ISRCTN16800789 https://doi.org/10.1186/ISRCTN16800789

A healthy future for young children in rural China: evaluating a community health worker program to improve maternal, newborn and child health

Submission date
09/07/2021

Recruitment status
No longer recruiting

Registration date
21/07/2021

Overall study status
Completed

Last Edited
20/11/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims

Despite China's rapid progress in maternal and child survival in recent decades, child malnutrition persists, infant and young child feeding (IYCF) practices remain poor, and preventable diseases and injuries are still dominant causes of child deaths in poorer rural areas. In particular, anemia, a common public health problem in many low- and middle-income countries (LMICs), affects half of the young children in northwestern China. Child anemia has irreversible consequences on health, development, educational attainment, and labor force participation. More generally, poor health and nutrition in early childhood also create large and long-term private and social costs and perpetuate poverty and inequality. These conditions are largely preventable through quality perinatal care, micronutrient supplementation, improved knowledge of nutrition and child feeding, increased awareness of danger signs and care seeking for illness, good sanitation and hygiene practices, and timely and complete vaccinations. However, coverage of many of these lifesaving interventions remains low for poor communities in rural China.

Home visiting programs delivered by community health workers (CHWs), especially integrated intervention packages, are a promising approach to improve maternal, neonatal, and child health in LMICs. Past studies have shown paraprofessional CHWs to be effective at promoting immunization uptake, increasing breastfeeding rates, and reducing child illness and death, even when the CHWs themselves lack formal professional training or tertiary education. However, existing studies have mainly been concentrated in in South Asia or sub-Saharan Africa and have focused on a narrow range of outcomes, such as breastfeeding promotion and immunization uptake. In rural China, there is virtually no evidence on CHW-delivered programs, as there has been only one CHW study to date. This study aimed to improve prenatal care by training local midwives, but the CHW program could not be fully carried out due to political, socio-economic, and logistical challenges. Thus, research on the feasibility and effectiveness of integrated CHW interventions is urgently needed, especially in rural China.

In short, integrated home visiting programs delivered by community health workers have the potential to improve child nutrition, health, and maternal mental health in low-resource settings,

but evidence on effective approaches is lacking, especially in rural China. To fill the evidence gap, the Healthy Future program aims to develop, deliver, and evaluate a stage-based home-visiting curriculum that targets infant nutrition, health, and maternal mental health in rural China. The curriculum focuses on six content domains: maternal nutrition, breastfeeding, complementary feeding, preventative health and daily care, maternal mental health, and uptake of government health services. Designed to be scalable, the intervention will be delivered by trained CHWs through home visits to pregnant mothers and caregivers of young children in rural China. The home visits will typically be conducted monthly, but will be more frequent during the first month after birth. In addition to the standard treatment that focuses on the primary caregiver alone, the study will also include an enhanced delivery mode that encourages engagement of both the primary and secondary caregivers in the household, who are usually mothers and grandmothers of young children.
The impact evaluation of the Healthy Future program is a collaboration among investigators from the School of Public Health at Sichuan University, the Stanford Center on China's Economy and Institutions and Department of Pediatrics at Stanford University, and the Gillings School of Global Public Health at the University of North Carolina at Chapel Hill, and the University of Nevada at Reno. This multi-disciplinary team consists of experts from diverse backgrounds, including economics, nutrition, pediatrics, and public health.

Who can participate?
Pregnant women beyond the second trimester and caregivers of healthy infants up to 6 months old at baseline. All participants must live in a rural household within one of the 80 sample townships in four rural counties of Sichuan Province, China. Families that meet the inclusion criteria will be enrolled at the beginning of the study through a door-to-door approach. For the first 6 months after the start of the intervention, the CHWs will continue to enroll pregnant women who become newly eligible to participate in the study.

What does the study involve?
Townships are randomly allocated to one of two groups. The control group do not receive the Healthy Future program. In the intervention group CHWs deliver the Healthy Future curriculum to pregnant women or caregivers of young children through monthly home visits. The frequency of home visits will increase during the first month after birth. All CHWs will be trained on basic early childhood health and nutrition, the Healthy Future curriculum, and standard operation procedures for intervention implementation. Within the intervention group, 20 townships will receive the standard treatment, while the other 20 townships will be assigned to an encouragement condition in which CHWs encourage participation of both primary and secondary caregivers during the home visits. To assess the impact of the intervention, the researchers will conduct surveys at the start of the study and after 6 and 12 months.

