Table 6. Results of chi-square test: relationship between the presence of subjective fall risk and the presence of fall during the previous year

	non-faller	faller	Total
SRRST = 0	4	2	6
SRRST ≥ 1	9	15	24
Total	13	17	30
SRRST ≤ 1	7	3	10
SRRST ≥ 2	6	14	20
Total	13	17	30
SRRST ≤ 2	10	6	16
SRRST ≥ 3	3	11	14
Total	13	17	30

The numbers were showed in the table.
The chi-square test showed that those with the SRRST score of 2 (or 3) or more had greater rate of presence of faller than those with the SRRST score of 1 (or 2) and below. There was no significant difference about rate of faller between those with the SRRST score of 0 and those with the SRRST score of 1 or more.

Table 7. Spearman correlation coefficient among subjective risk rating of specific tasks and functional status and activity

	SRRST
GS	0.102
1RM	-0.096
OLS	-0.433*
FR	-0.295
TUG	0.441*
WS	-0.305
BI	-0.278
TMIG-IC	-0.133

GS: grip strength, 1RM: one repetetion maximum of leg press machine, OLS: one legged standing time, FR: functional reach, TUG: timed up and go test, WS: walking speed, BI: Barthel index, TMIG-IC: Tokyo Metropolitan Institute of Gelontology - Index of competence, SRRST: subjective risk rating of specific tasks
*: $p < 0.05$

DISCUSSION

Fall prevention starts with screening for risk factors of falls such as physical factors and environmental factors, and investigates the relationship among the factors. For frail elderly people utilizing day-care services, the major risk factors of falls are related to mobility such as muscle weakness, postural balance disorders, gait dysfunction, and impaired ADL. In particular, physical impairment is more important factor for preventing falls[7,16]. Therefore, physical assessment is an important measure for prevent falls in persons who have fallen or at risk of falling[4]. However, the frail elderly with cognitive impairment or severe physical impairment have difficulties performing the assessments of mobility impairment although fall risks were increased[17]. Additionally, there are many frail elderly who cannot perform functional tests used to assess the fall risk. In a previous study, a subjective fall risk assessment based on observations by care staff was developed and its usefulness as a fall risk predictor was examined[5,6]. In this study, we examined the utility of a subjective assessment tool based on observations by care staff for identifying useful measures for screening the fall risk of specific tasks in ADL among frail elderly people.

Regarding inter-rater reliability, the ICCs for the SRRST of the four raters indicated moderate reproducibility (0.513 or more), and the reproducibility for the SRRST was slightly different for each of the four raters in this study. We calculated the ICCs for the SRRST of the two caregivers to verify the reproducibility within the same profession; the ICCs indicated moderate reproducibility (0.503 or more), too. The reason why inter-rater reliability had low values was that the scene and the perspective of evaluation of each rater was different because the results of the SRRST reflect the subjectivity of each rater. Therefore, when using the SRRST, it is necessary to compensate for the insufficient reliability by having comprehensive discussions about risks of falling with each rater, across professions, including the results of other assessments for falls if necessary. In contrast, the ICCs of in intra-rater reliability of each rater for the SRRST indicated high reproducibility (0.727 or more). The time needed to evaluate by the SRRST was about one minute on average, showing the SRRST was a clinically practical assessment.

In the comparative analysis of fallers and non-fallers, participants who had experienced falls showed significantly lower 1RM and higher SRRST, but other physical performance scores and functional statuses which are risk factors for falls did not show any significant differences. These results suggest that 1RM and the SRRST were factors closely related to falling in frail elderly, and those who had experienced falling had not single but more several subjective fall risks in the SRRST. And so, for comparison the association between different score of the SRRST and falling, the chi-square test revealed that those with the SRRST score of 2 (or 3) or more had greater rate of falling than those with the SRRST score of 1 (or 2) and below, although significant difference was not found between those with the SRRST score of 0 and those with the SRRST score of 1 or more. It is necessary to do more multidirectional assessment for predicting fall in terms of subjective fall risks, because fall that occurs during movements and behaviors at various situations in ADL cannot predict by single assessment for fall risks. The SRRST consist of subjective evaluation items of fall risks for typical and specific tasks in ADL, and might be able to detect multiple fall risks. Although the SRRST will need to validate the sensitivity and specificity for the predictive validity of fall risks, it was considered that those who were detected several subjective fall risks in the SRRST were had potentially high risk of falling.

In Spearman correlation analysis, the SRRST was associated with the OLS and TUG, moderately. Postural balance and gait disturbance as shown by lower OLS and higher TUG were important risk factors for predicting falling as well as lower muscle weakness[3,7,18]. Since the SRRST showed significant correlations with these indicators, the SRRST was considered an indicator of a major decline in physical performances affecting the fall, and had moderate concurrent validity. Moreover, it showed moderate correlation coefficient values, the SRRST had task specificity of movements and behaviors in ADL related to falling which was difficult to reflect by single element of physical performance.

One of the limitations of our study is that we analyzed retrospectively recalled falls. It is possible that underreporting of falls by participants may have led an underestimation of the rates of falls. Therefore, further investigation of the validity of these tests in predicting falls in frail elderly people using a prospective study design is recommended. Secondly, the investigations of the SRRST and the experience of falls were assessed at the same time in this cross-sectional study. Thus, the information of the experience of falls might affect subjective judgements of the raters, and these results cannot show the causal association between the SRRST and falling, sufficiently. Thirdly, this study was limited by the small subject sample. To overcome this limitation, further studies with a larger number of subjects should be performed to examine the relative risk of the SRRST for predicting falls in order to enhance the clinical usability by longitudinal study.

In conclusion, this study reported that the SRRST as a subjective fall risk assessment was feasible evaluation for the specific fall risks with moderate to high reliability and concurrent validity in frail elderly people. This study provides the evidence that subjective assessment by care staff might be able to predict risk in frail elderly people.

REFERENCES

1) Scott V, Votova K, Scanlan A, et al.: Multifactorial and functional mobility assessment tools for fall risk among older adults in community, home-support, long-term and acute care settings. Age Ageing. 2007, 36: 130–139.
2) Gates S, Fisher JD, Cooke MW, et al.: Multifactorial assessment and targeted intervention for preventing falls and injuries among older people in community and emergency care settings: systematic review and meta-analysis. BMJ. 2008, 336: 130–133.
3) Suzukawa M, Shimada H, Makizako H, et al.: Incidence of falls and fractures in disabled elderly people utilizing long-term care insurance. Nippon Ronen Igakkai Zasshi. 2009, 46: 334–340 (in Japanese).
4) Gillespie LD, Robertson MC, Gillespie WJ, et al.: Interventions for preventing falls in older people living in the community. Cochrane Database Syst Rev 2009.
5) Izumi K, Makimoto K, Kato M, et al.: Prospective study of fall risk assessment among institutionalized elderly in japan. Nurs Health Sci. 2002, 4: 141–147.
6) Nordin E, Lindelof N, Rosendahl E, et al.: Prognostic validity of the timed up-and-go test, a modified get-up-and-go test, staff's global judgement and fall history in evaluating fall risk in residential care facilities. Age Ageing. 2008, 37: 442–448.
7) American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention: Guideline for the prevention of falls in older persons. J Am Geriatr Soc. 2001, 49: 664–672.
8) Mathiowetz V, Kashman N, Volland G, et al.: Grip and pinch strength: normative data for adults. Arch Phys Med Rehabil. 1985, 66: 69–74.
9) LeBrasseur NK, Bhasin S, Miciek R, et al.: Tests of muscle strength and physical function: reliability and discrimination of performance in younger and older men and older men with mobility limitations. J Am Geriatr Soc. 2008, 56: 2118–2123.
10) Vellas BJ, Wayne SJ, Romero L, et al.: One-leg balance is an important predictor of injurious falls in older persons. J Am Geriatr Soc. 1997, 45: 735–738.
11) Duncan PW, Weiner DK, Chandler J, et al.: Functional reach: a new clinical measure of balance. J Gerontol. 1990, 45: M192–M197.
12) Podsiadlo D, Richardson S: The timed "up & go": A test of basic functional mobility for frail elderly persons. J Am Geriatr Soc. 1991, 39: 142–148.
13) Handa T, Sahara R, Yoshizaki K, et al.: Examination of Reliability and Validity of Walking Speed, Cadence, Stride Length –Comparison of Measurement with Stopwatch and Three-Dimension Motion Analyzer-. J Phys Ther Sci. 2007, 19: 213–222.
14) Mahoney FJ, Barthel DW: Functional evaluation: The Barthel Index. Maryland State Med J. 1965, 14: 61–65.
15) Koyano W, Shibata H, Nakazato K, et al.: Measurement of competence: reliability and validity of the TMIG Index of Competence. Arch Gerontol Geriatr. 1991, 13: 103–116.
16) Moreland J, Richardson J, Chan DH, et al.: Evidence-based guideline for the secondary prevention of fall in older adults. Gerontology. 2003, 49: 93–116.
17) Liu-Ambrose TY, Ashe MC, Graf P, et al.: Increased risk of falling in older community-dwelling women with mild cognitive impairment. Phys Ther. 2008, 88: 1482–1491.
18) Shumway-Cook A, Brauer S, Woollacott M: Predicting the probability for falls in community-dwelling older adults using the Timed Up & Go Test. Phys Ther. 2000, 80: 896–903.

International Journal of Nursing Studies 48 (2011) 1165–1172

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/ijns

The effects of multidimensional exercise treatment on community-dwelling elderly Japanese women with stress, urge, and mixed urinary incontinence: A randomized controlled trial

Hunkyung Kim [a,*], Hideyo Yoshida [a], Takao Suzuki [b]

[a] *Research Team for Promoting Independence of the Elderly, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan*
[b] *National Institute for Longevity Sciences, Aichi, Japan*

ARTICLE INFO

Article history:
Received 1 October 2010
Received in revised form 16 December 2010
Accepted 18 February 2011

Keywords:
Cure
Elderly women
Multidimensional exercise
Pelvic muscle exercises
Urinary incontinence

ABSTRACT

Background: Urinary incontinence is one of the most prevalent health problems and a significant cause of disability and dependence in the elderly. Pelvic floor exercise is effective in reducing stress urinary incontinence, but few studies have investigated the effect of behavioral management on urge and mixed incontinence.
Objectives: To determine the effects of multidimensional exercise treatment on reducing urine leakage in elderly Japanese women with stress, urge, and mixed urinary incontinence.
Design: Randomized controlled, follow-up trial.
Settings: Urban community-based study.
Participants: 127 community-dwelling women aged 70 and older with stress, urge, and mixed urinary incontinence were randomly assigned to the intervention ($n = 63$) or the control group ($n = 64$).
Methods: Urine leakage and fitness data were collected at baseline, and after the intervention and follow-up. The intervention group received a multidimensional exercise treatment twice a week for 3-month. After treatment, the participants were followed for 7-month.
Results: There were significant differences in changes of functional fitness and incontinence variables between the intervention and control groups. The intervention group showed urine leakage cure rates of 44.1% after treatment and 39.3% after follow-up ($\chi^2 = 21.96$, $p < 0.001$); whereas, the control group showed no significant improvement. The multidimensional exercise treatment was significantly effective in decreasing all three types of urinary incontinence. However, the effects of the exercise treatment were greater on stress urinary incontinence than on urge or mixed urinary incontinence. At the 7-month follow-up, while cure rates of all three types of urinary incontinence were significantly maintained, a slight reversal was seen only in the urge and mixed urinary incontinence ($\chi^2 = 10.28$, $p = 0.008$). According to the logistic regression model, urine leakage volume (adjusted odds ratio OR = 0.69, 95% confidence interval CI = 0.39–0.98), compliance (OR = 1.03, 95%CI = 1.01–1.16), and BMI reduction (OR = 0.67, 95%CI = 0.48–0.89) were significantly associated with the cure of urine leakage after intervention. The cure rate of urine leakage after the follow-up was significantly associated with compliance (OR = 1.13, 95%CI = 1.02–1.29) and BMI reduction (OR = 0.78, 95%CI = 0.60–0.96).
Conclusions: The intervention group showed higher urine leakage cure rates than control group. This result suggests that multidimensional exercise strategies may be effective for all three types of urinary incontinence. BMI reduction and compliance to the intervention was the consistent predictor for the effectiveness of the exercise treatment.
© 2011 Elsevier Ltd. All rights reserved.

