.9±5.0	18.2±4.01	17.8±3.7		
Usual walking speed (m/s)	I	1.1±0.3	1.1±0.2	1.2±0.2	(1,57)=13.03	0.001
	C	1.2±0.2	1.1±0.3	1.1±0.3		
Maximal walking speed (m/s)	I	1.7±0.4	1.8±0.5	1.8±0.4	(1,56)=4.24	0.044
	C	1.7±0.4	1.6±0.4	1.6±0.4		
Functional decline, yes (%)	I	50.0	16.7	16.7	16.67[a]	<0.001
	C	41.4	31.0	27.6	4.10[a]	0.109
Urinary incontinence, yes (%)	I	66.7	23.3	40.0	13.56[a]	0.001
	C	51.7	44.8	44.8	4.00[a]	0.135
Fear of falling, yes (%)	I	66.7	70.0	70.0	0.17[a]	0.920
	C	75.9	62.1	75.9	2.91[a]	0.234

[a] Cochran's Q-value.

Table 3
Improvement of MSGS according to maximum walking speed and adductor muscle strength tertiles in intervention group.

Survey variable	Changes compared to baseline[a]	Improvement of MSGS[†] n (%)	Cochran's Q-value	p	Post hoc[‡]
3-Month exercise (n = 8)					
Maximum walking speed	Increased	3 (37.5)	2.80	0.247	
	No change	4 (50.0)			
	Decreased	1 (12.5)			
Adductor muscle strength	Increased	3 (37.5)	0.50	0.779	
	No change	3 (37.5)			
	Decreased	2 (25.0)			
6-Month follow-up (n = 7)					
Maximum walking speed	Increased	5 (71.4)	6.50	0.039	In > De
	No change	1 (14.3)			
	Decreased	1 (14.3)			
Adductor muscle strength	Increased	3 (42.8)	0.57	0.713	
	No change	2 (28.6)			
	Decreased	2 (28.6)			

[a] Decreased (De) means lower range (0.0–33.3%), no change (no) means medium range (33.4–66.6%), and increased (In) means upper range (66.7–100%) of tertile.

exercise series at home was 3.8 times per week (23.3% performed everyday, 50.0% 2-3 times per week, 26.7% once or less per week), while the mean exercise time was 29.0 min.

The exercise group showed significant improvement compared with the control group in muscle strength, walking speed and balance. There was a significant group by time interaction for tandem walking ($F = 4.70$, $p = 0.036$), functional reach ($F = 4.18$, $p = 0.046$), adductor muscle strength ($F = 4.18$, $p = 0.045$), usual walking speed ($F = 13.03$, $p = 0.001$), and maximum walking speed ($F = 4.24$, $p = 0.044$) with significantly greater increases in the exercise group. The functional decline decreased significantly from 50.0% at baseline to 16.7% after the intervention and follow-up in the exercise group ($Q = 16.67$, $p < 0.001$), whereas the changes were not significant in the control group. Urinary incontinence was decreased significantly from 66.7% at baseline to 23.3% after the intervention and to 40.0% at the follow-up ($Q = 13.56$, $p = 0.001$) in the exercise group. However, no significant changes observed in the control group. There were no significant changes concerning fear of falling in either group (Table 2).

Fig. 2 shows the changes in the scores of multiple geriatric syndromes. As shown in Fig. 2, the intervention group showed greater and significant decrease compared with the control group ($F = 12.66$, $p = 0.001$). Within-group scores were compared, and significant changes were observed in intervention group, with the score of multiple geriatric syndromes decreasing significantly after 3-month exercise and at 6-month follow-up ($F = 16.89$, $p < 0.001$).

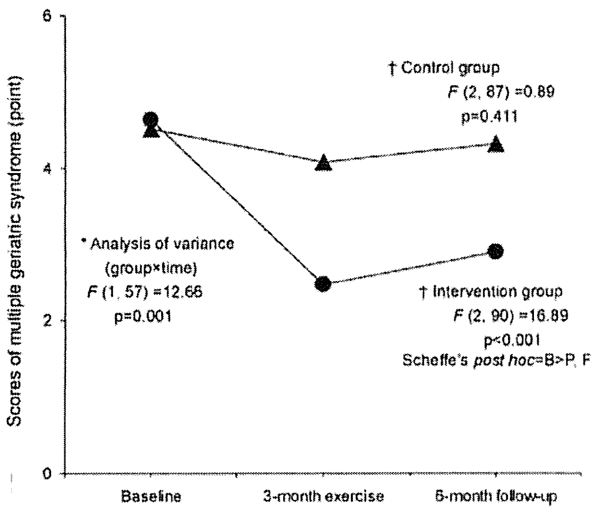

Fig. 2. Change in mean scores of MSGS at baseline, after 3-month exercise, and at 6-month follow-up in intervention (●) and control (▲) group. (*) Comparison of multiple geriatric syndrome scores between intervention and control group. (†) Comparison of within-group multiple geriatric syndrome scores at baseline (B), after the 3-month exercise (P), and at 6-month follow-up (F).

Eight subjects after 3-month intervention and seven subjects after 6-month follow-up were improved to normal status of multiple symptoms in the intervention group. Table 3 shows the distribution of the subjects who showed improvement to normal status of multiple symptoms according to the tertiles of maximum walking speed and adductor muscle strength. Within the subjects that showed improvement to normal status of multiple symptoms, a significantly higher proportion had an improved maximum walking speed at the 6-month follow-up ($Q = 6.50$, $p = 0.039$) compared with those having maintained or decreased walking speed. There was no difference at either time point in the proportion of the improved subjects with increased adductor muscle strength.

4. Discussion

This study demonstrates that the 3-month, multidimensional exercises, consisting of progressive strength training, balance and walking ability exercises along with PFM exercises, improved the usual walking speed, maximum walking speed, abductor muscle strength, tandem walking and functional reach in community-dwelling elderly women with MSGS. Furthermore, the increment of the physical fitness components appeared to contribute greatly to the improvement of the functional decline, urinary incontinence, and multiple symptoms. Therefore, the results of this study suggest that the improvements of the muscle strength, walking speed, and balance, which have been reported as risk factors for geriatric syndromes, may be effective in the improvement of geriatric syndrome.

Several studies of multidimensional intervention trials have reported beneficial effects (Tinetti et al., 1994; Shumway-Cook et al., 1997; Nelson et al., 2004; Gitlin et al., 2006; Kim et al., 2007). In a recent study, Gitlin et al. (2006) conducted a multidimensional home-based intervention in elder adults with functional difficulties, and confirmed that activity of daily living (ADL), instrumental ADL, self-efficacy, fear of falling, and home hazards were all improved and that the effects were sustained even after 6-month. Kim et al. (2007) assessed the effect of PFM and fitness exercises in improving urinary incontinence in elderly community-dwelling Japanese with stress urinary incontinence, and confirmed that decrease in BMI and increase in walking speed may contribute to the treatment of urinary incontinence.

In this study, the prevalence of the functional decline decreased significantly from 50.0% before the intervention to 16.7% after intervention and follow-up. The cure rate of urinary incontinence was 43.3% after the 3-month exercise and 26.7% at 6-month follow-up for the intervention group. On the other hand, no significant improvement was observed in the control group. The effects of this multidimensional exercise affecting only a single symptom of urinary incontinence or functional decline were consistent with previously reported studies. Although the previous studies using multidimensional intervention were targeted to treat only a single geriatric syndrome, the current study was aiming to treat MSGS. Our findings suggest that the multidimensional intervention was significantly effective in the improvement of geriatric syndrome.

