Author's response to reviews

Title: Impact Evaluation of a Healthy Lifestyle Intervention to Reduce Cardiovascular Disease Risk in Health Centers in San Jose, Costa Rica and Chiapas, Mexico

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Dear Sir or Madam:

Thank you for the opportunity to resubmit our manuscript titled: “Impact Evaluation of a Healthy Lifestyle Intervention to Reduce Cardiovascular Disease Risk in Health Centers in San Jose, Costa Rica and Chiapas, Mexico” (MS: 7629884140046962) and for sharing the thoughtful comments provided by the three reviewers. We have read through the reviewer comments and have prepared an improved manuscript for your consideration. In this letter, we respond to the specific comments about the previous version of the manuscript.

**Reviewer 1: Hector Balcazar**

1) The definition of health care worker. The study identifies different descriptions for health promoters, health care personnel, healthcare staff. It is not clear if primary health clinics utilized community health workers or a combination of both CHWs versus other clinic personnel (nurses, doctors, social workers, etc). Who actually deliver the intervention in these communities? Was it a combination of clinic staff (i.e. nurses, doctors, etc) and community health workers? Are community health workers the way they are defined in the U.S., members of the primary health team in the community sites utilized in both countries?

In both Costa Rica and Mexico, the government employs a figure called a health promoter who is a paid health care worker within the formal health care system whose job is focused on health promotion. The health promoters in each country work in collaboration with a team of health care providers whose jobs focus more on clinical care (nurses, doctors, and nutritionists). In this study, the health promoters were the key people responsible for implementing the intervention and the broader primary care team (doctors, nurses, and nutritionists) was invited to take part in the trainings and to lead the group sessions for patients as well. We have clarified this in the text.

2) The non-equivalent comparison groups. The information presented in the manuscript is sketchy regarding the definition and description of the comparison groups. It is not clear how these groups in both countries were selected? What process was used to select them?

In selecting the comparison health center to be used in each of the two country settings, the health centers were expected to offer similar health care services (laboratory, pharmacy, and clinical patient care), and have approximately the same number of patients with a similar socio-economic level. In addition, they were not to have regular contact between staff or patients from the intervention and comparison sites.

The manuscript describes a patient registry. Who was in charge of this process of selecting eligible patients for the comparison groups? Was the process done similarly in both countries?

The health center staff provided the list of patients identified as having diabetes, hypertension or both and the research team was in charge of selecting eligible patients at the comparison health center who fit the study’s inclusion criteria. The process was done similarly in both countries.
3) Data collection time frame versus intervention duration. The authors describe that there were three data points (baseline, mid-point, and 8 months), and that the study had a duration of 4 months in terms of enrollment. Given this information, several issues are in need of clarification. First, why was not considered 4 months a possible end point for testing pre–post changes if the intervention of six sessions was done within that time period? Second, what is the attrition rate differential at 4-months versus 8 months in terms of data collection versus participation in the intervention. How was data collection handled for the comparison groups? Was the mid-point done at 4 months?

We have added an explanation of the decision to follow up with patients at 8-months in the manuscript. The 8-month follow up was determined as the shortest time frame that would allow patients to participate in the 6 different educational sessions, taking into account that patients might not be able to attend the sessions each month due to scheduling conflicts. Data was handled for the comparison in the same way as for the intervention group, and midpoint was done at 4-months.

4) Possible sources of Bias. The authors do acknowledge the challenges of attrition and differential participation. In this regard, do the authors know how many eligible participants in both countries rejected to be part of the study? Was cardiovascular disease risk differential (with the WHO algorithm) a potential bias not accounted for in the multiple regression analyses as a source of confounding within each country? The attrition rates are problematic as the authors described. Can the authors present this information of attrition rates for the mid-point and follow-up data collection points versus intervention participation in education classes?

We agree that there are a number of possible sources of bias and appreciate the considerations raised by the reviewer and have made a point to highlight this issue in the discussion section. The number of participants who rejected to be part of the study was not documented. We considered using CVD risk level but chose to use the patients’ status as having diabetes or hypertension instead, given that the risk level is calculated with all of the primary variables in the analysis (age, sex, having diabetes or not, and blood pressure) – only smoking status was not included and very few participants smoked.

5) Conceptual Model versus Data Analytical Plan. The conceptual framework is a great informational piece described as part of the study. However, to make justice to the empirical integration of the data and the conceptual model, the author may want to say that their analytical framework and empirical analyses does not measure exactly all the steps in the model. For that SEM and other techniques are needs including path analyses. In addition, the component of usual care, as the authors know is problematic given the lack of data pertaining medication, assessment and follow up, etc. For example, home visits are part of a difficult variable to account for in the description of usual care.

We appreciate these comments and have included an explanation of the conceptual model vs. the data analytic plan in the discussion, and we have also commented on usual care being problematic in the limitations section.

6) Reliability of Data Instruments and Need For Sample Questions. Before I describe the need for more information regarding data instruments, I want to congratulate the authors for their great efforts to utilize adequate and empirically-based measures as much as possible. Having said that, can the authors provide some sample questions (one per instrument perhaps) to provide an idea of the validity of the instruments used? In terms of reliability/ internal consistency, what is the perspective of the authors for how well the indexes/scales performed? Do the authors conduct Cronbach’s alpha assessment when feasible?

We have included sample questions for all of the instruments used (with the exception of the International Physical Activity Questionnaire) in the methods section to provide an idea of the
validity of the instruments used. While we did not conduct Cronbach’s alpha assessments on the instruments, we consider that the sample questions will provide information to readers about the content that was used for measuring each one of the aspects of interest in the study.

Reviewer 2: Raghupathy Anchala

Major compulsory revisions:
1. Explanation for why a sample size of 75 was chosen. How was selection of patients done? Consecutive or purposive or random
   We have included an explanation for why a sample of 75 was chosen and have explained that selection of patients to participate was consecutive.

2. Table 3 heading is ambiguous. It is not clear to the reader. Ideally, each table or figure should be stand alone and be easily understandable. Suggest to give the title for table 3 in clear terms. The table should also report whether baseline differences have been adjusted – there is no mention of this. The note below the table only mentions - *Adjusted for age, sex, years of formal schooling, distance to the health center, working, lives alone and diabetic and/or hypertensive disease status. The interpretation of the coefficients need to be mentioned in the discussion section.
   We have changed the title for Table 3, have explained that we adjusted for baseline differences, and have included an interpretation of the coefficients.

3. Baseline differences – quite heterogenous: Higher SBP in intervention arm in costa rica when compared with control arm. Similarly, SBP in control arm in Chiapas is significantly more than intervention arm. Differences in proportion of obese and overweight between two arms at both the sites; higher proportion of comorbidity in control group vs intervention group in Chiapas (30% vs 9%). Have these baseline differences been adjusted or accounted for?
   As suggested, we updated our analysis by adjusting for baseline values.

4. Close to 1/3 patients were lost to follow up in both arms in costa rica, whereas in chiapas, at 8-months time point, data was captured for 58 participants from the intervention group (1/3rd lost to follow up) and 80 from the comparison group (only one patient lost). This could have seriously compromised the results and could explain average visit differences (1.4 versus 4). Authors need to state this as a key limitation or provide suitable justifications.
   We have stated this as a key limitation.

Minor compulsory revisions:
1. Was validation of heart healthy curriculum in local settings (spanish version after accounting for cultural and contextual differences) done? This must be stated as a lot of outcomes depend on patients comprehensions of these difficult to answer questions
   Validation of the heart healthy curriculum manual was done and we have stated it in the text.

a. The process of adaptation is clear. No details are presented as to how the questionnaires were validated.
   We have included an explanation of how the questionnaires were validated in each of the settings.

b. Line 169 - Situated group education- ambiguous – explain it in easily comprehensible terms to the reader
   We have added an explanation of situated group education and added a reference.

c. Line 180 – any reference/previous work that explains healthy heart
We have included a reference to the National Heart Lung and Blood Institute publication titled “Your Guide to a Healthy Heart”.

2. **What were the follow up rates in high risk group – how much was the attrition. Would this have a bearing on the outcomes**
   Patients with a high risk classification in both countries participated in the intervention.

3. **What were the Individual patient characteristics that were labelled as potential confounders? Randomisation would have taken care that these potential confounders are balanced equally in both the groups**
   We have specified the individual patient characteristics that were potential confounders that we included in the analysis. We agree with the reviewer that randomization would have taken care of the potential confounders, however in our study selection for intervention and comparison happened at the health center level rather than the patient level.

4. **What standard clinical care was received by usual care group?**
   Patients in the usual care group received a clinic visit with their primary care physician and laboratory tests. In Costa Rica, the usual care for patients with diabetes is every 3 months and for hypertension is every 4 months and patients receive their medications the day of the their clinic visit. For Chiapas, patients with diabetes and hypertension were seen every month and at the same monthly visit they have relevant lab tests done and pick up their medications. We have added this explanation to the text.

5. **Name and make of digital monitor? Was it calibrated? Did both centres have the same equipment?**
   The name and make of the digital monitor was CITIZEN, Model CH 432. It was calibrated and each of the country teams had their own monitor to use for the study. This information is included in the manuscript.

6. **Average of three measurements within 6 mm Hg was used – what was the time gap between the three readings – was it 5 min apart or just one minute apart**
   We have included in the manuscript that readings were done 2 minutes apart after a 10 minute seated rest.

7. **Individual patient characteristics - It would be better if works or not is defined better.**
   We have changed works or not to works currently or is not currently employed.

8. **Was the BP/diabetic status self reported by the patients or was it doctor certified**
   The BP and diabetic status was doctor certified.

9. **Line 356 – pl explain what both conditions were.**
   We have specified in the text that both conditions mean having both diabetes and hypertension.

10. **In Costa Rica 42% of patients enrolled in the intervention group did not attend any session and in Chiapas that percentage was 13%. What were the possible causes for this discrepancy? State plausible and more concrete reasons for this?**
    In Chiapas, patients are more accustomed to attend meetings organized by the health center staff (including talks and campaigns) and in Costa Rica this is not as common which may explain the discrepancy for the attendance being substantially higher in Chiapas than in Costa Rica. We have added this explanation to the other explanations for the possible discrepancy that are outlined in the discussion section.
11. Education – number of years studied. Lower education in chiapas but higher proportion of working population. Could this have created a bias on the outcomes measured? We have mentioned the difference in populations in the two country settings as a limitation in the discussion section.

12. Include different equipments and different standards of measurement as a limitation
The brand and model of equipment was the same but the instrument itself was different and we have included this as a limitation.

13. Analysis plan – please be explicit in stating whether a paired or unpaired t-test was done. Was unequal and equal variances looked for?
We have specified that we conducted an unpaired t-test with equal variances.

Minor Discretionary revisions
1. Table 2 - Blood glucose – was it random/Fasting/post prandial. Please be specific to mention it as fasting blood glucose
We have updated table 2 to specify that it was fasting blood glucose.

2. Redundant information - lines 131 to 135 (title need not be repeated as an intervention.
We have taken out the term “intervention” from line 132.

Reviewer 3: Heather M. Johnson, MD, MS

Major Compulsory Revisions
1. Please provide more details as to how the sample size estimate was determined. The limitation section mentioned the study was underpowered, but additional details about the basis of the calculation should be provided.
As explained previously, we have included an explanation of how the sample size estimate was determined.

2. Why was 8-months defined as the study end point?
Similarly, we have included an explanation of how the 8-month study end point was defined.

Minor Essential Revisions
1. What was the length of time for each health care worker training session?
We have updated the text to state that the health care worker training sessions were each 2 hours long.

2. Was there a checklist to ensure healthcare workers adhered to study protocol?
The extent to which the healthcare workers adhered to the protocol was noted by an observer from the research team. Quality criteria were used to assess each of the sessions; an explanation of these criteria and the process that was used is reported in an article currently under review by Castro et al. titled “Evaluation of the capacity of Primary Health Care personnel to change patients’ ability to control diabetes and hypertension with group participatory education: an intervention research study.” We have made reference to this complementary publication in our manuscript.

3. The authors state: “Intervention group participants also had to be willing to comply with proposed educational activities, including attendance at training sessions with support staff based at the health center.” Were there a minimum number of classes participants were
requested to attend?
Participants were invited and encouraged to attend all 6 sessions but there was not a minimum number of sessions that were requested.

4. Did the self-efficacy scale incorporate hypertension and diabetes topics? The authors state the scale was adapted from a previous diabetes questionnaire.
The self-efficacy scale incorporated both hypertension and diabetes topics and we have added this to our explanation in the text.

5. If appropriate for the journal, please give SD with age in Table 1.
We have added in SD with age in Table 1.

6. Please provide more details of global cardiovascular risk assessment (definitions of low, medium, high).
We have added in more details about the global cardiovascular risk assessment and defined the classification for low, medium and high risk.

7. How was the diagnosis of hypertension and / or diabetes type 2 defined (self-report, health record data)?
The diagnosis was confirmed by the patients’ healthcare provider and we have specified this in the text.

8. How were the exclusion criteria determined – self-report or health record data?
A screening questionnaire was used with patients to define who should be excluded from the study and patient records were then used to verify the information. We have included this explanation in the manuscript.

In addition to changes to the manuscript in response to comments made by reviewers, we have updated contact information for co-authors and have updated publications in our list of references to reflect manuscripts that have been published.

We look forward to your feedback on our revised manuscript and if you have remaining comments or questions, we would be most happy to work with you to continue to improve the manuscript.

Thank you for your consideration.

Sincerely,

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