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Perfecting Parenting: A government-led parenting training program in rural China

Submission date
25/05/2018

Recruitment status
No longer recruiting

Registration date
30/05/2018

Overall study status
Completed

Last Edited
19/06/2023

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Many children in rural China suffer from early cognitive or language delays. Early developmental delays have been linked to poor home learning environments during the first 1000 days of life. Earlier studies showed that parenting training on parent-child interaction can avert the emergence of early delays. Therefore, policymakers in low and middle-income countries no longer debate the effectiveness of early child development (ECD) services, but rather how quality ECD services can be delivered cost-effectively and at scale. Considering that ECD services can potentially be implemented and delivered at scale by the government, we mainly aim to assess whether government-led parenting training programs can work in rural China. Effectiveness of government-led programs will largely depend on supply-side incentives needed for frontline service providers to deliver quality services and demand-side incentives needed for caregivers to comply to the intervention program. With a view to stimulating demand-side compliance, we will additionally assess the impact of developmental feedback on parental uptake of ECD services and parenting behavior.

Who can participate?
All 6-36 month olds that are living in Ningshan County, Shaanxi Province, China at the start of the study will be invited to participate in the intervention study together with their main caregivers.

What does the study involve?
The intervention will consist of two intervention rounds:
(1) At the beginning of the first intervention round, all communities in Ningshan County will be allocated to control or treatment. Those in the control group will receive no intervention. Those in the treatment group will be invited to attend weekly parenting training sessions. In villages with more than 10 6-36 month olds (living within 1 km distance from the village center) weekly one-on-one parenting training sessions will be organized at a "parenting center". One-on-one parenting training will be delivered during home visits to caregivers and children who cannot visit the center frequently enough (e.g. due to illness or distance) and to caregivers living in villages with less than 10 6-36 month olds. In addition, group play and reading activities will be organized at the parenting center or in a centrally-located child-friendly space (in villages with less than 10 6-36 month olds). Each training session will involve a trained child developmental professional who will teach the caregiver age-appropriate activities to do with the child with the

aim of encouraging more and better parent-child interaction. Furthermore, all caregivers and children in the treatment group will be allocated to one out of 2 treatment arms: a "feedback" arm and a "no feedback" arm. Caregivers in the feedback arm will have the opportunity to receive monthly feedback over the phone on the developmental progress of their child. Caregivers in the no feedback arm will receive no feedback on top of the parenting training.
(2) During intervention round 2, all families residing in the sample county will be invited to attend weekly parenting training sessions. Families assigned to treatment during the first round of the intervention will continue to receive parenting training on parent-child interaction. Families assigned to control during the first round of the intervention will receive an integrated parenting training program combining parenting training on parent-child interaction with education on child nutrition. Families assigned to the feedback arm during the first round of the intervention will continue to receive developmental feedback.

What are the possible benefits and risks of participating?
This study is expected to benefit children whose caregivers participate in the parenting training sessions. Caregivers will learn new ways to interact with their children. We expect that engagement of caregivers in more interactive parent-child activities will improve child cognition, language, and social-emotional development. Residents who are randomized to the control group during intervention round 1 will have the opportunity to receive parenting training on parent-child interaction and child nutrition from intervention round 2 onwards. The parenting training program will continue after termination of the experiment and has large potential to be upscaled. By taking part in this study there are almost no risks of physical injury or harm. There is only a slight risk of infection with the HemoCue 201+ fingerprick blood tests. However, this test will be conducted by trained nurses using new and sterile cuvettes and it is a standard tool for public health assessment that has been shown to be safe.

Where is the study run from?
The study is being run from the Ningshan ECD Management Center, the Center for Experimental Economics in Education (CEEE) of Shaanxi Normal University, the Rural Education Action Program (REAP) of Stanford University, and the Zhejiang Parenting Action Research Center.

When is the study starting and how long is it expected to run for?
The study started on March 1, 2018 and is expected to run until October 30, 2019.

Who is funding the study?
Zhejiang Hupan Modou Foundation (China)

Who are the main contacts?
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Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PerfectingParenting-NS01

Study information

Scientific Title
A government-led parenting training program and early child development in rural Shaanxi Province, China: A randomized controlled trial

Study objectives
The main goal of this study is to single out a way in which a parenting training program can reach large numbers of children growing up in disadvantaged environments all over China. Therefore, we will study the effect of government-led parenting training programs on parent-child interaction and healthy child development. In addition, we aim to study whether providing monthly developmental feedback to caregivers can motivate caregivers to participate more often in parenting training and in interactive parent-child activities.

Ethics approval required

Old ethics approval format

Ethics approval(s)
We plan to submit an application for an ethics approval of the Institutional Review Board of Stanford University and the Institutional Review Board of Xi'an Jiaotong University on May 29, 2018.

Study design
Multicenter non-masked randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Early child development, child nutrition and growth.

Interventions
The intervention will comprise 2 intervention phases:
1. 01/06/2018 - 30/11/2018: Intervention Phase 1
First, communities will randomly be assigned to intervention and control. Thereafter, individual-level randomization will be used to assign all caregiver-child dyads in the intervention group to a "feedback" arm and a "no feedback" arm.
1.1. In the control group, there will be no intervention.
1.2. Families in the intervention group ("no feedback" and "feedback" arm) will be invited to participate in weekly parenting training sessions. In villages with more than 10 6- to 36-month olds (living within 1 km distance from the village center) weekly one-on-one parenting training sessions will be organized at a "parenting center". One-on-one parenting training will be delivered during home visits to caregivers and children who cannot frequent the center (e.g. due to illness or distant living location) and to caregivers living in villages with less than 10 6- to 36-month olds. In addition, group play and reading activities will be organized at the parenting center or (in villages with less than 10 6- to 36-month olds) in a centrally-located child-friendly space. The training session will involve a trained child developmental professional who will teach the caregiver age-appropriate games to play with the child with the aim of encouraging more and better parent-child interaction.
1.3. All families in the "feedback" arm will be offered the opportunity to receive feedback on their child's development on a monthly basis. Feedback will be delivered over the phone and via text messaging. During each phone call the Ages and Stages Questionnaire-3 (ASQ-3) will be

administered to assess child development. Caregivers will immediately receive quantitative feedback on the child's developmental progress based on the ASQ-3 scores. Text messages with developmental feedback will be sent to the child's biological mother.

2. 01/03/2019-31/08/2019: Intervention Phase 2
In Phase 2 of the intervention, all families residing in the sample county will be invited to attend weekly parenting training sessions. Families assigned to treatment during the first round of the intervention will continue to receive parenting training on parent-child interaction. Families assigned to control during the first round of the intervention will receive an integrated parenting training program combining parenting training on parent-child interaction with education on child nutrition. The feedback intervention will continue for children originally assigned to the "feedback" arm.

Intervention Type
Other

Primary outcome measure
1. Child skill development. Early skill development will be measured for all sample infants with the Ages and Stages Questionnaires-3 (ASQ-3) (communication, gross motor, fine motor, problem solving, personal-social), the short forms of the MacArthur-Bates Communicative Development Inventories, and the social-emotional questionnaire of the ASQ. In addition, the cognition, language, motor, and social-emotional scales of the third edition of the Bayley Scales of Infant and Toddler Development (Bayley-III) and the cognition, language, motor, social-emotion, and mental health scales of the Caregiver-Reported Early Development Instruments (CREDI) long form will be administrated for assessment of early skill development of 1 out of 5 (n=300) of the sample infants. These 300 infants will stratified by treatment status randomly be selected.
2. Child nutrition status will be assessed based on hemoglobin values
3. Child weight and height will be measured to evaluate child physical growth.

Skill development and growth will be assessed at baseline (June 2018) and during two rounds of follow-up data collection (December 2018, June 2019). Hemocue fingerprick blood tests will not be administered at baseline, because child nutrition won't be targeted during the first phase of the intervention and we, therefore, don't expect to find an effect on hemoglobin values during the first phase of the intervention.

Secondary outcome measures
1. Service quality (dosage and content) will be monitored using attendance registers.
2. Parental beliefs, knowledge and parenting behavior will be measured. More precisely, we plan to measure beliefs on returns on investments, parental locus of control (with the Parental Locus of Control - Short Form Revised; PLOC-SFR), parental knowledge on ECD (with the Knowledge of Infant Development Inventory-P; KIDI-P), parenting style (with the Parenting Style and Dimensions Questionnaire; PSDQ), and attributes of the home learning environment (with the Family Care Indicators survey; FCI survey).
3. Mental wellbeing of caregivers will be measured with the Depression Anxiety Stress Scales (DASS) and the Office of National Statistics (ONS) subjective wellbeing survey.
4. We will measure child temperament using the short forms of the Infant Behavior Questionnaire-Revised (IBQ-R) and the Early Childhood Behavior Questionnaire (ECBQ).
5. Additional information on trainer and household characteristics will be collected using a trainer questionnaire and a household questionnaire, respectively.

All secondary outcomes will be measured at baseline (June 2018) and the two rounds of follow-up (December 2018, June 2019).

Overall study start date
01/03/2018

Completion date
30/10/2019

Eligibility

Key inclusion criteria
All children residing in Ningshan County - a randomly selected poor, rural county in Shaanxi Province, China - aged 6 to 36 months at the beginning of the study on 01/06/2018 will be invited to participate in the study together with their main caregivers.

Participant type(s)
Other

Age group
Child

Lower age limit
6 Months

Upper age limit
36 Months

Sex
Both

Target number of participants
999 6- to 36-month-olds and their primary caregivers

Total final enrolment
946

Key exclusion criteria
We randomly selected one county from a list of all poor counties in Shaanxi Province. All counties that were not nationally-designated poverty counties were excluded from the list. We refined our sample to nationally-poverty counties because poor, rural areas are known to have larger problems with responsive parenting and child development.

We are not excluding any 6- to 36-month-olds living in Ningshan County on June 1, 2018.

Date of first enrolment
01/06/2018

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
China

Study participating centre
Ningshan County Management Center for ECD Services
China
711600

Sponsor information

Organisation
Rural Education Action Program (REAP), Freeman Spogli Institute (FSI), Stanford University

Sponsor details
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Encina Hall, E-407
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Sponsor type
University/education

Website
http://reap.fsi.stanford.edu/

ROR
https://ror.org/00f54p054

Funder(s)

Funder type
Not defined

Funder Name
Zhejiang Hupan Modou Foundation ()

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal one year after the end of the trial.

Intention to publish date
30/10/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/10/2022	19/06/2023	Yes	No
Results article	results	24/10/2022	19/06/2023	Yes	No