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 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:

Comments1: The diagnosis of cervical spondylosis of cervical type needs to be revised in accordance with international standard. Cervical spondylosis of cervical type is a Chinese old style diagnosis. In the international Disease Classification (ICD-10), the corresponding diagnosis should be M47.8 (other spondylosis # cervical spondylosis), or neck pain caused by cervical spondylosis.

Address: According to the diagnostic criteria published by Chinese Association of Rehabilitation Medicine (Professional committee of cervical spondylosis, Chinese Association of Rehabilitation Medicine. Guidelines of diagnosis, treatment and rehabilitation for cervical spondylosis (2010). Beijing: Chinese Association of Rehabilitation. 2010), cervical spondylosis of cervical type is in accordance with M47.812 in ICD-10 (other spondylosis without myelopathy or radiculopathy: cervical region). Its main symptom is neck pain, neck stiffness, sometimes accompanied by shoulder pain and stiffness. We agree with the reviewer’s comments that the diagnosis of cervical spondylosis of cervical type needs to be in accordance with international standard, and it has been revised to neck pain caused by cervical spondylosis (CS neck pain) in our manuscript.

Comments2: The sample size calculation basis is questionable. The sample size is calculated by the parameters from a low quality article published in Chinese (Reference 21). In contrast, in the previous work (e.g. Salter GC, Roman M, Bland MJ, MacPherson H. Acupuncture for chronic neck pain: a pilot for a randomised controlled trial.BMC MusculoskeletDisord. 2006 Dec 9;7:99., or Liang ZH, Di Z, Jiang S, Xu SJ, Zhu XP, Fu WB, Lu AP. The optimized acupuncture treatment for neck pain caused by cervical spondylosis: a study protocol of a multicentre randomised controlled trial.Trials. 2012 Jul 9;13:107.), in order to reach a significant level of 0.05 and power of 0.90, the sample of each group must exceed 200.
Address: We wished to estimate the sample size that would be sufficient to detect significant differences in the scores measured by the Northwick Park Neck Pain questionnaire at the end of treatments between the experimental and control groups. We re-selected a published study with similar intervention and similar patients group using same primary outcome instrument to estimate the sample size [Liang Z, Zhu X, Yang X, Fu W, Lu A. Assessment of a traditional acupuncture therapy for chronic neck pain: a pilot randomised controlled study. Complement Ther Med. 2011 Jan;19 Suppl 1:S26-32], the mean and standard deviation of the scores in neck pain were (20.7 ± 11.91) in experimental group and (24.04 ± 11.83) in the control group. The following formula was used to estimate the sample size for a two group trial:

\[ n_1 = n_2 = \frac{2 \left( \frac{z_{\alpha/2} + z_{\beta}}{M_1 - M_2} \right)^2 \delta^2}{\bar{\delta}^2} \]

Calculations were performed using 80% power, a 5% significance level. The required sample size was approximately 198 participants in each group. We plan to enroll 228 participants in each group, allowing for a 15% withdrawal rate.

Comments 3. The format of the reference does not comply with the requirements of BMC. I recommend the authors use the Endnote software to revise the reference session

Address: All references have been revised according to the requirements of BMC.

Comments 4. The authors claimed they followed the CONSORT and STRICTA guideline to report their study. However, they refereed two STRICTA guidelines (Reference 32 & 33) which are actually two versions of STRICTA. Please articulate which version they follow. And according to STRICTA 2010 (i.e. Reference 33), the details of needling and other components of treatment should be described. (Referring to http://www.stricta.info/checklist.htm).

Address: The CONSORT is the international norms of RCT, and STRICTA is the reporting standard about acupuncture intervention. We will report the clinical trial results according to rules of two standards. The details of needling and other components of treatment have been described in the section of methods.
Comments 5. The authors stated they used SAS 8.12 for randomization and SAS 9.2 for statistical analysis. Please explain why they used two different versions and if they really did so, please provide a proof document of their SAS license.

Address: In fact, we performed a randomization program of this trial by using SAS 8.12 versions. But we cannot provide a proof document of its license because we consign a statistics teacher in Fujian Medical University to perform the program. Our institution is planning to purchase SAS 9.2 software or more high versions. We are expecting that we can analyze data of this trial using SAS 9.2 version. In addition, the randomization program and basis statistical analysis could be also completed by using other statistical software, for example, SPSS, STATA software. So we do not think that we should mind the problem of different SAS software versions. But we agree with the reviewer’s comments that the software versions should be equal between the randomization program and statistical analysis.

If there is any problem, please contact me.

Best Wishes

Guo hua Zheng