

Testing the effectiveness of Integrated Early Childhood Development Services in rural China

Submission date 16/06/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/07/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/07/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

A large number of studies have shown that the brain of 0-3-year-old children experiences rapid development with the strongest ability to change and adapt as a result of experience. The critical period before age three is considered to be a crucial “window”, during which development outcomes can have significant and lasting effects, even into adulthood. Earlier studies have pointed out that the return on human capital investment gradually decreases with the increase of age, as the return on human capital investment is the highest for children in their very early stage of life. A feasible, effective way with relatively low execution cost to help rural children reaching their development potential through comprehensive early childhood development (CECD) services during this critical window of opportunity, and further improve the quality of China's future labor force is an important issue worthy of attention.

This study will systematically assess the impact and mechanism of CECD services, combining online and offline service provision, on the physical growth and capacity development among rural children aged 0-3 years. To do so, we propose to conduct a large-scale randomized controlled trial to deliver the CECD services in sample county in rural China, with the aid of trained parenting trainers, and a mobile application designed to help to manage and to monitor the provision of ECD services.

Who can participate?

Children aged between 6 and 24 months from the 50 villages involved can participate.

What does the study involve?

We plan to work together with social institutions and local government, empower them with training sessions so that they can serve as competent CECD service providers (i.e. parenting instructors), and make up for the commercial and social deficiencies in rural areas. The parenting instructors will visit the treatment group during weekly home visiting, demonstrate and guide these parents (caregivers) how to play and interact with the babies to help the development of thinking, language, movement, and social emotion by using the week-by-week parenting curriculum and toys (or picture books).

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 to interact with their children in a more stimulating manner. We expect that engagement of caregivers in more interactive parent-child activities will improve child thinking, language, and social-emotional development. By taking part in this study there are no risks of physical injury or harm.

Where is the study run from?

China Center for Agricultural Policy, Peking University (China)

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

From December 2019 to December 2023

Who is funding the study?

China Center for Agricultural Policy, Peking University (China)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

RCT-Jiangxi2020

Study information

Scientific Title

Randomized controlled trial of the effectiveness of comprehensive early childhood development (CECD) services in rural areas, China

Study objectives

Early childhood stimulation and improved parental practices will have positive effects on a child's cognitive, language, motor and socioemotional development

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/12/2019, Peking University Institutional Review Board (PU IRB), (Room 501, Yifu Building, Peking University Medical Department, No. 38 College Road, Haidian District, Beijing, 100191, China; llwyh@bjmu.edu.cn; +86 010-82805751), ref: IRB00001052-19132

Study design

Interventional single-centre cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Child development

Interventions

The overall treatment will comprise both online and offline service provision. The project team will entrust a software company to develop an "integrated ECD service provision and management application" (hereinafter referred to as the "APP"). This APP will serve not only as a tool to manage and monitor the intervention process but also as an online service provision platform that demonstrates scientific parenting knowledge in the form of videos, graphs, and text to caregivers.

During the preparation stage, researchers will recruit a certain amount of health care officials at the village level. Experts in preschool education, development psychology, and other related fields will be invited to train these health care officials who will become formal parenting

trainers after meeting the requirements of theoretical and practical evaluation. Meanwhile, researchers will purchase the matching toys and picture books used to complement with age-appropriate customized parent-child activities.

Participants will be randomly assigned to the "online service" group, "online & offline" group, or "control" group at the beginning of the intervention using a computerized random number generator. All participants, no matter which group they are assigned, will be assessed during baseline and evaluation surveys.

During the course of the intervention, families assigned to the control group receive no intervention; the parenting trainers will visit families in the treatment group during weekly one-on-one home visiting, or invite families to join the weekly training sessions which will be held in parenting centers. Parenting trainers will build a caring relationship with each family that forms the foundation for the intervention. During the training sessions, parenting trainers will demonstrate 2 age-appropriate, interactive caregiver-child activities targeting development in four developmental domains: cognition, language, motor, and social-emotional development. Each activity is fully-scripted in an ECD curriculum that is loosely based on the "Jamaica curriculum" developed by Sally Grantham-McGregor and further developed by local child development psychologists and ECD experts. Group play and reading activities will be organized at the parenting center in a centrally-located child-friendly space.

