

# Patterns of Adult Food Allergy (PAFA-Stage 1)

<b>Submission date</b> 22/07/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/08/2019	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/07/2019	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

elaine.gauson@manchester.ac.uk

## Contact information

### Type(s)

Public

### Contact name

Dr Elaine Gauson

### ORCID ID

<https://orcid.org/0000-0001-8384-0854>

### Contact details

Manchester Institute of Biotechnology

School of Biological Sciences

The University of Manchester

John Garside Building 1.028

Oxford Road

Manchester

United Kingdom

M13 9PL

+44 (0)161 3065 795

elaine.gauson@manchester.ac.uk

## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Quality of life

## **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(s)

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

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**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  
Newport  
Isle of Wight  
United Kingdom  
PO30 5TG

**Study participating centre**  
**University of Manchester**  
Manchester Institute of Biotechnology  
John Garside Building 1.021  
Oxford Road  
Manchester  
United Kingdom  
M13 9PL

**Study participating centre**  
**University of Southampton**  
Paediatric Allergy and Respiratory Medicine  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

## **Sponsor information**

**Organisation**  
Manchester University NHS Foundation Trust

**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

## 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes