Sharing Stories: A digital intervention for caregivers with young children in the COVID-19 era to promote child social, emotional and language development, responsive parenting and parental mental wellbeing in Zambia, Tanzania, and Uganda

Submission date 25/11/2020	Recruitment status No longer recruiting	Prospectively registered
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
02/12/2020	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
06/11/2023	Other	

Plain English summary of protocol

Background and study aims

Parents and caregivers of young children are facing substantial challenges in the COVID-19 era, with potential devastating impacts on the health, wellbeing, and development of young children globally, and especially in low resource settings. New modes of reaching caregivers are essential as traditional face-to-face approaches to group-based parenting programmes are not available. The Sharing Stories intervention is a fully digital programme, delivered to caregivers of young children over WhatsApp to promote child social, emotional and language development and positive, responsive parenting, combined with support for caregivers' mental wellbeing. The digital intervention is based on an in-person, evidence-based shared reading programme, which guides caregivers in how to use digital picture books in playful ways to support their children's learning and development. The key aim of the programme is to equip caregivers with a variety of skills that they can apply when sharing a picture book with their child. Importantly, these skills emphasise a learning through play approach, where shared reading techniques are applied to engage children in playful, positive and responsive way. In addition, caregivers receive intervention content to promote parental mental health and strategies for coping with stress.

Through partnering with the Regional Psychosocial Support Initiative (REPSSI) and the Africa Early Childhood Network (AfECN), the programme will be pilot tested in Tanzania, Zambia and Uganda. The aim of the study is to assess the differences in outcomes for caregivers and their children who participated in the Sharing Stories intervention; to assess the acceptability of the intervention and caregivers' participation and engagement; to determine barriers and facilitators of successful implementation.

Who can participate?

The intervention is designed for primary caregivers of children between the ages of 9 - 32 months. Primary caregivers with children in this age range, who have access to a working smartphone in their household and living in selected areas in Zambia, Uganda and Tanzania will be invited to participate.

What does the study involve?

The Sharing Stories intervention is delivered over a six-week period, with all content delivered to caregivers over WhatsApp. The intervention content focuses on the following:

- 1. Shared reading to encourage positive, responsive parenting: caregivers receive content on how to use shared reading to promote their children's learning and development through techniques such as pointing and naming; responding with encouragement and praise; mimicking actions; making links between the pictures and the child's life; talking about feelings; having conversations about what is happening in the story
- 2. Support for caregiver mental health and wellbeing: caregivers will also receive messages about the importance of taking care of themselves and staying healthy, strategies to cope with stress and difficulties in their life, and how to access support.

A weekly WhatsApp group chat session (lasting between 1-2 hours) is used to deliver the intervention content over 6 weeks, complimented by recap messages throughout the week. Each WhatsApp group consists of 30 to 40 participants, and is moderated by two trained intervention facilitators, fluent in the local languages. All intervention content is available in the local languages. Through WhatsApp, caregivers receive a combination of text and audio messages, photos, infographics and short video clips to promote responsive parenting through shared reading activities, and support for caregiver mental health and wellbeing. In addition, caregivers receive two digital picture books a week. Caregivers will receive a weekly data bundle for the duration of the 6 weeks to enable participation.

As part of the formative work, rapid consultations in each country were conducted with stakeholders (program staff and caregivers) to help inform the development of the digital intervention. Caregivers with young children (between the ages of 9-32 months) will be randomly assigned to either the intervention or comparison group. Participating caregivers will be assessed at baseline and post-intervention on measures of child social, emotional and language development; positive, responsive parenting behaviours; parenting stress and caregiver mental health. In addition, interviews will be conducted with the intervention facilitators and a selection of participating caregivers to obtain feedback on the acceptability of the intervention.

What are the possible benefits and risks for participating?

There are a number of potential benefits to the study. Participants are very likely to benefit from the ongoing engagement with new content on parenting, digital books for their young children, and support from peer parents and caregivers as well as from a structured curriculum. At a societal level, this study can potentially produce plans for developing and evaluating a cost-effective, scalable digital early childhood and parenting support intervention, which is deliverable in low and middle-income country (LMIC) contexts, for the improvement of parent and child wellbeing.

The potential risks include psychological distress when discussing issues relating to mental health and parenting, especially during this stressful global emergency, during the assessment and intervention sessions. In the event that a participant shows signs of extreme emotional

distress, researchers will follow their standard and already-established participant safety policy and make a referral to a local counselling and health service, under the guidance of the Principle Investigator, the in-country implementation partners and project managers.

Where is the study run from?

Stellenbosch University (South Africa) has partnered with the Regional Psychosocial Support Initiative (REPSSI) to implement the study in selected areas in Tanzania, Uganda and Zambia. REPSSI have an established presence in all three countries, and is working with a local organisation in each country to implement the research:

Zambia: ChildFund

Uganda: Community Transformation Foundation Network (COTFONE)

Tanzania: Kimara Peer Educators and Pastoral Activities and Services for People with AIDS Dar es

Salaam Archdiocese (PASADA)

When is the study starting and how long is it expected to run for? June 2020 – May 2021

Who is funding the study? LEGO Foundation (Denmark)

Who is the main contact?
Prof. Sarah Skeen, skeen@sun.ac.za

Contact information

Type(s)

Scientific

Contact name

Prof Sarah Skeen

ORCID ID

http://orcid.org/0000-0002-7464-2861

Contact details

Institute for Life Course Health Research Department of Global Health Stellenbosch University Tygerberg Cape Town South Africa 7505 +27 72 753 3155 skeen@sun.ac.za

Additional identifiers

EudraCT/CTIS numberNil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Does a digital intervention, delivered to caregivers with young children in Zambia, Tanzania and Uganda, promote child social, emotional and language development, responsive parenting and parental mental wellbeing when compared to a wait-list control group?

Acronym

Sharing Stories

Study objectives

Compared to control-group participants, children and their caregivers who receive the intervention will have:

- 1. Better child social and emotional development outcomes
- 2. Better child language outcomes
- 3. Less negative and more positive, responsive parenting behaviours

Compared to control-group caregivers, caregivers who receive the intervention will have:

- 4. Less parenting stress
- 5. Better parental mental health

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Approved 01/07/2020, Stellenbosch University Health Research Ethics Committee (Stellenbosch University, Private Bag X1, Matieland, 7602, South Africa; +27 (0)21 938 9657; elr@sun.ac.za), ref: N20/06/026 COVID-19
- 2. Approved 16/07/2020, ERES Converge IRB (33 Joseph Mwilwa Road, Rhodes Park, Lusaka, Zambia; +260 955 155 633; eresconverge@yahoo.co.uk), ref: No.2020-Jul-001
- 3. Approved 10/09/2020, National Institute for Medical Research (P.O. Box 9653, Dar es Salaam, 11101, Tanzania; +255 22 2121400; nimrethics@gmail.com), ref: NIMR/HQ/R.8a/Vol.IX/3507
- 4. Approved 27/08/2020, Mbarara University of Science and Technology, (P.O. Box 1410, Mbarara Uganda; +256 485433795; sec.rec@must.ac.ug), ref: MUREC 1/7

Study design

Pilot interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Prevention

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

Child social, emotional and language development, responsive parenting, parental mental wellbeing

Interventions

A pilot randomized control trial to evaluate a digital group-based parenting intervention for caregivers of young children aged between 9 and 32 months. Caregiver-child pairs are stratified based on child age (9 - 20 months and 21 - 30 months) and randomized to an intervention or waitlist control group using a sealed envelope. Data are collected at baseline and post-intervention. Data collectors are blinded to group allocation.

The intervention is based on the World Health Organization's Parenting for Lifelong Health shared reading programme and the WHO Thinking Healthy programme. The Parenting for Lifelong Health shared reading programme will be combined with specific content on caregiver mental health and wellbeing, adapted for digital delivery via WhatsApp.

Caregivers in the intervention group will receive all intervention content on WhatsApp over a six-week period, using a combination of text and audio messages, photos, infographics and short video clips. A weekly WhatsApp group chat session is used to deliver the intervention content, complimented by recap messages throughout the week. In addition, caregivers receive two digital picture books a week. Each group consists of 30 to 40 participants, moderated by two trained intervention facilitators, fluent in the local languages. All intervention content is available in the local languages. Caregivers will receive a weekly data bundle for the duration of the six weeks to enable participation.

Caregivers in the control condition will receive no intervention during the duration of the trial.

Intervention Type

Behavioural

Primary outcome measure

Measured at baseline and 6-weeks:

- 1. Child social and emotional outcomes, measured using the:
- 1.1. Caregiver Reported Early Development Instrument Socio-Emotional long form
- 1.2. The Strengths and Difficulties Questionnaire
- 1.3. The Child Behaviour Checklist (CBCL) attention and aggression subscales updated 02/06 /2021: the attention subscale was removed as hyperactivity-inattention is already measured by the Strengths and Difficulties Questionnaire (SDQ), which is included in the baseline and follow-up questionnaire

- 2. Child language outcomes, measured using the Caregiver Reported Early Development Instrument Language long form
- 3. Positive, responsive parenting behaviours, measured using the
- 3.1. Parent-Child Conflict Tactics scales
- 3.2. The Family Care Indicators

Secondary outcome measures

Measured at baseline and 6 weeks:

- 1. Parenting stress, measured using the Parental Stress Scale short form
- 2. Parental mental health, measured using the Patient Health Questionnaire-9 and the Generalized Anxiety Disorder-7

Overall study start date

01/06/2020

Completion date

31/05/2021

Eligibility

Key inclusion criteria

- 1. Primary caregivers of children between the ages of 9 32 months at enrolment
- 2. Living in selected areas
- 3. Have access to a working smartphone in their household

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

720 caregivers and their children

Total final enrolment

734

Key exclusion criteria

1. Caregivers aged under 18 years

Date of first enrolment

25/08/2020

Date of final enrolment

30/11/2020

Locations

Countries of recruitment

Tanzania

Uganda

Zambia

Study participating centre

Community Transformation Foundation Network (COTFONE)

Kyabakuza Trading Centre Buyinja Road Masaka Municipality P O Box 589 Masaka Uganda

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Study participating centre

ChildFund

Plot 9158, Lunsemfwa Road Lusaka Zambia

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Study participating centre

PASADA (Pastoral Activities and Services for People with AIDS Dar es Salaam Archdiocese)

Chang'ombe Dar es Salaam Tanzania 70225

Study participating centre Kimara Peer Educators:

P.O Box 77143 Dar es Salaam Tanzania

Sponsor information

Organisation

Stellenbosch University

Sponsor details

Private Bag X1 Matieland Stellenbosch South Africa 7602 +27 824483549 marlow@sun.ac.za

Sponsor type

University/education

Website

http://www.sun.ac.za/english

ROR

https://ror.org/05bk57929

Funder(s)

Funder type

Charity

Funder Name

The LEGO Foundation

Results and Publications

Publication and dissemination plan

We intend to publish at least 4 peer reviewed publications from the trial. We will also publish a policy brief. Findings will be presented at local and international conferences.

Intention to publish date

01/05/2022

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results article03/11/202306/11/2023YesNo