Reviewer’s report

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

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Reviewer: David M. Haas

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Review for manuscript BCAM-D-16-01309

In this manuscript the authors report results of an RCT of an herbal supplement given postpartum to increase the milk production and breastfeeding of women in a multicenter Chinese RCT. This interesting study demonstrated that only at day 3 was there an improvement in breastfeeding and at day 7 there was less formula used in the supplement group. I have a few questions/concerns for the authors.

1. Results from RCTS comparing proportions are more commonly reported as Relative Risks and confidence intervals, not a range of %s.

2. Was this trial registered in a trial registry?

3. Abstract conclusion states that the herbal drug was "well tolerance" Since these results are not presented in the abstract, it should not be in the abstract conclusion.

4. It is apparent that there was no blinding of the participants or providers. This should be explicitly stated. However, were the outcomes assessors blinded as to the group assignment? Or did the people asking about breastfeeding outcomes also know if the woman was taking the supplement or nothing?

5. The rate of breastfeeding in both groups was higher than baseline hospital data stated in the sample size calculation. Were there any other programs going on in all or some of the hospitals to promote more breastfeeding. These might have been hiring of lactation consultants, removing free formula for moms, other interventions to promote breastfeeding. These could be confounders to the results.

6. Did the authors analyze results by site? Were there any differences in the individual sites in the results?

7. Breastfeeding was defined as direct from the breast. Were women excluded if they were pumping?
8. Figure 1 shows that 34 women were excluded for "other" reasons post randomization. This can introduce bias and these women should be accounted for and explained better why they were randomized.

9. Results - the authors often state that rates were higher in the herbal group when there was not a statistically significant difference. This reveals a bias. Instead it should be stated that, "There was no clear difference between the groups in breastfeeding rates at day 1 or 7 or in the amount of formula supplementation on day 1 or 3."

10. Adverse events - The authors need to perform a statistical comparison of the rate of 5% complications/Adverse events to 0% in the control group. Also it is difficult to accept the final sentence in that section page 5 line 42 that says that no AEs were associated with the treatment when there were several that included infant effects and NONE in the control group.

11. Discussion line 52 page 5 states that the supplement resulted in "a significant increase formula intake volumes..." This is incorrect as the data in text and Table 2 show decreased formula consumption.

12. Conclusion page 6 is confusing. The authors state that the results do not support the use of the herbal supplement but then states that the "obvious benefit" needs to be considered. Without breast milk data on the supplement and infant outcome data longer than 7 days, safety cannot be assumed.

13. Table 1- the Pregnancy before number and Giving birth before number should likely be changed to gravidity and parity for consistency with other literature.

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

Yes

**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.

Yes
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

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