* Corresponding author at: Research Team for Promoting Independence of the Elderly, Tokyo Metropolitan Institute of Gerontology, 35-2 Sakaecho, Itabashi-ku, Tokyo 173-0015, Japan. Tel.: +81 3 3964 3241x3060; fax: +81 3 3964 2316.
E-mail address: kimhk@tmig.or.jp (H. Kim).

0020-7489/$ – see front matter © 2011 Elsevier Ltd. All rights reserved.
doi:10.1016/j.ijnurstu.2011.02.016

What is already known about the topic?

- Several factors such as overweightness, high body mass index, and increased abdominal fat have been associated with higher risk of urinary incontinence.
- Behavioral management is effective in the treatment of stress urinary incontinence and is therefore recommended as a first-line therapy.
- Compliance has a positive influence on the effects of the exercise treatment.

What this paper adds

- Multidimensional exercise treatment targeting pelvic floor muscles and abdominal fat and/or BMI reduction are equally effective in reducing stress, urge, and mixed urinary incontinence after the intervention and follow-up.
- BMI reduction as well as compliance to the prescribed exercise regimen was the most consistently significant predictors of the short- and long-term effectiveness to the behavioral therapy.
- Multidimensional exercise treatment should be considered for the elderly as a strategy for reducing incontinence and improving functional capacity.

1. Introduction

Urinary incontinence (UI) in elderly people is a common condition that contributes greatly to the loss of independence, decrease in quality of life, restriction of social activities, and increase in risk for hospitalization or long-term care. The estimated prevalence of UI ranged from 17 to 55% depending on the definition of UI, the population characteristics, and the methodological approach (Thom, 1998). A number of methods are used to treat or deal with UI. Pelvic floor muscle (PFM) exercise, devised by Kegel (1948), is recommended as a first line of treatment in the management of stress UI and many investigators have validated the short- and long-term effects on stress UI (Cammu and Van Nylen, 1995; Goode et al., 2003; Kim et al., 2007). PFM exercise is hypothesized to enhance urethral resistance by increasing the strength and endurance of the periurethral and perivaginal muscles and by improving the anatomic support given to the bladder neck and proximal urethra (Kegel, 1951; Bo et al., 1999). One previous study found that PFM exercise reduces urine leakage in urge and mixed UI because of inhibition of the bladder reflex associated with PFM contraction; however, this study had no control group (Nygaard et al., 1996).

Several studies have reported that obesity and high BMI are associated with UI (Bump et al., 1992; Brown et al., 1999). One study reported objective and subjective resolution of stress and urge UI after surgically inducing weight loss in morbidly obese women (Bump et al., 1992). These results suggest that weight reduction is desirable for UI treatment (Subak et al., 2005; Auwad et al., 2008; Wing et al., 2010). We hypothesized that fitness exercises focused on strengthening the abdominal muscles would reduce abdominal fat and/or BMI, and thereby reduce abdominal wall pressure, intravesicular pressure, and the risk of UI in elderly women.

We conducted a randomized controlled trial to measure the effects of a multidimensional exercise treatment (FPM and fitness exercises) on urine leakage episodes in community-dwelling elderly Japanese women with stress, urge, and mixed UI, and to identify the factors that influence the effectiveness of the trial.

2. Methods

2.1. Subjects

The subjects in this study were randomly selected from the Basic Resident Register of 5935 women aged 70 and older that resided in the Itabashi ward (district) of Tokyo as of April 1, 2006. Information about the study was mailed to potential subjects. The baseline survey was conducted in November 2006, and 957 (16.1%) women participated. Out of the participants, 416 (43.5%) were experiencing some urinary incontinence, and 194 (46.6%) were classified as experiencing urine leakage more than once a week.

The inclusion criteria were: (1) suffering from urge, stress, or mixed UI; (2) being ≥70 years old; (3) having urine leakage episodes more than once a week; and (4) completing a 1-week urinary diary. The exclusion criteria included (1) an unclear UI type; (2) having urine leakage episodes less than once a week; (3) not completing the 1-week urinary diary; (4) impaired cognition (a Mini-Mental State Examination score of <24) (Folstein et al., 1975; McDowell et al., 1999) and (5) unstable cardiac conditions such as ventricular dysrhythmias, pulmonary edema, or other musculoskeletal conditions. Sixty seven (34.5%) of the potential participants were excluded because they were classified into one or more of the exclusion criteria. The study protocol was approved by the Clinical Research Ethics Committee of Tokyo Metropolitan Institute of Gerontology (TMIG). The procedures were fully explained to all participants, and written informed consent was obtained (Fig. 1).

2.2. Randomization

Randomization was performed after the baseline assessment and completion of the 1-week urinary diary, and any variable that identified personal information was not included in the randomization process. The assigned identification numbers of 127 participants (stress = 37, urge = 47, and mixed = 43) were divided into two groups based on the computer-generated random numbers. One group was randomly assigned to the intervention group ($n = 63$), and the other to the control group ($n = 64$). There was no attempt to equalize the size of the groups based on their characteristics or to recruit subjects with specific characteristics. The randomization procedure was blinded, and the investigators that evaluated the effects of the exercise treatment were blind to the allocation of interventions.

2.3. Outcome measures

The primary outcome of this trial was the cure rate of urine leakage episodes, which was assessed by the self-

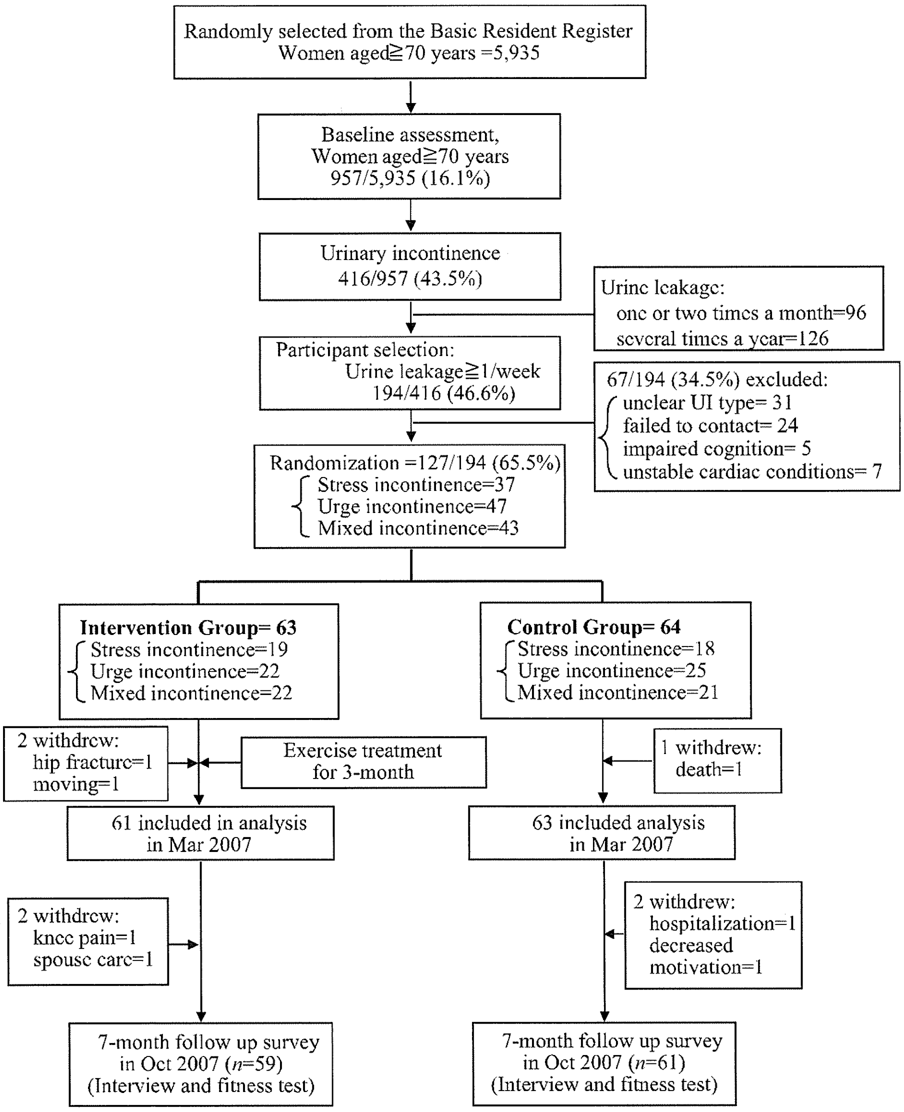

Fig. 1. Flow of the participants through the randomized controlled trial of exercise treatment and analyses.

reported urinary diary data (Wyman et al., 1988; Locher et al., 2001). The effects of the exercise treatment on urine leakage episodes were assessed based on the changes in the 5-point scale (1 = no urine leakage, 2 = less than once a week, 3 = once a week, 4 = two or three times a week, and 5 = everyday) recorded in the 1-week urinary diary, which was obtained pretreatment, after the 3-month exercise and 7-month follow-up. Complete cessation of urine leakage episodes was defined as cured.

2.3.1. *Interview survey and urinary diary*

A face-to face interview was conducted to assess temporary UI conditions based on the modified International Consultation on Incontinence Questionnaire (ICIQ) (Avery et al., 2004). The ICIQ was easily completed with low levels of missing data (mean 1.6%), good construct validity, and acceptable convergent validity. Reliability was good with moderate to very good stability in test-retest analysis and a Cronbach's alpha of 0.95 (Avery et al., 2004; Gotoh et al., 2009). The first question was "Have you experienced urine leakage during the previous year?" If the person responded that urine leakage episodes occurred more than once a week, to confirm the pretreatment frequency of urine leakage episodes, potential subjects were provided with a 1-week urinary diary. The subjects documented the time of every void and urine leakage episode, as well as the amount and circumstance of each episode. To confirm the changes of frequency, the urine leakage scores were calculated based on the self-reported 1-week urinary diary as follows: 0 = no urine leakage, 1 = less than once a week, 2 = once a week, 3 = two or three times a week, and 4 = every day.

UI type was classified based on inquiries about urine leakage in relation to 8 possible antecedents (Avery et al., 2004). Stress UI was recorded when urine leakage was associated with increased abdominal pressure such as coughing, sneezing, or participating in some other physical activity. Urge UI was recorded when urine leakage was reported to be associated with running water or an urge to void and not being able to reach the toilet in time. When the characteristics of both stress and urge UI types were present, it was defined as mixed UI.

The subjects were asked about the onset age and duration of UI, frequency of daytime and nighttime voiding, and chronic medical conditions.

2.3.2. Functional fitness test

Measurements of height and body weight were converted to body mass index (BMI, kg/m^2), waist circumference, and fitness test variables including grip strength, usual and maximum walking speed, and seated hip adductor muscle strength. The procedures for the fitness tests have been described in detail in a previous report (Kim et al., 2007).

2.4. Intervention

2.4.1. Intervention group

The participants attended an exercise treatment session 2 times a week for 3-months at the TMIG health promotion classes. The protocols of the PFM and fitness exercises have been published previously (Kim et al., 2007). The following exercises were performed by the participants.

2.4.2. Stretching exercise

Before the PFM exercise and muscle strengthening training, the participants performed 5–10 min of warm-up and stretching exercises, including shoulder rotation, waist rotation, and others.

2.4.3. PFM exercises

The subjects were trained to exert force only on the PFM without excessively straining the abdomen. The exercise regimen was designed to strengthen the fast- and slow-twitch muscle fibers located on the pelvic floor. The participants were initially instructed to perform 10 fast contractions (3 s) with a 5-s relaxation and 10 sustained contractions (8–10 s) with a 10-s relaxation between the contractions. The PFM exercise was performed in the sitting, lying, and standing positions with the legs apart, while emphasizing contraction of the PFM and relaxation of the other muscles.

2.4.4. Fitness exercises

Strength training of the thigh and abdominal muscles was performed between the PFM exercises. The fitness exercise included: lifting the foot (or both feet) and pointing toes then slowly pulling toes back toward the shin, slowly lifting one knee (or both knees), tilting the pelvis backward and forward, lifting the buttocks while on the back with the knees bent, raising one leg while lying on the back, and others. The ball exercises included actions like sitting on the ball, rolling the ball and the pelvis forward and backward, and moving from side to side, squeezing the thighs, lifting the ball with the legs, and others.

2.4.5. Control group

The control group received general education classes once a month for three months, where participants were educated on cognitive function, osteoporosis, and oral hygiene.

2.5. Follow-up

During the 7-month follow-up period, the participants attended 1-h exercise classes once a month at the TMIG health promotion center. The home-based program consisted of two to three sets of the 13 exercises and the PFM exercises that they had learned during the group exercise sessions. They were encouraged to perform the home-based exercises at least three times per week for approximately 30 min per day. To accurately monitor the exercise times and the number of sets performed during the follow-up period, a pamphlet illustrating the PFM and strengthening exercises and a recording sheet were distributed to the subjects. The subjects were asked to document the time and sets of exercises performed at home each day, the urine leakage episodes, and the amount and circumstances of each episode. The record sheets were collected once a month at the group exercise class and analyzed to calculate the mean exercise frequency per week and the mean exercise time per day. When a participant was absent from an exercise class, we mailed the record sheet to the individual.

2.6. Data analysis

The sample size was calculated to allow detection of a 20.0% reduction in urine leakage episodes between groups with 80% power and a significance level of 0.05 (Burgio et al., 2002).

The mean differences between groups were analyzed using the *t*-test for continuous variables and the chi-square test for categorical variables. To evaluate the differences between the groups in the effects of the intervention on selected continuous variables and urine leakage score at the baseline, after the 3-month exercise, and at the 7-month follow-up, a repeated-measures two-way analysis of variance (ANOVA) was performed. Significant interactions were analyzed to determine whether the effects were greater in the intervention or control group. A repeated-measures one-way ANOVA was also performed to evaluate the within group. A *post hoc* analysis was performed using the Scheffe method. The generalized estimating equation was used to compare the effects between the groups after 3-month exercise and at the 7-month follow-up on the cure rate of UI. The Kruskal–Wallis test was used to evaluate the differences of UI type in the effect of the exercise treatment on urine leakage episodes. The Cochran Q-test was used to evaluate the within-group differences in the effect of the exercise program on urine leakage episodes for baseline, 3-month exercise, and follow-up data.

Multiple logistic regressions were performed to identify variables that were associated with cured urine leakage after 3-month of exercise and at the 7-month follow-up after intervention. All analyses were performed using SPSS software, Windows version 15.0 (SPSS, Inc., Tokyo, Japan).

Table 1
Selected variables characteristics of participants at baseline by study group.

Variables[a]	Intervention group ($n = 63$)	Control group ($n = 64$)	p Value[b]
Age (yr)	76.1 ± 4.3	75.7 ± 4.4	0.625
Height (cm)	148.4 ± 5.8	148.9 ± 6.2	0.639
Body weight (kg)	51.8 ± 8.7	54.0 ± 7.9	0.202
BMI (kg/m^2)	23.4 ± 3.3	24.3 ± 3.0	0.195
Waist circumference (cm)	78.9 ± 10.2	78.5 ± 9.9	0.853
Grip strength (kg)	19.2 ± 4.6	18.6 ± 4.7	0.561
Adductor muscle strength (kg)	20.6 ± 6.9	21.5 ± 4.8	0.502
Usual walking speed (m/s)	1.2 ± 0.3	1.1 ± 0.3	0.282
Maximal walking speed (m/s)	1.7 ± 0.4	1.7 ± 0.4	0.423
Onset age of incontinence (yr)	71.3 ± 7.6	71.0 ± 7.1	0.865
Period of incontinence (year)	4.8 ± 6.4	4.6 ± 6.0	0.890
Frequency of toilet in daytime (times)	7.7 ± 3.1	7.4 ± 2.3	0.525
Frequency of toilet in night (times)	1.9 ± 1.2	1.8 ± 1.3	0.581
Frequence of urine leakage (%)			
Everyday	46.0	50.0	0.714
1 every two days	11.1	7.8	
More than once a week	42.9	42.2	
Amount of urine leakage, large (%)	23.8	32.8	0.210
Chronic medical conditions, yes (%)			
Hypertension	57.1	57.8	0.918
Hyperlipemia	36.5	40.6	0.712
Diabetes	17.5	15.6	0.780

[a] Data are presented as M (mean) and SD (standard deviation) for continuous variables, and percentage for categorical variables. BMI = body mass index.
[b] Two group t-tests for continuous variables and chi-square test for categorical variables.

3. Results

3.1. Subjects characteristics and compliance

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

The attendance rate during the 3-month exercise treatment ranged from 63.5% to 81.1%, with a mean of 70.3%. Seven participants (intervention group = 4, control group = 3) were unable to complete the study after

Table 2
Comparison of functional fitness and incontinence variables between intervention ($n = 59$) and control ($n = 61$) after 3-months of exercises and the 7-month follow-up.

Variables[a]	G[b]	Baseline	3-month exercise	7-month follow-up	ANOVA[c] G × T	p Value
Body Weight (kg)	I	52.0 ± 8.9	51.9 ± 8.8	50.9 ± 8.9	$F = 5.78$	0.018
	C	53.9 ± 8.2	53.9 ± 8.2	53.9 ± 8.1		
BMI (kg/m^2)	I	23.7 ± 3.4	23.5 ± 3.0	23.2 ± 3.1	$F = 11.49$	0.001
	C	24.1 ± 2.9	24.0 ± 2.7	24.4 ± 3.4		
WC (cm)	I	78.8 ± 10.3	77.8 ± 9.7	77.7 ± 9.9	$F = 4.06$	0.041
	C	79.3 ± 10.4	79.2 ± 10.5	78.9 ± 9.6		
UWS (m/s)	I	1.2 ± 0.2	1.2 ± 0.2	1.2 ± 0.2	$F = 2.79$	0.099
	C	1.1 ± 0.3	1.1 ± 0.3	1.1 ± 0.2		
MWS(m/s)	I	1.7 ± 0.4	1.8 ± 0.4	1.8 ± 0.4	$F = 5.10$	0.027
	C	1.7 ± 0.4	1.6 ± 0.3	1.6 ± 0.4		
GS (kg)	I	19.0 ± 4.7	20.7 ± 5.0	19.8 ± 5.7	$F = 0.37$	0.547
	C	19.0 ± 4.2	20.2 ± 3.5	19.5 ± 3.8		
AMS (kg)	I	20.5 ± 7.1	24.1 ± 7.7	24.3 ± 7.9	$F = 11.00$	0.001
	C	21.2 ± 4.8	22.1 ± 4.8	21.8 ± 4.9		
ULS (point)	I	5.0 ± 1.0	3.0 ± 2.0	3.6 ± 2.2	$F = 7.64$	0.007
	C	5.1 ± 1.0	4.4 ± 1.6	4.8 ± 1.6		
Cure of urine leakage	I	0.0	44.1	39.3	21.96	<0.001
	C	0.0	1.6	1.6		
Cure of urine leakage in intervention group	Stress	0.0	63.2[d]	66.7[e]	15.77	<0.001
	Urge	0.0	35.0[d]	26.1[c]	7.49	0.032
	Mixed	0.0	40.1[d]	30.0[e]	9.56	0.016

[a] Data are presented as mean and standard deviation.. WC = waist circumference; UWS = usual walking speed; MWS = maximum walking speed; GS = Grip strength; AMS = adductor muscle strength; ULS = urine leakage score.
[b] G = group, I = intervention group, C = control group.
[c] ANOVA = analysis of variance, T = time. Chi-square and p values are from generalized estimating equation. Conhran's Q-value.
[d] Kruskal–Wallis test: chi-square = 1.99, $p = 0.391$.
[e] Kruskal–Wallis test: chi-square = 10.28, $p = 0.008$. (Scheffe's *post hoc* = stress > urge, mixed urinary incontinence).

randomization due to hip fracture ($n = 1$), moving ($n = 1$), knee pain ($n = 1$), spouse care ($n = 1$), death ($n = 1$), hospitalization ($n = 1$), and decreased motivation ($n = 1$) (Fig. 1). The exercise frequency during the 7-month follow-up period was reported to be every day in 35.7% of the subjects, two to three times a week in 42.9%, and once or less per week in 21.4%. The mean exercise time was 29.3 min, and the mean number of contractions of the PFM was 52 times a day during the 7-month follow-up period.

3.2. Functional fitness and urinary incontinence

The comparison of the effects of the treatment on selected variables between the intervention and control group are summarized in Table 2. A repeated measures ANOVA and generalized estimating equation revealed significant increases in adductor muscle strength ($F = 11.00$, $p = 0.001$) and maximum walking speed ($F = 5.10$, $p = 0.027$) after the 3-month exercise and at the 7-month follow-up in the intervention group compared with the control group. Body weight ($F = 5.80$, $p = 0.018$), BMI ($F = 11.49$, $p = 0.001$), waist circumference ($F = 4.06$, $p = 0.041$), and the urine leakage score ($F = 7.64$, $p = 0.007$) decreased significantly in the intervention group, whereas no significant changes were seen in the control group. The women who reported no urine leakage episodes in their 1-week urinary diaries accounted for 44.1% of the intervention group and 1.6% of the control group after the 3-month exercise treatment, and 39.3% of the intervention group and 1.6% of the control group at the 7-month follow-up ($\chi^2 = 21.96$, $p < 0.001$). After the 3-month exercise, the cure rates of urine leakage increased significantly across the three subgroups of UI. At the 7-month follow-up, although slight decreases were observed in the cure rates of urine leakage related to urge and mixed UI, the cure rates of all three subtypes; stress (Q-value = 15.77, $p < 0.001$), urge (Q-value = 7.49, $p = 0.032$), and mixed (Q-value = 9.56, $p = 0.016$) UI were significantly maintained. However, the efficacy of the exercise treatment on stress UI was greater than the effects on urge or mixed UI after 7-month follow-up ($\chi^2 = 10.28$, $p = 0.008$; *post hoc* = stress > urge, mixed UI).