We analyzed the relationship between the increment of the physical fitness components and the improvement of the multiple symptoms, despite the small sample size. We found an increment rate of 9.6% in adductor muscle strength after the 3-month exercise and a rate of 12.3% after the follow-up in the intervention group, whereas the changes were not significant for the control group. This difference in the increment rate of muscle strength is not considered to account for the difference in geriatric syndrome improvement rate. However, the proportion of the subjects with improved to normal status of multiple symptoms was significantly higher among those who demonstrated an increase in maximum walking speed at 6-month follow-up ($Q = 6.50$, $p = 0.039$). These results suggest that the increment of walking speed is a major factor for the improvement of the multiple symptoms present in this population. The increased walking ability probably allowed the subjects to increase their physical activity and consequently contributed to the improvement of their functional capacity. But, the current study's results were obtained based on a small sample size. The above relationships need to be further researched in a population study which would contain a larger number of subjects and for a longer follow-up period.

Despite the fact that many studies have reported that exercise is effective in reducing the fear of falling in the elderly (Tennstedt et al., 1998), our intervention had no effect on the fear of falling in both groups. This may be explained by the characteristics of the intervention provided in the present study. Our multidimensional exercises focused on increasing the physical function and did not provide measures such as psychological care. These findings indicate that the comprehensive strategy designed to reduce MSGS in community-dwelling elderly women should include not only exercises addressing to the improvement of the physical functions, but should also incorporate psychological care focusing on reducing the fear of falling.

This study has several limitations. Firstly, the functional decline, urinary incontinence, and fear of falling were assessed using self-reported data obtained through a face-to-face interview, and they were not confirmed by objective and clinical methods. However, several previous studies have indicated that self-reported data have high validity, reliability and objectivity in the analyses of the functional decline, urinary incontinence, and fear of falling (Smith et al., 1990; Howland et al., 1993; Resnick et al., 1994). Therefore, the use of data collected from interviews or self-recording in analyses has minor influence on the interpretation of the results of this study. Secondly, although this study indicates that improvement of physical fitness components such as muscle strength and walking ability contributes to the treatment of geriatric syndrome, it provides no explanation of the mechanism of how increasing functional fitness component improves multiple geriatric symptoms.

5. Conclusions

This study assessed the effects of multidimensional exercises on functional decline, urinary incontinence, and fear of falling in community-dwelling Japanese elderly women with MSGS. The intervention program targeted modification of physical fitness may contribute to a reduction of the functional decline and urinary incontinence, but was not a diminishing symptom over time concerning the fear of falling. Therefore, the intervention strategies designed to reduce MSGS in elderly persons should include not only exercises aiming to the improvement of the physical functions, but should also incorporate psychological care focusing on the reduction of the fear of falling.

Conflict of interest statement

The authors have no conflict of interest to disclose.

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Effects of Exercise and Amino Acid Supplementation on Body Composition and Physical Function in Community-Dwelling Elderly Japanese Sarcopenic Women: A Randomized Controlled Trial

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OBJECTIVES: To evaluate the effectiveness of exercise and amino acid supplementation in enhancing muscle mass and strength in community-dwelling elderly sarcopenic women.

DESIGN: Randomized controlled trial.

SETTING: Urban community in Tokyo, Japan.

PARTICIPANTS: One hundred fifty-five women aged 75 and older were defined as sarcopenic and randomly assigned to one of four groups: exercise and amino acid supplementation (exercise + AAS; n = 38), exercise (n = 39), amino acid supplementation (AAS; n = 39), or health education (HE; n = 39).

INTERVENTION: The exercise group attended a 60-minute comprehensive training program twice a week, and the AAS group ingested 3 g of a leucine-rich essential amino acid mixture twice a day for 3 months.

MEASUREMENTS: Body composition was determined using bioelectrical impedance analysis. Data from interviews and functional fitness parameters such as muscle strength and walking ability were collected at baseline and after the 3-month intervention.

RESULTS: A significant group × time interaction was seen in leg muscle mass ($P = .007$), usual walking speed ($P = .007$), and knee extension strength ($P = .017$). The within-group analysis showed that walking speed significantly increased in all three intervention groups, leg muscle mass in the exercise + AAS and exercise groups, and knee extension strength only in the exercise + AAS group (9.3% increase, $P = .01$). The odds ratio for leg muscle mass and knee extension strength improvement was more than four times as great in the exercise + AAS group (odds ratio = 4.89, 95% confidence interval = 1.89–11.27) as in the HE group.

CONCLUSION: The data suggest that exercise and AAS together may be effective in enhancing not only muscle strength, but also combined variables of muscle mass and walking speed and of muscle mass and strength in sarcopenic women. J Am Geriatr Soc 60:16–23, 2012.

Key words: sarcopenic women; exercise; amino acid supplementation; muscle mass; muscle strength

Sarcopenia, defined as age-related involuntary loss of skeletal muscle mass and strength,[1,2] has been associated with physical disability, functional decline, falls, impaired mobility, and mortality in elderly people.[3,4] Therefore, treating or reversing sarcopenia is important in the maintenance of health and life expectancy in the elderly population. Although many factors, such as chronic disease, physical inactivity, and decreased muscle protein synthesis, may contribute to loss of muscle mass,[5–7] it has been suggested that only skeletal muscle disuse and undernutrition are potentially preventable or reversible with targeted interventions.[8]

Many studies have shown a strong relationship between resistance exercise and strength improvement, through which the efficacy of resistance exercise for the prevention and treatment of sarcopenia has been confirmed.[9] The previous studies have also shown that ingestion of essential amino acids can induce muscle protein anabolism in elderly adults.[10,11] One study showed that the combination of resistance exercise and essential amino acid supplementation (AAS) augmented muscle protein

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synthesis, suggesting it as a strategy to reverse sarcopenia[12] but in a small sample size. There are few randomized controlled trials (RCTs) on the effects of exercise and AAS on body composition and functional capacity.

The purpose of this study was to investigate the effects of exercise and AAS on muscle mass, strength, and walking ability in sarcopenic women.

METHODS

Subjects

A letter outlining the comprehensive geriatric health examination survey, describing its objective and the way that the personal data would be used, was mailed to the women randomly selected from the Basic Resident Register of 5,932 people aged 75 and older residing in the Itabashi ward of metropolitan Tokyo inviting them to participate in the study. Two thousand eighteen people responded to the mailed letters of invitation to participate in the study, with 1,670 people agreeing and 348 people declining to participate. The baseline assessment was conducted at the Tokyo Metropolitan Institute of Gerontology (TMIG) from October 12 to November 3, 2008. One thousand three hundred eighty-three women aged 75 and older were screened; 287 who originally agreed to participation were absent. Written informed consent was obtained for baseline screening; six people did not sign the informed consent form and were not included in this study.

Three hundred four of 1,377 women (22.1%) were operationally defined as sarcopenic (Figure 1), with selection based on categorization into one or more of the following inclusion criteria groups: appendicular skeletal muscle mass/height^2 less than 6.42 kg/m^2 and knee extension strength less than 1.01 Nm/kg[13,14] (n = 68), appendicular skeletal muscle mass/height^2 less than 6.42 kg/m^2 and usual walking speed less than 1.22 m/s (n = 65),[14] body mass index (BMI) less than 22.0 kg/m^2[14] and knee

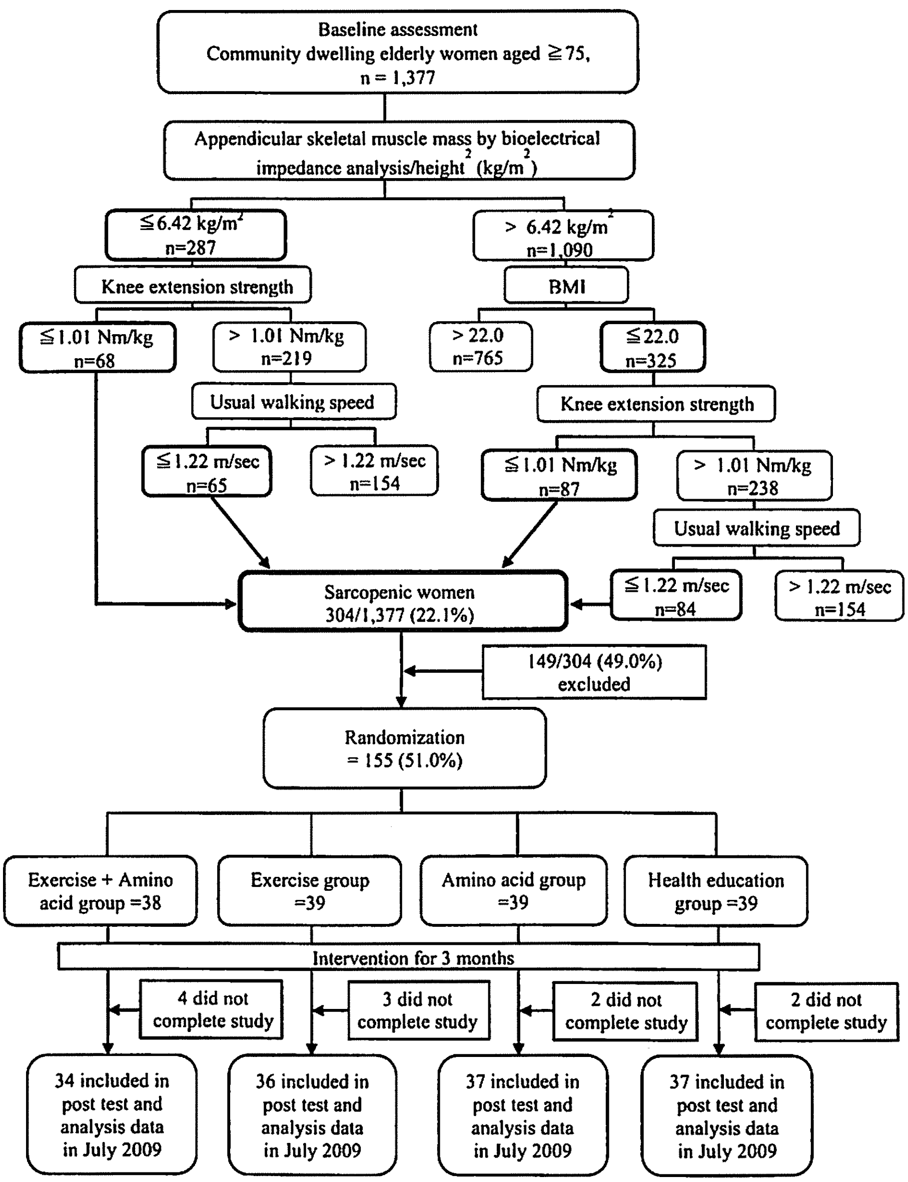

Figure 1. Algorithm for the selection of women who were operationally defined as sarcopenic and flowchart of participants in the randomized controlled trial of exercise and amino acid supplementation.

extension strength less than 1.01 Nm/kg (n = 87), and BMI less than 22.0 kg/m^2 and usual walking speed less than 1.22 m/s (n = 84). Exclusion criteria were severe knee or back pain; severely impaired mobility; impaired cognition (Mini-Mental State Examination (MMSE) score < 24);[16] missing baseline data; and unstable cardiac conditions such as ventricular dysrhythmias, pulmonary edema, or other musculoskeletal conditions. One hundred forty-nine (49.0%) of the potential sarcopenic participants were excluded because they were classified into one or more of the exclusion criteria or declined participation. The Clinical Research Ethics Committee of TMIG approved the study protocol. The intervention procedures were fully explained to all participants, and written informed consent was obtained (Figure 1).

Randomization

Randomization was performed after the baseline assessment; any variable that identified personal information was not included in the randomization process. Computer-generated random numbers were assigned to 155 participants who were then sorted and divided into four equal groups. The groups were randomly assigned to one of the four interventions groups: exercise + AAS (n = 38), exercise (n = 39), AAS (n = 39), or health education (HE; n = 39). All participants agreed to the group allocations that were mailed to them. There was no attempt to equalize the size of the groups based on their characteristics or to recruit subjects with specific characteristics. The co-investigators were blind to the randomization procedure and group allocations, separate physical therapy staff members who were also blind to the allocation of treatments collected data.

Outcome Measures

Outcome measures were evaluated according to data collected from interviews, body composition assessments using bioelectrical impedance analysis (BIA), and physical fitness tests at baseline and after the 3-month intervention.

Interview Survey

Face-to-face interviews were conducted to assess the individual's history of fractures and falls over the previous year, number of falls, cause of falls, urinary incontinence, exercise habits, smoking status, and MMSE score.

Body Composition Assessment

Measurements of height and weight were used to calculate BMI (kg/m^2). Body composition was measured using a segmental multifrequency BIA instrument that operated at frequencies of 5, 50, 250, and 550 kHz (Well-Scan 500, Elk Corp., Tokyo, Japan). Participants removed their socks, stood on two metallic electrodes on the floor scale barefoot, and held metallic grip electrodes placed in the palm of the hand with the fingers wrapped around the handrails. Using segmental body composition and muscle mass values of both legs, both arms, and the trunk, appendicular skeletal muscle mass and leg muscle mass values were obtained

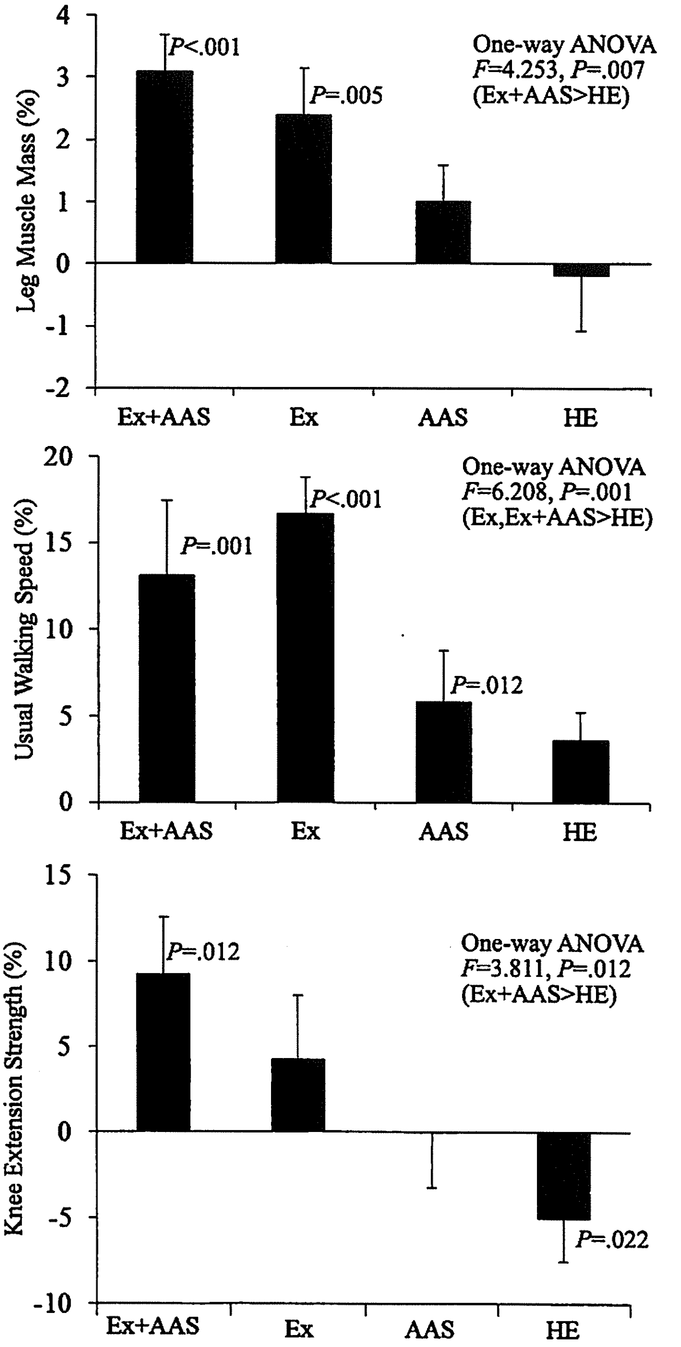

Figure 2. Mean percentage changes (standard errors) in leg muscle mass, usual walking speed, and knee extension strength after exercise (Ex), amino acid supplementation (AAS), both (Ex + AAS), or health education (HE). Bars indicate average changes from baseline to after the 3-month intervention. ANOVA = analysis of variance.

and used for analysis by summing the appropriate segmental muscle mass values.[13,17,18] Reliability of body composition measurements in all 155 participants in this study was not analyzed, although for the AAS group (n = 39), measurements were taken for a second time 1 week after baseline testing, and reliability was examined; the intraclass correlation coefficients (ICC) were: 0.98 for the right arm, 0.97 for the left arm, 0.97 for the right leg, 0.96 for the left leg, and 0.93 for the trunk.

Functional Fitness Test

Calf girth and functional fitness variables including usual and maximum walking speeds and knee extension strength were measured. In measures of walking speed, participants were allowed to use assistive walking devices only if they expressed strong concerns about walking without a device or if there was any danger of falling. The knee extension strength measurement was taken twice, and the higher value divided by body weight (Nm/kg) were analyzed. The procedures for the functional fitness tests have been described in detail in previous reports.[19,20]

Intervention

Exercise

A comprehensive physical fitness and muscle mass enhancement training program of moderate intensity was provided for the participants in the exercise groups. The exercise intervention consisted of 60-minute exercise sessions held at the TMIG twice per week for 3 months. Each exercise intervention group was divided into two subgroups, with participants exercising together within their assigned group in one of four exercise sessions offered per day.

Each exercise session consisted of a 5-minute warm-up, 30 minutes of strengthening exercise, 20 minutes of balance and gait training, and 5 minutes of cool down. The strengthening exercises were performed in a progressive sequence from seated to standing positions. For each type of exercise, participants were instructed to complete up to eight repetitions of the movements. When the exercises were properly executed without significant fatigue or loss of proper execution, the resistance was increased. The progressive resistance was provided through the use of resistance bands or ankle weights. Intensity was maintained at approximately 12 to 14 on the Borg Rate of Perceived Exertion scale.[21] The principal investigator, along with the exercise instructor and assistant trainers, assessed each individual's ability to increase intensity.

Chair exercise: The chair-seated exercises were used in the early stages of the program because the participants were frail older adults and it provided a secure and stable position. Repetitions of toe raises, heel raises, knee lifts, knee extensions, and others were performed while seated on a chair. Hip flexions, lateral leg raises, and repetitions of other exercises were performed standing upright behind the chair and holding the back of the chair for stability.

Ankle-weight exercise: To strengthen lower extremities, a fixed weight was placed on the ankle while participants performed strengthening exercises. Weights of 0.50, 0.75, 1.00, and 1.50 kg were prepared and used in accordance with each participant's strength level as the resistance progressively increased. The exercises performed using these ankle weights included seated knee flexion and extension and standing knee flexion and extensions.

Exercises using a resistance band: Resistance bands were used to strengthen the upper and lower body. Lower body exercises included leg extension and hip flexion. Upper body exercises included double-arm pull downs and biceps curls.

Balance and gait training: The balance training was focused on improvement of static, dynamic, and lateral balancing ability. Exercises included standing on one leg, multidirectional weight shifts, tandem stand, and tandem walk. Participants practiced proper gait mechanics that focused on the maintenance of stability during walking and increasing stride length, toe elevation of the forward limb, heel elevation of the rear limb, frequency of stepping, and heel–floor angle. Exercises included raising the toes (dorsiflexion) during the forward swing of the leg, kicking off the floor with the ball of the foot, walking with directional changes, and gait pattern variations.

Amino Acid Supplementation

Essential AAS was provided for the participants in the AAS groups every 2 weeks. Packets of powdered amino acid supplements (42.0% leucine, 14.0% lysine, 10.5% valine, 10.5% isoleucine, 10.5% threonine, 7.0% phenylalanine, and 5.5% other) were provided for the participants to be taken with water or milk, and they were instructed to take the 3-g supplement two times a day (6 g daily) every day for 3 months.[22] To monitor their amino acid intake accurately, participants were given record sheets that were collected every 2 weeks on which they recorded what time of day they took the supplement and the amount of amino acid taken every day.

Health Education

Participants in the HE group took a class once a month for 3 months, a total of three times. The classes focused on cognitive function, osteoporosis, and oral hygiene. Participants were asked to continue their regular lifestyle habits, and no specific instructions on diet or physical activity were given.

Data Analysis

Sample size calculations using univariate one-factor repeated-measures analysis of variance (ANOVA) to examine significant differences in means at baseline and after the 3-month intervention ($\alpha = 0.05$, power = 0.80) with an effect size of 0.15 required a sample size of 28 participants. Esimating a potential attrition rate of 25%, 38 subjects per group were required.[23] One-way ANOVA was used to test any differences in baseline measures and percentage changes between groups, and chi-square tests were performed on categorical variables. Percentage changes in muscle mass and functional fitness after the intervention were calculated using the following formula: % change = ((postintervention value–baseline value)/(baseline value) × 100). Two-way repeated-measures ANOVA was used to evaluate the differences in the effect of the intervention on the outcome measures between groups, and a post hoc test was done on variables showing significant differences to determine which groups were different. Multiple logistic regressions were performed to compare the effects of the four intervention groups on each outcome variable after 3 months of intervention. All analyses were performed using SPSS version 15.0 of Windows (SPSS, Inc., Tokyo, Japan).

RESULTS

The baseline demographic, fitness, and interview variables of the participants in the four groups are summarized in Table 1. All of the baseline characteristics were similar between the groups.

The mean attendance rates during the 3-month intervention were 70.3% in the exercise + AAS group, 80.5% in the exercise group, 72.2% in the AAS group, and 71.8% in the HE group. Eleven participants (exercise + AAS = 4, exercise = 3, AAS = 2, HE = 2) were unable to complete the study after randomization because of spouse care (n = 3), admission to nursing home (n = 2), lack of motivation (n = 2), severe knee or back pain (n = 1), death (n = 1), falls and hip fracture (n = 1), and hospitalization (n = 1; Figure 2).

In comparing the pre- and postintervention changes in body composition and functional fitness of the groups (Table 2), there was a significant group × time interaction for leg muscle mass ($F = 4.253$, $P < .007$; exercise + AAS > HE), usual and maximum walking speeds (exercise and exercise + AAS > HE), and knee extension strength ($F = 3.558$, $P = .02$; exercise + AAS > HE).

The within-group analysis showed significant changes in leg muscle mass in the exercise + AAS ($P < .001$) and exercise ($P = .005$) groups and changes in usual walking speed in the exercise + AAS ($P = .001$), exercise ($P < .001$), and AAS groups ($P = .01$). Knee extension strength improved significantly only in the exercise + AAS group ($P = .01$), no improvement was seen in exercise or AAS, and a statistically significant decrease was observed in the HE group ($P = .02$; Figure 1).

Table 3 shows the effects of the type of intervention on changes in combined variables of muscle mass and physical function. Significant increases in leg muscle mass and knee extension strength (odds ratio (OR) = 4.89, 95% confidence interval (CI) = 1.89–11.27) and leg muscle mass and usual walking speed (OR = 4.11, 95% CI = 1.33–13.68) were observed in only the exercise + AAS group.

DISCUSSION

Although many definitions of sarcopenia have been reported,[1 3,24] there has recently been a focus not only on the loss of appendicular skeletal muscle mass, but also on functional decline.[25] In this study, sarcopenic women were operationally defined based on declines in muscle strength or walking ability that accompany the loss of skeletal muscle mass or low BMI. Because defining sarcopenia was beyond the scope of this study, the focus of the discussion will be on the effects of the intervention. To evaluate the intervention effects, the changes observed in the single variables as well as the combined variables will be discussed.

Many studies have focused on exercise or nutrition as interventions to reverse sarcopenia, but the results of these studies have not always been consistent.[8,9,12,26]

This study demonstrated that appendicular muscle mass and walking speed increased with the combination of exercise and essential amino acid ingestion, as well as with the separate exercise and amino acid interventions, but muscle strength improved only with the combination of exercise and amino acid ingestion.

A recently published meta-analysis[9] and a Cochrane review article also confirmed that resistance training two to three times a week can improve physical function and functional limitations and can reduce disability and muscle weakness in older people.[27] Previous studies have demonstrated that resistance training in elderly people produces

Table 1. Selected Variable Characteristics of Participants at Baseline According to Study Group

Characteristic	Exercise + AAS (n = 38)	Exercise (n = 39)	AAS (n = 39)	Health Education (n = 39)	F-Value*	P-Value*
Age, mean ± SD	79.5 ± 2.9	79.0 ± 2.9	79.2 ± 2.8	78.7 ± 2.8	0.577	.63
Height, cm, mean ± SD	147.1 ± 6.7	147.7 ± 4.4	145.8 ± 4.5	146.5 ± 4.9	0.960	.41
Body weight, kg, mean ± SD	39.5 ± 5.5	41.1 ± 4.7	40.1 ± 3.2	40.4 ± 3.9	0.874	.46
Body mass index, kg/m^2, mean ± SD	18.3 ± 2.5	18.9 ± 2.0	18.9 ± 1.6	18.8 ± 1.7	0.745	.53
Calf girth, cm, mean ± SD	18.3 ± 2.5	18.9 ± 2.0	18.9 ± 1.6	18.8 ± 1.7	0.745	.53
Lean body mass, kg, mean ± SD	29.1 ± 3.4	30.0 ± 2.6	28.8 ± 2.0	29.3 ± 2.4	1.505	.22
Muscle mass, kg, mean ± SD	26.9 ± 3.1	27.7 ± 2.3	26.5 ± 1.8	27.0 ± 2.2	1.538	.21
Appendicular muscle mass, kg, mean ± SD	13.3 ± 1.6	13.7 ± 1.3	13.1 ± 1.0	13.3 ± 1.2	1.502	.22
Legs muscle mass, kg, mean ± SD	9.8 ± 1.2	10.1 ± 1.0	9.7 ± 0.7	9.9 ± 0.9	1.570	.20
Usual walking speed, m/s, mean ± SD	1.26 ± 0.27	1.29 ± 0.28	1.29 ± 0.20	1.18 ± 0.22	1.701	.17
Maximal walking speed, m/s, mean ± SD	1.62 ± 0.37	1.67 ± 0.31	1.67 ± 0.27	1.55 ± 0.32	1.150	.33
Knee extension strength, Nm, mean ± SD	45.9 ± 11.3	46.6 ± 11.1	46.7 ± 7.8	47.4 ± 10.5	0.139	.94
Falls, %	21.1	17.9	15.4	20.5	0.519	.91
Exercise habit, %	26.3	25.6	38.5	33.3	2.029	.57
Urinary incontinence, %	44.7	38.5	41.0	25.6	3.414	.33
Osteoporosis history, %	36.8	43.6	48.7	30.8	2.987	.39
Heart disease history, %	10.5	15.4	12.8	17.9	0.977	.81
Diabetes mellitus history, %	7.9	5.1	5.1	12.8	2.156	.54

* One-way analysis of variance for continuous variables and chi-square test for categorical variables.
AAS = amino acid supplementation; SD = standard deviation.

Table 2. Comparison of Muscle Mass and Functional Fitness Variables Between Groups After 3-Month Intervention

Variable	Group	Mean ± Standard Deviation: Baseline	After 3-Month Intervention	Analysis of Variance (Group × Time), *P*-Value	Post Hoc Analysis*
Muscle mass, kg	Exercise + AAS	26.76 ± 2.77	27.26 ± 3.04	*F* = 1.076, .36	
	Exercise	28.09 ± 1.90	28.51 ± 2.39		
	AAS	26.25 ± 1.81	26.53 ± 2.10		
	HE	27.48 ± 2.04	27.66 ± 2.23		
Appendicular muscle mass, kg	Exercise + AAS	13.25 ± 1.35	13.59 ± 1.53	*F* = 1.354, .26	
	Exercise	13.90 ± 1.06	14.19 ± 1.33		
	AAS	12.86 ± 0.99	13.03 ± 1.10		
	HE	13.57 ± 1.16	13.67 ± 1.05		
Legs muscle mass, kg	Exercise + AAS	9.76 ± 1.01	10.07 ± 1.13	*F* = 4.253, .007	Exercise + AAS > HE
	Exercise	10.28 ± 0.81	10.53 ± 1.05		
	AAS	9.55 ± 0.73	9.65 ± 0.83		
	HE	10.14 ± 0.87	10.11 ± 0.81		
BMI, kg/m^2	Exercise + AAS	18.30 ± 2.64	18.14 ± 2.68	*F* = 0.606, .61	
	Exercise	18.80 ± 1.30	18.50 ± 1.41		
	AAS	18.84 ± 1.43	18.56 ± 1.62		
	HE	18.83 ± 1.75	18.77 ± 1.67		
Usual walking speed, m/s	Exercise + AAS	1.27 ± 0.25	1.43 ± 0.29	*F* = 4.213, .007	Exercise and Exercise + AAS > HE
	Exercise	1.31 ± 0.24	1.50 ± 0.23		
	AAS	1.30 ± 0.18	1.36 ± 0.18		
	HE	1.19 ± 0.21	1.22 ± 0.23		
Maximum walking speed, m/s	Exercise + AAS	1.64 ± 0.34	1.92 ± 0.37	*F* = 9.374, <.001	Exercise and Exercise + AAS > HE
	Exercise	1.72 ± 0.27	2.04 ± 0.27		
	AAS	1.71 ± 0.28	1.92 ± 0.27		
	HE	1.57 ± 0.31	1.64 ± 0.31		
Knee extension strength, Nm/kg	Exercise + AAS	1.15 ± 0.27	1.23 ± 0.29	*F* = 3.558, .02	Exercise + AAS > HE
	Exercise	1.12 ± 0.30	1.14 ± 0.26		
	AAS	1.15 ± 0.25	1.14 ± 0.25		
	HE	1.14 ± 0.26	1.00 ± 0.26		

* A post hoc analysis was performed using the Scheffe method.
AAS = amino acid supplementation; HE = health education; BMI = body mass index.

Table 3. Change in Leg Muscle Mass and Functional Fitness After Intervention According to Study Group

Dependent Variable*	Adjusted Odds Ratio (95% Confidence Interval): AAS	Exercise	Exercise + AAS
Change in leg muscle mass and knee extension strength	1.99 (0.72–5.65)	2.61 (0.88–8.05)	4.89 (1.89–11.27)
Change in leg muscle mass and usual walking speed	1.35 (0.45–4.08)	2.41 (0.79–7.58)	4.11 (1.33–13.68)

Reference: health education.
* 1 = improve, 0 = no change or decrease.
AAS = amino acid supplementation.

9% to 15% increases in strength and approximately 5% in thigh muscle volume.[28,29] Also, many studies have shown that resistance training in elderly people must be conducted at high intensities and volumes to see improvements.[9,27] In contrast, less-intense resistance exercise programs have produced little or no strength gains.

The data in this study show improvements of 2.4% in leg muscle mass, 2.0% in appendicular muscle mass, and 4.3% in leg strength in the exercise group. The moderate-intensity exercise provided in this trial produced strength gains that were smaller than those seen in previous studies, but the combination of moderate intensity exercise and AAS increased muscle mass 3.1% and muscle strength 9.3%, gains that are comparable with those observed in previous studies of high-intensity exercise.[28]

The results of the current study showed that total muscle mass, appendicular muscle mass, and walking speed significantly increased in the exercise group, suggesting that exercise is effective in the improvement of muscle mass and functional fitness, but increases in muscle strength were not observed. These results indicate that exercise alone is insufficient for recovery in sarcopenic elderly women.

Previous studies have indicated that declines in muscle mass are related to declines in muscle protein synthesis rates in older adults and that leucine-enriched essential amino acid mixtures are primarily responsible for the amino acid-induced muscle protein anabolism in elderly people.[11,22] These studies investigated the effects of different amino acid dosages (from 6.7 to 20.0 g/d) on protein synthesis, and the 6.0-g/d dosage provided in this study is lower than in previous studies, but the mean weights of the subjects in such studies were from 71.0 to 81.3 kg, making the dosage of amino acid between 0.090 and 0.246 g/kg of body weight. The amino acid dosage in the current study was 0.151 g/kg, which is comparable with the amounts found in the literature.[11,22,26] The results of the current study showed that muscle mass, appendicular muscle mass, and leg muscle mass significantly increased in the AAS group, which is consistent with previous findings.

Many studies have demonstrated an increase in muscle mass from nutritional supplementation, but an increase in muscle strength does not always accompany an increase in muscle mass. A recent study concluded that essential AAS alone was not sufficient to increase muscle strength.[26] Similarly, although the results of the current study showed that AAS alone increased muscle mass, improvement in muscle strength was not observed. The results of the present study showed that muscle mass increased significantly with exercise or essential AAS, although muscle strength, measured according to knee extension strength, improved significantly only in the exercise + AAS group.

Next, the discussion will focus on the changes in the combined variables. One study that investigated the effects of resistance exercise and nutritional supplementation on muscle mass and strength in older adults concluded that high-intensity resistance exercise was beneficial in increasing muscle mass and muscle strength, but the nutritional supplementation, which contained only a small percentage of a soy-based protein within a mixture of mainly carbohydrates, did not contribute to those gains.[8] As illustrated in Figure 2, exercise alone was effective in enhancing single variables such as leg muscle mass or usual walking speed. Similarly, the AAS group improved usual walking speed, but rationally, to treat sarcopenia, improvements in single variables are not sufficient. Improvements observed in the combined variables would presumably lead to the most-efficient reversal of sarcopenia. Significant improvements in the combinations of leg muscle mass, knee extension strength, and walking speed were seen only in the exercise + AAS group. Although whether exercise + AAS was better than either intervention alone remains inconclusive, these results suggest that exercise + AAS may be necessary for benefits in muscle mass and strength.

This study has several limitations. First is the measurement of body composition estimated using BIA. Although magnetic resonance imaging (MRI), computed tomography, and dual-energy X-ray absorptiometry are common, accurate clinical methods of measuring muscle mass,[30,31] they are cost ineffective and are not always appropriate for field studies. BIA is simple, noninvasive, and inexpensive and has been widely used in field studies. The comparison of MRI and BIA measurements has revealed a strong correlation between the two, confirming the validity of the BIA method for muscle mass measurement in older adults.[13,17,18] Therefore, the validity of the data collected using BIA has little influence on the interpretation of the results of this study. Second, it has been reported that AAS enhances muscle protein synthesis,[11,22,32] but the mechanism of the increase in muscle mass from AAS was not explored in the current investigation. Therefore, the results of this study were interpreted based on the assumption that muscle protein synthesis had been enhanced. Third, the effects of the exercise + AAS should have been determined with the use of placebos, but placebo treatments were not provided in this study, so future research should include placebos to observe the effects of exercise and AAS on physical function and muscle strength. Fourth, the total number of dropouts in this study was 11 people, and they were not included in the data analysis. Many studies have used intention-to-treat (ITT) analyses to determine the effects of RCTs, and the use of ITT analyses are increasing, although one previous study found that only approximately 35% of 274 RCTs used ITT analyses.[33] The current study was not an ITT analysis because it confirmed that there were no significant differences between the dropouts and the participants who completed the study, and the exclusion of the 11 dropouts from the analysis did not affect the integrity of the baseline randomization. Finally, previous research has shown that milk contains essential amino acids.[34,35] Because some of the participants took the AAS with milk, the exact essential amino acid dosage in this study could not be determined, and the effect of drinking milk on the results of this study was not confirmed. Future research should avoid the intake of milk with amino acids when investigating the effects of amino acids on muscle strength and mass and physical function.

This study demonstrated that exercise and nutrition may be necessary for the basic treatment of increasing muscle mass and strength to reverse the effects of sarcopenia in community-dwelling sarcopenic women. Exercise and AAS together have significant effects on enhancing not only muscle strength, but also the combined variables of muscle mass and walking speed and of muscle mass and strength in this study population, but further follow-up studies on larger populations are required to confirm these results.

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Author Contributions: H. Kim developed the study concept and design, recruited subjects, developed the intervention program, analyzed and interpreted the data, and prepared the manuscript. S. Takao interpreted the data and reviewed the manuscript for accuracy. K. Saito assisted in AAS and supervised the interview survey. Y. Hideyo assisted in subject recruitment, supervised the

interviewers, and interpreted the data. M. Kobayashi assisted in AAS and subject recruitment and interpreted the data. H. Kato assisted in assisted AAS and body composition assessment. M. Katayama assisted in AAS and interview survey.

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RESEARCH ARTICLE Open Access

Relationship between subjective fall risk assessment and falls and fall-related fractures in frail elderly people

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Abstract

Background: Objective measurements can be used to identify people with risks of falls, but many frail elderly adults cannot complete physical performance tests. The study examined the relationship between a subjective risk rating of specific tasks (SRRST) to screen for fall risks and falls and fall-related fractures in frail elderly people.

Methods: The SRRST was investigated in 5,062 individuals aged 65 years or older who were utilized day-care services. The SRRST comprised 7 dichotomous questions to screen for fall risks during movements and behaviours such as walking, transferring, and wandering. The history of falls and fall-related fractures during the previous year was reported by participants or determined from an interview with the participant's family and care staff.

Results: All SRRST items showed significant differences between the participants with and without falls and fall-related fractures. In multiple logistic regression analysis adjusted for age, sex, diseases, and behavioural variables, the SRRST score was independently associated with history of falls and fractures. Odds ratios for those in the high-risk SRRST group (≥ 5 points) compared with the no risk SRRST group (0 point) were 6.15 ($p < 0.01$) for a single fall, 15.04 ($p < 0.01$) for recurrent falls, and 5.05 ($p < 0.01$) for fall-related fractures. The results remained essentially unchanged in subgroup analysis accounting for locomotion status.

Conclusion: These results suggest that subjective ratings by care staff can be utilized to determine the risks of falls and fall-related fractures in the frail elderly, however, these preliminary results require confirmation in further prospective research.

Background

Falls and fall-related fractures are a common cause of disability in elderly people [1], and preventing falls is an urgent medical and social issue. Numerous studies have identified factors that predict an increased risk of falls, and many validated assessment tools have been developed to determine fall risks for elderly people [2,3]. Although falls can be caused by multiple factors, mobility impairments such as gait and balance disorders are among the most common predisposing conditions [4,5].

Our previous studies have identified the best mobility tests [6] and a physical performance test [7] for predicting falls in the elderly. These objective measurements can be used to identify people who are appropriate for and who will gain benefit from targeted falls prevention interventions. However, we found that about half of the frail elderly subjects could not complete physical performance tests such as the functional reach test and tandem walk test [7]. In addition, cognitive impairment, particularly confusion, impaired orientation, and misperception of functional ability, is one of the most important risk factors for falls in elderly people [8,9] and is likely to be an important inclusion in a screening tool. Successful strategies for preventing falls in frail elderly people with cognitive impairments are yet to be identified conclusively [10] and appropriate screening tools for these individuals are needed.

Some subjective assessments by care staff have been developed for identifying fall risks in frail elderly adults [11-13]. In a residential facility, staff members possess knowledge of their residents' potential fall risk over a

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24-hour period, and this encompasses both predisposing and precipitating factors. Therefore, their global assessment of fall risk could have the highest predictive validity in relation to falls [13]. These global assessment scales are composed of one item, e.g. 'how do you judge the risk that Mr or Mrs × will fall within 6 months–high or low?' [11,13], which can be used easily in clinical settings, but a global assessment cannot identify specific fall risks and appropriate interventions in frail elderly persons who have multifactorial risks for falls. We determined seven specific tasks with high risks of falls based on a nationwide survey of falls in the frail elderly [7,14], and identified the relationship between these tasks and falls in our preliminary study [15]. However, it was not clear that these tasks were related independently with falls and fall-related fractures in a large population study.

The purpose of this study was to develop the subjective risk rating of specific tasks (SRRST) for screening for the risk of falls and fall-related fractures. Subjects were frail elderly people enrolled in the Tsukui Ordered Useful Care for Health (TOUCH) program which provides day-care services.

Methods

Participants

This study recruited 5,062 elderly participants (mean age, 82.6 ± 7.4 years) enrolled in the TOUCH program. To enrol in TOUCH, an individual must be aged 65 or older and have been certified as needing long-term care by the Japanese public long-term care insurance system [16]. The TOUCH sites are located throughout Japan and provide comprehensive, facility-based day-care services. TOUCH clients have some physical disability and frailty, as defined by the presence of weakness, reduced physical activity or slow gait, which is in accordance with the widely accepted definition of frailty [17]. We limited the participants of this study to those who were aged less than 65 years and who had missing value in measurements. Informed consent was obtained from all participants or a family member prior to their inclusion in the study and the Ethics Committee of the Tokyo Metropolitan Institute of Gerontology approved the study protocol.

Study procedures

This study was performed by cross-sectional design and falls and fall-related fractures were investigated retrospectively for a one-year period. Prior to the commencement of the study, all staff received a measurement manual which mentioned the correct protocols for administering all of the assessment measures included in the study.

Falls and fall-related fractures during the previous year

A fall was defined as "an event that resulted in a person coming to rest unintentionally on the ground or another lower level that did not result from a major intrinsic event or an overwhelming hazard" [18,19]. Falls and fall-related fractures were measured retrospectively for a one-year period via a self-report questionnaire and care records. A caregiver or family member provided information on the participant's annual incidence of falls and fall-related fractures when the trained nurses or care workers recognized that a participant had problems recalling such events.

Subjective risk rating of specific tasks (SRRST)

The SRRST was conducted by day-centre staff who had nursing, allied health or similar qualifications, and they were familiar with their clients. The staff answered the questions of the SRRST based on the present status of the participants. The SRRST consisted of the following items: 1) "Do you feel there is a risk of falls when the client (Mr or Mrs X) is walking?"; 2) "Do you feel there is a risk of falls when the client is transferring in bed room, toilet, or bath room?"; 3) "Do you feel there is a risk of falls when the client is toileting?"; 4) "Do you feel there is a risk of falls when the client is ascending or descending stairs?"; 5) "Do you feel there is a risk of falls when the client is wandering?"; 6) "Do you feel there is risk of falls because the client exhibits risky behavior?"; 7) "Do you feel there is a risk of falls because the client is agitated?". The response to each item in the SRRST was designated as "yes" (1 point) or "no or not applicable" (0 points) [15]. The information of the SRRST and history of falls was obtained at the same time. Prior to the commencement of the study, three raters completed the SRRST twice at weekly intervals (n = 4 × 2 × 30), and test-retest and inter-rater (one physical therapist, one nurse, and two caregivers) reliability comparisons of total scores revealed intraclass correlation coefficients (ICCs) of 0.84 to 0.96 and 0.81, respectively [20].

