Author's response to reviews

**Title:** Efficacy and safety of acupuncture in patients with cold hands sensation: study protocol for a randomized controlled pilot clinical trial

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Editors-in-Chief
Doug Altman
Curt Furberg
Jeremy Grimshaw

Dear Editors-in-Chief

I, along with my coauthors, would like to ask you to consider the attached manuscript entitled "Efficacy and safety of acupuncture in patients with cold hands sensation: study protocol for a randomized controlled pilot clinical trial" for publication in Trials as an original article.

This study is a randomized controlled pilot clinical trial of 5 weeks duration. Fourteen patients will be recruited and randomly allocated to 2 groups: an acupuncture plus medication group (experimental group) and a medication-only group (control group). All patients will take nifedipine (5 mg once daily) and beraprost (20 mg three times daily) for 3 weeks. The experimental group will receive additional treatment with 3 acupuncture sessions per week for 3 weeks (9 sessions total). The primary outcome will be measured by visual analogue scale. Secondary outcomes will be measured by blood perfusion in laser Doppler perfusion imaging of the hands, frequency and duration of episodes of cold hands, and heart rate variability. Assessments will be made at baseline and at 1, 3, and 5 weeks thereafter. This study will provide an indication of feasibility and a clinical foundation for a future large-scale trial.

We would like to publish in your journal because of its emphasis on improving communication about randomized controlled trials. We believe that the protocol of this study is relevant to the scope of your journal and will be of interest to its readership.

This manuscript has not been published or presented elsewhere in part or in entirety, and is not under consideration by another journal. All the authors have approved the manuscript and agree with submission to your esteemed journal. There are no conflicts of interest to declare.

Thank you for your consideration. I look forward to hearing from you.

Sincerely,
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