Author’s response to reviews

Title: The impact of a Cardiovascular Health Awareness Program (CHAP) on reducing blood pressure: a prospective cohort study

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Author’s response to reviews: see over
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To Dr. Ilow, Editor of BMC Public Health:

Re: MS-1696621490105714

Thank you for the reviewers’ comments on our manuscript. The reviewers’ comments were very helpful. We have revised the manuscript by highlighting the changes. In this cover letter, we have provided point-by-point responses to address those comments. We appreciate the time that you have taken to review our manuscript and look forward to hearing back from you soon.

Sincerely,

Chenglin Ye (PhD candidate)
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1. The authors need to expand the methods section to include more detail on the timing and organization (who does what) of the follow-up CHAP sessions. Ie CHAP screening sessions were held, on average, weekly or monthly between May 2008 and April 2010 and were run by study nurse and peer health educators or were the latter (date range?) sessions run independently of the original study by only the peer health educators? The authors should provide a clear idea of how independently the sessions were run subsequent to the official study or if this follow-up part was part of the original study?

**Response:**

The latter sessions were delivered after the completion of the RCT and were organized in the same way on a weekly basis. We have expanded the method section by adding the following details on those sessions.

On page 5, “These CHAP sessions were delivered after the completion of the main RCT weekly in 22 communities. Although those sessions were run independently of the main study, they were organized in the same way. Physician referral and local advertisements were the primary means of inviting potential participants. In those CHAP sessions, trained volunteer peer health educators assisted participants to take BP measurements with the BpTRU device and recorded self-reported CVD risk factors on the standardized risk profile form. An on-site community nurse was available to assess participants who had abnormal BP and trained volunteer peer health educators referred eligible participants to community pharmacists for a medication assessment. The medication assessment was a one-to-one meeting to ensure the safe and appropriate use of all types of medication.”

2. The authors could add much value to the manuscript by reporting on the blood pressure response in the 33% of baseline participants that did not report (or were not aware) they had hypertension. Further, we know that treatment of hypertension in diabetes is one of the single most important risk reduction strategies: for this reason it is of interest to comment on the blood pressure response of these individuals.

**Response:**

Among the participants who showed high BP at baseline, 33% of them did not report hypertension, suggesting that these individuals might not be aware of their condition. When we explored the group of participants who showed high BP at baseline, we did not find any significant difference in the BP change between the ones who reported hypertension and those who did not. On average, the ones who did not report hypertension only had 0.11% (p = 0.39) and 0.17% (p = 0.15) more reduction per month in SBP and DBP, respectively, than those who did. We have added these statements in the Discussion on page 11.

Further, for the participants who showed high BP at baseline, the ones who reported diabetes on average had 2.5 and 3.3 mmHg more reduction in SBP and DBP, respectively, than those who did not. For the participant who did not show high BP at baseline, the ones who reported diabetes on average had 2.9 and 3.0 mmHg more reduction in SBP and DBP, respectively, than those who did not. We have added these interpretations in the Results on page 9.

3. I can find nothing that specifically accounts for regression to the mean in the blood pressure values of those that had elevated pressures at baseline. The authors should be specific about this potential bias, and declare outright if they dealt with it or not. Its especially suspect, since those with high BP at baseline improved much more than those without (which is precisely what you'd expect with regression to the mean in the absence of any actual effect of the CHAP program). They also explicitly state, “Our study showed that the CHAP participants initially identified with high BP experienced a significant reduction of BP during repetitive visits. Participants who presented
with higher risks of developing cardiovascular diseases were more likely to attend multiple sessions”. Both these statements suggest regression to the mean is not just plausible, but likely, and the authors should speak to it, either in the discussion or the methods.

**Response:**

Limited by the design, we did not protect the study from regression to the mean (RTM) bias by randomly allocating the CHAP intervention to the participants who had high BP at baseline and those who did not. However, we tried to reduce the RTM bias by recording the average BP in each measurement. The first reading was automatically discarded and the mean value of the five subsequent measurements was recorded (on page 6). We also took into account the CHAP participants’ baseline BP (as a risk factor) in the model when estimating the rate of BP change (described in the footnote under Table 3). Both approaches were suggested by Barnett et al. to deal with MTR bias [1]. Using the standard formula [1], we calculated the effect of RTM in our sample to be approximately 2.0 and 0.6 mmHg for SBP and DBP, respectively. Both numbers imply a weak effect of RTM in the participants’ mean SBP and DBP. We have added these statements in the limitations on page 11.

4. On page 4 the authors mention, “The on-going goal is to develop CHAP as a sustainable community-owned program” It would be of value if the authors included a statement on how the program is being (or will be) sustained in the Ontario communities.

**Response:**

We have added the latest development of CHAP in on page 5.

“Today, 9 communities in Ontario have successfully adopted CHAP as their regular community program. A CHAP implementation guide that targets community end-users has been built to provide a ‘road map’ for new communities interested in implementing CHAP (www.chapprogram.ca).”

Small typo/grammatical corrections:

Page 4: last paragraph, line 4: “ admissions….of (not for) 9%”

Under Study design: should include a sentence that references the detailed study protocol.

**Response:**

We have revised the sentence and added a sentence that references the protocol under study design on page 6.

Page 6: last line: modelling is misspelt; should be: modeling.

**Response:**

We have made the correction.

Page 7: first line of second paragraph: should say, “the factors that WERE associated”

**Response:**

We have made the correction.

Page 8: second paragraph: second to last line should read, “ over an 18 MONTH period”; last paragraph, first line should read, “ from the logistic regression analyses examining”

**Response:**

We have made the correction.
- Major Compulsory Revisions

1. Page 2: Abstract: Results: 2nd and 3rd sentences: Confidence intervals with same lower and upper limits are given each with p<0.01. How is this possible?

Response:
We apologize for the confusion. To clarify the numbers, we have reported the estimate and its 95% confidence in three decimal places in the Abstract. They are 0.992 (95% CI: 0.991,0.994; p < 0.01) and 0.993 (95% CI: 0.991,0.994; p < 0.01), respectively.

2. Page 8: Statistical analysis: paragraph 2: 4th sentence: The confidence interval of (0.99990,1.001) includes 1 yet p<0.01. How is this possible?

Response:
We apologize for the inconsistence. We have corrected those p values on page 9 and in the Table 3.

3. Pages 11-12: Appendix: The bivariate linear mixed-effects model fitted to the data is given. Could the authors comment on why their suggested model did not take into account clustering of patients within communities. On page 2: Methods, it is reported that the data came from 22 midsized Ontario communities.

Response:
The 22 mid-sized communities in this study are similar in their demographic profile, e.g. population composition, income and residents’ education level. The distribution of BP is also similar although the number of total population varies. To explore the community effect on the BP change, we fitted the mixed-effects model by including an additional community factor, i.e. a 3-level model that accounted for visit, participant and community levels. The estimated rate of BP change was similar to that obtained from the 2-level model (only visit and participant levels). However, the estimates from the 3-level model resulted in a non-positive Hessian matrix, suggesting unstable estimates and potential over-specification of the model [2]. Thus, we reported the 2-level model, which provided stable estimates with a simpler covariance structure. We have added these statements in the Results on page 9.

4. Pages 17: Table 3: The fitted bivariate linear mixed-effects model did not account the multi-level nature of the data i.e. clustering of patients within communities. Would the results change if community effects were included?

Response:
Please refer to our responses to question 3 above.

5. Pages 17: Table 4: Could authors comment on the possible collinearity between the variables BMI, SBP and DBP.

Response:
We have examined the multi-collinearity among the risk factors by calculating their variance inflation factor (VIF). We did not find a strong multi-collinearity of any risk factor, i.e. VIF < 10. We have added this statement in the Results on page 9. Also, SBP is correlated with DBP and the covariance structure has been incorporated in the bivariate model reported.

6. Figure 1: This graph should be reconstructed as a bar chart/graph instead of a histogram. The bars should be separated by spaces.

Response:
We have revised the figure as suggested.
- Minor Essential Revisions
1. Figures 3 and 4 could be improved by using other line patterns instead of double lines for confidence interval bands e.g. dotted lines.

**Response:**
We have revised the figure as suggested.

References