

Response on Huma Riaz, et al. (J Pak Med Assoc. 72: 1904-1908, 2022)

## Effects of high-intensity multi-modal exercise training (HIT-MMEX) on bone mineral density and muscle performance in postmenopausal women. A Pilot randomized controlled trial

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Madam, Thanks for rightly appreciating the fact that the musculoskeletal health of post-menopausal women is a much-neglected area on behalf of researchers and clinicians at the national level. Despite the reported fact that around 7.2 million women in Pakistan have low bone mass, the prevalence is expected to raise up to 12.9 million by 2050<sup>1</sup>. There is an extreme paucity of experimental data on postmenopausal low bone mass from our part of the world. And the HIT-MMEX bone-targeted exercise trial is one of its kind to draw the attention of healthcare professionals and policymakers.

1. The authors of the mentioned study<sup>2</sup> have preferred to share the novel initial findings of The HIT-MMEX clinical trial with the readers. For which the sample size was properly calculated and mentioned<sup>3,4</sup>. However, as per suggestions of the research team, the same trial was continued to enroll more participants in the study to explore some other study variables and factors with more detail.
2. The published pilot study<sup>1</sup> with a sample size of 29 (which was properly calculated and mentioned)<sup>1,2,3</sup> aimed to determine the effects of high-intensity multimodal exercise training on bone density. The results have shown non-significant ( $p > 0.05$ ) results for one of the primary outcomes which is femoral neck bone mineral density. As per suggestions of the

research team, the same trial was continued to enroll more participants in the study to explore some other study variables and factors with more detail.

3. As per mentioned confounding factors, in the current study<sup>2</sup> participants taking any bone-affecting medications in the past one year were already excluded. Almost all the participants were housewives. Although Past, Current, and total bone-specific activity were noted but assumptions of covariate analysis were not met with this small sample size ( $n=29$ ).
4. Age group strata at the time of the pilot study were not homogenous that's why reporting of sub-group analysis based on age strata was not justifiable/preferred.
5. The consort diagram is attached herewith. (See supplementary file)

### References

1. Khan AH, Jafri L, Ahmed S, Noordin S. Osteoporosis and its perspective in Pakistan: A review of evidence and issues for addressing fragility fractures, *Annals of Medicine and Surgery* (2018), doi: 10.1016/j.amsu.2018.03.019
2. Riaz H, Babur MN, Farooq A. Effects of high-intensity multi-modal exercise training (HIT-MMEX) on bone mineral density and muscle performance in postmenopausal women. A Pilot randomized controlled trial. *J Pak Med Assoc* 2022; 72 (10)1904-08. DOI: <https://doi.org/10.47391/JPMA.5394>
3. Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat Methods Med Res*. 2016; 25:1057-73.
4. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceutical Statistics: J App Stat Pharmaceutic Indus*. 2005; 4:287-91.

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