

Randomized Controlled Trial of Physiotherapy for Postpartum Stress Incontinence: 7-Year Follow-Up

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Objective: To estimate the long-term effect of intensive, 6-week physiotherapy programs, with and without deep abdominal muscle (TrA) training, on persistent postpartum stress urinary incontinence (SUI). **Methods:** The study was a single-blind randomized controlled trial. Fifty-seven postnatal women with clinically demonstrated persistent SUI 3 months after delivery participated in 8 weeks of either pelvic floor muscle training (PFMT) (28) or PFMT with deep abdominal muscle training (PFMT + TrA) (29). Seven years post-treatment, 35 (61.4%) participants agreed to the follow-up; they were asked to complete a 20-min pad test and three incontinence-specific questionnaires with an assessor blinded to each participant's group assignment. **Results:** Of the 35 (61.4%) who agreed to the follow-up: 26 (45.6%) took the 20-min pad test (12 PFMT and 14 PFMT + TrA) and 35 (61.4%) completed the questionnaires (18 PFMT and 17 PFMT + TrA). The baseline clinical characteristics of the follow-up and non-follow-up participants were not significantly different; nor did they differ between PFMT and PFMT + TrA participants enrolled in the follow-up study. At 7 years, the pad test scores for the PFMT group did not differ statistically from those of the PFMT + TrA group. When combining both treatment groups, a total of 14/26 (53%) follow-up participants were still continent according to the pad test. **Conclusion:** The addition of deep abdominal training does not appear to further improve the outcome of PFM training in the long term. However, benefits of physiotherapy for postpartum SUI, although not as pronounced as immediately after the initial intervention, is still present 7 years post-treatment. *NeuroUrol. Urodynam.* 32:449–454, 2013. © 2013 Wiley Periodicals, Inc.

Key words: pelvic floor; physiotherapy; postpartum; rehabilitation; stress urinary incontinence

INTRODUCTION

Stress urinary incontinence (SUI) is an important health issue affecting up to 38% of premenopausal parous women.^{1,2} Those women who develop SUI during pregnancy or puerperium, without remission 3 months after delivery, have a high risk of symptom persistence 5 years later.³ Thus, special attention should be paid to this high-risk subgroup.

Three randomized controlled trials have focused on pelvic floor muscle (PFM) physiotherapy training as a treatment for persistent postpartum SUI.^{4–6} Pooled data from the three controlled trials suggests that PFM-trained women were significantly less likely to be urinary incontinent 6–12 months following delivery (about 20% less; RR 0.79, 95% CI: 0.70–0.90).⁷ The effect was greater in our trial (Dumoulin et al.)⁶ as compared to those of Glazener's⁵ and Wilson's⁴ in which the postpartum women received a less intensive intervention (i.e., more home vs. clinic based electrical stimulation and PFM training program) and had fewer contacts with the health professionals (three to four visits over a 6-month period vs. a weekly visit throughout an 8-week intensive intervention).

Although the effectiveness of PFM training has been demonstrated in the short term,⁷ it is unclear if the results can be maintained over time or subsequent to further deliveries. Only one of the three trials has looked at long-term continuity

of the effect.⁸ In a 6-year follow-up study to the initial index delivery study, Glazener et al.⁸ found no differences in the prevalence of urinary incontinence between the PFM-trained women and the control group that had received standard postnatal care (which included a brief description on pelvic floor exercises). However, Glazener's study included a less intensive PFM intervention and fewer patient and health professional contacts, which might have influenced the long-term efficacy.

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Additionally, based on cohort studies that indicate transversus abdominis muscle (TrA) contractions increase intra-vaginal pressure⁹ and induce bladder neck elevation,¹⁰ indirect training of the PFM via the TrA has been advanced as a new stand alone or combined treatment method for SUI in women.^{11,12} However, according to recent systematic reviews, there has only been one randomized control trial on SUI in women investigating the effect of TrA training alone, for which the results were inconclusive, and only one randomized control trial, our 2004 study,⁶ comparing the addition of TrA training to PFM training.^{13,14} The 2004 study compared PFM training with and without the addition of TrA training, applying the same amount of contraction time, frequency of training, and therapist sessions to each intervention group.⁶ In the short term, we found both interventions to be effective in treating SUI in women, but there was no significant additional effect from adding TrA to PFM training.⁶ However, the impact on the sustained long-term effect remained in question.

Thus, the aim of this study was to evaluate the long-term effect of an intensive 8-week physical therapy program of PFM training with and without the addition of TrA training on persistent postpartum SUI, 7 years post-treatment.

MATERIALS AND METHODS

Initially, women were recruited from 2001 to 2002 at Sainte-Justine Hospital's obstetrics clinic during their annual gynecological visit. All had SUI symptoms as defined by the International Continence Society¹⁵: one urinary incontinence episode at least once a week, 3 months or more after their last delivery. Women were excluded if they had SUI onset prior to pregnancy or delivery, previous surgery for SUI, a neurological or psychiatric disease or a major medical condition, or took medication that could interfere with their evaluation or treatment. Women were also excluded if they were pregnant, had a moderate to severe urogenital prolapse (Pelvic Organ Prolapse Quantification System stage II or higher),¹⁶ involuntary detrusor contractions during cystometry, and could not understand French or English instructions. A balanced block randomization schedule generated from a table of random numbers was used to achieve stratified randomization.¹⁷ Participants were stratified into three groups based on parity (primipara and multipara) and the severity of incontinence—based on pad test results (5–10 g and more than 10 g of leakage on pad test).¹⁸ A research investigator not involved in any of the interventions or outcome assessments told the women which group they were assigned to; evaluators and clinicians involved in the treatment groups had no access to the randomization procedure. Additionally, the evaluators were also blinded to the group allocations (they were kept from knowing to which group subject were assigned) and women were asked not to reveal their group allocation to evaluators.⁶

Women were allocated to a control group (8 weekly sessions of relaxation massage for the back and extremities with a physiotherapist) or to 8 weeks of PFM training with or without TrA training. Physical therapy sessions for the PFM training group consisted of a 15-min period of electrical stimulation followed by 25 min of PFM exercises. The PFM + TrA training group received an additional 10-min session of deep abdominal muscle exercises. In addition to a weekly physical therapy session throughout the 8-week period, both groups had either a PFM program with or without abdominal exercises to follow at home, once a day, 5 days a week.⁶ The primary outcome measure consisted of a modified 20-min pad test.¹⁸ The secondary outcome measures included a Visual Analog Scale (VAS—describes how the respondent perceives the

burden of incontinence),¹⁹ the Urogenital Distress Inventory (UDI),^{20,21} the Incontinence Impact Questionnaire (IIQ),^{20,21} and measurements of PFM function.²² Complete study methods, detailed interventions, and post-treatment outcomes were reported previously.⁶

Out of 64 women recruited, 62 completed the first phase of the randomized control trial. Post-treatment, more than 70% (31/43) of the women in the two treatment groups, 14/20 in the PFM training and 17/23 in the PFM + TrA training, were continent on pad testing compared with 0% (0/19) of women in the control group. The scores for the pad test, VAS, UDI, and IIQ improved significantly in both treatment groups (all $P < 0.002$), whereas no changes were observed in the control group.

Relying on these results and on the seminal work of Viktrup et al., which shows that women who develop SUI during pregnancy or puerperium without remission 3 months post-delivery have a 95% risk of symptom persistence 5 years later,³ we believed that for the majority of the women in the control group the incontinence burden would not have declined over time without an intervention. Ethically, we believed that the continued denial of treatment to this group would have served no scientific purpose. Participants from the control group (15 of the 19) were thus re-randomized to one of the treatment groups. In all, 57 postnatal women participated in 8 weeks of PFM training: 28 without and 29 with TrA training.

