October 2025

Women Supporting Women Using Local Solutions to Improve Infant and Young Child Feeding and Care Practices in Punjab, Pakistan

STUDY PROTOCOL

Study Overview

JUSTIFICATION.
This study responds to a call by the Pakistani government and public health researchers who have identified combatting child malnutrition as a high priority for Rahim Yar Khan (RYK) district in the province of Punjab. This study will focus on the proximal causes of malnutrition (inadequate diet and infections).

GOAL.
To rehabilitate moderately malnourished children 7-23 months of age and enable mothers to sustain this healthy growth at home by changing their infant and young child feeding (IYCF), care, hygiene, and health-seeking behaviors.

PURPOSE.
The OVERALL STUDY PURPOSE is to develop and evaluate a behavior change educational program to prevent malnutrition in the province of Punjab, Pakistan. The study has two main phases: the Formative Research Phase and the Intervention Phase.

The PURPOSE OF THE FORMATIVE RESEARCH is to identify uncommon but successful (i.e. *Positive Deviant*) IYCF behaviors practiced by local mothers of well-nourished children from economically disadvantaged homes, and to develop an education program informed by these best-practices and WHO guidelines.

The PURPOSE OF THE INTERVENTION PHASE is to deliver the educational program to mothers with undernourished children in the Intervention arm of the study who are equally disadvantaged, and to evaluate its impact on the growth of children.

STUDY HYPOTHESIS.
The primary hypothesis is that a higher proportion of Index children in the intervention compared to the control group will experience an average weight gain of 400g/month in the first 4 mos of the intervention.

STUDY OBJECTIVES.
1. Understand local perceptions, experiences, and cultural norms around IYCF practices and care,
2. Discover demonstrably successful IYCF behaviours and strategies using local resources,
3. Develop and implement a culturally appropriate and context-specific intervention,
4. Evaluate the intervention using two comparisons: (a) Within the intervention group: assess Index children's growth patterns and change in household behaviours/factors relevant to IYCF (e.g., knowledge, practice, beliefs and norms). (b) Intervention vs control group: compare average weight gain of Index children and household behaviours/factors relevant to IYCF (e.g., knowledge, practice, beliefs and norms)

Research Methods

IMPLEMENTATION OF THE INTERVENTION

SUMMARY

The project is now ready to move into the intervention, informed by the formative research phase, aligned with Objective #3. The intervention targets households with moderately malnourished children between 7 and 15 months of age, and will follow and support these households for a period of 6-months. Consent will be obtained from mothers via thumbprint or signature. Severely malnourished children, regardless of group, will be referred to local health facilities for care. Households in the control group will continue with their usual feeding and care practices.

This study is rooted in an asset-based approach grounded in the belief that in every community there are certain individuals whose uncommon behaviours enable them to find solutions to prevalent and seemingly intractable problems, The intent of the formative research phase supported by the CAC was to learn what is already possible within the community of Rahim Yar Khan and to amplifies these strategies to the wider community during the intervention phase. The intervention comprises of two major components: community sensitization and a 28-day behaviour change period.

COMMUNITY SENSITIZATION OVERVIEW

The community sensitization events will be held in each intervention cluster. These events will introduce the project to local families about complementary feeding for children 6-23 months of age. These sessions will be delivered using town-hall format with small group activities. Key messages supported with visuals and print materials from the 28-day behavior change program (discussed below) will be shared with the larger community. The objective of the community sensitization programs is to create community awareness about the project, share best practices related to complementary feeding with the wider community with the hope this will promote community buy-in as well as community and neighborhood support for households participating in the 28-day change program.

28-DAY BEHAVIOR CHANGE PRACTICE PROGRAM OVERVIEW

Prior to recruitment and starting the 28-day behavior change program, each child will undergo a health check by a physician at the local health facility, including anemia screening, and ensuring they are up to date with all required immunizations.

The 28-day behaviour change practice includes two sequential parts. The first part consists of bringing mothers and their moderately malnourished child together in a home-like setting (the Hearth) for a period of 2-weeks to rehabilitate their malnourished child and learn improved feeding, hygiene, and caregiving practices The Hearth sessions delivered over 14 days (6 hearth days plus 1 rest day/wk), and each session will last approximately 2.5 hrs. The second part consists of mothers practicing the learned behaviours in their home for another 2-weeks with support from the study staff. The Hearth/follow-up home visit model is based on the work of World Vision, which has shown that for some households, behaviour change, specifically in

feeding, caring, nurturing, and hygiene practices, may take up to 3 cycles to be fully adopted and for the child to regain a normal growth pattern. Hence, for children who do not reach their growth milestones after the first 28-day cycle, we will offer mothers the opportunity to participate in up to 3 cycles of the 28-day programs, with non-responders referred for medical evaluation. This length is deemed optimal to minimize dependency on the external rehabilitation process while allowing mothers the opportunity to "learn by doing", and subsequently practice the new behaviours at home. The sessions will be facilitated by trained staff, and will emphasize practical learning, including preparing meals based on locally available foods.