What are the possible benefits and risks of participating?
This study is expected to benefit those children whose caregivers participate in the community health worker intervention. By learning more about their children's nutritional needs and strategies for meeting these needs, the researchers expect that children's health, nutrition, and developmental outcomes will improve. It is hoped that the knowledge caregivers gain from participating in the intervention can also be applied to improving the feeding of other children and grandchildren living in the sample households.
Children will be tested for hemoglobin concentrations and anemia using finger-prick blood tests. There is a slight risk of infection. However, this test is the standard public health test and has been shown repeatedly to be safe. The risk is greatly reduced as trained nurses are used who clean the finger before testing. There is some discomfort associated with the test.

Where is the study run from?
1. West China School of Public Health, Sichuan University (China)
2. Stanford Center on China's Economy and Institutions, Stanford University (USA)
3. Gillings School of Global Public Health, University of North Carolina at Chapel Hill (USA)

When is the study starting and how long is it expected to run for?
January 2019 to October 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Yunwei Chen, ywchenn@stanford.edu

Contact information

Type(s)
Scientific

Contact name
Dr Yunwei Chen

ORCID ID
https://orcid.org/0000-0002-5144-925X

Contact details
Stanford University, 616 Jane Stanford Way, Encina Hall
Stanford
United States of America
CA 94305
-
ywchenn@stanford.edu

Type(s)
Scientific

Contact name
Dr Sean Sylvia

ORCID ID
https://orcid.org/0000-0002-9508-247X

Contact details
University of North Carolina
135 Dauer Drive
Chapel Hill
United States of America
27599
+1 (0)919 966 6328
sean_sylvia@unc.edu

Additional identifiers

Protocol serial number
44312

Study information

Scientific Title
Evaluating a community health worker program on child health and nutritional outcomes in rural China

Study objectives
1. Regular home visits by community health workers delivering a curriculum-based intervention will improve child health and nutrition outcomes and increase maternal well-being.
2. Households in which the community health worker engages with both the primary and secondary caregiver of the child see greater improvement in outcomes compared to households in which the community health worker engages only with the primary caregiver.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/04/2020, Stanford University Institutional Review Board, Protocol (1705 El Camino Real Palo Alto, CA 94306, USA; +1 (0)650 724 7141; irbeducation@stanford.edu), ref: 44312

Primary study design
Interventional

Study design
Multi-arm cluster-randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Early childhood health/nutrition and maternal well-being among rural households in China

Interventions
Sampling and randomization
Townships located in four nationally designated poverty counties in Nanchong prefecture in Sichuan Province are included in the sampling frame. A canvas survey was conducted between November 2018 and March 2019 to yield a list of towns. From the list, urban townships and townships with less than 10,000 people were excluded. From the remaining list of townships, 80 townships were randomly selected, stratified by county.

Following a survey in November 2019, the 80 towns were randomly allocated to one of the two main study arms. We randomized treatment allocation within each county: 10 towns in each county will be allocated to the treatment group, and 10 towns will be allocated to the control group. Within the 40 treatment towns, we conduct an individual RCT to randomize towns into the standard treatment arm or encouragement treatment arm.

Enrollment
Families that meet the inclusion criteria will be enrolled at the beginning of the study through a door-to-door approach. These participants will complete the baseline survey and invited later on to participate in the two follow-up surveys. For the first six months after the intervention initiation, the CHWs will continue to enroll pregnant women who become newly eligible to participate in the study. During enrollment, CHWs will collect basic information from newly-enrolled households, such as child age/gestational age of the mother. Participants will complete the midline and the endline surveys alongside participants enrolled at baseline.

The impact evaluation is designed as a nested cluster randomised controlled trial with townships randomly allocated to one of two main study arms:
1. Treatment arm: Healthy Future program (40 townships). CHWs in these townships will deliver the Healthy Future curriculum to pregnant women or caregivers of young children through monthly home visits. The frequency of home visits will increase during the first month after birth. The Healthy Future program aims to develop, deliver, and evaluate a stage-based home-visiting curriculum that targets infant nutrition, health, and maternal mental health in rural China. The curriculum focuses on six content domains: maternal nutrition, breastfeeding, complementary feeding, preventative health and daily care, maternal mental health, and uptake of government health services. Designed to be scalable, the intervention will be delivered by trained CHWs through home visits to pregnant mothers and caregivers of young children in rural China. The home visits will typically be conducted monthly, but will be more frequent during the first month after birth. In addition to the standard treatment that focuses on the primary caregiver alone, the study will also include an enhanced delivery mode that encourages engagement of both the primary and secondary caregivers in the household, who are usually mothers and grandmothers of young children.

2. Control arm: No intervention (40 townships). The Healthy Future program will not be delivered to families in these villages. This arm serves as the no-intervention “control” arm in the study.

Within the intervention arm, an encouragement overlay design is used to further randomize families into different conditions:
1. Standard condition (20 townships). CHWs in these townships will deliver the Healthy Future program to the primary caregiver of each child, typically the child’s mother.
2. Encouragement condition (20 townships). CHWs in these townships will invite both the primary and secondary caregiver of each child to participate in the Healthy Future program. The secondary caregiver is typically the child’s grandmother. CHWs in these townships will also be trained to encourage participation of both primary and secondary caregivers during the home visits, and will receive scripted guides within the Healthy Future curriculum to assist them in engaging both mothers and grandmothers during the home visit.

The impact evaluation will conduct repeated cross-sectional surveys at baseline, 6-month midline, and 12-month endline. After the initial recruitment at baseline, the researchers will continue enrolling pregnant women until the 6-month midline.

(added 08/06/2022)
An additional 39 control townships were added to meet the power requirements of the trial, leading to a final total of 119 townships (40 treatment and 79 control).

Intervention Type
Behavioural

Primary outcome(s)

1. Hemoglobin concentration of children aged 6 weeks - 18 months, measured using HemoCue 201+ test at baseline, 6 months and 12 months
2. Exclusive breastfeeding under 6 months (proportion of children aged <6 months who received only breastmilk in the previous day), measured using WHO Infant and young child feeding indicators at baseline, 6 months and 12 months
3. Dietary diversity (number of food groups consumed by children aged 6 – 18 months in the previous day), measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months

Key secondary outcome(s)

Current secondary outcome measures as of 20/12/2022:

Secondary Health Outcomes:
A. Secondary child health outcomes
1. Child growth indicators by WHO standards (i.e., length-for-age z-scores, weight-for-age zscores) measured by child's weight, age and height at baseline, 6 months and 12 months;
2. Anemia status (hemoglobin concentration <110 g/l) measured using HemoCue 201+ test at baseline, 6 months and 12 months;
3. Proportion of children aged <18 months who had any illness in the past 14 days, measured by caregiver report of illness symptoms at baseline, 6 months and 12 months;
4. Proportion of children aged <18 months who had any unintended injuries in the past 14 days, measured by caregiver report at baseline, 6 months and 12 months;
B. Secondary maternal well-being outcomes
1. Perinatal depression among pregnant women and mothers, measured using the Edinburgh Postnatal Depression Scale at baseline, 6 months and 12 months;
2. Mental health among caregivers, measured using the Depression, Anxiety, and Stress Scale at baseline, 6 months and 12 months;
Secondary Behavioral Outcomes:
A. Infant and young children feeding practices
1. Early initiation of breastfeeding: proportion of children born in the last 24 months who were put to the breast within 1 hour of birth, measured using WHO infant and young child feeding indicators at baseline and 6 months
2. Proportion of newborns who were given colostrum, measured using WHO infant and young child feeding indicators at baseline and 6 months
3. Proportion of children aged 6 – 12 months who were fed breastmilk in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
4. Children ever breastfed: proportion of children born in the last 24 months who were ever breastfed, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
5. Predominant breastfeeding under 6 months: proportion of children < 6 months who received breastmilk as the predominant source of nourishment in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
6. Continued breastfeeding at 1 year: proportion of children aged 12 – 15 months who received breast milk in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
7. Duration of breastfeeding: the age in months when children aged 0 – 18 months stopped receiving breastmilk, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
8. Initiation of formula feeding: the age in months when children aged 0 – 18 months started to

