Preventing early language delay: a pilot study

Submission date	Recruitment status No longer recruiting	Prospectively registered		
03/07/2007		☐ Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
05/09/2007		☐ Results		
Last Edited		Individual participant data		
05/09/2007	Mental and Behavioural Disorders	Record updated in last year		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N/A

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

Kev 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 summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes