

# Beyond “One-Size-Fits-All”: Evidence and Applicability in Selecting Sham Acupuncture for Insomnia RCTs [Response to Letter]

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## Dear editor

We thank Zhao et al for their insightful comments on our Bayesian network meta-analysis (NMA) on sham acupuncture for primary insomnia (PI).<sup>1,2</sup> We value this opportunity to respond and are pleased to engage in this constructive scholarly dialogue.

## Further Clarification on the Inertness of NISA

As Zhao et al correctly noted, an ideal control approach should consider physiological inertness. Their concern primarily stems from the limited number of studies that directly compare noninvasive sham acupuncture (NISA) with nonacupuncture therapy (NAT). We acknowledge this limitation. However, a key methodological context requires clarification: in acupuncture randomized controlled trials (RCTs), ethical considerations typically require that the intervention and control groups receive additional interventions beyond usual care. Accordingly, in our NMA, the NISA group essentially represented “NISA + usual care”, and the same applied to superficial acupuncture (SA).<sup>2</sup> The NAT group also received usual care, a design consistent with that of the two studies cited by Zhao et al.

Thus, comparing NISA with NAT is essentially a comparison between “NISA + usual care” and “usual care” alone. The absence of a statistically significant difference does not imply that NISA is therapeutically equivalent to usual care; instead, it suggests that NISA has low therapeutic activity and does not yield a significant additive effect. We agree that the limited direct comparison evidence is insufficient to conclude that NISA is completely inert, a viewpoint consistent with our original discussion, which stated that existing sham acupuncture techniques are not entirely inert and that their specific and non-specific effects require careful consideration in trial design.<sup>3</sup>

## Evidential Support for NISA as a Preferred Control

Despite the aforementioned limitations, based on the available evidence and our analytical results, we maintain support for our primary conclusion: in RCTs targeting PI, NISA is methodologically superior to SA as a sham control owing to its lower activity.

First, Bayesian NMA framework synthesizes evidence across the entire network of comparisons, which is a core methodological strength. In our analysis, NISA consistently ranked lowest on the Surface Under the Cumulative Ranking (SUCRA) curve for the primary outcome, Pittsburgh Sleep Quality Index (PSQI) scores, at both the treatment endpoint (20.4%) and 4-week follow-up (20%). These values were lower than those of SA (47.8% and 48%) and NAT (31.9% and 32.6%).<sup>2</sup> This quantitative ranking provides direct evidence for control selection, indicating that NISA has the weakest therapeutic effect among all interventions, consistent with the key principle for setting a sham control.

Second, neuroimaging studies have provided corroborative evidence. Functional magnetic resonance imaging (fMRI) demonstrates that verum acupuncture produces stronger and more specific activation in motor-regulation and limbic

system regions compared with the relatively weaker activation observed with NISA.<sup>4</sup> In contrast, another fMRI study found no significant differences in brain network modulation (particularly widespread signal deactivation) between superficial and therapeutic deep needling.<sup>5</sup> This neurophysiological evidence aligns with our NMA ranking results: the neural activity of NISA is relatively closer to “inert”, whereas SA may retain considerable neuromodulatory potential. This mechanistic difference helps explain why SA ranked higher in activity than NISA on the SUCRA curve.

## Contextualized Choice: Balancing Methodological Rigor and Practical Feasibility

Zhao et al also raised important practical constraints, including (1) The inapplicability of NISA to specific needling techniques such as scalp oblique insertion, (2) potentially compromised blinding with NISA in acupuncture-experienced populations, and (3) practical issues such as device adhesion difficulties and higher costs in some trials. These practical challenges cannot be denied. However, our recommendation is based on evidence from the included RCTs and is specific to PI; it seeks to clarify that, when conditions allow, NISA is a methodologically superior control because of its lower neural and clinical activity.

That said, this conclusion is not intended to propose a rigid, “one-size-fits-all” mandate. We agree with Zhao et al that the selection of sham acupuncture should be context-dependent. As mentioned in our original article, “In studies requiring horizontal or oblique needling, NISA may be inapplicable due to operational limitations”, making SA a more reasonable choice in such scenarios. We hope the evidence provided by our study will inform such decisions: researchers opting for SA should be aware that it may produce stronger non-specific effects, as suggested by the neuromodulatory effects indicated in fMRI studies,<sup>4</sup> compared with NISA, which could lead to a more conservative estimation of the specific efficacy of acupuncture.

## Conclusion

In summary, our methodological rigor and practical feasibility should be viewed as complementary rather than opposing principles. Our NMA provides the highest level of evidence currently available regarding the relative inertness of sham acupuncture controls in RCTs for PI, and this evidence should, therefore, serve as the primary guiding framework. The comments by Zhao et al supplement important practical considerations. Therefore, a more comprehensive and precise recommendation is as follows.

In RCTs of acupuncture for PI, NISA should be the preferred control when the trial design is feasible, and the participant characteristics allow for its use. When practical constraints preclude NISA, SA remains a methodologically acceptable alternative; however, researchers should note its potentially higher activity, which may lead to a more conservative estimation of the specific therapeutic effect of acupuncture.

## Data Sharing Statement

Data availability is not applicable as no data was generated or analyzed in this communication.

## Author Contributions

Yuting Wang – Conceptualization, Formal analysis, Investigation, Writing – original draft; Minmin Wu – Formal analysis, Supervision, Writing – review & editing; Jiongliang Zhang – Conceptualization, Formal analysis, Investigation, Writing – review & editing; Xinyue Li – Conceptualization, Formal analysis, Investigation, Writing – review & editing; Luwen Zhu – Formal analysis, Supervision, Writing – review & editing. All authors gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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## Disclosure

The authors declare no competing interests.

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