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## Letter to Editor on "A randomized, controlled, blinded, parallel-group, clinical trial to study the role of Ayurcov (AyurCoro3), a one-day regimen as an adjuvant therapy for COVID-19 disease management, at dedicated Covid Hospital (DCH) in India"

### ARTICLE INFO

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Dear Editor,

We read with interest the article by Sankhe et al.<sup>1</sup> on the role of Ayurcov (AyurCoro3), a one-day regimen as adjuvant therapy for COVID-19 disease management, published in your esteemed journal (March 2022). We appreciate the authors' efforts to investigate the effectiveness of Ayurvedic therapies among COVID 19 patients. There are, however, a few concerns about the methodological aspects of the study.

The author has highlighted the need to integrate Ayurveda medicines and therapies for effective COVID-19 management in the introduction. But this single-day interventional regimen (three times oral drugs and two times gargle) is neither supported by the classical Ayurvedic textual recommendations nor adequately supported by scientific evidence. Therefore, it seems unconvincing that a single day therapy of "Ayurcov" can affect the outcome in the COVID-19 patients.

We also observed that the formula used for sample size calculation in the manuscript is not appropriate for randomized controlled trials. Because of this, it is possible that primary outcome measures were not statistically significant.

Reporting of the primary outcome based on the presence of COVID-19 symptoms (Table no. 3) possibly fails to assess the small changes in the level of the improvement. Spinner et al.<sup>2</sup>, for example, have used an ordinal seven-point scale to evaluate the efficacy of COVID-19 therapeutics on clinical status. Also, while comparing the number of patients with presenting symptoms in both groups, the authors have reported statistical significance by binary logistic regression. However, binary logistic regression is not an appropriate statistical tool to obtain the effect size in randomized controlled trials as it may overestimate the effect size.<sup>3</sup> It would be prudent to use the z test for two independent proportions to determine statistical significance.

Hence, based on the above comments, we believe the results of the

current study should be interpreted cautiously.

### Funding source

None.

### Declaration of Competing Interest

None.

### References

- 1 Sankhe AP, et al. A randomized, controlled, blinded, parallel group, clinical trial to study the role of Ayurcov (AyurCoro3), one day regimen as an adjuvant therapy for COVID-19 disease management, at dedicated Covid Hospital (DCH) in India. *Complement Ther Med*. 2022;102824. <https://doi.org/10.1016/j.ctim.2022.102824>.
- 2 Spinner CD, et al. Effect of Remdesivir vs standard care on clinical status at 11 days in patients with moderate COVID-19. *JAMA*. 2020;324:1048.
- 3 Balasubramanian H, Ananthan A, Rao S, Patole S. Odds ratio vs risk ratio in randomized controlled trials. *Postgrad Med*. 2015;127:359–367.

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**Abbreviation:** COVID19, coronavirus disease of 2019.

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