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The allergy in the community trial: Reducing the burden of food allergy care in tertiary services

Submission date	Recruitment status	☐ Prospectively registered
03/02/2017	No longer recruiting	☐ Protocol
Registration date	Overall study status	☐ Statistical analysis plan
01/03/2017	Completed	☒ Results
Last Edited	Condition category	☐ Individual participant data
22/06/2020	Digestive System	

Plain English summary of protocol

Background and study aims
A food allergy is when the body's immune system reacts to specific types of foods. They can cause itchy throats, rashes, swelling of the face and other body parts, vomiting and even death. Food allergies are becoming more and more common in children and babies. This means that a lot of children end up on hospital waiting lists for specialist allergy advice. The current wait list time for an appointment with the allergy clinic at the Royal Children's Hospital (RCH) in Melbourne, Australia is around 18 months. Therefore, new ways of caring for babies and children with possible food allergies needs to be explored, such as encouraging community based care for children with food allergies by providing special training for paediatricians. This study aims to improve the management of food allergies in babies and children and to see if community pediatricians can look after children with possible food allergies in a similar way to the RCH allergy specialists.

Who can participate?
Families of children aged between 0-12 who are referred to the Royal Children's Hospital Allergy Clinic.

What does the study involve?
Families are allocated to one of two groups based on when they were recruited and if they are willing to participate in the study. Families in the first group receive the standard level of care at the Royal Children's Hospital (RCH) Allergy Clinic, which involves being placed on the waiting list to see an allergist specialist. Those in the second group are given care from a community pediatrician and are removed from the RCH allergy clinic waiting list. The community pediatricians are trained by allergist specialists. Children have two appointments with the community paediatrician to run tests for possible allergies and to be instructed on treatment and care. Children who do have a food allergy are followed up one year after their first appointment with the pediatrician or with their GP. Families fill in three surveys at the beginning of the study, and fill in follow up surveys six and 12 months after the treatment. These surveys ask about time taken to be seen by a doctor for the child's allergy, child's wellbeing, what happened during the visit to the general pediatrician or allergy clinician (including diagnoses made), family out of pocket costs for care and satisfaction with their care.

What are the possible benefits and risks of participating?
Children seen by a community pediatrician may benefit by having their food allergy assessed and managed sooner (and closer to their home) than they would have if seen at the Royal Children's Hospital allergy clinic. There are no notable risks to children or families by taking part in the trial.

Where is the study run from?
Murdoch Children's Research Institute, The Royal Children's Hospital (Australia)

When is the study starting and how long is it expected to run for?
July 2015 to July 2018

Who is funding the study?
Royal Children's Hospital Foundation (Australia)

Who is the main contact?
Professor Harriet Hiscock
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Study website
http://www.rch.org.au/ccch/research-projects/Allergy_in_the_Community_Trial_(ACT) /
https://www.mcri.edu.au/research/projects/allergy-community-trial-act

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
Reducing the burden of food Allergy Care in Tertiary services: A controlled trial

Acronym
ACT

Study objectives
The new model of community care, when compared to standard care delivered at the RCH Allergy Clinic, will result in more timely access to assessment and will be of comparable safety, quality and satisfaction. The new model will improve child and family quality of life 6 and 12 months post recruitment and will be of lower cost to the healthcare sector.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Committee Royal Children's Hospital, 10/07/2015, ref: 35133

Study design
Single-centre prospective controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Patient information material can be found at: http://www.rch.org.au/ccch/research-projects/Allergy_in_the_Community_Trial_(ACT)/

Health condition(s) or problem(s) studied
Food allergy

Interventions
Participants are allocated to the control or to the intervention group based on when they were recruited. During May and June 2016, general community-based pediatricians are trained in the diagnosis and management of simple food allergy (the intervention) by allergy specialists.

The control group consists of newly referred children who have simple food allergies that are recruited over an eight month period (August 2015 to May 2016) who remain on the Royal Children's Hospital (RCH) Allergy Clinic waitlist. These children are assessed and managed as per the RCH Allergy Clinic's usual procedures.

The intervention group consists of participants recruited from the RCH Allergy Clinic wait list. Participants are recruited over a eleven-month period (June 2016 to May 2017) and are offered the opportunity to be assessed and followed up by a general pediatrician for the initial diagnosis and then a GP or the general pediatrician for their annual follow up if a diagnosis of a food allergy is made. They are removed from the RCH waiting list once they are agreed to participate. Participants have one or two appointments with the pediatrician. The first appointment consists of the pediatrician taking a history and, if necessary, organizing tests for possible food allergy. The food allergy test involves participants giving a single blood sample which can measure up to 4 possible food allergies, as dictated by the clinical history. This appointment should only take 45 minutes. The second appointment (if needed) takes approximately 30 minutes. It consists of families receiving test results and follow up care if a food allergy diagnosis is confirmed. Children who receive a diagnosis of food allergy have an annual review appointment approximately 12 months after their initial appointment, either with the pediatrician or their GP, at the family's discretion.

Families fill in three surveys at the beginning of the study, and follow up surveys six and 12 months after the treatment. These surveys ask about time taken to be seen by a doctor for the child’s allergy, child's wellbeing, what happened during the visit to the general pediatrician or allergy clinician (including diagnoses made), family out of pocket costs for care and also satisfaction with their care.

Intervention Type
Other

Primary outcome measure
Time to assessment by an allergy clinician or general pediatrician is measured from the date of enrollment in the trial to the date of the first consultation as recorded on the community pediatrician-completed Consultation Records (new model) or the RCH electronic medical record system (IBA/EPIC, RCH Allergy Clinic) as soon as possible after the initial consultation has occurred.

Secondary outcome measures
Current secondary outcome measures as of 30/11/2017:
Child / family outcome measures:
1. Safety of care is measured by the number of food-related adverse events (including anaphylaxis), to any food, experienced by each child. A food-related adverse event is based on parent report of reactions the child had to any food in the last 6 months.
2. Parent satisfaction with the overall process is measured on a study-designed Likert scale where 1 = not at all satisfied and 7 = extremely satisfied and The Parent Medical Interview Satisfaction Scale (PMISS) collected via parent surveys at 6 and 12 months
3. Food allergy-related child anxiety and family quality of life are measured by the Food Allergy Quality of Life Questionnaire Parent Form (FAQLQ-PF) at baseline, 6 and 12 months
4. Health service use and costs for food allergies including use of pharmaceuticals, alternative therapies and other health professional attendances are collected via parent surveys at baseline, 6 and 12 months

Consultation outcomes:
1. Quality of care delivered by the clinician (community pediatrician and RCH allergy clinician) at the initial consultation(s) based on an assessment of the clinician's management as documented in the Consultation Record. The assessors will be blinded to the identity of the clinician but not to the clinician's discipline (ie community pediatrician or RCH allergist) as the consultation record form is slightly different for pediatricians and allergists.
2. Acceptability of the new model, measured by the proportion of eligible families in the intervention cohort who consent to attend and actually attended general pediatrician care.
3. Change in community-based pediatrician knowledge of food allergy diagnosis and management is measured using study-designed allergy questions to assess practices taught in the training, 11 items from the Chicago Food Allergy Survey for Primary Care Physicians, 7 items from the ASCIA Food allergy e-training for dieticians and health professionals survey, and 1 study designed item. Change in pediatrician perceived competency in managing food allergy is measured by study-designed, 5-point Likert scales at 4 and 14 months post completing the allergy training. For GPs, this is measured using study designed questions to test their knowledge of appropriate management at two months post completing the allergy training.
4. Healthcare costs of the allergy consultations are measured by information provided on the community-based pediatrician and allergy clinician Consultation Records at any time after the consultations have occurred, as well as, by direct observation of a subset of control group families on the day of their appointment at the RCH allergy clinic.

Previous secondary outcome measures:
Child / family outcome measures:
1. Safety of care is measured by the proportion of children reported to experience a food-related adverse event (including anaphylaxis) to any food they are suspected of being allergic to (for children who have not yet been seen by a clinician), the proportion of children reported to experience a food-related adverse event (including anaphylaxis) specific to a food that has been diagnosed to be an allergen (for children who have seen a clinician), collected via parent surveys at 6 and 12 months. Within the intervention cohort only, safety of care will also be measured by the proportion of children with conflicting history and serum specific results who are appropriately referred back to the RCH Allergy Clinic for care, as per the community-based pediatrician completed Consultation Record as soon as possible after the consultation has been completed (i.e. after the initial consultation and follow up consultation, if required).
2. Parent satisfaction with the overall process is measured on a study-designed Likert scale where 1 = not at all satisfied and 7 = extremely satisfied and The Parent Medical Interview Satisfaction Scale (PMISS) collected via parent surveys at 6 and 12 months
3. Food allergy-related child anxiety and family quality of life are measured by the Food Allergy Quality of Life Questionnaire Parent Form (FAQLQ-PF) at baseline, 6 and 12 months
4. Health service use and costs for food allergies including use of pharmaceuticals, alternative therapies and other health professional attendances are collected via parent surveys at baseline, 6 and 12 months

