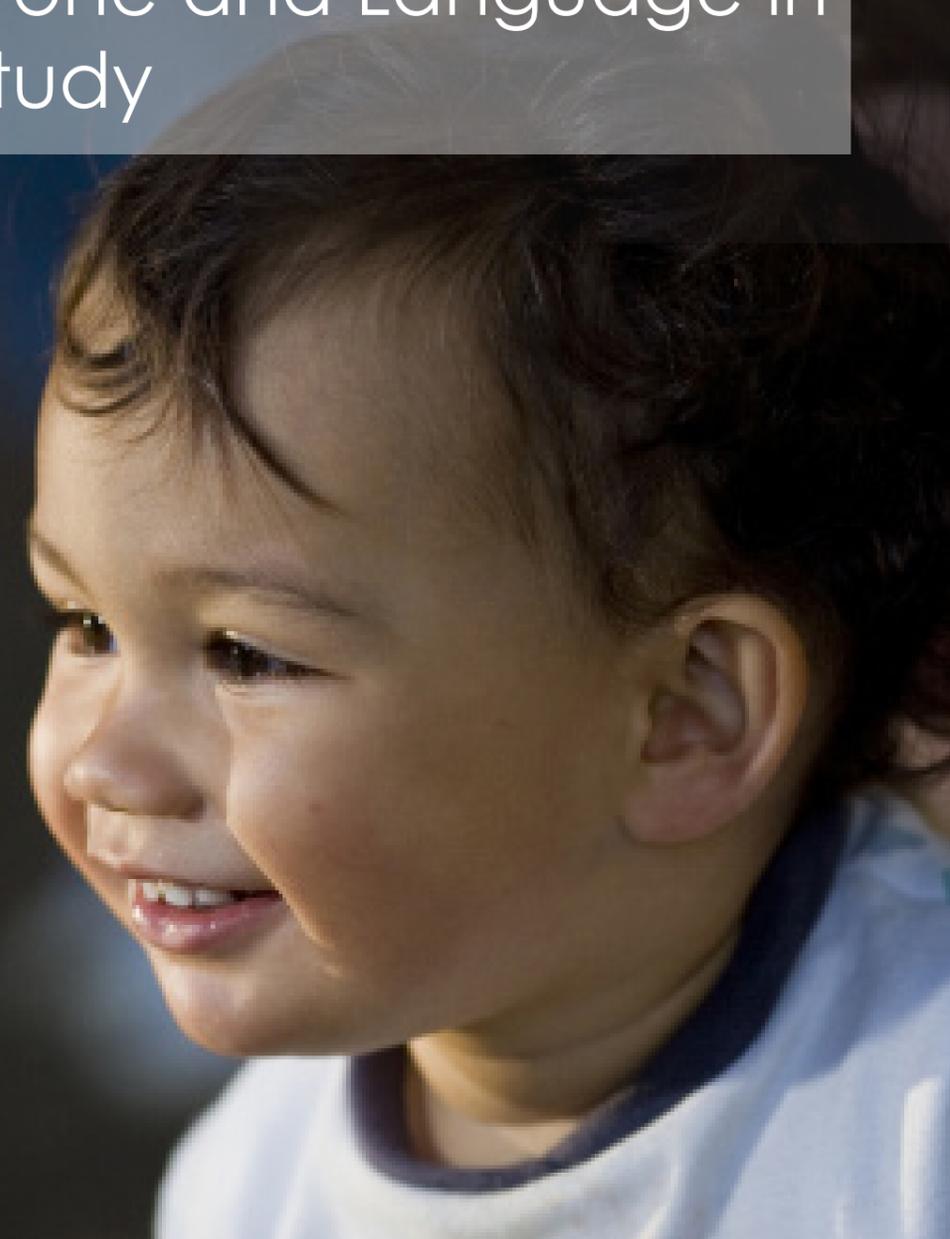


PARENT/GUARDIAN INFORMATION SHEET

The Testosterone and Language in Kids (TALK) study



TALK
Testosterone and Language
in Kids (TALK) Study

Joondalup Health Campus
Part of Ramsay Health Care

THE ORIGINS PROJECT

TELETHON KIDS INSTITUTE
Discover. Prevent. Cure.

What will you do with the umbilical cord blood?

We will analyse a small portion of the blood collected from the umbilical cord at birth for testosterone. By analysing testosterone concentration from the cord blood, we will be able to determine how much testosterone your child was exposed to when s/he was in the womb.

What will you do with the DNA?

We will examine both your and your child's DNA for genes that we know are associated with brain development. By analysing this DNA we will be able understand how the genetic code relates to brain development in the womb. Your DNA will be analysed by members of our team who are based at the Max Plank Institute in The Netherlands.

What are the possible disadvantages in taking part?

This research involves a small time commitment over 4 years, during which we will see you a number of times. This commitment is outlined in the table, and we will ensure that your time commitment is no more than this.

There is a very small chance that our DNA analysis may identify a gene variant that is known to be associated with a health concern. In such instances, you will be contacted by the study investigator to inform you of the finding. You may then choose whether you want more information. Details will be forwarded to your general practitioner who will guide you through the need for referral for genetic counselling and possible further testing. **There is no cost for taking part in this study.**

What are the possible benefits of taking part?

The results of the current study will help us to better understand how children develop the remarkable skill of language. You and your child could be involved in an important scientific advance.

Storage of Information

The information we collect from the questionnaires and clinical assessments will be entered immediately into a secure electronic database, apart from the Conners Early Childhood (EC) – parent survey which will be administered at Assessment - 6 when you child is 2.5 years of age. The Conners EC will be completed online as part of a digital form, maintaining the rights and confidentiality of participating families through the Multi-Health System's Inc (MHS) MAC Online Platform in partnership with Psychological Assessments Australia. The MHS's privacy policy can be viewed at <https://www.mhs.com/Privacy-Policy>. The Conners EC – digitised data will be stored on Canadian servers and complies with Canada's Personal Information Protection & Electronic Documents Act (PIPEDA). Information about this act can be found at <https://www.priv.gc.ca/en/privacy-topics/privacy-laws-in-canada/the-personal-information-protection-and-electronic-documents-act/pipeda/>. The PIPDA adheres to Australian Privacy Principal 8 and Section 16 of the Privacy Act and complies with the most stringent international privacy standards.

The information we collect from the questionnaires and the clinical assessments will be entered immediately into a secure electronic database called REDCap. All hard copies of questionnaires and the clinical assessment information will be kept in a locked filing cabinet at the Telethon Kids Institute which has secure access and is a staff keychain protected building.

The genetic information from your DNA will be stored in a secure electronic database in the Netherlands and at the Telethon Kids Institute.

We will retain all data collected for this study (including genetic information) indefinitely, with annual reviews.

As soon as you enter the study, your child and your family would be identified by a code number. The document matching your codenumbers and names will be kept separately from the study data.

No images collected as part of the TALK study will be published without separate consent from study families.

Ownership of the entire TALK dataset is by the team of researchers (listed here in) from the Telethon Kids Institute, the Joondalup Health Campus, University of Western Australia, Edith Cowan University, the University of Oxford and the Max Planck Institute. The TALK data will not be used for other future research studies unless prior ethical review is submitted to the Joondalup Health Campus Human Research Ethics Committee for approval.

Withdrawing consent

You are free to withdraw your consent to participate in this study at any time. Your decision to withdraw consent will not influence the care your child receives from any of the personnel involved in this study. If you withdraw consent, we will destroy the hard and electronic copies of the information collected for the TALK study.

What happens to the results of the study?

We would send you an end-of-year newsletter that gives results of our research. We also plan to publish our findings in scientific journals, including genetic information. Under no circumstances will identifying information be published. We would not normally give feedback about results for individual children. However, if we found results that might be useful for your child, we would be happy to write a report for you.

Who has approved the study?

The ethical aspects of this study have been approved by the Joondalup Health Campus Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in a research project, please contact JHC Executive Office on (08) 9400 9404. Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

Who to contact for more information or if you would like your child to participate in the study?

If you would like any more information about this study, please do not hesitate to contact TALK Study Coordinator who will be very happy to answer your questions.

Study Coordinator

T | (08) 6319 1133
M | 0468 578 851
E | TALKstudy@telethonkids.org.au

Thank you for your time.

Why are we doing this study?

The development of language is incredibly complex, and is important for a wide range of positive outcomes later in life, such as academic achievement, social ability and relationships. There is evidence that the left side of the brain is very important for language development, but at the moment we do not know how the left side of the brain becomes specialised for language. One interesting theory is that exposure to testosterone in the womb may have an influence.

The aim of the TALK study is to understand how testosterone exposure in the womb may be related to brain growth before birth, and language development after birth.

We will study 500 women from 18 weeks pregnancy until birth, and then their child until three years of age. The information we collect during this study will help us to better understand how children acquire the remarkable skill of language, and how we can best support children who have difficulties learning language.

Who is carrying out the study?

The study is being conducted by a team of researchers from the Telethon Kids Institute, the Joondalup Health Campus, University of Western Australia, Edith Cowan University, the University of Oxford and the Max Planck Institute.

Prof. Andrew Whitehouse (Study Leader, Telethon Kids Institute, Perth)

Prof. Murray Maybery (University of Western Australia, Perth)

Prof. Jeffrey Keelan (University of Western Australia, Perth) Dr. Anthony Murphy (Western Ultrasound for Women, Perth) Dr. Bridget Jeffery (Joondalup Health Campus, Perth)

Prof. Dorothy Bishop (University of Oxford, UK)

Prof. Simon Fisher (Max Planck Institute, The Netherlands)

Dr. Clyde Francks (Max Planck Institute, The Netherlands)

Mr. Chris Brennan-Jones (Telethon Kids Institute, Perth)

Paul Higginbotham, CEO, Earbus Foundation of WA

Dr Nicholas Badcock, (University of Western Australia, Perth) Dr

Donna Bayliss, (University of Western Australia, Perth)

Dr Leisa Armstrong, (Edith Cowan University, Joondalup)

Why have I been invited to take part?

You have been informed about this study because you are due to have your baby at Joondalup Health Campus. This study is part of the ORIGINS Project, and we are recruiting pregnant women at Joondalup Health Campus into this study until 500 people agree to take part.

Does my child have to take part?

Participation in this project is entirely voluntary, and you are under no obligation to take part in this study. You are able to take part in the ORIGINS Project, without participating in this smaller study component.

If you do decide to participate, you will be given this Information Sheet and you will be asked to sign a Consent Form. You will be able to withdraw at any time and without giving a reason. A decision to withdraw, or a decision not to take part, will not affect your family's health care in any way.

What will happen if I give permission to take part?

You will have been informed about this study by a team member. If you express interest in the study (or would like to have more information), then your details will be passed on to a staff member at the Telethon Kids Institute, who will call you to provide more information.

Once you have agreed to take part, you will then be informed about the study stages. The TALK study is now comprised of seven assessments (some of which may coincide with the assessment sessions of the larger - The ORIGINS Project) of which the sessions will be spread over a four year period. For the TALK study there will be two assessment sessions during your pregnancy, and five assessments after the birth of your child up to 3.5 years of age. These are detailed in the table below:

Session Name	Stage	What Happens?	Where does this happen?	How long does it take?
Assessment 1	18-20 weeks' pregnancy	Ultrasound measurements of your baby's brain	Joondalup Health Campus	20 minutes
Assessment 2	24 weeks' pregnancy	Ultrasound measurements of your baby's brain and a 10 minute video of your baby's hand movements.	Joondalup Health Campus	20 minutes
Assessment 3	While you are still in hospital after the birth	Child receives a hearing test.	Joondalup Health Campus	15 minutes
Assessment 4	When your child is between 6-9 months of age	Parent(s) complete questionnaires and child is given behavioural tests and a face photograph. A 10 minute video recording of parent and child playing with toys. Child completes short eye-tracking task.	Joondalup Health Campus OR ECU Joondalup	1 hour (plus 40 minutes for questionnaires)
Assessment 5	Child's 2nd birthday	Parent(s) complete questionnaires and child is given behavioural tests and a face photograph	Your home	70 minutes
Assessment 6	2.5 years of age	Parent(s) complete an online questionnaire	Your home	25 minutes
Assessment 7	3.5 years of age	Parent(s) complete questionnaires and child is given behavioural tests, eye tracking tasks and a functional Transcranial Doppler ultrasound (fTCD).	Joondalup Health Campus for face to face assessment and your home for questionnaires	1.5 hours (plus ~30 minutes for questionnaires)

Assessment 1 (18-20 week obstetric appointment):

Between 18-20 weeks pregnancy we will complete an ultrasound scan. An experienced ultrasonographer will record standard measurements of your baby, including head circumference, abdominal circumference and femur length, as well as 3D measurements of the volumes of your baby's developing brain. This will take place in the rooms of Dr. Bridget Jeffery at Joondalup Health Campus, and take approximately 20 minutes. We will provide you with an appointment card with contact details of Dr. Bridget Jeffery's receptionist to make an appointment at a time that suits you.

Assessment 2 (At your 24 week obstetric appointment):

At the end of the first ultrasound scan (Assessment 1), we will make another ultrasound appointment with you for when you are 24 weeks pregnant. We will take the same measurements of your baby that we took at Assessment 1. Additionally, a 10 minute video of your baby's hand movements will be taken. This will help us understand if your baby may be showing a hand preference at this early stage.

Assessment 3 (within 5 days of the birth):

Just prior to your discharge from hospital, your newborn baby will undertake a hearing test (in addition to the routine newborn screening) conducted by the Earbus Foundation of WA. A technician will visit you in the hospital room to conduct an Octoacoustic Emissions Test (OAE). An Automated Auditory Brainstem Response (AABR) test will be conducted as part of your routine newborn screening and we will ask for the release of these results to our study.

Assessment 4, 5, 6 and 7:

Assessments 4, will occur when your child is between 6-9 months of age.

Assessment 5 will happen when your child is 2 years old.

Assessment 6 will occur around 2.5 years of age.

The final assessment (7) will happen at 3.5 years of age

Assessment 4 session will take about 1 to 2 hours and take place at ECU Joondalup . There are **three** components to this assessment:



1. Caregiver questionnaires: Prior to the assessment session, you will be sent a series of questionnaires regarding your child's development. These questions will take no more than 60 minutes. These questionnaires will ask you about your child's language and behavioural development, as well as their hand preference, and can be completed in the comfort of your own home.



2. Behavioural examination: At the assessment session, your child will be asked to complete a series of behavioural games, which help us assess motor and language skills. All of these games are specifically designed to be fun for your child. **At the 6 month asessment**, we will also conduct a 10 minute video recording of you playing with your child with a set of toys. This recording will help us understand how parent interaction is related to language development.



3. Eye-tracking: Your child will also complete two short eye tracking tasks. The eye tracking task procedure is as follows:

A researcher will take a photo of the primary caregivers face as a 'familiar' image to use during the eye tracking task.

Your child will be seated in front of a monitor on their parent/ caregiver's lap or in a high-chair with child seat in front of a computer whilst a device measures where they look at the screen known as an eyetracker.

During this time a variety of social and non-social images will be presented. We will also use the image of your child's primary caregiver during this task.

At **assessment 5** when your child is about 2 years of age, we will ask you to only complete questionnaires about your child's development. These forms will be very similar to the caregiver questionnaires you completed about your child when they were 6-9 months old. A researcher from our team will make contact with you about a month before your child's 2nd birthday to confirm your address and ask for your preference of receiving these questionnaires either electronically or through post. These forms will take no longer than 70 minutes to complete.

At **assessment 6** when your child is around 2.5 years of age We will ask that you complete an online assessment about multiple areas of a child's functioning that may assist in the early identification of behavioural, social, and emotional problems. The measure is also able to be used as a method of determining whether major developmental milestones have been appropriately met.

Assessment 7 is the final time point of this study. This will occur when your child is around three and a half years of age. This is a face-to-face assessment where your child will be invited to take part in developmental and behavioural examination similar to Assessment 4 along with few additional questionnaires about your child's language, social-emotional and behavioural development.

This assessment will occur at ECU, Joondalup. At this assessment we will also study how your child's brain processes language. We will use do this using a functional Transcranial Doppler (fTCD) ultrasound. This is a small portable ultrasound . This machine uses ultrasound to detect the blood flow to either side the brain when your child speaks. This helps us to understand which brain hemisphere is used during their language production. The ultrasound procedure is as follows:

- Your child will be fitted with the headset.

- Your child will be then asked to watch 30 cartoon clips which are 12 seconds in length.

- After each clip, your child will be asked to describe what they saw in the video.

- This procedure is safe and non-invasive & painless. Our research staff is very experienced in fitting the headset and using this ultrasound with this to small children.

- We can provide you with a photo of the fTCD testing for you to see if you have any questions or concerns about this procedure and assessment. Please contact us directly on TALK study mobile: 0468 578 851.