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Patterns of Adult Food Allergy (PAFA-Stage 1)

Submission date
22/07/2019

Recruitment status
No longer recruiting

Registration date
08/08/2019

Overall study status
Ongoing

Last Edited
31/07/2019

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Many people in the UK suffer from food allergies and intolerances, which cause problems for them when choosing what to eat, buying food, and eating outside the home. Although this is well recognised in children, it affects many adults too. Researchers would like to find out how many adults in the UK have food allergies and intolerances. In this study a community survey in Greater Manchester, Isle of Wight, and Southampton will allow adults aged 18-70 to report their experiences of symptoms related to eating food, excluding food poisoning. The study locations are representative of populations within the UK and will allow us to collect food allergy information on a diverse range of ethnic groups and backgrounds.

Who can participate?
People aged between 18 and 70 years old registered with GP practice in Greater Manchester, Southampton, or Isle of Wight, and participants in one of the Isle of Wight FAIR food allergy cohorts

What does the study involve?
Volunteers are invited to take part in the questionnaire through their local GP surgeries and can respond online, by post, or telephone. Additionally, a group of participants from a previous food allergy study (Food Allergy and Intolerance Research [FAIR]) will be invited to complete a modified version of the community survey. All questionnaire responses are transferred to a secure online research platform (REDCap). Participants are identifiable only by their unique identification number (UID) linked to their questionnaire response. Participants are invited to indicate their interest in receiving further information to take part in allergy assessments.

What are the possible benefits and risks of participating?
The benefits to participants is that they will be invited to participate in Stage 2 of the study and will be further evaluated as to any food or associated allergy to e.g. pollen that they might have. Also, the data gathered in this study will contribute to our understanding of food allergy which will help update current public health policies regarding food allergy including prevention and treatment so may benefit patients in the future. There is a small potential risk of causing upset if for example an invitation letter is sent to a deceased person. Every effort will be made by the GP practice to use current up to date GP record information to contact potential participants to avoid this situation.

Where is the study run from?
Universities of Manchester, Southampton, and Amsterdam University Medical Centre with Manchester Foundation Trust, University Hospital Southampton and Isle of Wight NHS Trusts (UK)

When is the study starting and how long is it expected to run for?
November 2018 to October 2028

Who is funding the study?
Food Standards Agency

Who is the main contact?
Dr Elaine Gauson
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Study website
www.foodallergens.info

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 1

Study information

Scientific Title
Patterns and prevalence of adult food allergy in a UK population (PAFA-Stage 1)

Acronym
PAFA

Study objectives
Individuals affected by food allergy experience considerable illness, with all aspects of their lives being affected by a restricted diet and the risk of future reactions. Furthermore, individuals with IgE-mediated (immune response) allergies can experience severe, reactions which can be fatal. IgE- mediated food allergy is responsible for 65% of hospitalisations due to adverse reactions to food. Like many immune-mediated conditions, allergic disease, including food allergy, results from complex interactions between genetic and environmental risk factors which result in differences in incidence between rural and urban communities. More evidence is required about the prevalence of adult food allergy and intolerance such as the patterns and risk factors linked with its development in order to develop effective policies seeking to manage, prevent and treat such conditions. This information is also valuable for making decisions about which foods to include on priority lists for allergen labelling, such as Annex II of the Food information for consumers regulation (FIR) and to support approvals of novel foods and processes (including foods from Genetically Modified Organisms).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending. This study will be subject to an ethical approval submission to the Research Ethics Committee (REC) (IRAS number 260430) and the study team aim to submit this in July 2019.

Study design
Multicentre study which uses two complementary epidemiological approaches:
1. A cross-sectional study (community survey)
2. Follow-up of the Food Allergy and Intolerance Research (FAIR) food allergy cohorts (population cohorts)

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Home

Study type(s)

Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Adult food allergy

Interventions
Community Survey (Questionnaire 1A)
Adults aged 18-70 years old living in Greater Manchester, Isle of Wight and Southampton will be invited by their local GP to take part in a short questionnaire (Questionnaire 1A- 2 pages) about food allergy. Overall, an estimated 35,000 invites will be sent. The GP surgeries involved in the study will send a letter (Letter 1A) to potential participants informing them about the study along with the Participant Information Sheet (PIS 1A) (explains the study, the role of the participant, how data will be used, and important contact information of the study team), and a paper copy of the questionnaire with a paid reply envelope. This will be posted to potential participants using contact information held in GP records through an outsourced mailing company (e.g. Docmail which is routinely used by GP practices). At the bottom of the questionnaire a statement translated into languages relevant to the study population (e.g. Urdu and Hindi) will state that the study documents are also available in other languages upon request.
The questionnaire can be completed by participants in one of three ways; online using a unique link associated with a unique identification number (UID) provided to the participant, by completing the paper questionnaire and posting it back to their local study centre (Manchester Foundation Trust, University Hospital Southampton NHS Foundation Trust, and Isle of Wight NHS Trust), or by telephone (on NHS-based telephone number provided in the postal letter) with a member of the research team quoting their UID. The study researcher will enter the questionnaire responses given over the telephone by the participant into the e-Questionnaire directly. Postal responses will also be transcribed by a study researcher and entered into the e-Questionnaire using a computer based in the relevant NHS Trust. In addition, if potential participants have a mobile phone registered with their GP, they will receive a text message reminder (from their GP surgery via an EMIS approved text message service e.g. MJOG), with the link to the online questionnaire, a few days after receiving the written information through the post. A digital copy of the PIS will also be made available to participants who respond to the questionnaire on digital devices.

Cohort Survey (Questionnaire 1B)
In addition to the community survey, previous participants of the FAIR cohort will be re-contacted and invited to take part in the survey (subject to permission to obtain contact details being sought from CAG as part of this application). The original UID for FAIR cohort participants will be reused. Documents will be sent to each FAIR participant including an explanatory cover letter (Letter 1B) from the FAIR study team, the participant information sheet 1B (PIS 1B) and a food allergy questionnaire (Questionnaire 1B) with a reply paid envelope. The questionnaire will be the same as the community survey with the addition of a few questions about asthma, eczema and allergic rhinitis. Participants can respond to Questionnaire 1B using the same methods as the community survey (1a).

Participants of Questionnaire 1A and B will be eligible to enter a prize draw for £250 of vouchers (e.g. Amazon, or love2shop). All responses to the questionnaires (1A and B) will be gathered

together on a secure online research platform called REDCap, allowing for data sharing and analysis of pseudonymised data (personal information such as name and address will not be linked to questionnaire responses). It is estimated that there will be 10,000 responses from the community survey (1A) and 2,300 responses from the cohort survey (1B). Only those within the study team with permission to view and analyse the data will be granted access using a secure login and password. Participants will be asked at the end of the questionnaire "Can we contact you with information about the second stage of the study?". Participants that indicate an interest may be invited to take part in follow-up allergy assessment visit (blood and skin prick tests) as cases and controls based on their responses to the questionnaire.

Intervention Type
Other

Primary outcome measure
The estimated prevalence of self-reported adverse reactions to foods in UK adults measured using a community–based survey in the Greater Manchester area, Southampton and Isle of Wight and follow-up of a population-based cohort, FAIR. Participants will be invited to respond to the questionnaire in one of three ways; by post (paper), telephone, or online. Survey completed at a single timepoint.

The community-based survey will cover the following variables to describe demographics using simple descriptive statistics:
1. Age (18-29 years, 30-39 years, 40-49 years, 50-59 years, 60-69 years)
2. Gender (male, female, transgender, prefer to self-describe, prefer not to say)
3. Ethnicity (options under the categories: White/Caucasian, mixed/multiple ethnic groups, Asian /Asian British, Black/African/Caribbean/Black British, Other ethnic group)
4. Centre (Manchester, Southampton, Isle of Wight)

The community-based survey will cover the following variables to estimate the prevalence of self-reported adverse reactions to foods:
1. Presence of symptoms associated with IgE and non-IgE mediated adverse reactions to food(s) (symptoms: Itching, tingling or swelling in the mouth, lips or throat, a rash, nettle sting like rash or itchy skin, diarrhoea or vomiting (other than food poisoning), stomach cramps, other digestive problems, a runny or stuffy nose, red, sore or running eyes, difficulty swallowing, breathlessness, stiffness in your joints, fainting or dizziness, headaches)
2. Timing with regards to onset of adverse reactions to foods following consumption (0-2 hours, 2-4 hours, 4-12 hours, >12 hours)
3. How often they have experienced symptoms (Only once, 2-4 times, more than 4 times)
4. Food(s) towards which reactions are experienced (select options from list of 41 foods or answer alternative food in free text).
5. Whether they have been told by a doctor that they have a food allergy (yes/ no)

FAIR cohort survey will also include extra self-reported measures:
Additional yes/no questions about asthma, eczema, and hay fever are included in the survey

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/11/2018

Completion date
31/10/2028

Eligibility

Key inclusion criteria
1. Community survey
1.1. Must be aged between 18 and 70 years old
1.2. Registered with GP practice in Greater Manchester, Southampton, or Isle of Wight

2. Population cohorts
2.1. Participant in one of the Isle of Wight FAIR food allergy cohorts

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10,000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
30/08/2019

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester University NHS Foundation Trust (Wythenshawe)
Southmoor Rd
Wythenshawe

Manchester
United Kingdom
M23 9LT

Study participating centre
University Hospital Southampton NHS Foundation Trust
Mailpoint 18
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Isle of Wight NHS Trust (St Mary's Hospital)
Pankhurst Road
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Study participating centre
University of Manchester
Manchester Institute of Biotechnology
John Garside Building 1.021
Oxford Road
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M13 9PL

Study participating centre
University of Southampton
Paediatric Allergy and Respiratory Medicine
Tremona Road
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Sponsor information

Organisation
Manchester University NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Ownership of the data arising from this study resides with the Food Standards Agency. The Food Standard Agency has provided a perpetual licence for the University of Manchester, University of

Southampton and Amsterdam University Medical Centre to utilise the data for research and clinical activities. The study data will be analysed and disseminated via research publications in peer-reviewed journals. An anonymised dataset will be made available by the FSA to be accessed through the gov.uk website working with organisations such as ONS. The findings of the project will also be disseminated at conference presentations.

Intention to publish date
31/10/2021

Individual participant data (IPD) sharing plan
Data for publication will be re-coded and all links broken to any participant identifiable information. Individuals will not be identified. Summary statistics will be published rather than individual-level data. An anonymised dataset will be made available by the FSA to be accessed through the Government website working with organisations such as ONS. Participants may access the results of the study on these publicly available websites.

IPD sharing plan summary
Other