Author’s response to reviews

Title: A Childhood Immunization Education Program for Parents Delivered during Late Pregnancy and One-month Postpartum: A Randomized Controlled Trial

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Author’s response to reviews:

Dr. Maria Zalm
Editor-in-Chief
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Dear Dr Zalm,

Please find attached a revised version of our manuscript “A Childhood Immunization Education Program for Parents Delivered during Late Pregnancy and One-month Postpartum: A Randomized Controlled Trial”, by Hiroko Otsuka-Ono, Narumi Hori, Hiroshi Ohta, Yukari Uemura, and Kiyoko Kamibeppu, which we would like to resubmit for publication as a research article in BMC Health Services Research. The reviewer’s comments were highly insightful and enabled us to greatly improve the quality of our manuscript.
Our point-by-point responses to the reviewer’s comments are provided below.

We hope that the revisions in the manuscript and our accompanying responses are sufficient to make our manuscript acceptable for publication in BMC Health Services Research.

We look forward to hearing from you at your earliest convenience.

Yours sincerely,

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Responses to the Reviewer’s comments

Thank you for your insightful comments, which have helped us to significantly improve our paper.
Matthew F. Daley: General comments:

1. The authors present the findings of a randomized controlled trial of the effectiveness two educational sessions (one during pregnancy, one at one month of age) at improving immunization receipt. The primary outcome was self-reported hepatitis B vaccination at 2 months of age, a vaccine considered "optional" in Japan at the time of the study.

2. The topic is important, and the methods are appropriate to the question of interest.

3. This is a revision of a previously submitted manuscript; the authors appear to have addressed the majority of the issues raised by the prior reviewers.

4. Because of the large effect observed, I am going to speculate that "optional" vaccines are often ignored or de-emphasized in vaccination conversations in Japan for infants?

Response: We agree and likewise speculate that optional vaccines are often ignored or de-emphasized in vaccination conversations in Japan for infants.

Specific comments:

Title:

5. Good, although it may be helpful to include the timing of the intervention, such as "delivered during pregnancy and early infancy."

Response: We have added "delivered during late pregnancy and one-month postpartum" to the title.

Abstract

6. The phrase "vaccinations required under law are nevertheless voluntary" seems redundant with the immediately prior phrase.

Response: We have deleted "vaccinations required under law are nevertheless voluntary".

7. Results in abstract: for the knowledge and literacy scores, it is not clear what the numbers represent. These are scores on a 10-point composite scale?

Response: We have added ranges for the knowledge and literacy scores to the Results section of the Abstract. The scoring system was explained in the Methods section of the main text in original version of the manuscript. We have highlighted the relevant passage as follows:
Knowledge was measured on a 3-point Likert scale consisting of “I don't think so”, “I don't know” and “I think so”, and evaluated using scores of 1 (I don't know), 2 (incorrect answer), or 3 (correct answer). Basic knowledge consisted of 10 items and advanced knowledge of 5 items, with higher scores indicating greater knowledge.

Each item was rated on a 5-point scale, with potential responses ranging from 1, “strongly disagree” to 5, “strongly agree”. The mean score of the five items was used in the analyses, with higher scores indicating greater health literacy regarding immunization.

8. Are hepatitis B and rotavirus vaccines "recommended but optional?"

Response: As we noted in the Development and contents of guidebook subsection of the Methods, “optional vaccinations included those for hepatitis B and rotavirus at the time of the survey.” Optional vaccinations are "recommended but optional". All vaccines are in fact voluntary in Japan.

9. Were immunization rates self-reported on the follow-up survey? If so, please describe as self-reported in the abstract.

Response: We have added "self-reported" to the abstract.

Introduction

10. The introduction is well-written; however, it may be possible to shorten it while emphasizing the most important points.

Response: We have summarized parts of the Introduction.

Methods

11. I was confused by the sentence: "Participants assigned to the intervention group were provided with the guidebook and infant immunization schedule prior to the intervention after group assignment." This wasn't provided during the first educational session?

Response: We informed the participants that they were assigned to the intervention group, distributed the guidebook with an infant immunization schedule for them to read during the waiting time for the prenatal checkup, and then performed the intervention. We have added "so that they could read them during the waiting time for the prenatal checkup" to the Intervention subsection of the Methods.
12. I am not familiar with assessing knowledge using a 3-point Likert scale. Does this produce valid, reproducible results?

Response: Yes, use of a 3-point Likert scale is suitable for knowledge assessment and is reproducible.

13. Analyses: Assuming that hepatitis B vaccination was the primary study outcome, what was the analytical method to determine the effectiveness of the intervention? A Fisher's exact test, without controlling for any covariates?

Response: As this study was a randomized controlled trial, covariates were already controlled between the two groups.

Results
14. Clearly written
15. Excellent survey response rate.

Discussion
16. Regarding the sentence: "Intent among parents to immunize their child is a clear predictor of actual vaccination." While I agree in general, it is important to recognize that intention does not always predict behavior.

Response: We have replaced "clear" with "reliable" in this sentence.

17. Regarding the sentence: "Health literacy was higher…" Does this refer to immunization-specific health literacy?

Response: Yes it does. We have added "regarding immunization" to this sentence on health literacy in the Discussion section.

18. Regarding the sentence: "The main reason was that immunization education was sufficient for involving fathers in shared decision-making on optional childhood vaccinations." Do the authors have quantitative data to support this statement, or is it speculation?

Response: We have quantitative data to support this. The data are described in the Results and summarized in Table 3 and Table 4.
Competing interests

19. Appropriately acknowledged

Human subjects research protections

20. Appropriately acknowledged

Tables and Figures

21. Table 2: please consider adding "self-reported" to the title.
Response: We have added "self-reported" to the title of Table 2. Immunization status was self-reported by groups after the intervention.

References

22. There are several content and formatting issues with the references. For example, it is helpful to provide the Access Date for internet references.
Response: We have added the access date for internet references.