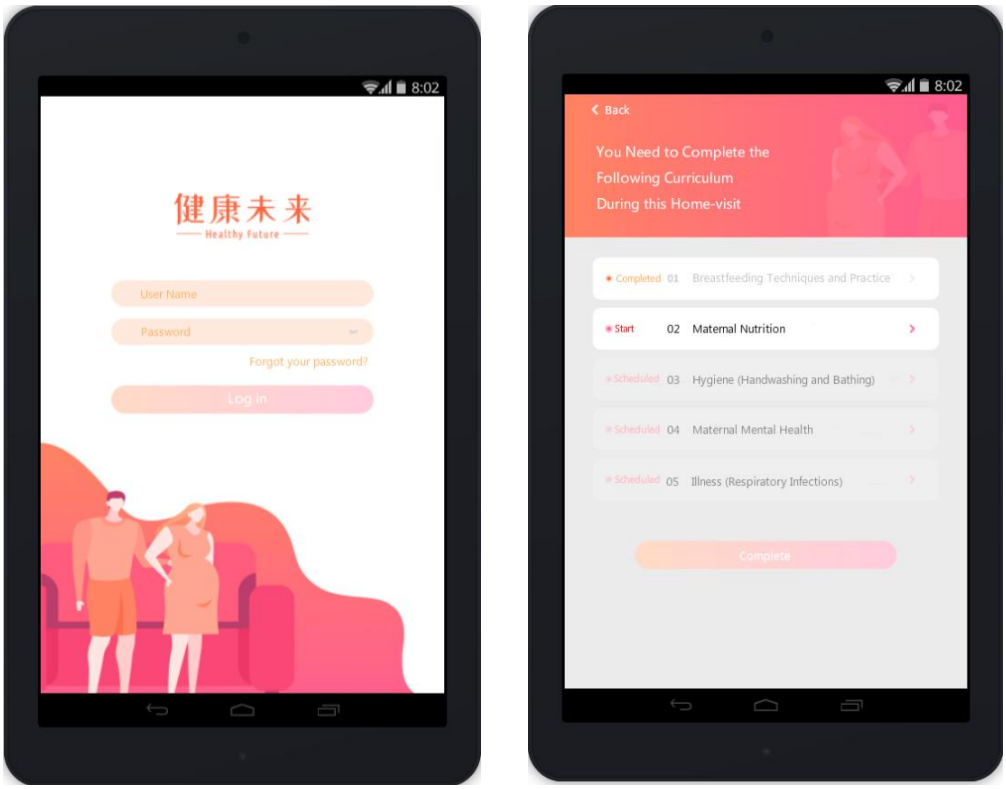
Effect of the mHealth-supported Healthy Future Programme delivered by community health workers on maternal and child health in rural China: Study protocol for a cluster randomised controlled trial

APPENDICES

Appendix A. Examples of the Healthy Future Tablet-based Application Interface



Appendix B. SPIRIT 2013 Checklist

Section/item	Item No	Description	Page Number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	13
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 13
	5b	Name and contact information for the trial sponsor	13
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	13
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	4-5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5, 8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8

Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8-9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5-7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	6-7
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	10
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10-11
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8-9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8-9

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	9
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	9
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10-11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Appendix E
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Appendix E
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	12
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	12
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	12

Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	13
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	13
	31b	Authorship eligibility guidelines and any intended use of professional writers	13
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	13
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix F
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Appendix C. Study Outcomes, Indicators, and Measures

