

# Preventing early language delay: a pilot study

|                                        |                                                               |                                                      |
|----------------------------------------|---------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>03/07/2007   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>05/09/2007 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>05/09/2007       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                               | <input type="checkbox"/> Results                     |
|                                        |                                                               | <input type="checkbox"/> Individual participant data |
|                                        |                                                               | <input type="checkbox"/> Record updated in last year |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Melissa Wake

**Contact details**  
Royal Children's Hospital  
Flemington Road  
Parkville  
Melbourne  
Australia  
3052  
+61 (0)3 9345 5761  
melissa.wake@rch.org.au

## Additional identifiers

## Study information

**Scientific Title**

**Acronym**  
LLL (Let's Learn Language)

**Study objectives**

To determine the feasibility of conducting a randomised controlled trial investigating a preventative approach to improve children's language development and behaviour problems at two years of age. Aims of this pilot were to:

1. Examine whether families whose children score at or below the 20th percentile on a standardised vocabulary measure agree to be randomised to a six-week Parent Language Program and to a non-intervention group
2. Compare the usefulness of two standardised vocabulary measures for post-test assessment: the SureStart 100 word Vocabulary Checklist (adapted from the MacArthur Bates Communicative Development Inventories [MBCDI] by Roy, Kersley and Law [2005]) or the Vocabulary Checklist from the complete MBCDI (approx 680 words divided into semantic categories)
3. Trial the videotaping of post-test assessment at 21 - 24 months
4. Solicit parents' evaluations of the program's content and format to provide information about program changes that may increase the feasibility of the Parent Language Program for families in Victoria

This is the pilot study to the randomised trial assigned to ISRCTN20953675.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Received ethics approval from The Royal Children's Hospital Ethics in Humans Research Committee (EHRC) on the 7th June 2007 (ref: 26073A).

### **Study design**

Pilot randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Early delay in acquiring expressive vocabulary

### **Interventions**

For each pair of eligible families recruited, one was randomly allocated to the Parent Language Program Group and one to the Usual Care Group. Masking occurred at randomisation, with group allocation concealed from the principal researcher and participants until allocation was complete. Group allocation was concealed from the researcher conducting follow-up direct assessments with intervention (Parent Language Program) families until data collection was complete.

Arm A - Parent Language Program Group:

A six-week parent language promotion program (six two-hour group sessions) adapted from the Hanen You Make The Difference™ program, offered to parents when children were 19 - 22 months old. The Parent Language Program teaches child-centred, interaction-promoting and

language-modelling responsive interaction strategies targeting the development of vocabulary and multi-word phrases. The Parent Language Program was conducted within the family's local community, facilitated by an early childhood professional.

Arm B - Usual Care Group:

Usual care from the Maternal and Child Health (MCH) nurses who provide a universal and free surveillance service to Melbourne families in the first five years of life (active control).

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

The primary outcomes are to pilot and refine:

1. Parent interest in, and attendance at, a six-week parent language promotion program
2. Organisation and format of the Parent Language Program sessions, adapted from You Make The Difference™ program
3. The sensitivity of the assessment tools used during the follow-up

### **Key secondary outcome(s)**

No secondary outcome measures

### **Completion date**

15/12/2006

## **Eligibility**

### **Key inclusion criteria**

1. Parents of 18 - 21 month-old toddlers
2. Attending any of eight well-child clinics within one Melbourne local government area
3. Identified by a brief, parent-reported vocabulary questionnaire as having minimal or no expressive vocabulary (e.g., scoring at or below the 20th percentile relative to age and sex norms)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Not Specified

### **Sex**

All

### **Key exclusion criteria**

1. Children with already-diagnosed (or a referral for) cognitive delay or major medical conditions
2. Children with symptoms of Autism Spectrum Disorder
3. Parents with insufficient English to attend a parent language program and complete brief written questionnaires

**Date of first enrolment**

15/06/2006

**Date of final enrolment**

15/12/2006

## Locations

**Countries of recruitment**

Australia

**Study participating centre**

Royal Children's Hospital

Melbourne

Australia

3052

## Sponsor information

**Organisation**

Murdoch Childrens Research Institute, Parkville (Australia)

**ROR**

<https://ror.org/048fyec77>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Murdoch Childrens Research Institute, Parkville (Australia)

## Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

| Output type                   | Details       | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Study website</a> | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |