EDiTS Study, Institute of Psychiatry, Psychology & Neuroscience
De Crespigny Park, London, SE5 8AF
Email: edits-study@kcl.ac.uk
Website: www.edits-study.org
Phone: +44 (0)207 848 0238 / 07880394296

Version 2. 31072025

Parent Information Sheet

Ethical Clearance Reference Number: HR-24/25-48980

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

Impact of education on children with tuberous sclerosis complex (TSC): Voices from a primary school aged children and families

Invitation

We would like to invite you to participate in this research project which forms part of a PhD project. 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 understand and identify educational experiences of children with tuberous sclerosis complex (TSC), and how the diagnosis impacts their experience in school. This will include the perspective of primary carers of children with TSC. The findings may inform the development of Continuing Professional Development (CPD) and early interventions to support individuals with TSC.

Why have I been invited to take part?

You are being invited to participate in this study because you have a child of primary school age (6-11 years) with a confirmed diagnosis of TSC. We will ask you to provide a confirmation letter signed by your GP to show the diagnosis of TSC. Upon confirmation, these letters will not be retained and appropriately destroyed.

All children and primary carers must be able to understand and communicate in English, including the use of symbols or written communication styles. For your child to participate in an interview, we would require them to be enrolled in education to directly refer to their likes and dislikes of their setting which includes mainstream, special education or home education settings.

What does this participation involve at each step?

Expressing interest

If you express interest, 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.

Scheduled Meetings

Our team will aim to meet with you and/or the family at least twice. The **first time** will include an introduction to the study with you (parent/carer) and thoroughly explain the use of pictures, photography or selecting personal items to represent your child's school experiences. The **second time** will include scheduling a face-to-face or online meeting with you and your child to show and tell the visual items as outlined in **Semi-structured interviews and Pictures and Photos** below.

Parent reporting

We will provide you with surveys and questionnaires about your perspectives of your child's access to education including their emotional, social and school abilities and characteristics of their TSC diagnosis. These will be provided via an online link to a secure platform, Qualtrics, or by post. A member of our research team will regularly be in contact to check your progress and answer any questions you may have.

Semi-structured Interviews

You and your child will be asked to participate in an online or face-to-face meeting with our research team to discuss school experiences with your child directly. These meetings may last approximately 60 minutes with regular breaks included. Your child may be asked to draw and share their personal experiences about school, their educators, including likes and dislikes. We ask that you be present with your child to support them to discuss or mitigate any emerging risks such as emotional dysregulation (e.g. meltdowns, tantrums).

- What is your favorite/ least favorite thing about school? Subject/class?
- What can you do best in school?
- Does anyone help you in class? Who/what helps you in class?
- How does this support make you feel?
- Do you think you are treated differently to other students?
- Does anything stop you from participating?
- What would you change to make school easier?

Pictures, Photos and Visual Items

You, your child or educational professional may be asked to take pictures of your child's school environment or personal items (e.g. homework, fidget item, utensils, etc) to capture ideas of what your child perceives as important and/or challenging in school. They will be asked to be supported by an educational staff or an appropriate adult, or the adult will take a picture where the child is unable to complete the task independently. We aim that this will not interrupt daily teaching time and can be done before, during or after lessons.

We ask that photos **should not** include other non-participants, or identifiable individuals, as consent or assent will/has not been obtained from other staff or pupils. If other children are in the pictures, these will not be accepted by the researcher/research team.

We will ask for your consent to share anonymized pictures (pictures without identifiable information) in our research publications (e.g. blog, lay summaries, theses) taken or created by your child only.

Where possible, your child and you will be invited to share additional information about these pictures to support the research team in understanding the picture.

Included questions related to the picture task:

- What do you see in this picture? What's the story behind this picture?
- What is happening in this picture?
- How does it relate to your TSC?
- What creates the challenge/problem? How do we educate others about this challenge?
- How do we make things better?

Recordings
Interview/meeting sessions will be audio and video recorded. Recordings will be saved on password protected and 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.

You 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).

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.

Incentives

We will cover any costs incurred by participation in the study (e.g. sending resources back to our research team). We will also provide you with a small gift (such as a t-shirt, toy, bag) to thank you for your participation in the study including a voucher equating to £25.

What are the possible risks of taking part?

During our meetings, this may cause you and/or your child some emotional discomfort, especially if discussing a sensitive topic about education and level of abilities. We acknowledge that this may be upsetting, and we will guide you and your family to appropriate support services, where necessary. Support lines will be available in our Signposting Support Sheet. We will request your GP information in our inclusion form. After consulting with our Chief Investigator(s), if we feel you and your family would require additional support from a GP referral following the presentation of any significant risk, we will inform you of this suggestion and provide a letter to your GP. No actions will be taken without your knowledge. Our research team will continue to check in with you via email and/or phone call to ensure your family's safety, as necessary.

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 newsletters, open platform social media posts and communication via the Tuberous Sclerosis Association (TSA).

Your participation in the study will help us to understand differences in the perceptions of children with TSC. This may help researchers to develop interventions to improve these experiences.

My Data, confidentiality and safety

Kings College London and our research team are responsible for looking after your information.

Categories of Personal Data	We will collect your personal data such as name, date of birth, gender, contact details, health data, ethnicity and education information.
Data Storage	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.
Data Sharing	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. Anonymized data, including direct quotes, will be shared with the Tuberous Sclerosis Association (TSA), who will use this information which includes but not limited to the development of lay summaries, open social media posts, and publications in their SCAN Magazine. More about the TSA can be found here: https://tuberous-sclerosis.org/
Data Retention	Consent forms and identifiable data will be stored securely for 5 years, in line with King's College London policies. Anonymized survey responses may be retained indefinitely for future academic analysis.
Anonymity in Research Outputs	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, date of birth, addresses or other identifiable data.
Archiving/Future Use	The data your family provided will be kept for a minimum of 10 years after completion of the EDiTS Study. Anonymized data may be archived for use in future studies subject to further ethical approval. 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 and King's College London policies. 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.

What if I change my mind about taking part?

You are free 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. You can withdraw your data from the project. 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, and all personal (demographic) information will be destroyed. However, we will keep any research data (e.g. surveys, questionnaires) we have already collected, including recordings. This will not be associated with your personal information.

For the participants who consent to participate in the online or face-to-face meetings, your data cannot be extracted or removed from the audio and video recordings. All data will be transcribed and anonymized once transcribed once the meeting is concluded. If you change your mind prior to participating in the meetings, you are free to withdraw without providing a reason.

How is the project being funded?

This study is taking place as a collaboration between King's College London and Tuberous Sclerosis Association (TSA). This study is funded and has been scientifically reviewed by a UK charity called 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 PhD project. Additional findings will be summarized in a lay article and presentations on behalf of the Tuberous Sclerosis Association, in their SCAN Magazine, events and social media platforms. All information will remain anonymized.

Who should I contact for further information, or if I have concerns?

If you have any questions or require more information about this project, please contact me using the following contact details:

If this project has harmed you in any way, or if you wish to make a complaint about the conduct of the project you can contact King's College London using the details below for further advice and information:

Dr. Charlotte Tye
Senior Lecturer in Psychology
charlotte.tye@kcl.ac.uk

Email: edits-study@kcl.ac.uk

By phone **or** text: +44 (0)207 848 0238 **or** 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 for considering taking part in this research.