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Authors' reply to: "Music and oral premedication for pain management during outpatient hysteroscopy: results from a randomised controlled trial"

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Dear Editor,

We thank the correspondent for the careful reading of our article[1] and for raising the question of post-randomisation exclusion, which gives us a welcome opportunity to clarify our methods and to add context that we believe strengthens confidence in our conclusions.

First, regarding the request to report the number of failed procedures in each randomised group: these data are already presented in our study flow diagram (Figure 1). Procedural failure occurred in three participants overall, none in the music group, one in the oral premedication group, and two in the control group. Procedural failure was therefore uncommon, and, importantly, no failure occurred in either of the active intervention arms.

Second, regarding the concern that excluding these participants may have biased the estimated treatment effects, we agree in principle. Post-randomisation exclusion can distort effect estimates, as elegantly demonstrated by Nüesch et al.[2] in the meta-epidemiological study the correspondent cites. However, several features of our data make a clinically meaningful bias unlikely in the present case. The failures were few and were not concentrated in any single arm. In all three instances the cause of failure was severe cervical stenosis requiring mechanical dilatation under general anaesthesia, an anatomical factor unrelated to the intervention being tested (music vs. oral analgesia vs. control), rather than a consequence of the allocated treatment. Most importantly, the bias described by Nüesch et al.[2] operates chiefly by exaggerating an apparent treatment benefit; our trial found no significant difference between groups in either the primary outcome (intra- and post-procedural pain) or the secondary outcomes. Reinstating three stenosis-related failures, distributed, if anything, away from the intervention arms, could not plausibly convert these null findings into a treatment effect, and would not alter our conclusion that neither intraoperative music nor oral ibuprofen–paracetamol premedication reduces pain compared with standard care.

Third, we fully agree with the correspondent that procedural failure is itself a clinically meaningful endpoint that merits consideration alongside pain

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intensity. Our study did report procedure completion as a secondary outcome, and completion rates did not differ significantly between the three groups (P=0.62), with pain and severe cervical stenosis being the principal causes of failure. We concur that future, adequately powered trials would benefit from pre-specified composite endpoints that integrate pain intensity with procedural success and, ideally, patient-reported acceptability, providing a more comprehensive assessment of clinical effectiveness. We are grateful for this constructive suggestion.

We thank the correspondent once again for the thoughtful comments and the opportunity to clarify these points.

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