

Cluster randomised control trial of an early childhood literacy intervention to improve literacy and language outcomes in preschool aged children

Submission date 23/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/06/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/10/2017	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.letsread.com.au/pages/clusterTrial.php?PHPSESSID=7da7edffe748e8a0e22a982b243c6f82>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LP0561522

Study information

Scientific Title

Cluster randomised control trial of an early childhood literacy intervention to improve literacy and language outcomes in preschool aged children

Acronym

LR CRCT - Lets Read Cluster Randomised Control Trial

Study objectives

This trial aims to examine the efficacy of Lets Read an initiative to promote reading with young children 0-5 years. This initiative has been designed to support and empower parents/carers to read with their child, and develop the building blocks that are needed to make the transition to school as easy as possible.

The components of Lets Read are:

1. Training community based professionals so they can show and support parents to have fun reading with their child and develop their childrens early literacy skills.
2. Resources to give to families, including parent information leaflets, DVDs, suggested book lists and age appropriate books.
3. A community approach to promote the importance of literacy through existing services and systems, to reach as many families as possible and sustain the program for the long term. Lets Read provides a Community Facilitator and a Community Guide to support the planning and implementation of the program in each community. Simple community messages have been developed to support the promotion of literacy.

The trialists hypothesise that, compared to the control group, benefits to the intervention group will comprise:

1. More parent-child interactive language, more literacy episodes and a better literacy environment in the home setting.
2. Better emergent and preschool language and literacy skills (expressive and receptive vocabulary, phonological awareness, and letter knowledge and print conventions).

The trialists will also examine within-cohort predictors of outcomes in the intervention group, hypothesising that the intervention will differentially benefit the most disadvantaged children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Royal Childrens Hospital Human Research Ethics Committee (HREC), 20/01/2006, ref: 25018C

Study design

Cluster-randomised controlled trial.

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Language and emergent literacy

Interventions

This cluster-randomised controlled trial is stratified at the level of the Local Government Area (LGA) and clustered at the level of the MCH centres. Clusters will be randomised according to a random number table.

Parents will be recruited consecutively when their infant is approximately 2-4 weeks of age. Over 2 months each MCH nurse will approach all parents of newborn infants attending their initial MCH centre visit to ascertain their interest in participating in the study. The Centre for Community Child Health (CCH) will telephone interested parents and mail the information sheet and consent form, and organise the baseline face-to-face interviews.

The program is a multi-contact intervention providing age appropriate advice at four routine individual well-child visits when the child is aged 4-8 months, 12 months, 18 months and 3.5 years. Nurses will remind parents to attend for these visits. The first point at which a parent will receive the intervention is when the child is between 4 and 8 months of age and attending their MCHC for a routine visit. At this time nurses will deliver, model and discuss the Let's Read intervention messages and distribute the first Let's Read take home pack (free story book, DVD or video, booklist and guidance messages). The three subsequent Let's Read visits will follow similar formats, each with a free book, booklist and messages tailored to the age of the child (the DVD will be given at the first visit only).

Intervention Type

Behavioural

Primary outcome measure

The following will be assessed annually from 12 months of age:

Measures of emergent literacy:

1. Who am I? An Australian measure for assessing the cognitive processes that underlie the

learning of early literacy and numeracy skills in 4-7 year olds. It provides three numerical sub-scores (copying, symbols and drawing) and a total score out of a possible 44. Normative data are available for more than 4,000 Australian children, and its inclusion at 4 years in the "Growing Up in Australia: Longitudinal Study of Australian Children" (LSAC; an Australian government initiative that addresses a range of questions about children's development and wellbeing) will provide comparative data for a further 10,000 children.

2. Children's Test of Non-Word Repetition (CTNWR) is a measure of phonological memory, which provides information about word decoding ability and word attack skills; it is highly reliable even in preschool children and published norms are available.

3. Concepts About Print (CAP) This is a checklist of knowledge a child has about books and the function and conventions of text and books.

4. Preschool and Primary Inventory of Phonological Awareness (PIPA) This measure has six subtests that assess a child's ability to detect, isolate, manipulate and convert sound units and is normed on Australian children.

Language measures:

5. Peabody Picture Vocabulary Test (PPVT): A widely-used measure of receptive vocabulary, with excellent norms; provides standard scores and is being used in both the "Early Language in Victoria Study" (a longitudinal study of language development in Victorian children funded by the National Health and Medical Research Council) and LSAC.

6. Clinical Evaluation of Language Fundamentals-Preschool (CELF-P): This widely-used language assessment tool provides Total, Receptive and Expressive Language standard scores.

Secondary outcome measures

The following will be assessed annually from 12 months of age:

1. Literacy activities and environment: STIM Q is an orally administered questionnaire that assesses cognitive aspects of the home environment. The READ subscale focuses on the number and variety of books in the home and frequency and quality of shared reading activities. It has a 0.55 correlation with the Home Observation for Measurement of the Environment (HOME) inventory, the gold standard of the environment.

2. Measure of language progress: Macarthur Communicative Development Inventories (MCDI; 12 months, 2 years, 3 years): The age-appropriate versions will be completed, i.e. at 12 months - MCDI (Words and Gestures) scale, which focuses on vocabulary comprehension and production; at 2 years - the MCDI (Words and Sentences) scale; and at 3 years the MCDI III, which includes a 100 item vocabulary list, twelve sentence pairs for assessing grammatical complexity and twelve yes/no questions concerning semantics, pragmatics and comprehension. Widely used in Australian and internationally, these measures are acceptable, well validated for English-speaking children, provide continuous standard scores, have known predictive value, and are felt to be among the most reliable early measures of language development.

3. Measure of developmental progress: Parents Evaluation of Developmental Status (PEDS): comprises ten questions eliciting parent concern about a broad range of developmental and behavioural domains, including receptive and expressive language, written at a Year 5 level. Sensitivities of 74-80% and specificities of 70-80% have been reported against gold-standard testing for developmental disabilities. The questions will be supplemented with similarly-formatted questions probing concerns about early interest in listening to and looking at books.

Overall study start date

09/03/2006

Completion date

30/12/2011

Eligibility

Key inclusion criteria

Parents of infants born May-July 2006 (2-4 weeks of age) attending their local Maternal and Child Health (MCH) centre in the cities of Moreland, Darebin, Hobsons Bay, Frankston and Dandenong.

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

At least 900 parents

Key exclusion criteria

Only parents who require the use of interpreters to verbally communicate will be excluded from the study.

Date of first enrolment

09/03/2006

Date of final enrolment

30/12/2011

Locations

Countries of recruitment

Australia

Study participating centre

Royal Children's Hospital

Victoria

Australia

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Sponsor information

Organisation

Australian Research Council (ARC)

Sponsor details

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Sponsor type

Government

Website

<http://www.arc.gov.au>

ROR

<https://ror.org/05mmh0f86>

Funder(s)**Funder type**

Government

Funder Name

Australian Research Council

Alternative Name(s)

arc_gov_au, The Australian Research Council, Australian Government Australian Research Council (ARC), ARC

Funding Body Type

Government organisation

Funding Body Subtype

Other non-profit organizations

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	2-year results	01/03/2011		Yes	No
Results article	4-year results	01/11/2012		Yes	No
Results article	results	01/03/2018		Yes	No