Before treatment, the urine leakage score was similar between the groups (Fig. 2). However, the urine leakage score significantly decreased after the 3-month exercise treatment and at the 7-month follow-up in the intervention group compared with the control group ($F = 7.22$, $p = 0.009$) (A). The effect of the treatment across the intervention period was assessed for each subgroup of UI (B). At baseline, the urine leakage scores were similar across the three subgroups, although the mixed UI subgroup had a slightly higher score. A repeated measures ANOVA also showed significant subgroup by time interaction ($F = 5.13$, $p = 0.008$). The stress subgroup showed a significant decline in urine leakage score after the 3-month exercise treatment and the 7-month follow-up ($F = 8.23$, $p < 0.001$). The urge ($F = 3.46$, $p = 0.034$) and mixed ($F = 4.10$, $p = 0.019$) subgroups each also showed significant declines in urine leakage scores after the 3-month exercise, although slight reverse patterns of increase were observed at the 7-month follow-up, these changes were not significant.

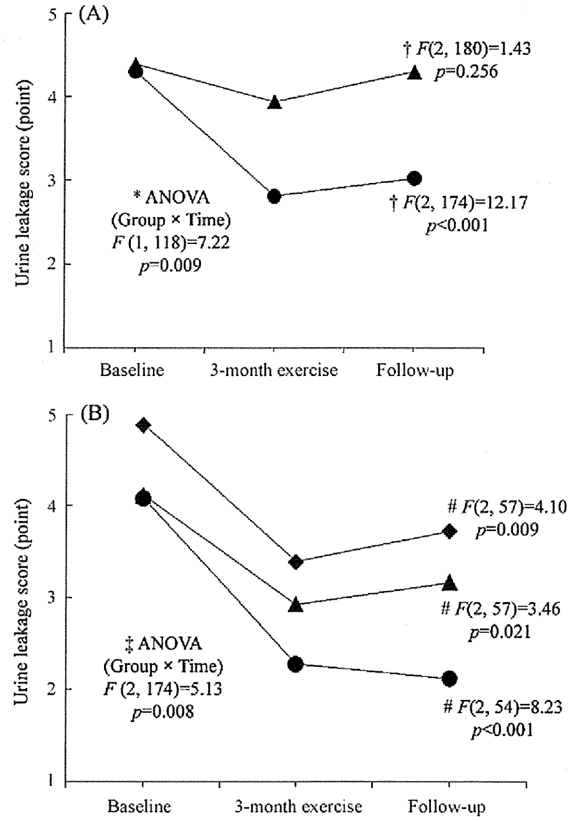

Fig. 2. Changes in the mean urine leakage score on a 5-point scale based on self-reported urinary diaries at the baseline, after 3-months exercise, and at the 7-month follow-up. (A) (●) intervention group; (▲) control group. (*) A comparison of urine leakage scores between the intervention and control groups ($F = 7.22$, $p = 0.009$. (†) A comparison of urine leakage scores at the baseline (b), after 3-months exercise (p), and at the 7-month follow-up (f) within group: intervention group ($F = 12.17$, $p < 0.001$; Scheffe's *post hoc* = b > p, f); control group ($F = 1.43$, $p = 0.256$). (B) (●) Stress incontinence; (▲) urge incontinence; (◆) mixed incontinence. (‡) A comparison of urine leakage scores among stress, urge, and mixed urinary incontinence in the intervention group. # A comparison of urine leakage scores at the baseline (b), after 3-months exercise (p), and at the 7-month follow-up (f) within group: stress incontinence ($F = 8.23$, $p < 0.001$; Scheffe's *post hoc* = b > p, f); urge incontinence ($F = 3.46$, $p = 0.021$; Scheffe's *post hoc* = b > p, f); mixed incontinence ($F = 4.10$, $p = 0.009$; Scheffe's *post-hoc* = b > p, f).

3.3. Predictor variables

As shown in Table 3, the amount of urine leakage (OR = 0.69, 95%CI = 0.39–0.98), compliance to the exercise treatment (OR = 1.03, 95%CI = 1.01–1.16), and BMI reduction (OR = 0.67, 95%CI = 0.48–0.89) were significantly associated with being cured of urine leakage after the 3-month exercise. The cure of urine leakage at the 7-month follow-up was significantly associated with compliance (OR = 1.13, 95%CI = 1.02–1.29) and BMI reduction (OR = 0.78, 95%CI = 0.60–0.96).

4. Discussion

While the ratio of participation by the random population was very low, a baseline of 957 people is an

Table 3
Adjusted OR for cure of urine leakage after intervention and the 7-month follow-up.

	After 3-month exercise			After 7-month follow-up		
Variable	Adjusted OR[a]	95%CI	*p* Value	Adjusted OR[a]	95%CI	*p* Value
Amount of urine leakage	0.69	0.39–0.98	0.049	0.78	0.26–1.88	0.600
Frequency of urine leakage	1.16	0.24–5.79	0.856	1.63	0.73–4.01	0.248
Compliance to exercise	1.03	1.01–1.16	0.048	1.13	1.02–1.29	0.031
Decreased of BMI	0.67	0.48–0.89	0.011	0.78	0.60–0.96	0.028
Increased of walking speed	0.97	0.91–1.04	0.414	0.99	0.94–1.06	0.913
Period of urine leakage	1.01	0.91–1.13	0.919	1.01	0.91–1.14	0.913

[a] Dependent variable; cure of urinary incontinence: 1 = cured, 0 = urine leakage. Independent variables: (a) Amount of urine leakage: large amount, 1 = requiring change of undergarments or soaked outerwear, small amount, 0 = wet undergarments. (b) Frequency of urine leakage: high frequency 1 = every day, low frequency, 0 = less than once every two days. (c) Compliance to exercise: full compliance, 1 = more than 60.0% attendance, partial compliance, 0 = less than 59.9% attendance. OR = odds ratio; CI = confidence interval.

acceptable sample size for analysis of UI in the community-dwelling elderly. Analysis of the efficacy of a 3-month exercise treatment for UI, demonstrated that exercise treatment was equally effective in reducing stress, urge, and mixed UI; although the cure rates of urine leakage were maintained until the 7-month follow-up for all the three types of UI, the efficacy of the treatment was greater for stress UI than urge or mixed UI in the intervention group. However, the changes of UI cure rate were not significant in the control group. These results suggest that improvements in primary outcomes may be observed in an intervention group but such improvements may not be expected in a control group.

PFM exercise is known to be an effective treatment for stress UI (Bo et al., 1990; McDowell et al., 1999; Kim et al., 2007). However, a previous study reported that the mean number of incontinent episodes per day decreased not only stress but also urge and mixed UI, so PFM exercises are equally effective against all three urodynamic conditions, and no urodynamic test is necessary before behavioral treatment (Nygaard et al., 1996). Another study showed that behavioral training achieved comparable improvements in urge UI (Burgio et al., 2002). These previous studies had no control or follow-up data. Recently, one study suggested that decrease in BMI and increase in walking speed may contribute to the decline in stress UI episodes, but they did not examine urge or mixed UI (Kim et al., 2007). In this study no significant relationship between hand grip strength and cure of urinary incontinence was shown. A significant relationship was seen between adductor muscle strength, maximum walking speed and cure of urinary incontinence.

After the 3-month intervention and 7-month follow-up, UI was defined as cured if no urine loss episodes were present in the 1-week urinary diary. Our trial confirmed that exercise treatment involving PFM training and fitness exercises can achieve a 63.2% cure rate in stress UI, a 35.0% in urge UI, and a 40.0% in mixed UI within the intervention group after 3-months of exercise. This exercise treatment had immediate effects in women with UI regardless of their urodynamic diagnosis, and the effects are comparable to those of the previous study. The efficacy of the exercise treatment was greater for stress UI than urge or mixed UI, and although the cure rates of urge and mixed UI showed slight decreasing trends after the 7-month follow up, the decreases were statistically not significant. Our data suggests that exercise treatment is more effective for stress UI than urge or mixed UI, and also raises the possibility that for both urge and mixed UI, a combined behavioral and drug therapy (Burgio et al., 2000) may be more effective than exercise treatment alone. However, this study does not provide an explanation for the slight reversal in the effectiveness of the treatment on urge and mixed UI after the follow up.

Many studies have indicated that BMI (Bump et al., 1992; Brown et al., 1999; Richter et al., 2010) and waist circumference (Krause et al., 2010) are a risk factor for UI, and decrease in BMI may contribute to the decline in stress UI episodes (Kim et al., 2007). Presumably, a decrease in BMI causes a decrease in abdominal-wall weight, decreasing intra-abdominal pressure and intra-vesicular pressure, which may have led to the improvement of stress UI. In this analysis, BMI reduction was significantly associated with the total cure rates of urge, mixed as well as stress UI, but the data does not explore the mechanism of how decreases in BMI improves urge and mixed UI. Also, previous studies have emphasized that compliance to exercise is the key factor to long-term success (Lagro-Janssen, 1998; McDowell et al., 1999). In this study, compliance to the multidimensional exercise treatment was the most significant and consistent predictor of efficacy post-intervention and follow-up. Our findings also support the idea that high compliance and BMI reduction have positive influences on urge, mixed and stress UI treatment. However, the current results were obtained based on a small sample size. The 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.

This study has several limitations. First, the assessments of UI type and urine leakage episodes were self-reported. This could have led to a reporting bias, as subjects with UI may have underreported their symptoms, but a urinary diary is a reliable method for assessing episodes of urine leakage (Wyman et al., 1988; Locher et al., 2001). Thus, this study provided data that was reliable for objective assessment of the behavioral treatment on urinary incontinence. Second, PFM strength, which is likely to have increased through the PFM exercises, was not measured. Therefore, whether the cure rate of urine leakage is correlated with the increase in PFM strength or functional fitness, or the decrease in BMI or abdominal fat could not be explored.

The results suggest that a multidimensional exercise intervention may be equally effective for treatment of stress, urge, and mixed UI. BMI reduction as well as compliance to the prescribed exercise regimen was a significant and consistent predictor of the effectiveness of the behavioral therapy. Thus, multidimensional exercise treatments should be considered for elderly women as part of a strategy for improving functional capacity and UI. Health care for UI patients should undertake a team approach where physical therapists, doctors and nurses work together. Nurses should not only objectively assess the urinary diaries collected, they will play a very important role for the prevention of UI and maintenance of cured UI cases by instructing changes in daily lifestyle among the elderly.

Acknowledgements

H. Kim: study concept and design, subject recruitment, developed the exercise treatment, analysis and interpretation of data, and preparation of manuscript. Y. Hideyo: assisted in the subject recruitment, supervised the survey, and interpretation of data. S. Takao: statistical design and interpretation of data, and revision of manuscript.

This research was supported in part by a Research Grant from the Ministry of Health and Welfare of Japan and a Grant-in-Aid for Scientific Research B from the Japan Society for the Promotion of Science (19300236) and was supported by the Sanitary Products Research Foundation of the KAO Corporation.

Ethical approval: The study protocol was approved by the Clinical Research Ethics Committee of Tokyo Metropolitan Institute of Gerontology. The procedures were fully explained to all participants, and written informed consent was obtained.

Conflict of interest: The authors have no financial or any other kind of personal conflicts with this manuscript.

Sponsor's role: Neither sponsors had any role in the design and conduct of the study, subject recruitment, collection, management, analysis, and interpretation of data or preparation of the manuscript.

References

Auwad, W., Steggles, P., Bombieri, L., Waterfield, M., Wilkin, T., Freeman, R., 2008. Moderate weight loss in obese women with urinary incontinence: a prospective longitudinal study. International Urogynecology Journal and Pelvic Floor Dysfunction 19, 1251–1259.

Avery, K., Donovan, J., Peters, T.J., Shaw, C., Gotoh, M., Abrams, P., 2004. A brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourology and Urodynamics 23, 322–330.

Bo, K., Hagen, R.H., Kvarstein, B., Jorgensen, J., Larsen, S., 1990. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: III effects of two different degrees of pelvic floor muscle exercises. Neurourology and Urodynamics 9, 489–502.

Bo, K., Talseth, T., Holme, I., 1999. Single blind, randomized controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. British Medical Journal 318, 487–493.

Brown, J.S., Grady, D., Ouslander, J.G., Herzog, A.R., Varner, R.E., Posner, S.F., 1999. Prevalence of urinary incontinence and associated risk factors in postmenopausal women. Obstetrics and Gynecology 94, 66–70.

Bump, R.C., Sugerman, H.J., Fantl, J.A., McClish, D.K., 1992. Obesity and lower urinary tract function in women: effect of surgically induced weight loss. American Journal of Obstetrics and Gynecology 167, 392–399.

Burgio, K.L., Goode, P.S., Locher, J.L., Umlauf, M.G., Roth, D.L., Richter, H.E., Varner, R.E., Lloyd, L.K., 2002. Behavioral training with and without biofeedback in the treatment of urge incontinence in older women: a randomized controlled trial. The Journal of the American Medical Association 288, 2293–2299.

Burgio, K.L., Locher, J.L., Goode, P.S., 2000. Multidimensional behavioral and drug therapy for urge incontinence in older women. Journal of the American Geriatrics Society 48, 370–374.

Cammu, H., Van Nylen, M., 1995. Pelvic floor muscle exercises: 5 years later. Urology 45, 113–117.

Folstein, M.F., Folstein, S.E., McHugh, P.R., 1975. Mini-mental state: a practical method for grading the cognitive state of patients for the clinician. Journal of Psychiatric Research 12, 189–198.

Goode, P.S., Burgio, K.L., Locher, J.L., Roth, D.L., Umlauf, M.G., Richter, H.E., Varner, R.E., Lloyd, L.K., 2003. Effect of behavioral training with or without pelvic floor electrical stimulation on stress incontinence in women: a randomized controlled trial. The Journal of the American Medical Association 290, 345–352.

Gotoh, M., Homma, Y., Funahashi, Y., Matsukawa, Y., Kato, M., 2009. Psychometric validation of the Japanese version of the International Consultation on Incontinence Questionnaire-Short Form. International Journal of Urology 16, 303–306.

Kegel, A.H., 1948. Progressive resistance exercise in the functional restoration of the perineal muscles. American Journal of Obstetrics and Gynecology 56, 238–248.

Kegel, A.H., 1951. Physiologic therapy for urinary stress incontinence. The Journal of the American Medical Association 146, 915–917.

Kim, H., Suzuki, T., Yoshida, Y., Yoshida, H., 2007. Effectiveness of multidimensional exercises for the treatment of stress urinary incontinence in elderly community-dwelling Japanese women: a randomized, controlled, crossover trial. Journal of the American Geriatrics Society 55, 1932–1939.

Krause, M.P, Albert, S.M., Elsangedy, H.M., Krinski, K., Goss, F.L., daSilva, S.G., 2010. Urinary incontinence and waist circumference in older women. Age Ageing 39, 69–73.

Lagro-Janssen, T., Van Weel, C., 1998. Long-term effect of treatment of female incontinence in general practice. British Journal of General Practice 48, 1735–1738.

Locher, J.L., Goode, P.S., Roth, D.L., Worrell, R.L., Burgio, K.L., 2001. Reliability assessment of the bladder diary for urinary incontinence in older women. Journal of Gerontology: Medical Sciences 56A, M32–M35.

McDowell, B.J., Engberg, S., Sereika, S., Donovan, N., Jubeck, M.E., Weber, E., Engberg, R., 1999. Effectiveness of behavioral therapy to treat incontinence in homebound older adults. Journal of the American Geriatrics Society 47, 309–318.

Nygaard, I.E., Kreder, K.J., Lepic, M.M., Fountain, K.A., Rhomberg, A.T., 1996. Efficacy of pelvic floor muscle exercises in women with stress, urge, and mixed urinary incontinence. American Journal of Obstetrics and Gynecology 174, 120–125.

Richter, H.E., Kenton, K., Huang, L., Nygaard, I., Kraus, S., Whitcomb, E., Chai, T.C., Lemack, G., Sirls, L., Dandreo, K.J., Stoddard, A., 2010. The impact of obesity on urinary incontinence symptoms, severity, urodynamic characteristics and quality of life. The Journal of Urology 183, 622–628.

Subak, L.L, Whitcomb, E., Shen, H., Saxton, J., Vittinghoff, E., Brown, J.S., 2005. Weight loss: a novel and effective treatment for urinary incontinence. The Journal of Urology 174, 190–195.

Thom, D., 1998. Variation in estimates of urinary incontinence prevalence in the community: effects of differences in definition, population characteristics, and study type. Journal of the American Geriatrics Society 46, 473–480.

Wing, R.R, Creasman, J.M., West, D.S., Richter, H.E., Myers, D., Burgio, K.L., Franklin, F., Gorin, A.A., Vittinghoff, E., Macer, J., Kusek, J.W., Subak, L.L, 2010. Improving Urinary Incontinence in Overweight and Obese Women Through Modest Weight Loss. Obstetrics and Gynecology 116, 284–292.

Wyman, J.F., Choi, S.C., Harkins, S.W., Wilson, M.S., Fantl, J.A., 1988. The urinary diary in evaluation of incontinent women: a test-retest analysis. Obstetrics and Gynecology 71, 812–817.

Geriatr Gerontol Int 2011; 11: 452–459

ORIGINAL ARTICLE: EPIDEMIOLOGY, CLINICAL PRACTICE AND HEALTH

Effects of exercise treatment with or without heat and steam generating sheet on urine loss in community-dwelling Japanese elderly women with urinary incontinence

Hunkyung Kim,[1] Hideyo Yoshida[1] and Takao Suzuki[2]

[1]*Research Team for Promoting Independence of the Elderly, Tokyo Metropolitan Institute of Gerontology, Tokyo, and* [2]*National Institute for Longevity Sciences, Aichi, Japan*

Aim: To determine the effects of exercise treatment with or without heat and steam generating sheet (HSGS) on reducing urine loss in community-dwelling elderly women with urinary incontinence (UI).

Methods: One hundred and forty-seven community-dwelling women aged 70 years and older with stress, urge and mixed UI were randomly assigned to exercise + HSGS ($n = 37$), exercise only ($n = 37$), HSGS only ($n = 37$) or an education group ($n = 36$). Exercise + HSGS, and exercise groups received exercise training twice a week for 3 months. When the HSGS was placed on the lower back, the temperature of the skin surface rose to 38–40°C and it continued to generate heat and steam for over 5 h. The HSGS group used one sheet per day continuously for 3 months. Urine loss and fitness data were collected at baseline and after intervention.

Results: The intervention groups showed significant improvements in muscle strength and walking speed compared to the education group. Exercise and HSGS showed urine loss cure rates of 54.1%, exercise 34.3% and HSGS 21.6% after treatment; whereas, the education group (2.9%) showed no significant improvement (χ^2=21.89, $P < 0.001$). Combining the HSGS to the exercise intervention showed a 61.5% cure rate for stress UI, 50.0% urge UI and 40.0% mixed UI.

Conclusion: This data suggests that exercise treatment with HSGS is more effective for treating urine loss regardless of UI type. The HSGS can be used as a supplementary treatment method to enhance the effects of exercise on women with urge, mixed and stress UI. **Geriatr Gerontol Int 2011; 11: 452–459.**

Keywords: elderly women, fitness exercise, heat and steam generating sheet, pelvic floor muscle exercises, urinary incontinence.

Introduction

Urinary incontinence (UI) is one of the most prevalent health problems among the elderly population. Several studies have assessed the association of UI with multiple factors, such as smoking, obesity, cognitive impairment,

Accepted for publication 6 March 2011.

Correspondence: Dr Hunkyung Kim PhD, Research Team for Promoting Independence of the Elderly, Tokyo Metropolitan Institute of Gerontology, 35-2 Sakaecho, Itabashi-ku, Tokyo 173-0015, Japan. Email: kimhk@tmig.or.jp

 doi: 10.1111/j.1447-0594.2011.00705.x

© 2011 Japan Geriatrics Society

nocturia and poor mobility.[1–3] Currently, a number of methods are used to treat or deal with UI including medication, surgery and behavior management. Behavioral therapy for UI is not a new topic, and several randomized control trials and systematic reviews have confirmed that pelvic floor muscle (PFM) training is an effective treatment for stress UI.[4,5] Even though many studies have validated the effectiveness of these behavioral therapies, reporting improvement rates from 17–84%,[6] such previous studies have focused exclusively on stress UI, and investigations on the effects of behavioral therapies on urge and mixed UI have been relatively limited.[7] Furthermore, several studies have suggested that abdominal and lower back heating may have positive effects on renal function such as renal sympathetic nerve activity suppression, promotion of bladder voiding and increasing frequency of urination.[8–10] Therefore, it can be speculated that heating methods will positively affect renal function.

The purpose of the current study was to investigate the effects of a 3-month exercise and/or heat and steam generating sheet (HSGS) intervention aimed to treat urine loss in community-dwelling women with UI.

Methods

The study population was randomly selected from the Basic Resident Register of 5935 women aged 70 years and older that resided in the Itabashi ward of Tokyo as of 1 April 2006. Information about the comprehensive health check-up was mailed to selected subjects. The recruitment survey was conducted in November 2006, where 957 women participated in baseline testing and 416 of them reported experience of urine loss over several times a year.

The inclusion criteria were: (i) suffering from urge, stress or mixed UI; (ii) being 70 years or older; and (iii) having urine loss episodes more than once a month. The exclusion criteria included: (i) an unclear UI type; (ii) having urine loss episodes less than once a month; (iii) impaired mental health (a Mini-Mental State Examination score of <24);[11,12] and (iv) unstable cardiac conditions such as ventricular dysrhythmias, pulmonary edema or other musculoskeletal conditions. One hundred and twenty-six (30.3%) potential subjects were excluded because they were classified into one or more of the exclusion criteria. The study protocol was approved by the Clinical Research Ethics Committee of Tokyo Metropolitan Institute of Gerontology (TMIG). The procedures were fully explained to all subjects and written informed consent was obtained (Fig. 1).

Randomization

After the baseline assessment, 147 participants (stress = 50, urge = 59 and mixed = 38) were randomly

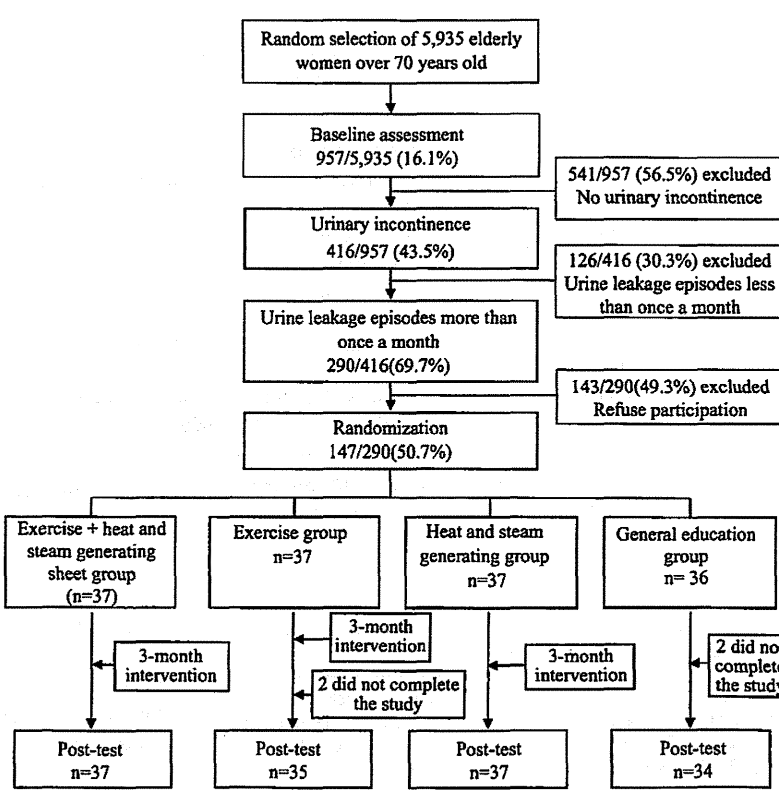

Figure 1 Flow chart of participant recruitment through the randomized controlled trial of exercise and/or heat and steam generating sheet trial.

