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ORIGINAL ARTICLE

Effects of wearing supportive underwear versus pelvic floor muscle training or no treatment in women with symptoms of stress urinary incontinence: an assessor-blinded randomized control trial

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Abstract

Introduction and hypothesis In our previous single-arm pilot study, we reported that ready-made supportive underwear (shaper) was effective in elevating the bladder neck and reducing urinary incontinence (UI) symptoms. The aim of this study was to determine the effects of wearing a shaper compared with pelvic floor muscle training (PFMT) at home using a training compact disc with music, or no treatment, in an assessor-blinded randomized control trial, on reducing UI symptoms.

Methods Participants aged 30–59 years with symptoms of stress urinary incontinence were randomly assigned to three groups: the shaper group, PFMT group, and no treatment group. The UI episodes/week and the Japanese version of the International Consultation on Incontinence Questionnaire Short-Form were compared between the baseline and the 6th or 12th week of the intervention period.

Results Eighty-nine women who completed the 12-week intervention period were analyzed. After the 12-week intervention period, the improvement rate in UI symptoms (ratio of the case number in which the UI episodes/week decreased at least 50% from the baseline) was 73.3% (22/30 women) in the shaper group, 74.2% (23/31 women) in the PFMT group, and 25.0% (7/28 women) in the no treatment group. The improvement rate in UI symptoms in the shaper and PFMT groups was significantly higher than that in the no treatment group (both $P < 0.001$).

Conclusions Wearing supportive underwear (shaper) was almost as effective as PFMT at home in reducing UI symptoms.

Keywords Pelvic floor muscle training · Randomized control trial · Stress urinary incontinence · Underwear

Introduction

Female stress urinary incontinence (SUI) is likely caused by the descent of the bladder neck and decreased support for the urinary tract because of pelvic floor relaxation of the anatomical structures and childbirth. SUI is highly prevalent among women aged 30–50 years, with a prevalence rate of 11.3 to 42.3% [1, 2]. Urinary incontinence (UI) symptoms affect the quality of life (QOL) related to daily, work-related, social, and sexual activities [3].

Pelvic floor muscle training (PFMT) is a rehabilitation method of strengthening the pelvic floor muscles by voluntary contraction and is the first choice in improving SUI [4]. PFMT is noninvasive and economical, with no side effects. The reported effectiveness rate of PFMT is 28.6 to 80.0% [5]. If the patient's motivation is clear and support is obtained from the caregiver, PFMT can be continued, and it may eliminate UI symptoms [4], while unsupervised PFMT is less effective than caregiver-supervised PFMT [6]. However, maintaining the

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patient's motivation and receiving continued support from a caregiver are often difficult.

We are developing a new treatment for women with SUI, in which the support power of underwear is used. In our previous single-arm pilot study [7], we reported that wearing ready-made supportive underwear (SLIM-up-Pant, stock number; EQ0832, Wacoal Corp., Kyoto, Japan; shaper) was effective in elevating the bladder neck and reducing UI symptoms. Therefore, the aim of this study was to determine the effects of wearing a shaper compared with PFMT at home using a training compact disc (CD) with music, or no treatment, in an assessor-blinded randomized control trial, on reducing UI symptoms.

Materials and methods

This assessor-blinded randomized control trial was conducted from February to May 2012 in Japan. The study protocol conformed to the provisions of the Declaration of Helsinki and was approved by the ethics review board of Shiga University of Medical Science (approval no. 23-119-1).

Participants

The participants were recruited by a recruitment agency (OGIS-RI, Osaka, Japan). The candidate participants were selected from parous women aged 30–59 years who registered with the recruitment agency. The inclusion criterion for participation was the presence of SUI symptoms at least once per week. The Japanese version of the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) [8] was used to diagnose the frequency of UI symptoms and UI type. Four questions were included in the ICIQ-SF: the frequency and amount of urine leakage, interference with everyday life, and perceived cause of leakage. In this study, women who have more leakage than "about once a week or less often" and who have urine leak when "coughing or sneezing" and/or "during physical activity" were selected as candidate participants. In addition, women with mixed urinary incontinence (MUI) were also included because the shaper was effective in reducing UI symptoms among women with MUI in the previous pilot study [7]. The exclusion criteria were current pregnancy, delivery within 3 months, previous and/or current treatments for UI, and waist size out of the specified range (waist measurement approximately 58–82 cm) for wearing the shaper. One hundred fifty candidate participants who matched the inclusion criteria were stratified into three age groups: 30–39, 40–49, and 50–59 years in order of registration. All candidate participants were subsequently assigned by a researcher (OH) to the shaper group, the PFMT group, or the no treatment group in a ratio of 1:1:1 according to the assignment table for stratified randomization created using a computer. The recruitment agency was asked to obtain verbal consent by telephone for participation in this study from the candidate participants. A researcher (OH) explained this study using an informed consent form for the participants who provided verbal consent, and all participants provided written informed consent.

As the intervention methods were clearly different, blinding of the assignment groups was difficult. The assigned groups were blinded to an assessor (NS) until the analysis. The participants did not meet other participants or assessors from the beginning to end of this study because necessary study materials were sent to their home by the recruitment agency and all programs were carried out at their home.

Intervention protocols

The intervention program is presented in Fig. 1. The study period was a total of 13 weeks, which consisted of a 1-week observation period (baseline) and a 12-week intervention period. The outcomes between the baseline and the 6th or 12th week of the intervention period were compared.

Shaper group

The participants in the shaper group wore the shaper (SLIM-up-PANT, stock number; EQ0826, Wacoal Corp., Kyoto, Japan) used in the previous pilot study [7] during a 12-week intervention period. The previous pilot study [7], which used magnetic resonance images in a sitting position, indicated that the bladder neck was significantly elevated (median, 11.5 mm; 95% confidence interval, 10.0–12.9 mm, 45 women) when a shaper was worn. In addition, the improvement rate in UI symptoms after 12 weeks of wearing the shaper was 85.4% (35/41 women). The shaper comprised a middle-length type underwear developed as a functional supportive underwear for muscle strengthening and the correction of body shape, but not for elevating the bladder neck and reducing UI symptoms. In the previous pilot study [7], we reported that women who wore the shaper reported that the shaper has moderate power of tightening the body compared with the general controlling underwear, and there were no side effects or adverse events due to wearing the shaper. In the present study, the participants in the shaper group were instructed to wear the shaper from waking up to bedtime during the 12-week intervention period and not to wear other supportive underwear and/or tights when wearing the shaper. Two shapers were sent to each participant in the shaper group. The participants were instructed to use a laundry net as much as possible to prevent fabric deterioration when washing the shaper via a washing machine.

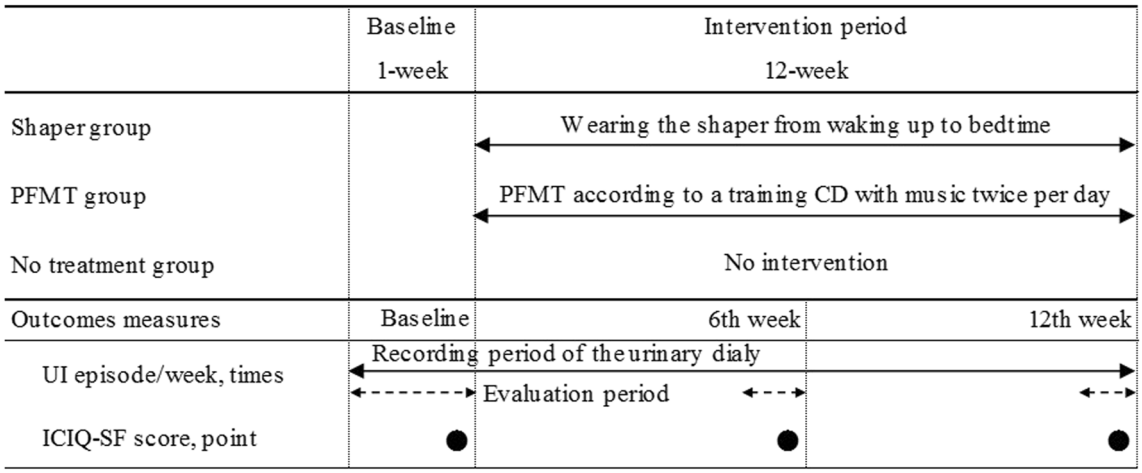

Fig. 1 Intervention protocol. CD, compact disc; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; PFMT, pelvic floor muscle training; UI, urinary incontinence

PFMT group

The participants in the PFMT group were instructed to perform the PFMT according to a training CD with music, "3 min exercise before going out" (Takumi Vision Co., Kyoto, Japan), at home twice per day during the 12-week intervention period. This training CD was made in Japan for home practice of the PFMT with reference to a previous study [9]. This training CD includes three versions of the song for use in the morning, daytime, and evening. Each song with rhythm and narration encourages the listener to perform voluntary pelvic floor muscle contractions for 26 times per 3 min. One training CD was sent to each participant in the PFMT group.

No treatment group

No intervention was administered to the no treatment group during the 12-week intervention period.

Outcome measures

The number of UI episodes per week (UI episodes/week) and the ICIQ-SF score comprised the outcome measures in this study. The primary outcome measure was the improvement rate in UI symptoms after the 12-week intervention period. The improvement rate in UI symptoms was defined as the ratio of the case number where the UI episodes/week had decreased at least 50% from the baseline. When the number of UI episodes/week after the 12-week intervention was 0, the UI symptoms were considered cured.

The UI episodes/week were based on a self-monitoring urinary diary. All participants were instructed to record the number of UI episodes in the urinary diary every day throughout the study period. Although a previous study has reported that reliability decreases with a long recording period of the urinary diary, a long-term diary is needed in a patient with rarer UI episodes [10]. The participants of the present study were instructed to update the urinary diary throughout the study period because of their possibly fewer UI episodes. The UI episodes/week were calculated from the urinary diary.

The ICIQ-SF is a frequently used questionnaire for the assessment of subjective UI symptoms and QOL [8], and its validity has also been reported [11]. The ICIQ-SF score is a total score of the following three items: the frequency and amount of urine leakage and the interference with everyday life (range: 0–21) [8]. When participants have UI symptoms, the ICIQ-SF score should be at least 3 points: a higher score indicates a severe condition. In this study, the participants were instructed to provide information regarding their UI symptoms for the previous 2 weeks.

Statistical analysis

The sample size was calculated based on the effect size = 0.7 estimated from the improvement rate in UI symptoms in the previous pilot study (85.4%) [7], with a two-sided alpha = 0.05 and adequate power = 0.8. The sample size was approximately 35 women per group considering dropout.

The characteristics of the participants in each group at baseline were compared by Kruskal-Wallis test and Fisher's exact test. Comparisons of the UI symptoms between the baseline and 6th or 12th week of the intervention period on the same group were performed with Wilcoxon-signed rank test and Bonferroni correction ($\alpha = 0.05/\ 3 = 0.016$) as well as the Hodges-Lehmann estimator for the 95% confidence interval (CI). Comparisons of the UI symptoms between each group at baseline and the 6th and 12th week of the intervention period were determined using the Mann-Whitney U test and Bonferroni correction ($\alpha = 0.05/\ 3 = 0.016$). Comparisons of the improvement rates in the UI symptoms with the no treatment group were performed via univariate logistic regression analysis with the presence or absence of UI symptoms as the

dependent variable. Cramer's V was calculated as the effect size in this study. SPSS 22.0 for Windows (IBM, Armonk, NY, USA) was used for the analysis. P values < 0.05 were considered statistically significant.

Results

One hundred ten women who were randomized to three groups consented to participate in this study, and 21 women were excluded because there was no UI episode at baseline. As a result, 89 women who completed the 12-week intervention period were analyzed (Fig. 2).

The median age of the participants was 44.0 years (interquartile range, 39.0–50.0), the rate of SUI was 64.0% ($n = 57$), and the MUI was 36.0% ($n = 32$). There was no significant difference in the characteristics of the participants between each group at baseline (Table 1).

Both the UI episodes/week and the ICIQ-SF score at baseline were not significantly different between each group. In the shaper and PFMT groups, both the UI episodes/week and the ICIQ-SF score were significantly decreased at the 6th week of the intervention period from the baseline, and the UI episodes/week further decreased at the 12th week of the intervention period from the baseline (both $P < 0.001$). In the no treatment group, the two outcome measures did not show significant reductions at the 6th and 12th weeks of the intervention period from the baseline (Table 2).

The improvement rate (included cure) in the UI symptoms was 73.3% (22/30 women) in the shaper group, 74.2% (23/31 women) in the PFMT group, and only 25.0% (7/28 women) in the no treatment group. The improvement rates in the UI symptoms in the shaper and PFMT groups were significantly higher than that of the no treatment group (both $P < 0.001$), and their cure rates were also significantly higher than that of the no treatment group ($P = 0.010$, 0.003). Cramer's V calculated from the improvement rate in UI symptoms was 0.483 in the shaper group and 0.491 in the PFMT group; thus, the effect size in this study was estimated as large (Table 3).

In this study, no side effects or adverse events due to the shaper or PFMT during the intervention period were reported.

Discussion

This study verified the effects of wearing a shaper compared with PFMT at home using a training CD with music or no treatment, in an assessor-blinded randomized control trial, on reducing UI symptoms. Both the UI episodes/week and the ICIQ-SF score in the shaper and PFMT groups were decreased at the 6th and 12th week of the intervention period from the baseline. The improvement rate in the UI symptoms in the shaper group after the 12-week intervention period was higher than that in the no treatment group and was almost the same as that in the PFMT group.

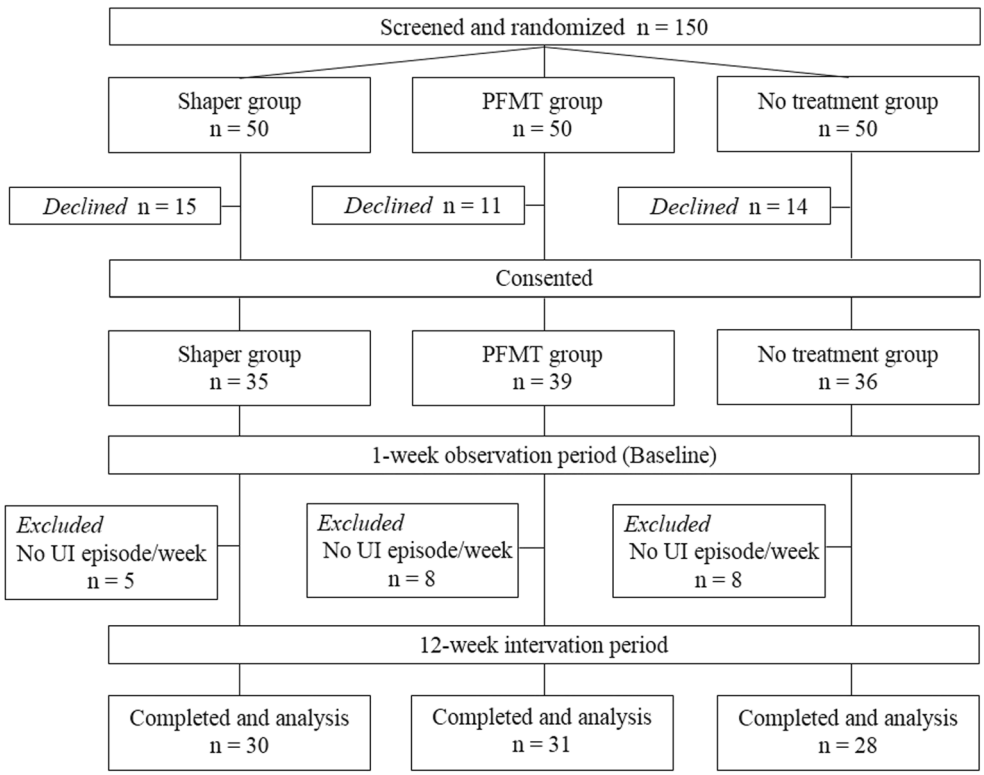

Fig. 2 Flow diagram of participants. SUI, stress urinary incontinence; UI, urinary incontinence

Table 1 Characteristics of participants in each groups at the baseline

	All $n = 89$	Shaper group $n = 30$	PFMT group $n = 31$	No treatment group $n = 28$	*P* value
Age, years	44.0 (39.0–50.0)	44.0 (39.0–49.0)	45.0 (39.0–50.0)	43.5 (38.3–50.0)	0.799[a]
Body mass index (kg/m^2)	21.3 (20.0–23.2)	21.4 (20.0–23.0)	20.1 (19.2–22.0)	21.0 (19.8–23.8)	0.549[a]
Parity, no.	2.0 (1.0–2.0)	2.0 (1.0–2.0)	2.0 (1.0–2.0)	2.0 (1.0–2.5)	0.526[a]
Type of UI					
SUI, *n* (%)	57 (64.0)	20 (66.7)	19 (61.3)	18 (64.3)	0.961[b]
MUI, *n* (%)	32 (36.0)	10 (33.3)	12 (38.7)	10 (35.7)	

Median (interquartile range)

PFMT pelvic floor muscle training, *UI* urinary incontinence, *SUI* stress urinary incontinence, *MUI* mixed urinary incontinence

[a] Kruskal-Wallis test

[b] Fisher's exact test

The improvement rate in the UI symptoms by wearing the shaper was 73.3% in this study, which was lower than the 85.4% in the previous pilot study [7]. The previous pilot study [7] was a single-arm study and did not blind the research hypotheses to the participants. In addition, the participants in the previous study [7] had high motivation and expectations that UI symptoms would improve because they applied for the study themselves. In the present study, to minimize these biases, participants were selected among women who registered with the recruitment agency and were then randomized. Participants with no UI episode at baseline were excluded from the analysis, as they might be naturally healed. In addition, the sample size of this study was estimated to be appropriate, as the effect size calculated from the results was large. Therefore, the improvement rate in UI symptoms by wearing the shaper is considered more reliable than the previous pilot study [7]. However, in the previous pilot study [7], the improvement rate in UI symptoms, which was based on the ratio of the UI episodes/week and the amount of urine leakage in the 1-h pad test, decreased at least 50% from the baseline. In this study, the 1-h pad test was not used as one of the outcome measures because this test has been reported to have a higher false-negative rate [12]. If the 1-h pad test was used as an outcome measure in this study in addition to the UI episodes/week similar to the previous pilot study [7], we speculated that the improvement rate in UI symptoms might be lower.

The improvement rate in UI symptoms by PFMT at home according to the training CD was 74.2%. A previous study had reported that the use of an audiocassette tape increased patient compliance for routine PFMT [9]. Similarly, in this study, the training CD with music could increase participant compliance and contributed to the increase in the improvement rate in UI symptoms in the PFMT group. However, as the ability of the participants in the PFMT group to perform pelvic floor muscle contraction was not assessed in this study, some participants possibly could not perform pelvic floor muscle contraction correctly. If all participants could perform pelvic floor muscle contraction correctly, we speculated that the improvement rate in UI symptoms in the PFMT group in this study might be higher.

The improvement rate in UI symptoms by PFMT has been reported at 28.6–80.0% in a systematic review [5], although the comparison of the results between each study was difficult because of the differences in the study protocols or training parameters. Therefore, comparing the effect of the shaper on the improvement rate in UI symptoms with those in other previous studies is difficult. In contrast, a previous meta-analysis that compared PFMT and no treatment indicated that PFMT provided high-quality evidence for improving SUI in women (risk ratio 17.33, 95% CI 4.31 to 69.74) [13]. In the present study, we confirmed that the shaper was as effective as PFMT at home in reducing UI symptoms, as the improvement rate in UI symptoms in the shaper group was higher than that in the no treatment group and was almost the same as that in the PFMT group.

In this study, the improvement rate in UI symptoms in the no treatment group was 25.0%. One of the factors for reducing UI symptoms in the no treatment group was potentially the enhanced awareness of the participants of their participation in this study or recording of the urinary diary. These issues might have led to a Hawthorne effect or a similar effect in behavioral therapy. Another factor for reducing UI symptoms may have been the natural course of symptoms due to seasonal change.

No side effects or adverse events caused by the shaper occurred during the intervention period in the present and previous pilot studies [7]. As a result, the present study also showed the safety of the shaper. However, as the participants did not wear the shaper for over 12 weeks in both studies [7], the effects and side effects of wearing the shaper for a long-term period are unknown. To clarify the safety of wearing the shaper, additional long-term evaluations may be necessary.

This study has several limitations. It was impossible to eliminate the Hawthorne effect as participants must update

Table 2 Comparison of UI symptoms between the baseline and the 6th or 12th week of the intervention period

	Shaper group; A $n = 30$			PFMT group; B $n = 31$			No treatment group; C $n = 28$			A vs B	A vs C	B vs C
	Median (*IQR*)	Difference from baseline		Median (*IQR*)	Difference from baseline		Median (*IQR*)	Difference from baseline				
		P value[a]	difference [95% CI][b]		*P* value[a]	difference [95% CI][b]		*P* value[a]	difference [95% CI][b]	*P* value[c]	*P* value[c]	*P* value[c]
UI episodes/week, times												
Baseline	3.0 (1.0–5.3)			2.0 (1.0–6.0)			3.0 (1.0–5.0)			0.813	0.701	0.834
6th week	1.0 (0.0–4.0)	0.001*	1.5 [0.5, 2.5]	1.0 (0.0–3.5)	0.003*	1.5 [1.0, 2.5]	2.0 (1.0–3.0)	0.047	0.5 [0.0, 1.5]	0.982	0.284	0.277
12th week	0.5 (0.0–2.3)	< 0.001*	2.0 [1.5, 3.0]	0.0 (0.0–2.0)	< 0.001*	2.0 [1.0, 3.5]	1.5 (1.0–3.0)	0.330	0.5 [−0.5, 1.5]	0.607	0.030	0.006*
ICIQ-SF score, point												
Baseline	5.5 (4.8–10.0)			7.0 (5.0–10.0)			7.0 (5.0–10.0)			0.277	0.572	0.481
6th week	5.0 (1.0–8.0)	0.001*	2.0 [0.5, 2.5]	6.0 (1.0–9.0)	< 0.001*	1.5 [0.5, 3.0]	6.0 (4.0–9.0)	0.023	1.5 [0.0, 2.5]	0.527	0.393	0.903
12th week	5.5 (4.0–8.3)	0.012*	1.0 [0.0, 2.5]	5.0 (1.0–7.0)	0.001*	2.5 [1.0, 4.0]	6.0 (4.3–10.0)	0.192	0.5 [−0.5, 1.5]	0.415	0.273	0.078

UI urinary incontinence, *ICIQ-SF* International Consultation on Incontinence Questionnaire-Short Form, *PFMT* pelvic floor muscle training, *IQR* interquartile range, *CI* confidence interval

[a] Wilcoxon-signed rank test and Bonferroni correction

[b] Hodges-Lehman estimator

[c] Mann-Whitney U test and Bonferroni correction

* $\alpha < 0.05/3 = 0.016$

Table 3 Comparison of the improvement rate of UI symptoms after 12-week intervention

	Shaper group $n = 30$				PFMT group $n = 31$				No treatment $n = 28$
	n (%)	Difference from no treantment group[a]			*n* (%)	Difference from no treantment group[a]			*n* (%)
		P value	OR [95% CI]	Cramer's *V*		*P* value	OR [95% CI]	Cramer's *V*	
Improvement or cure	22 (73.3)	< 0.001	8.25 [2.54, 26.78]	0.483	23 (74.2)	< 0.001	8.63 [2.67, 27.91]	0.491	7 (25.0)
Cure only	15 (50.0)	0.010	4.60 [1.38, 15.32]	0.338	17 (54.8)	0.003	5.59 [1.69, 18.51]	0.382	5 (17.9)

Improvement, decreased at least 50% of urinary incontinence episodes/week after the 12-week intervention from the baseline. Cure, decreased 100% of urinary incontinence episodes/week after the 12-week intervention from the baseline

UI urinary incontinence, *PFMT* pelvic floor muscle training, *OR* odds ratio, *CI* confidence interval

[a] Univariate logistic regression analysis. Dependent variable, presence or absence of improvement of UI symptoms; independent variable, types of intervention group

their urinary diary in this study. In addition, because the participants in the PFMT and no treatment groups did not control the types of their underwear, they might have worn other support underwear. Moreover, this study did not contribute positive and negative results in women with pelvic organ prolapse (POP) because the participants were not assessed for POP. Future studies are expected to employ controlled methods of intervention and unified outcome measures for comparison with previous studies. In addition, to obtain stronger results, additional long-term studies with many participants are necessary.

Despite these limitations, this study showed the effectiveness of the shaper in reducing UI symptoms following the previous pilot study [7]. The wearing of the shaper can be easily conducted without supervision at home and is expected to obtain the effects of reducing UI symptoms similar to PFMT. The shaper might contribute to the health care self-management of women with SUI.

In conclusion, the effects of wearing a shaper in reducing UI symptoms were verified by comparing PFMT at home using a training CD with music or no treatment, in an assessor-blinded randomized control trial. The shaper was almost as effective as PFMT at home in reducing UI symptoms. We suggest that wearing the shaper represents one method to improve SUI in women.

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Compliance with ethical standards

Conflicts of interest All authors received research grants from the Research Institute of Science and Technology for Society (Implementation-Support Program a Mechanism to deliver R&D Outcome to Society, 2011). The shapers used in this study were provided by Wacoal Corp. The authors declare that they have no conflict of interest.

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