Consultation outcomes:
1. Quality of care delivered by the clinician at the initial consultation is measured based on blinded assessment of the clinician's management documented in the Consultation Record any time after the initial consultation has occurred. Added 31/05/2017: Assessment is blinded to the identity of the clinician but not to the clinician's discipline; community pediatrician or RCH allergist, as the consultation record form is slightly different for paediatricians and allergists.
2. Acceptability of the new model, measured by the proportion of eligible families in the intervention cohort who consent to attend community-based pediatrician care at baseline.
3. Change in community-based pediatrician knowledge of food allergy diagnosis and management is measured using study-designed allergy questions to assess practices taught in

the training, 9 items from the Chicago Food Allergy Survey for Primary Care Physicians, 8 items from the ASCIA Food allergy e-training for dieticians and health professionals survey, as well as change in pediatrician competency and confidence in managing food allergy measured by study-designed, 5-point Likert scales at 6 months post completing the allergy training. For GPs, this is measured using study designed questions to test their knowledge of appropriate management at two months post completing the allergy training.
4. Healthcare costs of the allergy consultations are measured by information provided on the community-based pediatrician and allergy clinician Consultation Records at any time after the consultations have occurred, as well as, by direct observation of a subset of control group families on the day of their appointment at the RCH allergy clinic.

Overall study start date
10/07/2015

Completion date
01/07/2018

Eligibility

Key inclusion criteria
1. Families of children aged 0 to 12 years
2. Referred to the RCH Allergy Clinic waitlist by GPs (or non-paediatrician specialists)
3. Suspected/known simple food allergy to the following foods: peanuts, soy, wheat, cow’s milk, egg, shellfish, sesame, and treenuts (i.e. cashew nuts, walnut, almond, pecan, pistachio)

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
376

Total final enrolment
373

Key exclusion criteria
1. Complex food allergy
1.1. History of anaphylaxis as the primary presentation for new assessment or review (difficulty breathing, persistent cough, wheeze, change in voice, or pale and floppy/collapse within 2 hours

of food ingestion)
1.2. Severe eczema as the primary presentation (these children often have more complex allergies)
1.3. Multiple food group allergy (i.e. clinical reaction to > 3 foods; each treenut is treated as a different food)
2. Drug allergy, or any other non-food allergy (e.g. dust, chemicals)
3. Urticaria with no identified allergen (ie unknown if allergy is food or non-food related)
4. Insufficient English to complete questionnaires
5. Children referred by a pediatrician or allergist (these children are fast tracked for an allergy appointment at The RCH)
6. Children referred by The RCH Dermatology department (these children usually have severe eczema as the primary presentation)
7. Children referred specifically for oral food challenges. These challenges need to be done in a hospital setting. These include children who have been seen previously by an RCH allergy clinician, and have been referred for oral food challenge/s
8. Referrals initially made outside the study period

Date of first enrolment
06/09/2015

Date of final enrolment
30/05/2017

Locations

Countries of recruitment
Australia

Study participating centre
The Royal Children's Hospital
50 Flemington Road
Parkville
Melbourne
Australia
3052

Sponsor information

Organisation
Murdoch Children's Research Institute

Sponsor details
Murdoch Childrens Research Institute
Royal Children's Hospital
50 Flemington Road
Parkville, Melbourne, Victoria

Australia
3052

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/048fyec77

Funder(s)

Funder type
Charity

Funder Name
Royal Children’s Hospital Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal and planned presentation at relevant conferences.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Harriet Hiscock (Harriet.hiscock@rch.edu.au).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2020	22/06/2020	Yes	No
Results article	results	01/08/2020	22/06/2020	Yes	No