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Preventing early language delay: a pilot study

Submission date
03/07/2007

Recruitment status
No longer recruiting

Registration date
05/09/2007

Overall study status
Completed

Last Edited
05/09/2007

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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).

Primary study design
Interventional

Study design
Pilot randomised controlled trial

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes