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Research

Pelvic floor muscle training increases pelvic floor muscle strength more in post-menopausal women who are not using hormone therapy than in women who are using hormone therapy: a randomised trial

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KEY WORDS

Menopause hormone therapy
Physical therapy
Pelvic floor muscle
Exercise
Urinary incontinence

ABSTRACT

Question: Are there differences in the effectiveness of pelvic floor muscle training on pelvic floor muscle strength and urinary incontinence symptoms in postmenopausal women who are and are not using hormone therapy? **Design**: Randomised, controlled trial with concealed allocation, blinded assessors, and intention-to-treat analysis. **Participants**: Ninety-nine postmenopausal women, 38 of whom were using daily systemic oestrogen/progestogen therapy. **Intervention**: The experimental group (n = 51) received an intensive supervised pelvic floor muscle training protocol, and the control group (n = 48) received no intervention. The randomisation was stratified by hormone therapy use. **Outcome measures**: Change in pelvic floor muscle strength assessed with manometry at 12 weeks. Prevalence and severity of urinary incontinence symptoms were assessed using questionnaires. **Results**: Eighty-eight women provided data that could be included in the analysis. Pelvic floor muscle training increased pelvic floor muscle strength by 8.0 cmH_2O (95% CI 3.4 to 12.6) in women not using hormone therapy and by –0.9 cmH_20 (95% CI –6.5 to 4.8) in women using hormone therapy (interaction $p = 0.018$). A sensitivity analysis showed that the greater training effect in women who were not using hormone therapy was still apparent if the analysis was conducted on percentage change in strength rather than absolute change in strength. There was also a significantly greater effect of training in women not using hormone therapy on prevalence of urinary incontinence symptoms (ratio of odds ratios = 7.4; interaction $p = 0.028$). The difference in effects on severity of urinary incontinence symptoms was not statistically significant (interaction $p = 0.37$). **Conclusion**: Pelvic floor muscle training increases pelvic floor muscle strength more in women who are not using hormone therapy than in women using hormone therapy. **Trial registration**: ClinicalTrials.gov NCT02549729. **[Ignácio Antônio F, Herbert RD, Bø K, Rosa-e-Silva ACJS, Lara LAS, Franco MdM, Ferreira CHJ (2018) Pelvic floor muscle training increases pelvic floor muscle strength more in post-menopausal women who are not using hormone therapy than in women who are using hormone therapy: a randomised trial. *Journal of Physiotherapy* 64: 166–171]**

Introduction

Menopause may be accompanied by symptoms such as dyspareunia, bleeding during intercourse, urinary tract infection, urinary incontinence, and vasomotor symptoms including hot flushes with or without night sweats. After menopause, the decrease of oestrogen can affect the tissues that are responsive to this hormone.[1,2] The pelvic floor muscles (PFM), the vagina and the urinary tract have oestrogen, androgen and progesterone receptors.[1,3–5]

Menopausal symptoms are often treated with hormone therapy. Based on systematic reviews and according to the International Menopause Society,[6] menopause hormone therapy should be recommended in the presence of significant symptoms or oestrogen deficiency.[7,8] For vasomotor symptoms, oral hormone therapy is still considered to be the most effective therapy for women who do not have contraindications such as high risk of cardiovascular disease or breast cancer.[7,8]

A small trial has suggested that systemic combined hormone therapy could have a positive effect on urethral continence mechanisms and reduce urinary incontinence.[9] However, several large trials and systematic reviews have concluded that systemic hormone therapy does not reduce urinary incontinence and can even increase the risk of developing both stress and urgency urinary incontinence.[10–14] In contrast, many trials and systematic reviews have shown that PFM training can increase PFM strength and reduce the prevalence and severity of urinary incontinence.[15,16]

It has been suggested that oestrogen may play an important role in PFM function.[1,5] According to some authors, oestrogen therapy or

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combined therapy (oestrogen and progesterone) partially prevents age-related sarcopenia and may even restore muscle function lost during the onset of menopause.[17–19] The literature is scarce in relation to studies about PFM strength and systemic hormone therapy. A search in three databases (PubMed, LILACS and PEDro) revealed no randomised clinical trial comparing the effect of PFM training in postmenopausal women using and not using systemic hormone therapy. It is unclear whether hormone therapy modifies the effect of PFM training and if so, whether it enhances or reduces the effect.

