Author’s response to reviews

Title: The effect of youths as change agents on cardiovascular disease risk factors among adult neighbours: a cluster randomised controlled trial in Sri Lanka

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Author’s response to reviews:

Editor Comments:

Thank you very much for reviewing our manuscript. We attached "Response_to_Reviewer0315_submit" as a supplemental file which described this response.

Please see our responses below.

1)-1. Table 2: The table would benefit from an easy to follow indication of which outcomes are difference in means and which are ORs. Also, what variable are presented as mean (SD) and what data is median (IQR) ?

Ans. Median (IQR) was only one variable of “sedentary time.” We added the symbol “+” for the median (IQR) in Table 2.
1) Baseline data presented in Table 1 and Table 2 is not identical (e.g. the baseline BMI and blood pressure in intervention and control groups). Please correct.

Ans. To ensure the data were identical between Table 1 and Table 2, we added the subtitles “primary outcomes” and “secondary outcomes” under the related items in Table 1 and moved the BMI categories from “primary outcomes” to above the “primary outcomes.” We deleted the subtitle “Blood pressure” from Table 1 and Table 2 as indicated.

2) Page 6, line 94 states: “The intervention period was 12 months and its effect were assessed by comparing the difference of outcome measures (i.e. body weight [or BMI] and blood pressure) of selected adults between the intervention and control groups.”

Consider making it more clear that this is a pre-post measurement design, e.g. by writing: The intervention period was 12 months and its effects were assessed by comparing the difference in outcome measures (i.e. body weight [or BMI] and blood pressure) between randomly selected adults (measured at both pre- and post-test) living in communities assigned to intervention or control groups.

Ans. Thank you for your valuable comments and providing an example of revising. As you mentioned, we revised as below.

Page 6-7 Line 106-109: The intervention period was set as 12 months. Its effects were assessed by comparing the differences in outcome measures (i.e. changes in body weight [or body mass index, BMI] and blood pressure from pre-trial to post-trial) between selected adults living in communities assigned to intervention or control groups.

3) Page 7, line 118: Did the change agents receive any compensation for their time-use?

Ans. They did not receive any compensation for their time. Facilitators supported the youths so they could conduct health promotion activities at times convenient to them. We added the following in the “1) Recruitment and training of youths” section.

Page 8, Line 138-139: No youth change agents of youths received any compensation for this work.

4) Page 10, line 167-168: "We performed baseline survey for participated adults before the intervention". This is a crucial point and both reviewer 2 and I was unsure about the design. Please make this crystal clear.
Ans. We revised the sentence by adding the reason below.

Page 11 Line 192-194: The baseline survey including outcome assessment were performed before change agents began their activities in the community to prevent confounding effects of the intervention.

5) Page 12: Please describe all equipment as Brand, City, [state], Country

Ans. We added the cities where the head companies that manufactured the equipment were located.

Page 13 line 231: digital weighing scale (Rossmax WB220, Berneck, Switzerland)

Page 13-14 line 232-233: portable stadiometer (seca 213, Hamburg, German)

Page 14 line 235: automatic blood pressure monitor (A&D UA-621, Tokyo, Japan)

6) Page 14, line 237 states: "The main analysis was based on the intention to treat. We performed analyses among those who completed both baseline and the follow-up surveys"

You also write (same page, line 242);

"Missing data of sedentary time at the follow-up survey (n =1) were replaced with baseline data (last-observation-carried-forward analysis)"

This statements are contradictions as a true intention to treat analysis would have included n=303 in the intervention group and n=288 in the control. These are the numbers given by the randomization procedure and analysis of these individuals is the only way to ensure unbiased comparison between groups. You have missing data before the baseline assessment due to refusals and non-attendance (normal with a cluster-randomized design) in addition to missing data owing to non-attendance at follow-up. Please modify the ITT-statement and discuss in the limitations section.

Ans. As you mentioned, a better application of the ITT approach is possible if complete outcome data are available for all randomized subjects [Gupta 2011].

Gupta (2011) stated that in most cases missing data could also be handled by using the last observation carried forward (LOCF) method if the baseline data are available. This study also used the LOCF method for missing data on sedentary time at the follow-up survey (n = 1). We added the following in the limitations.
Page 25, Line 435-438-410: Fifth, although this study applied an ITT approach [29], we excluded refusals and non-attendance at the follow-up survey from all randomized subjects (303 subjects in the intervention group and 288 subjects in the control group).

6)-2. The last-observation carried forward method is mentioned in line 242. Although this method is weak there is a low risk of bias when few valued are imputed. Would e.g. a multiple imputation procedure (or multilevel approach as suggested by reviewer 2) not be a viable option to maintain the missing data due to non-attendance at follow-up?

Ans. Thank you for providing a valuable suggestion. It is one of the ways of using a multiple imputation and multilevel approach to handle missing data. However, these methods are recommended if the missing data make up less than 5% of the total data [Schafer 1999]. This study had only one missing data point for “sedentary time.” In this case, the last observation carried forward (LOCF) method may be more appropriate than multiple imputation. Therefore, we retained the LOCF method.

7) Page 17, Line 295: there were no statistically significant [difference in] odds of being engaged. Please add 'difference in'.

Ans. Thank you for pointing it out. I revised it.

Page 20, Line 353-355: With regard to health-related lifestyle in secondary outcomes, there were no statistically significant differences in the odds of being engaged in recommended levels of leisure-time physical activities between the two groups at the follow up.

8) I made the following remark following initial submission of the manuscript;

Following from point 3 - please include in your discussion a reflection on whether the intervention here is really a combination of 'screening' (the baseline measurements of BMI and blood-pressure) in combination with youth as change-agents? My point is whether one can trust that individuals not included in the baseline survey will be as responsive to the broad community-delivered intervention as those who participated in the baseline survey? Perhaps additional details of the local context (for example the role of community-feeling or interaction with neighbours) would make this clearer.

Which was answered by the following; Answer 4)-1. This study is randomized controlled design. In addition, the effect of health surveys conducted before the intervention was exclude since control group had health surveys as well as intervention group. Therefore, we can expect the
similar effect of the intervention on adults in other regions where this study did not select. The strengthen of randomised controlled design.

I disagree with the answer. Having your BMI or blood pressure measured may in itself be a public health intervention due to increased awareness of one's health. Any (hypothetical) effects of this 'intervention' would be identical between control and intervention conditions in the study – this is correct. However, my point is whether the combination of a health screening AND youth change agents would yield benefits GREATER than the sum of their individual effects (if any). The adults randomly selected to be measured in the study are meant to be representative of adults in the communities but these adults receive 2 interventions (one of which is also provided to the controls) while remaining adults receive only 1 intervention. It is therefore, in my opinion, worthy of discussion whether adults not taking part in health surveys (but only exposed to the change agents) could also expect the observed effect-sizes.

Ans. We agree that a baseline assessment could play the role of an individual intervention or be part of an intervention. This is common to any trial employing a baseline or repeated measurements in human subjects. Unfortunately, it is beyond the scope of our study to quantify the effects of the baseline survey on our observed results. However, we have acknowledged that measuring the health status of individuals through anthropometric measurements could serve as an intervention on its own or in combination with other behavioral modification. The empowerment of communities to take their own anthropometric measurements and blood pressure was the first step in the intervention, demonstrating your point.

Page 25-26, Line 446-449: ..., and 3) there was a possibility of some influence of the health survey, which was conducted before the trial, on health behaviours for both the intervention group and the control group, although we could not assess whether this health survey attenuated or promoted the effect of change agents of youth.

9)-1. I agree with not showing the p-values in table 1 as all differences in the distribution of data in the groups are – by definition – due to change owing to the randomization (Palesch 2014; doi: 10.1161/STROKEAHA.114.006138)

Ans. Thank you for providing your valuable comments; we have accordingly remained these indications without providing p-values in Table 1.

9)-2. Regarding the comment from the second reviewer on the conduct of the statistical analysis, there are certainly more than one way to analyze this design. While the post-test/pre-test adjusted for pre-test is not incorrect, there may be value in using the multilevel approach suggested by the reviewer (group assignment x time interaction with random effect at the participant) to account
for measurements being nested within participants. Particularly since the authors are already using a multilevel approach to appropriately model the nested GN divisions. This could be extended with the additional benefit of ensuring that individuals with complete baseline – but missing follow-up – data could be kept in the analysis.

Ans. According to Twisk et al. (2014), if a study has two follow-up measurements from a baseline (time 0, 1, and 2), we can include a time variable in the model to investigate the interaction between intervention assignment and time. However, we did not use the interaction between intervention assignment and time, since this study performed one follow-up and did not yield repeated-measurement data. We investigated changes of outcomes from baseline to the end of the follow-up. We added a detailed analysis in the manuscript in conjunction with the statistician.

Page 17-18, Line 288-308: We used two levels of multilevel models to account for the clustering of neighbours within GN divisions as a random effect in addition to individual level as a fixed effect. To take into account the difference at baseline, the model was adjusted for the baseline value of the outcome [25. Twisk et al. 2018]. To investigate the difference in means from baseline to follow-up, we extracted values at baseline from the values at the end of the follow-up. Finally, for the following binary outcomes (i.e. leisure-time physical activities, vegetables, fruits, snacks, sugar-sweetened beverage, current smoking, and alcohol intake), we used a multilevel logistic regression model comparing the outcomes with the low levels as a cut-off point as reference. The models were as follows:

Multilevel linear regression

\[
\text{outcome}_{(ij, \text{follow up})} - \text{outcome}_{ij, \text{baseline}} = \mu + b_i + \alpha \cdot \text{intervention}_{ij} + \beta \cdot \text{continuous outcomes}_{(ij, \text{baseline})}
\]

Multilevel logistic regression

\[
\logit \ Pr (\text{binary outcomes}_{(ij, \text{follow up})}) = \mu + b_i + \alpha \cdot \text{intervention}_{ij} + \beta \cdot \text{binary outcomes}_{(ij, \text{baseline})}
\]

where the probability of individual i in GN division j having a given outcome at the end of the follow-up (follow up) was modelled by intervention assignment (intervention group or control group), controlling for outcomes at baseline (baseline) and random intercepts for GN divisions (bi). The adjusted mean or odds ratio (OR) for the logistic regression model and the 95% confidence interval (CI) for the linear regression model were calculated for continuous and binary outcomes, respectively.
Response to reviewer 1

Thank you very much for reviewing our manuscript. We greatly appreciate your comprehensive and critical suggestions. Please see our responses below.

Introduction

1)-1. Pg 3, line 54 - the prevalence presented seems low, considering is overweight. Is not related to obesity?

Ans. The prevalence of obesity was 6.8 % of the total (3.5 % in men and 10.0 % in women) in Sri Lanka [3. World Health Organisation 2016]. We added the prevalence of obesity in addition to that of overweight. Even if the prevalence of overweight/obesity is low, as you mentioned, we decided to describe the current situation of the risk factors for NCDs in Sri Lanka.

Page 4, Line 56-58: Regarding the risk factors of NCDs in Sri Lanka, the prevalence of overweight and obesity is 18.9 % and 3.5 % in men and 32.9 % and 10.0 % in women [3], …

1)-2. The background subsection very well introduced the subject of the paper. However, I have a suggestion: it would improve if it have presented the author hypothesis: Why do you think an intervention targeting children would change adult's habits and health? Why this make sense? I know you presented some studies, but it would be nice to go further and explain theoretically this relation. We usually see studies investigating the opposite direction: how parent's habits can influence children habits.

Ans. Most studies used adults as non-professional healthcare workers. Proposing to transmit healthy habits from youths to adults is unique, as you mentioned. In light of this characteristic of the intervention, we described the hypothesis as below.

Page 5, Line 75-88: These approaches are also beneficial for youths themselves in improving their self-efficacy by experiencing community empowerment [11], as well as their health in later life [12]. Interestingly, the above-mentioned study in Sri Lanka [9] presented a case report in which some children involved their neighbourhood homes in the health promotion (e.g. playing games and exercising with their parents). However, no study has examined whether youths, including children, who received health education can improve the health of community adults who are not their parents or relatives. One study [13] suggested that certain segments of society may be more receptive to youth-led engagement than others, which could be applied to non-professional healthcare workers of youths. It is important to ascertain whether youths can take on the role of non-professional youth healthcare workers (or change agents, as termed in the present
study), because this approach has the potential to improve the health status of many more adults than could previous approaches targeting children’s parents.

Methods

2)-1. Pg 5, line 89 - How many Divisional Secretariat (DS) division are in the city? What are the generalization/external validity consequence of this method (it could be included in the discussion part)?

Ans. There are 13 DS divisions in Colombo district. We selected one eligible Divisional Secretariat (DS) division (Seethawaka) based on the logistical feasibility of the study as described in the manuscript. The Seethwaka DS division has a sociodemographic profile highly comparable with other suburban DS divisions in Sri Lanka, making the results more generalizable. However, the non-random nature of the selection of one DS division limited the generalizability of the study, which we have acknowledged as a limitation.

Page 25, Line 445-446: 2) we selected one DS division based on logistical feasibility before the randomization setting, …

2)-2. Explain better what is DS and Grama Niladari (GN) divisions.

Ans. We added an explanation of the DS and DN divisions in the method section.

Page 6, Line 101-102: The districts of Sri Lanka are divided into administrative sub-units known as Divisional Secretariat (DS) [14. Ministry of Home affairs].

Page 7, Line 112-113: Grama Niladari (GN) division, which is a sub-unit of a DS, has the role of ensuring an administrative system at the rural level on par with the requirements of public policies [14].

2)-3. I think it would be nice to explain better about youth club. What are the sociodemographic characteristics of the members? How it differentiates from general population? Who are the youths registered at the Divisional Secretary?

Ans. The sociodemographic characteristics of the members of the youth clubs were not collected, as that was not an objective of the study. We obtained a list of the registered youth clubs from the Divisional Secretariat, and all these clubs had members aged 18–24 years, usually with equal proportions of men and women. Each youth club had 15–25 members actively participating in the club activities.
3) Pg 6, line 97 - Please explain how the sample was calculating and how you get from 68 to 24 GN division.

Ans. We described the methodology as follows.

Line 260-273: The number of GNs required per arm in a cluster randomized trial was calculated according to the following:

\[ \left( \frac{\left(2\left(z_{\alpha/2}+z_\beta\right)\right)^2 \left(\sigma^2\right)(1+\left(m-1\right)\rho)}{\left(\mu_1-\mu_2\right)^2} \right)^{\frac{1}{2}} \]

Where \( Z_{(\alpha/2)} \) and \( Z_\beta \) are the \( \alpha/2 \)th and \( \beta \)th percentage points of the standard normal distribution, \( (\mu_1-\mu_2) \) represents the clinically important difference in treatment means, \( \sigma^2 \) is the total variance in the outcome, \( m \) is the cluster size, and \( \rho \) is the ICC [24]. Taking into account the clustering (cluster size = 20 and intraclass correlation coefficient = 0.01, with a design effect of 1.19), the sample size was 400 adults total in 20 GN divisions. Based on the calculated sample size, 24 GN divisions out of the 68 available GN divisions were selected randomly from a list of the GN divisions. In the event of the selection of GN divisions separated by less than 3 km, they were excluded and replaced by other GN divisions to avoid any possibilities of contamination by the intervention. The 24 GN divisions were then allocated by a lottery method where 12 GN divisions were allotted to the control arm and 12 GN divisions to the intervention arm.

4) Pg 7, line 121 - explain about the theory that based intervention (theory-driven experience of several years?).

Ans. The overall strategy was based on health promotion strategies using the models explained in previous studies conducted by us and other researchers in health promotion, which is included that in our manuscript. We described the theory-driven experience in the “Activity of youths in the community” section.

Page 8-9, Line 142-146: The overall strategy was based on health promotion strategies using the models explained in previous studies conducted by us and other researchers in health promotion [9. Gunawardena et al. 2016, 16. Galmangoda Guruge et al, 2017]. These strategies primarily rely on the empowerment of communities to identify the determinants of undesired behaviours and community actions towards more desirable behaviours.

5) Pg 7 - how was the procedure of recruitment youths? Did they receive any payment?

Ans. Youths did not receive any payment. We added the following sentence in the manuscript.
No youth change agents of youths received any compensation for this work.

6) Pg 8, line 141 - coconut oil for cooking - was it considered a healthy or unhealthy habit? Is this habit common in the region? Some official organization worldwide have discouraged the use of coconut oil, based on scientific evidence.

Ans. As you suggested, some official organizations may have discouraged the use of coconut oil. However, coconuts are the main source of fat in Sri Lanka. The Food Based Dietary Guidelines from the Nutrition Division Ministry of Health [18] describes the proper amount of use (or intake) of coconuts oil for Sri Lankans.

7) Table S1 - the dietary patterns targeted on intervention were developed considering any national food guideline or scientific review of literature? Rice, for example, can be part of a healthy diet when eaten in moderation. How are the Sri Lanka population food habits? Is it similar to population worldwide, increasing the consumption of ultra-processed food? Or the consumption of natural food as rice is considered a bad habit?

Ans. Rice is one of the main staple foods of Sri Lanka. As you mentioned, rice can be part of a healthy diet when eaten in moderation. We can observe an increase in the consumption of processed food with a high salt content even in Sri Lanka. However, people who usually consume rice run the risk of over-consumption. We do not have available data for Sri Lanka, but the trend is observable in other Asian countries; for example, the Vietnamese diet is highly dominated by rice and its by-products, and the nutritional balance of the traditional diet is high in carbohydrates [Dien le N, Thang NM, Bentley ME. Food consumption patterns in the economic transition in Vietnam. Asia Pac J Clin Nutr. 2004;13:40-47].

8) Pg 8, line 130-132: it seems that the intervention was focused on monitoring lifestyle habits. Please explain better how youths encouraged them to adopt improved behaviors. Any theory driven?

Ans. We described how youths encouraged adults to adopt improved behaviors in “2) Activity of youths in the community” section. Basically, we supported adults in their intended health behaviors. We showed an example of how youths encouraged adults when adults seemed to have no intention to perform physical activities.

Adults recorded their body weight and blood pressure as measured by the youths in a chart. Adults chose lifestyle behaviours that they would try to change under their own
initiative rather than as urged by youths or facilitators. If adults showed no intention to do physical activities, youths visited their houses to invite them to the community group’s outdoor physical activities or games.

9) Pg 9 and 10, outcomes - it is not clear if the 292 adults also received the intervention by the youths. Or if they were just located in the intervention area.

Ans. All adults were measured and their body weight and blood pressure recorded by youths. Although most adults received some support from the youths to improve their health behaviours, we did not record them. Therefore, there was possibility that there were adults who did not receive a direct approach from change agents of youths. However, we expected that adults might receive not only a direct approach from change agents but also receive a spillover effect [Benjamin-Chung et al. 2018] of change agents on health behaviours among adults. We added this limitation as follows.

Page 25, Line 437-442: Sixth, although most of the adults received support from the youths to improve their health behaviours, we did not record them. Therefore, there was a possibility that there were adults who did not receive a direct approach from youths, whereas we expected that adults might receive not only a direct approach from change agents but also a spillover effect [30. Benjamin-Chung et al. 2018] of the change agents on health behaviours among adults in the community.

10) Pg 9, line 160 - The method of "dropping pins on road maps" is robust? Or the researcher may choose, for example, area known as with better sociodemographic characteristics?

Ans. The method of "dropping pins on road maps" was robust. We added “randomly” to the sentence.

Page 11, Line 184:… by randomly dropping pins on road maps of the entire study area.

11) Pg 10, line 171 - insert BMI in extension, before citing the abbreviation.

Ans. Thank you for pointing this out. I added the “body mass index” before the abbreviation.

Page 7, Line 107-108: … (i.e. body weight [or body mass index, BMI] and blood pressure)
12) Pg 11, line 188 - you considered that an individual has adequate intake when they eat snacks twice/day; and sugar-sweetened beverages, once/day?? It is TOO MUCH. Why not choose cut-off based on percentiles as done for vegetables?

Ans. For reference, we show the distribution of frequency of snacks and sugar-sweetened beverages at baseline among the 483 adults below. As we were not sure whether the cut-off point based on the distribution was a recommended level like that for vegetables, we decided this cut-off according to the reference [15. Ministry of Health, Nutrition and Indigenous Medicine, and World Health Organization 2011; 16. Hu 2013]. Therefore, we retained the original cut-off points.

<table>
<thead>
<tr>
<th>Frequency of snacks at baseline</th>
<th>Numbers (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not take snacks</td>
<td>86 (17.8)</td>
</tr>
<tr>
<td>Once a day</td>
<td>216 (44.7)</td>
</tr>
<tr>
<td>2 times a day</td>
<td>146 (30.2)</td>
</tr>
<tr>
<td>3 times a day</td>
<td>28 (5.8)</td>
</tr>
<tr>
<td>4 or more times a day</td>
<td>7 (1.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Frequency of sugar-sweetened beverages at baseline</th>
<th>Numbers (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never or seldom(&lt; 1/week)</td>
<td>298 (61.7)</td>
</tr>
<tr>
<td>1-3 days/week</td>
<td>114 (23.6)</td>
</tr>
<tr>
<td>4-6 days/week</td>
<td>36 (7.5)</td>
</tr>
<tr>
<td>1 time/day</td>
<td>22 (4.6)</td>
</tr>
<tr>
<td>2 times/day</td>
<td>7 (1.5)</td>
</tr>
<tr>
<td>3 or more times/day</td>
<td>6 (1.2)</td>
</tr>
</tbody>
</table>
Results

13) Table 1 - if the paper is going to be submitted to an international journal, is not better to present income in dollars? Or at least present the exchange rate?

Ans. As you mentioned, we added the exchange rate instead.

Foot note in Table 1: †The rate of Sri Lankan Rupees into Us Dollar (USD) in 7th of July 2017 was 1 Rp = 0.0067 USD.

14) Pg 15, line 270 - but they are statistically similar?

15) Table 1 - I suggest to insert p value, in order to compare control and intervention group.

Ans 14-15). We understand this suggestion. However, we decided to remain the original indication after discussions with the editor regarding the necessity of p-values in Table 1:

Editor comment 9)-1. I agree with not showing the p-values in table 1 as all differences in the distribution of data in the groups are – by definition – due to change owing to the randomization (Palesch Stroke. 2014;45(12):e244-6, doi: 10.1161/STROKEAHA.114.006138)

16) Table 2 - For the categorical variables, it is not possible to evaluate the evolution between baseline and follow-up. You may present the percentage of these variables in baseline and follow-up.

Ans. We indicated the proportions of categorical variables at baseline in Table 1. To prevent overlaps between Table 1 and 2, we decided to retain only the indication of proportions at the end of the follow-up in Table 2 following the previously used indications [9]. We added “Mean ± SD, median (IQR)*, or number (%) at the end of the follow-up” in the title of Table 2.

Discussion

17) Pg 19, line 334 - 337 This could be better explained in the Methods section.

Ans. We moved these sentences to the Method section in lines 158-162 and simplified the description in the discussion section.

Page 10, Line 163-168: According to the change agents’ case reports on behavioural change made by change agents, some adults recorded their expenses for unhealthy foods such as snacks on a monthly basis, motivating themselves to cut their spending on such foods. Some adults
reported reducing their excess dietary intake, such as rice servings, fast foods, and the use of cooking oil and sugar.

Page 22, Line 391-393: According to the case reports reported by youths, some adults tried to cut their spending on unhealthy foods and reducing their excess dietary intake by recording dietary habits.

Response to reviewer 2

Thank you very much for reviewing our manuscript. We greatly appreciate your comprehensive and critical suggestions. Please see our responses below.

Abstract:

1) Line 36 it is not clear what "material difference" means, and whether this helps with clarity.

Indicate in the results what are primary (BMI weight) and secondary outcomes (e.g. fruit servings)

Ans. We revised it to read “no statistically significant difference” from “no material difference”.

We added a definition of the primary outcome and secondary outcome in the abstract.

Page 3, Line 37-38: There was no statistically significant difference in blood pressure between the two groups.

Page 2, Line 28-30: The control group received no intervention. Body weight and blood pressure as primary outcomes and lifestyle of adults as secondary outcomes were measured pre- and post-intervention.

Page 2, Line 34: Regarding primary outcome, the intervention group showed …. 

Page 3, Line 38-39: As regards diet of the secondary outcome, …

2) Line 64: sentence beginning with "Besides" does not seem to link well with preceding and following question. The sentence is not clear.

Ans. We deleted “Besides” as below.

Page4, Line 67: Besides, A few intervention studies provided training programs for school-aged children
3) Line 64: the use of the term "health promotions" is irregular.

Ans. We revised “promoting healthy habits” in page 4, line 68 in the introduction.

4) Line 74: the phrase "health of community adults" is not clear.

Ans. Previous studies reported the effect of change agents of children on their parents. One of the original features of this study is to clarify the effect of change agents of youths on adults who are not their parents or relatives. We added the explanation of “health of community adults.”

Page 5, Line 80-82: However, no study has examined whether youths, including children, who received health education can improve the health of community adults who are not their parents or relatives.

Introduction:

5)-1 The end of the introduction indicates that the study investigated the effect of "change agents" on youth body weight and blood pressure. The idea of a change agents has not been introduced very well in the introduction to substantiate this as the rationale for the study. I would suggest developing the evidence for this in the introduction.

Ans. Most studies used adults as non-professional healthcare workers, although this study used youth change agents. Based on this characteristic of the intervention, we described the hypothesis as below.

Page 5, Line 75-88: These approaches are also beneficial for youths themselves in improving their self-efficacy by experiencing community empowerment [11], as well as their health in later life [12]. Interestingly, the above-mentioned study in Sri Lanka [9] presented a case report in which some children involved their neighbourhood homes in the health promotion (e.g. playing games and exercising with their parents). However, no study has examined whether youths, including children, who received health education can improve the health of community adults who are not their parents or relatives. One study [13] suggested that certain segments of society may be more receptive to youth-led engagement than others, which could be applied to non-professional healthcare workers of youths. It is important to ascertain whether youths can take on the role of non-professional youth healthcare workers (or change agents, as termed in the present study), because this approach has the potential to improve the health status of many more adults than could previous approaches targeting children’s parents.
5)-2. Perhaps even state explicitly what the primary outcomes are, and maybe even secondary if sufficient space the secondary outcomes. This would help link with the title of the paper, which is changes in risk factors. The primary and secondary outcomes are all risk factors.

Ans. Thank you for your valuable suggestion. We revised the statement of the objective in the introduction by describing which outcomes are primary and which are secondary in the introduction.

Page 6, Line 93-95: on body weight and blood pressure as primary outcomes and health-related lifestyle (e.g., physical activity and dietary intake) as secondary outcomes among community adults over a 12-month intervention.

6) It may be helpful to introduce a hypothesis or hypotheses at the end of the introduction.

Ans. The response is same as for 5)-1. We described the hypothesis of this study in the introduction.

7) Study design:

More explicit information is needed on how randomisation was done (e.g. number generator, and the person was blind to allocation etc.)

Ans. We revised the randomization of the selection of GN divisions in the “Sample size” section as below.

Regarding the blinding, we described the number generator and masking (blinding) in the “Study settings, randomisation, and masking” section of the “study design” section (Page 7, Line 117-121).

We described it as follows.

Line 260-273: The number of GNs required per arm in a cluster randomized trial was calculated according to the following:

\[
(2(z_{(α/2)}+z_β))^2 (σ^2)(1+(m-1)ρ))/ [(μ_1-μ_2)]^2
\]

Where \( Z_{(α/2)} \) and \( Z_β \) are the \( α/2 \)th and \( β \)th percentage points of the standard normal distribution, \((μ_1-μ_2)\) represents the clinically important difference in treatment means, \( σ^2 \) is the total variance in the outcome, \( m \) is the cluster size, and \( ρ \) is the ICC [24]. Taking into account the clustering (cluster size = 20 and intraclass correlation coefficient = 0.01, with a design effect of 1.19), the sample size was 400 adults total in 20 GN divisions. Based on the calculated sample size, 24 GN divisions out of the 68 available GN divisions were selected randomly from a list of
the GN divisions. In the event of the selection of GN divisions separated by less than 3 km, they were excluded and replaced by other GN divisions to avoid any possibilities of contamination by the intervention. The 24 GN divisions were then allocated by a lottery method where 12 GN divisions were allotted to the control arm and 12 GN divisions to the intervention arm.

Page 7, Line 119-122: Due to the nature of the intervention, it was not possible to mask the intervention allocation from the participants or youths who were involved in the intervention. However, the youths involved in outcome assessment were masked concerning the intervention allocation at both baseline and follow-up surveys.

Intervention:

8)-1 The intervention needs more detail. Line 120-121 indicates that the intervention was based on "our theory driven experience of several years (9)". This is not sufficient justification for the intervention and needs greater support. Currently it is not clear what the "intervention logic" is; how youth are trained; what mechanisms/processes are used by the youths to ensure consistency and fidelity of intervention delivery. The researchers and the readers need to know whether intervention components were delivered as designed/intended.

Ans. (This response is the same as 4. to Reviewer 1) The overall strategy was based on health promotion strategies using the models explained in previous studies conducted by us and other researchers in health promotion, which we included in our manuscript. We described the theory-driven experience in the “Activity of youths in the community” section.

Page 8-9, Line 142-146: The overall strategy was based on health promotion strategies using the models explained in previous studies conducted by us and other researchers in health promotion [9. Gunawardena et al. 2016, 16. Galmangoda Guruge et al, 2017]. These strategies primarily rely on the empowerment of communities to identify the determinants of undesired behaviours and community actions towards more desirable behaviours.

8)-2. What is the dosage of the different components? Is it the same? Has this been measured? Why and what is the rationale for communities not receiving the same intervention? Evidence for this issues need to be presented. This is critical if the results are to be interpreted as an RCT.

Ans. Although most of the adults received some support from youths for improving health behaviours, we did not measure whether the same intervention was performed for all adults. Therefore, there was a possibility that there were adults who did not receive a direct approach from youth change agents. However, we expected that adults might receive not only a direct approach from change agents but also receive a spillover effect [Benjamin-Chung et al. 2018] of change agents on health behaviours among adults. We added this limitation as follows.
Page 25, Line 437-442: Sixth, although most of the adults received support from the youths to improve their health behaviours, we did not record them. Therefore, there was a possibility that there were adults who did not receive a direct approach from youths, whereas we expected that adults might receive not only a direct approach from change agents but also a spillover effect [30. Benjamin-Chung et al. 2018] of the change agents on health behaviours among adults in the community.

9) Line 124 uses the term "unhealthy lifestyle behaviours. This is inconsistent with the term "risk factors" used throughout the manuscript. I would suggest using the one description.

Ans. We changed from “CVD risk factors” to “unhealthy lifestyle behaviours” to maintain a consistent expression throughout the manuscript.

Page 8, Line 136-139: Prior to the intervention, facilitators trained the youths to identify behaviours linked to CVD risk factors, such as low levels of physical inactivity, unhealthy diet, tobacco and alcohol use, and poor mental wellbeing. No youth change agents of youths received any compensation for this work.

10) Line 179 the Acronym METs has been used but has not been defined.

Ans. Thank you for pointing this out. We added “metabolic equivalents” before METs.

Page 12, Line 207: 4.5 Metabolic-equivalents (METs)

11) Line 191 USA drinking guidelines used. Does Sri Lanka have and drinking guidelines? If not justify why using USA and not another countries guidelines.

Ans. We tried to find the drinking guidelines for Sri Lankans. However, the Ministry of Health, Nutrition, and Indigenous Medicine indicated the guidelines for preventing alcoholism (i.e., male drinkers who consume ≥ 60g of pure alcohol and female drinkers who consume ≥ 40g of pure alcohol on average per occasion are classified as high-end level drinkers) [18]. We decided to adopt US guidelines [20. Dietary Guidelines in the United States] because the guideline was official and provided a realistic cut-off.

Statistical analysis:

12) It is not clear whether the data is repeated cross-sectional or the same people in pre and post measures. This needs to be made explicit.
Ans. The data in this study were not repeated measurement data and we investigated the same people in the pre and post-measures. To provide a more explicit description of this analysis, we added that we used two levels of multilevel models to account for the clustering of neighbours within GN divisions in addition to the individual level. We added the sentence as below.

Page 16, Line 280-281: We further investigated the same people pre- and post-intervention.

Page 17, Line 287-288: We used two levels of multilevel models to account for the clustering of neighbours within GN divisions as a random effect in addition to individual level as a fixed effect.

13) If it is the same person pre and post, individuals are nested within themselves and need to be modelled this way. If repeat cross-section a GEE analysis would seem the way to manage the analysis.

Ans. As described above, we investigated the same people in pre and post-measures. Therefore, we did not use GEE analysis.

14) Should the intervention effect be interpreted as adjusting for baseline measures or with a intervention#time interaction?

Ans. We refer you to the response in 15), with a similar response to the editors.

15) How these issues/decisions have been managed need to be made explicit. I would advise checking with a statistician about the way the data has been managed/analysed.

Ans. We confirmed the analyses in this study with a statistician. We added the statistician as an author.

We also received a related suggestion regarding statistical analyses from an editor. We responded to the editors as follows.

Editor comments 9)-2. Regarding the comment from the second reviewer on the conduct of the statistical analysis, there are certainly more than one way to analyze this design. While the post-test/pre-test adjusted for pre-test is not incorrect, there may be value in using the multilevel approach suggested by the reviewer (group assignment x time interaction with random effect at the participant) to account for measurements being nested within participants. Particularly since the authors are already using a multilevel approach to appropriately model the nested GN
divisions. This could be extended with the additional benefit of ensuring that individuals with complete baseline – but missing follow-up – data could be kept in the analysis.

Ans. According to Twisk et al. (2014), if a study has two follow-up measurements from baseline (time 0, 1, and 2), we can include a time variable in the model to investigate the interaction between intervention assignment and time. However, we did not investigate the interaction between intervention assignment and time, since this study performed one follow-up and did not yield repeated measurement data. We investigated changes of outcomes from the baseline to the end of the follow-up. We added a detailed analysis in the manuscript that we confirmed with the statistician.

Page 17-18, Line 288-308: We used two levels of multilevel models to account for the clustering of neighbours within GN divisions as a random effect in addition to individual level as a fixed effect. To take into account the difference at baseline, the model was adjusted for the baseline value of the outcome [25. Twisk et al. 2018]. To investigate the difference in means from baseline to follow-up, we extracted values at baseline from the values at the end of the follow-up. Finally, for the following binary outcomes (i.e. leisure-time physical activities, vegetables, fruits, snacks, sugar-sweetened beverage, current smoking, and alcohol intake), we used a multilevel logistic regression model comparing the outcomes with the low levels as a cut-off point as reference. The models were as follows:

Multilevel linear regression

\[
\text{outcome}_{ij,\text{follow up}} - \text{outcome}_{ij,\text{baseline}} = \mu + b_i + \alpha \cdot \text{intervention}_{ij} + \beta \cdot \text{continuous outcomes}_{ij,\text{baseline}}
\]

Multilevel logistic regression

\[
\logit \Pr (\text{binary outcomes}_{ij,\text{follow up}}) = \mu + b_i + \alpha \cdot \text{intervention}_{ij} + \beta \cdot \text{binary outcomes}_{ij,\text{baseline}}
\]

where the probability of individual i in GN division j having a given outcome at the end of the follow-up (follow up) was modelled by intervention assignment (intervention group or control group), controlling for outcomes at baseline (baseline) and random intercepts for GN divisions (bi). The adjusted mean or odds ratio (OR) for the logistic regression model and the 95 % confidence interval (CI) for the linear regression model were calculated for continuous and binary outcomes, respectively.
Results

16)-1. I am not clear on how the mean differences presented in Table 2 have been calculated from the regression analyses.

Ans. We revised the statistical analysis for greater specificity.

Page 17, Line 290-291: To investigate the difference in means from baseline to follow-up, we extracted values at baseline from the values at the end of the follow-up.

16)-2. The table (Table 2) could be improved. As different metrics are use in the columns it can be confusing to read. Can a subscript be used to indicate to the reader whether the number is using mean, IQR or percentage? Indicate in the footnote what a positive and negative number means.

Ans. We added the symbol ‘+’ for the median (IQR) in Table 2. In addition, we added symbol ‘–’ for ‘Change from baseline’ and ‘―’ for ‘Difference in means’.

We indicated in the footnote the meanings of minus and plus values as below.

– Change from baseline = outcome values at the end of the follow-up – outcome values at baseline

— The analysis of ‘difference in means’ was used the calculated outcome of ‘change from baseline’.

17) Adequate drinks is an unusual description. As there is no safe level of alcohol, I would suggest this change to low risk drinking level.

Ans. There is no safe level of alcoholic drinks, as you point out, and we revised the description from “adequate drinks” to “low risk of drinking level” while retaining the same cut-off value for drinks per day.

Page 13, Line 218-219:… as indicating a low risk of drinking level, …

18) I would recommend the text reports explicitly the primary and secondary outcomes.

Ans. We added an identification of the primary outcome and secondary outcome in the results paragraph.
Page 19, Line 335-336: With respect to the primary outcomes at the follow-up, the intervention group had …

Page 20, Line 346: Blood pressure, which was one of the primary outcomes, did not significantly …

Page 20, Line 352: With regard to health-related lifestyle in secondary outcomes, …

19) Discussion:

Generally fine. It could be improved in discussing how the findings could be applied and systemically scaled up. It could also refer to the ideas I have raised above about the consistency/fidelity of the intervention delivery. The issues around dosage could also be raised.

Ans. If we adopt youths as non-professional healthcare workers, we can expect health promotions to prevent NCDs to perhaps be more scaled up in low- and middle-income countries. We described this in the following sentence while adding a new paragraph in the discussion.

Page 24, Line 415-422: It remains to be determined whether the present findings are applicable to other settings and how the present approach of community health promotion by youth club could be scaled up in a wider context. Besides the presence of active youth club or similar association in the community, it is necessary to develop a facilitator-support system from which youths can receive comprehensive guidance. Youths should be guided to promote their awareness, understanding, and tolerance of other people, cultures, and societies so that they can provide standardized and high-quality intervention universally by as change agents.

Query of additional revision

We revised this manuscript and tables with using a track change. We also colored red to the revised sentence which was major points of the revision.

1. Although the results did not change, we corrected the cut-off point of fruit intake from two to one serving/day after rechecking the distribution of servings per day. According to the distribution and a guideline of Sri Lanka, we decided to use one serving/day as a cut-off for fruit intake.

Page 12, Line 209-212: We defined “adequate intake” as consuming two servings/day or higher for vegetables and one serving/day or higher for fruits, which roughly corresponded to the 50th to 75th percentile (1.5 to 3.5 servings/day for vegetables and 0.8 to 1.5 servings/day for fruits) of all participants at baseline.
2. We used 4.5 METs of moderate-intense physical activity or 7.5 METs of vigorous-intense physical activity as a recommended leisure-time physical activity [14. Churilla et al. 2008]. Since we previously did not consider hours per week, which Churilla et al. indicated, we reanalyzed the data with the moderate-intense physical activity and vigorous-intense physical activity. Even after the recalculation, the associations did not change.

Page 12, Line 206-209: We defined “recommended leisure-time physical activity” as over three hours/week of 4.5 metabolic-equivalents (METs) of moderate-intense physical activity or over one hour/week of 7.5 METs of vigorous physical activity, according to the review for leisure time physical activity [17. Churilla et al. 2008].

3. We have added Dr. Yohei Kawasaki, a statistician who supported our statistical analyses, as co-author.