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A study of the effectiveness and scalability of a group-based early childhood development program in China

Submission date 06/07/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 08/07/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 15/10/2024	**Condition category** Other	[_] Individual participant data [X] 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 households is underinvestment in developmental opportunities for young children by caregivers. The purpose of this study is to evaluate the effectiveness and scalability of a group-based (i.e., two providers for 10 caregiver-child dyads) intervention providing parental training to primary caregivers of young children. We will study whether such program can effectively improve ECD and caregiver outcomes among communities in need (i.e., communities with a prevalence of developmental delay exceeding 20%).

Who can participate?

Primary caregivers and children (6 - 24 months of age) with a rural household registration status living in the selected communities at the time of baseline data collection.

What does the study involve?

The study will be undertaken in approximately 30 randomly selected clusters in six counties in Zhejiang Province, China. After baseline screening of the prevalence of delay, clusters with a prevalence of delay below 20% will be excluded from the intervention study. In each of the remaining clusters, we will randomly select 20 caregiver-child dyads. In the selected study sample, half of the caregiver-child dyads (i.e., 10 dyads in each cluster) will randomly be assigned to the parenting training intervention (treatment arm); and, the remainder of the sample (i.e., 10 dyads in each cluster) will be given no intervention, this group will be 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 approximately 660 caregiver-child dyads. Primary outcomes include ECD outcomes. Secondary outcomes include parental investment in stimulative parenting practices and materials; parental self-efficacy; and caregiver mental health outcomes.

What are the possible benefits and risks of participating?

This research will generate rigorous evidence on the impact of group-based ECD programs on child psychosocial stimulation, 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?
Zhejiang University School of Medicine Pediatrics Hospital

When is the study starting and how long is it expected to run for?
June 2024 to September 2025

Who is funding the study?
1. Zhejiang University Qingshan Institute for Advanced Studies in Business (China)
2. Private donations

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ZHEJIANG2024

Study information

Scientific Title
A study of the effectiveness and scalability of a group-based early childhood development program for rural caregiver-child dyads in Zhejiang Province, China

Study objectives
The purpose of this study is to explore effective ways to implement early development services for children aged 0-3 years by providing parenting guidance to parents (primary caregivers) of children aged 0-3 years with rural household registration in Zhejiang Province who live in both urban and rural areas. In this way we aim to inform decision-making with regard to national policies on early development services for children aged 0-3 years. The project will cover five to six districts and counties in Zhejiang Province (depending on the prevalence of developmental delay in the areas). Intervention will be delivered to approximately 300 families assigned to the intervention group.

Specific research objectives:
1. To assess the current status of early childhood development of children aged 0-3 years in rural households in Zhejiang Province and the current parenting behaviors of their primary caregivers; and to explore possible differences depending on their area of residence (urban and rural).
2. To set up a total of 24 parenting centers in five to six districts and counties in Zhejiang Province, and to provide free "two-to-ten" parenting courses to families with children aged 0-3 years old in rural areas, so as to promote children's cognitive, language, and socio-emotional development, as well as in other developmental domains.
3. Effectively organizing and implementing an easy-to-operate and scalable service model for the early development of children aged 0-3 years through multisectoral cooperation and coordination (including the China's Health Commission, China's Education Bureau, the Ministry of Human Resources and Social Affairs).
4. Invite leaders from China's National Health Commission, the Maternal and Child Health Center, and other departments and the national project team to guide the implementation and evaluation of the project, so as to promote the results of the project as a national "template" for early development services for children aged 0-3 years.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/07/2024, Zhejiang University Medical School Ethics Committee (866 Yuhangtang Rd, Xi Hu Qu, Hangzhou, Zhejiang, 310027, China; +86-571-87951395; yjsy-yb@zju.edu.cn), ref: 2024-IRB-0209-P-01

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life, Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Early childhood developmental delay

Interventions
The present study is a prospective, randomized, controlled, single-center study. The subjects were randomized using a block group randomization method, with the intervention and control groups assigned in a 1:1 ratio. Using a random number generator subjects were assigned to treatment and control.
Intervention group: group-based (i.e., two parenting training providers per 10 caregiver-child dyads) parenting instruction sessions were provided.
Control group: no parental care instruction program was provided.

To be more specific, in this study, a randomized controlled trial was conducted to randomly divide primary caregivers of children aged 0-3 years old with rural household registration in urban and rural communities in Zhejiang Province into an intervention group (providing parenting support) and a control group (not providing parenting support). Prior to the start of the parenting support intervention, the project team conducted a baseline survey of the primary caregivers and children in the intervention and control groups to assess early childhood development outcomes under the status quo. After determining the prevalence of delay in each community, the project team will set up parenting centers (e.g., community-, township-, and village centers) in the sample districts and counties of Zhejiang Province, where more than 20% of children are found to be delayed at baseline. Interactive teaching aids and equipment for the "two-to-ten" program are provided at each site to support the "two-to-ten" parenting guidance activities and promote the cognitive and language development of local children aged 0-3.

Based on the needs of the "two-to-ten" parenting program, the project team will select and train the required parenting trainers in the project sites. Through rigorous training and qualification, the child care workers will be able to master the content of the "two-to-ten" curriculum and provide individualized support to each child to promote his/her cognitive and language development. In each of the sample districts covered by the intervention program, two Parenting Teachers will be responsible for the specific curriculum intervention in each district and county. They will conduct weekly "two-to-ten" parenting coaching with the primary

caregivers of the children in the intervention group for a total of one year, during which time the parents of the children in the intervention group will receive weekly "two-to-ten" parenting group activities at the local parenting center site, which will focus on parental counseling and coaching for early childhood development. During this period, parents of children in the intervention group will receive weekly "two-to-ten" parenting instruction at the local parenting center site, which focuses on early childhood development. The parenting guidance is designed to provide systematic parenting support to ensure that children receive ongoing care and education from their caregivers.

Intervention Type
Behavioural

Primary outcome measure
All measures will be collected at baseline and at follow-up (i.e., after completion of the one-year intervention program):
Infants:
1. Birth information (only at baseline)
2. Basic demographic characteristics (only at baseline)
3. Bayley Scales of Infant and Toddler Development, third edition (Bayley-III)
4. Brief Infant-Toddler Social and Emotional Assessment (BITSEA)
5. Ages & Stages Questionnaires (ASQ-3)

Secondary outcome measures
All measures will be collected at baseline and at follow-up (i.e., after completion of the one-year intervention program):
1. Caregivers:
1.1. Chinese Version of the Parenting Sense of Competence Scale (C-PSOC)
1.2. Parenting Cognitions and Conduct Toward the Infant Scale (PACOTIS)
1.3. Depression Anxiety Stress Scale (DASS-21)
1.4. Center for Epidemiologic Studies Depression Scale (CES-D)
1.5. Parenting Stress Index Short Form (PSI-SF)
1.6. Multidimensional Scale of Perceived Social Support (MSPSS)

2. Parenting environment:
2.1. Composition of family members
2.2. Family socio-economic status (adult education, job, income, family property) (only at baseline)
2.3. Parents' migration history (only at baseline) and current place of residence
2.4. Health status of family members
2.5. Information on the network of social relationships among the sample families

Overall study start date
28/06/2024

Completion date
30/09/2025

Eligibility

Key inclusion criteria

1. Children aged 6 - 24 months of age and their caregivers living in the sample region at the time of baseline data collection
2. With a rural household registration status (hukou)
3. Wiling to participate in the parenting support program
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)
Carer, Other

Age group
Mixed

Sex
Both

Target number of participants
660

Key exclusion criteria
1. Children and caregivers residing in clusters with a low prevalence of developmental delays (i. e., a prevalence of less than 20%)
2. Children and caregivers that are not residing in the region
3. Children with urban household registration status
4. Children with severe disabilities
5. Caregivers that are unwilling or unable to give informed consent
6. Caregivers who are unwilling to participate in the intervention program

Date of first enrolment
26/07/2024

Date of final enrolment
20/08/2024

Locations

Countries of recruitment
China

Study participating centre
Zhejiang University School of Medicine Pediatrics Hospital
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Sponsor information

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Zhejiang University Qingshan Institute for Advanced Studies in Business

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Sponsor type
University/education

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan
The dataset generated and analyzed during the current study will be available upon request from Dr. Yun Shen (shenyun_@zju.edu.cn). 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 file	in Chinese		08/07/2024	No	No