Not all households will require 3 cycles; those whose children achieve the desired weight gain of 400 g (as recommended by WHO guidelines) may graduate earlier. This model is not intended to treat acute malnutrition or wasting but rather to address chronic malnutrition resulting from inadequate feeding and caregiving practices, which requires sustained engagement to reverse.

Following the hearth sessions, mothers will continue with a 14-day at-home practice period, during which they apply the newly learned behaviours in their household setting. Study staff will visit each home three times a week for 1.5 hours to reinforce behaviours, monitor child growth, and provide ongoing support.

If after each 28-day cycle the child meets their growth milestones, home visits will shift to monthly check-ins for up to 6 months. If the child falls short of meeting the growth milestone, families will be invited to repeat the 28-day Hearth and home practice cycles up to three times.

To reinforce the intervention, supplemental printed materials will be distributed to households during the 28-day program. These materials will be developed in collaboration with the CAC and based on findings from formative research. Designed to be accessible to illiterate populations, the materials will feature culturally relevant visuals with minimal text and be tailored for both men and women. An estimated 5,000 copies will be produced for dissemination to those participating in the 28-day behavior change program as well as the sensitization program.

EVALUATION

The project will evaluate the intervention's effectiveness, study Objective #4. Evaluation tools have been adapted from existing validated instruments, informed by the formative research phase, reviewed by the CAC for clarity and cultural appropriateness and pilot tested. All tools have been translated to the local Punjabi dialect spoken by both Punjabi and Saraiki tribes residing in Rahim Yar Khan. Both the Treatment and Control Arm households will undergo the similar evaluations.

The evaluation will involve two major data collection strategies.

BASELINE AND FOLLOW-UP SURVEYS

Interview-assisted surveys will be conducted with mothers. These surveys will gather information on demographics, child health status, infant and young child feeding (IYCF) practices, hygiene behaviours, healthcare-seeking behaviours, gender norms, psychosocial factors, and available resources. Baseline surveys will be conducted after households have

consented to participate. Follow-up (Endline) survey will be conducted 6-months after the baseline surveys. With the exception of demographic information, which will only be obtained once at baseline, both baseline and endline surveys will obtain the same information. A third survey will be conducted 12 months post-intervention, if funding permits.

ANTHROPOMETRIC MEASUREMENTS (Weight and Height).
Anthropometric data will be collected by trained study staff to measure children's height and weight. Measurements will be taken with calibrated tools to minimize observer bias, and analyzed using WHO Anthro software to determine nutritional status based on standard Z-scores (weight-for-age, height-for-age, and weight-for-height). Children will be classified as underweight, stunted, wasted, or well-nourished. For the Treatment and Control Arm children, arthrometric measurements will be obtained at the time of recruitment, part of the baseline survey, during monthly follow-up, and part of the endline survey Additionally, for the children in the Treatment Arm, weight will be collected during the 28-day behavior change practice program (Days 1, 13, and 28).

Inclusion Criteria

INTERVENTION PHASE

Eligible participants must meet all of the following conditions:

Child-Level Criteria:

- While children in the intervention phase will range from ages 7-23 months, At the time of recruitment children will range from Ages: 7–15 months.
    - Priority will be given to younger children, aged 7–11 months followed up by 12-15 months, to allow completion of the intervention and follow-up visits before the child turns 24 months of age, as complementary feeding refers to feeding practices between the ages of 6-24 months.
    - Moderate malnutrition, defined by: Weight-for-age Z-score between -2 and -3 standard deviations.

Household-Level Criteria:

- Households will be eligible to participate if:
    - They meet the classification of very poor or poor (based on community-defined wealth stratification).
    - Have access to clean water and sanitation.
    - Food secure at time of recruitment, defined as:
        - On government assistant program or at least one adult has permanent employment, or two or more have temporary employment.

- Ownership of at least one simple livestock (e.g., chicken, goat, or sheep).
- Access to a kitchen garden, or willingness to establish one with study support

Mother Eligibility Criteria:
The household is eligible only if the mother meets all of the following:

1. Mother is the primary caregiver for the Index Child (responsible for daily care, including supervision, bathing, and feeding).
2. Mother is alive and at least 18 years old.
3. Mother is currently breastfeeding the Index Child and willing to continue until the child reaches 2 years of age.
4. Mother expresses an interest in participating in the PD/Hearth program.
5. Mother agrees to attend up to three Hearth sessions.
6. Mother is willing and able to contribute to one of the following for Hearth sessions:
    - "Special" food items (e.g., apple, banana, carrot, chickpea, egg, garlic, lentils, rice, spinach, tomato, etc.), or
    - Other essential items (e.g., utensils, bowls, spoons, soap, nail cutter, towels, water, mat, salt, matchstick).
7. Mother provides permission for study follow-ups as outlined above.
8. Mother agrees to a full medical check-up for the Index Child at the nearest public health facility, including a one-time hematocrit finger-prick test (Hb test).
9. Mother provides informed consent via thumbprint or written signature.

Exclusion Criteria

Child-Level Exclusions:

- Children who are Severely malnourished, mildly underweight or of normal weight.
- Children with Physical disabilities: difficulty in seeing, hearing, picking up small objects with his/her hand.
- Children with chronic illnesses that may interfere with normal growth (based on past or current medical history):
    - Malabsorption
    - Chronic Kidney Disease
    - Inflammatory Bowel Disease
    - Congenital Heart Disease
    - Endocrine Disorders (e.g., hypothyroidism, growth hormone deficiencies)
    - Chronic Respiratory Diseases (e.g., asthma, lung diseases)
    - Congenital or Acquired Immunodeficiency, and Neurological Disorders

Household-Level Exclusion:

- Households who do not meet the inclusion criteria.

Recruitment Methods

1. SETTING

The intervention will be conducted in three Union Councils (UCs): Wah Kohna, 139/P, and Rahim Yar Khan Deh. These UCs were purposively selected based on population need and prior engagement during the formative phase. Our recruitment strategy is progressive: we will maximize recruitment from 1 UC first and only move to the next UC when we have maximized recruitment of households from that UC.

2. SAMPLE SIZE

We aim to recruit 100 households in the intervention group. Similarly, for the comparison group (Control Arm) we will conduct the study in three UCs: Kot Mehdi Shah, Balouqi Wali, and Ameen Garh, and recruit 100 households in the comparison group-Based on power calculations 100 households in each of the groups will allow us to detect a meaningful difference in child weight gain (≥400 grams) with 80% power. To address potential attrition, we are building in a 20% buffer.

3. GATEKEEPERS

Lady Health Workers (LHWs) will act as trusted intermediaries, identifying eligible households and introducing the study to the households. For villages, tibbas, or basties not previously included in the FGDs or PDIs, the research team will collaborate with the CAC and local community leaders to raise awareness about the study. Public announcements and town hall meetings will be organized to inform community members. Interested households will be encouraged to register their names with designated gatekeepers, who will then share this information with the recruitment team.

4. ELIGIBILITY ASSESSMENT

To determine eligibility for participation, each Index Child will undergo a multi-step assessment process.

- Assessment of the child's nutritional status. Only those children identified as being moderately malnourished admitted into the study. Children will be assessed by the field staff through anthropometric measurements: weight, length/height, and mid-upper arm circumference (MUAC) and using standardized WHO growth reference tools. Children will only be included if they are classified as moderately underweight (weight-for-age Z-score between -2 and -3 SD). Severely malnourished children will be referred immediately to a health facility for medical care. All measurements will be conducted by trained staff following strict protocols to ensure consistency and accuracy.

To be eligible for the Treatment Arm. All children meeting the classification of moderate malnutrition will undergo a complete medical at the local health facility, including confirmation of their nutritional status and update of their vaccination record. Eligibility will be determined by working with the Lady Health Worker affiliated with the respective household, who will rule out children with chronic disease according to the exclusion list. A final confirmation from the health facility will be sought after consent is obtained to assess whether the child is well enough to participate in the 28-day behavior change (Hearth) program.

- To be eligible for the Control Arm. All children meeting the classification of moderate malnutrition will be assessed for chronic illness. Initial assessment will be done by asking mothers about their child's health and final eligibility confirmed by Lady Health Workers' medical records.

- Assessment of the household eligibility. Households will undergo an assessment of their wealth ranking and food security status. Study staff will use the Final Recruitment Screening Form to confirm and document eligibility for participation. The recruitment forms for both the treatment and control arms are attached in Section 9.5.

