Author's response to reviews

Title: Cluster randomized controlled trial protocol: Addressing Reproductive Coercion in Health Settings (ARCHES)

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Author's response to reviews: see over
February 23, 2015

April Joy U. Rada
Journal Editorial Office
BioMed Central
236 Gray’s Inn Road
London WC1X 8HB
United Kingdom

Dear BMC Editorial Office,

Please find enclosed a slightly revised version of the manuscript entitled “Cluster randomized controlled trial protocol: Addressing Reproductive Coercion in Health Settings (ARCHES)”, which my coauthors and I are submitting for exclusive consideration of publication as a study protocol in BMC Women’s Health and which adheres to your journal’s suggested guidelines, including those from the CONSORT group. We confirm that this manuscript has not been published elsewhere and is not under consideration by another journal. All authors have approved the manuscript and agree with its submission to BMC Women’s Health. The slight revisions from the January, 2015, submissions were part of our comprehensive and complete response to issues you identified in your previous review (shown in italics below), which we have addressed point-by-point (shown in bold-face).

Editorial Requirements:

· Ethics and funding proofs:

As you may be aware, it is the policy of the journal not to peer review study protocols where ethical and external funding approval have been obtained, as these processes usually involve peer review and as there is little possibility to change a protocol after enrolment begins.

Therefore, could you please respond to the following points below and provide the requested responses in your cover letter.

1. Ethical and Funding Approval Documentation
Before we can proceed with your submission, can you please forward copies of all ethical approval and funding approval for our records. These documents should be sent as email attachments to the following email address, BMCSeriesEditorial@biomedcentral.com. Please DO NOT upload these documents as additional files in the submission system. If your documents are not in English, please could you provide translated versions of the relevant parts. These should be endorsed and signed by a contactable person at the institution. Please also include the original documents. Can you please confirm in your cover letter that you have forwarded the requested documentation to BMCSeriesEditorial@biomedcentral.com.
Thank you. We have submitted these requested documents to 
BMCeriesEditorial@biomedcentral.com.

2. Funding
A study is considered to be externally funded if the authors have been awarded a grant for the study by a major funding body (e.g. governmental funding/ award from a charitable foundation). If a study has not received external funding, then the study protocol will be sent for peer-review with a member of our Editorial Board. If a study has received funding/assistance from a commercial organization, this should be clearly stated in the 'competing interests' section of your manuscript, and the study protocol will be sent for peer-review by a member of our Editorial Board. Can you please confirm whether your study protocol has undergone peer-review by the funding body.

Yes, we confirm that our study has undergone peer-review by the funding body, the NIH. We have submitted the most recent NIH Award Letter for our study to BMCeriesEditorial@biomedcentral.com.

3. Study status
The protocol must be for a study that is ongoing. An ‘ongoing’ study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at.

We confirm that our study is ongoing; we are still analyzing data for the primary trial report, for an anticipated original trial report submission later this year.

4. Related Articles
Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal. If so, can you please provide a list of the related articles.

We have not published nor submitted any analyses pertaining to the effects of the intervention under trial. We have only published articles using baseline (pre-intervention data). The following are the two peer-reviewed journal articles that we have published thus far.

1. Recent partner violence and sexual and drug-related STI/HIV risk among adolescent and young adult women attending family planning clinics
By: Decker, Michele R.; Miller, Elizabeth; McCauley, Heather L.; et al.
SEXUALLY TRANSMITTED INFECTIONS Volume: 90 Issue: 2 Pages: 145-149 Published: MAR 2014

2. Recent reproductive coercion and unintended pregnancy among female family planning clients
By: Miller, Elizabeth; McCauley, Heather L.; Tancredi, Daniel J.; et al.
CONTRACEPTION Volume: 89 Issue: 2 Pages: 122-128 Published: FEB 2014

· Line Numbering:

Please revise your manuscript to include line and page numbers. Authors are asked to ensure that line numbering is included in the main text file of their manuscript at the time of submission to facilitate peer-review. Once a manuscript has been accepted, line numbering should be removed from the manuscript before publication. For authors submitting their manuscript in Microsoft Word please do not insert page breaks in your manuscript to ensure page numbering is consistent between your text file and the PDF generated from your submission and used in the review process.
We have added line numbers.

· Trial Registration:

Please list your trial registry, along with the unique identifying number and the date of registration (e.g. Trial registration: Current Controlled Trials ISRCTN73824458. Registered 28 September 2004). Please note that there should be no space between the letters and numbers of your trial registration number. We recommend manuscripts that report randomized controlled trials follow the CONSORT extension for abstracts (http://www.consort-statement.org/index.aspx?o=1190).

We have added the trial registration date to our abstract. We agree that the abstract should follow the CONSORT extension for abstracts and have followed it to the fullest extent that it is applicable for manuscripts describing the trial protocol but which are not reporting the results of the trial!

· We note that it is mentioned within the manuscript that a waiver for written informed consent was obtained to reduce the risk for breach of confidentiality and also waiver for parental consent for participants aged 16 and 17. Please confirm who provided the waiver for written informed consent and whether this was obtained from the institutional review board. Please include a statement within the manuscript for clarification.

Thanks for bringing the lack of clarity in this paragraph to our attention. We have revised the paragraph for clarity. The waivers were granted by the University of Pittsburgh IRB.

This is a protocol for a multi-site randomized control trial of a brief intervention integrated into family planning care that is designed to reduce risk for intimate partner violence victimization, reproductive coercion and unintended pregnancy. As we describe in the manuscript, the trial is sponsored by the National Institute of Child Health and Human Development (HD064407, PI: Miller/Silverman) and enrollment of the 3,687 patients at study baseline has already been completed at the study sites. Prior to data collection and throughout the conduct of the study, we have maintained the ethical approval of the relevant institutional review board (documentation available upon request). Together, as I understand your journal's policies, this constitutes peer review, so that a list of suggested external peer reviewers is not necessary.

Thank you very much for consideration of this study protocol. I am confident that this protocol will be widely accessed, both because of the significance of this large intervention trial and also because of the highly effective methods used to attain an impressively high retention rate among trial participants. If you have any questions or concerns, please feel free to contact me as the corresponding author at my email address (dijtancredi@ucdavis.edu), via telephone (916.734.3293) or at my postal address.

Thank you very much for consideration of this study protocol. I am confident that this protocol will be widely accessed, both because of the significance of this large intervention trial and also because of the highly effective methods used to attain an impressively high retention rate among trial participants. If you have any questions or concerns, please feel free to contact me as the corresponding author at my email address (dijtancredi@ucdavis.edu), via telephone (916.734.3293) or at my postal address.

Sincerely,

Daniel J. Tancredi, PhD
Associate Professor