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Study title: Early Development in Tuberous Sclerosis (EDiTS)

Chief Investigators: Dr Charlotte Tye & Prof Patrick Bolton

Parent Overview Information Sheet – typically developing infants

We have asked you to consider agreeing to your baby taking part in the EDiTS 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 time to read the following information carefully, and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Overview

The overall goal of the study is to design and test a set of novel home- and lab-based assessments to chart the development of babies, which can be used in a range of studies of typical development as well as developmental problems like tuberous sclerosis complex (TSC).

Why am I being asked to participate?

Current assessments for infants are not well suited for detecting sudden changes in development. Tracking the development of cognitive skills in typically developing infants will help us to understand how development is different in babies with clinical problems, such as tuberous sclerosis complex (TSC). TSC is a rare genetic disorder associated with poor developmental outcome (see http://www.tuberous-sclerosis.org/ for more informtation on TSC).

Finding certain assessments that can provide an early 'read out' of development is important. We have developed a series of assessments that can be done either at the family home or in our specialist research centre in London. We are interested to see whether differences in very early development (e.g. cognitive ability, eye movements, behaviour) are associated with a diagnosis of TSC. We are also interested in the views of parents enrolled in the study on the test procedures and home-based assessments.

In order to test whether there are specific differences in early development, we will compare these measures between infants who have been diagnosed with TSC and infants who are typically developing.

How will families be recruited?

Families will hear about this study through parent organisations and support groups, the Tuberous Sclerosis Association, clinical sources (GP clinics, specialist UK TSC clinics and fetal medicine units), online

advertising, and printed adverts placed in the university campus, hospitals and clinics. We are also contacting families through the Centre for Brain and Cognitive Development (CBCD) database. Families will be asked to take part in a minimum of three lab- or home-based sessions over a period of approximately four to eight months (once every two to four months).

What does the research involve?

If you wish to participate, a researcher will contact you to collect background information in order to determine whether this study is suitable for your baby. 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. If the study is suitable, we will then arrange a convenient time to visit you to conduct the three sessions with you and your baby. We can come to visit you at your home, or if you prefer, at your local clinic or our research centre.

What will happen during the testing sessions?

A typical visit will last between 3-4 hours, including time for breaks. During the visit, your child will complete a number of short tasks and games, each examining a different area of development, and varying according to the age of your child (see also the flowchart enclosed with this pack). These may include watching animations on a screen or playing with you and the researcher. We will use an eye-tracker to record your baby's eye movement patterns while they are watching the screen (see Eye-Tracking Information Sheet enclosed with this pack). These tasks and games are designed to be fun and stimulating for babies. You will be present with your child throughout and are welcome to ask questions at any time.

Because we know that babies have a limited attention span, a subset of the tasks and games will be completed at a visit. There are different types of tasks and games and different methods of measuring responses that we would use with you and your baby.

For babies aged 1-month, 5-months, 10-months and 14-months, we will ask you to visit London to collect more extensive information using EEG technology (see EEG information sheet enclosed with this pack) at the Birbeck Babylab, Henry Wellcome Building, Birkbeck, Malet Street, London, WC1E 7HX or the Centre for the Developing Brain, King's College London, based at St. Thomas' Hospital, London SE1 7EH. We can help you with travel and accommodation arrangements for this. If you prefer, we can see you at home instead.

Please note that we always adapt sessions to each child's individual needs. While the tasks we use target the development of specific abilities over time, each session is adapted for each child's specific age and individual needs. This means that we take as many breaks as your child needs to feed, rest, or play. We will do our best to make your visit as comfortable and enjoyable as possible. After your last session you may be asked to fill in an anonymous feedback form, which will help us to improve our project in the future.

Permitting funding and ethical approval, we will ask to see all participants at 24 months and/or 36 months of age to assess developmental outcome. If you agree to take part, you will be asked whether you are happy to be contacted about participation in future studies. Your participation in this study will not be affected should you choose not to be recontacted.

Questionnaires and Interviews

We will give you a number of questionnaires about your child's behaviour and development to fill out at home or during our visit. These usually take 1 hour to complete at each time point. At some time-points we might require more detailed information that we can ask you in person or over the phone. These questions will be about your/your child's medical history. To help with this, we will ask to take a look at your baby's 'red book' (personal child health record). You may find some of the questionnaires relate to sensitive topics, but you do not have to answer any question you do not wish to answer. You can discuss any questions you find difficult to answer with us on the phone or at the visit.

Videotapes

Lab and home visits of you and your child will be videotaped by research assistants. Videotapes in the study will be used for research purposes only. Only researchers involved in the study and our collaborators will watch these videotapes. No personal information will be shared on these videotapes. Videotapes will be kept securely in locked filing cabinets, in a locked room or on password protected and/or encrypted computers. We have enclosed an additional consent form if you are happy for use your child's photo or video for research and clinical purposes.

Optional MRI scan

We also plan to invite families to London to have an optional research brain MRI scan when your baby is aged 5 months of age, at the Centre for the Developing Brain, King's College London, based at St. Thomas' Hospital,,London SE1 7EH. We can help you with necessary travel and accommodation arrangements. This will help us to understand how cognitive development is associated with brain development in typical development and babies with developmental problems like TSC. During the examination we will collect imaging data on your baby's brain. An expert will then look at the scans and we will send you a written report. It is not likely that the scan results would have any immediate health implications. If unexpectedly we see any significant problem on the scan we will contact you and arrange a discussion about this with you to explain what we have seen and advise what should be done.

We have enclosed a more detailed Frequently Asked Questions sheet about MRI brain scans in this pack and a separate consent form.

Optional collection of a DNA sample

We would like to ask your permission to obtain DNA samples from your child at each time-point using a cheek swab and/or a saliva sample. The cheek swab is done by gently wiping a cotton wool bud on the inside of your child's cheek and the saliva sample by allowing your child to suck the end of the cotton wool bud. We can let you do it, while one of us helps if you prefer. The procedure does not take long and does not involve any risks or side effects. It collects a few cheek cells or saliva, from which we can then extract DNA that will be analysed to help us find out more about the genetic factors involved in the cognitive development of babies. The DNA sampling in this research does not qualify as genetic testing because these samples cannot be used for diagnostic or prognostic purposes. The DNA samples will be transferred to the Institute of Psychiatry, King's College London, for storage and analysis.

We have enclosed a more detailed Frequently Asked Questions sheet about obtaining DNA samples in this pack and a separate consent form. We would also stress that this aspect of your visit is entirely optional. If you feel that you do not wish to become involved in the DNA component of the study, you can still participate in the main study. We have enclosed a separate consent form for the DNA component of the study.

Expenses and payments

We are able to reimburse any costs incurred by you (travel, meals, accommodation, etc) involved in participating in the study. We will also provide you with a small gift at each time-point (such as a t-shirt, toy or bag), to thank you for your ongoing 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 in widespread use in infant research and have been used for many years. There is no evidence of any disadvantages or risks associated with taking part in the study.

Who is organising and funding the research?

This study is being done as a collaboration between the Department of Child and Adolescent Psychiatry at King's College London and the Centre for Brain and Cognitive Development at Birkbeck. This study is funded by a UK parent charity called the Tuberous Sclerosis Association. This study has been scientifically reviewed and given a favourable opinion by the Tuberous Sclerosis Association.

How will the data be used?

We take confidentiality very seriously. We keep personal information (like names and addresses) separate from all study data. Your personal information will only be accessed by member of the research team, or by appropriately trained members of the regulatory authorities or our sponsoring organizations. Personal information is kept in locked file cabinets or on password protected and/or encrypted computers. No personal information will be shared with researchers outside the research team.

The research data collected will be coded so that all identifying information is removed. Data is identified by a unique code that allows different pieces of data from your child to be associated with each other, but not with any personal information. Data coded in this way is called pseudonymized data. Personal and pseudonymized data are stored separately. Research data may be shared with other approved researchers, but only using a secure electronic database and after removing identifying information about the participants. We will use your child's pseudonymized data to publish scientific reports with important discoveries. We will also communicate our findings to the public through our website and other sources. Published reports on the results will not mention individuals.

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.

What will happen if I don't want to carry on with the study?

You can choose to leave the study at any time. Participation in any part of the study is entirely voluntary, and you may choose to end the session at any time. Whether or not you participate in the study does not affect your clinical care in any way. 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 withdraws from the study we will destroy your personal information. 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 Investigators, Dr Charlotte Tye or Professor Patrick Bolton, at:

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De Crespigny Park, London SE5 8AF
Phone: 0207 848 5388 / 5325
Email: charlotte.tye@kcl.ac.uk / patrick.bolton@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 by phone on 0207 848 5388 by post at: Institute of Psychiatry, PO80, De Crespigny Park, London, SE5 8AF or by email at edits-study@kcl.ac.uk

Thank you for your interest!