© 2011 Japan Geriatrics Society

assigned to the general education ($n = 36$), HSGS ($n = 37$), exercise ($n = 37$) or exercise + HSGS ($n = 37$) groups with an allocation ratio of 1:1 according to computer-generated random numbers. There was no attempt to equalize the size of the groups based on their characteristics or to recruit subjects with specific characteristics. The investigators were blind to the allocation of interventions.

Outcome measures

The primary outcome variable of this study was the cure of urine loss episodes, which was assessed by interview.[13] Complete cessation of urine loss episodes was defined as cured. The secondary outcomes were functional fitness and changes in frequency of urine loss episodes, which was assessed based on changes in a 5-point scale obtained in the interviews conducted pretreatment and after the 3-month intervention.

Interview survey

A face-to-face interview was conducted to assess temporary UI conditions based on the modified International Consultation on Incontinence Questionnaire (ICIQ).[14] The first question was "Have you experienced urine loss during the previous year?". If the participant responded "yes", we then asked the frequency, volume and circumstance of urine loss. The frequency of UI was assessed based on a 5-point scale by interview (1, every day; 2, once every 2 days; 3, once or twice per week; 4, once or more per month; 5, several times per year). Those whose response ranged 1–4 were classified as potential subjects. The same 5-point scale was presented to the participants after the 3-month intervention. The changes in the 5-point scale were converted to the following 6-point scale in order to assess improvements observed in urine loss frequency from baseline to after the 3-month intervention: 0 for no urine loss, 1 for several times per 3 months; 2 for one to three times per month, 3 for one to two times per week, 4 for once every 2 days, and 5 for every day.

Urinary incontinence type was assessed based on all answers to the following question: "When do you experience urine loss? 1, before reaching the toilet; 2, while coughing, sneezing or laughing; 3, while sleeping at night; 4, while physically active or exercising; 5, upon re-dressing after urinating; 6, for no apparent reason; 7, all the time; 8, while working with water, touching water or drinking cold water."[14] Participants were classified as having stress UI when urine loss was associated with increased abdominal pressure, as in responses 2 and/or 4. Participants were classified as having urge UI if they responded with 1 and/or 8. When characteristics of both stress and urge UI types were present, it was defined as mixed UI. Urine loss volume was assessed based on the answer to the question: "How much urine is leaked each time? 1, wets or dampens undergarment; 2, requires a change in undergarment; 3, soaks through to outer clothing; 4, runs down the leg(s) and onto the floor."

The subjects were asked about the onset age and duration of UI, frequency of daytime and nighttime voiding, and chronic medical conditions such as heart disease, diabetes, hypertension and osteoporosis.

Functional fitness test

Measurements of height and body weight were converted to body mass index (BMI, kg/m^2), and fitness test variables including grip strength, one-leg standing time with eyes open, usual and maximum walking speed, and seated adductor muscle strength were taken. The procedures for the fitness tests have been described in detail in a previous report.[15]

Intervention

Exercise group

The exercise group participants attended an exercise training session 2 times a week for 3 months at the TMIG health promotion classes. The following exercises were performed by the participants.

Stretching exercise

The participants performed 5–10 min of warm-up and stretching exercises, including shoulder rotation, waist rotation and others.

PFM exercises

The participants were informed that straining the abdomen increases abdominal pressure and exerts pressure on the PFM. The subjects were trained to exert force only on the PFM without excessively straining the abdomen. The exercise regimen was designed to strengthen the fast- and slow-twitch muscle fibers located on the pelvic floor. The participants were initially instructed to perform 10 fast contractions (3 s) with a 5-s rest and 10 sustained contractions (8–10 s) with a 10-s rest between the contractions. The PFM exercise was performed in the sitting, lying and standing positions with the legs apart, while emphasizing contraction of the PFM and relaxation of the other muscles.

Fitness exercises

Strength training of the thigh and abdominal muscles were performed between the PFM exercises. The exercises included chair exercises, weight-bearing exercises, ball exercises, and others.

© 2011 Japan Geriatrics Society

HSGS group

The HSGS is a thin, flexible filmed sheet (120 mm × 204 mm; Kao, Tokyo, Japan), that generates heat and steam immediately after unsealing. When the sheet is placed on the body, the temperature of the skin surface rises to 38–40°C and it continues to generate heat and steam for over 5 h.[16] The participants gathered at TMIG classes every 2 weeks, where HSGS were provided for 2 weeks and the urinary diaries were collected. The participants in the HSGS group were asked to place the HSGS on their lower back once a day immediately after waking up. The participants recorded the time of day that they placed and removed the sheet in their urinary diary.

Exercise + HSGS group

The participants were instructed to perform a combination of the same intervention as the exercise group as well as the HSGS group.

General education group

General education classes were held (topics including cognitive function, osteoporosis and oral hygiene) once a month, a total of three times.

Urinary diary

A urinary diary was distributed to the participants in the exercise, HSGS and exercise + HSGS groups where they recorded times of urination (number of times during the day [waking up in the morning to sleeping at night] and number of times during the night [sleeping at night to waking up in the morning]), time of defecation, presence or absence of UI, time of loss, volume of loss and actions taken at the time of loss.[17] The urinary diaries were collected every 2 weeks and were monitored for any changes in UI for 3 months.

Data analysis

Means and standard deviations were calculated for continuous variables, and a one-way ANOVA was performed to measure significant differences in baseline values and urine loss score post-treatment between the intervention groups, and the χ^2-test was used for categorical variables. Scheffé's post-hoc method was performed when significance was found. A repeated-measures ANOVA (4 × 2) was performed to find differences in pre- and post-intervention functional fitness and urine loss score between groups, and paired student's t-tests were done on pre- and post-intervention measures to find changes within groups. A Kruskal–Wallis test was used to measure the difference in cure rates between the intervention groups. All analyses were performed using SPSS ver. 15.0 for Windows and $P < 0.05$ was considered statistically significant.

Results

Table 1 shows the baseline comparisons in anthropometric values, physical fitness measures and interview survey results among the exercise + HSGS, exercise, HSGS and general education groups. There were no significant differences between the groups in all variables including age, walking speed, adductor muscle strength, duration and onset age of urine loss, frequency of urine loss episodes, and chronic medical conditions.

In comparing the pre- and post-intervention changes in physical fitness between groups (Table 2), there was a significant group × time interaction in adductor muscle strength and usual walking speed, where the exercise + HSGS group was significantly greater than the other groups.

The within group analysis showed that grip strength ($P = 0.001$), one-leg standing time with eyes open ($P = 0.033$), adductor muscle strength ($P < 0.001$) and usual walking speed ($P = 0.020$) changed significantly in the exercise + HSGS group; grip strength and adductor muscle strength significantly improved and BMI decreased in the exercise group; and grip strength and adductor muscle strength significantly improved in the HSGS group (Table 2).

The cure rates of UI after the 3-month intervention were 51.4% in the exercise + HSGS group, 34.3% in the exercise group, 21.6% in the HSGS group and 2.9% in the general education group ($\chi^2 = 21.89$, $P < 0.001$). Analysis of stress UI cure rates revealed 61.5% in the exercise + HSGS group, 53.8% in the exercise group, 25.0% in the HSGS group and 9.1% in the general education group ($\chi^2 = 8.94$, $P = 0.030$). Urge UI had a 50.0% cure rate in the exercise + HSGS group, 16.7% in the exercise group, 13.3% in the HSGS group and 0.0% in the general education group ($\chi^2 = 12.88$, $P = 0.005$). No significant differences were observed in mixed UI cure rates (Table 3).

In comparing the pre- and post-intervention urine loss scores between the groups (Fig. 2), there was a significant group × time interaction in stress and urge UI, and the exercise + HSGS group showed a significantly larger decrease in urine loss score compared with the other three groups. At baseline, there were no significant differences in urine loss scores (based on the converted 6-point scale) between the stress, urge or mixed UI groups. However, there was a significant improvement in stress and urge urine loss scores (urine loss scores of participants who had stress and urge UI) after the 3-month intervention. The stress urine loss score post-intervention was significantly lower in the

© 2011 Japan Geriatrics Society

Table 1 Selected variable characteristics at baseline by study group

Variable	Ex + HSGS (n = 37) M ± SD	Ex (n = 37) M ± SD	HSGS (n = 37) M ± SD	GE (n = 36) M ± SD	P-value†
Age (years)	75.7 ± 4.6	76.7 ± 3.6	75.8 ± 4.4	75.8 ± 3.6	0.688
Height (cm)	148.4 ± 4.9	149.0 ± 6.1	148.3 ± 5.4	149.8 ± 5.8	0.638
Weight (kg)	50.3 ± 8.2	53.5 ± 8.0	54.8 ± 9.1	52.4 ± 7.1	0.113
GS (kg)	18.3 ± 4.0	19.9 ± 4.9	19.1 ± 3.7	18.2 ± 5.0	0.368
UWS (m/s)	1.2 ± 0.3	1.2 ± 0.3	1.1 ± 0.2	1.2 ± 0.3	0.774
MWS (m/s)	1.7 ± 0.4	1.8 ± 0.4	1.7 ± 0.3	1.7 ± 0.4	0.820
AMS (kg)	20.3 ± 6.1	21.6 ± 5.4	20.9 ± 4.9	22.0 ± 4.3	0.598
OLS (s)	30.5 ± 22.5	35.6 ± 25.3	29.2 ± 22.6	41.1 ± 22.6	0.121
DUS (years)	3.5 ± 5.6	5.2 ± 5.5	4.0 ± 5.8	5.9 ± 8.3	0.376
OAUS (years)	72.1 ± 6.7	71.4 ± 6.9	71.8 ± 7.4	69.9 ± 9.3	0.608
FSUL (points)	4.2 ± 1.3	4.4 ± 1.2	4.5 ± 1.2	4.1 ± 1.3	0.436
FTDT (times)	7.6 ± 2.9	7.2 ± 2.8	6.9 ± 2.5	7.3 ± 1.9	0.729
FTNT (times)	1.5 ± 0.9	1.9 ± 1.3	1.7 ± 1.2	1.6 ± 1.1	0.440
Frequency of urine loss episodes (%)					
Daily	29.7	29.7	37.8	30.6	0.493
1 every 2 days	5.4	8.1	2.7	5.6	
1–2 per week	21.6	32.4	37.8	19.4	
1–3 per month	43.2	29.7	21.6	44.4	
Chronic medical conditions (yes, %)					
Heart disease	11.8	29.4	26.5	32.4	0.131
Diabetes	26.3	21.1	15.8	36.8	0.465
Hypertension	19.4	29.2	29.2	22.2	0.659
Osteoporosis	20.6	17.6	23.5	38.2	0.177

GS, grip strength; UWS, usual walking speed; MWS, maximum walking speed; AMS, adductor muscle strength; OLS, one-leg standing time with eyes open; DUS, duration of urine loss; OAUS, onset age of urine loss; FSUL, frequency score of urine loss; FTDT, frequency of toilet in the daytime; FTNT, frequency of toilet in the night time; Ex, exercise group; HSGS, heat and steam generating sheet group; GE, general education group; M, mean; SD, standard deviation. †One way ANOVA for continuous variables and χ^2-test for categorical variables.

exercise + HSGS group compared with the HSGS and general education groups; and the urge urine loss score was significantly lower in the exercise + HSGS group compared with the general education group.

