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Efficacy of Zinc Biofortified Rice for Preventing Zinc Deficiency in Bangladesh: A Randomized Control Trial

INFORMATION SHEET

Who is conducting the research

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Why is the research being conducted?

Zinc deficiency is highly prevalent among children and women in low- and middle-income countries (LMICs), mostly due to inadequate intake of zinc. Zinc is more commonly found in animal source food, which are expensive and thus unaffordable for people with lower income. There are many ways to improve zinc status in a community, and some of them are very expensive and not a long-term solution for countries like Bangladesh. One of the effective ways of improving zinc status is consuming zinc-rich rice which has been developed through a type of breeding called conventional breeding. This rice, known as biofortified rice, has been developed by Bangladesh Rice Research Institute (BRRI), which is a government organization, and no genetic engineering has been done to develop this. Unfortunately, previous research projects aiming to evaluate the efficiency to improve zinc status, were not able to report favourable results. Hence, we are about to conduct a well-designed study that is likely to yield positive results. The results from this study will help government to formulate an effective national policy to reduce zinc deficiency in the country.

What you will be asked to do

Once you agree to participate in our study, we will ask you a few questions about yourself (your general health, education, employment), your family (number of members, number of children) and your household (construction materials and assets). These questions will only be asked to have a better idea about you and your living condition. We will, then, ask you about your dietary intake in the last 7 days (foods you have taken and their approximate amount). After that, we will take some body measurements (your height, weight, and mid-upper arm circumference) to get an idea about your nutritional status. We will request you to visit our study office where, we will collect a small amount (5mL) of blood sample from you. From that blood sample we will measure several parameters such as concentration of zinc and some other chemicals in your blood that indicates inflammation in your body (AGP and CRP). The results of these tests will be provided to you if you want.

After collection of these data, you will be assigned to one of the two study groups using a lottery. In one group participants will receive zinc rich rice, while in the other group, participants will receive normal rice (that contains low amount of zinc). You will not be made aware of which arm you have been assigned to. Even the study staff (field workers and investigators) will not be aware about your group. For the following three months, you will receive approximately 2 kg of rice per day for you and your family member. Our study staff will describe the ideal way to cook rice without excess water and we will request you to follow the cooking procedure throughout the study period for the best results.

Our study staff will also provide you a measuring bowl at the beginning of the study and a card with pictures every two weeks, The pictures will show different portion sizes of rice measured using the measuring bowl. You would have to approximately note how much rice you are consuming at every meal. Our study staff will replace the completed card with a new one every two weeks.

During the three months our research assistants will visit you bi-weekly and ask if you had any common illness over the past weeks. We might also select your house randomly and collect a small (around 50 gram) sample of cooked rice. If we do that, we will also want to know the detailed procedure of cooking that rice sample. Every month we will do a pregnancy test from your early morning urine with your consent.

After three months we will stop providing raw rice for you and your family. We will once again

collect information about your dietary intake over the last week and take your body measurements again. We will also collect blood sample from you and perform the same test from the blood sample.

The basis by which participants will be selected or screened

We have asked you to participate in this study, because you are a woman aged between 20 and 29 years, neither pregnant nor lactating, living in this area, are apparently healthy, have not received any micronutrient supplementation in the last three months and are not recipient of ration from any social safety net programs. We are particularly recruiting non-pregnant non-lactating women because the population group had higher level of zinc deficiency reported in previous micronutrients status survey. The age group is selected because it has highest pregnancy rate, and it is important to correct zinc deficiency before entering pregnancy for the betterment of mother and child. We are asking about micronutrient supplementation and whether you receive any ration support, because consuming other micronutrients might affect our study results and if you are already a recipient of rice from government, then it rice is most likely to be fortified with other micronutrients.

The expected benefits of the research

The primary benefit of your participation is that it will help us evaluate the efficacy of zinc rich biofortified rice in improving the zinc nutrition status. If the research findings are positive, they may help policy makers to make a policy so that these zinc rich rice can be distributed at an affordable cost, which will benefit the all the people in the country.

Other benefits of participation include you get to know the results of biochemical analysis of your blood sample, and anthropometric measurements. You will also receive, as part of the research study, rice supply (2 kg per day) for you and your family members throughout the study. You will also receive a small amount of money to compensate your wage loss and transport cost, when you visit our study office to provide the blood sample.

Risks to you

We do not anticipate any significant risk to you by participating in this study. The personal information we will collect will be strictly anonymous, except for your name and contact number provided for consent. If you feel uneasy answering some of the questions, and you can choose not to answer them.

We will collect a small amount of blood at two different time-points during the study. You would feel a little discomfort while collecting blood, especially when the needle is inserted. However, we want to ascertain you that, we will maintain strict aseptic precautions (such as cleaning the site of blood collection with antiseptic solution, using disposable syringe etc) to protect you from any infection. On very rare cases, there might be bruising or collection or blood underneath the skin following blood collection, but these don't happen very often.

There is an extremely rare chance of experiencing any side effects due to consumption of the study rice. However, we will monitor for that using our weekly morbidity questionnaire and take appropriate measures when necessary (treatment or referral)

Your consent

What is Personal Information

Personal information is defined as information or an opinion, including information or an opinion forming part of a database, whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion. Personal Information can be almost any information that is associated with an identifiable living individual. It can include a name, address, date of birth, gender, correspondence, audio recordings, images, alpha-numerical identifiers, and combinations of these.

How are we going to use your Personal Information?

We will collect personal information from you through the following questionnaires: baseline/endline questionnaire, dietary intake questionnaire, and morbidity information questionnaire. In addition to these, the consent for will also contain your name and contact details. All personal information you provide us will be in a de-identified, anonymous form and cannot be linked to your name or contact details. All data collected from you will only be used for research or academic purpose, i.e., publishing an article in a research journal or presenting the findings in a conference or seminar, teaching in classroom. When presenting the study findings in an article or a seminar, your name and contact details will not be shown. In addition to this we will be happy to provide a plain summary of our research findings upon request from you in a way that is most convenient for you.

As part of the documentation process, we might take photos of data and sample collection, rice distribution that might involve you, but these will be only used for academic/research purposes.

Who are we going to give this Personal Information to

Only the study investigators from Griffith University (QLD, Australia) and BRAC James P Grant School of Public Health, BRAC University (Dhaka Bangladesh) will have access to the personal information provided by you.

How will this Personal Information be stored?

All data will be deidentified while being entered into a secure electronic database in a computer server at Griffith University Research Storage Platform (https://research-storage.griffith.edu.au/). Any documents containing information which can be used to identify participants (name, address, phone number) will be securely kept in a cabinet, accessed only by the investigators. Research data will be retained in a password protected electronic file at Griffith University for a period of five years from the date of the final publication before being destroyed.

Your participation is voluntary

Your participation in the study is completely voluntary. You retain to withdraw your consent at any time without surrendering any health or other benefits. Your decision to consent or withdraw will have no impact on your relationship with researchers, other participants, or with collaborating institutions (Griffith University and BRAC James P Grant School of Public Health, BRAC University).

Questions / further information

If you have any questions or concerns about this research project, or you wish to ask follow-up questions in the future, please contact:

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The ethical conduct of this research

This study has been approved by the Institutional Review Board of BRAC James P Grant School of Public Health, BRAC University [IRB-2024-IS-08]. If you have any questions regarding your rights and participation as a participant, please contact with Ms. Tanzima Parvin, IRB Contact, BRAC James P Grant School of Public Health. Ms. Parvin can be reached at Tel: +8801940659195. Similarly, the study has also been approved by Griffith University Ethics Committee [REF: 2023/611]. Griffith University conducts research in accordance with the National Statement on Ethical Conduct in Human Research in Australia. If you have any concerns or complaints about the ethical conduct of the research project please contact the Manager, Research Ethics on +61 7 3735 4375 or research-ethics@griffith.edu.au.

Feedback to you

If you want to receive the results of biochemical analysis we will share the results in a timely manner, and in a way that is most convenient for you.

Privacy Statement – non disclosure

The conduct of this research involves the collection, access, storage and/or use of your identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. A de-identified copy of this data may be used for other research purposes, including publishing openly (e.g., in an open access repository). However, your anonymity will at all times be safeguarded. For further information consult the University's Privacy Plan at https://www.griffith.edu.au/about-griffith/corporate-governance/plans-publications/griffith-university-privacy-plan or telephone (07) 3735 4375.