Perfecting Parenting: An evaluation of an integrated parenting program in rural China

Submission date 12/09/2018	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 23/10/2018	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 07/12/2021	Condition category Other	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 are currently at risk of missing out on their full developmental potential.

These early delays have been linked to poor parenting practices. First, studies found that the average engagement of caregivers in interactive caregiver-child activities in rural China was low. For example, only 11 percent of parents reported that they told a story to the child on the day before. Second, common problematic feeding practices, such as feeding the child a diet with a low nutrient density, have also been linked to poor child development. Third, early development may be hampered by lacking health promoting behaviours of caregivers, for instance, late initiation of toothbrushing.

Earlier intervention studies in rural China have convincingly shown that parenting training programs focusing on caregiver-child interaction can effectively reduce the emergence of early cognitive delays. This study aims to assess whether a parenting program combining training on child psychosocial stimulation with information on child nutrition and health promotion can adjust problematic parenting skills and practices and improve early child development, health, nutrition, and physical growth outcomes.

Who can participate?

All 6-18 month olds that are living in the selected villages in rural Hebei Province and Yunnan 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 6-18 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 will receive no intervention. Caregivers and children in the intervention group were invited to participate in biweekly parenting training sessions delivered at home by a community health worker. Caregivers are taught how to interact with their children in ways that can improve their cognition, language, motor, and social-emotional development. Caregivers also receive information on feeding practices (e.g. breastfeeding) and health promoting parenting practices (e.g. tooth brushing). Data collected

for the study include measures of child development, health, nutrition, and growth, as well as measures of caregivers' knowledge on and behaviour towards best parenting and feeding practices. The study takes place over 31 months.

What are the possible benefits and risks of participating?

This study is expected to benefit children whose main caregivers participate in the intervention study. Child early development, health, nutrition, and physical growth status may improve in response to more stimulating home learning environments, better feeding practices and health promotion. It is also hoped that caregivers may apply taught parenting skills and practices to improve developmental outcomes of other children living in the household and neighbourhood. Moreover, this curriculum may be scalable if proven successful. There are no known risks to participants taking part in this study.

Where is the study run from? Centre for Chinese Agricultural Policy (CCAP), Chinese Academy of Sciences (CAS) (China)

When is the study starting and how long is it expected to run for? June 2015 to December 2017

Who is funding the study? Save the Children Hong Kong (China)

Who is the main contact? Prof. Dr. Renfu Luo luorf.ccap@igsnrr.ac.cn

Contact information

Type(s) Public

Contact name Prof Renfu Luo

Contact details No. Jia 11 Datun Road, Anwai Beijing China 100101

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers PerfectingParenting-YH01

Study information

Scientific Title

Using community health workers to deliver an integrated parenting program in rural China: A cluster-randomized controlled trial

Study objectives

We hypothesize that participation in our parenting intervention will lead to significant improvements in parenting knowledge, skills, and practices as well as child development, health, and nutrition outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Stanford University Institutional Review Board Protocol, 26/10/2012, reference number 25734

Study design

Interventional single-centre non-masked cluster randomised controlled trial

Primary study design Interventional

Secondary study design Cluster randomised trial

Study setting(s) Home

Study type(s) Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Parenting attitudes, knowledge, and practice Early child development, child health, child nutrition and physical growth

Interventions

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

Families assigned to the control group receive no intervention.

Families in the intervention group are invited to participate in biweekly parenting training sessions delivered at home over a period of two years. During each home visit, community health workers introduce 2 age-appropriate, interactive caregiver-child activities targeting development in four developmental domains: cognition, language, motor, and social-emotional development. Each activity is fully-scripted in an ECD curriculum that is loosely based on the "Jamaica curriculum" developed by Sally Grantham-McGregor and further developed by local

child development psychologists and ECD experts. The curriculum previously underwent field testing and evaluation in rural China by our government partners at the National Health and Family Planning Commission (NHFPC) and our evaluation team. In addition to parenting training on interactive activities, caregivers receive stage-based information on child health and nutrition during each home visit. Community health workers provide information on child nutrition and health promotion based on fully-scripted, structured conversations developed by experts of the Capital Institute of Pediatrics (CIP) of the Chinese Academy of Medical Sciences (CAMS). No further follow-up treatment is planned.

Intervention Type

Behavioural

Primary outcome measure

The following will be assessed at the baseline and during three rounds of follow-up at the end of each intervention year:

1. Children's cognitive, language, motor, and social-emotional development, assessed using:

1.1. Cognition, language, motor and social-emotional scales of the third edition of the Bayley Scales of Infant and Toddler Development (Bayley-III)

1.2. Scales for communication, gross motor, fine motor, personal-social, problem solving, and overall development of the third edition of the Ages & Stages Questionnaire (ASQ-3)

1.3. The Ages & Stages Questionnaire: Social-Emotional (ASQ:SE)

2. Child health status, assessed using carer-reported health measures included in the household questionnaire

3. Child micronutrient status, assessed using haemoglobin values measured with fingerprick blood testing

4. Child weight, measured in kg using a scale

5. Child height, measured in cm using a recumbent baby length scale for 0-2 year olds and a child height scale for children over 2 years of age

Secondary outcome measures

The following are assessed prior to treatment assignment (baseline) and during two rounds of follow-up at the end of each intervention year:

1. Caregivers' attitudes, knowledge, and behaviour with regard to early child psychosocial stimulation, health promotion, hygiene, and feeding practices, assessed using a comprehensive household questionnaire administered to the primary caregiver of the child,

2. Quality of the home learning environment, assessed using the Family Care Indicators (FCI) survey

3. Caregivers' perceived social support and parental mental wellbeing, assessed using:

3.1. Parenting and Family Adjustment Scale (PAFAS)

3.2. Depression Anxiety and Stress Scale (DASS)

3.3. Office of National Statistics (ONS) subjective wellbeing survey

Overall study start date

01/06/2015

Completion date

31/12/2017

Eligibility

Key inclusion criteria

All babies aged 6-18 months at the start of the study (and their main caregivers) who live in the sample villages

Participant type(s)

Other

Age group

Mixed

Sex Both

Target number of participants

We aimed to include at least 40 villages with an estimated 10 participating households per village. After allowing for attrition, we expected to enroll at least 400 households in the study, amounting to around 800 individuals (400 caregivers + 400 children).

Key exclusion criteria

Rich urban areas
 Children with severe anaemia after initial blood tests (these children were then referred to a doctor for treatment)

Date of first enrolment 01/09/2015

Date of final enrolment 01/11/2015

Locations

Countries of recruitment China

Study participating centre Nortwest Socio-economic Development Research Center, School of Management, Northwest University No. 229 North Taibai Avenue Northwest University Xi'an China 710068

Study participating centre Centre for Chinese Agricultural Policy (CCAP), Chinese Academy of Sciences No. 11A, Datun Road, Anwai Beijing China 100101

Sponsor information

Organisation Rural Education Action Program (REAP), Freeman Spogli Institute (FSI), Stanford University

Sponsor details 616 Serra Street Encina Hall E501 Stanford United States of America 94305

Sponsor type University/education

ROR https://ror.org/00f54p054

Funder(s)

Funder type Not defined

Funder Name Save the Children Hong Kong

Results and Publications

Publication and dissemination plan Planned publication in a high-impact peer reviewed journal one year after the end of the trial.

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

The dataset generated during and analysed during the current study will be available upon request from Professor Luo Renfo, luorf.ccap@igsnrr.ac.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?
<u>Results article</u>		09/09/2019	07/12/2021	Yes	Νο