Participant Information Sheet

Family experiences of EEG testing and infantile epilepsy diagnosis: Online Survey study (EPIC FAMILY)

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

Why have I been invited to take part?

We are asking parents or carers to take part in a survey if:

- They have a child who has had an Electroencephalogram (EEG) for suspected epileptic seizures, including infantile spasms.
- Their child was under two years of age at the time of EEG.
- Their child received the EEG in the UK.
- They are English language speaking and able to complete an online survey.

What is the purpose of the study?

Epilepsy is one of the most common neurological problems in young children, especially under age 5. But in babies, it can be hard to recognise because seizures don't always look typical. Movements like brief staring, twitching, or unusual movements, may be seen as normal behaviours and get overlooked. This can delay diagnosis, which may affect brain development, learning, and mental health.

Sometimes the healthcare professionals you see may not have experience in recognising all the seizure types in babies. To confirm epilepsy, hospital doctors need to do a special test called an **EEG** (electroencephalogram), which can help to confirm or rule out epilepsy. If a child might have epilepsy, it is important they get an EEG test quickly. This test can help doctors understand what is going on however, it can sometimes take a long time to get a hospital appointment and to have the test done.

In recent years, these tests have increasingly been conducted by the hospital team in the patient's home (sometimes called an 'ambulatory' EEG). However, this approach is highly labour-intensive and time-consuming. Additionally, it can be challenging for parents to bring their baby to the hospital and support the testing process over an extended period. For these reasons, our team of researchers want to create a 'remote' EEG that will be available for family members to use in the community (at home or at the GP for example). This device would not require a doctor's referral or a hospital visit for setup; instead, it could be easily put in place by families in their own homes. This could allow families to have an EEG more quickly if there are suspicions their child may have epilepsy, without the need for a referral to a hospital. This research is called the **EPIC Project** (Enabling the early and equitable diagnosis of epilepsy in infants in the community).

Before we develop the remote EEG device, we want to learn from families who have had experience of EEG testing for suspected or confirmed epilepsy in an infant. To do this, we are inviting you to take part in a study, called **EPIC Family** to complete an online survey. The survey will ask families about their experiences and views. This can help us understand what families feel worked well and what could be improved. We're also interested in families' views on our remote EEG. We want to make sure it's something that families would find easy to use, helpful and as stress-free as possible for children and families.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw and not finish the survey without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you or your child receives, or your legal rights. Please take as much time as you need to consider if you would like to take part in our study.

If you do decide to take part, you can keep this information sheet and provide consent online before you complete the survey.

What will happen if I take part?

The survey will include questions about your child's EEG testing, diagnosis and experiences, and will ask you to share your thoughts on a remote EEG device that could help detect epilepsy earlier in infants at home, rather than in a hospital. The survey is intended to be anonymous and no personal data will be requested. We expect the survey will take around 15-20 minutes to complete. The survey will be conducted through a platform called Jisc, the University of Edinburgh's approved secure online survey tool.

You can complete the survey online at any time or anywhere that is suitable to you, there is no requirement for you to attend any hospital or healthcare practice. The survey might address some sensitive topics, so you may wish to complete it in a private setting. You can share as much or as little information about your experience as you feel comfortable with. We ask that you do not include any identifiable information about yourself or your child, including names, hospitals, doctors' names, dates of birth, etc.

At the end of the survey, there will be an option for you to:

1) Express your interest in taking part in an online Focus Group to further discuss your experiences with our research team. This would involve meeting with a small number of other families online to discuss your views on the topics in more detail.
2) Express your interest in hearing more about 'family representative' opportunities in the wider **EPIC Project**. These opportunities might include providing feedback on our study, providing suggestions to make our device as easy to use and as

accessible as possible, or helping shape communication with the public. You will not be asked to share any personal experiences, unless you would like to.

If you are interested in finding out more about the Focus Group or Family Representative roles, you can provide your contact details (email or phone number). This will be securely stored on a password protected University database, accessible only to the research team. Your personal contact information will be kept separately to the information provided in the survey, and there will be no way to link survey information to your details.

Providing your contact details at this stage does not mean that you are obliged to take part in further studies or take on any roles. The research team will only contact you to send you information and you will be given time to make any decisions.

What are the possible benefits of taking part?

There are no direct benefits to you taking part in this study, but we hope the results from this study might help to improve care for children with epilepsy and improve the experiences of their families.

What are the possible disadvantages of taking part?

It is possible that completing this survey could be upsetting or cause you distress. You can stop or pause at any time. Our team has also compiled a Family Resource Leaflet which provides information on available support. This can be found at (https://usher.ed.ac.uk/research/medical-informatics/projects/epic)

What if there are any problems?

If you have a concern about any aspect of this study, please contact epic.team@ed.ac.uk who will do their best to answer your questions.

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

You can choose to withdraw from the study at any time, up to the point you submit (complete) the survey. Once you press the submit button, we will not be able to remove your data as it cannot be linked back to you.

What happens when the study is finished?

The University of Edinburgh will securely store the information we collect for 10 years, following the end of the EPIC Project. It may also be used in the future for other research projects, but only if those projects have been approved by an ethics committee. If your data is used in this way, it will be fully anonymised, this means that anything that could identify you will be removed.

As the online survey does not collect any identifiable information, there will be no way for us to directly inform you of the study results, however, the findings will be published on our project website (https://usher.ed.ac.uk/research/medical-informatics/projects/epic) and shared with epilepsy charities and community groups.

Will my taking part be kept confidential?

Survey

All the information we collect during the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. The survey data is fully anonymised as no personal identifiable information is collected. The anonymised survey data will be securely archived for 10 years and then destroyed.

Focus Group

If you decide to opt-in to be contacted by our research team to find out more about the focus group or family representative opportunities, your contact details will be securely kept in an encrypted folder within the University of Edinburgh server. Only the research team will have access to this folder. Following the completion of the study and your involvement, your contact information will be securely destroyed.

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

You can find out more about how we use your information

- by sending an email to epic.team@ed.ac.uk or
- by ringing us on 07471 400 322

For further information about how the University of Edinburgh will use your personal data please see https://data-protection.ed.ac.uk/privacy-notice-research

What will happen to the results of the study?

You or your child will not be identifiable from any published results.

We plan to write up the results of this study as research papers which may be published in medical and/or research journals. Our results might also be presented at conferences.

We will also write a summary of our results for the public and this will be posted on our study website: https://usher.ed.ac.uk/research/medical-informatics/projects/epic In addition, we'll share our findings with the charity organisations that helped promote this study and ask them to pass the information on to their communities.

Who is organising and funding the research?

The study has been organised by the EPIC study team, located at the University of Edinburgh, and sponsored by ACCORD (Academic and Clinical Central Office for Research and Development) (AC25187). The study is being funded by UK Research and Innovation and Engineering and Physical Sciences Research Council (EPSRC). The researchers involved in this study have been employed by the University of Edinburgh to conduct this study.

Who has reviewed the study?

All research is looked at by an independent group of people called an Ethics Committee. A favourable ethical opinion has been obtained from Edinburgh Medical School Research Ethics Committee (EMREC@ed.ac.uk) (25-EMREC-084).

Clinicians and family representatives have helped design this survey to make sure it is easy to understand, asks questions that matter to patients and parents, and collects useful information. They were also involved in planning how the survey will be shared to ensure it reaches as many people as possible.

Researcher Contact Details

If you have any further questions about the study, please contact The EPIC study team on 07471 400 322 or email on: epic.team@ed.ac.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the study, please contact Dr Tallur (Paediatric Neurologist): Krishnaraya.KamathTallur@nhs.scot

Complaints

If you wish to make a complaint about the study, please contact: resgov@accord.scot