PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	The restaurant interventions for salt reduction in China: protocol for a randomized controlled trial
AUTHORS	Du, Wenwen; Zhang, Jiguo; Li, Yuan; He, Feng; Zhou, Xue; Xu, Zhihua; Gao, Yifu; Yin, Lei; Chang, Xiaoyu; Yan, Wei; Tan, Monique; MacGregor, Graham; Luo, Rong; Zhang, Puhong; Wang, Huijun

VERSION 1 – REVIEW

REVIEWER	Laura Hopkins Baldwin Wallace University
REVIEW RETURNED	14-Apr-2020

GENERAL COMMENTS	Overall formatting comments: - Throughout the document, past tense vs. present perfect tenses is used interchangeably when referring to past research. Please change to past tense everywhere. - Overall, there are tense changes - past vs. present vs. future- when discussing the current research study. It is understandable that this can be confusing as the research is ongoing. Please review and be consistent. - Throughout the paper, you refer to the one year study. Sometimes you use the word, sometimes you use the numeric. Please adhere to journal guidelines and be consistent throughout. Specific Feedback: Page 4, line 58: Delete the comma after 'globally' Page 5, line 4: Is there more recent data than 2010-2012? line 18: What specifically is the population consuming? You state it is above recommendations, but what are they consuming? line 29: What is the first? At home? Page 6, line 20: Put aims at the end of the introduction. Be clear with the aims. The outcomes you present are not necessarily consistent with the aims. line 33: How were the restaurants selected? How were the provinces and counties selected? Page 7, line 4: What specifically are the assessment surveys? line 12: What if a restaurant fell into 2 different classifications? How were they designated? What is the justification for using this classification system? line 29: What was the baseline assessment? You mention several different assessments throughout, but they are very confusing and not clearly defined. I see that they are in figure 2, but consider adding text as well. line 49: Do not capitalize the S in skills

	Page 11, line 1: is it really random? Or is it a convenience sample? How are you randomizing? Please explain your sampling better. line 16: Monthly supervision records? Where were these described? What do these entail? Data collection on primary outcome not addressed in the data collection section. Consider moving some text from the previous section to this section. What are the confounding variables? Linear mixed model - what are the effects? What are your levels/effects? Economic and process evaluation: you don't talk about this in your aim. Your outcome measures need to be consistent with your aims. Page 13, line 8: You need more clarification on how you are going to address the current pandemic. Also, are all restaurants closed? Are they functioning in any capacity? For example, here in the US, restaurants are allowed to do carry out options. Is that the case there or are they simply all closed? If there are differences - some open, some closed, some carryout - how are you documenting this? Are you able to document this? Other comments: - Was consumer consent waived? Please address this.

REVIEWER	Simon Capewell Liverpool University, UK Capewell has recently chaired, vice-chaired or energetically supported committees at Action on Sugar (founder member), American Heart Association (Leadership Cabinet), Consensus Action on Salt (CASH), European Society of Cardiology (Policy), Health Equalities Group (Trustee), NICE (2005-2014), Obesity Health Alliance (Steering Group), Society for Social Medicine (President 2015 & 2016), UK Faculty of Public Health (Vice President for Policy, 2015-2018), UK Health Forum (Trustee 2008-2018), and World Health Organisation (expert advisor).
REVIEW RETURNED	17-Jul-2020

GENERAL COMMENTS	The restaurant interventions for salt reduction in China: randomized controlled trial protocol. Du et al. This protocol describes RIS, a multi-centre RCT to evaluate the effectiveness of interventions designed for salt reduction in almost 200 restaurants in six provinces across China. As BMJ Open states: For studies that are ongoing, it is generally the case that very few changes can be made to the methodology. As such, requests for revisions are generally clarifications for the rationale or details relating to the methods. If there is a major flaw in the study that would prevent a sound interpretation of the data, we would expect the study protocol to be rejected. MAJOR CONCERNS None

