Author's response to reviews

Title: Cultural adaptation of a brief motivational intervention for heavy drinking among Hispanics in a medical setting

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Author's response to reviews:

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June 26, 2015

Natalie Pafitis
Senior Executive Editor, BMC Public Health
BioMed Central
236 Gray’s Inn Road
London, WC1X 8HB, UK

Dear Executive Editor:

My colleagues and I are pleased to submit our revised manuscript entitled “Cultural adaptation of a brief motivational intervention for heavy drinking among Hispanics in a medical setting.” We believe this work represents a novel project since no studies have assessed the effectiveness of a non-adapted brief motivational intervention compared to a culturally adapted brief intervention among heavy drinking men of Mexican origin within a medical setting. We appreciate reviewer suggestions regarding details about the study protocol and methods. We have made an effort to address each of the concerns raised by this review. The responses follow the text of this letter.

The enclosed manuscript has not been previously published or currently submitted for publication elsewhere. The methods described by this manuscript
have been approved by the Institutional Review Boards of the appropriate institutions involved in this project (Hospital and University) and are compliant with the Helsinki Declaration. The authors have given approval of submission of their work for consideration of publication in BMC Public Health.

I appreciate your assistance with our submission.

Sincerely,

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Responses to reviewers

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.

The present study has been granted IRB approval by The University of Texas at El Paso (UTEP) and University Medical Center (UMC) of El Paso. At this point, the letter of approval from UMC will be sent as an attachment to BMCSeriesEditorial@biomedcentral.com. The letter of approval from UTEP has already been sent and received by BMC.

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.

The present study is funded by the Patient-Centered Outcomes Research Institute (PCORI; PI: Craig Field, PhD) Grant No. 1306-03852. As such, the present study has undergone peer-review by the funding organization. Supporting documentation regarding the funded status of this grant will be sent to BMC.

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.

Per the provided definitions, this study is ongoing. Data collection has started very recently.

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.

There have been no publications or journal submissions of the results of this study. Currently, no data or analyses/results are available.

In addition, we would need you to address the following request below.

1.) Ethics statement
Research involving human subjects (including human material or human data) that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/en/30publications/10policies/b3/index.html). A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.

Approval from the Institutional Review Boards from both The University of Texas at El Paso and University Medical Center (UMC) of El Paso has been received. The ethical guidelines for research with human subjects followed by the present study protocol are compliant with the Helsinki Declaration. Details were added on page 10 of the manuscript.

2.) Please provide the date of registration alongside your Trial Registration Number (TRN).

Trial registration clinicaltrials.gov identifier: NCT02429401; Registration date: April 28, 2015. This was included on page 4 of the manuscript.