Author's response to reviews

**Title:** Improving chronic disease prevention and screening in primary care: results of the BETTER pragmatic cluster randomized controlled trial

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**Author's response to reviews:** see over
10 October 2013

Dear BMC Family Practice Editors,

Re:  Improving chronic disease prevention and screening in primary care: results of the BETTER pragmatic cluster randomized controlled trial

Thank you for the review of this manuscript. We provide below a point-by-point response to the reviewers’ comments and a revised manuscript with track changes. No changes have been made to the Additional Files.

We look forward to a final decision regarding this manuscript.

Yours sincerely,

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Response to Reviewers’ Comments

We thank the reviewers for their positive feedback and for their helpful suggestions to improve the clarity of the manuscript. We provide point-by-point responses to the reviewers’ comments and changes to the manuscript are identified by track-changes.

Reviewer #1:
Major Compulsory Revisions:
None

Minor Essential Revisions:
None

Discretionary Revisions:
The following comments are meant to enhance the project’s value and the value of this paper to primary care physicians and organizations that support health care excellence.

1) How were the eight primary care practices identified? Within these practices how are the participating physicians identified from the larger group of clinicians?

Response: Eligibility criteria for primary care practices were:
• primary care team practices [Lines 143 to 147];
• minimum of 2 years of use of an EMR [line 147 to 148];
• urban practices in one of two provinces [line 141].
The participation of primary care practices was by purposive sampling based on eligibility criteria and a mix of academic teaching practices and community non-teaching sites in different locations [line 141 to 143]. Participating primary care team practices were randomly assigned to the practice-level intervention with a Practice Facilitator or control [line 166 to 168].

Within each primary care team practice, 4 Primary Care Physicians (PCPs) agreed to participate [line 166]. Participating PCPs were randomly assigned to the patient-level intervention with a Prevention Practitioner or control [line 168 to 169].

2) How were the 28 outcomes identified?

Response: The 28 outcomes were identified through a comprehensive literature search and iterative process of harmonizing clinical practice guidelines across the topic scope. This work was conducted by a Clinical Working Group comprised of clinicians with expertise in the clinical area. This is described Lines 224 to 226 and 239 to 243. Appendix 2 provides a full list of the 28 actions, pre-defined targets and supporting references. A manuscript providing full details of this process is currently in press [Lines 226 to 227].

3) It is stated that the prevention practitioner is a new role in primary care. That may be true for the range of services provided here. However, the notion of facilitators
and other outreach workers supporting practices, either as their staff or provided by external organizations, is not new.

Response: We state that the Prevention Practitioner is a “modification of practice facilitation” [Line 436]. We have revised the text to emphasize that is a modification of the facilitator role [Lines 123 to 127 and 437 to 440].

4) The background and methods section set the stage well.
5) On page 8 the setting described is Primary Care Team Practices in Canada with some explanation that these practices are the patient’s medical home. Some readers of the journal will understand this but others will not. Please consider a more detailed explanation and how these practices might be described in the UK and elsewhere.

Response: We have added text to give more detail [Lines 144 to 147].

6) On page 10, the authors describe the one-hour single visit with the nurse practitioner, nurse, or dietitian. Readers may be interested to know where this concept came from and whether it has ever been shown to be useful as a one-time visit. There is a relevant paper cited but more detail is needed here. It is not clear to me whether the one hour visit really made a meaningful difference for patients even though statistically significant. The extra visit may not be worth the effort for the patient and the practice.

Response: The Prevention Practitioner intervention is the novel approach tested in this trial. The intervention was developed following a review of the literature and an analysis of the barriers and facilitators to optimum evidence-based prevention and screening for chronic diseases in primary care (details of this process are the topic of a separate paper currently being written). This study provides the first evidence that the intervention does lead to an increase in the number of evidence-based targets achieved by patients. The reviewer is correct that we have not shown long-term benefit, which is beyond the scope of this trial [Lines 429 to 431]. However, the 28 actions were selected because “they have been shown to lead to clinically important benefits…” [Lines 236 to 239]. See also, response to question 16.

7) The authors should be commended for their description on page 12 of the outcome assessment. Also the primary outcomes are described in an exemplary way on page 15.

8) On page 12, we are told the patients are mailed a survey at T0 and T1. What was the return rate and how did it vary across the four strata?

Response: The return rates at each time point and across strata are presented in the Consort Diagram Figure 2. They are as follows:
- T0: 775/789 = 98.2% return rate; >90% across all four strata.
- T1: 644/789 = 81.6% return rate; >76% across all four strata.
This information has been added to the text [Lines 315 to 317].
9) On page 13 and elsewhere, the authors refer to the PP and PF interventions. I found this difficult to track and would have preferred that the authors provide the formal name of the interventions each time they are referenced.

Response: We have revised the text so that names are written in full.

10) On page 13, the authors state that the cost of the intervention included time to train the practitioners. I may have missed it but I would like to know more about the training approach in the time it took.

Response: Training of the practitioners consisted of 1) participation in the Clinical Working Group; 2) a two-day training workshop followed by a one-day training workshop which took place before the intervention started; 3) during the intervention period there was the opportunity to participate in a one-hour monthly teleconference that was facilitated by a member of the Clinical Working Group. We have revised the text to include these details [Lines 184 to 189].

11) I also found it confusing that the cost of training was somehow excluded from the cost of the intervention.

Response: We thank the reviewer for identifying this inconsistency, which was a typographical error on our part. The cost of the training was included in the intervention costs and we have now corrected the text [Line 292].

12) On page 15 the authors describe a very modest impact of the PF only group. While this is appropriately handled here, I would like to see more attention to this in the discussion section.

Response: It is difficult to determine for certain why the Practice Facilitator intervention was not more effective. We speculate that it might be that the seven-month timeframe was too short to detect a signification effect. Since the outcome was measured at the patient-level (which is the most relevant approach) it is likely that the patient-level intervention with the Prevention Practitioner had more direct impact on the patient whereas the Practice Facilitator had only indirectly impact on the patient. We have added text to this effect [Lines 379 to 383].

13) On page 15 and elsewhere I continued to appreciate the wisdom of the authors in doing a separate analysis for patients with mental health issues.

14) Page 16 refers to various costs as presented in figure 4. I found this narrative hard to follow.

Response: We have revised Figure 4 [Page 30] by adding the values directly into the figure. We hope that this makes it clearer.

15) I found the references to Baskerville on pages 16 and 17 to be confusing. You may want to consider whether this should be described another way.
Response: We have revised the text and hope that the revision makes it clearer [Lines 373 to 376].

16) On page 17 it appears that the authors are advocating continued use of the nurse or nurse practitioner one-hour session with patients even though the impact was modest. As noted previously, given the staff and patient time to discuss and the patient inconvenience of an extra visit I find this hard to defend, as mentioned earlier, but maybe I'm missing the point.

Response: The trial showed that the Prevention Practitioner intervention resulted in a 32.5% increase in chronic disease prevention and screening actions of patients, with an effect size of 1.45 at the cost of $26.43 per additional action met. The effect size is substantially larger than the effect size of 0.56 for practice facilitation shown in the Baskerville meta-analysis [Lines 373 to 376]. Although we conclude that the intervention is economically attractive when considering the long-term costs of managing these chronic diseases, we do state that “decision makers must consider how much they are willing to pay” [Line 400 to 401].

17) The discussion on page 18 is excellent including identifying the health outcomes that were not impacted.

18) The conclusion section on pages 18 and 19 is very helpful. Either here or elsewhere, I would like the authors to provide some thoughts on how this work might go from this clinical trial to practical application in real-world practice in Canada, United Kingdom, and elsewhere.

Response: We have added text to illustrate the steps we are taking to update and disseminate the training materials developed for the trial, and to test adaptations of the intervention to different settings [Lines 443 to 447].

Level of interest: An exceptional article

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests: I declare that I have no competing interests.

Reviewer #2

The authors investigated the effects of a quality improvement program for primary care aimed at improving preventive and screening activities for chronic diseases in routine care. They compared a practice-oriented (improvement of medical records management) and a patient-oriented intervention (improvement of registration, action, and lifestyle advice). It showed that the patient-oriented approach was effective.
I really like the rationale behind this study. It is extremely difficult to really change the way routine primary care handles chronic diseases. In my view the researchers investigated a very relevant and doable intervention, which can be an example for daily practice as well as for further research. I also really like the way the researchers used the electronic medical records, which was central in the recruiting, intervention and outcome measurement, because it really makes this study very pragmatic. So in my view this is a very relevant study, and I don't have major comments.

Minor essential comments
19) I don’t see why the authors name their trial a factorial trial. In my view, judged by the way they analyze the outcomes, it is a trial with four arms.

Response: In this study we have two interventions allocated over four arms as presented in the trial schema (Figure 1): practice-level intervention only; patient-level intervention only; both practice- and patient-level interventions; control [Lines 169 to 172]. This is a classic 2x2 factorial design. However, because the interaction between the patient-level and practice-level interventions was not significant, the data can be analyzed as a 4 arm study to simplify the analysis.

20) The use of abbreviations makes it difficult to read/understand the paper. I suggest try to avoid them as much as possible. In my view all abbreviations used can be avoided by one word descriptions (for example PCP=physician).

Response: We have removed abbreviations wherever possible (specifically all instances of PP, PF, PCP and CEA have been written in full (see also Reviewer 1, question 9).

21) Third paragraph of the introduction: “a multifaceted multi-level implementation strategy to improve an integrated approach to prevention and screening..” This is a very difficult way of presenting what’s new about your intervention. I suggest to spend a few more words on exactly what has been missing in the previously studied interventions and what is new in your intervention. Also to make it easier for policy makers and physicians to understand your concept.

Response: Thank you for this suggestion. We have revised the text accordingly [Lines 123 to 129].

22) I have some concerns about the way the outcome was measured. It can easily happen that outcome registration has improved in intervention groups, so are we looking at better registration or better care. For example the registration of a smoker is very easy to change (but someone has to do it). Getting someone to quit smoking is however very difficult. Both are outcome indicators and grouped together in a summary score. So it makes you think whether the effect observed is merely an effect on better registration or really better care/health improvement. There is very little text on this issue, so maybe spend a few words on that in the methods (if it just needs clarification) or in the discussion (if it is a limitation).
Response: For 23 of the 28 actions included in the SQUID, the targets are relevant clinical outcomes and were not considered to be ‘met’ unless that target was achieved. Full details are provided in Appendix 2. For example, FBS had to be completed in order for #1 to be considered ‘met’. Similarly, BP had to be checked (#3) and, depending on the result, the next appropriate action taken; Framingham improved (#7), mammogram completed and the result available in the chart (#10). The exceptions are #6, 14, 17, 20, 23 where the action was considered met if it was ‘registered’ in the EMR. These actions were only included in the SQUID calculation for those patients who did not have the information registered in the EMR at baseline and were balanced across randomization groups (Table 2). It was decided to include these in the SQUID because the evidence review supported the importance of capturing this data in the EMR. We agree with the Reviewer that there is a big difference between capturing smoking status in the EMR vs smoking cessation. We do note in the limitations section that, although the trial was not powered to test the effect on each action separately, the effect was not detected for difficult to change lifestyle factors such as smoking cessation and weight control. However, an improvement was found for diet and exercise [Lines 411 to 415]. We have added text to the limitations section to note the limitation regarding ‘registration’ [Lines 416 to 420].

23) The concept of ‘eligible actions’, and when are they met, is quite unclear from the main text. The reader has to go to the appendix to understand this. An example in the methods would improve this in my view.

Response: We have added an example in the methods section [Lines 251 to 256].

24) It would be interesting to know how many primary care practice teams had to be contacted to get 8 teams willing to participate in the study. This will illustrate the willingness of health care organization to participate in such a quality improvement program. If this was difficult it should be mentioned as a limitation of the study, or at least a concern that we have to deal with in the future.

Response: Please see response to Reviewer 1, question 1. All practices approached through purposive sampling agreed to participate.

25) In the two-way GEE analysis the authors adjusted for confounding, but I can’t find for which confounders they adjusted.

Response: The adjusted analysis and list of covariates are presented in Appendix 4 which is referenced in the Results [Line 340].

26) I really miss a paragraph in the discussion where suggestions for the future are given. How should the intervention be adapted and what are the main objectives of future research?

Response: We have added a paragraph to describe some of the further work that is ongoing [Lines 442 to 446].

Once again, thank you very much for your positive comments and helpful suggestions.