

UCL GREAT ORMOND STREET INSTITUTE OF CHILD HEALTH

COGNITIVE NEUROSCIENCE AND

NEUROPSYCHIATRY SECTION

Study title: Speech and Language Neurobiology

Information for guardians of SLD participants

## INTRODUCTION

We are trying to find out if people who have difficulties with speech or language have genetic changes to their DNA, or have some very subtle differences in their brains, even though their brains look normal on standard clinical brain scans. To do this, we need to study the genetic makeup of people who have speech-language difficulties. We need to compare their brains to those of people who have no problems, using advanced techniques.

To understand if some disorders are passed on from generation to generation, we need to look at children with speech and language disorders.

We would like to ask if you would agree for your child to take part in this study, which will be conducted at the Great Ormond Street Institute of Child Health, University College London (UCL), in collaboration with research teams in Australia.

*Note that your child’s clinical care will not be affected, whether you take part or not.*

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1. **Aims of the project**

To find out the genetic and brain differences between people with developmental speech-language disorders and people who develop speech and language typically.

1. **Why is the project being carried out?**

Children are very good at learning new skills, such as those involved in speaking and learning the language in their environment. Young people with development speech-language disorders struggle expressing themselves or understanding others. We think this could be due to differences in their genetic makeup and/or subtle differences in the development of connections (“wiring”) within the brain. These connections cannot be seen on standard clinical brain scans though.

New types of genetic analyses now allow us to search for genes related to speech-language difficulties in families where several members have a speech-language disorder. These technique also allow us to look at individuals where we think their speech-language difficulties may have a genetic basis (i.e. in severe and persistent speech disorder), even though the other family members show no difficulties. We hope to discover genes that are associated with what can be debilitating communication difficulties in young people and into adulthood.

New types of brain scans now allow us to map connections important for skilled speech, language, and cognition. We also propose to compare the brain scans of people with speech-language disorders to those of age-matched typical peers.

This project will help identify the genetic and brain causes of speech-language disorders. We hope the results of this study will help us develop new therapy methods for children with developmental speech-language disorders.

1. **Why is my child invited to take part?**

We are inviting your child to take part because we would like to have genetic samples and brain images from children who have speech and/or language difficulties. We are collaborating with clinicians around the UK to contact families who may be interested in taking part.

1. **What will happen in the study?**

If you wish your child to participate, please contact the researchers Daisy Thompson-Lake or Dr Frederique Liegeois who are members of our research team (contact details at the end of this document).

The team will offer you two options.

1. Send you consent forms via post or email, that you will send back to us.
2. Send you a link to an electronic consent form via a secure system (RedCap). Redcap will store the consent form automatically on our secure server. You will be able to save a pdf copy of your consent form for your records.

The research team at UCL will answer any questions you have, and organise a date for you to visit the Great Ormond Street Institute of Child Health in London. The visit has three parts:

* You will visit us with your child for testing across speech, language and cognitive skills (see Appendix for details).
* We will ask your child to provide a saliva sample by spitting into a collection kit. We will give you a spit kit to give us around 1 teaspoon of saliva. You can do this in a private room if you wish.
* There may also be a brain scan at Great Ormond Street Hospital. We will explain the process to you and your child in detail. You can decide whether or not your child will take part in this part of the study.

The assessment rooms and scanner are located in buildings close to each other, and all testing/scanning would take place on the same day. In total your visit would last about 4 hours (with plenty of breaks).

We can also arrange the assessments across two visits if this is more convenient for you, or can offer home visits for the speech and cognitive assessment only.

To allow for a precise analysis of speech and language skills, we will video and audio record the testing. These recordings will be archived on a secure database at UCL and will only be shared with people within the team who have authorized access. They will be destroyed 3 years after the end of the study. They will only be shared outside the team if you give us we have your written permission.

When you arrive on the day of your visit, we will answer any questions you may have. We will go through the consent forms you sent us. If you sent us an electronic consent form, we will then ask you to sign it before we begin.

1. **Are there any risks or discomforts?**

Speech, language and cognitive assessments: There are no risks associated with the tests themselves. Your child may get tired during the testing session, but we will offer regular breaks and can stop the session whenever your child wishes.

Providing a saliva sample:

There are no risks or side effects from a saliva sample. Some people may be embarrassed about spitting into a container. We will offer your child a private space for collection of the sample.

