

May 8, 2026

ClinicalTrials.gov
U.S. National Library of Medicine
National Institutes of Health

Subject: Registration of Cluster Randomized Controlled Trial

Dear Sir/Madam,

I am writing to submit our study for registration on ClinicalTrials.gov.

The study entitled, “The Effectiveness of Positive Deviance/Hearth (PDH), a Local Dietary Approach, to Treat Uncomplicated Moderate Acute Malnutrition (MAM) in Children 6–59 Months in Mymensingh, Bangladesh”, is a cluster randomized controlled trial designed to evaluate the effectiveness of the Positive Deviance/Hearth (PDH) approach compared with standard care for the treatment of uncomplicated moderate acute malnutrition among children aged 6–59 months.

This study will be conducted in Mymensingh, Bangladesh, and aims to generate evidence on the use of a locally based dietary rehabilitation approach to improve nutritional recovery and reduce relapse among children with MAM. The trial will follow all applicable ethical and regulatory requirements, and approval has been or will be obtained from the appropriate institutional review boards and relevant authorities prior to implementation.

We respectfully request registration of this trial on ClinicalTrials.gov. Relevant study details, the statistical analysis plan, and supporting documentation have been provided as part of the submission package.

Please do not hesitate to contact us should additional information or clarification be required.

Sincerely,

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The Effectiveness of Positive Deviance/Hearth (PDH), a Local Dietary Approach, to Treat Uncomplicated Moderate Acute Malnutrition (MAM) in Children 6–59 Months in Mymensingh, Bangladesh

**Study Protocol with Statistical Analysis Plan and Informed
Consent Forms**

May 5, 2026; V3

Diane Baik

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ABBREVIATIONS

AM	Acute Malnutrition
CHWs	Community health workers
FGD	Focus Group Discussions
HAZ	Height-for-Age Z-score
ICDDR,B	International Centre for Diarrhoeal Disease Research, Bangladesh
IYCF	Infant and Young Child Feeding
LAZ	Length-for-Age Z-score
LSHTM	London School of Hygiene and Tropical Medicine
MAM	Moderate Acute Malnutrition
MUAC	Mid-Upper Arm Circumference
N/A	Not Applicable
PDH	Positive Deviance/Hearth
RUTF	Ready-to-Use-Therapeutic Foods
SAM	Severe Acute Malnutrition
SD	Standard Deviation
SFF	Specially Formulated Foods
SOC	Standard of Care
UNICEF	United Nations International Children's Emergency Fund
WASH	Water and Sanitation, Hygiene
WAZ	Weight-for-Age z-score
WHO	World Health Organization
WHZ	Weight-for-Height z-score
WLZ	Weight-for-Length z-score

KEYWORDS: Acute Malnutrition, Wasting, Uncomplicated Children, Dietary, Food Approach, Non-Specially Formulated Food, Local Nutritious Foods, Rehabilitation, Recovery, Relapse

STUDY SUMMARY

TITLE	Evaluation of Positive Deviance/Hearth for Treating Uncomplicated Moderate Acute Malnutrition in Bangladesh
DESIGN	Cluster randomized control trial
AIMS	To evaluate the effectiveness of Positive Deviance/Hearth to rehabilitate uncomplicated moderate acute malnutrition (MAM) in children 6-59 months of age in Bangladesh.
OUTCOME MEASURE	Primary outcome includes recovery of children aged 6-59 months of age from MAM without medical complications where recovery is defined as WHZ/WLZ ≥ -2 or MUAC ≥ 125 mm (based on admission criterion), and absence of bilateral pitting oedema.
POP & ELIGIBILITY	Children 6-59 months in age in Purbadhala Upazila, Mymensingh Division, Bangladesh
TREATMENT	Using locally available nutritious foods (as part of PDH) to rehabilitate uncomplicated MAM in children 6-59 months of age
DURATION	9 months total research duration

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Sponsor

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1. BACKGROUND

Acute malnutrition (wasting) remains one of the most urgent public health challenges affecting children under five globally. Moderate acute malnutrition (MAM)¹ alone affects an estimated 31.7 million children, the majority of whom live in non-humanitarian, food-secure settings such as South and Southeast Asia. Bangladesh continues to face persistently high rates of wasting—approximately 11% nationally—despite decades of progress in stunting and underweight reduction (2). In Mymensingh Division, recent screening data indicate prevalence consistently above 10%, with pockets surpassing WHO’s “critical” threshold. These trends underscore the need for new, sustainable, community-based approaches to MAM management.

Current treatment approaches for MAM largely rely on specially formulated foods (SFFs), including ready-to-use supplementary foods and fortified blended foods. However, evidence shows these products improve recovery only moderately and are limited by high cost, frequent stockouts, and lack of integration within routine health and nutrition systems. As a result, MAM services in Bangladesh remain minimal, with children frequently receiving no targeted support until they deteriorate to severe acute malnutrition (SAM). The 2023 WHO guideline recognised these constraints and noted a major evidence gap: no eligible studies have evaluated non-SFF, sustainable, food-based approaches for treating MAM in children under five.

Positive Deviance/Hearth (PDH) offers a promising alternative. PDH is a community-driven, low-cost nutrition rehabilitation programme that uses locally available nutritious foods, hands-on cooking practice, caregiver behaviour-change support, and structured home follow-up. Unlike product-based approaches, PDH strengthens caregiver skills, builds local capacity, and is sustainable without external food commodities. Evidence from programme evaluations and a 2023 meta-analysis suggests PDH can improve weight-for-age, weight-for-height, and dietary practices, but rigorous trials examining PDH for MAM treatment are lacking.

Given Bangladesh’s food-secure environment, strong community health platforms, and high MAM burden, it is an ideal context to test PDH as a sustainable treatment model. This study aims to evaluate the effectiveness of PDH compared with Standard of Care (SOC) for treating uncomplicated MAM, contributing urgently needed evidence to national policy, global guidelines, and future scale-up strategies.

¹ MAM in children under 5 years is defined as a weight-for-height (WHZ) or weight-for length z-score (WLZ) below -2 and equal to and above or equal to -3 on the WHO growth chart or mid-upper-arm-circumference (MUAC) less than 125mm and above or equal to 115cm and without bilateral pitting oedema that starts in the feet and can progress up the legs, face, and body (1).

1.1 Overview of Positive Deviance/Hearth (PDH), a non-SFF approach

PDH was developed in Vietnam in 1990 by Save the Children and Tufts University. It is a community-based, non-SFF approach for treating uncomplicated underweight and MAM and SAM children who pass the appetite test, while promoting caregiver behaviour change. PDH identifies “Positive Deviants” – families with low income but successful practices that enable their children to be well-nourished without external interventions. Most PDH programs admit children with $WAZ < -2$ and discharge at $WAZ \geq -2$.

A formative research, including 24-hour recall, observation walks, market surveys, and seasonal calendars, identifies locally available, low-cost, nutrient-dense foods for PDH menus. Caregivers participate in 12-day education sessions (referred to as ‘Hearth’), contributing local ingredients (e.g. blackjack, wild green leafy plant in Zambia high in vitamins, iron, and zinc; very low in cost) or resources (e.g., firewood or drinking water). Meals meet calorie ($\geq 600\text{kcal}$), protein ($\geq 25\text{g}$), vitamin A ($\geq 300\text{RAE}$), vitamin C ($\geq 15\text{mg}$), iron ($\geq 8\text{mg}$), and zinc ($\geq 3\text{mg}$) requirements and use an electronic menu calculator (3). Meals including snacks are small (250–300g), culturally acceptable, and easy to consume. Volunteers provide two weeks of follow-up visits to reinforce behavior changes. Children are discharged after 90 days (12 weeks) if they reach $WAZ \geq -2$. Sample menus used to rehabilitate underweight children across Asia and Africa was published by World Vision.

2. AIM AND OBJECTIVES

2.1 AIM

The overall aim of this study is to evaluate the effectiveness of the Positive Deviance/Hearth (PDH) programme as a sustainable, community-based, non-specially formulated food (non-SFF) approach for treating children aged 6–59 months with uncomplicated moderate acute malnutrition (MAM) in food-secure, resource-constrained settings in Bangladesh.

2.2 SPECIFIC OBJECTIVES

1. To compare the proportion of children aged 6–59 months with uncomplicated MAM who achieve nutritional recovery² within 3 months between those receiving PDH plus Standard of Care and those receiving Standard of Care alone.
2. To compare the percentage of children aged 6–59 months with uncomplicated MAM who have sustained recovery at 6 months after recovery within 3 months between those receiving PDH + Standard of Care and those receiving Standard of Care alone (Sustained recovery is defined as remaining either $MUAC \geq 125\text{mm}$ or $WHZ/WLZ \geq -2$) after 6 months from treatment.

² Nutritional Recovery is defined at Day 90 as: $WHZ/WLZ \geq -2$ or $MUAC \geq 125\text{ mm}$ (based on admission criterion), and $WAZ \geq -3$, and absence of bilateral pitting oedema.

3. To qualitatively assess caregivers', volunteers', and Ministry of Health authorities' perceptions of the feasibility, acceptability, system integration, and readiness for scale-up of the PDH approach for uncomplicated MAM management within Bangladesh's routine health system.

2.3 Secondary outcomes will be assessed, including:

- Recovery of MAM with stricter definition (including $WAZ \geq -3.0$) within 3 months,
- Average daily weight gain
- Average MUAC and WAZ at 3 months,
- Defaulting rates,
- Non-Response at 4 months (not achieving anthropometric recovery within 4 months of initiating treatment – after going through 2 rounds of Hearth and follow-up conducted at Day 30 after 2nd round of Hearth)
- Sustained Recovery at 6 months (with/without $WAZ \geq -3.0$ in recovery criteria)
- Difference in Sustained Recovery comparing recovery criteria (with/without $WAZ \geq -3.0$ in recovery criteria)

Exploratory Outcomes:

- Behaviour change including: Minimum dietary diversity, Meal frequency, Minimum acceptable diet, unhealthy food consumption, child illness symptoms, health seeking behaviour, handwashing, caregiver wellbeing, and cost-effectiveness of PDH
- Comparison of MAM recovery for high risk vs. low risk MAM (if any of the following are present)
 - High Risk: MUAC 115-119mm or WHZ between -2.5 to -3.0; with one of the contextual or household risk factors including:
 - Weight loss in past 30 days
 - Child < 12 months
 - Low birthweight or preterm history
 - Caregiver unable to provide adequate feeding or care do to working mother and requires migration
 - Food insecurity or lack of access to nutritious foods (more than 6 months of the year)
 - Poor access to functioning latrine
 - Maternal mental health issues
 - Low Risk: MUAC >119mm or WHZ >-2.5; with no contextual or household risk factors listed above.
- Changes in WHZ/WLZ, WAZ, AND HAZ/LAZ at 3 months

Qualitative Primary Research Question: How do caregivers, volunteers, and MOH staff perceive the feasibility, acceptability, and potential scalability of the PDH approach for the management of moderate acute malnutrition within routine health and community systems?

Secondary Research Questions:

1. What factors influence the adoption of the PDH approach by health workers, community volunteers, and local systems? (RE-AIM: Adoption)

2. How is the PDH approach implemented in practice, and what facilitators and barriers affect its delivery and fidelity? (RE-AIM: Implementation)
3. How do stakeholders perceive the sustainability and integration of PDH within existing nutrition and primary health care services? (RE-AIM: Maintenance)
4. What system-level conditions, adaptations, and resources do stakeholders identify as necessary for PDH to be scaled beyond the study setting? (Scale-up assessment informed by ExpandNet concepts)

The study will conduct:

- 4 Focus Group Discussions (FGDs) with PDH caregivers and 4 FGDs with volunteers (only PDH arm)
- 4 Key Informant Interviews (KIIs) with Ministry of Health staff (with the Upazilla Health and Family Planning Officer, District Civil Surgeon, Divisional Director, and National Director of Institute of Public Health and Nutrition).
- 2 Key Informant Interviews (KIIs) with World Vision staff (community development facilitator and program manager)

Using small set of overarching questions about PDH's impact and scalability structured by the RE-AIM (4), ExpandNet (5–7) frameworks, and icddr,b's validated tools for assessing acceptability, feasibility, and scalability.

5. To explore the cost-effectiveness of the PDH approach compared to SOC-only, assessed as cost per child recovered at Day 90 using the Innovation for Poverty Action Cost-Effectiveness Analysis and icddr,b's excel costing tool (8).

These objectives align with global research gaps identified by WHO and respond to the national need for evidence on sustainable food-based approaches to MAM management in Bangladesh.

3. RESEARCH DESIGN/METHODOLOGY

3.1 STUDY DESIGN

This study is a cluster-randomized controlled superiority trial conducted in 28 villages in Purbadhala Upazila, Mymensingh Division, Bangladesh. Villages serve as clusters and will be randomized 1:1 to either:

(1) PDH + Standard of Care (SOC), or (2) SOC-only.

3.2 RATIONALE FOR CLUSTER DESIGN

Cluster randomization minimizes contamination because caregivers within the same village frequently share feeding practices, food resources, and caregiving behaviours.

3.3 STUDY POPULATION

Children aged 6–59 months with uncomplicated MAM, defined as:

- WHZ/WLZ < -2 and ≥ -3 OR MUAC < 125mm and ≥ 115 mm,
- No bilateral pitting oedema,

- No medical complications, and
-

3.4 RECRUITMENT

A census and village-wide anthropometric screening will be conducted 2–4 weeks pre-baseline to identify eligible children. If more than 20 eligible children are identified in a village, all MAM children will be included in the PDH programme, but simple random sampling will be used from those who meet the inclusion criteria to select the children to be admitted for the study. Randomization sequence generator will be used online. A local academic partner, icddr,b will be used to collect the data at Baseline, Day 90 (3 Month) and Day 180 (6 month). The scope of work for the local partner, icddr,b, can be found in [Appendix E](#).

3.4.1 Inclusion/Exclusion Criteria

A detailed summary of the inclusion and exclusion criteria can be found in Table 1. Below is a description of the specific criteria used to assess each potential child participant in the study:

1. **Age of child:** All children included in the study must be **6-52.9 months of age at Baseline**.
2. **Measure MUAC, weight and height/length, and assess for oedema:**
 1. Measure MUAC
 2. Check for Oedema
 3. Measure weight and height/length
 4. If child meets the criteria below, child can potentially be enrolled in study:
 - i. WHZ/WLZ <-2 and ≥ -3 and/or MUAC $<125\text{mm}$ and $\geq 115\text{mm}$
 - ii. No Oedema on feet

Children severely wasted (MUAC $<115\text{mm}$ and/or WHZ or WLZ <-3.0) will be referred to the Referral Facility and given Nutritional Management, which is a therapeutic food equivalent to F100 that is recommended by the World Health Organization (WHO) for the management of SAM in recovery phase.

3. **Check for Medical Complications:** All children 6-52.9 months of age will be screened with the Ministry of Bangladesh IMCI protocol to ensure they do not have any medical complications (e.g. no features of severe illness as defined by Integrated Management of Childhood Illness – no severe nausea/vomiting, no severe dehydration or pneumonia) (see [Appendix F](#) for National IMCI screening questions and [Appendix G](#) for the referral protocol). Children with medical complications will be referred to appropriate health services and not included in the study. Any child who progresses to SAM and where SFF treatment is available in the area, the child will be referred to the health centre to receive SFF treatment and removed from the study. If SFF treatment is not available at the health centre, and the child does not have medical complications, the child will continue with the PDH programme. If the child has medical complications, and there is no SFF treatment at the health centre,

the child will be referred to the district or provincial hospital and excluded from the study.

Table 1 – Summary of Study Inclusion and Exclusion Criteria and Referral Protocol

	Inclusion	Exclusion	Next Steps if Child falls in Exclusion Criteria
Age of Child	6-52.9 months of age at time of Baseline	<6 months of age or 52.9 months and older	Encourage caregiver to continue taking children regular Growth Monitoring and Promotion (GMP)
Acute Malnutrition Status	<ul style="list-style-type: none"> • WHZ/WLZ <-2 and ≥-3 and/or • MUAC <125mm and ≥115mm and • No Oedema on feet 	<ul style="list-style-type: none"> • WHZ/WLZ <-3 or ≥-2 and • MUAC <115mm and ≥125mm or • Has Oedema on feet 	For SAM children, refer child to outpatient or inpatient facility (Refer to Appendix G for exact protocols to follow)
Medical Complications	No medical complications (e.g. features of severe illness as defined by Integrated Management of Childhood Illness in Appendix F – no severe nausea/vomiting, no severe dehydration or pneumonia)	Yes, child has medical complications	Refer child to health facility. Ensure caregiver has transportation to go and follow-up within 2-3 days to ensure medical treatment was given to child
Multiple children between 6-59 months in household	If multiple children in one household are 6-52.9 months of age, include the youngest child	Do not include older children in study if multiple children in one household are 6-52.9 months of age	
Child resides in study area	Child resides in study area and will not leave the study area for more than 2 weeks in the upcoming 3 months	Do not admit child who lives outside the study area routinely or will be outside of the study area for more than 2 weeks in the upcoming 3 months	
Verbal/Written Consent	Verbal/Written consent provided by caregiver	Do not admit children if caregiver refuses to provide verbal/written consent	
Next Step	If all above inclusion criteria are met, include child into study	If child falls into any exclusion criteria, refer to the Next Steps column to know how to proceed	

3.5 METHODOLOGY

A mass nutrition screening/census will be conducted in all 20 villages to identify the potential child participants for the study that meet the inclusion criteria 2-4 weeks prior to the Baseline assessment. In addition, formative research will be conducted including a wealth ranking, transect walk, market survey, focus group discussion, seasonal calendar, and positive deviance inquiry (PDI) including 24-hour recall will be conducted to identify the major challenges contributing to malnutrition in the community, including behaviours, cultural beliefs, and food taboos. Positive Deviant households, which are low resource (poor) households with healthy children will be interviewed and observed in a 1-2 hour interview/observation session using tools from *World Vision's Positive Deviance/Hearth Training of Facilitators Manual*³ to identify local solutions and design them into six key messages for the Hearth (Education) sessions. The formative research results will be used to also design the nutrient-dense rehabilitation menu that will be cooked by the participant caregivers during the Hearth sessions. The participant caregivers will contribute most of the ingredients for the rehabilitation menu as well. Hearth sessions will run for 1-2 days per day for 12 days in total. Table 2 outlines the interventions and protocols for PDH and SOC.

Table 2 – Nutritional protocol and interventions for PDH and SOC

Topics	PDH	SOC
Program preparation and design	<ul style="list-style-type: none"> Formative research conducted using WV PDH Trainer of Facilitator manual to design 6 key contextualized messages and design 2 nutrient-dense meals (Hearth meal) consisting of locally available low cost foods Ensure all children are given age appropriate immunization, deworming, and Vitamin A in past 6 months at least 2 weeks before starting Hearth sessions 	<ul style="list-style-type: none"> Maintain regular standard of care services at Health Centre Screening acute malnutrition and referral of children to health centre for infant and young child feeding counselling for MAM children and refer to IMAM services for SAM children
Admission Criteria	<ul style="list-style-type: none"> WHZ/WLZ <-2 and ≥-3 or MUAC <125mm and ≥115mm No medical complications (e.g. no features of severe 	<ul style="list-style-type: none"> WHZ/WLZ <-2 and ≥-3 or MUAC <125mm and ≥115mm No medical complications (e.g. no features of severe

³ <https://www.wvi.org/nutrition/publication/pd-hearth-training-facilitators-manual>

	<p>illness as defined by Integrated Management of Childhood Illness – no severe nausea/vomiting, no severe dehydration or pneumonia) (9)</p> <ul style="list-style-type: none"> • No Oedema on feet • Refer to PDH programme 	<p>illness as defined by Integrated Management of Childhood Illness – no severe nausea/vomiting, no severe dehydration or pneumonia) (9)</p> <ul style="list-style-type: none"> • No Oedema on feet • Refer to IYCF counselling session at health centre
Treatment Frequency and Group Size	<ul style="list-style-type: none"> • 12 Days of Hearth (8-10 caregivers-children pair per Hearth session) (about 2 hours per session) • Caregivers bring all low cost, nutrient-dense ingredients for Hearth meal and cook it together to practice and learn (if too poor, caregivers are allowed to bring firewood or water to be used at the session); children fed Hearth meal (consecutive 12 times), Caregivers given 6 key Hearth messages twice in 12 days (1 message per day) 	<ul style="list-style-type: none"> • Basic health and nutrition services (including growth monitoring promotion, IYCF counselling, vitamin A supplementation, deworming, and immunization if operating at health centre)
Source of Food Contribution	<ul style="list-style-type: none"> • Caregivers bring most ingredients for Hearth meal and cook it together to practice and learn (use low cost, nutrient-dense foods identified through formative research) 	N/A
Follow-up protocol	<ul style="list-style-type: none"> • 2 weeks of Follow-up by volunteers using mobile phones (2-3 times a week to ensure behaviour change sustained at home) 	<ul style="list-style-type: none"> • SOC group will be provided opportunity to join PDH program at end of study •

	<ul style="list-style-type: none"> • Repeat Hearth if child did not rehabilitate at 3 months (max. of 3 rounds) • Hearth sessions repeat once every 3 months • 	
Data Collection Periods	<ul style="list-style-type: none"> • Assess monitoring of weight, height/length, and MUAC at Day 1, Day 12, Day 30, 60 using volunteers • Assess recovery at 3 months (Day 90) • Assess sustained recovery at 6 month follow-up (Day 180) 	<ul style="list-style-type: none"> • Assess monitoring of weight, height/length, and MUAC at Day 1, Day 12, Day 30, 60 using volunteers • Assess recovery at 3 months (Day 90) • Assess sustained recovery at 6 month follow-up (Day 180)
Dosage of non-SFF	Supplementary Nutrient Dense Hearth Meal given for 12 days: <ul style="list-style-type: none"> • Calorie (600–800 kcal), protein (25–27g), vitamin A (300 RAE), vitamin C (15–25mg), iron ($\geq 8\text{mg}$), and zinc ($\geq 3\text{mg}$) requirements - electronic menu calculator used 	According to MOH guidelines, health centres should provide IYCF counselling to caregivers to cook nutrient-dense meal at home
Criteria for Cured/Recovered	<ul style="list-style-type: none"> • WHZ/WLZ ≥ -2.0 and/or MUAC $\geq 125\text{mm}$ (dependent on which criteria the child was admitted on) and WAZ ≥ -3.0 up to Day 90 • No Oedema on feet • The children who did not recover after 1 round of Hearth in the first 3 months will repeat in another round of Hearth (recovery criteria will be assessed looking at 	<ul style="list-style-type: none"> • WHZ/WLZ ≥ -2.0 and/or MUAC $\geq 125\text{mm}$ (dependent on which criteria the child was admitted on) (recovery criteria will be assessed looking at children with/without WAZ ≥ -2 at 3 months recovery in addition to above definition of recovered) • No Oedema on feet

	children with/without WAZ \geq -2 at 3 months recovery in addition to above)	
Criteria for Defaulter	<ul style="list-style-type: none"> Absent more than 2 times over 90 days from Hearth session Child moves away from study area or leaves the study area for more than 2 weeks during the 3 month duration of the study 	<ul style="list-style-type: none"> Child moves away from study area or leaves the study area for more than 2 weeks during the 3 month duration of the study
Sustained Recovery	<ul style="list-style-type: none"> Remains WHZ/WLZ\geq-2.0 and/or MUAC\geq125mm (dependent on which criteria the child was admitted on) (compare to group who had WAZ\geq-3.0 at 3 months) at 6 months 	<ul style="list-style-type: none"> Remains WHZ/WLZ\geq-2.0 and/or MUAC\geq125mm (dependent on which criteria the child was admitted on) (compare to group who had WAZ\geq-3.0 at 3 months) at 6 months
CHW Supervision	<ul style="list-style-type: none"> Project staff supervise Hearth volunteers monthly 	<ul style="list-style-type: none"> Health Centre staff supervise community health workers according to MOH guidelines and protocol
Referral to Health Facility	<ul style="list-style-type: none"> Child referred to health facility if child is SAM (MUAC<115mm and/or WHZ/WLZ<3.0 or oedema present), or has medical complications or poor appetite If child does not gain minimum 400g within 30 days after second round of Hearth, child is referred to health facility for underlying medical complications 	<ul style="list-style-type: none"> Child referred to health facility if child is SAM (MUAC<115mm and/or WHZ/WLZ<3.0 or oedema present), or has medical complications Refer child to IYCF counselling sessions if child is MAM

The selected villages will be mobilized and invited to participate in the study (see community invitation letter attached in [Appendix H](#)). Formation of clusters to be included in the study will be identified using a mass nutrition screening conducted 2-4 weeks prior to conducting the baseline assessment.

Sample Size. Sample size calculation was made using R Studio. Assuming a conservative intra-cluster correlation coefficient (ICC) of 0.1 based on results of another study assessing stunting in Bangladesh⁴, then with 10 clusters in each arm – each recruiting 20 children (having adjusted for a 20% loss-to-follow up rate), we would have 90% power to detect a 25% inter-group difference in the percentage of children recovered within 3 months comparing the PDH+SOC group vs. SOC only group and estimating the recovery from uncomplicated MAM to be 5% for the SOC only group, a conservative difference in recovery because Asia seems to have a trend of slower rehabilitation than most African countries (10,11), using a two-sided statistical test at the 5% level of significance. Cluster will be defined by 250 homesteads based loosely on existing administrative villages seeking to maximize the distance between clusters. Randomized clusters with similar SES and MAM prevalence will be assigned 1:1 to PDH+SOC and SOC only groups. Therefore, with a cluster size of 20 and 20 children per cluster, a total of 400 children 6-59.9 months of age will be recruited in this Bangladesh study.

8 total Focus Group Discussions (FGD) will be conducted with 10 caregivers per FGD (4 FGDs) and 10 PDH volunteers per FGD (4 FGDs) in 4 randomly selected villages (in only the PDH arm), 4 key informant interviews (KIIs) including Ministry of Health staff, and 2 KIIs with World Vision Bangladesh staff. A total of 886 participants will be included in the study (400 caregivers + 400 children 6-59 months of age + 80 FGD participants in FGDs + 4 KII with MOH staff + 2 WVB staff = 886 participants).

Sampling. An initial nutrition assessment will be conducted 2-4 weeks before collecting baseline data in the Purbadhala Upazila. The list will be utilized to group villages in close proximity with similar number of households with under five children and SES into clusters and to estimate the number of eligible MAM children per cluster to ensure adequate sample size is met. All uncomplicated MAM and SAM children will be included in the study, but only MAM children will be included in the sample size. At times when there are <6 MAM children to run a Hearth session, some children who are not AM, but has a WAZ<-2 may be included in the PDH program, but not in the study. Simple random sampling will be used from those who meet the inclusion criteria to select the children to be admitted for the study. Randomization sequence will be generated using an online sequence generator (12) to select the clusters and assign them to the PDH+SOC or SOC only group. Due to the nature of the interventions, this is not a fully blinded study. CHWs and project staff must know if they are implementing PDH+SOC so they know how to treat the MAM children and follow-up. However, since clusters are divided at village level, it will reduce contamination between the intervention and control groups (see Figure 1 for detailed sampling diagram).

⁴ <https://journals.plos.org/globalpublichealth/article?id=10.1371/journal.pgph.0004890>

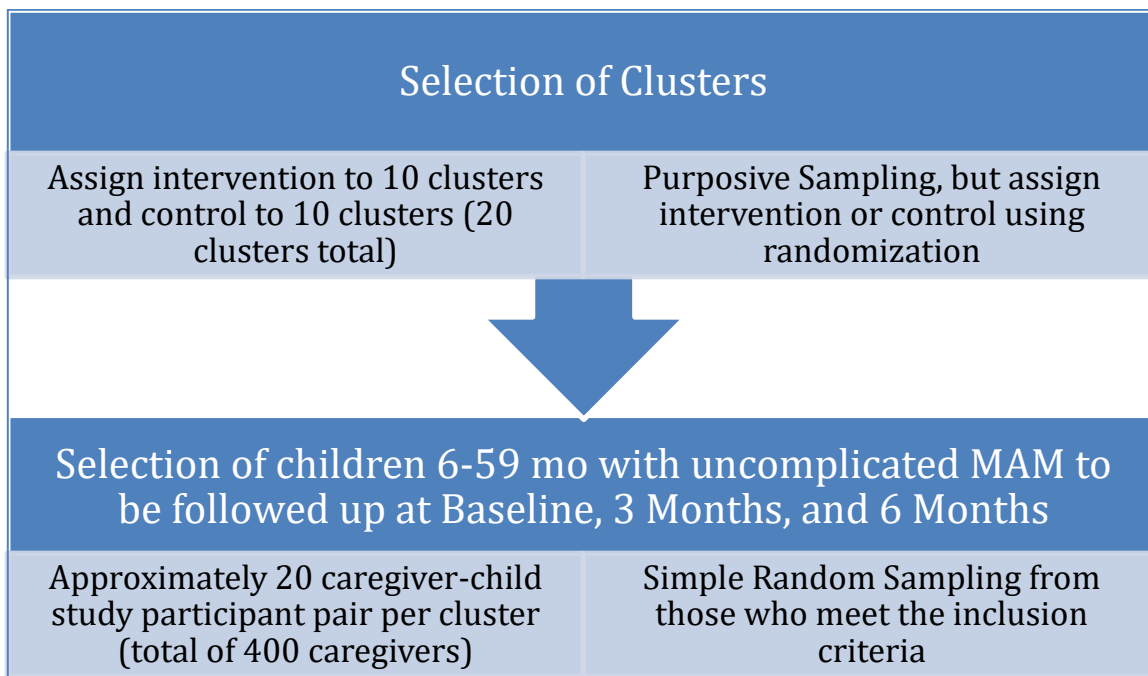


Figure 1. Sampling flow diagram

For the study, a mass nutrition screening/census will take place in all 20 villages (April/May 2026) prior to the Baseline (May 2026) to ensure adequate MAM children are identified in each village. If additional villages are needed to meet the sample size, additional villages may be added.

A baseline assessment will be conducted once the child-caregiver participant pairs consent to being included in the study. The SOC or PDH+SOC intervention will be randomly assigned to each cluster and the selected clusters will be far apart enough that contamination will be prevented.

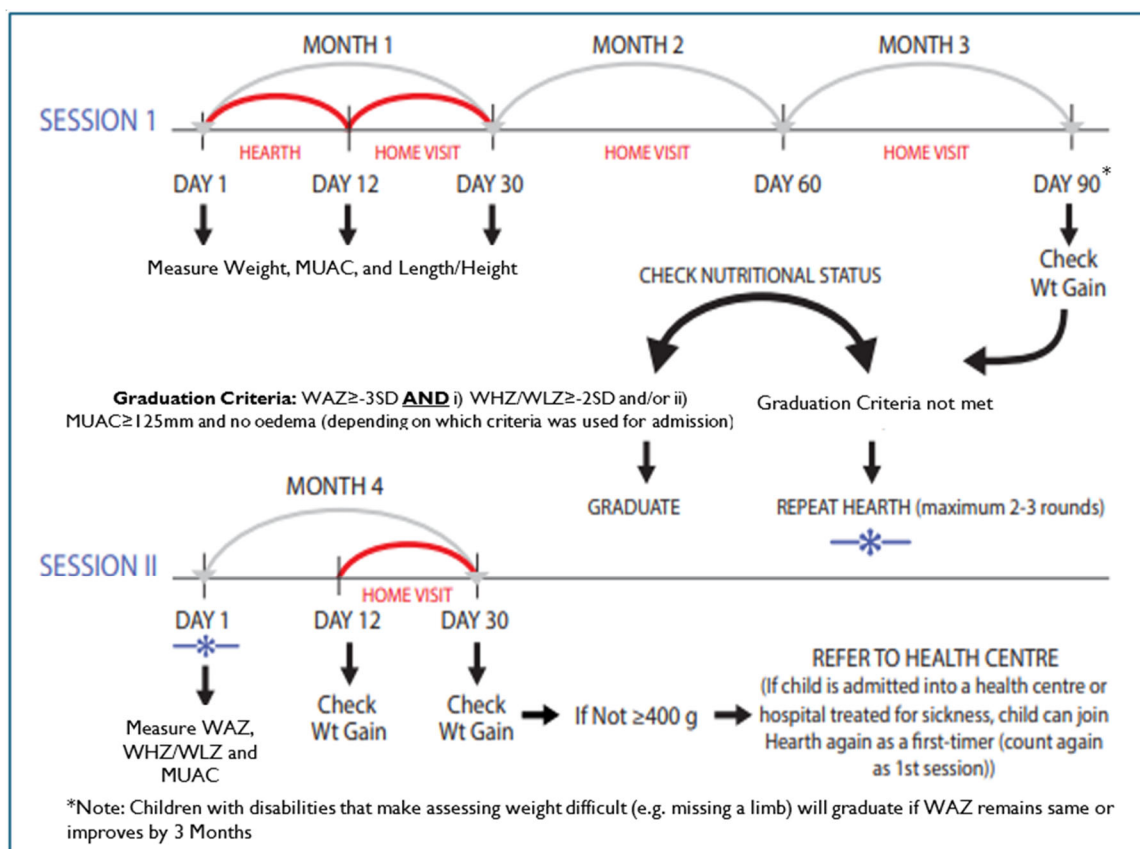


Figure 2. Schedule of enrolment, interventions, and assessment (PDH protocol)

The PDH cluster child-caregiver participants pairs will begin PDH within 2 weeks of the baseline assessment. All PDH education sessions will begin within the first 2 weeks of June 2026, following the PDH protocol in Figure 2. SOC services will be provided by health workers and volunteers, supported by World Vision. PDH will be implemented by PDH volunteers with support from World Vision. All refresher trainings for IMCI, GMP, and anthropometry will be provided by World Vision and PDH volunteer training will be provided by World Vision Bangladesh using the *PDH Volunteer Training Manual*⁵.

