

# Further data analysis of the EAT study

Maes o ddiddordeb ymchwil: [Food hypersensitivity](#)

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## Background

The Enquiring About Tolerance (EAT) study was commissioned to investigate the best time to introduce allergenic foods into the infant diet in order to minimise the risk of development of allergic disease later in life, including food allergy.

Further analyses of the EAT study dataset has now been commissioned to add to existing knowledge in two particular areas. The first is investigating whether the introduction of solids has an impact on sleep behavior of infants. The second area is investigating further the factors that impacted on the ability of the 'Early Introduction Group' of the EAT study to follow the early food introduction regime.

The results from this study will add to the evidence base for effective communication with families on the risks and benefits of solid food introduction and for informing communication and policy strategies implementing infant feeding advice and guidelines.

## Research approach

The EAT study recruited 1303 mothers and their infants onto the study from November 2009-July 2012. All mothers on the study were 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) followed standard UK government advice and were asked to exclusively breastfeed for around 6 months, after which introduction of allergenic foods was a matter of parental choice.

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

It was important that breast milk remained an important part of all infants' diet during the first year of life, so all mothers in the study were encouraged to breast feed for at least six months regardless of study group.

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

The first key objective for these further analyses was to analyse data surrounding infants' duration of sleep, amount of time to settle to sleep and frequency of night waking's. There is currently the suggestion that introduction of solid foods into an infants' diet has no impact on sleep duration juxtaposed with the historical belief that introducing solids early helps infants to sleep better. The unique design of the EAT Study has allowed these conflicting beliefs to be studied.

The second research objective is to study the adherence to the EAT Study protocol. Only 42.8% of families were able to follow the early introduction protocol, as opposed to 92.9% who were able to follow the standard introduction protocol. Further investigation of the factors that impacted on adherence of the 'Early Introduction Group' to the study regime is required and would help better understanding of issues faced if this feeding pattern was followed.

## Results

The first area of further investigation found that following the early introduction of solids, infants in the Early Intervention Group (EIG) slept significantly longer and woke significantly less frequently than infants in the Standard Introduction Group (SIG).

Differences between the two groups peaked at six months, with the early introduction group sleeping for a quarter of an hour (16.6) minutes longer per night (almost 2 hours longer per week) and their night waking frequency decreased from just over twice per night to 1.74 times, which is a 13% decrease on average.

Most clinically important, very serious sleep problems, which were significantly associated with maternal quality of life, were reported significantly less frequently in the EIG than in the SIG.

## Publications

Logan K, Perkin MR, Marris T, Radulovic S, Craven J, Flohr C, Bahnson HT, Lack G. [Early Gluten Introduction and Celiac Disease in the EAT Study: A Prespecified Analysis of the EAT Randomized Clinical Trial](#). JAMA Pediatric 2020.

Marris T, Perkin MR, Logan K, Craven J, Radulovic S, Mclean IWH, Versteed SA, van Ree R, Lack G. [Bathing frequency is associated with skin barrier dysfunction and atopic dermatitis at three months of age](#). Journal of Allergy and Clinical Immunology: In practise 2020. 8(8): 2820-2822.

Perkin MR, Logan K, Bahnson HT, Marris T, Radulovic S, Craven J, Flohr C, Versteeg S, van Ree R, Lack G, [EAT Study Team. Efficacy of the EAT study amongst infants at high risk of developing food allergy](#). Journal of Allergy and Clinical Immunology 2019. 114(6):1606-1614.

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Voorheis P, Bell S, Cornelsen L, Gideon L, Perkin MR, [EAT Study Team. Challenges experienced with early introduction and sustained consumption of allergenic foods in the Enquiring About Tolerance \(EAT\) study: A qualitative analysis](#). Journal of Allergy and Clinical Immunology 2019. 144(6):1615 -1623

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[of early introduction of solids with infant sleep: a secondary analysis of a randomized clinical trial. JAMA paediatrics 2018, 172\(8\), e180739.](#)

Perkin MR, Logan K, Tseng A, Raji B, Ayis S, Peacock J, Brough H, Marrs T, Radulovic S, Craven J, Flohr C, Lack G; [EAT Study Team. Randomized Trial of Introduction of Allergenic Foods in Breast-Fed Infants. N Engl J Med. 2016. 5;374\(18\):1733-43.](#)

Perkin MR, Logan K, Marrs T, Radulovic S, Craven J, Flohr C, Lack G; [EAT Study Team. Enquiring About Tolerance \(EAT\) study: Feasibility of an early allergenic food introduction regimen. Journal of Allergy and Clinical Immunology 2016. 137\(5\):1477-1486.e8.](#)

Perkin MR, Craven J, Logan K et al. [The association between domestic water hardness, chlorine and atopic dermatitis risk in early life: A population based cross-sectional study. Journal of Allergy and Clinical Immunology 2016. 138\(2\):509-516.](#)

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

Flohr C, England K, Radulovic S, et al. [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.](#)

Vincent, R, MacNeill, SJ, Marrs, T, et al. Frequency of guideline-defined cow's milk allergy symptoms in infants: Secondary analysis of EAT trial data. *Clin Exp Allergy*. 2021; 00: 1– 12. doi: [10.1111/cea.14060](#)

## **Research report**

[Association of early introduction of solids with infant sleep. A secondary analysis of a randomized clinical trial](#)