Author's response to reviews

Title: Testing a Spanish-language colorectal cancer screening decision aid in Latinos with limited English proficiency: results from a pre-post trial and four month follow-up survey

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Author's response to reviews: see over
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Adrian Aldcroft
Executive Editor
BMC Medical Informatics and Decision Making

Dear Mr. Aldcroft:

We very much appreciate the thoughtful comments and suggestions from the peer reviewers on our manuscript, *Testing a Spanish-language colorectal cancer screening decision aid in Latinos with limited English proficiency: results from a pre-post trial and four month follow-up survey*. We have revised the paper in response to the Minor Essential and Discretionary Revisions suggested by these reviewers. This cover letter outlines our point-by-point response as noted below. Reviewer comments appear in **bold**, followed by our response, indicating specifically how we have revised the manuscript. In this letter, quotation marks identify actual text, and we use *italics* when helpful in highlighting how the text has been revised.

REVIEWER 1 Comments

Minor Essential Revisions:
1) The major issue with this paper is that without a control group concluding that the decision aid is “efficacious” does not completely align with the study design. Please address this in the discussion. (The language used in the “conclusion” paragraph of the abstract seems more appropriate – “…appeared to promote…” and “…may be an effective tool…”)

Response: We have reworded the first part of the discussion, removing the term “efficacious” from the first sentence, which now reads “We found that viewing a Spanish-language decision aid for CRC was associated with increased screening-related knowledge, self-efficacy, and intent among Latinos with LEP, demonstrating that the information provided by the decision is accessible and compelling to this target population.”

2) Discussion. 1st sentence of 3rd paragraph. Please clarify “…we also found that one in five respondents actually completed a screening test, with more than half completing a colonoscopy.” This is not consistent with the last paragraph in the results section that states, “Of these 13, seven completed FOBT, five completed colonoscopy, and one reported both tests.”
Response: We appreciate the reviewer bringing this discrepancy to our attention. The word “colonoscopy” has been changed to “FOBT”. So, the 1st sentence of 3rd paragraph now reads “we also found that one in five respondents actually completed a screening test, with more than half completing FOBT.”

3) Methods. Participant recruitment and eligibility. More detail with regards to the recruitment process is warranted especially given the lack of a control group. For example, did the fliers and newspaper advertisement include that this research project was related to cancer and specifically CRC thus potentially creating additional selection bias? Similarly, how were participants recruited via mailings and phone calls?

Response: We considered the potential for selection bias. In an attempt to mitigate this somewhat, we made sure our recruiting materials specifically did not mention CRC or use the term “colon cancer”. We did, however, use the term “cancer prevention” and agree that in a pre-post study such as ours this could have added to possible selection bias. In the revised manuscript we have provided additional detail regarding the recruitment materials and processes, by adding the following text to the first paragraph of the methods section: “Recruiting materials, including fliers and mailings, described the research as being related to “health education materials” and to “cancer prevention”. However, the materials did not include terms specific to CRC such as “colon cancer”. After the mailing, we recruited some participants via a follow-up phone call inquiring about their interest in participating.”

4) Methods. Decision aid content and format. 2nd paragraph. More detail regarding the “pre-printed, color brochures” would be helpful. What was the content of these brochures and were participants given specific instructions with the brochures. Although the authors note in the limitations paragraph that written materials alone have had little effect in English speaking populations, the brochures may confound the impact of the DA itself.

Response: We appreciate this suggestion and have made the following changes:

In the first paragraph of the subheading “Decision aid content and format”, we have added additional language about the table comparing the key characteristics of the two screening tests. We have added the following sentence to this paragraph: “A table comparing these key characteristics of the screening modalities is reviewed orally by the narrator in the video.”

We have also provided additional detail to the second paragraph regarding the content of the brochures as well as the instructions given to participants by adding the following:
“The brochures also included the above noted table of comparing the screening options. After a brochure was selected, viewers were promoted to show the brochure to their physician and to discuss their preferences and readiness for screening.”

Regarding the concern that the brochures could confound the impact of the DA itself, we would like to clarify that the brochures are actually part of the multimedia decision aid intervention (so they cannot be a confounder). This is noted in the first sentence of the paragraph in question, which reads “The decision aid was a multimedia intervention that included a 14-minute Spanish-language video (see Figure 1 for sample screen shots) plus a printed brochure.” To make this clearer to readers, we have also added the phrase “including the brochures” to the last sentence of this paragraph. This sentence now reads “A copy of the decision aid, including the brochures, can be obtained from the authors by visiting the decision aid website.”

