Reviewer's report

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

Version: 2  Date: 3 April 2015

Reviewer: Raghupathy Anchala

Reviewer's report:

Overall a well written manuscript with a clear question and testable hypothesis. The authors have documented what was feasible, what was achieved and what was not achieved in this complex intervention. For such complex interventions, the MRC guidelines lay out a series of steps (building upon each previous step) and I commend the authors for following an evidence based pathway to demonstrate the effectiveness of the intervention in near real world settings. However, the following mentioned key points, if incorporated or corrected will add weightage and rigor to this manuscript.

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
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.
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?
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.

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
   a. The process of adaptation is clear. No details are presented as to how the questionnaires were validated.
   b. Line 169 - Situated group education- ambiguous – explain it in easily comprehendible terms to the reader.
   c. Line 180 – any reference/previous work that explains 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
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
4. What standard clinical care was received by usual care group
5. Name and make of digital monitor? Was it calibrated? Did both centres have the same equipment?
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
7. Individual patient characteristics - It would be better if works or not is defined better.
8. Was the BP/diabetic status self reported by the patients or was it doctor certified
9. Line 356 – pl explain what both conditions were.
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?
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?
12. Include different equipments and different standards of measurement 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?

Minor Discretionary revisions
1. Table 2 - Blood glucose – was it random/Fasting/post prandial . Please be specific to mention it as fasting blood glucose
2. Redundant information – lines 131 to 135 (title need not be repeated as an intervention.)
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests