

# Improving outcomes of preschool language delay in the community

**Submission date**  
23/02/2010

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
23/06/2010

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
29/01/2016

**Condition category**  
Mental and Behavioural Disorders

☐ Individual participant data

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

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
HREC 3011A

## Study information

**Scientific Title**  
Improving outcomes of preschool language delay in the community: a large-scale randomised controlled trial

## **Acronym**

L4L (Language for Learning)

## **Study objectives**

This trial aims to trial a population approach to improving language and important related outcomes in 4 year olds with language delay. We hypothesise that:

1. Compared to the control group, benefits to the intervention group at 5 and 6 years will include better mean scores on standardised tests of:

1.1. Expressive/receptive language (primary outcomes) and vocabulary

1.2. Other secondary outcomes:

1.2.1. Social skills and relationships

1.2.2. Emotional and behavioural well-being

1.2.3. Early literacy

1.2.4. Health-related quality of life

1.2.5. "School readiness", measured by the Australian Early Development Index

2. The intervention will be acceptable and cost-effective (against common decision thresholds)

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics in Human Research Committee of the Royal Childrens Hospital, Melbourne, Australia, pending approval as of 24/02/2010

## **Study design**

Large-scale single-centre randomised (concealed randomisation) controlled trial nested within a cross-sectional study

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

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

Language delay at four years of age

## **Interventions**

Allocation to the intervention group will be a simple randomisation using computerised sequence generation, conducted by an independent statistician and concealed from the principal researchers to the end of the study's life and participants until allocation is complete. Group allocation will be concealed from researchers conducting 5- and 6-year follow-up direct assessments until data collection is complete.

Arm A: Intervention group -

A 20-session, year-long program will be offered to parents of children who have a language delay at four years of age, when their child turns approximately 50 - 52 months old. It comprises 18 weekly sessions in three 6-week bursts starting every 3 months; the 5-year-old blinded assessment; and an exit feedback/planning session in the following month. Sessions will be delivered in a private room at a local centre (e.g., Maternal and Child Health Centres [MCH]) by a trained researcher-therapist experienced with parents and children and knowledgeable about

child health and development. Sessions include activities that encompass four domains, chosen for their importance to language, social and educational outcomes and demonstrated feasibility for standardised large-scale intervention delivered without specialised speech pathologist skills.

**Arm B: Usual care group -**

Usual care from the MCH nurses who provide a universal and free surveillance service to Melbourne families in the first 5 years of life (active control).

### **Intervention Type**

Other

### **Phase**

Not Applicable

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

Direct assessment of child's expressive and receptive language ability and expressive and receptive vocabulary; all collected at 5 and 6 years.

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

1. Parent reported pragmatic skills, behaviour, health related quality of life and service utilisation
2. Direct assessment of child's word recognition, sentence comprehension and a proxy for non-verbal intelligence quotient (IQ)
3. Teacher reported language, social, emotional, cognitive and physical wellbeing

### **Completion date**

01/03/2014

## **Eligibility**

### **Key inclusion criteria**

The trial will involve all subjects who as babies and toddlers participated in two completed population-based trials - Let's Read and Let's Learn Language (ISRCTN20953675). These were conducted in eight local government areas across Melbourne, Australia. Children will be invited into the new trial as they turn 4 years old.

Eligible participants will be

1. Children who, at 4 years of age, have expressive and/or receptive language scores more than 1 SD below the normative mean on the CELF-P2
2. Their parents

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

4 years

**Upper age limit**

4 years

**Sex**

All

**Key exclusion criteria**

1. Intellectual disability
2. Major medical conditions
3. Hearing loss greater than 40 dB Hearing Loss (HL) Scale in the better ear
4. Autism spectrum disorders
5. Parents who need an interpreter

Most such children are already excluded as they have demonstrated competence in their previous research trial.

**Date of first enrolment**

01/03/2010

**Date of final enrolment**

01/03/2014

**Locations****Countries of recruitment**

Australia

**Study participating centre**

Royal Children's Hospital

Parkville

Australia

3052

**Sponsor information****Organisation**

Royal Children's Hospital (Australia)

**ROR**

<https://ror.org/02rktxt32>

**Funder(s)**

**Funder type**

Research council

**Funder Name**

National Health and Medical Research Council (Australia) - Project Grant Application (ref: 607407)

**Alternative Name(s)**

National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Australia

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2013		Yes	No
<a href="#">Results article</a>	results	01/10/2015		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes