

The benefits of early book-sharing study

Submission date 09/02/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/02/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/03/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The Benefits of Early Book-Sharing (BEBS) study is evaluating a parenting intervention programme delivered to families in Khayelitsha, South Africa. This programme involves training parents and other carers 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 aspects of parenting, be of benefit in terms of child self-regulation and behaviour. This study investigates to see whether BEBS 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 (or other primary caregivers) of children aged between 23-27 months.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 are enrolled in the BEBS 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 BEBS programme. The intervention consists of 60-90 minute sessions run weekly for eight consecutive weeks, delivered to groups of 4-6 caregivers 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, carers receive a 'picture book of the week' to take home with them. Carers 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 carers 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?

The research team has a base in Khayelitsha where the study will be run. The study is run by researchers at Stellenbosch University, Oxford University, and the University of Reading.

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

February 2016 to May 2017

Who is funding the study?

South African Medical Research Council, through the Sexual Violence Research Initiative (SVRI) (South Africa)

Who is the main contact?

Professor Mark Tomlinson

Contact information

Type(s)

Scientific

Contact name

Prof Mark Tomlinson

ORCID ID

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Contact details

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7600

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The Benefits of Early Book Sharing (BEBS) study: a randomised controlled trial conducted in South Africa of a book sharing intervention to improve child cognitive and socio-emotional development

Acronym

BEBS

Study objectives

In a sample of two year old children, compared to control group children whose carers do not receive the index intervention, those whose carers do receive the book-sharing training programme will evidence:

1. Significantly better outcomes on measures of language and sustained attention
2. Significantly more pro-social behaviour and less aggression

Secondary hypotheses as of 27/07/2016:

1. Compared to control group children, intervention group children will evidence significantly better social understanding
2. Compared to control group caregivers, caregivers who receive the programme will evidence significantly more sensitivity, reciprocity and mental state talk with their children, both in book-sharing and non-book-sharing contexts
3. Compared to control group caregivers, caregivers who receive the programme will evidence significantly less negative and more supportive parenting in challenging contexts
4. Improvements in child language and attention will be mediated by improvements in maternal sensitivity and reciprocity in the book-sharing context
5. Improvements in child social understanding, prosocial behaviour and aggression will be mediated by increases in maternal sensitivity and mental state talk in both booksharing and non-book-sharing contexts, and by a reduction in negative parenting and an increase in supportive parenting in challenging contexts.

Original secondary hypotheses:

Compared to control group carers who do not receive the intervention, carers who receive the programme will evidence significantly more:

1. Sensitivity and reciprocity with their children, both in book-sharing and non-book-sharing contexts
2. Increased mental state talk, both in book-sharing and non-book-sharing contexts
3. Improvements in child language and attention will be mediated by improvements in maternal sensitivity and reciprocity in the book-sharing context; and
4. Improvements in child pro-social behaviour and aggression will be mediated by increases in maternal sensitivity and mental state talk in both the book-sharing and the non-book-sharing contexts

Ethics approval required

Old ethics approval format

Ethics approval(s)

Health Research Ethics Committee at Stellenbosch University, 08/02/2016, ref: N15/09/084

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

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

Interventions

Interventions as of 27/07/2016:

Participants are randomly allocated to one of two groups:

1. The intervention is a dialogic book-sharing programme. It is targeted at caregivers with children between the ages of 23-27 months at the time of baseline assessment. Primary caregivers attend sessions with their children over eight weeks. The sessions are run at the research base in Khayelitsha. A trained facilitator from the community 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 carers 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 carers, highlighting how the book should be used at home. Finally, each carer is given 10 minutes of individual guidance in applying the session principles when book-sharing with their child. The carer and child leave with 'the book of the week' and carers are encouraged to spend at least 10 minutes a day sharing the book with their child.
2. A wait-list control group constitutes the second arm of the trial. The control group 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.

Original interventions:

Participants are randomly allocated to one of two groups:

1. The intervention is a dialogic book-sharing programme. It is targeted at caregivers with children between the ages of 20-24 months at recruitment. Primary caregivers attend sessions with their children over eight weeks. The sessions will be run at the research base in Khayelitsha. A trained facilitator from the community will deliver the sessions, each of which focuses on different and incremental techniques for caregivers to apply during book sharing. Groups will consist of 4 to 5 carers and their children. Each session will consist of a presentation to the group of the principles relevant to that session (using PowerPoint slides and illustrative video

material); and this group session will end with 'the book of the week', where the trainer discusses a book with the carers, highlighting how the book should be used at home. Finally, each carer will be given 10 minutes of individual guidance in applying the session principles when book-sharing with their child. The carer and child will go home with 'the book of the week' and carers will be encouraged to spend at least 10 minutes a day sharing the book with their child.

2. A wait-list control group will constitute the second arm of the trial. The control group will not receive the intervention during the intervention period, but will receive it upon completion of follow-up assessments.

Intervention Type

Behavioural

Primary outcome measure

Primary outcome measures as of 27/07/2016:

1. Child language is assessed using the:

1.1. MacArthur Communication Development Inventory (CDI) expressive and receptive subscales are administered at baseline, post-intervention and at the 6-month follow up

1.2. Child comprehension and expressive language are directly assessed using adapted versions of the Peabody Picture Vocabulary Test (PPVT) and the Expressive One Word Picture Vocabulary Test at baseline and post-intervention

1.3. The newly developed standardised isiXhosa version of the Peabody will be administered at the 6-month follow-up assessment, as will the Bayley Scale of Infant Development language subscales

2. Child attention is assessed, using the Early Childhood Vigilance Task, at baseline, immediately following the intervention, and at the six month follow-up.

3. Child pro-social behaviour is assessed using the Strengths and Difficulties Questionnaire and a pro-social helping task, at baseline, immediately following the intervention, and at the six-month follow-up.

4. Child aggression is assessed, using the aggression scale of the Child Behaviour Checklist, at baseline, immediately following the intervention and at six-month follow-up. Direct measures of child aggression and defiance/non-compliance are obtained from coded video data of two parent-child interaction tasks: a "Don't touch" prohibition task, and a "Clean up" compliance task. These are administered at baseline, immediately following the intervention, and at the six-month follow-up.

Original primary outcome measures:

1. Child language (MacArthur Communication Development Inventory – expressive and receptive language sub scales, Peabody Picture Vocabulary Test, Bayley Scale of Infant Development - language sub scales) immediately following the intervention and at a six month follow-up

2. Child attention (Early Childhood Vigilance Task), immediately following the intervention and at a six month follow-up

2. Child pro-social behaviour/aggression (Child Behaviour Checklist, Strengths and Difficulties Questionnaire, Pro-social helping task), immediately following the intervention and at a six-month follow-up

Secondary outcome measures

Secondary outcome measures as of 27/07/2016:

1. Child social understanding is measured by:

1.1. The Wellman Theory of Mind Scale is administered at baseline, immediately following the intervention, and the six-month follow-up

- 1.2. An emotion recognition and emotion understanding pictorial task is administered at the six-month follow-up assessment
2. Parental sensitivity and reciprocity is assessed, by direct observation of parent and child parent and child in both a book-sharing and a non-book sharing context, at base-line, immediately following the intervention, and at the six-month follow-up
3. Parental discipline is assessed, using a discipline and violence self report questionnaire, at baseline, immediately following the intervention and at a six-month follow-up. Parenting is also directly assessed in a prohibition and compliance task, at baseline, immediately following the intervention, and at the six-month follow-up

Moderators:

The influence of three potential moderators will be examined, with assessments made at baseline, immediately following the intervention, and at the six-month follow-up:

1. Parental stress, using the Parenting Stress Index
2. Caregiver mental health, using the Patient Health Questionnaire-9, and the Self Reporting Questionnaire-20
3. Intimate partner violence, using the WHO measure on domestic violence

Exploratory Outcome Measures:

1. Mental State Talk will be coded from video recordings of interactions during book-sharing, and during a narrative cartoon task, with assessments made at baseline, immediately following the intervention and at a six-month follow-up
2. The child's home language environment will be assessed, in a sub-sample, using a LENA digital recorder that captures language heard by the child over the course of a typical day, with assessment made at a six-month follow-up
3. The child's physiological response to emotional displays (i.e. pictures of happy, sad, fearful, angry children) is being assessed, in a sub-sample, using a functional infra-red thermal imaging camera, with assessments made at baseline and at six-month follow-up

Original secondary outcome measures:

1. Child social understanding (Wellman Theory of Mind Scale, Emotion recognition task) immediately following the intervention and at a six-month follow-up
2. Parental sensitivity (Direct observation of parent and child in free-play, clean up task, don't touch task, narrative cartoon explanation, and book sharing. Immediately following the intervention and at a six-month follow-up
3. Parental discipline (Discipline and violence self report questionnaire, Directly observed parenting in a prohibition task). Immediately following the intervention and at a six-month follow-up

Moderators:

1. Parental stress (Parenting Stress Index)
2. Caregiver mental health (Patient Health Questionnaire-9, Self Reporting Questionnaire-20)
3. Intimate partner violence (WHO measure on domestic violence)

Overall study start date

01/01/2015

Completion date

22/08/2016

Eligibility

Key inclusion criteria

Inclusion criteria for children include:

1. Ages 23-27 months at baseline assessment
2. Has an adult primary caregiver who lives in the household who consents to participate in the study

Inclusion criteria for adults include:

1. Age 18 or older
2. Serves as the primary caregiver of the child participant
3. Lives in the house at least 4 nights per week

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

140 infant-caregiver dyads

Key exclusion criteria

Either the caregiver or the child has a chronic illness or disability that would prevent them from fully participating in the intervention.

Date of first enrolment

22/02/2016

Date of final enrolment

29/07/2016

Locations

Countries of recruitment

England

South Africa

United Kingdom

Study participating centre

Stellenbosch University

Matieland

Stellenbosch

South Africa
7602

Study participating centre
University of Oxford
Oxford
United Kingdom
OX1 2JD

Study participating centre
University of Reading
Reading, Berkshire
United Kingdom
RG6 6UR

Study participating centre
The Masiphathisane Centre
Catholic Welfare and Development Offices
Khayelitsha
South Africa
-

Sponsor information

Organisation
Stellenbosch University

Sponsor details
Private Bag X1
Matieland
7602
Stellenbosch
South Africa
7600

Sponsor type
University/education

Website
<http://sun025.sun.ac.za/portal/page/portal/Arts/Departments/psychology>

ROR

<https://ror.org/05bk57929>

Funder(s)

Funder type

Research council

Funder Name

South African Medical Research Council

Alternative Name(s)

SAMRC

Funding Body Type

Government organisation

Funding Body Subtype

Other non-profit organizations

Location

South Africa

Results and Publications

Publication and dissemination plan

The trialists intend to publish at least 6 peer-reviewed publications from the trial. They will also publish a policy brief. Findings will be presented at local and international conferences.

Intention to publish date

31/10/2017

Individual participant data (IPD) sharing plan

Not provided at time of registration

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?
Protocol article	protocol	09/03/2017		Yes	No
Results article		30/10/2021	13/03/2023	Yes	No