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Study title: Early Development in Tuberous Sclerosis (EDiTS)

Chief Investigator: Dr Charlotte Tye

Ethical Clearance Reference Number: 15/LO/1949

Parent Overview Information Sheet: Preschool Phase

We would like to tell you about the preschool phase of our research study Early Development in Tuberous Sclerosis (EDiTS) to see if you and your child would be interested in taking part. Before you decide if you would like to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information and discuss with friends, family and your GP if you wish. If anything is unclear, or you have further questions, please do not hesitate to contact us.

Overview and aims

The overall goal of the EDiTS study is to identify differences in the development of children with a rare genetic disorder, tuberous sclerosis complex (TSC), and to find out whether these differences predict later behaviour (e.g. social communication, attention and cognitive ability). The findings from this study will improve our understanding of the association between TSC and different behavioural outcomes, such as autism and ADHD. In addition, the findings may inform the development of early interventions to improve behavioural outcomes and quality of life.

To do this, we need assessments that are sensitive to changes in development that may be associated with behavioural outcomes (e.g. behavioural and brain development). We have developed a series of assessments that are suitable for detecting these changes in preschool children and can be done within the family home.

In order to test whether there are specific differences in the development of children with TSC, we will compare these measures to children who do not have TSC. We will also compare these measures to children with an elevated likelihood of neurodevelopmental conditions.



Who is organising and funding the research?

The local team at King's College London is led by our Principle Investigator Dr Charlotte Tye, who is a Researcher and Lecturer at the Institute of Psychiatry, Psychology & Neuroscience. We have a team of research assistants helping to collect and analyse the data too. This study is taking place as a collaboration between King's College London, the Centre for Brain and Cognitive Development at Birkbeck and the University of Birmingham. This study is funded and has been scientifically reviewed by two UK charities called the Tuberous Sclerosis Association and the Baily Thomas Charitable Fund.

Why am I being asked to participate?

You have been invited to take part in the preschool phase of the EDiTS Study because you have a child aged 3-5 years old with or without a diagnosis of TSC. You must be at least 16 years old to participate, and able to understand and communicate in English.

How will families be recruited?

We will be directly contacting families that previously participated in the infant phase of the EDiTS study to join this preschool follow-up phase. In addition to this, we are recruiting new families to join this study through the Tuberous Sclerosis Association, as well as databases at the Centre for Brain and Cognitive Development. Families will hear about this study through parent organisations and support groups, clinical sources (such as specialist UK TSC clinics) and printed adverts placed in the university campus, hospitals and clinics. We will also advertise on social media and place adverts in local schools/parent forums.

What does the study participation involve, step by step?

Expressing your interest

If you wish to participate as a new family (i.e. you were not involved in the EDiTS infant phase), a researcher will contact you to collect background information in order to decide whether this study is suitable for your child. 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.

We will be directly in contact with families that have already taken part in the infant phase of the EDiTS Study to ask whether they would like to participate in this phase, if they have consented to be contacted again.

For all suitable participants, we will then arrange to visit your home to complete some tasks with your child and set you up with equipment and instructions, including a tablet and a 'sleep watch', to complete the testing with your child. Alternatively, we can complete a subset of these tasks over a video call and send you the equipment via post.

Testing sessions

The activities that you/your child will be involved in are:



1. A visit from our research team

Our research team will contact you to meet with you and your child at your home to complete a series of tasks and fun activities related to their learning and development. This may include your child playing with the researchers and measuring their social, behaviour and communication skills. In total this should take up to 3.5 hours to complete. You will be present with your child throughout and are welcome to ask questions at any time. We will do our best to make the whole session as comfortable and enjoyable as possible. Due to COVID-19 restrictions, we are taking extra precautions to ensure your safety at home (see Appendix A). We will follow government guidelines, including wearing PPE (face shields/gloves), social distancing where possible and disinfecting all equipment before and after use. If you prefer, we can complete a subset of these activities remotely via a video call. If you have any concerns or would like further information, please contact the research team (edits-study@kcl.ac.uk).



2. Parent-report questionnaires and interviews

We will provide you with a number of questionnaires to fill out online/by post about your child's behaviour and development. This will include questions about your child's behaviour, social skills, attention and developmental ability. A member of our research team will regularly be in contact to check your progress and answer any questions you may have.



3. Games on a touchscreen tablet

Using a tablet provided by our research team, we ask that your child completes a set of fun, interactive games on the 'Pip and the Brain Explorers' touchscreen app. Each task includes an animated cartoon and practice trials and the task itself and is set to your child's own pace. We will show you how this works when we visit you, and we will also send you some guidance (a training video) on how to play the games with your child. This means you can take as many breaks as your child needs to rest or play. The maximum time it will take to complete the games is 1 hour and 30 minutes, including breaks. The games don't have to be completed all at once. Please read the 'Touchscreen Pip App Information Sheet' for more information.

Once you have completed the app, you will be asked to repeat the games after one week. We will check in with you while you are completing the games.



4. Measuring sleep

Over 10 days, we will ask you to place a watch (provided by our researchers) on your child's wrist to measure sleep and general movement throughout the day and night. You will be asked to download the e-SNORE mobile app on your own smartphone mobile device where you can report more about your child's movement, sleep, behaviour and any seizures they may have. A member of our research team will check in regularly to make sure you are on track and to answer any questions you have. Please also read the 'Actiwatch and E-SNORE Information Sheet' for more information.

After completing all of these tasks, we will ask that all equipment listed above is returned by post to the research centre. We will arrange this with you and postage will be paid beforehand. After you've completed this, we will ask you to fill in an anonymous feedback form, which will help us to improve our project in the future.

Videotapes

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 approved collaborators will have access to and watch these videotapes. No personal information will be shared on any video recordings. Video recordings will be saved on password protected and/or encrypted computers. We have enclosed an additional 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.

Will I be reimbursed for my time?

We will cover any costs incurred by participation in the study (e.g. sending equipment back to us). We will also provide you with a small gift (such as a t-shirt, toy or bag) to thank you for your participation in the study.

Are there any risks of taking part?

This project has received clearance from the NHS National Research Ethics Committee (REC Ref: 15/LO/1949). All our techniques are widely used in early childhood research and have been for many years. There is no evidence of any disadvantages or risks associated with taking part in the study.

Are there any benefits of taking part?

You will have the opportunity to learn more about research on the development of children with TSC and how it interacts with different areas of behaviour and functioning. We will keep you informed about the progress of the study and key findings by newsletter and social media. Your participation in the study will help us to understand differences in the development and behaviours of children with TSC compared to children without TSC, and whether any of these

differences predict later outcomes. This may help researchers to develop treatments to improve these outcomes.

Is my data kept private?

All information collected in the EDiTS preschool 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 personal information separate from research data. Your personal information will only be accessed by named members of the research team, or by appropriately trained members of regulatory authorities or our sponsoring organizations. Personal information will be kept securely in locked file cabinets, in locked rooms or on password protected and/or encrypted computers. No personal information will be shared with researchers outside the research team.

The data your family provides will be kept for a minimum of 10 years after completion of the EDiTS Study. The data may be retained for use in future studies subject to further ethical approval. We will not pass your family's personal information on to any other organisations.

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, maybe used in future studies subject to further ethical approval. Any data sharing and transfer arrangements are compliant with GDPR and King's College London policies. We will not pass your family's personal information on to any other organisations.

Your data will be processed in accordance with the UK GDPR Data Protection Act 2018. 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/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research>

You can find out more about how we use your information by reading King's College London's core privacy notice at <https://www.kcl.ac.uk/terms/privacy.aspx>, or by contacting Albert Chan (the Data Protection Officer for King's College London) on email at info-compliance@kcl.ac.uk or telephone at 0207 848 7816.

When might confidentiality be broken?

In line with the law, we will never share your data outside the research team. The only exception to this is if we are concerned that you or your child's well-being or safety is at risk. In some cases, we may 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 concern will be communicated to you as protocol permits.

Will my doctor be informed about my taking part in the study?

If your child has TSC, 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 they can advise on your suitability to take part.

Do I have to take part?

No. Your child's participation is entirely voluntary, choosing not to participate will not disadvantage you or your child in any way. Your clinical care will not be affected in any way and neither will your participation in any future research. If you decide to take part, we will ask you to sign a consent form and you will be given a copy of this consent form to keep. 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, your personal information will be destroyed. We will keep any research data we have already collected, including videotapes. This will not be associated with your personal information.

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 (contact details are at the top and bottom of this information sheet). You can also contact the Principal Investigator, Dr Charlotte Tye at:

Department of Psychology, Institute of Psychiatry, Psychology & Neuroscience, De Crespigny Park, London SE5 8AF

Phone: +44 (0)207 848 0238 / 07880394296 Email: charlotte.tye@kcl.ac.uk

In the event that something does go wrong and you are harmed during the research, then you may have grounds for legal action for compensation against King's College London, but you may have to pay your legal costs. King's College London maintains adequate insurance to cover any liabilities arising from the study.

Further information and contact details

If you have any questions about the research at any time, please contact the EDiTS research team via the details below.

Email: edits-study@kcl.ac.uk

By phone or text: 07880394296

By post: Department of Psychology, Institute of Psychiatry, Psychology & Neuroscience, De Crespigny Park, London, SE5 8AF

Thank you for reading this information sheet and considering taking part in this research!

Appendix A

In light of the Covid-19 pandemic, we are aware that in-person data collection poses a safety risk to both researchers and participants. We have developed a Covid-19 mitigation protocol which adheres to government and King's College London guidelines in order to reduce the risk of exposure and ensure the safety of those attending home visits.

Prior to the home visit

In preparation, families will be asked to complete a Covid-19 screening questionnaire prior to their visit. If families report any symptoms (e.g., high fever, dry continuous cough or loss of taste/smell), they will be informed that they cannot part-take in the visit, but where possible their visit will be rearranged. We will also ask vulnerable families to not host home-visits, to minimise their risk of infection. Researchers will take a COVID-19 test before attending families' homes. COVID-19 tests will be repeated regularly (twice a week, or whenever attending a home visit if less frequent). Parents will be reminded that they are eligible for 2 lateral flow tests a week if their children attend school. If any of the testing team develop symptoms or are feeling unwell before the home visit, they will be asked to stay home and follow government guidelines.

All equipment will also be cleaned, disinfected and quarantined 72 hours before being taken to a home visit.

If home visits cannot take place due to government issued COVID-19 restrictions at the time of testing, there is a distance protocol in place for remote testing to ensure the safety of both our researchers and participants. Families will be offered the option to complete a subset of activities remotely via a video call/telephone.

At the home visit

When travelling to the home visit, the testing team will follow COVID-19 travel guidance. Researchers will travel by car where possible in order to reduce the risk of transmission via public transport.

In accordance with government guidelines, families will be assured that study team members will follow social distancing measures (i.e., standing within two metres of a participant only when necessary for the task and for the shortest amount of time required) and remaining in Personal Protective Equipment (face shields, surgical splash proof masks and gloves) for the full duration of the visit. The size of the testing team will also be limited to two to reduce the number of people entering families' homes. Testing will take place in the largest room of the family home to enable a 2m+ distance between the parent and the researcher where possible. Rooms will be ventilated by leaving windows open whenever weather allows, and doors will be left open during testing.

Frequent hand washing for researchers will be maintained throughout the day and we will request that all families do the same. Staff on the home visit will bring their own face masks, visors, gloves and antibacterial wipes to clean any surfaces (e.g. tabletops and door handles) they have been in contact with. Regarding masks and tissues, we will take the 'catch it, bin it, kill it' approach. Participants and researchers will sanitize their hands after touching their mask or a tissue and masks will be disposed of when leaving the home. Some assessments may require close contact with a child or parent, which we may ask the parent to help with where appropriate to minimise the duration of close contact.

Researchers will work through a priority-ordered protocol with the participants and any elements of the protocol that can be completed remotely (e.g. questionnaires) will be done so before the visit.

Following the home visit

All equipment used at the home visit will be appropriately cleaned, disinfected and quarantined for 72 hours following the visit. Researchers will rely on the NHS track and trace system to be alerted of any potential exposure to the virus, however will also ask families to contact a member of the research team if they receive a positive COVID test result within 14 days after the visit.