

## Letter to the Editor

# Authors Reply: Regarding “Stress management and *in Vitro* Fertilization (IVF): A pilot randomized controlled trial”

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*To the Editors,*

Komiya et al recently sent a letter to the editor<sup>1</sup> raising issues of reliability and validity of our study “Stress management and *in Vitro* Fertilization (IVF): A pilot randomized controlled trial”.<sup>2</sup> Their comments focused on the default of the registration, the absence of any mention of case dropout, the ambiguity in the details of IVF treatment and the lack of specific figures on the background of the participants.

However, the principles of CONSORT 2010 cannot be applied to Pilot Randomized and Feasibility Trials, only to Randomized Trials (RTs) or Randomized Controlled Trials (RCTs). Similarly, the CONSORT Extension 2016 suggested some principles for Pilot and Feasibility Trials, but again it does not directly apply to internal pilot studies, non-randomized pilot and feasibility studies, or phase II studies.<sup>3,4</sup> Many international journals do not require registration for Pilot and Feasibility Trials, but only for RTs or RCTs,<sup>5</sup> granted that clinical trial registration is not an indicator of low risk of bias.<sup>6</sup>

Thanks to the useful comments by Komiya et al, our article<sup>2</sup> now includes online “Supplementary Materials” in which we clarify all their points one by one. Specifically, the Material and Method section of Supplementary Materials includes details for the Registration, the Flow Chart and the IVF Treatment, and the Results section includes details for the Background of the Participants. Thus, we believe that the level of reliability and validity of the study can be now examined and ensured.

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