Author’s response to reviews

Title: Efficacy of Chinese herbal medicine Zengru Gao to promote breastfeeding: a multicenter randomized controlled trial

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Efficacy of Chinese herbal medicine Zengru Gao to promote breastfeeding: a multicenter randomized controlled trial

Dear Dr. Tom Rowles,

We thank Angela Lupattelli, David M. Haas, Luis Vitetta for their helpful comments. We largely agree with the points raised and considered many of them in the revised version of the manuscript. In the following, our changes are listed next to the points raised.

Sincerely yours,
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Reviewer reports:

Angela Lupattelli (Reviewer 2): The paper has improved substantially, and all concerns have been addressed.
Reply: Thank you for your positive and encouraging comment.

David M. Haas (Reviewer 3): Please include all comments for the authors in this box rather than uploading your report as an attachment. Please only upload as attachments annotated versions of manuscripts, graphs, supporting materials or other aspects of your report which cannot be included in a text format.
Reply: Done.

In this revised manuscript, the authors again provide the results of their RCT comparing the herbal Zengru Gao to nothing in an effort to increase breastfeeding. The responses to the reviewer comments are well referenced and in general very responsive. Several of the items however are explained in the reviewer comment response but are not actually put into the text of the manuscript- for instance the response states the trial registry but they did not add that to the actual methods of the text. This really should be done. A few other comments/questions.

Reply: We very much appreciate the careful reading of our manuscript and your valuable suggestions. We have carefully considered the comments and have revised the manuscript accordingly in this version. Methods section, study design, Trial registration number ChiCTR-IPR-15007376 was added.

1. Table 2. It is odd that the only real results table covers a secondary outcome. it would be much better to have the primary outcomes- full breastfeeding, partial breastfeeding (reported by themselves and then as the combined outcome) in the main result table.
Reply: We agree. We included a new table (Table 2) showing the primary outcomes.

2. The authors clarified why women were excluded post-randomization. However, some of these reasons are not valid for excluding the women. For instance, it is noted that they were excluded if they could not be reached by telephone. Does this mean that they didn't have a way to contact the women or that they tried and were unable to? Either way, the women would be in the hospital and could have gotten results for day 1. Thus, they may not be analyzable for all time points but they would have valid data for day 1 and maybe 3. Also, the team should have known if there would be NO way for the women to be contacted during the screening process and thus they would have been excluded before randomization.

Reply: Thank you very much! Sorry for the confusion. China is a place of culture and tradition. Chinese women have practiced zuo yuezi, otherwise known as the confinement time. Zuo yuezi refers to the time after giving birth when a woman needs to heal from the birthing process. If done in the traditional way, it comprises of staying inside, avoiding disturbing. The tradition makes some Chinese mothers as quickly as possible to leave the hospital. Thus clinicians found it particularly difficult to explain the compliance was important to some potential participants. Actually, these participants who no response to phone calls and choose to pump breast milk lack any data post randomization.

3. The same thing is asked about the women excluded for pumping. If a woman didn't start pumping until day 4, she would have data on outcomes at day 1 and 3 and those should have been included.

Reply: Please refer to the above response.

4. Full and partial breastfeeding should be reported individually as well as a composite.

Reply: Breastfeeding patterns can vary over the first period postpartum, and this fact makes definitions for outcome measure a challenge. As suggested full and partial breastfeeding were reported individually in the revised manuscript (Table 2).

5. Table 2- was formula consumed measured for all women? For those who were fully breastfeeding, I assume that their volume would be recorded as 0. The analysis should also be run only for women who were partial breastfeeding. That way the rates of full breastfeeding women are not confounding the comparison.
Reply: Yes, full breastfeeding women were not included.

6. The overall conclusion of the paper that Zengru Gao "enhanced breastfeeding success" is still not supported by the data. The small improvement on day 3 is not seen at the end of the study on day 7. Thus the conclusion should rather be that the herb did not show a clear difference, although there was some improvement seen at day 3.

Reply: In the revised version of the manuscript, we show the results of full and partial breastfeeding in separately. Now, Zengru Gao enhanced breastfeeding success during one week postpartum is supported by reliable information.

7. In the discussion, much of the high rate of success in this population may be attributable to the intensive counseling and following of the study nurse who was likely encouraging breastfeeding to all participants - hopefully no matter what group they were in. This might be an explanation for the high rates of success and should be in the discussion.

Reply: Yes, you are absolutely right about this point. We added the following sentence to the discussion section: Much of the high rate of success in this population may be attributable to intensive counseling and following of the study nurse who was likely encouraging breastfeeding to all participants.

8. The authors state that they did not record any complications in the control group. Please clarify (in the text) if this was that there were no complications in that group or if the study team just didn't ask women in the control group if they had any complications. If a clinician was involved in determining if a side effect was due to the medication, was that person blinded to the group? I assume not and that it was a clinician who was involved with the study. This is a big problem with risk of bias. Thus it is really not valid to state there is no increase in adverse effects as it was not objectively evaluated.

Reply: the study team didn't ask women and record any complications in the control group. Assessors who involved in determining if an adverse event was due to the medication were blinded to the group.

Luis Vitetta (Reviewer 4): Thank you for inviting me to review the manuscript titled: Efficacy of Chinese herbal medicine Zengru Gao to promote breastfeeding: a multicenter randomized controlled trial. After having read the revised version of the manuscript I suggest that the authors note the following and provide appropriate responses.
1. In the abstract line 29 please state what was the early postpartum period...perhaps provide a range in days or weeks as this will provide additional clarity.

Reply: We are very appreciated with this important suggestion by the reviewer and agree with this. The first 2–3 weeks of breastfeeding constitute the critically important learning period and the time when routine breastfeeding education and support from medical and community sources is most needed [1,2]. Even so, little attention has focused on this critical period in terms of services to support and encourage mothers who have elected to breastfeed [3]. Due to the cost of clinical trial and the current state of feasibility from the perspective of our clinical trial sites, we choose one week as follow up period. Further investigation may extend investigation period.

2. Please begin the discussion with what the study found and not more introductory remarks. Subsequently the results of the current study should be discussed within the boundaries of other studies.

Reply: We agree to this point and reorganized this entire paragraph in the new version of the manuscript.

3. I am assuming that the numbers in Table 1 (in columns 2–4) refer to a mean and SD...please amend accordingly.

Reply: We are very sorry for our mistake. We have now amended this in Table 1.

4. The English language needs to be checked prior to a decision being made by the editors.

Reply: The revised version of the manuscript was corrected by a native English speaker. Now we believe the revised paper will provide a more readable description on the method and the main results of this study.

References
