Author's response to reviews

Title: Using a systematic review in clinical decision making: a pilot parallel, randomized controlled trial

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Author's response to reviews: see over
## Responses to Peer Review Comments

<table>
<thead>
<tr>
<th>Comment</th>
<th>Author Response</th>
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<tbody>
<tr>
<td><strong>Reviewer 1</strong></td>
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<tr>
<td>1. The abstract background is currently methods. From reading the abstract it is not at all clear why this study was conducted, why it is necessary to conduct this study and the context. The research need of this work needs to be made clear.</td>
<td><strong>COMPLETED</strong>&lt;br&gt;Page 2&lt;br&gt;The following sentences were added to the Abstract Background:&lt;br&gt;“Evidence suggests that systematic reviews are used infrequently by physicians in clinical decision making. One proposed solution is to create filtered resources so that information is validated and refined in order to be read quickly. Two shortened systematic review formats were developed to enhance their use in clinical decision making.”</td>
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<td>2. The authors refer to their own pervious work in methods. They need to describe in sufficient detail to be understood by someone not familiar with their work what the methods undertaken were. In particular: a. it is not clear how the systematic review format was developed</td>
<td><strong>COMPLETED</strong>&lt;br&gt;Page 5-6&lt;br&gt;The following sentence was enhanced:&lt;br&gt;“Briefly, prototypes for two formats of a shortened systematic review were developed in collaboration with a human factors engineer based on principles of user-centered design and included a mapping exercise to identify obstacles described by clinicians in using clinical evidence in decision making, a heuristic evaluation of the prototypes, and a clinical content review of the re-formatted reviews.[21] Iterative focus groups were then conducted in order to refine the format of the prototypes, followed by usability testing to test the layout, design, and presentation during individual sessions.[22-23] The focus groups and usability testing were completed with primary care physicians and refinements were made in an incremental process, following each round of data collection. A case study is included in the first shortened format to present contextualized information (case-based format), and the second shortened format integrates evidence and clinical expertise (evidence-expert format). This iterative development process identified component elements of the layout and placement of information resulting in templates for each of the shortened formats.”</td>
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<td>b. what were the differences between the</td>
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| control and test groups | Page 8  
The following sentence was enhanced:  
“Participants were randomly assigned to the control (full-length systematic review) or two intervention groups (evidence-expertise or case-based shortened systematic review format) using random permuted blocks of varying sizes.” |
|-------------------------|--------------------------------------------------|
| 3. Recruitment rate is very low, especially as this is the pilot for an online RCT.  
Was a followup email sent? | COMPLETED  
Page 7  
The information is was present in the manuscript:  
“Participants were sent an initial email inviting them to participate and up to three follow-up reminder emails at one week intervals.” |
| How will authors address this issue in the RCT? Will the participants be from the same cohort used in the pilot (in which case recruitment rate may end up being even lower)? | COMPLETED  
Page 14  
The following sentence was enhanced:  
“The response rate for the pilot study is low at 4.3% and suggests that sources and recruitment strategies other than Scott’s Directory should be considered such as partnering with a physician professional association or general medicine journal…..” |
| 4. Is this a feasible and sustainable method for providing access to systematic reviews? | COMPLETED  
Page 4  
The following sentence was enhanced:  
“We developed two shortened systematic review formats to enhance their use in clinical decision making that could be offered as a companion product to a full-length systematic review.” |
| Will not some context be lost in the process? | NOT APPLICABLE  
Page 4  
This question will be addressed in the full trial. We were careful to follow guidance by Thabane and colleagues (2010) and state the purpose of both the pilot study and the randomized controlled trial so that readers would have the opportunity to understand that this question is dealt with in the trial:
"The purpose of the full-scale randomized controlled trial is to determine the impact of two distinct shortened systematic review formats compared with a traditional full-length presentation of a systematic review on generalist physicians' understanding of evidence, and their ability to apply it to a patient in a clinical scenario."

| 5. How is this proposed format different from the summary that is already provided in systematic review abstracts and exec summaries? | COMPLETED  
Page 6  
The following sentence was enhanced:  
"The following systematic review was selected for the pilot study and the shortened formats are available in Appendix B..."  
The shortened formats were added as an Appendix and can be viewed in Appendix B. |
|---|---|
| 6. Is this method to be applied to individual systematic reviews or will it also be used to conduct analysis of multiple systematic reviews on the same subject? | COMPLETED  
Page 6  
The following sentence was added:  
"As a result, templates were identified that can be used with for individual systematic reviews to create the shortened formats." |
| Reviewer 2 | COMPLETED  
Page 14  
The following sentence was enhanced:  
"The response rate for the pilot study is low at 4.3% and suggests that sources and recruitment strategies other than Scott’s Directory should be considered such as partnering with a physician professional association or general medicine journal..."