For the costing analysis, the project expenditure will be documented every quarter for the PDH+SOC treatment arm and the SOC-only arm; WV's project implementation costs will be captured through quarterly budget reports (evaluation and research costs will be excluded). Furthermore, caregivers and volunteers will be asked to estimate the time they spent attending Hearth sessions and in the follow-up visits so the productivity costs of caregivers and volunteers' time could be costed using the PACE excel costing tool and icddr,b's costing tool. The local MOH staff will also be interviewed to assess the productivity costing of the SOC-only arm.

⁵ <https://www.wvi.org/nutrition/publication/positive-deviance-hearth-volunteer-training-manual>

3.6 DATA COLLECTION SCHEDULE

Data collection will be conducted by a local academic partner, International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b) to safeguard against potential bias (see Figure 3 for details).

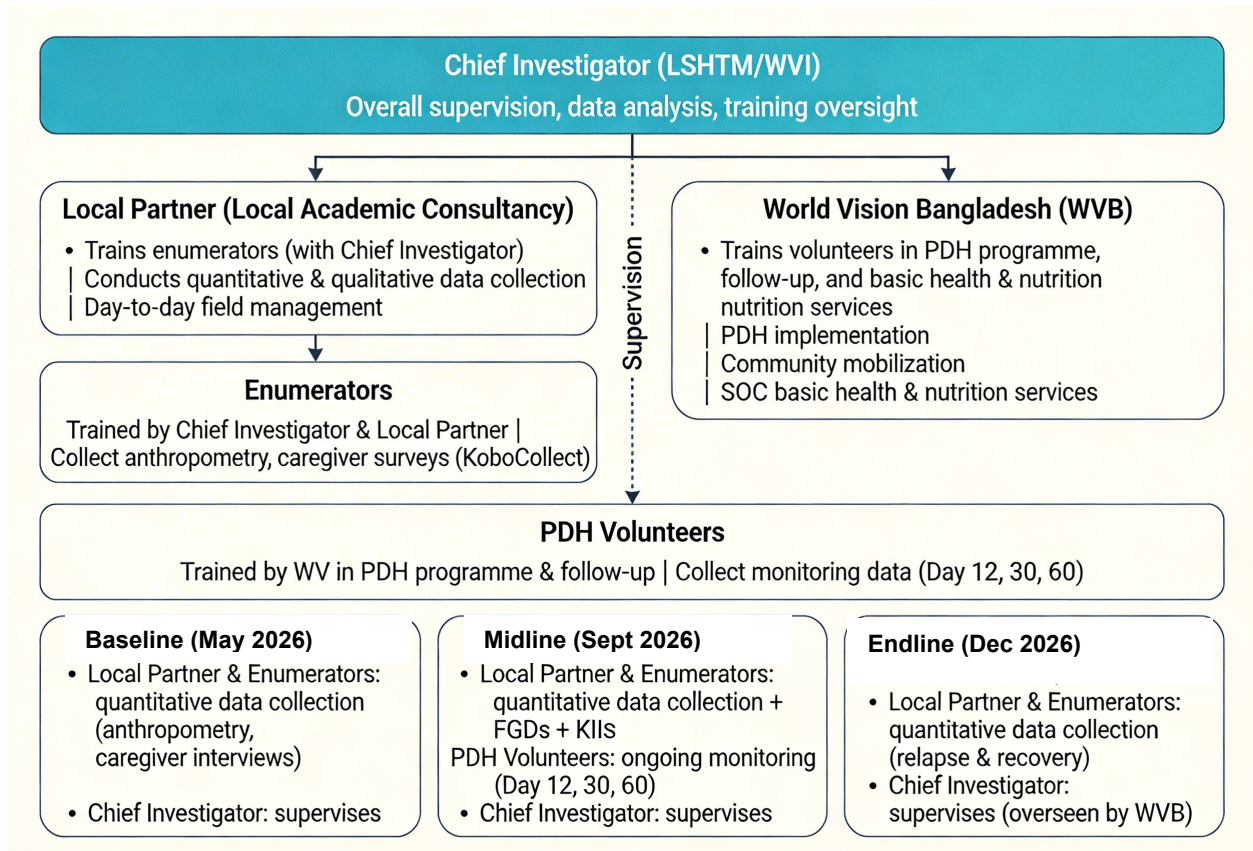


Figure 3. Organogram of data collection process and key persons responsible

Icddr,b, under the supervision of the Chief Investigator, will conduct the enumerator trainings prior to each data collection period. A standardization exercise with children will be included as part of the enumerator's anthropometry training. The Emergency Nutrition Assessment (ENA) software will be used at the end of each day to assess the anthropometry data quality and refresher trainings will be provided to enumerators as needed before the next day's data is collected. All quantitative and qualitative questionnaires will be field tested to ensure translation from English to Bangla was done smoothly. Enumerators will use KoboCollect to enter data into password protected phones. The Kobo tool will have warnings and prompts to ensure implausible data is flagged upon data entry and data could be rechecked immediately. Data will be uploaded to a server in Bangladesh and all data will be de-identified prior to exporting outside the country. Only the supervisory local partner and chief investigator will have access to the identifiable data. For more information on data management procedures, refer to [Appendix B](#).

Data will be collected at:

- Baseline (Day 1 quantitative assessment collected by local partner)
- Day 12, Day 30, Day 60 (monitoring data collected by volunteers)
- 3 Month (primary, secondary, and exploratory outcomes; quantitative and qualitative assessments collected by local partner)
- 6 month (sustained recovery and recovery after 2nd round of Hearth collected by local partner)

3.7 MEASUREMENTS

Quantitative Data (Day 1, 3 month, and 6 month):

- Child anthropometry: weight, MUAC, height/length using WHO techniques.
- Caregiver interviews covering feeding practices, WASH, food security, illnesses, and household factors.

Qualitative Data (Day 90):

- 8 Focus Group Discussions (PDH caregivers and volunteers, 4 each),
- 4 Key Informant Interviews (Ministry of Health staff)
- 2 Key Informant Interviews (World Vision staff) regarding costing

3.8 RANDOMIZATION

Each village will be assigned a number (1–20) and will be randomly assigned to PDH+SOC or SOC-only using the Emergency Nutrition Assessment (ENA) software.

3.9 REFERRAL MECHANISM

Any child showing medical complications during screening or follow-up will be immediately referred to the nearest health facility following the National Integrated Management of Childhood Illness (IMCI) protocols (Refer to [Appendix F](#)). Any identified SAM children will be referred to outpatient facilities and if the child has poor appetite in PDH (see [Appendix J](#)) or other medical complications, child will be referred to the in-patient facilities (as per the [national CMAM guidelines](#)) and transportation will be provided by World Vision. All referral cases and adverse events will be recorded and reported to the Data Security and Management Board (DSMB). The DSMB charter can be found in [Appendix I](#). In addition, WV staff and health workers will follow-up with these household within 2-3 days of referral to ensure medical treatment was sought.

3.10 DATA COLLECTORS

A local academic or data collection consultancy will conduct all quantitative and qualitative data collection. All enumerators will be trained by the local partner, under the supervision of the chief investigator and will work in pairs (approximately 18 enumerators in 9 pairs).

Trainings and Tools. An 8-day training will be provided for PDH using *World Vision's Positive Deviance/Hearth (PDH) Training of Facilitators Manual* and on Child-Caregiver Clubs using the *Child-Caregiver Club Training Manual* and a 3-Day refresher training will be given after the first month. All CHWs and enumerators will be trained in how to collect height/length (using laser device), weight, and MUAC measurements accurately as mentioned in Study 1.

4. STATISTICAL ANALYSIS

Statistical analysis will be conducted at the individual level with appropriate adjustment for clustering within 20 clusters. Descriptive summaries of participant characteristics by arm will be tabulated. Descriptive statistics for continuous variables will include the mean differences with 95% confidence interval and for binary outcomes effect estimates will be presented as risk ratios (RR) or odds ratios (OR) with 95% confidence intervals. The main analysis of the primary and secondary outcomes will be intention-to-treat given that this is a superiority trial. Additionally, per-protocol analyses will be presented for all secondary outcomes. The primary outcome will be compared between the PDH and SOC using Generalized Estimating Equation (GEE) to account for clustering at the village-level and repeated measurements over time. If GEE fails to converge, the Difference-in-Difference model will be used to measure effects (see [Appendix A](#) for the detailed statistical analysis plan).

For the qualitative data analysis, FGDs and Key Informant Interviews will be recorded and transcribed verbatim in Bangla translated into English using MS Word, and checked by bilingual enumerators for accuracy. Transcripts will be uploaded to NVIVO or MAXQDA and analyzed using both deductive (predefined themes) and inductive (emerging themes) coding by the chief investigator. A code mapping exercise will be conducted and finalized as a codebook. Frequency analysis will be used to measure how often themes appear and report as raw counts or percentages.

5. DATA MANAGEMENT

The detailed data management plan of the software and devices to be used to collect and analyze the data for the study can be found in [Appendix B](#).

6. ETHICAL CONSIDERATIONS

Ethical approval was received from LSHTM's ethics committee (Ethics Ref: 32954) and Dhaka University of Health Economics Ethics Committee (IHE/IRB/DU/04/2026/Final). Additional ethical approval is being sought from icddr,b's ethics committee as per icddr,b's protocol. Written consent will be sought by all caregivers prior to collecting any data including taking anthropometric measurements and conducting caregiver surveys by trained enumerators. The consent form will include a statement about agreeing to participate in the study and that all information gathered are free to be used under the condition of keeping the identity of the child and caregiver, confidential and that they are able to withdraw from the study at any time. In addition, written consent will be sought prior to conducting Focus Group Discussions and Key Informant Interviews and the information sheet and consent forms can be found in [Appendix C](#). See ethics training certificate of the Chief Investigator in [Appendix D](#).

7. DISSEMINATION PLAN

The dissemination plan ensures that findings from the PDH MAM trial are shared with all relevant scientific, governmental, and community stakeholders in Bangladesh and internationally. Key components include:

11.1 National-Level Dissemination

- Presentation of results to the Ministry of Health and Family Welfare (MOH), including the Institute of Public Health Nutrition (IPHN).
- Policy briefings for district and upazila health authorities in Mymensingh Division.
- Sharing findings with community health worker supervisors, Health Assistants, and local partners involved in intervention delivery.

11.2 Community Dissemination

- Village-level dissemination meetings with caregivers, PDH volunteers, and community leaders.
- Use of simplified Bengali-language summaries and visual materials to ensure accessibility.
- Feedback sessions to support future local scale-up of PDH practices.

11.3 Academic Dissemination

- Submission of at least one manuscript to a peer-reviewed open-access global nutrition or public health journal.
- Presentation of findings at national and international conferences related to maternal–child nutrition, public health, community-based management of malnutrition, and implementation science.
- Inclusion of results in the PhD thesis submitted to LSHTM.

11.4 Global Nutrition and Humanitarian Community

- Sharing findings with UNICEF, WHO, the Global Nutrition Cluster, and the Complementary Feeding Collective.
- Uploading anonymised datasets and study tools to Open Science Framework (OSF) repository with a DOI to enable transparent and responsible data reuse.

11.5 World Vision

- Dissemination workshops with World Vision Bangladesh and World Vision International technical teams.
- Integration of findings into World Vision’s internal PDH guidance, training materials, and operational recommendations for non-SFF MAM treatment in food-secure contexts.

All dissemination will maintain strict confidentiality. No identifiable information will appear in reports, presentations, or publications.

8. TIMELINE

Phase	Key Activities	Timeline	Persons Responsible
Preparation & IRB	Ethics submission and approval, staff mobilization,	Oct 2025 – Feb 2026	LSHTM/WVI/WVB

	caregiver survey and KII/FGD tools development and translation, KoboTool Development		
Formative Research	PDH – Situational Analysis and Positive Deviance Inquiry	April 2026	WVB
Enumerator Training	Training Enumerators in Anthropometry Techniques, Caregiver Survey, KII/FGD tools	May 2026	Icddr,B (overseen by LSHTM/WVB)
Baseline Data Collection	Quantitative data collection	May 2026	Icddr,B (overseen by LSHTM/WVB)
PDH Implementation SOC Implementation	PDH rollout in 10 intervention villages Provide basic health and nutrition services to SOC villages	June-Aug 2026 & Sept-Nov 2026	WVB
Midline Data Collection (includes qualitative data)	Follow-up at Month 3 Quantitative Data collection & FGD/KIIs	Sept 2026 for Enumerator Training & Data Collection	Icddr,B (overseen by LSHTM/WVB)
Sustained Recovery – Endline Evaluation (includes qualitative)	6-month follow-up of recovered children (Quantitative Data collection)	Dec 2026 for Enumerator Training & Data Collection	Icddr,B (overseen by LSHTM/WVB)
Dissemination	Final data sharing and report dissemination	February 2026	LSHTM/icddr,b

9. EXPECTED TANGIBLE DELIVERABLES

Deliverables	Tasks	Actors	End Date
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1	Study Protocol for the overall research	Develop the research proposal for the pilot of the laser height/length measuring device with detailed timeline and budget for FY24	Diane Baik (LSHTM/WVI), WVB, Local Academic Partner	Oct. 2025
2	Submit IRB package for local and international approval	Consolidate all the docs needed for the IRB package Submit the IRB package to Dhaka University	Mezan/Diane/Grana	Nov. 2025
3	Get IRB approval	Pay for IRB when approved	Mezan/Diane Baik	Jan. 2026
4	PDH, CCC, and Anthro refresher training workshop and conducting formative research (Situational Analysis and PDI to design Hearth messages and menus)	Facilitate refresher training workshop for Commune Health workers and volunteers	WVB and Diane Baik (Share all findings with Diane from Formative Research)	May 2026
5	Logistical Field Prep	Book hotels, mobilize community, mobilize volunteers, health centre staff and experts (WVB)	Mezan/Diane	April 2026
6	Baseline Evaluation Data Collection	Conduct data collection	Local academic partner WVB Diane Baik	May 2026
7	PDH Implementation in 14 villages	Begin conducting PDH in 14 villages (some villages may need to implement 2 Hearth sessions at one time)	WVB	Jun-Aug 2026 & Sept-Nov 2026

8	Data Analysis Output	Data analysis led by Diane	Icddr,B & Diane Baik	June 2026
9	Midline Evaluation Data Collection	Follow-up at Month 3	Icddr,B & Diane Baik	Sept 2026
10	Data Analysis Output	Data analysis led by Diane	Icddr,B & Diane Baik	Oct 2026
11	Sustained Recover Endline Evaluation Data Collection	Follow-up at Month 6	Icddr,B & Diane Baik	Dec 2026
12	Sustained Recovery Analysis Output	Data analysis led by Diane	Icddr,B & Diane Baik	Feb 2027
13	Manuscript Draft #1 (quantitative paper)	Delegate different sections of manuscript to various team members to write up	Diane Baik Icddr,b WVB	May 2027
14	Qualitative Data Analysis Output	Data analysis led by Diane	Diane Baik, icddr,b	June 2027
16	Manuscript Draft #2 (qualitative paper)	Delegate different sections of manuscript to various team members to write up	Diane Baik Local Academic Partner WVB	Aug 2027
17	Dissemination Workshop	Develop PowerPoint presentation	Organized by WVB and Diane Baik All	November 2027

10. BUDGET



Budget PDH MAM
Research Proposal (f

11. Conflict of Interest Statement

The Chief Investigator (CI) is a staff member of World Vision International (WVI), an organization that has adopted the Positive Deviance/Hearth (PDH) approach as a core programming strategy since 2010. The CI has professional experience in health and nutrition programming and has previously engaged with PDH within a programmatic context. This institutional affiliation and prior exposure may create a potential for perceived or unintentional bias in study design, implementation, analysis, or interpretation.

The CI acknowledges that professional investment in community-based nutrition approaches, including PDH, could consciously or unconsciously influence expectations regarding study outcomes. Recognizing this, several safeguards have been incorporated to minimize bias and maintain scientific rigor.

Safeguards to Mitigate Bias

1. **Pre-specification of Outcomes and Analysis Plan**

All primary and secondary outcomes, definitions (including recovery and relapse criteria), and statistical analysis methods are pre-specified in the study protocol, research proposal, and statistical analysis plan prior to data analysis. Any deviations will be transparently documented and justified.

2. **Trial Registration and Transparency**

The study will be prospectively registered in a recognized clinical trial registry. The protocol and analysis plan will be time-stamped to reduce risk of selective reporting or post hoc analytic decisions.

3. **Separation of Roles**

The various stakeholders will have distinct roles. WV staff will focus on implementation of the PDH program and implementing the basic health and nutrition services for the standard of care group, including conducting the volunteer training and follow-up and daily programme implementation. The local partner/consultancy (third-party) will conduct all the evaluations and data collection. The CI will supervise and oversee the overall training and data collection on the ground at Baseline, Midline, and Relapse/Endline evaluation. Data collectors will be trained on standardized measurement procedures and will not be involved in program implementation or supervision decisions.

4. **Independent Oversight and Analysis**

Statistical analysis will be verified by CI's statistician supervisor who is not an employee of World Vision and icddr,b's lead biostatistician. Supervisory oversight from the academic institution (LSHTM) provides an additional layer of independence.

5. **Commitment to Reporting Regardless of Findings**

The research team commits to reporting findings transparently, irrespective of whether results are favourable, null, or unfavourable to the PDH approach. Publication decisions will not be contingent upon outcome direction.

Reflexive Practice in Qualitative Components

For qualitative data collection and interpretation, reflexive memo-ing and team-based analysis will be conducted by the local partner to critically examine assumptions and interpretations. The CI will lead the qualitative data analysis after all translation and

transcription is complete. Coding will be done by two individuals to minimize bias. Divergent or negative perspectives will be actively sought and reported.

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Evaluation of Positive Deviance/Hearth (PDH) for Treating Uncomplicated Moderate Acute Malnutrition (MAM) in Mymensingh, Bangladesh

Statistical Analysis Plan (SAP)

Version: 1.0

Date: May 5, 2026

APPROVAL

The undersigned hereby declare that they have prepared/examined the Statistical Analysis Plan and agree to its form and content. In addition, they confirm that to the best of their knowledge the Statistical Analysis Plan contains all information relevant for the conduct of Statistical Analysis of the study.

Prepared by: Chief Investigator

Diane Baik

_____05/05/2026_____

Date

Approved by: Senior Statistician/Supervisor

Dr. Charles Opondo, PhD

Date

REVISION HISTORY:

VERSION	AUTHOR	DATE OF IMPLEMENTATION	DESCRIPTION OF MODIFICATION
1	Diane Baik	May 5, 2026	First version

1. Scope

This Statistical Analysis Plan (SAP) outlines the statistical methods and summaries that will be provided for analyzing the effect of the Positive Deviance/Hearth (PDH) programme plus Standard of Care (SOC) versus SOC alone on Moderate Acute Malnutrition (MAM) recovery outcomes in a cluster-randomized controlled trial (cRCT) conducted in Purbadhala Upazila, Mymensingh Division, Bangladesh. The document has been written based on information contained in the study protocol Version 3.0 (05/05/2026). The study aims to assess:

1. The impact of PDH+SOC vs. SOC-only on anthropometric recovery (WHZ/WLZ, MUAC, WAZ) and other nutrition outcomes over time.
2. The treatment effect of PDH+SOC vs. SOC-only on the primary outcome (MAM recovery within 3 months), secondary outcomes (Average daily weight gain, non-response, sustained recovery at 6 months, etc.), and exploratory outcomes (behaviour change, caregiver wellbeing, admission type WHZ/WLZ vs. MUAC, etc.).

2. Introduction

Acute malnutrition (wasting) remains a major global health issue, affecting 31.7 million children under five, particularly in non-humanitarian, food-secure settings like South and Southeast Asia. In Bangladesh, wasting prevalence is still high (~11%), with some areas (e.g., Mymensingh) exceeding critical thresholds. Despite progress in other nutrition indicators, MAM remains insufficiently addressed, highlighting the need for sustainable, community-based solutions.

Current MAM treatment relies heavily on specially formulated foods (SFFs) such as Ready-to-use supplementary food (RUSF) and fortified blends. However, these approaches have key limitations:

- Only moderate improvements in recovery
- High cost and supply chain issues (e.g., stockouts)
- Poor integration into routine health systems

As a result, many children with MAM receive no treatment until their condition worsens to SAM. The 2023 WHO guidelines highlight a critical evidence gap: lack of rigorous studies on non-SFF, food-based approaches for MAM treatment.

Positive Deviance/Hearth (PDH) is a promising alternative. It is a community-based, low-cost intervention that uses:

- Locally available nutritious foods
- Caregiver education and behavior change
- Practical cooking sessions
- Follow-up home visits

Unlike SFF-based models, PDH focuses on sustainability, local capacity building, and long-term behavior change. Existing evidence (including a 2023 meta-analysis) suggests PDH improves child growth and feeding practices, but robust clinical trials for MAM treatment are lacking.

Given Bangladesh's high MAM burden, strong community health infrastructure, and food-secure context, it is well-positioned to test PDH as a sustainable alternative. This study aims to compare PDH with Standard of Care (SOC) to generate evidence for policy, global guidelines, and scale-up strategies.

2.1 Summary of PDH Approach

PDH is a community-driven nutrition rehabilitation model developed in Vietnam (1990). It targets children with uncomplicated undernutrition (including MAM) and emphasizes behavior change using local solutions.

Key features:

- Identifies “positive deviant” families who achieve good nutrition despite poverty
- Uses formative research (diet recalls, market surveys, seasonal calendars) to design local menus
- Conducts 12-day “Hearth” sessions where caregivers prepare nutrient-dense meals
- Meals meet defined nutritional requirements using low-cost, locally available foods
- Caregivers contribute ingredients/resources, reinforcing ownership
- Includes follow-up home visits to sustain behavior change
- Children are typically discharged after ~12 weeks if nutritional recovery is achieved

Overall, PDH emphasizes practical learning, cultural acceptability, and sustainability without reliance on external food products.

2.2 Hypothesis and Objectives:

Primary Objective:

1. Determine the treatment effect and impact of a non-SFF treatment intervention, Positive Deviance/Hearth (PDH), to treat ($WHZ/WLZ \geq -2.0$ or $MUAC \geq 125mm$ (dependent on which criteria the child was admitted on; if child admitted for both WHZ/WLZ and $MUAC$ then recovery defined by either WHZ/WLZ or $MUAC$ will be used), and no oedema) uncomplicated MAM children 6-59 months of age compared to a SOC only group after a 12-week program in Purbadhala Upazila.

Hypothesis 1: The PDH+SOC program is more effective in rehabilitating uncomplicated MAM children compared to the SOC only group.

Secondary Objectives:

1. Examine treatment effect on recovery of MAM with a stricter definition (WHZ/WLZ \geq -2.0SD or MUAC \geq 125mm (dependent on which criteria the child was admitted on; if child admitted for both WHZ/WLZ and MUAC then recovery defined by either WHZ/WLZ or MUAC will be used), and WAZ \geq -3.0 and no oedema), comparing average daily weight gain, weight-for-age z-score (WAZ), and MUAC.
2. Assess sustained recovery at 6 months (sustained recovery defined by WHZ/WLZ \geq -2.0 or MUAC \geq 125mm (dependent on which criteria the child was admitted on; if child admitted for both WHZ/WLZ and MUAC then recovery defined by either WHZ/WLZ or MUAC will be used), and no oedema).
3. Sustained recovery will be compared by regular recovery definition or stricter recovery definition including WAZ \geq -3.0.
4. Assess recovery after 2 rounds of Hearth and determine sustained recovery and sustained recovery with stricter recovery (definition including WAZ \geq -3.0), defined as a child sustaining recovery at 6 months (WHZ/WLZ \geq -2.0 or MUAC \geq 125mm).
5. Assess non-response at 4 months (30 days after second round of Hearth).
6. Estimate the incremental costs and cost per beneficiary of PDH at 6 months.

3. Study Methods

3.1 Protocol version

This analysis plan is based on the current version of the protocol; Version 3.0, 5 May 2026.

3.2 Study Design

- **Design:** Cluster-randomized controlled superiority trial with two parallel groups: an intervention arm allocated to receive PDH and standard of care (SOC) and a control arm allocated to receive SOC-only.
- **Number of Clusters:** 20 clusters (10 per arm), each including 20 children/families (outcomes assessed in one child per family, where the youngest child will be selected if there are multiple children per family)
- **Time Points of data collection:**
 - Baseline (only Quantitative data collection) (Day 1)
 - Monitoring (Day 12, Day 30, Day 60 – both arms, collected by volunteers)
 - Midline (Quantitative and Qualitative data collection)/Primary Outcome (3 month)
 - Endline (Quantitative and Qualitative data collection)/ Sustained Recovery (6 month)
- **Arms:**
 - PDH+SOC (Intervention Arm): Positive Deviance/Hearth using locally available nutrient-dense foods + standard health and nutrition services

- SOC-only (Control Arm): Standard health and nutrition services only

3.3 Randomization

Treatment allocation will be random and in a 1:1 ratio between groups. The random allocation sequence will be computer generated. A preliminary mass nutrition survey will be conducted about 2 weeks before baseline (April 2026) with all children 6-52.9 months of age in 20 purposively selected clusters. Stratifying the randomization based on the village's demographic characteristics and acute malnutrition prevalence, a computer will be used to randomly allocate 10 clusters to PDH+SOC and 10 clusters to SOC-only, a total of 20 clusters. Quantitative data collectors will be blinded from which clusters received which intervention during baseline, midline, and endline data collection.

3.4 Sample size

Assuming a conservative intra-cluster correlation coefficient (ICC) of 0.1 based on results of another study assessing stunting in Bangladesh⁶, then with 10 clusters in each arm – each recruiting 20 children (having adjusted for a 20% loss-to-follow up rate), we would have 90% power to detect a 25 percentage point absolute inter-group difference or greater in the proportion of children recovered at 90 days comparing the PDH+SOC group vs. SOC only group using a two-sided statistical test at the 5% level of significance. This is based on estimating the recovery from uncomplicated MAM to be 5 percentage points in the SOC only group, a conservative difference in recovery because Asia seems to have a trend of slower rehabilitation than most African countries (19,39). Cluster will be defined by 250 homesteads based loosely on existing administrative villages seeking to maximize the distance between clusters. Randomized clusters with similar SES and MAM prevalence will be assigned 1:1 to PDH+SOC and SOC only groups. Therefore, with a cluster size of 20 children and 20 clusters, a total of 400 children 6-59.9 months of age will be recruited in this Bangladesh study. At baseline, the eligible children to be selected will include ages 6-52.9 months as the study will take place for 6 months. Thus, to ensure the study observes the growth of only children 6-59.9 months of age, recruitment will be of children up to 52.9 months of age to ensure at 6 months follow-up, all children will be under 60 months.

A total of 4 Focus Group Discussions (FGD) will be conducted with 10 caregivers per FGD and 4 FGDs with 10 PDH volunteers per FGD in 4 randomly selected clusters (in only the PDH arm), four key informant interviews (KIIs) including Ministry of Health staff, and two KIIs with World Vision Bangladesh staff. A total of 886 participants will be included in the study (400 caregivers + 400 children 6-59 months of age + 80 FGD participants in FGDs + 4 KII with MOH staff + 2 WVB staff = 886 participants).

⁶ <https://journals.plos.org/globalpublichealth/article?id=10.1371/journal.pgph.0004890>

3.5 Sampling

A preliminary nutrition survey will be conducted in the Purbadhala Upazila in April and May 2026. The list will be utilized to group villages in close proximity with similar number of households with under five children and SES into clusters and to estimate the number of eligible MAM children per cluster to ensure adequate sample size is met. All uncomplicated MAM and SAM children will be included in the study, but only MAM children will be included in the sample size. At times when there are less than 6 MAM children to run a Hearth session, some children who are not AM, but has a WAZ<-2 may be included in the PDH program, but not in the study. Simple random sampling will be used from those who meet the inclusion criteria to select the children to be admitted for the study. Randomization sequence will be generated using an online sequence generator (70) to select the clusters and assign them to the PDH+SOC or SOC only group. Due to the nature of the interventions, this is not a fully blinded study. CHWs and project staff must know if they are implementing PDH+SOC so they know how to treat the MAM children and follow-up. However, since clusters are divided at close village level, it will reduce contamination between the intervention and control groups (see Figure 1 for detailed sampling diagram). Furthermore, data collectors at baseline, midline, and endline will be blinded; unaware of which clusters were assigned the PDH+SOC or SOC alone. The quantitative data analysts (chief investigator and lead biostatistician from icddr,b (local academic partner institution)) will also be blinded and unaware which group belongs to the intervention or comparison group until the results are finalized. Thus, the data collection and analysis will be double blinded reducing bias in the results.

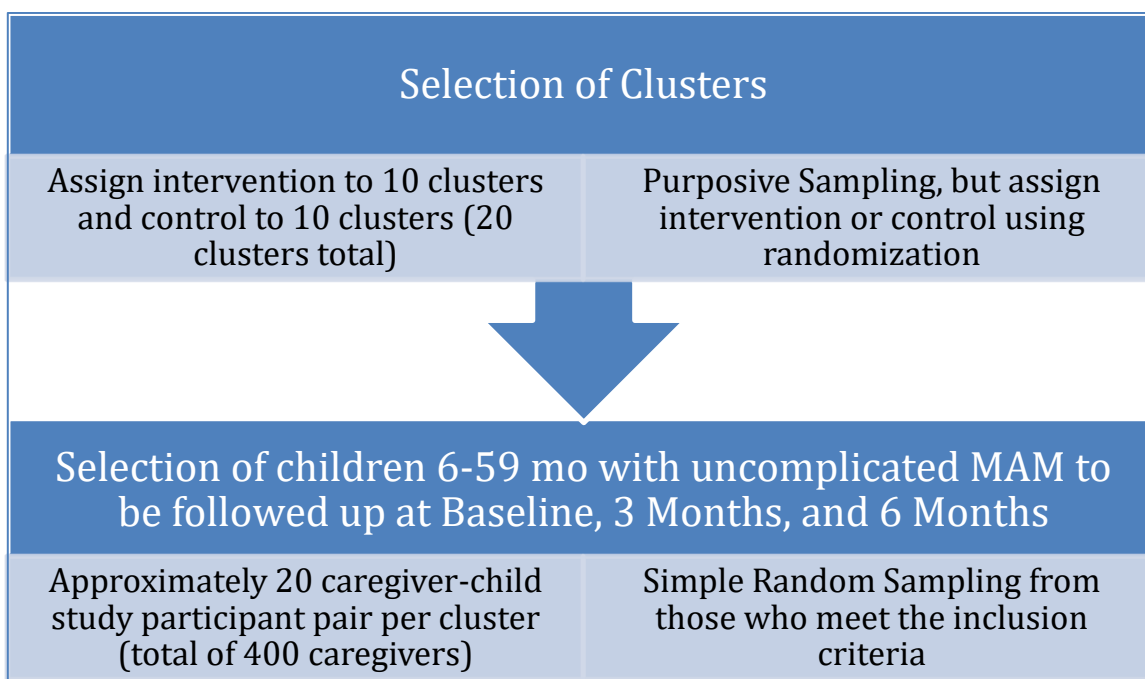


Figure 1. Sampling flow diagram

4. Outcomes

4.1 Quantitative Research:

Outcome Name	Type	Definition	Time Point	Variable Construction / Formula	Notes
Recovery (assessed in different ways):					
Primary Outcome: Rehabilitation of MAM (Primary)	Binary	Child no longer MAM: WHZ/WLZ ≥ -2.0 or MUAC ≥ 125 mm (based on admission criterion), and no bilateral pitting oedema	Within 3 months	1 = meets all criteria; 0 = does not	Standard Anthropometric Recovery
Secondary Outcomes:					
Recovery of MAM (stricter definition)	Binary	WHZ/WLZ ≥ -2.0 or MUAC ≥ 125 mm (based on admission), and WAZ ≥ -3.0 , and no bilateral pitting oedema	Within 3 months	1 = meets all criteria; 0 = does not	
Average daily weight gain (g/kg/day)	Continuous	Average rate of weight gain during follow-up	Baseline \rightarrow 3 months	(Weight at 3 months – Weight at baseline) / number of days	Average Weight Gain (g)/kg/day) formula: Weight Gain (g/kg/d) = {discharge weight in g – minimum weight g} / {minimum weight in kg x number of days between date of minimum weight and discharge day} Average Weight Gain = sum to weight gains (g/kg/day) / number of children

Weight-for-age (WAZ)	Continuous	Average WAZ (SD)	3 months	Average WAZ at 3 months	
MUAC (mm)	Continuous	Average MUAC (mm)	3 months	Average MUAC	
Non-Response	Binary	Not achieving anthropometric recovery within 4 months of initiating treatment (2 rounds of Hearth and follow-up at 30 days after 2 nd round)	4 months	1 = Non-Response; 0 = Recovered	Recovered definition: WHZ/WLZ ≥ -2.0 SD or MUAC ≥ 125 mm (based on admission criterion), and absence of bilateral pitting oedema.
Relapse:					
Sustained Recovery (standard definition)	Binary	Child who met rehabilitation criteria at 3 months and sustained recovery for at least 6 months (if recovered by WHZ/WLZ then sustained WHZ/WLZ or if recovered by MUAC then sustained MUAC)	6 months	1 = sustained; 0 = not sustained	Discharge Criteria within 3 months: Recovered definition: WHZ/WLZ ≥ -2.0 or MUAC ≥ 125 mm (based on admission criterion), and absence of bilateral pitting oedema.
Alternative Sustained Recovery Definition (including WAZ)	Binary	Child who met stricter rehabilitation criteria (including WAZ ≥ -3.0) at 3 months and sustained recovery for at least 6 months (if recovered by WHZ/WLZ then sustained WHZ/WLZ or if recovered by MUAC then sustained MUAC)	6 months	1 = relapsed; 0 = not relapsed	Discharge Criteria within 3 months: Stricter Recovered definition: WHZ/WLZ ≥ -2.0 or MUAC ≥ 125 mm (based on admission criterion), and absence of bilateral pitting oedema and WAZ ≥ -3.0

Exploratory Outcomes:					
MAM Admission type:					
Diagnosis type at enrollment (WHZ/WLZ vs. MUAC)		Diagnosis of MAM through WHZ/WLZ vs. MUAC vs. Both		1=WHZ/WLZ; 2=MUAC; 3=Both	
Behaviour Change:					
Minimum Dietary Diversity (MDD)	Binary	Child meets WHO MDD definition	From enrollment to end of treatment at 3 month	1 = meets MDD; 0 = does not	
Meal Frequency	Binary	Meets minimum meal frequency standard	From enrollment to end of treatment at 3 months	1 = meets meal frequency; 0 = does not	
Minimum Acceptable Diet (MAD)	Binary	Meets combined MDD + meal frequency	From enrollment to end of treatment at 3 months	1 = meets MAD; 0 = does not	
Unhealthy Food Consumption	Continuous/Binary	Consumption of unhealthy foods/beverages	From enrollment to end of treatment at 3 months	1 = yes; 0 = no	Yes to any of the questions of eating unhealthy foods

Child Illness Symptoms	Binary	Presence of illness (e.g., diarrhea, fever, ARI)	From enrollment to end of treatment at 3 months	1 = any symptom; 0 = none	Yes to any of the IMCI screening questions
Care-seeking Behaviour	Binary	Care sought for illness episode at health centre or hospital	From enrollment to end of treatment at 3 months	1 = yes; 0 = no	Yes if caregiver took child to health centre or hospital for child illness
Handwashing Practices	Binary	Reporting of washing hands at all 5 critical time points	From enrollment to end of treatment at 3 months	Define components clearly (index or individual variables)	
Caregiver Mental Health:					
Caregiver Wellbeing	Continuous/Binary	Caregiver mental health or wellbeing score	From enrollment to end of treatment at 3 months	Based on tool used (e.g., summed score)	
Cost-effectiveness					

Cost effectiveness of PDH	Continuous	To assess the cost-effectiveness of PDH, taking into the costs of program design, implementation, and caregiver time.	From enrollment to 6 months	Based on costing tools and quantitative data from primary outcome	
Recovery:					
High vs Low Risk MAM Recovery	Binary + Stratified	Recovery (as defined above) stratified by risk group at baseline/admission	From enrollment to end of treatment at 3 months	Risk group defined in notes; compare recovery proportions between groups	High Risk: MUAC 115–119 mm or WHZ –2.5 to –3.0 AND ≥1 contextual risk factor; Low Risk: MUAC >119 mm or WHZ >–2.5 AND no contextual risk factors
Recovery after 2nd round of Hearth	Binary	Child no longer MAM: WHZ/WLZ ≥ –2.0 or MUAC ≥ 125 mm (based on admission criterion), and no bilateral pitting oedema after 2 rounds of Hearth	6 months	1 = meets all criteria; 0 = does not	Standard Anthropometric Recovery
Change in WHZ/WLZ	Continuous	Change in WHZ/WLZ	From enrollment to end of treatment at 3 months	WHZ at 3 months – WHZ at baseline	

Change in WAZ	Continuous	Change in WAZ	From enrollment to end of treatment at 3 months	WAZ at 3 months – WAZ at baseline	
Change in HAZ/LAZ	Continuous	Change in HAZ/LAZ	From enrollment to end of treatment at 3 months	HAZ at 3 months – HAZ at baseline	

4.1.1 The primary outcome is:

- i) Rehabilitation of uncomplicated MAM within 3 months, defined as WHZ/WLZ ≥ -2.0 or MUAC ≥ 125 mm (based on admission criterion), **and** absence of bilateral pitting oedema.

4.1.2 The secondary outcomes are:

- Recovery of uncomplicated MAM within 3 months, defined as WHZ/WLZ ≥ -2.0 or MUAC ≥ 125 mm (based on admission criterion), **and** WAZ ≥ -3.0 , **and** absence of bilateral pitting oedema,
- Average MUAC (mm) at 3 months,
- Average daily weight gain (g/day) at 3 Months,
- Non-Response at 4 months, and
- Sustained Recovery at 6 months
- Sustained Recovery at 6 months with stricter recovery definition (including WAZ ≥ -3.0 SD)
- Cost per beneficiary
- Difference in sustained recovery comparing discharge criteria at 6 months after enrolment (just WHZ/WLZ ≥ -2.0 or MUAC ≥ 125 mm and also the inclusion of WAZ ≥ -3.0)
- Comparison of MAM recovery for high risk vs. low risk MAM (if any of the following are present)
 - **High Risk:** MUAC 115-119mm or WHZ between -2.5 to -3.0; with one of the contextual or household risk factors including:
 - Weight loss in past 30 days
 - Child < 12 months
 - Low birthweight or preterm history
 - Caregiver unable to provide adequate feeding or care do to working mother and requires migration
 - Food insecurity or lack of access to nutritious foods (more than 6 months of the year)
 - Poor access to functioning latrine
 - Maternal mental health issues
 - **Low Risk:** MUAC >119 mm or WHZ >-2.5 ; with no contextual or household risk factors stated above.
 - Recovery after 1st or 2nd round of Hearth within 3 Months

Exploratory Outcomes:

- Household behaviour changes: child minimum dietary diversity, meal frequency, minimum acceptable diet, consuming unhealthy food and beverages, illness symptoms, and care-seeking behaviour, WASH practices, and caregiver wellbeing
- Changes in WHZ/WLZ, WAZ, HAZ/LAZ, and MUAC at 3 Months,

4.2 Timing of Outcomes and Assessments

Outcomes will be assessed according to the following schedules:

Timing	Outcome
April/May 2026 (Nutrition Survey)	Village Demographic Information including MAM Prevalence and Identifying Eligible Children for the Study for Randomization Purposes
3 Months	Recovery from MAM (adj. and unadj. for Caregiver Psychological Distress, caregiver SES, and disaggregated by high vs. low risk MAM on admission, LBW) Recovery from MAM + WAZ > 3 Rate of Weight Gain (g/kg/day) MUAC (mm) Non-Response Defaulting Behaviour changes in: Child minimum dietary diversity, meal frequency, minimum acceptable diet, consuming unhealthy food and beverages, illness symptoms, care-seeking behaviour, and WASH practices.
6 Months	Recovery after 2nd round of Hearth within 3 Months Sustained Recovery (total and disaggregated by high risk vs. low risk) Sustained Recovery difference with inclusion of additional WAZ in discharge criteria of children at 3 months

4.3 Timing of Data Analysis

Anthropometric data quality checks will be conducted using the Emergency Nutrition Assessment software (ENA) at the end of each day of data collection. All analyses will be conducted following a database lock which will be done after the final participant has completed follow-up and data has been cleaned at 3 months and again at 6 months. Quantitative data collectors will be blinded during data collection and the data analysis team will also be blinded during the data analysis.

5. Trial datasets

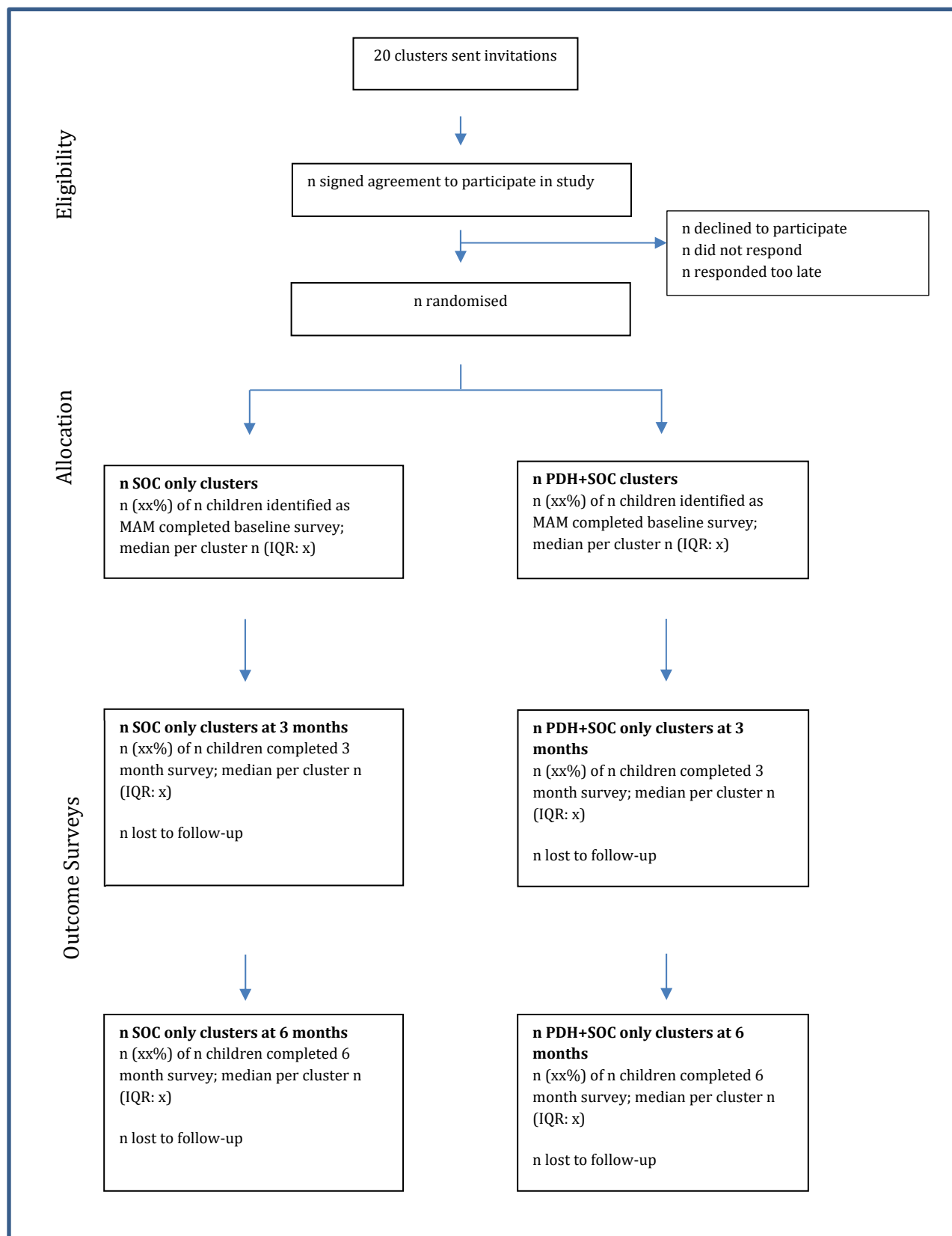
5.1 Analysis Levels

Statistical analysis will be carried out at the individual level with adjustment for clustering.

5.2 Intention-to-treat dataset

The primary analysis will follow the intention-to-treat principle, whereby all enrolled children will be analyzed according to the intervention group to which their cluster was randomized, regardless of their level of participation in PDH activities or adherence to the protocol.

Per-protocol (PP) analysis will also be conducted, restricted to children who completed the full 10 or more days of Hearth programme (PDH arm) and attended ≥ 2 of 3 monthly GMP sessions (both arms). PP analyses will be presented for all secondary outcomes as sensitivity analyses.



6. Study population

6.1 Trial flow chart

The number of participants screened, included in enrolment, allocation, follow-up and analysis will be described as per CONSORT 2010 guidelines (Figure 2). Reasons for exclusions, withdrawals, and lost to follow-ups will be described, including number of consent refusals.

6.2 Screening data

The total number of children 6-52.9 months of age will be screened and admitted to PDH and will be described for the study period.

6.3 Eligibility

The number of participants screened for eligibility and outcome of screening will be presented, including reasons for ineligibility. This will include the number and proportion of children:

- Child is not between 6-52.9 months of age at Baseline;
- Child does not meet the inclusion criteria for WHZ/WLZ and/or MUAC; (WHZ/WLZ < -2 and ≥ -3 and/or MUAC $< 125\text{mm}$ and $\geq 115\text{mm}$);
- Child has oedema;
- Child has medical complications and/or does not pass the IMCI screening including fever, nausea/vomiting, acute respiratory illness (refer to Study Protocol V3.0, 5 May 2026);
- Deteriorates to SAM and must be removed from the study and referred to the health centre for specially formulated food (SFF) treatment;
- Another child from the household is already admitted into the study;
- Refuses to receive age-appropriate immunization and Vitamin A and deworming minimum 2 weeks before the intervention begins if did not receive in the past 6 months;
- Child lives outside the study area routinely or will be outside of the study area for more than 2 weeks in the upcoming 3 months
- Parent/Caregiver unable or unwilling to attend PDH from start;

- Parent/Caregiver does not provide written or oral consent to screen for the trial;
- Parent/Caregiver does not provide informed consent for the study; and
- And any other reason.

6.4 Withdrawal/Follow-up

The number and proportion of participants who temporarily or permanently withdraw from the intervention will be described. For temporary withdrawals, the number and proportion of those restarting the intervention at a later stage will be described. The number and proportion of participants who permanently withdraw from the study will be described with reasons for withdrawal. The proportion of participants who are followed up at 30 days will be described with further description of how many non-attenders were contacted by telephone and outcome (alive; died) ascertained.

Further details about consent and withdrawals can be found in Figure 2.

6.5 Baseline characteristics

Tabulation of demographic and other characteristics will be done using the intention-to-treat datasets. No significance tests will be performed to test for differences at baseline unless multiple variables appear to have significant imbalance between the study arms. Descriptive statistics for continuous variables will include the mean, standard deviation, median, interquartile range and the number of observations.

Categorical variables will be presented as numbers and percentages. Analysis will be performed with number of participants in each arm as the denominator. No significance tests will be performed to test for differences at baseline unless multiple variables appear to have significant imbalance between the study arms.

Baseline characteristics of caregivers and children will be tabulated by treatment arm (see Table 1).

Table 1. Baseline characteristics		
	Intervention group	Comparison group
Children 6-59 months of age		
Total number		
Age at baseline, months		
Data missing		
Weight at baseline, kg		
Height at baseline, cm		
MUAC, cm		
Gender		
Female		
Male		
Weight-for-age z-score (WAZ), mean (SD)		

Weight-for-height/length z-score (WHZ/WLZ), mean (SD)		
Height/length-for-age z-score (HAZ/LAZ) , mean (SD)		
Acute malnutrition using MUAC, n (%)		
Acute malnutrition using WHZ/WLZ, n (%)		
Acute malnutrition using MUAC and/or WHZ/WLZ, n (%)		
Low birth weight, n (%)		
Child disability, n (%)		
Mothers		
Total number		
Age (actual or estimated), years		
Data missing		
Highest level of education, n (%)		
Never attended		
Pre-primary		
Grade 1 to 5		
Grade 6-9		
SSC, HSC, Graduate or equivalent		
Don't know		
Household		
Average household size		
Monthly income (\$)		
10,000TK or less		
10,001-15,000Tk		
Above 15,000Tk		
Data missing		
Wealth ranking		
Poor		
Non-Poor		
Access to safe drinking water, n (%)		
Access to clean latrine, n (%)		
Access to health services, n (%)		
Proper disposal of child feces, n (%)		
Handwashing station with soap and running water exists in home, n (%)		
Reported handwashing at all six critical time points, n (%)		
Child food security exists, n (%)		
Household is involved in other World Vision programmes, n (%)		

7. Protocol Adherence

Adherence to the intervention will be monitored through attendance records at Hearth sessions and Household follow-up observation checklists completed by volunteers. The

program fidelity will be assessed using World Vision's (WV) Implementation Quality Assurance tool that scores the program against a list of essential elements for PDH completed by WV staff. For the adherence to the standard of care will be monitored through the IYCF session attendance record tracked by volunteers. Adherence will be defined as follows:

For the PDH + SOC arm, participation in the Positive Deviance/Hearth programme should commence within two to three weeks of cluster-level randomisation. The target is attendance at scheduled PDH group sessions (typically held over 12 consecutive days with 1 day break after the first 6 days) and consistent practice of recommended positive deviance behaviours at home, monitored through 2 household follow-up visits and 2 phone calls by volunteers. It is recognised that full attendance at every session may not always be achievable due to caregiver work and household demands. Default is defined by missing more than 2 days within 12 days of Hearth or missing 2 follow-ups in the 2 household follow-up visits and/or 2 phone calls in the following 2 weeks following the first 12 days of Hearth. Adherence is not applicable for the SOC-only group following the national protocol.

For the SOC-only arm, receipt of standard Ministry of Health nutrition services should continue as per routine practice. Enumerators will collect data from both groups at Baseline, Midline (3 months) and Endline (6 months). Volunteers will record monitoring weight, height/length, and MUAC at Day 12, 30, and 60 for both groups. Deviations from the randomised treatment allocation – including non-attendance or dropout from PDH sessions – will be noted and tabulated (see Table 2). These deviations will inform the per-protocol sensitivity analysis as specified in Section 4 of this SAP.

Table 2 – Example of adherence table				
Domain	PDH + SOC Arm	SOC-Only Arm	Measurement Tools / Data Source	Definition / Notes
Adherence to Intervention	Attendance at PDH group sessions (12 days) and practice of behaviours at home	Referral to health centre for IYCF counselling	- Hearth session attendance records - Household follow-up observation checklists - SOC adherence will not be tracked as per national protocols	PDH and/or SOC participation should begin within 2-3 weeks of cluster randomization
Adherence Criteria	Target: Attendance at all PDH sessions and engagement in home practices	Continued participation in routine MoH services (at least once a month)	Attendance logs and follow-up records	Recognizes that full attendance may not always be feasible due to caregiver constraints
Default Definition	Missing >2 days within 90 days or left study area for more than 2 weeks during the 3 month study period	Left study area for more than 2 weeks during 3 month study period	Attendance records	Used to define non-adherence in PDH arm only
Home Practice Monitoring	Practice of positive deviance behaviours assessed via 2 household visits and 2 phone calls	Not applicable	Household observation checklists and call logs	Assesses behavioural adherence
Program Fidelity	Assessed using PDH implementation quality standards	Not applicable	World Vision Implementation Quality Assurance Tool	Measures adherence to essential PDH program elements
Standard of Care (SOC) Adherence	Referral to health centre for IYCF counselling in addition to PDH	Referral to health centre for IYCF counselling	Not applicable as per National Protocol	
Intervention Receipt (Actual Exposure)	Attendance, dropout, and additional interventions recorded	Not applicable	Trial monitoring forms	Collected in PDH arm only
Deviations from Allocation	Non-attendance, dropout, or receipt of non-study interventions	Not applicable	Trial records and monitoring logs	Will be tabulated and used for per-protocol sensitivity analysis for PDH group
Use in Analysis	Inform per-protocol and sensitivity analyses	Not applicable	SAP Section 4	Does not affect primary ITT analysis

8. Data Management

8.1 Data Management

Data will be managed centrally by a clinical trials data management team (icddr,b), supervised directly by the chief investigator (LSHTM). The chief investigator will be responsible for the development of the statistical analysis plan and leading the execution of the pre-planned data analysis and any subsequent secondary analyses while the local lead biostatistician will be responsible for overseeing data management on the ground. WV project staff will be responsible for overseeing program fidelity, making monthly supervision visits, monitoring of program data collection by volunteers, and adherence by caregivers. Quality control through supervision visits will be performed at each site by WV project staff. Each site will have a data manager responsible for local query management and ensuring case report forms (CRFs) are correctly filled out. Any discrepancies will be immediately addressed. All data stored in the database will be anonymized with no identifying details.

8.2 Confidentiality

The following measures will be taken to ensure participant confidentiality:

- Trial data for each participant will be identified by a unique child ID number.
- The local trial register linking personal information and child ID numbers, and all personal information of participants, will be kept separate from the CRFs.
- Trial documents will be kept securely under lock and key in the research offices and will not be accessible, other than the researchers.
- Data will be entered by trial ID number in the password-protected data management system to which only trial staff will have access.
- The trial report will not contain the names of any participants.

9. Statistical Methods

9.1 Statistical software

RStudio Version 2026.01.1+403 will be used for quantitative analysis and NVIVO Version 16 will be used for qualitative data analysis.

9.2 Methods

9.2.1 Primary analysis

The primary outcome (e.g., recovery from MAM) will be compared between the PDH intervention and control groups using Generalized Estimating Equations (GEE) to account for clustering and repeated measurements over time (see Table 3). If GEE fails to converge, Difference-in-difference (DID) will be used to measure effects.

For binary outcomes (e.g., recovery, discharge, relapse) effect estimates will be presented as risk ratios (RR) or odds ratios (OR) with 95% confidence intervals (CI). For continuous outcomes (e.g., MUAC, weight-for-height z-score), effect estimates will be presented as mean differences with 95% CI. The primary model will include: Time (baseline vs midline vs. endline), treatment group (PDH vs. control), Time × Treatment interaction term (primary estimate of intervention effect) – whether the change over time is different between groups (PDH vs. control; High vs. Low-risk MAM within PDH). For recovery from MAM, analyses will be conducted **unadjusted** and **adjusted for caregiver psychological distress** to assess whether caregiver mental health influences recovery outcomes.

Robust standard errors will be used to account for clustering.

All analyses will follow the intention-to-treat principle, with participants analyzed according to their original cluster allocation regardless of adherence.

9.2.2 Secondary outcomes analysis

Secondary outcomes will be analyzed using regression models appropriate to the outcome type, while accounting for clustering at the cluster level and repeated measures where applicable. Logistic mixed-effects models will be used for binary outcomes (e.g., recovery, relapse), linear mixed-effects models for continuous outcomes (e.g., weight gain, MUAC change), and time-to-event models for time to recovery.

- Binary outcomes (e.g., recovery, discharge, defaulting, behavioural indicators):
 - **Analyzed using logistic GEE models or DID**
 - Results presented as Crude Effect (risk ratios (RR)/ odds ratios (OR)) with 95% confidence intervals (CI)
- Time-to-event outcomes
 - Using monitoring data
 - Time-to-event outcomes, including time to recovery and time to relapse, will be analyzed using **Cox proportional hazards regression models** to estimate hazard ratios with 95% confidence intervals, including shared frailty to account for clustering
 - Robust standard errors will be used to account for clustering at the cluster level.
- Continuous outcomes (e.g., rate of weight gain, rate of MUAC gain):
 - **Analyzed using linear GEE model or DID**
 - Results presented as mean differences with 95% CI

Behavioural outcomes will be analyzed as binary or categorical indicators, depending on their definition. These analyses will assess whether participation in PDH is associated with improved child feeding, health-seeking, and WASH practices.

All secondary outcome analyses will report effect estimates with 95% CI, corresponding p-values, and both adjusted and unadjusted models, where applicable.

9.2.3 Subgroup analysis

Pre-specified subgroup analyses on the primary outcome will explore whether the effect of PDH varies across key characteristics, such as child age group (6-23.9 months and 24-59 months), gender, caregiver psychological distress, caregiver's SES, and child's birthweight (Low Birth Weight <2500g).

The average weight gain and average MUAC (mm) at 3 months and non-response will be stratified in its analysis by the admission WHZ/WLZ or MUAC status (admitted for WHZ/WLZ or MUAC or both) and number of Health rounds attended. Furthermore, the complete dataset will also be analyzed by subgroups: high and low risk MAM as indicated previously.

Interaction terms between treatment and subgroup variables will be included in the models. Results will be presented with p-values for interaction and 95% confidence intervals.

	Intervention group (n=)	Comparison group (n=)	Crude Effect (95% CI)	p-value	Adjusted Effect (95% CI)*	p-value
Risk Ratio (95% CI)						
Primary						
Recovery* from MAM (%)	n/N (%)	n/N (%)	RR / OR	p-value	RR / OR	p-value
High Risk MAM at Baseline	n/N (%)	n/N (%)	RR / OR		RR / OR	
Low Risk MAM at Baseline	n/N (%)	n/N (%)	RR / OR		RR / OR	
In 1 st Round of Hearth	n/N (%)	n/N (%)	RR / OR		RR / OR	
In 2 nd Round of Hearth	n/N (%)	n/N (%)	RR / OR		RR / OR	
Secondary						
Discharged* from MAM (%)	n/N (%)	n/N (%)	RR / OR	p-value	RR / OR	p-value
High Risk MAM at Baseline	n/N (%)	n/N (%)	RR / OR		RR / OR	
Low Risk MAM at Baseline	n/N (%)	n/N (%)	RR / OR		RR / OR	
In 1 st Round of Hearth	n/N (%)	n/N (%)	RR / OR		RR / OR	
In 2 nd Round of Hearth	n/N (%)	n/N (%)	RR / OR		RR / OR	
Non-Response (%)						
Sustained Recovery at 6 months(%)	n/N (%)	n/N (%)	RR / OR	p-value	RR / OR	p-value
Minimum acceptable diet (%)	n/N (%)	n/N (%)	RR / OR	p-value	RR / OR	p-value
Consumption of unhealthy foods/beverages (%)	n/N (%)	n/N (%)	RR / OR	p-value	RR / OR	p-value
Child illness symptoms (%)	n/N (%)	n/N (%)	RR / OR	p-value	RR / OR	p-value
Care-seeking behaviour (%)	n/N (%)	n/N (%)	RR / OR	p-value	RR / OR	p-value
Hazard Ratio (95% CI)						
Time to recovery	Median (IQR)	Median (IQR)	HR	p-value	Adjusted HR	p-value
Time to relapse at 6 months	Median (IQR)	Median (IQR)	HR	p-value	Adjusted HR	p-value

Mean Difference (95% CI)						
MUAC (mm)	Mean (SD)	Mean (SD)	Mean Diff	p-value	Adjusted Mean Diff (GEE)	p-value
WAZ (SD)	Mean (SD)	Mean (SD)	Mean Diff	p-value	Adjusted Mean Diff (GEE)	p-value
Average weight gain per day (g/kg/day)	Mean (SD)	Mean (SD)	Mean Diff	p-value	Adjusted Mean Diff (GEE)	p-value
Change in WHZ/WLZ	Mean (SD)	Mean (SD)	Mean Diff	p-value	Adjusted Mean Diff (GEE)	p-value
Change in WAZ	Mean (SD)	Mean (SD)	Mean Diff	p-value	Adjusted Mean Diff (GEE)	p-value
Change in HAZ/LAZ	Mean (SD)	Mean (SD)	Mean Diff	p-value	Adjusted Mean Diff (GEE)	p-value
Change in MUAC (mm)	Mean (SD)	Mean (SD)	Mean Diff	p-value	Adjusted Mean Diff (GEE)	p-value
Caregiver wellbeing score	Mean (SD)	Mean (SD)	Mean Diff	p-value	Adjusted Mean Diff (GEE)	p-value
Handwashing	Mean (SD) or %	Mean (SD) or %	Mean Diff	p-value	Adjusted Mean Diff (GEE)	

10. Statistical and analytical issues

10.1 Adjustment of covariates

The primary analysis will not adjust for key baseline covariates unless multiple variables appear to have significant imbalance between the study arms at baseline.

10.2 Sensitivity Analyses

Sensitivity analyses regarding missing data such as best- and worst-case scenario may be conducted for the primary outcomes.

10.3 Dropouts and Missing data

The Chief Investigator and local academic partner will be responsible for reviewing all data at the end of each data collection day and contacting enumerator teams about any missing data. Missing data will be chased until received, confirmed as not available, or the trial is at the analysis stage. Data quality will be assessed using the Emergency Nutrition Assessment (ENA) tool developed by the SMART group. Attendance in Hearth sessions and IYCF group sessions and volunteer follow-up visits and overall trial monitoring will be assessed through biweekly reports using a PDH supervision checklist from volunteers over the first 3 month-period.

Only a small amount of missing data is expected and it is not likely that it will have to be accounted for in any analysis. We would consider using inverse probability weighting if missing data were larger than expected and/or there was differential attrition between the trial arms. We would also attempt to ensure that the reason for the differential attrition was fully understood.

Sensitivity analyses (as detailed above) will however be conducted for the primary outcome.

10.4 Outliers

Any unusual values/potential outliers will be queried. If the value is found to be correct, then it will be included in all analyses.

10.5 Statistical interim analyses and stopping guidance

A joint hybrid **Data Safety Monitoring Board (DSMB)** and **Trial Steering Committee (TSC)** composed of three members, including 2 independent co-chairs, an epidemiologist and two technical experts familiar with nutritional studies in low-income settings and clinical

trial methodology, will be established prior to the start of the trial to oversee participant safety, trial conduct, and data integrity.

Given the low-risk nature and relatively short duration (6 months) of the PDH MAM trial, the DSMB and TSC functions will be combined into a single independent committee. The DSMB/TSC will operate independently of the trial team and will review study progress and safety data in strict confidence.

The DSMB/TSC will review monthly **summary reports** of adverse events (AEs) including fever, diarrhea, cough, serious adverse events (SAEs) including anaphylaxis, hospitalization for more than 24 hours, and death, recruitment, retention, and protocol adherence throughout the study period. All suspected adverse events will be monitored by the field site investigator and assistant investigator who will review and report these to the CI, who will then report to the local Ethics Committee and LSHTM Ethics Committee. The DSMB/TSC will also receive the information on adverse events. Formal meetings will be held at pre-specified time points with DSMB/TSC, with additional ad hoc meetings convened if triggered by safety concerns or unexpected findings.

Due to the relatively short duration of the trial, **formal interim analyses for efficacy are not planned**. However, the DSMB/TSC will review accumulating data from monthly summary reports, including **unblinded safety data**, to assess emerging safety signals and the overall benefit–risk balance. Unblinded data will be available to the DSMB/TSC but will remain blinded to the Chief Investigator and lead biostatistician from icddr,b.

Based on these reviews, the DSMB/TSC may make recommendations to the Chief Investigator and Sponsor regarding:

- Continuation of the trial without modification
- Modifications to the protocol or implementation procedures
- Additional data collection or analyses
- Temporary pause of recruitment
- Early termination of the trial in the event of safety concerns or other ethical considerations

Rather than applying formal statistical stopping rules, decisions will be based on **ongoing review of safety data, trial conduct, and emerging evidence**, including any unexpected adverse patterns or concerns regarding participant safety.

The DSMB/TSC will document all deliberations and provide written recommendations following meetings. The Chief Investigator will be responsible for implementing any agreed actions, and all decisions will be recorded in the Trial Master File.

10.6 Multiple Comparisons/Multiplicity

The number of primary and secondary outcomes that will be tested for significant differences between arms is small and thus no formal adjustment for multiple comparisons will be made.

11. Safety monitoring

Information on adverse events (AEs), serious adverse events (SAEs), and deaths among enrolled children will be collected and reported in both the PDH intervention and SOC only arm throughout the study period using CRFs. Given the low-risk nature of the PDH intervention and short duration of study, safety monitoring will focus on child morbidity, hospitalizations, deaths, withdrawals, and other safety-relevant indicators, regardless of attribution to the intervention.

A Joint Hybrid Data Safety Monitoring Board (DSMB) and Trial Steering Committee (TSC) will oversee participant safety, trial conduct, and data integrity. The DSMB/TSC will review monthly summary reports of AEs and SAEs, monitor recruitment, retention, withdrawals, and protocol adherence, assess emerging safety signals and the overall benefit–risk balance of the intervention, and request additional data if unusual or concerning patterns are identified.

Summary safety data will be shared regularly with the DSMB/TSC, with unblinded reports available to the committee while remaining blinded for the Chief Investigator.

The DSMB/TSC will meet at pre-specified time points and may convene additional ad hoc meetings if safety concerns arise. During these meetings, the committee will review both operational updates and safety data and may hold closed sessions to independently assess unblinded data and make recommendations.

Based on these reviews, the DSMB/TSC may recommend continuation of the trial without modification, modifications to the protocol or safety monitoring procedures, temporary pause of recruitment, additional data collection or analyses, and early termination of the trial if necessary.

All AEs and SAEs will be documented and included in routine safety reports. Reporting to the Sponsor and relevant ethical review committees will be conducted in accordance with study requirements, including periodic progress and safety reporting.

All DSMB/TSC deliberations, recommendations, and actions will be formally documented and maintained in the Trial Master File.

References:

Study Protocol V3. 5 May 2026

Data Management Plan

1. Describe your research

Data collection tools

I will create the following items as part of the research planning process:

Study 1:

1. A phone application to collect the height/length measurements and time measurements of children 6-59 months of age.

Study 2:

1. A phone application and paper copy of the survey tool to collect data from caregivers of children 6-59 months of age with uncomplicated MAM covering data collection of weight, MUAC, height/length measurements of children, food security, income, 24-hour dietary recall, water and sanitation practices, health check, disability status, and treatment adherence.
2. A FGD interview guide with project staff and volunteers to assess program fidelity of the PDH and SOC interventions.

Data

```
Jxlgdqfhrq#z uwqj#d#Gdw#P dqdjhp hqw#Bdq#Edq#h#rxqg#dw#  
kwsv=22okwp 1vkdhsrlqwfrrp 2v1hv2lqwdghw0eudu|0dufklyh0dgg0rshq0uhvhdufk0  
vhuylfhv2VhSdjhv2Uvhvdufk0Gdw0P dqdjhp hqwdvs{##  
dqg#kws=22vhuylfhghvn1okwp 1df1xn#  
Dgylfh#lqg#lhhgedfn#Edq#h#rewlqhg#urp ##  
uhvhdufkqgdwp dqdjhp hqwC okwp 1df1xn##
```

Using the above, I will collect the following data:

Study 1:

1. Quantitative data will be collected for each child. Approximately 400 children will be measured and stored as MS Excel file. KOBOLLECT will be used to design the phone application.

Study 2:

1. Quantitative survey data will be collected from caregivers of children 6-59 months of age with uncomplicated MAM. Approximately 400 child-caregiver pairs will be included in the survey. Data will be collected using KOBOLLECT phone application and stored as an MS Excel file.
2. Audio recordings of the FGDs with caregivers and PDH volunteers will be recorded and stored in MP3 format.
3. Transcripts of the focus group discussions will be stored in MS Word format in Bangla and translated to English.

2. What hardware and software will be used in your research?

The quantitative survey will be developed using KoboCollect and collected using Android-based phones/tablets. Resulting data will be imported into Excel and Emergency Nutrition Assessment 2008 (ENA2008) software to analyze the quality of the data every day after data collection. The data quality of the enumerators for height/length-for-age and weight-for-height/length data will be compared to the international WHO reference standards to identify any enumerators that need to be retrained due to digit preferences or flags in children's weight-for-height/length z-scores ± 5.0 , according to WHO growth standards (13). Any data that needs to be re-measured will be re-measured the following day. The data will then be imported to R-Studio will be used for further cleaning, processing and analysis.

3. What data-related activities will be performed during the research?

Task	Description
Survey Data	
Develop survey questionnaires	Investigate similar studies and develop a protocol for data collection, including a set of questions to collected the quantitative data height/length and weight (resource 1 & 7)
Field test draft questionnaire	Trial with key stakeholders and obtain feedback. Revise accordingly.
Setup questionnaire on tablet	Design question form using KoboCollect and field test it on phone
Perform survey	Perform survey in the selected project areas and capture data using KOBOLLECT (resource 1 & 7). Check data quality every day after data collection using ENA2008 software (resource 12 & 13) and remeasure children as needed the next day.
Prepare data for analysis	Clean and anonymise using MS Excel (resource 14 & 15) and process data for analysis using R-Studio. (resource 4 & 9) Generate R-Studio code (resource 16 & 17).
Analyze data	Perform analysis outlined in research protocol.
FGD and Interview recordings	

Develop Interview Guide	Investigate similar studies and develop a set of questions to guide discussion (resource 5&6)
Field Test draft questions	Circulate to relevant stakeholders and obtain feedback. Revise accordingly.
Organizing and host FGDs and INTERVIEWSs	Organise and host 6 FGDs and 4 Interviews. Record discussion.
Process and translate FGD and Interview audio recordings from Bangla to English	The Google Cloud voice-to-text software will be used to create an initial transcript in Bangla, which my Bangladeshi enumerators will use MS Word to translate to English and revise the translation as needed. I will manually review using MS Word. In addition, I will anonymise and code each transcript (resource 10 & 11)
Analyze FGD and Interview transcripts	Perform analysis using MAXQDA.

4. What quality checks will you perform to ensure resources are fit for purpose?

Interviews & FGDs:

- Before: Review question list, test recording device to ensure setup correctly, ensure recording device is charged, bring backup device 'just in case', confirm participant(s) will attend interview
- During: Use checkpoints to check relevant details are provided, ask question in different ways to confirm answers, check device is still working and recording.
- Following: Check participant consent has been obtained, check question list has been addressed, check audio has recorded correctly.

Surveys:

- Before: Train volunteers on survey tools, train volunteers in anthropometric measurements and how to measure child weight, height and length, and take MUAC using Measuring Child Growth training manual which includes standardization exercise, ensure KOBOLLECT form includes validation to flag required information, test recording device to ensure setup correctly, ensure recording device is charged, bring backup device 'just in case'.
- During: Ensure KOBOLLECT form includes validation to flag required information, use ENA2008 software every day to check data quality of anthropometric measurements
- Following: Check participant consent has been obtained

5. How will you address ethical & legal issues within your research?

Study	Participants	Local Ethical Approval from Dhaka University of Health Economics	Ethical Approval LSHTM
Study 2	Quantitative Survey: Written consent forms completed before data collected during	December 2025/January 2026	Planned November to December 2025

	Baseline (Day 1), Day 90 and 120		
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The consent forms will provide participants with information on the purpose of the research, how data will be managed and analysed, and plans for data sharing. I will discuss the process with them to collect data and provide them with the opportunity to ask questions. Participant identifiable information will be stored in the country in which it was collected. Data will be anonymised prior to analysis and sharing with others.

6. What documentation will be created to ensure resources can be understood?

A document will be written on the data collection workflow to be applied. This will provide details of the collection technique(s) applied (e.g. Computer-assisted Personal Interview), who will perform the task (if more than one person), as well as hardware and software to be used. This will be supported by collection forms that outlines questions to be raised and expected/permitted responses. This document will be written prior to the start of collection and updated/expanded over time.

Survey data will be supported by a codebook necessary to understand its content. This will provide details on the response type for each question (i.e. free text, controlled list), permitted values and their meaning (e.g. 0 = no, 1 = yes), measurements used, the meaning of abbreviations and acronyms, processing actions performed (e.g. as a result of cleaning and redaction), weighting applied.

Interview and focus group transcriptions will be supplemented by documentation that describes issues encountered and decisions made when translating content from Bangla to English, labelling applied for redactions and other changes, the coding scheme developed and used to structure content for analysis, and non-verbal responses (e.g. tone of voice, physical behaviour).

STORAGE AND SECURITY

7. Where will resources be stored at key stages of your research?

Data Classification

Resources will be classified as follows under the LSHTM Data Classification and Handling Policy

- *Confidential*: Interviews and FGD recordings (resource 5 & 6). The first 'raw' version of survey data and interview FGD transcripts will be Confidential, but derivatives may be classed as Internal if they can be sufficiently de-identified.
- *Internal*: De-identified survey datasets (resource 3 & 9) and interview transcripts (resource 5 & 6), subject to the above de-identification process. If transcripts cannot be de-identified, interview summary notes will be created.

- *Public:* Collection tools (Resource 1, 5, 6, 7) and document review notes are based upon public sources and can be made available accordingly. The anonymised survey data (Resource will be made available publicly).

Storage location

Survey data will be captured via the KOBACOLLECT survey tool and temporarily held on Android phones deployed for use in the field. If an internet connection is available, captured information will be securely transferred to the KoboCollect server operated by World Vision. Following completion of caregiver surveys and verification of the ID numbers, the de-identified dataset will be exported and transferred to the LSHTM secure server. Audio recordings of interviews and focus group discussions will be captured on encrypted Android phones. Following completion, they will be moved to LSHTM's secure storage facility for processing. This system uses user authentication to limit access to specific users only. Audio recordings will be encrypted for transcription and translation into English. In advance of this activity, the enumerators will be asked to sign a contract agreement, which outlines various conditions of use, e.g. they will store the data securely, will not share it with others, and will delete it once work has been completed. Following completion, transcripts will be encrypted and transferred to LSHTM for processing. These will be stored on the institution's secure server throughout the time they are held. Anonymised survey data and document review notes will be stored in the storage area allocated to the researcher by their university. These will be shared with my supervisor and other advisors.

8. What labelling conventions will you apply to manage your resources?

Filenames will be labelled using key characteristics that will allow relevant files to be located quickly, while protecting participants from identification. For instance, collectionMethod_IDnumber_resourceType_versionNo.fileformat. E.g. FG1_01_audio_v1.wav, FG_01_transcript_v1.1.docx. Questions and recorded responses will be labelled using an identifier (e.g. q03exp) to enable link-up between the two

9. How will you keep data safe and secure? (choose one or more)

Only anonymised data will be used - personal, sensitive, or otherwise confidential data is not needed for the research		Store personal details in a separate secure location & link it via an identifier	X	Delete personal & confidential details at earliest opportunity (specify when below)	X
Use digital storage that require a username/password or other security feature	X	Physical security (such as locked cabinet or room)		Protect portable devices using security features, e.g. biometric	X
Encrypt storage devices	X	Encrypt during transfer	X	Avoid cloud services located outside the relevant jurisdiction (e.g. GDPR compliant area)	
Take 'Information Security Awareness training'	X	Ensure backups are also held securely	X		

Notes:	
Identify additional steps you will take to avoid, reduce, or eliminate risks that may affect your resources.	

ARCHIVING & SHARING

10. What resources should be kept as evidence of your research?

I will keep the following resources for 10 years:

- Collection tools (resource 1-3, 7-9)
- Anonymised survey data (resource 4 & 9)
- Anonymised interview transcripts (resource 10)
- Anonymised focus group transcripts (resource 11)
- ENA2008 and Excel data (resource 12-15)
- R-Studio files (resource 16 & 17)

The following resources will be deleted when no longer needed (most likely following allocation of grade)

- Participant identifiable details captured during survey (resource 2 & 8) – deleted in compliance with GDPR
- Audio recordings of interviews (4) and focus groups (6) – deleted in compliance with GDPR
- Document review notes (10 & 11) – notes will have been incorporated into thesis and no longer required.
- Anonymised survey data (resource 4 & 9) – deleted in accordance with data provider agreement and GDPR. Primary copy will continue to be kept by the PI.

11. Where will these resources be hosted?

The anonymised survey data, interviews transcripts and FGD transcripts will be uploaded to the OSF data repository and made available for 10 years, in accordance with the institutional research data management policy. Transcripts will be verified and recordings will be deleted and interview summary notes will be uploaded to the repository.

12. When will the resources be made available? (choose one or more)

During the research life		At the same time as findings are published in an academic journal	X	A set time after research end, e.g. 12 months. Specify below	
Resources already available (provide details below)		On completion of my thesis	X	Other (provide details below)	
Further information / Other					

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13. How will you make other researchers aware that the resources exist?

Publish a metadata record describing the resources in a repository or other catalogue	X	Obtain a Digital Object Identifier (DOI) or other permanent ID	X
Cite resources in future research papers, e.g. in the data access statement or reference list	X	Cite resources in project reports	X
Publish a description for the project website		Write and publish a Data Paper	
Add resources to a list of your academic outputs	X		
Other measures / Further details			

14. What steps will you take to ensure resources are easy to analyse and use in future research? (choose one or more)

Prepare a codebook or other documentation that provides an accurate description of content		Store resources in open file formats such as CSV, Rich Text, etc. See https://ukdataservice.ac.uk/learning-hub/research-data-management/format-your-data/recommended-formats/	x
Write a user guide that provides a high-level overview of research		Apply a standard licence that allows a broad range of uses (e.g. Creative Commons, Open Data Commons)	
Designate a corresponding author / data custodian who will handle data-related questions		Use domain-specific standards that make it easy to import and analyse data	
Other / Further information			

15. If resources can be made available, but not openly, what conditions on access/use must be met?

E.g. data can be used for specific types of research only. Leave blank if not applicable.

Requirement:	To be addressed by:
N/A	

RESOURCING

16. What are the primary data management challenges in your research?

Language barrier working in Bangla and requiring development of parallel sets of all documents in English and Bangla.

17. How can LSHTM & others help you to better manage your data?

I would appreciate IT support in encrypting android tablets or phones for data collection.

Appendix C – Information Sheet and Consent Form

<to be read in conjunction with guidance >

V1.0; November 17, 2025

Participant Information Sheet

Title of Project: Evaluation of the Effectiveness of Positive Deviance/Hearth (PDH) to treat Uncomplicated Moderate Acute Malnutrition in Children 6-59 months of age in Bangladesh

Introduction

We would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. One of our team will go through this information sheet with you, and answer any questions you may have. Ask questions if anything you read is not clear or you would like more information. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

What is the purpose of the study?

The London School of Hygiene and Tropical Medicine (LSHTM) are conducting research in assessing the effectiveness of a dietary intervention called, “Positive Deviance/Hearth (PDH)” to rehabilitate moderate wasted children without medical complications between 6-59 months of age in Bangladesh.

Why have I been asked to take part?

You have been invited because you have a child between 6-59 months of age who is moderately wasted (malnourished) and we would like to assess the effectiveness of the PDH program to treat undernourished children rather than relying on product-based therapeutic foods. This research will help us understand whether it is feasible to rehabilitate undernourished children using locally available nutrient-dense foods. If successful, the local food-based approach will be much lower-cost and sustainable where you do not need external intervention to rehabilitate undernourished children at home.

Do I have to take part?

No. It is up to you to decide to take part or not. If you don't want to take part, that's ok. Your doctor will still care for you and your decision will not affect the quality of care you receive.

We will discuss the study together and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form.

What will happen to me if I take part?

Your child will be included in a nutrition education program and you will learn how to use local foods to improve your child's health by community health workers. Your child's weight,

height and arm circumference will be measured by health workers. Measurements will be recorded using pen and paper and using a mobile phone or tablet. You will be asked some additional questions about your household's current practices and what your child ate in the last 24 months.

What will I have to do?

You will have to bring your child to be measured (weight, height/length, and arm circumference), and you will be asked a series of questions, which you can choose to answer or not. This could possibly take about 1 hour today. You and your child will also be included in a nutrition education program for 12-days and followed up once a month for up to 3 months. After 3 months, your child will be measured again and you will be asked the same series of questions, which you can choose to answer or not.

