Dear Dr. Swaminathan,

Thank you for sending us your paper, manuscript BMJ-2020-055688 entitled "Associations of cereal grains intake with cardiovascular disease and mortality across 21 countries in the Prospective Urban and Rural Epidemiological Study: A prospective cohort study." We sent it for external peer review and discussed it at our manuscript committee meeting. We recognise its potential importance and relevance to general medical readers, and we are pleased to offer publication in the BMJ if you are able to revise as we suggest.

We hope very much that you will be willing and able to revise your paper as explained below in the report from the manuscript meeting and we look forward to reading the revised version in due course.

Please remember that the author list and order were finalised upon initial submission, and reviewers and editors judged the paper in light of this information, particularly regarding any competing interests. If authors are later added to a paper this process is subverted. In that case, we reserve the right to rescind any previous decision or return the paper to the review process. Please also remember that we reserve the right to require formation of an authorship group when there are a large number of authors.

When you return your revised manuscript, please note that The BMJ requires an ORCID iD for corresponding authors of all research articles. If you do not have an ORCID iD, registration is free and takes a matter of seconds.

Yours sincerely,

John Fletcher
Dr John Fletcher
Associate Editor
The BMJ
jfletcher@bmj.com

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**Report from The BMJ’s manuscript committee meeting**

These comments are an attempt to summarise the discussions at the manuscript meeting. They are not an exact transcript.

Members of the committee were: Elizabeth Loder (chair); Rafael Perera (statistician); Tiago Villanueva; Wim Weber; Joseph Ross; Tim Feeney; David Ludwig; JinLing Tang; John Fletcher
Decision: Put points

Detailed comments from the meeting:

1. Nutritional epidemiology is a popular topic with our readers and there is a lot of interest in the respective merits of whole or refined grains. Thank you for thinking of us.

2. We thought confounding by poverty could account for some of the associations observed. Refined grain consumption might be associated with deprivation in low income countries. Might you consider separating your results by country income level (such as low, medium and high) to explore confounding and different effects?

3. In the abstract please give some sense of what “high intake” means. Can you quantify it in terms of servings or frequency or other suitable measure?

4. Please include a declaration of public and patient involvement. How were the members of the community at various sites involved in helping with the study? Please share this information. Please also include a statement about your plans for disseminating the findings from your study.

5. Please also revise your paper to respond to all of the comments by the reviewers. Their reports are available at the end of this letter, below.

In your response please provide, point by point, your replies to the comments made by the reviewers and the editors, explaining how you have dealt with them in the paper.

** Comments from the external peer reviewers**

Reviewer: 1

Recommendation:

Comments:

- Originality - does the work add enough to what is already in the published literature? If so, what does it add? If not, please cite relevant references. It depends a bit on how the study is interpreted.

- Importance of work to general readers - does this work matter to clinicians, patients, teachers, or policymakers? Is a general journal the right place for it? Studies of diet are always popular.

- Scientific reliability
  This is a difficult question. Observational studies of diet are notoriously difficult to interpret, because diet is very strongly associated with socio-economic position which is a key determinant of health. As such, it is always difficult to know whether studies of diet give attributes of the people who eat a specific diet or the actual effects of diet.

  What is unusual about this paper is that the minimally adjusted (age, sex and centre) results are pretty much null but the association is much stronger after adjustment. In addition, that adjustment is for factors that are not clearly justified as confounders, when it is well known that adjusting for mediators or "colliders" can generate biased associations.

- Research Question - clearly defined and appropriately answered?
  The results are presented in the abstract, “What this study adds” as showing an association for ‘refined grains’. However, page 7 line 36/7 says “refined grains included only refined wheat products”. It would...
be better if the Methods had a section entitled “exposures” where it was explained why this
categorization was chosen, how it corresponds to other similar studies and exactly what it represents. It
then should be made clear throughout the paper that the key exposure is “refined wheat”.