The results from the second phase of the randomized control trial confirmed the initial results with a 76% cure rate in the PFM training group and 77% in the PFM + TrA group. No additional effects from adding TrA exercises to the training were noted. The final study results were reported previously.⁶

Seven years post-treatment, and subsequent to the approval of Sainte-Justine Hospital's ethics committee, the participants were invited, by telephone, to participate in a follow-up study. If their telephone number was no longer valid, up to date numbers were obtained from the participant clinical file or a search of the internet phonebook. After providing written, informed consent, a urology nurse, who was unaware of the participants' original treatment allocations, asked the women to complete the same outcome measure as in the initial trial: the modified 20-min pad test with standardized bladder volume¹⁷ and the three incontinence-specific questionnaires, that is, the UDI, IIQ, and VAS.^{19,20,21}

The modified 20-min pad test is a urine-loss quantification method based on the measurement of weight gain in an absorbent sanitary pad during a test period under standardized conditions;¹⁸ in this study, the standard test was modified by substituting 10 jumping jacks for the standard jumping exercises.⁶ As for the initial randomized controlled trial, participants with pad weight-gains of <2 g were considered continent.¹⁸ Construct validity and test-retest reliability of the modified 20-min pad test have been demonstrated in reference to the target population of our study.¹⁸

Secondary outcomes comprised three questionnaires.^{19,20,21} Assessment of the symptoms associated with SUI utilized the French and English versions of the UDI, a 19-item questionnaire on lower urinary-tract symptoms.^{20,21} Assessment of the psychological impact of urinary incontinence utilized the French and English versions of the IIQ: the 26 items focus on daily living, social interactions, sex life and self-perception.^{20,21} Higher scores for these questionnaires indicate worse conditions.^{20,21} Both questionnaires have acceptable levels of reliability, validity, and responsiveness, and have been used in several clinical trials.^{20,21} Finally, the participants' perceived burden of incontinence was evaluated using a VAS,¹⁹ which

has proven to be valid, reproducible and responsive to treatment for urinary incontinent women.¹⁹

For the statistical analysis, a Mann–Whitney’s *U*-test was used to compare follow-up participants to non-follow-up participants in regard to baseline characteristics [age, body mass index (BMI), parity, and severity of symptoms at the start of the initial study]. Then, the outcome measures at the 7-year follow-up for both follow-up training groups were compared using the Mann–Whitney’s *U*-test. Finally, the results for both follow-up groups were combined to compare three conditions: baseline, post-treatment and 7-year follow-up scores for all four outcome measures. A non-parametric Friedman rank (*Fr*) test for multiple comparisons between conditions was used and if the obtained *Fr* value was significant, that is, one of the conditions differed from at least one other condition, a simple post hoc procedure was used to evaluate how many conditions differed from each other. Two-sided *P*-values <0.05 were considered significant. All analyses were performed using SPSS 11.0 (SPSS, Inc., Chicago, IL).

RESULTS

At the 7-year point, 35 (61.4%) of the 57 participants who had completed the initial study agreed to the follow-up, of which 26 (45.6%) took the modified 20-min pad test (12 from the PFM training and 14 from the PFM + TrA training) and 35 (61.4%) completed the questionnaires (18 from the PFM training and 17 from the PFM + TrA training). Among the 22 who did not participate, 10 had changed phone numbers, 11 did not want to participate for various reasons (e.g., one had moved; others had family problems or were too busy with

family or work). The flow of participants through each phase of the randomized control trial is presented in Figure 1.

The baseline clinical characteristics (i.e., age, parity, BMI, symptom severity) of the follow-up participants as compared to those of the non-participants were not significantly different; nor did they differ between the PFM-trained and PFM + TrA-trained participants enrolled in the follow-up study, except in the IIQ pretreatment values (*P* = 0.029). These results are presented in Tables Ia, Ib, and II. Parity was unchanged for 85.7% (30/35). Five women had had at least one further delivery (two in the PFM training group and three in the PFM + TrA training group): four had given birth one more time and one woman twice. Because of the difference in the baseline characteristics for IIQ scores, outcome-measure comparisons between PFM training and PFM + TrA training at 7 years was calculated for the pad test, UDI, and VAS only. The medians of PFM-trained group and PFM + TrA-trained group for Pad tests, UDI and VAS scores are presented in Table II. At 7 years, there was no significant effect of group (PFM-trained group were not statistically different than those of the PFM + TrA-trained group) *P* > 0.10. The effect size of the Mann–Whitney’s *U*-test was small to medium at *r* = 0.11.

When combining both treatment groups, at 7 years, a total of 53% (14/26) of the participants were still continent according to the modified pad test. Importantly, 63.2% (12/19) of the women who participated in the follow-up study and who were continent immediately after the initial intervention were still continent. Incontinence-specific signs as measured by the modified pad test, the VAS (incontinence burden) and the IIQ (quality of life) were significantly lower than pretreatment measurements. Incontinence symptoms, as measured

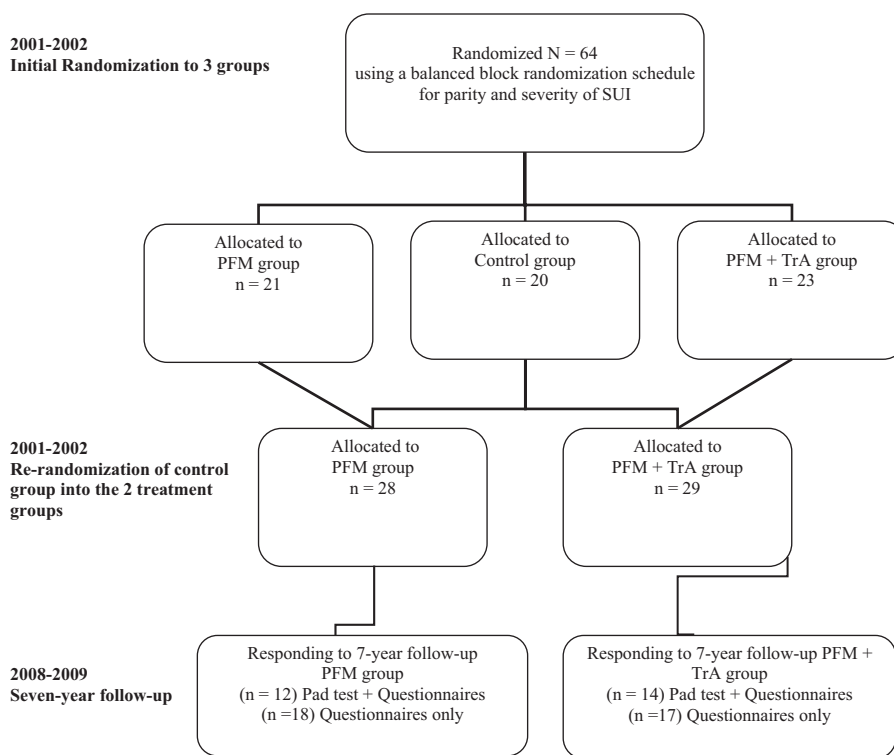


Fig. 1. Trial profiles showing the flow of participants through each stage of the randomized trial comparing PFM and PFM + TrA training groups.

TABLE Ia. Baseline Clinical Characteristics of Responders and Non-Responders at Entry (3 Months and More After Delivery)

	Responders (N = 35)	Non-responders (N = 22)	Mann-Whitney's <i>U</i> -value ^a	<i>P</i> -value ^a
Age (years)	36 (33–39)	36.5 (34–39)	353.00	0.59
Parity	2 (2–3)	2 (1.5–2)	384.00	0.76
Body mass index	22.60 (20.81–24.80)	23.82 (22.16–26.09)	304.00	0.18

Data presented as medians with 25th and 75th percentiles in parentheses.

^aMann-Whitney's *U*-test.

