

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Prevalence of risk factors of non-communicable diseases in Kerala, India; results of a cross-sectional study
AUTHORS	Sarma, P; Sadanandan, Rajeev; Thulaseedharan, Jissa Vinoda; Soman, Biju; Srinivasan, Kannan; Varma, R; Nair, Manju; Pradeepkumar, AS; Jeemon, Panniyammakal; Thankappan, KR; Kutty, Raman

VERSION 1 – REVIEW

REVIEWER	Dr. Anand Krishnan Centre for Community Medicine AIIMS, New Delhi
REVIEW RETURNED	21-Jan-2019

GENERAL COMMENTS	<p>Abstract:</p> <p>Objective: “using the state representative data” can be deleted</p> <p>Participants: A description of sampling process can be given rather than just saying “representative”</p> <p>Main Outcome : Did they use a PA score?.</p> <p>Results: Sodium intake is not given. Hypertension prevalence by gender can be deleted if required to maintain word count.</p> <p>Conclusion: As this is the first definitive survey for the state of Kerala, there is no point comparing it with NFHS (different age group) or localized surveys and this can be deleted. Last line can be retained.</p> <p>Main Paper:</p> <p>Sample Size: Why did they take an expected prevalence of 5% (for which risk factor based on which study)?</p> <p>Urinary Sodium: Urinary sodium estimation based on a single sample is used only at population level and only means should be reported. It is not advisable to use it to estimate individual salt intake and report as < 5 gm or > 5 gms. The Kawasaki Formula is used to estimate urinary excretion of sodium (not sodium chloride). Sodium level has to be multiplied by 2.54 to get salt (sodium chloride) intake. It is not clear whether this has been done.</p> <p>Diet Score: As explained earlier, it may not be appropriate to use the estimated salt intake (which can vary widely on a day-today basis) for individual level score development. Simplest is to use</p>
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	<p>the combined fruit and vegetable intake (Mean servings) for this. Also it is inappropriate to use tertiles to define poor diet (with the reported levels of f& V and salt intake, more than three fourths would easily be having poor diet) and it is a definition which should be based on nutritive value rather than on distribution.</p> <p>As is the convention, BMI and obesity can come later and I see no need for it to be first in the result.</p> <p>Interpretation of Alcohol use needs some context as Kerala has experimented with total and partial ban on alcohol sales from 2015. This needs to be provided in the discussion section.</p> <p>As BP/FBS was measured on only one occasion (as different from times), it might be more appropriate to use the term raised blood pressure and raised FBG (rather than disease entities)</p> <p>NFHS studies a very different age and unless authors adjust for that that comparison is not valid.</p> <p>The need and rationale for setting up a cohort is not clear. Surveillance does not need a cohort.</p> <p>Table 2/ I suggest that they delete the n column from the table as anyhow the sampling weights including response weights would have been used to arrive at the mean.</p> <p>Figure 2 could show cumulative proportion as those who have 3 are also eligible to be in 2RF group.</p>
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REVIEWER	Samwel Maina Gatimu Aga Khan University, Nairobi, Kenya
REVIEW RETURNED	11-Mar-2019

GENERAL COMMENTS	<p>The paper is timely and provides added evidence on non-communicable diseases in India. It is well written and informative. However, the authors should consider revisions of the following:</p> <p>a) Review the use of both the standard deviation and standard error in describing the sample means. The authors could review these two paper for insights (https://bjanaesthesia.org/article/S0007-0912(17)38467-2/fulltext and https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1255808/)</p> <p>b) Minor grammatical and typographical errors should be addressed</p> <ul style="list-style-type: none"> • Page 11, Line 50: Insert comma after “In total...” • Spacing before percentages or bracketed information e.g. Line 52 and 54-54 [female(63%)]; Page 13, Line 30; Page 14, Line 15-16 and Line 35; • Page 12, Line 28: “Both tobacco and alcohol use was...” should be revised to “Both tobacco and alcohol use were...” • Revise Page 12 Line 3-6 to make it clearer • Page 15, Line 8-16: The sentence beginning with “The control rate...” is unclear and should be revised to make it clearer <p>c) It would be of interest to highlight why consecutive sampling of households was preferred to random sampling (Page 5, Line 54-55)</p> <p>d) Kindly clarify the first sentence on Page 9, Line 5-11 under quality control</p> <p>e) Consider combining some sentences under the “Sociodemographic characteristics” for better readability (Pg. 11, Line 47-55; Pg. 12, Line 3-8).</p>
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	f) Page 12, Line 45: "...per day was reported..." should be revised. The salt consumption was assessed based on the laboratory test of the urine (Page 9, Line 52-55) and not reported by the participants. g) Page 8 Line 50: The term internet is capitalised. Is there a need for emphasis?
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REVIEWER	Li Chen Augusta University
REVIEW RETURNED	08-Apr-2019

GENERAL COMMENTS	<p>The study design and sampling method are good. Most measurements and questionnaires are validated.</p> <p>Was the diet score constructed by the authors? There are several validated diet scores (HEI, AHEI). The results would be more comparable to other studies by using the widely applied scores.</p> <p>In the section of "Number of NCD risk factors", please explain why these factors were included as risk factors, and why the number of risk factors are important.</p> <p>The authors reported the prevalence of many risk factors and diseases, and the prevalence was further stratified by gender. It would be better to provide p-values that show whether the prevalence between the male and the female are statistically different.</p> <p>The authors mentioned in the introduction section, the significance of this study is to provide information in estimating disease burden, planning resource allocation and strategic investment in prevention and management of NCDs. Therefore, from the health policy viewpoint, the prevalence of risk factors in different areas (urban/rural), and social groups (below/above poverty line) would be more important than between different gender.</p>
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REVIEWER	Éimhín Ansbro London School of Hygiene and Tropical Medicine, United Kingdom
REVIEW RETURNED	18-Apr-2019

GENERAL COMMENTS	<p>Thank you for the opportunity to review this cross-sectional survey of NCD risk factors in Kerala, India using the WHO STEPS approach. You used multi-stage cluster based sampling to identify a representative sample of the state and report very high prevalence of hypertension and diabetes at 30.4% and 19.2%, respectively, defined based on biochemical measures and self-report of existing diagnoses.</p> <p>ABSTRACT Could you include the sampling method in the abstract. I would suggest that you include absolute numbers as well as proportions throughout the paper.</p> <p>BACKGROUND The background is clear and informative. Could you also include previously determined prevalence for Hypertension and Diabetes (distinguished by type if available) in Kerala so your results can be compared to these and to inform your sample size calculation? The expected prevalence in sample size calculation seems very low. Did you mean 0.5 i.e. 50%? How many strata did you use?</p> <p>The first sampling stage is not very clearly described. It could help to add: "A multi-stage cluster sampling strategy was adopted to</p>
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	<p>identify a representative sample of eligible participants for the cross-sectional survey conducted in Kerala's 14 districts.” Could you very briefly describe what if any differences there are between municipal corporations vs. municipalities and why a) all of the corporations were sampled and b) 20 of the 87 municipalities were sampled. What was the source of list of households in each ward? Did you weight for population density in the districts?</p> <p>Study measurements How was it ensured that study participants had fasted for 8 hours before capillary blood glucose measurement if this was a door-to-door household survey and all measurements were undertaken in the person's home? Were the samples perhaps taken on return the next morning when the urine samples were collected? Later in this section you say these were random (non-fasting) samples. It would be important to clarify this. Was the poor diet score derived from the literature or somehow validated?</p> <p>RESULTS In the results section, you mention prevalence of Type 2 diabetes – you otherwise refer to a generic category of “diabetes” throughout the paper. Did you distinguish between types of diabetes or document what type of medication those in treatment were taking e.g. oral hypoglycaemics alone vs. insulin alone vs both? Did you have data on the number of people with hypertension who were unaware of their diagnosis and who were aware but not in treatment, and among those in treatment how many achieved control? This information would help in planning interventions in terms of primary screening and treatment and/or retention in care (see below). Did you stratify prevalence by rural/urban setting or by socioeconomic status?</p> <p>DISCUSSION It would be interesting to include some analysis of why the rates of CVD risk factors and particularly diabetes are so high in this population compared to other global regions and to briefly discuss what features distinguish Kerala from other parts of India. You briefly mention that the very high rates of dysglycaemia you report will pose a challenge to the existing health system. You could expand on this particularly to delineate the numbers unaware of their diagnosis i.e. what is the implication for screening and provision of adequate services for those identified by screening; the numbers with known diagnoses but not in treatment i.e. what are the potential barriers to treatment initiation and continuity; and those in treatment but not controlled i.e. what are the challenges to providing good quality, consistent care and to treatment concordance from the patient perspective. You might consider mentioning any successful or otherwise approaches to primary and secondary prevention of cardiovascular disease previously implemented in Kerala or elsewhere in India. Some discussion of WHO's recommendation to use a cardiovascular risk based approach to management of hypertension and diabetes would be relevant also. You mention the move towards Universal Health Care in Kerala in your limitation section and it would be interesting to expand on this further in your discussion, particularly the given</p>
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	<p>the socioeconomic disparities in risk factor prevalence you allude to.</p> <p>Minor comments:</p> <p>Page 7 – line 13/14 repetition of the word “marked”</p> <p>Page 8 – line 37-40 – repetition of “computer tablets” in the same sentence</p> <p>Page 14 – line 18 – did you mean here to refer only to hypertension and not to both hypertension and diabetes as you give a single comparator from each study?</p> <p>Page 14 – line 32 – there seems to be a word missing in this sentence</p>
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REVIEWER	Dr Mohammad Akhtar Hussain University of Western Australia
REVIEW RETURNED	07-May-2019

GENERAL COMMENTS	<p>I must congratulate authors for carrying out this study which is important for policy planning at the state level. The article is very well written; however, I have some suggestions to improve it further.</p> <ol style="list-style-type: none"> 1. in the abstract, authors have mentioned that spot urine sample was used to estimate dietary intake of salt while in the main text it was mentioned that Modified Kawasaki formulae were used to estimate the 24-hour urinary excretion of sodium chloride. Given that urinary excretion of sodium depends on many factors, how dietary intake of salt was estimated from spot urine test, please clarify. 2. The method used for Sample size calculation is confusing and needs rephrasing and more clarification. 3. Authors have discussed about the uncontrolled diabetes and hypertension. However, how they have defined uncontrolled diabetes and hypertension is missing in the text. It would be better to mention these definition in the method section. 4. Authors have documented the prevalence of hypertension and diabetes based on measurement as well as self report. I would suggest to also describe what percentages of all hypertensive and diabetes were on medication and what proportion of those uncontrolled. Was there any information available which can help in identification of risk factors for uncontrolled diabetes and hypertension. If there are information available then it should be added in the manuscript to provide more detailed picture. 5. The font type and size should be uniform with that of the main text fonts.
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VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Abstract:

Objective: "using the state representative data" can be deleted

REPLY

Done. Modified to "To estimate the prevalence of non-communicable disease (NCD) risk factors in Kerala."

Participants: A description of sampling process can be given rather than just saying "representative"

REPLY

Done. Modified to include the multistage cluster sampling

Main Outcome : Did they use a PA score?.

REPLY

We have used the QPAG and that is mentioned in Methods session under definitions (Page 10)

Results: Sodium intake is not given. Hypertension prevalence by gender can be deleted if required to maintain word count.

REPLY

Thank you. That is included now.

Conclusion: As this is the first definitive survey for the state of Kerala, there is no point comparing it with NFHS (different age group) or localized surveys and this can be deleted. Last line can be retained.

REPLY

Thank you. Unnecessary details removed

Main Paper:

Sample Size: Why did they take an expected prevalence of 5% (for which risk factor based on which study)?

REPLY

Thank you. Modification done on page 7(based on the physical inactivity rate of men in rural area (4.7%) in our previous study) 7

Urinary Sodium: Urinary sodium estimation based on a single sample is used only at population level and only means should be reported. It is not advisable to use it to estimate individual salt intake and report as < 5 gm or > 5 gms. The Kawasaki Formula is used to estimate urinary excretion of sodium (not sodium chloride). Sodium level has to be multiplied by 2.54 to get salt (sodium chloride) intake. It is not clear whether this has been done.

REPLY

Thank you for the valuable input. We had already followed the Kawasaki formula and estimated the salt intake using the formula you have mentioned. It is made explicit in the manuscript now (page 10)

Diet Score: As explained earlier, it may not be appropriate to use the estimated salt intake (which can vary widely on a day-to-day basis) for individual level score development. Simplest is to use the combined fruit and vegetable intake (Mean servings) for this. Also it is inappropriate to use tertiles to define poor diet (with the reported levels of f& V and salt intake, more than three fourths would easily be having poor diet) and it is a definition which should be based on nutritive value rather than on distribution.

REPLY

Thank you. Taking your advice the Poor Diet Score is completely removed and the mean values of salt intake in g/day are given.

As is the convention, BMI and obesity can come later and I see no need for it to be first in the result.

REPLY

Done on Results section and on table 2 & 3

Interpretation of Alcohol use needs some context as Kerala has experimented with total and partial ban on alcohol sales from 2015. This needs to be provided in the discussion section.

REPLY

Done in the discussion section. Page 15

As BP/FBS was measured on only one occasion (as different from times), it might be more appropriate to use the term raised blood pressure and raised FBG (rather than disease entities)

REPLY

Thank you again for the valuable input. The terms are changed throughout the manuscript

NFHS studies a very different age and unless authors adjust for that that comparison is not valid.

REPLY

Done

The need and rationale for setting up a cohort is not clear. Surveillance does not need a cohort.

REPLY

That part is removed and more clarity is brought in. Page 17

Table 2/ I suggest that they delete the n column from the table as anyhow the sampling weights including response weights would have been used to arrive at the mean.

REPLY

Table 2 and 3 are modified. 95% CI are given and it is explicitly made clear that sampling weights are used to estimate the parameters and the CI

Figure 2 could show cumulative proportion as those who have 3 are also eligible to be in 2RF group.

REPLY

Figure 2 is modified

Reviewer: 2

The paper is timely and provides added evidence on non-communicable diseases in India. It is well written and informative. However, the authors should consider revisions of the following:

REPLY

Thank you for the nice words.

a) Review the use of both the standard deviation and standard error in describing the sample means.

The authors could review these two paper for insights ([https://bjanaesthesia.org/article/S0007-0912\(17\)38467-2/fulltext](https://bjanaesthesia.org/article/S0007-0912(17)38467-2/fulltext) and <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1255808/>)

REPLY

Thank you, the references were very useful. The necessary modifications are done. Standard deviation is used only to describe the age and other baseline parameters. For comparison 95% CI are given after accounting for sample weights as we have used cluster design.

b) Minor grammatical and typographical errors should be addressed

• Page 11, Line 50: Insert comma after "In total..."

REPLY

Thank you Modifications done.

• Spacing before percentages or bracketed information e.g. Line 52 and 54-54 [female(63%)]; Page 13, Line 30; Page 14, Line 15-16 and Line 35;

REPLY

Thank you. Modifications done

• Page 12, Line 28: “Both tobacco and alcohol use was...” should be revised to “Both tobacco and alcohol use were...”

REPLY

Thank you. The sentence is modified

• Revise Page 12 Line 3-6 to make it clearer

REPLY

Thank you. The sentence is modified

• Page 15, Line 8-16: The sentence beginning with “The control rate...” is unclear and should be revised to make it clearer

REPLY

Thank you. Necessary modifications done.

c) It would be of interest to highlight why consecutive sampling of households was preferred to random sampling (Page 5, Line 54-55)

REPLY

Thank you. Because of the rubran (rural and urban) housing pattern in Kerala, households are spread out over a vast area. So we had to adopt to cluster sampling strategy.

d) Kindly clarify the first sentence on Page 9, Line 5-11 under quality control

REPLY

Thank you for pointing out the error. Necessary modifications were done

e) Consider combining some sentences under the “Sociodemographic characteristics” for better readability (Pg. 11, Line 47-55; Pg. 12, Line 3-8).

REPLY

Thank you for the comments. Some sentences were modified, though not the entire paragraph.

f) Page 12, Line 45: “...per day was reported...” should be revised. The salt consumption was assessed based on the laboratory test of the urine (Page 9, Line 52-55) and not reported by the participants.

REPLY

Thank you. The entire paragraph is modified as we are giving the mean salt intake per day in grams now.

g) Page 8 Line 50: The term internet is capitalised. Is there a need for emphasis?

REPLY

Thank you. Modifications were done

Reviewer: 3

1.The study design and sampling method are good. Most measurements and questionnaires are validated.

REPLY

Thank you for the nice words

2.Was the diet score constructed by the authors? There are several validated diet scores (HEI, AHEI). The results would be more comparable to other studies by using the widely applied scores.

REPLY

Thank you for the advice. We have looked into those scores. Unfortunately we had not collected data to support those scores, as we had followed the WHO STEPS strategy. Anyhow we took your advice and removed the Poor Diet Score that we had included in the earlier version of the manuscript. Thank you.

3.In the section of “Number of NCD risk factors”, please explain why these factors were included as risk factors, and why the number of risk factors are important.

REPLY

Thank you. In Kerala we are observing a sort of clustering of multiple risk factors which are important in the clinical management. These are very important in the population strategy of prevention. In Kerala we are spearheading such a campaign along with the state government.

4. The authors reported the prevalence of many risk factors and diseases, and the prevalence was further stratified by gender. It would be better to provide p-values that show whether the prevalence between the male and the female are statistically different.

REPLY

Thank you for the suggestion. We have included the 95%CI in all the tables and those are mentioned in the text appropriately.

5. The authors mentioned in the introduction section, the significance of this study is to provide information in estimating disease burden, planning resource allocation and strategic investment in prevention and management of NCDs. Therefore, from the health policy viewpoint, the prevalence of risk factors in different areas (urban/rural), and social groups (below/above poverty line) would be more important than between different gender.

REPLY

Thank you. We take your point and have included estimates for rural urban difference also. One of my colleagues is working on the policy aspect of the NCD epidemic in Kerala and we shall be sharing the data with her. Because of word limit constraints we could not include those aspects in this manuscript. Anyhow thank you for the valuable suggestion.

Reviewer: 4

1. Thank you for the opportunity to review this cross-sectional survey of NCD risk factors in Kerala, India using the WHO STEPS approach. You used multi-stage cluster based sampling to identify a representative sample of the state and report very high prevalence of hypertension and diabetes at 30.4% and 19.2%, respectively, defined based on biochemical measures and self-report of existing diagnoses.

REPLY

Thank you for the nice words

ABSTRACT

1. Could you include the sampling method in the abstract. I would suggest that you include absolute numbers as well as proportions throughout the paper.

REPLY

Thank you. Necessary modifications are done.

BACKGROUND

2. The background is clear and informative. Could you also include previously determined prevalence for Hypertension and Diabetes (distinguished by type if available) in Kerala so your results can be compared to these and to inform your sample size calculation? The expected prevalence in sample size calculation seems very low. Did you mean 0.5 i.e. 50%? How many strata did you use?

REPLY

Thank you for rising the important points. The section is modified to include the reference for sample size calculation, which is based on our own earlier study. The rate of physical inactivity in rural men was 4.7% which is one of the least prevalent risk factors. We took that as we had stratified our sample into male female and rural urban. Actually, this is based on a national sampling strategy to access NCD risk factors.

3. The first sampling stage is not very clearly described. It could help to add: "A multi-stage cluster sampling strategy was adopted to identify a representative sample of eligible participants for the cross-sectional survey conducted in Kerala's 14 districts."

REPLY

Thank you the modifications done.

4. Could you very briefly describe what if any differences there are between municipal corporations vs. municipalities and why a) all of the corporations were sampled and b) 20 of the 87 municipalities

were sampled. What was the source of list of households in each ward? Did you weight for population density in the districts?

REPLY

Thank you. Municipal corporations are large urban areas, and we have only six such corporations. We have taken clusters from all of them to ensure urban representation. Municipalities are smaller townships, some areas, might not be that different from some advanced rural panchayats. So, we have included a representative sample from them (based on population proportional to size) method. Yes, all estimates are calculated after giving due weightage to the sampling design. Due corrections were done in the calculation of the confidence limits as well.

Study measurements

5. How was it ensured that study participants had fasted for 8 hours before capillary blood glucose measurement if this was a door-to-door household survey and all measurements were undertaken in the person's home? Were the samples perhaps taken on return the next morning when the urine samples were collected? Later in this section you say these were random (non-fasting) samples. It would be important to clarify this.

Was the poor diet score derived from the literature or somehow validated?

REPLY

Samples were taken after overnight fasting. Clear instructions were given to the participants to have dinner before 10 pm on the survey night. Urine sample bottles were given to them and explained how to take early morning sample, after leaving initial few drops of urine. Blood samples were collected in the morning itself, after getting their convenient timings. In case of inconvenience, samples were collected on another day.

The Poor Diet score was designed by us, and it is not a validated scale. Taking your valid concern, we have removed that from the manuscript.

RESULTS

6. In the results section, you mention prevalence of Type 2 diabetes – you otherwise refer to a generic category of “diabetes” throughout the paper. Did you distinguish between types of diabetes or document what type of medication those in treatment were taking e.g. oral hypoglycaemics alone vs. insulin alone vs both?

REPLY

Thank you for pointing out the error. We should not have used diabetes or Type 2 diabetes; we have taken only one reading of the fasting blood sugar. We have removed those. Instead we call it raised Fasting Blood Glucose (FBG). However, those on treatment of diabetes (either oral medicine or on insulin) were referred as diabetic. We have not collected data on whether they were on oral drugs or injections. We are more interested to see what proportion of the known diabetic were having normal blood glucose levels.

7. Did you have data on the number of people with hypertension who were unaware of their diagnosis and who were aware but not in treatment, and among those in treatment how many achieved control? This information would help in planning interventions in terms of primary screening and treatment and/or retention in care (see below).

REPLY

Thank you for the reminder. We have included those figures in the revised version.

8. Did you stratify prevalence by rural/urban setting or by socioeconomic status?

REPLY

Thank you for the valuable input. We have included rural urban estimates also in the revised manuscript.

DISCUSSION

9. It would be interesting to include some analysis of why the rates of CVD risk factors and particularly diabetes are so high in this population compared to other global regions and to briefly discuss what

features distinguish Kerala from other parts of India. You briefly mention that the very high rates of dysglycaemia you report will pose a challenge to the existing health system. You could expand on this particularly to delineate the numbers unaware of their diagnosis i.e. what is the implication for screening and provision of adequate services for those identified by screening; the numbers with known diagnoses but not in treatment i.e. what are the potential barriers to treatment initiation and continuity; and those in treatment but not controlled i.e. what are the challenges to providing good quality, consistent care and to treatment concordance from the patient perspective. You might consider mentioning any successful or otherwise approaches to primary and secondary prevention of cardiovascular disease previously implemented in Kerala or elsewhere in India. Some discussion of WHO's recommendation to use a cardiovascular risk based approach to management of hypertension and diabetes would be relevant also. You mention the move towards Universal Health Care in Kerala in your limitation section and it would be interesting to expand on this further in your discussion, particularly the given the socioeconomic disparities in risk factor prevalence you allude to.

REPLY

Thank you. We have earnestly tried to incorporate your suggestions but for the word restraints, not much could be done in this manuscript. We promise you that we shall come up with these issues in another paper.

Minor comments:

Page 7 – line 13/14 repetition of the word “marked”

Page 8 – line 37-40 – repetition of “computer tablets” in the same sentence

Page 14 – line 18 – did you mean here to refer only to hypertension and not to both hypertension and diabetes as you give a single comparator from each study?

Page 14 – line 32 – there seems to be a word missing in this sentence

REPLY

Thank you for pointing out the omissions. Modifications were done.

Reviewer: 5

I must congratulate authors for carrying out this study which is important for policy planning at the state level. The article is very well written; however, I have some suggestions to improve it further.

REPLY

Thank you for the nice words

1. in the abstract, authors have mentioned that spot urine sample was used to estimate dietary intake of salt while in the main text it was mentioned that Modified Kawasaki formulae were used to estimate the 24-hour urinary excretion of sodium chloride. Given that urinary excretion of sodium depends on many factors, how dietary intake of salt was estimated from spot urine test, please clarify.

