

Preventing early language delay: a pilot study

Submission date 03/07/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/09/2007	Condition category 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

Study website

<http://www.rch.org.au/emplibrary/ccch/TheLetsLearnLanguage.pdf>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Prevention

Participant information sheet

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

15/06/2006

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

Age group

Not Specified

Sex

Both

Target number of participants

Target sample size was 100 to identify 20 eligible children. Recruitment status achieved was 103, which identified 30 eligible children.

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)

Sponsor details

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Sponsor type

Research organisation

Website

http://www.rch.org.au/rch/index.cfm?doc_id=1495

ROR

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

Funder(s)**Funder type**

Research organisation

Funder Name

Murdoch Childrens Research Institute, Parkville (Australia)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration