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RESPONSE TO LETTER

Efficacy of Moxibustion Smoke for Stage 1 Post-Stroke Shoulder-Hand Syndrome: Protocol for a Multi-Center, Single-Blind Randomized Sham-Controlled Trial [Response to Letter]

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Dear editor

In a letter to editor titled "Efficacy of Moxibustion Smoke for Stage 1 Post-Stroke Shoulder-Hand Syndrome: Protocol for a Multi-Center, Single-Blind Randomized Sham-Controlled Trial [Letter]", Chen et al kindly mentioned some issues to discuss and offered some suggestions for our study protocol. As a result of their constructive recommendations, this study will be carried out in an even more accurate and scientific manner. Therefore, we'd be delighted to answer their questions.

To begin with, the visual analogue scale (VAS) for pain was designated as the primary outcome because pain contributes to the further exacerbation of regional edema and motor dysfunction in patients with shoulder-hand syndrome.[1–3] Given that a VAS for pain is a subjective rating, this measure could be affected by psychological factors. In order to mitigate such effects and maintain adequate blinding, we have referenced some additional prior publications.[4,5] Before treatments, the patients will be informed that they will receive either traditional moxibustion with a variety of levels of moxibustion smoke concentration (MSC) and heat sensation, or minimal moxibustion with relatively lower levels of MSC and heat sensation, both of which are associated with positive outcomes in clinical practice. A blinding assessment will be conducted upon the completion of all interventions. Our intention is that priming participants with this information in advance will help to counteract the effects of any type of bias, as well as the Hawthorne effect, that might otherwise occur.

The moxibustion apparatus applied in this study, the Happy-all Moxibustion Device (manufactured by the Chongqing Happy-all Medical Device Co., Ltd), has already been thoughtfully designed with considerations to prevent burns to the regional skin by either adjusting the distance between the moxa and skin, or the number of open ventilation holes in the wall of the apparatus. In our study, since indirect moxibustion will be utilized with the goal of producing a comfortable sensation of radiant heat,[6] the dermal temperature in the region receiving moxibustion will also be recorded using a non-contact thermometer (BOSCH GIS500, Germany) after the moxa has been lit. According to our pre-test assessment, the regional dermal temperature ranges from approximately 38°C to 45°C, a spectrum that is not expected to pose a significant risk of burns to the skin. The application of an ointment barrier could potentially influence clinical effects through reducing the amount of radiant heat that is locally absorbed, as well as permeation of the local acupoints by moxibustion smoke, so we have decided against utilizing such a barrier. However, we feel that the above measures are more than adequate to ensure a safe and clinically effective study.

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Disclosure

The authors report no conflicts of interest in this communication.

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