



PARENT/GUARDIAN INFORMATION SHEET
(Perth Site)

The CUB Study

Communicating and Understanding your Baby

Why are we doing this study?

Early intervention can play an important part in reducing disability that is associated with autism spectrum disorder (autism). Early intervention typically starts after a child receives a diagnosis, most often between the ages of 2 and 6 years of age. At present, we don't know whether commencing early intervention before this age, particularly during the first year of life, may also provide developmental benefits to the child.

One way to investigate this idea is to study family members of individuals with developmental disorders such as Autism, ADHD or intellectual disability. Autism is known to be heritable (to 'run in families'), and relatives of individuals with a developmental disorder have a higher chance of being diagnosed with autism compared to the general population.

This research will test a new program that runs from the third antenatal trimester to when the baby is 8 months of age. We want to test whether this program may help parents understand more about their baby's early social and communication skills, and in the process assist their baby's development. This research is important because it will help us to understand how we can best support parents of newborn children, and whether a program provided very early in development may deliver benefits to the family and child.

Who is carrying out the study?

The study leaders are Professor Andrew Whitehouse (Telethon Kids Institute, Perth) and Dr Kristelle Hudry (La Trobe University).

Why have I been invited to take part?

You and your family have been invited to take part because you are pregnant, and you have a biological relative who is diagnosed with a neurodevelopmental disorder.

Does my child have to take part?

Participation in this project is entirely voluntary. If you do decide to participate, you will be given this information booklet and you will be asked to sign a consent form.

What will happen if I give permission to take part?

The study is trialing a new program. We are conducting what is called a 'randomized controlled trial', which means that we are investigating whether this new program may provide benefit when we compare it to current healthcare practice. Once contact has been made with the research team, we will inform you of what the study involves and provide you with an opportunity to ask any questions.

If you agree to take part in the study, you will be randomly allocated to receive one of two programs - you will not be able to choose which group you are in:

1. Developmental monitoring means that we will monitor your child's development during the first two years of life, with three assessments at the Telethon Kids Institute (Subiaco).

2. The new program involves enhancing interactions between you and your baby. In addition to the three assessments at the Telethon Kids Institute (Subiaco), if you are allocated to this group you will be required to attend:

- **Group Sessions:** One group session with other parents during your third pregnancy trimester. These occur at the Telethon Kids Institute (Subiaco, Perth).

- **Individual Sessions:** Seven individual sessions with you and your baby, when your baby is between 1 and 8 months old. Each session will be around 1 hour in length and will take place in your home. The content will be tailored to what the family and clinician would like to focus on. We ask that you nominate one parent to be present during each session to enable continuity of the program. However, we would also encourage a second parent if available to attend as many sessions as possible. At various points, we will also ask your views on the program.

Assessments for all participants	When?	What happens?	Where does this happen?	How long does it take?
Study entry assessment	Pregnancy	Parents complete questionnaires.	In your home.	1 hour.
Newborn assessments	Two occasions. When your baby is 1 and 4 months of age.	Parents complete questionnaires and your baby will receive a behavioural assessment and EEG.	1 month: In your home 4 months: Telethon Kids Institute (Subiaco)	1.5 hours each.
Infant and child assessments	Two occasions. When your baby is 9 and 24 months of age.	Parents complete questionnaires and your baby will complete developmental tests and an EEG.	Telethon Kids Institute (Subiaco)	2 hours each.
Treatment group only	When?	What happens?	Where does this happen?	How long does it take?
Program period	Third trimester to when your baby is 8 months of age.	Families receiving the program will have 1 antenatal group session and 10 individual sessions from birth to when the child is 8 months old.	The antenatal session occurs at the Telethon Kids Institute. The individual sessions take place in your home.	Antenatal session is 3 hours, and postnatal sessions are 1 hour each.

What is the aim of the new therapy program?

The group session (third pregnancy trimester) includes information about the skills and abilities of newborn babies. The individual sessions involve working with our clinician to understand more about your baby, and how you can tailor your own interactions style to meet your baby's needs. We will video record you interacting with your baby, and explore strategies that we hope will help reinforce positive interaction with your baby. The ultimate aim of this therapy is to help your baby's social and language development.

What information will be collected?

We will conduct four assessments with you and your baby, when s/he is 1 month, 4 months, 9 months and 24 months of age. We will collect information through three methods:

1. Questionnaires: We will ask for information about you and your family, as well as about your baby's development.

2. Developmental assessments: We will conduct behavioural assessments with your child, which will help us monitor his/her development. Some of these assessments will be video-recorded. We will use these videos to help understand more about your baby's development. We will also video record you interacting with your baby.

3. EEG: Some of the assessments involve recording an electroencephalography (EEG) with your baby. EEG is a simple way of measuring brain activity. This involves sitting comfortably with your baby on your lap facing a screen. We will measure the size of your baby's head, so we can select the appropriate EEG net. The EEG net that we use contains lots of small sponges that are soaked in warm water with some baby shampoo. The net will be gently placed on your baby's head, similar to a swimming cap. The picture below shows you what your baby will look like. We will then show your baby a short video clip and some images of black-and-white checkerboards while we measure your baby's brain activity. The total recording will be less than 20 minutes.



How do I get to the assessment sessions?

We will provide you detailed information about how to get to the assessment location. If you need assistance to get to the assessments, we will be able to provide this for you.

Is there any cost to take part?

There is no cost to take part. However, the research involves a time commitment over the final trimester of pregnancy and the first two years of your child's life, during which we will see you a number of times. This commitment is outlined in the table on the inside of this booklet. We will ensure that your time commitment is no more than this.

What are the possible benefits of taking part?

The program that we are researching may enhance your daily interactions with your baby. All children will receive developmental monitoring by expert researchers over the course of the child's first two years of life. If we identify any developmental concerns for your baby, we will promptly offer to refer you to the appropriate services.

Will we be disadvantaged by taking part?

No. Our study is experimental, and based on current scientific evidence. We have no reason to believe that any child will be disadvantaged by not receiving this program. All children will receive developmental monitoring by our research team at 1, 4, 9 and 24 months of age.

Storage of your information

Research into child development is complex and these studies can take several years. We plan to keep all information collected for this study. As soon as you enter the study, your child and family will be given a code number. All of the information that we collect will be labelled with this code number, and not your name. This will ensure your information is kept private. The information from the surveys and behavioural tests will be kept in a locked filing cabinet at the Telethon Kids Institute (for Perth participants) or La Trobe University (for Melbourne participants). This information will also be stored in an electronic database. This database will be secured with passwords, and only seen by the researchers in this study. The videos will be stored on a secure server at the Telethon Kids Institute (for Perth participants) or La Trobe University (for Melbourne participants).

Use of your information

The information we collect is very valuable to researchers. There may be occasions where the data we collect from you and your child is shared with other researchers (where ethical approval from an ethics committee is obtained).

Withdrawing consent

You are free to stop taking part in this study at any time. Your decision to stop will not influence the care your child receives from anyone in this study. If you would like us to destroy your information, let us know and we will do so.

What happens to the results of the study?

We will use the information we collect to publish scientific reports with important discoveries. We will also communicate our findings to the public through presentations. Published reports on the results will not mention any identifying information, such as names or addresses. 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 Ramsay Health Care WA | SA Human Research Ethics Committee (RHC WA | SA HREC). If you have any complaints or reservations about any ethical aspect of your participation in a research project, please contact the Consumer Liaison Office at Joondalup Health Campus on (08) 9400-9404 who will direct your complaint to the most appropriate person. Any complaint you make will be investigated by an independent party, treated in confidence, and you will be informed of the outcome.

Who do I contact for more information? If you would like any more information about this study, please do not hesitate to contact Amy Deverell who will be very happy to answer your questions.