Early parent-child intervention with Dialogic Book-Sharing and its benefits on child development and parenting

Submission date	Recruitment status Recruiting	Prospectively registered		
20/10/2023		[X] Protocol		
Registration date	Overall study status Ongoing Condition category	Statistical analysis plan		
02/11/2023		Results		
Last Edited		Individual participant data		
16/01/2025	Other	[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

The study is evaluating a parenting intervention programme delivered to families in Italy. This programme involves training parents to share picture books with their children, employing techniques such as pointing and naming things on a page and following the child's interest. The programme uses 'dialogic' book-sharing techniques – that is, it encourages and supports the child's active involvement in a two-way interchange about the book. It is thought that such techniques will, in addition to leading to improvements in the child's cognitive development and certain and aspects of parenting, be of benefit in terms of child self-regulation and behaviour. This study investigates to see whether DBS programme results in a number of benefits including improvements in the child's language and attention skills and good behaviour and also with the parents interactions with their children compared to families that do not receive the intervention.

Who can participate?

Parents of children aged between 14-20 months.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 are enrolled in the programme. Those in group 2 are placed on a waitlist, which means that they have no intervention from the research team until the study period is finished, after which they will receive the programme. The intervention consists of 60-90 minute sessions run weekly for 4 consecutive weeks, delivered to groups of parents and their children. The sessions include group and individual activities and make use of teaching materials, including PowerPoint slides, videos to illustrate particular learning points, and practical exercises. The facilitators who deliver the programme provide instruction aimed at promoting good book-sharing skills. As part of the programme, at the end of each weekly session, parents receive a 'picture book of the week' to take home with them. Parents are encouraged to apply what they have learned during the session with their children at home using the picture book.

What are the possible benefits and risks of participating?

Discussing parenting experiences and other topics in the intervention sessions and the assessments may cause emotional discomfort to some participants. In the event that participants show signs of distress or concern, these will be explored and, where appropriate, staff will arrange referral to local counselling and health services. Previous research suggests that the book-sharing training programme will be of benefit to the development of the great majority of children, in terms of their language and attention; and the quality of interactions between parents and their children is also likely to improve. Should this study achieve its aims, it will provide evidence for the benefit of a cost-effective community-based intervention for the promotion of child cognitive, social and emotional development.

Where is the study run from?

Observatory of Perinatal Clinical Psychology, Department of Clinical and Experimental Sciences, University of Brescia (Italy)

When is the study starting and how long is it expected to run for? September 2022 to December 2025

Who is funding the study?

Observatory of Perinatal Clinical Psychology, Department of Clinical and Experimental Sciences, University of Brescia (Italy)

Who is the main contact? Professor Loredana Cena, loredana.cena@unibs.it

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

NP 5205

Study information

Scientific Title

Early parent-child intervention with Dialogic Book-Sharing: effects on parenting and child communicative and socio-emotional development

Study objectives

Dialogic Book-Sharing programme delivered to parents has an effect on: b) increasing the child's linguistic, cognitive, attention and behavioural development; a) enhancing parent-child interaction; c) improving the parent's mood (anxiety, depression, and stress) and d) decreasing amount of screen time compared to an increase in parent-child book sharing at home

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 27/09/2022, Ethics Committee of Spedali Civili, Brescia (Piazzale Spedali Civili, 1, Brescia, 25123, Italy; +39 3039951; comitatoetico.documentazione@asst-spedalicivili.it), ref: NP 5205

Study design

Single centre individual randomized controlled trial design with wait-list control group

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Parenting practices, and early childhood development (language, cognition, social and emotional learning)

Interventions

Participants are randomly allocated (using a random number generator) to either the index group or the control condition:

1. The intervention is a dialogic book-sharing programme. It is targeted at caregivers with children between the ages of 14-20 months at the time of baseline assessment. Primary caregivers attend sessions with their children over 4 weeks. A trained facilitator delivers the sessions, each of which focuses on different and incremental techniques for caregivers to apply during book sharing. Groups consist of 4 to 6 parents and their children. Each session consists of

a presentation to the group of the principles relevant to that session (using PowerPoint slides and illustrative video material); and this group session ends with 'the book of the week', where the trainer discusses a book with the parents, highlighting how the book should be used at home. Finally, each parent is given 10 minutes of individual guidance in applying the session principles when book-sharing with their child. The parent and child leave with 'the book of the week' and parent are encouraged to spend at least 10 minutes a day sharing the book with their child.

2. A wait-list control group that does not receive any input from the research team during the intervention period, but they will receive the intervention programme upon completion of follow-up assessment.

First baseline data collection before the intervention (approximately 30 minutes) Dialogic Book Sharing intervention: 4 weeks Second data collection after the intervention (approximately 30 minutes) Follow-up data collection after 6 months (approximately 30 minutes)

Intervention Type

Behavioural

Primary outcome(s)

In each assessment session (Baseline pre-treatment, Post-treatment and 6 months Follow-up), the parent is invited to participate in a video recording of a 5-minute parent-child interaction and asked to complete a self-report questionnaire taking approximately 30 minutes, including questions on:

- 1. Parent's socio-demographic details (age, nationality, educational level, professional occupation, economic condition), and information about pregnancy and post-partum period;
- 2. Child's linguistic developement assessed using The MacArthur-Bates Communicative Development Inventory (CDI Fenson et al., 2000);
- 3. Child behavior assessed with The Achenbach System of Empirically Based Assessment (ASEBA) Child Behavior Checklist $1\frac{1}{2}$ -5 (Achenbach, 2001);
- 4. Parental mood (anxiety, depression, stress) assessed with the Hospital Anxiety and Depression Scale (HADS Zingmond and Snaith (1983) and the short form of the parenting Stress Index (PSI-SF; Abidin, 1995).

Key secondary outcome(s))

There are no secondary outcome measures

Completion date

19/12/2025

Eligibility

Key inclusion criteria

- 1. Mothers and fathers who are able to speak and read Italian
- 2. Children aged 14-20 months at the time of the baseline assessment

Participant type(s)

Other

Healthy volunteers allowed

Age group

Mixed

Sex

All

Key exclusion criteria

- 1. Children who have a diagnosed physical or intellectual impairment;
- 2. Mothers and/or fathers with a diagnosed physical or psychiatric condition that could compromise their ability to participate in the intervention program.

Date of first enrolment

24/03/2023

Date of final enrolment

19/12/2025

Locations

Countries of recruitment

Italy

Study participating centre

University of Brescia

Centres of Observatory of Perinatal Clinical Psychology, Department of Clinical and Experimental Sciences, viale Europa 11
Brescia Italy
25123

Sponsor information

Organisation

University of Brescia

ROR

https://ror.org/02q2d2610

Funder(s)

Funder type

University/education

Funder Name

Università degli Studi di Brescia

Alternative Name(s)

University of Brescia, unibs.official, Universitas Studiorum Brixiæ, UNIBS

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Italy

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>		16/06/2024	19/06/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes