

Discussion of Certain Limitations in the Design of a Randomized Controlled Trial of Acupuncture and Strategies for Their Improvement [Response to Letter]

Yiming Chen ^{1,2}, Hongyu Xie¹, Min Ye¹, Lele Zhang¹, Aihong Yuan ^{1,2}

¹Department of Acupuncture, the First Affiliated Hospital of Anhui University of Chinese Medicine, Hefei, Anhui, 230031, People's Republic of China;

²Key Laboratory of Xin'an Medicine, Ministry of Education, Hefei, Anhui, 230038, People's Republic of China

Correspondence: Aihong Yuan, Department of Acupuncture, the First Affiliated Hospital of Anhui University of Chinese Medicine, 117 Meishan Road, Shushan District, Hefei, Anhui, 230031, People's Republic of China, Email yuanah2023@163.com

Dear editor

We sincerely thank Dr. Rui Chen et al for their interest in and thoughtful comments on our article.¹ We also appreciate the opportunity to respond to their comments. Below, we provide point-by-point responses to the key issues raised.

Considerations on Deqi Sensation and Electroacupuncture Stimulation

Quantitative control in clinical trials of acupuncture has always been a point of concern. “Deqi”, as a subjective, composite perception experienced by patients, is often difficult to standardise consistently.² In our trial design, to eliminate human factors in the administration of acupuncture and electroacupuncture, acupoints, depth, manipulation, and all parameters of electrical stimulation were standardised. However, the drawback of this standardized approach is that it cannot guarantee a sustained and consistent “deqi” sensation for every participant. This is because acupuncture is inherently a personalized treatment modality, and the perception of needling varies from person to person.³ In clinical practice, an electrical stimulation intensity of 2 mA is tolerable for almost all patients, but some individuals may experience no sensation at all. We did not adjust the stimulation intensity based on individual tolerance levels. The stimulation intensity needed to be kept consistent. However, we will add patient-reported records of the sensation of electrical stimulation and the “deqi” sensation for use in subsequent analyses.

Limitations of the Sham Electroacupuncture Control

Blinding in acupuncture remains an issue without a perfect solution.⁴ There are currently many different forms of sham acupuncture, including no manipulation at all, direct placement of a blunt needle, bracket-assisted placement of a blunt needle, superficial needling, and needling at non-acupoints.⁵ With the exception of the first method, each of the other methods provides some degree of pressure and pain sensation to the participant's skin, and all can stimulate mechanoreceptors. We believe that the placement of a bracket on the skin itself is more likely to generate mechanical stimulation. Moreover, the irregular shape of the knee joint makes it difficult to stabilise the bracket. Additionally, if the blunt needle does not create a sensation of skin penetration, participants can easily detect that they are not being acupunctured. This will undoubtedly eliminate the placebo effect and the expectancy effect, thereby further influencing the participants' central nervous signals.

The focus of our planned brain imaging analysis is to determine the most specific effects of real acupuncture, as compared with the microstimulation and expectancy effects of a blunt needle. Therefore, the cutaneous microstimulation produced by sham acupuncture will not affect our analysis.

Concerns About Unblinding and Its Psychological Contamination of the “Skin-Brain Axis”

As noted above, blinding in acupuncture clinical trials is a problem that is difficult to solve perfectly. We have done our best to minimise the risk of unblinding in this trial. Nevertheless, 100% blinding is unattainable. We will use Bang’s Blinding Index to ultimately assess the success of blinding.

We will include participants’ Bang’s Blinding Index and Patients’ Expectancy Scale for Acupuncture scores as covariates in the regression model to control for the substantial psychological effects of unintended unblinding.

We would like to express our sincere gratitude again to Dr. Rui Chen et al for their suggestions on our trial, as well as for this valuable opportunity for communication. We believe these suggestions will contribute to the improvement of our research. We will subsequently strive to complete this trial.

Disclosure

The authors report no conflicts of interest in this communication.

References

1. Chen Y, Xie H, Ye M, et al. Evaluating the effect of electroacupuncture in knee osteoarthritis: protocol for a multicenter randomized controlled trial. *J Pain Res.* 2026;19:1–14.
2. Kong J, Gollub R, Huang T, et al. Acupuncture *De Qi*, from qualitative history to quantitative measurement. *J Altern Complementary Med.* 2007;13(10):1059–1070. doi:10.1089/acm.2007.0524
3. Zhong Z, Yao L, Liu Y, et al. Objectivization study of acupuncture Deqi and brain modulation mechanisms: a review. *Front Neurosci.* 2024;18:1386108. doi:10.3389/fnins.2024.1386108
4. Liu T, Jiang L, Li S, et al. The blinding status and characteristics in acupuncture clinical trials: a systematic reviews and meta-analysis. *Syst Rev.* 2024;13(1):302. doi:10.1186/s13643-024-02692-0
5. Hu H, Hu T, Han D, et al. Establishment of appropriate sham acupuncture and successful patient blinding. *Acupuncture Med.* 2021;39(2):159–160. doi:10.1177/0964528420924035

Dove Medical Press encourages responsible, free and frank academic debate. The content of the Journal of Pain Research ‘letters to the editor’ section does not necessarily represent the views of Dove Medical Press, its officers, agents, employees, related entities or the Journal of Pain Research editors. While all reasonable steps have been taken to confirm the content of each letter, Dove Medical Press accepts no liability in respect of the content of any letter, nor is it responsible for the content and accuracy of any letter to the editor.

Journal of Pain Research

Publish your work in this journal

The Journal of Pain Research is an international, peer reviewed, open access, online journal that welcomes laboratory and clinical findings in the fields of pain research and the prevention and management of pain. Original research, reviews, symposium reports, hypothesis formation and commentaries are all considered for publication. The manuscript management system is completely online and includes a very quick and fair peer-review system, which is all easy to use. Visit <http://www.dovepress.com/testimonials.php> to read real quotes from published authors.

Submit your manuscript here: <https://www.dovepress.com/journal-of-pain-research-journal>

Dovepress
Taylor & Francis Group

<https://doi.org/10.2147/JPR.S632432>