ISRCTN26100642 https://doi.org/10.1186/ISRCTN26100642

How parental support helps young children in migrant families in China develop better: a new study

Submission date
23/09/2024

Recruitment status
No longer recruiting

Registration date
01/10/2024

Overall study status
Completed

Last Edited
30/09/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Many young children in low- and middle-income countries are at risk of developmental delays, which can affect their future health, education, and wellbeing. This study focuses on children in migrant families in China, who often face additional challenges due to limited access to quality services. The aim is to see if a parental support program can help improve the development of these children and enhance the parenting environment.

Who can participate?
The study involves caretaker-child pairs (dyads) with children aged 6-30 months living on the campus of Foxconn in Zhengzhou, China.

What does the study involve?
Participants will take part in weekly one-on-one training sessions for caretakers (usually mothers or grandmothers) and their children. These sessions will focus on interactive parenting practices and will run over a period of 8 months. The training is based on a program called Reach Up and Learn.

What are the possible benefits and risks of participating?
The potential benefits include improved child development in areas like cognitive, language, motor, and social-emotional skills, as well as better parenting skills and investments. There are no significant risks mentioned, but participants will be informed of any potential risks before joining the study.

Where is the study run from?
The study is being conducted on the campus of Foxconn, the world's largest Apple production supplier, located in Zhengzhou, China.

When is the study starting and how long is it expected to run for?
November 2023 to January 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
For any inquiries, please contact the principal investigator, Professor Yiwei Qian, at qianyw@swufe.edu.cn

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Yiwei Qian

Contact details
55 Guanghua Village Street, Qingyang District
Chengdu
China
610074
+86(28)87357744
qianyw@swufe.edu.cn

Additional identifiers

Study information

Scientific Title
Effect of a parental stimulation Intervention on early childhood development among migrant population in China: a stepped-wedge randomized trial

Study objectives
The overall goal of this study is to examine the effectiveness of a parental stimulation intervention on early childhood development and parenting environment among the migrant population in China. The hypotheses are as follows: (1) the parental stimulation intervention improves the cognitive, language, motor, and social-emotional development of migration children under age three; (2) the parental stimulation intervention has positive effects on parental skills and parenting investments; (3) the parental stimulation intervention enhances employee mental wellbeing, job satisfaction, and retention.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/11/2023, The research ethics committee of China Center for Behavioral Economics and Finance (CCBEF) (555 Liutai Ave., Wenjiang District, Chengdu, 611130, China; +86-029-87098046; ccbef@swufe.edu.cn), ref: None provided

Primary study design

Interventional

Study design
Stepped-wedge individual-level randomized controlled trial

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Prevention of developmental delay in 6 - 36-month-age children of migration households

Interventions
The study will employ a stepped-wedge trial design, where the intervention will be rolled out to different groups at different time points randomly. The study sample comprises 300 caretaker-child dyads with children aged 6-30 months living on the campus of Foxconn – the world's largest Apple production supplier in Zhengzhou China. The trial will be conducted over 8 months, divided into four 2-month time windows. The first two months are free of intervention. Eligible caretaker-child dyads will be randomly assigned to one of the three groups, and each group will start to receive the intervention in different time windows from months 3 to 8, randomly and respectively. The intervention consists of weekly one-on-one parental training sessions for caretakers (mothers or grandmothers typically) and their children on interactive parenting practices, with a curriculum loosely adapted from Reach Up and Learn. The curriculum was designed to be stage-based and age-appropriate, and each session contained modules focusing on two of the following four developmental domains: cognition, language, motor, and social-emotional development. The standard of care is access to the parenting center, which contains a large play area, providing age-appropriate toys and baby books for rural families, to encourage free play. There are also group activities scheduled every day to facilitate engagement in the parenting center. Both the treatment and control groups receive standard of care. Randomization will be done in the office by a computer.

Intervention Type
Behavioural

Primary outcome(s)
The following primary outcome measures will be assessed at baseline (month 0) and months 2, 4, 6, and 8:
1. Child cognitive development is measured using Ages & Stages Questionnaires, Third Edition (ASQ-3)
2. Child language development is measured using Ages & Stages Questionnaires, Third Edition (ASQ-3)
3. Child motor development is measured using Ages & Stages Questionnaires, Third Edition (ASQ-3)
4. Child social-emotional development is measured using Ages & Stages Questionnaires: Social Emotional (ASQ:SE)
5. Child social-emotional development is measured using Devereux Early Childhood Assessment for Infants Record Form
6. Child cognitive, language, and motor development is measured using Bayley Scales of Infant and Toddler Development: Third Edition (Bayley-III)

Key secondary outcome(s)

The following secondary outcome measures will be assessed at baseline (month 0) and months 2, 4, 6, and 8:
1. Child screen-use time is measured using self-made items
2. Parenting investment and skills are measured using Family Care Indicators (FCI)
3. Parental expectation and parenting information sources are measured using self-made items
4. Parenting interaction quality is measured using self-made items
5. Parenting self-efficacy is measured using the Brief Parental Self-Efficacy Scale (BPSES)
6. Parenting stress is measured using the Parenting Stress Index-Short Form (PSI-SF)
7. Depressive symptoms of the primary caretakers are measured using the Center for Epidemiological Studies - Depression Scale (CES-D) and Patient Health Questionnaire (PHQ)

Completion date
05/01/2025

Eligibility

Key inclusion criteria
Caretaker-child dyads with children aged 6 - 36 months at baseline living on the campus of Foxconn

Participant type(s)
Resident

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Months

Upper age limit
36 Months

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
05/01/2024

Date of final enrolment
11/01/2024

Locations

Countries of recruitment
China

Study participating centre
Foxconn Zhengzhou Branch
Zhenggang 4th Street, Zhongmu County
Zhengzhou
China
451161

Sponsor information

Organisation
Southwestern University of Finance and Economics

ROR
https://ror.org/04ewct822

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from emails to Professor Yiwei Qian (qianyw@swufe.edu.cn)

IPD sharing plan summary
Available on request