5) Methods. Phase 1 outcome measures, 1st and 2nd paragraph. The authors note that the survey knowledge items as well as the intent and self-efficacy measure were either developed by the authors or adapted from measures used in prior CRC screening studies. How were these measures and items developed and adapted? Were Spanish versions of these items tested and validated among the target population or only translated from the English versions? The same potential limitation should be considered for “Phase 2 outcome measures.”

Response: We have provided the following additional information regarding how these measures were developed or adapted, including that we had previously pre-tested the measures in the target population:

“Spanish language versions of the intent and self-efficacy outcome measures were pre-tested in n=18 members of the target population in a previous study phase, along the knowledge items described above.”

For Phase 2 outcome measures we have added the following sentence with a reference to the NCI HINTS survey: “These items were adapted from items used in a nationally representative survey that included Spanish speakers.”

6) Results, 1st paragraph / Table 1. Include source of participant recruitment (i.e. community bulletin boards, clinic registry via FQHC or academic medical center.

Response: We have added the figures for general recruitment source category (% recruited from clinic registry sources vs from community advertisements) to this paragraph and to Table 1.
7) Results, 1st paragraph / Table 1. If available, include if, or % of, participant and provider were language concordant

Response: These data are not available.

8) Results, 2nd paragraph and Figure 2. Include N for knowledge, self-efficacy, and intent scores.

Response: N=80 for all these outcomes. We have added “(n=80)” to the first sentence of the text and to Figure 2 title.

9) Results, Table 2. Please clarify if * and p<0.001 for change is for each outcome or as a composite.

Response: We have clarified the p values in the legend below Table 2.

10) Discussion, 2nd paragraph, end of 3rd sentence. Please provide a reference for “In one survey, less than one third of Spanish speaking Latinos had discussed CRC screening with a physician within the past two years.”

Response: We have done so.

11) Discussion, 3rd paragraph, second sentence. Please provide a reference for “...other evidence suggests it is unlikely that 19% of unscreened members of this target population would become current with CRC screening...”

Response: We have done so.

Discretionary Revisions:

1) Although the authors note that a separate manuscript detailing the formative process of the decision aid development is under review, additional detail in this paper would be helpful for readers to better understand the adaptation of the previously developed English version of the DA.

Response: We appreciate this suggestion, however, our adaptation process is described in the paragraph with the subheading “Decision aid development and initial message testing”. This includes the theoretical basis, the focus group process, a listing of the key emergent themes from the focus groups, and a brief synopsis of findings from
usability and cognitive testing. As we mentioned in the paper, “A more detailed description of this formative research process and a qualitative analysis of focus group data is the subject of a separate manuscript (currently under review).”

We think adding further detail about this adaptation process is beyond the scope of this paper and would detract from the topic of the present manuscript.

2) Outstanding local efforts to promote CRC screening, including those done through the NC Community Health Center Association potentially impact the results of this study and may further limit generalizability. Please consider addressing in the discussion.

Response: In response to this suggestion, we have modified the second sentence of the limitations paragraph to read as follows:

“Because we used a one group (pre-post) design without a separate control group, we are unable to determine whether ongoing efforts by local or regional organizations to promote CRC screening influenced screening behavior among our participants.”

REVIEWER 2 Comments:
Reviewer: Myriam Torres

Reviewer’s report:
The article is really good and very well written. It definitely addresses a huge need in the Latino community. My only suggestion is to include a line or two describing how the initial baseline pre-test and post-test was administered. Considering the low levels of education of the participants I imagine it was face-to-face?

Response: We appreciate this reviewer’s enthusiasm for our study and manuscript. We added the following clarifying statement in the Data Collection subheading paragraph:

“After viewing the decision aid, participants completed a second oral (face-to-face) survey that measured screening knowledge, self-efficacy, and intent.”

Level of interest: An article of outstanding merit and interest in its field

Additional Revision by Authors to Acknowledgement section
We have added the following sentence to the acknowledgement section:

Parts of these data were presented at the 33rd Annual Meeting of the Society for Medical Decision Making, October 2011, Chicago, IL.
Once again, we appreciate the thoughtful comments by the reviewers. We think the manuscript is improved by their suggestions and our revisions. Please do not hesitate to contact us if you need additional information.

Sincerely,

Daniel Reuland, MD, MPH