**Reviewer's report**

**Title:** Effect and safety of acupuncture for Hwa-byung, an anger syndrome: a study protocol of a randomized controlled pilot trial

**Version:** 0  **Date:** 13 Oct 2017

**Reviewer:** Wai Tong Chien

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The protocol is an innovative and potential effective TCM interventions for people with Hwa-byung (an anger syndrome), which may be new to most researchers in psychiatry. The protocol has been written satisfactory and included most of the important information clearly for a pilot clinical trial proposal. However, there are several points to be clarified or addressed before further consideration of publication:

1. Throughout the protocol, the aspects of assessment or evaluation of feasibility and acceptability are not clear, thus needing restructuring or clarification. There are inconsistencies in the aim/objectives such as "to determine the study feasibility of acupuncture treatment..." in the abstract, "clinical outcomes will be sued to investigate the acceptability and tolerability of the acupuncture in Clinical outcome section, "The acceptability of the treatment will also be evaluated according to basic information about the effect and safety" in the discussion". In addition, some terms have been used inconsistently, such as "harms" in the abstract and "safety" in the protocol content; "acceptability", "tolerability", "integrity of study protocol" in relation to feasibility, so on.
2. One personal query is about the open access and international acceptability of the trial registration site - CRIS.
3. In the background, 2nd paragraph, you mentioned the HB is often treated as a "novel anger disorder" and it is not clear whether it is classified in DSM-V or other psychiatric disorder diagnosis system or not. Please clarify. And you also mentioned in the 3rd paragraph that there are "limited quantity and quality of studies investigating the effects of pharmacological and psychosocial intervention for HB. Please describe the important and latest research evidence on this issue and any conclusion or recommendations from the available recent research. For the effect of acupuncture in HB in the 4th paragraph, you mentioned that studies reported significant improvements in the main symptoms of HB, which study(ies) are you referring to? And if that is the case, why you have to pilot test about this intervention for HB again? You also need to specify what the clinical guideline for HB in 2013 is referred to and is that an evidence-based or standard one used by researchers or clinicians?
4. The study design can be restructured or reworded as it is not clear: "this study is a randomized, controlled, parallel clinical trial."
5. For settings, describe or clarify what is the "academic hospital setting" referred to? Are they inpatients? For the approach and recruitment of patients, it is unclear to just mentioned "when they are found eligible for the study, they will be randomly assigned..." in the setting section. How and where to approach and assess them?

6. For recruitment, a total of 26 participants will be used. Please give rationale for 26 participants (13 for each group). In addition, not sure how to ensure enough subjects responded to the advertisements. Please clarify.

7. For randomization, there should be possible reasons for that "if randomization cannot be performed, the number and reason for the lack of randomization will be recorded in a screening log..."; and, what are the expected number of this non-randomisation encountered?

8. For sample size calculation you mentioned about no previous similar studies on this topic. Therefore, the sample size will be decided according to the minimum number needed to achieve feasibility and on the number of people available to be recruited from the clinical trial site. This is fully unclear to me. You should know and estimate the total patient population in the setting, the minimum number of sample expected. Otherwise, I can't understand how can you estimate the total number of participants is 26 (in the recruitment section).

9. some unclear issues in the sample inclusion and exclusion: (a) why they should be aged 20 or above? Any reasons behind? (b) what are the main criteria of HBDIS? (c) what are the serious psychiatric or neurologic disorders meant? How to consider its severity as "serious"? (d) why not including those with the use of medication related to HB and its if often they are not medically treated when being diagnosed? Could it be difficult to find some HB patients without medication use? (e) what is meant by "a seriously unstable medical condition"? Any example? (f) if they are recruited from hospital setting, why "residents of collective dwelling facilities" will be found? (g) it is a vague and invalid exclusion criterion: "lack of eligibility for the trial for other reason as determined by the principal investigator."

10. For the acupuncture procedure, sham control and acupoints, you need to specify the standard or guidelines used and its reference.

11. In section 8.3, you mentioned "medications that participants have been taking before the start of this study will be maintained unless the medications affect the assessment of the results." It is vague what kinds of medications referring to and would this be contradicted with the above mentioned exclusion criterion on those with the use of medication related to HB?

12. For trial feasibility, it is not clear about its aspects of assessment. How is it related to integrity of study protocol and acceptability? The integrity of protocol will be assessed with a binding index but it is not clearly described. How is the validity of this index?

13. The primary outcome and one secondary outcome are in the form of VAS scale. There is not any reliability and validity results described.
14. For data collection, it is not clear about the experience of KMD and what was the training provided?
15. For statistical analysis, the statistical tests for or approaches to outcome analysis at multiple time-points are limited. The compliance and completion of the intervention should be defined. The effect size should specify which time point(s) are referred to?
16. For safety as one important objective, more detail of reporting procedure and forms used for adverse effects should be given.
17. For discussion (and methods), there should have been clear, structured description and discussion of all aspects of feasibility and acceptability to be assessed or evaluated. The sentence "The acceptability of the treatment will also be evaluated according to the basic information about the effect and safety." On p. 10 is unclear.

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