Addressing inequalities in the management of food allergy in South Asian adults – a qualitative study shaping composite supportive interventions (The FAIR Study)

Healthcare Professional Participant Information Sheet

Researchers at University Hospitals Birmingham NHS Foundation Trust, University of Birmingham and University of Surrey have designed a new intervention to support food allergy self-management in South Asian adults (aged ≥16 years) with a clinically diagnosed food allergy. They would like to find out about your views on the intervention as a healthcare professional and how it could help patients from a South Asian background (e.g., Indian, Sri Lankan, Pakistani, Bangladeshi) with food allergy.

Before you decide if you would like to participate, please take time to read the following information.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear or if you would like more information before you make your decision.

Description of the proposed study

We would like to understand your views on newly developed interventions, aiming to improve self-management in patients from a South Asian background with food allergy. The design and content of this intervention has been informed by the views of other healthcare professionals who review patients with food allergy as well as South Asian adults with food allergy. We are now interested to hear healthcare professionals and patients thoughts of this intervention, including its feasibility in routine clinical practice.

Your feedback will help shape the further development of these interventions.

Invitation to participate

You are being invited to take part in this study because you have identified yourself as a healthcare professional who reviews and manages patients from a South Asian background (aged ≥16 years) diagnosed with food allergy.

What would taking part involve?

If you are happy to participate, you will be invited to take part in a focus group with other healthcare professionals who review and manage patients from a South Asian background with food allergy. Before the start of the focus group you will be asked to complete a consent form, showing you understand the research and that you want to participate in the research. During the focus group, the researcher will share the content of the interventions with the group members and you will be able to share your views on the intervention. The focus group will last around 90 minutes, depending on how much the group have to say. Focus groups will take place at Birmingham Heartlands Hospital or online.

To be able to take part in this research, please note the focus group's format as follows:

- All group members will respect everybody's opinions.
- All group members will ensure what is discussed in this focus group remains' within this

focus group. Group members will not discuss other member's confidential information with people outside of the group.
• When one person is speaking, others in the group will listen to what they have to say.
• When one person is speaking, other members will wait for them to finish speaking before they speak.

During the focus group you can choose to skip any questions that you find difficult. You are free not to answer any questions that are asked, without giving a reason. At any point during the focus group you can choose to stop and withdraw from the study.

With your permission we will audio record the focus group and take notes. Your name will be removed from the recording so no one will know it was you. The recording will be typed into a document (transcribed). This process will involve removing any information which may identify you e.g. names, locations etc. The digital recording from your focus group will either be transcribed by an external agency approved by University of Birmingham, or by a member of the research team, within 48 hours of the research being conducted. Once the audio recording has been transcribed and anonymised, your data cannot be withdrawn. Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

What are the possible benefits of taking part?

While there are no direct benefits to you of taking part in this study, understanding healthcare professional's views on our new intervention content will be very helpful to us find new and betters ways to support patients from a South Asian background manage their food allergy. All travel costs to participate in this study are reimbursed.

What are the possible disadvantages and risks of taking part?

If you decide to take part in this research, you may need to take time out of your day to travel to and from your focus group location. Efforts will be made to lessen this burden by arranging a convenient time and place for focus group to be held.

We do not expect there to be any risks to you in taking part in this study. However, in the unlikely event that you become upset during the group discussions, you will have the option to stop participating in the research and the researcher will support you.

What if there's a problem?

If you have any concerns about taking part in this study, please speak to a member of the research team in the first instance, and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If you are unhappy with their response or wish to make a complaint you can do so via the Sponsor's Research Governance Office by emailing:
Researchgovernance@contacts.bham.ac.uk

If you wish to raise a concern about how your data is being used you can contact the University's Data Protection Officer by emailing: Dataprotection@contacts.bham.ac.uk

What will happen if I don't want to carry on with the study?

You are free to stop the interview and withdraw from the study at any point without giving a reason. After your interview you will have 48 hours to withdraw your data, after this point your interview transcript will have been anonymised and cannot be withdrawn.

How will my information be kept confidential?

Your participation in this research will be kept confidential. A code will be attached to all the data you provide to maintain confidentiality. We will ensure that anything you have told us that is included in the reporting of the study will be anonymous.

Your personal data (name and contact details) will only be used if the researchers need to contact you to arrange the focus group or collect data. Analysis of your data will be undertaken using coded methods. The data we collect will be stored in a secure document store (paper records) and electronically on a secure encrypted mobile device or password protected computer server.

Confidentiality may need to be broken in cases where sensitive information is disclosed that could reveal potential harm to yourself or another person, which will be discussed with the research participants and escalated to the research team. Should there be any concerns over the welfare of any person, the focus group will be stopped and local safety procedures followed, in addition the University of Birmingham's protocol for information sharing will be implemented.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your

- Initials
- Name
- Contact details
- Job role
- Gender
- Ethnicity

People will use this information to do the research or to check your data to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your data in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to
- by sending an email to The Data Protection Office at dataprotection@contacts.bham.ac.uk

Results of the study

The results of this study may be published in scientific journals and/or presented at conferences. Anonymised quotes may be used in any reports or publications resulting from the research. If the results of the study are published, your identity will remain confidential.

A summary of the study results will be available for participants when the study has been completed and the researchers will ask if you would like to receive a copy.

Who is organising, insuring and funding this study?

This study is organised by researchers at University Hospitals Birmingham, University of Birmingham and University of Surrey. The study is funded by the National Institute for Health and care Research (NIHR).

This study is sponsored by the University of Birmingham, the University has in place Clinical Trials indemnity coverage for this study, which provides cover for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the study and may alternatively, and at the discretion of the University provide cover for non-negligent harm to participants. University of Birmingham employees are indemnified by the University insurers for the design or co-ordination of the study they undertake whilst in the University's employment. The NHS has a duty of care to its employees and patients and in the event of clinical negligence being proven, compensation will be available via the NHS indemnity.

How have patients and the public been involved in this study?

Our Patient and Public Involvement (PPIE) group of patients with lived experiences of food allergy and representatives from UK Allergy charities have reviewed this document and helped create the questions you will be asked during the interview. The PPIE group meet with the research team regularly to make sure their ideas and suggestions are at the centre of this project.

Who has reviewed this study?

This study has been given a favourable ethical opinion by the [Name] Research Ethics Committee (date).

What if relevant new information becomes available?

If relevant new information becomes available, the research team will respond to this accordingly in a timely manner.

What to expect during the consent process

If you would like to take part in the research, please contact a member of the research team, whose details can be found below. A member of the research team will send you two forms to complete and return to the research team. The first is a consent form, which will ask you if you understand the research and are willing to take part in the research. The second will ask you questions about yourself. If you are willing to consent to the study and you meet the requirements for this research, a researcher will contact you to organise a suitable time and date for your interview.

Further information and contact details

If you would like further information about this research, please contact a member of the research team, whose details can be found below.
To speak to an independent advisor, you can contact: Patient Advice and Liaison Service (PALS) at University Hospitals Birmingham NHS Foundation Trust. Email: pals@uhb.nhs.uk Tel: 0121 424 0808

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