Author's response to reviews

Title: The uptake and effect of a mailed multi-modal colon cancer screening intervention: a pilot controlled trial The uptake and effect of a mailed decision aid on colon cancer screening: a pilot controlled trial The uptake and effect of a mailed decision aid on colon cancer screening: a pilot controlled trial

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Author's response to reviews: see over
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Dear Editor

Thank you for the opportunity re-submit our manuscript, “The update and effect of a mailed multi-modal colon cancer screening intervention: a pilot controlled trial”, for consideration as an original research in Implementation Science. We appreciate the reviews comments and suggestions and believe that the revised manuscript is much clearer and detailed.

Thank you for re-considering our work. Please contact Dr. Lewis should you have any further questions or concerns.

Respectfully,

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Responses Wave 1

Reviewer 1 report: Dr Hub Wollersheim

1) First the title suggests that the decision aid was the effective part of the multi-component intervention. No data support that suggestion.

We have changed the title. The title is now "The uptake and effect of a mailed multi-modal colon cancer screening intervention: a pilot controlled trial".

2) Second, not much background information is given. How did the decision aid look like? Which information did the video contain? This is especially important as colon cancer screening is less accepted by MD's and the community than other types of screening. Furthermore it is harder to explain as there are several screening options.

We have described the decision aid in much more detail in paragraph 2 page 7. The edited paragraph is below.

"The decision aid used in this study was created by the Foundation for Informed Medical Decision Making in conjunction with one of the authors (MP). The program is approximately 35 minutes long. A moderator leads a discussion about colon cancer and colon cancer screening. The first section describes colon cancer and the risk of getting colon cancer for those at average risk. The next sections of the decision aid video describe the different types of colon cancer screening tests including: fecal occult blood test, sigmoidoscopy, a combination of fecal occult blood test and sigmoidoscopy and, colonoscopy. Each test was described in terms of how the test is completed, how often it needs to be completed, the amount of time needed to complete the test, effectiveness in finding polyps and cancer, convenience, discomfort, and risks associated with the test. Patient testimonials are interspersed for each testing option where patients describe their experiences with specific tests."

3) How does the screening program patient could directly access look alike? What tests and follow up was offered? Was it in the hospital?

We have added a more detailed description of how patients could access screening tests directly on the bottom of page 7 and top of page 8. The paragraph now reads:

"Detailed instructions on how to access the screening test of choice were included in the intervention package. For fecal occult blood testing, standing orders were implemented in the practice. A nurse facilitator was available by phone so patients could request fecal occult blood cards be sent to them and
returned to the practice in a prepaid envelop. For flexible-sigmoidoscopy and colonoscopy patients were provided the number to the gastroenterology suite affiliated with UNC hospital. Schedulers in the gastroenterology suite were instructed to schedule patients who requested either test."

4) Although there is a small table 2 about patient characteristics to exclude bias the table does not give much information. Which factors could influence patient's decisions and how were these divided between both groups?

The intent of the study was to test the effect of the intervention on a large number of patients, similar to a large simple trial. We wanted to limit non-participant bias which is a problem in the U.S. with screening studies. To make the larger trial feasible, we needed to rely on our patient database, which has limited data on patient characteristics. We realize that unmeasured factors could have a differential effect on the intervention and control groups and have clarified that in more detail in the limitations sections on page 14 last paragraph. We added the following to the limitations sections:

"Third, the study was non-randomized, which could introduce bias if there were unmeasured differences between the intervention and control group patients. Because we had a very limited number of patient characteristics available in our database we are not able to exclude differences between the groups as a possible cause for our finding. Although age, gender, and race were similar between the groups, insurance status was not available and could bias the control group to no screening if there were fewer insured patients in the control group."

5) There is no information why the non responders did not attend. It would have been a pity if this had not been asked during the telephone survey. The information is important as it should be used to improve further interventions.

If we understand correctly, the reviewer would like more information from the calls we made to those who did not respond to the intervention. In response, we have added more detail from the telephone interviews among those who remembered receiving the mailing. We have added two additional sentences to the second paragraph on page 11 and a new paragraph-the third paragraph on page 11 under the "responses to telephone interview" section. The text now reads:

"Of the remaining 30 people, 23 remembered receiving the package. Among these 23 patients, 14 reported that they had looked at the information, and 6 reported that they had watched the video. When asked about screening, 11 reported that they were interested in getting screened and 8 had tried to schedule a screening test. From the medical record review we found that 3 had obtained a screening test."

"We asked those who had not watched the video why they had not watched it: 10 reported that they had not had time, 2 stated they did not have insurance so it was not worth it to them to watch the video, 2 reported that they were too scared of cancer to
watch the video, 1 reported that they did not have either a DVD or VHS player, 1 had left the practice, and 1 did not provide an answer. We asked 15 of the 23 whether they liked receiving the decision aid; 12 liked receiving the package and 3 reported that they did not.

6) Why were the reminder-telephone calls not considered an intervention?

We agree that the calls could have reminded the patients about screening and been activating. However, we designed them to collect information about our secondary outcome and not to encourage screening. We also were not planning to perform calls for the larger trial.

We have moved the text describing the calls in the Methods section under the secondary outcomes section on page 9 to help clarify our intent with the calls.

We also added a more detailed description of the content and intent of the calls. We added this sentence to the second paragraph:

"The intent of the calls was not to try to encourage screening, but to determine several secondary outcomes."

We added an additional paragraph to clarify the content of the calls in the last paragraph on page 9.

"In both the post-video questionnaire and the telephone interview we asked questions about the acceptability of the intervention to those who were eligible for screening by asking if they liked receiving the decision aid in the mail. We also measured interest in screening and asked if they had attempted to schedule a screening test since receiving the intervention."

7) In the primary outcomes on page 10 123 patients are mentioned. I cannot find the details of the 14 patients that were excluded and the reasons for that.

The 14 patients either responded in the written survey that they were up to date with screening or were at high risk. We originally excluded these in calculating our screening proportion 16% (20/123). Given that these are self-reported outcomes, we have revised our analytic process to be consistent with an intention to treat analysis. Therefore, the new proportion screened in the intervention group is 15% (20/137) and for the control group is 4% (4/100). The difference is 11% with 95% CI of 3;18% p=0.01)."

We have updated the relevant areas in the text to reflect the new analysis. We have added the following text in the methods section on page 8 in the final two sentences.
"Our primary analysis was based on an intention to treat. We included all patients in the intervention group even if they subsequently reported being at high risk or previously screened. This analysis allows for the most conservative estimate of the intervention effect."

On page 14 relatively tight confidence intervals are mentioned. I could not find these figures in the result section

These have been re-calculated as described above and placed with the results in the appropriate areas throughout the manuscript.

Reviewer 2

1) What were the system changes that allowed patients to access screening tests without a provider visit? Standing orders, a protocol, nursing support? A description of the system changes should be included.

We have included a more detailed description of the system changes we put in place in the Description of the Intervention section with a new paragraph on the bottom of page 7 and the top of page 8. Please see response to review #1 above under comment #3.

2. In "Results-primary outcomes" (p.10), did any of those who were screened also complete the intervention? If not, is it possible to say that the intervention was responsible for the increase in screening, or could it be due to other factors? This should be discussed in the Limitations section.

We believe that the reviewer is asking whether the intervention is responsible for the increase in screening in the intervention group compared to the control group, and if so, which part of the intervention was responsible for the differences. As suggested by the reviewer, we are not able to say definitively whether the intervention was the cause of the differences in screening rates among the 2 groups. We have more clearly addressed that the differences could have occurred because of unmeasured factors between the groups. Please see our response to reviewer #1 comment 4 above.

To address the question of which part of the intervention was responsible for the differences we have added the following to the limitations section on the bottom of page 14 and top of page 15.

"Although we found a difference in screening rates between intervention and control groups, we are unable to identify which part of the intervention was responsible for the difference in screening."
In addition, to further explore the effect of the intervention, we included more detail from the written surveys and the telephone interviews.

Under "Responses to mailed surveys" we have added the additional text on the top of page 11:

"Five of these 12 obtained a screening test, 4 of whom had watched the video."

Under "Responses to telephone interviews" we have added the additional text below:

"Of the remaining 30 people, 23 remembered receiving the package. Among these 23 patients, 14 reported that they had looked at the information, and 6 reported that they had watched the video. When asked about screening, 11 reported that they were interested in getting screened and 8 had tried to schedule a screening test. From the medical record review we found that 3 had obtained a screening test."

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct) 1. typo page 9: "like" should be "liked"
2. In "Results-response to mailings" (p. 10), it says that 137 patients were in the intervention group. In other sections of the manuscript, the number of intervention patients is also 137. Table 2, however, indicates that there were 144 intervention patients. Which is correct? The table was in error and has been corrected.
3. Also in "Results-response to mailings" (p. 10), the percent from whom there was no response seems that it should be 64%, not 58% when comparing with Figure 1, because 64% includes the 9 that were returned as undeliverable. Both the text and Figure 1 were incorrect. The correct % is 52% (71/137). We have modified the text under responses to mailing to on page 10 to read:

"Nine of the mailings were returned as undeliverable due to incorrect addresses (6%), and 71 (52%) did not respond."

4. In "Secondary outcomes-responses to mailed survey" (p.11), what were the scores on the Likert scales for interest and intent described in Methods? What were the values assigned to the numbers on the Likert scale? Also, what was the acceptability of the intervention, also a question that was asked according to the Secondary outcomes section of the Methods?
We have attempted to clarify what we measured with the written survey and the telephone interviews in the methods under secondary outcomes. We have revised the method section on page 9 under secondary outcomes to read:

"For the intervention group, we attempted to determine several secondary outcomes either through in the post-video questionnaire for patients who responded to the intervention by completing the written survey or via telephone interview for those that did not respond to the written questionnaire. Two months after the initial mailings, we attempted to contact via telephone those who had either not responded to the mailing (non-respondent) or those who had sent the materials back without a written response (non-participant). We made five call attempts to each non-respondent or non-participant. The intent of the calls was not to try to encourage screening, but to determine several secondary outcomes.

In both the post-video questionnaire and the telephone interview we asked questions about the acceptability of the intervention to those who were eligible for screening by asking if they liked receiving the decision aid in the mail. We also measured interest in screening and asked if they had attempted to schedule a screening test since receiving the intervention."

In the Results section, we have added the responses to these measures in both the written survey responses and the responses to telephone interviews.

Under "Responses to mailed surveys" we have added the additional text on the top of page 11:

"Five of these 12 obtained a screening test, 4 of whom had watched the video."

Under "Responses to telephone interviews" page 11 paragraph 2 we have added the additional text below after the first sentence:

"……..We were able to reach and interview 55 of these 97 people (57%). We found that 21 were either up to date with screening or at high risk. Of the remaining 30 people, 23 remembered receiving the package. Among these 23 patients, 14 reported that they had looked at the information, and 6 reported that they had watched the video. When asked about screening, 11 reported that they were interested in getting screened and 8 had tried to schedule a screening test. From the medical record review we found that 3 had obtained a screening test."

Discretionary Revisions (which the author can choose to ignore)
1. Under "Patient Ascertainment" (page 5), why is barium enema not included in the database that tracks colorectal cancer screening test results? Is it because this modality is not used at this institution for screening, or is there another reason?

Correct, barium enema is not used in our clinic for colon cancer screening.

2. Do you have any reasons for the low uptake of the intervention (based on the phone interviews, or other) that you can discuss?

As discussed above we have expanded the secondary outcomes section on page 11 and under comment #4 above.