Author's response to reviews

Title: Effectiveness of Acupuncture Intervention for Neck Pain Caused by Cervical Spondylosis: Study Protocol for a Randomized Controlled Trial

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Author's response to reviews: see over
Dear editor

The manuscript entitled “Effectiveness of Acupuncture Intervention for Cervical Spondylosis of Cervical Type: Study Protocol for a Randomized, Double-blind Placebo-controlled Trial” (MS:7768553758500625) has been re-revised in accordance with the reviewer’s comments. The newly revised manuscript is now submitted with this letter for consideration of publishing.

Many thanks for the comments from the reviewers and the followings are author’s responses:

Comments 1. The authors shall provide a proof that they have a licensed SAS, for example, the license number, or they can use other software with legal access.

Address: Data analysis will be carried out by using another statistical analysis software IBM SPSS 20.0, and its authorization code is 61624e46c5e9d7871e28.

Comments 2. On page 5-6, the authors mentioned that “all participants will receive 25mg diclofenac sodium three times a day if their visual analogue scale (VAS) scores are exceeded 5”, these extra use of medication will produce confounding influence to the baseline data, thus a corresponding analysis method is needed to present in statistical analysis section.

Address: the amount of extra used diclofenac sodium between experiment and control groups will be analyzed, and the general linear model will be applied to adjust the confounding influence if necessary. It has been added in the revised manuscript.

Comments 3. On page 7, the authors state the “intent-to-treat” strategy will be applied in data analysis, but nothing in detail was described afterwards. Thus they should at least explain what their ITT will be performed in their analysis.

Address: An intention-to-treat (ITT) analysis is based on the initial randomized assignment and not on the treatment eventually received when the results of trial were analyzed. ITT analysis is intended to avoid various misleading artifacts, and can provide unbiased comparisons among the treatment groups. Therefore, the principle of ITT has become widely accepted for the analysis of controlled clinical trials. The simple description about ITT analysis has been added in our revised manuscript.

Comments 4. On page 8, the discussion section is too simple. I think the
author should explain the novelty of their protocol. And on page 6, the rationale of sham acupuncture should be explained in this section or in the discussion section.

Address:
The novelty of this protocol includes as following: first, its study design is in accordance with CONSORT statement of randomized controlled trial; second, the sample size is enough to ensure adequate test-performance; third, the full implementation of the randomization and blind method is used in the protocol; in addition, the rational control (sham acupuncture) is applied to control placebo effect. All above novelty on study design has been described in the discussion section.

To assess the efficacy of acupuncture, placebo effect should be avoided. Due to acupuncture’s invasive nature, the major challenge in the efficacy research of acupuncture is in the design of an appropriate placebo control group. At present, “am acupuncture” is considered as the most commonly proposed placebo control. In practice, sham acupuncture comes in several varieties, such as the needles being inserted into non-traditional sites, or the depth being inserted into the body is not the same actual as active acupuncture, whether at traditional or non-traditional points. In this protocol, sham acupuncture will be performed by the sham treatment at non-acupoint site which lie in 1.5cm away from the proper treatment sites. Furthermore, the depth of the inserted needles will be controlled within 15 mm.

The description about sham acupuncture has been revised in the discussion section.

If there is any problem, please contact me.

Best Wishes

Guo hua Zheng