REPLY

Yes, we agree that there are constraints to this approach and some of the researchers have challenged the method. We have included references both in favour and against the method in our discussion.

10. Kawasaki T, Itoh K, Uezono K, et al. A simple method for estimating 24 h urinary sodium and potassium excretion from second-morning voiding urine specimen in adults. *Clin Exp Pharmacol Physiol* 1993;20(1):7-14.

11. Johnson C, Mohan S, Praveen D, et al. Protocol for developing the evidence base for a national salt reduction programme for India. *BMJ Open* 2014;4:e006629. doi:10.1136/bmjopen-2014-006629

12. Johnson C, Mohan S, Rogers K, et al. Mean Dietary Salt Intake in Urban and Rural Areas in India: A Population Survey of 1395 Persons. *J Am Heart Assoc* 2017;6. doi:10.1161/JAHA.116.004547

Teramoto T, Kawamori R, Miyazaki S, et al. Sodium intake in men and potassium intake in women determine the prevalence of metabolic syndrome in Japanese hypertensive patients: OMEGA Study. *Hypertens Res* 2011;34:957–62. doi:10.1038/hr.2011.63

24. He J, Gu D, Chen J, et al. Gender Difference in Blood Pressure Responses to Dietary Sodium Intervention in the GenSalt Study. *J Hypertens* 2009;27:48–54. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2882679/> (accessed 15 Jun 2019).

25. Rhee M-Y, Kim J-H, Shin S-J, et al. Estimation of 24-Hour Urinary Sodium Excretion Using Spot Urine Samples. *Nutrients* 2014;6:2360–75. doi:10.3390/nu6062360

2. The method used for Sample size calculation is confusing and needs rephrasing and more clarification.

REPLY

Thank you. The section is modified. (page 5)

3. Authors have discussed about the uncontrolled diabetes and hypertension. However, how they have defined uncontrolled diabetes and hypertension is missing in the text. It would be better to mention these definition in the method section.

REPLY

Thank you. The terms are removed and the contexts are made very explicit in the text (Page 13)

4. Authors have documented the prevalence of hypertension and diabetes based on measurement as well as self report. I would suggest to also describe what percentages of all hypertensive and diabetes were on medication and what proportion of those uncontrolled. Was there any information available which can help in identification of risk factors for uncontrolled diabetes and hypertension. If there are information available then it should be added in the manuscript to provide more detailed picture.

REPLY

Thank you. Overall control rates and control rates among those on treatment are given separately in the current version of the manuscript. 5. The font type and size should be uniform with that of the main text fonts.

VERSION 2 – REVIEW

REVIEWER	Anand Krishnan All India Institute of Medical Sciences, New Delhi
REVIEW RETURNED	03-Jul-2019

GENERAL COMMENTS	It needs some English improvement and editing- urbanite/rural folks
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REVIEWER	Samwel Maina Gatimu Aga Khan University, Kenya
REVIEW RETURNED	02-Jul-2019

GENERAL COMMENTS	This is a much improved manuscript addressing most of the reviewers comments. The authors should consider revising the patients and public involvement section to focus it on "patients and public involvement" and move the acknowledgement to the "Acknowledgement section".
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	The authors should also consider proofreading the draft for grammatical and typographical issues such as spacing and punctuations.
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REVIEWER	Dr Éimhín Ansbro London School of Hygiene and Tropical Medicine
REVIEW RETURNED	09-Jul-2019

GENERAL COMMENTS	<p>Thank you for the opportunity to review this revised version of your paper. The paper is now clearer. It makes a valuable contribution to the literature and will support public health policy and planning for NCD care in Kerala.</p> <p>I would suggest one last review of the document without tracked changes as there are still a number of missing words or typos throughout the manuscript. e.g. Results section of the abstract, 5th sentence: "overall" needs to be capitalised. Patient and public involvement, 2nd sentence : "The thank the project team...." In the discussion section, the final sentence of the third paragraph: "...rate of pre-diabetes to diabetes Indians...". One additional minor comment, I would suggest that you are consistent and use a space before each open bracket.</p> <p>I'm not sure your data support the statement that this study could provide the first indication of reversal of NCD risk factors in Kerala unless you can support this by providing evidence of previously higher rates of salt intake in Kerala and some explanation for why these higher rates might have dropped - e.g. public policy to reduce salt in processed foods. The lower rates you found compared to studies of other states may reflect methodological differences or, perhaps, different dietary habits in Kerala compared to other states. Further research would be required to clarify this.</p> <p>I would also suggest that you bring the reference to the Universal Health Coverage initiative in Kerala from the limitations section into the discussion and link this to your comment about strengthening primary care in Kerala etc. You could also link this to the different control rates among urban vs. rural-dwelling people with self-reported diabetes in treatment.</p> <p>I did not see any reference to one of the reporting checklists being used. My apologies if I have missed it.</p>
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REVIEWER	Dr Mohammad Akhtar Hussain Menzies Institute for Medical Research, University of Tasmania, Hobart, Australia
REVIEW RETURNED	05-Aug-2019

GENERAL COMMENTS	Thank you! Authors have addressed all the concerned raised by reviewers. I consider this article to be acceptable for publication; However, there are some minor grammatical and English language editing needed which I think can be corrected at the final editing process.
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VERSION 2 – AUTHOR RESPONSE

Reviewers' Comments to Author:

Reviewer: 1

It needs some English improvement and editing- urbanite/rural folks

Reply:

We did a thorough copy-editing.

Reviewer: 2

This is a much improved manuscript addressing most of the reviewers comments.

Reply:

Thank you.

The authors should consider revising the patients and public involvement section to focus it on "patients and public involvement" and move the acknowledgement to the "Acknowledgement section".

Reply:

Done. Page 1 Line 22 & Page 6, Line 23.

The authors should also consider proofreading the draft for grammatical and typographical issues such as spacing and punctuations.

Reply:

Thorough proofreading is done

Reviewer: 4

Thank you for the opportunity to review this revised version of your paper. The paper is now clearer. It makes a valuable contribution to the literature and will support public health policy and planning for NCD care in Kerala.

Reply:

Thank you.

I would suggest one last review of the document without tracked changes as there are still a number of missing words or typos throughout the manuscript. e.g. Results section of the abstract, 5th sentence: "overall" needs to be capitalised. Patient and public involvement, 2nd sentence : "The thank the project team...." In the discussion section, the final sentence of the third paragraph: "...rate of pre-diabetes to diabetes Indians...". One additional minor comment, I would suggest that you are consistent and use a space before each open bracket.

Reply:

We did a thorough copy-editing.

I'm not sure your data support the statement that this study could provide the first indication of reversal of NCD risk factors in Kerala unless you can support this by providing evidence of previously higher rates of salt intake in Kerala and some explanation for why these higher rates might have dropped - e.g. public policy to reduce salt in processed foods. The lower rates you found compared to studies of other states may reflect methodological differences or, perhaps, different dietary habits in Kerala compared to other states. Further research would be required to clarify this.

Reply:

We have modified the relevant section, making it a probable explanation. (Page 16 Line 18)

I would also suggest that you bring the reference to the Universal Health Coverage initiative in Kerala from the limitations section into the discussion and link this to your comment about strengthening primary care in Kerala etc. You could also link this to the different control rates among urban vs. rural-dwelling people with self-reported diabetes in treatment.

Reply:

Modified (Page 18 Line 3)

I did not see any reference to one of the reporting checklists being used. My apologies if I have missed it.

Reply:

We rechecked the manuscript and ensured proper referencing. The reference for the STROBE checklist is given under the table of the checklists in the Annexure for the STROBE checklist (Cuschieri S. The STROBE guidelines. Saudi J Anaesth 2019;13:S31–4. doi:10.4103/sja.SJA_543_18)

Reviewer: 5

Thank you! Authors have addressed all the concerns raised by reviewers. I consider this article to be acceptable for publication; However, there are some minor grammatical and English language editing needed which I think can be corrected at the final editing process.

Reply:

Thank you. We did a thorough copy-editing.