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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

Flávia Ignácio Antônio [a], Robert D Herbert [b], Kari Bø [c], Ana Carolina Japur Sá Rosa-e-Silva [d], Lúcia Alves Silva Lara [d], Maira de Menezes Franco [a], Cristine Homsi Jorge Ferreira [a]

[a] Department of Health Sciences, Ribeirão Preto Medical School, University of São Paulo, Ribeirão Preto, Brazil; [b] Neuroscience Research Australia (NeuRA), Sydney, Australia; [c] Norwegian School of Sport Sciences Department of Sports Medicine, Oslo and Akershus University Hospital, Department of Obstetrics and Gynecology, Lørenskog, Norway; [d] Department of Obstetrics and Gynecology, Ribeirão Preto Medical School, Univesity of São Paulo, Ribeirão Preto, Brazil

KEY WORDS

Menopause hormone therapy
Physical therapy
Pelvic floor muscle
Exercise
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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* XX: XX–XX]**

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.

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