Potential confounding factors of falls

With reference to previous studies [2,21-24], we selected two demographic variables, eight primary diseases or general health statuses, and two behavioural variables as possible confounding factors of falls (Table 1). The demographic variables were sex and age. Primary diseases or general health status were recorded by the care staff, who identified the chronic condition from care records or symptoms. The following diseases and general health status were included in the analysis: history of stroke with symptoms of hemiparesis, knee osteoarthritis with pain, Parkinson disease, dementia, poor vision, urinary incontinence or frequency, psychotropic use, and walking aid use. Absence of habitual exercise and daily use of slippers or sandals were investigated as behavioural variables.

Table 1 Number of participants with falls and fall-related fractures and odds ratios of potential risk factors

	Single fall		Recurrent falls		Fractures	
	Number (%)	Odds ratio (95% CI)	Number (%)	Odds ratio (95% CI)	Number (%)	Odds ratio (95% CI)
Subjective risk rating of specific tasks						
Risk of falls during walking, yes	1068 (41.5)†	2.21 (2.01-2.43)	633 (24.6)†	3.15 (2.71-3.66)	123 (4.8)†	1.83 (1.36-2.46)
Risk of falls during transferring, yes	823 (41.7)†	1.80 (1.66-1.96)	504 (25.5)†	2.43 (2.14-2.76)	103 (5.2)†	1.89 (1.43-2.51)
Risk of falls during toileting, yes	568 (42.9)†	1.66 (1.53-1.80)	361 (27.3)†	2.18 (1.93-2.47)	65 (4.9)†	1.49 (1.11-2.00)
Risk of falls during stair ascending/ descending, yes	1140 (39.2)†	2.13 (1.93-2.36)	685 (23.6)†	3.55 (2.99-4.22)	139 (4.8)†	2.10 (1.53-2.90)
Risk of falls during wandering, yes	453 (44.9)†	1.68 (1.55-1.83)	289 (28.7)†	2.16 (1.90-2.44)	66 (6.5)†	2.18 (1.63-2.91)
Risk of falls because of risky behaviors, yes	672 (41.6)†	1.66 (1.53-1.80)	424 (26.3)†	2.24 (1.98-2.54)	79 (4.9)†	1.55 (1.17-2.06)
Risk of falls because of agitation, yes	479 (45.0)†	1.70 (1.57-1.85)	316 (29.7)†	2.32 (2.05-2.62)	55 (5.2)†	1.55 (1.14-2.11)
Potential confounding factors						
Age, years‡	82.9 ± 7.5		83.0 ± 7.5		84.3 ± 6.9†	
Falls or fractures						
No falls or fractures	82.5 ± 7.4		82.6 ± 7.4		82.6 ± 7.4	
Sex, female	1062 (30.1)	0.97 (0.89-1.06)	560 (15.8)	0.90 (0.79-1.03)	151 (4.3)†	1.77 (1.24-2.52)
Stroke, yes	345 (32.0)	1.07 (0.97-1.18)	175 (16.2)	0.99 (0.85-1.16)	41 (3.8)	1.03 (0.74-1.45)
Knee osteoarthritis and pain, yes	659 (36.7)†	1.36 (1.26-1.48)	362 (20.1)†	1.41 (1.25-1.60)	77 (4.3)	1.26 (0.95-1.67)
Dementia, yes	670 (34.3)†	1.23 (1.13-1.34)	387 (19.8)†	1.40 (1.23-1.58)	80 (4.1)	1.18 (0.89-1.57)
Poor vision, yes	239 (37.9)†	1.30 (1.16-1.45)	131 (20.8)*	1.32 (1.12-1.56)	26 (4.1)	1.13 (0.74-1.73)
Parkinson disease, yes	163 (44.7)†	1.53 (1.35-1.73)	104 (28.5)†	1.85 (1.55-2.20)	16 (4.4)	1.20 (0.73-1.98)
Use of psychotropics, yes	525 (37.0)†	1.33 (1.22-1.45)	283 (19.9)†	1.33 (1.17-1.52)	57 (4.0)	1.12 (0.82-1.51)
Urinary incontinence or frequency, yes	702 (36.2)†	1.35 (1.25-1.47)	403 (20.8)†	1.53 (1.35-1.73)	82 (4.2)	1.24 (0.94-1.65)
Absence of habitual exercise, yes	975 (33.7)†	1.31 (1.20-1.43)	561 (19.4)†	1.58 (1.38-1.81)	110 (3.8)	1.06 (0.80-1.41)
Use of slippers or sandals, yes	415 (36.3)†	1.27 (1.16-1.39)	185 (16.2)	0.99 (0.85-1.14)	63 (5.5)†	1.73 (1.28-2.32)
Use of walking aid, yes	887 (36.7)†	1.49 (1.37-1.63)	492 (20.3)†	1.60 (1.41-1.82)	109 (4.5)†	1.51 (1.14-2.01)

*$p < .05$, †$p < .01$, ‡Mean ± standard deviation.

Statistical analysis

Each SRRST item and potential confounding factor was compared between the participants with and without a single fall, recurrent falls, and fall-related fractures using *t*-tests for age and chi-square tests for categorical variables. Odds ratios (ORs) of potential risk factors were also calculated for categorical variables.

Multiple logistic regression analysis was performed to explore the independent associations between total SRRST score and falls and fall-related fractures with potential confounding factors. Multiple logistic regression models included total SRRST score as an independent variable, which was categorized into no risk (0 point), low risk (1 to 2 points), moderate risk (3 to 4 points), and high risk (≥ 5 points). The SRRST categories were assessed by their P-values for trend and were used to calculate the OR and 95% confidence interval (95% CI) relative to the category of 'no risk' for each higher category. Covariates were added sequentially to the logistic model to evaluate the associations at different levels of adjustment. Model 1 included the SRRST category plus age and sex, and model 2 included the model 1 variables plus other possible confounding factors. The participants were divided into dependent walking and independent walking groups for subgroup analysis. Logistic regression analysis (model 2) was performed in each group. The validity of the model was quantified using the C-Index and Hosmer-Lemeshow statistic for goodness of fit. Sensitivity and specificity statistics were used to determine the ability of classification in the SRRST. Sensitivity and specificity for falls and fall-related fractures were calculated in each SRRST score. Cut-points for maximizing the sensitivity and specificity for each score were determined using the closest-to-(0, 1) criterion [25]. All data management and statistical computations were performed using the SPSS 17.0 software package (SPSS Inc., Chicago, IL, USA).

Results

The participants were recruited from 88 TOUCH demonstration sites (35% of all sites) and completed the investigation. About 65% of the TOUCH sites (about 19,800 elderly people) could not complete the investigation. Table 2 shows the characteristics of the participants (Table 2).