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Healthy future: a community health worker program to improve maternal, newborn and child health in rural China

Submission date
23/03/2019

Recruitment status
Stopped

Registration date
26/03/2019

Overall study status
Stopped

Last Edited
07/01/2026

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
Integrated home visiting programs delivered by community health workers have the potential to improve child nutrition, health, and maternal well-being in low-resource settings, but evidence on effective home-visiting approaches and approaches that engage multiple caregivers are lacking, especially in rural China where grandmothers play an important role in child care and family decision-making. This study aims to develop and evaluate the effectiveness of a home visiting program delivered by community health workers in improving maternal, newborn, and child health in rural China.

Who can participate?
Families with pregnant women or children under 6 months of age are invited to participate in the 12-month study.

What does the study involve?
The study collects data from rural households to assess the health status of young children and to understand caregivers' feeding behaviors, knowledge, and attitudes that influence child and maternal health. Half of these surveyed households will receive home visits by trained community health workers. During these home visits, community health workers will deliver health and nutrition information to caregivers following a curriculum developed by the study team.

What are the possible benefits and risks of participating?
By participating in the study, caregivers will gain health and nutrition knowledge and learn about the health status of their children. There is a slight risk of infection associated with the finger prick blood tests. However, the test (HemoCue 201+) is a standard public health procedure in the study setting and has been shown to be safe. The risk is greatly mitigated as we are using trained nurses.

Where is the study run from?
Center of Experimental Economics in Education, Shaanxi Normal University, Shaanxi Province in northwestern China

When is the study starting and how long is it expected to run for?
Funding for the study was obtained in January 2016. Formative field work started in June 2016. Study enrollment will begin in April 2019. The intervention is expected to complete in May 2020. The endline survey is scheduled to be completed by August 2020

Who is funding the study?
The Enlight Foundation

Who is the main contact?
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Healthy future: a community health worker program to improve maternal, newborn and child health in rural China – a cluster randomized controlled trial

Study objectives

The principal study hypothesis is that families living in communities receiving the Healthy Future program will have better child and maternal health outcomes after 12 months compared to those living in control communities. In addition, within the treatment communities, those assigned to the encouragement condition where both primary and secondary caregivers are encouraged to participate in the intervention will have better child and maternal health outcomes compared to the standard treatment condition that targets the primary caregivers of young children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 30/05/2018, Stanford University Human Subjects Research Institutional Review Board (3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306; irb2-manager@lists.stanford.edu; +1-650-723-2480), ref: 44312
2. Approved 15/08/2018, University of North Carolina at Chapel Hill Non-Biomedical Institutional Review Board (720 Martin Luther King Jr. Blvd. Bldg # 385, Second Floor, Chapel Hill, NC 27599-7097; 919-966-3113; irb_questions@unc.edu; +1-919-966-3113), ref: 18-1705
3. Approved 08/03/2019, Shaanxi Normal University Scientific Ethics Committee (620 West Chang An Road, Chang An District, Xi'an, Shaanxi Province, China, 710119; xswyh@snnu.edu.cn; +86-(0)29-85310612), ref: N/A

Study design
Cluster non-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Iron deficiency anemia in children, low breastfeeding rates, poor complementary feeding practices and poor caregiver mental health

Interventions
Control group: no intervention
Treatment group: Healthy Future program for 12 months, from May 2019 to May 2020
- Caregivers in the treatment group will receive a caregiver education intervention that aims to improve early childhood nutrition and health, and maternal well-being through monthly home visits by trained community health workers. The intervention ranges in coverage from the second trimester of pregnancy to when the child turns 18 months of age, depending on child age at enrolment.
- Half of the treatment villages will receive an encouragement condition where both primary and secondary caregivers of young children are encouraged to participate in the home visit activities. By comparison, the standard condition will target the primary caregivers.
- In communities that receive free micronutrient supplements for young children as part of a government program, the community health workers will assist with delivering these micronutrient packages to recipient households.
Following the baseline survey, villages will be randomly allocated to each of the two main study

arms. Within the treatment arm, half of the villages will be randomized to standard or encouragement treatment conditions. Randomization will be stratified at the county level.

A canvass survey was conducted in two government-designated poverty counties in Shaanxi Province between November 2018 and March 2019 to yield a list of villages and number of eligible families in each village. From the list, villages with less than 5 pregnant women or children below 6 months of age were excluded. Using the final list of villages, 130 villages will be randomly selected and randomly allocated to each of the two main study arms using computer-generated random numbers. Within the treatment arm, half of the villages will be randomized to regular or encouragement treatment conditions.

The study will collect data from three main sources: community health worker (CHW) survey, household survey, and program administrative records:
- The CHW survey will capture information on CHW-related factors that might moderate the intervention effect, such as their age, education, general health, social capital, and knowledge related to child nutrition and feeding practices. The CHW survey will be conducted during the CHW training.
- The household survey component includes the baseline survey and two follow-ups conducted at six months (midline) and 12 months after the intervention initiation (endline). The survey will collect information from caregivers of the index child. In addition to the questionnaire-based data collection, anthropometric measurements (height and weight) will be taken for the index child in each household. Moreover, a nurse will administer the HemoCue 201+ test, a finger-prick blood test, to assess hemoglobin levels and address any medical problems caregivers have regarding the test.
- Program administrative data will be routinely collected by CHWs during home visits using computer tablets, including the modules delivered, length of the home visits, and attendance of family members.

Intervention Type
Behavioural

Primary outcome(s)
At baseline, 6 months, and 12 months:
1. Hemoglobin concentration among children aged 0 – 18 months, measured by HemoCue 201+ test
2. Exclusive breastfeeding under 6 months: proportion of children aged <6 months who received only breastmilk in the previous day, measured by caregiver questionnaire
3. Dietary diversity: number of food groups received by children aged 6 – 18 months in the previous day, measured by caregiver questionnaire

Key secondary outcome(s))
At baseline, 6 months, and 12 months:
1. Child Health, including:
1.1 BMI z-scores among children aged <18 months, measured by physical exam
1.2 Anemia status among children aged <18 months, measured by HemoCue 201+ test
1.3 Incidence of illness or injury among children aged <18 months, measured by caregiver questionnaire
2. Child Feeding Practice, measured by caregiver questionnaire
3. Attitude, Efficacy, and Knowledge, measured by caregiver questionnaire
4. Health Care Utilization, measured by caregiver questionnaire
5. Maternal Well-being, measured by caregiver questionnaire

Completion date
01/07/2020

Reason abandoned (if study stopped)
Disruption due to COVID-19 pandemic

Eligibility

Key inclusion criteria
1. Pregnant women or caregivers of children 0 to 6 months of age
2. Wiling to participate in the HF program
3. Willing to participate in the impact evaluation, including the household surveys, anthropometric measures, and hemoglobin tests
4. Ability and willingness to give informed oral consent

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
592

Key exclusion criteria
1. Does not reside in the study communities at the time of enrolment.

Date of first enrolment
04/04/2019

Date of final enrolment
01/01/2020

Locations

Countries of recruitment
China

United States of America

Study participating centre

Rural Education Action Program (REAP), Stanford University
616 Serra Street
Stanford
United States of America
94305

Study participating centre
Gillings School of Global Public Health, University of North Carolina at Chapel Hill
135 Dauer Dr
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Study participating centre
Center of Experimental Economics in Education, Shaanxi Normal University
No. 620, West Chang'an Avenue
Xi'an
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710119

Sponsor information

Organisation
Stanford University

ROR
https://ror.org/00f54p054

Funder(s)

Funder type
Charity

Funder Name
Enlight Foundation

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/10/2025	21/10/2025	Yes	No
Results article		29/12/2025	07/01/2026	Yes	No