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INFORMATION SHEET FOR PARENTS

Ethical Clearance Reference Number:

Co-production of research priorities for infant epilepsy: the Brain development in Early Epilepsy Parent Priorities (BEE-PP) Project.

We would like to invite you to participate in the Brain development in Early Epilepsy Parent Priorities (BEE-PP) Project. Before you decide whether you want to take part, it is important for you to understand why this study is being carried out and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. You can contact the study team on beestudy@kcl.ac.uk if you have any questions.

What is the BEE Study?

BEE stands for... **B**rain development in **E**arly Epilepsy

The BEE Study is our wider research programme in which the BEE-PP Project sits. 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, including difficulties with social communication (e.g., autism spectrum disorder). In addition, the findings may inform the development of early interventions to improve behavioural outcomes.

Why does the BEE Study matter?

Epilepsy is a common childhood disorder of the brain where children experience seizures (also called 'fits'). The BEE Study is focused on early epilepsy. In early epilepsy, seizures start at around 4-months old and the most common seizure types are focal seizures and infantile spasms. Children with these particular seizure types and children who have their first seizure before 2-years old often find their behaviour and development is affected, including difficulties with social communication (e.g., autism spectrum disorder). These difficulties can cause stress for the child and their family, impacting wellbeing and quality of life.

What is the BEE-PP Project?

BEE-PP stands for... **B**rain development in **E**arly Epilepsy – **P**arent **P**riorities

The overall goal of the BEE-PP Project is to produce, in partnership with parents/carers of children with early epilepsy, a set of priorities for research on early behaviour and development in early epilepsy. In research, this is known as co-production. Co-production is the process of sharing power and responsibility throughout a research project and assumes that those best placed to design and deliver research are those affected by it. The study also aims to understand the impact of early epilepsy on child and family wellbeing.

Why does the BEE-PP Project matter?

It is important for us, as researchers on epilepsy, early behaviour and development, to understand features of early behaviour and development that impact wellbeing and to identify priorities for research. This knowledge will inform our wider research programme,

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the BEE Study, such that our research reflects the experiences and priorities of those affected by it. In research this is known as conducting Patient and Public Involvement (PPI). PPI is the active collaboration between patients, the public and researchers in the research process to conduct research 'with' and 'by' those affected by it, rather than using those individuals as subjects. An example of this is involvement in prioritising research topics and this is what we aim to achieve via the BEE-PP Project.

Why have I been invited to take part?

You are invited to take part because you have a child aged 4-weeks – 15-years 11 months old who was diagnosed with epilepsy between 4-weeks and 24-months old. Their seizures must not be provoked by acute conditions, such as fevers, infections, trauma, electrolyte disturbances, transient metabolic, and/or endocrine disorders. You must be at least 16 years old to take part, and able to understand and communicate in English.

What does the project involve?

Families will be asked to take part in an online survey and an optional online focus group and follow-up activities, including reviewing project outputs and writing a blog post on participation in the project. For more information on each part of the project please see below.

What will happen if I take part in the online survey?

You will be asked to complete an online survey asking about the impact of early epilepsy on your child's and family's wellbeing, as well as your priorities for research on early behaviour and development in early epilepsy. The former will include questions about the impact of your child's epilepsy on their emotions and behaviour, your family's daily life, your wellbeing and your child's sibling(s), if they have any. The latter will ask about your concerns to establish areas important to your family, such as your child's social development or sleep, as well as specifically about your priorities for research (e.g., determinants of quality of life and determinants of co-occurring conditions, such as autism spectrum disorder).

If you complete the online survey, you will have the option to enter a prize draw to win a voucher worth £25. You do not have to consent to enter the prize draw to complete the online survey. Entering the prize draw is completely optional. Whether you choose to enter the prize draw or not it will not have any negative consequences on your participation in the BEE-PP Project or any other future research.

We will also ask for your consent to be contacted about other studies in the future. You do not have to consent to this to take part in the project, and not consenting to this will not have any negative consequences on your participation in the BEE-PP Project. If you do choose to consent to this, we will add you to a contact list that we may use to send information about future studies that are relevant to families with early epilepsy. You can contact us to be removed from this list at any time.

What if I don't feel comfortable answering some of or all the questions in the online survey?

