Reviewer's report

Title: Acupuncture in patients with cold hands sensation: study protocol for a randomized controlled pilot clinical trial

Version: 3 Date: 5 June 2014

Reviewer: Seok-Jae Ko

Reviewer's report:

Following revisions are minor essential revisions.

1. Some information required to randomized controlled study on acupuncture were missing. Please provide rationale for selecting specific acupoints.

2. There is no information of other components of treatment. Please provide other interventions (e.g. moxibustion, exercises, lifestyle advice) administered to acupuncture or control group. If no other interventions are administered, clarify it. Other components of treatment include setting and context of treatment such as instructions to practitioners.

3. Descriptions of acupuncturists are missing (e.g. qualification or years in acupuncture practice).

4. Please clarify hypothesis and objective of the study. What kind of effect do you expect from the acupuncture?

5. What kind of method did you use for randomization concealment? Clarify method used to implement the random allocation sequence.

Below options are discretionary revisions. If you have not taken up the study yet, please consider following suggestions.

1. Though considering this study to be a pilot study, sample size seems too small. If the results conclude that acupuncture is statistically effective, it would be doubtful to be generalized.

2. According to your context on manuscript, there is no established standard therapy for cold hand sensation and high incidents of unwanted side effect by using calcium channel antagonist or prostaglandin. It seems no benefit to use nifedipine and beraprost group, unless the medications act as a positive control. Why don’t you consider the study design of acupuncture group vs wait-list group without any medication?

3. This study did not use sham acupuncture control. Why don’t you implement questionnaires evaluating expectation or credibility of acupuncture to minimize bias from un-blinded study?

Level of interest: An article of importance in its field
Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests.