

## COMMENTARY ON “EFFECTS OF INCENTIVE SPIROMETER ADDED TO STANDARD REHABILITATION IN PREVIOUSLY HOSPITALIZED ADULTS WITH POST-COVID-19 CONDITION: A RANDOMIZED CONTROLLED TRIAL”

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*To the Editor,*

The recently published article, “Effects of Incentive Spirometer Added to Standard Rehabilitation in Previously Hospitalized Adults With Post-COVID-19 Condition: A Randomized Controlled Trial” by Kloni et al. (1) offers valuable insight into rehabilitation strategies for individuals experiencing persistent respiratory impairment following coronavirus disease. The authors should be commended for employing a randomized design to evaluate an accessible intervention in a clinically important yet evolving field of post-COVID-19 rehabilitation.

While the study contributes meaningful preliminary evidence, several methodological and analytical considerations may further strengthen interpretation of the findings.

First, although multiple clinically relevant outcomes, including pulmonary function, dyspnoea, mobility, endurance, quality of life, muscle strength, and functional independence – were assessed, the sample size estimation appears to have been derived from a single respiratory endpoint. In randomized studies evaluating numerous outcomes, explicit pre-specification of outcome hierarchy and clarification regarding multiplicity handling are important to reduce the possibility of inflated type I error and selective emphasis on statistically significant findings (2, 3). Future investigations may benefit from clearly distinguishing confirmatory from exploratory outcomes and reporting multiplicity-adjusted inference where appropriate.

Second, additional transparency regarding the analytical strategy may improve reproducibility and interpretation. The authors report baseline-adjusted comparisons between groups; however, further clarification regarding model specification, assumptions, and adjusted effect estimates

would enhance methodological transparency. Current recommendations for randomized trials support covariate-adjusted analyses, particularly analysis of covariance (ANCOVA), because such approaches may improve precision and reduce residual baseline imbalance (4, 5). More detailed reporting of these procedures could strengthen confidence in the robustness of treatment estimates.

Third, the choice of pulmonary outcome measurement warrants consideration. Incentive spirometry primarily aims to promote inspiratory effort and lung expansion, whereas peak expiratory flow (PEF), the principal respiratory endpoint, predominantly reflects expiratory airflow. Although improvement in PEF may indicate respiratory benefit, broader pulmonary function measures including indices reflecting lung volume and ventilatory performance could potentially offer a more comprehensive assessment of physiological recovery and intervention-specific mechanisms in individuals with post-COVID-19 condition (6, 7).

Additionally, while statistically significant improvements were observed for selected outcomes, contextualizing these findings through clinically meaningful thresholds or effect-size interpretation may improve understanding of their practical relevance to patient recovery. Statistical significance alone may not always translate into meaningful functional improvement in rehabilitation settings (8).

These observations are intended in a constructive spirit and should not detract from the contribution of this study. Rather, the work by Kloni et al. provides an important foundation for future investigations seeking to refine respiratory rehabilitation approaches for individuals with post-COVID-19 condition through transparent analytical reporting and comprehensive physiological assessment.

## RESPONSE TO COMMENTARY ON “EFFECTS OF INCENTIVE SPIROMETER ADDED TO STANDARD REHABILITATION IN PREVIOUSLY HOSPITALIZED ADULTS WITH POST-COVID-19 CONDITION: A RANDOMIZED CONTROLLED TRIAL”

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To the Editor,

We thank the author for their interest in our study and for their constructive comments.

Regarding sample size estimation, we acknowledge that the calculation was based on peak expiratory flow (PEF), which served as the primary respiratory endpoint. At the time the study was designed, evidence regarding the effects of incentive spirometry in individuals with post-COVID-19 condition was limited, and the available literature provided the basis for estimating the expected treatment effect (9). While several additional outcomes were assessed to capture the multidimensional nature of post-COVID-19 condition, multiplicity was addressed through application of the Benjamini–Hochberg false discovery rate correction, as reported in the Methods section (2).

We fully agree that baseline-adjusted analyses, such as ANCOVA, represent the gold standard for parallel-group randomized trials due to their superior ability to optimize statistical precision and mitigate residual baseline imbalances (4, 10). In our study, a change-score approach ( $Y_{\text{follow-up}} - Y_{\text{baseline}}$ ) was utilized to assess the intervention effect. We acknowledge that this simpler approach generally exhibits lower statistical power than an ANCOVA model. However, because our randomization process was highly successful, resulting in well-balanced baseline characteristics and outcome measures between the 2 groups, the risk of bias due to regression to the mean or baseline confounding is minimized. While we recognize that an ANCOVA model

would have provided narrower confidence intervals, we are confident that our simpler, transparent change-score analysis offers a conservative and valid estimate of the treatment effect (4, 10).

We appreciate the authors' comments regarding the choice of pulmonary outcome measures. Although incentive spirometry primarily targets inspiratory effort and lung expansion, PEF was selected because it is a practical, inexpensive, and clinically accessible measure that can be readily implemented in rehabilitation settings (11). We agree that future investigations incorporating additional measures of pulmonary function, including inspiratory parameters and lung volume assessments, may further elucidate the physiological mechanisms underlying recovery.

Finally, we agree that clinical relevance is an important consideration when interpreting rehabilitation outcomes. Accordingly, in the Discussion we contextualized the observed improvements using available evidence regarding clinically meaningful changes in both PEF and MRC dyspnoea scores (12, 13). The significant between-group differences observed in these outcomes were interpreted not only statistically but also in terms of their potential functional relevance for individuals with post-COVID-19 condition.

We thank the author for their thoughtful observations and welcome continued discussion aimed at strengthening the methodological and clinical evidence base for post-COVID-19 rehabilitation research.

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