

THE BEEP STUDY FOOD CHALLENGE



Your child is invited to a food challenge as part of the BEEP study

- It is important you understand why this part of the study is being done, and what it will involve for you and your child.
- Please take time to read this leaflet, and ask us if you would like more information.
- It is for you to decide if you want your child to have a food challenge or not. If you agree to take part, your child will have a food challenge at a time that is convenient for you. If you choose not to take part, your child will continue in the BEEP study in the normal way without a food challenge.
- Thank you for reading this information.

Important things you need to know before a food challenge

- If your child is given an antihistamine medicine during the week before their food challenge, please let the BEEP food allergy nurse know (see contact details on the right) before you come to the hospital. We will need to discuss whether your child needs to stop taking these or whether we need to rearrange your appointment, because antihistamines can interfere with the result of a food challenge. Other medicines do not affect the food challenge.
- If your child is unwell during the week before their food challenge, please let the food challenge team know, using the contact details found in this information sheet, before you come to the hospital. Ongoing symptoms such as coughing, wheezing or active eczema can make it difficult to interpret the result of a food challenge and we may need to rearrange your appointment.
- Please bring any favourite foods (such as yoghurt, banana or a fruit puree) with you that may be used to disguise the taste of the new food, in case your child is reluctant to eat it.
- Please bring your child's usual cup or bottle if appropriate, a packed lunch of familiar foods to give your child after the food challenge, a favourite toy or comforter, and any medications that your child usually takes.
- A parent / legal guardian must attend on the day of the food challenge to sign the consent form and supervise your child.

Contents

1. What is a food challenge?
2. Why are you offering this for my child?
3. What will happen if my child has a food challenge?
4. Possible risks?
5. Possible benefits?
6. Will this be confidential?
7. Results of the food challenge
8. What if there is a problem?
9. Who reviewed the study?

How to contact us

To make changes to your child's food challenge appointment, or to ask any questions about this part of the BEEP study, please contact the study team:

[insert name]

BEEP Research Nurse

[insert e-mail/phone number]

1. What is a food challenge?

During a food challenge your child is given small portions of a food every 30 minutes to confirm whether or not they have a food allergy. The portions of food are given gradually, starting with a very small quantity, so that any allergic reaction is usually mild. Food challenges take place in hospital, so that all treatments are available in case of an allergic reaction.

2. Why are you offering this for my child?

We are offering your child a food challenge because the answers you have given as part of the BEEP study show that they have a possible food allergy.

3. What will happen if my child has a food challenge?

Your child will visit Sheffield Children's Hospital, or St. Mary's Hospital, Paddington, London. A parent or legal guardian will need to stay with your child throughout the procedure. We will give your child small portions of a food (milk, egg or peanut) every 30 minutes, and carefully observe them to see whether or not they have an allergic reaction. If an allergic reaction occurs, we will treat your child with medication and observe them until symptoms have settled. If no allergic reaction occurs, your child can continue to eat the food at home. In total your child will spend approximately 4 hours in hospital on a children's ward. There are toys and books available. Following the food challenge we will write a letter to your GP with the results and, where appropriate, a recommendation for further assessment.

4. Possible risks?

If your child is not allergic to the food being given, then there is no risk to having a food challenge. If your child is allergic to the food being given, they are likely to have an allergic reaction during the food challenge. Most allergic reactions cause mild symptoms such as a rash, itching, coughing or sneezing, and settle within 1-2 hours. Occasionally allergic reactions may cause more severe symptoms such as vomiting, stomach ache, wheezing or drowsiness. Allergic reactions will usually be treated with a dose of antihistamine. It is very rare for a child to need treatment with other medicines or EpiPen for an allergic reaction during a food challenge, but all treatments are available in the hospital.

Your child's participation in the food challenge is voluntary and if you decide not to have a food challenge this will not affect your continued participation in the BEEP study; we

will still ask you to complete yearly questionnaires until your child is 5 years old.

You are free to withdraw from the food challenge at any time without giving any reason, and without your legal rights being affected. If you withdraw consent then the information collected up to that point cannot be erased and this information may still be used in the BEEP study analysis.

5. Possible benefits?

The food challenge will tell you for certain whether or not your child has a food allergy. Knowing your child **does or does not** have a food allergy may be helpful for you and your GP. The food challenge may also help us know whether moisturisers prevent food allergy, so may benefit other children in the future. You will be reimbursed for your travel and reasonable childcare costs for your other children, when you bring your child for their food challenge.

6. Will this be confidential?

We will follow ethical and legal practice and all information about you and your child will be handled in confidence.

If you take part in this part of the BEEP study, some parts of your child's medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you and your child as a research participant and we will do our best to meet this duty.

All information which is collected about you and your child during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate.

To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

<https://www.nottingham.ac.uk/utilities/privacy.aspx>.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

You and your child's personal data (address, telephone number) will be kept for 3 years after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted). All other research data will be kept securely for 7 years. After this time you and your child's data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team, given permission by the data custodian, will have access to you and your child's personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

7. Results of food challenges

We will publish the results of the BEEP study in scientific journals and send you a copy unless you ask us not to.

8. What if there is a problem?

If you have concerns about the study you should speak to the BEEP team. If you remain unhappy you can formally complain via the Patient Advisory and Liaison Service [insert PALS details]. If something goes wrong and you are harmed during the study, there are no special compensation arrangements. If you are harmed due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

9. Who reviewed the study?

This study has been reviewed and given favourable opinion by the West Midlands Solihull Research Ethics Committee, who look after the rights, wellbeing and dignity of people invited to take part in research. The Trial Steering Committee and study funder (NIHR HTA) have also approved including the allergy testing. The allergy tests are funded by grants from Sheffield Children's Hospital Charity and Imperial Healthcare Charity.