	MINOR CONCERNS Very few. INTRODUCTION The authors make a strong case for salt reduction as a top public health priority in China. Such interventions are potentially powerful, equitable and cost-saving. Good description of context. a) Restaurant dishes often have a high sodium content, and b) Their Beijing-based pilot study suggested that approximately 40% people's salt intake was consumed outside the home. Action on Salt China are also running three other RCTS evaluating diverse interventions in schoolchildren and their families; in home cooking; and a comprehensive approach. (The latter is likely to have the biggest effect, given the ubiquitous Effectiveness Hierarchy PLOS ONE, (2017). 12(5). doi:10.1371/journal.pone.0177535). RIS is likely to a) make a useful additional contribution to a comprehensive strategy, and b) help increase public and political acceptability of salt reduction interventions & policies. METHODS AND ANALYSIS In this restaurant-based intervention study (RIS), comprehensive intervention activities based on social cognitive theory have been designed to a) encourage salt reduction in all restaurant foods, and b) encourage consumers to choose lower-salt options when eating out. It thus addresses supply side, demand side, and public attitudes. The RIS baseline survey was conducted in May 2019. Randomization is stratified – good. Sample size calculation looks reasonable. Primary outcome: change in the sodium content of the 5 best-selling dishes. Electronic data recording platform (EDC): Data will be collected and recorded on an electronic data recording platform (EDC), using a mobile EDC app. Very sensible. Are there any mechanisms for data validation? Are there any mechanisms for the detection of minor keying errors? Statistical analysis and Economic evaluation Appear reasonable. Process evaluation using mixed methods. Excellent, and potentially very useful. PPI and Ethics appear satisfactory. COVID19 issues have been identified, and considered as well as possible.

	They obviously represent the single biggest risk to successful trial completion. Fingers crossed! Nil else

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Laura Hopkins

Institution and Country: Baldwin Wallace University

1. Overall formatting comments:
- Throughout the document, past tense vs. present perfect tenses is used interchangeably when referring to past research. Please change to past tense everywhere.
- Overall, there are tense changes - past vs. present vs. future- when discussing the current research study. It is understandable that this can be confusing as the research is ongoing. Please review and be consistent.
Responses: We have checked the whole manuscript carefully and changed the sentences to past tense in most places except for a few of sentences conferring the future plan where future tense has been used.

2. Throughout the paper, you refer to the one year study. Sometimes you use the word, sometimes you use the numeric. Please adhere to journal guidelines and be consistent throughout.
Responses: We used the numeric to express numbers in the manuscript.

3. Specific Feedback:
Page 4, line 58: Delete the comma after 'globally'
Responses: Done.

4. Page 5, line 4: Is there more recent data than 2010-2012?
Responses: This is the newest national nutrition and health survey in China. The next wave of survey will be conducted in 2022.

5. line 18: What specifically is the population consuming? You state it is above recommendations, but what are they consuming?
Responses: We have added the Chinese population consumption in the sentence.

6. line 29: What is the first? At home?
Responses: Yes, home is the first major location of eating in Chinese population. Added in the sentence.

7. Page 6, line 20: Put aims at the end of the introduction. Be clear with the aims. The outcomes you present are not necessarily consistent with the aims.
Responses: We have added the objective of the study at the end of the introduction.

8. line 33: How were the restaurants selected? How were the provinces and counties selected?
Responses: To account for geographical, economic and dietary disparities, we selected 6 provinces of China, which were consistent with other RCTs of ASC, covering north (Heilongjiang, Hebei,

Qinghai) and south (Hunan, Sichuan and Jiangxi) China. In each province, 2 counties of similar socioeconomic levels in the provincial capital city were selected. According to the inclusion and exclusion criteria, 192 restaurants were selected from the 12 counties, including 16 restaurants (4 large, 8 medium and 4 small restaurants) in each county.

9. Page 7, line 4: What specifically are the assessment surveys?
Responses: They refers to baseline and follow-up survey, before and after the 1-year intervention. We have added them in the manuscript.

10. line 12: What if a restaurant fell into 2 different classifications? How were they designated? What is the justification for using this classification system?
Responses: We already have explained this in “randomization” as following:
After baseline assessment, restaurants were randomly allocated to either the control group or the intervention group (96 restaurants in each group). The randomization was stratified by the size of restaurants and carried out using computer generated random numbers by a statistician who was not involved in the study and blind to the identity of the restaurants. Following the baseline survey, the restaurants in the intervention group implemented a series of intervention activities aiming to reduce salt. The intervention duration is 1 year. The restaurants in the control group operated as usual.

