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Effect of the mHealth-supported Healthy Future programme delivered by community health workers on maternal and child health in rural China: study protocol for a cluster randomised controlled trial

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ABSTRACT

Introduction Millions of young rural children in China still suffer from poor health and malnutrition, partly due to a lack of knowledge about optimal perinatal and child care among rural mothers and caregivers. Meanwhile, there is an urgent need to improve maternal mental health in rural communities. Comprehensive home visiting programmes delivered by community health workers (CHWs) can bridge the caregiver knowledge gap and improve child health and maternal well-being in low-resource settings, but the effectiveness of this approach is unknown in rural China. Additionally, grandmothers play important roles in child care and family decision-making in rural China, suggesting the importance of engaging multiple caregivers in interventions. The Healthy Future programme seeks to improve child health and maternal well-being by developing a staged-based curriculum that CHWs deliver to mothers and caregivers of young children through home visits with the assistance of a tablet-based mHealth system. This protocol describes the design and evaluation plan for this programme.

Methods and analysis We designed a cluster-randomised controlled trial among 119 rural townships in four nationally designated poverty counties in Southwestern China. We will compare the outcomes between three arms: one standard arm with only primary caregivers participating in the intervention, one encouragement arm engaging primary and secondary caregivers and one control arm with no intervention. Families with pregnant women or infants under 6 months of age are invited to enrol in the 12-month study. Primary outcomes include children's haemoglobin levels, exclusive breastfeeding rates and dietary diversity in complementary feeding. Secondary outcomes include a combination of health, behavioural and intermediate outcomes.

Ethics and dissemination Ethical approval has been provided by Stanford University, Sichuan University and the University of Nevada, Reno. Trial findings will be disseminated through national and international peer-reviewed publications and conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will be the first randomised controlled trial in rural China integrating mHealth technologies with community home-visiting interventions in improving maternal and child health in remote rural areas.

⇒ The tablet-based mHealth system serves as a job aid for frontline community health workers (CHWs), supervisors and research teams to ensure rigorous intervention delivery and supervision.

⇒ The intervention curriculum is stage-based and tailored to the stage of pregnancy/age of the child, with highly scripted content to facilitate delivery by minimally trained CHWs.

⇒ Implementation of the study requires in-person interactions between CHWs and families, which can be threatened by the COVID-19 pandemic and control policies, such as lockdowns or stay-at-home orders.

⇒ Engaging secondary caregivers in the encouragement arm can be challenging, because scheduling home visits when both caregivers are present can be difficult.

INTRODUCTION
Background and rationale

Despite China's rapid progress in 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 mortality and morbidity in poorer rural areas.[1–4] In particular, anaemia, a common public health problem in many low-income and middle-income countries

(LMICs), affects half of the young children in rural China.[5 6] Child anaemia has irreversible consequences on health, development, educational attainment and labour force participation.[7–10] More generally, poor health and nutrition in early childhood create large and long-term private and social costs and perpetuate poverty and inequality.[11–13] These conditions are largely preventable through increased caregiver knowledge of nutrition and child feeding, micronutrient supplementation, quality perinatal care, good sanitation and hygiene practices, and awareness of danger signs and care-seeking for illness.[14–16]

Maternal mental health is another urgent public health issue in LMICs, and China is no exception.[17–20] Perinatal maternal mental disorders, primarily depression and anxiety, not only affect women's well-being, but are also associated with adverse child outcomes such as compromised physical and cognitive development and increased risk for later common mental disorders.[21–27] Maternal mental health presents a particular challenge in China due to the absence of a national surveillance system and the lack of mental health services, especially in rural areas.[28–30]

In this protocol, we propose to assess the effectiveness of a comprehensive home visiting programme delivered by community health workers (CHWs) in promoting child health and maternal well-being in rural China (henceforth called the 'Healthy Future' programme). Home visiting programmes delivered by CHWs are a promising strategy to improve maternal, neonatal and child health in LMICs. Studies in other settings have shown CHWs to be effective in promoting essential newborn care, raising knowledge of early childhood nutrition, increasing breastfeeding and optimal feeding practices and improving maternal mental health and antenatal care, even when the CHWs themselves lack formal professional training or tertiary education.[15 31–42] However, there is virtually no evidence on the effectiveness of CHW-delivered interventions in addressing maternal and child health challenges in rural China. The only CHW study to date in this setting focused narrowly on promoting prenatal care by training local midwives, and the study was not fully implemented due to political, socioeconomic and logistical challenges.[43] Thus, research on the feasibility and effectiveness of integrated CHW interventions is urgently needed in rural China.

Additionally, there is increasing recognition of the role of family members (especially grandmothers) in maternal and child health. Evidence from studies across Africa, Asia and Latin America reveals that children and mothers are often embedded in multi-generational families where senior members significantly influence the practice of younger mothers and the well-being of children.[44–48] There have been calls for increased engagement of family members in maternal and child health programmes.[49] Most interventions, however, continue to target only mothers, overlooking the role of other key family members, with limited evidence of the impact of interventions that engage key family members globally.[50 51]

Rural China presents a rich cultural setting to study the effects of community interventions that engage family members. Due to massive rural-to-urban migration and patrilocal norms, women from rural areas typically go to their husbands' villages during pregnancy, live with their in-laws and sometimes return to cities—for example, to seek employment—after the first 6–12 months of the child's life.[52 53] As a result, grandparents, especially paternal grandmothers, often assume partial or full caregiving responsibilities for their grandchildren, demonstrating the importance of engaging multiple caregivers in interventions.[54 55] The patrilocal living arrangements and migration patterns in rural China also place mothers in an especially vulnerable situation during the perinatal period. Because pregnant women and new mothers often live with their in-laws even after the husband has gone back to work, they are without their usual community and social support systems.[52] Evidence suggests that relationship problems with in-laws are associated with maternal stress and depression in China, implying a need for greater support for mothers and between mothers and grandmothers.[17 18 56] CHW-delivered community programmes have the opportunity to enhance maternal health and well-being through the engagement of key household members as allies to foster social support and reduce maternal stress.[14 36 57–59] Evaluating interventions that engage multiple family members in the context of rural China will provide local contextual knowledge and add to the global evidence base for such interventions.

To address these evidence gaps, we developed a stage-based home visiting curriculum for CHWs in rural China to deliver to pregnant mothers and caregivers of young children through home visits. The curriculum focuses on six content domains: breastfeeding, complementary feeding, preventative health and daily care, maternal nutrition, caregiver mental health and uptake of government health services. In addition, the curriculum allows CHWs to engage multiple family members in the home visiting sessions. A three-arm cluster randomised controlled trial was subsequently designed to evaluate the effectiveness of two delivery conditions of the Healthy Future programme—a single caregiver condition and a multi-caregiver condition—compared with no programme.

To ensure rigorous and reliable delivery of the staged-based curriculum by CHWs, as well as to aid in CHW supervision during the evaluation, the Healthy Future programme uses mobile health (mHealth) technologies. Evidence shows that the use of mobile tools in CHW programmes improves the quality of services and programme monitoring.[60–62] Our programme includes a mHealth system with a tablet-based application (henceforth called the 'Healthy Future app') to be used by CHWs for home visit scheduling and curriculum delivery. The tablet-based Healthy Future app automatically assigns tailored contents to each home visit based on the pregnancy stage or baby's age. The app also enables real-time data collection, which is used by supervisors to monitor the timeliness, completeness and quality of home visits
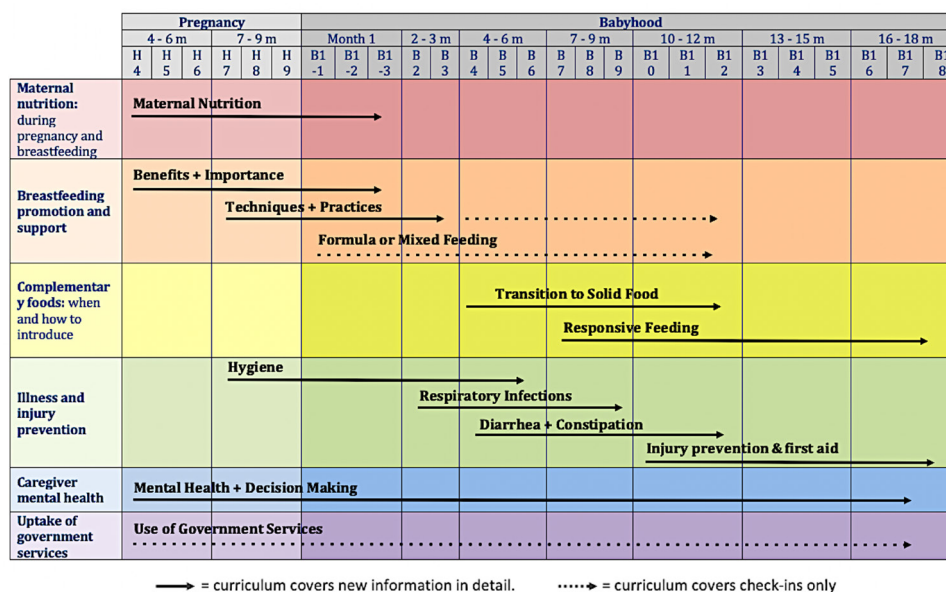
Figure 1 Healthy Future home visiting curriculum design.

delivered by CHWs, and by the research team to collect data on short-term behavioural outcomes of caregivers.

Study objectives

The main objective of the study is to assess the impact of the Healthy Future programme on maternal and child health in rural China through a cluster randomised controlled trial. The intervention is a 12-month home visiting programme in which CHWs deliver stage-based health and nutrition information to pregnant women and caregivers of young children with the assistance of the Healthy Future app. The trial compares maternal and child outcomes among three randomly assigned groups: (1) a standard treatment group that focuses only on pregnant women or primary caregivers of young children; (2) an encouragement treatment group that promotes both primary and secondary caregivers in the participation; and (3) a control group not receiving the intervention. The main research questions are:

▶ Does the Healthy Future programme improve maternal and child health in rural China?

▶ Does the Healthy Future programme that engages multiple caregivers have a larger effect on maternal and child health in rural China than the programme that only targets primary caregivers?

INTERVENTION DESIGN
Curriculum development and training

Figure 1 presents the Healthy Future curriculum outline, covering the 2-year period from the second trimester of pregnancy to 18 months after birth. With funding from private donors, the curriculum was developed by a multidisciplinary team from local and US academic institutions with diverse backgrounds, including economics, nutrition, paediatrics and public health, in conjunction with China's Ministry of Health. The curriculum content was informed by local qualitative research, subject matter expertise of the team, WHO and American Academy of Pediatrics guidelines, a variety of child care guides, and evidence from previous child health and nutrition research and programming in other low-income settings. The tablet-based Healthy Future app was designed to aid in the delivery of the wide-ranging content, including breastfeeding, complementary feeding, preventative health and daily care, maternal nutrition, caregiver mental health and uptake of government health services. The curriculum modules completed pilot testing before the intervention started to ensure that the content and activities were acceptable to CHWs and caregivers in rural areas of China.

The Healthy Future curriculum has several features that distinguish it from existing CHW home visiting programmes. First, it is stage-based, timed to the stage of pregnancy/age of the child. Visits are performed monthly with more frequent visits in the first month after childbirth. Second, it is highly scripted to facilitate delivery by minimally trained CHWs. Third, it is organised in a modular format: the CHWs are asked to cover three to five 'essential' modules according to the child's age while 'elective' modules are provided depending on the needs of each caregiver and child. For instance, if a caregiver chooses to formula feed her child, we provide her with formula-feeding information in an 'elective' module. This modular format also enables the CHWs to repeat key messages at multiple stages of a child's development or adjust the schedule if needed. For example, although the curriculum covers most breastfeeding content during pregnancy, it is designed to re-emphasise key points in the first 6 months of a child's life to promote exclusive breastfeeding. In addition, if a family starts the programme at a later stage, the CHW can easily pull from relevant modules designated to an earlier month. Many modules are accompanied by infographic-style videos to

enhance engagement and learning. Finally, each home visit includes at least one hands-on activity to better engage caregivers, encourage recommended behaviours and build necessary skills. For example, pregnant women can practice different breastfeeding positions on a baby doll under the guidance of the CHW.

All recruited CHWs complete a 5-day baseline training provided by members of the research team prior to the start of the intervention, as well as a 2-day refresher training at the midline of the intervention (around 6 months after the initial training). Any CHW recruited after the baseline training will receive a 2-day condensed training. The training covers background information on early childhood health and nutrition, the Healthy Future curriculum, content delivery and interpersonal skills and standard operation procedures for intervention implementation. Emphasis is placed on effective interaction and dialogue rather than didactic information sharing. The training also includes multiple role-play sessions to let the CHWs practice conducting home visits; familiarise themselves with the curriculum content, delivery format and tablet-based application; and receive feedback on their communication styles.

mHealth integration

To reduce the logistical complexity and monitor the quality of home visits, the research team worked with a software company to develop a Healthy Future mHealth system with the server hosted by the Aliyun infrastructure. The mHealth system was developed starting in March 2020 and pilot testing was completed by May 2021. The whole system has been fully operational since the start of the intervention.

The first component of the system is the Heathy Future app, an android tablet-based application for CHWs to schedule home visits and deliver the curriculum. The Healthy Future app automates the assignment of stage-based content to each home visit based on the stage of pregnancy or age of the child; enables record keeping and data collection; and includes adaptive surveys to track caregiver knowledge, participation and practice after each home visit. The app is not available on Google Play due to its intended purpose of rigorous service delivery and supervision rather than public use. CHWs receive tablets with the Healthy Future app installed and learn to use the Healthy Future app during the 5-day curriculum training before the intervention starts. Instructions, question prompts, response options and memory aids help to ensure appropriate and consistent content delivery across families and CHWs and over time. Online supplemental appendix A shows a few examples of the Healthy Future app interface.

The second component is a web-based administrative portal for supervisors to remotely access tablet-collected data and monitor CHWs. Data are also aggregated and analysed through a dashboard for tracking the timeliness, frequency, completeness and quality of home visits delivered by CHWs. The supervisor can thus identify if one home visit only lasts for a few minutes, or one CHW delivers significantly shorter home visits than the others, and can take appropriate action.

Overall, the mHealth system is expected to ensure better service delivery and supervision, ultimately increasing caregiver knowledge of optimal practice and improving child health and maternal well-being. The app works better with the internet connected for loading the content needed for each home visit or for scheduling home visits. Therefore, we recommend that CHWs connect to their personal mobile hotspots when conducting home visits and we provide a monthly internet stipend to cover unlimited data. The app can also function offline, and the data stored locally will be pushed to the server once the connection is restored.

Theory of change

The theory of change for the Healthy Future programme is shown in figure 2. The theory of change diagram lists the main process and outcome indicators we will use to measure intervention impact and the key assumptions along with the steps in the theory of change pathway. We define the primary outcomes of interest as children's haemoglobin (Hb) concentrations, exclusive
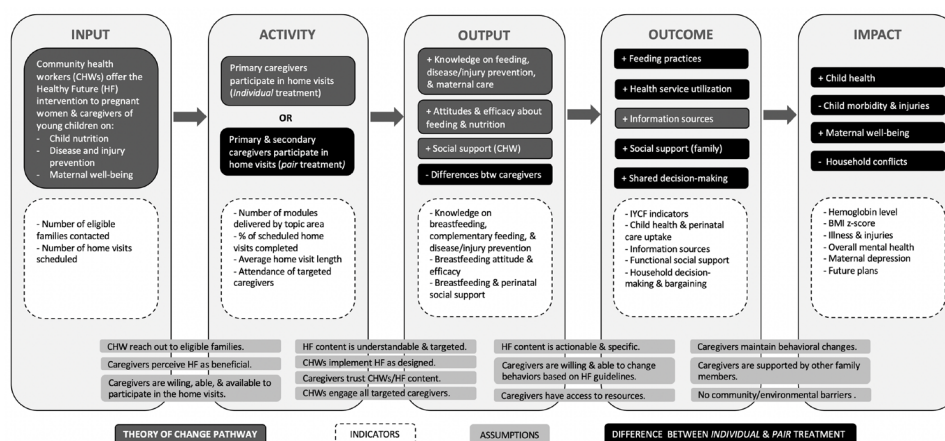

Figure 2 Theory of change of the Healthy Future programme. IYCF, infant and young child feeding.

breastfeeding rates of children younger than 6 months and dietary diversity in complementary feeding of children older than 6 months. The secondary outcomes are a combination of health, behavioural and intermediate outcomes. The diagram highlights that participation in home visits provided by trained CHWs can enhance the attitudes, efficacy and knowledge of caregivers regarding maternal and child health (intermediate outcomes), which, in turn, can lead to behavioural changes (behavioural outcomes) that result in better maternal and child health (health outcomes).

Although the standard and encouragement conditions follow the same theory of change, the two treatment arms are expected to differ in impact. Compared with the standard treatment, the encouragement condition engages both primary and secondary caregivers (mostly mothers and grandmothers) in the home visits and has the potential benefit of narrowing the gap in attitudes and knowledge between family members. Given the importance of grandmothers in household decision-making, the encouragement condition aims to amplify the intervention effects on behavioural change, foster family support to individual caregivers and encourage shared household decision-making by aligning caregivers' preferences. As a result, the encouragement condition is expected to further improve child health, support maternal well-being and reduce household conflicts compared with targeting the primary caregivers alone.

In addition, CHW-level, caregiver-level, child-level and household-level characteristics are expected to moderate the steps along the theory of change pathway. First, CHW-related factors, such as age, education and prior knowledge and beliefs, may directly affect caregiver participation in, and learning from, the home visits. Second, given the intervention's focus on individual behavioural change, caregiver-related factors may influence each step along the pathway. These factors may include caregivers' age, education, employment status, health and relationship with the child and other household members. Third, child-related factors, such as sex, age and birth outcomes, may determine to a large extent their response to changes in caregivers' practices. Finally, household-level factors, such as family structure, wealth and available community resources, are likely important determinants of adherence to recommended practices and the likelihood that caregivers will sustain behavioural changes.

METHODS AND ANALYSIS

This protocol was developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guideline.[63 64] The checklist is in online supplemental appendix B.

Study timeline

The study team was officially formed in January 2019, with the first phase focusing on curriculum development. As of late 2019, sampling, the baseline survey, and randomisation had begun, and the intervention was set to begin in early 2020. The COVID-19 outbreak, however, caused disruption to the study. From March 2020 to May 2021, the team focused on developing the mHealth system. In June 2021, the study resumed and completed a new round of baseline survey, CHW recruitment and training and participant enrolment in July 2021. By the time this protocol is submitted, the home visiting intervention has started (in August 2021) and is expected to run for 12 months.

Study setting

The study is being conducted in Nanchong Prefecture in Sichuan Province, China. Nanchong is a relatively poor prefecture in Southwestern China, and seven out of the nine counties in the prefecture have been nationally or provincially designated as poverty-stricken counties. The sampling frame for the study includes 119 rural townships from four nationally designated poverty counties in Nanchong prefecture. All townships in each county are included except for urban townships and those rural townships that do not have at least 10 000 people. These exclusion criteria ensure a rural sample and adequate statistical power for the analysis.

Trial randomisation

The Healthy Future programme evaluation is a stratified multistage cluster-randomised controlled trial of townships allocated to programme or control arms within four county strata. We used cluster randomisation to avoid within-township contamination since the programme is delivered at the township level by CHWs. In the first stage, 40 of the 119 townships (10 per county) were randomly allocated to receive the Healthy Future programme. The remaining 79 townships serve as the no-intervention 'control' arm of the study. In the second stage, an encouragement overlay design was used to randomise 20 of the 40 townships (5 per county) into the standard treatment arm and the other 20 townships (5 per county) into the encouragement treatment arm. In standard treatment townships, CHWs deliver the Healthy Future programme to pregnant women or the primary caregiver of each child, typically the child's mother. In encouragement townships, CHWs invite both the primary and secondary caregivers of each child to participate in the Healthy Future programme. The secondary caregiver is typically the child's grandmother. CHWs in encouragement townships receive additional training on ways to encourage participation of both primary and secondary caregivers during the home visits. Scripted guides are built into the Healthy Future curriculum to assist these CHWs in engaging both mothers and grandmothers during the home visit.

Eligibility criteria and recruitment strategy
Participant recruitment

Pregnant women and caregivers of infants 0–6 months of age living in the study townships were identified through

two channels. First, a list of target families was provided by local township health centres responsible for supervising health services for young children and pregnant women in their catchment areas (e.g., child vaccinations and prenatal check-ups). Second, a list of pregnant women was obtained from county-level hospitals to identify pregnant women who bypass local township health centres for perinatal care. This strategy ensures a comprehensive list of eligible participants in the study townships.

Participants who met the following inclusion criteria among the 119 rural townships were enrolled in the baseline survey and will be invited to participate in two follow-up surveys:

► Pregnant women in the second trimester onwards or caregivers of children 0–6 months of age.
► Willing to participate (and have their child participate) in the Healthy Future surveys, including the household surveys, anthropometric measures and Hb tests.
► Able and willing to give informed consent.

After the baseline survey, the participants from the 40 treatment townships were eligible to receive the Healthy Future intervention. Families willing to participate in the Healthy Future programme were enrolled at the beginning of the study through a door-to-door approach. For the first 6 months after the programme initiation, CHWs continue to enrol participants who become newly eligible to participate in the study until the midline. During this on-going enrolment, CHWs collect basic information from households, such as the child age/gestational age of the mother. Participants enrolled postprogramme initiation will complete midline and endline surveys alongside participants enrolled at baseline. Information missed at baseline, such as household-level characteristics, is collected at the time of the midline survey for these families. We use the baseline strategy of listing and enrolling pregnant women at the midline survey to ensure sufficient power at endline for estimating the treatment effects on exclusive breastfeeding, one of our primary outcomes.

CHW recruitment

CHWs in the treatment townships who deliver the Healthy Future programme were recruited by the local township health centres of each treatment township and selected through an interview process by the study team. The programme recruited one CHW for each treatment township, with a total of 40 CHWs hired. Inclusion criteria for CHWs are as follows:

► Female with middle school education or higher.
► Long-term township resident without plans to leave the study area during the study period.

CHWs are employed by the study and are compensated based on the number of families they manage. Each month, CHWs receive a monthly base pay of ¥500 plus ¥70 subsidy for each family they manage. For example, the average number of families per township is 16 and a CHW managing 16 families receives a salary of ¥1620 per month.

At the start of the intervention, members of the research team accompanied CHWs to treatment households to introduce the Healthy Future programme. After the start of the programme, monthly check-ins with the CHWs are conducted to provide support and identify challenges in programme implementation. In addition, monitoring data are collected on the frequency and timing of home visits as well as information about changes in caregiving practices through the Healthy Future app. Treatment households are contacted periodically to assess their satisfaction with the home visits and interactions with the CHW. In the case of poor-performing CHWs, members of the research team conduct in-person observations of home visits to identify areas for improvement and provide feedback to the CHW.

Masking

Families in the control group are not informed about the Healthy Future programme and are only invited to participate in three surveys. The survey enumerators are separately recruited before each of the surveys. Masking of treatment conditions to enumerators is impossible because enumerators will work with CHWs to survey the CHW-enrolled families. However, enumerators are blinded to treatment arm allocation and main outcomes. CHWs in the two treatment arms are separately trained and managed by different supervisors. CHWs are instructed only on curriculum delivery and are blinded to the trial design and assessment procedures. Data analysts are blinded to the identity of the study arms.

Participant timeline

The baseline survey, CHW training and participant enrolment were completed in July 2021. The Healthy Future home visiting intervention started in August 2021 and is expected to last for 12 months. The impact evaluation includes three waves of surveys at baseline, 6-month midline and 12-month endline. The evaluation design is presented in figure 3. Due to COVID-19 outbreaks and related lockdowns in the study areas, the midline survey and CHW refresher training were delayed for 3 months. By the time this protocol is submitted, the trial will have completed the midline survey data collection. The protocol was written before midline data were collected, cleaned and analysed. Any changes will be marked when reporting results in future publications.

Outcomes

The trial uses three primary study outcomes to assess the impact of the Healthy Future programme:

► Hb concentration among children aged 6 weeks to 18 months.
► Exclusive breastfeeding, defined as the proportion of children under 6 months of age who received only breastmilk in the previous day.[65]
► Dietary diversity, calculated using the number of food groups consumed by children aged 6–18 months in the previous day.[65]
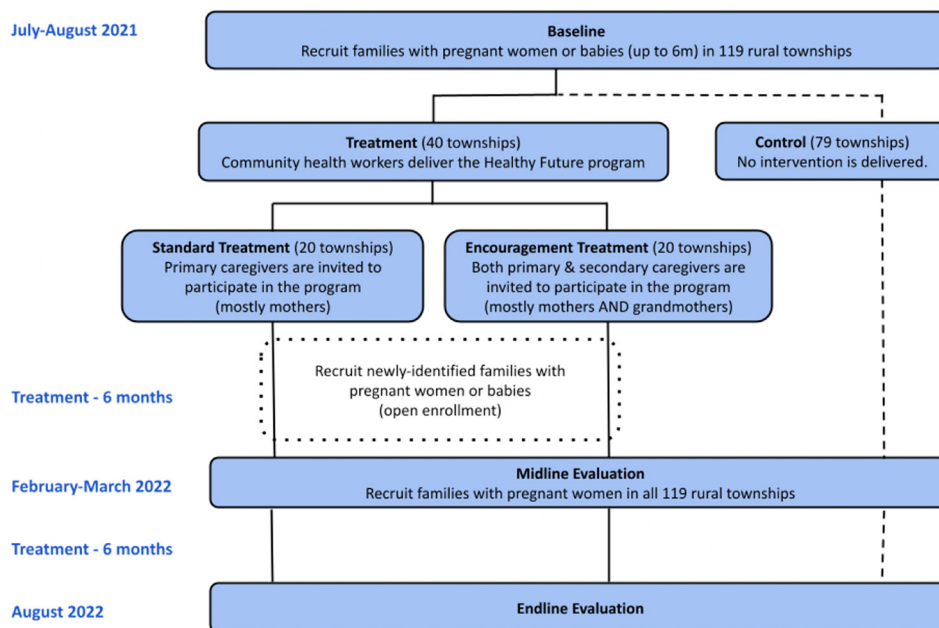
Figure 3 Impact evaluation design.

Since anaemia poses a serious public health problem affecting 40%–55% of young children in rural China and inadequate IYCF practices are largely responsible for this nutritional deficiency,[1 5 6 66 67] our primary outcomes focus on Hb concentration and optimal feeding practices among children. In each household survey, trained nurses collect samples for determination of Hb concentrations from all participating children using a HemoCue Hb 201+ finger prick system (Hemocue, Angelholm, Sweden). For exclusive breastfeeding and dietary diversity, we follow WHO guidelines to administer a 24-hour dietary recall survey instrument about the foods and liquids the child consumed the day before the survey.[65]

Secondary outcomes consist of a combination of health, behavioural and intermediate outcomes. Secondary child health outcomes include child growth indicators by WHO standards (i.e., length-for-age, weight-for-age, etc.),[68] anaemia status (Hb<110g/L) and occurrence of any illness and unintended injuries. Secondary maternal well-being outcomes include maternal and caregiver mental health, measured by the Edinburgh Postnatal Depression Scale[69 70] and the Depression, Anxiety, and Stress Scales-21.[71] Behavioural outcomes comprise a list of indicators on IYCF practices,[65] caregiver hygiene practices, healthcare utilisation (use of formal care among children and prenatal visits during pregnancy) and mother's feeding practices (dietary diversity and folic acid consumption during pregnancy). Intermediate outcomes include caregiver's knowledge and attitudes,[72 73] mother's self-efficacy in breastfeeding,[74–76] social support[77–81] and joint household decision-making.[82 83] We also consider process indicators for evaluation, such as the number of completed home visits and stage-appropriate modules, and caregiver participation. A detailed list of outcomes and measures is included in online supplemental appendix C.

Sample size and power calculations

Sample sizes are estimated based on minimal detectable differences between treatment and control conditions at the 5% two-tailed significance level for the three primary outcome indicators: Hb level, exclusive breastfeeding rates and dietary diversity in complementary feeding. Our cluster trial randomises 40 out of 119 township clusters to treatment. We do not consider a 1:1 allocation ratio within four county strata because of the significant costs of recruiting and managing CHWs in treatment townships. Given our previous field research, we assume 10 eligible families per township cluster for a total of 1190 samples in all arms and 400 samples in the treatment at baseline. We conservatively estimate that loss to follow-up (including out-migration and pregnancy miscarriage) during the 12-month period will be 15%. To compensate for attrition, we consider the time between the intervention initiation and the midline survey as an open enrolment period when CHWs can continue to enrol families who become newly eligible to participate in the study.

Using the parameters from our previous research and conservative estimates based on similar programmes, the power calculations for the three primary outcome indicators are as follows.

Hb level

Assuming an intracluster correlation (ICC) of 0.035, our trial has 81% power to detect a 0.2 standardised difference in Hb level between treatment and control arms at 12 months.

Exclusive breastfeeding

Assuming an ICC of 0.01 and a baseline exclusive breastfeeding rate of 37%, this sample size yields a power of more than 99% to detect a 15-percentage-point difference

between treatment and control arms in exclusive breast-feeding rate at 12 months.

Dietary diversity (no baseline)

Assuming an ICC of 0.025, the trial has 84% power at 12 months to detect a 0.2 standardised difference in dietary diversity in complementary feeding of children aged 6–8 months in treatment vs control arms.

Data collection

The data for the impact evaluation come from three main sources: CHW surveys, household surveys and administrative programme records.

CHW surveys

The CHW survey is conducted on the first day of the CHW baseline training and the refresher training at the midline. The CHW survey captures information on CHW-related factors that might moderate the intervention effect, such as their age, education, general health and prior knowledge and beliefs related to child health and nutrition practices.

Household surveys

The household survey component includes a baseline survey and two follow-up surveys conducted at 6 months (midline) and 12 months (endline). The survey team uses tablet-based Survey Solutions data entry software for data collection. Prior to conducting the survey, the questionnaire is programmed into enumerator tablets and includes range checks, structure checks and internal consistency checks. The enumerators are recruited before each survey and receive 2-day training in data collection. The household surveys include various modules aimed at gathering information from caregivers of the index child (see online supplemental appendix D for a list). In addition to questionnaire-based data collection, trained nurses collect anthropometric measurements (height and weight) and Hb concentrations of the index child in each household. A household survey typically lasts 2 hours.

Families are designated as lost to follow-up if they leave the study area during the two follow-up surveys. Such families will be followed up via a short phone survey to collect primary information, such as the reasons for migration or discontinuation.

In addition to the three household surveys, CHWs also collect household data using a structured questionnaire included in the Healthy Future app at the end of each home visit. The questionnaire is adapted to the stage of pregnancy/age of the child and includes questions regarding perinatal nutrition, breastfeeding and complementary feeding, child illness symptoms and recent doctor visits.

Programme administrative records

The Healthy Future app collects programme administrative data on home visits. The administrative data include the date and time of home visits, modules delivered, length of home visits, attendance of family members and reasons for not completing home visits.

Data management and monitoring

All data collections are performed electronically on tablets. CHWs use the Healthy Future app to perform home visits, and the administrative record is uploaded to the central server after each home visit. In most cases, CHWs use personal mobile hotspots (compensated with a monthly stipend) to connect the tablet to the internet while performing home visits. When running offline in rare circumstances, the app stores data locally, then pushes it to the server once the connection is restored. As for household surveys, enumerators use tablet-based Survey Solutions data entry software. The survey data are collected offline in the field and uploaded on a daily basis during the survey period. Four China-based field managers and one US-based data manager independently review all collected data for consistency and accuracy. In the case of missing and inconsistent data on household surveys, enumerators are sent back to the field for revisions. Incomplete home visits are assessed by the field team and followed up whenever possible. Any issues in the field are shared with the research team and discussed on a weekly basis. The research team is independent of the field team and advises the field team in case of any issues.

Additionally, a trial monitoring team is established to audit the CHW performance. The monitoring team randomly calls three participant families at the end of each month to assess the families' satisfaction with CHW performance. The monitoring team also conducts in-person observation of home visits with at least one visit per CHW every 3 months to oversee trial conduct. Interim analyses will be performed after the midline to assess the interim results and other unintended effects of the intervention. The interim results will be shared with the research team, and the research team will decide if the trial needs to be modified or discontinued in case of adverse events.

Statistical methods

The overall approach for estimating the impact of the Healthy Future programme is to regress outcomes measured at the follow-up surveys on dummy variables indicating treatment assignment, baseline controls and county stratum fixed effects using the following specification:

$$Y_{ijct} = \alpha + \beta T_j + \gamma Y_{ijc0} + \theta X_{ijc0} + \tau_c + \varepsilon_{ijct}, \ t = \{1, 2\}$$

Y_{ijct} is the outcome of interest for the index child or caregiver i in township j of county c measured at time t (1 for the midline and 2 for the endline); T_j is a dummy variable indicating if the township j is assigned to the treatment arm; τ_c is a set of strata (county) fixed effects; and X_{ijc0} is a vector of baseline control variables at the child, caregiver and household levels selected using the machine learning methods.[84 85] Standard errors are clustered at the township level using the cluster-corrected

Huber-White estimator. The main parameter of interest, β, represents the average treatment effects (ATE) and is interpreted as the causal effects of offering the Healthy Future programme. We will also use an instrumental variable approach to estimate the ATE on the treated. Online supplemental appendix E presents a detailed preanalysis plan, including testing for heterogenous treatment effects using a data-driven algorithm,[86] adjusting for multiple outcomes[87] and dealing with missing data and attrition.[88]

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Ethics and dissemination

Research ethics approval

The study has been approved by the institutional review boards (IRBs) at Sichuan University (Protocol K2019046), Stanford University (Protocol 44312) and the University of Nevada, Reno (Project 1737966-1).

Protocol amendments

Protocol modifications will be fully disclosed in future publications. In case of any changes, the protocol in the clinical trial registry and IRBs will be updated accordingly.

Informed consent

All caregivers must give informed oral consent for their own and their infants' participation in the study. Enumerators trained in the informed consent process will explain the study risks and benefits, answer any questions and gather informed oral consent. We do not collect written consent as many rural caregivers in China, particularly grandmothers, are not literate. Online supplemental appendix F provides a model consent form.

Confidentiality

Only the field investigators and the project coordinators have access to personal data for intervention implementation before and during the trial. Deidentified data are available to the research team or other scientists under a cooperation agreement. All data are password protected at all stages. No participant's identity will be shared in any format to protect confidentiality.

Dissemination policy

The full protocol will be publicly available in an open-access format. The study findings will be published in economics, medical and public health journals, as well as Chinese or English policy briefs. Only researchers and investigators who meet ICMJE criteria for authorship will be included as coauthors. Other contributors, such as enumerators, CHWs or participants, will be acknowledged in the paper publication.

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