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Preventing early language delay in the primary care setting: cluster randomised trial

Submission date	Recruitment status	[ ] Prospectively registered
03/07/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/10/2011	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

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 trial a preventive approach to lowering the proportions of slow-to-talk toddlers who progress to expressive language and externalising behaviour problems at ages two and three years.

We hypothesise that:
1. Compared with the non-intervention (control) group at 24 and 36 months, the intervention group will comprise:
1.1. Fewer children with delays in early expressive vocabulary acquisition
1.2. Higher mean vocabulary and Mean Length of Utterance (MLU) scores, as well as scores on standardised measures of receptive and expressive language
1.3. A greater number of responsive linguistic interactions between parents and children
1.4. Lower mean scores on a standardised measure of externalising behaviour problems
2. The intervention will be more efficacious for disadvantaged children
3. The intervention will be acceptable and cost-effective

This is the resulting randomised trial from the pilot study registered under ISRCTN45091963.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received approval from the Ethics in Human Research Committee of the Royal Children's Hospital (Australia) on 2nd March 2007 (ref: EHRC 26028B).

Study design
Cluster randomised controlled trial, nested in a preceding population survey process.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Early delay in acquiring expressive vocabulary

Interventions
Cluster randomised controlled trial, with cluster at the level of the well-child centre. Masked randomisation is due to occur in January 2008 after the study team has recruited all clusters. Allocation to 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 two- and three-year follow-up direct assessments until data collection is 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 of slow-to-talk toddlers when the children turn 19 - 20 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 will be conducted at local community centres, 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
1. Parent-report of child's expressive vocabulary
2. Direct assessment of child's receptive language ability, childs mean length of utterance in morphemes from videotaped short narrative
3. Parents' use of responsive language facilitation strategies derived from the videotaped language sample

All collected at two and three years.

Secondary outcome measures
1. Direct assessment of child's expressive language abilities
2. Parent-report of child's externalising behaviour problems

Both collected at two and three years.

Overall study start date
01/05/2007

Completion date
30/11/2009

Eligibility

Key inclusion criteria
1. Parents of 12 month-old infants
2. Attending community well-child clinics across three Melbourne local government areas from May to November 2007
3. Parents whose toddlers, at 18 months, are 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 is 1000 to identify 200 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. Children with cleft palates
4. Parents with insufficient English to attend a Parent Language Program and complete brief written questionnaires

Date of first enrolment
01/05/2007

Date of final enrolment
30/11/2009

Locations

Countries of recruitment
Australia

Study participating centre
Royal Children's Hospital
Melbourne
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Sponsor information

Organisation
Murdoch Childrens Research Institute, Parkville (Australia)

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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 council

Funder Name
National Health and Medical Research Council (Australia) - Strategic Award (ref: #384491)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/08/2011		Yes	No