

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

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Dear editor

We are writing to convey our appreciation for the RCT titled “Comparative Effects of Two Acupuncture Protocols in the Management of Chronic Insomnia” recently published in Nature and Science of Sleep.¹ To improve the interpretation and generalizability of its findings, we raise targeted methodological questions as follows.

Blinding Effectiveness and Reporting

The study adopted a single-blind design, with the treatment group in the prone position and the control group in the supine position, plus distinct acupoint combinations. The single-blind design (prone vs supine posture + distinct acupoint combinations) may lead to unblinding, as posture and acupoint differences are easily distinguishable.² We inquire: 1) Were post-treatment blinding evaluations (eg, Bang's Blinding Index²) conducted to verify whether participants guessed their group correctly? 2) How might potential unblinding affect the validity of subjective outcomes (eg, ISI, BAI scores)?

Sample Size Calculation and Effect Size Mismatch

The authors hypothesized an additional 4.60-point reduction in ISI scores for the treatment group compared to the control group, with a superiority cut-off of 1.4. This led to a calculated sample size of 38 cases per group (accounting for 20% attrition). Yet the actual between-group difference was only 1.87 points (7.58 vs 5.71 points)—far below the hypothesized effect size. The hypothesized 4.60-point additional reduction in ISI scores (leading to 38 cases per group) was much higher than the actual 1.87-point difference. We ask: 1) Does the smaller actual effect size indicate overestimation of therapeutic efficacy in study design? 2) How does this mismatch affect the robustness of the superiority conclusion, despite the clinically meaningful ISI reduction?

Baseline Educational Level Imbalance and Confounding Control

Table 1 shows a statistically significant difference in educational level between groups ($P=0.012$): the treatment group had a higher proportion of high school education (34.2% vs 13.2%) and a lower proportion of graduate education (13.2% vs 31.6%) compared to the control group. Table 1 shows a significant baseline imbalance in educational level ($P=0.012$), which may confound subjective outcomes.³ We wonder: 1) Was educational level included as a covariate in statistical analyses? 2) If not, how might this imbalance affect the interpretation of between-group differences?

Hypnotic Medication Use and Outcome Confounding

The study included participants with stable sedative-hypnotic use (≥ 3 months) or no medication use. However, the management of hypnotic drugs during the 10-session treatment and 4-week follow-up was not clearly reported. The management of hypnotic medication during treatment and follow-up was not clearly reported. We ask: 1) Were participants allowed to adjust medication dosage/type during the study, and was data on such changes collected? 2) Did the authors control for medication use as a confounding variable in outcome analyses?

This study provides valuable evidence for acupuncture in CID treatment. Addressing the above questions will strengthen its methodological rigor. We appreciate the authors' efforts and look forward to their response.

Data Sharing Statement

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

Author Contributions

Gongyue Zhou: Conceptualization, Methodology, Formal Analysis, Writing-Original Draft. Pei Shen: Data Curation, Investigation, Writing-Original Draft. Yijia Wan: Conceptualization, Supervision, Resources, Funding Acquisition, Writing-Review & Editing.

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Disclosure

The authors declare that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this communication.

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