

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 to 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 Planck 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 the clinical assessment will be entered immediately into a secure electronic database. The hard copies of this information will be kept in a locked filing cabinet at the Telethon Kids Institute.

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 code numbers 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.

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 Study Coordinator, Alexis Harun. She will be very happy to answer your questions.

Alexis Harun | Study Coordinator

T | (08) 9489 7927 E | Alexis.Harun@telethonkids.org.au

Thank you for your time.



PARENT/GUARDIAN INFORMATION SHEET

The Testosterone and Language in Kids (TALK) study



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, 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

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 comprised of six assessment sessions (some of which will coincide with the assessment sessions of the ORIGINS Project), and these will be spread over a four year period. There will be two assessment sessions during your pregnancy, and four assessments after the birth of your child up until his/her third birthday. 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 child is 6 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.	Your home OR Joondalup Health Campus	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 OR Joondalup Health Campus	1 hour (plus 1 hour for questionnaires)
Assessment 6	Child's 3rd birthday	Parent(s) complete questionnaires and child is given behavioural tests, a face photograph and a functional Transcranial Doppler ultrasound (fTCD).	Your home OR Joondalup Health Campus	2 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, and 6:

Assessments 4, 5 and 6 will occur when your child is 6 months of age and around their 2nd and 3rd birthday. These assessment sessions will take approximately 1 to 2 hours each at the Joondalup Health Campus. There are three components to these assessments:

- **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.
- **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 assessment, 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.

- **Face photo:** A 3-dimensional photograph will be taken of your child's face using a special camera. There is increasing evidence that testosterone exposure in the womb may be related to the shape of the face in childhood. The 3-dimensional photograph will enable us to examine the dimensions of your infant's face with sub-millimetre precision.

At the assessment around your child's third birthday (Assessment 6), we will study how your child's brain processes language. We do this using functional Transcranial Doppler (fTCD). 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 language. 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 painless, and we are very experienced in fitting this to children. We have provided a photo of the fTCD testing for you.



Will you be using other information of my family collected as part of ORIGINS?

Yes, we will request permission from you to access the questionnaire information you have previously provided to the ORIGINS project. We will ask your consent to examine the umbilical cord blood that was collected at the birth of your baby, as well as the DNA collected on you and your child.

We will also request permission from you to share the information we collect as part of the TALK study with the ORIGINS study team. 3D facial images and video recordings will not be shared.