

Participant Information Sheet Parents or guardians

Study Title

Supporting self-management for young people with food allergy at risk of anaphylaxis:
developing digital resources

What is it like to be a young person with severe food allergy who could have anaphylaxis, or their parent or carer?

Researchers: Elizabeth Angier, Ingrid Muller, Leanne Morrison, Paul Turner, Miriam Santer

You are invited to take part in a research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information. You may like to discuss it with others, but it is up to you to decide whether or not to take part. If you are happy to take part you will be asked to sign a consent form.

What is the study about?

Anaphylaxis is a severe and potentially life-threatening allergic reaction to a trigger, such as a known food. Symptoms can include difficulty in breathing or speaking, collapse, or rash.

We would like to understand what it is like for young people who live with severe food allergy and risk of anaphylaxis symptoms. We'd also like to hear from their parents and carers too. We're keen to find out when and where young people and their parents or carers seek help, support or information for severe reactions to food, such as anaphylaxis, and how this affects their daily life. Knowing more about this will help us to provide better support for young people with this condition and their parents or carers. We hope to design a digital resource that can help young people with self-management of their food allergy with the information we obtain.

This study is funded by the Natasha Allergy Research Foundation and is being run (and sponsored) by the University of Southampton.

This is a PhD project, and the researcher has worked in the allergy community and with allergy support groups and has an interest in improving allergy care for young people.

Why have I been invited?

You have been asked to take part in this study because:

- You are the parent or carer of someone with this condition.

We are interested in talking to parents or carers of young people from different backgrounds with different levels of severe food allergy and anaphylaxis.

We anticipate including a maximum of 65 people in the study 20 of which will be parents or carers.

Do I have to take part?

No. You can decide whether you want to take part or not. If you decide to take part, you will sign a consent form to show you have agreed to take part. For young people aged under 16 then the parent or carer will also need to sign a consent form.

What will happen to me if I take part?

The researcher will contact you to arrange a time to have a chat about your experiences of severe food allergy and anaphylaxis. This can be by phone or videoconference (e.g., TEAMS or Zoom) depending on what you prefer. The call will take 30 minutes to an hour. With your permission, this conversation will be recorded and transcribed (to written text). All personal details that could identify who you are will be removed.

The research project is expected to last four years.

Are there any benefits in my taking part?

You will be given a **£15 gift voucher** for taking part in the study. You will also help researchers understand how to better support young people with anaphylaxis and their parents or carers.

Are there any risks involved?

There are minimal risks to taking part in this study. You may find it upsetting to talk about your experiences. If this happens, we will stop the interview and give you details where you can get advice and support. If we think that you or someone else might be at risk of harm we will share our concern with your GP.

What data will be collected?

The researcher will ask questions about what it is like for you to be a parent or carer of someone who lives with severe food allergy who may be at risk of anaphylaxis, including:

- How you manage their severe food allergy on a day-to-day basis
- Your thoughts and feelings about health.

You will also be asked your age gender and ethnicity. You do not have to answer any questions if you do not want to.

What happens to the data being collected?

After the call, the recording will be put on a university password-protected computer and deleted from the recording device. The recording will be typed up by a professional transcriber or a member of the research team. They will keep everything they hear private

and will type code names instead of your name and any other names or places, so no-one can find out who you are. We will delete all audio recordings after checking the transcripts. Only the written transcripts will be analysed.

We will review what you have told us and put that together with what other parents or carers in your situation tell us. This will help us find out what can be helpful. Your personal details and code name will be stored separately from the typed-up record of the call and audio-recordings; all of this information will be stored securely on computers at the University of Southampton and will only be accessible by the research team. We will delete the personal details that match your code name at the end of the study.

Will my participation be confidential?

Your participation and the information we collect about you will be kept strictly confidential. We will not share the audio recordings of what you tell us with anyone who is not a member of the research team. We follow strict regulations about how health research is carried out. At times, individuals from regulatory authorities may require access to the information we collect about you to check that we are carrying out the research correctly. Only individuals from regulatory authorities will be able to see your information. These people have a duty to keep your information strictly confidential.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part. You can let the study team know by following this link if you want to take part.

What happens if I change my mind?

You have the right to change your mind and withdraw without giving a reason and without your routine care being affected.

If you decide this during the interview this will be stopped at the time. Withdrawal of data after the data has been coded and processed would not be possible. You can contact the study team on this email to withdraw.

What will happen to the results of the research?

Your personal details will remain strictly confidential. A summary of what we find out will be published in scientific journals and presented at research conferences and shared with charities. You can receive a copy of the results if you wish. We may use short written quotes from the interview but none of your personal details that could identify you will be used (like your name).

What do I need to do now ?

Please either follow the QR code and link to leave your details and the study team will contact you, or if you prefer to fill in the reply slip which can be returned by freepost and we will contact you.

If you have any questions about this study, please see our study website XXX or contact:

Elizabeth Angier
Primary Care Research Centre
University of Southampton
Aldermoor Close
Southampton
SO16 5ST

Email: eea1u17@soton.ac.uk

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researcher (eea1u17@soton.ac.uk) who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Thank you for taking the time to read the information sheet
and considering taking part in the study.

This page explains how health researchers use information from patients. If you are asked to take part in research, you can ask what will happen in the study.

What is patient data?

When you go to your GP or hospital, the doctors and others looking after you will record information about your health. This will include your health problems, and the tests and treatment you have had. They might want to know about family history, if you smoke or what work you do. All this information that is recorded about you is called patient data or patient information.

