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Parent/Guardian Information Sheet for the Primary School Phase of EDiTS

Study REC ref: 15/LO/1949; IRAS Ref: 168272

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

Early Development in Tuberous Sclerosis (EDiTS)

Invitation

We would like to invite you to participate in this research project called Early Development in Tuberous Sclerosis (EDiTS) study. Before you decide whether you want to take part, it is important for you and your child to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others and/or the research team, if you wish. Please reach out to our team via email, or you can request a phone call if you require more clarity.

What is the purpose of the project?

The purpose of the project is to continue to understand and identify differences in the development of children with a rare genetic condition, called tuberous sclerosis complex (TSC), and to find out whether these differences predict later outcomes (e.g. social communication, cognitive ability, and school outcomes). The findings from this study will improve our understanding of the association between TSC and different behavioral outcomes. The findings may inform the development of early interventions to support behavior, cognition and quality of life.

Our team has developed and will continue to use a series of assessments and tools that are suitable to detect changes over time which can be done remotely, in the family home, or in schools. To understand differences, two groups of children, including children with a diagnosis of TSC and typically developing children, their primary carers and educational professionals will be invited to take part in this study.

Why have I been invited to take part?

You are being invited to participate in the primary school phase of the EDiTS study because you have a child of primary school age (6-11 years) with or without a diagnosis of TSC. All children and primary carers must be able to understand and communicate in English.

Children **without a diagnosis of TSC** will be included if they **do not** have an immediate, or first-degree, biological family member (e.g. mother, father, brother, sister) with a confirmed diagnosis of

any neurodevelopmental condition (e.g. autism, ADHD), neurological condition (e.g. epilepsy, cerebral palsy) or other genetic conditions (e.g. Fragile X, Down Syndrome).
For those who are returning, our research team will discuss with the primary carers whether the child has developed any medical conditions that might make it difficult for the child to take part in this research.

What does this participation involve at each step?

Expressing interest

If you express interest as a new family, meaning you were not involved in our previous phases (infant and preschool), then our research team will collect background information to determine if this study is suitable for you and your family. You can choose to join our database for future studies that may be a better fit.

Our team will directly contact our previous families who provided consent and who took part in the EDiTS Study to confirm if they would like to join for this phase.

For families who meet our criteria, we will arrange a meeting online to complete tasks with you and your child. We can send you equipment via post and pre-paid packaging for you to return to us, where necessary.

Testing Sessions

Our research team will contact you to schedule a meeting with you and your child to complete a series of virtual or in-person tasks and game related activities about their learning and development. This may include the child interacting with the research team via smart device or face-to-face to measure their social, behavior and communication skills. In total, this may take up to 3 hours to complete with breaks. We ask that you will be present with your child throughout and are welcome to ask any questions at any time. The researcher will take great care to explain the tasks throughout and make the sessions as comfortable as possible. If you have any concerns or would like further information, please contact the research team (edits-study@kcl.ac.uk).

Parent report measures

We will provide you with questionnaires to complete online or by post. The questionnaires will include content about you and your child's behavior, social skills, attention and other developmental abilities. A member of our research team will regularly be in contact to check your progress and answer any questions you may have.

Tablet based games

Using a tablet provided by our research team or your personal device (e.g. smartphone, tablet, laptop or desktop computer), we ask that your child completes a set of interactive games on the 'Pip and the Brain Explorers' touchscreen app. This is free to download if using your own devices. Each task includes an animated cartoon and practice trials. The task itself is set to your child's own pace. We will show you how this including 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.

School based information

Our research team will be in contact with you to provide your child's school/tutor with a questionnaire, if enrolled. Parents will be provided with an envelope or documents via an online link to send directly to the school. In the first instance, our research team will not approach schools. However, if there are difficulties with communication, we will be happy to follow-up with school with an official letter. These questionnaires are collected to understand your child's behaviors, social and communication skills in a secondary environment.

If your child is not in formal education, tutoring or training, then this section does not apply to you.

Online and home visits will be video recorded for the purpose of data analysis. We will remind you and your child of this at the beginning of our visits. 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. Video recording is not mandatory for your participation.

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. Once you have read the information sheet, please contact us if you have any questions that will help you decide about taking part. If you decide to take part, we will ask you to sign a consent form and will give you a copy of this to keep**.**

We will obtain assent from your child as an ongoing form of your child's agreement to engage with the researchers in an informed and meaningful way. This will be done through ongoing conversation or nonverbal communication.