5. CONSENT PROCESS

If the above eligibility criteria are met, on the same day, study staff will discuss the details of the consent process with the household and prepare for the signing of the consent document. The households in the treatment arm will then visit the health facility within one week for medical clearance. One week later, staff will visit the household to collect the signed consent form and conduct the baseline survey. Clearance from the health facility must be obtained before the household begins Hearth sessions. This clearance serves as a second check for exclusion due to disabilities or chronic disease.

To ensure that every participant fully understands the nature of the study before deciding to take part, the informed consent process will be conducted with care, cultural sensitivity, and attention to literacy needs. All consent materials will be provided in Punjabi and Saraiki, the local languages most commonly spoken in the study communities. Trained field staff will visit households in person to explain the study using simple, conversational language. They will walk families through all key aspects of participation, including the purpose and title of the research, the expected duration and structure of the study, what will be asked of them, and what potential risks or benefits may arise.

As this is a community-based study intended to test the feasibility of this intervention in rural Pakistan, the consent process will carefully explain the purpose, procedures, and expectations. This will include what health assessments will be conducted, how data will be collected and stored, and the confidentiality protections in place. Importantly, participants will be reminded that their involvement is entirely voluntary, and they may withdraw at any time without penalty or consequence, as outlined clearly in the consent form. While the study will obtain written

consent at the time of recruitment, on-going verbal consent will be sought at critical junctures to reaffirm willingness to participate. For example, for the Treatment Arm, this will include prior to engaging with hearth cycles 2 and 3 if participants are eligible, and prior to conducting follow-up surveys at 6 and 12 months. At households' request, trusted community members may also be engaged to help explain the protocol and answer questions. Each participating household will receive a printed copy of the consent form for their own records.

As is typical in Pakistan, the mother of the Index Child will be asked to provide consent by signing the form to confirm her understanding and agreement. If the father is available, the father may also provide consent. In households where literacy is limited, participants will be offered the option to give consent using a thumbprint, in keeping with ethical research standards.
Refer to Section 9.2 for the consent forms.

Procedures

PROCEDURES FOR PARTICIPANTS IN THE TREATMENT ARM

28-Day Behavior Change Practice Program.

The study's community-based intervention model consists of a 28-day behavior change practice program: groups session in a home-like setting (Heath) where mothers and the moderately malnourished Index Child (and interested family) will come together to learn new ways of cooking and practicing successful behaviours to rehabilitate their malnourished child., followed by home practice. Each 28-day program cycle consists of two components:

1- Group Hearth Sessions (2 weeks in duration): Mothers and their Index Child will attend the hearth in small groups (typically 15 mother–child pairs). Sessions will focus on knowledge about complementary feeding, active feeding, hygiene, caregiving, and health-seeking behaviours. Mothers will take part in cooking and caring demonstrations, rotating through roles to build hands-on skills. Accompanying family members may participate to support learning and adoption of new behaviours.

2- Home Practice (2 weeks in duration): After the group sessions, field staff will visit each home three times per week to support the mother's practice of newly learned behaviors. Each visit will last approximately 1.5 hours and will reinforce positive changes and problem-solve emerging challenges.

Mothers are expected to contribute some items of their choice to the hearth (e.g., food items for 1-2 children: egg, rice, vegetables, or water, or household materials (e.g., utensils for their child: spoon, cup/ bowl, or soap) to the sessions, ensuring that activities reflect real-life constraints and available resources. It is hoped active participation will promote engagement and help transition practices in the home setting. The project will contribute cooking pots, utensils and most of the food for the 2-week home-like sessions.

Assessment

Anthropometric Assessment. Each Index Child's weight and height will be measured at the start and end of each hearth session, and at the end of the 2-week home visits (Day 1, Day 13, Day 27 of each cycle). If, by the end of the cycle, the child has not gained at least 400g, they will be invited to repeat the cycle—up to a maximum of three cycles. Children failing to any gain weight between cycles will be referred to a public health facility for medical evaluation. Z-Scores will be calculated to quantify the child's nutritional status. Mid-Upper Arm Circumference (MUAC) will be taken to assess for wasting. During the follow-up period, the child's weight will be monitored monthly for up to six months post-intervention.

Health assessment.

Baseline health assessments will be conducted at local public health facilities within two weeks prior to the first Hearth session for participants in the treatment arm. Each Index Child will receive a full medical examination by a physician, a Hematocrit (Hb) test via finger prick, and verification and updates for routine immunizations.

All children showing "failure to thrive" (e.g., no weight gain or weight loss after a Hearth cycle) will be referred for medical assessment within five days, and accompanied by study staff.

Results of participants' health assessments will not be shared or retained by the research team. This assessment will be conducted solely to confirm that the child meets eligibility criteria and is well enough to participate in the 28-day behaviour change program. This information is sufficient for enrollment purposes, and no medical or health records beyond the anthropometric measurements will be collected, stored, or used as study data

Data collection

Data will be collected using structured tools and include:

Baseline and follow-up household surveys (at 6 months, and possibly 12 months post-intervention if funding permits): surveys will assess 24-hour food recall and indicators on feeding practices, WASH, gender roles, and health-seeking behaviour. Study survey instrument is attached to Section 9.5.

All data will first be recorded on paper and later digitized by trained personnel.

PROCEDURES FOR PARTICIPANTS IN THE CONTROL ARM

Participants in the control group will be enrolled after staff use the Final Recruitment Screening for Control Form to confirm eligibility, and households that express interest will be invited to join. Unlike the intervention group, control participants will not undergo a health facility–based assessment at baseline, will also not participate in the 28-day behavior change practice program, and will instead continue to receive routine care from LHWs and access health services as usual.

They will participate in the baseline and follow-up household surveys (at 6 months, and possibly 12 months post-intervention if funding permits): surveys will assess 24-hour food recall and indicators on feeding practices, WASH, gender roles, and health-seeking behaviour. Study survey instrument is attached to Section 9.5.

Anthropometric Assessment. Each Index Child's weight and height will be measured at the time of baseline and endline survey. Z-Scores will be calculated to quantify the child's nutritional status. Mid-Upper Arm Circumference (MUAC) will be taken to assess for wasting. During the follow-up period, the child's weight will be monitored monthly for up to six months post-baseline.

Time to Participate

For Treatment arm:

If a household were to partake in one hearth cycle and complete the full 6-month participation we will be offering, we can estimate the total time participants would need to commit is 40 hours over a 6-month period.

- initial recruitment assessment 0.5 hours,
- consent signing 0.5 hours,
- baseline survey 1.25 hours,
- final 6-month survey 1 hour,
- anthropometric measurement 1.5 hours (0.25 hours x 6, includes measurement taken at baseline, follow-up, and final assessment).
- 28-Day Behavior Change Practice Program. Hearth Sessions Total 34.5 hours: 12 days per cycle, 2.5 hours per day, for total = 30 hrs. Home-visits during the second half of the program total of 4.5 hours (1.5 hours three time a week for two weeks),
- Health Assessment at the medical facility may take up to 1 hour for medical screening, immunization checks, and collection of baseline height and weight measurements.

If the household participates in three hearth cycles, the time the staff will spend at the family's home is estimated to be 74.5 hours.

For Control arm:

If a household were to complete the full 6-month participation, we can estimate the total time participants would need to commit is 4.75 hours.

- initial recruitment assessment 0.5 hours,
- consent signing 0.5 hours,
- baseline survey 1.25 hours,
- final 6-month survey 1 hour,

- anthropometric measurement 1.5 hours (0.25 hours x 6, includes measurement taken at baseline, follow-up, and final assessment).

Obtaining Consent

On the day of final recruitment, details of the study and the consent process will be explained to mothers. Households will then have one week to reflect on the information provided. During a home visit one week later, and just before the baseline survey, trained staff will obtain informed consent from the mother of the index child. The staff has gone through training to ensure they communicate the following in lay-person language, and in a clear and respectful manner: research time-frame; title of research; researchers involved; purpose of research; description of research; potential harms and benefits; treatment alternatives; statement of confidentiality; information and data to be collected; how long the data will be kept, how it will be stored and who can access it; any conflicts of interest; a statement of the participant's right to withdraw from participation at any point; and a declarative statement of understanding that the potential participant agrees to and signs.

- A copy of the consent form will be provided to the parents of Index child.
- Parents will authorize by signing the consent form that they have read and understand this consent form, and volunteer to participate in this research study.
- For eligible participants with limited literacy, parents will authorize using thumbprint signature that they understand the consent form and volunteer to participate in this research study.

Informed Consent from the Treatment Arm households will be obtained 1 week after communicating the study information with the participants, and 1-2 weeks prior to the 28-Day Behavior Change Practice sessions, and before participants participate in the baseline survey.

Informed Consent from the Control Arm households will be obtained 1 week after communicating the study information with the participant, and before participants in the baseline survey.