When information about your health care joins together with information that can show who you are (like your name or NHS number) it is called identifiable patient information. It's important to all of us that this identifiable patient information is kept confidential to the patient and the people who need to know relevant bits of that information to look after the patient. There are special rules to keep confidential patient information safe and secure.

What sort of patient data does health and care research use?

There are lots of different types of health and care research.

If you take part in a clinical trial, researchers will be testing a medicine or other treatment. Or you may take part in a research study where you have some health tests or answer some questions. When you have agreed to take part in the study, the research team may look at your medical history and ask you questions to see if you are suitable for the study. During the study you may have blood tests or other health checks, and you may complete questionnaires. The research team will record this data in special forms and combine it with the information from everyone else in the study. This recorded information is research data.

In other types of research, you won't need to do anything different, but the research team will be looking at some of your health records. This sort of research may use some data from your GP, hospital or central NHS records. Some research will combine these records with information from other places, like schools or social care. The information that the researcher collects from the health records is research data.

Why does health and care research use information from patients?

In clinical trials, the researchers are collecting data that will tell them whether one treatment is better or worse than other. The information they collect will show how safe a treatment is, or whether it is making a difference to your health. Different people can respond differently to a treatment. By collecting information from lots of people, researchers can use statistics to work out what effect a treatment is having.

Other types of research will collect data from lots of health records to look for patterns. It might be looking to see if any problems happen more in patients taking a medicine. Or to see if people who have screening tests are more likely to stay healthier.

Some research will use blood tests or samples along with information about the patient's health. Researchers may be looking at changes in cells or chemicals due to a disease.

All research should only use the patient data that it really needs to do the research. You can ask what parts of your health records will be looked at.

How does research use patient data?

If you take part in some types of research, like clinical trials, some of the research team will need to know your name and contact details so they can contact you about your research appointments, or to send you questionnaires. Researchers must always make sure that as few people as possible can see this sort of information that can show who you are.

In lots of research, most of the research team will not need to know your name. In these cases, someone will remove your name from the research data and replace it with a code number. This is called coded data, or the technical term is pseudonymised data. For example, your blood test might be labelled with your code number instead of your name. It can be matched up with the rest of the data relating to you by the code number.

In other research, only the doctor copying the data from your health records will know your name. They will replace your name with a code number. They will also make sure that any other information that could show who you are is removed. For example, instead of using your date of birth they will give the research team your age. When there is no information that could show who you are, this is called anonymous data.

Where will my data go?

Sometimes your own doctor or care team will be involved in doing a research study. Often, they will be part of a bigger research team. This may involve other hospitals, or universities or companies developing new treatments. Sometimes parts of the research team will be in other countries. You can ask about where your data will go. You can also check whether the data they get will include information that could show who you are. Research teams in other countries must stick to the rules that the UK uses.

The bigger research team may include people who check the quality of the research. Regulators may also need to check the research. They will compare the recorded research

data with your health records. They might read your health records through a secure internet connection or at the hospital or clinic. All the computers storing patient data must meet special security arrangements.

If you want to find out more about how companies develop and sell new medicines, the Association of the British Pharmaceutical Industry has [information on its website](#).

What are my choices about my patient data?

- You can stop being part of a research study at any time, without giving a reason, but the research team will keep the research data about you that they already have. You can find out what would happen with your data before you agree to take part in a study.
- In some studies, once you have finished treatment the research team will continue to collect some information from your doctor or from central NHS records over a few months or years so the research team can track your health. If you do not want this to happen, you can say you want to stop any more information being collected.
- Researchers need to manage your records in specific ways for the research to be reliable. This means that they won't be able to let you see or change the data they hold about you. Research could go wrong if data is removed or changed.

What happens to my research data after the study?

Researchers must make sure they write the reports about the study in a way that no-one can work out that you took part in the study.

Once they have finished the study, the research team will keep the research data for several years, in case they need to check it. You can ask about who will keep it, whether it includes your name, and how long they will keep it.

Usually your hospital or GP where you are taking part in the study will keep a copy of the research data along with your name. The organisation running the research will usually only keep a coded copy of your research data, without your name included. This is kept so the results can be checked.

If you agree to take part in a research study, you may get the choice to give your research data from this study for future research. Sometimes this future research may use research data that has had your name and NHS number removed. Or it may use research data that could show who you are. You will be told what options there are. You will get details if your research data will be joined up with other information about you or your health, such as from your GP or social services.

Once your details like your name or NHS number have been removed, other researchers won't be able to contact you to ask you about future research.

Any information that could show who you are will be held safely with strict limits on who can access it.

You may also have the choice for the hospital or researchers to keep your contact details and some of your health information, so they can invite you to take part in future clinical trials or other studies. Your data will not be used to sell you anything. It will not be given to other organisations or companies except for research.

Will the use of my data meet GDPR rules?

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

Universities, NHS organisations and companies may use patient data to do research to make health and care better.

When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a 'legitimate interest' in using patient data.

Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'.

If they could do the research without using patient data they would not be allowed to get your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

What if I don't want my patient data used for research?

You will have a choice about taking part in a clinical trial testing a treatment. If you choose not to take part, that is fine.

In most cases you will also have a choice about your patient data being used for other types of research. There are two cases where this might not happen:

1. When the research is using anonymous information. Because it's anonymous, the research team don't know whose data it is and can't ask you.
2. When it would not be possible for the research team to ask everyone. This would usually be because of the number of people who would have to be contacted. Sometimes it will be because the research could be biased if some people chose not to agree. In this case a special NHS group will check that the reasons are valid. You can opt-out of your data being used for this sort of research. You can ask your GP about opting-out, or you can [find out more](#).

Who can I contact if I have a complaint?

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer.

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).