Discussion

This study demonstrated that although the 3-month exercise or HSGS interventions alone were effective in improving functional fitness and reducing urine loss, the combination of exercise and HSGS was more effective not only in the treatment of UI, but also in the improvement of functional fitness in urban community-dwelling elderly women with stress, urge and mixed UI. It can be suggested that adding HSGS to exercise therapies (PFM exercises as well as muscle strength training) may increase the likelihood of curing UI.

Exercise therapies aimed to treat UI, especially PFM exercises, have been used as an effective treatment for stress UI since Kegel's first validation of an 84% cure rate,[18] which has since been broadened to 17%–84% by Bo *et al.*,[19] Burns *et al.*[20] and Cammau *et al.*[21]

It has also been reported in recent investigations that PFM exercises and muscle strength training targeting abdominal fat reduction can increase cure rates of stress UI as well. Many studies have focused only on the treatment of stress UI.[5,15,18–20] However, one study demonstrated that 44.8% of community-dwelling Japanese elderly women are categorized into stress UI, 34.8% are urge UI and 20.4% are mixed UI, which means urge and mixed UI account for more than half of the UI cases in Japanese elderly women.[22] Even though people with urge and mixed UI experience greater frequency and volume of incontinence episodes, efforts focusing on treatment of urge and stress UI are currently very limited.

Many recent studies have indicated that heating different parts of the body can cause changes in the autonomic nervous system. It has been reported that mild heat stimulation to the lower back and abdominal region suppresses the sympathetic nervous system and accelerates the parasympathetic nervous system while increasing blood flow to the muscles.[8–10,16,23] It has also been proposed that muscular hypertrophy due to an

© 2011 Japan Geriatrics Society

Table 2 Comparison of selected variable between groups after the 3-month interventions

Variable	G	Baseline	3-month intervention	ANOVA (time × group)	*P*-value
BMI (kg/m²)	Ex + HSGS	22.8 ± 3.3	22.9 ± 3.1	*F* (3,129)	0.211
	Ex	24.0 ± 3.3	23.1 ± 2.8≠	=1.526	
	HSGS	24.8 ± 3.6	24.6 ± 3.4		
	GE	23.2 ± 2.7	23.2 ± 2.7		
Grip strength (kg)	Ex + HSGS	18.4 ± 4.2	19.8 ± 4.3≠	*F* (3,110)	0.629
	Ex	19.6 ± 4.9	20.9 ± 4.7≠	=0.581	
	HSGS	19.2 ± 3.5	20.3 ± 3.0≠		
	GE	17.5 ± 4.9	18.1 ± 4.2		
One-leg standing time (s)	Ex + HSGS	31.6 ± 22.2	37.5 ± 24.4≠	*F* (3,124)	0.155
	Ex	32.7 ± 25.8	35.7 ± 24.7	=1.779	
	HSGS	29.9 ± 22.9	26.3 ± 24.5		
	Co	39.9 ± 22.4	41.0 ± 21.4		
Adductor muscle strength (kg)	Ex + HSGS	20.3 ± 6.3	24.7 ± 6.1≠	*F* (3,115)	0.002
	Ex	21.1 ± 6.3	24.9 ± 8.1≠	=5.108	
	HSGS	20.6 ± 4.9	22.7 ± 5.4≠		
	GE	21.4 ± 4.7	22.5 ± 5.5		
Usual walking speed (m/s)	Ex + HSGS	1.2 ± 0.3	1.4 ± 0.2≠	*F* (3,129)	0.030
	Ex	1.2 ± 0.3	1.3 ± 0.2	=4.798	
	HSGS	1.1 ± 0.2	1.2 ± 0.3		
	GE	1.2 ± 0.3	1.2 ± 0.2		
Maximum walking speed (m/s)	Ex + HSGS	1.7 ± 0.4	1.8 ± 0.3	*F* (3,114)	0.051
	Ex	1.7 ± 0.4	1.8 ± 0.4	=2.661	
	HSGS	1.6 ± 0.3	1.7 ± 0.4		
	GE	1.7 ± 0.4	1.7 ± 0.4		

≠Paired Student's t-test of the baseline and 3-month intervention within-group difference, $P < 0.05$. G, group; Ex, exercise group; HSGS, heat and steam generating sheet group; GE, general education group.

Table 3 Cure rate of urinary incontinence according to urinary incontinence (UI) type and intervention group

Type of UI	Ex + HSGS (*n* = 37)	Ex (*n* = 35)	HSGS (*n* = 37)	GE (*n* = 34)	χ^2 value	*P*-value†
Stress UI	61.5 (8)	53.8 (7)	25.0 (3)	9.1 (1)	8.94	0.030
Urge UI	50.0 (7)	16.7 (2)	13.3 (2)	0.0 (0)	12.88	0.005
Mixed UI	40.0 (4)	30.0 (3)	30.0 (3)	0.0 (0)	3.02	0.389
Total cure rate	51.4 (19)	34.3 (12)	21.6 (8)	2.9 (1)	21.89	<0.001

†Kruskal–Wallis test. UI, urinary incontinence; Ex, exercise group; HSGS, heat and steam generating sheet group; GE, general education group.

increase in skeletal muscle protein content from thermal loading may occur.

In this study, we demonstrated the efficacy of the exercise + HSGS intervention across UI types. As a result, it can be suggested that therapies combining HSGS with exercise can increase the cure rate of UI, regardless of UI type. The fact that exercise is an effective treatment for stress UI has been discussed extensively. The mechanism explaining the increased effectiveness in treating UI by placing a HSGS on the lower back needs further discussion, but heating the lower back does seem to have physiological effects on the nervous and muscular systems. In this study, we confirmed the synergistic effect of UI treatment, regardless of UI type, by adding a sheet that heats the lower back to a frequently used behavioral therapy for UI. The use of the HSGS may slightly increase the cost of treatment. However, thermal therapy with the HSGS is cost-efficient because it is inexpensive and accessible for use.

Therefore, the HSGS method can be an effective supplementary UI treatment method. This study has several limitations. First, changes in urine loss were assessed based on subjective self-reported data, and they were not confirmed by objective and clinical

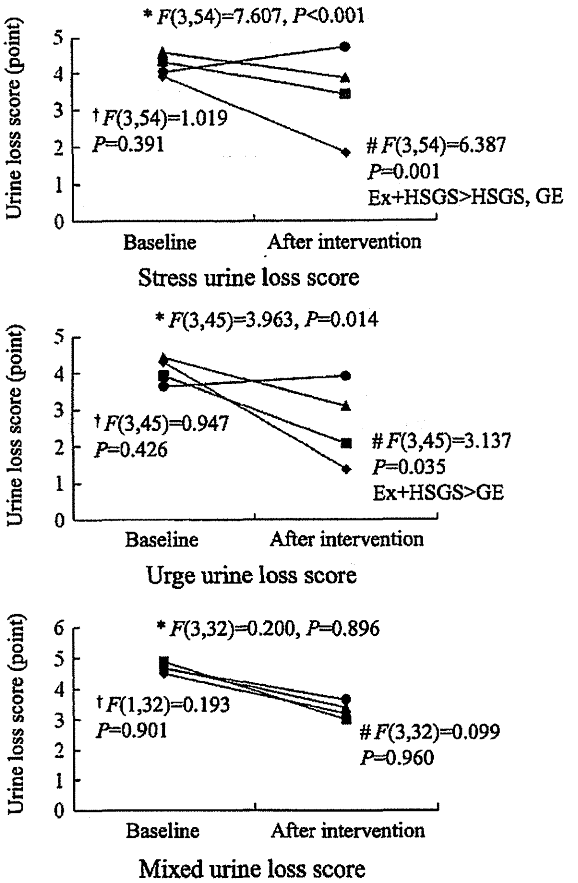

Figure 2 Changes in the mean urine loss score on the 6-point scale based on interview response at baseline and after 3-month intervention. (◆) Exercise + heat and steam generating sheet group;(■) exercise group; (▲) heat and steam generating sheet group; (●) general education group. *Comparison of urine loss scores between groups at baseline and after 3-month intervention (time × group). †Comparison of urine loss scores between groups at baseline. #A comparison of urine loss scores between groups after 3-month intervention. Ex, exercise group; GE, general education group; HSGS, heat and steam generating sheet group.

methods. However, previous studies have reported the validity of self-reported information in older adults.[24] The use of data collected from interviews has little influence on the interpretation of the result of this study. Second, as indicated that measurement of PFM strength was difficult, hip adductor muscle strength was used to assess physical fitness instead of measuring PFM strength directly. Hence, whether the cure of UI was due to an increase in PFM strength, a decrease in abdominal fat, or an increase in muscle strength or walking ability could not be determined. Third, the mechanism of the physiological changes that occurred with placement of a HSGS on the lower back could not be explained. Further investigation is necessary on a large population for more accurate results.

Acknowledgments

This research was supported in part by a Research Grant from the Ministry of Health and Welfare of Japan, a Grant-in-Aid for Scientific Research B from the Japanese Society for the Promotion of Science (19300236) and by the Sanitary Products Research Foundation of the Kao (Tokyo, Japan). The authors have no financial or any other kind of personal conflicts with this manuscript. Neither sponsors had any role in the design and conduct of the study; subject recruitment; collection, management, analysis and interpretation of data; or preparation of the manuscript. E. Hosoi cooperated in the revision of manuscript.

References

1 Landi F, Cesari M, Russo A, Onder G, Lattanzio F, Bernabei R. Potentially reversible risk factors and urinary incontinence in frail older people living in community. *Age Ageing* 2003; **32**: 194–199.
2 Brown JS, Grady D, Ouslander JG, Herzog AR, Varner RE, Posner S. Prevalence of urinary incontinence and associated risk factors in postmenopausal women. *Obstet Gynecol* 1999; **94**: 66–70.
3 Miu DK, Lau S, Szeto SS. Etiology and predictors of urinary incontinence and its effects on quality of life. *Geriatr Gerontol Int* 2010; **10**: 177–182.
4 Kegel AH, Calif LA. Progressive resistance exercise in the functional restoration of the perineal muscle. *Am J Obst & Gynec* 1948; **56**: 238–248.
5 Bo K, Talseth T, Holme I. Single blind, randomized controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ* 1999; **318**: 487–493.
6 Bo K. Pelvic floor muscle exercise for the treatment of stress urinary incontinence: an exercise physiology perspective. *Int Urogynecol J* 1995; **6**: 282–291.
7 Nygaard IE, Kreder KJ, Lepic MM, Fountain KA, Rhomberg AT. Efficacy of pelvic floor muscle exercises in women with stress, urge, and mixed urinary incontinence. *Am J Obstet Gynecol* 1996; **174**: 120–125.
8 Tsai TJ, Chen CF. Effects of heat therapy on renal hemodynamics, compensatory hypertrophy and glomerulonephritis in rats. *Nephron* 1993; **63**: 207–213.
9 Nagashima Y, Oda H, Igaki M *et al.* Application of heat- and steam-generating sheets to the lumbar or abdominal region affects autonomic nerve activity. *Auton Neurosci-Basic* 2006; **126–127**: 68–71.
10 Kenney MJ, Claassen DE, Bishop MR, Fels RJ. Regulation of the sympathetic nerve discharge bursting pattern during heat stress. *Am J Physiol Regulatory Integrative Comp Physiol* 1998; **275**: 1992–2001.
11 Folstein MF, Folstein SE, McHugh PR. "Mini-mental state": a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975; **12**: 189–198.
12 McDowell BJ, Engberg S, Sereika S *et al.* Effectiveness of behavioral therapy to treat incontinence in homebound older adults. *J Am Geriatr Soc* 1999; **47**: 309–318.

