Author’s response to reviews

Title: THE EFFECT OF A CLINICAL DECISION SUPPORT SYSTEM ON PROMPTING AN INTERVENTION FOR RISKY ALCOHOL USE IN A PRIMARY CARE SMOKING CESSATION PROGRAM: A CLUSTER RANDOMIZED TRIAL

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Reviewer's report

Reviewer: 1

The authors emphasis in the conclusion that the intervention might have changed the way practitioners offer the resource as a significant change was seen in patients' acceptance of the resource. Nonetheless, this was not part of the research. Based on the measures even though the word 'might' is used, this conclusion is to my opinion to strong and needs to be formulate with more caution as it needs research into practitioners' behaviour to confirm this. I would recommend a reformulation in the abstract conclusion, contribution to the literature and also in the conclusion of the main text.
Response: Thank you for the comment. We have addressed your concern, as well as those of Reviewer #2, by providing a more cautious conclusion. We have revised the abstract conclusion (line 35-36), contribution to the literature (lines 51-52) and also in the conclusion of the main text (line 339-341)

It is not clear what is meant by 'alcohol resource', is this the workbook, is this referral? The authors should elaborate on this in an early state and explain this a bit more in the methods. I assume referral (to whom?) is also available for the practitioners in the control group. Had the practitioners in the intervention group and control group the same possibilities with regard to offering 'resources', in other words was the only difference the prompting for risky alcohol use?

Response: Thank you for your comment. It is true that the only difference between the two groups was receiving the prompt for risky alcohol use. Both groups had access had the same possibility of offering the resources. They would have to calculate the scores and know which resource to use without being prompted by the CDSS.

In order to clarify what we meant by ‘alcohol resource’ we have added a brief explanation of the two main elements of the resource: “an alcohol reduction workbook for patients drinking above CCS (Canadian Cancer Society) guidelines and an abstinence resource for patients who score above 20 points in the AUDIT cut-off” in the abstract (lines 13-16) in the methods section (lines 118-121) and in the outcome section (lines 189-191)

Figure 1 shows a lost to follow-up of practices for the secondary outcome (i.e. 93 vs 86 practices (intervention) and 92 practices vs 83 practices (control) which is not explained. Why is there a lost to follow-up as this data is derived from the electronic system if I understood it correctly? Similar why lost to follow-up for the tertiary outcome in participating practices, what is the explanation?

Response: Thank you for pointing this out to us, we realize how this could be confusing. We have added a note to Figure 1, explaining why the samples for our primary, secondary and tertiary outcomes are different. Our primary outcome (the offer of an alcohol resource) has all practices that were randomized and that recruited at least one eligible patient during the study period. Practitioners in 17 practices in the intervention group and 19 practices in the control group did not use the online portal to complete the baseline assessment for their patients, during the study period, and thus did not recruit any eligible patients. For our secondary outcome (the acceptance of an educational alcohol resource by patients exceeding alcohol use guidelines) the sample consisted only of practices that offered the resource at least on one occasion. In the intervention arm 7 practices never offered the resource, and in the control arm 9 practices never offered the resource. Our tertiary outcome was abstinence from smoking, and alcohol consumption within CCS guidelines, measured via a 6-month follow-up survey sent to all eligible patients. In the intervention group, 1,332 patients (46% of eligible patients) that had
received care from 89 practices answered the survey; patients from 4 practices did not answer the follow up survey. In the control group 1,346 patients (48% of eligible patients) that had received care from 85 practices answered the survey; patients from 7 practices did not answer the follow up survey.

This paper would be even more interested, as it might give a more detailed insight, if not only per protocol analysis was carried out with regard to the last outcome, but if a secondary analysis could be added with including those patients who actually accepted the offered resources. As those patients (intervention 280 and control 203) received the health promotion and/or referral to addiction treatment (?). All other patients didn't receive the resources (so had less chance to change their behaviour).

Response: Thank you for the suggestion. We agree that this would be an interesting exploratory analysis. The effectiveness of the resources was not one of the study’s research questions, and was not specified in our protocol; nevertheless, an effort to understand the effectiveness of the resources might be justifiable. However, we think that there are problems that make this analysis inadvisable to include in this paper.

