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A roadmap to executive function and language

Submission date 07/02/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 06/03/2020	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 03/06/2026	**Condition category** Other	[_] Individual participant data

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?
1. Linda Forssman
Linda.Forssman@psyk.uu.se
2. Janna Gottwald
Janna.Gottwald@psyk.uu.se

Contact information

Type(s)
Scientific

Contact name
Dr Linda Forssman

ORCID ID
https://orcid.org/0000-0003-0208-4212

Contact details
Uppsala Child and Babylab
Department of psychology
Von Kraemers allé 1A
Uppsala
Sweden
752 36
+46 (0)18 471 5751
Linda.Forssman@psyk.uu.se

Type(s)
Scientific

Contact name
Dr Janna Gottwald

ORCID ID
https://orcid.org/0000-0001-5497-4001

Contact details
Uppsala Child and Babylab
Department of psychology
Von Kraemers allé 1A
Uppsala
Sweden
752 36
+46 (0)18 471 2113
Janna.Gottwald@psyk.uu.se

Additional identifiers

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

Primary study design
Interventional

Study design
Randomized controlled trial

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 (≈ 18 months of age) and then again at a second follow-up (≈ 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-incongrunt 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
Sweden
75236

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?
Results article		26/06/2025	03/06/2026	Yes	No
Protocol article		24/09/2022	29/09/2022	Yes	No
Other publications	Longitudinal study results part of the “The Roadmap to Executive function and Language” (REaL) research project	07/02/2025	03/06/2026	Yes	No