• Overall design of study - adequate?
To be fair, it is hard to think of a better design to answer this specific question. However, to date,
observational studies of dietary items, such as vitamin supplements, have not turned out to be reliable
guide to effective interventions, while it has been difficult to check other observed associations. So, it
raises the question of whether it would be better to work out which particular dietary constituents
(proteins, fatty acids, etc), are harmful or protective and then deduce from that the effect of particular
types of food. It would also provide a framework for addressing other questions about dietary items

• Participants studied - adequately described and their conditions defined?
This is a well-known study.
It would be helpful to have a table showing the exposures by confounders, so that we can see what
factors are contributing the change in estimates after adjusting, or maybe it could be stated in the text,
as it would help the reader interpret the different models.

• Methods - adequately described? Complies with relevant reporting standard - Eg CONSORT for
randomised trials? Ethical?
The methods would be better with more clearly headed sub-sections.
Please provide more detail about the 200kcal white bread exposure (Table 4)
Please explain in more detail about the “Cox frailty” model. What was the rationale for using it? What is
the underlying time variable? Does it require the Cox proportional hazard assumption? If so, please
explain how it was tested.
Please justify in detail each variable included in the model as a confounder, i.e., a common cause of both
the relevant dietary intake and the outcomes.
Please give the rationale for any subgroup analysis and the methods used to test for differences by
subgroup

• Results - answer the research question? Credible? Well presented?
Please give the follow-up rate for the study.
Please give the model when quoting results in the text.
Please note that the “base model” showed whole grains to be protective.
Please check the text for white rice. Supplementary Table 1 appears to show higher white rice intake to
be protective in the base and minimally adjusted models.

• Interpretation and conclusions - warranted by and sufficiently derived from/focused on the data?
Message clear?
Please make it clear throughout that “refined grains” means “refined wheat products”, and that any
comparisons are drawn with a similar exposure
Please revise the interpretation and conclusions after reviewing whether the models interpreted were
adjusted correctly, or explain clearly the rationale for preferring one model rather than another.

• References - up to date and relevant? Any glaring omissions?
Maybe the study recently published in the BMJ on refined carbohydrates is also relevant

• Abstract/summary/key messages/What this paper adds - reflect accurately what the paper says?
Maybe these could be revised when the interpretation of the study is more nuanced and reflects the
finding about refined wheat grain.

CM Schooling 29th March 2020

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Reviewer: 2

Recommendation:
In this manuscript, the authors analysed data from 21 countries in the PURE study, and reported on the associations between refined grains, whole grains and white rice with risks of mortality and cardiovascular outcomes, as well as the cross-sectional associations of these foods with blood lipids and blood pressure at baseline. The higher risk associated with refined grains is consistent with existing literature, while the null association for whole grains is inconsistent with inverse associations reported in previous studies; and there had been few previous studies which examined white rice. This is a large study, and so the data presented is valuable since there has been limited evidence previously from lower to middle income countries, however, I have some queries regarding the analyses, and some suggestions for the authors to consider.

1) In my view, the major advantage of the PURE study over that of other large existing cohorts mostly based in Europe and the US is the range of countries included, which allows a unique opportunity to explore possible heterogeneity by region/income level. The countries included are also likely at different stages of the nutrition transition model, which means consumption of the same food groups might mean different things in different countries, for example, refined grains and other processed foods might be consumed more by high socio-economic status participants in the lower income countries who could afford the purchase, but the same foods are more likely to be consumed by lower socio-economic status groups in high income countries. Therefore, I think it would both be interesting and of value to present stratified analyses by region/country income level, alongside the main analyses.

2) The authors presented analyses in 4 or 5 categories of grain consumption, using the lowest category as the reference group. While this allows easy interpretation of the findings, in the case of whole grains, this meant using zero consumption as the reference group, which might not be appropriate since total non-consumers are likely to be different from consumers in many other ways, so residual confounding might be present. Therefore, alternative (using a different reference group) or complementary presentations (modelling the association continuously, or explore possible non-linear effects) could be considered to ensure the robustness of the findings. In particular, as shown in Table 1, there were substantial variations in whole grain consumption by regions, and so there might be some clustering by region in categorisation of the whole grain variable, which may not completely accounted for in the statistical modelling. It would therefore seem important to explore possible heterogeneity in whole grain intake by region as well.

3) For the categorisation of the main exposures, the authors used grammes of intake of each food, and secondarily adjusted for energy in the statistical modelling. By doing this, a participant who eats 100g of refined grains on a 1200kcal diet would be put in the same category as another participant who eats 100g of refined grains on a 2500kcal diet, despite the fact that refined grains would make up a much larger proportion of the diet in the first participant. Adjustment for total energy in the modelling is likely not sufficient to remove the confounding here when the exposure is analysed categorically, since participants are not allowed to move across the exposure categories, and this could sometimes attenuate associations to the null or in the opposite direction. Alternative methods of energy adjustment, such as nutrient residuals method (PMID: 9094926, 10084242) which accounts for energy intake when categorising the exposure, should be considered instead.

4) Statins and blood pressure medication were adjusted for in secondary analyses, but the results were not presented in the tables. Since these are likely important confounders, was there any reason for not including these variables in the fully adjusted model? Alcohol intake and household wealth would also appear to be possible confounders, but these do not appear to be adjusted for?

5) On a stylistic note, the results for refined grains and whole grains were presented as tables while the results for white rice was presented as a figure in the main results, but I think unless there is a clear reason for doing so readers might find it easier to interpret the findings if they were all in a consistent format. In the main results tables/figures, footnotes defining composite events and major CVD would also be helpful.
6) Some additional details in text about the outcome ascertainment process would also helpful, without the need to check previous publications. Specifically, it is not clear to me from the current text whether the participant or their physician filled out the case report form, the format of the questions asked, or how the end of follow-up was determined (was it possible to get a precise date of diagnosis?). Proportion loss to follow up should also be reported.

7) Proportion of missing covariates and method of dealing with this should be reported. It would also be informative to report the treatment of covariates in the modelling, whether they are adjusted as continuous or categorical variables, and if categorical, what are the categories.

8) Some summary information of the results of outcome adjudication might be useful to report.

9) In the abstract, it would be helpful to clarify what the highest and lowest category of consumption refers to.

10) In the what’s already known on the topic box, I suggest removing the statement that high carbohydrate intake is linked with high mortality, since previous studies have in fact suggested whole grains and refined grains drive the associations differently, so I think it is misleading to report on total carbohydrates.

Additional Questions:
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Please enter your name: Tammy Tong

Job Title: Nutritional Epidemiologist

Institution: University of Oxford

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Reviewer: 3

Recommendation:

Comments:
I read, with interest, the paper by Swaminathan entitled "Associations of cereal grain intake with cardiovascular disease and mortality across 21 countries in the Prospective Urban and Rural Epidemiological study: a prospective cohort study". This large prospective study, enrolling over 137,130 participants, covers a wide range of urban and rural locations, and captures wide variation in carbohydrate intakes, specifically with respect to whole and refined grains. Major limitations of this study center on (1) the methodology applied to estimate whole-grain intake and (2) the fact that only one estimate of intake was captured at baseline. Both of these limitations may lead to considerable misclassification of dietary exposures. In addition, the discussion could be improved and additional supplementary tables included.

Major comments:
In contrast to other previously published studies (summarized in several meta-analyses to date - Tang et al 2015 Am J Cardiol; Aune et al. 2016 BMJ; Bechthold et al. 2019 Crit Rev in Food Sci & Nutr; Ye et al. 2012 J Nutr; Reynolds et al. 2019 The Lancet; Chen et al 2016 Am J Clin Nutr; Li et al 2016 Medicine; Zong et al. 2016 Circulation; Johnsen et al. 2015 Br J Nutr; Schwingshackl et al. 2017 Am J Clin Nutr), no association was observed between higher whole-grain intake and reduced risk of cardiovascular disease (CVD) and total mortality. It is possible that disparate findings in this study may be attributed to difference in the estimation of whole-grain intake. In this study, whole-grain intake is expressed as grams of whole-grain product or intact whole grain, and I believe this is leading to considerable misclassification. For example, in Table 4, whole grains that are intact and cooked were translated into 1 cup (i.e. 100 grams). If the authors did not estimate the whole grain content on a dry-weight basis and, instead, estimated the whole grain content in the prepared product/cooked basis (which includes water), this would lead to extreme misclassification. Using data from this publication (Ross et al.2015 https://doi.org/10.3945/ajcn.114.098046), for example, 200 grams of cooked oatmeal (prepared/wet weight) should not be estimated as 200 grams of whole grain. Rather the whole grain amount should be calculated on the dry basis, which translates into 34 grams of whole-grain food (before cooking). This is because oatmeal is 100% whole grain and, thus, has almost equivalent grams of whole-grain in the dry portion of the food. In contrast, for example, a 40 gram portion of ready-to-eat breakfast cereal that is classified as a ‘whole-grain food’ should not be calculated as 40 grams of whole grain because the actual amount of whole grain in the food could range from 6-38...
grams. If the estimated whole-grain intake is calculated for whole-grain food products and intact whole grains as they are prepared (such as cooked barley, oat and maize porridges, bulgur, cracked wheat, etc.), and if the calculations are not based on the dry weight, this will lead to considerable misclassification. Typically, this type of misclassification is considered ‘non-differential’ and can attenuate associations; however, given the fact that this study combines the data from different countries and region, the type of error introduced may be systematic error. Could the authors confirm how whole-grain intake was estimated on dry weight? For example, in the meta-analysis by Chen and colleagues 2016 (Chen GC, Tong X, Xu JY, Han SF, Wan ZX, Qin JB, et al. Whole-grain intake and total, cardiovascular, and cancer mortality: a systematic review and meta-analysis of prospective studies. Am J Clin Nutr. 2016;104(1):164-72) whole-grain products were reported in grams, the authors multiplied product weights by 0.57 (16/28=0.57; 28 g of whole-grain products approximates 16 g of whole grain) to estimate whole-grain intake.

With respect to the exposures, it would be helpful if the authors provided the following information:
1. What are the whole and refined grain line items on each of the country-specific questionnaires, and what are the corresponding portion sizes? This information could be provided in a supplementary table.
2. In a supplementary table, please provide data on the individual food groups with respect to the increasing categories of whole and refined grain intake. For example, in the refined grain group, did higher intake of sweet/dessert contribute more in that category?
3. Methods section should clearly define whole grain and refined grain intake (i.e. the foods included), rather than presenting this is a supplementary table.
4. If the authors run the analysis based on whole and refined grain estimated as ‘servings per day’ (as derived from the country-specific FFQ), are results consistent with what is observed in the current analysis (grams of whole-grains)?
5. What is the justification for excluding popcorn as a whole grain?
6. Why did refined grains only contain ‘wheat’ products? For example, with ready-to-eat-breakfast cereals, puffed rice or cornflakes are considered refined grains.
7. Most observational studies examining the relationship between refined grain and disease outcomes or mortality have included white rice as a refined grain, and, conversely, brown rice as a whole grain. Could the authors comment on the justification for not including white rice with refined grains, and, conversely, not including brown rice in the whole grain category?
8. Refined grains include desserts and pastry. When thinking about refined grain equivalents, to whole-grains, these foods are not typically included in the refined grain category. Suggest creating two refined grain exposure categories, with and without the desserts and pastry.
9. What is the justification for grouping North America with Europe?

Minor comments:
Introduction
-Page 5, lines 33-40: Split this into two sentences. Also, consider adding the following references:

Methods
-Page 6, Line 54: Were the blood samples collected fasting?
-Page 9, line 53: Type error: ”?350 g”

Statistical Analysis
-Is the refined grain intake association independent of saturated fat or sodium intake?
-Refined grains include sweet-baked desserts—does exclusion of these foods from the refined grain category change the association?
-Did you test for interaction by sex?
-Did the authors look at the percent energy from carbohydrates as the exposure variable of interest rather than absolute grams of carbohydrate?
Discussion

- Page 11, lines 48-50: “...data were reanalyzed by comparing the risks...” can you clarify what this means?

- Page 11, lines 52-57: Why did you choose to analyze by 200kcal increase when others, such as the reference in the line just before this, analyze based on gram increases?

- Page 12, lines 17-27: Can you say the observed result only because of the reduction in high GI foods when there was also an increase in low GI/high fiber (more WG) foods?

- Page 12, line 43: The inverse associations of WG intake with total and CVD mortality has been reported in more than "a few" meta-analyses. Consider also adding the following references:
  Reynolds et al. 2019 The Lancet
  Chen et al 2016 Am J Clin Nutr
  Li et al 2016 Medicine
  Zong et al. 2016 Circulation
  Johnsen et al. 2015 Br J Nutr
  Schwingshackl et al. 2017 Am J Clin Nutr

- Page 13, line 6-8: You mention that there is no standard definition for WG and that it varies between countries. Can you comment on any notable differences in how WG foods were captured on the different FFQs?

- Page 13, lines 15-20: Can you provide a reference supporting the claim that nutrients such as fiber, vitamins, minerals, and antioxidants are removed during processing of WG products?

Page 14, lines 22-24: Why would you expect that rice and refined wheat have opposing effects on the risk of CHD?

Additional Questions:

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Please enter your name: Nicola McKeown

Job Title: Scientist

Institution: JM USDA HNRCA at Tufts University

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Reviewer: 4 BMJ Statistician

Recommendation:

Comments:
BMJ.55688: Associations of cereal grains intake with cardiovascular disease and mortality across 21 countries in the Prospective Urban and Rural Epidemiological Study: A prospective cohort study

Stats Report:

The present manuscript presents results from the PURE study on the association between white flour (referred to as refined grains), whole grains, and white rice with cardiovascular outcomes and all cause mortality. The data collected is impressive and unique, potentially providing high level evidence of this association.

Given that the data were collected across 21 countries, there are some issues regarding the analysis and the presentation of these data that I consider will need addressing to be able to properly evaluate these findings.

Major issue: Substantial heterogeneity of exposure and possibly of outcomes across the different countries/regions.
According to Table 1, there are substantial differences in the levels of exposure (for the three exposures) across the regions. It is unclear if within the presented regions, there is some homogeneity within their countries. This creates a critical problem. The use of frailty models, although in principle accounts for potential differences in hazards by centre, has as a basic assumption the independence between frailty and the included covariates (exposures). This is untestable, however, given that for some of the observed categories of the exposure, most of the data come from a single region (if not country), this is likely to represent a substantial confounding issue. If this is the case, the analysis as presented would be invalid.

I can think of two potential alternatives (the authors are likely to imagine others): a) to carry out stratified analyses by country using quantiles or exposure as continuous and obtain a pooled estimate of the HR’s (based on meta-analysis) or b) to standardise intake within region/centre so that it is possible to carry out a one-step multivariable analysis based on similar (relative) exposures. It might be possible from this to then back-transform to specific (absolute) exposure levels.

Regardless of approach used for the analysis, an exploration of country and regional differences is required given the substantial differences in exposure. Please provide these either as a Tables or as Figures (forest plots). The variation observed by country is likely to be of substantial interest. This is critical for our understanding of the perceived differences in socio-economic and health development issues in the countries studied.

Major issue: Choice of categories for exposures
Related to the point above, the current exposure categories used cover the range of response across all participating countries. However, there appears to be in some instances countries/regions with minimal numbers in these categories. For example, based on Tables 1 and 2, it would appear to me that most (all?) of the >=350g/d group comes from China. The use of different number of categories for the different exposures (four for whole grains and five for the other two) also makes comparisons across exposures difficult.

Major issue: Full reporting of regional differences for all outcomes
In the current version of the manuscript, stratified analyses by region are provided only for white rice exposure. Given that the manuscript explores the association for three exposures, please report (in the supplementary material) the same stratified analyses for the white flour and whole grains.

Please also provide information on the total number of events per region in Table 1.

Major issue: choice of covariates in the model
Based on the reported results, the choice of covariates has a substantial impact on the findings. In particular, please clarify why the ‘Minimally adjusted model’ includes fruit and vegetable intake and diary intake. There could be issues of collider bias created by the inclusion of some of the covariates into the model. Clarify which model was regarded as the primary analysis and why.

Minor issue: Definition of refined grains
The definition of refined grains used in the study is at odds with common understanding of this term. For example, from the US Department of Agriculture website: ‘Some examples of refined grain products are white flour, de-germed cornmeal, white bread, and white rice.’ Therefore the term used needs to be justified or clarified to focus on white flour only.

Additional Questions:
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Institution: University of Oxford

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