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The Authors Respond

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To the Editors

We agree with Shinozaki et al. regarding the expected bias of an intention-to-treat analysis to estimate the per-protocol effect (a problem well understood by trialists) and the possibility of lack of generalizability due to non-randomized concomitant interventions. We prefer to reserve the term “bias” for lack of internal validity.^{1, 2}

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Conflicts of Interest:

The authors declare no conflict of interest.