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Author Response to Hedges

Thank you for the opportunity to respond to Hedges and colleagues. Despite a highly organized campaign, Hedges and colleagues were unsuccessful in their attempt to prevent an important non-pharmaceutical intervention (NPI) RCT from being completed. Their letter to the Tri-council Federal Office Panel on the responsible conduct of research, the organization that creates framework and guidance for the ethical conduct of research in Canada, was ineffectual in stopping the trial. Our research protocol was reviewed by ten independent research ethics boards and judged to be both ethical and scientifically valid. Inconsistency in guideline recommendations around the use of medical masks or N95 respirators is indisputable proof of equipoise.

With respect to their letter to the Editor in Chief of *Annals of Internal Medicine*, Hedges and colleagues are incorrect about an absence of occupational hygiene expertise; we did include both an occupational health physician and an occupational health and safety sector professional. We are surprised that they agree with the comment from Brosseau about the control group not wearing a mask at all, which would have been clearly unethical. Hedges and colleagues cite a paper that provides no epidemiologic evidence as “thorough” and cite one paper that summarizes poorly designed observational studies from China and another that provides no data. Their comments about the use of respiratory PPE as well as other design aspects of the trial show that they fail to understand that pragmatic randomized trials compare interventions the way they are used in the field. Their suggestion that PAPRs should have been used in Egypt is completely inappropriate. Hedges and colleagues misinterpret the results by focusing on subgroup analyses, a practise well established to be problematic (1).

We believe this was a well conducted pragmatic randomized trial. As with all studies, there were limitations which we acknowledged. Despite being aware of our prior response to similar criticisms, why Hedges and colleagues (and some others that commented) persist in their extensive and highly organized campaign to discredit this study is an important question. Rigid confirmation bias (2), ideological bias, and in some cases financial bias may play a role. Hedges and colleagues are fully aware that our trial showed no safety concern. Hopefully their organized campaign will not dissuade others from conducting similar pragmatic NPI trials (3), the lack of which has been considered a pandemic tragedy (4). Disinformation and the inability to proceed with high quality trials of NPIs is what truly has posed a threat during the pandemic.

REFERENCES

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Disclosures:

Disclosures can be viewed
at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M22-1966.