Author’s response to reviews

Title: PRENACEL - a mHealth messaging system to complement antenatal care: a cluster randomized trial

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Author’s response to reviews:
Dear Reviewers,

Many thanks for your feedback. Please find below my point-by-point response.

With thanks and best wishes,

Joao Paulo

Reviewer #1: GENERAL COMMENTS

While the aim of the study is clear, I don’t think that the objectives have been achieved. Reading the paper, it seems that the study is comparing "women's knowledge on pregnancy care" vs "no knowledge on pregnancy care." I say this because, under the intervention sub-section (lines 140-182) the authors provide a very comprehensive description of how the intervention PHCU staff were trained, and the messages that were sent to the participants. For example, in lines 162-164, it is stated that participants in the intervention group were sent messages on information about the physiology of pregnancy and childbirth; elements of antenatal care; postpartum care and contraception; and psychosocial aspects of pregnancy and the postpartum period. Furthermore, these messages were sent to the intervention group at each stage of the woman's gestational age. However, this was not done in the control group. The researchers could have provided this information to the women in the control group as well at a never-to-be-repeated (one-off) meeting at the start of the study so that there is certainty that both the women in the intervention group and those in the control group have the same level of understanding on pregnancies and danger signs in pregnancy. Thus, given the way the study is presented, I don't think that there is an incremental analysis of the effectiveness of the SMS vs Routine ANC.

JPS: I would like to thank the reviewer for this comment. However, I respectfully disagree with his gentle observation. The intention of the study was to test a SMS package as a mean to deliver health education to pregnant women. In a way, and using the reviewer’s terms we were indeed trying to compare “women’s knowledge on pregnancy care” vs “no knowledge on pregnancy care”, but that would only be possible if a short message service (SMS) was an effective mean to deliver health education. Please consider that “health promotion and education” is one of the essential signal functions of antenatal care, and all women in the study should have received the essential counselling and information about pregnancy and childbirth as part of routine antenatal care. So, as a pragmatic trial trying to determine the incremental effect
of the SMS on routine antenatal care, it is my understanding that it wouldn’t be appropriate to have the control group receiving a health education intervention in addition to routine care. If we were to have both groups receiving interventions, we wouldn’t be able to determine the incremental effect of the SMS on routine care, but only the relative effect of SMS to the other health education intervention.

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There is potential contamination and researcher bias in the study. In lines 176-179, the authors state that women in the intervention group could send questions, complaints or feedback via the system (SMS free of charge). These questions were answered by health providers who were members of the research team and provided guidance accordingly. My view is that these acts can influence the impact of the intervention on the antenatal care score (ANCS).

JPS: Contamination bias is usually defined as the systematic error that occurs when members of the 'control' group inadvertently receive the treatment or are exposed to the intervention, thus potentially minimizing the difference in outcomes between the two groups. I am not familiar with a standard definition of “researcher bias”, but I understood from the reviewer comment as the systematic error introduced by the researchers themselves, intentionally or unintentionally, that mislead the research they carry out. I once again respectfully disagree with the reviewer’s observation. As described in the study methods we were testing a bi-directional short message service able to send and receive messages. Our program sent culturally relevant and gestational age appropriate content, but also was able to answer specific queries. As described in the manuscript the intervention was only delivered to women in the intervention group, which minimizes the risk of significant contamination. One could say that, by design, contamination bias is ruled out. I do not regard the feature of being able to answer questions as part of the intervention constitutes research bias. Nonetheless, we appreciate this comment and took measures to further clarify the bi-directional nature of the intervention.

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The Methods section should be shortened and made much more consistent.

JPS: we have revised the text to ensure consistency and shortening it as well.

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Results and discussion sections are too long and should be streamlined extensively to make the article more focused and concise. For instance, in the discussion section, some of the
triangulating evidence is misplaced while the section reads as a repeat of the results section. Furthermore, the discussion section is presented in a way that suggests author bias towards the SMS (mHealth) system. I think the authors should strive to balance the discussion between the SMS system and the Routine ANC. Aren't there any positives from the routine ANC system considering that the study was an applied research?

JPS: we have revised the text accordingly.

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SPECIFIC COMMENTS

Abstract is unclear

JPS: We have re-written the abstract in order to improve readability.

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Line 29, how is adherence defined? Adherence to what?

JPS: Adherence as medical term is defined as “the extent to which the patient continues the agreed upon mode of treatment under limited supervision when faced with conflicting demands” (The American Heritage® Science Dictionary. Houghton Mifflin Company. 8 Sep. 2017. <Dictionary.com http://www.dictionary.com/browse/adherence>). In response to the reviewer comment (“Adherence to what?”), line 29 read “adherence to antenatal care (ANC) practices”. In this context, adherence is meant to convey the extent to which the pregnant woman continues the practices recommended during antenatal care. Nevertheless, since we are using this term also in connection to the PRENACEL program, we decided to modify the line 29 to “the coverage of recommended antenatal care (ANC) practices.”

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Line 30, This is just a cluster randomised trail. Why is the word "parallel" included?

JPS: Although parallel group designs are a frequent feature of cluster randomized trials, the parallel group design is not a mandatory feature of cluster randomized trials. Cluster randomized trials can adopt the crossover design, stepped wedge design, or the incomplete cross forward designs as alternatives to the parallel designs (Hooper R, Bourke L. Cluster randomised trials with repeated cross sections: alternatives to parallel group designs. BMJ. 2015 Jun
Following the recommendations of the CONSORT Statement, the authors decided to specify the parallel design for clarity.

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Line 42-43, several numbers are presented but not clearly explained. i.e. 157 passively recruited. Does this mean that the balance of 770-157 were not passively recruited? Secondly, only 116/157 received and read all SMS. What is the implication of this on the results?

JPS: The text was modified to address this comment.

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The Abstract only refers to two study groups but in line 265-269 there are 3 study groups.

JPS: The text was modified to address this comment.

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Plain English summary

Line 72-73. There is need for consistency in the usage of words. In the Abstract the authors use the word "routine" but in line 72-73 they use the word "standard".

JPS: The text was modified to address this comment.

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Background

In line 102-104, the authors indicate that previous studies looked at, "decreased perinatal mortality." They then conclude that none of the earlier studies assessed m-Health interventions as a means to improving adherence to recommended antenatal care practices. I argue that by studying the final outcome (i.e. perinatal mortality) the earlier studies would have in fact also indirectly looked at the effect of m-Health interventions on improving adherence to recommended antenatal care practices. Thus, the authors may wish to revise lines 102-107.

JPS: While other studies may have assessed the overall impact of health care and other health determinants by looking at perinatal mortality, it is unclear how this impact was produced. This
is the reason why this study focus primarily on process indicators instead of health outcomes. We revised the text to highlight our interest in the improvement of specific antenatal care practices.

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Methods

Line 116-117, how were the 4 maternity hospitals distributed between the intervention group and the control group?

JPS: the maternities were not allocated between the intervention and the control group. The maternities were the place where the study outcomes were assessed and were not part of the intervention. We revised the methods section to clarify this point.

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Line 130-139, the study period is not clear. The authors present the period April 1st and June 30th, 2015 which I think relates to the characteristics or eligibility criteria for the study population i.e. pregnant women should have a gestational age of 20 weeks or less to qualify for the study. The second criteria for inclusion is contained in line 134-137 which states that, "all women who gave birth in the participating maternity hospitals between August 3rd and June 30th, 2015, and who had received antenatal care at control or intervention PHCUs, were recruited to participate in the study". This is not clear and confusing. August comes after June. Furthermore, in line 237, there is also reference to August 2015-March 2016 which further creates confusion on the study period.

JPS: We revised this section accordingly.