Therefore, the research questions for this randomised, controlled trial were:

1. Are there differences in the effectiveness of PFM training on PFM strength in postmenopausal women who are and are not using hormone therapy?
2. Are there differences in the effectiveness of PFM training on prevalence and severity of urinary incontinence symptoms in postmenopausal women who are and are not using hormone therapy?

Method

Design

This was an assessor-blinded, randomised, controlled trial with concealed allocation and intention-to-treat analysis. The trial was registered on 1 September, 2015 and the first participant was randomised on 17 September, 2015. Women who met the eligibility criteria and consented to participation were stratified on use or non-use of hormone therapy and then randomised to PFM training or the control condition (no PFM training). Outcome measures were recorded at baseline at at the end of the 12-week intervention period.

Participants, therapist, centres

Participants were women, independent of their PFM strength and continence status, who had undergone menopause in the preceding 10 years and either: had been using daily systemic combined oestrogen/progestogen therapy (oestradiol 1 mg and norestiterone acetate 0.5 mg) for between 3 and 24 months; or had not used hormone therapy for $\geq$3 months. To be eligible, women also had to be able to contract their PFM and have not previously performed PFM training. Menopause was defined as cessation of menstrual cycles for $>$12 months.[20] Exclusion criteria were vasculopathy, diabetes mellitus, genital prolapse, neuropathy, thyroid disease, hyperprolactinaemia, and intolerance of or discomfort with PFM strength assessment (pain, gel allergy or other discomfort).

Before evaluation of the ability to contract the PFM, all the participants received information about the procedures, an explanation of the basic anatomy of the PFM, and instructions on how to correctly contract their PFMs.[21,22] Evaluation of the ability to perform a correct PFM contraction was conducted with women in the supine position with knees and hips in a flexed and abducted position, and with their feet on a bench. The first evaluation was performed by one of the examiners using digital palpation. Only women with a grade $\geq$1 on the modified Oxford grading scale were included.[23]

Recruitment and data collection were performed at the Health School Center of Ribeirão Preto Medical School of the University of São Paulo (FMRP-USP) and in the Rehabilitation and Hydrotherapy Center of Piumhi-MG.

Intervention

Experimental group

The intervention consisted of supervised physiotherapy sessions in groups of a maximum of four participants. The PFM training consisted of 10 maximal voluntary contractions maintained for at least 6 seconds. At the end of a set of 10 contractions, five rapid contractions were performed. The interval between contractions was 6 seconds. The sets were performed in four positions: lying in lateral decubitus, sitting, kneeling on all fours, and standing.[21,24] Two trained physiotherapists, who were not involved in the assessments, supervised the exercise sessions twice a week for 12 weeks.

Participants in the intervention group were also instructed to perform daily PFM training at home, except on the days of supervised training, following written instructions and they were asked to record frequency of training every week. Participants' adherence to supervised PFM training sessions was monitored by the physiotherapists. In the supervised sessions, participants were encouraged to continue home PFM training with appropriate intensity, frequency and duration. All women were re-evaluated 12 weeks after the first evaluation.

Control group

The control group did not receive any treatment or instructions to perform PFM training. However, after the study was completed women in the control group were invited to perform the same supervised PFM training protocol.

Outcomes measures

Primary outcome

The primary outcome was change from baseline to 12 weeks in PFM strength assessed with manometry[a]. For this assessment women were asked to perform three maximal voluntary contractions. The verbal instruction was to pull the PFMs in and up as strongly as possible, to hold for 6 seconds and then to relax completely. The peak value of the contraction was registered in cmH_2O. The rest interval between each contraction was 12 seconds. Only contractions with visible inward movement of the perineum were considered to be valid.[21,25] The mean of three maximal voluntary contractions was used in the analysis.[26]

Secondary outcomes

The International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) was used to evaluate prevalence and severity of urinary incontinence symptoms. This questionnaire was originally validated by Avery et al.[27] and translated and validated to Portuguese by Tamanini et al.[28] The ICIQ-UI SF questionnaire consists of six questions about urinary incontinence reports in the last 4 weeks. Three of the questions are scored. Question 3 is related to the frequency of urinary loss (0 = never, 1 = once a week or less, 2 = two or three times a week, 3 = once a day, 4 = several times a day, and 5 = all the time). Question 4 seeks to estimate the amount of urine the patient loses (0 = none, 2 = a small amount, 4 = a moderate amount, 6 = a large amount). Question 5 evaluates how much the urinary loss interferes in the woman's everyday life on a scale of 0 to 10, in which 0 represents not at all and 10 represents a great deal. From the answers obtained in Questions 3, 4 and 5, a total score is obtained that can vary from 0 to 21. Klovning et al.[29] classified scores as mild (1 to 5), moderate (6 to 12), severe (13 to 18), or very severe (19 to 21).

Randomisation

The randomisation procedure was conducted using computer-generated random numbers and participants were stratified on hormone therapy use. The list with the random numbers was kept with a secretary who was not involved with the research. A secretary not involved in recruitment or assessment performed the allocation of participants into control and PFM training groups. The allocation was revealed to assessors and assistant researchers after completion of the trial.

One physiotherapist with 9 years of clinical experience performed the first and second assessment of all participants. The first assessment was conducted prior to randomisation. Two assistant researchers recruited the participants and administered the questionnaires. When performing the clinical measurements, the physiotherapist and the two assistant researchers were blinded to the participants' allocations to the control or intervention groups and also to the participants' hormone therapy status. When performing the clinical measurements, the assessor was also blinded to the participants' answers on the questionnaire.

Data analysis

The effects of PFM training and the moderating effect of hormone therapy on the effect of PFM training were estimated using linear models that incorporated group (intervention or control), hormone therapy (user or non-user) and the group-by-hormone therapy interaction. Linear regression was used to estimate effects on change in PFM strength and severity of urinary incontinence symptoms, and logistic regression was used to estimate effects on prevalence of urinary incontinence. The effect of PFM training in each of the hormone therapy strata was obtained using the appropriate contrast. The moderating effect of hormone therapy on the effect of PFM training was given by the interaction. Effects were expressed as mean differences and their 95% confidence intervals. A sensitivity analysis was performed to adjust for baseline imbalances in the ICIQ score. Analysis was by intention to treat.

Results

Flow of participants through the study

Figure 1 presents the flow of participants through the study. Participants' characteristics are reported in Table 1. From these 99 women, a total of 38 (38%) were receiving hormone therapy at baseline. In the control group, 17/48 (35%) women were using hormone therapy compared to 21/51 (41%) in the experimental group. From the 99 randomised participants, 11 (four experimental and seven control) were unavailable for reassessment at 12 weeks and not included in the analysis. Reasons reported for unavailability included lack of time to perform the second evaluation and illness.

Table 1
Baseline characteristics of participants, and of the subgroups of the 38 participants using hormone therapy and the 61 participants not using hormone therapy.

Characteristics	Participants	Con (n = 48)	Exp (n = 51)
Age *(years)*, mean (SD)	All	53.1 (4.4)	52.9 (4.1)
	Using HT	53.6 (4.1)	53.4 (3.4)
	Not using HT	51.9 (4.9)	52.2 (4.9)
BMI *(kg/m^2)*, mean (SD)	All	28.3 (4.8)	28.5 (5.4)
	Using HT	28.8 (5.1)	28.4 (5.5)
	Not using HT	27.3 (4.1)	28.6 (5.5)
Gestations *(n)*, mean (SD)	All	2.8 (1.4)	2.7 (1.7)
	Using HT	2.7 (1.4)	2.8 (1.4)
	Not using HT	3.1 (1.4)	2.5 (2.1)
Caesareans *(n)*, mean (SD)	All	0.9 (1.1)	1.0 (0.9)
	Using HT	0.8 (1.0)	1.0 (1.0)
	Not using HT	1.1 (1.2)	1.0 (0.9)
Vaginal births *(n)*, mean (SD)	All	1.6 (1.6)	1.1 (1.4)
	Using HT	1.6 (1.5)	1.3 (1.6)
	Not using HT	1.5 (1.7)	1.0 (1.3)
HT use, n (%)	Yes	17 (35)	21 (41)
	No	31 (65)	30 (59)

Con = control group; Exp = experimental group; HT = hormone therapy.

Compliance with the trial protocol

Follow-up data were available for 88 women. Table 2 shows the adherence of the participants in the experimental group with the PFM training. Adherence to the PFM training protocol by participants in the experimental group was generally good.

Effects of PFM training

Data on PFM strength, prevalence and severity of urinary incontinence symptoms at baseline and 12 weeks are given in Table 3. Individual participant data are presented in Table 4, which is available on the eAddenda. At baseline, women using hormone therapy had stronger PFMs and a lower prevalence of urinary incontinence than women not using hormone therapy.

In the mixed population consisting of women with and without hormone therapy, PFM training increased PFM strength by a mean

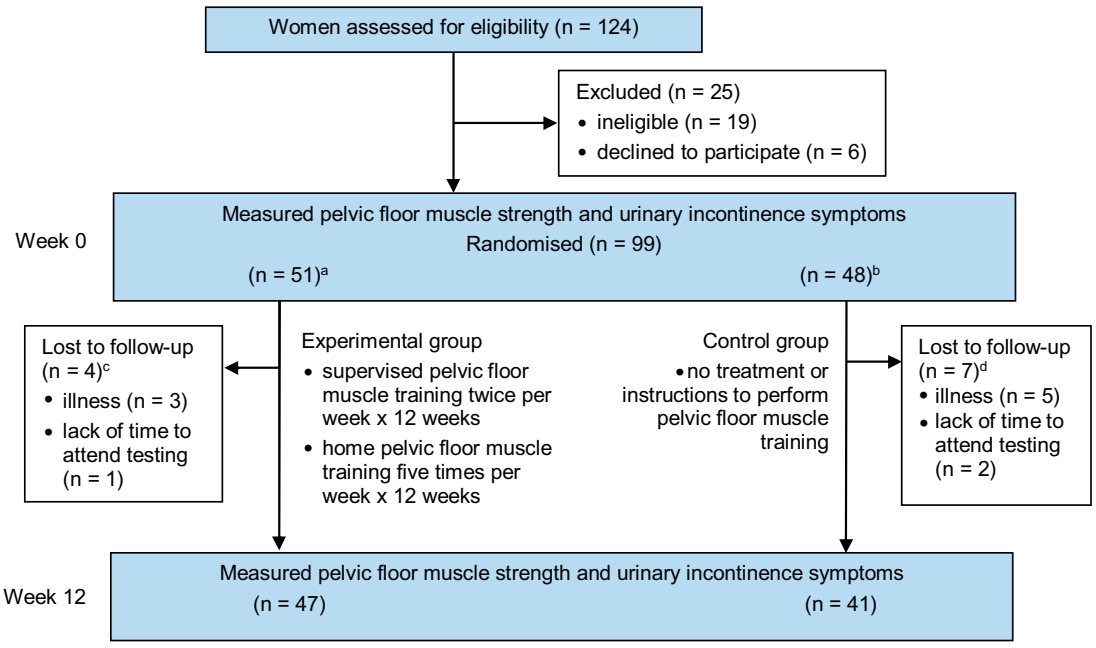

Figure 1. Design and flow of participants through the trial.
[a] 21 were using hormone therapy
[b] 15 were using hormone therapy
[c] 2 were using hormone therapy
[d] 1 was using hormone therapy

Table 2
Number (%) of participants meeting adherence categories for supervised pelvic floor muscle training sessions and home pelvic floor muscle training.

Training	Adherence category	PFM training with HT (n = 19)	PFM training without HT (n = 28)
Supervised	≥20 sessions	17 (89%)	23 (82%)
	15 to 20 sessions	2 (11%)	5 (18%)
	<15 sessions	0 (0%)	0 (0%)
Home	≥36 days	11 (58%)	16 (57%)
	25 to 36 days	7 (37%)	10 (36%)
	<25 days	1 (5%)	2 (7%)

HT = hormone therapy, PFM = pelvic floor muscle.

Table 3
Primary and secondary outcomes by group and subgroup.