11. line 29: What was the baseline assessment? You mention several different assessments throughout, but they are very confusing and not clearly defined. I see that they are in figure 2, but consider adding text as well.
Responses: Done.

12. line 49: Do not capitalize the S in skills
Responses: Done.

13. Page 11, line 1: is it really random? Or is it a convenience sample? How are you randomizing? Please explain your sampling better.
Responses: We modified the sampling paragraph and deleted “random” in sampling method. We selected restaurants in each country mainly according to the above inclusion and exclusion criteria.

14. line 16: Monthly supervision records? Where were these described? What do these entail?
Responses: We described this at the end of “data collection”.

15. Data collection on primary outcome not addressed in the data collection section. Consider moving some text from the previous section to this section.
Responses: Done.

16. What are the confounding variables?
Responses: Potential confounding variables included restaurant size, cooking method and dish category, etc.

17. Linear mixed model - what are the effects? What are your levels/effects?
Responses: The effects of the restaurant intervention package were explored on the primary or secondary outcomes.
The primary outcome was the difference between the intervention and control group in the change of the sodium content of the 5 best-selling dishes from baseline to the end of the trial.
Secondary outcomes included the differences between the intervention and control group in: (1) monthly use of salt and main salty condiments by the restaurant chefs; (2) salt-related knowledge, attitude and practice (KAP) in restaurant customers.
In the linear mixed model, the effects will be determined considering group (intervention, control), time

(baseline, follow-up), and interaction of group*time, at level 1 (dishes) and level 2 (restaurants).

18. Economic and process evaluation: you don't talk about this in your aim. Your outcome measures need to be consistent with your aims.
Responses: Economic and process evaluation were done to help understand the feasibility and potential impact of scaling up the intervention package. Thus, we do not consider them as the outcome measures of this trial.

19. Page 13, line 8: You need more clarification on how you are going to address the current pandemic. Also, are all restaurants closed? Are they functioning in any capacity? For example, here in the US, restaurants are allowed to do carry out options. Is that the case there or are they simply all closed? If there are differences - some open, some closed, some carryout - how are you documenting this? Are you able to document this?
Responses: Due to the pandemic of novel coronavirus disease (COVID-19) in early 2020, restaurants were temporarily closed in all the provinces of China. According to the feedback from the 12 counties, all of restaurants in our study closed from late January to early April. There were few differences among our restaurants.

20. Other comments:
- Was consumer consent waived? Please address this.
Responses: Yes, we added in “ethics and dissemination”.

Reviewer: 2
Reviewer Name: Simon Capewell

Institution and Country: Liverpool University, UK

This protocol describes RIS, a multi-centre RCT to evaluate the effectiveness of interventions designed for salt reduction in almost 200 restaurants in six provinces across China.

As BMJ Open states: For studies that are ongoing, it is generally the case that very few changes can be made to the methodology. As such, requests for revisions are generally clarifications for the rationale or details relating to the methods. If there is a major flaw in the study that would prevent a sound interpretation of the data, we would expect the study protocol to be rejected.

MAJOR CONCERNS
None

MINOR CONCERNS
Very few.

INTRODUCTION
The authors make a strong case for salt reduction as a top public health priority in China. Such interventions are potentially powerful, equitable and cost-saving.

Good description of context. a) Restaurant dishes often have a high sodium content, and b) Their Beijing-based pilot study suggested that approximately 40% people’s salt intake was consumed outside the home.

Action on Salt China are also running three other RCTS evaluating diverse interventions in schoolchildren and their families; in home cooking; and a comprehensive approach. (The latter is

likely to have the biggest effect, given the ubiquitous Effectiveness Hierarchy PLOS ONE, (2017). 12(5).doi:10.1371/journal.pone.0177535).

RIS is likely to a) make a useful additional contribution to a comprehensive strategy, and b) help increase public and political acceptability of salt reduction interventions & policies.