© 2011 Japan Geriatrics Society

13 Wyman JF, Fantl JA, McClish DK, Bump RC. the Continence Program for Women Research Group. Comparative efficacy of behavioral interventions in the management of female urinary incontinence. *Am J Obstet Gynecol* 1998; **179**: 999–1007.
14 Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P. A brief and robust measure for evaluating the symptoms and impact of urinary incontinence. *Neurourol Urodynam* 2004; **23**: 322–330.
15 Kim H, Suzuki T, Yoshida Y, Yoshida H. Effectiveness of multidimensional exercises for the treatment of stress urinary incontinence in elderly community-dwelling Japanese women: a randomized, controlled, crossover trial. *J Am Geriatr Soc* 2007; **55**: 1932–1939.
16 Seto H, Ikeda H, Hisaoka H, Kurosawa H. Effect of heat- and steam-generating sheet on daily activities of living in patients with osteoarthritis of the knee: randomized prospective study. *J Orthop Sci* 2008; **13**: 187–191.
17 Locher JL, Goode PS, Roth DL, Worrell RL, Burgio KL. Reliability assessment of the bladder diary for urinary incontinence in older women. *J Gerontol Med Sci* 2001; **56A**: M32–M35.
18 Kegel AH. Physiologic therapy for urinary stress incontinence. *JAMA* 1951; **146**: 915–917.
19 Bo K, Hagen RH, Kvarstein B, Jorgensen J, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: III. Effects of two different degrees of pelvic floor muscle exercises. *Neurourol Urodyn* 1990; **9**: 489–502.
20 Burns PA, Pranikoff K, Nochajski TH, Hadley EC, Levy KJ, Ory MG. A comparison of effectiveness of biofeedback and pelvic muscle exercise treatment of stress incontinence in older community-dwelling women. *J Gerontol Med Sci* 1993; **48**: M167–M174.
21 Cammu H, van Nylen M. Pelvic floor muscle exercises: 5 years later. *Urology* 1994; **45**: 113–117.
22 Kim H, Yoshida H, Suzuki T. Risk factors associated with urinary incontinence in community-dwelling elderly women. *Nippon Ronen Igakkai Zasshi* 2008; **45**: 315–322. (in Japanese with English Abstract).
23 Chen C, Chien C, Wu M, Fu T. Role of renal nerves on renal function change after back heating in rat. *Neurosci Lett* 1994; **174**: 154–156.
24 Shaw C, Matthews RJ, Perry SI *et al.* Validity and reliability of an interview-administered questionnaire to measure the severity of lower urinary tract symptoms of storage abnormality: the Leicester urinary symptom questionnaire. *BJU Int* 2002; **90**: 205–215.

© 2011 Japan Geriatrics Society

理学療法学　第38巻第1号　10～16頁（2011年）

研究論文

要介護高齢者における運動機能と6ヵ月後のADL低下との関係*

鈴川芽久美[1)2)3)]　島田裕之[4)#]　渡辺修一郎[5)]
小林久美子[2)]　鈴木隆雄[1)4)]

要旨

【目的】本研究は要支援・要介護高齢者を対象として，運動機能と6ヵ月後のADL変化との関係を検討した。【方法】対象は通所介護サービスを利用していた高齢者175名（81.4 ± 6.4歳）とした。運動機能検査は，握力，5回椅子立ち座り，開眼片足立ち，歩行速度，timed "up & go" testとした。ADLの評価にはfunctional independence measureの運動13項目を用い，これらをセルフケア，排泄コントロール，移乗移動にカテゴリー分類した。6ヵ月後に各カテゴリー内の1項目でも得点低下を認めた対象者を，各カテゴリーにおけるADL低下群，低下を認めなかった者はADL維持向上群とした。分析はADL低下とベースライン時の運動機能検査値との関係を検討するため，多重ロジスティック回帰分析を実施した。【結果】多重ロジスティック回帰分析の結果，ADLの移乗移動の低下とtimed "up & go" testとの有意な関係が認められた（オッズ比1.11，95%信頼区間：1.02-1.20，$p < 0.05$）。【結論】高齢者の移乗移動能力低下の予測のためにtimed "up & go" testは有益であると考えられた。セルフケアと排泄コントロールの低下については運動機能検査値のみではなく，他の因子を加えた検討が必要と考えられた。

キーワード　TUG，FIM，移乗移動

はじめに

地域在住高齢者の運動機能と日常生活活動（activities of daily living：ADL）の縦断研究により，運動機能は将来のADL障害を予測でき，運動機能が低い者ほどADL障害発生率が高いことが報告されている[1-5)]。ここでの地域在住高齢者とはADLに障害を持たずに地域で生活している者を指すが，Guralnikらはこれらの対象者においてADL障害発生の追跡調査を実施し，ベースラインにおける立位バランス，通常歩行速度，椅子からの立ち上がり時間を統合した運動機能（summary performance scores；0-12点）が低い群（4～6点）は，高い群（10～12点）に対して4年後のADL障害発生の危険性が4倍になることを明らかにし，通常歩行速度のみでもsummary performance scoresと同様にADL障害の危険性を予測することが可能であるとした[3)]。我が国においてもFurunaらは，秋田県南外村での悉皆調査で4年間の追跡をした結果，握力，開眼片足立ち，閉眼片足立ち，通常歩行速度，最大歩行速度，指タッピング検査を統合した指標において，得点が低い高齢者は，手段的日常生活活動（instrumental activities of daily living：IADL）を維持することが困難であることを報告し，特に最大歩行速度がADL障害発生の重要な予測因子であるとしている[4)]。また，Friedらは運動機能以外の因子も含めてADL障害発生の危険因子を検討し，加齢，独居，慢性疾患の数，うつ状態，膝筋力低下，バランス機能低下はADL障害と関連しないが，歩行や階段を昇る速度の低下とADL障害は関連が認められたとしている[6)]。これらの報告から，地域在住高齢者のADL障害の危険性と運動機能とは関連し，特に歩行機

* The Relationship between Physical Performances and ADLs Decline During 6 Months in Frail Elderly People Utilizing Long-term Care Insurance
1) 首都大学東京大学院
Megumi Suzukawa, RPT, MSc, Takao Suzuki, MD, PhD: Graduate School of Tokyo Metropolitan University
2) 株式会社ツクイ
Megumi Suzukawa, RPT, MSc, Kumiko Kobayashi: Tsukui Corporation
3) 東京都健康長寿医療センター
Megumi Suzukawa, RPT, MSc: Tokyo Metropolitan Institute of Gerontology
4) 国立長寿医療研究センター
（〒474-8511　愛知県大府市森岡町源吾35）
Hiroyuki Shimada, RPT, PhD, Takao Suzuki, MD, PhD: National Center for Geriatrics and Gerontology
5) 桜美林大学大学院
Shuichiro Watanabe, MD, PhD: Graduate School of Gerontology, J. F. Oberlin University
E-mail: shimada@ncgg.go.jp
（受付日　2009年11月26日／受理日　2010年10月26日）

能低下と密接な関連を有するといえる。また，疾病後の医学的リハビリテーション対象者における ADL 再獲得に関連する要因の知見についても十分な蓄積がある。たとえば脳卒中患者の機能予後に関していえば，Jongbloed の総説が有名である[7]。彼女は 33 編の論文から機能的予後に負の効果を持つ要因として，再発，年齢，失禁，視空間失認があり，入院時の機能状態が退院時の状態を予測する重要な因子であることを報告した。ただしこれらの予測因子は，対象集団の性質や分析時間（発症からの期間）の相違によって異なってくる[8]。

医学的リハビリテーションを終え，あるいは受けることなく維持期にある要介護認定を受けた高齢者（要介護高齢者）は，すでに ADL 障害を有し，健常高齢者と比較して短期間で状態が増悪する危険性が高い。また，加齢や疾病の他に活動性や社会的要因も ADL を低下させる要因となり，維持期において ADL 低下を促進する特徴的な要因の存在も示唆されている。たとえば，ナーシングホームに入居し ADL 障害をもつ高齢者を 6 ヵ月間追跡した Buttar らの調査では，31％の ADL 低下者を認め，その関連因子として認知機能低下，尿失禁，低食欲，脳卒中の既往，疼痛，呼吸機能低下，多剤服用といった多彩な予測因子が明らかとされたが，運動機能は有意な関連因子として結論づけられなかった[9]。我が国における在宅介護サービスを利用する要介護高齢者の前方視的な変化を functional independence measure（FIM）でみた先行研究によれば，わずか 4 ヵ月間で有意に ADL が低下したとされ，関連因子は在宅期間が 1 年未満であること，給付費上限に対する介護サービス利用率が低いことであった[10]。ただし，この調査では運動機能の評価は実施されていない。また前述した Buttar らの調査で用いられた運動機能の評価は動作の自立度を評価するカテゴリー尺度であったため，ADL 低下に関する予測感度が低かったものと考えられる。

先行研究において，健常高齢者における ADL 障害発生と運動機能との関連は明らかにされ，発症から早期の医学的リハビリテーション対象者における機能的予後の予測因子についても十分な知見があるが，維持期における要介護高齢者の ADL 障害と運動機能との関係に関しては，維持期要介護高齢者が有する多彩な問題の陰に隠され，明確な知見が十分に集積しているとはいえない状況にある。

ADL の低下予防や向上は，理学療法の中核的目標であり，この目標を効率的に達成するためには，対象者の低下している ADL と関連の強い運動機能を明らかとして，その運動機能に着目する必要がある[11]。本研究では，要介護高齢者に対して運動機能検査と 6 ヵ月間の ADL の追跡調査を実施し，ADL と運動機能との関係を明らかにすることを目的とした。

対象および方法

1. 対象

対象は，通所介護サービスを利用していた要介護高齢者 175 名（81.4 ± 6.4 歳）であった。要介護度の内訳は，要介護 1 が 51.4％，要介護 2 が 27.4％，要介護 3 が 17.1％，要介護 4 が 4.0％であった。取り込み基準は通所介護サービスを利用していた高齢者とし，表 1 に示す実施除外基準にあてはまらず，すべての検査の実施が可能である者とした。認知機能は mental status questionnaire（MSQ）[12] を用い，誤答数が 9 もしくは 10 であった者は除外した。なお追跡期間においても疾病の再発や新規の発症による機能低下はなかった。対象者の属性の詳細は表 2 に示した。

2. 方法

ADL は FIM の運動 13 項目を用い[13]，ベースライン時と 6 ヵ月後に評価を実施した。FIM の運動項目には，セルフケア（食事，整容，清拭，更衣上，更衣下，トイレ動作），排泄コントロール（排尿，排便），移乗移動（移

表 1　実施除外基準

絶対除外基準
1. 最近 6 ヵ月以内に心臓発作，脳卒中を起こした
2. 炎症症状の活動期である
3. 血圧値が収縮時 180 mmHg 以上，または，拡張期血圧 110 mmHg 以上ある
4. 安静時脈拍数が 120 以上である
5. 医師から運動中止を命じられている
かかりつけ医あるいは健診担当医師の判断によって可
1. 脳血管疾患やアルツハイマー病などで重度の認知症があり，測定が不可能と思われる
2. 心臓病や糖尿病をもつ
3. 急性期の整形外科的疼痛，および，神経症状がある
4. 骨粗鬆症で，かつ，圧迫骨折の既往がある