Lay title: LEAP-CP: Learning through Everyday Activities with Parents for infants at high risk of Cerebral Palsy

Scientific title: Community-based parent delivered early detection and intervention program for infants at high risk of cerebral palsy in a low-resource country: A randomised controlled trial

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BACKGROUND AND RATIONALE

One in seven people globally has a disability, forming the world's largest and most disadvantaged minority [1]. Among these, cerebral palsy (CP) is the most common childhood physical disability, with one in three children with CP unable to walk, and one in four are unable to talk [2]. A staggering 80% of the global burden of CP is in low and middle income countries (LMIC), where individuals and their families are frequently trapped in the negative downward cycle of disability and poverty [3]. Individuals with a disability and their families in LMIC have increased rates of premature mortality and associated morbidities, and are economically disadvantaged by productivity loss, costs of intervention and equipment, as well as consequences of social stigma [1].

Significant gains have been made in the past decade in reducing infant mortality in LMIC [4]. With a renewed global international development strategy pledged by the United Nations Sustainable Development Goals (2015-2030), it is pertinent to shift attention from not only infant survival, but also to improved quality of life and developmental outcomes [5]. The Australian Government has committed to provide leadership in disability inclusive development, enabling individuals with disabilities and their families in LMIC to forge a path out of poverty, and realise their potential [6]. This political agenda will be secured through establishing research and programmatic leadership in the Asia-Pacific region, Australia's immediate global neighbour.

West Bengal is an easterly state in India, and with a population of 90 million people, it is considered one of the most densely populated geographies in the world. The Indian National Rural Health Mission has been instrumental in establishing a community health worker program to meet primary health needs in rural areas across the country (known as ASHA, Accredited Social Health Activists) [7]. Lay health workers have been used as effective change agents across Asia, Sub-Saharan Africa and Latin America, to improve outcomes for both communicable and non-communicable diseases [8], and as such, the current project aims to adapt this model to disability. CIA (KB) has invested significantly in the disability sector in neighbouring Bangladesh, and CID (NK) has extensive networks across Bangladesh, India, Pakistan and South Asia. Dr Bhattacharya leads the Apollo Hospital in Kolkata, which has developed the first Child Development Centre in Eastern India. These

factors collectively make West Bengal an important location for piloting and implementing innovative interventions and service delivery models for disability in LMIC, that are highly scalable and transposable in other LMICs.

Recent scientific advances now allow reliable detection of CP from as young as 3 months, and research into brain development in the first year of life supports the universally agreed proposition that earlier interventions in infants at high risk of CP are worthwhile [9]. Despite this state of science, children in LMICs frequently receive diagnosis as late as 5 years, missing a significant window of opportunity for improved outcomes. Children with CP in these settings also face numerous barriers to accessing medical and rehabilitation interventions, including economic, geographical and social [1]. In addition to the impact of disability on the child, there is strong evidence of higher prevalence of poor mental health in mothers of children with CP [10], for which there are demonstrated improvements consequent to early intervention for their child [9].

In order to impact on the social inclusion and workforce productivity of individuals with a disability in these contexts, it is essential to establish innovative, accessible and feasible means to detect infants at risk of CP, and develop early intervention programs that can be delivered at scale. A community-based intervention of environmental enrichment and nutritional support, delivered by parents in the home is a viable solution in low resource settings.

AIMS AND HYPOTHESES

Early detection of children at high risk of cerebral palsy (CP) in low income countries

1. To determine the predictive validity of General Movements (GMs) assessment administered at 3 months for detecting CP at 12 months in high risk infants in Bangladesh.
   Hypothesis 1: The GMs assessment, when administered to infants at risk in West Bengal, will have predictive validity to detect CP at 18 months equivalent to that in high income countries.

Early intervention for children at high risk of cerebral palsy in low income countries

2. To determine the efficacy of a community-based parent-delivered intervention on children's developmental outcomes for those at high risk of CP.
   Hypothesis 2: Children with CP who receive the intervention will have higher scores on the Pediatric Evaluation of Disability Inventory-Computer Assisted Tests (PEDI-CAT) compared to children in standard care.
3. To determine the efficacy of a community-based parent-delivered intervention on caregiver's mental health outcomes.
   Hypothesis 3: Mothers who engage with the intervention will have improved depression and anxiety scores compared to caregivers with standard care.

RESEARCH PLAN:

Study design: This study is a randomised, double-blinded controlled trial of a novel intervention (LEAP-CP: Learning through Everyday Activities with Parents) compared to Standard Care.

Participants: 142 infants at high risk of cerebral palsy ('absent fidgety' on the General Movements (GMs) Assessment, or 'abnormal' on the Hammersmith Infant Neurological Examination (HINE)) aged 12-26 weeks corrected age (C.A.) will be recruited to this study.

Recruitment: The caregiver and their infant will be recruited to the study between 12-26 weeks, as shown in Figure 1. Mothers who have had birth complications (eg. delayed cry, hospital admission) will be referred by health professionals or Community Health Workers/ Traditional Birth Attendants from regional and tertiary hospitals, community health centres or in the community. Regular meetings will be held with referring partners to receive new referrals and provide study updates.

Consent: A two-stage consent process will be adopted for this study. Caregivers will first provide informed consent for the eligibility assessment (GMs or HINE). Infants who are eligible for the study will then provide informed consent for the clinical trial.

Inclusion/ Exclusion Criteria: To participate, infants must live in one of the study geographical areas, be aged 12-26 weeks C.A. and be assessed in the following ways to be determined at 'high risk' of CP:

- 12-17 weeks C.A. with absent fidgety movements on GMs assessment (98% predictive of CP). This will be videoed by Community Coordinators on their smart phone using the *Baby Moves* App. Description of the infant's motor type and topography will also be recorded from the GMs assessment.
- 18-26 weeks C.A. and score as 'abnormal' on the Hammersmith Infant Neurological Examination (HINE, 90% predictive of CP).

Sample size calculation: The primary hypothesis is that the community-based intervention will improve children's normative standard scores on the PEDI-CAT at 12 months by 0.5SD compared to standard care. 64 children per group will be required to detect this change (α=0.05, β=0.8). Accounting for 10% attrition, this equates to 142 infants.

***Randomisation and blinding*:** Infants will be randomised to the intervention or standard care using simple randomisation based on computer generated sequences. The clinician completing the eligibility assessment will be unaware of the group allocation. Caregivers/ infants receiving the intervention, Community Disability Workers administering intervention, researchers assessing the outcomes and analysing the data will all be masked to group allocation.

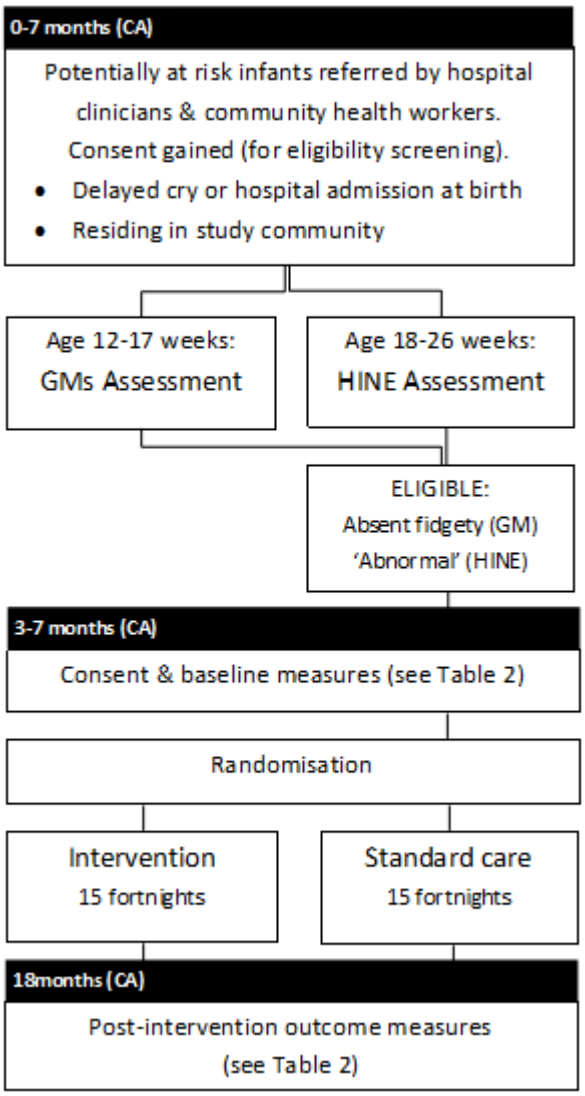

Figure 1. Referral Pathways

Intervention:

The LEAP-CP intervention is a multidisciplinary family-centred intervention delivered peer to peer in the home during 15 fortnightly 2-hour visits (over a 7-10 month period, allowing for missed visits due to illness and family/ religious events). During the visit, the Community Disability Worker (peer trainer) will (1) gather feedback and troubleshoots the previous fortnight's activities, (2) deliver the therapeutic modules, (3) deliver the educational module. The caregiver will be provided with written and pictographic information of the three modules each fortnight to facilitate their use of the strategies each day during the upcoming fortnight.

Therapeutic Modules:

The therapeutic modules are first modelled with the infant by the CDW, and then the caregiver encouraged to engage with their infant, with CDW coaching. The therapeutic modules consist of:

1. Multidimensional activity based curriculum for infants aged 3-18 months, based on the Creative Curriculum Learning Games [11] as a framework for structure and approach. Culturally modified activity cards are translated into Bengali, and include pictographic prompts for 'how to make this game easier' and 'how to encourage practice in other situations'. The CDW will present four activity cards to the caregiver each fortnight from

which the caregiver selects two to learn and deliver with their infant during the fortnight (total of 30 games for the program duration). The four options will be selected based on the infant's age and developmental stage, with guidance from the Community Coordinator. The literature highlights the importance of collaborative selection of therapeutic activities [12]. When delivering a game, the CDW ensures that the infant can complete at least part of the task actively, to ensure optimal motor learning.

2. Individualised goal-directed module: Specific goal-based strategies will be introduced using strategy sheets developed for the study by a multidisciplinary team of clinicians specialised in cerebral palsy (physiotherapy, occupational therapy, speech pathology, psychology and physician). Caregivers will be supported to choose a self-generated intervention goal in visit number 2, individualised to their infant. Each goal area includes red flags for referral for complex and high risk presentations. As a goal is achieved, caregivers will be encouraged to choose a new goal. If the infant remains on a goal without progress for greater than 4 visits (2 months), caregivers will be encouraged to choose a new goal.

Table 1. Parent Educational Modules:

Module 1. Building rapport and program overview (Novak 2006) [12] *Time dependent: First visit*	***Rationale***: It is essential for the Community Disability Worker (CDW) and caregiver/ infant to have a warm, trusting and collaborative relationship. Developing this relationship will facilitate honest conversations, sensitive coaching, and a better understanding of the infant in the family context. It is important for the family to have a clear understanding of the program and CDW role to ensure accurate and realistic expectations. ***Key concepts***: - Introduction of CDW, caregiver and infant - Building rapport and general observation of preferred play activity - What does the LEAP/ SC program cover (frequency of visits, content)
Module 2. Setting goals and problem solving approach (Novak 2006) [12] *Time dependent: Session 2-3*	***Rationale***: Collaborative goal setting encourages collaboration and motivation, and improves intervention outcomes. ***Key concepts***: - Identify infant and family strengths/ abilities - Discuss caregiver's needs and priorities for their infant and family (development and care) - Goal setting with the COPM - Introduction of a problem solving approach and caregiver coaching
Module 3. Living a meaningful life (Whittingham 2013, 2014) [13]	***Rationale***: Parents of recently diagnosed (at risk) infants will likely be experiencing associated grief. Furthermore, these families are at increased risk of poor mental health and relational difficulties. ***Key concepts***: - Dealing with grief - Finding hope to live a meaningful life - Parent self-care
Module 4. Breastfeeding (WHO 1993) [14]	***Rationale***: Any breastfeeding (partial or exclusive) in the first year of life in low-income countries is associated with greater than 2-fold protection against mortality compared

Time dependent: Before infant is 6 months CA	with no breastfeeding. Meta-analysis supports that breastfeeding counselling increases the duration of breastfeeding. ***Key concepts***: - Importance of exclusive breastfeeding - What is optimal breastfeeding - Observation of a feed (with support strategies)
Module 5. Parent-infant bonding and interaction (Care for Child Development modules; Whittingham 2013, 2014) [13]	***Rationale***: A responsive, emotionally available parent-infant relationship affects the infant's chances for survival, their chances of learning (psychosocial development) and psychological health long term. ***Key concepts***: - Increasing caregiver's awareness of infant movements and behaviours (reading their cues) - Building a warm connection between caregiver and infant - Responding consistently and positively to the infant (praise and advise the caregiver on care practices)
Module 6. Encouraging your baby's active and independent play (Law 2011) [15]	***Rationale***: Motor learning theory suggests that infants generate efficient solutions for functional motor goals and tasks based on specific child, task and environmental factors. Systematic review of early intervention in infants at risk of cerebral palsy supports the inclusion of infant-initiated movement as a key ingredient for motor outcomes. ***Key concepts***: - Importance of infant being active in task engagement. - How to encourage active play: activity selection (just right challenge) and providing appropriate physical support and cues
Module 7. Introduction of complementary feeding (WHO 2004) [16] *Time dependent: 6 months CA*	***Rationale***: After six months, other foods need to be added to complement breastfeeding to meet energy requirements. Many young children, particularly in low-income countries, do not receive adequate complementary feeding, resulting in malnutrition. ***Key concepts***: - Importance of complementary feeding - Family beliefs and community practices - Preparing safe and nutritious early foods - Foods for energy and specific nutrients - Observation of a snack (with support strategies)
Module 8. Infant health (WHO, 2014) [17]	***Rationale***: The survival of infants through their early years depends on the adults who care for them. They need protection from illness and injury, and when they are sick they need good medical care. Infant mortality rates in Bangladesh are 31/1000 live births (2015) compared to 3/1000 in Australia. One in 4 infants with CP is expected to have epilepsy. ***Key concepts***: - Reflux: signs, basic management and when to seek help - Epilepsy: signs and when to seek help - Diarrhoeal disease: basic management and when to seek

	help - Other common health concerns and health seeking behaviour
Module 9. Growth monitoring (WHO 2009) [18] *Time dependent: Session 8-10*	***Rationale***: It is important to look at the trajectory of the infant's growth, as such a minimum of three measurement points are needed. This monitoring point also provides further opportunity for counselling around dietary intake and expected monthly weight gain. ***Key concepts***: - Length and weight (converted to Z scores using WHO guidelines). - Head circumference and Mean Upper Arm Circumference. - 24 hour recall of dietary intake - Counselling regarding recommended daily intake (food groups).
Module 10. Adding repetition and variability to your baby's play (Fetters 2010) [19]	***Rationale***: A lack of variability in play can be a barrier to the development of skilled, functional action. Variability allows exploration and problem solving through trial and error, and assists in building complexity and generalisation of the learning task. ***Key concepts***: - Building on parent observation skills - Moving and sitting - How to set up the infant's environment to encourage repetition and variable practice - How much variability is beneficial to learning, and how much is too much?
Module 11. Creating enriched environments to encourage independent play (Morgan 2013) [20]	***Rationale***: Providing stimulating toys and other learning opportunities in the infant's home encourages motor learning and other developmental outcomes. ***Key concepts***: - How to create an enriched environment at home, using home-based objects and toys - Choosing the right toy for the right skill - Using hands for reaching - Making home-made toys
Module 12. Responding to your baby's cues and communication (Pepper & Weitzman 2004) [21]	***Rationale***: Language stimulation and caregiver's responsiveness to infant cues have demonstrated effectiveness in supporting communication development. One in 4 children with cerebral palsy is reported as unable to talk. ***Key concepts***: - Child lead interaction - Observe, Wait, Listen - Adding language to interaction - Creating communication opportunities
Module 13. Finding joy in your baby (Whittingham 2013, 2014) [13]	***Rationale***: Caregivers of an infant with a disability in low-income countries reflected overwhelming experiences of emotional distress related to their child's condition. A warm parent-infant bond arising from positive interactions affects

	the infant's chances for survival, their chances of learning (psychosocial development) and psychological health long term. ***Key concepts***: - Creating space for positive emotions with your baby: mindfulness - Become an accepting space for your baby
Module 14. Sharing books with your baby (Pepper & Weitzman 2004) [21]	***Rationale***: Sharing books with your baby supports communicative and cognitive development, as well as providing time for togetherness. ***Key concepts***: - Why reading is important, even with babies - How to read (with and without literacy) - Making your own books
Module 15. Connecting with your community (Nakamanya 2015, Whittingham 2015) [13]	***Rationale***: Caregivers of infants with a disability in low-income countries often face additional stigma from their communities, families and spouse, resulting in keeping their infant indoors and being socially isolated. Building positive social networks, and meeting and sharing experiences with similarly affected mothers has been associated with more positive maternal care. ***Key concepts***: - CDW discusses feasibility of facilitating a local parent support network with other mothers in the program. - Maximising social support from family and friends - Exploring connection to universal services in the community, such as playgroups. - Access to health and therapy services.

Dose: The intervention will commence at 3-6 months C.A. at a dose of 20 minutes per day for 5 days per week (1.6 hours) up to 6 months C.A. (total dose 19.2 hours); then graduate to 30 minutes per day for 5 days per week (2.5 hours per week) from 6-9 months C.A. (total 30 hours); then 40 minutes per day for 5 days per week (3.3 hours per week) from 9-12 months C.A. (total 40 hours). In addition, there will be approximately 15 hours of direct intervention administered during home visits by either the parent or CDW. The overall dose will be 104.2 hours for the intervention.

Service Delivery with Community Disability Workers (CDW)
A caregiver enrolled in the intervention will be trained as a Community Disability Worker (CDW) to deliver the intervention (peer to peer). One caregiver will be employed as a CDW for each community cluster (approximately six infants). They will receive a five day training package at the onset of the program (with the Chief Investigator, an Australian Post-doctoral fellow and speech pathologist). This will include topics such as:

- Building rapport and a positive therapeutic relationship with caregivers
- Exploring customs, beliefs and family culture
- Using everyday opportunities and routines to encourage infant development
- Observation skills and coaching

Fig 2. Represents 1 community cluster. Centralised community coordinator trains 5 CDWs working with 6 infant-mother dyads

- Motor training and therapeutic principles
- Understanding typical development and development in cerebral palsy.
- Ethics and research practices

CDWs will also receive training for 3 hours each fortnight with the Community Coordinator (Bangladesh trained therapist or allied health professional) to support them in the specific content of the program (therapeutic and educational modules). During this fortnightly session, they will also have opportunity for supervision, debriefing, and troubleshooting.

Concurrent therapies: Any concurrent therapies provided to the infants in either arm of the study will be recorded by the CDW on the HRU form during their fortnightly visit.

Adverse events: Any adverse events associated with the program will be screened at 6 and 12 months using open-ended questions by non-treating personnel.

Fidelity: Intervention dose will be measured by (1) token counting; (2) videoed activities; (3) CDW feedback. Two fortnights per caregiver will be randomly selected to estimate the frequency the caregiver applies the intervention strategies. Caregivers are asked to tie a knot in a string for every 10 minute interaction with their infant, to estimate the total fortnightly interaction time. Caregivers with literacy will complete a paper version. In addition, 10 minutes of interaction will be videoed by the CDW to quantify the use of the previous fortnight's strategies by the caregiver. The CDW will also record feedback from the caregiver, including successes and challenges to implementation. Frequency and duration of access to local therapy services will be recorded fortnightly on the Health Resource Use Form, and included in the analysis.

Standard Care is based on the Integrated Management of Childhood Illness Key Family Practices (WHO). This includes counselling on breastfeeding and introduction of complementary nutrition, hygiene practices, immunisation counselling, and management of the sick child. The same service delivery model and visiting schedule will be utilised as for the intervention arm, with a different CDW visiting Standard Care families to avoid contamination.

Outcome measurement:
Pre-/ post-intervention assessments will be conducted by an assessor masked to intervention status. Post-assessments will be conducted at 18 months corrected age for all infants (regardless of study entry age) to ensure consistency between infants' final assessment. All questionnaires will be back-translated (English to Bengali and back) to ensure translation accuracy.

Table 2. Assessments for Intervention and Standard Care Study Arms

	Intervention		**Standard Care**	
	Infant Completed	**Caregiver Completed**	**Infant Completed**	**Caregiver Completed**
Eligibility Assessment (12-26 weeks)	GMs or HINE	NA	GMs or HINE	NA
Baseline Assessment (3-7 months)	S1. PDMS-2 S2. BSID-III S3. Growth Ax S5. HINE*	P1. PEDI-CAT P3. DASS S4. HRU form S6. HOME C. PC C. PMT C. MSPSS	S1. PDMS-2 S2. BSID-III S3. Growth Ax S5. HINE*	P1. PEDI-CAT P3. DASS S4. HRU form S6. HOME C. PC C. PMT C. MSPSS
Assessments during	S3. Growth Ax	P2. COPM	S3. Growth Ax	C. Diet history

Intervention Period		C. Diet history S4. HRU form		S4. HRU form
Post-Assessment (18 months)	S1. PDMS-2 S2. BSID-III S3. Growth Ax S5. HINE S7. CP diagnosis C. GMFCS/ motor type	P1. PEDI-CAT P2. COPM P3. DASS S4. HRU form S6. HOME	S1. PDMS-2 S2. BSID-III S3. Growth Ax S5. HINE S7. CP diagnosis C. GMFCS/ motor type	P1. PEDI-CAT P3. DASS S4. HRU form S6. HOME

*If this has not been administered for eligibility assessment; P indicates primary measures; S indicates secondary measures; C indicates covariate

Primary Infant Outcome Measures:

- The infant's functional outcomes will be assessed using the **Pediatric Evaluation of Disability Inventory-Computer Adaptive Test (PEDI-CAT)**. This is a parent-reported measure of their child's independence in self-care, mobility and social function (aged birth-20 years). The PEDI-CAT has been Rasch-analysed in both children with disabilities and those with typical development. The computerised adaptive version, based on Item-Response Theory, has been shown to increase accuracy and efficiency of administration [22]. The raw scores will be converted to standardised scores using normative data (0-100) to measure change in function. The PEDI-CAT has been used in non-Western cultural contexts [23].
- The **Canadian Occupational Performance Measure (COPM)** will be used to assist parents in setting and prioritising goals and measuring parent-perceived change of their infant's performance of the goal and own satisfaction with progress. This assessment will be administered by the Community Disability Worker (trained in its administration) in a semi-structured interview as part of Educational Module 2 (goal setting) for the intervention arm only. It was considered unethical to set goals with the standard care arm if these goals will not be targeted therapeutically. Post-intervention assessment will be administered by an independent rater at 18 months C.A.

Secondary Infant Outcome Measures:

- The infant's motor outcomes will be assessed using the **Peabody Developmental Motor Scales – Second edition (PDMS-2)**, a commonly used measure of motor skills in infants and children aged birth to 6 years. It has demonstrated validity (discriminative, and concurrent with the Bayley [24] and Gross Motor Function Measure [25]) and responsiveness in infants with CP [26, 27].
- The infant's cognitive outcomes will be assessed using the **Bayley Scales of Infant Development III (BSID-III)**, the gold standard norm-referenced assessment of infant development (0-3 years) [28].
- **Nutritional status** will be determined using length/ height and weight which will be converted to z scores using the World Health Organization age and gender referenced data [18]. Head circumference and mid-upper arm circumference will also be recorded.
- The **Health Resource Use Form**, will be provide health economic outcome data, as well as being included as a covariate in analyses. It was developed for a large population-based study in Australia [29] and has been previously modified and used by our team in Bangladesh [30].
- **Hammersmith Infant Neurological Examination (HINE)** will be used to assess infant neurological status and CP severity. The HINE at 3-6 months has been shown to have strong and significant correlations with the GMFCS at 2 years [31]. For infants who had the HINE administered for their eligibility assessment, only a post-intervention HINE will be administered.
- **Home Observation for Measurement of the Environment (HOME) Inventory – Infant and Toddler Version** is a measure of the quality and quantity of parent and home stimulation, covering six domains of parent responsivity, acceptance, and involvement; and the home

physical environment including availability of learning materials, and variety of stimulation [32]. A cultural and linguistic modification has been developed for Bangladesh, and used across a number of studies [33-38].

- **Diagnosis of cerebral palsy** at 18 months will be provided by an Australian qualified paediatrician according to published guidelines [39], based on clinical history (on the Physician Checklist) and videoed motor patterns. This method has been used in our previous research [30].

Primary Caregiver Outcome Measure:

Caregiver outcomes will be assessed using the **Depression, Anxiety, Stress Scale – Short Form (DASS)**, a self-reported norm-referenced measure of depression, anxiety and stress [40]. An official Bengali translation is available on the measure website [41].

Co-variates and descriptive measures:

- **Physician checklist (PC)**: developed for a large population-based study in Australia [29] and used by the CIA in Bangladesh [30], gathers birth and developmental history from the caregiver. Questions include preterm status, birth complications, presence of seizures and medications.
- **Gross Motor Function Classification System (GMFCS):** five level classification of children's functional gross motor function. The <2 year old age band will be used to classify gross motor function at the completion of the study (18 months C.A.) [42].
- **Motor type** (spasticity, dyskinesia, hypotonia) **and distribution** (number of limbs) will be classified by an Australian physiotherapist from video according to the Surveillance of CP in Europe [43]. This methodology has been used in this research team's previous research in Bangladesh [30].
- **Diet history** of a typical day in the previous week will be used as a measure of habitual dietary intake. This will be in the form of a structured open-ended interview using household implements to aid estimation of portion size, followed by prompts of specific food groups to clarify intake of foods that may have been omitted. CDWs will receive training developed by a qualified dietician in administering this technique.
- **Poverty Measurement Tool (PMT)** will provide a measure of poverty/ economic status [44]. This scale was developed in rural Bangladesh to provide a measure of poverty, defined as 'inadequate fulfilment of basic needs, such as food, clothing, shelter, health, education and social involvement'. Scores range from 24-72 with increasing values indicating increasing poverty. The scoring cut-points were validated against wealth rankings of households using participatory rural appraisal methods. It has excellent test-retest reliability and strong internal consistency.
- **Multidimensional Scale of Perceived Social Support (MSPSS)** measures caregiver's cognitive social capital, defined as a subjective measure of what people feel, such as notions of trust and reciprocity [45]. The MSPSS is a 12 item scale with four items for each source of support, with items rated on a seven point scale. The measure has good cross-cultural stability, strong internal consistency when tested in a range of samples in a developing country, and was significantly associated with two measures of depression and anxiety (the Beck Depression Inventory and the State-Trait Anxiety Inventory) [46].

