

A New Measure of Egg Consumption and the Effect of Social Marketing Eggs

ClinicalTrials.gov Identifier: NCT04461106

Date: 5/10/2022

INFORMED CONSENT DOCUMENT

Project Title: Phase 2: A Randomized Controlled Effectiveness Trial to Evaluate the Impact of Social Marketing on Egg Consumption Among Vulnerable Malawian Infants.

Principal Investigator: Mark Manary

Research Team Contact: Dr. K. Maleta Telephone 0999921656
Dr. M. Manary Telephone 0995157793

Your child is invited to participate in a research study conducted by Dr. Manary and colleagues.

1. The purpose of this research is to see what types of foods your child is consuming.
2. If you agree to participate in this study, your participation will only occur today. We will ask you some questions about your child's health, dietary intake, and your household. We will also take measurements of your child, such as their height, weight, and arm size. Finally your child will be asked to provide a urine sample which will be collected in a sterile cup or by affixing a plastic urine collection bag to your child's private area.
3. There is no cost to you for being in the study. The research project will provide all medicines, tests and medical care free to you.
4. There are no known health risks associated with the methods used for this study.
5. There are no specific benefits to your child. Doctors will use the information to better understand what foods are being consumed by children in this community.
6. Other than non-participation in the research, there are no alternatives.
7. All reasonable measures to protect the confidentiality of your child's records and your child's identity will be taken. There is a possibility that your child's medical record, including identifying information, may be inspected and photocopied by government or University officials or members of the Human Studies Committee.
8. Compensation for participation: MK2800 given after participation.
9. If you have any questions or concerns regarding this study, if any problems arise, or there any feelings of pressure to participate, you may call the Principal Investigator Dr. Ken Maleta at the College of Medicine on Mahatma Gandhi Road, Blantyre, Malawi at 09-99921656. You may also ask questions or state concerns regarding your or your child's rights as a research subject to COMREC Secretariat at 01871911 ext 334 at the College of Medicine.
10. University of Malawi investigators and their staffs will try to reduce, control, and treat any complications from this research. If you feel that you are injured because of the study, please contact

the Investigator and/or the Human Studies Committee Chairman.

11. You (your child) will be informed of any significant new findings developed during participation in this research that may have a bearing on your (your child's) willingness to continue in the study. The investigator may withdraw you (your child) from this research if circumstances arise (such as non-compliance with the protocol and non-tolerance of a study medication) which warrant doing so.

12. This research is not intended for the purpose of diagnosing or treating any medical problems not specifically stated in the purpose of the research.

I have read this consent form and have been given the opportunity to ask questions. I will also be given a copy of this consent form for my records. I hereby give my permission (or give permission for my child) to participate in the research described above.

I voluntarily agree to take part:

Parent's name _____

Date _____

Name of child _____

Witness's name _____

Witness's signature _____

Researcher with primary responsibility

Dr. Ken Maleta at the College of Medicine on Mahatma Gandhi Road, Blan