receive formula, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
9. Proportion of children aged 6-8 months who received solid, semi-solid or soft foods in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
10. Initiation of complementary feeding: the age in months when children aged 0 – 18 months started to receive solid, semi-solid or soft foods, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
11. Minimum dietary diversity: proportion of children aged 6 – 18 months who received foods from at least 4 food groups in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
12. Minimum meal frequency: proportion of children aged 6 – 18 months who received solid, semi-solid, or soft foods the minimum number of times or more in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
13. Minimum acceptable diet: proportion of children aged 6 – 18 months who had at least the minimum dietary diversity and the minimum meal frequency in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
14. Consumption of iron-rich or iron-fortified foods: proportion of children aged 6 – 18 months who received an iron-rich or iron-fortified food or supplement that contains iron in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
B. Caregiver hygiene practices
1. Hygiene practices among caregivers, measured using caregiver self-reported frequency of hand washing at baseline, 6 months and 12 months
C. Health care utilization:
1. Use of formal care for last illness among children aged 0 – 18 months, measured by caregiver self-report at baseline, 6 months and 12 months
2. Number of prenatal visits among mothers during most recent pregnancy, measured by mother self-report at baseline, 6 months and 12 months
D. Maternal feeding practices
1. Dietary diversity (number of food groups) consumed by pregnant women and breastfeeding mothers, measured by mother self-report using WHO dietary diversity indicators at baseline, 6 months and 12 months
2. Proportion of pregnant women and mothers of children aged <18 months who used folic acid and iron supplements during current/most recent pregnancy, measured by mother self-report at baseline, 6 months and 12 months
Secondary Intermediate Outcomes:
A. Knowledge, attitude, and efficacy
1. Knowledge about breastfeeding and complementary feeding among caregivers, measured using breastfeeding knowledge questions developed by the research team at baseline, 6 months and 12 months
2. Knowledge about disease prevention and hygiene among caregivers, measured using health and hygiene knowledge questions developed by the research team at baseline, 6 months and 12 months
3. Attitude about breastfeeding among caregivers, measured using Iowa Infant Feeding Attitude Scale at baseline, 6 months and 12 months
4. Efficacy in breastfeeding among breastfeeding mothers, measured using Breastfeeding Self Efficacy Scale (Short Form) at baseline, 6 months and 12 months
5. Efficacy in preparation to breastfeed among pregnant women, measured using Efficacy in Preparation to Breastfeed Scale at baseline and 6 months
B. Social support
1. Social support among caregivers, measured using the Multidimensional Scale of Perceived

Social Support and Breastfeeding Family Support Scale at baseline, 6 months and 12 months
2. Joint household decision-making among caregivers, measured using household decision making scale questions developed by the research team at baseline, 6 months and 12 months

———

Previous secondary outcome measures as of 19/12/2022:

Child health:
1. Child growth indicators by WHO standards (i.e., length-for-age z-scores, weight-for-age z-scores) measured by child's weight, age and height at baseline, 6 months and 12 months
2. Anemia status (hemoglobin concentration <70 g/l) measured using HemoCue 201+ test at baseline, 6 months and 12 months
3. Proportion of children aged <18 months who had any illness in the past 14 days, measured by caregiver report of illness symptoms at baseline, 6 months and 12 months
4. Proportion of children aged <18 months who had any unintended injuries in the past 14 days, measured by caregiver report at baseline, 6 months and 12 months

Feeding practices:
1. Early initiation of breastfeeding: proportion of children born in the last 24 months who were put to the breast within 1 hour of birth, measured using WHO infant and young child feeding indicators at baseline and 6 months
2. Proportion of newborns who were given colostrum, measured using WHO infant and young child feeding indicators at baseline and 6 months
3. Proportion of children aged 6 – 12 months who were fed breastmilk in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
4. Children ever breastfed: proportion of children born in the last 24 months who were ever breastfed, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
5. Predominant breastfeeding under 6 months: proportion of children < 6 months who received breastmilk as the predominant source of nourishment in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
6. Continued breastfeeding at 1 year: proportion of children aged 12 – 15 months who received breast milk in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
7. Duration of breastfeeding: the age in months when children aged 0 – 18 months stopped receiving breastmilk, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
8. Initiation of formula feeding: the age in months when children aged 0 – 18 months started to receive formula, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
9. Proportion of children aged 6-8 months who received solid, semi-solid or soft foods in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
10. Initiation of complementary feeding: the age in months when children aged 0 – 18 months started to receive solid, semi-solid or soft foods, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
11. Minimum dietary diversity: proportion of children aged 6 – 18 months who received foods from at least 4 food groups in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
12. Minimum meal frequency: proportion of children aged 6 – 18 months who received solid,

semi-solid, or soft foods the minimum number of times or more in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
13. Minimum acceptable diet: proportion of children aged 6 – 18 months who had at least the minimum dietary diversity and the minimum meal frequency in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
14. Consumption of iron-rich or iron-fortified foods: proportion of children aged 6 – 18 months who received an iron-rich or iron-fortified food or supplement that contains iron in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months

