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Testing the effectiveness of comprehensive early childhood development (CECD) services in rural areas of China

Submission date
06/05/2019

Recruitment status
No longer recruiting

Registration date
17/05/2019

Overall study status
Completed

Last Edited
03/06/2021

Condition category
Other

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

Plain English summary of protocol

Background and study aims
A growing number of studies point to the importance of early childhood intervention for fulfilling childhood development potential. The critical period before age three is considered to be a crucial “window”, during which interventions designed to improve child development can have significant and lasting effects, even into adulthood. Moreover, intervention during this time period is considered to be the most cost-effective from a policy perspective.

This project seeks to explore the most cost-effective interventions and associated implementation protocols to help to young babies and children living in rural China to reach their full developmental potentials. To do so, we propose to conduct a large-scale randomized controlled trial to measure the impact of a Comprehensive Early Childhood Development (CECD) intervention on parental knowledge, attitude, behavior and, most importantly, on child development outcomes.

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 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 cognition, language, motor 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?
Participants may benefit from improved neurodevelopment and quality of life. There will be no risk for participants to be part of this trial, according to our study design.

Where is the study run from?
1. China Center for Agricultural Policy - Peking University
2. School of Economics and Management - Jiangxi Agricultural University

When is the study starting and how long is it expected to run for?
January 2018 to October 2018

Who is funding the study?
China Center for Agricultural Policy - Peking University, China.

Who is the main contact?
Prof. Renfu Luo,
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
AEARCTR-0003316

Study information

Scientific Title
Cluster Randomised 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 04/07/2017, Peking University Institutional Review Board (PUIRB) (Room 501, Yifu Building, Peking University Medical Department, No. 38 College Road, Haidian District, Beijing, China; llwyh@bjmu.edu.cn; +86 010-82805751), ref: IRB00001052-17056

Primary study design
Interventional

Study design
Cluster randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Child development

Interventions
We will implement the intervention in each of our 50 treatment villages. During the weekly home visits, the parenting instructors will demonstrate and guide the parents (caregivers) how to play and interact with the babies to help the development of cognition, language, motor and social emotion by using the week-by-week parenting curriculum and toys (or picture books). After that, the parenting instructors will tell the parents (caregivers) nutrition and health knowledge for the child at that age. And finally the parenting instructors will give the curriculum and toys of the week to the family and collect the curriculum and toys used last week.

The initial phase of the trial has two data collection rounds: a baseline survey (completed) and one at endline. These data include detailed family characteristics and parental characteristics that will allow us to understand the heterogeneity of outcomes for different groups, plus a ten-minute video for each of our treatment household recording the interaction between the child and caregiver. We will videotape during both baseline and endline survey to observe subtle changes in terms of the quality of interaction as well as the child's performance.

Intervention Type
Behavioural

Primary outcome(s)
1. Test scores of Caregiver Reported Early Childhood Development Instruments (CREDI) and Bayley Scales of Infant Development (BSID) at baseline and follow-up (50-weeks).
2. Number of children delayed in cognitive, language, motor and social-emotion development at follow-up (measured using the above tools)

Key secondary outcome(s)
1. Changes in parenting practices and parental adjustment, assessed from reports of mothers using Parenting and Family Adjustment Scales (PAFAS) from baseline to follow-up.
2. Parental knowledge of normative infant development, assessed using Knowledge of Infant Development Inventory (KIDI) from baseline to follow-up.
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) from baseline to follow-up.
4. Parenting Pressure measured by Parenting Depression Index (PD) from baseline to follow-up.

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Children aged between 6 and 24 months
2. Able and willing to cooperate with the examination

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Months

Upper age limit
24 Months

Sex
All

Total final enrolment
635

Key exclusion criteria
1. Parents do not consent

Date of first enrolment
08/01/2018

Date of final enrolment
08/10/2018

Locations

Countries of recruitment
China

Study participating centre

China Center for Agricultural Policy - Peking University
Wangkezhen Building
Peking University
No.5 Yiheyuan Road
Haidian District
Beijing
China
100871

Study participating centre
School of Economics and Management - Jiangxi Agricultural University
1101 Zhimin Avenue
Qingshanhu Economic and Technological Development Zone
Nanchang
Jiangxi
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Sponsor information

Organisation
UBS Optimus Foundation

Organisation
National Natural Science Foundation of China

Funder(s)

Funder type
University/education

Funder Name
China Center for Agricultural Policy, Peking University

Results and Publications

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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2020	03/06/2021	Yes	No