Indicators	Targets	Domain	Measures	Survey Modules (Appendix D)
Primary Outcomes				
1. Haemoglobin concentration	Children 6 weeks-18 months	Child Health	Average, level	A12 Physician Exam of Children
2. Exclusive breastfeeding	Children 0-5 months	Child Feeding Practice	Proportion, fed exclusively with breastmilk in the previous day	A6 IYCF Practice
3. Dietary diversity	Children 6-18 months	Child Feeding Practice	Average, food groups in the previous day	A6 IYCF Practice
Secondary Health Outcomes				
A. Secondary child health outcomes				
1. Child growth indicators by WHO standards (i.e., length-for-age, weight-for-age, etc.)	Children 0-18 months	Child Health	Average, Z-scores	A12 Physician Exam of Children
2. Child anaemia status	Children 0-18 months	Child Health	Proportion, haemoglobin concentration<110 g/L	A12 Physician Exam of Children
3. Occurrence of any illness	Children 0-18 months	Child Health	Proportion, any illness in the past 14 days	A9 Child Disease and Health Services
4. Occurrence of any unintended injuries	Children 0-18 months	Child Health	Proportion, any unintended injuries in the past 14 days	A9 Child Disease and Health Services
B. Secondary maternal well-being outcomes				
1. Perinatal depression	Mothers	Maternal Health	Index, Edinburgh Postnatal Depression Scale	B11 EPDS
2. Caregiver mental health	Primary & Secondary Caregivers	Maternal Health	Index, Depression, Anxiety, and Stress Levels (DASS 21)	C6 & D6 DASS 21
Secondary Behavioural Outcomes				
A. IYCF Practices				
1. Early initiation of breastfeeding	Children 0-18 months	Child Feeding Practice	Proportion, put to the breast within 1 hour of birth	A6 IYCF Practice
2. Newborn given colostrum	Children 0-18 months	Child Feeding Practice	Proportion, given colostrum	A6 IYCF Practice
3. Children fed breastmilk	Children 6-12 months	Child Feeding Practice	Proportion, fed breastmilk in the previous day	A6 IYCF Practice
4. Children ever breastfed	Children 0-18 months	Child Feeding Practice	Proportion, ever breastfed	A6 IYCF Practice
5. Predominant breastfeeding	Children 0-5 months	Child Feeding Practice	Proportion, received breastmilk as the predominant source in the previous day	A6 IYCF Practice
6. Continued breastfeeding at 1 year	Children 12-15 months	Child Feeding Practice	Proportion, received breastmilk in the previous day	A6 IYCF Practice
7. Duration of breastfeeding	Children 0-18 months	Child Feeding Practice	Median age month, when stopped receiving breastmilk	A6 IYCF Practice
8. Initiation of formula feeding	Children 0-18 months	Child Feeding Practice	Median age month, when started receiving formula	A6 IYCF Practice
9. Introduction of complementary feeding	Children 6-8 months	Child Feeding Practice	Proportion, received solid, semi-solid or soft foods in the previous day	A6 IYCF Practice
10. Initiation of complementary feeding	Children 0-18 months	Child Feeding Practice	Median age month, when started receiving solid, semi-solid or soft foods	A6 IYCF Practice
11. Minimum dietary diversity	Children 6-18 months	Child Feeding Practice	Proportion, received foods >=4 food groups in the previous day	A6 IYCF Practice
12. Minimum meal frequency	Children 6-18 months	Child Feeding Practice	Proportion, received meals >= minimum number of times in the previous day; (min=2 if 6-8 months; min=3 if 9-18 months; meals include snacks)	A6 IYCF Practice

13. Minimum acceptable diet	Children 6-18 months	Child Feeding Practice	Proportion, received min dietary diversity AND min meal times in the previous day	A6 IYCF Practice
14. Consumption of iron-rich or iron-fortified foods	Children 6-18 months	Child Feeding Practice	Proportion, received iron-rich food or supplements in the previous day	A6 IYCF Practice A8 Infant Micronutrient Supplements
B. Caregiver hygiene practices				
1. Caregiver hygiene practices	Primary & Secondary Caregivers	Caregiver's Hygiene	Frequency, hand washing	C4 & C5 & D4 & D5 Hygiene and handwashing
C. Healthcare Utilization				
1. Use of formal care	Children 0-18 months	Health Care Utilization	Proportion, use of formal care for last illness	A9 Child Disease and Health Services
2. Prenatal visits	Mothers	Health Care Utilization	Average, prenatal visits among most recent pregnancy	B10 Perinatal Visits
D. Maternal Feeding Practices				
1. Women's dietary diversity	Pregnant women & breastfeeding mother	Mother Feeding Practice	Average, food groups	B3 Perinatal Nutrition
2. Consumption of folic acid and iron supplements during pregnancy	Mothers	Mother Feeding Practice	Proportion, used folic acid and iron supplements during most recent pregnancy	B9 Perinatal Care
Secondary Intermediate Outcomes				
A. Knowledge, attitude, and efficacy				
1. Knowledge on feeding, disease prevention, and hygiene	Primary & Secondary Caregivers	Caregiver's Knowledge	Index, knowledge scale (possibly construct index using GLS weighting)	C2 & D2 Feeding Knowledge
2. Attitude about breastfeeding	Primary & Secondary Caregivers	Caregiver's Attitude	Index, Iowa infant feeding attitude scale	C1 & D1 Breastfeeding Attitude
3. Efficacy in breastfeeding	Breastfeeding mothers	Mother's Efficacy	Index, efficacy scale	B4 Breastfeeding efficacy
4. Efficacy in preparation to breastfeed	Pregnant women	Mother's Efficacy	Index, efficacy scale	B5 Efficacy in Preparation to Breastfeed
B. Social support				
1. Caregiver social support	Primary & Secondary Caregivers	Caregiver's support	Index, perceived social support	C7 & D7 Perceived Social Support
2. Joint household decision-making	Primary & Secondary Caregivers	Joint Household Decisions	Index, household decision making scale	C8 & D8 Household decision making
Process Indicators				
1. Home visits delivered	Program administration	Program administration	Number & Proportion & Time length, home visits delivered	Program administrative records
2. Age-specific modules delivered	Program administration	Program administration	Number & Proportion & Time length, modules completed	Program administrative records
3. Caregiver participation	Program administration	Program administration	Number & Proportion, home visit participation of primary & secondary caregivers	Program administrative records
Other Moderators				
CHWs' characteristics	CHWs	Demographics	Include age, education, residency, knowledge, etc.	CHW survey
Caregivers' characteristics	Caregivers	Demographics	Include age, education, health, employment, migration, etc.	Household surveys
Households' characteristics	Households	Demographics	Include family structure, wealth, living places, etc.	Household surveys
Children's characteristics	Children	Demographics	Include birth date, gender, birth weights and lengths, etc.	Household surveys

Appendix D. Household Survey Modules

Form A. Main Survey Form	Form B. Mother's Form	Form C. Primary Caregiver's Form	Form D. Secondary Caregiver's Form
A1. Born-baby Information	B1. Maternal Migration History	C1. Breastfeeding Attitude	D1. Breastfeeding Attitude
A2. Unborn-baby Information	B2. Breastfeeding Details	C2. Feeding Knowledge	D2. Feeding Knowledge
A3. Household Roster	B3. Perinatal Nutrition	C3. Feeding Information Sources	D3. Feeding Information Sources
A4. Household Information	B4. Breastfeeding Efficacy	C4. Hygiene and Handwashing	D4. Hygiene and Handwashing
A5. Parental Migration	B5. Efficacy in Preparation to Breastfeed	C5. Infant Hygiene	D5. Infant Hygiene
A6. IYCF Practice	B6. Hughes Breastfeeding Support Scale	C6. Depression, Anxiety, and Stress	D6. Depression, Anxiety, and Stress
A7. Infant Monthly Dietary History	B7. Breastfeeding Coping Plan	C7. Perceived Social Support	D7. Perceived Social Support
A8. Child Micronutrient Supplements	B8. Pregnancy History	C8. Household Decision-making	D8. Household Decision-making
A9. Child Disease and Health Services	B9. Perinatal Care		
A10. Household Expenditure	B10. Perinatal Visits		
A11. Physician Exams of Mothers	B11. Edinburgh Postnatal Depression Scale		
A12. Physical Exam of Children			

Appendix E. Healthy Future Impact Evaluation Pre-Analysis Plan

E.1 General Econometric Framework

I. Impact evaluation of the Healthy Future program

Our first approach for evaluating the impact of the Healthy Future program is to regress the outcomes of interest at the follow-up surveys on a treatment indicator on township assignment, baseline controls, county stratum fixed effects using the following specification:

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

Y_{ijct} is the outcome of interest for the unit i (child, mother, or caregiver depending on the outcome of interest) in township j of county c measured at time t (=1 or 2 for midline or endline, respectively). T_j is a dummy variable indicating if the household lives in a township j that receives the intervention. τ_c denotes strata (i.e., county) fixed effects. Standard errors are clustered at the township level using the cluster-corrected Huber-White estimator.