Attitude, efficacy, and knowledge:
1. Breastfeeding attitude among caregivers, measured using Iowa Infant Feeding Attitude Scale at baseline, 6 months and 12 months
2. Efficacy in breastfeeding among breastfeeding mothers, measured using Breastfeeding Self-Efficacy Scale (Short Form) at baseline, 6 months and 12 months
3. Efficacy in preparation to breastfeed among pregnant women, measured using Efficacy in Preparation to Breastfeed Scale at baseline and 6 months
4. Knowledge about breastfeeding and complementary feeding among caregivers, measured using breastfeeding knowledge questions developed by the research team at baseline, 6 months and 12 months
5. Knowledge about disease prevention and hygiene among caregivers, measured using health and hygiene knowledge questions developed by the research team at baseline, 6 months and 12 months

Health care utilization:
1. Proportion of children aged 0 – 18 months that have completed vaccines according to government schedule, measured from vaccination records at baseline, 6 months and 12 months
2. Number of prenatal visits among mothers during most recent pregnancy, measured by mother self-report at baseline, 6 months and 12 months
3. Proportion of pregnant women and mothers of children aged <18 months who used folic acid and iron supplements during current/most recent pregnancy, measured by mother self-report at baseline, 6 months and 12 months

Maternal well-being:
1. Social support among caregivers, measured using the Multidimensional Scale of Perceived Social Support and Breastfeeding Family Support Scale at baseline, 6 months and 12 months
2. Mental health among caregivers, measured using the Depression, Anxiety, and Stress Scale at baseline, 6 months and 12 months
3. Perinatal depression among pregnant women and mothers, measured using the Edinburgh Postnatal Depression Scale at baseline, 6 months and 12 months
4. Household decision-making among caregivers, measured using household bargaining questions developed by the research team at baseline, 6 months and 12 months

———

Previous secondary outcome measures:

Child health:
1. Body mass index (BMI) z-scores measured by child's weight, age and height at baseline, 6 months and 12 months
2. Anemia status (hemoglobin concentration <70 g/l) measured using HemoCue 201+ test at baseline, 6 months and 12 months

3. Proportion of children aged <18 months who had any illness in the past 14 days, measured by caregiver report of illness symptoms at baseline, 6 months and 12 months
4. Proportion of children aged <18 months who had any unintended injuries in the past 14 days, measured by caregiver report at baseline, 6 months and 12 months

Feeding practices:
1. Early initiation of breastfeeding: proportion of children born in the last 24 months who were put to the breast within 1 hour of birth, measured using WHO infant and young child feeding indicators at baseline and 6 months
2. Proportion of newborns who were given colostrum, measured using WHO infant and young child feeding indicators at baseline and 6 months
3. Proportion of children aged 6 – 12 months who were fed breastmilk in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
4. Children ever breastfed: proportion of children born in the last 24 months who were ever breastfed, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
5. Predominant breastfeeding under 6 months: proportion of children < 6 months who received breastmilk as the predominant source of nourishment in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
6. Continued breastfeeding at 1 year: proportion of children aged 12 – 15 months who received breast milk in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
7. Duration of breastfeeding: the age in months when children aged 0 – 18 months stopped receiving breastmilk, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
8. Initiation of formula feeding: the age in months when children aged 0 – 18 months started to receive formula, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
9. Proportion of children aged 6-8 months who received solid, semi-solid or soft foods in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
10. Initiation of complementary feeding: the age in months when children aged 0 – 18 months started to receive solid, semi-solid or soft foods, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
11. Minimum dietary diversity: proportion of children aged 6 – 18 months who received foods from at least 4 food groups in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
12. Minimum meal frequency: proportion of children aged 6 – 18 months who received solid, semi-solid, or soft foods the minimum number of times or more in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
13. Minimum acceptable diet: proportion of children aged 6 – 18 months who had at least the minimum dietary diversity and the minimum meal frequency in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months
14. Consumption of iron-rich or iron-fortified foods: proportion of children aged 6 – 18 months who received an iron-rich or iron-fortified food or supplement that contains iron in the previous day, measured using WHO infant and young child feeding indicators at baseline, 6 months and 12 months

Attitude, efficacy, and knowledge:
1. Breastfeeding attitude among caregivers, measured using Iowa Infant Feeding Attitude Scale at baseline, 6 months and 12 months

2. Efficacy in breastfeeding among breastfeeding mothers, measured using Breastfeeding Self-Efficacy Scale (Short Form) at baseline, 6 months and 12 months
3. Efficacy in preparation to breastfeed among pregnant women, measured using Efficacy in Preparation to Breastfeed Scale at baseline and 6 months
4. Knowledge about breastfeeding and complementary feeding among caregivers, measured using breastfeeding knowledge questions developed by the research team at baseline, 6 months and 12 months
5. Knowledge about disease prevention and hygiene among caregivers, measured using health and hygiene knowledge questions developed by the research team at baseline, 6 months and 12 months

Health care utilization:
1. Proportion of children aged 0 – 18 months that have completed vaccines according to government schedule, measured from vaccination records at baseline, 6 months and 12 months
2. Number of prenatal visits among mothers during most recent pregnancy, measured by mother self-report at baseline, 6 months and 12 months
3. Proportion of pregnant women and mothers of children aged <18 months who used folic acid and iron supplements during current/most recent pregnancy, measured by mother self-report at baseline, 6 months and 12 months

Maternal well-being:
1. Social support among caregivers, measured using the Multidimensional Scale of Perceived Social Support and Breastfeeding Family Support Scale at baseline, 6 months and 12 months
2. Mental health among caregivers, measured using the Depression, Anxiety, and Stress Scale at baseline, 6 months and 12 months
3. Perinatal depression among pregnant women and mothers, measured using the Edinburgh Postnatal Depression Scale at baseline, 6 months and 12 months
4. Household decision-making among caregivers, measured using household bargaining questions developed by the research team at baseline, 6 months and 12 months

Completion date
30/10/2022

Eligibility

Key inclusion criteria
Community-level inclusion criteria:
1. Located within four selected nationally designated poverty counties
2. Support from the township health centers and county maternal and child hospitals
3. At least one CHW candidate who is willing to participate in the training for the Healthy Future program
4. At least 12 households with pregnant women or children under 12 months of age

Individual-level inclusion criteria:
1. Pregnant women or caregivers of children 0-6 months of age
2. Wiling to participate in the Healthy Future program
3. Willing to participate in the impact evaluation, including the household surveys, anthropometric measures, and hemoglobin tests
4. Able and willing to give informed consent

Participant type(s)

Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
1689

Key exclusion criteria
1. Babies over 6 months at the time of enrollment
2. Babies and pregnant women who do not live in the township most of the time (e.g., live in the county seat; have a home in the township but typically stay somewhere else for work)
3. Infants with serious congenital diseases, infectious diseases, genetic metabolic diseases or other disabilities

Date of first enrolment
25/07/2021

Date of final enrolment
27/05/2022

Locations

Countries of recruitment
China

United States of America

Study participating centre
Sichuan University West China School of Public Health
Department of Health and Human Behavior
Qingyang Qu, Shuncheng St, 25210B1-B2
Chengdu
China
610017

Study participating centre
Stanford Center on China's Economy and Institutions
616 Jane Stanford Way

Stanford
United States of America
94305

Study participating centre
Stanford Medical School
Department of Pediatrics
291 Campus Drive
Stanford
United States of America
94305

Study participating centre
University of North Carolina-Chapel Hill
Gillings School of Global Public Health
135 Dauer Drive
Chapel Hill
United States of America
27599

Study participating centre
University of Nevada
Reno School of Public Health
1664 N. Virginia Street
Reno
United States of America
89557

Sponsor information

Organisation
Stanford University

ROR
https://ror.org/00f54p054

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
De-identified participant data can be made available upon reasonable request from Dr Sean Sylvia (sysylvia@email.unc.edu) or Dr Yunwei Chen (ywchenn@stanford.edu) after June 2024. Participant data include household survey data and program administrative data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		20/01/2023	20/11/2024	Yes	No
Other publications	Maternal empowerment, feeding knowledge, and infant nutrition	07/06/2024	07/06/2024	Yes	No
Protocol file			21/07/2021	No	No