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.

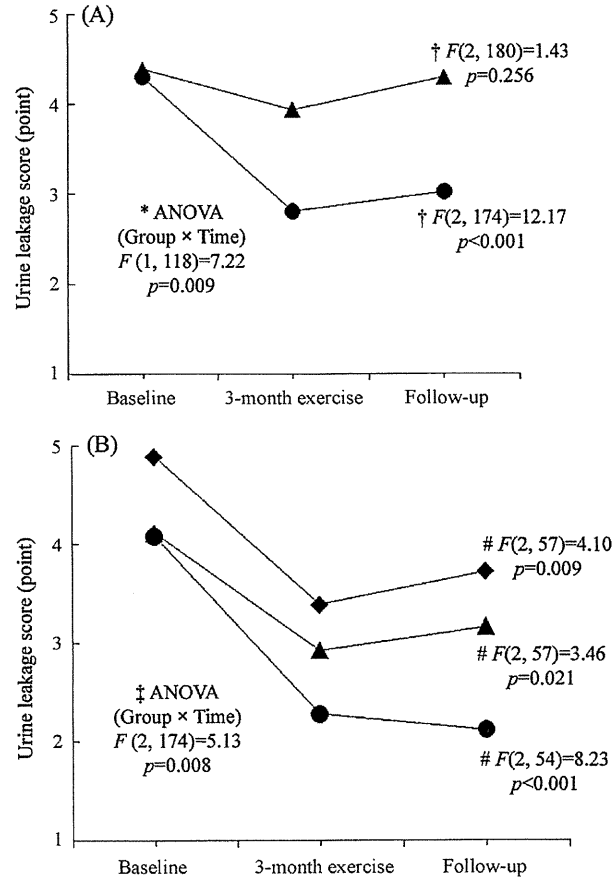

Fig. 2. Changes in the mean urine leakage score on a 5-point scale based on self-reported urinary diaries at the baseline, after 3-months exercise, and at the 7-month follow-up. (A) (●) intervention group; (▲) control group. (*) A comparison of urine leakage scores between the intervention and control 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.

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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

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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,

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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

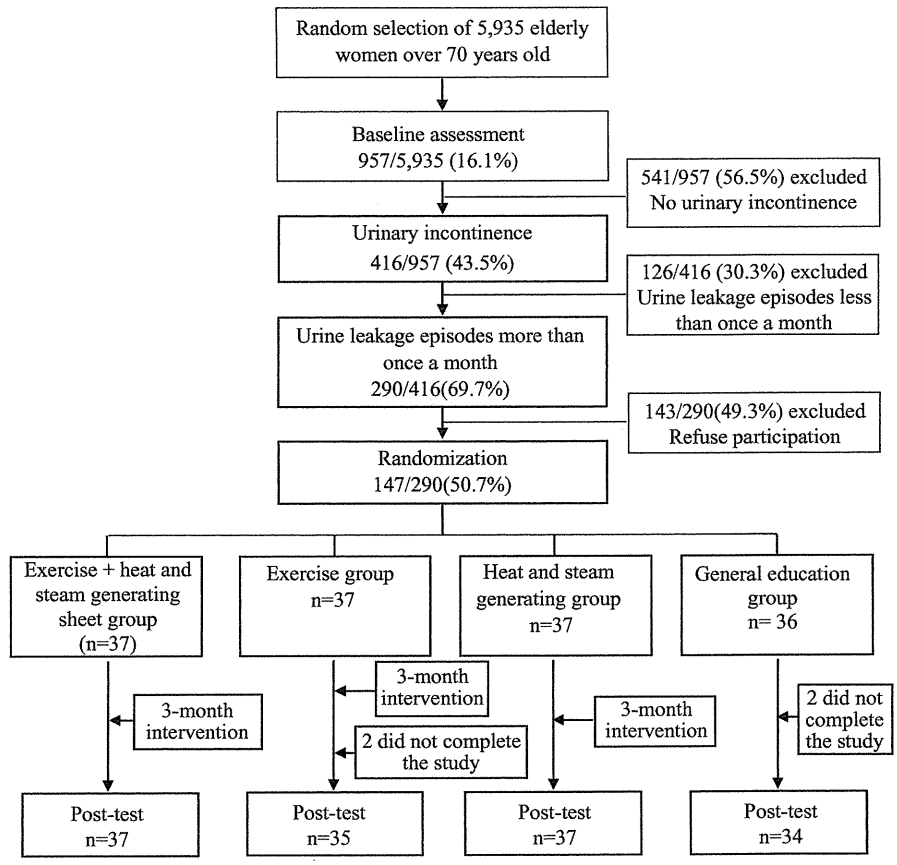

Figure 1 Flow chart of participant recruitment through the randomized controlled trial of exercise and/or heat and steam generating sheet trial.

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.