In principle, this analysis would answer questions about the overall and differential effectiveness of the resources. However, people accepting them are a small and self-selected group, making the generalizability of these results unclear. It is also not completely clear that there is reason to expect a substantial group difference, and our power to detect one would be very limited. Group sizes are 280 and 203, but the abstinence outcome is rare overall (4%) and is missing for half of participants. This means that even fairly large effect sizes would be non-significant, even if abstinence is much more common in this subgroup. (Accurate power would require essentially doing the analysis, but a group difference of 14% v. 7%, for example, would be non-significant with 50% missing data.) It is therefore unlikely that results would support secure inferences, while the possibility of chance findings would remain.

Next, the authors mention that all practitioners, prior to the start, were offered a webbased SBIRT training. Do the authors know how many practitioners and who did actually follow this training, and if they do know. Can you relate this to the primary outcome. In other words, does adherence to the training have an impact on the primary outcome? Insight would be helpful for further implementation recommendations.

Response: Thank you for your comment. Unfortunately we did not measure which individual practitioners participated in the training because of the variety and turn over of practitioners at various sites. In other words we kept the training pragmatic, and thus we cannot analyze the effect of the training on the offering an educational alcohol resource. We have added this to our limitations section (lines 330-333).
Minor comments: It would help the reader if in the footnote table 2, also the number of inappropriate offer (n=45) was mentioned.

Response: Thank you for your comment, we have added an additional sentence at the end of the first footnote to table 2 to mention that in total 45 participants in the control arm were offered an inappropriate resource. This is important because the CDSS provided to the intervention arm did not allow for the practitioner to offer an incorrect resource.

Table 2, it would help the reader to add a footnote, first two outcomes are derived from electronic system at practitioners level and 3rd outcome is derived from a patient questionnaire. This also explains different number in the denominator.

Response: Thank you for pointing this out. We have added the following note to our Table 2: “The first two outcomes, offer of appropriate resource and acceptance of offered resource, were derived from the electronic system and were measured at time of patient enrollment to the study while the third outcome, abstinence from smoking and drinking within CCS guidelines, was derived from a patient questionnaire, 6 months after enrollment.”

Reviewer: 2

Title The title is rather long and unwieldy; maybe the authors can find a shorter, catchier title.

Thanks for your suggestion. We have changed our title to:

Technology-based interventions to promote the delivery of SBIRT for alcohol use in primary care to patients quitting smoking: A cluster randomized trial of a prompt versus passive access to resources

Abstract, results section: From figure 1, 15,222 patients were screened for alcohol use; please correct or explain the difference. Furthermore, the results reported in this section of the abstract refer to the patients who were enrolled. Thus, I suggest to rephrase this section as follows: "From the 15,222 patients screened for alcohol abuse, 5,715 were enrolled in the study."

Response: Thank you for your comment; we have reviewed the sentence to: “Two hundred and twenty one clinics across Ontario were randomized for this study; 110 to the intervention arm and 111 to the control arm. From the 15,222 patients that enrolled in the smoking cessation program, 15,150 (99.6% of patients) were screened for alcohol use, and 5,715 patients were identified as drinking above CCS guidelines” (lines 22-25)
Abstract, conclusion: The authors write "A CDSS may not increase the likelihood of practitioners offering an educational alcohol resource, though it might change the way practitioners offer the resource. However, in the conclusion of the end of the paper the write: "This large study (...) shows that the provision of a CDSS may not increase practitioner adherence to guidelines but may improve practitioner performance once they adhere to them". "Practitioners' performance" is not the same as "the way practitioners offer". Since the authors use "practitioners' behaviour" in the discussion, I would suggest to use it in the conclusions as well (behaviour towards...)

Response: Thank you for the comment. We have revised this sentence in order to address your concern as well as that of Reviewer 1. The sentence now reads: “A CDSS may not increase the likelihood of practitioners offering an educational alcohol resource, though it may have influenced patients’ acceptance of the resource” (line 34-36)

Main text: Background section: - Page 5, lines 49 and 54: "integration is critical given the substantial gap" and "practitioners non-adherence has been identified as one of the most critical gaps": week style (word repetitions); please change 2nd sentence, e.g. "issues, obstacles or barriers" instead of "gaps". –

Response: Thanks for pointing this out; we have revised our second sentence according to your suggestion, it now reads: “This is critical given the substantial barriers between evidence-based knowledge and practice across all health care disciplines” (line 56-57)

Page 6, line 70: Please give examples in which clinical settings CDSS has been shown to be effective. Are there other references than Bright et al? –

Response: Thanks for your feedback. We have added more details and references on where CDSS have been shown to be successful: “Researchers have shown the effectiveness of CDSS in improving prescribing practices (23-25), reducing medication errors (25, 26) improving preventive care (such as vaccination, smoking cessation, breast cancer screening) (27), and in ordering and recommending patients to clinical studies (25).” (lines 73-76)

Page 6, lines 78-81: "A cluster randomizes trial..." This is not part of the introduction/background, but should be moved to the method section

Response: Thanks for your comment. The CONSORT checklist for cluster randomized control trails specifies that in the introduction we add the rationale for using a cluster design and to specify whether objectives pertain to the cluster level, the individual participant level or both. Thus we have left this sentence in the introduction/background section.
I strongly advise against the use of the acronym COMBAT. COMBAT is already used and a registered trial (although completed): https://urldefense.proofpoint.com/v2/url?u=https-3A__clinicaltrials.gov_ct2_show_NCT01838863&d=DwIF-g&c=vh6FgFnduejNhPPD0fl_yRaSfZy8CWbWnIf4XJhSqx8&r=hPPEyZbOxUiv5aU_i6VDVg0BvNvaLoMYXhq_BeVmVj8&m=cDjNSE9zNp7EAvVZ7mZ08SdcTO9lrD6hl92wQhKRZyo&s=GoJQQbKk7KVPQGi5UjbPSXhRsBLTL6K2yHrx8vAJocl&e= Publication to COMABAT trial in Lancet: Moore HB et al. Plasma-first resuscitation to treat haemorrhagic shock during emergency ground transportation in an urban area: a randomised trial. Lancet 2018, online first. Connected to my previous comment: Did the authors register their trial? If so, please mention the trial registration.

Response: Thanks for your comment. We did register the trial, with ClinicalTrials.gov, number NCT03108144, on April 11, 2017. This is documented this on page 5, lines 38-39. Given that we did register the trial, and we published a protocol paper using the acronym COMBAT, we have opted to continue using this acronym.

Method section: Clinic randomization: - Page 8, lines 134/135. I do not understand: How can clinics be NOT blinded to randomisation assignment and yet NOT be informed of their allocation? Sample size determination –

Response: Thanks for your comment; we have added the following sentence to explain this better: “Specifically clinics were informed that alcohol use was being addressed in the STOP study; but were not informed that some clinics were receiving a CDSS (which alerted practitioners of patients drinking above CCS guidelines and guided them to provide an appropriate alcohol intervention and offer an appropriate alcohol resource) while others were not receiving the CDSS.” (lines 149-153)

Page 11, line 204: missing a spacebar "to be 5.308".

Response: Thanks for noticing this; we have added a space bar (line 221)

Statistical methods: - Page 12, line 212: please use "sex" instead of "gender". How did the author find out about members of First Nation?

Response: Thanks for your suggestion, we have changed the word “gender” for “sex”, and added clarified that all the variables listed were self-reported variables asked in the baseline assessment (line 230-231)
Did the authors consider a sub-analysis with First Nation Members only? Did the authors consider interaction analyses?

Response: Thanks for your suggestion. We agree that the idea of exploring interactions is an interesting one, but we believed that there were good reasons for not performing these analyses. Interactions would constitute subgroup analyses -- i.e., we would be looking for differential effects across levels of our other variables. These would create a risk of false positive results, and would lead to other important problems of interpretation, especially as these tests were not specified in our protocol. Existing guidelines do not support subgroup analysis in our context (e.g., Burke, J. F., Sussman, J. B., Kent, D. M., & Hayward, R. A., 2015. Three simple rules to ensure reasonably credible subgroup analyses. Bmj, 351, h5651.)

There are also two practical issues. First, we had no overall effect for two of our outcomes, and only a small one for the one outcome (acceptance of the resource). This makes it less likely that there are meaningful variations across participant characteristics, as different groups would probably need to have sizeable effects in opposite directions. Second, our interactions would have relatively low power -- we would often be looking for differences across relatively small subgroups (particularly in the case of First Nations participants), so would be only be able to detect large effect differences. As already suggested, such differences are unlikely to be present.

Discussion: Page 14, line 272: Reference 40 is superscripted

Response: Thanks for noticing this; we have corrected this reference so that it is not superscript anymore. (Line 291; now reference 44)