Author’s response to reviews

Title: EFFECT OF MOBILE-HEALTH ON MATERNAL HEALTH CARE SERVICES UTILIZATION IN EASTERN ETHIOPIA: STUDY PROTOCOL FOR RANDOMIZED CONTROLLED TRIAL

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EFFECT OF MOBILE-HEALTH ON MATERNAL HEALTH CARE SERVICES UTILIZATION IN EASTERN ETHIOPIA: STUDY PROTOCOL FOR RANDOMIZED CONTROLLED TRIAL.

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Reviewer #1: What does "critically ill" mean? With the aim of having more powerful results and improving the external validity of this study, I suggest to define more carefully the mothers who can't receive this type of intervention.

Response:

Participants: Inclusion and exclusion criteria
The Participants will be recruited from the two districts (Haramaya and Kombolcha Districts) based on pre-set eligibility criteria (pregnancy, gestational age, ownership of mobile phone and willingness to participate). The participant will be included in the trial if gestational age is less than sixteen weeks, own mobile phone and has willingness to participate. The Potential trial participants will be identified by the field workers based enrollment criteria. For all eligible participants, the field workers will explain about the study by reading the participants information sheets; if the study subjects are willing to participate, written informed voluntary consent will be obtained and baseline data collection will be made.

In this trial study women who fulfill enrollment criteria for the study but critically ill at time of enrollment will be excluded from the study. Critically ill women mean those pregnant mothers who unable to respond to interview questions because of illness. In addition, women with any systemic illness during this time will be excluded from study. Pregnant women with any systemic illness need a special Antenatal care follow up which will set precondition for the women to have good maternal health care services use and hence excluded to reduce the effects of this condition.

Reviewer #1: Secondly, in your sample size determination and statistical analysis, you don't consider the design of the study. This is a clustered trial (two districts, more health centers) and the data structure has to be accounted. In the sample size calculation you have to quantify the "design effect". In the analysis you have necessary to account the cluster introducing at least cluster as fixed or random (preferably random, in my opinion) effect.

Responses: Sample size and power Analysis

It is known that in clustered RCT the study subjects within the cluster are more likely to interact, and respond in the same manner and no longer be assumed to act independently. This can leads to a loss of statistical power. This intracluster dependence can be quantified by intracluster correction coefficient (ICC). In the current study, sample size was calculated by concerning achievement of adequate power through inflating sample size with Design effect (DE).

Hence, the estimated sample size per group is inflated by considering ICC of 0.001 and DE required for this sample size calculated by DE=1+(n-1)ICC. If n is member of cluster, DE=1+
0.245~1.3. Thus, final sample size required for this study will be 320 for each control and treatment groups.

Moreover, for the primary outcomes, Generalized Estimating Equation (GEE) models will be used to account for within the cluster correlation.

Reviewer #1: You have data collection in three phases: don't you think it could be possible to have ad interim looks to the data and consider possible stopping rules for the study?

Responses: The termination of interventions will be made only if the participants will have no willingness to participate in the study or declare to stop the participation. In this case the termination will be made by investigators. For the rest of participants, the stopping criteria /termination criteria from this study depends on time limit of pregnancy termination for every women who will be included in study. So, this study will be continued for every mothers until delivery. Assume that all mothers may give birth at different gestational ages including those mothers who may give premature birth and their status of delivery will be traced by flied workers and health professionals at health center.

Reviewer #1: Concerning the primary outcome: you call it "level of antenatal...". It's only my opinion, but this could be misleading for the reader in that it sounds like a continuous measurement. I suggest to use the word "proportion of antenatal..."

Response:

Primary outcome variables

Proportion of Antenatal care services use

Proportion of Institutional delivery

Secondary outcome variables
Proportion of Postnatal Care services use

Pregnancy outcome

Reviewer #1: you should have your manuscript reviewed by someone who is fluent in English.

Response: Lastly the language editing was made by fluent in English.

In the end I would like to thank you for constrictive comments and review. I am very happy to get this comments. I think I have addressed all the comments accordingly

sincerely

Tilaye Feto