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

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

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/m^2)	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

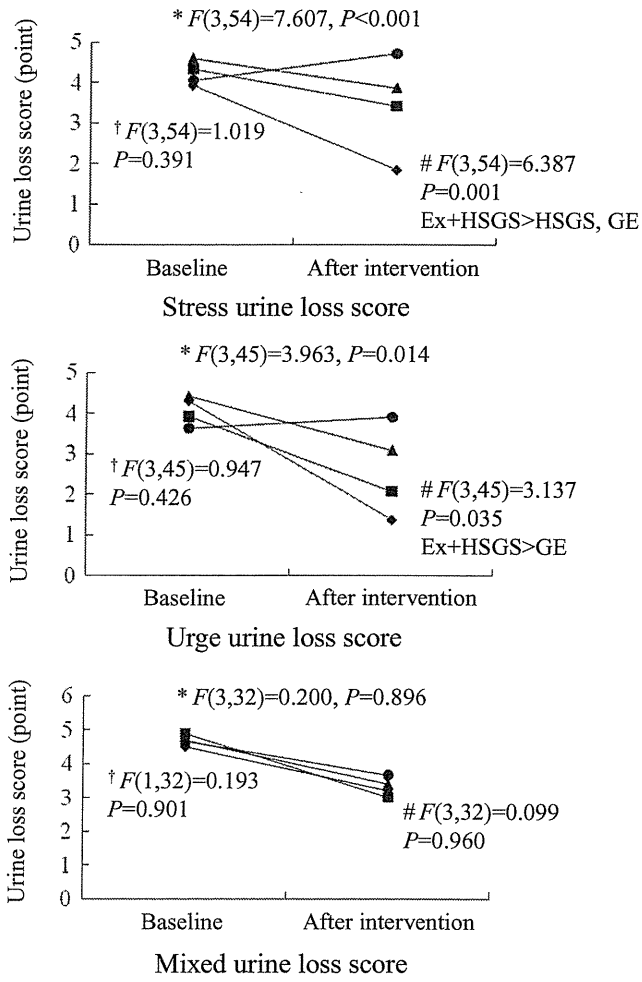

Figure 2 Changes in the mean urine loss score on the 6-point scale based on interview response at baseline and after 3-month intervention. (◆) Exercise + heat and steam generating sheet group;(■) exercise group; (▲) heat and steam generating sheet group; (●) general education group. *Comparison of urine 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.

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〈原　著〉

温泉施設を用いた複合的介入プログラムの有効性に関する研究
—無作為化比較試験による検討—

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要　約　**目的**：温泉は古くから治療目的などにも用いられてきたが，温泉施設を高齢者に対する健康増進を目的とした介入事業の拠点として用いる有効性について検討した研究は極めて少ない．そこで我々は，運動・栄養指導，温泉入浴からなる複合介入プログラム“すぷりんぐ”を開発し，その効果を無作為化比較試験によって検討した．**方法**：65歳以上の特定健診該当者を対象に公募により本プログラムへの参加者を募集した．68名が事前調査に参加し，60名（72.7歳±6.0）がプログラムへの参加に同意した．参加者を無作為に介入群31名と対照群29名の2群に割付け，交差法により前期に介入群，後期に対照群に対して複合介入プログラムを3カ月間（週2回，90分）実施した．介入群プログラム終了時（3カ月後：第2回調査）と対照群プログラム終了時（6カ月後：第3回調査）に調査を実施し，プログラムの短期・長期的効果の検討を行った．**結果**：介入に起因した傷害，事故の発生はなく，介入群の平均プログラム出席率は76%であった．性・年齢・BMIを調整した一般線型モデルの結果，第2回調査時には対照群に比べ，介入群の握力と開眼片足立ちに有意な改善が認められた（各々$p=0.028$，$p=0.003$）．また，第3回調査において，介入直後に確認された握力と開眼片足立ちの有意な改善の維持が認められ（各々$p=0.001$，$p=0.024$），改善傾向が見られたWHO-5の有意な維持・改善が示された（$p=0.027$）．交差後の対照群の介入プログラム出席率も平均81%と比較的高く，対照群への介入時においても傷害，事故の発生は確認されなかった．**結論**：温泉施設を活用した複合的介入プログラムである“すぷりんぐ”は身体機能を中心とした高齢者の健康増進に寄与するプログラムであることが示された．また，その継続的効果とプログラムの出席率・安全性が確保されていることから，温泉施設を高齢者に対する健康増進を目的とした介入事業の拠点とする意義は高いものと考えられる．

Key words：高齢者，温泉，運動介入，栄養介入

（日老医誌　2011；48：352–360）

緒　言

我が国の天然資源である温泉は，湯治に代表されるように古くから治療目的に用いられており，現在ではクアハウスやスーパー銭湯に代表されるように身近な，レジャー目的としても地域住民の憩いの場となっている．温泉入浴の効能は，循環，代謝，神経・免疫・内分泌機能の分野から検討されているが[1)~3)]，温泉施設を高齢者に対する健康増進を目的とした介入事業の拠点として用いる有効性について検討した研究はほとんど見られない．

上岡ら[4)]は中高年女性を対象として，週1回，12週間の温泉入浴と生活・運動指導からなるプログラムの有効性を無作為化比較試験（randomized control study，以下，RCTと略す）によって検証している．その結果，介入群では運動機能の改善は認められないものの，尿酸値の有意な改善や緊張状態といった心理指標の改善傾向を報告している．またKamiokaら[5)]は中高年女性を対象に，週1回，3カ月から6カ月の生活・運動指導に温泉入浴を組み合わせた介入プログラムの効果をRCTによって検討している．その結果，6カ月介入群ではHbA1cの有意な低下や心理指標などの有意な改善が確

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認され，その効果が6カ月後の追跡調査においても認められたことを報告している．その一方で3カ月間の介入では，介入直後に改善が見られた項目においても，1年後の追跡調査では介入前と同じ程度に戻っていたことを報告しており，3カ月間の介入では長期的効果が乏しいことを示唆している．

以上の温泉入浴を取り入れた介入研究を概括すると，高齢者に対する健康増進効果や適切な介入方法については一致した見解が得られていないといえる．地域資源である温泉施設を利用することにより，介入への動機付けを高め，ひいては介入効果が高まる可能性も考えられる．加えて，運動および栄養介入と温泉入浴による相乗効果があるのかもしれない．そこで本研究では温泉利用型健康増進施設（以下，温泉施設と略す）を用いた運動教室・栄養教室・温泉入浴からなる複合プログラム，通称“すぷりんぐ”を開発し，地域在住高齢者に与える効果をRCTにより検証すること，および健康増進を目的とした介入事業を温泉施設で行う意義について検討することを目的とした．

方　法

群馬県草津町在住の65歳以上特定健診該当者全2,167名を対象に公募により本プログラムへの参加者を募集した．68名が事前調査に参加し，医師から運動教室への参加が禁忌と判定された8名を除く60名（平均年齢±標準偏差：72.7±6.0歳，65～93歳）がプログラムへの参加に同意した．事前調査後，乱数表を用いて参加者を介入群31名，対照群29名に無作為に割り付けた（図1）．町内にある温泉施設を主会場として介入群には3カ月間（2009年10月～12月：前期介入，週2回，1回90分）の複合プログラムを実施した．プログラムの構成は運動教室，栄養教室，温泉入浴とした．運動教室は計11回実施し，健康運動指導士3名が指導を担当した．運動内容は自重やゴムチューブを用いた筋力トレーニングであり，対象者の体力に合わせて立位，座位を適宜選択できるように配慮し（2名の健康運動指導士が運動状況を観察し，運動負荷が強すぎると判断した場合に座位を勧めた），運動強度は主観的運動強度尺度であるBorg Scale[6][7]で12～14（ややきつい）に対応する内容を間欠的に実施した．栄養教室は，管理栄養士により適正体重を目指したグループワーク形式の講義と自己の食習慣チェックおよび調理実習を計6回行った．毎運動及び栄養教室の終了前には，6～7名の小グループ単位で約15分間，日常の運動や食習慣について各自の目標，状況，工夫についての情報交換を行い，保健師がファシリテーターとなり行動変容や健康行動の自主化を試みた．基本的には目標設定とセルフモニタリングを繰り返し，対象者の行動変容に対する自己効力感を高めるよう支援した．目標は実行可能な範囲で設定することにより，各人の達成感を高めるものとした．また毎運動教室終了時には30分程度の温泉入浴を課した．本研究で利用した温泉施設の泉質は酸性塩化物硫酸塩泉であり，泉温94.6℃（浴槽内水温は42℃～46℃に調整），pH1.7であった．他方，対照群に対しては月一回の座学中心の健康教室を行った．同教室の内容は直接，本プログラムとは関連がないよう認知症や老年病の概論についての講演会とした．

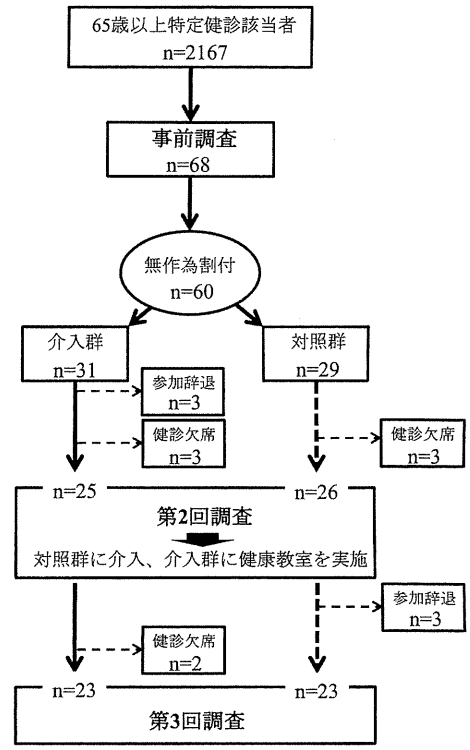

図1　本研究の流れと解析対象者の推移

介入期間終了後に介入後調査（以下，第2回調査と略す）として事前調査と同様の調査を行い，その後介入群と対照群を入れ替え，上記と同様の介入を行った（2010年1月～3月：後期介入）．後期介入終了後にも追跡調査（以下，第3回調査と略す）を行い，本プログラムの3カ月間の短期的効果と，その後3カ月間の持続効果を検討した．評価項目は体組成[8]について体重，筋肉量，脂肪量，運動機能[9][10]について握力，開眼片足立ち，通常・最大歩行速度，Timed Up & Go Test（以下，TUGと略す），健康関連QOLについてSF-8[11]，WHO-5[12]および血液検査とした．

体組成に関しては，多周波数（1 kHz，5 kHz，50 kHz，

250 kHz，500 kHz，1MHz）の8点接触型電極法により左右腕，胴体，左右脚の抵抗値を基に筋肉量，体脂肪量を求めるBody Composition Analyzer（InBody720，Biospace社製）を用いて計測した．

握力はスメドレー式握力計を用いて利き手で2回測定し，大きい値を代表値とした．開眼片足立ちは60秒を上限値とし，ストップウォッチを用いて2回測定し，大きい値を代表値とした．歩行速度は3mと8mの地点にテープで印を付けた11mの歩行路を直線歩行し，3m地点と8m地点の間5mの歩行時間を測定し，歩行速度（m/分）を算出した．快適な速さでの歩行を1回（通常歩行速度），最大努力下での歩行（最大歩行速度）を2回測定し，最大歩行速度は最速値を代表値とした．TUGは椅子座位から3m前方のポールを回って着座するまでの時間をストップウォッチにて測定した．本研究では最大努力下で2回測定し，早い値を代表値とした．

SF-8は日本でも広く用いられている健康関連QOL尺度であり，SF-36の簡略版として健康関連の8領域［身体機能，日常生活役割機能（身体），体の痛み，全体的健康観，活力，心の健康，社会生活機能，日常生活役割機能（精神）］を測定することができる．WHO-5はWHOが開発した精神的健康状態を測定する尺度であり，5つの質問項目から構成されている．得点（素点）の範囲は0～25点で，0点はQOLが最も不良であることを示しており，25点はQOLが最も良好であることを示している．13点未満の得点は精神的健康状態が低いことを表している[13]．

分析方法については，参加者の属性及び測定項目の群間差はχ^2乗検定，対応のないt検定によって検討した．プログラム前後における測定項目の変化（短期的効果）に関しては性，年齢を調整した一般線型モデルによって検討を行い，解析対象者は事前調査と第2回調査の両調査に参加した者とした．プログラム終了3カ月後を含めた変化（長期的効果）に関しては，第3回調査を含む3回の調査全てに参加した介入群を対象として，一般線型モデルによって時間の変化の主効果を検討した．統計解析はSPSS18.0を用いて行い，両側検定にて危険率5%未満を有意水準とした．

なお，本研究計画は平成21年度第一回東京都健康長寿医療センター研究所倫理委員会によって審査され，承認されており，研究内容はヘルシンキ宣言に基づくものである．

結　果

本プログラムへの参加に同意した60名（平均年齢±標準偏差：72.7歳±6.0）の調査結果の一覧を群別に表1に示した．事前調査の結果，基礎疾患の有無や既往歴，現病歴（高血圧，脂質異常症，糖尿病，心疾患，脳血管障害）に関しては群間差は認められなかった．また，事前健診の前6カ月間およびその後の介入期間の3カ月間に脳卒中発作，心血管イベントその他，特記すべき疾病の発症，症状の変化，治療内容の変化がないことを確認した．一方体重，BMI，筋肉量，中性脂肪，WHO-5に介入群と対照群の間に有意な差が認められた．そのため，統計解析においてはBMIを調整変数として追加投入することとした．

介入3カ月後の第2回調査結果を表2に示した．介入群においては3名が就労，多忙などの自己の都合によりプログラムの継続を辞退した．また介入群，対照群ともに3名が第2回調査を欠席したため51名（介入群：25名，対照群：26名）を解析対象とした．介入群の平均教室出席率は76%であった．介入プログラム及び施設，温泉入浴に起因した傷害，事故の発生は確認されなかった．

3カ月の介入の結果，介入群は対照群に比べ握力と開眼片足立ちに有意な改善が認められた（各々$p=0.028$；$p=0.003$）．他方，WHO-5や全体的健康感得点に関しては改善傾向が確認されたが有意差が認められるには至らなかった．

前期介入終了3カ月後の持続効果を表3に示した．交差後の対照群への介入（後期介入）では3名が自己の都合によりプログラム参加・継続を辞退した．第3回調査においては，介入群の2名が欠席したため，介入群23名を解析対象とした．対照群の平均教室出席率は81%であった．前期介入同様に，後期の介入においても傷害，事故の発生は確認されなかった．

前期介入終了3カ月後の第3回調査では，介入直後に確認された握力と開眼片足立ちの有意な改善の維持が認められ（各々$p=0.001$，$p=0.024$），第2回調査時に改善傾向が見られたWHO-5の有意な改善が示された（$p=0.027$）．また，有意差には至らなかったが最大歩行速度やTUGに改善傾向が認められた．一方，介入直後に比べHbA1cは有意な上昇が（$p<0.001$），日常生活機能（精神）得点においては有意な減少が確認された（$p=0.043$）．

考　察

本研究では，温泉施設を用いた運動教室，栄養教室，温泉入浴からなる複合プログラム“すぷりんぐ”が地域在住高齢者に与える効果，及び高齢者の健康増進を目的

表1　対象者の事前調査時の群別属性

	介入群（n＝31） Mean±SD	対照群（n＝29） Mean±SD	P値
男女比（人）	9：22	9：20	0.866
年齢	73.2±6.9	73.0±4.9	0.573
既往歴 高血圧（あり/なし）	13：18	12：17	0.965
既往歴 高脂血症（あり/なし）	11：20	13：16	0.460
既往歴 糖尿病（あり/なし）	5：26	7：22	0.438
既往歴 心疾患（あり/なし）	10：21	6：23	0.277
既往歴 脳血管障害（あり/なし）	2：29	2：27	0.973
身長（cm）	151.4±6.5	154.6±9.1	0.121
収縮期血圧（mmHg）	121.9±21.6	123.9±19.6	0.710
拡張期血圧（mmHg）	70.2±10.2	70.8±9.8	0.807
体重（kg）	50.6±10.2	58.0±9.5	0.006**
筋肉量（kg）	18.6±4.1	21.2±4.6	0.025*
体脂肪率（%）	29.6±8.6	31.9±6.0	0.233
BMI（kg/m^2）	22.0±3.6	24.1±2.5	0.012*
通常歩行速度（m/分）	84.7±14.4	88.4±13.4	0.316
最大歩行速度（m/分）	122.2±29.1	124.7±25.8	0.737
握力（kg）	22.0±7.0	25.6±7.7	0.060†
開眼片足立ち（秒）	36.0±21.0	40.4±21.4	0.422
Time Up & Go test（秒）	6.03±1.57	5.76±1.25	0.460
T-CHO（mg/dL）	193.8±25.4	200.5±36.2	0.404
HDL-C（mg/dL）	55.5±14.5	56.7±18.6	0.774
TG（mg/dL）	139.3±64.4	187.7±85.8	0.016*
LDL-C（mg/dL）	113.6±20.4	114.0±31.0	0.947
Alb（g/dL）	4.1±0.2	4.2±0.2	0.077†
HbA1c（%）	5.4±0.5	5.5±0.6	0.560
WHO-5（点）	17.9±4.5	20.1±3.5	0.045*
SF-8 全体的健康感得点（点）	50.6±5.9	52.7±5.7	0.169
SF-8 身体機能得点（点）	51.1±4.4	52.7±3.1	0.118
SF-8 日常役割機能（身体）得点（点）	51.6±4.8	53.3±2.3	0.082†
SF-8 体の痛み得点（点）	49.6±9.4	52.4±8.0	0.217
SF-8 活力得点（点）	50.8±6.3	52.0±5.8	0.425
SF-8 社会生活機能得点（点）	50.1±8.0	53.0±4.7	0.096†
SF-8 心の健康得点（点）	51.8±6.7	54.1±5.0	0.147
SF-8 日常生活機能（精神）得点（点）	52.0±3.8	53.1±3.1	0.241
SF-8 身体的サマリースコア（点）	49.1±5.0	51.0±3.8	0.100
SF-8 精神的サマリースコア（点）	51.0±5.1	52.6±4.5	0.191

†：P＜0.10，*：P＜0.05，**：P＜0.01

とした介入事業を温泉施設で行う意義についてRCTによって検証することを目的とした．

介入群に関しては3カ月の介入によって握力と開眼片足立ちに有意な改善が認められた．本プログラムでは握力向上を目的としたゴムチューブを用いた上肢運動や，バランス機能の向上を目的とした体重移動を意識させる歩行運動を取り入れている．このような運動構成が握力と開眼片足立ちの有意な改善につながったものと推測される．高齢者における握力の低下はADLの低下や転倒発生率，死亡率とも強い関連性が報告されており[14)~16)]，上肢を中心とした総合的な筋力として捉えられている[17)18)]．また，開眼片足立ち能力の低下に関しても転倒発生率や虚弱傾向，移動能力の低下との関連性について多くの報告があり[19)20)]，両者ともに高齢者の機能予後を見る上で重要な身体機能項目である．握力と開眼片足立ちに改善が認められたことから，本プログラムは短期的効果として地域在住高齢者に対する身体機能向上に寄与し，ひいては介護予防に貢献する可能性が示唆された．

プログラム終了3カ月後に行った第3回調査の結果，介入群では第2回調査にて有意な改善が見られた握力と開眼片足立ちの成績が維持され，WHO-5は有意な改善が示された．待機期間中である第2回調査と第3回調査の間は，介入群は対照群同様に月1回の座学の健康教室を開催した．運営の都合上，介入群に対する健康教室は

