

Participant Information Sheet: For Caregivers

Study title:

The Urban Infant Foodscape: a mixed methods study to explore food system related risks for enteric infection in young children

You are being invited to take part in a research study led by the Centro de Investigação e Treino em Saúde da Polana Caniço, of the National Institute of Health (INS CISPOC) in Mozambique and the London School of Hygiene and Tropical Medicine (LSHTM) in England. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please ask us if there is anything that is not clear or if you would like more information, and please take time to decide whether you wish to take part.

The following is to explain the details of the study:

1. What is the purpose of the study?

The purpose of the study is to find out the level of food-related infection in young children (between the ages of 6 and 24 months) living in your neighbourhood and to understand risks associated with this. We will be looking at risks in households, in the marketplace and throughout the food supply chain. This information will later be used to help us to design an intervention that aims to protect children from food-related illness.

2. Why have I been chosen?

You are being asked to participate in this study because you are the caregiver of a child who is between the age of 6 months and 24 months and who is living in this area of Polana Caniço. Your household was randomly chosen for participation in study from a list of households in this area who have at least one child in this age group.

3. Do I have to take part?

It is up to you to decide whether to join the study. We will describe the study and go through this information sheet and, if you agree to take part, we will then ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason. If you decide to withdraw, with your permission, we will record your reason for not participating. Your decision to join the study will not affect the health services that are available to you or your child.

4. What will happen to me if I take part?

If you agree to take part in this study, I will ask you to take part in the following 4 activities:

- a. Today, if you agree to participate in the study, we will ask you to answer some questions regarding your household, and regarding the living conditions in your household and compound, including questions on electricity, water and sanitation, livestock and animals, hygiene, and foods your child consumes, as well and how they are stored and prepared. This will take no more than 30 minutes of your time, and we will conduct the interview here at your home or at another location of your choosing.

- b. Today, we will also ask you to permit us to take a very small sample of food that you would feed to the child in your care if they were hungry. We will take this away to our laboratory for testing.
- c. We will also take a small sample of your household drinking water for testing in the laboratory.
- d. Today we will ask you to provide permission for a stool sample to be taken from your child so that we can test for food-related infections. We will give you two diapers and ask you to fit one onto your child. When the child defecates in the diaper, we will ask you to carefully store the diaper in a sealed bag that we will supply and immediately contact us so that we can collect the diaper and transport it to the laboratory for testing. If your child is unable to provide a stool sample today, we will supply diapers for 2 further days. If we are still unable to collect a stool sample after day 3, a trained, registered nurse will conduct a rectal swab instead. The nurse will perform the rectal swab in your presence, and the procedure will take only around 10-20 seconds.
- e. Today, we will ask you to provide permission for a blood spot sample to be taken from your child by a trained medical nurse. This procedure will involve your child receiving a small finger prick so that the nurse can take a few drops of blood from your child's finger. The nurse will perform the finger prick in your presence.

We aim to complete all four of the above activities with you in a household visit of approximately 60 minutes (apart from the stool sample, which we will collect when it is ready).

After we have completed the above activities, will also be asking some, but not all, caregivers to partake in some further activities later. We will inform you a short time after our first visit if you have been selected for participation in the following activities:

- f. Food preparation observations followed by a short interview: a field worker will organise a time with you when they can observe the preparing and serving of food to your child. Field workers will be observing what food your child eats, how it is prepared and served. Observations will last between 1-2 hours. Directly after the observation the field worker ask to take a small sample if the food you have prepared and will conduct a short interview with you so that they can better understand what they have observed. Questions will be focused on the food your child ate and how it was prepared and served. These interviews should last no longer than 20 minutes. We will be audio recording the interview to make sure we remember accurately all the information. The researchers will transcribe the recording before deleting it and will keep the transcript in a secure location and the data will only be used by researchers involved in this study.
- g. Food purchasing observations: A researcher will accompany you on your shopping trip to purchase food for you child. The researcher will be observing and taking notes about what foods you purchase and from where. After you have purchased the food, the researcher will ask you to provide a small sample that will be transported to the laboratory for testing. The researcher will then conduct a short interview with you to better understand what they have observed and your purchasing decisions. The interview should last no longer than 15-20 minutes and the researcher will audio record the interview to remember what you have said.
- h. Focus group discussions: we will ask you to join a group discussion with between 5-10 other caregivers from this area. The topics to be discussed will include the foods your child consumes, where they are purchased, how they are prepared and served and difficulties you face in keeping food safe. The group discussion will be facilitated by a researcher, will last about 1-1.5 hours and will take place in a venue in this neighbourhood. We will be audio recording this discussion so we can accurately remember what was said. As this is a group discussion, things you say will be shared

with other group members, but it is important that, once the discussion is over, privacy is respected. Group members will be asked to keep what they have heard in the discussion confidential.

5. What are the possible disadvantages and risks of taking part?

The blood sample and rectal swab (where it is necessary) may cause some initial discomfort to your child but does not pose any significant risk to your child's health or wellbeing. All samples will be taken by trained and registered nurses, and you will be able to oversee the whole procedure.

6. What are the possible benefits of taking part?

We cannot promise the study will help you but the information we collect will help us to design an intervention that may lead to a reduction in food-related illness in young children.

7. Will my taking part in the study be kept confidential?

Yes. All information collected about you during the research will be kept strictly confidential, and all data will be anonymised before analysis and publication.

8. What will happen if I don't want to carry on with the study?

You can decide to stop participating in the study at any time, even after your child has provided samples. If you withdraw from the study, you can decide whether you want us to destroy the questionnaire and all samples taken from your children or the household, or whether you allow us to use these previously collected data.

9. Who will pay the costs that I may incur through participating in this study?

The only costs that you will potentially incur relate to mobile phone use (when we ask you to contact us to collect the child stool sample or to arrange your attendance at a group discussion) and providing small samples of food for us to test. To offset these costs, 50 meticals of airtime will be given to the participants for study phone follow-ups and you will be compensated with 20 meticals when we take a small food sample. There will be no reimbursement for any other items, and we will not pay you for participation.

10. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the local study supervisor, XXX (*to be filled*), who will try to answer your questions. If you wish to complain formally, or have any concerns about any aspect of the way you have been treated, you should immediately inform the Principal Investigators (Oliver Cumming, Department of Disease Control, Faculty of Infectious Tropical Disease, London School of Hygiene and Tropical Medicine, United Kingdom; oliver.cumming@lshtm.ac.uk, +44 (0) 20 7636 8636, Edna Viegas, Centro de Investigação e Treino em Saúde da Polana Caniço-Instituto Nacional de Saúde, ednaviegas@gmail.com, 82 30 60 500,. The London School of Hygiene & Tropical Medicine holds insurance policies which apply to this study. If you experience harm or injury because of taking part in this study, you may be eligible to claim compensation.

11. What will happen to the samples and the results of the research study?

All food, stool, and water samples will be analysed in a laboratory here in Maputo. We will test for the presence of pathogens. Some small parts of the stool (or rectal swabs where stool has not been obtained) and the blood samples we collect will be sent to the LSHTM laboratory in England for more extensive analysis, but without your name on it. Stool (or rectal swabs) will be analysed for gastrointestinal pathogens, while blood will be tested for immune responses related to common infectious diseases. If your child tests positive for the pathogens that we detect in the Nairobi/Maputo laboratory, we will pass this information onto the head of your local Healthcare facility who will contact you if they think your child needs treatment. It is your choice to bring your child into the facility for treatment once informed. ILRI will cover the costs of the treatment associated with these tests. The healthcare facility will keep your child's results strictly confidential. Blood and stools samples that are transported to the UK will be stored in a freezer in the LSHTM laboratory for future analyses on enteric infection, gastrointestinal pathogens, and subsequent immune responses. The remaining bulk stool samples will be stored in a freezer in the Maputo laboratories to allow further analyses in the future on enteric infection, gastrointestinal pathogens, and subsequent immune responses. Anonymised data and samples may be shared with other researchers for future studies – you will not be identifiable so these results will not be reported back to you.

All the data from the questionnaires, observations, interviews and the samples will be analysed by researchers working with the London School of Hygiene and Tropical Medicine and INS CISPOC. Overall results of the study will be shared after completion of the study. They will be published in a study report, communicated between study partners and may also be published online. All findings that are reported will be anonymised so that they cannot be linked back to you, your household or any other individual. Findings will also be summarized anonymously and presented to key stakeholders, which may include some members of your community, to help us in designing the intervention.

12. Contact Details

If you have any questions about your rights as a research participant, please contact:

National Health Bioethics Committee (CNBS), Av. Eduardo Mondlane/Salvador Allende, P.O Box 264, Maputo, Mozambique. Tel: +258 21 427 131/4 or mobile: +258 82 406 6350

You will be given a copy of the information sheet and a signed consent form to keep.

Thank you for considering taking the time to read this sheet.