ISRCTN13421990 https://doi.org/10.1186/ISRCTN13421990

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

Submission date
06/07/2024

Recruitment status
No longer recruiting

Registration date
08/07/2024

Overall study status
Completed

Last Edited
11/11/2026

Condition category
Other

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

Plain English summary of protocol

Background and study aims

In China, underinvestment in developmental opportunities for young children by caregivers is a major cause of poor early childhood development (ECD) in rural households. The purpose of this study is to evaluate the effectiveness and scalability of a one-to-five group-based intervention (i.e., one training provider per five caregiver-child dyads providing parental training). 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%). Additionally, the study will explore the potential benefits of involving non-primary caregiving fathers and the use of conditional cash transfers (CCTs) within such interventions.

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 60 randomly selected geographical sample sites across twelve 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 sample sites, 10 caregiver-child dyads will be randomly selected and divided into two age-based groups: (1) caregiver-child dyads below the overall sample mean (i.e., approximately 5 children aged 6-15 months) and (2) caregiver-child dyads above the overall sample mean (i.e., approximately 5 children aged 16-24 months). At each sample site, one of these age groups will be randomly assigned to the parental training intervention (treatment group), while the other age-group will be given no intervention (control or dummy intervention group), resulting in a total of 120 clusters (i.e., one treatment and one control cluster per sample site). Additionally, caregiver-child dyads in the treatment group will be assigned to a randomized father invitation arm or a randomized encouragement CCT incentive arm. In the father invitation arm (30 clusters from all 12 counties, with 2 or 3 clusters per county), fathers will be invited to join the parental training sessions once a month, either alone or with the primary caregiver. Caregiver-child dyads assigned to the CCT incentive arm (30 clusters from 6 counties) will receive

a financial incentive conditional on their attendance and participation, over a period of eight weeks.

The intervention will last nine months. Approximately 600 caregiver-child dyads from families with children aged 6-24 months in the selected villages will be tested. Primary outcomes include ECD outcomes. Secondary outcomes include parental investment in stimulative parenting practices; caregiver beliefs; caregiver mental health outcomes; and caregiver perceived social support.

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 include improved cognitive and non-cognitive skills of children, improved peer support and caregiver mental health. If this intervention is successful, its findings could inform future programs and policies aimed at improving the well-being of children and their caregivers 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 October 2025

Who is funding the study?
1. Tsingshan Institute for Advanced Business Studies of Zhejiang University (China)
2. ZJU-GENSCI Children's Health Research & Development Center
3. Private donations

Who is the main contact?
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Additional identifiers

Protocol serial number
ZHEJIANG2024

Study information

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

Study objectives
Current study objectives as of 14/08/2025:
This study aims to evaluate the impact of a randomised controlled trial testing the effects of a father-inclusive group-based parenting intervention by providing parenting guidance to parents (primary caregivers) of children aged 0-3 years with rural household registration in Zhejiang Province, living in both urban and rural areas. The project will cover twelve counties in Zhejiang Province (depending on the prevalence of developmental delay in the areas). Intervention will be delivered to 60 clusters (i.e., approximately 300 families) assigned to the intervention group. Half of the treatment group (caregiver-child dyads from 30 clusters, from all 12 counties, with 2 or 3 clusters per county) will be assigned to the father invitation arm.

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 behaviours 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 60 parenting centres in twelve counties in Zhejiang Province, and to provide free "one-to-five" 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. To assess whether inviting non-primary caregiving fathers (either alone or together with the primary caregiver) can improve the effectiveness of the parenting programme.
4. 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).
5. 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.

Previous 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

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Quality of life, Treatment

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

Interventions

Current interventions as of 14/08/2025:
The present study is a group-based prospective, cluster-randomized controlled, superiority trial. Using a random number generator subjects were assigned to treatment and control. Intervention group: group-based (i.e., one parental training provider per five caregiver-child dyads) parenting instruction sessions will be provided. Fathers in the father invitation arms will be invited to join the sessions once a month (either alone or together with the primary caregiver). Caregivers assigned to the CCT incentive arm will receive a financial incentive conditional on their attendance and participation.

Control group: no parental care instruction programme 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). In addition, caregiver-child dyads in the intervention group are assigned to a randomized father invitation arm or a randomized encouragement CCT incentive arm. 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, in order 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 centres (e.g., community-, township-, and village centres) 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 "one-to-five" programme are provided at each site to support the "one-to-five" parenting guidance activities and promote the cognitive and language development of local children aged 0-3.

Based on the needs of the "one-to-five" parenting programme, the project team will select and train the required parenting trainers at the project sites. Through rigorous training and qualification, the childcare workers will master the content of the "one-to-five" curriculum and be able to provide individualized support to each child to promote his/her cognitive and language development. In each county, two or three training providers will be responsible for delivering the specific curriculum intervention at the sample sites. They will conduct weekly "one-to-five" parental training sessions with the primary caregivers of the children in the intervention group at the local parenting service station, for a total of nine months. The sessions will focus on parental counselling and guidance for early childhood development, providing systematic parenting support and ensuring that children receive ongoing care and education.

Fathers of the caregiver-child dyads that have been assigned to the father invitation arm will be invited to attend the parental training sessions on a monthly basis, either alone or together with the primary caregiver. These sessions will follow the same scripted curriculum as the other sessions in the programme.

Caregiver-child dyads assigned to the CCT arm will receive a financial incentive conditional on their attendance and participation (i.e., 100 RMB within one to two days after attending a parenting session). The CCT arm will be implemented over a period of eight weeks (from 9 December 2024 to 7 February 2025), and is designed to encourage caregivers to attend the parental training sessions.

Previous 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(s)
Current primary outcome measures as of 14/08/2025:
All measures will be collected at baseline and at follow-up (i.e., after completion of the 9-month intervention program):
1. Bayley Scales of Infant and Toddler Development, third edition (Bayley-III)
2. Brief Infant-Toddler Social and Emotional Assessment (BITSEA) (only at baseline)
3. Ages & Stages Questionnaire: Social-Emotional (ASQ:SE) (only at follow-up)

Previous primary outcome measures:
All measures will be collected at baseline and at follow-up (i.e., after completion of the 1-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)

Key secondary outcome(s)
Current secondary outcome measures as of 14/08/2025:
All measures will be collected at baseline and at follow-up (i.e., after completion of the 9-month intervention program):
1. EuroQol Toddler and Infant Populations (EQ-TIPS)
2. Child Screen Time (7 self-made items)
3. Family Care Indicators (FCI)
4. Karitane Parenting Confidence Scale (KPCS) (only at baseline)
5. Chinese Version of the Parenting Sense of Competence Scale (C-PSOC) (only at baseline)
6. Parenting Cognitions and Conduct Toward the Infant Scale (PACOTIS)
7. Child Gender Socialization Scale (CGSC)
8. Depression Anxiety Stress Scale (DASS-21)
9. Parental Stress Scale (PSS)
10. Multidimensional Scale of Perceived Social Support (MSPSS)

Previous secondary outcome measures:
All measures will be collected at baseline and at follow-up (i.e., after completion of the 1-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

Completion date
31/10/2025

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. Willing 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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 14/08/2025:
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 who are not residing in the region
3. Children whose mothers have an urban household registration status
4. Children with severe disabilities
5. Caregivers who are unwilling or unable to give informed consent
6. Caregivers who are unwilling to participate in the intervention program

Previous 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 who are not residing in the region
3. Children with urban household registration status
4. Children with severe disabilities
5. Caregivers who 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
Hangzhou
China
310027

Sponsor information

Organisation
Zhejiang University Qingshan Institute for Advanced Studies in Business

Funder(s)

Funder type
Other

Funder Name
Tsingshan Institute for Advanced Business Studies of Zhejiang University

Funder Name
ZJU-GENSCI Children's Health Research & Development Center

Funder Name
Private donations

Results and Publications

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?
Basic results			11/11/2026	No	No
Protocol file	in Chinese		08/07/2024	No	No