



Cognition in Children with Epilepsy Participant/Parent Information Sheet

Study Name: Cognition in Children with Epilepsy

UCL Ethics ID: 26439/001

Principal Investigator: Dr Aswin Chari

Principal Investigator Contact: aswin.chari.18@ucl.ac.uk

You/your child 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 your time to read the following information carefully and discuss it with others if you wish. Please do not hesitate to contact us if anything is unclear or if you would like more information. 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 at any time and without having to give a reason.

You/your child can take part in the study if:

- You/your child are 5-20 years old
- Are formally diagnosed with epilepsy
- Are primarily English-speaking

You may **not** take part in this study if:

- You are below 4 years old or above 20 years old
- You do not have epilepsy
- You are unable to complete an online cognitive assessment

Thank you for reading this.

1. INTRODUCTION TO THE STUDY

This study aims to attain a profile of cognitive function in children with epilepsy using the online Cognitron platform. We would like to know more about epilepsy as a whole as well as offer insight into how far it affects a person's cognition. It is very important for us to underline that in this study, participants' data will be completely anonymised and stored on a secure platform.

2. STUDY PROCEDURE

What is the purpose of the study?

The study aims to attain a profile of cognitive function in children with epilepsy using the online Cognitron platform. Epilepsy is known to affect 1% of the population and can reduce an individual's quality of life by causing seizures and behavioural or cognitive difficulties. Currently, developmental and cognitive assessments in children are not widely available and we want to find out whether an online assessment can be helpful in improving our knowledge of how epilepsy affects cognition and development. With the results from this study, we hope to create a fuller understanding of epilepsy as well as offer insight into how far it affects a person's cognition.

Why have I been invited?

You have been invited to participate by your own choice upon seeing the advertisements for the study on social media platforms, dedicated groups, or word of mouth.

Do I have to take part?

It is up to you/your child to decide whether or not to take part. If you decide to participate, you will be given this information sheet to keep and asked to agree to a consent form on the next page. If you decide to take part, you are still free to withdraw at any time and without giving a reason. To do so, just quit the browser. However, since the data is unidentifiable, we will not be able to identify and delete your data once you withdraw.

What will happen to me if I take part?

Should you choose to participate in this study, you will go through the following steps outlined below. At any time, you are free to abandon the study.

If you/your child is aged 5-14, the parent will provide consent to participate but the child may provide assent to participate as well. If you are aged 15+, the participant will provide consent but the parents may also provide support to participate.

After consenting to partake, you will be asked a few questions regarding age, gender and epilepsy diagnosis of the person with epilepsy (you or your child). Then, you will be directed to a set of cognitive tests, which will vary slightly depending on the participant's age. If you are a parent, please complete the initial questions for your child and then hand over them for the cognitive tests.

The whole set of questions will take no more than 20-30 minutes to complete, depending on the speed with which you/your child answers.

What are the possible disadvantages and risks of taking part?

The study has no adverse health effects or risks. All performance and questionnaire data will be stored in an anonymised format. It will be stored in a secure database on the Imperial Cognitron server, which applies state-of-the-art security measures. Data will be analysed and reported in this anonymised format by the principal investigator and researchers.

The website will use standard security measures for any server on the Internet. This server has been used for the large Great British Intelligence Test, part of the BBC Horizon project and on many studies since that have investigated the impact of COVID-19 on cognition.

What are the possible benefits of taking part?

There are no health or financial benefits to taking part in the study. However, there is the benefit of helping researchers better understand what happens to cognition in children with epilepsy.

What if something goes wrong?

If you wish to complain or have any concerns about any aspect of the way you have been treated during this study, then you should immediately inform the Principal Investigator (Dr Aswin Chari – aswin.chari.18@ucl.ac.uk).

What will happen to the results of the research study?

After we have analysed the data, we aim to publish it in a major research journal. We will also share the results with the groups that supported the study, through webinars and reports. The participants' identities will remain anonymous throughout.

Who is organising and funding the research?

This study was organised by Dr Aswin Chari, who is based in the Developmental Neurosciences Division at the UCL Great Ormond Street Institute of Child Health. The study is not funded.

Who has reviewed the study?

This study was given ethical approval by the UCL Research Ethics Committee and approved by the Developmental Neurosciences Division Chair at the Great Ormond Street Institute of Child Health

Contact for Further Information

For further information, please email Dr Aswin Chari: aswin.chari.18@ucl.ac.uk

We thank you dearly for your time and participation!

TRANSPARENCY NOTICE

Summary Information sheet

In this research study, we will use information from you. We will only use information that we need for the research study. All results will be fully anonymised at all times.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study, we will save some of the data in case we need to check it **AND** for future research.

We will ensure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

HOW WILL WE USE INFORMATION ABOUT YOU?

Research Study Title: Cognition in Children with Epilepsy.

University College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

We will need to use information from you for this research project.

This information will include your age, type & frequency of seizures, current medications, and surgical history. People will use this information to analyse cognitive data.

People will not be able to see your name or any contact details. Your data will be completely anonymous.

LEGAL BASIS

As a university, we use studies to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use information from people who have agreed to participate in research. This means that when you agree to participate in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](#)

SHARING YOUR INFORMATION WITH OTHERS

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we may share your data with certain third parties.

- Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services,

or suppliers who help us carry out any of the activities described above). Our third-party service providers are required to enter into data processing agreements with us. We only permit them to process your data for specified purposes and in accordance with our policies.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR 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 as results are anonymous.

- 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 we hold about you.
- **If data will be used for future research:** If you agree to take part in this study, your data used for future research will not be able to be linked back to you.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information

- by asking one of the research team
- by sending an email to the Principal Investigator at aswin.chari.18@ucl.ac.uk

COMPLAINT

If you wish to raise a complaint on how we have handled your data, please contact the Principal Investigator in the first instance. If something is not addressed by this initial contact, you may contact the Chair of the UCL Research Ethics Committee at ethics@ucl.ac.uk.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful, you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.