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RESPONSE TO LETTER

Response To: "Comparison of High-Intensity Electromagnetic Therapy and Pelvic Floor Muscle Exercises in Women with Urinary Incontinence: A Randomized Controlled Trial [Response to Letter]"

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Dear editor

We thank Joshi and Bhullar for their careful reading of our randomized controlled trial and for their constructive comments. We appreciate the opportunity to clarify the participant denominators used in the electromyographic analyses, inconsistencies in the presentation of King's Health Questionnaire (KHQ) data, the interpretation of within-group findings, the calculation of the KHQ total score, and the difference between the initially registered and final sample size.

Participant Numbers and EMG Analyses

The authors correctly noted an inconsistency in the number of participants reported for the PFMT group in Table 5. The study included 44 participants, with 22 participants in each group, and all 44 participants completed the study.

During the conduct of the study, an **interim analysis** had been performed when follow-up EMG data were available for 13 participants in the PFMT group. During preparation of the final manuscript, the results of this interim EMG change-score analysis were inadvertently retained in Table 5 instead of being replaced with the final analysis based on all 22 participants in the PFMT group.

We therefore returned to the final participant-level dataset and repeated the EMG change-score analyses using **22 participants in the HIFEM + PFMT group and 22 participants in the PFMT group**.

The corrected analyses yielded the following results:

- **Work Average**: HIFEM + PFMT Δ = 13.05 ± 5.40 μV; PFMT Δ = 7.83 ± 6.14 μV; between-group difference = 5.22 μV (95% CI 1.70 to 8.74), Hedges' g = 0.89, p = 0.0046, Holm-adjusted p = 0.065.
- **Work Peak**: HIFEM + PFMT Δ = 22.41 ± 10.07 μV; PFMT Δ = 12.39 ± 8.31 μV; between-group difference = 10.03 μV (95% CI 4.41 to 15.65), Hedges' g = 1.07, p = 0.00085, Holm-adjusted p = 0.013.
- **Maximum voluntary contraction**: HIFEM + PFMT Δ = 33.24 ± 5.91 μV; PFMT Δ = 22.52 ± 10.48 μV; between-group difference = 10.72 μV (95% CI 5.50 to 15.94), Hedges' g = 1.24, p = 0.00020, Holm-adjusted p = 0.003.
- **Rest Average**: HIFEM + PFMT Δ = −0.30 ± 0.27 μV; PFMT Δ = −0.21 ± 0.19 μV; p = 0.181, Holm-adjusted p = 1.000.

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Importantly, although the numerical estimates changed after replacing the interim analysis with the final complete dataset, the **overall pattern of multiplicity-adjusted findings remained unchanged**. Work Peak and maximum voluntary contraction remained statistically significant after Holm correction, whereas Work Average and Rest Average did not.

The UDI-6 finding also remained statistically significant after Holm correction, while ICIQ-SF did not. Thus, the principal adjusted findings of the study continue to indicate significant between-group differences for **Work Peak, maximum voluntary contraction, and UDI-6**. This is consistent with the principal interpretation presented in the published article.

We acknowledge that the interim analysis should not have appeared in the final table and apologize for this oversight.

Consistency of KHQ Values Across Tables 3–5

We also thank the authors for identifying inconsistencies among the KHQ values presented in Tables 3–5. Their example regarding the PFMT General Health domain correctly demonstrates an inconsistency in the published tables.

Re-examination of the final dataset and the original analysis tables showed that several **baseline PFMT KHQ descriptive values were incorrectly transferred into Table 3 during manuscript preparation**.

For example, the correct PFMT General Health values were approximately **34.09 at baseline and 15.90 after treatment**, corresponding to a change of approximately −18.18. Similarly, the PFMT Physical Limitations score changed from approximately **28.02 to 22.72**, corresponding to −5.30, and the summed KHQ domain score changed from approximately **376.22 to 154.49**, corresponding to −221.73.

These values are consistent with the baseline-to-post-treatment change scores reported in Table 5. The inconsistency therefore arose from transcription of baseline descriptive values into Table 3 rather than from the KHQ change-score calculations.

Accordingly, Table 3 requires correction to reflect the values in the final dataset.

Importantly, none of the KHQ between-group comparisons remained statistically significant after Holm adjustment. The principal interpretation of the study was therefore not dependent on the KHQ findings.

Interpretation of Within-Group KHQ Findings

We thank the authors for noting the apparent inconsistency regarding the Personal Relationships domain. Re-examination of the final dataset showed that the values reported for this domain in Table 3 were affected by the same transcription issue described above.

In the final dataset, the correct PFMT Personal Relationships score was approximately 19.70 at baseline and 4.55 after treatment, corresponding to a mean change of approximately −15.15. The within-group change was statistically significant, whereas the change in Physical Limitations remained nonsignificant.

Therefore, the narrative statement that Physical Limitations was the only KHQ domain without a significant within-group improvement in the PFMT group is consistent with the final dataset.

We thank the authors for drawing attention to the discrepancy in the published table.

We also emphasize that within-group analyses were considered supplementary and were not the primary basis for evaluating comparative treatment effectiveness. As described in the Statistical Analysis section, the principal comparative analyses were based on between-group differences in change scores, with effect sizes, confidence intervals, and multiplicity adjustment.

Clarification of the KHQ "Total Score"

We agree that the method used to derive the variable reported as the **KHQ Total Score** should have been stated more explicitly.

In our analysis, this variable represented the **arithmetic sum of the KHQ domain scores included in the analysis**. It was not intended to imply a separately validated global KHQ construct.

We therefore agree that a more precise term would be:

"summed KHQ domain score".

This variable was included as an additional descriptive composite. Importantly, its between-group change did not remain statistically significant after Holm correction and therefore did not contribute to the principal conclusions of the study.

Difference Between Registered and Final Enrollment

The authors also noted that the ClinicalTrials.gov record initially listed an expected enrollment of 40 participants, whereas the published study included 44 participants.

The original sample-size calculation identified a required sample of 40 participants. A **10% allowance for potential dropout** was subsequently incorporated into the final recruitment target, resulting in 44 participants, with 22 participants allocated to each group. This is stated in the Methods section of the published article.

The difference therefore reflects the addition of the anticipated dropout allowance and not an expansion of the sample in response to the observed treatment results.

We acknowledge that the ClinicalTrials.gov enrollment field should have been updated to reflect the final actual enrollment of 44 participants.

Regarding outcome hierarchy, pelvic floor muscle activity assessed using surface EMG-biofeedback was treated as the primary outcome, whereas urinary symptoms and quality-of-life outcomes were considered secondary outcomes in the final report.

Overall Interpretation

After reviewing the final participant-level dataset, we identified two separate reporting issues:

1. an **interim PFMT EMG analysis based on 13 participants was inadvertently retained in Table 5 instead of the final 22-participant analysis**, and
2. several PFMT baseline KHQ descriptive values were incorrectly transferred into Table 3.

We have repeated the relevant analyses using the final dataset of 22 participants per group.

Although the corrected EMG analysis produces somewhat different change-score estimates, effect sizes, and p-values, the **principal multiplicity-adjusted interpretation remains unchanged**. Following Holm correction, statistically significant between-group differences remain for **Work Peak EMG activity, maximum voluntary contraction, and UDI-6**, whereas Work Average, Rest Average, ICIQ-SF, and the KHQ outcomes do not remain statistically significant.

The published article itself emphasized that the principal interpretation should be based on adjusted between-group analyses and that secondary and KHQ findings should be interpreted cautiously.

We sincerely thank Joshi and Bhullar for identifying these inconsistencies. Their comments allowed us to re-examine the final dataset and clarify the distinction between the interim and final analyses. We believe that correction of the affected table values will improve the transparency and reproducibility of the report while preserving the principal conclusions supported by the final dataset.

Disclosure

The authors report no conflicts of interest in this communication.

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