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A study of the effectiveness, scalability, and sustainability of early childhood development services in rural China

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06/09/2022

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No longer recruiting

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14/09/2022

Overall study status
Completed

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03/03/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In China, a major cause of poor early childhood development (ECD) in rural areas is under-investment in psychosocial stimulation by caregivers, which is compounded by high rates of mental health issues among caregivers, such as depression and anxiety. The purpose of this study is to evaluate the effectiveness of an integrated intervention of parenting training and caregiver mental health promotion on child development outcomes and caregiver well-being among rural households in China. We will study whether a local-led program can effectively improve ECD and caregiver mental health outcomes among vulnerable communities; and whether an integrated ECD and caregiver mental health intervention can improve the impacts on child and caregiver outcomes compared to a single intervention.

Who can participate?
Caregivers and children (6-24 months of age) living in the villages at the time of the survey

What does the study involve?
The study will be undertaken in 125 rural villages in Ya'an, a prefecture in Sichuan Province, China. In the study, 25 communities will be randomly given the parenting training intervention (intervention arm 1); 25 communities will be given the caregiver mental health intervention (intervention arm 2); 25 communities will be given both interventions (intervention arm 3); and, 50 communities will be given no intervention, this group is called the control or dummy intervention group. The intervention will last one year. Families with children aged 6-24 months in the selected villages will be tested, totalling 1250 caregiver-child groups. Primary outcomes include ECD outcomes and caregiver mental health. Secondary outcomes include parental investment in stimulative parenting practices and materials; parenting discipline style; beliefs and skills on stimulating parenting; parental self-efficacy related to boosting parenting; social connectedness between caregiver and trainers, and between caregivers and other caregivers; structural and functional social support (community/family); positive perception of daily chores; parental stress; physical health; beliefs about mental health stigma; and primary and secondary caregiver bandwidth.

What are the possible benefits and risks of participating?
This research will generate rigorous evidence on the impact of government-administered ECD programs on child psychosocial stimulation, and caregiver mental health and well-being. The potential benefits of this study are improved cognitive and non-cognitive skills of children and improved mental health of caregivers. Additionally, if this intervention is successful, it can inform, future programs and policies that benefit child and caregiver well-being in China. There are no possible risks of participation.

Where is the study run from?
1. Stanford University (United States of America)
2. Southwestern University of Finance and Economics (China)

When is the study starting and how long is it expected to run for?
July 2022 to February 2025

Who is funding the study?
1. Xinhe Foundation (China)
2. Private donations

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Scientific

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Additional identifiers

Protocol serial number
YAAN2022

Study information

Scientific Title
A study of the effectiveness, scalability, and sustainability of early childhood development services in rural China

Study objectives
The main objective is to study whether a local-led program can effectively improve early child development (ECD) and caregiver mental health outcomes among vulnerable communities by coordinating service delivery across rural areas in Sichuan Province, China. Led by the local All-China Women's Federation, the program will follow a hierarchical model to distribute ECD services (parenting training and mental health support) across the prefecture, focusing on vulnerable rural households. At the prefecture and county levels, ECD Supercenters take advantage of urban infrastructure and human resources to coordinate program activities and train parenting trainers to deliver the intervention. At the local community level, parenting trainers based in smaller Child Centers will invite caregivers to attend one-on-one parenting training sessions and/or group-based mental health workshops. To maximize adherence, parenting trainers will conduct home visits to households that cannot visit the Center Centers. This hierarchical model could distribute relatively abundant ECD resources from cities and counties to villages. Such a program has the potential to effectively reach the most disadvantaged children, who may not be reached by traditional programs, and also has the potential to function as a highly effective and durable policy tool to drive equitable human capital accumulation, urbanization, and economic growth.

Considering that caregiver mental health is an important determinant of child development, we aim to investigate synergies in program delivery and program impacts when combining a parenting training program and a caregiver mental health program. There may be program delivery synergies in which the total cost of delivering multiple interventions is lower when they are administered jointly than when they are delivered separately. The integration of program components can also lead to concurrent and dynamic synergies between the impacts of program components. In the case of concurrent parenting training and mental health programs, interventions targeting caregiver mental health may increase the impacts of parental training on ECD outcomes, raising the productivity of psychosocial stimulation interventions during this stage as well as later stages of childhood.

