Letter to the Editor

The discussion on the validity of sham controls and patient blinding in a sham-controlled acupuncture trial

Yuansen Ge

Department of Oncology, Tangshan Hospital of Traditional Chinese Medicine, Tangshan, Hebei, China

ARTICLE INFO

Article history:
Received 28 July 2021
Revised 15 August 2021
Accepted 5 October 2021
Available online 13 October 2021

Keywords:
Acupuncture trial
Blinding
Sham controlled

We read with interest the recent study1 by Mikiyung Kim and colleagues. In their novel study, they made great efforts to implement a sham controlled design in a trial involving patients with major depressive disorder. Patients in the treatment and control groups, respectively, received real and sham electroacupuncture/moxibustion treatments. They found that the mean changes of the Hamilton rating scale for depression (HRSD) at week 5, 9, and 13 were not significantly different between the two groups. Herewith, we raise some concerns about the study. We think that raising and clarifying these points is not merely of scientific but also of clinical importance.

First, successful blinding of patients is vital in sham controlled trials. Many differences might occur in the unblinded performance of the trial that could distort results. For example, patient expectations could be affected, which might influence results.2−3 In this sham controlled trial of Kim et al.,1 a survey using a questionnaire was conducted to ensure whether successful patient blinding was achieved, but it was rated only after the first treatment session in both groups. This is an unusual measurement time-point in relation to similar studies. Given that a total of 20 sessions of real or sham electroacupuncture/moxibustion were performed over 8 weeks, it is more reasonable to investigate the the credibility of patient blinding at the end of the study following similar studies.4 In this scenario, the claimed successful patient blinding in this sham controlled trial is questionable, which subsequently influences the validity and reliability of study results.

Second, we carefully read the detailed descriptions regarding the sham electroacupuncture/moxibustion method in the pre-published protocol.5 In details, the needle tip of a Park sham placebo device (PSD, Dong-Bang AcuPrime Ltd., Exeter, UK) did not penetrate the skin and the electrosimulator was connected to the PSD needles attached to nonacupoints on both legs in the control group – but the electric current was not delivered, however the device made the same beeping sounds as though it was delivering electric current. Nevertheless, given that all sham acupoints were located within the range of patient vision and the treatment course lasted for 8 weeks, it seems impractical to achieve successful patient blinding over such a long treatment course if the sham electroacupuncture method was obviously different from real electroacupuncture. Further, based on the reported low dropout rate (20%), it is safe to assume that the joint “sham” moxibustion is probably “not sham” at all, only in this case the patients in the control group were blinded and had a high compliance rate. As the authors speculated, the feasibility of the sham moxibustion device used in their study was questionable; it seemed to have a substantial thermal stimulus, which might lead to therapeutic effects, whether specific or non-specific, skewing results in the study. Additionally, the study reported that the patients in the sham controlled group generally had mild depression based on the baseline HRSD scores, which is notably different from the treatment group where patients generally had moderate depression. In this scenario, both the specific and non-specific therapeutic effects in the sham-controlled group might greatly surpass the intentions of

1 Corresponding author at: Department of Oncology, Tangshan Hospital of Traditional Chinese Medicine, Tangshan, Hebei Province, 063000, China.
E-mail address: thevervecn163.com

https://doi.org/10.1016/j.imr.2021.100795
2213-4220 © 2021 Korea Institute of Oriental Medicine. Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/)
the authors. This could help explain how that the mean changes of the HRSD at week 5, 9, and 13 were not significantly different between the treatment group and the sham control group.

To conclude, appropriate sham devices for electroacupuncture and moxibustion are urgent warranted, which will contribute to real sham-controls and successful patient blinding in acupuncture randomized trials in the future.

**Author contribution**

This is the sole author’s work.

**Conflict of interest**

The author has no competing interests to declare.

**Funding**

This work was supported by the Project of Hebei Provincial Administration of Traditional Chinese Medicine [grant number 2020392].

**Ethical statement**

Not applicable.

**Data availability**

Not applicable.

**References**

1. Kim M, Choi EJ, Kwon OJ, et al. Electroacupuncture plus moxibustion for major depressive disorder: A randomized, sham-controlled, pilot clinical trial. Integr Med Res. 2021;10(3).
2. Psaty BM, Prentice RL. Minimizing bias in randomized trials: the importance of blinding. JAMA. 2010;304(7):793–794.
3. Strite SA, Stuart ME. Importance of blinding in randomized trials. JAMA. 2010;304(19):2127–2128.
4. Xu S, Yu L, Luo X, et al. Manual acupuncture versus sham acupuncture and usual care for prophylaxis of episodic migraine without aura: multicentre, randomised clinical trial. BMJ. 2020;368:m697.
5. Kim M, Choi EJ, Kim SP, et al. Electroacupuncture plus moxibustion therapy for patients with major depressive disorder: study protocol for a randomized controlled trial. Trials. 2017;18(1):16.