Author’s response to reviews

Title: Study protocol for a stepped-wedge randomized cookstove intervention in rural Honduras: Household air pollution and cardiometabolic health

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Version: 1 Date: 07 Jun 2019

Author’s response to reviews:

Dear Editorial Office,
Via email, I answered the questions with Marie-Victoire Cosson. The string of emails providing the clarifications is copied below. She has since processed the study protocol. Please let me know if i can provide further clarification. Best,

Maggie Clark

On 6/4/19, 7:31 AM, "Marie-Victoire Cosson" <marie-victoire.cosson@springernature.com> wrote:

Dear Maggie,

Thank you for your fast response. No, this is fine, it answers my questions very well. I am proceeding with your manuscript right away.

Kind regards,

Marie

-----Original Message-----

From: Clark,Maggie [mailto:Maggie.Clark@ColoState.EDU]
Sent: 04 June 2019 14:24
To: Marie-Victoire Cosson
Subject: Re: Your submission to BMC Public Health - PUBH-D-19-02071

Dear Marie,

NIH holds peer review study sections that review all submissions that are then scored by the peer-review panel. NIH then funds based on scores and funding priorities. The grant that was submitted to NIH (and funded). It was very similar that the current protocol but I would say that the statistical analysis is now more complete (and in-line with household air pollution trials in my field). So, in response to your question, NIH's funding system via peer-review, reviewed all the items you listed except for the current data analysis. At the submission time, we had proposed a simpler "t-test" at a single post-intervention time point for the intention-to-treat analysis (our current protocol we utilize all 6 of the study visits for the intention-to-treat analysis - and this description in our protocol paper is much more detailed).
I hope this makes sense. It's customary to make changes in the protocols like this if the aims don't change (still the same research questions) without a "re-review" by the NIH. The NIH does have a system with annual checks/reports for which any substantial design/aim changes would be reviewed and we participated in this process (but an analysis model change like the one I describe here would not be subject to that review). I hope this makes sense. Do you need any additional information?

Thank you and kind regards,

Maggie

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Maggie L. Clark

Assistant Professor, Epidemiology
Environmental and Radiological Health Sciences
Colorado State University

On 6/4/19, 3:39 AM, "Marie-Victoire Cosson" <marie-victoire.cosson@springernature.com> wrote:

Dear Maggie,

Thank you very much for the clarifications. Just to be sure we are on the same page, can you confirm that NIH has reviewed the methodology, the design, the recruitment, the aims, the sample size, the data analysis and all other major points of this study protocol?

The writing of the study protocol does not necessarily needs to be peer reviewed by the funders so I just need you to confirm my previous question.

Thank you very much, and I will proceed with your submission as soon as I hear back from you,

Kind regards,

Marie

-----Original Message-----

From: Clark,Maggie [mailto:Maggie.Clark@ColoState.EDU]
Sent: 03 June 2019 20:45
To: Marie-Victoire Cosson
Dear Marie-Victoire,

I am writing to respond to the inquiries outlined below. Bonnie Young submitted all IRB/ethics approvals in the online portal. Please see the most recent approval in ApprovalLetter_IRB_2018 (inside that document the expiration is specified as Dec 19, 2019). It is also attached here.

As far as the Funding Proof, I'm attaching 3 Notice of Awards (NOA) from NIH that represented the data collection years for this project (through summer 2018). NIH funds projects after peer-review (as was the case here); however, this write-up of the protocol was not reviewed by the funders. I believe that is what you are asking but please let me know if you need additional information.

Finally, yes, the CSU ethics approval covers all sites involved in the study.

Thank you,

Maggie

Editor Comments:

- Thank you for providing us with the ethical and Funding proof. However it came to our attention that the ethic proof is old and more expired. Do you have a more recent one? If so, please send it to Marie-Victoire Cosson <marie-victoire.cosson@springernature.com>.

- Could you please also send to the same email address the Funding proof and confirm whether the funding body peer-reviewed this study protocol.

- Could you please confirm whether the Ethic approval granted by the Colorado State University covers all the sites involved in the study?

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Maggie L. Clark

Assistant Professor, Epidemiology
Environmental and Radiological Health Sciences Colorado State University
On 5/31/19, 6:09 AM, "em.pubh.0.6399d0.2b492573@editorialmanager.com on behalf of BMC Public Health Editorial Office" <em.pubh.0.6399d0.2b492573@editorialmanager.com on behalf of em@editorialmanager.com> wrote:

PUBH-D-19-02071

Study protocol for a stepped-wedge randomized cookstove intervention in rural Honduras: Household air pollution and cardiometabolic health


BMC Public Health

Dear Dr Clark,

Thank you for submitting your manuscript, "Study protocol for a stepped-wedge randomized cookstove intervention in rural Honduras: Household air pollution and cardiometabolic health" (PUBH-D-19-02071), to BMC Public Health.

Before it can be sent out for review, please carry out the corrections, below.

Please submit your revised manuscript by accessing the following site:

https://www.editorialmanager.com/pubh/

If you have forgotten your password, please use the 'Send Login Details' link on the login page at https://www.editorialmanager.com/pubh/. For security reasons, your password will be reset.

Please note, if your manuscript is accepted you will not be able to make any changes to the authors, or order of authors, of your manuscript once the editor has accepted your manuscript for publication. If you wish to make any changes to authorship before you resubmit your revisions, please reply to this email and ask for a 'Request for change in authorship' form which should be completed by all authors (including those to be removed) and returned to this email address. Please ensure that any changes in authorship fulfil the criteria for authorship as outlined in BioMed Central's editorial policies (http://www.biomedcentral.com/about/editorialpolicies#authorship).
Once you have completed and returned the form, your request will be considered and you will be advised whether the requested changes will be allowed.

By resubmitting your manuscript you confirm that all author details on the revised version are correct, that all authors have agreed to authorship and order of authorship for this manuscript and that all authors have the appropriate permissions and rights to the reported data.

Please be aware that we may investigate, or ask your institute to investigate, any unauthorised attempts to change authorship or discrepancies in authorship between the submitted and revised versions of your manuscript.

We look forward to receiving your revised manuscript before 14 Jun 2019.

Best wishes,

Marie-Victoire Cosson

BMC Public Health
https://bmcpublichealth.biomedcentral.com/

Editor Comments:

- Thank you for providing us with the ethical and Funding proof. However it came to our attention that the ethic proof is old and more expired. Do you have a more recent one? If so, please send it to Marie-Victoire Cosson <marie-victoire.cosson@springernature.com>.

- Could you please also send to the same email address the Funding proof and confirm whether the funding body peer-reviewed this study protocol.

- Could you please confirm whether the Ethic approval granted by the Colorado State University covers all the sites involved in the study?