Reviewer’s report

Title: Nepal Pioneer Worksite Intervention Study to Lower Cardio-metabolic Risk Factors: Design and Protocol

Version: 0 Date: 20 Sep 2018

Reviewer: Michael Wirth

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Review for BCAR-D-18-00582

Overall: This protocol described the implementation of a worksite intervention to reduce cardio-metabolic risk factors in Nepal. A diet-based program is going to be designed for use in the cafeteria. After that, participants will be randomly assigned to a cafeteria-only intervention or an individual-based program using the DPP. This is an interesting topic that warrants further study. However, there were some limitation/questions, that I listed below with the design. There also were points that needed further clarification. These also are listed below.

Abstract:

1. In your first sentence, what about increasing physical activity as well?

2. I see you have the different arms listed in the second phase in the data analysis plan section of the Abstract. They need to be listed or at least made clearer under the Methods/Design section.

3. Can you list ideas for what the individual behavioral interventions may include in parentheses or just list the DPP?

Introduction:

4. I think it is important to highlight the number of people who work in places where worksite programs could be offered. In other words, how many people work in office buildings in Nepal. My colleagues and I have done some work in Asia and we know there are places where small percentages of the population actually work in places where a worksite program could be conducted. How much of the population could you really get to with a worksite program in Nepal if this was expanded on a large scale?

5. What are the major gaps that your protocol addresses that needs to be filled compared to what has been done previously? You provided me evidence that this work has been effective before, so why do this study? I am assuming part of that argument is that there is limited work in areas in low and middle income countries.
6. You mention cafeteria-based intervention, can you put in parentheses very broadly what this means? Are you referring to providing healthy foods, doing cooking demonstrations, creating a reward system for selecting health foods…etc)?

Methods and Materials:

7. What is the difference between the cafeteria intervention in stage 1 and the cafeteria-intervention in stage 2?

8. I think the study design section needs a little more detail that incorporates the various time points and what is happening at each one.

9. When describing the hospital setting, are there any gyms or facilities on site that can be used to help facilitate the physical activity components? Are there showers and locker rooms accessible by the employees?

10. Are there any other employee wellness programs available that may contaminate your protocol?

11. What about shift workers? In looking at your eligibility, I don't see any mention of this. Shift workers are going to have a hard time participating in worksite interventions, especially if the cafeterias are not running at full capacity. They also may not be able to easily conduct the individual behavioral component if selected for that study arm. Also, their biological measures are going to be strongly influenced by their shifts, especially their metabolic markers. If they are not excluded, there needs to be strong justification and explanation of how these issues will be overcome.

12. Why is your inclusion of HbA1c set to 5.7-6.4%, but your blood sugar is ≥ 100? So, they can have diabetes based on blood sugar criteria, but not HbA1c%?

13. If you are screening everyone anyway on HbA1C and glucose, why exclude those taking T2DM medications? Many people take such medications, but are still poorly controlled and could easily meet your other inclusion criteria.

14. I think the repeat baseline term in the Table is confusing, what is that?

15. For the blood pressure, what happens if for some reason the first reading is really high, let's say 160 over 100, but the next two are around 110 over 70. The first reading is clearly an outlier and would drive their average value up beyond what is normal for that person. Do you have plans to modify how blood pressure is averaged in these situations?

16. Is any software going to be used for the 24-hour dietary recall or are you manually going to have dieticians compare recalls to the food composition table?
17. Also, what days are eligible for recalls? The standard practice is to do 2 weekdays and 1 weekend day. So, if only doing to days, are you going to include weekends?

18. I am assuming the blood draws will occur in the morning, correct? Again, if you are including shift workers, this issues needs to be dealt with: are you collecting bloods (even if it is in the morning for all people) before or after a work shift?

19. What was the basis for the decreases in values of the outcomes? Were those cut-points for successful decreases based on past literature?

20. With the t-test and regression analyses you mentioned, several assumptions need to be met. Although most of your outcomes are normally distributed which usually means the model residuals will be normally distributed, that doesn't guarantee that the assumptions will be upheld for those analyses. Do you have plans to move to other analyses such as the Wilcoxon rank sums test or quantile regression if necessary?

21. What statistical software will you be using?

22. For the behavioral classes outside of the worksite, what type of facility or setting will that be in?

23. How will you make adjustments for any contamination? I am referring to the last sentence in the minimization of contamination section.

Discussion:

24. Can you provide any further details on how this could be scaled up? Also, what happens if you find the individual-level intervention doesn't work compared to the environmental or vice-versa? Would you still scale everything up at that point or focus on what the components that worked?

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

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