Incentives

We will cover any costs incurred by participation in the study (e.g. sending equipment back to our research team). We will also provide you with a small gift such as an e-voucher to thank you for your participation in the study.

What are the possible risks of taking part?

This project has received clearance from the NHS National Research Ethics Committee (Study REC ref: 15/LO/1949; IRAS Ref: 168272). All our techniques are widely used in childhood research and have been for many years. There is no evidence of any disadvantages or risks associated with taking part in the study.

During our meetings, there are possibilities that you and/or your child may experience some discomfort, especially if engaging in an activity or discussion. We acknowledge that behaviors and emotions may be variable. We will allow time for you and/or your child to take breaks. In any event where behaviors may present a significant risk you, your family or the research team, we will terminate the session and contact you to reschedule, when appropriate. We acknowledge that this may be upsetting, and we will guide you and your family to appropriate support services. Support lines will be available in our support lines information sheet.

What are the possible benefits of taking part?

You will have the opportunity to gain experience and understand more about research and the development of children with a diagnosis of TSC. Our team will continue to provide updates about our progress for the study and key findings via biannual newsletters, social media posts and communications via the Tuberous Sclerosis Association (TSA).

Your participation in the study will help us to understand differences in the development and behaviors of children with TSC compared to children without TSC, and how development across time predicts later outcomes. This may help researchers to develop treatments to improve these outcomes.

How will we use information about you?

We will need to use information from you, your child, and medical records for this research project. This information will include your personal information such as name, date of birth, gender, contact details, health data, ethnicity and education, held by the EDiTS research team.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. Your personal information will only be accessed by specific members of the research team, or by appropriately trained members of regulatory authorities or our sponsoring organizations. No personal information will be shared with researchers outside the research team.

King’s College London is responsible for looking after your information. We will keep all information about you safe and secure. We will keep all personal information separate from research data. Personal information will be kept securely in locked file cabinets, in locked rooms or on password protected and/or encrypted computers.

International Transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

Consent forms and identifiable data will be stored securely for 5 years, in line with King’s College London policies. Anonymised survey responses may be retained indefinitely for future academic analysis.

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, such as video tapes.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- 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.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study in the EDiTS Study database.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at http://www.hra.nhs.uk/patientdataandresearch
- https://www.kcl.ac.uk/research/research-environment/rgei/research-ethics/use-of-personal-data-in-research; or
- by asking one of the research team via email at edits-study@kcl.ac.uk

- by sending an email to our Data Protection Officer at info-compliance@kcl.ac.uk
- by phone or text our EDiTS Study mobile monitored by King's College London: +44 (0)207 848 0238 or 07880394296
- By post:
  FAO The EDiTS Team
  Department of Psychology
  Institute of Psychiatry, Psychology & Neuroscience
  De Crespigny Park
  London
  SE5 8AF

Who will my data be shared with?

Your information will be shared with the immediate research team only. Where data will be shared with third parties include details of how the data will be transferred securely. If there are any limits to confidentiality, such as some instances where the researcher might be obliged to break confidentiality due to the nature of a disclosure being made or concern of risk of harm to themselves or others.

With your consent, we will keep your contact details for 5 years so that we can contact you about future research projects of a similar nature.

Will my doctor's office be notified about me taking part in this study?

If your child has TSC, we will inform your general practitioner (GP) and/or lead clinician(s) that you are taking part in the study. This is to ensure that your clinician/s is/are aware of the additional assessments we request with your child and so that they can advise on your suitability to take part.

What if I change my mind about taking part?

You are free to withdraw at any point of the project, without having to give a reason. Withdrawing from the project will not affect you or your clinical care in any way.

How is the project being funded?

This study is taking place as a collaboration between King's College London and the Tuberous Sclerosis Association. This study is funded and has been scientifically reviewed by the Baily Thomas Charitable Fund, and partially by one of our PhD student's funding committees, London Interdisciplinary Social Sciences Doctoral Training Partnership (LISS DTP).

What will happen to the results of the project?

The results of the project will be reported in part of a graduate and undergraduate projects at King's College London. Additional findings will be summarized in layperson articles and presentations on behalf of the Tuberous Sclerosis Association, in their SCAN Magazine, events and social media platforms. All information will remain anonymized.

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, or contact the Principal Investigator, Dr. Charlotte Tye at charlotte.tye@kcl.ac.uk

You may also contact the King's Research Governance Office: rgo@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 but you may have to pay your legal costs. King's maintains adequate insurance to cover any liabilities arising from the study.

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