Author’s response to reviews

Title: Effectiveness of a decision aid for promoting colorectal cancer screening in Spain: a randomized trial

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Author’s response to reviews:
Santa Cruz de Tenerife, September 6, 2018

Dear Editor Dr. Dirk Krüger:

Please find enclosed our revised manuscript entitled “Effectiveness of a decision aid for promoting colorectal cancer screening in Spain: a randomized trial" (MIDM-D-17-00233) by Lilisbeth Perestelo-Perez, Amado Rivero-Santana, Alezandra Torres-Castaño, Vanesa Ramos-Garcia, Yolanda Alvarez-Perez, Nerea Gonzalez-Hernandez, Andrea Buron, Michael Pignone, and Pedro Serrano-Aguilar, for its consideration as an original article in BMC Medical Informatics and Decision Making.
We would like to thank the reviewers and you for your careful revision and thoughtful comments on our paper. All the comments have been carefully taken into consideration for the preparation of our revised. We appreciate the constructive feedback that without doubt has improved our original.

Yours sincerely,

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Technical Comments:
- Please proofread your manuscript one last time to make sure there are no language or grammar errors. If English is not your first language then we would recommend to ask a colleague who is a native speaker to proofread the paper.
We have reviewed the correctness of English language.
- Please include the ethics committee reference number.
We have added the ethics committee reference number in the manuscript (file number: 2013/21).
- Please include the tables in the main text of your manuscript.
We have included the tables in the main text of our manuscript.
- Please ensure you have a conclusion section.
Done.

- Please ensure all section titles follow our information for authors:

Done.

Reviewer reports:

Adam Dunn (Reviewer 1): Thank you for the opportunity to review this manuscript. The study is a trial of the effectiveness of a decision aid for colorectal cancer screening and is relevant to the scope of the journal. The authors have revised the manuscript relative to the comments and suggestions I made. However, it is difficult to see whether all of the responses to other reviewers have been adequately addressed. It would have been useful to include the specific text that was changed and what it was changed to in the response to reviewers (even though that would make the response very long, I think it is worth it).

Note: In the first review of our manuscript (May 2018), we sent the answers to editor and reviewers with the track changes. However the editorial office asked for a revised manuscript without marks. In this new revision of our manuscript, and according to the reviewer’s suggestion, we have highlighted in red in the manuscript the sentences and paragraphs changed in response to the reviewers.

- Last paragraph of the introduction: we have changed that paragraph to clarify the aim of the study, in response to reviewers 2 and 5, who considered the inclusion of center B (participants previously invited to participate in the screening program) as a selection bias.

- First paragraph of method: the sentence “although it was expected to be accessible in the next years” was included in response to reviewer 6, who stated that it had no sense to assess intention to be screened in a center A, since the program was not accessible at that moment for that sample. The sentence “(but not specific information about the procedure)” was included in response to reviewer 5, who interpreted that having been invited to participate in the screening program (participants from center B) was equivalent to having been exposed to the DA intervention.

- Second paragraph of method: the text was changed to explain with more clarity the procedure of the study, in response to reviewers 4 and 5, who raised doubts about randomization, implementation of the intervention and timing of the outcome measures assessment.
- First paragraph of “Decision aid” subsection: we modified the text to explain in more detail the development and content of the DA, in response to reviewers 2, 3, 5 and 6.

- First paragraph of “Measures” subsection: we included a definition of decisional conflict, and reported the number of items and their scoring, in response to reviewer 5.

- Second paragraph of “Measures” subsection: we included the sentence “The content of all items was explained in the DA”, in response to reviewer 5, who was unsure about this issue.

- First paragraph of “Statistical analyses” section: we modified the text in order to be more explicit about the ANOVAs performed (in response to reviewer 5, who thought that previous redaction was confusing), and to explain why we applied Yates’ correction in χ² analyses (requested by reviewer 4).

- Results, fifth paragraph: we added that the mentioned analyses were not significant when Yates’ correction was applied, following the critique of reviewer 4.

- Results, last paragraph: following the suggestion of reviewer 5, we included center as a covariate in the described analysis.

- Discussion, fifth paragraph: we have included some sentences in order to explain how we tried to minimize potential biases in the implementation of the intervention (e.g., absence of blinding, novelty effect), in response to some reviewers’ (1, 2 and 4) concerns or doubts about the procedure. At the final of the paragraph, we have included two sentences highlighting what this study adds to the field, in response to reviewer 7.

- We have included a “Conclusion section”.

I still believe it is a mistake to describe something as "near significant" in a published article because it is likely to be heavily criticised by readers. A hypothetical example: if the trial was underpowered to detect effects for an outcome (primary or secondary), it should be stated directly (it may still be worth publishing because meta-analyses based on individual participant data will still yield new knowledge). If the study was powered to detect the effect for the outcome but did not find a significant effect, that is a different story. Both should be explained carefully and in an objective manner.

According to the reviewer’s critique, we have removed all mentions to near-significant results or p-values at the limit of significance (results, second paragraph; discussion, third and fourth paragraph), and we have included a sentence about the statistical power of the study regarding the intention measure (discussion, fourth paragraph).
I checked the link: " http://www.pydesalud.com/toma-de-decisiones-encancer-colorrectal/ " and also receive "no encontrado".

There is an error in the URL transcribed by the reviewer (a hyphen is missed). The correct URL is:  http://www.pydesalud.com/toma-de-decisiones-en-cancer-colorrectal

If problems to access continue, please try to access first to the web home: www.pydesalud.com then click on Cáncer colorectal (in the list of diseases, on the right), and then click on Toma de decisiones en detección precoz de Cáncer colorectal (in the list of topics, on the right). Then, name, surname and email are required to access to the DA.

A reviewer mentions a protocol, but I did not see any information about a prospective registration of the trial listed in the manuscript text. This would have alleviated many of the concerns of the reviewers (and potential readers), and it is unfortunate that this is not made available in advance. Perhaps a useful thing to consider for future studies. Many journals would require this.

Contrary to other randomized trials on decision aids carried out by our team (EudraCT: 2010-023912-14, NCT03254771, NCT02757781), we did not register a protocol for this study. We agree with the reviewer and we will consider his suggestion for future studies.

Pedro Pereira Rodrigues (Reviewer 2): The authors have addressed all my comments, with adjustments and/or explanations of their choices. Although the study still presents limitations, I now believe they do not prevent the report to be disseminated.

We thanks Professor Pereira Rodrigues for his in-depth review of the manuscript.

Peter Loewen, PharmD (Reviewer 4): The authors have appropriately addressed the reviewers' comments. Despite the authors' affirming the validity of the URL for the DA, I remain unable to view it at the URL provided by them: http://www.pydesalud.com/toma-de-decisiones-en-cancer-colorrectal/

It continued to produce a "Pagina no encontrada" error from their "PyDeSalud" server. This would require resolution prior to publishing the paper.

There is an error in the URL transcribed by the reviewer (a hyphen is missed). The correct URL is:  http://www.pydesalud.com/toma-de-decisiones-en-cancer-colorrectal
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