Child survival, health and development 14 years post-randomisation of successful Participatory Learning and Action community mobilisation intervention in rural Bangladesh.

Short proposal prepared by Prof. Ed Fottrell, UCL Institute for Global Health, UK.

Budget (in USD)

Category	Centre for Health Research and Implementation, Bangladesh	UCL Institute for Global Health, UK	TOTAL
Staff	67,338.28	110,554.60	177,892.88
Equipment/survey materials	113,093.70		113,093.70
Travel	15,000.00	6,900.00	21,900.00
Indirect	19,543.09	11,745.46	31,288.55
TOTAL	**214,975.07**	**129,200.00**	**344,175.07**

Timeline

Proposed start: 1st April 2023

- Detailed protocol development – April-May 2023
- Ethical approvals – May-June 2023
- Community engagement & outreach – June 2023
- Initiation of survey work – July 2023
- Completion of survey work – April 2024
- Initiation of analysis – April 2024
- Completion of analysis – May 2024
- Sharing preliminary analysis with GiveWell – May 2024
- Submission for publication – June 2024

Total Duration: 15 months

Title of project: Child survival, health and development 14 years post-randomisation of successful Participatory Learning and Action community mobilisation intervention in rural Bangladesh.

Researchers involved:

Name	Title	Institution	Role
Edward Fottrell	Professor of Epidemiology & Global Health	UCL Institute for Global Health	Lead academic
Carlos Grijalva-Eternod	Senior Research Associate, Mr		Scientific coordination and analysis
Sam Julier	Research Finance Coordinator, Mr		Financial and administrative management
Kishwar Azad	Project Director, Professor of Paediatrics	Diabetic Association of Bangladesh Centre for Health Research and Implementation	Bangladesh lead academic
Abdul Kuddus	Deputy Project Director, Dr		Project implementation lead
Naveed Ahmed	Project coordinator, Dr		Project implementation and analysis
Sanjit Shaha	Senior Manager-Monitoring and evaluation		Data collection and processing
Tasmin Nahar	Senior Manager-Participatory Groups		Community Engagement

Introduction

Participatory women's groups (PWG) community mobilisation interventions have been widely studied in the context of neonatal mortality, but their potential to affect longer-term child survival and development remains unknown. One such PWG intervention, originally delivered in rural Bangladesh in 2009–2011 as part of a cluster randomised controlled trial, covered approximately 46,000 reproductive-age women (15–49 years) during preconception, pregnancy and the postpartum period. The intervention showed a 38% reduction in neonatal mortality, and improved hygienic delivery and essential newborn care practices[1]. It used a participatory learning and action (PLA) cycle of monthly meetings facilitated by lay women. In the PLA cycle, women themselves identified and prioritised local health challenges, and then designed, implemented and evaluated their own solutions. The initial intervention and evaluation focused on neonatal mortality, but the PWGs continued to meet and proceeded through PLA cycles focused on child health and women's and reproductive health, with encouraging results regarding breastfeeding, nutritional practices and hygiene[2,3].

Two years after the PWG intervention that reduced neonatal mortality and improved essential newborn care practices, we observed growth differences in children born to mothers actively participating in the intervention, compared with a random sample of children from non-exposed mothers in control clusters[4].

Now 14-years post randomisation, we seek to answer the following research questions:

1) Is there a difference in post-neonatal survival (from 1 month to 14 years) between children born in clusters where the PWG intervention was delivered compared to control clusters where no intervention was delivered?
2) Do growth differences observed in directly exposed children in intervention clusters compared to control clusters in 2013 persist in 2023 and are there any differences between a random intervention sample (i.e., not necessarily directly exposed) compared to control?
3) Are there any physical or cognitive developmental or health marker differences between children born in intervention clusters compared to control?
4) What are the associations between growth and anthropometric measures of children in 2013 and their survival in 2023?

[1] Fottrell E, Azad K, Kuddus A, et al. The effect of increased coverage of participatory women's groups on neonatal mortality in Bangladesh: A cluster randomized trial. JAMA Pediatr 2013;167:816–25. doi:10.1001/jamapediatrics.2013.2534

[2] Younes L, Houweling TA, Azad K, et al. The effect of participatory women's groups on infant feeding and child health knowledge, behaviour and outcomes in rural Bangladesh: a controlled before-and-after study. J Epidemiol Community Health 2015;69:374–81. doi:10.1136/jech-2014-204271

[3] Harris-Fry HA, Azad K, Younes L, et al. Formative evaluation of a participatory women's group intervention to improve reproductive and women's health outcomes in rural Bangladesh: a controlled before and after study. J Epidemiol Community Health 2016;70:663–70. doi:10.1136/jech-2015-205855

[4] Fottrell E, Ahmed N, Nahar B, et al Growth and body composition of children aged 2–4 years after exposure to community mobilisation women's groups in BangladeshJ Epidemiol Community Health 2018;72:888-895.

Study design

Cohort follow-up of registered births 12-14 years after birth and 14 years after cluster randomisation within the PWG community mobilisation trial in Faridpur, Bogra and Moulvibazar districts, Bangladesh.

Approximately 20,000 livebirths were recorded during the PWG trial between 2009 and 2011. We will seek to follow-up all registered births to assess survival status and, if deceased, measure date of death and conduct a verbal autopsy assessment to ascertain probable cause of death.

Within the sub-sample of approximately 2,500 children who participated in the 2013 follow-up assessment of growth, plus an additional random sub-sample of approximately 1,250 children from intervention clusters, we will seek to measure physical and cognitive development indicators and biomarkers of health status and non-communicable disease risk.

Primary outcome

Post-neonatal child mortality defined as death after 28 days and before survey date (i.e., between 1 month and up to 14 years of age). Date of death will be recorded to calculate age at death, which in turn can be used to estimate age-specific (e.g., 1-59 month) mortality rates. Mortality rates will be reported as deaths per 1,000 livebirths within this cohort and hazard ratios will be estimated.

Secondary outcomes (recorded in a sub-sample of participants):

Outcome	Definition	Rationale
Body Mass Index*	weight (kg)/height(m)^2	Marker of ponderal growth (weight for height)
Head circumference*	cm	Marker of cranial growth/brain size.
Mid-upper arm circumference*	cm	Marker of muscle and fat, indicator of potential malnutrition
Chest circumference*	cm	Marker of thoracic organ growth
Sub-scapular skinfold thickness	cm	Marker of central sub-cutaneous fat
Triceps skinfold thickness*	cm	Marker of peripheral sub-cutaneious fat
Waist & hip circumference	cm	Marker of abdominal obesity
Height for age*	index against growth references	Marker of linear growth (tallness)
Random blood glucose	Blood glucose concentration in mmol/l	Identification of risk of diabetes
Systolic and diastolic blood pressure	Seated blood pressure (mmHg); average of 3 readings.	Indicator of cardiovascular health
Grip strength	KG	Indicator of muscle strength and development
Cognitive development	Rapid Neurodevelopmental Assessment (RNDA) [5]	Indicator impairments and disabilities in neurodevelopmental domains such as motor skills, vision, hearing, language, cognition, and behaviour.

*Anthropometric z-scores will be calculated using WHO growth standards for height and BMI and using internally derived z-scores for weight, head circumference, chest circumference, mid-upper arm circumference, triceps and subscapular skinfold thickness.

[5] Muslima, H., Khan, N. Z., Shilpi, A. B., Begum, D., Parveen, M., McConachie, H., and Darmstadt, G. L. (2016) Validation of a rapid neurodevelopmental assessment tool for 10- to 16-year-old young adolescents in Bangladesh. Child: Care, Health and Development, 42: 658– 665. doi: 10.1111/cch.12362.

Sample selection
Between 2009-2011 we registered all births that took place in 18 unions (administrative areas) across Bogra, Faridpur and Moulvibazar districts and recorded neonatal survival. We will attempt to re-visit all registered births from this period in the current study.

For the sub-sample assessment of physical and cognitive development and health of children we will a) follow-up the 2587 children included in our 2013 follow-up, plus b) an additional random sample of 1250 children selected from intervention clusters. The reason for this additional sample is to have a general population sample from intervention clusters (the previous intervention cluster was selected based on direct intervention exposure by participants mothers).

Inclusion criteria reflect those applied in our 2009-2011 trial, i.e., children born to women permanently residing in the study 18 unions during the trial period.

Community engagement
A series of community engagement initiatives will be employed prior to data collection to raise community awareness of the study, gain community consent for the project and foster community facilitation and participation in the work. Study findings will also be fed-back to community representatives at the end of the study.

Data capture
Data will be gathered through household visits and interview surveys by teams of data collectors trained in survey methods, anthropometrics, and verbal autopsy. Data will be entered onto tablets using ODK software and will be transferred to a server on a weekly basis.

Data quality will be ensured through fieldworker training and supervision, internal consistency, completeness, and plausibility checks within the ODK data entry system, a system of field-based data quality checks, re-capture, and correction as appropriate, and Dhaka-based data quality checks.

Data collection will be supervised by field supervisors and district managers, with overall coordination and management led by the Monitoring and Evaluation manager based in Dhaka.

Data capture is expected to take approximately nine months.

Power
Nine union (clusters) per arm and approx. 20,000 births registered in 2009-2011 (i.e. approx. 1111 births per cluster), an estimated coefficient of variation between clusters within strata (district) of 0.15, baseline 1-59 month mortality rate 1.1% (11 per 1000 live births), 65% follow-up rate will give approximately 60-65% power to detect a 40% relative reduction in 1-59 month mortality (i.e. an absolute reduction of 440 per 1000 live births in intervention clusters compared to control clusters), at a 95% significance level.

Analysis
Participants will be assigned to the cluster in which their birth or death was registered, and intention-to-treat analysis will only include those who permanently resided in the study areas, as determined by the birth registration and survey process. Analysis of secondary outcomes will only include those who were successfully interviewed.

Analysis will be based on cluster-level summaries using regression techniques that take the stratified and clustered study design into account.

To account for potential confounding and to facilitate comparisons with the previous trial, adjustments for maternal age at time of child's birth, maternal education, and household assets at time of child's birth will be made using a 2-stage analysis. At the first stage, a regression model will be fitted that incorporates the strata (as a fixed effect) and all covariates of interest (but not the intervention effect). Fitted values from the model will be used to compute a residual for each cluster, and these residuals will the then replace the cluster-specific observations in the analysis, following the methods detailed by Hayes and Moulton (2009). Analysis of child growth indicators will be presented stratified by maternal BMI categories as done in the 2013 follow-up.

Random effects linear regression will be used to compare cluster mean child growth, development and health indicators between the intervention and control arms.

Analysis for the primary outcome will be conducted blind to cluster allocation. Blinded results of the primary outcome will be shared with the wider study team and GiveWell, only then will trial arms be identified, and all further analysis will be completed unblinded, and if necessary, effect measures will be 'reversed' to present the effect of the intervention relative to control.

Ethical Approvals
All research activities will be subject to review and approval of the ethical review boards of UCL and the Diabetic Association of Bangladesh; and ethical approval must be obtained from both boards before any data collection can begin.

Transparency
We commit to:

- Publication of study protocol, including analysis plan
- Noting and notifying GiveWell of deviations from the protocol and analysis plan
- Making datasets and/or analysis code publicly accessible

Depending on journal restrictions, we will seek to release pre-prints/working paper versions of study papers within six weeks of submitting papers to a journal when a long (6mo+) lag time is expected for publication.