

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 07/27/2016

ClinicalTrials.gov ID: [Not yet assigned]

Study Identification

Unique Protocol ID: R/139470-11-1-INFERENCE

Brief Title: Supporting Children's School Readiness.

Official Title: A Randomised Control Trial to Test the Effect of Parents' Inference-eliciting Questions During Shared Book Reading on 4-year-olds' Listening Comprehension.

Secondary IDs:

Study Status

Record Verification: July 2016

Overall Status: Not yet recruiting

Study Start: July 2016

Primary Completion: March 2018 [Anticipated]

Study Completion: July 2018 [Anticipated]

Sponsor/Collaborators

Sponsor: University of Sheffield

Responsible Party: Principal Investigator

Investigator: Danielle Matthews [dmatthews]

Official Title: Reader in Cognitive Development

Affiliation: University of Sheffield

Collaborators: University of Leeds

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board: Approval Status: Approved

Approval Number: 006705

Board Name: Department of Psychology Ethical Review Board

Board Affiliation: The University of Sheffield

Phone: (+44) (0)114 22 26516

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Data Monitoring?: No

Plan to Share Data?: Yes

Yes. IPD will be archived in accordance with the guidelines and protocol of the University of Sheffield, the UK Data Archive and the ESRC's Research Data Policy.

With parents' permission, data will be made available in a timely manner, after outcomes have been published together with appropriate metadata in line with ESRC policy around data archiving.

Oversight Authorities: United Kingdom: Research Councils UK

Study Description

Brief Summary: The aim of this project is to test whether training parents to ask their children 'inference-eliciting' questions during book reading is effective in promoting story comprehension for 4-year-olds from a range of socio-economic backgrounds.

Detailed Description: Language comprehension relies on the ability to make local and global inferences (e.g., inferring what a pronoun refers to, or inferring why a protagonist in a story did something based on information distributed through the text). These skills develop in the preschool years and are demonstrated when children make sense of stories that are read to them. While important for later reading ability and academic success, relatively little is known about whether anything can be done to improve inference-making skills in the preschool years. One possibility is that parent-child book reading would help. During book reading, some parents naturally ask their children questions about the story that would require them to make inferences about the text. The current study is designed to test whether doing this promotes children's ability to make inferences. Half the parents in this study will be given books with inference eliciting questions added to them and will be provided with training about how to ask these questions and respond to their children's answers. The other half of the parents will be given a maths exercise book and asked to spend the same amount of time per day working through this.

Conditions

Conditions: Language Development

Keywords: Language Development
Shared Picture Book reading
Preschoolers
Inference making

Study Design

Study Type: Interventional

Primary Purpose: Basic Science

Study Phase: N/A

Intervention Model: Parallel Assignment

Number of Arms: 2

Masking: Double Blind (Subject, Caregiver, Investigator)

Allocation: Randomized

Endpoint Classification: Efficacy Study

Enrollment: 120 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Language comprehension intervention	Behavioral: Language comprehension intervention

Arms	Assigned Interventions
The intervention will run for 4 weeks. Caregivers will be provided with storybooks (e.g., Percy the Park Keeper) that have been amended to include inference-eliciting questions. Caregivers will be trained (with a video) to ask these questions and respond to their children's answers during shared reading sessions. They will be asked to read one book per day. Caregivers will keep a reading diary.	
Active Comparator: Counting intervention The intervention will run for 4 weeks. Caregivers will be provided with a book 'At home with counting' that is made up of age appropriate maths exercises. Caregivers will trained (with a video) to work through one page of the book per day. This should take the same amount of time as the activity in the language intervention condition. Caregivers will keep a counting diary.	Behavioral: Counting intervention

Outcome Measures

Primary Outcome Measure:

1. Children's ability to answer inference questions (compared to a baseline measure).
[Time Frame: Baseline: when child is 4 years 3 months - 4 years 6 months. Post test: 4 weeks post intervention]
[Safety Issue: No]
An age-appropriate test of inferencing ability has been developed for this study including vignettes developed by the Language and Reading Research Consortium. Children listen to short vignettes and are then asked questions that require them to make local and global inferences based on the information in the stories.

Secondary Outcome Measure:

2. Change in NFER baseline assessment
[Time Frame: Baseline: when child is 4 years 3 months - 4 years 6 months. Post test: 4 weeks post intervention]
[Safety Issue: No]
This is an age appropriate test of maths and language ability.

Eligibility

Minimum Age: 50 Months

Maximum Age: 56 Months

Gender: Both

Accepts Healthy Volunteers?: Yes

Criteria: Inclusion Criteria:

Children are:

First born Full term (i.e. born no more than 3 weeks prematurely) With birth weight over 2.5 kg Being raised as monolingual English speakers

Exclusion Criteria:

Neither caregivers nor infants have any significant known physical, mental or learning disability.

Contacts/Locations

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References

Citations:

Links:

Study Data/Documents: