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Koga (2020) performed a randomised, open-label clinical trial with 62 participants to have rice or grains other than rice, as staple foods for three daily meals across an eight-week period. The authors suggested there was an improvement in sleep quality index scores after the intake of rice, but the difference didn't reach statistical significance.

Objectives

- To test the hypothesis that having rice as staple food influenced physical and mental health.
- To explore the causative role of blood metabolites in any effect found.



Intervention/ Comparators

Rice (Rice-diet group)
vs
Grains other than rice (No-rice-diet group)

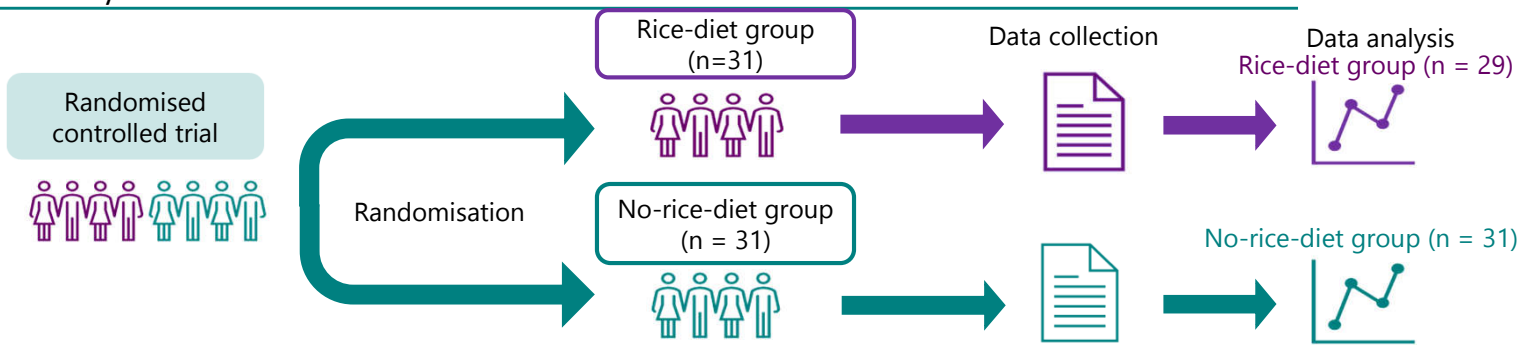


Table 1. Sources of bias in this study

KEY RESULTS

- None of the differences in primary outcome measures reached statistical significance.** The lowest p-value was for sleep quality, which was non-significant at $p < 0.08$.
- Cluster analysis was used to identify 'responders' and 'non-responders' in the rice-diet group only.** Out of 175 metabolites assessed in the rice group, 16 were reported as having a statistical difference before and after the study within the responder and non-responder groups, but not both.

Sources of bias	Suggestions for future studies
Lack of blinding <ul style="list-style-type: none"> Study participants were not kept "blind" to which staple food was being received. It was unclear if data collectors, outcome assessors, data analysts and investigators were kept "blind" in the study. 	Although it is impossible to "blind" the study participants, it is feasible to "blind" the data collectors, outcome assessors, data analysts and investigators to reduce bias.
Outcome reporting bias <ul style="list-style-type: none"> It stated "a significant interaction between 0 and 4 weeks was indicated" but the data was not provided throughout the study. 	It is suggested to report all the data that was analysed in the study to provide complete evidence to the readers.
Data-dredging bias <ul style="list-style-type: none"> Only the rice-diet group was further divided into non-responder and responder subgroups based on the effect on sleep quality, which was not planned in the clinical trial protocol. 175 metabolites were measured. Only sixteen were identified or reported. 	It is recommended to avoid further division of rice-diet group into non-responder and responder subgroups to reduce the bias on probing of the data in unplanned way.

Abbreviations: PHQ Patient Health Questionnaire, STAI State-Trait Anxiety Inventory, PSQI-J Japanese version of the Pittsburgh Sleep Quality Index

Study Design Weaknesses

- The no-rice-diet group was allowed rice intake at dinner to prevent withdrawal.
- A sample size of 62 participants may not be adequate to detect a weak effect.
- Eight weeks may not be enough to reflect any long-term effect of rice-based diet.
- A crossover randomised clinical trial design is recommended for future studies.
- The study was not structured to identify any causative relationship between changes in metabolites and sleep quality.

Study Participants

- The study participants were all from Japan, where rice is the main staple. It is the control, 'no-rice', group that experience the biggest change from their normal dietary habits.

Conclusions

- The authors incorrectly state "Sleep quality index scores showed significant improvement after the rice-based intervention.". There was no statistical difference in sleep quality.
- The authors incorrectly state "...our findings suggest that controlling oxidative stress through the intake of a rice-centered diet may be key to improving sleep quality." The data presented was not sufficient to establish a difference in oxidative state between the control and intervention groups, and the study was not designed to identify causative relationships between metabolites and sleep quality.



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