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: 03 Nov 2017

Reviewer: Daniel Bressington

Reviewer's report:

Thank you for submitting your work to Trials. The paper reports a study protocol for a pilot RCT of acupuncture for Hwa-byung (HB).

The paper is generally well written and structured, with good use of English language. The topic is interesting, albeit it rather limited in relevance to only Korean settings (given that HB is a Korean-bound cultural syndrome).

I have some comments and suggestions, which the authors can consider to improve the clarity of the manuscript.

It would be useful (for the acupuncture uninitiated readers) to provide a summary of the hypothetical therapeutic mechanisms of acupuncture therapy (either in the introduction/background or the discussion).

It is clear that HB is a Korean culturally bound syndrome, but as the journal has an international readership it would be useful to briefly mention the relevance of the proposed study beyond Korea. For example, is HB ever reported in other Asian settings? Or is there anything in the protocol which would be helpful/transferrable for researcher/clinicians in other international settings?

The mention of the various acupuncture points (i.e. GV20) in the summary may not be necessary, as this information will not mean much for many readers. Similarly, it would be useful to mention where these are located in the methods section (currently the location of non-acupuncture points are detailed, but not the real points).

The background mentions that previous studies report the effectiveness of acupuncture for HB. If previous studies were effective, why conduct the proposed study? The rationale for conducting the study should be clearer/stronger (this is briefly mentioned in the discussion, but would probably be better placed in the background section).

The final paragraph of the introduction uses the past tense, whereas future tense is used elsewhere. Please correct this for consistency.

Study design - blinding should be mentioned here.
Setting of study: (line three) currently states: "randomly assigned into two groups" should read: "randomly assigned into ONE OF two groups"

Sample size:

More justification should be provided for such a small sample size. Also, the data analysis mentions using means and standard deviations - but with such a small sample size this may not be appropriate?

Serotonin levels:

The rationale for measuring serotonin levels should be provided (i.e. how do these relate to HB?). In addition, details about the process of serotonin sample collection and analysis should be given.

Exclusion criteria:

Examples of "serious psychiatric disorders" and "neurological disorders" could be provided to add to clarity. Please also mention how these will be determined (i.e. diagnosed by whom and using which diagnostic criteria?).

Similarly, "lack of eligibility…. For other reasons as determined.." - it would be useful to know what might these reasons be, otherwise the PI could exclude people that are not felt to respond to treatment, hence biasing results.

Allowed or prohibited concomitant treatment:

Psychotropic medications are mentioned as these might affect the results, but what about medications for gastrointestinal disorders or treatment for palpitations (as these are also symptoms of HB)?

What will the researchers do if participants report use of prohibited treatments during the trial/at follow-up?

Outcome measures:

The validity/psychometric properties of the Korean versions of assessments should be provided.
Level of interest
Please indicate how interesting you found the manuscript:

An article of limited interest

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All images and figures within the manuscript should be genuine i.e. without evidence of manipulation. No specific feature within an image may be enhanced, obscured, moved, removed, or introduced. If you have concerns about the veracity of the figures you should choose the first option below.

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