表2　介入前後の比較

	事前調査 介入群（n＝25） Mean±SD	事前調査 対照群（n＝26） Mean±SD	第2回調査 介入群（n＝25） Mean±SD	第2回調査 対照群（n＝26） Mean±SD	P値 時間	P値 群	P値 交互作用
収縮期血圧（mmHg）	124.9±22.9	122.7±19.4	120.6±15.4	123.3±24.2	0.637	0.726	0.247
拡張期血圧（mmHg）	71.9±10.3	70.0±9.8	68.1±10.9	69.2±11.4	0.367	0.440	0.254
体重（kg）	52.0±10.3	57.6±9.9	52.2±10.2	57.9±10.0	0.119	0.034*	0.518
筋肉量（kg）	19.0±4.3	21.0±4.6	19.1±4.3	21.2±5.0	0.012*	0.054†	0.185
体脂肪率（%）	30.3±8.7	32.0±6.1	30.7±8.9	31.9±7.2	0.479	0.805	0.963
通常歩行速度（m/分）	86.5±13.0	88.0±14.0	87.6±14.5	86.2±13.8	0.641	0.962	0.413
最大歩行速度（m/分）	126.9±26.7	122.9±26.4	126.3±23.3	128.7±34.0	0.101	0.967	0.183
握力（kg）	22.7±7.4	25.7±8.0	24.4±7.9	25.8±8.1	0.117	0.147	0.028*
開眼片足立ち（秒）	37.9±20.7	43.4±20.3	43.6±23.3	38.0±21.6	0.676	0.979	0.003**
Time Up & Go test（秒）	5.66±1.00	5.80±1.32	5.54±1.50	5.46±1.13	0.024*	0.971	0.118
T-CHO（mg/dL）	189.9±22.4	198.8±37.6	197.6±33.1	202.1±35.6	0.424	0.343	0.687
HDL-C（mg/dL）	54.5±15.6	55.3±18.5	55.8±16.2	55.6±16.1	0.509	0.614	0.957
TG（mg/dL）	147.7±63.8	186.6±88.6	141.6±85.4	164.5±121.0	0.099†	0.326	0.316
LDL-C（mg/dL）	109.8±18.3	113.7±32.0	116.0±27.2	116.8±29.1	0.460	0.798	0.610
Alb（g/dL）	4.15±0.17	4.23±0.19	4.27±0.24	4.28±0.20	0.189	0.343	0.343
HbA1c（%）	5.4±0.5	5.5±0.6	5.5±0.5	5.6±0.7	0.085†	0.600	0.951
WHO-5（点）	18.1±4.5	20.0±3.7	20.1±4.5	20.2±4.0	0.706	0.251	0.073†
SF-8 全体的健康感得点（点）	51.0±5.7	52.2±5.6	51.7±5.6	50.4±5.2	0.033*	0.835	0.061†
SF-8 身体機能得点（点）	50.9±4.8	52.7±3.2	49.3±5.1	49.3±9.1	0.839	0.276	0.374
SF-8 日常役割機能（身体）得点（点）	51.5±5.2	53.5±2.2	49.6±7.2	49.0±8.8	0.722	0.427	0.324
SF-8 体の痛み得点（点）	52.0±8.2	52.7±7.7	51.1±9.7	51.0±8.8	0.419	0.723	0.847
SF-8 活力得点（点）	52.1±5.7	52.1±5.9	52.7±5.8	51.2±6.5	0.953	0.745	0.282
SF-8 社会生活機能得点（点）	51.0±7.2	53.4±4.0	51.0±6.4	51.1±6.8	0.456	0.260	0.314
SF-8 心の健康得点（点）	53.8±5.6	54.0±5.2	53.2±6.1	52.4±7.2	0.831	0.999	0.547
SF-8 日常生活機能（精神）得点（点）	52.3±3.8	53.0±3.3	52.3±3.5	52.5±2.9	0.797	0.444	0.610
SF-8 身体的サマリースコア（点）	49.3±5.3	51.1±3.8	48.0±6.4	47.6±8.2	0.531	0.426	0.246
SF-8 精神的サマリースコア（点）	52.4±4.4	52.5±4.5	52.9±5.0	52.4±4.9	0.819	0.951	0.593

†：P＜0.10，*：P＜0.05，**：P＜0.01

温泉施設から離れた別の温泉施設で行ったが，介入プログラム同様の高い出席率が得られ，対象者の健康意識の維持がうかがえた．施設の変更や，プログラムの終了にかかわらず介入終了後の長期的効果が示されたことから，本プログラムが日常生活における健康行動を促進するような行動変容を促すものであった可能性が考えられる．

行動科学に基づいた行動変容型プログラムは一般成人のみならず，高齢者に対しても身体活動を促進することが報告されている[21]．本プログラムでは教室終了毎に健康活動を自主化することを目的としたグループワークを実施した．その手法は自己効力感の向上に主眼を置いたBandura[22]の理論に依るものである．運動・栄養教室と併せて効果的に行動変容を促したことが，寒冷地であるため冬季に高齢者が閉じこもりがちになる草津町においても介入効果の維持に寄与したものと推察される．加えて，コミュニティーサロンともいえる温泉施設の性質が健康行動を促進する一因となっていた可能性も考えられる．自主的な運動活動などにおいては集団型で，かつ住民間の交流を図る形での活動運営が好ましいことが示唆されている[23]．本研究は，地域資源である温泉施設での健康増進プログラムが参加者同士の交流や利用のしやすさといった点から健康行動の動機付けができる可能性を示しており，温泉施設での健康増進を目的とした保健事業実施は，事業への参加・活動維持の面から大きな可能性を持っていると考えられる．

介護予防事業に代表されるような高齢者を対象とした介入事業においては特定高齢者の様な虚弱傾向にある高齢者の低い出席率，継続率が課題となっており，全国自治体を対象とした実態調査では，本人に生活機能低下の自覚がないことや，住民に身近な場所で開催できていないことが挙げられている[24][25]．本研究では，研究参加者の年齢層が65歳から93歳と幅広いにもかかわらず介入・対照両群において比較的高い介入教室への出席率が得られた．その理由の一つとして，公募により研究参加者を募ったため，健康に対する意識が高い高齢者が集

表3　事前検査から第3回調査までの推移

	事前調査 Mean±SD	第2回調査 Mean±SD	第3回調査 Mean±SD	P値
収縮期血圧（mmHg）	123.8±20.9	118.3±13.9	126.2±20.1	0.101
拡張期血圧（mmHg）	71.0±10.4	66.1±10.3	66.8±12.0	0.050†
体重（kg）	52.4±11.2	53.3±10.6	52.3±11.2	0.334
筋肉量（kg）	19.4±4.6	19.5±4.6	19.4±4.6	0.582
体脂肪率（%）	29.6±8.8	30.8±8.4	29.7±8.3	0.286
通常歩行速度（m/分）	84.9±13.4	88.1±15.3	91.3±16.9	0.052†
最大歩行速度（m/分）	124.8±28.1	126.9±22.7	127.4±21.7	0.740
握力（kg）	22.1±7.8	23.9±8.3	23.9±7.8	0.001**
開眼片足立ち（秒）	35.9±21.0	42.8±23.7	43.2±23.4	0.024*
Time Up & Go test（秒）	5.8±1.1	5.6±1.6	5.4±1.4	0.115
T-CHO（mg/dL）	187.4±23.2	194.4±34.3	194.1±27.6	0.426
HDL-C（mg/dL）	53.4±16.1	54.1±16.3	52.6±15.6	0.739
TG（mg/dL）	143.1±65.6	144.0±91.0	141.3±79.8	0.981
LDL-C（mg/dL）	109.2±19.1	114.6±28.5	115.0±23.9	0.385
Alb（g/dL）	4.15±0.17	4.26±0.24	4.18±0.23	0.182
HbA1c（%）	5.5±0.6	5.5±0.5	5.7±0.6	0.001**
WHO-5（点）	18.5±4.3	20.1±4.6	20.0±3.9	0.027*
SF-8 全体的健康感得点（点）	50.5±5.8	51.5±5.9	50.6±6.3	0.700
SF-8 身体機能得点（点）	50.6±5.1	49.6±4.9	49.6±5.5	0.592
SF-8 日常役割機能(身体)得点(点)	52.1±4.8	49.8±6.7	51.1±5.3	0.077†
SF-8 体の痛み得点（点）	51.5±8.4	50.8±8.9	51.3±8.8	0.866
SF-8 活力得点（点）	52.3±5.6	51.8±5.8	51.5±6.5	0.816
SF-8 社会生活機能得点（点）	50.8±7.7	51.8±5.6	51.4±6.8	0.602
SF-8 心の健康得点（点）	54.2±5.3	53.7±5.6	54.0±5.6	0.587
SF-8 日常生活機能(精神)得点(点)	52.6±3.6	52.6±3.3	50.8±5.4	0.043*
SF-8 身体的サマリースコア（点）	49.0±5.3	47.8±6.6	48.4±6.0	0.493
SF-8 精神的サマリースコア（点）	52.8±4.5	53.3±4.8	52.3±5.1	0.421

n＝23，†：P＜0.10，*：P＜0.05，**：P＜0.01

まっていたことも考えられる．しかしながら，一方で本プログラムが参加者の体力レベルに合わせて座位でも行いやすい運動で構成されていることから，年齢や体力レベルにかかわらず参加者が同一カリキュラムに参加することが可能であったためとも考えられる．また，本プログラムが代替医療，健康増進，リラクゼーション，地域交流などの多面的機能を持つ温泉施設を拠点としていたためとも推測される．つまり，高齢者の自主活動の場として一般的な公民館や地区会館などとは異なり，温泉施設は利用目的が健康志向に合致しやすいため，介入終了後も健康行動を継続しやすい可能性がある．更に，本プログラムは特殊な運動器具や広いスペースを必要としないため，今後は地域の公衆浴場の有効活用，活性化に寄与する可能性も推察される．しかしながら，高齢者の入浴においては温熱環境の急激な変化や浴室環境に起因した疾患・事故死が報告されている[26]．そのため，本プログラムの一般化に際しては，室内温度の一定化などの浴室内環境を考慮する必要があり，心疾患を中心とした循環器疾患者や虚弱な高齢者に対しては医師の判断が必要である．

本研究では第3回調査時にHbA1cに有意な上昇が認められた．機序は不明であるがHbA1cは冬季に上昇する傾向が大規模調査より示されており[27]，本研究で確認された上昇も季節変動の範囲であると考えられる．また，同様に第3回調査において日常生活機能（精神）得点に有意な減少が認められた．これは介入群の1名が第3回調査の直前に眼科手術を行ったためと推測され，この参加者は総じてQOL指標の成績が低く，分析から除外した場合には日常生活機能（精神）得点の低下は有意差が見られなくなった．

本研究では自己免疫疾患に有用であるとされる酸性塩化物硫酸塩泉を用いたが[1)3)]，本研究で得られた結果が泉質特有であったかは明らかではない．温泉入浴と運動・栄養介入の併用効果について泉質の違いによって検討している研究は極めて少ない．しかしながら異なる泉質を用いた場合でも一定の効果が得られていることを考慮す

ると，温熱効果なども含めた複合的な要因が作用していると考えられ，温泉ではない入浴施設でも効果が得られるのではないかと推測される[4)5)]．

本研究の特徴は温泉施設を利用した複合プログラムが地域在住高齢者に与える効果をRCTによって検証している点である．しかしながら，本研究の限界としては温泉入浴のみの介入効果を検討していない点が挙げられる．大塚[28)]は運動・栄養教室と温泉入浴からなるプログラムを高齢者に実施し，開眼片足立ちや6分間歩行距離などの運動機能とQOL（Quality Of Life，生活の質）に改善が認められたことを報告している．この研究では温泉入浴のみの高齢者を対照群としているが，対照群にはQOLの改善が認められず，温泉入浴が高齢者のQOLに与える効果は乏しいことを指摘している．しかしながら，対照群は保健事業に参加せず，運動機能測定を拒否した高齢者で構成されており，研究結果にはサンプリングバイアスが生じている可能性がある．また，入浴頻度・期間が不明瞭なため，研究デザイン上のクオリティが担保されていない．また一般成人に関しては温泉入浴頻度が高いほどQOLが上昇傾向にあるとの報告も見られ[29)30)]，対象者の世代により得られた見解は異なる．本研究で，温泉入浴のみのプログラムを設定しなかった理由は以下の2つである．一つは，草津町をはじめ全国の温泉保養地に共通する過疎化の問題がある．介護予防事業は2006年度に創設された後，二次予防事業（旧特定高齢者施策）の全高齢者人口に占める出席率の目標は，5%であるのに対して実績の全国平均は0.5%と低調である．地元職員らの懸命な広報活動をもってしても，草津町の高齢者人口を勘案すると，温泉入浴のみ群を設定しうるほどの研究対象者の増員は望めなかった．第二の理由は，同町では各家庭への温泉の配給はないが，個人的に温泉を引き入れたり，無料の共同温泉浴場が町内に散在しており，高齢者の多くが，日常的に温泉を利用する環境下にあるため，温泉入浴の単独効果を検証しにくい点であった．

引き続き，同地域において追試験を行うとともに，新たに大都市部フィールドにおいて温泉入浴のみの群を設定した同様の介入試験を実施することが望まれる．

結　論

温泉施設を活用した複合介入プログラムである“すぷりんぐ”は身体機能を中心とした健康増進効果が期待でき，ひいては介護予防に貢献する可能性が示唆されるプログラムであるといえる．加えて，健康行動を継続する行動変容を促進する可能性が示され，その継続的効果とプログラム出席率・安全性が確保されていることから，温泉施設を高齢者に対する健康増進を目的とした介入事業の拠点とする意義は高いものと考えられる．

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A randomized controlled trial of the effects of a comprehensive intervention program for community-dwelling older adults

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Abstract

Aim: The objective of this study was to evaluate the effects of a comprehensive intervention program named SPRING, which utilizes a hot spring facility, in community-dwelling older adults in a randomized controlled trial.

Methods: A total of 60 community-dwelling elderly people (mean age, 72.7 ± 6.0 years) participated in this program. After baseline investigation, participants were randomly assigned to an intervention group (n = 31) or a control group (n = 29). The intervention group participated in a comprehensive intervention program (including exercise classes, nutrition classes and bathing) twice a week for 3 months. After 3 months and 6 months, we evaluated the effects of the intervention.

Results: The attendance rate of the intervention group was 76%, and there were no accidents or injuries associated with this program. After 3 months, grip strength and one-leg standing with eyes-open scores significantly improved among the intervention group, compared with the control group ($p = 0.028$; $p = 0.003$, respectively). On follow-up, grip strength, one-leg standing with eyes-open scores and the World Health Organization Well-Being Index (WHO-5) scores were statistically significantly maintained or had improved in the intervention group ($p = 0.001$; $p = 0.024$; $p = 0.027$, respectively).

Conclusion: The comprehensive intervention program SPRING may improve physical function among community-dwelling older adults. In addition, SPRING may have long-term beneficial effects for older adults.

Key words: *Older adults, Spa, Exercise intervention, Nutrition intervention*

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