Genetic tests:

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| The genetic tests we perform may tell us something about you or your wider family. This may have an impact on how family members relate to one another. We are only searching for genes that are related to speech-language disorders, but it is possible that we may find genes responsible for other genetic conditions that you do not know about. If we find that your child has any genetic condition that you do not know about, we will contact you to discuss the findings and refer your family to a genetic counsellor.  |
| Your child may be required to inform insurance companies or employers in the future of any genetic information that is learnt about them through this project. By chance, we may discover that parents and children or siblings may not be biologically related. Information regarding paternity or maternity will **not** be available through this project. If any new information about possible risks becomes known during the project, we will tell you immediately. If you have any questions with regards to any of this information then please contact us.  |

Scanning: Great Ormond Street Hospital as made a video explaining what it is like to have an MRI scan when you are a hospital patient (<https://www.youtube.com/watch?v=oYDaPHf4ESQ>). As your child will have a research scan, she/he will be NOT be sedated during the scan and can watch a movie. We would encourage you to watch this video with your child before attending. We will explain every step to you on the day. The MRI scanning is quite noisy, but your child’s ears will be protected by headphones, and your child can watch a DVD during the scan. The scan will last about 20 minutes.

If your child does not like the feeling of being confined for too long, or does not like the noise, she/he can press a buzzer and will be taken out of the scanner immediately. For safety reasons, people with implanted metal devices or other metal objects in their body may not be able to receive an MRI examination. If you have any queries regarding the presence of metallic implants, surgery or metallic dental work, please let us know.

Procedures regarding the identification of abnormality on MRI:

Although very unlikely, there is a possibility that an abnormality may be picked up during the research scan. A neuroradiologist will look at your child’s scans. If anything atypical is found, we will discuss this with you, and we will inform your GP promptly with your permission. Please note however that your child will have a research scan. Research scans are not optimized to detect abnormalities, which means they may not detect some types of brain conditions.

**Please complete your child’s GP contact details on the form provided and bring this with you to your child’s appointment.**

1. **What are the potential benefits?**

This research project may not bring any immediate benefits to you and your child. However, we hope that in due course, the information we obtain from this research project will help improve the quality of life for children with developmental speech-language disorders.

If you wish, you can receive a report about your child’s strengths and weaknesses from the assessments we carry out.

Once your child has taken part in this project, you can ask us to send the results to your child’s clinical care team. This may help them make decisions about what to do next to help your child. Speak to us if you would like us to do this.

1. **Reimbursement**

We will reimburse the travel expenses you incur during your visit as well as lunch. We can give your child a picture of their brain to take home if they wish.

1. **How will identifiable data be stored?**

Identifiable data relating to participants (such as dates of birth, names, addresses, medical conditions) are entered in the Patient Identity Database together with a unique number (“patient identify number or PIN”). The database is specific to this study and is held on the University College London (UCL) SLMS Data Safe Haven. This is a technical environment for receiving, handling and storing sensitive data securely, which has been certified to ISO27001 standard and conforms to the NHS information Governance Toolkit. Only team members who have undergone information governance training can access the database.

1. **Who will have access to my data?**

Only researchers involved in the study will have access to your child’s data collected during this study.

When you agree to take part in a research study, the information about your child’s health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your child’s information will only be used by organisations and researchers to conduct research in accordance with the *UK Policy Framework for Health and Social Care Research***.**

This information will not identify your child and will not be combined with other information in a way that could identify your child. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your child’s care. It will not be used to make decisions about future services available to your child, such as insurance.

UCL will keep your child’s name, your name and contact details, and speech-language diagnosis confidential and will not pass this information to external collaborating institutions. UCL researchers will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from external collaborating sites and regulatory organisations may look at your medical and research records to check the accuracy of the research study. External collaborating sites will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

UCL will keep identifiable information about your child from this study for three years after the study has finished.

Individuals from the Sponsor and Regulatory Authorities may also require access to your child’s data for routine monitoring and auditing purposes.The use of some types of personal data information is safeguarded by the 2018 Data Protection Act (DPA). The DPA places an obligation on those who record or use personal information, but also gives rights to people about whom information is held~~.~~ If you have any questions about data protection, contact a member of the research team.

Data sharing

We will ask if you allow us to share the data we collect with other scientists, for studies that have also been reviewed and approved by an Ethics Committee. You are free to answer "YES” or "NO".

* If you choose "YES", we will only share pseudonymized data. This meansother researchers will only be given your child’s data with their code (PIN). These data will be kept at UCL for 15 years and then be destroyed.
* If you choose "NO", then the data we collect will only be used for the purpose of the present study.

