

LETTER TO THE EDITOR

Importance of a Proper Design for Sham Acupuncture Treatment



To the Editor

I am much very interested in the article by Greenlee et al [1] describing an acupuncture trial protocol for breast cancer patients, which included true and sham groups for multi-modal acupuncture treatments (auricle and body). I respectfully wish to express my opinions of the sham-treatment design of the auricular acupuncture. Fig. 1 illustrates the differences between the true and sham treatments based on the descriptions on page 155 of the article.

To confirm the efficacy of acupuncture, researchers need to show that true acupuncture outperforms the sham treatment for patients who are convinced that the sham treatment is the true one. In the abovementioned article, the sham auricular acupuncture might not have effectively

convinced the patients of that because the sham treatment produced zero feelings of puncture, not to mention the fact that auricular skin has a relatively high epidermal nerve density and is tactilely sensitive [2].

In addition, acupuncture treatments always have three components: nonspecific effects of practitioner–patient contact, “tactile stimulation” from mechanical needling into soft tissues, and “meridian-based stimulation” as needles are inserted into the acupuncture points. These components together can initiate complex interactions that affect the interpretations of the efficacy. As the above-mentioned sham auricular acupuncture produced a non-needling stimulation only, I would suggest that in future research on this subject, adhesive 0.3-mm press needles, which are commercially available and can puncture the skin shallowly and precisely, be used. In my opinion, without a well-designed sham treatment, no study will be able to show any advantage of real acupuncture or the study might show an advantage that may have been accidentally generated by an imperfectly designed sham treatment.

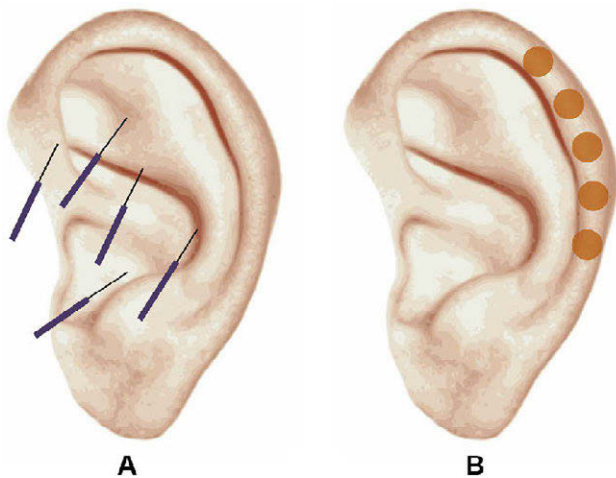


Figure 1 True and sham auricular acuapunctures. (A) True treatment: five needles of 15 mm and 38 gauge. (B) Sham treatment: five adhesives without a pellet or needle.

Disclosure statement

The authors declare that they have no conflicts of interest and no financial interests related to the material of this manuscript.

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Reply

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To the Editor

We carefully read and considered the comments of Y.M. Wong regarding his suggestion on an appropriate procedure for the application of sham auricular acupuncture. His first comment expressed concern about the importance of showing that “true acupuncture outperforms sham acupuncture and that patients must be convinced that the sham treatment is the true one.” We have controlled for this in a number of ways in our current multisite acupuncture trial to reduce aromatase inhibitor-related joint symptoms in breast cancer patients [1]. First, as referenced in our manuscript, we have previously performed two pilot studies of the auricular procedure in this same patient population [2,3]. The first study was a crossover design where the patients received only the true acupuncture protocol [2]. The results showed a difference in the outcome of interest between the active and delayed arms. The second study was a randomized, blinded, sham-controlled trial that utilized the same sham procedure as reported in the current study, and we specifically mentioned this concern in the Results section [3]. We noted that there was no significant difference between the perception of receiving the true acupuncture and the sham arm ($p = 0.08$) at our study endpoint at 6 weeks. Moreover, all seven patients (100%) who had ever received prior acupuncture (> 6 months prior) thought that they were in the true acupuncture group, although four of them (57%) were randomized to the sham arm. In addition, other studies have published results showing differences in effects when utilizing a non-needle control for the auricular acupuncture sham procedure [4,5].

Second, we agree with Wang that the auricular skin has a high epidermal nerve density and is tactilely sensitive. To that point, any auricular sham that uses needles, pellet, adhesive, heat, or laser application may affect the tactile sensitivity of the ear. If that is the case, then none of these procedures are truly inert as all of them stimulate the connective tissue. If we utilize this rationale, inert sham or control groups that would be adequate controls for this concern would best be non-interventional (i.e., nonmanipulative) methods that allow for a comparison between the effects of acupuncture needling and those nonspecific effects. We also recognize that this is a common methodological concern faced by researchers when designing rigorous clinical trials of acupuncture needling, as well as in many procedure-based intervention studies.

Third, we also agree with Wang that acupuncture trials need to be rigorously designed in order to test the true effect of acupuncture. The overarching goal of most acupuncture trials is to demonstrate a difference between a “true” acupuncture protocol and either a “sham” or a “no” acupuncture protocol. Our study tests the differences between three arms, true acupuncture, sham acupuncture, and waitlist control, allowing us to observe the differences in effects between a sham protocol and a lack of acupuncture all together.

In summary, we acknowledge that there are a variety of methods for a good sham acupuncture intervention, including nonspecific needling of auricular points, and thank the author for raising this issue.

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Reply Letter

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