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Simply leave it blank and move on to the next one. You may complete the questionnaire in your own time. You may end your participation at any time, for any reason, and we will not ask you why. These decisions are entirely yours and we respect your wishes.

What will happen if I take part in the optional online focus group?

You are invited to take part in an optional 2-hour recorded online focus group, via the conferencing platform Microsoft Teams (for more information on video/audio recordings see below). Within the focus group you will be asked to discuss in detail topics commonly raised in responses to the online survey on the impact of early epilepsy and priorities for research. This discussion will take place with other parents/carers of children with early epilepsy and adult epilepsy patients and/or charity representatives. You will also have the opportunity to discuss topics important to you and your family as well as those identified by the online survey. Other activities in the focus group will include sharing thoughts and ideas via short surveys and digital collaborative noticeboards. You do not have to agree to take part in the optional focus group to participate in the project and taking part is entirely optional.

Furthermore, if you consent to take part in the online focus group, you will be invited to take part in two optional follow-up activities. This includes reviewing outputs from the project (parent-voiced video of research priorities, formal reports and summary infographics) and/or writing a short 200–500-word anonymous blog post reflecting on your experience in the project. You do not have to agree to take part in these additional follow-up activities to take part in the online focus group and taking part is entirely optional.

If you express an interest in taking part in the online focus group and follow-up activities, you will be contacted with more information about these activities and separate consent forms. We can reimburse parents for their participation in the focus group and follow-up activities. For more information see ‘Benefits of taking part in the online focus group’ below.

Video/audio recording

With your permission we request that the online focus group is recorded via the online conferencing platform, Microsoft Teams. A video recording of the focus group will only be used for research purposes, such as assisting the identification of participants in the audio recording. An audio recording of the focus group will be used for research and publication purposes, including conferences, in the media, on the BEE Study website, and for training purposes. The main use of the focus group audio recording will be to generate a parentvoiced video of research priorities. Only researchers involved in the study will have access to and watch and/or listen to these recordings, with the exception of audio that is used for publications. Video and audio recordings will be saved on password protected and/or encrypted King’s College London computers, accessible only to researchers involved in the study.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in any way. If you choose to take part, you will be asked to provide your consent.

What are the possible risks of taking part?

There are no risks to taking part. The project will involve completing questionnaires that ask about your family’s demographics, the impact of early epilepsy on your family (e.g., your child’s emotions and behaviours, your wellbeing, your family’s daily family life) and your priorities for research into early behaviour and development in early epilepsy (e.g., determinants of quality of life). The start of the survey contains links to services and helplines if you feel distressed while completing the survey and would like to seek support.

These links will also be shared at the end of the survey. This project also involves the option to take part in an online focus group, which will also involve the discussion of topics covered by the online survey as well as personal experiences. Focus group facilitators will not be able to directly provide support or advice but will signpost you towards appropriate resources if you feel distressed.

What are the possible benefits of taking part?

You will have the opportunity to learn more about research on epilepsy, early behaviour and development. Your participation in the project will help us to understand priorities for research on early behaviour and development in early epilepsy and the impact of early epilepsy on wellbeing. This will inform the design of our wider research programme, the BEE Study. Children with early epilepsy and their families will also benefit from subsequent research projects informed by parent priorities for research into early behaviour and development in early epilepsy identified by this project.

Benefits of taking part in the online survey:

You will have the option to be entered into a prize draw to win a voucher worth £25 if you complete the online survey. You do not have to consent to enter the prize draw to complete the online survey. Entering the prize draw is completely optional. Whether you choose to enter the prize draw or not it will not have any negative consequences on your participation in the BEE-PP Project or any other future research.

Benefits of taking part in the online focus group:

The BEE-PP Project is funded by King's College London and The Wellcome Trust and through this budget we can reimburse parents for their attendance at the online focus group and completion of follow-up activities. Other benefits include the opportunity to meet with and share experiences with other similar families and charity and patient representatives.

Rates of payment have been set in accordance with National Institute for Health Research (NIHR) INVOLVE guidelines. Further information can be found here:

<https://www.nihr.ac.uk/documents/payment-guidance-for-members-of-the-publicconsidering-involvement-in-research/27372> Focus group attendance rate:

£50 for a 2-hour meeting

Associated follow-up activity rates:

£50 reviewing outputs and resources

£25 writing an anonymous 200–500-word blog post reflecting on experience

Data handling and confidentiality

All information collected in the BEE-PP Project will be stored securely and be kept confidential. We will keep all identifiable information (e.g., names and email addresses) separate from project data. Yours and your child's identifiable data will only be accessed by members of the research team. Personal information will be kept on password protected and/or encrypted computers at King's College London. Your answers to the online survey will be stored anonymously on our server or on password protected and/or encrypted computers at King's College London, separate from personal information. No identifiable information about you or your child will be shared outside of the research team and published data will be anonymised. However, it is possible that you could be identified by direct quotes and audio clips published as part of project outputs.

We will retain your data for the duration of the project and for as long as the topic is relevant, to allow for data analysis and dissemination of our results to the wider community. All archived data will be stored in a confidential format, except for audio and video recordings. Due to the nature of this data including voices and images it is classed as

personal data by UK GDPR Data Protection Act 2018. This data will be archived separately from all other identifiable information and project data. With your permission we will retain your contact details because we may receive funding to conduct future studies on early epilepsy, behaviour and development, and we would like to let you know about these opportunities. 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.

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

Your data will be processed in accordance with the General Data Protection Regulation 2018 (GDPR). If you would like more information about how your data will be processed in accordance with GDPR please visit the link below:

<https://www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-londonstatement-on-use-of-personal-data-in-research>

What will happen to the findings of the project?

We will provide information about the findings of this study on the BEE Study website (<Beestudy.co.uk>) and social media, as well as with relevant charities helping with our research (Epilepsy Research UK, Young Epilepsy, Autistica) who will also share this information. Publications will include a detailed lay report and summary infographics of project findings, as well as a video of parent-voiced priorities for research. We also expect to publish findings in scientific journals and present findings at academic conferences. It is likely our research will be used to inform future research and research funding.

What if I change my mind about taking part?

If you decide to take part, you may withdraw at any point during the survey without giving a reason before submitting your answers by closing the browser. You may also withdraw your responses up to 30 days after submission by contacting the research team (contact details can be found at the top and end of this information sheet). We aim to publish summary data shortly after survey completion and use this information to inform topics covered in the optional focus group. For this reason, it will not be possible to withdraw your data 30 days after you have submitted the survey.

If you decide to take part in the optional focus group and follow-up activities, you may also withdraw at any point without giving a reason. If you decide you no longer want to take part in the focus group before it has started, we would appreciate it if you could inform us of your decision to no longer take part, so we have the opportunity to invite another parent/carer to attend the focus group. However, we understand that under some circumstances this might not be possible (e.g., an unforeseen emergency at the time of the focus group).

It will not be possible to withdraw audio and video recordings of the online focus group as there will be a singular audio and video recording of the meeting. Therefore, it will not be possible to remove audio and video recordings of single participants. However, you may withdraw the use of quotes and audio clips in publications up to 30 days after focus group attendance by contacting the research team (contact details can be found at the top and end of this information sheet). Video recordings will only be used for research not publication purposes (see Video/audio recordings). We aim to rapidly review responses and publish outputs. For this reason, it will not be possible to withdraw the use of quotes and audio clips in publications 30 days after you have attended the focus group.

It will not be possible to withdraw output reviews and anonymous blog posts after submission as we aim to rapidly review responses and publish outputs.

Who should I contact if something goes wrong?

If this project has harmed you in any way or if you wish to make a complaint about the conduct of the project you can contact King's College London using the details below for further advice and information:

The Chair, Psychiatry, Nursing and Midwifery Research Ethics Subcommittee, King's College London, rec@kcl.ac.uk

Who should I contact for further information?

If you have any questions or require more information about this project, please contact the BEE-PP Project team using the following details:

Email: beestudy@kcl.ac.uk

Website: www.Beestudy.co.uk

Phone: (+44) 020 7848 5272

Address: Dr Charlotte Tye, Institute of Psychiatry, Psychology and Neuroscience – PO80, De Crespigny Park, Denmark Hill, London, United Kingdom, SE5 8AF.

Thank you for reading this information sheet and considering taking part in this study.

I have read and understood this information about the BEE-PP Study.

Yes/No