



Parent/Guardian and Participant Information and Consent for community-based research

Preventing early language delay: does a parent language program make a difference?

What is the research project about?

Some children speak very few words at 18 months. Research shows that parent language programs can help children learn new words and sentences faster. However, these programs have mainly been run in clinics. We want to know if it can help when offered to a whole community. We are hoping to see how well all toddlers are talking at 18 months, within three local government areas (LGAs) in Melbourne. We will then invite parents of all toddlers who aren't speaking much into our language program study. Over the next few months, we will see how well the children learn new words and sentences. We also want to know whether the program helps with children's behaviour.

Who are the researchers?

The project is based at the Centre for Community Child Health at the Royal Children's Hospital. The team includes researchers from different areas of child health.

- Associate Professor Melissa Wake, Paediatrician
- Professor Sheena Reilly, Speech Pathologist
- Dr Sharon Goldfeld, Paediatrician
- Associate Professor Luigi Girolametto, Speech and Language Therapist
- Dr Obioha Ukoumunne, Statistician
- Lisa Gold, Health Economist
- Pam Muth, Policy Advisor, Department of Human Services, Victoria
- Jane Sheehan, Project Manager
- Anna Price, Research Assistant

What does being in this research project involve?

Three Melbourne councils are taking part in the project.

There are three stages to this project. We hope about a thousand children will take part in Stages 1 and 2, and about 200 of these children will also take part in Stage 3.

In **Stage 1**, your baby will be around 12 months old. We will ask you to fill out a short questionnaire about your child's communication. We will also ask some general information about you. This will take about 10 minutes.

In **Stage 2**, your baby will be nearly 18 months old. We will ask you to fill out another short questionnaire about your child's words and behaviour. This will take 10-15 minutes. We think about 200 children will be saying very few words at 18 months. We will only follow these families in Stage 3.

In **Stage 3**, we will offer six 2-hour group sessions to about half of the 200 families. Children will be about 20-22 months old at this time. About 5-8 parents will attend each session. **Stage 3** is called a randomised controlled trial. This means that we will put your child into either the '*language program*'

group or the 'usual care' group by chance. This is like tossing a coin - you have the same chance of being in either group. What group you are in will depend on which Maternal & Child Health nurse you see. Your nurse won't know which group you are in until afterwards. As children turn 2 years old, we will ask families in both groups to fill out a short written questionnaire and be seen by the research team. We will repeat this when children turn 3 years old. This is explained in more detail below.

What if I'm in the 'language program' group?

A child health professional will run the parent language sessions. Each group will be held once a week for six weeks. We will teach parents ways to bring on their child's language, like learning new words and joining words into sentences. Parents will learn how to use everyday activities (like reading and play) to do this.

One or both parents can attend the parent language sessions. They will be held near where you live. We can provide childcare during the sessions. We will arrange the date and time of the sessions with you by phone.

You can go to your Maternal & Child Health visits as usual. Your nurse will discuss normal development (including language) and do all their usual routine health checks. You can talk to your MCH nurse about any concerns about your child's language and behaviour.

What if I'm in the 'usual care' group?

You can go to your Maternal & Child Health visits as usual. Your nurse will discuss normal development (including language) and do all their usual routine health checks. You can talk to your MCH nurse about any concerns about your child's language and behaviour. You won't have to go to the group sessions.

What happens after the groups?

For toddlers who are slow to talk at 18 months:

- We will contact 200 Stage 3 families as children turn 2 years old. This includes all families in the 'language program' and 'usual care' groups. We will send you a questionnaire to complete (this will take about 30 minutes). We will make a time to see you and your child for some face-to-face language and communication activities (about 30 minutes). We would like to video some of these activities. We will see you either at home, or somewhere convenient for you.
- We will send a final questionnaire as children turn 3 years old (about 30 minutes). We will see you and your child for some more language activities (about 30 minutes). We would also like to video your child telling a story.

We won't analyse the information we collect while we're doing the 2 and 3 year old visits. This will happen later, back at our research office.

For toddlers who are saying plenty of words by 18 months:

- We will send you a summary report at the end of the project, if you would like one.

Will this project help me? Will it help other people?

If you are in the 'language program' group, it might help your child's language and behaviour. This is what the project is trying to find out.

If you are in Stage 3, researchers will assess your child's language when they are 2 and 3 years old. If we notice any big problems, we will be able to tell you.

It will show whether this program helps children's language when it's offered to a whole community. This may help governments and councils make better decisions about what children's programs they support.

How much time will it take? Are there any risks?

Being in the project will take some of your time. You will need to fill out questionnaires. If your child is slow to talk, there is a 50:50 chance we will ask you to attend six group sessions. The follow-up visits at 2 and 3 years will also take some of your time (about 1-1½ hours altogether).

The group leader will be fully trained in the program. From similar programs overseas, we expect that parents will be very positive about the program. We don't think the project will harm you or your child. If you have concerns, you can talk with a project team member, other professional, or the RCH Consumer Liaison (see below) at any time.

How will you keep my information confidential?

We will keep your information in a special database that needs a password. This will be stored on a computer in a locked office at the Centre for Community Child Health. Only members of the research team will be able to use the database. We will keep your surveys in a locked filing cabinet in the same office. If we write or talk about the project, you will not be able to be identified. Your results will be kept securely until your child is 25 years old. Then we will destroy them with a secure shredder/protected waste at the Royal Children's Hospital.

Can I find out the results of the project? How?

While the project is running, we will send you a short newsletter about once a year. After the project ends, we will send you a summary of the results if you would like one. We are happy to talk with you about the project's results at any time. We will also put a report on the Centre for Community Child Health's website, and send it to your Maternal & Child Health nurse. For Stage 3 families, we will send you a short report about your child's language after they turn 3.

Other Issues

You can decide whether or not to take part in this research project. Later, you can decide to leave the project at any time (you don't have to tell us why). You may like to discuss taking part with your family or with another professional. You can ask for more information before deciding.

Questions about the project?

Call Jane Sheehan on (03) 9345 5934 or Melissa Wake on (03) 9345 5934.

Concerns about the project and want to speak to someone independent?

Call the RCH Consumer Liaison officer on (03) 9345 5676, Monday to Friday 9am-5pm.

Thank you very much.

A/Prof Melissa Wake, Paediatrician

This page has some important general information about taking part in research studies approved by the Royal Children's Hospital. Details about this study are on the Information Sheet/Letter.

Your rights as a Participant are:

1. To choose to take part or not to take part
2. To withdraw from the study at any time
3. To have the study fully explained to you

You should feel free to ask the researchers any questions about the study.

Other information you should know about being part of this study

1. Your answers to the questions on this study will be kept private. This is subject to legal requirements.
2. No information from this study will reveal your identity
3. You should have been told what you need to do for this study, and how long it will take.
4. If you do not wish to take part in this study, this will not affect your relationship with the Royal Children's Hospital.
5. This research project has been approved by The Royal Children's Hospital Ethics in Human Research Committee.

If you have any concerns about the study, and would like to speak to someone independent of the study, please contact The RCH Consumer Liaison, Clinical Support Services Team at the Executive Office. Telephone 9345 5676 (Monday to Friday 9am-5pm).

If you would like more information about the study or if you have any questions about the study, the person to contact is:

Name: Melissa Wake

Contact telephone: (03) 9345- 5934