Author’s response to reviews

Title: PRENACEL Partner - Use of Short Message Service (SMS) to encourage male involvement in prenatal care: a cluster randomized trial

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Author’s response to reviews:

Reply to reviewers – december 2019
Firstly, we would like to acknowledge all the criticism, suggestions and guidance of the reviewers. This information greatly improves our work.

Reviewer reports:

Reviewer #1: Abstract
1. Background, Aim, Methods, Results, and Conclusion shall start at new line.
The summary has been corrected according to the orientation given
2. Line 72: What are some criteria?
This has been corrected in the abstract. These criteria have been predetermined and are presented in the methods section.

Background
3. The background section focused only on partners' role on maternal health. This might be good to understand the role of the partners. However, the authors fail to come up with evidences that indicate the use of SMS and/or other technologies on male involvement in prenatal care or other health services.
4. In addition, the author did not address why they wanted to conduct this study i.e. what is unknown about the topic. Is their lack of evidences on the use of SMS on partners' involvement? Or Is there any methodological flaw in the existing evidences?
These are important notes for the introduction. This article is part of a larger project focusing on improving and providing reproductive health for both men and women, but in this article we prioritize partner information and as described in the article there is more content related to women and evidence for the use of technologies and the role of the partner are further explored in the discussion of the article. The lack of knowledge on the topic would be what or how best to include pregnant women partners in prenatal care. And our study showed that using SMS seems to be a promising way to bring partners closer together. And this was improved in the introduction of the article.

Methods
Design and setting
5. Some of the information described under study design and setting section of the methods (Lines 231 -236) could be data collection instruments section.
6. Similarly, the information described in paragraph 2 of the same section methods (Lines 237 -241) could be moved to ethical approval section. In this section, it may be enough to describe the study design and some information about the study area such as the number of health facilities.
These two issues have been corrected in the text.
Study population
7. I wonder why partners and pregnant women who attended prenatal care at health units that were not selected were considered as exclusion criteria (Line 256-257). Exclusion criteria should be related to the study participants and the contexts. Here, in the process, some might be selected and some might not be selected and that is not part of exclusion criteria.
Because this is a pilot study not all health units were included. We have now corrected the “design and setting” section and it is possible to see that the municipality where the study was conducted had a total of 48 health care units and other private health units, in our study we selected only the 20 health care units with the largest number of pregnant women. This is why it is important to emphasize this exclusion criterion.

Study period
8. I do not think the study period section deserves a standalone title. The period could be described under study design and setting section.
It was corrected
9. All the information described in this section should have the sub-title or be moved to data collection procedures.
It was corrected
Sample size

10. The sample was obtained by convenience. Why did you use convenience? Randomized control trial is one of the strongest designs for evidence generation, and sample size determination should be based on reasoning and considering the assumptions in sample size determination. Yes, actually the cluster randomized controlled trial is one of the strongest studies to generate evidence, and this criterion was respected in the line of research with pregnant women. But as we depended on women's acceptance to initiate and collect data with partners and did not have an estimate of this acceptance we relied on partner membership data in the prenatal program offered by the municipality. It would be very difficult to stipulate what this population would be to perform the sample size test, so the sample was by convenience.

Result
11. In the result section, I expected interpretation of results that could be understood by readers easily. For example, simply saying partners in the intervention group were more frequently present at birth, favoring childbirth companionship is not enough? It should be describe in number with its interpretation. We thought it would be important to give a statistical interpretation of the results and an overview of the profile of the partners participating in the study, but we consider it important to make the understanding easier and we will simplify the understanding of the results. This information appears at the beginning of the discussion section.

Discussion
12. In discussion section, authors tried to compare and contrast their findings with previous studies. However, I believe it needs additional evidences that support or refute the current study, and the authors are expected to give rationale or argument why this current study is in line with or contrary to other studies. Yes, we agree with the point of view. As the literature is constantly changing and updated, it is important to review the findings to verify the most current evidence on the subject. We made some updates incorporating new data presented in the discussion of similar studies to confront our findings and what has been discussed on the subject.

13. Finally, this type of study is prone to bias because it is a community level trial in which the feasibility (ethical as well as financial), information contamination, counterfactual problems, etc. are the major concern. The authors are expected to address all these issues and how they managed it. Of course, studies are subject to bias. We are sure that we did our best to avoid biases during the study, particularly in organizing data collection, verification and the quality of data obtained for further analysis, including data contamination, so the division into 3 groups, and the others are described as limitations of the study in the discussion section. Certainly many other precautions would become important and we only realize when the project is already underway. But as mentioned and cited in the article this is still a pilot study to verify the findings and substantiate a larger project, involving even other municipalities and regions.

Reviewer #2: Good article.
Needs some correction of grammar before final submission.
We appreciate the compliment to the article and certainly when the final version is accepted it will go through an English language revision.

Reviewer #3: Dear Authors:
I really appreciated your work, having already followed the previous publication and noted that the study is part of a more ambitious project to implement the use of SMS during prenatal care with assessment of various outcomes. So, I feel comfortable to recommend the publication of the article.

Some minor points that I suggest to be improved:

1. Consider omitting or modifying reference 32, which is not essential, and is a Portuguese book that is difficult to find for readers of this journal.

2. There are several references out of format. Look at the rules of the journal and try to standardize them. Considerations 1 and 2 have been modified in accordance with the reviewer's guidelines.

3. About the sample size: I understand that the calculation was made for the original study for other purposes and there is no specific calculation to determine differences between PRENACEL and non-PRENACEL men. I think this needs to be explained as it is a limitation of the study, or explained in a better way. A calculation assuming 37% participation of men in prenatal care is not sufficient to determine the sample size in this type of study. This suggestion is relevant and other reviewers also raised this issue, because of this we made modifications to the text to better explain the sample calculation and include as a limitation of the study in the discussion section.

4. In the Results section you state: "No statistically significant association was found among the sociodemographic 377 variables of the individuals in each group." This was not an objective and it is not necessary to test if baseline characteristics are statistically different in a cluster-randomized trial (randomization is supposed to generate groups with similar characteristics). In response to the reviewer, we will consider suppressing this information as it is not really the objective of the study and the study design itself allocates to comparable groups.

5. I think the discussion is good but it is also important to indicate what the study brings again, and I think at least in terms of Brazil this experience was pioneering.

6. Please indicate in the discussion that the limitation of the study is not only the small sample size but the fact that the calculation was not made for the outcomes evaluated in the present study. Thanks for the suggestion; we will reinforce these information in the discussion.

Reviewer #4: Abstract

Aim

Could be of interest to state was is considered as a "useful supplement", that is to say to define an outcome in the abstract

It was corrected
inconsistency
Line 82 "The majority of the men (57.5%) cohabited with their partner"
Line 367 (results) "the majority of the interviewed men (95.2%) lived with their partner"
This error occurred that in an initial analysis we had separated partners who were legally married from those who lived together and had a relationship but were not legally married. But in the table and for a statistical analysis we decided to join these groups, but we did not correct in the summary. Thank you for the observation and this has been corrected.

summary

Line 137: please correct: would be/ is

Line 141: please correct: men who x not received

Line 143 please correct: participated of more prenatal

Line 144: please correct were present in the childbirth

other English is to be modified
The considerations have been corrected and after the final version is approved the text will undergo a review of the English language.

Background:
Consider shortening
No clear objective is given, "the adherence and involvement in the PNC" is not clear nor appealing information about how partners are involve in PNC and childbirth before PRENACEL would be appreciated (% of partners present at childbirth ?)
We corrected the introduction of the article in order to make it objective and to better lead to our goal.

design and settings

control group is recruited after childbirth. This can constitute a bias and should be discussed.
The control group was only followed and could not know about the project and the intervention to avoid any contamination of the data and at the end, after childbirth, the 3 groups: PRENACEL, Non-PRENACEL and the control received the interview.

main objective is not clearly defined: partner attended at least one PNC, number of consultations attended or partner present at childbirth ?
The main objective of the study is the greater inclusion of pregnant partners during pregnancy and childbirth. For this, the outcomes analyzed were: if the partner was present at least one prenatal consultation with his pregnant partner and the number of consultations prenatal care in which he participated and the presence of the partner at the time of delivery. But as already mentioned in the "Plain English Summary" we corrected to facilitate the understanding of the objectives.

Results
Line 82 "The majority of the men (57.5%) cohabited with their partner"
Line 367 (results) "the majority of the interviewed men (95.2%) lived with their partner"
This issue has already been corrected.

"No statistically significant association was found among the sociodemographic variables of the individuals in each group" association with ?
no statistically significant difference ?
shouldn't obstetrical characteristics be compared as well ?
This first part of the analysis was made only with data from table 2 on the sociodemographic profile of the interviewees. Analysis was performed to verify if the groups were comparable. But according to another reviewer's suggestion this type of result is already expected for studies involving randomized controlled trials and we will suppress this information from the text as it leads to misinterpretation of the main outcomes studied in this paper.

Among the 186 partners, 82.8% of them attended the PNC of their companion "To attend the PNC" is not defined.
If it means "partner has attended at least one PNC consultation", please be explicit in the design and settings section.
Yes, this is the interpretation. We are sorry, but we have corrected the text to make this idea explicit. This first analyzed variable is nominal qualitative (having attended at least one prenatal visit - yes or no) and the next is a quantitative variable (how many prenatal visits attended - one consultation at five or six or more) and therefore the difference in percentages. We improve writing to make it easier to understand.

"ITT, we compared the PRENACEL group (who received the messages) and the non-PRENACEL group (partners who did not receive the messages, but belonged to the intervention PHCUs)"
Results: "There was no statistically significant difference when we compared whether or not partners participated in PNC, either by ITT or PP." and "We also calculated the RR and CI 95% between PRENACEL and nonPRENACEL groups (Intervention group)" isn't it the ITT analysis?
The ITT analyzes were performed with the PRENACEL group plus the non-PRENACEL group, whose partners were from the intervention health facilities, versus the control group. After analysis between the two groups, PRENACEL versus Not PRENACEL, and this analysis is neither ITT nor PP.

Giving the absolute values in this section is necessary to interpret the RR and the significance of the results.
The absolute values were presented in the table 3.

Results section seems confusing to me and needs to be reorganised (its then pp)
With the suggestions given by the reviewers the results section and also the introduction were organized for better understanding.

Discussion

Recruitment of control group after childbirth is not discussed although it can provides bias

Selection bias should be discussed
These questions related to methodological procedures and participant recruitment were included in the text.

People who accept the program attend more PNC consultations but how many? is this figure of relevant significance?
One to five prenatal consultations or 6 or more consultations, as described in the table.

Outcome "numbers of PNC attended" divided in 1-5 and 6+ should be discussed
At least detailed in tables
In Brazil, the program related to reproductive health considers as one of the criteria for an adequate prenatal that the couple (especially the pregnant woman) should attend at least 6 prenatal consultations. Therefore, if the pregnant woman's partner answered in the affirmative that she participated in prenatal care, we separated the number of consultations with a cut of 1 to 5 consultations and 6 or more consultations, considering the prenatal program criteria. And with this cut you can perform the statistical analysis.
This information was considered in the text.

Obstetrical outcome could influence participation post partum and should be compared

This is an important concern. In the database study it was found that we had 26 cases in which the woman reported having been a risk pregnant woman in the current pregnancy (with complications) being 12 cases in the Non-PRENACEL group, 8 cases in the control group, 6 cases in the PRENACEL group. And the statistical test showed that there is no difference between the groups, neither by intention to treat (ITT) nor by protocol (PP), regarding the complication during pregnancy.
More information related to maternal outcomes related to pregnant women is described in the recent publication available at the link: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0102-311X2019001205012&lang=pt

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Table 2: p values would be of interest
This issue has been fixed.

Study flow : characteristics of women not interested in partner participations should be discussed (more than half)

This analysis could not be performed. Because it was just an initial interview to offer the intervention of the messages, collect the initial data (full name, age and phone number) and verify the acceptability of the pregnant women in relation to the partner's participation, only then did we contact the partners to offer the intervention and collect the initial data.

It really is an important issue to be discussed and reconsidered in project implementation; which issues lead women to accept or not partner participation.