METHODS AND ANALYSIS
In this restaurant-based intervention study (RIS), comprehensive intervention activities based on social cognitive theory have been designed to a) encourage salt reduction in all restaurant foods, and b) encourage consumers to choose lower-salt options when eating out. It thus addresses supply side, demand side, and public attitudes.

The RIS baseline survey was conducted in May 2019.

Randomization is stratified – good.

Sample size calculation looks reasonable.

Primary outcome: change in the sodium content of the 5 best-selling dishes.

Electronic data recording platform (EDC):
Data will be collected and recorded on an electronic data recording platform (EDC), using a mobile EDC app. Very sensible.

1. Are there any mechanisms for data validation?
2. Are there any mechanisms for the detection of minor keying errors?
Responses: Yes. First, to ensure the data validation and detection of keying errors, the EDC system set rules of logic jump for associated questions, and abnormal values recognition. Second, to guarantee the integrity and authenticity of data collection, local researchers were given different level of authority according to their roles. Finally, any changes made are clearly recorded in the EDC system.

Statistical analysis and Economic evaluation
Appear reasonable.

Process evaluation using mixed methods.
Excellent, and potentially very useful.

PPI and Ethics appear satisfactory.

COVID19 issues have been identified, and considered as well as possible.
They obviously represent the single biggest risk to successful trial completion.
Fingers crossed!

VERSION 2 – REVIEW

REVIEWER	Laura Hopkins Baldwin Wallace University, United States
REVIEW RETURNED	23-Aug-2020

GENERAL COMMENTS	Overall, the manuscript is well-prepared and adds great value to the current literature. However, I still have concerns about how the aims/objectives are presented and the level of detail of the statistical analyses. Aims/Objectives: You present economic and process evaluation methods, but in your response to reviewers you state that this was not an outcome of interest. This does not make sense - then why present it? This is in fact a feasibility outcome. Your methods/results need to align with your objectives so that it is clear for the reader. What are your feasibility outcomes? What are your effectiveness outcomes? Present clearly and in order. Otherwise, it is difficult for the reader to follow. Second, your linear mixed model analyses need to be more clear. Based on my last review, you added your confounding variables. However, you don't list all of them. You should not list 'etc.', they should all be listed. Second, you later list these as your effects. So are these included as confounding variables or random effects? Your model needs to be explicitly clear to the reader in order to assess whether or not the interpretation of findings is accurate.

VERSION 2 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:
Reviewer: 1
Reviewer Name: Laura Hopkins
Institution and Country: Baldwin Wallace University, United States
Overall, the manuscript is well-prepared and adds great value to the current literature. However, I still have concerns about how the aims/objectives are presented and the level of detail of the statistical analyses.
1. Aims/Objectives: You present economic and process evaluation methods, but in your response to reviewers you state that this was not an outcome of interest. This does not make sense - then why present it? This is in fact a feasibility outcome. Your methods/results need to align with your objectives so that it is clear for the reader. What are your feasibility outcomes? What are your effectiveness outcomes? Present clearly and in order. Otherwise, it is difficult for the reader to follow.

Responses: Thanks. We added the feasibility outcomes in the paragraph of “Outcome measures”, following the effectiveness outcomes. Then we changed the position of “Economic and process evaluation”, and put it into the paragraph of “Outcome assessments”, renamed as “Feasibility outcome assessments”, following the effectiveness outcome assessments.

2. Second, your linear mixed model analyses need to be more clear. Based on my last review, you added your confounding variables. However, you don't list all of them. You should not list 'etc.', they should all be listed. Second, you later list these as your effects. So are these included as confounding variables or random effects? Your model needs to be explicitly clear to the reader in order to assess whether or not the interpretation of findings is accurate.

Responses: We considered “area, restaurant size, cooking method and dish category” as the confounding variables in the model, rather than random effects. Thus, we rewrote the statistical analysis to make it clear.

VERSION 3 – REVIEW

REVIEWER	Laura Hopkins Baldwin Wallace University, United States
REVIEW RETURNED	04-Oct-2020

GENERAL COMMENTS	My previous comments were addressed adequately. The manuscript reads more clearly and the outcomes align with the stated objectives. The statistical analyses are more clearly outlined.