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Line 227-235, sub-section on intervention cost could be removed. There was no comparison of costs between the SMS (mHealth) intervention with the Routine ANC system. Are the SMS (mHealth) costs incremental to the already existing routine ANC costs?

JPS: We removed the cost related section of this paper.
Results

Line 318-320 are unclear. Please revise.

JPS: Revised accordingly.

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PRENACEL costs (line 343-356) could be removed. There was no comparison of costs between the SMS (mHealth) intervention with the Routine ANC system. Are the costs presented in the paper incremental to the already existing routine ANC costs?

JPS: We removed the cost related section of this paper.

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Discussion

In lines 376 and 446-447 the authors state that the study was conducted in a Brazilian city with a very high HDI and that there could have been more impact if the study was conducted in a lower resource setting. This is not true as it depends on a number of factors including the health seeking behaviour, catchment population, annual growth rate and/or total fertility rate, level of education etc. Therefore, I propose that the authors should remove this limitation. Furthermore, the limitations are too many and some of them could be removed or qualified.

JPS: Revised accordingly.

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Line 413-415 ….."PRENACEL is a relatively inexpensive intervention that could be replicated in low-income environments, as long as cell phone coverage is present". PRENACEL is inexpensive relative to what? Please remove all information on PRENACEL costs so that the article is concise and focused.

JPS: Revised accordingly.
Line 460-462. "Implementing mHealth programs on a larger scale, especially in low resources settings is necessary to determine their real-word impact". This sentence should be deleted.

JPS: Revised accordingly.

Reviewer #2: Review comments of REPH-D-17-00197 (An innovative antenatal messaging system (mHealth) to complement antenatal care: a cluster randomized trial)

The authors did a great job and addressed a very important health issue. Even with the about free antenatal care offered to pregnant women with the goal of limiting maternal mortality, adherence remains an issue. M-health services have been shown to improve on the demand of important health packages. The paper is well written, with acceptable English and the message is easy to assimilate. I however have a few worries that could make the paper better.

JPS: Thank you

Comments

Background:

Line 84: the talk on the MDG which are out of date is not very good. It could be precised that Brazil failed to attain the fifth MDG. Your statement makes the reader to feel Brazil is still working on that goal. I say this because maternal mortality reduction is an integral part of the SDGs. Will it not be better to see it as compromising the effective attainment of the current SDG agenda?

JPS: We revised the background section in line to the reviewer suggestion

Methods: This study seems to have no methodology issues but my first impression is that this section is too long and cumbersome. Authors must find a way to pass their message in a contracted and concised manner. This looks more like the method section of a thesis. Please review.
JPS: We revised the methods section trying to streamline it, but also striking a balance to comply with CONSORT statement.
Concerning the study population section, what rational do you have for not including women aged below 18, and considering women with GA 20 weeks or less. Including this to your methodology will reduce questions.

JPS: we added this information as suggested.

The section on study period is too long and off track. Most of the things said there do not fall in to the study period but is part of procedure of implementation.

JPS: the section was revised accordingly.

Results: this section is well structured and answers the objective of this study. I however do not see which position the PRENACEL cost section occupies in the results. I think if this section must be included, it should be included at the end of the methodology section.

JPS: Based on the comments of both reviewers, we decided to exclude the results related to costs from this manuscript.

Discussions

Line 368-369. I think the message you want to pass out is the increased percentage of women with more antenatal care visits. When you say your results are comparable?? I will want to say, Tanzania and Brazil are two very different countries with different socioeconomic and cultural backgrounds.

JPS: Revised accordingly.
Line 402-403. I don't think your study evaluates the quality of antenatal care services and the qualification of the health personnel in this domain…. Your conclusions and recommendations should therefore be well formulated

JPS: Revised accordingly.

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Line 412-419. I think these are advantages of the study and the PRENACEL system not strength of your study. Please review

JPS: Revised accordingly.