Dr Charlotte Tye, BEE Study,
Institute of Psychiatry, Psychology & Neuroscience,
De Crespigny Park, London, SE5 8AF
Email: beestudy@kcl.ac.uk
Website: www.*beestudy.co.uk*
Phone: +44 (0)207 848 0238

Study title: Brain development in Early Epilepsy (BEE)

Principal Investigator: Dr Charlotte Tye

Ethical Clearance Reference Number: 21/LO/0813 IRAS Ref: 292574

Parent Overview Information Sheet

We are inviting you and your baby to take part in the Brain development in Early Epilepsy (BEE) Study. Before you decide whether you would like to take part, it is important for you to understand why the research is being done and what it will involve. This information sheet has two sections: **Section 1** is a general overview of the study and **Section 2** describes what the study involves in more detail. Please take time to read the information carefully, and discuss it with friends, relatives and your GP if you wish. Take time to decide whether or not you wish to take part. If you decide to take part or you would like more information, please contact us (details provided at the top and bottom of this information sheet).

Section 1: BEE Study Summary

The overall goal of the BEE Study is to identify differences in the development of babies with epilepsy, and to find out whether these early differences predict later behaviour. The findings from this study will improve our understanding of the association between epilepsy and different behavioural outcomes, such as difficulties with social communication (e.g. autism spectrum disorder). In addition, the findings may inform the development of early interventions to improve behavioural outcomes in the future. The study is funded by an Epilepsy Research UK and Autistica fellowship, and co-sponsored by King's College London and Guy's and St Thomas' NHS Foundation Trust.

To achieve this, we have developed baby-friendly assessments that are sensitive to changes in development that may be associated with behavioural outcomes (e.g. behavioural and brain development). All of our assessments can be completed in the family home, including EEG to record babies' brain activity, play-based tasks, questionnaires and interviews with parents to better understand babies' brain, cognitive and behavioural development. We are aiming to complete these assessments with parents and babies with epilepsy at multiple time-points, starting around the time of their first seizure, then again at 10, 14 and 24 months old. Our goal is to recruit a total of 80 infants (aged between 1 and 10 months) with diagnosed or suspected infantile spasms and/or focal seizures to take part. By tracking these changes in development over the first two years of life, we hope to be able to inform ways to support children with early-onset epilepsy.

In order to test whether there are specific differences in early development in babies with epilepsy, we will compare these measures to babies who do not have epilepsy. We will also compare these measures to babies with an elevated likelihood of having a condition affecting the brain and development.

If you are interested in participating, please read on to find out more about the BEE Study.

Section 2: Detailed information about the BEE Study

Who is organising and funding the research?

The study is co-sponsored by King's College London and Guy's and St Thomas' NHS Foundation trust. This study is part of a wider collaboration between the co-sponsors, and Birkbeck, University of London. The Chief Investigator is Dr Charlotte Tye, who is based in the Department of Psychology at King's College London. This study is funded by two UK research charities called Epilepsy Research UK and Autistica. Autistica is a charity which funds and campaigns for research to understand the causes of autism, improve diagnosis, and develop evidence-based interventions for those who need support. Epilepsy Research UK is a medical research charity dedicated to funding and supporting research into epilepsy. This study has been scientifically reviewed and given a favourable opinion by Epilepsy Research UK and Autistica, including review by patient representatives.

Why am I being asked to participate?

You have been invited to take part in the BEE Study because you have a baby aged between 4 weeks and 10 months old with a diagnosis or possible diagnosis of epilepsy (infantile spasms and/or focal seizures). You must be at least 16 years old to participate, and able to understand and communicate in English.

How will families be recruited?

Families will hear about the BEE Study through a variety of routes including, clinical sources (lead clinician(s) and specialist clinics), parent organisations and support groups, Epilepsy Research UK, Autistica and other charities, social media and online advertising.

How will families be involved?

Families will be asked to take part in one session by telephone/video at entry to the study around the time of seizure presentation (between 1 and 10 months old) and three home-based sessions when your baby is around 10, 14 and 24 months old (see Visit Flowchart included in this pack).

If you wish to participate, a researcher will contact you to collect background information in order to determine whether this study is suitable for you and your baby. If the study is not suitable for your family, you can choose to join our database to hear about other future studies that might be a better fit. If the study is suitable, we will contact you to arrange the remote session and a convenient time to visit and conduct the home-based sessions with you and your baby.

If further funding and ethical approval are secured, we will ask to see all participants at 36 months of age and beyond to assess developmental outcome. If you agree to take part in the BEE Study, you will be asked whether you are happy to be contacted about participation in future studies. Should you choose not to be recontacted, your participation in this study, any future research and clinical care, will not be affected.

What will happen during the remote testing session?

A typical remote session will take approximately 6 hours to complete over a two-week period. You may

complete the tasks in your own time and take as many breaks as you require. You will be asked to record videos of you and your baby completing a number of short tasks and games, each examining a different area of development, and varying according to your child's age. You will be provided with written instructions on how to complete these short tasks and games and will be able to contact the research team if you are unsure what to do. You will also be asked to complete some activities as part of the TeachBRITE app, which suggests individualised tasks for you to complete with your baby to track their developmental ability. You will be provided with a unique code to access the app and may download the app on to a compatible device. In addition, you will be asked to provide some information about yourself, your child and your family via online surveys or phone interviews. These questions will relate to you and your child's health and wellbeing and your child's development and behaviour. Some of these questionnaires are compulsory for you to be included in the study, however your decision to take part in the study as a whole is completely optional. For information on what will happen during the remote testing session please see the Remote Testing Session Information Sheet.

What will happen during the home-based testing sessions?

Assessments with your baby will last approximately 3 hours, including time for breaks. During the visit, your child will complete a number of short tasks and games, each examining a different area of development, and varying according to your child's age (see the Visit Flowchart included in this pack). These may include watching animations on a screen or playing with you and the researcher. We will use an eye-tracker to record your baby's eye movement patterns and EEG to record your baby's brain activity while they are watching animations on a screen (see Eye-Tracking Information Sheet and EEG Information Sheet included in this pack). These tasks and games are designed to be fun and stimulating for babies. You will be present with your child throughout and are welcome to ask questions at any time.

We know babies have a limited attention span, and therefore the duration of the tasks and games we will use have been shown to be acceptable to babies. In addition, we will use different types of tasks and games and different methods of measuring responses with you and your baby, to ensure you are not doing the same activity for too long. While the tasks we use target the development of specific abilities over time, each session is adapted for each child's specific age and individual needs. This means that we take as many breaks as your child needs to feed, rest, or play. We will do our best to make your visit as comfortable and enjoyable as possible. After your last session you may be asked to fill in an optional anonymous feedback form, which will help us to improve our project in the future.

Questionnaires and Interviews

We will give you a number of questionnaires about your child's behaviour and development to fill out in your own time or during our visit. These usually take around 2 – 2.5 hours to complete at each time point and can be completed online, on the phone/video or in person, at your preference. At some time-points we might require more detailed information that we can ask you in an interview in person or over the phone. These will include questions about your child's motor abilities (such as whether they can grasp objects or crawl), vocalizations (for example, the sounds your baby makes), as well as their behaviour in everyday settings. Some of these questionnaires and interviews are compulsory for you to be included in the study, however your decision to take part in the study as a whole is completely optional.

We will also ask you to provide some information about you (and your partner, if this applies) as this will help us to find out more about your family. The questions relate to your medical history, personality traits and wellbeing. You may find some of the questions relate to sensitive topics, for example symptoms of depression or anxiety. If you do not feel comfortable answering any of these questions, you do not have to answer them. If you wish, you may discuss any questions you find difficult to answer with us on the phone or when we visit you. The start of the online survey or postal questionnaire pack contains links to services and helplines if you feel distressed and would like to seek support. These links will also be shared at the end of the survey or questionnaire pack.

For the remote testing session, interview measures will be completed over the phone/video call and will take approximately 1.5 hours to complete. During home visits, interviews can be completed during the visit or over the phone/video call at your preference and will take approximately 1 hour to complete. With your permission, we will also request information from your child's Personal Child Health Record (i.e., Red Book). This will help us to get information about how babies are in their everyday environment.

Video recordings

With your permission we request remote and home-based sessions of you and your child to be recorded on video. During home-based assessments, this will be carried out by research assistants. Video recordings of the study sessions will only be used for research purposes. Only researchers involved in the study and our collaborators will have access to and watch these videotapes. Video recordings will be saved on password protected and/or encrypted King's College London computers, accessible only to researchers involved in the study. We have enclosed an additional optional consent form if you are happy for us to use your child's photo or video for dissemination (e.g. conferences, publications) and training purposes.

Clinical records

With your permission, we will also request information from your baby's clinical records, including EEGs that have been conducted as part of their routine clinical care. This will help us to understand how brain and cognitive development is associated with certain features of epilepsy. An expert member of the research team working at Guys' and St Thomas' NHS Foundation Trust will look at the clinical EEGs. This will involve access to identifiable data. This review will not inform clinical care.

Will I be reimbursed for my time?

You will not be directly reimbursed for your participation in the study, but we will provide you with a small gift at each time-point (such as a t-shirt, toy, a tote bag, or voucher to the value of £10) to thank you for your ongoing participation in the study.

Are there any risks of taking part?

This project has received clearance from the NHS National Research Ethics Committee *(<21/LO/0813>).* All our techniques are widely used in infant research and have been for many years. There is no evidence of any disadvantages or risks associated with taking part in the study. Should there be safeguarding/clinical concerns or risk identified at any point in the study, we may raise this with your child's lead clinician or general practitioner. For more information see below section on '*When might confidentiality be broken*?'

Could Covid-19 restrictions affect my ability to take part?

It is likely that we will be living under some Covid-19 restrictions for some time, so we are taking extra precautions to ensure your safety at home. We will follow government guidelines, including wearing PPE (face masks, shields and gloves), social distancing where possible, and disinfecting all equipment before and after use. If you have any concerns, please contact the research team (beestudy@kcl.ac.uk).

Are there any benefits of taking part?

You will have the opportunity to learn more about research on epilepsy, behaviour and early development. We will keep you informed about the progress of the study and key findings by newsletter and social media. We will ask for your consent to store your contact details to share this information with you. Your participation in the study will help us to understand differences in early development of babies with epilepsy, and whether any of these differences predict later behavioural outcomes. This may inform the development of interventions to improve outcomes in the future.

Data handling and confidentiality

All information collected in the BEE Study will be stored securely and kept confidential. At the beginning of the study, your child will be given a unique ID number. This will provide a secure link between your child and any personal or identifying information (such as names and addresses), to allow different pieces of data to be associated with each other. We will keep all identifiable information separate from research data. You and your child's identifiable information will only be accessed by members of the research team, or by appropriately trained members of regulatory authorities or our sponsoring organizations on a strict need to know basis. The only exception to this is identifiable video recordings/pictures of you or your child that you may consent to being published for research purposes. This is completely optional and will not affect your study participation if you choose to not consent to this. Personal information will be kept securely in locked file cabinets, in locked rooms or on password protected and/or encrypted computers at King's College London. No identifiable information about you or your child will be shared with researchers outside the research team or your child's care team.

The data will be securely stored in this form for 25 years after we complete data collection. This is because we may receive funding to conduct future follow-up studies of children who have participated in our research, and we would like to let you know about these opportunities. You can ask for us to break this link at any time. If you do not wish to hear about future opportunities for you and your child, please let us know and we will remove your contact details from our database.

Research data may be shared with other approved researchers, but only using a secure electronic database and after removing all identifying information. In addition, retained data may be used in future studies subject to further ethical approval. Any data sharing and transfer arrangements are compliant with UK GDPR Data Protection Act 2018 and King's College London and Guy's and St Thomas' NHS Foundation trust policies (see below).

How will you use information about me?

We may need to use information from you, your child and your child's medical records for this research

project. This information will include:

- Name
- Contact details (postal address, email address, telephone number)
- NHS number
- Identifiable video recordings/images of you and your child for research purposes (this is entirely optional and we will need your consent before using this information)

People will use this information to do the research or to check your records to make sure 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 my choices about how my 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 records 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 that we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can I find out more about how my information is used?

You can find out more about how we use your information at:

- NHS Health Research Authority: www.hra.nhs.uk/information-about-patients
- King's College London privacy notice: www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research
- Guy's and St Thomas' NHS Foundation Trust privacy notice: www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx
- By contacting the Data Protection Officers based at King's College London (Albert Chan: info-compliance@kcl.ac.uk) or at Guy's & St Thomas' NHS Foundation Trust
- By asking one of the research team (see contact details at beginning and end of this leaflet).

When might confidentiality be broken?

In line with the law, we will never share your identifiable data outside the research team or your child's clinical care team without your consent. The only exception to this is if we are concerned that you or your child's well-being or safety is at risk. If there is a serious risk concern, we may have to share this with key researchers on the study team (Dr Charlotte Tye and Professor Tony Charman) and your child's clinical care team. We may also have an obligation to disclose information to statutory authorities. If this were the case, the research team will follow standard safeguarding protocols and any safeguarding concerns will be communicated to you as protocol permits.

What will happen with the results of the study?
We will use data collected during the study to publish reports in scientific journals so that our findings will be peer-reviewed. We will also communicate our findings to the public through our website and other sources, including Epilepsy Research UK and Autistica. Published reports on the results will not mention individuals.

Will my doctor be informed about my taking part in the study?
We will inform your general practitioner and/or lead clinician(s) that you are taking part in the study. This is to ensure that your doctor is aware of the additional assessments we will be doing with your child and so that he or she can advise on your suitability to take part.

Do I have to take part?
Taking part in this study is entirely voluntary, you do not have to take part. You should take time to read all the information sheets, ask any questions and consider the answers, before deciding whether to take part or not. If you decide to take part, you will be asked to sign a consent form to show you have agreed to take part. Whether or not you decide to take part, the healthcare services or care you and your child receive and your participation in any future research will not be affected.

What will happen if I do not want to carry on with the study?
Participation in the study is entirely voluntary. In order for you to participate in the study, you are required to complete a core set of assessments, however you can choose to leave the study or terminate any study session at any time. Whether or not you participate in the study your clinical care or that of your child will not be affected in any way, neither will your participation in any future research. If you become unable to provide informed consent for your child, and no-one else can consent for your child, we will withdraw your child from the study. If your child is withdrawn from the study, we will keep any research data we have already collected, including videotapes. We will retain the minimal identifiable personal data required for audit purposes but destroy the rest securely.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions:
Principle Investigator: Dr Charlotte Tye
Email: charlotte.tye@kcl.ac.uk
Phone: +44 (0)207 848 0238

If you remain unhappy and wish to complain formally, you can do so through the channels below. If you were recruited to the study via an NHS route (e.g. your local GP):

- Guy's and St Thomas' Patients Advice and Liaison Service (PALS) on 020 7188 8801, pals@gstt.nhs.uk. The PALS team are based in the main entrance on the ground floor at St Thomas' Hospital and on the ground floor at Guy's Hospital in the Tower Wing.

- Guy's and St Thomas' governance offices at R&D@gstt.nhs.uk.

If you were recruited to the study via a non-NHS route (e.g. support groups/social media):

- King's College London research integrity office on +44 (0)20 7848 1288, research-integrity@kcl.ac.uk. The office is located at Waterloo Bridge Wing, Franklin Wilkins Building, Stamford Street, SE1 9NH.

In the event that something does go wrong, and you are harmed during the research you may have grounds for legal action for compensation against Guy's and St Thomas' NHS Foundation Trust and/or King's College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). King's College London maintains adequate insurance to cover any liabilities arising from the study.

Who should I contact for further information?
If you have any questions or require more information about this research, please contact the BEE Study team using the following details:
Email: beestudy@kcl.ac.uk
Phone: +44 (0)207 848 0238
Address*:* Dr Charlotte Tye, BEE Study, Institute of Psychiatry, Psychology & Neuroscience, De Crespigny Park, London, SE5 8AF

Thank you for your interest!