In this study, we propose to evaluate a local-led program to improve child development and caregiver well-being in rural China. China is an ideal setting to examine the efficacy of ECD service systems for several reasons. First, there is a demonstrated need for ECD intervention due to high rates of developmental delays concentrated among rural populations. At the same time, China has a well-established government and civil society infrastructure to upscale effective interventions. Whereas few LMICs have the resources to implement public

interventions at scale, China has one of the largest public service bureaucracies in the world, with large amounts of resources dedicated to supporting child and caregiver well-being. Several recent policies from China's central government have also demonstrated a commitment to increasing ECD programming across the nation, with a special focus on supporting ECD needs in vulnerable rural communities. With local partners responsible for implementing and monitoring the intervention program, this program can easily be developed by other local groups for similar implementation.

This project also has implications for ECD programs and public service systems around the world. To date, several countries have begun upscaling ECD programs, including Brazil (Primeira Infância Melhor), Mexico (Centro de Desarrollo Infantil), South Africa (Integrated Programme for Early Childhood Development), and Peru (Cuna Mas). Many of these programs have adopted a regionally integrated approach, in which smaller local centers receive training from larger hubs and, in turn, deliver ECD resources to underserviced communities. However, less is known about the impacts of these programs on child development or caregiver well-being. Evaluating the returns to public investment in local programs will inform policymakers seeking effective solutions to promote ECD and caregiver well-being and reduce regional disparities in human capital at scale.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/08/2022, Stanford University Institutional Review Board (Research Compliance Office, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306, USA; +1 650 723-2480; adam.bailey@stanford.edu), ref: 63680

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Caregiver mental health promotion

Interventions
The Ya'an Project is a curriculum-based caregiver education intervention that aims to improve early childhood psychosocial development and maternal well-being through caregiver training classes by parenting trainers. There are two curricula implemented in this intervention.

The parenting training curriculum was loosely based on the Reach Up and Learn curriculum and adapted by the research team in collaboration with early childhood development experts in China. Weekly stage-based, age-appropriate sessions were developed targeting children 6-36 months of age. Each weekly session contains modules focusing on two of four developmental modules: cognition, language, motor, and social-emotional skill development. At the end of each

session, caregivers are encouraged to take toys and books home and to practice the activities at home daily. This curriculum has been demonstrated to be effective at improving the cognitive development of young children in multiple randomized controlled trials across China.

The mental health curriculum is adapted from the World Health Organization Thinking Healthy Programme, an evidence-based psychosocial intervention providing psychoeducation and coaching based on principles of cognitive behavioral therapy. Structured forms of talk therapy are used to disrupt and alter the cycle of unhealthy thinking (cognitions), leading to unhelpful emotions which can result in undesirable actions (behaviors). In a safe environment, caregivers are encouraged to voice their problems, share their experiences of childrearing, and receive social support, therefore improving their relationship with their children and with the people around them. Although the WHO-designed curriculum only covers the first ten months after childbirth, the outcome of other research has extended and implemented the curriculum for caregivers of children up to 3 years of age. In this study, we will adapt the curriculum to be culturally appropriate to rural households in rural China. For example, we will adjust the language in the sessions to make it more accessible to older and less-educated grandmother caregivers, who are typically responsible for taking care of left-behind children in rural areas.

The following data will be collected at baseline and endline (i.e., after 1 year) on tablets:

Child survey. The child survey will collect information from caregivers of the index child on various topics. In addition to the questionnaire-based data collection, anthropometric measurements (height and weight) will be taken for the index child in each household. Full list of survey data is below:
• Birth information
• Basic demographic characteristics
• Bayley Scales of Infant and Toddler Development, third edition (Bayley-III) (baseline and endline)
• Wechsler Preschool and Primary Scale of Intelligence (follow-up)
• Length & weight
• Brief Infant-Toddler Social and Emotional Assessment (BITSEA)
• New Wolke social-Emotional Behavior Ratings

Primary caregiver survey. The primary caregiver survey will capture information on the caregiver who spends the most time raising the child. The information may influence their parenting skills, as well as mental health outcomes. Full list of survey data is below:
• Family Care Indicators (FCI)
• Home Observation Measurement of the Environment (HOME Inventory) short form
• Depression Anxiety Stress Scale, 21 items (DASS-21)
• Center for Epidemiologic Studies Depression Scale (CES-D)
• Strengths and Difficulties Questionnaire-Parent Report for the child (SDQ-PR)
• Parenting Daily Hassles (PDH) scale
• Chinese version of the Mental Health Literacy Scales (MHLS-C)
• Parenting Stress Index (PSI)

Household survey. The household survey component will measure characteristics of sampled households, such as family composition, socioeconomic status, etc. The full list of survey data is below:
• Household composition (roster of family members living in the home)
• Household socioeconomic status (adult education, employment, income, family assets)
• Parental migration histories and geographic living location
• Health status of adults in the household

Parenting trainer survey. In addition, we will collect information on the parenting trainers working at the parenting centers. Data will include those on ECD knowledge, work relationships with center participants, as well as demographic characteristics of the parenting trainers. The full list of survey data is as follows:
• Knowledge on ECD
• Relationship between trainer and caregiver
• Socioeconomic status (employment, geographic living location, education)

Village characteristics. Characteristics on the communities will also be collected to reflect the community at the time of baseline surveying. The characteristics we are interested in are those that follow:
• Urbanization level
• Population size
• Prevalence of out-migration
• Per capita GDP
• Availability and accessibility of public health and education services

In-app data collection. In addition, the following monitoring data will be collected by the parenting trainers using an app on a monthly basis on tablets during the one-year intervention:
• Number of one-on-one training sessions delivered to each child (with location, date and duration of each visit and number of books and toys borrowed to each child delivered).
• Reasons for missed training sessions (e.g., due to illness, weather, death in family, refusal, child or caregiver unavailable for another reason, parent trainer schedule conflict, or other reasons).

Intervention Type
Behavioural

Primary outcome(s)
The following primary outcomes will be recorded on tablets at baseline and endline (i.e., after 1 year at the end of the trial):
1. Early childhood development outcomes measured using:
1.1. Bayley Scales of Infant and Toddler Development, third edition (Bayley-III)
1.2. Caregiver Reported Early Development Instrument – short form (CREDI-SF)
1.3. Brief Infant-Toddler social and Emotional Assessment (BITSEA)
1.4. New Wolke social-Emotional Behavior Ratings

2. Mental health of caregivers (both primary and secondary) measured using:
2.1. Depression Anxiety Stress Scale, 21 items (DASS-21)
2.2. Patient Health Questionnaire (PHQ-9)
2.3. Center for Epidemiologic Studies Depression Scale (CES-D)

Key secondary outcome(s))
The following secondary outcomes will be recorded on tablets at baseline and endline (i.e., after 1 year at the end of the trial):
1. Parental investment in stimulative parenting practices and materials measured with
1.1. Family Care Indicators (FCI)
1.2. Home Observation Measurement of the Environment (HOME Inventory) short form

2. Parenting style measured with:
Parenting Styles and Dimensions Questionnaire (PSDQ)

3. Social connectedness between caregiver and trainers, and between caregivers and other caregivers measured with:
Social Connectedness Scale

4. Structural and functional social support (community/family) measured with:
Multidimensional Scale of Perceived Social Support (MSPSS)

5. Positive perception of daily chores measured with:
Parenting Daily Hassles (PDH) scale

6. Parental stress; physical health measured with:
Parenting Stress Index (PSI)

7. Beliefs about mental health stigma measured with:
The Chinese version of the Mental Health Literacy Scales (MHLS-C)

8. Cognitive bandwidth measured with:
Cognitive-control-demanding tasks

Completion date
28/02/2025

Eligibility

Key inclusion criteria
1. Caregivers of a child 6-24 months of age living in the village at the time of surveying
2. Children aged 6-24 months at the time of surveying (born between February 1st, 2020, and March 1st, 2022)
3. Wiling to participate in the parenting center programs (parenting training and mental health)
4. Willing to participate in the impact evaluation, including the child surveys, caregiver surveys, and household surveys
5. Able and willing to give informed consent

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Children with a severe disability
2. Caregivers that are unwilling or unable to give informed consent
3. Caregivers who are unwilling to participate

Date of first enrolment

08/10/2022

Date of final enrolment
01/05/2024

Locations

Countries of recruitment
China

Study participating centre
Ya'an ECD management centre
-
Ya'an
China
625100

Sponsor information

Organisation
Stanford University, Stanford Center on China's Economy and Institutions, Freeman Spogli Institute

ROR
https://ror.org/00f54p054

Funder(s)

Funder type
Charity

Funder Name
Xinhe Foundation

Funder Name
Private donors

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated and analyzed during the current study will be available upon request from Professor Qian Yiwei (qyw.ray@gmail.com). De-identified data may be made available to researchers upon request and after careful reviewing of the research aim of the applying researcher. Oral consent was obtained from the interviewees and trial participants before survey administration and treatment enrollment. All datasets will be de-identified by removal of names, household IDs and village IDs.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/11/2023	30/11/2023	Yes	No
Other files	Pre-analysis plan	20/06/2024	21/06/2024	No	No