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

Submission date
13/02/2023

Recruitment status
No longer recruiting

Registration date
27/02/2023

Overall study status
Completed

Last Edited
22/02/2023

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Additional identifiers

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

Primary study design
Interventional

Study design
Interventional multi-center single-blind cluster randomized controlled trial

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
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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. 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?
Results article	cognition	11/05/2017	20/02/2023	Yes	No
Results article	parenting program outcomes	14/09/2020	20/02/2023	Yes	No