

# Factors Influencing Adherence to Early Introduction of Allergenic Foods in the Enquiring About Tolerance (EAT) Study

Maes o ddiddordeb ymchwil: Food hypersensitivity

Hyd yr astudiaeth: 2016-10-13

Cod prosiect: FS101178

Cynhaliwyd gan: Kings College, London

### **Background**

The purpose of Enquiring About Tolerance (EAT) Study was to examine whether early introduction of certain allergenic food into the diet of infants has an effect on the subsequent development of food allergy.

Further analyses of the EAT Study dataset adds to existing knowledge. These particular analyses sought to identify the factors that impacted negatively on the ability of parents in the 'Early Introduction Group' of the EAT Study to adhere to the early food introduction regime.

It is hoped the results from these analyses will add to the evidence base for effective communication with families on the risks and benefits of allergenic food introduction, and for informing communication and policy strategies implementing infant feeding advice and guidelines.

# Research Approach

The EAT (Enquiring About Tolerance) study recruited 1303 mothers and their infants onto the study from November 2009-July 2012. All mothers on the study were asked to breastfeed exclusively until their infants were 3 months of age, at which point they were randomly split into two groups.

One group (the Standard Introduction Group; SIG) followed standard UK government advice and were asked to exclusively breastfeed to around 6 months of age, after which introduction of allergenic foods was a matter of parental choice.

The second group (the Early Introduction Group; EIG) was asked to introduce at intervals 6 allergenic foods from the age of 3 months alongside continued breastfeeding with the help of a dietician and support from the study team.

Breast milk remained an important part of all infants' diet during the first year of life and all mothers in both study groups were encouraged to adhere to this.

All infants were closely monitored until 3 years of age when the impact of the intervention on food allergy, and other additional allergy endpoints (such as eczema and asthma) were assessed and compared between the two study groups.

Approximately only 43% of families were able to follow the early introduction protocol, as opposed to approximately 93% who were able to follow the standard introduction protocol. Further analyses were conducted to identify the factors that impacted on adherence of the EIG to the study regime.

Non-adherence to the study regimen could be compromised in three ways: delayed introduction, insufficiency in the amount fed, and/or insufficiency in the total number of foods being consumed. Adherence to the regimen was evaluated by the documented responses.

#### Results

#### Factors influencing adherence to early introduction of allergenic food in the EAT Study

Analyses were performed to identify factors that were responsible for non-adherence.

Key factors were divided into two groups:

**Factors influencing non-adherence at enrolment:** The following 3 factors were found significantly associated with non-adherence:

- non-white ethnicity;
- · increased maternal age;
- · lower maternal quality of life.

**Factors influencing non-adherence post-enrolment:** The following 2 factors were significantly related with non-adherence

- feeding difficulties (by 4 months of age).
- parent reported IgE-type symptoms in response to allergenic food consumption (by the age of 6 months of age)

Eczema and presence of IgE-sensitisation to one or more foods at enrolment were not associated with non-adherence. Non-white ethnicity was associated with high rates of non-adherence while also being one of the groups shown to be most at risk of developing food allergy within the EAT Study population.

# Factors affecting adherence to a proscriptive regimen of early allergenic food introduction in the EAT Study: a qualitative analysis

It was envisaged that proscriptive early introduction regimen might be challenging and EIG families were presented with an open-text question to express any problems they were experiencing with the regimen in recurring online questionnaires. The objective of this qualitative analysis was to analyse these open-text questionnaire responses to identify key challenges associated with the introduction, and regular consumption, of required amounts of allergenic foods.

These analyses identified the three key themes that describe the challenges experienced:

**Infant food refusal**. This was the most dominant theme. The main categories representing these themes were:

- infant struggles to swallow the food
- the infant dislikes the taste of the food
- the infant has an ailment preventing consumption

**Concerns about perceived reactions and intolerances**. This theme was always present but diminished over time. The main categories of this theme were the caregivers having concerns about:

- · digestive issues
- skin issues
- actual food allergies /intolerances

**Practical problems**: This theme increased in prevalence throughout the study, becoming a key issue in the late-period. The main categories representing this theme were:

- lifestyle inconveniences
- food preparation issues

Understanding the challenges experienced with allergenic food introduction and sustained consumption could be an important precursor if developing specific communication and support strategies.

## **Published papers**

Logan K, Perkin MR, Marrs T, Radulovic S, Craven J, Flohr C, Bahnson HT, Lack G. <u>Early Gluten Introduction and Celiac Disease in the EAT Study: A Prespecified Analysis of the EAT Randomized Clinical Trial.</u> JAMA Pediatric 2020.

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Flohr C, Perkin M, Logan K, et al. <u>Atopic dermatitis and disease severity are the main risk factors</u> for food sensitization in exclusively breastfed infants. J Invest Dermatol 2014. 134:345-50.

Flohr C, England K, Radulovic S, et al. <u>Filaggrin loss-of-function mutations are associated with early-onset eczema, eczema severity and transepidermal water loss at 3 months of age. Br J Dermatol 2010. 163(6):1333-6.</u>