The link between your child’s identity and the PIN will be destroyed three years after the end of this study. After that time, it will be impossible to find out your child’s identity.

We will also ask you whether you would like to be contacted again for future studies. Again answering yes or no is entirely up to you.

DNA sample storage

Please note that this is an international project and the genetic analysis will be carried out in Australia. We will send saliva samples to members of the research team in Melbourne in a pseudonymized manner. These international collaborators *will not be able to identify participants* as no personal information will be sent abroad. The DNA samples will be stored in a depository in Melbourne so that they can be analysed in the future, using improved analysis methods for instance. The samples will be stored indefinitely, unless you ask us to destroy them at a specific time. The saliva samples will only be kept at UCL in a locked cabinet for a maximum of 3 weeks before being sent to Melbourne.

1. **Does my child have to take part in the study?**

No, there is no pressure for your child to take part in this project and you are free to withdraw at any time without affecting the health care you receive.

1. **How will I find out about the results of the study?**

On request, a report will be sent to you after the study has been completed, to inform you about the findings. Any results that are published will not contain any references to your child’s name and will be fully anonymised.

1. **What are the arrangements for compensation?**

Research can carry unforeseen risks and we want you to be informed of your rights in the unlikely event that any harm should occur as a result of taking part in this study. This research is covered for negligent harm only, which may apply in the event of any significant harm resulting from involvement in the study. The UCL insurance and indemnity scheme will apply for any research activities undertaken at UCL ICH.

1. **Who has reviewed the study?**

This project has been approved by an independent Research Ethics Committee (the Yorkshire and the Humber (Sheffield) committee).

1. **Who do I speak to if problems arise?**

If you have any complaints about the way in which this research project has been, or is being conducted, please in the first instance discuss them with the researcher. The researcher will then put you in touch with the relevant persons.

1. **What if I would like more information before I decide if I would like to take part?**

If you have any questions about the study please do not hesitate to contact a member of the research team, we are always happy to answer any questions you may have! Our contact details are below. In the first instance, please address any questions to Dr Liegeois, the Chief investigator in the UK. We also have a website <https://www.ucl.ac.uk/child-health/centre-research-excellence-speech-and-language> which has information about the study.

**UK Research team**

All researchers have police clearance to work with children.

**Main contact with familes:**

Researcher: Daisy Thompson-Lake

Cognitive Neuroscience and Neuropsychiatry Section

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**Chief Investigator:** Dr. Frederique Liegeois

Cognitive Neuroscience and Neuropsychiatry Section

UCL Great Ormond Street Institute of Child Health
30 Guilford Street

London WC1N 1EH

Tel: 0207 905 2728

Email: f.liegeois@ucl.ac.uk

**International Project Lead:**

Prof. Angela Morgan, Royal Children’s Hospital, Melbourne, Australia

**Please note that we cannot ensure the security of our email service. If email is most convenient for you, please email** ich.speechlanguage@ucl.ac.uk **to register your interest including a telephone number and a convenient time to telephone. A member of the research team will contact you. Appendix: details about brain scan and assessments**

Speech, language and cognitive assessments: These will take place in a quiet room at the UCL Institute of Child Health by amember of the research team. Your child will be asked to carry out age appropriate picture naming tasks, as well as tasks such as pointing to pictures and explaining the meaning of words. We will also ask your child to do some movements with their face and mouth such as smiling, puckering their lips and moving their tongue.

We will always describe what we will be doing before starting the tests and give clear instructions so that your child understands what will happen. People usually find these tasks quite fun. Altogether, these tests will take about 2-3 hours to complete, with a lunch break in the middle. Your child will also be offered 5 minute breaks between tasks, during which light refreshments will be provided.

Brain scanning: MRI (magnetic resonance imaging) brain scans will be performed at Great Ormond Street Hospital by an experienced radiographer. MRI scanning is a technique used for creating high quality pictures of the brain using a strong magnetic field. The radiographer will perform all necessary safety checks and will explain the procedure to you in detail. He/she will then position your child to make sure they are comfortable on the MRI table. The radiographer leaves the scanning room, but you or the researcher may remain with your child. The radiographer can communicate with your child at any time via an intercom system. Continual observation is provided throughout the procedure. During each scan it is important your child keeps as still as possible, so we can get the best quality scans. Please see the picture below.

An MRI brain scanner

We will perform a structural scan: This will provide a very detailed picture of your child’s brain, and takes about 20 minutes to perform. During the scanning, your child can watch a DVD of their choice.