X_{ijc0} is a vector of baseline control variables at the child, caregiver, household, and CHW level. We will select from hundred potential covariates using the post-double-selection LASSO method of Belloni, Chernozhukov, and Hansen and the Stata pdslasso command by Ahrens, Hansen, and Schaffer.[82,83] We note that different baseline variables may predict different outcomes, and we will use different control variables across regressions.

The treatment indicator, T_j , takes the value one if the family lives in the treatment township. This approach identifies an intent-to-treat (ITT) parameter, taking into account that some families in the treatment group may not participate in the program. The main parameter of interest, β, represents the Average Treatment Effects (ATE) and is interpreted as the causal effects of the Healthy Future program. We also expect imperfect compliance within the treatment arm, because families make participation decisions. Thus, we will use an Instrumental Variable (IV) approach to estimate the average treatment effects on the treated (ATT) among those families who comply with the assignment to treatment.

II. Comparison of two treatment arms

For the comparison between the two modes of treatment implementation, we use the following specification:

$$Y_{ijct} = \alpha + \beta_1 T_j^S + \beta_2 T_j^E + \theta X_{ijc0} + \tau_c + \varepsilon_{ijct} \quad (2)$$

This specification is similar to equation (1), but replaces the treatment indicator with two arm indicators. T_j^S is an indicator for assignment to the standard arm and T_j^E is an indicator for assignment to the encouragement arm.

Additionally, we expect the encouragement arm will increase the participation of secondary caregivers in the program. Thus, the encouragement arm assignment serves as a valid instrument that exogenously changes the participation probability of secondary caregivers, but does not directly affect the outcomes. Thus, we will use an IV approach to estimate the effects of engaging secondary caregivers.

III. Specific analyses and hypothesis testing: test the ATE and ATT of the Healthy Future program on primary outcomes

- Hypotheses Testing:

1. Hypothesis A: the Healthy Future program will improve child haemoglobin level, exclusive breastfeeding rate, and child dietary diversity.
2. Hypothesis B: the encouragement arm that engages multiple caregivers will have a more significant impact than the standard arm that only targets primary caregivers in improving child haemoglobin level, exclusive breastfeeding rate, and child dietary diversity.

- Trial Arm Comparison
  1. Test the impact of receiving intervention versus no intervention (40 treatment townships vs. 79 control townships);
  2. Test the additional impact of receiving the encouragement intervention, compared to the standard intervention (20 townships in encouragement intervention vs. 20 townships in standard intervention vs. 79 control townships).
- Primary outcomes
  1. Child haemoglobin level among children aged six weeks to 18 months;
  2. Exclusive breastfeeding among children younger than six months;
  3. Dietary diversity among children older than six months.

E.2 Subgroup Analyses and Interaction Effects

We will also test whether the treatment effect is heterogeneous with respect to observable characteristics in children, caregivers, households, and CHWs. We will use a data-driven algorithm such as causal trees by Athey and Imbens to discover subgroup heterogeneous treatment effects.[84]

I. Test for heterogeneous effects

In general, if the characteristic is binary, we test for heterogeneous effects by including the binary variable and the interaction with the treatment arm assignment. If the characteristic is continuous, we will try for heterogeneous effects in two ways: (1) Assuming linear effects, we will include the continuous variable in the regression with an interaction term with the treatment arm assignment; and (2) Allowing for non-linear effects, we will create a binary variable from the continuous variable to indicate whether the value is above the median. We will include this binary variable along with its interaction with the treatment arm assignment.

II. Specific analyses: test the heterogeneous effects of the Healthy Future program (by the child, caregiver, household, and CHW characteristics) on primary outcomes

- Trial Arm Comparison
  1. Test the impact of receiving intervention versus no intervention (40 treatment townships vs. 79 control townships);
  2. Test the additional impact of receiving the encouragement intervention, compared to the standard intervention (20 townships in encouragement intervention vs. 20 townships in standard intervention vs. 79 control townships).
- Outcomes
  1. Child haemoglobin level among children aged six weeks to 18 months;
  2. Exclusive breastfeeding among children younger than six months
  3. Dietary diversity among children older than six months

E.3 Adjusting for Multiple Outcomes

In addition to the three primary outcomes, we also examine other child and maternal health outcomes and the mechanisms through which the intervention does or does not have effects.

