Author’s response to reviews

Title: Cluster Randomized Evaluation of The Nia Project: Study Protocol

Authors:

Eunice Muthengi (emuthengi@popcouncil.org)
Karen Austrian (kaustrian@popcouncil.org)

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Responses to Reviewers:

Reviewer #1:

"The article touches upon an important topic, and a highlighted need to strengthen the evidence around MHM impacts as well as key elements. The use of 'hardware' and 'software' are a bit jarring as terms given we are talking about girls' bodies in terms of MHM supplies, and you may want to reconsider this use."

Edits have been made to this terminology to use different language, replacing hardware with ‘products’ and software with ‘empowerment’.

"In general, I found the article a description of the Nia Project to set up an evaluation that has yet to come. Without the evaluation results, it is unclear how the article will advance the field. It would be recommended to restructure the article to be a review of current evidence and practices, highlighting the Nia project, exploring if the Govt of Kenya's alternate programme was evaluated or has yielded results - than to title this as the results of evaluation when even the methodology section is set in the future "the analysis will do XX, it will highlight XX"."

As this manuscript is under the “study protocol” category, there would not be evaluation results at this stage. The purpose is to put in the literature the details of the study and plans prior to the results being determined. The title of manuscript also indicates that it is a study protocol.

A discussion of the Government of Kenya’s sanitary pad distribution program has been included.

"The topic is so important, and the paper very well written - it is just difficult to understand what we are to get out of a paragraph long discussion that sets up a planned evaluation, and no conclusions. For this reason, I have put it as 'minor revisions'."
Again, as this manuscript is in the “study protocol” category, there would be no conclusions on what has been learned, but on what we hope this study will contribute to policy and the literature. Text has been added to clarify the purpose of this contribution.

Reviewer #2:

"Study protocol for a RCT on effects of distribution of disposable sanitary pads, and reproductive health education, separately and/or combined.

In relation to the quality of the RCT design a statistician should provide comments on the quality and potential shortcomings of the RCT design. The instrument used to collect data seems to collect a lot of additional interesting information that is not mentioned in the article."

The protocol of this study was reviewed, advised on and approved by the study’s Research Advisory Committee (RAC) which is comprised of three researchers with both strong statistical expertise, as well as content knowledge on menstrual hygiene management and adolescent girls.

The range of topics covered on the girls survey instrument are included in the description of the study instruments.

"Cost-effectiveness analysis is mentioned in the paper but no methodology for it is described."

Thank you for that observation. The cost-effectiveness analysis has been removed from the protocol and mentions of it removed from the manuscript.

"Rigorous evaluation of programmes is very important in order to improve programming and avert unintended effects and it is good to see efforts to that effect. It would maybe be useful to present the findings together with more qualitative data looking at programme implementation and acceptability to the beneficiaries?"

As this manuscript describes only the study protocol, it would not be appropriate to also include results. Qualitative data will be collected prior to the final quantitative data collection that does look at program implementation and acceptability. When the study findings are published, that evaluation will make use of both quantitative and qualitative data.

"The results of the study are going to inform further programming and health policy. Will this mean that in case no statistically significant effects can be found, girls no longer are entitled to receive comprehensive reproductive health education and/or denied access to affordable sanitary pads?"

The results of this study would not negate the fact that girls have the right to manage their menstruation comfortably and with dignity and to be able to access reproductive health education. If there are no statistically significant effects it would call for further exploration into
whether or not distribution of sanitary pads is effective as an intervention to improve girls schooling outcomes and/or if the way that reproductive health education was delivered in the Nia Project is the most effective in improving reproductive health outcomes for girls.