

EAT



Enquiring About Tolerance

Thank you for your interest in the EAT Study.

Volunteering for a clinical research study is a personal decision that requires careful consideration of the potential benefits and risks involved. To help you make an informed choice, this booklet has been prepared by the EAT Study team as a brief introduction, to answer a few of the many questions you might have about the study and what it means to participate.

What are the goals of the EAT Study?

The EAT Study aims to find out how to best prevent food allergy in young children. Current UK Government guidelines recommend exclusive breastfeeding until about six months of age and no early introduction of the foods associated with food allergies ("allergenic foods") as a means of prevention. However, there are other countries, such as Israel, Ghana and others in Africa and Asia, where allergenic foods (peanuts) are a regular part of an infant's diet. Yet, in these countries, peanut allergy is diagnosed far less often than in the UK. So which approach - avoidance or consumption - is right? The EAT Study aims to help provide an answer to this question in order to help decrease the enormous burden that food allergy has on our children.

What about breastfeeding?

Breastfeeding is best for your baby. We are aiming for all the mothers who take part in our study to achieve the UK Government recommended aim of at least 6 months of breastfeeding.

How could delaying eating allergenic foods prevent food allergy?

The idea behind the current recommendations is that a baby cannot have a reaction to these foods if they are not eating them. In the EAT Study following the current UK Government infant feeding guidelines will be the first approach that will be compared for preventing food allergies.

How could eating allergenic foods prevent food allergy?

The experience of the countries mentioned above with early introduction of peanuts has also been suggested for other foods. A study has found that delaying the introduction of wheat into an infant's diet was associated with an increased chance of wheat allergy.

Taken together with laboratory evidence, this could mean that by regularly exposing a child's developing immune system to the allergenic foods early in their development, the body gradually learns to accept the presence of the food without causing an allergic reaction.

Early introduction of solids into an infant's diet is not new. A generation ago (1975), 49% of infants in the United Kingdom had been given solids by 8 weeks of age.

A diet that includes regular, measured consumption of some of the main allergenic foods (cow's milk, sesame, wheat, egg, fish and peanut) is the second approach to food allergy prevention that will be tested in the EAT Study.

Why should I be concerned about food allergies in my child?

Food allergies affect 6% of children. Whilst the severity of reactions to foods can vary, food allergies must be taken very seriously. The reaction to a food may be severe - even life-threatening. Whilst the majority of children outgrow allergies to certain foods (cow's milk and egg), for other allergenic foods, such as peanut, sesame and fish, the allergy is more likely to be lifelong. With no cure at present, people allergic to these foods must take extraordinary precautions to avoid all traces of the food.

Who can take part in the EAT Study?

Participation in the EAT Study is open to all mothers planning on exclusively breastfeeding their infant for at least 3 months. Exclusive means that your infant has no other milk (e.g. cow's milk formula) or solid foods before this stage. You must also not be planning on leaving England or Wales in the next couple of years.

If we decide to participate, what will we need to do?

Infants enrolled in the study will be randomly assigned to one of two groups, either the "early introduction" group or the "standard introduction" group. Because the EAT Study is a

randomized study, assignment to one group or another is entirely left to chance, and neither parents nor doctors have any influence on the process. If your child is assigned to the "early introduction group", you will be asked to continue to breastfeed your baby until at least six months of age. You will also introduce first baby rice and then some cow's milk based yoghurts from 3 months of age. Subsequently you will introduce the other allergenic foods – peanut, sesame, fish, wheat and egg. By six months of age in addition to still being breastfed your child will be consuming these foods at least twice per week.

If your child is assigned to the "standard introduction group" you will be asked to follow the standard UK Government infant feeding guidelines: exclusive breastfeeding until around six months of age and no early introduction of the allergenic foods. After 6 months the UK Government leaves it up to your discretion when you want to introduce these allergenic foods. The study will last until your child is 3 years of age. We will see all the children at enrolment onto the study (at 3 months of age), when they are 1 year old and then at 3 years of age when they finish the study. All the assessments will take place at the Evelina Children's Hospital at St Thomas' Hospital.

Is it difficult to follow the dietary recommendations?

Mothers in the "early introduction" group will be given a personalised diary by one of the study registered dieticians giving you a timetable of which foods are to be introduced and in what order. They will be able to help with practical advice and information to assist you in introducing these foods into your child's diet. EAT Study dieticians will also be available to answer specific questions or provide advice as needed by participants.

What happens during the study visits?

Clinic visits allow EAT Study specialists to assess the health of each child and their progress in the study, as well as provide an opportunity for parents to raise any questions or concerns directly with the clinical study team. A typical study visit will entail an examination for eczema, tests to determine whether your child is allergic to the allergenic foods (early introduction arm), and the collection of a blood sample to assess your child's health and their immune system's reaction to the foods. The doctors may also ask about medical and dietary histories of your child and family.

What happens if my child is already allergic to the foods?

Children enrolled in the EAT study in the "early introduction" group will be screened for evidence of pre-existing food allergies. Any infant with a result suggesting a possible allergy to one of the foods will be given their first planned exposure to the food under the medical supervision of EAT Study specialists at Evelina Children's Hospital at St Thomas' Hospital. In this environment, any resulting allergic reaction can be diagnosed quickly and appropriate medical interventions to reverse the reaction may begin without delay.

How will you find out if my child develops a food allergy?

During the course of the study, we will contact you on a regular basis to ask if your child has had any symptoms suggestive of a food allergy. You will also be able to contact us by telephone if you think your child may have had a reaction to a food. If the symptoms are suggestive of food allergy we will arrange for your child to be assessed at the Evelina Children's Hospital. EAT Study staff will provide individual counselling on treating and dealing with childhood allergies and continue to monitor your child's progress for the duration of the study. Referrals will be made outside the study as appropriate.

Are there any other risks to participating in the study?

While every precaution has been and will be taken to ensure the safety of all procedures and recommendations involved in the EAT Study, volunteering for a clinical research study generally carries some potential risk to its participants, both known and unknown. EAT Study staff will explain the potential risks to you in detail and answer any questions you might have before you decide to participate.

What if I still have questions?

Our doctors and nurses will be happy to answer any questions you might have about participating in the EAT Study and may be contacted on 020 7188 4877 or visit our website at www.eatstudy.co.uk or email us at EatStudy@gstt.nhs.uk. We also encourage you to discuss enrolling your child in the EAT Study with your spouse, friends and family doctor, in order to assist you in making a confident informed decision on whether to participate.