I. Test for mechanisms and multiple outcomes:

We will test for treatment effects on secondary health outcomes and behavioural and intermediate outcomes, with a detailed list in Appendix D. Some outcomes may use multiple interrelated indicators or survey items for measurement. To adjust for multiple inferences (the increasing probability of rejecting a test with the number of tests carried out), we use the following procedure: (1) We will construct a summary index for outcomes that cannot be measured directly using the indicators or survey items. (2) In the absence of a validated scale, we will construct summary indices using the GLS weighting procedures by Anderson.[85] The index is a weighted mean of the standardized values with higher values indicating a better desirable outcome. (3) If tests using a given index are significant, we will also test the individual indicators that make up the index for exploratory analyses. While using a summary index presents a general effect of the intervention that is robust to concerns about multiple inferences, presenting statistical tests on individual variables makes it possible to assess the magnitude of the impact.

II. Specific analyses: test the secondary health outcomes and the mechanisms by which the Healthy Future program affects the child and maternal health, using a list of secondary health, behavioural, and intermediate outcomes variables.

- We test the ATE and ATT estimates for each of the secondary outcome variables in Appendix D.
- Trial Arm Comparison
    1. Test the impact of receiving intervention versus no intervention (40 treatment townships vs. 79 control townships);
    2. Test the additional impact of receiving the encouragement intervention, compared to the standard intervention (20 townships in encouragement intervention vs. 20 townships in standard intervention vs. 79 control townships).
- Outcomes
    1. Each of the secondary health, behavioural, and intermediate outcomes

E.4 Dealing with Missing Data and Attrition

We will address missing data in two ways: (1) if the data are missing completely at random, observations with missing data will be deleted from the analysis (i.e., listwise deletions); and (2) Otherwise, we will conduct missing value imputations using multiple imputation techniques.

We will also assess attrition rates across intervention arms. Families will be considered attritted if they are not present during the midline/endline survey. Information on these families and the reasons for attrition will be analysed. If differential attrition rates happen across arms, we will use the Lee trimming method to construct bounds around estimates of treatment effects.[86]

Appendix F. Model Informed Consent Form

Hello! You have been invited to participate in a survey project run by Sichuan University, West China School of Public Health. The purpose of this project is to learn about the nutritional knowledge and practices of your family. *[For families that will receive healthcare worker visits: "The purpose of this project is to learn about the impact of community health worker visits on the child health knowledge and practices of your family."]* We want to learn because we know that good nutrition is important for healthy child development.

To test your child's nutritional status, our trained nurses will take one drop of blood from his / her finger. Your child will feel some discomfort when we administer the test, but the test is safe, and will tell us whether your child is getting enough iron in his / her diet.

If you are currently pregnant, we will also invite you to participate in the same finger-prick blood test. Your hemoglobin measurement is a standard test for pregnant women to evaluate physical status and anemia.

We will also ask you some questions regarding the health of your family and your baby.

We will come back after six months and 12 months to repeat these tests. This will help us chart your child's development.

[For families that will receive health worker visits: "Later in the year, we will invite you to receive monthly home visits from a trained local health worker, who will provide information on child health and nutrition as your child grows."]

We estimate that it will take you about 2 hours to complete the survey. *[Each visit from the health worker will last no more than 1 hour.]*

By participating in our study, you will learn about the health of your child. *[For families that will receive healthcare worker visits: You may also receive helpful information about how to care for your baby.]* We do not foresee any risks associated with this study. We will keep all of your and your child's information private. **We cannot and do not guarantee or promise that you will receive any benefits from this study.**

Please understand that your participation is voluntary. You can withdraw your consent or discontinue participation at any time without penalty. Even if you decide to participate, you may decline to answer particular survey questions at any time. Your individual privacy will be maintained in all published and written data resulting from the study.

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you may contact Dr. XXX.

You should also contact her at any time if you feel you have been hurt by being a part of this study, if you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant.

If you agree to participate in this research, please indicate this to me.

YOUR VERBAL AGREEMENT INDICATES THAT YOU UNDERSTAND EVERYTHING THAT I HAVE SAID SO FAR, AND THAT YOU HAVE DECIDED TO PARTICIPATE.