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Parent and Baby Project

Submission date
25/03/2025

Recruitment status
Recruiting

Registration date
23/04/2025

Overall study status
Ongoing

Last Edited
08/05/2025

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background: Around 1-in-20 UK pre-school children have food allergies. These may be life-long. Allergic reactions sometimes require an adrenaline injection. They may be life-threatening. For the last 30 years, government has recommended that the introduction of solids is delayed until babies reach 6-months of age. Recent large international trials show that introducing common food allergens before 6-months-of-age can prevent food allergies. However, a previous UK trial established that UK parents were unable to introduce common food allergens earlier. Importantly, a recent trial demonstrated that only small tastes of food need to be introduced alongside breast feeding to prevent food allergy. A new approach to support parents/carers to introduce small tastes of food earlier needs to be developed and assessed.

Objectives: To see if we can prevent children developing food allergies by: (1) Working with parents/carers/guardians and healthcare professionals to produce an approach where small tastes of peanut and hen's egg are introduced from 17-weeks, (2) assessing ease and convenience of the approach, (3) assessing whether the approach can reduce food allergies without affecting children's health in other ways,(4) is affordable, and (5) plan its use across the National Health Service (NHS).

Methods: (1) Test out the new approach to allergy prevention with a diverse group of parents, carers and healthcare professionals and make any improvements, with 200 parents and carers in four diverse areas in the North-East and South-Coast; then (2) 3000 parents and carers from across UK will have an equal chance of receiving the new advice to introduce tastes from 17-weeks or from around 6-months. We will see whether early introduction of regular, small tastes of hen's egg and peanuts reduces food allergies at 12-months of age, does not impact on breast feeding and (3) is affordable. Food allergy will be diagnosed using the usual NHS approach (history, skin, blood tests or food challenge).

Patient and public involvement (PPI): The original idea came from participants in previous food allergy prevention studies. They found it difficult to introduce large amounts of food allergens before 6-months. The programme has been developed with a diverse group of parents and carers of children with and without food allergy. For example, they suggested recruiting from vaccination clinics. They felt the proposed design is feasible. Further PPI work with a wider group is ongoing. The PPI panel would be involved in the design, running, interpretation, and circulation of the programme results.

Impact: We will: (1) publish the results in medical journals, (2) present the findings at relevant medical conferences, (3) share the results with research participants and (4) other interested groups. If the new approach is successful, we will (5) work with NHS organisations to introduce it into clinical practice across the UK. If parents/carers start to introduce small tastes of food allergens earlier, the number of babies who develop food allergy could be reduced. This would positively impact families, NHS and society.

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
351201

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 57927, NIHR206263, RHM CHI1267

Study information

Scientific Title
Preventing food allergy in infants with early introduction of complementary feeding: feasibility and cluster randomised controlled trial

Study objectives
We hypothesise that a multi-level, online behavioural intervention aimed at supporting parents /carers to introduce regular, small tastes of hen's egg and peanut at 17-weeks of age, earlier than the current practice of introducing complementary feeding at around 6-months (26-weeks) will reduce the likelihood that infants have IgE-mediated food allergy at 52-weeks of age.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/04/2025, East of England - Cambridge South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 104 8096; cambridgesouth.rec@hra.nhs.uk), ref: 25/EE/0067

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Preventing food allergy in infants

Interventions
Feasibility: Cluster Controlled Feasibility Trial

We plan to recruit from four sites, allowing us to recruit a socioeconomically and ethnically diverse group. The proposed intervention group includes Newcastle, which covers a large, ethnically mixed inner-city population, and Southampton, which covers a large, less ethnically diverse inner-city and rural population. The proposed control sites are South Tees, which is a smaller, ethnically diverse city population, and the Isle of Wight, which is a small, ethnically less diverse, semi-rural population. All four areas are socioeconomically diverse. Allocating the two large sites to intervention in the feasibility study will allow a different group of general practices to be used for recruitment in the effectiveness trial to prevent contamination if the site is randomized to control.

The intervention site feasibility objectives (recruitment rate, acceptability, safety, age of introduction and frequency of consumption, proportion assessed at 30-weeks of age) mean that participants will need to be followed to 30-months of age. Participants will also be assessed at 52-weeks of age to provide them with the benefit of a food allergy assessment, but the data will not be used as part of the assessment of trial feasibility.

The control site feasibility objectives (recruitment rate, safety, age of introduction and frequency of consumption, proportion assessed at 30- and 52-weeks of age) mean that participants will be followed to 52-weeks of age.

This design has been chosen for efficiency as it allows the control groups to be recruited before the intervention is finalized. The feasibility study outcome will be collected in the same time period, minimizing the length of the program.

Effectiveness Trial (WP3)

A phase 3 cluster randomized controlled trial design. Again, the trial will use a cluster design with each site being a different hospital (although some Trusts may cover more than one hospital). This approach is taken to avoid contamination of the control group given it is a multilevel intervention, i.e., aimed at HCPs as well as parents/carers. An internal pilot would assess recruitment in the first 6-months of recruitment.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
New onset IgE-mediated food allergy at 52-weeks of age to peanut and/or hen’s egg on the basis of IgE-mediated symptoms and evidence of specific IgE-sensitisation

Key secondary outcome(s))
Measured at 52 weeks' of age using patient records and questionnaire:
1. New onset IgE-mediated food allergy at 52-weeks of age to any food.
2. Age of introduction of peanut, hen’s egg, and cow’s milk, and consumption frequency (information will also be collected about other allergenic foods, including those frequently consumed by specific population groups such as lentils).
3. Resource use and quality of life.
4. Growth (reported weight and length at 12-months of age).
5. Breastfeeding.
6. Adverse events (AEs) elicited by:
- Questionnaires (such as choking, anaphylaxis, allergic reactions).
- Medical notes review (such as respiratory tract infections).

Completion date
31/12/2028

Eligibility

Key inclusion criteria

1. Infants aged 0-3 months and their parents/carers
2. Willing and able to give written informed consent

Participant type(s)
Carer, Other

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
0 months

Upper age limit
3 months

Sex
All

Key exclusion criteria
1. Pre-existing food allergy to both peanut and hen's egg.
2. Previous child enrolled in the feasibility or effectiveness trial to prevent an infant experiencing environmental exposure to a food allergen when they are not eating; this does not exclude twins or other multiples being recruited into the study as one time point into the same cluster and therefore allocation.
3. Any major feeding issues unless feeding/gastroenterology clinic say are happy that infant is included.
4. Severe neurodisability that would make early complementary feeding inappropriate.
5. Significant developmental delay (e.g., extremely preterm infants, infants with genetic conditions such as trisomy 21) that would make early complementary feeding inappropriate.
6. Inherited metabolic disorders that necessitate specific feeding regimes.

Date of first enrolment
31/05/2025

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Isle of Wight NHS Trust Nmp
St Mary's Hospital
Parkhurst Road
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PO30 5TG

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
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Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
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Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes