ISRCTN15854033 https://doi.org/10.1186/ISRCTN15854033

The “Digital Plus” approach to upscaling early childhood development services: evaluating the effectiveness of a mixed online-offline caregiver education program in rural China

Submission date
28/06/2024

Recruitment status
No longer recruiting

Registration date
13/02/2025

Overall study status
Completed

Last Edited
21/04/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Rates of developmental delay remain high among young children in many low- and middle-income countries. One effective way to promote early childhood development in these settings is through programs during which trainers visit caregivers in the home and teach them activities and skills to stimulate their child’s development. However, such programs have typically been costly and difficult to expand across wide areas or large populations. This study, conducted in rural China, seeks to determine if delivering the training partially through a specially designed digital app can increase the scalability of a parenting training program without compromising its effectiveness.

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

What does the study involve?
The study will be undertaken in 80 villages in three rural counties in a province in central China. Caregivers in 40 villages will receive training for one year, with the first two months of training occurring in person, and the next ten months occurring over the app (with in-person visits every two months to check in). Caregivers in the other 40 villages will not receive any training and will serve as the control group. The primary outcome will be early childhood development. Secondary outcomes will include caregiver mental health, caregivers’ usage and attitudes toward digital programs, caregivers’ attitudes and feelings about parenting, and the amount of time and resources that caregivers put into stimulating their child’s development.

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. The potential benefits of this study are improved

cognitive and non-cognitive skills of children. If successful, the intervention will also offer broader insights that can inform future programs and policies to promote early childhood development at scale in rural 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)
3. Zhongnan University of Economics and Law (China)

When is the study starting and how long is it expected to run for?
July 2023 to April 2026

Who is funding the study?
1. Xinhe Foundation (China)
2. Private donations
3. Give2Asia

Who is the main contact?
Kelly Reiling, kreiling@stanford.edu

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Prof Yiwei Qian

Contact details
Research Institute of Economics and Management
Southwestern University of Finance and Economics
Chengdu
China
610074
+86 18123223929
qianyw@swufe.edu.cn

Type(s)
Scientific, Principal investigator

Contact name
Prof Shanshan Li

Contact details
Zhongnan University of Economics and Law
Wuhan
China
430000
+8615209295373
lishanceee@163.com

Type(s)
Public

Contact name
Ms Kelly Reiling

Contact details
Stanford University
616 Jane Stanford Way
Stanford
United States of America
94305
+1-650-723-4581
kreiling@stanford.edu

Additional identifiers

Protocol serial number
CFRD2024

Study information

Scientific Title
Evaluating the effectiveness and sustainability of mixed online-offline deployment in providing early childhood development services at scale in rural China

Acronym
Digital Plus for ECD

Study objectives
Past research has established that home visit-based parent education programs promote cognitively stimulating parenting practices and early child development in households with children under the age of 2 years. The study objective is to determine whether mixed offline and online delivery of parenting training can maintain intervention effectiveness while reducing costs and increasing scalability. While parenting training will be conducted via in-person home visits during the first two months of the intervention, most training beyond this point will occur via prerecorded video through a specially designed app, reducing the number of trainers needed to deliver the training throughout the study period. On the village level, the intervention will be implemented by two types of municipal government-affiliated authorities overseeing women's and family issues in rural areas of China, peer mothers (tongban mama) and children's committee directors (ertong zhuren). Moreover, local doctors will be asked to send reminder texts to caregivers in the treatment group to remind them to engage with online training materials.

By reducing the number of staff needed overall to conduct training and entrusting most village-level implementation to local authorities in the municipal and medical systems, the project design has the potential to be significantly upscaled or expanded to remote areas with relatively low additional cost. Various steps will be taken to offset the potential negative impacts of offline delivery on the training's effectiveness in promoting ECD, including conducting additional in-home visits every two months during the primarily online delivery period. Therefore, it is hypothesized that this mixed online-offline study design will produce

significantly positive effects on ECD outcomes comparable to those found in past, fully offline parenting training interventions.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/03/2024, China Center for Behavioral Economics and Finance Research Ethics Committee (555, Liutai Avenue, Wenjiang District, Chengdu, 611130, China; +86 (028) 87098046; ccbef@swufe.edu.cn), ref: n/a

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Improvement in early childhood psychosocial development among rural children in China

Interventions
The Digital Plus project seeks to develop, deliver, and evaluate a multi-stage, mixed-format caregiver education program to target early childhood psychosocial development in rural China. The intervention contains two arms, one that receives the early childhood development education services (treatment) and one that does not (control), and will occur in two phases.

The first phase is fully offline and will last 2 months. During this phase, caregivers in the treatment group will receive weekly in-home, in-person lessons from parenting trainers recruited for this project. The content of the lessons mostly consists of an activity-based parenting training curriculum that is based on the preexisting Reach Up and Learn curriculum and was adapted by the research team with assistance from early childhood development experts in China. In the adapted curriculum, parenting trainers will conduct one session per week that guides caregivers through interactive activities that are designed to stimulate the early development of children between 6 and 36 months old across four dimensions: cognitive, language, motor, and social-emotional skill development. Trainers will also lend caregivers toys and books and instruct them to use these materials to practice that week's activities before the next session. In addition to the activity-based curriculum, trainers will also deliver feedback about the caregiver's interactions with the target child using a handbook developed by the research team in partnership with experts from China.

The second phase contains mixed online and offline deployment and will last ten months. During this phase, caregivers will continue to receive activity-based lessons following the parenting curriculum, but the lessons will take the form of prerecorded videos delivered through an app developed for this project. Community health workers will continue to lend caregivers toys and books related to each week's lesson and will be on hand to assist caregivers if they have questions. Once every two months, the parenting trainers will conduct another home visit to answer questions and offer feedback on the caregiver's interaction skills using the handbook.

Updated 21/04/2026:
A midline survey was conducted between October and November 2025 using the following instruments: Bayley-3, Parenting Stress Scale, Family Care Indicators (FCI), Responsive Caregiving Rating Scale (RCRS), Parental Self-efficacy Scale (BPSES), Child screen exposure, Parenting beliefs and attitudes, and Questions on project perception.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 10/09/2025:

Early childhood psychosocial development will be measured using the following scales at baseline and endline (i.e., after 1 year at the end of the trial):
1. Bayley Scales of Infant and Toddler Development, third edition (Bayley-III)
2. Ages and Stages Questionnaires: Third version
3. Ages and Stages Questionnaires: Social-emotional (ASQ:SE)
4. New Wolke Social-Emotional Behavior Ratings

———

Previous primary outcome measure:

Early childhood psychosocial development will be measured using the following scales at baseline and endline (i.e., after 1 year at the end of the trial):
1. Bayley Scales of Infant and Toddler Development, third edition (Bayley-III)
2. Ages and Stages Questionnaires: Social-emotional (ASQ:SE)
3. New Wolke Social-Emotional Behavior Ratings

Key secondary outcome(s))
Current secondary outcome measures as of 10/09/2025:

The following secondary outcome measures will be assessed at baseline and endline (i.e., after 1 year at the end of the trial):
1. Parenting and attachment style, measured with:
1.1 The Mother's Object Relations Scale – Short Form (MORS-SF)
2. Parenting stress, measured with the Parenting Stress Scale
3. Parental investments in stimulating parenting practices and materials, measured with:
3.1. The Family Care Indicators (FCI)
3.2 Questions of expense on child-rearing
3.3 Responsive Caregiving Rating Scale (RCRS)
4. Parenting self-efficacy, measured with the Parental Self-efficacy Scale (BPSES)
5. Caregiver mental health, measured using:
5.1. The Patient Health Questionnaire (PHQ)
5.2. The Depression, Anxiety, and Stress Scales, 21 items (DASS-21)
6. Positive perception of daily chores, measured with the Parenting Daily Hassles Scale (PDH)
7. Structural and functional social support (community/family), measured with the Multidimensional Scale of Perceived Social Support (MSPSS)
8. Caregiver digital literacy, measured using an adapted version of the eHealth Literacy Scale (eHEALS)
9. Child Health

9.1 Child sleep habits measured with the revised short form of the Brief Infant Sleep Questionnaire (BISQ-R SF)
9.2 Child physical activity time measured with self-designed a series of questionnaire items
9.3 Child screen exposure measured using self-made questions.
10. Caregiver perceptions of parenting
10.1 Parenting belief and attitudes toward parenting role measured with self-made questions.

Updated 21/04/2026:

Three additional tools were used at baseline but omitted from the original registration. They will also be used at endline:
1. Household expenditure on child rearing measured using Questions on childcare expenditure (self-made)
2. Parental gendered beliefs about child emotions measured using The Parents' Gendered Emotion Beliefs scale (PGEB)
3. Intra-household decision-making dynamics measured using Questions on intra-household decision-making (self-made)

Three tools were collected at baseline only and will NOT be collected at endline:
1. Child developmental milestones measured using Ages and Stages Questionnaires (ASQ-3)
2. Caregiver depression measured using Patient Health Questionnaire (PHQ)
3. Caregiver parenting stress from daily hassles measured using Parenting Daily Hassles Scale (PDH)

———

Previous secondary outcome measures:

The following secondary outcome measures will be assessed at baseline and endline (i.e., after 1 year at the end of the trial):
1. Parenting and attachment style, measured with:
1.1. The World Value Survey
1.2 The Mother’s Object Relations Scale – Short Form (MORS-SF)

2. Parenting stress, measured with the Parenting Stress Index

3. Parental investments in stimulating parenting practices and materials, measured with:
3.1. The Family Care Indicators (FCI)
3.2. Home Observation Measurement of the Environment – Short Form (HOME-SF)

4. Parenting self-efficacy, measured with the TOol to measure Parenting Self-Efficacy (TOPSE)

5. Caregiver mental health, measured using:
5.1. The Patient Health Questionnaire (PHQ)
5.2. The Depression, Anxiety, and Stress Scales, 21 items (DASS-21)

6. Positive perception of daily chores, measured with the Parenting Daily Hassles Scale (PDH)

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

8. Caregiver digital literacy, measured using a self-designed questionnaire

9. Caregiver and child screen exposure measured using data collected by devices

Completion date
30/04/2026

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
3. Willing 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)
Population

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
900

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

Date of first enrolment
01/08/2025

Date of final enrolment
20/03/2026

Locations

Countries of recruitment
China

Study participating centre

Zhongnan University of Economics and Law
182 Nanhu Boulevard
Wuhan
China
430000

Sponsor information

Organisation
Stanford Center on China's Economy and Institutions (SCCEI)

Funder(s)

Funder type
Charity

Funder Name
Give2Asia

Funder Name
Xinhe Foundation

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 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 will be 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		19/11/2025	21/11/2025	Yes	No
Other files	Parenting Trainer Facilitator Manager Interview Guide	07/04/2026	08/04/2026	No	No
Other files	Primary Caregiver Interview Guide	07/04/2026	08/04/2026	No	No