Outcomes	Week 0				Week 12			
Participants	All (n = 88)	Exp (n = 47)	Con (n = 41)	*p*	All (n = 88)	Exp (n = 47)	Con (n = 41)	*p*[a]
PFM strength *(cmH_2O)*, mean (SD)								
All	37.4 (22.1)	38.5 (23.6)	36.1 (20.4)	0.61	41.5 (22.6)	44.7 (24.0)	37.8 (20.5)	0.02
Using HT	34.7 (22.1)	35.7 (24.6)	33.5 (19.5)	0.72	39.2 (23.2)	44.0 (25.5)	33.8 (19.5)	0.001
Not using HT	41.4 (21.6)	42.6 (22.0)	40.0 (21.8)	0.73	45.0 (21.3)	45.8 (22.2)	44.1 (21.0)	0.76
Prevalence of UI, n/N (%)								
All	47/88 (53.4)	21/47 (44.7)	26/41 (63.4)	0.09	42/88 (47.7)	17/47 (36.2)	25/41 (61.0)	0.02
Using HT	30/53 (56.6)	11/28 (39.3)	19/25 (76.0)	0.01	26/53 (49.1)	8/28 (28.6)	18/25 (72.0)	0.002
Not using HT	17/35 (48.6)	10/19 (52.6)	7/16 (43.8)	0.74	16/35 (45.7)	9/19 (47.4)	7/16 (43.8)	0.83
UI severity *(0 to 21)*, mean (SD)								
All	5.0 (5.6)	3.8 (5.0)	6.4 (6.0)	0.03	3.7 (4.8)	1.9 (2.9)	5.8 (5.7)	0.08
Using HT	5.2 (5.5)	3.0 (4.5)	7.6 (5.5)	0.001	3.8 (4.9)	1.3 (2.3)	6.7 (5.4)	0.43
Not using HT	4.7 (5.8)	5.0 (5.5)	4.4 (6.4)	0.76	3.5 (4.7)	2.7 (3.5)	4.4 (5.9)	0.08

HT = hormone therapy, PFM = pelvic floor muscle, UI = urinary incontinence.
[a] Significance of the between-group comparison (difference in mean change for PFM strength and UI severity, and odds ratio for prevalence of UI) at 12 weeks.

of 4.5 cmH_20 (95% CI 0.8 to 8.1, $p = 0.018$) and reduced the prevalence of urinary incontinence (OR 0.36, 95% 0.14 to 0.94, $p = 0.02$). The effect of PFM training on severity of urinary incontinence symptoms (mean increase of 1.4 points, 95% CI −0.2 to 3.0, $p = 0.08$) was not statistically significant.

The primary analysis examined the effect of PFM training on the groups of women who were and were not using hormone therapy, and tested whether the effect of PFM training differed across these two groups. PFM training increased the strength of women who were not using hormone therapy by a mean of 8.0 cmH_20 ($p = 0.001$), but had little or no effect (−0.9 cmH_20, $p = 0.76$) on women who were using hormone therapy (Table 5; Figure 2). The difference between the effects of PFM training in women who were and were not using hormone therapy was statistically significant ($p = 0.018$). A qualitatively similar interaction was still apparent ($p = 0.014$) if change in strength was expressed as percentage change in strength rather than absolute change in strength.

Secondary analyses showed that PFM training greatly reduced the prevalence of urinary incontinence amongst women who were not using hormone therapy (OR 0.16; $p = 0.002$), but had little effect on women who were using hormone therapy (OR = 1.2, $p = 0.83$). The interaction was statistically significant ($p = 0.028$). PFM training did not reduce severity of urinary incontinence in women using hormone therapy (mean change −2.3, $p = 0.08$) and in women not using hormone therapy (−0.8, $p = 0.43$). This interaction was not statistically significant ($p = 0.37$).

Adjusting for baseline imbalances in ICIQ score had little effect on the estimated effects on strength and the interaction remained significant ($p = 0.035$) but reduced the magnitude of the interaction effect on urinary incontinence prevalence to the extent that the effect became statistically non-significant ($p = 0.68$).

Discussion

The primary aim of the present study was to evaluate and compare the effects of PFM training on PFM strength in postmenopausal women using and not using hormone therapy. The study found that 12 weeks of PFM training produced significant increases in PFM strength. There was a large effect in the group not using hormone therapy but no evidence of an increase in strength in women using hormone therapy. There was also a statistically significant effect of PFM training on prevalence of urinary incontinence in the whole population. It was not clearly demonstrated that the effect of PFM training on urinary incontinence prevalence or on severity of urinary incontinence symptoms was superior in women not using hormone therapy.

The present study appears to be the first randomised, controlled trial to specifically investigate the effect of a PFM training intervention on PFM strength and urinary incontinence in postmenopausal women using and not using combined systemic hormone therapy. Other strengths of the study included the: randomised design; allocation concealment; use of experienced and blind assessors; use of reliable, responsive and valid methods to evaluate both PFM strength and urinary incontinence; high adherence to the PFM training protocol; and few losses to follow-up.

One important limitation was that the PFM training and control groups were not balanced at baseline with respect to urinary incontinence prevalence and severity of urinary incontinence symptoms. When the analyses were adjusted using the baseline scores of the ICIQ-SF, the differences in effects of PFM training for women using and not using hormone therapy on prevalence of urinary incontinence symptoms disappeared. However, differences in effects of PFM training for women using and not using hormone therapy on PFM strength were still statistically significant. Thus, the interaction between hormone therapy and group was robust for the strength outcome, but not for the urinary incontinence outcome.

Strength training has been shown to increase the number of satellite cells in muscles of young and postmenopausal women, preserving and improving muscle mass and function.[30,31] The current study sustained an intensive PFM training protocol

Table 5
Effect of pelvic floor muscle training by group and subgroup.

Outcome	Participants	Effect (95% CI)[a]	*p* interaction[b]
Change in PFM strength *(cmH$_2$O)*	All	4.5 (0.8 to 8.1)	0.018
	Using HT	8.0 (3.4 to 12.6)	
	Not using HT	−0.9 (−6.5 to 4.8)	
Prevalence of urinary incontinence	All	0.36 (0.14 to 0.94)	0.028
	Using HT	−0.16 (0.05 to 0.52)	
	Not using HT	1.20 (0.30 to 4.40)	
Change in severity of urinary incontinence *(0 to 21)*	All	−1.4 (−3.0 to 0.2)	0.372
	Using HT	−0.8 (−2.9 to 1.3)	
	Not using HT	−2.3 (−4.9 to 0.2)	

Con = control group, Exp = experimental group, HT = hormone therapy, PFM = pelvic floor muscle.
[a] For change in PFM strength and severity of urinary incontinence, effects are mean differences between the experimental and control groups. For prevalence of UI, effects are odds ratios.
[b] The *p*-value for the interaction tests the hypothesis that the effect of PFM training differs in women with and without HT.

for 12 weeks, and obtained high adherence of the participants; both these factors (duration of the training program and adherence to the training protocol) influence the efficacy of PFM training.[16] Several randomised trials have showed an improvement in PFM function in postmenopausal women after PFM training;[32–36] however, none of these studies assessed the interaction of the effects of training with hormone therapy. Most of these studies included only incontinent women, whereas the current study included continent and incontinent postmenopausal women.

Literature on the effects of hormone therapy on PFM and urinary incontinence is sparse and the results are conflicting. Some authors have reported that hormone therapy can improve muscle mass, including the mass of PFMs;[37,38] however, none of these studies had randomised controls. One randomised, controlled trial in postmenopausal women did not find an independent effect of hormone therapy in improving general muscle strength, and a retrospective study that explored the effects of menopause and hormone therapy on urinary incontinence found that using hormone therapy was positively associated with symptoms of nocturia, urgency urinary incontinence, and low urethral pressure.[39,40]

The main indications for prescribing hormone therapy for postmenopausal women are moderate to severe hot flushes, vaginal dryness, fatigue, irritability, sleep disturbance, and depression. A limitation of the current study was that there was no information about use of antidepressants and vaginal topical oestriol for these symptoms prior to the study, and no information about the use of antidepressants during the study. It is plausible that symptoms in women using hormone therapy could affect adherence to PFM training, but adherence was similar in the groups using and not using hormone therapy.

The mechanism by which systemic combined hormonal therapy could influence the prevalence of urinary incontinence is not well established. Two high-quality randomised, controlled trials and a systematic review have indicated that hormone therapy increases the risk of both stress and urgency urinary incontinence.[41–44]

Regarding topical oestrogen treatment, a systematic review demonstrated that this might cure or improve urinary incontinence.[44] Two small randomised trials showed that PFM training was more effective than topical oestrogen treatment for stress urinary incontinence.[45,46] It is not well known why topical treatment would be more effective than systemic hormone therapy, but this may be related to the fact that topical oestrogen can be used as an isolated active component and might not be delivered with other hormones that could worsen urinary incontinence symptoms. Future larger studies should investigate the impact of topical hormone therapy associated with PFM training on muscle mass and urinary incontinence.

This study concluded that in postmenopausal women, PFM training increases PFM strength more in women not using hormone therapy than in women using hormone therapy. More high-quality randomised trials are required to confirm whether PFM training produces greater reductions in urinary incontinence in postmenopausal women who do not use hormone therapy.

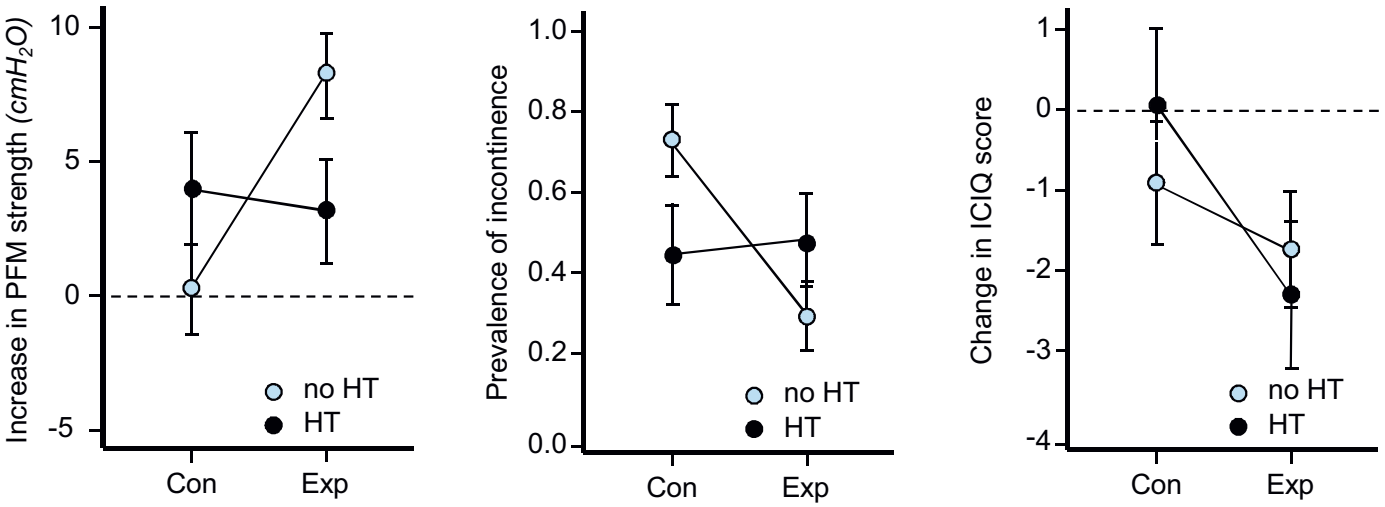

Figure 2. Effects of pelvic floor muscle training on the primary outcome (pelvic floor muscle strength) and secondary outcomes (prevalence of urinary incontinence and severity of urinary incontinence) in women using and not using hormone therapy.

What was already know on this topic: Menopause may be accompanied by vasomotor and other symptoms including urinary incontinence. Hormone therapy is recommended in the presence of significant symptoms. However, it is unclear whether hormone therapy modifies the effect of pelvic floor muscle training.

What this study adds: In post-menopausal women, pelvic floor muscle training increases pelvic floor muscle strength significantly more in those who are not using hormone therapy than in those using hormone therapy. Similarly, there was also a significantly greater effect of training in women not using hormone therapy on prevalence of urinary incontinence symptoms.

Footnotes: [a] Peritron, Cardio-Design, Australia.

eAddenda: Table 4 can be found online at https://doi.org/10.1016/j.jphys.2018.05.002.

Ethics approval: The Ethics Committee of the Clinical Hospital of Ribeirão Preto Medical School, University of São Paulo approved this study (approval number 105 932). All participants gave written informed consent before data collection began.

Competing interests: Nil.

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