Analysis:

Descriptive statistics (frequencies, means and 95% confidence intervals) will be used to describe each of the samples (at baseline and post-intervention). Intention to treat analysis will be used to compare outcomes post-intervention, using the PEDI-CAT as the primary outcome measure. Between-group differences on the PEDI-CAT normative standard score (continuous data) will be compared using multivariate linear regression, adjusting for differences between sample characteristics (e.g. age, gender, epilepsy, GMFCS, motor type, preterm status, home environment, economic status). Secondary analyses will consider gains on motor or cognitive outcomes (Peabody Developmental Motor Scales and BSID-III Cognitive Scale), caregiver outcomes and health economics. All analyses will be conducted using STATA 13, with significance set at $p<0.05$.

Community Involvement and Sustainability:
The local community will be involved at all levels of the intervention, including in the study governance, leadership and participation. In program leadership, the CI will capacity-build a local counterpart to oversee the training, as well as up-skilling community coordinators to coordinate at the grass-root level. Use of a "train the trainer" model will ensure long-term sustainability and empowerment of mothers.

Feasibility:
Each year in Kolkata and its surrounds approximately 1,6000 infants are born with CP, thus recruitment of sufficient numbers is highly feasible. Utilising the extensive networks of the Kolkata Apollo Hospital and National Institute of the Mentally Handicapped, we anticipate strong referral pathways. The intervention, delivered in the home by local community members for 15 fortnights is expected to be a low study burden for participants, increasing retention. Based on a previous three year intervention study of at risk infants in LMIC which reported a 7% attrition rate, our participation numbers of n=142 infants (which allows for 10% attrition) are expected to be maintained. Delivering health interventions through lay health workers has been shown to be effective in Bangladesh, and transposable and scalable to other settings. The academic guidance and world-class disability leadership offered by both my in country host institutions and home institution will ensure successful project implementation, and maximum future impact. I have already secured partial funding through the prestigious Endeavour Queen Elizabeth II Diamond Jubilee Fellowship, awarded to the top female researcher, to conduct the field work in West Bengal.

Outcomes and Significance:
The proposed study is expected to result in a number of important outcomes spanning several tiers of society, including child, caregiver/ family; and health systems. Studies in LMIC have shown positive effects of early interventions for the general population and other at risk groups (e.g. low birth weight) with significant improvements in children's cognition, language and social-emotional development. It is anticipated that the proposed intervention package, designed specifically for infants at risk of CP, will result in significant improvements in their language, cognition, mobility and activities of daily living. Consequently, these changes to children's developmental trajectories are likely to improve their participation in education, employment and community. Early interventions for infants with a disability have also been associated with reductions in maternal anxiety and depression [9]. In a country where women are often more socially isolated, which is further compounded by the stigma of having a child with a disability, such improvements in maternal mental health are expected to be significant for families and communities. By empowering mothers as disability resource champions in their local communities, this intervention is also expected to have a lasting and far-reaching benefit, beyond the duration of the study. India has effectively implemented the Community Health Worker model over a number of decades. Building on this model, of up-skilling community members with minimal formal education to deliver community-based healthcare, the proposed project is expected to result in a cost-effective and feasible model of care for infants with cerebral palsy that is highly scalable and transposable to other LMIC.

Timeline:

Year	Location	Activities
2016	Australia	Project set-up (ethics, piloting, training).
2017	India	Rolling recruitment (15 fortnight intervention cycles).
2018	India	Rolling recruitment (15 fortnight intervention cycles).
2019	Australia	Data analysis and manuscript submission. Conference attendance.

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