

No One-Size-Fits-All Placebo: Advocating Context-Driven Placebo Control Selection in Acupuncture Randomized Controlled Trials for Insomnia [Letter]

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Dear editor

Randomized controlled trials (RCTs) are gold standard for evaluating intervention efficacy. Yet, for complex physical interventions like acupuncture, establishing an adequate placebo control remains challenging.¹ Common placebo procedures include shallow needling (SN), non-penetrating needle device (NPND), non-acupoint needling, and needling at acupoints not traditionally indicated for the target condition, either alone or in combination.² A critical question is which placebo technique is optimal.

Wang et al recently addressed this using a Bayesian Network Meta-Analysis (NMA) in primary insomnia (PI). They concluded that NPND is preferable to SN as a placebo control in acupuncture RCTs for PI, citing comparable effects on reducing PSQI scores and altering objective sleep parameters, but a lower overall ranking for NPND on the SUCRA curve, suggesting weaker therapeutic activity.³

While we acknowledge the rigor of this study, we respectfully offer a different perspective to stimulate further discussion.

Evidence for NPND Inertness Remains Restricted

An ideal control should be physiologically inert, exerting no therapeutic effect while ensuring participant blinding.¹ Validating NPND necessitates rigorous demonstration of inertness. Wang et al reported no significant difference between NPND and non-acupuncture controls in improving subjective sleep—but this relied on only two trials: one with a no-treatment control (n = 16)⁴ and another permitting any insomnia treatment except acupuncture and herbal medicine—potentially including CBTi or hypnotics (n = 49).⁵ This limited evidence introduces substantial uncertainty. Furthermore, if NPND produces outcomes comparable to conventional treatments, it might possess intrinsic efficacy rather than being inert. Future studies should compare within-group outcomes before and after NPND intervention to confirm inertness.

Beyond Efficacy: Practical Considerations in Placebo Selection

Wang et al's conclusion—that NPND is preferable to SN based exclusively on therapeutic outcomes in sleep—oversimplifies the methodological complexity of acupuncture RCTs. Practical factors must also be considered.

First, insomnia treatment often involves head acupoints (eg, GV20, EX-HN1),⁶ typically needled transversely ($\leq 15^\circ$ relative to the skin surface). NPND like Streitberger or Park devices relies on adhesive bases and perpendicular application, making them unsuitable for simulating transverse needling. Moreover, in participants with abundant scalp

hair, device adhesion is often compromised, potentially necessitating shaving—a requirement that further undermines feasibility in clinical trials.

Second, blinding efficacy with NPND may be inadequate in participants familiar with acupuncture. Pilot data from our previous RCT on perimenopausal insomnia revealed that participants could readily distinguish NPND from real needles based on tactile sensation and perceived penetration. Consequently, we substituted NPND with SN at non-insomnia-relevant acupoints. The sham group achieved a Bang's Blinding Index of -0.14 (within -0.20 to 0.20), indicating successful blinding.⁷

The Unique Advantages of SN as a Control Should Not Be Overlooked

Beyond enhancing blinding credibility through a more authentic needling sensation, SN offers additional advantages over NPND, including: (1) Superior cost-effectiveness and accessibility, as it utilizes standard acupuncture needles instead of costly specialized devices; (2) Enhanced clinical relevance and external validity, by reframing the research question around a clinically meaningful dose-response relationship (ie, therapeutic deep needling versus minimal shallow needling), the findings of which directly inform real-world practice; (3) Greater ethical acceptability, owing to the mild physiological stimulus provided even at non-indication points, thereby alleviating concerns associated with administering a completely inert intervention.

While NPND remains appropriate in certain contexts—such as acupuncture-naïve populations in Western settings, or trials restricted to perpendicularly needled acupoints (eg, HT7, PC6)—SN may be preferable in East Asian participants familiar with acupuncture, in RCTs involving scalp acupoints, or when budget constraints are considerable.

Conclusion

In RCTs of acupuncture for insomnia, placebo selection should not only consider inertness but also other factors such as blinding effect, applicability across different needling techniques, costs, cultural context, and ethics. Rather than pursuing a single “ideal” placebo, we recommend making context-specific choices tailored to the study population, clinical setting, and research objectives. Adopting such a nuanced and flexible approach can enhance the internal validity of RCTs while ensuring the clinical relevance of the findings.

Abbreviations

CBTi, Cognitive Behavioral Therapy for Insomnia; NMA, Network Meta-Analysis; NPND, Non-Penetrating Needle Device; PI, Primary Insomnia; PSQI, Pittsburgh Sleep Quality Index; RCT(s), Randomized Controlled Trial(s); SN, Shallow Needling; SUCRA, Surface Under the Cumulative Ranking; TCM, Traditional Chinese Medicine.

Data Sharing Statement

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

Author Contributions

Fei-Yi Zhao – Conceptualization, Formal analysis, Investigation, Writing – original draft; Wen-Jing Zhang – Formal analysis, Supervision, Writing – review & editing; Qiang-Qiang Fu – Conceptualization, Formal analysis, Investigation, 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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