Reviewer’s report

Title: Effectiveness of acupuncture for breast cancer related lymphedema: Protocol for a single-blind, sham-controlled, randomized, multicenter trial

Version: 0 Date: 20 Jul 2017

Reviewer: Yan Zhang

Reviewer's report:

This protocol is of interest of the journal, but it has following shortcomings to be addressed.

1. Introduction: "background" is the only subheading in introduction, please consider removing it.

   (1) P3, line 9-11: It needs more background information/data in China where the study takes place in. Just citing US data appears insufficient.

   (2) P3, line 13-15: Health insurance coverage is not the best indicator of economic burden on the society, authors may want to add other indicators such as loss of productivity etc.

   (3) P3, line 16: "there is no way to forecast whether an individual patient will develop lymphedema or not.", I find it difficult to draw the same conclusion as authors stated based on the cited article, there are also other articles indicating risk factors for BCRL. I suggest authors to revisit this statement and make conclusion with caution. In addition, adding background information regarding risk factors of BCRL will help the readers to understand why certain variables are chosen for this study.

   (4) P3, line 44-55. The research aims are too vague to measure, and those actually sound more like the research approaches. I suggest the authors to have more specific questions or hypotheses written so to better lead the statistical analysis later.

2. Method

   (1) Study Setting/Design: I suggest the authors to summarize their study design such as a multi-center two-arm (?) randomized clinical trial before describing the setting. Also, please provide average numbers of the breast cancer patients seen annually at each center for readers to understand how representative the sample might be. P4, ling 5-8, the description of intervention is confusing, I suggest the authors to describe the intervention group and control group separately.
(2) Eligibility criteria: There is a conflicting information regarding BMI. It includes BMI 18-28 and excludes overweight women. However, the general cutoff for overweight is BMI 25-29.9. Please explain the discrepancy.

(3) Intervention: are sham-acupuncture performed at the same points as real acupuncture group? Please describe the main characters of Steinberger needle and why is it considered to be ideal for sham acupuncture instead of just citing it. Is a decongestive therapy standard treatment for BCRL? Please describe why it is chosen for both intervention and control groups.

(4) Outcome, Measures, and data collection: The method section lacks appropriate description of measures of the outcomes. For instance, for the primary outcome-ARLVR: how limb volume is measured? It states "to take assessments of both limbs by perometer (p6-7)", what is a perometer? How is that measured? I suggest the authors to add proper measurement description for each outcome, particularly for lymphedema, then describe the data collection accordingly, such as when are baseline, pre-intervention, mid-point, and end-point data collected etc.

(5) Sample size estimation: although there were not identical studies done, there are similar trials conducted before. For instance, Cassileth's study published in 2013 used the a ratio outcome to assess acupuncture for lymphedema(https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3738927/). Consult with a biostatistician to obtain more accurate estimated effect size.

(6) Data management: There is no adequate description of data management; most of that paragraph is about loss to follow-up. P. 13-22 should be moved to other section describing potential risks in data collection procedure.

(7) Statistical analysis: I am concerned about the test proposed. As there are only two groups (real vs sham acupuncture) to compare, ANOVA will NOT be the proper test. If the authors tried to compare three sites, then you can use ANOVA, but that is not research questions of this study. Overall the statistical analysis section is inadequate; please consult a statistician to rewrite. If the test changes, you will need to perform sample estimation again to get new adequate number.

3. Discussion: information about Steinberger needle (p9, line 9-28) should be moved into methods. Information about perometer (p9. Line 28-39) should be moved into methods.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No
**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Yes

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Unable to assess

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

**Quality of written English**
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

**Declaration of competing interests**
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.
I declare that I have no competing interests

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal