TIGER

Trial of food allergy (IgE) tests for eczema relief

Does dietary advice based on routine food allergy tests improve disease control compared with standard care in children with eczema?

An individually randomised controlled trial of test-guided dietary advice for children with eczema, with internal pilot and nested economic and process evaluations

Matthew Ridd, Stephanie MacNeill, Miriam Santer, Tom Blakeman, Hannah Wardman, Ingrid Muller, Joanna Coast, Kirsty Garfield, Robert Boyle, Rosan Meyer, Isabel Skypala, Shoba Dawson, Hannah Morgans, Julie Clayton, Sara Brown, Hywel Williams.

www.bristol.ac.uk/eczema-allergy-study tiger-study@bristol.ac.uk @eczema_allergy

Background

- **Many parents of children with eczema worry that a food allergy is the underlying cause.** It can be difficult to work out just on symptoms if any given food is causing problems.
- **Parents often ask doctors about food allergy tests.** Access to food allergy tests to guide dietary advice is limited and use of them variable.
- **If parent's concerns are not taken seriously, they may be reluctant to use prescribed creams** which they think, treat the symptoms, not the cause of eczema; **and restrict their child's diet**, which can lead to problems with the child's growth and health, feeding difficulties and even increase the risk of them developing a food allergy.
- **Systematic reviews have identified a lack of good quality trials** that answer the research question, "Does dietary advice based on routine food allergy tests improve disease control compared with standard care in children with eczema?"

Objectives

- Determine the clinical effectiveness of test-guided dietary advice versus standard care, for the management of eczema.
- To evaluate the cost effectiveness of test-guided dietary advice in children with eczema.
- To assess adherence to, and safety of, test-guided dietary advice in children with eczema.
- To identify sub-groups who may preferentially benefit from food allergy testing.

Eligibility criteria

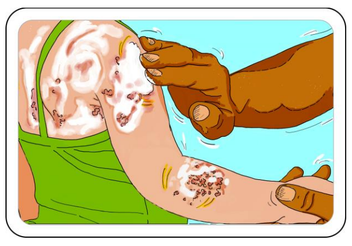
Inclusion:

- eczema diagnosed by a healthcare professional; and
- aged between 3 months and less than 2 years of age; with
- Mild or worse eczema (Patient Orientated Eczema Measure >2)

Exclusion:

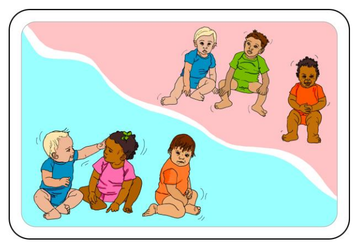
- confirmed or probable immediate (IgE-mediated) food allergy to the study foods; and/or
- previous SPT or IgE blood test for the study foods

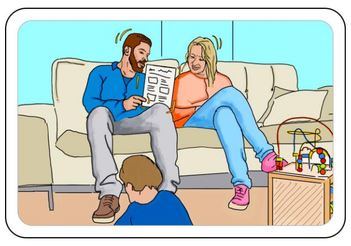
Randomised controlled trial



493 children recruited from ~84 GP surgeries. Potentially eligible children identified by electronic medical record search, and parents invited by letter/text.

Participants will be randomised 1:1 (stratified by eczema severity and centre) to intervention or standard care groups

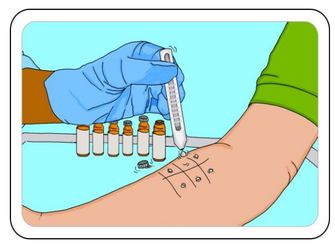


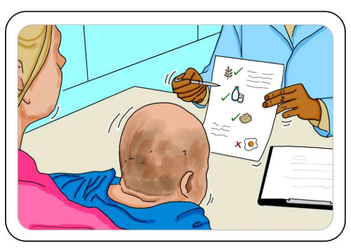


Everyone given a "Good eczema care" leaflet, with information about standard care. Optional DNA saliva sample collected.

Intervention

Children undergo skin prick tests to cow's milk, hen's egg, wheat and soy.





Based on findings, parents advised for each food to include, undertake a home dietary trial of inclusion/exclusion or exclude.

For safety, some children may need an oral food challenge at a local allergy centre.

Everyone followed-up for 36 weeks. Primary outcome RECAP (parent completed measures of eczema control) collected four-weekly for 24 weeks.

Process evaluation

- To assess fidelity, dose and reach of the intervention; clarify causal mechanisms; and identify contextual factors associated with variation in outcomes.
- Qualitative (interviews, observations and audio-recordings) and quantitative methods.

Health economic evaluation

- To compare the costs and consequences and estimate the cost-effectiveness of test-guided dietary advice versus standard care, for the management of eczema.
- The primary perspective will be NHS, with secondary analyses including non-NHS costs at 36 weeks follow-up.

FUNDED BY NIHR | National Institute for Health and Care Research

The study is funded by National Institute for Health and Care Research (NIHR) HTA programme (NIHR133464). The views expressed are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care. The study was developed with support from the UK Dermatology Clinical Trials Network (UK DCTN). The UK DCTN is grateful to the British Association of Dermatologists and the University of Nottingham for financial support of the Network.