ISRCTN03981121 https://doi.org/10.1186/ISRCTN03981121

Improving outcomes of preschool language delay in the community

Submission date	Recruitment status	[ ] Prospectively registered
23/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/01/2016	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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Direct assessment of childs expressive and receptive language ability and expressive and receptive vocabulary; all collected at 5 and 6 years.

Secondary outcome measures
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

Overall study start date
01/03/2010

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

Age group
Child

Lower age limit
4 Years

Upper age limit
4 Years

Sex
Both

Target number of participants
Target sample size is 1500 to identify 240 eligible children

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)

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Sponsor type
Hospital/treatment centre

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http://www.rch.org.au

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)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2013		Yes	No
Results article	results	01/10/2015		Yes	No