These numbers bring to the surface the obvious questions of "is this the most appropriate process to obtain potential participants for the full scale trial?" and "is online the ideal venue for future work with this population?" - the authors do a fair job reflecting on these poignant questions, yet I would encourage a robust reflection on these points in the discussion. Given the small sample size and small proportion of respondents, I would encourage the authors to include details as to whether their sample is at all representative of the family medicine and general internal medicine population listed in the Scott's directory. This would be particularly important moving forward as the question that nags at a reader is "are these participants typical family medicine/general internal medicine MDs." This would be important to identify this now as then changes can be made to the recruiting process for the full scale trial (if this sample is not representative of the population).
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<th>Reviewer 3</th>
<th>COMPLETED</th>
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| 1. There seems to be a big jump between the outcomes of your systematic review and the development of your intervention – you need to add some more information in here to act as a bridge as it is unclear how you got from one to the other, and what the process is for making the shortened review (even if it’s brief); I can see from the later sections that you have included this in the description of the pilot study – a summary sentence(s) of this would be useful in the introduction. | Page 4  
The following sentence was added:  
“The prototypes were developed using a rigorous process including a mapping exercise, a heuristic evaluation, and a clinical content review which was followed by focus groups and usability testing with clinicians.” |
| 2. The tile describes the study as a pilot parallel, randomised controlled trial, but the paragraph towards the end of the introduction describes that “The purpose of the full-scale randomized controlled trial...”. Although I see that you explain further down in this section that the study presented in this manuscript is a pilot for the larger proposed project, I think this needs to be made clear at the start of the section – I don’t think you need to do much new writing, just a bit of re-organising of this section. | Page 4  
We were careful to follow Thabane and colleagues (2010) guidance to provide the purpose for both the pilot and trial so readers can put the pilot study into context. To clarify that the trial is forthcoming, the tense of this sentence was changed to the future:  
“...an online randomized controlled trial is planned to make comparisons to a full-length systematic review where the purpose of the full-scale randomized controlled trial will be to determine the impact of two distinct shortened systematic review formats compared with a traditional full-length...” |
**Methods:** 3. I assume that participants were also asked about their knowledge of the chosen systematic review prior to participation; if not, this could be a major confound if some participants had read the journal article before participating.

**NOT APPLICABLE**

This will be addressed in the full trial as it does not fall within the purpose/objectives of the pilot study. We were careful to follow guidance by Thabane and colleagues (2010) and state the purpose of *both* the pilot study and the randomized controlled trial so that readers would have the opportunity to understand that this is an appropriate issue for the full trial. The purpose and objectives of the pilot study are clearly stated as:

“The purpose of the pilot study is to test methods and procedures in order to refine the processes for the larger scale trial.

The objectives of the pilot study were to determine the feasibility of: 1) assessing participants’ answers; and 2) recruiting participants in a timely manner. *A priori*, we identified that the pilot study would be considered feasible if the following were met,

1. To measure independent reviewers agreement of respondents’ answers with a kappa statistic of 0.60 or greater. Values of kappa between 0.40 and 0.59 have been considered to reflect fair agreement, between 0.60 and 0.74 to reflect good agreement and 0.75 or more to reflect excellent agreement.[19]

2. To recruit a total of 54 physicians for participation within a six month time-frame.

3. To have $\geq 80\%$ of participants who started the pilot study read the systematic review and complete the questions related to the clinical scenario within a six month time-frame.”

4. This is a well presented paper, but you need to make a stronger case as to why you need to pilot these specific issues in the introduction. I understand that the MRC says that you should do pilots for a variety of reasons, but the case for testing these aspects prior to a trial needs to be made explicit and supported with appropriate evidence regarding need.

**COMPLETED**

Page 5

The following sentence was added to clarify this point:

“It identifies that large-scale evaluations can be undermined by difficulties such as acceptability, compliance, and the delivery of the intervention.[18] The piloting stage provides the opportunity to estimate rates of recruitment and retention, and calculate appropriate sample sizes [18].”
| 1. The sentence that starts “we chose a full-length systematic review...” needs to be shortened – it is too long and a bit wordy. | **COMPLETED**  
Page 6  
The text was split into 2 sentences:  
“We chose a full-length systematic review to be used for the pilot study from a list of recently published systematic reviews supplied by the Health Information Unit at McMaster University (Canada) [24] that scored 6 or better (out of 7) on the McMaster PLUS scale. These studies are rated by clinicians who are trained to assess rating articles they believe would be important to practicing primary care physicians.” |
| 2. An enhanced explanation of the sample would be useful | **NOT COMPLETED**  
Pages 7, 9, 10-11  
All information available about the sample is presented on Pages 7, 9, 10 and 11 and in particular in detail in Table 1. We collected nothing further, thus no more information is available. |
| 3. The intervention section states that participants were asked to read the document in Figure 1 – as far as I can see, this is the CONSORT diagram? | **COMPLETED**  
Page 8  
The reference to Figure 1 was moved to the end of the next sentence to reduce confusion. |
| 4. It would be useful if you could state why twice as many participants were allocated to the control group. | **COMPLETED**  
Page 8  
The following sentence was enhanced:  
“Twice as many participants were allocated to the control group due to the intervention having two shortened formats.” |
| 5. You need to say a bit more about the two assessors so we can establish their suitability for this task. | **COMPLETED**  
Page 8-9  
The following sentence was enhanced:  
“Answers provided by the participants were compared independently by two physicians (NP, SES) to the expert panel answers by two assessors who were blinded to allocation. Disagreements were resolved by discussion or a third assessor (an internal medicine physician) if agreement could not be reached.” |
| 6. It would be useful to say how many consented to participate in the study before you say how many dropped out and how many completed. Maybe you could direct them to the CONSORT flow diagram here? | **COMPLETED**  
Page 10  
The following sentence was altered:  
“Sixty seven participants were randomly allocated to the intervention or control group, eleven people partially completed the study…” |
<table>
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<tr>
<th>Results:</th>
<th>COMPLETED</th>
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<tr>
<td>7. The following changes would help this part of the results section “This area was re-developed so that [the assessment of] each individual participant’s answers could be saved before moving on to the next submission.”</td>
<td>Page 12</td>
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<tr>
<td></td>
<td>The sentence was changed and now reads as follows: “This area was re-developed so that the assessment of each individual participant’s answers could be saved before moving on to the next submission.”</td>
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</table>

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<tr>
<th>8. You either need to explain how you came up with the figures in the rate of recruitment part of the manuscript, or you need to direct readers to the appropriate appendix.</th>
<th>COMPLETED</th>
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<tr>
<td></td>
<td>Page 13</td>
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<td></td>
<td>The following sentence was moved from Page 11 (the beginning of the Results section) to Page 13 (were Rate of Recruitment was reported): “Formulae and results for calculating outcome measures are shown in Appendix E.”</td>
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<tr>
<th>9. The sentence that starts “The participants that were locked out (but finished the study) were not used...” needs some punctuation – it is too long.</th>
<th>COMPLETED</th>
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<tr>
<td></td>
<td>Page 13</td>
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<td>The text was split into 2 sentences: “The participants that were locked out (but finished the study) were not used to calculate the mean time to complete the study. The three hours of inactivity would have falsely inflated the times since respondents indicated they were locked out due to being called away to complete another task, not due to needing this amount of time to complete the study.”</td>
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<tr>
<th>Introduction:</th>
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<tr>
<td>1. The use of “online medical product” is somewhat confusing.</td>
<td>Page 3</td>
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<td></td>
<td>The sentence was changed to read: “A recent systematic review of secondary sources (such as Clinical Evidence) concluded that no single online medical information tool product is ideal and no single source should be relied upon to provide answers to clinical questions”</td>
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