

# A roadmap to executive function and language

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<b>Registration date</b> 06/03/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/10/2022	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Children's cognitive development, literacy, and educational outcomes are influenced by the quality of the family environment. Early intervention programs that promote positive parenting behaviors and child cognition have great potential to positively influence children's school readiness and thereby support social equality. The aim of this study is to evaluate the effects of a book-sharing intervention for caregivers and their 10-month-old children.

### Who can participate?

Caregivers who have a child that is 10 months old (+/- 4 weeks) at the time of enrolment

### What does the study involve?

Participating parent-infant pairs are randomly allocated to an intervention group or an active control group. The intervention group participate in a group-based book-sharing program. The intervention will be delivered weekly for five consecutive weeks to groups of around 4-6 parent-child dyads. Each session (60 min) includes the presentation of a picture-book that they take home to share with their child, presentation of the session's specific topic, group discussions and individual feedback. The sessions focus on teaching different interactive scaffolding techniques for caregivers to use during picture book-sharing with their child. The active control group participants will meet for five consecutive weeks in groups consisting of around 4-6 parent-child dyads. Each session (60 min) includes receiving information about children's general psychological development and the opportunity to play together with different toys. Data will be collected at the start of the study, after the intervention and at two follow-ups when the infants are 18 and 24 months of age. Outcome data will be collected using child-friendly assessments with eye tracking, EEG system, video-recorded observations, tablet-based tasks and parental reports.

### What are the possible benefits and risks of participating?

There are no direct benefits of participating in the study, but participating will contribute to new knowledge regarding young children's cognitive and socio-cognitive development. However, if the intervention is successful, it is possible that short-term improvements in parent-child interaction and in the child's cognitive development can be seen in the intervention group. The intervention group and the active control group also have the opportunity to connect with other families through the planned group sessions. There are no known risks associated with participating in the study. All measurement methods and paradigms are well established within

psychological research of infants and young children worldwide. In addition, the study methods have been used extensively at Uppsala Child and Baby Lab over the past 20 years without incidents and without any risks being identified.

Where is the study run from?

Uppsala Child and Baby Lab, Department of Psychology, Uppsala University (Sweden)

When is the study starting and how long is it expected to run for?

September 2019 to October 2022

Who is funding the study?

1. Riksbankens Jubileumsfond
2. Majblommans Riksförbund
3. Swedish Research Council

Who is the main contact?

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## Contact information

### Type(s)

Scientific

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

P18-0300:1

**Study information****Scientific Title**

The impact of book-sharing on infant language and cognitive development: a randomized controlled trial

**Acronym**

REaL

**Study objectives**

The researchers expect intervention effects on child cognition, social-cognition and neurophysiological outcome, as well as parental scaffolding abilities.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 03/06/2019, Etikprövningsmyndigheten (Swedish Ethical Review Authority, Box 2110, 750 02 Uppsala, Sweden; +46 (0)10 475 08 00; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: 2019-03140

**Study design**

Randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Other

### **Participant information sheet**

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

### **Health condition(s) or problem(s) studied**

Developmental psychology, child cognitive and socio-cognitive development

### **Interventions**

Participating families are randomly allocated to an intervention group or an active control group.

Intervention group: participate in a group-based book-sharing program. The intervention will be delivered weekly for five consecutive weeks to groups of around 4-6 parent-child dyads. Each session (60 min) includes the presentation of a picture-book that they take home to share with their child, presentation of the session's specific topic, group discussions and individual feedback. The sessions focus on teaching different interactive scaffolding techniques for caregivers to use during picture book-sharing with their child.

Active control group: participants will meet for five consecutive weeks in groups consisting of around 4-6 parent-child dyads. Each session (60 min) includes receiving information about children's general psychological development and the opportunity to play together with different toys.

Both groups take part in lab assessments at baseline, post-assessment, at a first follow-up ( $\approx$  18 months of age) and then again at a second follow-up ( $\approx$  24 months of age).

### **Intervention Type**

Behavioural

### **Primary outcome measure**

1. Child language assessed using:

1.1. Swedish Early Communication Development Inventory (parent report) at baseline, post-assessment, 1st and 2nd follow-up

1.2. Word-picture matching preferential looking paradigm (eye tracking) at baseline, post-assessment, 1st and 2nd follow-up

1.3. Word-picture matching congruent-incongruent paradigm (eye tracking; EEG) at baseline and post-assessment

2. Child joint attention: responding and initiating joint attention from the Early Social Communication Scales (video record) at baseline, post-assessment, and 1st follow-up

3. Child executive function assessed using:

3.1. The Early Executive Functions Questionnaire (parental report) at baseline, post-assessment, 1st and 2nd follow-up

3.2. "Executive Function Lab Tasks" - structured observation: Working memory, Shifting, Inhibitory Control (video record) at 1st and 2nd follow-up

## Secondary outcome measures

Parental scaffolding and sensitivity: parent-child structured observation - observation of scaffolding skills when helping child explore a difficult toy and during shared picture-book reading (video record) at baseline and post-assessment

## Overall study start date

02/09/2019

## Completion date

31/10/2022

# Eligibility

## Key inclusion criteria

1. Family of a 10-month-old child (+/- 4 weeks)
2. Same caregiver can participate in baseline and post-assessment, as well as the five group sessions (intervention/control group sessions)
3. Swedish is spoken at home

## Participant type(s)

Healthy volunteer

## Age group

Mixed

## Sex

Both

## Target number of participants

140 parent-child dyads

## Total final enrolment

115

## Key exclusion criteria

1. Child outside the age range at time of baseline assessment
2. Swedish is not spoken in the home
3. Child is born premature
4. Child disability that is likely to interfere with delivery of the intervention

## Date of first enrolment

10/01/2020

## Date of final enrolment

05/08/2021

# Locations

## Countries of recruitment

Sweden

**Study participating centre**  
**Uppsala Child and Babylab**  
Department of psychology  
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75236

## Sponsor information

**Organisation**  
Uppsala University

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uu@uu.se

**Sponsor type**  
University/education

**Website**  
<https://www.uu.se/en/>

**ROR**  
<https://ror.org/048a87296>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Riksbankens Jubileumsfond

**Funder Name**

Vetenskapsrådet

**Alternative Name(s)**

Swedish Research Council, VR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Sweden

**Funder Name**

Majblommans Riksförbund

**Alternative Name(s)**

Mayflower Association, Majblommans Association

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Associations and societies (private and public)

**Location**

Sweden

## Results and Publications

**Publication and dissemination plan**

The researchers are currently writing up the study protocol to be submitted to the journal Trials. The researchers expect to publish the findings from the current project in highly ranked international peer-reviewed journals, preferably with open access. Results will also be presented at international conferences. The researchers will make an effort to communicate their results to the wider public via local and national media, by using social media channels (e.g., the Uppsala Child & Baby Lab's Facebook and Twitter accounts) and the lab webpage (babylab.se).

**Intention to publish date**

01/06/2023

**Individual participant data (IPD) sharing plan**

The generated dataset will be stored in a publicly available repository to be made available one year after the completion of the study. The study data will be stored in servers at Uppsala

university. Datasets generated during and/or analyzed during the study will be anonymized and shared on Open Science Framework (osf.io). These datasets will include all eye-tracking data and EEG data. For ethical reasons, data from video-based assessments and questionnaire data will only be available as summarized scores. Matlab-based analytical code for analyzing eye tracking and EEG data will be available in publications.

## IPD sharing plan summary

Stored in repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		24/09/2022	29/09/2022	Yes	No