

# Perfecting Parenting: integrated evaluation of micronutrient deficiencies and parenting practices in rural China

<b>Submission date</b> 13/02/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/02/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/02/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Studies have shown that children growing up in poor, rural Chinese regions during the first years of life are at high risk of developmental delays. Given that approximately half of all Chinese infants in China are currently growing up in rural regions, a large share of all Chinese children is at risk of missing out on their full developmental potential. Earlier interventional studies implemented in low- to middle-income countries have convincingly shown that parenting training programs focusing on caregiver-child interaction can effectively reduce the emergence of early cognitive delays. Thus, this study aimed to assess whether a parenting training program done in rural China, combining training on child psychosocial stimulation with information on child nutrition, can adjust problematic parenting skills and practices and improve children's early child development, health, nutrition, and physical growth outcomes.

### Who can participate?

All 18- to 30-month-old children living in the sample villages in rural Shaanxi Province, China, at the start of the study, with their main caregivers.

### What does the study involve?

Participating villages are randomly assigned to intervention and control. All 18- to 30-month-olds and their main caregivers living in villages assigned to intervention are selected to participate in a parenting program. Those in the control group received no intervention. Caregivers and children in the intervention group are invited to participate in weekly parenting training sessions delivered at home by a parenting trainer. In these sessions, caregivers are taught how to interact with their children in ways that can improve their cognition, language, motor, and social-emotional development.

### What are the possible benefits and risks of participating?

This study is expected to benefit children whose main caregivers participated in the intervention study. Child early development, nutrition, and physical growth status are hypothesized to improve in response to more stimulating home learning environments. It was also hoped that caregivers may apply taught parenting skills and practices to improve the developmental

outcomes of other children living in the household and neighborhood. Moreover, this curriculum is designed to be scalable if proven successful. There are no known risks to participants taking part in this study.

Where is the study run from?

131 villages in Shaanxi Province (China)

When is the study starting and how long is it expected to run for?

April 2014 to April 2015

Who is funding the study?

1. International Initiative for Impact Evaluation (3ie) (USA)
2. UBS Optimus Foundation (Switzerland)
3. Bank of East Asia (Hong Kong)
4. China Medical Board (USA)
5. Huaqiao Foundation (China)
6. Noblesse

Who is the main contact?

Mrs Alexis Medina, amedina5@stanford.edu (USA)

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
PerfectingParenting-QC01, 25734

## **Study information**

**Scientific Title**  
A cluster-randomized controlled trial to measure the impact of a combined nutrition and parenting intervention on child and parent outcomes in rural China

**Study objectives**  
We hypothesize that participation in our parenting intervention will lead to significant improvements in parenting practices as well as short- and long-term child cognitive development and nutrition outcomes.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Approved 29/10/2013, Stanford University Human Subjects Research Institutional Review Board (1705 El Camino Real, Palo Alto, CA 94306, USA; +1 (650) 723-2480; irbnonmed@stanford.edu), ref: 4593

**Study design**

Interventional multi-center single-blind cluster randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Evaluation of parenting attitudes, knowledge, and practice on rural Chinese children's early development, health, nutrition, and physical growth.

### **Interventions**

All communities (villages) in the sample are randomly assigned to intervention and control using a computerized random number generator.

Families assigned to the control group received no intervention.

Families in the intervention group are invited to participate in weekly parenting training sessions delivered at home over a period of six months. During each home visit, trained members from the National Health and Family Planning Commission (NHFPC) introduce two age-appropriate, interactive caregiver-child activities targeting development in four developmental domains: cognition, language, motor, and social-emotional development. Each activity was fully scripted in an early child development curriculum that was loosely based on the "Jamaica curriculum" developed by Sally Grantham-McGregor and further developed by local child development psychologists and early child development experts.

No further follow-up treatment is planned.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

1. Children's cognitive, language, motor, and social-emotional development are measured using the following methods at baseline and endline:
  - 1.1. Cognition, language, motor, and social-emotional development measured using scales of the first edition of the Bayley Scales of Infant and Toddler Development (Bayley-I) for younger children, and the Griffith Mental Development Scales (GMDS-ER 2–8) for older children
  - 1.2. Communication, gross motor, fine motor, personal-social, problem-solving, and overall development measured using scales of the third edition of the Ages & Stages Questionnaire (ASQ-3)
  - 1.3. Ages & Stages Questionnaire: Social-Emotional (ASQ:SE)
2. Child micronutrient status measured using hemoglobin values in fingerprick blood testing at baseline and endline
3. Child height and weight measured using scales at baseline and endline

### **Key secondary outcome(s)**

Caregivers' attitudes, knowledge, and behavior with regard to parenting practices measured using a comprehensive household questionnaire administered to the primary caregiver of the child at baseline

**Completion date**

01/04/2015

## Eligibility

**Key inclusion criteria**

All babies aged 18 to 30 months at the start of the study (and their main caregivers) who lived in the sample villages.

**Participant type(s)**

Other

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Total final enrolment**

592

**Key exclusion criteria**

1. Babies from rich urban areas
2. Babies with severe anemia after initial blood tests (these children will then be referred to a doctor for treatment)
3. Babies outside of the age range (18-30 months)

**Date of first enrolment**

01/04/2014

**Date of final enrolment**

30/04/2014

## Locations

**Countries of recruitment**

China

United States of America

**Study participating centre**

Rural Education Action Program (REAP)

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## Sponsor information

### Organisation

Stanford University

### ROR

<https://ror.org/00f54p054>

## Funder(s)

### Funder type

Research organisation

### Funder Name

International Initiative for Impact Evaluation (3ie)

### Funder Name

UBS Optimus Foundation

### Alternative Name(s)

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

Switzerland

### Funder Name

China Medical Board

### Alternative Name(s)

China Medical Board, USA, CMB

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United States of America

**Funder Name**

Bank of East Asia

**Funder Name**

Huaqiao University

**Alternative Name(s)**

HQU

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

China

**Funder Name**

Noblesse

## Results and Publications

**Individual participant data (IPD) sharing plan**

The dataset generated during and analyzed during the study is available upon request from Dr Dorien Emmers, [dorien.emmers@kuleuven.be](mailto:dorien.emmers@kuleuven.be). 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?
<a href="#">Results article</a>	cognition	11/05/2017	20/02/2023	Yes	No
<a href="#">Results article</a>	parenting program outcomes	14/09/2020	20/02/2023	Yes	No