

Appraisal

Correspondence: Transparency to fully understand randomised controlled trials

I have read the research article conducted by Antônio et al,¹ which examines the effect of pelvic floor muscle training in groups stratified by hormonal therapy use. I appreciate the authors' effort to conduct this randomised controlled study. Since the intervention was described in detail, readers might be able to apply the training protocol to their clinical settings.

However, I have two concerns about inadequate reporting of the method in this study. First, sample size calculation of participants was not mentioned; therefore, readers cannot anticipate the impact of a Type II error on statistically non-significant results.²

Second, there was no information about adverse events. Although the intervention itself is non-invasive, a previous study reported some adverse events such as pain.³ If the reasons for dropout from the intervention group (such as illness) were related to intervention, caution should be exercised.

These two points are important components to fully understand the study, as described in the Consolidated Standards of Reporting Trials (CONSORT) statement.⁴ Readers should be aware of the concerns when they interpret the results.

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Correspondence: Author response to Ariie

We appreciate Mr Takashi Ariie's interest and comments regarding our publication.

The first concern raised by Mr Ariie is not justified because we rejected the null hypothesis.¹ Our study showed that pelvic floor muscle training increases pelvic floor muscle strength more in women not using hormone therapy than in women using it (interaction $p = 0.018$). There could not have been a Type II error because we found an interaction.

The second concern was regarding pelvic floor muscle training side effects. The systematic review cited by Mr Ariie included 21 trials involving 1281 women (665 pelvic floor muscle training, 616 controls).² From these trials, only one reported adverse events with pelvic floor muscle training.³ This specific trial included 66 participants, among whom only four mentioned side effects related to treatment: 'one mentioned pain and three an uncomfortable feeling during the exercises'. It is unclear whether the pain and discomfort was caused by the pelvic floor muscle training itself; it could be related, for example, to the women's posture during the exercise. Considering this information from the available trials related to this topic, we believe that it is unlikely that there are significant side effects of pelvic floor muscle training. However, we agree that side effects should be investigated, reported and better discussed in future studies.

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