

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: October 26, 2016

ClinicalTrials.gov ID: NCT02659579

Study Identification

Unique Protocol ID: ES/M003752/1

Brief Title: Evaluating the Effectiveness of the Reader Organisation's Get Into Reading Intervention

Official Title: Evaluating the Effectiveness of the Reader Organisation's Get Into Reading Intervention

Secondary IDs:

Study Status

Record Verification: October 2016

Overall Status: Active, not recruiting

Study Start: February 2016 []

Primary Completion: July 2017 [Anticipated]

Study Completion: July 2017 [Anticipated]

Sponsor/Collaborators

Sponsor: Caroline Rowland

Responsible Party: Sponsor-Investigator

Investigator: Caroline Rowland [crowland]

Official Title: Prof

Affiliation: University of Liverpool

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved

Approval Number: RETH000871

Board Name: Research Ethics Subcommittee for Non-Invasive Procedures

Board Affiliation: University of Liverpool

Phone: 0151 794 8290

Email: ethics@liverpool.ac.uk

Address:

Data Monitoring: No
FDA Regulated Intervention: No

Study Description

Brief Summary: The investigators will evaluate the effectiveness of a parent-child shared reading intervention run by The Reader Organisation. The investigators will be asking parents and children across Liverpool to either (i) attend a weekly shared reading programme or (b) to attend a weekly children's reading group at a library. The investigators will look at how the reading groups affect children's language development, by comparing children's language development before having gone to these groups and after they have attended these groups.

Detailed Description: This is a Randomised Control Trial to test whether The Reader Organisation's Shared Reading Programme is more effective at improving the language development of children than a free library reading group. **Intervention group:** Fifty parents of children (3 to 4-years of age) will be recruited to take part in a 8 weeks long shared reading programme. The shared reading programme is comprised of two different modules: a) 'Magical Storytimes', in which a collection of shared book reading sessions are led by a project worker and b) 'Stories for You and Yours', in which parents will be taught how to choose books and read interactively with their child. **Control group:** Fifty further families, matched for age and background will be recruited to a reading control group and asked to attend a weekly shared reading group at a library where parents/ children will read in a shared pre-school library reading group, coordinated by a group facilitator. **Location:** The Shared Reading Programme will take place in the child's nursery (in nurseries across Liverpool). **Control group** parents and children will attend a weekly reading group at a library. All standardised tests, for all children, will take place in the child's nursery. Language gains from pre- to post- intervention will be measured.

Conditions

Conditions: Language Development
Keywords: Shared Book Reading
Vocabulary
Language Development
Young Children
Randomised Control Trial

Study Design

Study Type: Interventional
Primary Purpose: Other
Study Phase: N/A
Interventional Study Model: Parallel Assignment
Number of Arms: 2
Masking: Single (Outcomes Assessor)
Allocation: Randomized
Enrollment: 100 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
<p>Experimental: The Reader Organisation's Shared Reading Programme</p> <p>In the Reader Organisation's Shared Reading Programme, parents and children will attend The Reader Organisation's weekly shared reading programme for 8 weeks. The programme consists of two different modules. Parents will attend 'Magical Storytimes' with their children, in which a collection of shared book reading sessions are led by a project worker. Parents will also attend sessions on their own ('Stories for you and Yours') in which they will be informed how to choose books and read interactively with their child.</p>	<p>Behavioral: The Reader Organisation's Shared Reading Programme</p> <p>In The Reader Organisation's Shared Reading Programme, parents and children will attend weekly shared book reading sessions for 8 weeks which focus predominately on how to read interactively with children.</p>
<p>Active Comparator: Shared Reading control</p> <p>In the Shared Reading control parents and children will attend a weekly shared reading group at a library for 8 weeks where parents/children will read in a shared reading group which will be coordinated by a group facilitator.</p>	<p>Behavioral: Shared Reading control</p> <p>Parents and children will attend a weekly shared reading group at a library for 8 weeks</p>

Outcome Measures

Primary Outcome Measure:

1. Change in baseline language skills: British Picture Vocabulary Scale: Third edition
The British Picture Vocabulary Scale: Third edition (BPVS3) will be administered to children baseline, 4 weeks, and 6 months after intervention. The BPVS3 assesses a child's receptive vocabulary; for each question, the researcher says a word and the child responds by selecting a picture from four options that best illustrates the word's meaning.
[Time Frame: Baseline and 4 weeks after intervention and 6 months after the intervention]

Secondary Outcome Measure:

2. Change in baseline language skills: Clinical Evaluation of Language Fundamentals - Preschool 2 UK.
The Clinical Evaluation of Language Fundamentals - Preschool 2 UK (CELF Preschool-2) will be administered to children at baseline, 4 weeks, and 6 weeks after intervention. The CELF Preschool-2 is a published measure of linguistic knowledge of individual children which measures a broad range of language skills in young children. Specifically, we will use three subset tests from the CELF Preschool-2. The "sentence structure" subset will measure the children's understanding of simple and complex sentence structures. A sentence is read to the child and the child chooses, from a set of pictures, which picture "goes with" that sentence. The "word structure" subset measures the children's understanding of simple and complex word structures. A sentence is read about a particular picture and the child is asked to finish the sentence. The "expressive vocabulary" subset evaluate a child's ability to label pictures of people, objects, and actions.
[Time Frame: Baseline, 4 weeks after intervention and 6 months after the intervention]
3. Parent Child Questionnaire
The Parent Child Questionnaire contains 78 items and assesses: satisfaction with parenting, parent's interaction with and knowledge of his or her child, parent's perception of how he/she communicates with a child, parents' experience of disciplining their child, parent's ability to promote a child's independence and parents' attitudes about gender roles in parenting.
[Time Frame: Baseline and 4 weeks after intervention]
4. Family Questionnaire
The Family Questionnaire records relevant demographic information (e.g. socio-economic status, parents' education, family language use, ethnicity, children's medical history) that was devised for the Economic Social Research Council funded United Kingdom Communicative Development Inventory study. This allows us to create a composite individual

socio-economic background variable using maternal education and household income in order to identify high and low socio-economic status families and to confirm that the participant children are typically developing monolinguals.

[Time Frame: Baseline]

5. Family Reading Questionnaire

The Family Reading Questionnaire examines frequency of storybook reading, reading requests and child library visits, number of books and children's books in the home, parental reading habits, reading onset, and frequency of parent teaching behaviours about reading, such as teaching about print knowledge (e.g. how often do you teach your child how to print words/read words?) questions about book choice (e.g. books read in the last week, child's favourite book).

[Time Frame: Baseline and 4 weeks after intervention]

6. Children's Title Checklist

The Children's Title Checklist indirectly measure a child's storybook exposure by assessing the parent's knowledge of children's book titles (Children's Title Checklist). The Children's Title Checklist consists of 40 titles of popular children's books and 20 foils.

[Time Frame: Baseline and 4 weeks after intervention]

7. Children's Author Checklist

The Children's Author Checklist indirectly measures a child's storybook exposure by assessing the parent's knowledge of authors. The Children's Author Checklist consists of 40 names of authors of popular children's books and 20 foils.

[Time Frame: Baseline and 4 weeks after intervention]

8. The Reader Organisation's Baseline Questionnaire

The Reader Organisation's Baseline Questionnaire assess parents' attitudes towards reading and barriers towards reading.

[Time Frame: Baseline]

9. The Reader Organisation's Follow Up Questionnaire

The Reader Organisation's Follow Up Questionnaire assess parents' attitudes towards reading and barriers towards reading. Parents are also asked questions about their own experience of the intervention itself.

[Time Frame: 4 weeks after intervention]

10. Leuven Scale during Dyadic Videoed Book-Reading Sessions

The Leuven scale will be used to assess the child's active engagement during videoed dyadic book-reading sessions. There are 5 levels of engagements: extremely low (e.g. the child shows hardly any activity), low (e.g. the child shows some degree of activity which is often interrupted), moderate (e.g. the child is busy the whole time, but without real concentration), high (e.g. there are clear signs of involvement, but these are not always present to their full extent) and extremely high (e.g. during the observation of learning the child is continually engaged in the activity and completely absorbed in it).

[Time Frame: Baseline and 4 weeks after intervention]

Eligibility

Minimum Age: 36 Months

Maximum Age: 59 Months

Sex: All

Gender Based:

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

All families will be included unless they fit the exclusion criteria below.

Exclusion Criteria:

This is a study of typically developing English-learning children. The following exclusion criteria are designed to exclude families in which the target child is at risk of atypical or delayed language acquisition:

- Children born before 37 weeks gestation (premature)
- Children who weighed less than 5lb 9oz at birth (low birth weight)
- Children who have had an ear infection/glue ear for longer than 3 months, 4-6 ear infections within a 6 month period or another identified hearing problem (e.g. at newborn hearing screening)
- Children with an identified developmental disability (e.g. Cerebral Palsy, Autism Spectrum Disorder, Fragile X syndrome, Muscular dystrophy, Di George syndrome, Down's syndrome, Williams syndrome)
- Children with a hearing or visual impairment
- Children who hear another language (not English) for 1 day or more in a typical week (please note that this also excludes children of parents who do not speak English)
- Children whose parents have a learning disability which puts their children at risk of language delay and excludes the parents from giving informed consent on their own and on their children's behalf.

Contacts/Locations

Central Contact Person: Caroline F Rowland, PhD
Telephone: 01517942942
Email: crowland@liverpool.ac.uk

Central Contact Backup: Jamie Lingwood, PhD
Telephone: 0151 794 1398
Email: Jamie.Lingwood@liverpool.ac.uk

Study Officials: Caroline F Rowland, PhD
Study Principal Investigator
University of Liverpool

Locations: United Kingdom
Liverpool Language Lab at the University of Liverpool
Liverpool, Merseyside, United Kingdom, L69 7ZA
Contact: Caroline F Rowland, PhD 01517942942
crowland@liverpool.ac.uk
Sub-Investigator: Jamie Lingwood, PhD

IPDSharing

Plan to Share IPD: Yes
With the consent of participating adults, the data will be donated to the UK data archive.

Supporting Information:

Time Frame:
Access Criteria:
URL:

References

Citations:

Links:

