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ORIGINAL ARTICLE

Effect of pelvic floor muscle training program in reducing postpartum levator hiatus area in Japanese women: A prospective cohort study using three-dimensional ultrasonography

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Abstract

Aim: To assess the effect of a pelvic floor muscle training (PFMT) program on postpartum levator hiatus area.

Methods: A prospective cohort study was conducted at a clinic in Japan. Training and control groups were recruited from outpatient pregnant women at two separate time periods. Only the training group underwent the PFMT program, including education for home PFMT, home PFMT, and follow-up instructions. Education for home PFMT was held by 1 month postpartum to acquire the correct contraction of the pelvic floor muscle. Home PFMT was prescribed between 1 and 5 months postpartum; during this period, follow-up instructions were provided to keep the women motivated. Before and after home PFMT, the levator hiatus area was measured using ultrasonography.

Results: In total, 44 women in the training group and 45 in the control group were analyzed. There were 36 women who reached a high adherence to three daily sets of home PFMT. The reduction in the levator hiatus area at rest was not statistically higher in the training group than that in the control group. For the subgroup with high adherence, the reduction in the area at rest was significantly higher by 4.43% in the training group than that in the control group (19.90% vs. 15.49%).

Conclusions: Although the PFMT program did not significantly reduce the postpartum levator hiatus area at rest, performing at least three sets of home PFMT each day significantly reduced the levator hiatus area by 4.43%.

Clinical trial registration: UMIN Clinical Trials Registry (ID; UMIN 000026188, Date; 17 February 2017).

KEYWORDS

pelvic floor, pelvic organ prolapse, postpartum period, training, ultrasonography

1 | INTRODUCTION

Pelvic organ prolapse (POP), which is a common problem in women, is defined as the downward descent of one or more of the anterior vaginal wall, posterior vaginal wall, uterus, or the apex of the vagina (Haylen et al., 2016). In a general population aged 45–85 years, vaginal palpation was reported to detect POP of at least stage 2 by the

quantification system in 38.5% (Slieker-ten Hove et al., 2009). POP can affect the bladder, bowel, and sexual function and may cause substantial discomfort and a variety of symptoms, such as vaginal bulged sensation, low back pain, urinary frequency, and incomplete defecation (Haylen et al., 2016). It can impair activities of daily living and lower the quality of life of the affected women. The lifetime risk of surgery for POP was estimated to be as high as 19% in a general female population (Smith, Holman, Moorin, & Tsokos, 2010), and the annual direct cost of POP surgery was estimated as 1,012 million USD in the United States (Subak et al., 2001). Indeed, POP is a major disease that can adversely affect women's health and the social economy.

The levator ani muscle (LAM) is an essential part of the pelvic floor and has been thought to play an important role in supporting and preserving the function of pelvic organs (Ashton-Miller & DeLancey, 2007; DeLancey, 1994). The levator hiatus (LH) is located in between the V-shaped LAM and serves as an opening through which the urethra, vagina, and anorectum pass. The size of the LH is strongly associated with the clinical signs and symptoms of POP (Dietz, Shek, De Leon, & Steensma, 2008). In fact, significant correlations between the LH size and POP have been reported; the degree of pelvic organ descent became more severe as the LH area increased (Dietz, Shek, & Clarke, 2005). Several other studies consistently showed that the LH area was larger in women with POP than in those without POP (Chen, Song, Jiang, Hong, & Ye, 2011; Dietz et al., 2008; Dou et al., 2018; Khunda, Shek, & Dietz, 2012). Furthermore, each cm^2 increase in LH area was shown to increase the risk for POP by 11% (Dietz, Franco, Shek, & Kirby, 2012), and expansion of the LH area was an independent risk factor and possible predictor of POP (Dietz et al., 2012; Herschorn, 2007).

Childbirth is one of the significant factors that can expand the LH. In the third trimester of pregnancy, the LH area has been reported to increase by 27% (Shek, Kruger, & Dietz, 2012). During subsequent vaginal delivery, the LAM is stretched to as high as 3.3 times the original length (Lien, Mooney, DeLancey, & Ashton-Miller, 2004), thereby further expanding the LH. Clearly, childbirth leads to persistent LH expansion (Wang et al., 2001), which can increase the risk for POP later in life, although it is important to note that the cause of POP is multifactorial. Compared with nulliparous women, those who delivered twice had a relative risk of 8.4 for developing POP (Mant, Painter, & Vessey, 1997). Therefore, methods to address and recover postpartum LH are required.

We focused on pelvic floor muscle training (PFMT) as a way to promote the recovery of postpartum LH and developed a PFMT program that suits the clinical practice in Japan. PFMT has been demonstrated to strengthen the pelvic floor muscles (PFM) and reduce bothersome urinary incontinence after delivery (Boyle, Hay-Smith, Cody, & Morkved, 2012). Therefore, it is currently regarded as the first-line therapy for women with urinary incontinence. Recently, several researchers have shown that PFMT was effective in reducing the symptoms of POP (Hagen et al., 2014; Hagen & Stark, 2011) and in reducing the LH area in middle-aged women with POP stages 1, 2, and 3 (Braekken, Majida, Engh, & Bo, 2010). However, there is scant research on the association between PFMT and postpartum recovery of LH area.

The purpose of this study is to assess the effect of our PFMT program on the LH area in postpartum women. We considered that this study would provide new evidence that can be useful for preventing the bothersome long-term complication of POP in postpartum women.

2 | METHODS

2.1 | Research design

In this prospective cohort study, we evaluated the effect of a PFMT program on the postpartum LH area of women who were seen at a single obstetrics and gynecology clinic in Japan from February 2017 to June 2018. This clinic values natural childbirth and handles low-risk pregnant women without general complications and obstetrical risk factors. The recruitment of women for each group (i.e., training and control) was performed in two separate time periods. First, pregnant women who visited the outpatient clinic for maternity checkup were asked to participate in the control group. After obtaining the required number for the control group, we started to recruit women for the training group at the same clinic. The women in the control group were recruited from February 2017 to June 2017 and were followed up until December 2017. The women in the training group were recruited from July 2017 to December 2017 and were followed up until June 2018.

2.2 | Participants

The inclusion criteria were singleton pregnancy, third trimester of pregnancy (i.e., approximately 30–36 gestational weeks), age $\geq$ 20 years, ability to understand Japanese, and provision of written informed consent. Women who met the following criteria were excluded: (a) neurological disease; (b) inability to contract the PFM correctly at 1 month postpartum; (c) difficulty to follow-up until 5 months postpartum; and (d) judged to be

inappropriate for participation in this study because of maternal complications, abnormal fetus, and other reasons.

Based on a previous report (Asai et al., 2016), the sample size was calculated according to an estimated effect size of .7 for PFMT to reduce the LH area. Assuming that a nonparametric test would be needed, a sample of 35 women in each group was required (two-sided $\alpha = .05$, power of 80%). To allow for 20% dropout, we decided to include at least 45 women per group.

A total of 119 women (55 in the control group and 64 in the training group) received verbal invitation by the researcher for assessment of eligibility. Those who were interested in participating received additional verbal and written information from the researcher. All participants provided written informed consent before enrollment into the study. This study was approved by the Research Ethics Committee of Yamanashi University (No. 1569, approved on November 9, 2016).

2.3 | Intervention

2.3.1 | Pelvic floor muscle training program for the training group

The training group underwent a specially designed PFMT program that comprised three steps, including education for home PFMT, home PFMT, and follow-up instructions (Figure 1). Education for home PFMT was performed three times by 1 month postpartum and home PFMT was performed at 1–5 months postpartum. During home PFMT, follow-up instructions were offered twice. All interventions were led by a single researcher, who was a certified midwife and trained in the instructions for PFMT.

Education for home PFMT

The aims of this education for the training group were to: (a) motivate to perform home PFMT; (b) help learn and perform the correct PFM contraction; and (c) inform the protocol for home PFMT. This education consisted of three appointments with the researcher at around 36 gestational weeks, 1–5 days after delivery during the hospital stay, and approximately 1 month postpartum (Figure 1).

In the first appointment at around 36 gestational weeks, each participant was individually instructed on pelvic floor anatomy, physiology, and the way to contract the PFM. First, the researcher used anatomical models and illustrations to teach the location and function of the PFM. The researcher explained how childbirth affects the PFM and results in future disorders in order to motivate the participants to perform PFMT. Second, using the same teaching tools, the researcher explained and demonstrated a correct PFM contraction, which was defined as squeezing around the pelvic opening and inward lifting of the perineum (Bo, Morkved, & Aschehoug, 2015) without visible movements of the outer abdominal, hip adductor, and gluteal muscles (Bo et al., 2015). Moreover, the researcher carefully instructed and encouraged the participants to try PFM contraction, as if to stop the flow of urination in a sitting position. According to a previous research, as high as 24% of women could not perform the correct PFM contraction initially, but proper instruction and feedback improved the performance (Kandadai, O'Dell, &

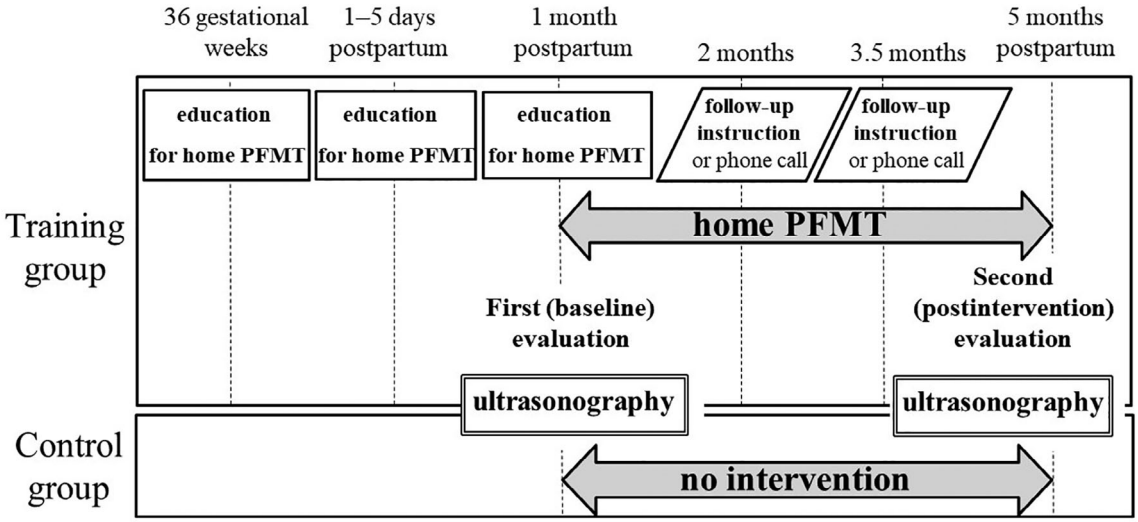

FIGURE 1 Research outline of the schedule of intervention and evaluation. The training group underwent a PFMT program that comprised three steps, including education for home PFMT, home PFMT, and follow-up instructions. PFMT, pelvic floor muscle training

Saini, 2015). Thereafter, correct PFM contraction was verified in the participants by vaginal examination and visual observation of inward perineal movement while contracting the PFM (Bo, Kvarstein, Hagen, & Larsen, 1990). Feedback on the performance was provided to the participants, and repetitive practices were done. All women in the training group accepted a leaflet that contained descriptions of the instructions above.

On the second appointment at 1–5 days after delivery, the participants were individually notified about home PFMT at their convenient time during their hospital stay. On the third appointment at approximately 1 month postpartum, correct performance of PFM contraction in the supine position was confirmed again by vaginal examination. Moreover, the researcher showed again the daily protocol of home PFMT and gave a new home PFMT leaflet, which contained the number of contractions and the sustaining times.

Home PFMT

A total of 16 weeks (approximately 1–5 months postpartum) of home PFMT was prescribed to the women in the training group (Figure 1). The daily protocol comprised three sets of 8–12 PFM contractions, which was considered to be the effective dosage based on a previous study (Bo, Hagen, et al., 1990). Because postpartum women tend to have less spare time for PFMT, the researcher in this study suggested to the participants to do PFMT while breastfeeding. For that reason, we counted the effective dosage as six sets of five contractions and recommended one set of PFMT every breastfeeding during daytime. In short, the daily protocol of home PFMT was performed in six sets of five contractions, and all women were encouraged to contract the PFM as hard as possible for 6–8 s and at intervals of approximately 6 s. At the end of each contraction, the participants were asked to add three fast contractions (Bo, Hagen et al., 1990). There was no strict requirement on posture when performing PFMT as long as the participants were comfortable.

The women in the training group were asked to record in a training diary the number of PFMT sets performed in 1 day. In this study, adherence was defined as the extent to which home PFMT was performed, and high adherence was defined as completing at least 50% of the prescribed home PFMT (i.e., average of ≥3 sets in 1 day for 16 weeks).

Follow-up instructions

All women in the training group were invited to the clinic twice, at approximately 2 and 3.5 months postpartum, to receive follow-up instructions during the period of home PFMT (Figure 1). The purpose of these instructions was to keep them motivated in continuing to do home PFMT and, consequently, achieve high adherence. Women received invitations and were notified about a designated date by postal mail, which was sent a week before each follow-up instruction.

During these instructions, the participants received individual biofeedback training that was led by the researcher. Biofeedback is a process of recording biological signals, such as electrical activity, using an electronic device while contracting the PFM; this signal is presented as a visible or audible feedback to women (Herderschee, Hay-Smith, Herbison, Roovers, & Heineman, 2011). Because biofeedback training can inspire confidence on performance and improve motivation and training adherence (Herderschee et al., 2011), it has been commonly utilized in clinical practice to assist PFMT. In this study, surface electromyography with vaginal probe (Myo Trac3™; Thought Technology, Montreal, Quebec, Canada) was used. The vaginal probe was connected to a computer screen that displayed a graph of muscle electrical activity, which showed a higher waveform with stronger PFM contraction. Each participant inserted the vaginal probe herself and was encouraged to repeatedly contract the PFM as strong as possible while looking at the display. Through this process, the researcher intended to make the participants more aware of the PFM function and to improve their motivation for home PFMT. Moreover, all participants were advised to tighten each contraction as strong as possible when performing home PFMT, as they did under electromyography.

After biofeedback training, adherence to home PFMT was checked based on the training diary. Participants who did not perform sufficient home PFMT were asked for their reasons and received some advice from the researcher to increase the frequency of PFMT. For participants who did not come for follow-up instructions, the researcher made a phone call within a few days after the scheduled date of follow-up instruction, to confirm the implementation of home PFMT. The researcher gave them verbal encouragement to continue home PFMT.

2.3.2 | Control group

As part of routine care, customary leaflets about postpartum instructions from the clinic were distributed to all women in the control group. Apart from a brief introduction on PFMT in the leaflet, no specific education or supervision on PFMT was given to this group. However, for ethical reasons, they were not discouraged from trying PFMT by themselves.

2.4 | Measurements and evaluations

Evaluation of the LH area measurements are reproducibly achieved using three-dimensional (3D) ultrasound (Dietz et al., 2005). All women in both groups were invited for 3D transperineal ultrasonography before and after home PFMT at approximately 1 and 5 months postpartum (Figure 1). The participants were informed of the dates of two consecutive evaluations during their hospital stay and on the day of the first evaluation, respectively. Moreover, reminders were sent by postal mail 1 week before the scheduled date of evaluation.

All ultrasound volumes were obtained with an UGEO WS80A ultrasound system (Samsung Electronics Japan, Tokyo, Japan) which was equipped with an abdominal 4–8 MHz curved array convex volumetric ultrasound transducer. All ultrasonography procedures were performed in supine position immediately after voiding. The volumetric ultrasound transducer which was covered with plastic wrap and sufficient ultrasound gel was placed on the perineum in the midsagittal plane. The position of the transducer was adjusted to properly capture two-dimensional (2D) midsagittal images, which clearly encompassed the symphysis pubis, urethra, vagina, anorectal junction, and the back sling of the LAM (Dietz, 2015) (Figure 2A). The 3D function was then activated, and high-quality was applied and the acquisition angle was set to a maximum of 80°. All images were recorded as 3D static volume data obtained at rest, during maximum PFM contraction, and during maximum Valsalva maneuver. The efficacy of PFM contraction and Valsalva maneuver were ascertained by observing 2D midsagittal images before acquiring the volume data. All volumes were saved on the ultrasound machine for offline analysis.

Following the volume data acquisition, we measured the LH area using the same ultrasound system and a linear reconstruction method previously described (Youssef et al., 2015; Youssef et al., 2016). The LH area measurements based on this method are reported to be in good agreement with the values based on the 3D rendering method (Youssef et al., 2015; Youssef et al., 2016), which was considered reliable (Dietz, Wong, & Shek, 2011). The linear reconstruction application is known as Oblique View™ (Samsung Electronics Japan, Tokyo, Japan) in our ultrasound system. In this application, the operator can depict a line obliquely and choose to trace a line in the desired plane, which allows slicing of a volume along any required plane without rotating the 2D image. On this application of Oblique View™, we selected the minimal hiatal dimension in the midsagittal plane, which was identified as the minimal distance between the hyperechogenic posterior aspect of the symphysis pubis and the hyperechogenic anorectal junction (Figure 2, dotted line of panel a) based on the methodology previously described (Dietz et al., 2005). Thereafter, the axial view of the minimum levator hiatal dimension was automatically described as a single 2D slice. We additionally applied a contrast-enhancing technique commercially known as Oblique View Extended Imaging: OVIX™ (Samsung Electronics Japan, Tokyo, Japan). This is a thick-slice technique that markedly reduces the speckle artifact, thus improving resolution (Dietz, 2008). By combining this technique with the image, the contrast-enhanced thick slice of the LH was described (Figure 2B). The LH areas were measured and determined for this slice using

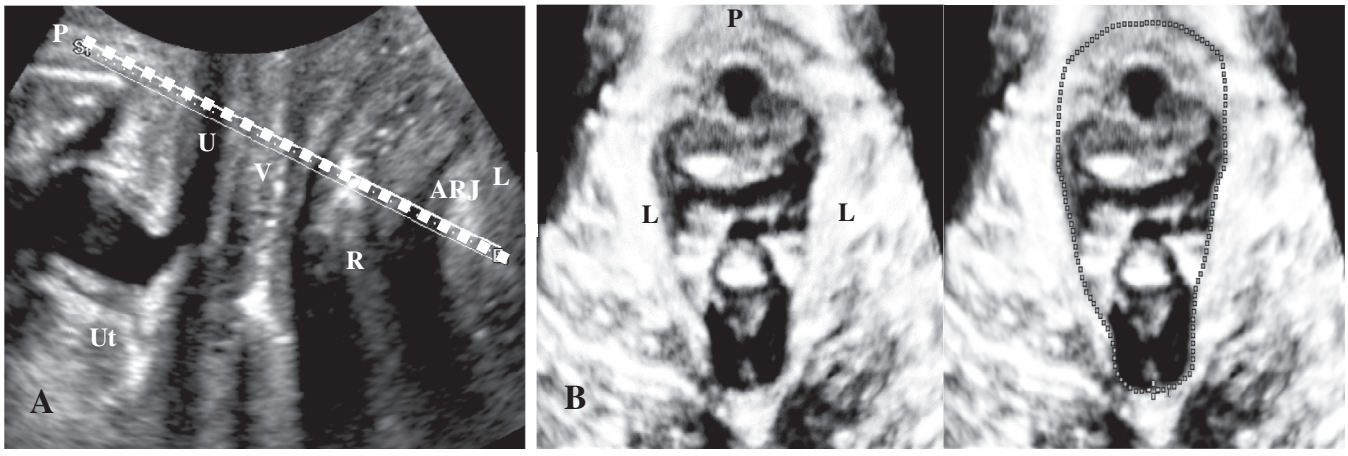

FIGURE 2 Ultrasonography images. (A) Determination of the plane of minimum levator hiatal dimension in a midsagittal plane. Dotted line shows the location of the plane of minimum hiatal dimension that is identified as the minimal distance between the symphysis pubis (P) and the anorectal junction (ARJ). (B) Area measurement of the levator hiatus in the axial plane of the minimum dimension. P, symphysis pubis; U, urethra; V, vagina; Ut, uterus; R rectum; ARJ, anorectal junction; L, levator ani

the pubovisceral muscle, symphysis pubis, and inferior pubic ramus as the borders (Figure 2B). The slice thickness of the OVIX™ line was set at 1 mm.

All ultrasonography examinations were performed by the same researcher who led the PFMT program for the training group. This researcher had been sufficiently trained on transperineal ultrasonography.

The primary outcome was the relative change in the LH area at rest, which was defined as the value of absolute change (the value at 1 month − the value at 5 months) divided by the value at 1 month postpartum. The relative changes in PFM contraction and Valsalva maneuver were measured as the secondary outcomes. Demographic and obstetric data were collected from the electronic medical records of the clinic.

2.5 | Statistical analysis

The program SPSS version 25.0 (IBM, Armonk, NY, USA) was used for statistical analysis. Descriptive statistics were used to show the characteristics of the population, and each background variable was presented as number with percentage for categorical data or as mean with standard deviation for continuous data. Comparison of the continuous data on background variables between groups was performed by Student's *t* test, for normally distributed data, or the Mann–Whitney *U* test, for non-normally distributed data, and that of the categorical data was performed by the Chi-squared or Fisher's exact test.

The outcome data on LH area were reported as median and interquartile range (lower and upper

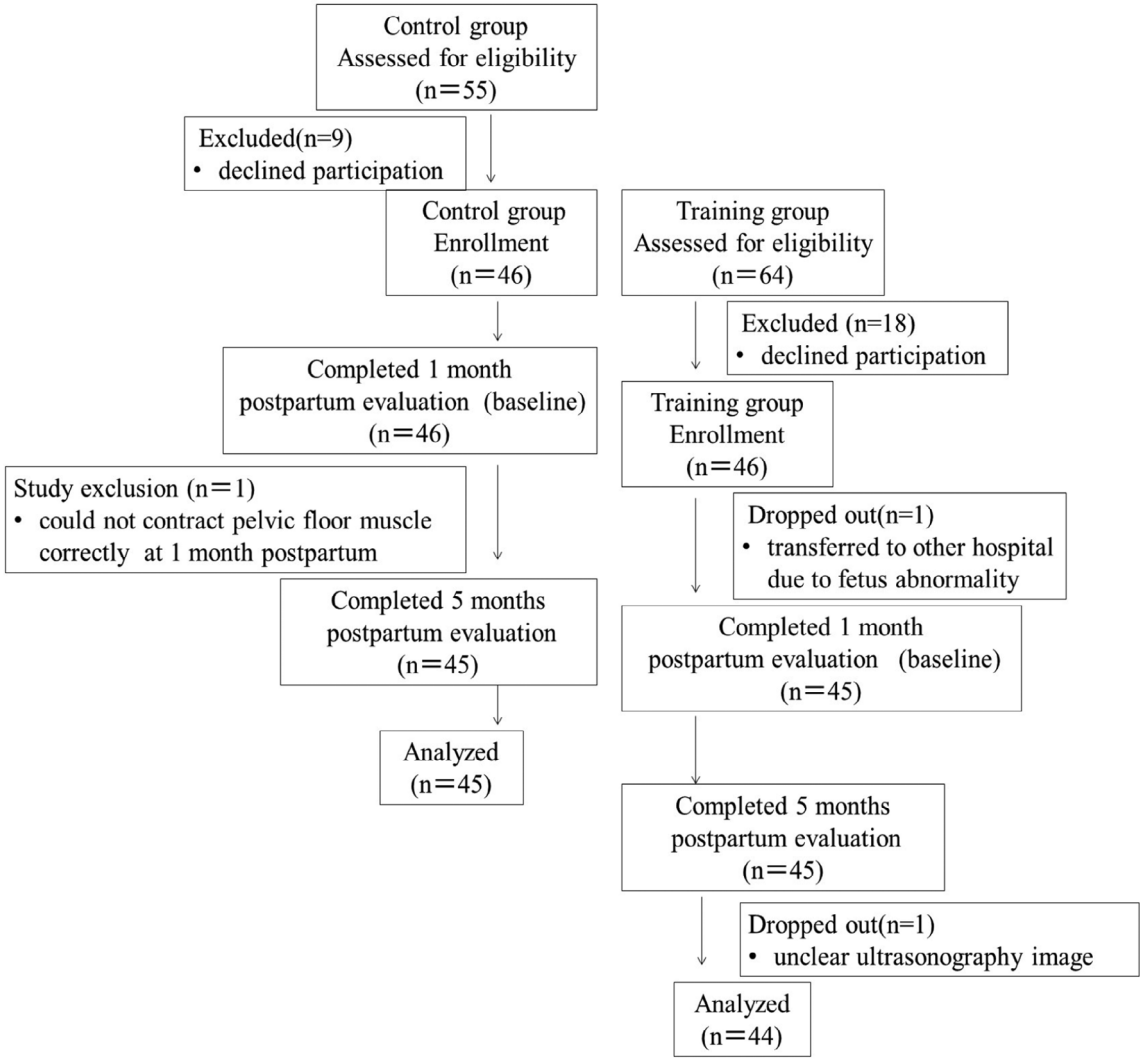

FIGURE 3 Flowchart of inclusion into the study

quartiles). The values of LH area were checked for normality by the Shapiro–Wilk test, which revealed a non-normal distribution. Therefore, between-group comparisons were analyzed using a nonparametric test (i.e., Mann–Whitney *U* test). The principal analysis was done on a modified intention-to-treat basis (Lang, Secic, & Lang, 2006). Additional per-protocol analysis was performed on the subgroup with high adherence to home PFMT. All tests were two-sided and the significance level was set at $p < .05$.

3 | RESULTS

3.1 | Recruitment and retention

Figure 3 shows the flowchart of participant inclusion, with descriptions of the numbers and reasons for dropout. Of the 119 women approached, 27 (nine in the control group and 18 in the training group) declined to participate; therefore, 46 women in each group (total 92)

TABLE 1 Background characteristics of the women in the training and control groups

	Training group		Control group		
	n	Mean ± *SD* or *n* (%)	*n*	Mean ± *SD* or *n* (%)	*P* value[a]
Age (years)	44	31.1 ± 3.8	45	30.7 ± 5.1	.725
Height (cm)	44	159.4 ± 5.8	45	158.9 ± 5.3	.646
Weight at 1 month postpartum (kg)	44	55.8 ± 8.9	45	57.4 ± 10.2	.557
Body mass index at 1 month postpartum (kg/m^2)	44	21.9 ± 2.7	45	22.6 ± 3.1	.209
Parity	44		45		.666
0 (primipara)		21 (47.7)		23 (51.1)	
1		14 (31.8)		16 (35.6)	
2		9 (20.5)		6 (13.3)	
Gestational age at delivery (days)	44	278.9 ± 7.4	45	280.3 ± 7.1	.336
Mode of delivery	44		45		.508
Cesarean section		0 (0)		2 (4.4)	
Normal vaginal delivery		40 (90.9)		38 (84.4)	
Vacuum delivery		4 (9.1)		5 (11.1)	
Forceps delivery		0 (0)		0 (0)	
Length of labor (min)	44		43		
Total		510.3 ± 344.0		580.7 ± 437.5	.417
First stage		444.6 ± 311.6		514.1 ± 400.6	.310
Second stage		59.9 ± 77.3		61.4 ± 66.9	.980
Episiotomy	44	7 (15.9)	43	9 (20.9)	.546
Perineal tear	44		43		.669
None		4 (9.1)		7 (16.3)	
I		6 (13.6)		7 (16.3)	
II		32 (72.7)		28 (65.1)	
III		2 (4.5)		1 (2.3)	
IV		0 (0)		0 (0)	
Intrapartum epidural	44	2 (4.5)	43	1 (2.3)	1.000
Neonatal birth weight (g)	44	3018.2 ± 356.5	45	3119.1 ± 435.4	.236
Neonatal head circumference (cm)	44	32.8 ± 1.5	45	33.2 ± 1.5	.235

Note: Data are presented as mean ± *SD* or *n* (%).
Categorical data were analyzed by Chi-squared or Fisher's exact test especially when >20% of cells had expected frequencies of <5.
[a]Continuous data were tested with Student's *t* test (for normally distributed data) or Mann–Whitney *U* test (for non-normally distributed data).

were enrolled in the study. One of the 92 women was excluded because she could not do correct PFM contraction at 1 month postpartum. Two women in the training group dropped out before and after the evaluation, respectively, due to fetus abnormality (transferred to other hospital) and unclear ultrasonography image (operational mistake). All the other women returned for the second evaluation at 5 months postpartum. In total, 89 (96.7%) of 92 women were included for analysis (45 in the control group and 44 in the training group), including the intention-to-treat analysis.

3.2 | Background characteristics

As presented in Table 1, both groups were similar in background characteristics, including age, body mass index, parity, gestational age at delivery, delivery mode, and other obstetrical factors. Most women underwent normal vaginal delivery, and none underwent forceps delivery.

3.3 | Compliance

All the 44 women in the training group completed the three appointments for education for home PFMT by 1 month postpartum and started home PFMT. The average duration of the prescribed home PFMT was 117.4 (*SD*, 3.9) days. All women returned their training diaries after the training period. Based on these diaries, home PFMT was performed at an average of 4.4 sets (range, 1.37–5.97 sets) per day. Of the 44 women, 36 (81.8%) reached an adherence of ≥50% to the prescribed home PFMT (high-adherence group) and the remaining eight (18.2%) were judged and classified as the low adherence group.

Of the 44 women, 34 (77.3%) participated in at least one follow-up instruction; 16 attended twice and 18 attended once. More home PFMT sets were performed as the number of participations in the follow-up instructions increased. In particular, the number of PFMT sets in 1 day was 3.8 for women who did not attend at all, 4.2 for women who attended once, and 5.0 for women who attended twice. All the absentees responded to a phone call from the researcher after each session.

In the control group, three women stated they had done PFMT by themselves at 1–5 months postpartum. However, the PFMT was performed as only 10–20 PFM contractions in 1 week. No participant performed regular and continuous PFMT throughout this period.

TABLE 2 Levator hiatus measurements before and after home PFMT and the differences in the changes between two groups (intention-to-treat analysis)

Variable	1 month postpartum (cm^2)			5 months postpartum (cm^2)			Absolute change (cm^2)[a]			Relative change (%)[b]				
	Training group (n = 44)	Control group (n = 45)	p value[c]	Training group (n = 44)	Control group (n = 45)	p value[c]	Training group (n = 44)	Control group (n = 45)	p value[c]	Training group (n = 44)	Control group (n = 45)	Difference between groups	95% Confidence interval	p value[c]
LH area														
At rest	14.99 (13.34–16.99)	15.39 (13.40–16.63)	.951	12.33 (10.75–13.33)	12.74 (11.20–13.90)	.307	2.89 (1.90–4.07)	2.13 (1.52–3.37)	.134	19.42 (14.43–24.64)	15.49 (11.51–19.93)	3.24	-0.24 to 6.45	.070
During contraction	13.61 (12.06–14.50)	13.32 (11.60–14.85)	.652	10.20 (9.44–11.86)	10.88 (9.98–12.58)	.120	2.69 (1.93–3.46)	2.04 (1.37–2.95)	.034	19.68 (14.46–25.23)	16.28 (12.03–19.36)	4.03	1.00 to 7.52	.009
During Valsalva	17.99 (14.95–20.66)	18.10 (15.07–21.96)	.883	13.99 (12.22–16.11)	14.52 (12.41–16.53)	.594	3.44 (2.23–5.05)	2.89 (1.79–4.30)	.231	19.32 (13.21–25.32)	16.29 (11. 89–22.85)	2.73	-1.19 to 6.50	.203

Note: Data are presented as median (interquartile range).
Data are non-normally distributed.
Abbreviations: PFMT, pelvic floor muscle training; LH, levator hiatus.
[a]Absolute change is the value at 1 month postpartum minus the value at 5 months postpartum.
[b]Relative change is the absolute change divided by the value at 1 month postpartum.
[c]Mann–Whitney *U* test

3.4 | Outcome measurements

In both groups, the first ultrasonography was evaluated at 24.2 days (range, 21–28 days) after delivery. The second (postintervention) ultrasonography evaluation was conducted at 141.3 days (range, 132–167 days) after delivery in the training group and at 143.2 days (range, 134–153 days) after delivery in the control group. No significant difference was found between both groups in the interval between delivery and ultrasonography evaluations.

Table 2 shows the LH area measurements at baseline (1 month postpartum) and postintervention (5 months postpartum), as well as the absolute and relative changes in each group. At baseline, no significant differences between groups were found for the LH area at rest (p = .951), during contraction (p = .652), and during Valsalva maneuver (p = .883). In both groups, the LH area measurements at 5 months postpartum decreased, relative to the measurements at 1 month postpartum. The reduction in the LH area at rest was larger in the training group (19.42%, 2.89 cm^2) than in the control one (15.49%, 2.13 cm^2), but the difference between the groups was not significant in terms of relative reduction in the LH area at rest (difference of 3.24%; 95% CI −0.24–6.45, p = .070). The reduction in the LH area during contraction was significantly larger by 4.03% in the training group (19.68%, 2.69 cm^2) than in the control group (95% CI 1.00–7.52, p = .009). The LH area during Valsalva maneuver reduced by 19.32% (3.44 cm^2) in the training group, and no significant difference between groups was found in the relative reduction in the LH area during Valsalva maneuver (difference of 2.73%; 95% CI −1.19–6.50, p = .203).

Table 3 shows the results of per-protocol analysis (n = 81). In this analysis, the women in the training group who had low adherence were excluded, but all the women in the control group were included, because they did not engage in continuous PFMT. The reduction in the LH area at rest was significantly larger by 4.43% in the training group than in the control group (19.90% vs. 15.49%; 95% CI 1.09–7.54, p = .011). The difference between groups in the relative reduction remained significant for the LH area during contraction (p = .001). Moreover, the LH area during contraction at 5 months postpartum was significantly smaller in the training group than in the control group (p = .024). On the other hand, the difference in the relative reduction in LH area during Valsalva maneuver remained statistically insignificant (p = .054). No adverse effects were reported by the training group.

TABLE 3 Levator hiatus measurements before and after home PFMT and the differences in the changes between two groups (per protocol)

Variable	1 month postpartum (cm^2)			5 months postpartum (cm^2)			Absolute change (cm^2)[a]			Relative change (%)[b]				
	Training group (n = 36)	Control group (n = 45)	p value[c]	Training group (n = 36)	Control group (n = 45)	p value[c]	Training group (n = 36)	Control group (n = 45)	p value[c]	Training group (n = 36)	Control group (n = 45)	Difference between groups	95% CI	p value[c]
LH area														
At rest	14.56 (13.31–16.83)	15.39 (13.40–16.63)	.648	11.67 (10.54–12.94)	12.74 (11.20–13.90)	.058	3.07 (2.21–4.07)	2.13 (1.52–3.37)	.034	19.90 (16.34–25.14)	15.49 (11.51–19.93)	4.43	1.09 to 7.54	.011
During contraction	13.38 (11.92–14.23)	13.32 (11.60–14.85)	.932	10.02 (9.22–11.46)	10.88 (9.98–12.58)	.024	2.72 (2.06–3.57)	2.04 (1.37–2.95)	.010	20.19 (16.74–26.72)	16.28 (12.03–19.36)	5.06	1.91 to 8.71	.001
During Valsalva	17.99 (14.47–20.64)	18.10 (15.07–21.96)	.985	13.78 (11.92–15.93)	14.52 (12.41–16.53)	.321	3.92 (2.49–5.15)	2.89 (1.79 -4.30)	.090	21.80 (14.67–27.15)	16.29 (11. 89–22.85)	4.35	−0.08 to 8.58	.054

Note: This per protocol analysis was carried out based on women in the training group who had high adherence (n = 36) and all women in the control group (n = 45). Data are presented as median (interquartile range).

Data are non-normally distributed.

Abbreviations: LH, levator hiatus; PFMT, pelvic floor muscle training.

[a]Absolute change is the value at 1 month postpartum minus the value at 5 months postpartum.

[b]Relative change is the absolute change divided by the value at 1 month postpartum.

[c]Mann–Whitney U test.

4 | DISCUSSION

According to the intention-to-treat analysis, our PFMT program did not reduce the postpartum LH area at rest; this result was probably accounted for by the participants who performed PFMT below our recommended protocol. In fact, in the subgroup with high adherence, the PFMT program significantly reduced the LH area at rest. This clearly indicated that postpartum PFMT itself was effective in reducing the LH area. In a previous report, supervised PFMT decreased the LH area at rest by 6.3% in middle-aged women who were diagnosed as having POP (Braekken et al., 2010). Our results, which were based on a population of postpartum women, supported the findings of that report and added information on the effect of PFMT on pelvic floor morphology. Expansion of the LH has been regarded as one of the risk factors for POP (Andrew, Shek, Chantarasorn, & Dietz, 2013; Dietz et al., 2008; Dietz et al., 2012). Therefore, the recommendation to perform at least three sets of home PFMT per day was reasonable to hasten the postpartum recovery of LH. However, it was not apparent from our study whether reducing postpartum LH area would actually be effective in preventing the bothersome symptoms of POP during later life. Thus, longer follow-up will be necessary to clarify this.

For women with low adherence to home PFMT, an additional strategy would be needed to enhance the effectiveness of this PFMT program. Indeed, previous reports showed that continued adherence was the key to enhance the training effectiveness (Kim, Yoshida, & Suzuki, 2011) and that intensive follow-up training by an instructor was more effective, compared with non-intensive PFMT (Bo, Hagen et al., 1990). In this study, follow-up instructions during the period of home PFMT were held twice, which were fewer than the instructions for the other intensive programs (Boyle et al., 2012; Soave et al., 2019). Some studies on PFMT effects considered a protocol with 1-weekly supervised session as an intensive program (Soave et al., 2019). Therefore, closer follow-up may be desirable to maximize the effect of a PFMT program (Bo, Hagen et al., 1990; Morkved & Bo, 1997). However, going outside can be difficult for postpartum women who are engaged in constant baby care. In fact, in this study, 23% of the women in the training group never attended the follow-up instructions. Therefore, increasing the participation in follow-up instructions should be the priority. According to a previous web-based survey, the environmental conditions (e.g., distance to the venue, time of the day, and presence of a baby-sitting service) of the instruction can greatly affect participation in a PFMT program (Moossdorff-Steinhauser et al., 2015). Therefore, mother-friendly plans, such as baby-sitting services and flexible choice of dates, should be considered so that postpartum women can easily access the follow-up instructions. In turn, this can improve the participation in the follow-up instructions and enhance adherence to PFMT.

For the secondary outcomes, we found that the LH area during contraction consistently decreased more in the training group than in the control group. The LH area during contraction reflected PFM strength better than did the LH area at rest, and it was shown to significantly correlate with PFM strength (Bo et al., 2014). Therefore, we considered that the enhanced PFM strength through PFMT resulted in consistently larger reduction in LH area during contraction in the training group than in the control group. In contrast, the reduction in LH area during Valsalva maneuver did not significantly differ between the groups, probably because the intensity of the maneuver can largely differ among women. In fact, some women in this study hesitated to perform a strong Valsalva maneuver, despite the researcher's encouragement. These individual technical variations made it difficult to detect a difference between groups. Therefore, a study that controls the Valsalva maneuver may detect the difference in the LH area during Valsalva maneuver between the groups. In addition, regarding the measurements during contraction, a significant difference between groups was observed in the relative reduction and also in the LH area at 5 months postpartum on per-protocol analysis. Therefore, we considered that a larger population may have shown this difference in the LH area at rest and during Valsalva maneuver. Therefore, further studies are needed.

As far as we can ascertain, very few researchers have measured the LH area before and after postpartum PFMT. The strengths of this study included the longitudinal comparison design; the low dropout rate; the use of ultrasonography measurements, which has been shown to have good intrarater and interrater reliability; and the clinical acceptance of this program. This program was principally based on self-training. Furthermore, education on correct PFM contraction was performed at approximately 36 gestational weeks and at 1 month postpartum, when vaginal examinations are routinely scheduled at several hospitals in Japan. Therefore, it can be easily incorporated into routine clinical practice. Another advantage was the lack of continuous PFMT in the control group, which made it easy for us to detect the effectiveness of PFMT.

4.1 | Limitations

Several limitations of this study have to be acknowledged. This study did not perform random assignment of participants to the training and control groups. Therefore, some undetected selection bias or potential confounding factors may have affected the results. The second limitation was about blinding; the entire procedure of data collection (recruitment, intervention, and measurements) was conducted by the same researcher/assessor who was not blinded to the allocation. Third, data collection was undertaken at a single clinic that values natural delivery, wherein low-risk pregnant women were registered and were provided continuous careful management. Therefore, the incidence of cesarean section in our population was very low. Moreover, the participants were healthy pregnant women who were in good enough physical and mental condition to undergo a PFMT program. Only few cases had obstetric causes of additional LH expansion, such as operational delivery by forceps or vacuum (Krofta, Otcenasek, Kasikova, & Feyereisl, 2009; Shek & Dietz, 2009, 2010). Therefore, our results can be generalized only to healthy women who are expected to undergo natural delivery.

5 | CONCLUSIONS

Although our PFMT program did not significantly reduce the postpartum LH area at rest, performance of at least three sets of home PFMT in 1 day for 16 weeks significantly reduced the LH area at rest by 4.43% and had a positive effect on the recovery of pelvic floor morphology.

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DISCLOSURE

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AUTHOR CONTRIBUTIONS

All authors were involved in the research concept and study design. S.T. was in charge of whole data collection, data analysis, and drafting the manuscript. Y.K. and T.T. contributed to supervising the whole study process and revising the manuscript critically for important intellectual context. All authors read and approved the final manuscript.

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