Author's response to reviews

Title: Wrist-Ankle Acupuncture (WAA) for precompetition nervous syndrome: study protocol for a randomized controlled trial

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Version: 4 Date: 22 July 2015

Author's response to reviews: see over
Dear editors and reviewers:

Thank you for your kind and useful comments. They are so important for the trial. According to the comments, the protocol has been revised again. The details are as following.

Major Compulsory Revisions#

1. How is the precompetition nervous syndrome diagnosed? You should address the diagnostic criteria of the disease.

It is disappointing that we couldn’t find any generally recognized disease diagnostic criterion in all the literature of sports psychology. Precompetition nervous syndrome is excessive nervous and anxious response to the environment of high pressure before sport competition. Only within the specific time, the excessive nervous and anxious appears. Once without the competition environment, all the symptoms will disappear soon. Under this particular situation, every athlete may have different degrees of psychological stress changes. It is different from other diseases; actually it can’t be called a disease, technically just a syndrome. So in the paper, all the word “patient” have been corrected as “participant”.

On the other hand, we refer to the method of Sports psychology (Adult education cooperation group of national sports colleges and universities. Sports psychology. 1st ed. Beijing: People's sport publishing press; 1999.) to recruit potential participants in our trial. “Those who have two or more than two major symptoms of excessive nervous and anxious, insomnia, fear of failure, inattention could be recruited. One item in the questionnaire is to distinguish if these symptoms are response before the competition.”

2. You should write clearly the time point of evaluation, and note that how to determine the efficacy of treatment.

All the participants will be asked to complete two identical scale questionnaires and physical conditions examinations before and after the treatment for assessing the anxiety condition. The first questionnaire and physical conditions examination need to be completed 30 minutes before the treatment, while the second one will be collected 30 minutes after the treatment. CSAI-2 is the primary outcome to assess competitive anxiety and the efficacy of treatment. The Scale is composed of three subscales, each subscales score respectively, each has 9 items; Scores are from 9 to 36, the higher score means the higher of the cognitive state anxiety, the somatic state anxiety and the state self-confidence.

3. Sample size calculation and statistical analysis.

Why the sample size is 75, as you said the proportion of 1:1 assigned to two groups?

I am sorry, 75 here is really a mistake. The sample size should be 76, according to 15 % dropout rate and the proportion of 1:1. In order to get a rigorous and correct calculation of sample size, we went to consult the statisticians and revise the sample size calculation in the main text. The final sample size is 100, with 50 for each group.
The sample size is estimated based on changes of CSAI-2 before and after treatment from a pilot study. The pilot study was a two-arm design with WAA group and sham acupuncture group. The means of changes of WAA group and sham acupuncture group are 1.9 and -2.0 respectively, while the standard deviations are 6.9 and 5.5. The software Power Analysis and Sample Size (SAS; version 9.3) was used to perform the sample size calculation. The sample size was calculated with a significance level of 0.05 and power of 0.80. The result was a total required sample size of 86, with 43 for each group. With a maximum dropout tolerance of 15%, 7 patients are needed for each group. Therefore, 100 participants are needed for the trial, with 50 for each group.

Minor Essential Revisions

1. The language and grammar needs further revising or polishing. You can consult the professional personage to help modify.

Thank you for your kind advice. I have consulted the English native language personage to modify my paper. Some language and grammar had been revised.

2. Please note the literature reference format and details, such as the references 4 and 5.

I have revised the format and details of literature reference. References 4 and 5 are also been noted with right format and more details. Thank you very much.

PS: there is one mistake of exclusion criteria in the previous version. It has been corrected in the latest version.

The right exclusion criteria should be as following:

Exclusion criteria:

3) Depression trend (depression self-rating scale score ≥ 41).

Best regards!

Yours sincerely,

Shuang zhou, on behalf of all the authors