


Methodological Comments to “Comparative Effects of Two Acupuncture Protocols in the Management of Chronic Insomnia: A Randomized Controlled Trial” [Response to Letter]

Mingyue Xia , Lianbo Li, Zhen Liu, Yunfei Chen

Department of Acupuncture and Moxibustion, Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine, Shanghai, People's Republic of China

Correspondence: Yunfei Chen, Department of Acupuncture and Moxibustion, Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine, Shanghai, People's Republic of China, Tel/Fax +86-21-65162628, Email icyf1968@163.com

Dear editor

We sincerely thank Zhou et al for their interest in our randomized controlled trial and for their thoughtful and constructive methodological comments.^{1,2} We appreciate the opportunity to clarify these important methodological issues and respond to each point as follows.

Blinding Effectiveness and Potential Unblinding

We agree that when sham acupuncture is used as a control, formal assessment of blinding is essential, as differences in needling sensations between sham and verum acupuncture may enable participants to infer their group allocation.³ However, the present study differs fundamentally from trials employing sham controls. In this trial, both groups received verum acupuncture as active interventions, as specified in the Intervention section. Identical manual manipulations—including twirling, lifting–thrusting, and pressing—were applied after needle insertion in both groups to elicit *deqi* sensations (eg, soreness, numbness, heaviness, or distension). As a result, participants in both groups experienced comparable needling sensations, and the sensory discrepancy typically observed between sham and verum acupuncture was absent.

The difference between the two interventions concerned acupoint combinations. According to Standardized Manipulations of Acupuncture and Moxibustion – Part 20: Basic Techniques of Filiform Needle (GB/T 21709.20—2009), body position during acupuncture should facilitate accurate acupoint localization, procedural feasibility, and patient comfort.⁴ Accordingly, different positions were adopted to support correct needling in the two protocols. We do not consider posture differences per se to increase the risk of unblinding, as *deqi* sensations allow patients to perceive the approximate location of needling regardless of position. To support participant blinding, individuals were informed that they would receive one of two acupuncture protocols both used clinically for insomnia, without disclosure of any hypothesis regarding superiority. All participants were treated equivalently, and treatment sessions were arranged in separate rooms or at different times to minimize inter-participant communication.

In summary, both groups of subjects received effective acupuncture interventions instead of placebos, which may have reduced the difference in the expected effect.

Sample Size Estimation and Observed Effect Size

Regarding sample size considerations, the study was powered during the design phase based on preliminary data and published studies, which suggested relatively substantial differences in ISI score improvement between groups. Accordingly, a relatively large between-group difference was assumed to ensure adequate statistical power, consistent with standard practice in randomized controlled trial design.⁵ In the completed study, the observed between-group difference (1.87 points) was indeed smaller than the initially assumed effect size used for sample size estimation. This reflects the inherent



uncertainty of effect sizes in clinical research. Based on the observed effect size, a supplementary post hoc analysis indicated that the study had moderate statistical assurance for detecting smaller, yet clinically meaningful, superiority differences.

This study was a superiority trial, and the observed between-group difference exceeded the pre-specified superiority margin ($\Delta = 1.4$), supporting the statistical conclusion of superiority, despite the effect size being smaller than originally anticipated. We also acknowledge that the smaller actual effect size may influence interpretation and generalizability. Accordingly, the clinical significance of these findings is presented cautiously and conservatively in the Discussion and Conclusion sections. Notably, both groups demonstrated significant pre-to-post improvements in ISI scores, indicating clinically meaningful effects for both acupuncture protocols, with between-group differences primarily observed in specific psychological symptom domains (eg, anxiety- and depression-related measures), which are exploratory findings with potential clinical relevance.

Baseline Educational Level Imbalance and Confounding Control

As described in the Methods section, participants were randomly assigned using a concealed and reproducible randomization procedure performed by an independent statistician. Despite randomization, the observed imbalance in educational attainment likely arose by chance rather than systematic bias. Because educational level may influence subjective outcome measures, we conducted a post-hoc ANCOVA as a sensitivity analysis, incorporating educational attainment as a covariate. Educational level was not significantly associated with post-treatment ISI scores ($\beta = -0.43$, $P = 0.644$), and adjusting for it did not materially change the estimated between-group difference ($P = 0.810$). These results were consistent with the main analysis, suggesting that the baseline imbalance in educational level appears unlikely to have meaningfully influenced the primary findings.

Management of Hypnotic Medication Use

According to the eligibility criteria, participants were required to meet one of the following conditions prior to enrollment: stable use of sedative sleep aids for at least 3 months, or no medication use prior to study enrollment. Consequently, from the three months preceding study initiation through the end of the follow-up period, participants were required to continue their pre-existing sedative-hypnotic medications at a stable dosage. During the study period, participants were not permitted to increase the dosage or switch to other hypnotic agents, unless such changes were deemed medically necessary.

The use of non-psychiatric medications, including antihypertensive, lipid-lowering, glucose-lowering, or heart rate-controlling agents, was permitted to continue as usual. All medications taken by participants during the study period were systematically documented in the case report forms (CRFs) at each study visit, including any clinically indicated changes. This protocol-based requirement ensured that hypnotic medication use remained stable throughout both the treatment and follow-up phases, thereby minimizing the potential confounding effects of medication changes on outcome measures. Given the stability of hypnotic medication use across groups, medication variables were not included as covariates in the primary outcome analyses. We agree that clearer reporting of medication management is essential for transparency and reproducibility, and we appreciate the opportunity to further clarify this aspect of the study.

We thank Zhou et al for their thoughtful comments. We hope that our clarifications address the methodological concerns and provide additional context for interpreting our findings. We believe that this discussion contributes to the ongoing refinement of research methodology in acupuncture trials.

Data Sharing Statement

Data sharing is not applicable as no new data were created or analyzed in this communication.

Author Contributions

Mingyue Xia: Conceptualization, Methodology, Formal Analysis, Writing-Original Draft; Lianbo Li: Data Curation, Investigation, Writing-Original Draft. Zhen Liu: Funding Acquisition, Writing-Review & Editing. Yunfei Chen: Conceptualization, Supervision, Resources, 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.

Disclosure

The authors declare no conflicts of interest related to the content of this communication.

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