Reviewer’s report

Title: Effect of acupuncture on patients with insomnia: A study protocol for a randomized controlled trial

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Reviewer: Wing-Fai Yeung

Reviewer’s report:

I thank the Editor for giving me a chance to review the manuscript for Trials. The manuscript written by Hua et al. is a protocol of a randomized controlled trial of acupuncture treatment for insomnia. The study aims to compare acupuncture and sham acupuncture (needling at 1-cm away from true acupoint) in improving subjective insomnia symptoms. The study will add knowledge to the current evidence regarding acupuncture treatment for insomnia. However, some parts of the protocol are unclear. I hope my suggestions would further improve the study.

Major Compulsory Revisions

Introduction

1. The authors cited recent systematic reviews of acupuncture for the treatment of insomnia. However, there are 2-3 RCTs published recently but not included in the reviews. It would be helpful if the authors briefly described the recent RCTs, especially for the RCTs which compared acupuncture with sham/placebo acupuncture.

2. Any justification for including EEG and heart rate variability as outcomes?

Method

3. The writing of hypothesis is strange. The authors may consider rephrasing it. First, the authors mentioned acupuncture will be compared to a “placebo control”, but the authors later used the term “sham”. Second, the sentence “insomnia symptoms will be measured with ISI” should not be placed here.

4. Objectives, the points will look better if they begin with “to examine…”, or “to compare” etc.

5. Sleep log is used for only 2-day which is obviously too short. Sleep log is usually used for at least 1 week. Some standard assessments for insomnia are not used e.g. objective actigraphy/polysomnography. The authors may need to discuss these limitations. It would be helpful for the author to look at this paper:

6. The description of intervention is somehow unclear and is not detail enough to allow other researchers to replicate the treatment protocol. It is stated that “acupuncture treatment (or sham acupuncture treatment if in the control group) followed by intradermal acupuncture (IDA)” does it mean that each subject will receive 2 types of acupuncture treatments? In addition, “acupuncture injection” is used. Does it mean acupuncture needle insertion?

7. It seems that sleep log has not been mentioned in the secondary outcome.

8. Randomization is not described properly. I am puzzled how and why "randomization will be done seven to nine times among four or six patients who passed the screening test." Instead, the authors should describe how the random sequence would be generated and the allocation concealment would be ensured.

9. Statistical method, I highly suggest the authors consulting a statistician in writing the part on statistical analysis. It is incorrect to use ANOVA comparison between 2 groups. Moreover, the primary endpoint has not been defined.

10. Monitoring, please specify the person/organization who will be responsible for monitoring.

Minor Essential Revisions
1. Assessment, trial was wrongly spelled as trail.
2. DSM, fifth ed should be written as DSM-5, not DSM-IV. Moreover, the reference [10] wrongly cited DSM-IV.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I am a Co-I of an ongoing trial of acupuncture in combination with auricular acupuncture for insomnia.