What are the possible risks and disadvantages?

There are minimal risks from your participation in this study. One of the main risks is the breach of confidentiality. For example, if any of the study reports or data reveals your name or identity. However, our study team will avoid recording your name and your child's name by de-identifying all information. Only the primary research will hold the file with your child and your name and stored in a secured facility and on a password protected computer. All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The London School of Hygiene and Tropical Medicine Ethics Committee and Dhaka University. In addition, the child could be distressed because we are measuring his/her weight, height/length, and arm circumference, but we will try our best to keep the child happy and measure quickly. You could also feel distressed seeing your child crying and you could always ask us to stop at any time.

What are the possible benefits?

1. How this study can help your child:

- Better and more nutritious foods
- Faster weight gain and stronger immunity
- Close monitoring to keep your child healthy
- Lower chance of becoming malnourished again

2. How this study can help you:

- Learn to cook **easy, tasty, nutritious meals** with foods you already have
- Learn good hygiene and feeding habits
- Build confidence in caring for your child
- Meet other mothers and learn together

3. How this study can help your household:

- The skills you learn can help **all your children**
- You will be helping your community by improving programs for other families

There are no costs for you to participate in this study.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions <contact number>. If you remain unhappy and wish to complain formally, you can do this by contacting The Research Governance and Integrity Office (RGIO) at rgio@lshtm.ac.uk or +44 (0) 20 7927 2626.

The London School of Hygiene and Tropical Medicine holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim compensation.

Can I change my mind about taking part?

Yes. You can withdraw from the study at any time. You just need to tell the health worker or health centre nurse that you don't want to be in the study anymore.

You can withdraw from treatment but keep in contact with us to let us know your progress. Information collected may still be used.

How will we use information about you?

We will need to use information from your child for this research project.

This information will include your WV identification number.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

World Vision Korea is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Names will be de-identified from reports (a code rather than your name will be used on study records for analysis).
- Your name and other facts that might point to you will not appear when we present this study or publish its results.
- All data will be stored on a laptop that is password protected and will be transferred with encryption

As a university, we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research.

International transfers

We may share data about you outside the UK for research related purposes to:

- *Analyze the data further*

If this happens, we will only share the de-identified data that is needed. This may not be possible under certain circumstances – for instance, if your child has additional medical complications, we will refer your child to the health centre and may need to reveal your identity to the appropriate health staff. If your data is shared outside the UK, it will be with the following organisations:

- *Ministry of Health Bangladesh*
- *World Vision*

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Deidentifying the dataset
- Bangladesh and US are the two countries that your data will be shared with and they have adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes ensuring the data is secured in a password protected server to protect unauthorised access, use, changes or sharing
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for the minimum period of time required by we will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- **You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study.**
- If you agree to take part in the study, you will have the option to take part in future research using your data saved from this study. The study's anonymised data will be made publicly available on LSHTM Compass

Where can you find out more about how your information is used?

You can find out more about how we use your information

- At www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to DPO@lshtm.ac.uk

What will happen to the results of this study?

The study results will be published in a medical journal so that other academics and international development organizations can learn from them. Your personal information will not be included in the study report and there is no way that you can be identified from it.

Who is organising and funding this study?

<London School of Hygiene & Tropical Medicine is organizing the research and World Vision Korea is funding it. LSHTM is the one leading the research and will have full responsibility for the project including the collection, storage and analysis of your data, and will act as the supervisor for all data collected for the study. This means that we are responsible for looking after your information and using it properly.

Who has reviewed this study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed

and given favourable opinion by The London School of Hygiene and Tropical Medicine Research Ethics Committee. The Dhaka University of Health Economics Ethics Committee has also reviewed the study and have agreed that it is okay for us to ask people to take part.

Further information and contact details

Thank you for taking time to read this information sheet. If you think you will take part in the study please read and sign the consent form.

If you would like any further information, please contact the research coordinator who can answer any questions you may have about the study.

Contact details: Mezanur Rahman, MD MdMezanur_Rahman@wvi.org; +88 01713490725

Title of Project: Evaluation of the Effectiveness of Positive Deviance/Hearth (PDH) to treat Uncomplicated Moderate Acute Malnutrition in Children 6-59 months of age in Bangladesh

Name of PI/Researcher responsible for project: Diane Baik

Statement	Please initial or use thumb print
I confirm that I have read and understood the information sheet dated <u>November 17, 2025</u> for the above named study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily. OR I have had the information explained to by study personnel in a language that I understand. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
I understand that my consent is voluntary and that I am free to withdraw this consent at any time without giving any reason and without my/the participant's medical care or legal rights being affected.	
I understand that the data collected during the study may be looked at by authorised individuals from London School of Hygiene and Tropical Medicine, World Vision, Ministry of Health Bangladesh, where it is relevant to the participant's taking part in this research. I give permission for these individuals to have access to these records.	
I understand that data about my child may be shared via a public data repository or by sharing directly with other researchers for this study or future studies, and that your child will not be identifiable from this information	
I agree to my child taking part in the above named study.	

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Printed name of participant/Representative

Signature of participant/Representative
(or thumbprint/mark if unable to sign)

Date

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Printed name of person obtaining consent

Signature of person obtaining consent

Date

The participant/representative is unable to sign. As a witness, I confirm that all the information about the trial was given and the participant/representative consented to taking part (**only required if the participant/representative is unable to read or write*)

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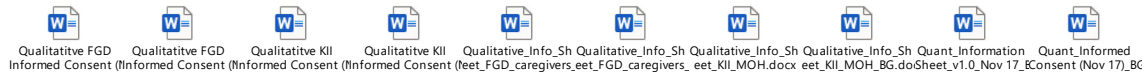
Printed name of impartial witness*

Signature of impartial witness*

Date

[*Only required if the participant is unable to read or write.]

The FGD and KII information sheets and consent forms can be found here:



- 1. Qualitative FGD informed consent form for PDH Caregivers**
- 2. Qualitative FGD informed consent form for PDH volunteers**
- 3. Qualitative KII informed consent form for MOH staff**
- 4. Qualitative KII informed consent form for WV staff**
- 5. Quantitative Caregiver Interview informed consent form**
- 6. Qualitative Info Sheet for PDH Caregivers**
- 7. Qualitative Info Sheet for PDH volunteers**
- 8. Qualitative Info Sheet for MOH staff**
- 9. Qualitative Info Sheet for WV staff**
- 10. Quantitative Caregiver Interview Info Sheet**

Appendix D – Ethics Course Certificate and Approvals for Research Degree Students



This is to certify that

Diane Baik

successfully completed the

Research Ethics

e-learning course

with a score of

80.00 %

Comprising of modules covering:

- Introduction to the History of Research Ethics
- Fundamental Ethical Principles, including:
 - Respect for persons
 - Beneficence
 - Justice
- Responsibilities of Research Ethics Committees
- Understanding Vulnerability
- Privacy and Confidentiality

On

January 27, 2025

Provided by

London School of Hygiene & Tropical Medicine

This course meets the requirements for protection of human subjects training required by individuals involved in the design and/or conduct of National Institutes of Health (NIH) funded human subjects research.



Certificate of Completion

This is to confirm that

Diane Baik

successfully completed the online course:

Good Research Practice /Responsible Conduct of Research

comprising of:

- Principles of Good Research Practice
- Practical elements of research integrity
- Risk Management
- Confidentiality and data protection practicalities
- Essential documents and data management basics
- Quality Control and Quality Assurance

with a score of

100.00 %

on

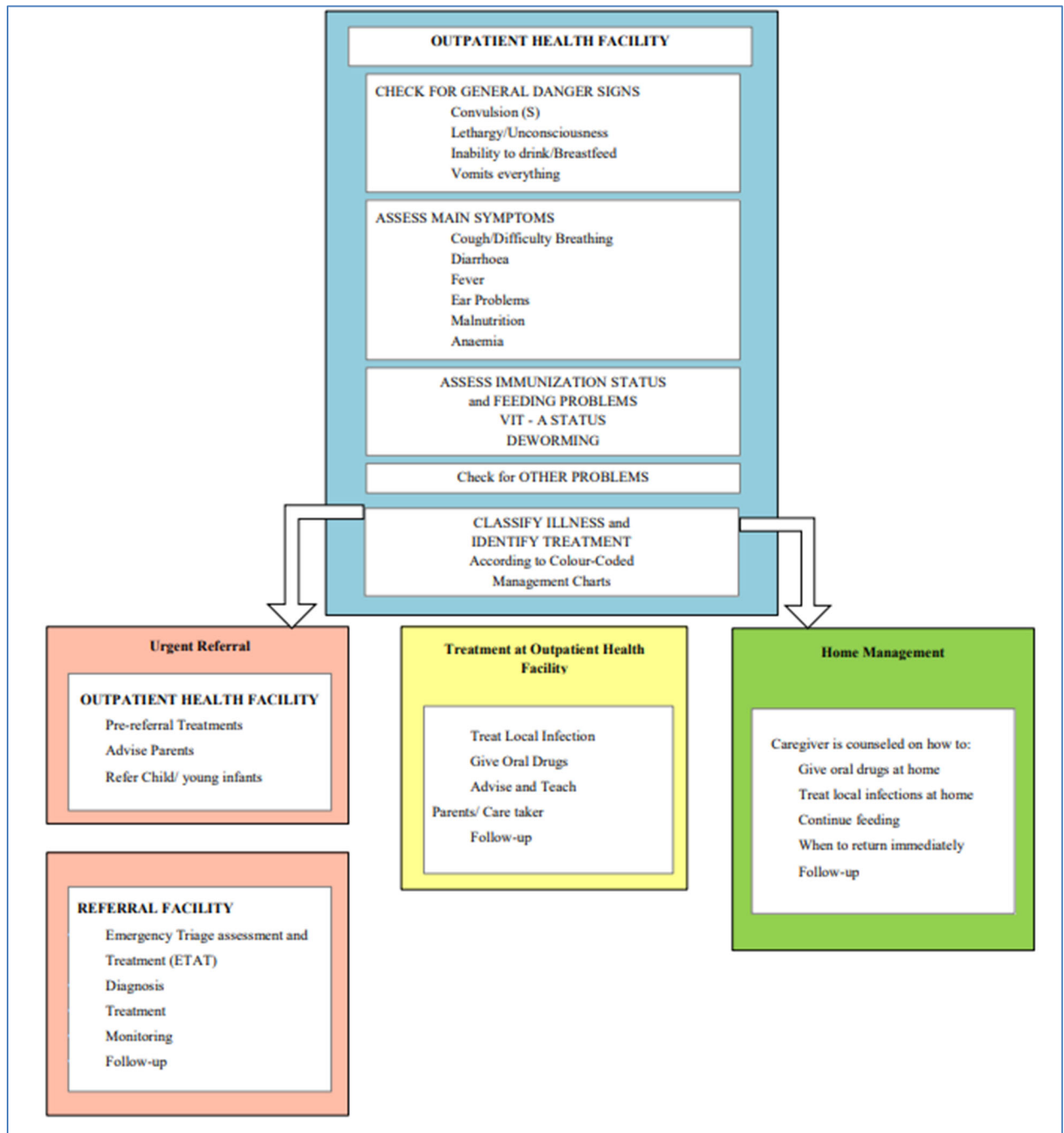
April 10, 2025

Appendix E – Scope of Work for Local Data Collection Partner

Appendix F – Bangladesh’s National IMCI Protocol (14)

Sign	Transfer to Inpatient Care	Home visit
Oedema	Any grade of oedema	
Appetite	Poor appetite or unable to eat	Any child with mild illness or problems with treatment
Vomiting	Persistent vomiting (>3 times per hour)	
Temperature	Fever (>39° C or 102.2° F axillary)	
	Hypothermia (<35° C or 95° F axillary)	
Respiratory rate	Rapid breathing according to IMCI guidelines for age: ☼ ≥60/minute for children <2 months ☼ ≥50/minute for children 2 - 12 months ☼ ≥40/minute for children 12-59 months	
Anaemia	Severely pale (severe palmer pallor) with or without difficult breathing	
Infection	Extensive infection requiring parenteral treatment	
Alertness	Very weak, apathetic, unconscious, convulsions	
Hydration status and dehydrating diarrhoea	Dehydration based primarily on a recent history of diarrhea, vomiting, fever or sweating	
	Not passing urine for last 12 hours and/or recent appearance of clinical signs of dehydration as reported by the caregiver	
Weight changes	- Weight loss for 3 consecutive weeks - Static weight after 5 weeks	Weight static or loss in any follow up visit
Return from inpatient care/refuses inpatient care		Return from inpatient care
		Mother/caregiver refuses inpatient care
Not recovering/ non-responder	If not recovered after 3 months refer for medical evaluation	
Absence		Absent for one or more weeks
Default		Absent for three consecutive weeks

Appendix G – SAM/Medical Complication Referral Protocol (14)



Appendix H – Community Invitation Letter to Participate in Study



Invitation to
Participate in PDH M



Invitation to
Participate in PDH M

Appendix I – Data Security and Management Board Charter



DSMB Charter
(Draft v3) (clean).doc

Appendix J – Appetite Test Guidance for PDH Participant Children

Please see below for the procedure to conduct an appetite test.

1. Ask the caregiver to wash their hands and the child's hands with soap.
2. Offer the nutrient-dense meal (Hearth meal) and encourage the mother/caregiver offer small amounts of the meal to the child by hand or spoon, in the same way feeding is normally done and watch to see if the child eats. This is called an "appetite test".
3. If the child is reluctant to eat, the caregiver should move to a quiet and private area to encourage the child to take the nutrient-dense meal. This may take up to **45 minutes**. Explain the test clearly so the caregiver understands the child should try to eat **voluntarily**, without force.
4. Allow enough time. The test should take **20-45 minutes**, allowing the child to eat at their own pace. No rushing, no forcing, no pressure.
5. Observe the child. The health worker should watch for:
 - Does the child show interest?
 - Are they swallowing normally?
 - Do they refuse repeatedly or seem unable to eat?
6. Determine whether appetite is "good enough" according to the National Protocols (11). Use minimum thresholds as:
 - **6-11 months** approximately $\frac{1}{2}$ to 1 tablespoons $\approx 10g$
 - **12-23.9 months** approximately 1-2 tablespoons $\approx 20-40g$
 - **24 months and older must eat approximately $\frac{1}{3}$ of a meal ($\approx 80 g$ or 5.5 tablespoons)**
 - (It may be hard to estimate the amount of food eaten, but the **child must eat a reasonable amount spontaneously.**)
4. Decide the treatment pathway
 - **If the child eats the minimum amount:**
→ **include in the study**
 - **If the child refuses or cannot eat enough:**
→ refer to **inpatient care** for further assessment, management of complications, and feeding support.
5. Document the result:

Record if the child has good appetite or not and whether the child was referred to inpatient care. Ensure caregivers of children referred to inpatient care (district or provincial hospital) have transportation to go to the inpatient care and follow-up within a two to three days to ensure the child is receiving medical attention.

It may be hard to estimate the amount of food eaten, but the **child must eat a reasonable amount spontaneously**. Appetite test will be conducted in a central location in each village

one day before baseline data collection to ensure children are eligible to be admitted into the study just before enrollment. It will be repeated on the first day of Hearth and/or IYCF counselling session.

6. **Basic immunization, Vitamin A, and deworming given 2 weeks before admitting into PDH:** Children should have received age-appropriate immunization and if the child is 12 months or older, the child should have received Vitamin A supplementation and deworming in the past 6 months. If the child has not received age-appropriate immunization and/or Vitamin A or deworming in the past 6 months, health workers should provide the immunization, Vitamin A and/or deworming minimum 2 weeks before the interventions begin.

Table 1 – Guidance and checklist for volunteers to check prior to admitting children into Hearth sessions

	If child...	Then...
Appetite Test	Failed Appetite Test	Refer child to inpatient care (Appendix F)
Medical Complications	Has medical complications	Refer child to health facility. Ensure caregiver has transportation to go and follow-up within 2-3 days to ensure medical treatment was given to child
Basic immunization, Vit. A, Deworming	Did not receive age-appropriate immunization and Vitamin A or deworming in the last 6 months before joining Hearth sessions	Inform caregiver in the importance of immunization and administering Vitamin A and/or deworming to child and ask for permission to have child immunized and/or Vitamin A/deworming provided.