EMERGE Reading Pilot Study: Adaptation and scaling of early reading interventions in Kenya (Phase 1)

Submission date	Recruitment status	[X] Prospectively registered
21/01/2016	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
22/01/2016	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
25/11/2019	Other	

Plain English summary of protocol

Background and study aims

Learning to read can be a complicated process, especially for children in less developed countries. Regardless of the language a child learns to read in, a good reader will be able to identify works on a page and take meaning from those words. Children who can read well (fluency) are often able to achieve more academically, and so better programs are needed to help teach children to read better. This initial study is going to look at a random group of households in the Nyanza province (Kenya) in order to try and find a good way of helping children to improve their reading fluency. The study will compare a range of different programs, each more intense than the last, in order to try and find out whether using children's story books in addition to parent training can help improve vocabulary skills and early language development in the short-run. The study will also look at the way parents and children use the storybooks, how parents change their priorities and behaviors after they learn more about reading with their children, and what level of intensity of the intervention is needed to achieve an impact.

Who can participate?

Households with children between the ages of 2 and 6 years old who live near to a small primary school in Nyanza province (Kenya).

What does the study involve?

Participating households are randomly allocated to one of five study groups. Those in the first group do not receive any books and continue as usual. Those in the second group are given a set of children's storybooks in English, Luo and Swahili. Those in the third group also receive the story books, but the parents of the children are given training to help them with dialogic reading skills. This is where the adult helps the child to learn to read by using questions about the books and praising the child's efforts to take part in the reading experience, such as by naming objects or actions in the book. Those in the third group receive the story books and parent training, but as also given extra training and SMS reminders encouraging them to stay involved with the project and to be more aware of strategies to help their children. Those in the fifth group receive the same as the forth group, except that they also receive home visits to help them,

answer any questions and allow them to give feedback about the project. At the start of the study and again after five weeks, the children have their vocabulary tested and parents/care givers complete a survey in order to find out if their reading habits have changed.

What are the possible benefits and risks of participating? Households taking part in the study benefit from receiving children's story books and some parents will benefit from learning new skills for reading with their children. There are no risks for participants taking part in the study.

Where is the study run from?
The study takes place in households in the Nyanza province (Kenya)

When is the study starting and how long is it expected to run for? October 2015 to December 2016

Who is funding the study? World Bank Group (USA)

Who is the main contact? Dr Owen Ozier

Contact information

Type(s)

Scientific

Contact name

Dr Owen Ozier

ORCID ID

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Contact details

The World Bank 1818 H St NW Mail Stop MC3-311 Washington DC United States of America 20433

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

EMERGE Reading Pilot Study: Adaptation and scaling of early reading interventions in Kenya to improve early childhood development (Phase 1)

Acronym

EMERGE

Study objectives

The aim of this study is to investigate:

- 1. Whether the distribution of children's storybooks, in addition to a training component for parents, improves vocabulary skills and early language development in the short-run
- 2. Whether parents and children make use of the storybooks, and if so, how often and what activities they substitute away from in order to devote more time to reading activities
- 3. Whether parents exhibit differential sensitivity to cues from their children as a result of the intervention
- 4. Which of the intervention delivery method being piloted leads to the highest up-take
- 5. Whether different sub-populations respond different to the four intervention variants
- 6. Whether illiterate parents use the books with their children

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. University of California, Berkeley Institutional Review Board, 27/05/2015, ref: 2014-09-6699
- 2. Human Subjects Committee for Innovations for Poverty Action, 03/12/2015, ref: 5691
- 3. Maseno University Ethics Review Committee, 03/11/2014, ref: 00118/14

Study design

Multi-arm clustered randomized control trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Poor early development of cognition and language in children

Interventions

The intervention has 5 study arms, with increasing levels of intensity of the intervention. Households in the same primary school catchment areas are randomly assigned to one of the 5 study arms using the Stata software package.

Group 1: Participants in this arm do not receive the intervention (comparator arm)

Group 2: Participants receive a set of children's storybooks in English, Luo and Swahili

Group 3: Participants receive the same intervention as group 2, in addition to a parent training on dialogic reading skills, and SMS reminders to keep parents engaged with the books (added 23 /02/2016)

Group 4: Participants receive the same intervention as group 3, in addition to a booster training to keep parents engaged with the books and aware of strategies for reading and exploring the books with their children (added 23/02/2016)

Group 5: Participants receive the same intervention as group 4, in addition to home visits to encourage parents and to address individual parent's questions, and allow for practice and feedback

Participants in all groups are followed up after 5 weeks.

After data is collected to determine short-run impacts, the remaining eligible households who have not received an intervention will receive the same books as all others.

Previous:

Group 3: Participants receive the same intervention as group 2, in addition to a parent training on dialogic reading skills

Group 4: Participants receive the same intervention as group 3, in addition to a booster training and SMS reminders to keep parents engaged with the and aware of strategies for reading and exploring the books with their children

Intervention Type

Other

Primary outcome measure

- 1. The number of books in the home is measured by an enumerator's observation in the home at 5 weeks
- 2. Frequency of book use is measured by survey at baseline and endline (5 weeks)
- 3. Expressive and receptive vocabulary are measured by assessing children using adaptations of the British Picture Vocabulary Scale and purpose-specific illustrations at baseline and endline (5 weeks)

Added 27/04/2016:

4. Comprehension is measured by questions specific to storybook content at endline (5 weeks)

Secondary outcome measures

- 1. Home stimulation practices are measured by a Mother-Child observation conducted by an enumerator at baseline and endline (5 weeks)
- 2. Program take-up by intervention delivery method and sub-population include primary outcome measures, but with sub-populations divided according to baseline characteristics, including direct assessments of caregiver literacy based on reading a sentence in each of three languages. This will be assessed at endline (5 weeks)

Overall study start date

Completion date

31/12/2016

Eligibility

Key inclusion criteria

- 1. Children aged between 2 to 6 years old and their primary care giver
- 2. Living within 1km of a small primary school (<20 children per class) in Nyanza province

Participant type(s)

Healthy volunteer

Age group

Mixed

Sex

Both

Target number of participants

10 communities, in which 50 households are randomly selected and assigned, for an estimated sample size of 750 children and 500 adult caregivers; an estimated 1250 in total.

Total final enrolment

867

Key exclusion criteria

Developmental delays or health conditions that would interfere with a child's ability to take a standard developmental assessment or participate in the intervention (i.e. blindness and deafness).

Date of first enrolment

27/01/2016

Date of final enrolment

30/11/2016

Locations

Countries of recruitment

Kenya

Study participating centre Nyanza province

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Sponsor information

Organisation

The World Bank (USA)

Sponsor details

1818 H Street NW Washington DC United States of America 20433

Sponsor type

Industry

ROR

https://ror.org/00ae7jd04

Funder(s)

Funder type

Industry

Funder Name

World Bank Group

Alternative Name(s)

World Bank, The World Bank, Grupo Banco Mundial, Banco Mundial, Groupe Banque Mondiale, Banque Mondiale, , Группа Всемирного банка, , WBG

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United States of America

Results and Publications

Publication and dissemination plan

Planned publication of study results in a peer-reviewed journal.

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2020	25/11/2019	Yes	No