

A roadmap to executive function and language

Submission date 07/02/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/03/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/10/2022	Condition category 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

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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), ref: 2019-03140

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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

Von Kraemers allé 1A

Uppsala

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Sponsor information

Organisation

Uppsala University

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

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?
Protocol article		24/09/2022	29/09/2022	Yes	No