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**PROFESSIONAL - INFORMATION SHEET**

**Delphi Survey**

(Version 2, 24.04.2018)

 **Project title: Core Health Outcome in Childhood Epilepsy (CHOICE)**

You are being invited to take part in a research study. Before you decide 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 with.

**Part 1** – Information about the purpose of the study and what will happen to you if you take part

**Part 2** – In-depth information about the conduct of the study

Please ask us if there is anything that is not clear to you, or you would like more information. Take your time to decide whether or not you wish to take part.

 **PART 1**

**What is the purpose of this research?**

We are a group of researchers from King’s College London dedicated to researching childhood epilepsies. This piece of research is part of a larger research project called CASTLE (changing agendas on sleep treatment and learning in epilepsy). Past research investigating interventions for childhood epilepsy have focused on stopping or reducing seizures. However, we think it is important to look at other outcomes such as a child’s learning, mental health and social support. We think it is important to include parent’s, children’s and **professional’s** opinions on what should be measured in clinical effectiveness trials. Our aim is to conduct a survey with children, parents and professionals to establish a core set of outcomes to be used in childhood epilepsy research.

**What type of professional can take part?**

We are looking for opinions of professionals who work with children with **rolandic epilepsy.** This includes: paediatric neurologists, neurologists, paediatricians, psychology professionals, epilepsy nurses, teachers etc. If your profession isn’t listed here but you think that your professional role is relevant for the survey, please get in contact with us using the email address at the end of the information sheet and we will inform you if you can take part. If you know any other relevant professionals that would like to take part, please feel free to direct them to the study website. Please do not share the link to the survey.

**Why is the focus of this research on rolandic epilepsy?**

Epilepsy is an umbrella term that covers many different types of epilepsy. The focus of this research is on improving outcomes for children with common epilepsies. Rolandic epilepsy is the most common type of childhood epilepsy. Seizures typically start at age 5 and cease by the time the child reaches adolescence. Rolandic epilepsy is idiopathic, and we do not know what causes it or why it occurs. Other types of epilepsies have different symptoms and seizures and therefore might make reaching consensus on outcomes difficult. For example, professionals that work with children with very severe syndromes might have different perspectives. This is why we have decided to focus on rolandic epilepsy for this particular study. However, the findings may be generalised to other childhood epilepsies.

**What will I have to do?**

If you are a professional that works with children with epilepsy, you have been invited to take part in an online survey known as a ‘**Delphi Survey’.** A Delphi survey takes part in **two** different rounds and is a survey designed to help achieve consensus on a topic between different groups of people. The online link to the survey should have been provided to you in the email that contained this information sheet (please contact us on the email address at the end of this information sheet if you haven’t received it).

1. In the first round - you will be presented with a list of outcomes that have been measured in previous studies of childhood epilepsy. You will be asked to rate how important you think they are on a scale of 1 (not important) to 9 (critical). You will also be given an option to add comments or any outcomes you think are missing. The link will be available for approximately 2 weeks and then the first round of the survey will close.
2. Round 2 – approximately 2-4 weeks later you will receive an email asking you to log back in to the survey. You will be asked to complete the same task of rating the outcomes from 1-9, but this time you will be able to see your previous scores from round 1, and the scores of other **all other participants from round 1.** The link to complete round 2 will be available for approximately 2 weeks. We may send email reminders if you haven’t completed the second round within the first week.

**It is important that if you volunteer to take part that you take part in both rounds of the survey so that we can gather meaningful data.**

**Do I have to take part?**

No. Your participation and is entirely voluntary. You can withdraw at any point of the study without giving a reason and it will not affect your legal rights. Completing this survey will be regarded as your implied consent to take part. Implied consent is an *assumption* or indication that a person has knowingly agreed to participate in research by performing a research activity or task. In this case, completing the survey will be regarded as implicit consent.

**Will the data be confidential?**

Yes. Only the researchers will have access to the data. Any identifying information for you will be removed before it is used in research publication. All personal information will be kept in a secure unit at King’s College London.

**What are the risks & benefits?**

The survey is very low risk. There are no direct benefits to taking part, but your opinions on the survey could help future research into childhood epilepsy.

**What happens next?**

You should have been provided a link to the Delphi survey in an email. If you have not received this link, please contact the email address below. To take part, please press the link and fill in the registration questions. This will then provide you with a unique log in I.D. Please fill out the survey. You will be sent an email reminded when part 2 is ready to start. You will need the unique I.D to log back in, so please keep it safe. If you lose your log in details, please contact the email address below.

**What happens after the survey?**

We will be conducting a face-to-face consensus meeting after the final round of the survey. This consensus meeting will last around 1-2 hours and will take place within a month of the final round of the survey. The idea is to gather some volunteers from the survey to help us decide on any outcomes that did not reach consensus. We would like parents, children and health professionals to take part. If you are interested in this, please tick ‘yes’ to the question on the registration form that asks ‘Would you like to take part in the consensus meeting?’. More information will be sent you after the survey for you to decide whether or not you would like to take part. It is entirely voluntary and you do not have to take part even if you tick ‘yes’ on the registration form.

**Questions**

If you have any further questions about the survey or consensus meeting, please do not hesitate to contact one of our research team.

**Contact details:**

* **Holly Crudgington**

Study Coordinator (CHOICE)

castle-study@kcl.ac.uk

* **Professor Deb Pal**

(Paediatric Neurologist, Chief Investigator)

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**Our address:**

King’s College London

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**This completes Part 1 of the Information Sheet.**

**If the information in Part 1 has interested, you and you are considering participation please continue to read the additional information in Part 2 before making any decision.**

**PART 2**

**What happens if I don’t want to carry on with the study?**

You can withdraw from the study at any time, even if you have registered for the first round of the survey. If you withdraw from the study, we would still like to use any information we might have already collected. However, if you want us to destroy the information we have collected from you, we will.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (020 7848 5162).

**Will my taking part in this study be kept confidential?**

Yes. We will collect information about you which could identify you personally (for example, because the information includes your name or email address). The information will be stored on computers owned by King’s College London university. These computers will be securely controlled by the research team, under the direct responsibility of Professor Deb Pal. We will use the information we collect from the survey to questions relevant to this project. The university and the hospital has a duty to ensure research conducted here is of the highest standard and auditors from the hospital may need to review any information we hold about you. The auditors will maintain the highest standard of confidentiality. Procedures for handling, processing, storage and destruction of your data are compliant with the Data Protection Act 1998.

**What will happen to the results of this study?**

The results of this research study will be published in scientific journals and may be discussed at scientific meetings. The outcomes from the survey will be used to inform a later clinical trial called CASTLE (changing agendas on sleep treatment and learning in childhood epilepsy) www.castlestudy.org.uk You will not be personally identified in any way.

**Who is funding the research?**

This study is funded by the National Institute of Health Research (NIHR) Programme Grants for Applied Research RP-PG-0615-20007. Neither the views and opinions expressed in this brochure are those of the NHS, NIHR or the Department of Health. King’s College London is sponsoring the research.

**Who has reviewed the study?**

This study has been reviewed and given favorable opinion by the Proportionate Review Sub-Committee of the North Eat – Newcastle & North Tyneside 1 Research Ethics Committee.

**Thank you for considering to take part in this research project, and taking the time to read the information sheets.**