Each 30- to 45-minute session includes:

1. Discuss parental expectations and concerns about the child as well as the child's present and anticipated developmental progress
2. Demonstrate age-appropriate games and guide the caregiver to play with the child with the aim of encouraging more frequent quality parent-child interaction, using the week-by-week parenting curriculum and toys (or picture books)
3. a 5- to 10-minute videotaped recording of the parent and child engaging in activities designed for the week

The research team will conduct interventions in three successive phases:

1. Phase 1, between 01/09/2020 and 01/09/2021. Participants in the sample county are all 6-24 months old at the beginning of phase 1.
 - 1.1. The online service group will have free access to the information about scientific parenting presented in the APP
 - 1.2. The online & offline group will be invited to the nearest parenting center, or home-visited by the parenting trainers, in addition to free access to the APP
 - 1.3. The control group will receive no intervention
2. Phase 2, between 01/10/2021 and 01/10/2022. Additional children aged 0-17 months old will be invited to participate at the beginning of phase 2.
 - 2.1. The online service group of newly enrolled caregivers whose children are 0-17 months old, and caregivers whose children were in the control group in phase 1 (now 18-36 months old in phase 2) will have free access to the APP
 - 2.2. The online & offline group of newly enrolled caregivers whose children are 0-17 months old, and caregivers whose children were in this group in phase 1 (now 18-36 months old in phase 2) will be invited to the nearest parenting center, or home-visited by the parenting trainers, in addition to free access to the APP
3. Phase 3, between 01/11/2022 and 01/11/2023. Additional children aged 0-17 months old will be invited to participate at the beginning of phase 3.
 - 3.1. The online service group of caregivers of children who were newly enrolled in phase 2 (now 12-29 months old in phase 3), and caregivers whose children were in the control group during phase 1 (now 30-48 months old in phase 3) will have free access to the APP

3.2. The online & offline group of newly enrolled caregivers whose children are 0-11 months old, and caregivers whose children were in this group in phase 1 (now 30-48 months old in phase 3) will be invited to the nearest parenting center, or home-visited by the parenting trainers, in addition to free access to the APP

Intervention Type

Behavioural

Primary outcome measure

1. The cognitive, language, motor and socioemotional development of children measured using test scores of the Caregiver Reported Early Childhood Development Instruments (CREDI), the Chinese Communicative Development Inventory (CDI), the Infant Behavior Questionnaire (IBQ), the Early Childhood Behavior Questionnaire (ECBQ), and the Chinese version of Infant-Toddler Social and Emotional Assessment (CITSEA) at baseline and 1 year
2. The number of children delayed in cognitive, language, motor and social-emotion development measured using the Caregiver Reported Early Childhood Development Instruments (CREDI), the Chinese Communicative Development Inventory (CDI), the Infant Behavior Questionnaire (IBQ), the Early Childhood Behavior Questionnaire (ECBQ), and the Chinese version of Infant-Toddler Social and Emotional Assessment (CITSEA) at 1 year
3. Physical growth measured using child weight, height, health condition, and quality of sleep between baseline and 1 year

Secondary outcome measures

1. Changes in parenting attitude and practices, assessed from reports of caregivers using Parenting Practice Questionnaire (PPQ) at baseline and 1 year
2. Parental knowledge of normative infant development, assessed using Knowledge of Infant Development Inventory (KIDI) at baseline and 1 year
3. Aspects of the quality and quantity of psychological stimulation and cognitive support available in the home environment, assessed using the Home Observation for Measurement of the Environment Inventory (HOME) at baseline and 1 year
4. Mental wellbeing of caregivers, assessed using the Depression, Anxiety, and Stress (DASS) instrument at baseline and 1 year
5. Involvement of caregivers, assessed using the frequency of participation of offline caregiver-child activity sessions, accessing frequency of scientific parenting information, such as daily child care, scientific feeding, safety protection, disease prevention, and early development and education, demonstrated on the APP, between baseline and 1 year
6. Quality of caregiver-child interaction, assessed using weekly 5- to 10 minutes video will be coded as quantitative data to show the quality of interaction weekly from baseline to the end of the intervention
6. Quality of ECD service provision, assessed using the dosage and content which will be recorded in the APP, caregiver's formal feedback on the quality of service, and on the parenting trainer after attending each parenting training sessions. This will be collected at between baseline and 1 year

Overall study start date

10/12/2019

Completion date

31/12/2023

Eligibility

Key inclusion criteria

1. Children residing in the sample county, within one of the 50 villages involved
2. Aged 6 to 24 months at the beginning of the study (intervention phase 1) will be invited to participate together with their primary caregivers
3. Aged 0-17 months (intervention phase 2 or 3)

Participant type(s)

Healthy volunteer

Age group

Child

Upper age limit

24 Months

Sex

Both

Target number of participants

Total sample size is 800 families with children who were in our desired age range

Key exclusion criteria

A Diagnosis that would require more professional services, including but not limited to visual, hearing, or intellectual disabilities, ASD, and children whose primary caregiver has a mental disorder.

Date of first enrolment

20/08/2020

Date of final enrolment

31/08/2020

Locations**Countries of recruitment**

China

Study participating centre

China Center for Agricultural Policy

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Funder(s)

Funder type

Government

Funder Name

China Center for Agricultural Policy, Peking University

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

the datasets generated and/or analysed during current study will be included in the subsequent results publication.

IPD sharing plan summary

Other