TABLE Ib. Baseline Clinical Characteristics of PFMT Group and PFMT + TrA Group at Entry (3 Months and More After Delivery) and at 7-Year Follow-Up

	PFMT Group Entry (N = 28)	PFMT + TrA Group Entry (N = 29)	Mann-Whitney's <i>U</i> -value ^a	<i>P</i> -value ^a	PFMT subgroup 7 years (N = 18)	PFMT + TrA subgroup 7 years (N = 17)	Mann-Whitney's <i>U</i> -value ^a	<i>P</i> -value ^a
Age (years)	36.00 (33.00–39.00)	36.00 (34.00–39.00)	431.00	0.69	42.00 (39.75–45.25)	44.00 (41.00–46.00)	181.50	0.34
Parity	2.00 (2.00–3.00)	2.00 (1.50–2.00)	431.50	0.37	2.00 (2.00–3.00)	2.00 (2.00–3.00)	129	0.56
Body Mass Index	24.15 (22.52–26.07)	22.29 (20.54–25.19)	284.00	0.06	25.00 (21.60–28.00)	21.00 (20.55–25.75)	91.50	0.07

Data presented as medians with 25th and 75th percentiles in parentheses.

^aMann-Whitney's *U*-test.

by the UDI, were also lower than at pretreatment, but did not reach significance. Baseline comparisons of the combined treatment groups for all outcome measures, post-treatment and at the 7-year follow-up, are presented in Table III.

Finally, only 13 of the 35 follow-up participants reported that they continued to do PFM exercises regularly. Noteworthy, at 7 years, 69% (9/13) of those still doing the PFM exercises were continent on pad testing.

DISCUSSION

Seven years after an intensive 8-week physical therapy program for persistent postpartum SUI, there were still no statistically significant differences between the PFM training and PFMT + TrA training interventions as measured by the modified pad test, UDI and VAS scores, even among those who had not had a further pregnancy. When combining both treatment groups, one woman out of two was continent according to pad testing. Incontinence-specific signs, symptoms, and quality of life remained significantly better than pretreatment, although, not as good as immediately after treatment. Notably, two-thirds of those women who were continent immediately after treatment remained continent at 7 years.

Strengths and Weakness

The non-response rate at 7 years was around 40%. However, responders from both groups were similar to non-responders in terms of age, parity, BMI, and urinary incontinence severity at baseline. The original study was powered with the modified pad test as a primary outcome measure to provide 80% power to detect a statistically significant group-by-time-interaction at the 0.05 significance level if the active treatments (PFMT + TrA) induced medium to large effect sizes. Although it was not possible to rule out a Type II error, due to the small follow-up sample size, the results immediately after the intervention for the primary outcome measures in addition to those of the post-treatment and the 7-year follow-up, and results for the secondary outcome measures support the finding of no difference between the two groups, PFM and PFMT + TrA.

The PFM-training intervention effect was still present, although reduced after 7 years. This was not unexpected, particularly given the fact that only 54% (19/35) of the participants continued to practice PFM exercises regularly. The effect might have persisted in more participants if there had been greater adherence to the PFM exercise regime, perhaps

TABLE II. Primary and Secondary Outcome Measure of PFMT Group and PFMT + TrA Group at Entry (3 Months and More After Delivery) and at 7-Years Follow-Up

	PFMT subgroup entry (N = 18)	PFMT + TrA subgroup entry (N = 17)	Mann-Whitney's <i>U</i> -value ^a	<i>P</i> -value ^a	PFMT subgroup 7 years (N = 18)	PFMT + TrA subgroup 7 years (N = 17)	Mann-Whitney's <i>U</i> -value ^a	<i>P</i> -value ^a
Pad test (g)	13.00 (7.00–34.00)	10.00 (6.00–48.00)	146.00	0.82	2.50 (0.25–17.25), N = 12	2.00 (1.00–6.00), N = 14	79.5	0.82
VAS (/10)	8.00 (6.75–8.00)	7.00 (4.50–8.00)	112.00	0.16	5.50 (3.75–7.00)	3.00 (1.00–7.00)	108.00	0.13
UDI (/57)	12.00 (10.00–13.25)	10.00 (6.5–13.50)	112.50	0.18	9.00 (6.75–15.50 10 (7–15))	7.00 (2.00–12.5) 6 (2–10)	105.00 91.50	0.10 0.05
IIQ (/90)	26.00 (16.75–41.00)	14.00 (3.00–28.00)	87.00	0.03	–	–	–	–

VAS, Visual Analog Scale; UDI, Urogenital Distress Inventory; IIQ, Incontinence Impact Questionnaire.

Data presented as medians with 25th and 75th percentiles in parentheses.

^aMann-Whitney's *U*-test.

TABLE III. Comparison of the Combined Treatment Groups Between Entry, Post-Treatment and 7-Year Follow-Up

	Combined group			Friedman rank test	Post hoc comparisons
	At entry	Post-treatment	7-Year follow-up		
Pad test, g (n = 26)	10 (7–32)	1 (0–3)	2 (1–9)	32.49*	E-PT** E-F** PT-F**
UDI (n = 35)	11 (8–13)	5 (2–9)	7 (6–14)	17.96*	E-PT** E-F PT-F
IIQ (n = 35)	24 (11–35)	8 (1–13)	11 (3–24)	30.24*	E-PT** E-F** PT-F**
VAS (n = 35)	7 (6–8)	3 (1–6)	5 (2–7)	23.40*	E-PT** E-F** PT-F

Data presented as medians with 25th and 75th percentiles in parentheses.

Friedman rank test post hoc comparisons E = Entry; PT = post-treatment; F = 7-year follow-up.

* $P \leq 0.05$.

** $P \leq 0.01$.

through reinforcement or reminders; however, this hypothesis needs to be tested in a controlled trial.

In spite of the worsening of all outcomes measures at the 7-year follow-up point, as compared to those taken immediately after treatment, the modified pad test, IIQ and VAS outcomes were still significantly better than the baseline measures. This contrasts with Glazener's study where a moderate short-intervention effect was no longer present in the long term.⁸ Many factors might explain the differences in the short- and long-term follow-up effects between Glazener's study and ours; of which, close supervision by a trained professional, the use of weekly electrical stimulation and the addition of biofeedback to the PFM training program used in our study may be the defining factors, contributing to greater initial improvement as well as the long-term effect.⁶ Other studies have found that PFM exercises conducted under the close supervision of a trained professional have proven more effective than those performed at home.^{23,24} Additionally, the use of biofeedback in conjunction with PFM training has also been shown to enhance the effect of PFM training.²⁵

To date, our study is the longest follow-up study of a post-natal SUI treatment trial. Although more favorable to the PFM than the PFM + TrA training, the limitations of this study in relation to its design (per protocol follow-up design vs. intention to treat), the sample size and the absence of covariate analysis (other than a further pregnancy and PFM practice) confirm the need for a larger randomized control trials with built-in long-term follow-ups.

According to our follow-up randomized control trial, the addition of deep abdominal (TrA) training does not appear to improve the long-term outcome of PFM training. The small follow-up participant sample size at 7 years and the small to medium effect size of our statistical tests are recognized as important study limitations. Using our data, we calculated using G*power 3.1.2. that a sample size of 366 women (183 in each group) would be required to compare groups with a large effect size ($\alpha = 5\%$, power 80%). Therefore, further research with larger groups would be required to compare the short- and long-term impact of these two PFM training programs. A large and costly trial may not be the best use of research funds, particularly as the difference in outcomes between two active treatments is expected to be small.

However, of greater interest, the benefits derived from physical therapy for persistent postpartum SUI, although not as pronounced as immediately after the initial intervention, seem to continue 7 years post-treatment in follow-up participants for both groups, particularly in those women who continue to adhere to the PFM exercise regime. Further research with larger groups is required in order to study whether and how post-treatment benefits can be maintained in the long term.

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